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ANNEXURE-A

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COMMISSIONERATE
Health & Family Welfare Services

No. DD/SSU/Covid-19/SOPs/42/20-21

Date: 20th July 2020

Revised Standard Operating Procedure for CCC

Subject: Standard Operating Procedure for admission and management of COVID-19 positive cases at COVID Care Center (CCC)

Reference:
1. No: DHS/PS/97/2020-21 regarding guidelines for establishing and managing Covid Care Centre (CCC) dated 22.06.2020
2. No: DHS/PS/115/2020-21 Standard Operating Procedure for admission and management of COVID-19 positive cases at COVID Care Center (CCC) dated 02.07.2020

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In view of evolving situation of COVID-19 in the state, Covid Care Centers (CCC) are being established both in government and private. These shall be set up in suitable hostels, hotels, schools, stadiums, lodges, etc. The Covid positive person/ patient shall be admitted to these CCCs by the triage team based on below mentioned criteria either in Government or Private institution as preferred by the patient. The patient/relative shall sign the prescribed consent form (Annexure-1) in case he/she is going to a private institution.

The following persons shall be admitted directly to COVID care Centre (CCC) after triage:

- All asymptomatic/mild symptomatic persons who meet one or more of the following criteria:
  - Persons of any age:
    - who are not eligible for home isolation.
    - who opt for isolation at CCC.
  - Body temperature > 38^0 C (> 100.4^0 F) for more than 24 hours.
  - If the person has the following co-morbidities like hypertension, diabetes mellitus, obesity, thyroid disease; they are well managed and under good clinical control as assessed by medical officer/physician.

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- Shall not have any comorbid conditions like kidney diseases including persons on dialysis, heart diseases, stroke, tuberculosis, cancer, people living with HIV, immune-compromised, on steroids and immune-suppressants, etc.

- Persons being admitted to CCC shall have
  - Oxygen saturation ≥ 95%
  - Respiratory rate < 24/min
  - Pulse rate <100/min

Criteria	COVID care Centre* (CCC)	Dedicated COVID Health Centre (DCHC) (Beds with Oxygen facility)	Dedicated COVID Hospital (DCH) (ICU Beds Available)
Clinical condition	Asymptomatic or Mild	Moderate	Severe
Measure Oxygen Saturation with fingertip Pulse oximeter	SpO_2 more than 94%	SpO_2 between 90 to 94%	SpO_2 less than 90%
Pulse Rate	<100/ min	100-120/min	>120/ min
Systolic Blood Pressure	-	-	<100 mm Hg
Respiratory Rate	< 24/ min	24-30/min	>30/min
Co-morbid Conditions	Hypertension, diabetes mellitus, obesity, thyroid disease under good clinical control as assessed by medical officer/physician Without any other comorbid conditions	With co-morbid conditions Pregnant women- 4 weeks before expected date of delivery (EDD)	with comorbid conditions

All Asymptomatic/mild symptomatic COVID-19 patients admitted in CCC should undergo screening for the following at the time of admission.

- Collect SRF ID and personal ID.
- Temperature screening using thermal scanner.
- SpO_2 and pulse rate using fingertip Pulse oximeter.
- Blood pressure using BP apparatus.
- Random Blood sugar using glucometer.
- Medical history, enquiring about comorbid conditions and verifying records, if available.
- All other cases shall be shifted to DCHC or DCH based on the severity of symptoms.

Every COVID Care Centre should be linked to one or more Dedicated COVID Health Centers (DCHC) and at least one Dedicated COVID Hospital (DCH) for referral purpose.

Every COVID Care Centre must also have a dedicated Basic Life Support Ambulance (BLSA) equipped with sufficient oxygen support on 24x7 basis, for ensuring safe transport of a case to dedicated higher facilities if the symptoms progress from mild to moderate or severe.

Responsibilities of Doctors and Paramedical staff.

- Daily examination of the persons for any complaints and if necessary, treat accordingly (Annexure-1).
- Case sheets shall be maintained for each patient separately.
- Daily statistics like bed occupancy, status of patients and referral/ discharges should be updated to BBMP officer/THO in the online platform.
- Regular Monitoring shall be done of the below parameters:
    - Body temperature
    - Pulse Rate
    - Blood Pressure
    - Respiratory Rate
    - SpO_2– saturation as shown by fingertip pulse Oximeter
    - Symptoms as described by the patients with special attention to difficulty in breathing/persistent pain or pressure in the chest,etc.
    - Above (a to f) to be monitored once at the beginning of each shift compulsorily.
- If any patient progresses to show moderate or severe symptoms, shall be shifted to a Dedicated COVID Health Centre/Dedicated COVID Hospital at the earliest. The CCC nodal person shall be responsible for the same.

Human resources requirements:

- Doctors – one per 100 persons for 8 hrs shift (to be provided by the health/medical education dept. in case of government managed CCC)
- Staff nurses – one per 50 persons for 8 hrs shift. (to be provided by the health/medical education dept. in case of government managed CCC)
- Support staff for food/supervision – one per 100 persons for 8 hrs shift.
- Staff for cleaning – one per 50 persons for 12 hrs shift.
- Data entry operator – one per 500 persons for 12 hrs shift.
- Security personnel and marshals – one per 100 persons for 12 hrs shift.

The staff should reside at CCC in a separate area/block. They shall work for 10 days at CCC (one cycle) and then go home for 4 days.

After one cycle of duty the staff, before going home shall be tested using rapid antigen kit.

Required amenities for Covid care Centre (CCC):

A Covid Care Center shall have:

- Have restricted access to general public.
- Have a help desk.
- Have beds 1 meter apart with side locker & charging point for mobile/laptop, etc.
- Have one pedestal fan, one chair/stool.
- Separate areas for asymptomatics and mild symptomatics.
- Have a separate section/ward for male and female patients
- Has 24 X 7 Electricity with power back up & Water supply.
- Have a nursing staff and doctor at station for 24X7 care.
- Shall have adequate supplies of PPE Kits, N-95 Masks, triple layered surgical masks, gloves, hand sanitizers, thermal scanners, pulse oximeters, glucometer,

BP apparatus, stethoscopes, medicines like hydroxy chloroquine, vitamin-c, zinc and others including emergency drugs, dressing material and first aid kit, oxygen cylinder with tubing/oxygen concentrator, nebulizer, portable ECG machine. (The requirements of supplies is given in the Annexure-2)

- Have adequate bath and toilet facilities (@1 bath and toilet for 20 persons)
- Have adequate ventilation and lighting facility
- Have monitoring facility using CCTV camera installed.
- Have 24X7 ambulance service to shift patients whenever necessary-one ambulance per 250 persons
- Have a linkage with dedicated covid-19 health center or dedicated covid hospital.
- Bed sheet and pillow covers shall be changed daily.
- Separate areas for donning/wearing and doffing/removing PPE kit.
- Facility for disinfection & sterilization of patient linen & equipment (Mechanized Laundry).
- Availability of broadband Internet connectivity with computers and DEOs for providing the COVID-19 patients data.
- Garbage Management inside and outside the COVID Care Centre, linkages with solid waste management.
- To ensure that the biomedical waste generated in the CCC is sent to designate common waste treatment facility/agency.

Food and Nutrition

- Nutritious diet shall be provided to the patient as per the Annexure-3.
- Proper food arrangements three times a day along with snacks for the patients, Doctors, Officers and others.
- Breakfast shall be provided by 7.00 AM, Lunch to be provided at 1.00 PM, and Dinner by 7.00 PM.

Ancillary services

- Separate entry and exit shall be provided for the positive persons and doctors /staff at the facility.
- To ensure complete sanitation inside and outside the CCC.

Patient monitoring

- A common facility for thermal scanning and pulse oximetry can be set up for temperature and oxygen saturation check
- A staff nurse/trained health worker can record everybody's temperature and pulse oximeter reading thrice a day

Discharge of the patient

For asymptomatic/mild symptomatic individuals:

- They shall be discharged based on the following criteria;
  - No Fever and No Symptom/s for the last 3 consecutive days before discharge (without antipyretics)
  - Maintains saturation above 95% for the last 3 consecutive days (without oxygen support)

- Symptomatic individuals with a positive COVID test report, , ***shall be discharged 10 days from the date of onset of symptoms***
- Asymptomatic individuals with a positive COVID test report, who continues to remain asymptomatic during their stay in the CCC, ***shall be discharged 10 days from the date of swab collection.***
- There is **no need for RT-PCR/CBNAAT/True-NAT test/Rapid antigen test** before discharge of the patient.
- At the time of discharge, the patient shall be advised for home quarantine and self-monitoring their health for another 14 days.

Management of Logistics at CCC:

A. Supply of equipment and medicines to government managed CCC.

The Karnataka State Drugs Logistics & Warehousing Society (KSDLWS) will provide the necessary drugs, equipment and other supplies to government managed CCCs. In greater BBMP area the nodal officer for CCC will send the requirement for 15 days to Additional Director, KSDLWS. In districts DCs will manage this from drugs, equipment and other supplies available with them for Covid-19.

B. Supply of food:

The BBMP/District Administration will make arrangement for supply of food for patients (as per diet chart) and to the staff.

C. Other essentials:

- Standard IEC material and displays
- Large plastic bags
- Appropriate clinical waste bags
- Linen bags
- Sharps containers
- Collection container for used equipment
- Standard protocols for hand hygiene, sample collection and BMW displayed clearly
- Standard Infection prevention and control protocols
- Standard Clinical management protocols

D. Disinfection and IPC:

- The doctor and care giver shall be trained on IPC protocol.
- Setup a trolley outside the changing room to hold PPE (triple layer medical mask, gloves) and linen. Used PPEs should be collected in waste disposal bins (touch-free bin) and disposed off as per the Biomedical Waste Management guidelines.
- Ensure suitable arrangements for hand washing and sufficient availability of supplies including alcohol-based hand rub near the point of care and the room door.
- Used linen, pillow covers, towels shall be changed daily and kept in a disposable bag for washing with commonly used detergents.
- Cleaning and regular disinfection (using 1% sodium hypochlorite solution) of frequently touched surfaces (door knobs, elevator buttons, hand rails, benches, washroom fixtures, etc.) to be carried out thrice daily in all common areas.
- Effective and frequent sanitation, thrice a day, within the facility premises shall be

maintained with particular focus on lavatories, drinking and hand washing stations/areas.

- No aerosol generating procedure shall be carried out in the Covid Care Facility.

E. Transportation:

Have 24X7 ambulance service to shift patients whenever necessary

F. Testing:

The staff should reside at CCC in a separate area/block. They shall work for 10 days at CCC (one cycle) and then go home for 4 days.

After one cycle of duty, the staff before going home shall be tested using rapid antigen kit.

G. CCC in-charge nodal officer:

District Administration/BBMP shall appoint a Group-A officer as Centre in charge who shall be stationed in the CCC and manage the HR and logistics of the Centre (Annexure-4, CCC Arrangement template ; Annexure-5, Monitoring Checklist for Covid Care Centre)

H. Daily reporting:

The CCC will ensure compulsory daily reporting of the admissions, discharges, medical condition of patients in the software recommended by the state government.

Establishing CCC by private medical establishments in collaboration with hotels/ staying facilities and RWAs, AoAs is mentioned in Annexure-6.

20.3.20

Commissioner
Health & Family Welfare Services

To:

1. **All Dist. Health & FW Officers**
2. **All Dist. Surgeons of Dist. Hospitals**
3. **All Divisional Joint Directors**
4. **Chief health officer, BBMP, Bengaluru**

Copy to:

1. **The Commissioner, BBMP, Bengaluru.**
2. **The Special Commissioner (Health & Planning) BBMP, Bengaluru.**
3. **Sri. Rajendra Kumar Kataria, Special Officer Covid Care Centers, Bengaluru.**
4. **Mission director, National Health Mission, & OSD, SSU, Health and Family Welfare Services, Bengaluru.**
5. **All Deputy Commissioners.**

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Annexure -1
Management and treatment Plan for COVID-19 persons at CCC

Recommended Investigations	Complete Blood Count Random Blood Sugar HbA1C (if known diabetic)
	Electrocardiogram (ECG)

Note: Any other investigations as deemed necessary by the attending medical officer/physician

Recommended Treatment Protocol	
Treatment	**Precautions**
1. Tab Hydroxychloroquine Sulphate (HCQS) – 400 mg BD for 1 Day followed by 200 mg 1-0-1 for 4 Days 2. Tab Zinc 50 mg 0-1-0 for 7 Days 3. Tab Vitamin C 500 mg 1-1-1 for 7 days	Vitals should be re-assessed regularly Contraindications for HCQS: 1) QT interval > 500ms 2) Porphyria 3) Myasthenia Gravis 4) Retinal Pathology 5) Epilepsy

- **Additional Medications**
  - All persons to continue the regular medications for the pre-existing comorbid illnesses like Hypertension, Diabetes Mellitus, Hypothyroidism, etc.
  - Tab Pantoprazole 40 mg 1-0-0 (empty stomach), if required
  - Antitussive cough syrups – For dry cough
  - Tab Cetrizine 10 mg 0-0-1 – For running nose if required
  - Tab Paracetamol 500 mg/ 650 mg SOS – For Fever

- **Tab Hydroxychloroquine Sulphate (HCQS) Prophylaxis** for the staff
  - Tab HCQ 400mg 1-0-1 (BD) on First day followed by 400mg/week under medical supervision

However, the treatment protocol as advised by physician shall be followed.

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Annexure –2

Requirements for COVID Care Center (CCC)

1. **Access considerations**
   - Parking space including Ambulances, etc.
   - Ease of access for delivery of food/medical/other supplies
   - Differently-abled Friendly facilities (preferably)
2. **Ventilation capacity:** Well ventilated preferably natural
3. **Basic infrastructure/functional requirements:**
   - Rooms/Dormitory separated from one another may be preferable with in-house capacity of 5-10 beds per enclosure.
   - Each bed to be separated 1meter (3 feet) apart from all sides.
   - Lighting, well-ventilation, heating, electricity, ceiling fan.
   - Potable water to be available.
   - Functional telephone system for providing communications / Desktop.
   - Laundry services.
   - Sanitation services/Cleaning and House keeping.
   - Properly covered bins for waste disposal.
4. **Space requirements for the facility:**
   - Administrative offices
   - Reception area
   - Logistics areas/drug stores
   - Rest rooms- doctors/nurses/supporting staffs
   - Donning and doffing areas
   - Clinical examination room/ nursing station / Sampling area
   - Laundry facilities (on- or off-site)
   - Mess/Meal preparation (on- or off-site)
   - Holding area for contaminated waste
   - Wash room/Bathroom/Toilet separate for male and female
   - In house accommodation for working staff
5. **Social support resources/ Recreational areas (preferable)**
   - Television and radio/Reading materials/ indoor recreation area
   - Tele-counseling services.
6. **Securing Entry and Exit points**

   - In order to prevent and control infection in the facility, strategic points in the facility needs to be identified including the administrative area where a person entering inside CCC to get proper awareness and training on infection prevention and control (IPC) measures
   - A well informed and trained security to check (main entrance gate of the area) and a guard (24X7) with registers for entry and exit.
   - Only authorized & trained persons or those designated in work areas to permit to enter the CCC.

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Annexure-3
Model Diet Plan

(Similar diet plan may be suggested as per staple diet suitable locally)

On Rising	Coffee/ Tea/ Milk						
Day	Mon	Tue	Wed	Thu	Fri	Sat	Sun
Break-fast 7:00 AM	Rava Idli	Pongal	Set Dosa	Rice Idli	Bisibele Bath	Chow Chow Bath	Set Dosa
Mid-Morning 10:00 AM	Watermelon	Papaya	Muskmelon	Watermelon	Papaya	Muskmelon	Papaya
	Ragi Ganji	Palak Soup	Rava Ganji	Carrot Soup	Ragi Ganji	Tomato Soup	Rava Ganji
Lunch 1:00 PM	Pulka- 2 nos + Palya + Rice + Dal + Curd						
Evening 5:30 PM	Elaichi Banana + Marie Biscuits – 3 Nos/ Protein biscuits- 2 Nos/ Fresh Dates- 2 Nos + Mango bar (Vit-C rich)						
Dinner 7:00 PM	Pulka- 2 nos + Palya + Rice + Dal + Curd						
Bedtime 9:00 PM	Flavoured Milk						

Do's and Don'ts

Do's

- Eat whole grains such as brown rice, whole wheat flour, oats, millets, etc.
- Include beans, lentils & pulses as these are good sources of protein
- Include fresh fruits & vegetables (fruits & vegetables like red capsicum, carrots, beetroot & greens etc.)
- Drink 8-10 Glasses of water and Hydrate yourself. Water helps to flush out toxins
- Citrus fruits like lemons & oranges are a good source of Vit C which is key in improving immunity levels & to fight off infections
- Include spices like ginger, garlic & turmeric which are natural immunity boosters
- Eat home-cooked food. Use low fat and less oil for cooking food
- Wash fruits & vegetables before use Include Low-fat milk & yogurt as they are good sources of protein & calcium

Don'ts

- Strictly avoid alcoholic drinks

Annexure-4

CCC Arrangement template

CCC Number			
Location: Address			
Contact Number:			
Strength: beds			
Nodal Officer : Name & mobile number			
Admin Officer of the institution: Name & mobile number			
Arrangements		**Name and Contact Number**	**Person Incharge**
Medical Staff	Doctors		
	Nursing Staff		
Triage Team			
Housekeeping staff			
Medical Supplies	Medicines and diagnostic equipment		
	PPE and others		
Personal supplies			
Furnishings (beds, linen, etc.)			
Food and drinking water			
Waste disposal including bio-medical waste			
Funds for local expenses			
Ambulance arrangement			
Health checkup protocol and reporting arrangements			
Training of all staff			< .. date .. >
Certification of CCC (ready for operation)			< .. date .. >

Annexure-5

Monitoring Checklist for Covid Care Canter

I. General Information

1. Name of the CCC	
2. Type of CCC Government/Private/ Others(specify)	
3. Address of the Covid Care Facility a. Village/Ward b. Taluk c. District d. State e. Email ID f. Contact no	
4. Name of Nodal Officer and designation a. Email ID b. Contact no	
5. Name of the In charge medical officer/physician a. Email ID b. Contact no	
6. Total number of isolation beds	
7. **Details of CCC**	
a. Is there separate entry / exit for the isolation area?	Yes/No
b.Dedicated space for staff to put on PPE while entering the isolated area	Yes/No
c.Dedicated space for staff to take off PPE near exit?	Yes/No
d.Isolation facility has separate area for isolating symptomatic and asymptomatic cases	Yes/No
e.Is the distance between two beds in isolation wards/rooms more than 1 meter (3 feet)?	Yes/No
f.Is there adequate natural ventilation?	Yes/No
g.Is the facility air-conditioned, does it follow CPWD* guidelines?	Yes/No
h.Are washrooms available as 1 toilet per 20 persons?	Yes/No
i.Is there a separate washroom available for the symptomatic and asymptomatic cases?	Yes/No

8. Logistics		
a. Triple layer mask,	Yes/No	Quantity
b. N-95 Masks		
c. Goggles/Face shield	Yes/No	
d. Examination gloves	Yes/No	
e. Reusable vinyl or rubber gloves	Yes/No	
f. Stethoscope	Yes/No	
g. Sphygmomanometer	Yes/No	
h. Medicines like hydroxy chloroquine sulphate		
i. Dressing material and first aid kit	Yes/No	
j. Oxygen cylinder with tubing/oxygen concentrator	Yes/No	
k. Nebuliser,	Yes/No	
l. Portable ECG machine.	Yes/No	
m. Emergency medicines-Like Atropine, Adrenaline, CPM, Dexamethasone, Cetirizine, PCT, Pantoprazole, Dextrose IV Fluid, RL,NS etc.	Yes/No	
n. Large plastic bags	Yes/No	
o. Disposable waste bags	Yes/No	
p. Collection Bin for used PPE	Yes/No	
9. Infection prevention control		
a. Doctor/ care giver trained on infection control protocols	Yes/No	
b. Functioning hand washing stations (including water, soap and paper towel or air dry) at isolation area	Yes/No	
c. Does the facility have uninterrupted running water supply?	Yes/No	
d. Is there posters to reinforce hand washing and PPE at hand washing stations	Yes/No	
10. Ambulance support		
a. Ambulance facility for transporting patients from isolation area?	Yes/No	
b. List of contact numbers of ambulance service provider displayed at isolation area?	Yes/No	

*For air-conditioning / ventilation, the guidelines of CPWD shall be followed which inter alia emphasizes that the temperature setting of all air conditioning devices should be in the range of 24- 30°C, relative humidity should be in the range of 40-70%, intake of fresh air should be as much as possible and cross ventilation should be adequate.

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Annexure-6

Establishing CCC by private medical establishments in collaboration with hotels/ staying facilities

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COMMISSIONERATE
Health & Family Welfare Services

NO: DHS/PS/77/20-21 Date : 09.07.2020

CIRCULAR

Sub: Establishing of COVID Care Centres (CCC) by private medical establishments in collaboration with hotels/staying facilities

Ref: 1. Circular from Commissioner-HFW regarding guidelines for establishing and managing COVID Care Centre (CCC) dated 22.06.2020
2. Circular by ACS HFW regarding guidelines for isolation of Covid positive person at home dated 04.07.2020

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The private medical establishments which are registered under KPME (Karnataka Private Medical Establishments Act) will be allowed to establish and manage COVID Care Centres for COVID positive persons (followed by triaging by the hospital) in collaboration with hotels/staying facilities. Separate registration or permission for such hotels will not be required but such an arrangement shall be duly informed to concerned District health and family welfare/Chief Health Officer-BBMP officer through a letter/e-mail. This arrangement shall be the joint responsibility of private medical establishment and hotel.

These CCCs in private sector are specially identified hotels/staying facilities where "Asymptomatic/mild symptomatic COVID positive persons" can be kept under optimum medical observation and care till their recovery. Such an arrangement will improve availability of beds in hospitals for those who are moderately or severely affected by COVID-19.

The private medical establishments shall ensure:

1. Guidelines from Government of Karnataka regarding establishing and managing CCC issued from time to time shall be strictly followed (annexure-1)
   a. Ensuring only eligible COVID positive persons are admitted to CCC with due information to district/BBMP health authorities
   b. Availability of medical staff at facility and tele-monitoring as per guidelines
   c. Health monitoring of COVID positive person
   d. Treatment protocol
   e. Availability of medical supplies
   f. Adequate training of CCC staff on infection, prevention protocols
   g. Appropriate diet and ancillary services

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h. Bio-medical waste disposal as per guidelines
i. Discharge protocols
j. Ensure to enter details of CCC, like infrastructure and patients (admitted/discharged) in the software application provided by the state government for monitoring the movement of patients

2. It is important that 24X7 ambulance service is readily available to shift patients whenever necessary

3. All charges of CCC (Category wise package rates) shall be displayed and communicated to the COVID positive person well in advance and there shall be no scope for any conflict in this regard. The maximum ceiling limit for the charges is as follows:

Sl. No.	Type of Hotel	Per day maximum Ceiling
1	Economy/ Budget	Rs: 8,000
2	3-Star	Rs: 10,000
3	5-Star	Rs: 12,000

4. A three tier approach is recommended:
   a. The hotel staff like cooks, back office, admins, etc. shall not come in contact with COVID positive persons
   b. The food delivery personnel and others shall serve Covid positive persons in the rooms under supervision and care
   c. Medical and health staff shall monitor health condition of Covid positive persons thrice daily and shall be available round the clock (24 X 7)

5. The private medical establishment shall ensure daily reporting to District Surveillance officer (DSO) regarding number of persons admitted, discharged, referred and health status. Details of DSOs is attached with this letter as annexure-2

Commissioner
Health & Family Welfare Services
Government of Karnataka

To,

1. Commissioner, BBMP,
2. Deputy Commissioners of all districts
3. CEOs of ZP of all districts
4. DHOs and DSOs of all districts
5. CHO–BBMP

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12. **Information Education Communication (IEC):**
Display charts about COVID-19 Dos and Don'ts shall be prominently exhibited inside the rooms, halls and outside the premises to educate the patients and the residents. Wall mounted TV services may also be provided only with the silent display of news regarding COVID.

The SOP on running CCC is attached with these guidelines

Commissioner
Health and Family Welfare

To
All the RWAs/ADAs through the Commissioner, BBMP.

Copies for kind information:
1. Additional Chief Secretary, Health & Family Welfare Department.
2. Additional Chief Secretary, Urban Development Department.
3. Commissioner, BBMP
4. Mission Director, National Health Mission
5. Deputy Commissioners, Bengaluru Urban & Rural districts.
6. Director, Health & Family Welfare Services.
7. Director, Medical Education

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COMMISSIONERATE

Health & Family Welfare Services

No. COM/HFW/PS/2020-21 Date : 10.07.2020

Guidelines for establishing COVID care centres managed by Resident Welfare Association/Apartments Owners Association /Companies in their own premises

Background:

Government of Karnataka is establishing COVID care centres (CCC) for isolation and management of asymptomatic and mild symptomatic COVID 19 cases in govt/private institutions like Shri Shri Ravishankar ashram, BIEC, Haj bhavan, GKVK, etc. In this context a number of Resident Welfare /Apartments Owners Association have come forward to facilitate home isolation and management of positive persons in their premises for the benefit of residents/communities in their walled/gated community.

In this regard the government has decided to involve the community organisations in the management of mild and asymptomatic COVID-19 positive persons by themselves. It is noteworthy to mention here that various RWAs/AOAs have shown interest for managing COVID Care Centres.

1. **Facilities needed:**

a) Vacant houses, community halls and flats within the apartment(s)/community.
b) Seperate accommodation for women and children.
c) Individual occupancy in a room of 10 x10 feet preferably with attached bathroom and toilet.
d) In the absence of individual rooms, 4 to 6 COVID positive persons shall be accommodated in a hall having attached bath and toilet/s.
e) Temporary partitions of either PVC or side screen shall be provided for individual privacy keeping a physical distance of minimum of six feet between the two beds.
f) Beds, mattresses, furnishings and linens, uninterrupted water and power supply shall be available.
g) Homemade food either from the patient's house or from a common kitchen shall be arranged.
h) Ancillary services like garbage management, sanitation and logistics should be managed exclusively and separately for the COVID block. Especially the biomedical waste shall be treated with 1% hypochlorite solution for a contact period of one hour should be assured before final disposal.
i) If citizens of a group of individual houses in a street or neighbourhood are willing and have an independent unoccupied house or community hall they are encouraged to run CCC facilities akin to RWAS.

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2. **Eligibility for admission in community managed Covid care centre (CCC):**
   All Asymptomatic and mild symptomatic COVID positive persons except the following

   a) > 60 years of age.
   b) With comorbid conditions like hypertension, diabetes, severe obesity, thyroid disease, cancer, kidney diseases include patients on dialysis, heart diseases, stroke, Tuberculosis, People living with HIV, immune-compromised, on steroids and immune-supressants.
   c) Pregnant women and lactating mothers.
   d) Children below 10 years of age.
   e) Any other serious medical/psychological condition.

3. **Medical care at Covid care centre (CCC):**

a) Access to public shall be restricted.
b) The RWA / AOA / Company should have a tie up with medical team (or with a doctor residing in the premises) for triaging & regular clinical support of the patients.
c) Nursing staff will conduct temperature measurement and pulse oximetry, monitor other symptoms, record the temperature and spO_2 with fingertip pulse oxymetery thrice a day, and shall have tele consultation with the doctor for any instructions.
d) Linkage with an affiliated private hospital, dedicated COVID-19 health center or hospital for referring the COVID positive person in case of need.
e) Adequate supplies of PPE Kits, N-95 Masks, triple layered surgical masks, gloves, hand sanitizers, thermal scanners, pulse oximeter, glucometer, BP apparatus, stethoscope, medicines like hydroxy chloroquine, vitamin-C, zinc, etc shall be available.
f) In case of emergency, ambulance services shall be obtained from government ambulance service 108/private ambulance.
g) The COVID positive person shall be under the care of RWAs; attending doctor and staff nurses will all be under the supervision of the jurisdictional MOH/DHO/HD of BBMP or THO/DH & FWO of the department.
h) Data entry – the nursing officer shall maintain patient charts and records (for requisite parameters), and the doctor shall officially verify the record data and advise.

4. **Required amenities for Covid care centre (CCC):**

a) Support staff for food/supervision- will be present 24/7, in two or three shifts designated only for the care of patients in the ratio of 1:12 per COVID positive person.
b) Designated security personnel shall supervise the CCC.
c) 24/7 Electricity with power back up & Water supply.
d) Monitoring facility using CCTV camera installed (optional).
e) Facility for disinfection & sterilization of linen & utensils of COVID positive person.
f) Availability of broadband Internet connectivity with computers and DEOs for providing the COVID-19 patients data.

5. **Daily monitoring and medical supervision of the COVID positive persons by the medical and health team:**

a) Thrice daily temperature & SpO2 recording using fingertip pulse oximeter.

b) 24/7 monitoring by medical officer.

c) Attending to medical and other complaints.

6. **Food and Nutrition:**

a) Nutritious diet should be provided to the patients using the suggested diet plan as per government advice, but catering to the patient's individual tastes, allergies and dietary requirements. Food will be delivered from the concerned patient's home to the Centre for the staff to give to the patients. Disposable Plates and cutlery shall be used.

b) Proper food arrangements three times a day along with snacks for the patients and the nursing staff.

c) Breakfast, lunch and dinner to be provided at appropriate times convenient to the patient by the patient's family.

d) Consumption of tobacco and alcoholic drinks is strictly prohibited.

7. **Ancillary services:**

a) Dedicated area of donning and doffing of PPE for health care workers.

b) Garbage Management inside and outside the COVID Care Centre.

c) To ensure that the biomedical waste generated in the CCC is sent to designate bio-medical processing Centre

d) To ensure complete cleanliness inside and outside the CCC

8. **Testing:**

Covid-19 Testing for the patients should be done as per the testing guidelines issued by the GOK from time to time. Any other test required as per the doctor's assessment should be made available from the nearest health facility.

9. **Daily reporting:**

The CCC will ensure daily reporting of the admissions, release from isolation and medical condition of patients in the software recommended by the state government/report to district surveillance officer (DSO)

10. **Others:**

The RWAs/AOAs shall enter details of CCCs capacity, admission/release of persons in state government software application without fail.

The CCC facility will be used by the local RWA/AOA residents only.

The COVID positive persons shall be allowed to use their laptop, mobile, tablet, books and other reading materials, etc.

11. **Discharge/Release from isolation**

To be followed as per GOK guidelines issued from time to time in consultation with treating doctor.

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12. Information Education Communication (IEC):

Display charts about COVID-19 Dos and Don'ts shall be prominently exhibited inside the rooms, halls and outside the premises to educate the patients and the residents. Wall mounted TV services may also be provided only with the silent display of news regarding COVID.

The SOP on running CCC is attached with these guidelines

Commissioner
Health and Family Welfare

To
All the RMAs/ADAs through the Commissioner, BBMP.

Copies for kind information:

1. Additional Chief Secretary, Health & Family Welfare Department.
2. Additional Chief Secretary, Urban Development Department.
3. Commissioner, BBMP
4. Mission Director, National Health Mission
5. Deputy Commissioners, Bengaluru Urban & Rural districts.
6. Director, Health & Family Welfare Services.
7. Director, Medical Education

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ANNEXURE-B

सत्यमेव जयते

Select Language: English

Public Authorities Available

RTI Online

Version 2.0

An Initiative of Department of Personnel & Training, Government of India

Final Status of CSIRH/R/T/20/00024

Applicant Name	JAGDISH CHANDA
Date of receipt	26/04/2020
Request Filed With	CSIR Hqrs.,New Delhi
Text of Application	Please provide the guidelines of the present social distancing measures advised by your organisation that we have to follow. And based on which research paper or papers these guide lines have been framed. How many meters apart we the people will stay away from each others. When the thermal scanners were first started in India for novel corona virus positive patients (henceforth will be called as covid-19 patients) detection purpose. Were the thermal scanners made for Industrial purpose or clinical purpose or both types were used. What are the tolerance limit of temperature range of these thermometers. At what distance range these thermal scanners are being suggested to use. Were these distance range followed for 100% of people in all the airport and at other places where these measures of thermal scanning were taken. If not what is approximate guess that you predict that covid 19 positive patients have been let go undetected and spread the virus. What are the authenticity of RT PCR Test KIT that is being used for detecting covid-19 positive cases.Please inform whether these test kit are procured from which companies and which countries. Do the suppliers manual of these test kits have regulatory status saying the test kit is for research uses only and not for diagnostic purpose. If yes then on what basis these tests are used for detecting covid -19 positive patients. how many maximum tests per patients are scheduled to be done for getting confirmation. if a patient gets positive on first test and then does he or she have the option to do repeat tests. If on repeat tests he or she comes negative will it be considered negative. Is it true that these test of RT PCR KIT cam result up to 50% false positive cases. If yes why it is not being discontinued immediately please explain in detail. If a covid 19 positive patient with his own free will decides to choose Ayurveda or Homeopathy or Unani treatment and decides not go for traditional allopathy treatment will he be allowed to choose that. If not what are the basis of that. What are the laws based on which that option is not given to that patient. Is it not a violation of his or her fundamental right. What are the treatment protocol decided for the covid-19 patients. What are the proven research data based on which these treatment protocol has been framed.
Request document *(if any)*	document not provided
Status	REQUEST DISPOSED OF as on 07/05/2020
Date of Action	07/05/2020
Remarks	Reply :- Ref: Application no. T- 00024 of Shri Jagdish Chandra The requisite information Received from concerned custodian of information ie. Mission Directorate is as under : Point no. 4 :- Individuals have limited options as corona virus has been declared pandemic. A patient may infect other in community so he is not allowed any other option than modern medicine. Remaining points of your RTI application pertain to CSIR-NCL, CSIR-CCMB & DGHS, so that your RTI application has been transferred to CSIR NCL, CSIR CCMB & DGHS u/s 6(3) of RTI act 2005. You are requested to contact CPIO/FAA of above mentioned three separate Public Authority in case of appeal. If you are not satisfied with the above information you may file first appeal to the first Appellate Authority with in 30 days from the date of this information. The address of First Appellate Authority is as under. Shri A K Kundalia Senior Principal Scientist & First Appellate Authority CSIR Anusandhan Bhawan 2 Rafi Marg New Delhi 110001 Phone no. 23470313, email akk@csir.res.in Yours faithfully (Sanjay Kumar)

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DS and CPIO
Date: 07.05.2020

Print

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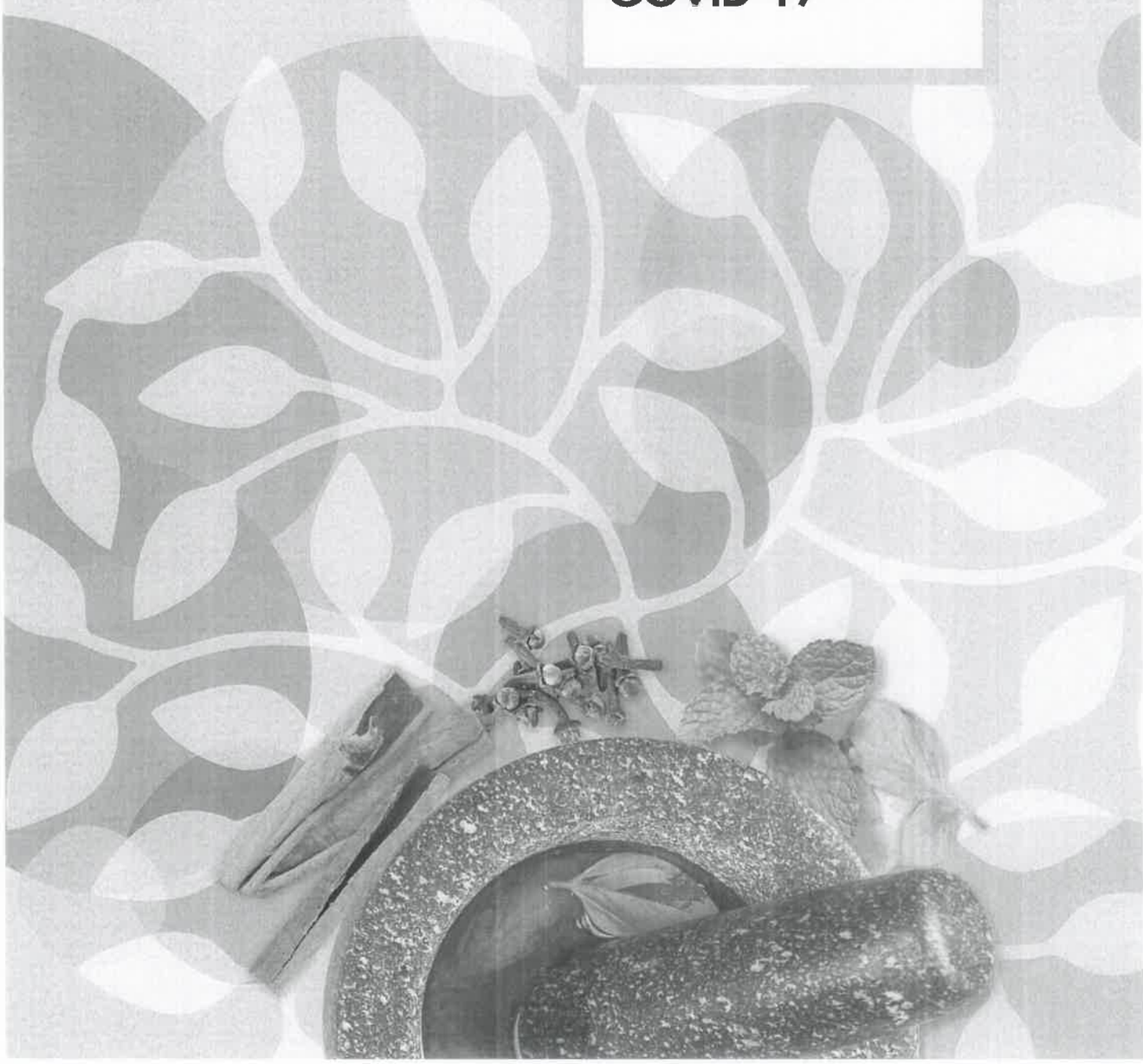
ANNEXURE-C

Government of India
MINISTRY OF
AYUSH
भारत सरकार

GUIDELINES
for
AYURVEDA
PRACTITIONERS
for
COVID 19



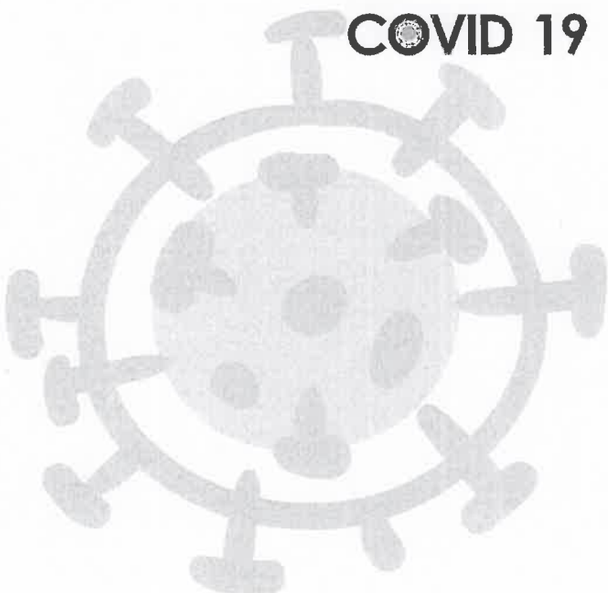
GUIDELINES

for

AYURVEDA PRACTITIONERS

for

COVID 19



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CONTENTS

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Flow chart of protocol of management of COVID -19

Target Group 1: Quarantine and Home isolation subjects with or without Corona positive test and health workers

Target Group 2: Subjects with Mild, Severe Symptoms, Comorbid & Immuno-compromised condition

Target Group 3: Vulnerable group (Pregnant & Lactating women, Children & Geriatric subjects)

Target Group 4: Post treatment restorative healthcare

COVID 19 Management based on Target groups & Interventions

Preventive

Target Group 1

General public & Health workers

Suspected and quarantined

Immuno-compromised

Therapeutic

Mild (Fever/URTI)

Target Group 2

Mild with co-morbid conditions

Conventional Management + Add on Target Group 2

Mild with Vulnerable population

Target Group 2 + 3 + Conventional support

Moderate

(Pneumonia with no signs of severe disease)

(RR 15 to 30/min. SpO2 90%-94%)

Target Group 2 + Conventional Management

Moderate with co-morbid conditions

Conventional Management + Add on Target Group 2

Moderate with Vulnerable population

Conventional support + Target Group 2 + 3

Severe

(RR >30/min, SpO2 less than 90%)

Conventional Management + Add on Target Group 2

Severe with co-morbid conditions

Conventional Management + Add on Target Group 2

Severe with Vulnerable population

Conventional + Add on therapy with Target 2 + Target 3

Promotive

Target Group 4

Post Recovery Maintenance

(To prevent recurrence and health restoration)

Target Group 4 - For all category

Stand alone Management

Stand alone with Target Group 2 Management

Conventional Management along with Target group 2 Management

Target Group 2 + 3 and Conventional Management

Conventional Management and Target Group 2 + 3 as add on therapy

Stand alone therapy in Target Group 4

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Preamble

In the wake of COVID 19, an infectious disease caused by a newly discovered coronavirus, entire mankind across the globe is suffering. Till date, no medicine or therapy has demonstrated promising results in either preventing the disease or improving its prognosis to prevent this infection. The best ways of preventing COVID19 infection are breaking the chain, enhancing an individual's body immunity, identifying the infection early and timely medical care. The Ministry of AYUSH is committed to help the nation with the large resource of time-tested traditional knowledge practiced in this continent for the benefit of mankind. The Ministry has already published a series of measures to improve individual's natural defence system (immunity) in addition to the personal hygiene and social distancing measures.

Ayurveda documented epidemics/pandemics under the context of Janapadodhvamsa (conditions devastate the human settlements). Similarly, infectious diseases have been considered under Sankramika rogas. Pollution of air, water, climate and environment is responsible for the spread of diseases on such a large scale resulting in Janapadodhvamsa. Causes of vitiation of air, water, climate and place along with their characteristics have been enumerated in classics[1]. Improper disposal of waste, distribution of polluted water, air pollution, indulgence in unhealthy and unwholesome activities, failure of judgment and misunderstanding of situation etc. also result in reasonable damage to the health of the society; ultimately leading to Janapadodhwamsa. Such conditions will manifest in symptoms like cough, breathlessness, fever etc[2]. In Ayurveda, initial phases of the manifestation can be comparable to AgantujaVataKaphajaJwara. Uncontrolled conditions, further vitiate other Doshaas and other Rasa, Rakta, Mamsadi dushyas thus entering into Sannipataja condition.

This document "Protocol for Ayurveda Practitioners" is a guideline for the use of registered Ayurveda Practitioners only. There are four sections covering the whole spectrum of COVID 19 infection management. The draft deals with the symptomatology in these three stages:

1. 1st stage – Swasa-Kasa symptoms with Jwara (COVID 19 positive or negative with mild symptoms)
2. 2nd stage – Vata-Kapha pradhan Jwara (Fever) (COVID 19 positive with specific symptoms at moderate level)

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3. 3rd Stage – Vata-KaphajaSannipatikaJwara(Fever)(COVID 19 positive with severe symptoms with respiratory distress etc.)

Segmentation of subjects - Target Groups and management principle

	Target groups	Treatment
1	Target Group 1: Quarantine and Home isolation subjects without Corona positive test and health workers	Preventive treatment
2	Target Group 2: Subjects with Mild, Severe symptomatology , Co-morbid and Immuno-compromised conditions	Symptomatic treatment
3	Target Group 3: Vulnerable Subjects (Pregnant &Lactating women, Children, Geriatric subjects)	Integrated Care (Ayurveda management along with existing medicines under regular observation)
4	Target Group 4: Post treatment restorative healthcare	Treatment for recovery and Rejuvenation

All the standing instructions issued by Health authorities (Ministry of Health & Family Welfare, World Health Organization and state and local health authorities) are to be adhered completely and Ayurveda Management may stand as 'ADD ON' to the present contemporary line of management.

The medicines recommended here are based on Essential Drugs List, Standard Treatment Guidelines, Ayurvedic Pharmacopoeia of India, Ministry of AYUSH Govt. of India along with considerations from other recommendations issued by various health authorities across India. The practicing Vaidya has to have his/her own discretion in selecting medicines based on the stage of the disease, symptom complex and availability of the drugs in their locality. Use of Mask, Hand Sanitization, Social/Physical distancing to break the chain healthy nutritious diet and measures of improving immunity and all other general health care measures are to be advised as per the guidelines issued by health authorities from time to time.

General Disclaimer

- *Physicians have their own discretion to select drugs based upon the stage of the disease, symptom complex and availability of the medicines in his locality.*
- *Patients need to have a general consultation/advice of qualified physicians before starting any intervention.*
- *Drug allergy and Herb-Drug Interaction information wherever is anticipated, consultant physicians has to take care of this.*
- *Use of drugs in vulnerable populations is at the prudence of the consulting physician.*
- *Physicians have to document the cases of treating patients in the format specified. (CRF)*
- *Drugs mentioned in the guidelines are to be used with caution during pregnancy.*
- *Dose for children should be adjusted according to age.*
- *In all severe cases and life threatening conditions, immediate medical care should be provided and, Ayurvedic drugs may be used as adjuvants along with contemporary management with proper consent procedures.*
- *Patients in whom already some medications are going on for health issues such as hypertension, diabetes, cancer-chemotherapy etc. are to be continued.*
- *While selecting the medicines, Physicians are should be cognizant as to refrain from prescribing sugar containing dosage forms for diabetics and high fat/salt containing formulations for hypertensive and so on prescribe sugar containing dosage forms in Diabetes patients, high fat/salt containing drugs in patients of hypertension etc.*

Target group 1

Quarantine and Home isolation in subjects with COVID positivity, it would not be prudent to give only preventive care or without Corona positive test and health workers

Ayurveda's intensive information on preventive care drives through the vastness of Dinacharya (daily regime) and Ritucharya (Seasonal regime) to maintain healthy life. The simplicity of awareness about oneself and the harmony each individual can achieve by uplifting and maintaining their immunity is highly emphasized across Ayurveda's classical scriptures. Further, Ayurveda emphasizes on PREVENTION first. In that direction Svasthahitadravyas (recipes for healthy) have been indicated in the form of Rasayana&Vajikarana. Ojus is considered as responsible for Vyadhikshamatva (immunity). It is achieved by two approaches viz., VyadhiBalaVirodhitva&Vyadhyutpadaka Pratibandhakatva. Among them Vyadhibalavirodhitva is achieved by improving the immunity of an individual's body, while Vyadhyutpadaka Pratibandhakatva is created by using recipes which are specific in preventing disease.

Awareness about the mode of spread of this disease is highly recommended to prevent oneself from falling prey to the same. As per WHO advisory, people can get infected by COVID-19 from others who have the virus. The disease can spread from person to person through small droplets that are spread when an infected person coughs or sneezes.

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1.1 Preventive Measures

1. Stay aware of the latest information on the COVID-19 outbreak available on official websites of national public health authorities. Follow advice given by your healthcare provider, your national health authorities or your employer on how to protect yourself and others from COVID-19.

2. Hygiene

a) Wash hands frequently with an alcohol-based hand rub or wash them with soap and water. Washing hands with soap and water or using alcohol-based hand rub kills viruses that may be on hands.

b. Physical touch and shaking hands to greet are to be avoided.

c. Spitting in the public is discouraged.

d. Frequent touching of eyes, nose and mouth that can pick up viruses is to be avoided. Once contaminated, hands can transfer the virus to your eyes, nose or mouth. From there, the virus can enter your body and can cause infection.

e. Usage of gloves can be encouraged whenever possible.

f. Practicing good respiratory hygiene is to be encouraged. This means covering mouth and nose with bent elbow or tissue paper / handkerchief when one cough or sneeze. After coughing or sneezing dispose of the tissue paper / wash the handkerchief.

3. Social Distancing

a. Advice maintaining social distance of at least 1 meter (3 feet) with anyone who is coughing or sneezing. Advice also not to go into crowded places like parks, markets and religious places.

b. Advice to stay home to the best possible extent and reschedule traveling, if any.

c. If anyone has fever, cough and difficulty breathing, advice to consult a physician immediately and all instructions are to be followed meticulously.

4. Additional care is to be observed in case of elderly, children, or if the individual is immunocompromised or with comorbidities or in case of women during and after childbirth.

5. **COVID-19 positive women** can breastfeed if they wish to do so. They should be encouraged to practice all hygienic / preventive measures mentioned above.

6. **DIET:** Proper nutrition is to be ensured through freshly cooked hot food considering individuals digestive power.

Intake of comfortable warm fluids boiled with medicinal herbs (preferably Shunthi, Dalchini, Trikatu) should be used as a regular drink to maintain hydration.

- Freshly prepared Laghu-supachyaahara (easily digestible, light diet).
- Preferable vegetables are Shigru (Moringa Oleifera Lam), Karvellaka (Momordica Charantia Linn), Patola (Tricosanthes dioica. Roxb), Mudga (Vignaradiata (L.) R. Wilczek), Patha (Cissampelos parietal Linn.), Vaastuka(Chenopodium album L.), Jivanti (Leptadenia reticulate (Retz.) Wight &Arn), Tanduliyak (Amaranthus spinosus L.), Kakamachi (Solanumnigrum Linn), Draksha (Vitis vinifera L.), Kapittha (Feronia limonia (Linn.)), Dadima (Punica granatum Linn), Lashuna (Allium sativum L.) etc. are to be taken. (Ref: Yoga Ratnakara, Jwara Chikitsa, By Vaidya Lakshmipati Shastri, Chaukhamba Prakashan Varanasi, Edition 2018, Pg no. 251-253 & Govindadasa. Bhaishajya Ratnavali. Shastri RD, editor. 18th ed. Varanasi: Chowkambha Samskrita Samstana; 2005. Jwara Adhikara)
- Restrict use of sweet food items sweets and food which is heavy to digest. (Yoga Ratnakara) Also advise not to use chilled, fried, oily, fermented food items, cold and refrigerated food / beverages.

7. Cope up with stress.

It is normal to feel stressed, scared or angry during the lockdown period. Talking to people can help to cope with stress. Contact friends and family as frequently as possible.

Encourage maintaining a healthy lifestyle. Proper diet, sleep, exercise and social contacts with loved ones at home and by email and phone with other family and friends can be encouraged.

Also encourage reading books, listening to light music as per the interest to counter stress.

Avoid smoking and consumption of alcohol or other drugs to deal with stress. Consultations can be provided, if physical and mental health needs are required.

Child's reactions are to be encouraged to be addressed in a supportive way. Let their concerns be listened carefully and extra time, love and attention to be given.

8. **Exercise and meditation,** daily practice of Yogasana, Pranayama for at least 30 minutes as advised by Ministry of AYUSH is to be practiced.

9. **Adequate sleep** of 7-8 hours at night is essential and should be encouraged. Preferably, advice to avoid day time sleep.

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10. If any comorbidities exist; medicines as prescribed are to be encouraged to be taken under supervision. Avoid self-medication.

11. Seasonal regimen (Rutucharya) under the consultation / supervision of Ayurveda Physician is always to be encouraged.

12. Usage of adequate Personal Protective Equipment (PPE) during medical practice as advised by health care authorities is to be encouraged.

1.2 Contemporary Guidelines:

WHO has adapted guidelines for the clinical management of severe acute respiratory infection when SARS-CoV 2 infection is suspected. It is intended for clinicians involved in the care of adult, pregnant, and paediatric patients with or at risk for severe acute respiratory infection (SARI) when infection with the COVID-19 virus is suspected[1].

1.3 Immunity Enhancers - Single Drugs:

1. Guduchi[2] Consuming 500 to 1000 mg of aqueous extract of Guduchi (Tinospora cordifolia (Thunb.Miers)
2. Amla[3] Consumption of fresh Amla fruit (Indian gooseberry – Embilica officinalis L/ Phyllanthus emblica L) or Amla candy is also advisable.
3. Haridra[4] Gargling with warm water added with turmeric powder (Curcuma longa L) and a pinch of salt or Turmeric (Curcuma longa L)
4. Tulasi[5] Frequent sipping of water processed with Tulsi (basil leaves – Ocimum tenuiflorum L Merr (synonym Ocimum sanctum L) is advised.
5. Ashwagandha root powder 3-5gm twice a day with warm milk or water/ ashwagandha extract 500mg twice a day with warm water

1.4 Immunity Enhancers - Formulations:

- CHYAWANPRASH AVALEHA[6] - 10 - 12 gm / 1 Spoon
- DRAKSHAVALEHA - 10 - 12 gm / 1 Spoon
- INDUKANTAM GRUTHAM - 10 - 12 gm twice daily before food, when hungry
- ARAVINDASAVA - 15 - 20 ml with equal quantity of warm water after food
- BALACHATURBHADRA CHURNA - 1 - 2 gm with honey
- HARIDRA KHANDA - 3 - 5 gm intermittently with honey/ warm water

1.5 Lifestyle Tips (Dinacharya) For Boosting Immunity

Early Morning Regime (4.30am to 8.30am)

- Wake up between 4:30 - 5:00 in the morning or 45 minutes before sunrise.
- Drink 1-3 glasses of warm water
- Gandusha / Kavala (Oil Pulling) 1 tablespoon of sesame or coconut oil for Kavala followed by warm water rinse.
- Gargle with warm water added with a pinch of turmeric and salt, Triphala, and Yashtimadhu. ShuddhaTankana (2% aqueous solution), Madhoodaka (5% aqeuous solution) also can be used for Kavala graha.
- Nasal Health – Pratimarsha Nasya (2 drops of sesame / coconut oil each nostril).
- Daily practice of Yogasana, Pranayama and meditation for at least 30 minutes as advised by Ministry of AYUSH
- Warm water bath

After Noon Regimen

- Don't sleep during the daytime
- Involve in Work from Home/Indoor recreational activities like Studies, Reading, Painting, Gardening, Playing-listening Music, Social Media etc.

Evening Regimen

- Meditation / Pranayama – 30 minutes
- Indoor Recreational Activities

Dietetic Rules

- Eat only when hungry, in the appropriate amount according to the digestive power (Neither too less nor more).
- Always take a fresh & warm diet.
- Eat easily digestible foods.
- Eat a night meal 3 hours after sunset or till 8 pm.

Sleep atleast 2-3 hours after dinner. Adequate sleep is very important for health.

1.6 Other General Measures:

Dhupana - (fumigation) of the house every evening with antimicrobials such as Neem leaf, Sarshapa (Brassica campestris L), Loban (gum bezamin/benzoin - StyraxbezoinDryand), Karpura (Cinnamomum camphora (L) J.Presl.), Ghee etc. Also usage of Aparajita Dhooma Choorna (A.h. Jwara Chikitsa) as per availability can be adopted.

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Target group 2

Subjects with Mild, Severe Symptoms

Comorbid & Immuno-compromised conditions

2.1 Management of Mild Symptoms

Sore throat is one of the main features or the first clinical presentation of the COVID 19 infection among clinical features of the disease. It is followed by fever, myalgia, dry cough, dyspnea in mild state and severe dyspnea of Pneumonia in severe state, multi-organ failure followed by fibrosis of lungs and death. A small percentage of cases are asymptomatic and some uncommon clinical manifestations include loss of smell and taste (Rasa-Gandha Bodha Nipata).

Showing Stages and Medicines with Doses for Mild Symptoms

Stages	Clinical Presentation	Medicines		Doses** & Timing
Uncomplicated illness	Fever, cough, sore throat, nasal congestion, malaise and headache	First Line (Jwara-Angamarda Predominant)	• Mahasudarshana GhanVati -	500mg –TDS
			• Sanjeevani Vati*	125 mg TDS
			• Samshamni Vati	500 mg TDS
			• Talishadi churna+ • Yastimadhu churna	2 g +1g- TDS
			• Sitopaladi churna	3G –TDS
			• Lozenges- Vyoshadivati*/ • Lavangadivati/ • Yashtimadhughanvati	2 tab –TDS
			• ChaturthakaJvaraharakwatha(Giloya stem either dry or wet - 5gms+ Amalaki-Dry-5gms+ Nagarmotha-5gms decoction with 200ml of water and reduced it up to 100ml) • PathyadiKashayam /GuduchyadiKashayam / BharangyadiKashayam	- 10 gm boiled in one glass of water , reduced to half BD empty stomach
		Second Line (Shwasa Kasa Predominant)	• Trikatu Siddha jala*	3g boiled in 1 liter of water
			• Vyaghri Haritakileha * • Agastya Rasayana • Kantakari Avaleha *	10gm –BD
			Gargle with warm water mixed with rock salt and turmeric	QS
			• Amritarishta	20 ml-BD with equal amount of water
			• Shadanga –paniya	
			• Gargling with YashtimadhuPhanta -3 to 4 times daily (200 ml lukewarm water + 5gms Yashtimadhuchurna)	QS
			• Shwasakuthara Rasa + NaradiyaLakshmivilasa Rasa	250 mg each with Honey TID
	For Myalgia		• Ashwagandharishta and / or Balarishta • Rasnasaptakakwatha*	15-20 ml with equal amount of water three times a day - 10 gm boiled in one glass of water , reduced to half BD empty stomach
Mild Pneumonia	Difficulty in breathing/ fast breathing >40 breaths/min	First Line	• Dhanwantara Gutika	2 tablets with Jeeraka water
			• Sameerapannaga Rasa* / Shrungarabhra Rasa	250mg – BD with honey
			• Marsha Nasya* (Shirovirechana) with AnuTaila / Shadbindu Taila / Sarshapa Taila	dose as per age
			• Steam inhalation with Ajwain / Pudina / Eucalyptus oil	Once/ twice in a day
		Second Line	• Somasava*	10 ml – BD mixed with equal amount of water
			• Dashmularishta*	20 ml – BD mixed with equal amount of water
		Second Line	• Dashamoolakwatha* with Pippalichoorna prakshepa (1gm)	10 gm boiled in one glass of water , reduced to half BD empty stomach

* Not for pregnant and lactating women
** Dose shown here are adult dose, for children it is to be converted to child dose, as per age

All the patients should be advised to take Rasayana drugs as given in this guideline along with the addition of Deepana and Pachana drugs.

Note: Ushna and Teekshna drugs, drugs having contraindication in pregnancy are not to be prescribed to pregnant ladies.

2.2 Management Guidelines for Severe Symptoms Disclaimer:

The below medicines are recommended with or without the conventional medicines as per the condition/decided by the physician.

Prescribed Medicines for COVID 19 cases

1. Uncomplicated Cases	Prescribed Medicines
1.1 Fever (Jwara)	1. MahaSudarshanghanVati*- 500 mg TDS with lukewarm water 2. Amritarista 15-20 ml tid with water after food 3. Amritottara Kashaya 15 ml tid with water before food 4. Vishamajwarantakalauha* with gold - 125 mg bid with water - High fever with debility 5. Mrityunjaya rasa* - 125 mg tid with water - Uncontrolled fever with myalgia 6. Samshamanivati 500 mg. 2 tab BD after food 7. ArkaYavani* - 10 – 25 ml QID with water - Deepanapachana Jwara, Aruchi 8. Pathyadi Kashayam* /Guduchyadi Kashayam / Bharangyadi Kashaya* - freshly prepared 30 – 40 ml BD before food 9. Chaturthaka Jvaraharakwatha(Giloya stem either dry or wet -5gms+ Amalaki-Dry-5gms+ Nagarmotha-5gms decoction with 200ml of water and reduced it up to 100ml) 10. Tribhuvanakirti rasa* 125 mg BD after food with shunthijala or water 11. Bilwadivati 1 TDS

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1. Uncomplicated Cases	Prescribed Medicines
1.2 Sore throat	1. Vyoshadivati/ LavangadiVati/ Khadiradivati -2 tab TDS 2. Laxmivilasa rasa 125 mg tid with tamboolaswarasa after food
1.3 Nasal congestion (Pratishyaya)	1. Haridrakhand- 3 - 5 gm BD with lukewarm water/ milk 2. Laxmivilasa rasa 125 – 250 mg BD with tamboolaswarasa after food
1.4 Myalgia (Parshwa - shoola, Shirashoola, Angamarda)	1. Rasnasaptak*- Kwath- 30 - 40ml BD before food 2. Ashwagandharista 15 – 20 ml BD with water 3. Balarishta 15 – 20 ml BD with water 4. Devadaryadikwatha* 30 - 40 ml BD before food 5. Dashamoolakwath* 30 - 40 ml BD before food 6. Godantibhasma 500 mg – 1 gm BD/TDS daily with ghee, sugar, warm milk or water
1.5 Cough (Vataja Kasa)	1. Talisadi Churna (4 g)+ Madhuyashtichurna (2 g) BD with honey/ lukewarm water 2. Sitopaladichurna 3-6 gm with honey BD/ TDS or as required 3. Tankanabhasma* – 250 – 500 mg BD 4. Dashamoolakatutrayadi Kashaya* 20 – 30 ml TDS with water before food
1.6 Dehydration features (Trishana due to Jwara)	1. Shadangapaneeya 40 ml tid/as per requirement

2. Pneumonia – Shwasapradhanakasa

1. Sanjeevanivati*- 125mg TDS/ Gorochanadivati*- 125 mg TDS with luke warm water
2. Somasav/Pushkaramoolasava*- 10 – 20 ml with equal amount of water BD
3. Talisadi (4g)+Madhuyashtichurna (2gms) + Sameerapannaga rasa* 125 mg- twice in a day with honey / luke warm water
4. Pushkaramoolasava 15 – 20 ml BD/TDS with equal water
5. Agastya Haritaki*/Vyaghriharitaki*/Chitrakaharitaki Avaleha* – 10 – 12 gm BD after food with water
6. Kantakariavaleha*10 – 12 gm BD after food
7. Dashamoolakatutrayadi Kashaya* 20 – 30 ml TDS with water before food
8. Vasakasava* 15 – 20 ml TDS with water after food
9. Bharangyadikwatha* 30 - 40 ml BD before food
10. Chandramrita rasa* – 250 mg BD with honey or tamboolaswarasa or vasa swarasa or ardrakaswarasa

3. Acute Respiratory Distress Syndrome - Shwasa

1. Inhalation with Karpoora and Nilgiritaila
2. ShwasKuthar Rasa* (125 - 250 mg) with Kantakari* (2 g) and pippalichurna (1 gm) given with mustard oil and jaggery
3. Mallasindoora* 125 mg + Talisadichurna 3gms + Shringabhasma 125 mg+ Abhrakabhasma 125 mg, with honey BD after food
4. Local application of saindhavaditaila to chest followed by Nadiswedana

4. Immunocompromised conditions – Reduced Vyadhikshamatwa

1. Samshamani Vati 500 mg tablet, 2 tablet BD after food
2. Agastya Haritaki Rasayana* 10 -12 gm BD after food
3. ChitrakaHaritaki Rasayana* 10 -12 gm BD after food
4. Chayavanaprashavaleha 10 -12 gm BD after food
5. Bramha Rasayana 10 -12 gm BD after food

6. Swarnamalinivasanta rasa 125 mg BD after food with water
7. Guduchi Rasayana

**Contraindicated in Pregnancy and lactating women*

2.3 Co- morbidities

2.3.1 Diabetes

If Diabetes is associated with the above symptoms, the following medicines may be prescribed in addition to existing medicines being consumed (Ref. Above Table)

- Nishamalaki Churna + Musta Churna – 3-6 gm BD with water before food
- Jambuchruna* 3 -6 gm with water before food
- Guduchichurna 3-6 gm with water before food
- VasantaKusumakara Rasa - 125 – 250 mg BD with water after food
- Abhrakabhasma 125 – 250 mg twice a day with honey or ghee or triphalakwatha or guduchiswarasa or ardrakaswarasa
- Other medications as per symptoms mentioned in point number 1.1 - 1.6, 2, 3

*** Avoid Talishadi and Madhuyashti Churna & somasava*

2.3.2 Cardio-vascular diseases

In case Cardio-vascular diseases are associated with the above symptoms, the following medicines may be prescribed in addition to above medicines (Ref. Above Table)

- Ashwagandha Churna (3 gm)+ Arjuna Churna (3 gm)- BD with milk/water before food
- Prabhakar Vati* 125 – 250 mg- 1 TDS after food - In patients with history of IHD/MI
- Hridayarnava rasa* 125 mg BD after food
- Arjunarista 15 – 20 ml BD with water after food
- Saraswatarista 15 – 20 ml BD with water after food
- Kooshmanda Rasayana 10 -12 gm BD

- Dhanwantargutika* 250 – 500 BD with decoction of Jeeraka or warm water
- Sarpagandhaghanavati* 250 – 500 mg OD/BD a day with milk or water
- Navajeevana rasa* 62.5 – 125 mg BD a day with milk
- Other medications as per symptoms mentioned in point number 1.1 - 1.6, 2, 3

2.3.3 Renal diseases

In case Renal diseases are associated with the above symptoms, the following medicines may be prescribed in addition to above medicines (Ref. Above Table)

- Dashamula Kwath* (freshly prepared 30 - 40 ml) BD before food
- Varunadikwatha* - freshly prepared 30 – 40 ml BD with water - For renal compromised condition
- Trinapanchamoolakwatha – freshly prepared 30 – 40 ml BD - For renal compromised condition
- Chandraprabha Vati* 2 tablets (250 mg) BD/TDS after food with water
- Shilajitwadi Lauha (250mg)- BD before food with warm water
- Vettumaran Gulika* 250 – 375 mg twice or thrice daily with warm water
- Other medications as per symptoms mentioned in point number 1.1 - 1.6, 2, 3

**Contraindicated in pregnancy and lactating mother*

2.4 Preferable Diet

- Eat freshly prepared warm food when hungry.
- Liquids – Instead of Tea, either of the following are advised
  - Herbal tea prepared from ½ inch ginger + 2 Black pepper + ¼ cinnamon or lemon grass, tulsi leaves in 2 cups boiled water reduce it to 1Cup & add honey 1 teaspoon
  - 1 cup hot cow's milk + dry Ginger powder/Haridra ½ teaspoon
- Cereals – Shalishashtika (Old Rice) / Laja/ Godhuma (Wheat) / Yava (Barley)
- Pulses - Mudga (Phaseolus radiatus Linn), Masur (Lens culinaris Medic), Kulattha (Dolichos biflorus Linn.), Chanaka, Moth
- Vegetables - Vaartak (Solanum melongena L), Karkotak(Momordica dioica Roxb. ex Willd.), Shigru (Moringa oleifera Lam), Karvellaka

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(Momordica charantia Linn), Patola (Tricosanthes dioica. Roxb), Patha (Cissampelos parieta Linn.), Vaastuka (Chenopodium album L.), Jivanti (Leptadenia reticulata (Retz.) Wight &Arn), Tanduliyak (Amaranthus spinosus L.), Kakamachi (Solanum nigrum Linn), Guduchi (Tinospora cordifolia. (Thunb.) Miers.)

- Fruits - Draksha (Vitis vinifera L.), Kapittha (Feronia limonia (Linn.)), Dadima (Punicagranatum Linn) can be taken.
- Condiments and spices: Cardamom/dry ginger/ black pepper/ long pepper/ garlic

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Target group 3

Vulnerable Group (Pregnant & Lactating women, Children & Geriatric subjects)

3.1 Introduction

Children, pregnant women, elderly people, malnourished people, and people who are ill or immune-compromised, are particularly vulnerable to any health disasters and they face relatively high risk of the disease burden associated with emergencies. These groups of population need special care in terms of prevention and management. The best way of prevention is boosting the immunity and here are some proven immune boosters or Rasayana drugs which can be prescribed to the vulnerable groups. Postpartum and lactating women may continue with feeding the baby, and a prophylactic dose may be given to breast fed children also.

These vulnerable groups, if they fall in suspected, quarantine or isolated cases with or without Covid 19 test positive mild or severe symptoms, the management is the same as described in Target Group 2.

The following are some of the commonly prescribed Rasayana medicines in each category, however Physicians should confirm the absence of fever and other symptoms and the appetite is improved, if appetite is poor Deepana and Pachana drugs may be added.

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3.2 Rasayana for Children

- Indukanta Ghritam– 5 – 10 ml in two divided doses with warm milk
- Kalyanaka Ghrita 5 – 10 ml in two divided doses with warm milk
- Aravindasavam - 5 – 15 ml in two divided doses with warm water after food.
- Balachaturbhadra Churna - 1-2 gm dose with honey two times a day

Dose of medicines in Children

- Above 15 years - Adult dose
- Between 10-15 years - ¾ of Adult dose
- Between 5-10 years - ½ of Adult dose
- Below 5 years - ¼ of Adult dose

Specific Dose calculation:

Child dose = (Adult Dose /16) X Age of Child

3.3. Rasayana for pregnant and lactating women

The following drugs may be used specifically in pregnancy and lactating women:

- **Phala Sarpis*** - 10 - 12gm in two divided doses with warm water
- **Kalyanaka Ghrita*** - 10 - 12gm in two divided doses with warm water
- **Ashwagandha Rasayana*** - 10 -12 gm twice daily with warm milk.
- **Soubhagya Shunti Leha*** - 10 - 12 gm twice daily with warm milk in empty stomach
- **Daily use of Milk with Ghee** (cup of milk with a teaspoon of ghee)
-

**Disclaimer – The Rasayana drugs should be consumed after recovery from the fever and once Agni is stabilized during pregnancy*

3.4 Rasayana for Geriatric subjects

The following Rasayana medicines may be administered in elderly population such as-

- **Chayvanaprasha Avaleha** - 10 - 12 gm twice daily with warm milk.

- **Ashwagandha Avaleha** - 10 - 12 gm twice daily with warm milk.
- **Brahma Rasayana** - 10 - 12 gm twice daily with warm milk.
- **Daily use of Milk with Ghee** (cup of milk with a teaspoon of ghee)
- **Shilajeet Rasayana** [prepared by giving 7 times Bhavana of all the medicines - Triphala, Musta, Guduchi (Tinospora Cordifolia), Pippali etc.) -Ref. A. H. 39/133-142]
- **Khadiradi Rasayana** [Ref. A. H. 39/152]
- **Shatavari Siddha Ghrita** [Ref. A. H. 39/156]

The following Rasayana Yoga in Vardhamana Krama may also be advised with strict supervision of attending Physician:

- **Vardhamana Pippali Rasayana** [Kasa, Shwasa, Galagraha, Vishama Jwara -Ref. A. H. 39/101-102]
- VardhamanaGuduchi Rasayana [Ref. A. H. 39/104-105]
- **Vardhamana Musta Rasayana** [Ref. A. H. 39/104-105]
- **Vardhamana Triphala Rasayana** [Ref. A. H. 39/104-105]

3.5 Rasayana for immune-compromised subjects

1. Samshamani Vati 500 mg tablet, 2 tablet BD after food
2. Agastya Haritaki Rasayana* 10 -12 gm BD after food
3. Chitraka Haritaki Rasayana* 10 -12 gm BD after food
4. Chayavanaprashavaleha 10 -12 gm BD after food
5. Bramha Rasayana 10 -12 gm BD after food
6. Swarnamalinivasanta rasa 125 mg BD after food with water
7. Guduchi Rasayana

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Target group 4

Post treatment restorative healthcare

4.1 Introduction

Along with the daily spikes in confirmed coronavirus cases and deaths, a third, more hopeful number is also ticking upward: the number of people who have recovered from COVID-19. Public health experts have said covid-19 is unique and complex. The growing number of recoveries comes with a growing number of questions about what it means to overcome COVID-19: about a patient's contagiousness, subsequent immunity to the disease, and long-term effects. Much about the aftermath of the illness remains unclear or unknown, and there is even uncertainty about the term "recover" in the coronavirus context.

According to the Ministry of Health's discharge policy for covid-19 cases, a patient is discharged only after two samples test negative within 24 hours and there's evidence of chest radiographic clearance and viral clearance in respiratory samples. Early evidence suggests that coronavirus victims may experience lingering health effects of COVID-19, even after testing negative. Medical experts in Hong Kong who have observed discharged COVID-19 patients report the patients had shortness of breath and may have lost some lung function, but the researchers were unsure how long those ailments would last.

4.2 Contemporary Guidelines

Post discharge there is a requirement to self-quarantine for another 14-day period. If these guidelines are followed, it still ensures that there is no further spread of the virus.

4.3 Management

According to Ayurveda concepts, there will be Dhatu-Kshaya & AgnimandyaAvastha Post COVID 19 infection. Hence, Dhatuposhana and Rasayana sevana with drugs like Draksha (Vitis vinifera L.) & Vasa (Justicia adhatoda L.) for at-least 45 days and to combat the residual effects of the virus on the body – Vishaghnachikitsa with Shirisha (Albizia lebbeck (L.) Benth.) or Haridrachurna (Curcuma longa) are suggested after clinical recovery. Hepatoprotective and renal protective drugs like Amalaki Churna (Emblica officinalis GAERTN.), Bhumyamalaki (Phyllanthus niruriL.) etc. may be given for 45-60 days after clinical recovery to combat toxicity produced from antiviral drug therapy. Deepana Pachana drugs like Shadanga Paneeya may be used in case of Diarrhoea, vomiting or loss of appetite. Fecal shedding has been demonstrated from some patients and a viable virus has been identified in a limited number of case reports. Kriminashaka therapy with Vidanga Churna, Vilwadigutika, Neelithulasyadi Kashayam may be used in such cases.

4.4 Formulations - With Posology

Disclaimer - Any of the following medicines as per the availability and choice of physician, depending upon individuals Agni status may be prescribed.

4.4.1 Initial Stage

- INDUKANTHAM KASHAYAM1 15ml + 45 ml warm water twice before food along with MAHASUDARSHAN GHAN VATI[2] twice before food 0R
- AMRITARISHTAM[3] - 15 - 20 ml with equal quantity warm water twice after food along with AGNITUNDI VATI 01 Tab BID with Lukewarm water

Once Agni - Digestive capacity is regained - INDUKANTAM GHRITAM[4] 10 - 12 gm twice daily whenever hungry. Rasayana and other immune boosting drugs in group 1 can be also be utilized judiciously as per the discretion

4.4.2 Rasayana

- DRAKSHARISHTA[5] 15 - 20 ml thrice a day with equal volume of water after meal or
- DRAKSHADI LEHA[6] 10 - 12gm thrice a day 1 hour before meal (Draksha is having specific potential to rejuvenate lungs) OR
- VASAVALEHA/ KANTAKARYAVLEHA[7] – 10 - 12 gm thrice a day 1 hour before meal (Vasa/kantakari is a very useful drug for jvara, kasa, pitta vriddha conditions; so it would be helpful in removing the residual khavaigunya in srotasas)
- CHYAWANPRASH[8] 10 - 12 gm/ ASHWAGANDHA LEHA[9] 10 - 12 gm thrice a day before meal
- VARDHAMANA PIPPALI RASAYANA
- VASANTA KALPA

4.4.3 Kriminashaka/Vishahara

VIDANGA CHURNA[10] 3 - 6 g with honey at night after 1 hour of meal/

VILWADI GUTIKA - 1 tab thrice after food

4.4.4 Digestive Disorders

DADIMASHTAKA CHURNA[11]- 3 - 6 gm thrice a day - 1 hour before meal with lukewarm water or Takra (freshly prepared sanskarita with panchakolachurna)

ASHTACHOORNAM - 3 - 6 gm twice a day with ghee and honey

4.4.5 Hepatoprotective Drugs

AMALAKI CHURNA12 3 - 6 gm or Triphalachurna 3 - 6 gm empty stomach in the morning with lukewarm water or

KALAMEGHA CHURNA - 3 - 6 gm empty stomach in the morning with lukewarm water.

4.4.6. Nephro-protective Drugs

- RASAYANA CHURNA 3 - 6 gm empty stomach in the morning with lukewarm water
- PUNARNAVASAVAM - 15 - 20 ml with equal quantity of water
- CHANDRAPRABHA VATI - 2 tablets (250 mg) BD/TDS a day with warm water, after food
- GOKSHURADI GUGGULU - 2 tablets (500 mg) BD/TDS day with warm water, after food

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4.4.7 Duration of Intake of Medications

The above said medications alike Dhatu Poshana and Rasayana be provided for a time period of 45 days as per the discretion of physician

Other groups of drugs which are protective in nature can be provided for 45-60 days as per discretion of the practitioner.

4.5 Preferable Diet habits / Ahara

Chew a piece of ginger with a pinch of rock salt (Lavanadrak) 15 to 20 minutes before food improves the appetite. Light to digest food preparations like Tarpanalaja saktu (powder of roasted grains) mixed with honey, sugar and fruit juices, Yush of mung dal or lentil, Soups of vegetables, Meat soup, Khichadi of rice and mung dal (Green Gram), Phulka with cows ghee, Vegetables like gheya, turai, bhindi, sitaphal etc. should be taken. Spices like jeera, black pepper, garlic, coriander, ginger, Ajwain should be used in cooking.

4.6 Yoga Practices

The following Yoga-Asanas can be practised for 15 to 20 minutes to improves flexibility of the body and relieve mental stress

- Sukshmavyayama (warm up) loosening exercises for all joints
- Sitting postures like padmasana, sukhasana, vajrasana, paschimottanasana
- Yogasana in supine position: pawanmuktasana, halasana, matsyasana
- Yogasana in Prone position: bhujangasana, shalabhasana
- Relaxing postures: Shavasana, Makarasana
- Pranayama: Deep Breathing, Nadishodhana pranayama, Bhramari Pranayama 10 repetitions each
- Meditation – 10 minutes

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CASE RECORD FORM (CRF-COVID19)

***For the use of Registered Ayurveda Practitioners**

Date of Screening			
DEMOGRAPHICS			
NAME:			
Last	First	M. I.	
Birth date:____/____/____		Age:_____	
Sex:❑F❑M			
FATHER'S/HUSBAND'S NAME			
MOTHER'S NAME			
ADDRESS Phone No: Email:			
Healthcare Worker? ❑Yes ❑No ❑Unknown			
Laboratory Worker? ❑Yes ❑No ❑Unknown			
Pregnant? ❑Yes ❑No ❑Unknown ❑N/A Ifyes:Gestational weeks assessment [__][__]weeks			
CHIEF COMPLAINTS			
History of self-reported feverishness or measured fever of≥38°C	❑Yes ❑No		
Cough	❑Yes ❑No		
Dyspnoea (shortness of breath) OR Tachypnoea*	❑Yes ❑No		
Sore throat	❑Yes ❑No		
Runny nose	❑Yes ❑No		
General weakness	❑Yes ❑No		
Headache	❑Yes ❑No		
Irritability/confusion	❑Yes ❑No		
Nausea/Vomiting	❑Yes ❑No		
Diarrhea	❑Yes ❑No		
Others:			
TRAVEL HISTORY			
Undertaken international travel in the last 14 days	❑Yes ❑No		
Undertaken Domestic travel in the last 14 days	❑Yes ❑No		
CONTACT HISTORY			
Contacts of laboratory confirmed cases	❑Yes ❑No		
Asymptomatic direct and high risk contacts of a confirmed case	❑Yes ❑No		

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DATE OF ONSET AND VITAL SIGNS	
Symptom onset (date of first/earliest symptom)	[_
Temperature	[__][__].[__]°C
Heart rate	[__][__][__]beats/min
Respiratory rate	[__][__]breaths/min
BP	[__][__][__](systolic)[__][__][__](diastolic)mmHg
Severe dehydration	☐ Yes ☐ No ☐ Unknown
Sternal capillary refill time >2seconds	☐ Yes ☐ No ☐ Unknown
Oxygen saturation:	[__][__][__]%on ☐ roomair ☐ oxygen therapy ☐ Unknown
Glasgow Coma Score	(GCS/15)[__][__]
Malnutrition	☐ Yes ☐ No ☐ Unknown
Mid-upper arm circumference	[__][__][__]mm
Height:	[__][__][__]cm
Weight:	[__][__][__]kg
CO-MORBIDITIES *(Unk=Unknown)*	
Chronic cardiac disease (not hypertension)	☐ Yes ☐ No ☐ Unk
Hypertension	☐ Yes ☐ No
Chronic pulmonary disease	☐ Yes ☐ No ☐ Unk
Asthma	☐ Yes ☐ No ☐ Unk
Chronic kidney disease	☐ Yes ☐ No ☐ Unk
Chronic liver disease	☐ Yes ☐ No ☐ Unk
Chronic neurological disorder	☐ Yes ☐ No ☐ Unk
Diabetes	☐ Yes ☐ No ☐ Unk
Current smoking Yes No Unk specify:	☐ Yes ☐ No ☐ Unk
Tuberculosis	☐ Yes ☐ No ☐ Unk
HIV	☐ Yes-onART ☐ Yes-notonART ☐ No ☐ Unknown
Malignant neoplasm	☐ Yes ☐ No ☐ Unk
Other ☐ Yes ☐ No ☐ Unk Ifyes,specify	
MEDICATION HISTORY	
Angiotensin converting enzyme inhibitors (ACE inhibitors)?	☐ Yes ☐ No ☐ Unk
Angiotensin II receptor blockers (ARBs)?	☐ Yes ☐ No ☐ Unk
Non-steroidal anti-inflammatory(NSAID)?	☐ Yes ☐ No ☐ Unk
Others(if any, Please specify)	

Ayurveda Examination

Samprapti

	Vata	Pitta	Kapha
Anubandhya dosha	☐	☐	☐
Anubandh dosha	☐	☐	☐
Avaraka dosha	☐	☐	☐
Ksheen dosha	☐	☐	☐

Ksheen dhatu

- Rasa ☐ • Meda ☐ • Shukra ☐
- Rakta ☐ • Asthi ☐
- Mamsa ☐ • Majja ☐

Dushya (Involved)

- Rasa ☐ • Meda ☐ • Shukra ☐
- Rakta ☐ • Asthi ☐
- Mamsa ☐ • Majja ☐

Stages of disease (Roga Kriya Kala):

- Sanchaya ☐
- Prakopa ☐
- Prasara ☐
- Sthan Sanshray ☐
- Vyakti ☐
- Bheda ☐

Ashtavidha Pariksha:

Nadi:	Mala:	Mutra:
Jivha:	Shabda:	Sparsha:
Drik:	Akriti:	

Dashavidha Pariksha:

Prakruti: **Vikruti:**

Satva: Pravara/ Avara/ Madhyama

Sara: Twak/Rakta/Mamsa/Meda/Ashti/Majja/Shukra

Samhanana: Samyak/Madhyama/Heena Pramana: Supramanita/Adhika/Heena

Satyma: Ahara Shakti: Abhyavarana_____: Jarana_____

Vyayama Shakti: Vaya:

Srotas Pariksha

Pranavaha Pariksha

Alpa Alpa Swasa (Shortened Breathing)	☐
Atisrama Swasa (Increased respiration rate)	☐
Abhikshana Swasa	☐
Kupit Swasa (Vitiated breathing)	☐
Sashula swasa (Dyspnoea with pain)	☐

Rasavaha Srotas Pariksha

Mukha vairsya (Bad taste in mouth),	☐
Hrillasa (Water brash)	☐
Arasajnata (Tastelessness)	☐
Gaurava (Feeling of heaviness)	☐
Tandra (Stupor)	☐
Anga marda (Body ache)	☐
Jwara (Fever)	☐
Pandu (Anaemia)	☐
Avsada (Depression)	☐
Karshya (Emaciation)	☐
Klibya (Loss of libibo)	☐
Agnimandya (Diminished appetite)	☐

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Provisional Diagnosis

Final Diagnosis

Summary: _____

_____

Ayurveda Management of the case of COVID19

Intervention	Details of Intervention	Dose	Anupana	Treatment Duration

Assessment

A. Clinical Symptoms	BT (0-5 Scale)	AT (0-5 Scale)
1. Fever		
2. Sore Throat		
3. Cough		
4. Dyspnoea (shortness of breath)		
5. Sore throat		
6. Runny nose		
7. Generalweakness		
8. Headache		
9. Irritability/confusion		
10. Nausea/Vomiting		
11. Diarrhea		
12. Others (_____)		

B. Viral clearance time [If the case is Positive]:_____days

(Viral presence will be determined using RT-PCR to detect SARS-CoV-19 RNA. Throat swabs for viral RNA will be taken daily while in hospital until there have at least 2 consecutive negative results. Virus will be defined as cleared when the patient has had ⩾2 consecutive negative PCR tests. The time to viral clearance will be defined as the time following randomization to the first of the negative throat swabs)

Others

- Number of days free from mechanical ventilation:_____Days
- Duration of mechanical ventilation:____Days
- Duration of hospitalization/ Length of hospital stay on survivors:____Days
- Other secondary infections/ Presence of other secondary infections:

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Adverse Events if any

	1.	2.	3.	4.
Adverse Experience				
Date Started **Time:** **Date Stopped**				
Pattern **Isolated/** **Intermittent/** **Continuous**				
Severity **Mild/Moderate/** **Severe**				
Relationship to study Medication **Unrelated-1;Possible -2;** **Probable-3**				

Physician initials

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Consent Form

Hospital/Medical College/Clinic Name:_____

Name of the Vaidya/Doctor:_____

Qualification:_____

Address:_____

Phone:_____

Email:_____

Information about the patient:

Name: Mr./Ms./Mrs._____

Age:_____ Years

Address:_____

I, the undersigned, do hereby state and confirm as follows:

1. I have been explained the following in terms and language that I understand. I have been explained the following in ..... (name of the language or dialect) that is spoken and understood by me.

2. I have been explained; I have been provided with the requisite information; I have understood; and thereafter I consent, authorize and direct the above named Vaidya/doctor and his / her team with associates or assistants of his / her choice to perform the proposed treatment / intervention / procedure / surgery mentioned hereinabove.

3. I have been explained and have understood that due to unforeseen circumstances during the course of the proposed treatment / intervention / procedure / surgery something more or different than what has been originally planned and for which I am giving this consent may have to be performed or attempted. In all such eventualities, I authorize and give my consent to the medical/ surgical team to perform such other and further acts that they may deem fit and proper using their professional judgment.

4. I have been explained and have understood the alternative methods and therapies of the proposed treatment / intervention / procedure / surgery, their respective benefits, material risks and disadvantages.

5. I have been explained and have understood that the proposed treatment / intervention /procedure / surgery has certain material risks / complications and I have been provided with the requisite information about the same. I have also been explained and have understood that there

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are other undefined, unanticipated, unexplainable risks / complications that may occur during or after the proposed treatment / intervention / procedure / surgery.

6. I state that the Vaidya/doctor has answered all my questions to my satisfaction regarding the proposed treatment / intervention / procedure /surgery.

7. I have been explained and have understood that despite the best efforts there can be no assurance about the result of the proposed treatment / intervention / procedure / surgery. I further state and confirm that I have not been given any guarantee or warranty about the results of the proposed treatment / intervention / procedure / surgery.

8. I have been explained and have understood that despite all precautions complications may occur that may even result in death or serious disability.

9. I have been advised of the option to take a second opinion from another doctor regarding the proposed treatment / procedure / surgery.

10. I state that after explaining, counseling and disclosures I had been given enough time to take decision for giving consent.

11. I have signed this consent voluntarily out of my free will and without any kind of pressure or coercion.

Date & Time of giving consent:

Patient's / Guardian's Signature / Thumb impression:

Patient's / Guardian's Name:

Witnesses:

(Not compulsory. This part should be filled only in high risk cases; or when the patient / patient's guardian is illiterate or not conversant with English; or when the patient has been unable to personally sign this consent for any reason.)

We confirm that the aforesaid has been explained to the patient / patient's guardian in the terms and language that the patient / patient's guardian understand in our presence. We further confirm that the patient / patient's guardian has put his / her signature / thumb impression on this consent in our presence.

Witnesses No. 1's Signature: Witnesses No. 1's Name:

Witnesses No. 2's Signature: Witnesses No. 2's Name:

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Doctor-in-charge / Principal Surgeon / Principal Interventionist's Signature:

Time and Temperature chart for the month of _____

Day	Hourly Temperature															
	7:00	8:00	9:00	10:00	11:00	12:00	1:00	2:00	3:00	4:00	5:00	6:00	7:00	8:00	9:00	10:00
1																
2																
3																
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Classical references of compound formulations

Note: for detailed use and dose, please refer the main document under relevant chapters and sections

Sr.No.	Name of drug	Reference
1.	Abhraka Bhasma	Ayurveda Prakasha 2/97-98
2.	Abhraka Bhasma	Ayurveda Prakasha 2/97-98
3.	Agastya Haritaki	Ashtanga Hridaya, Chiktsasthana, 3/125-130
4.	Agastya Haritaki Rasayana	Ashtanga Hridaya, Chiktsasthana, 3/125-130
5.	Amritarista	Bhaishajya ratnavali, Jwaradhikara,690-693
6.	Amritottara Kashaya	Sahasrayogam, Kashaya prakaranam,. p. 4
7.	Arjunarista	Bhaishajya Ratnavali, Hridrogadhikara, 73-75
8.	Arka Yavani	Arkaprakasha, Shataka, 3:7
9.	Ashwagandharista	Bhaishajya Ratnavali, Murrchadhikara, 13-19
10.	Balarishta	Bhaishajya Ratnavali, Vatavyadhyadhikara, 569-572
11.	Bharangyadi Kashayam	Sahastrayaoga, Kashayaprakaran, 36
12.	Bharangyadi kwatha	Sahastra Yoga, Kashaya Prakarana, 36
13.	Bilwadi vati	Ashtang Hridayam, Uttarasthana, 36/84-85
14.	Bramha Rasayana	Ashtang Hridayam, Uttarasthana, 39/15-23
15.	Chandramrita rasa	Rasamrita, Rasayogavigyana, 9/64-67
16.	Chandraprabha Vati	Sharangdhara Samhita Madhyama Khand, 7/40-49
17.	Chaturthaka Jvarahara kwatha	
18.	Chayavanaprashavaleha	Charaka Samhita, Chikitsasthana, 1(1), 62-74
19.	Chitraka haritaki Avaleha	Bhaishajya Ratnavali, Nasa Rogadhikara, 31-33
20.	Chitraka Haritaki Rasayana	Bhaishajya Ratnavali, Nasa Rogadhikara, 31-33
21.	Dashamoola katutrayadi Kashaya	Sahasrayoga, Kashayaprakarana, 107
22.	Dashamoola kwatha	Bhaishajya Ratnavali, Kasarogadhikara, 380-384
23.	Devadaryadi kwatha	Bhaishajya Ratnavali, Strirogadhikara, 380-384
24.	Dhanwantar gutika	Sahastrayoga, Gutikaprakarana 56
25.	Godanti bhasma	Rasatarangini 11/238
26.	Gorochanadi Vati	Vaidya Yoga ratnavali, Gutika Prakarana, 77
27.	Guduchyadi Kashayam	Sahastrayaoga, Kashayaprakaran, 38
28.	Haridrakhand	Bhaishajya ratnavali, Shitapittaudardkothadhikara, 12-16
29.	Hridayarnava rasa	Rasendra Sara Samgraha, Hridrogchikitsa, 1-3
30.	Kanthakari avaleha	Sharangdhara Samhita Madhyama Khand, 8/5-9
31.	Khadiradi vati	Yogaratnakara, Kasachikitsa, pg 353-354
32.	Kooshmanda Rasayana	Sharangdhara Samhita, Madhyama Khanda, 8/22-28
33.	Lavangadi Vati	Vaidyak Jeevam, Kasashwasa Chikitsa, 7
34.	Laxmivilasa rasa	Bhaishajya Ratnavali, Rasayanadhikara, 55-68
35.	Maha Sudarshanghan Vati (Dried aqueous extract of Mahasudarshan Churna)	Sharangdhara Samhita Madhyama Khand, 6/26-36

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Sr.No.	Name of drug	Reference
36.	Mallasindhoora	Siddha Bheshaja Manimala 5/37
37.	Mrityunjaya rasa	Bhaishajya ratnavali, Jwaradhikara, 409 – 418
38.	Navajeevana Rasa	Ayurveda Sara Samgraha, Rasa Rasayana Prakarana, Chapter 5, pg 382
39.	Pathyadi Kashayam	Sharangdhara Samhita Madhyama Khand, 2/143-145
40.	Prabhakar Vati	Bhaishajya Ratnavali, Hridrogadhikara, 67
41.	Pushkaramoolasava	Gadanigraha, Asavadhikara, 6
42.	Rasnasaptaka Kwatha	Sharangdhara Samhita, madhyama Khand, 2/86-87
43.	Saindhavadi taila	Bhaishajya Ratnavali Nadivranadhikara, 31
44.	Sameerapannaga rasa	Ayurveda Aushadhiguna Dharma Shastra, Part IV, pg 88
45.	Samshamani vati	Siddhayoga Samgraha, Jwaradhikara, pg 183
46.	Sanjeevani vati	Sharangdhara Samhita Madhyama Khand, 7/134-137
47.	Saraswatarista	Bhaishajya Ratnavali, Rasayanadhikara, 178-191
48.	Sarpagandha ghana vati	Siddhayogasangraha, Bhrama-Anidra-Unmadarogadhikara
49.	Shadanga paneeya	Charaka Samhita, Chikitsa Sthana
50.	Shilajitwadi Lauha	Bhaishajya Ratnavali, Rajyakshmadhikara: 166
51.	Shringa bhasma	Rasa Tarangini 12/104
52.	Shwas Kuthar Rasa	Yoga Ratnakara, Shwasa Chikitsa, pg 373
53.	Sitopaladi churna	Sharangdhara Samhita Madhyama Khand, 6/134-137
54.	Somasava	
55.	Swarnamalini vasanta rasa	Siddha Bheshaja Manimala, Jwaraprakarana, 60-62
56.	Talisadi Churna	Sharangdhara Samhita Madhyama Khand, 6/130-133
57.	Tankana bhasma	Rasatarangini 13/79-81
58.	Tribhuvana kirti rasa	Yogaratnakara, Jwarachikitsa, pg 241
59.	Trinapanchamoola kwatha	Bhaishajya Ratnavali, Mutrarogadhikara
60.	Varunadi kwatha	Chakradatta, Ashmari Chikitsa, 29
61.	Vasakasava	Gadanigraha, Prayoga Khanda, Asavadhikara, 152-154
62.	Vasanta Kusumakara Rasa	Rasendra Sara Samgraha, Rasayana Vajikarana Adhikara, 80-85
63.	Vettumaran Gulika	Sahastrayoga, Jwaradhikara, 147
64.	Vishamajwarantaka lauha	Rasendra Sara Sangraha, Jwaradhikara, 271-277
65.	Vyaghri haritaki	Bhaishajya Ratnavali, Kasarogadhikara, 43-46
66.	Vyoshadi Vati	Sharangdhara Samhita Madhyama Khand, Uttarasthana, 7/22-23

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Disclaimer

These guidelines are in addition to the standard treatment guidelines of Ministry of Health and Family Welfare, Govt of India and also vetted by the Interdisciplinary AYUSH Research and Development Task Force setup by Ministry of AYUSH, Govt of India

GUIDELINES for
AYURVEDA PRACTITIONERS for COVID 19

The COVID-19 pandemic is defining the global health crisis of our time and transpire to be the greatest challenge we have faced since the Second World War. The number of deaths and incidence of infection are rising at an alarming rate throughout the world. The situation has materialized to be much more than a health crisis with a potential to create devastating situations at social, economic and political levels. Till date, no effective management to address this infection has been discerned and attempts are being made to integrate a few traditional interventions along with standard treatment protocols of COVID-19. It has further been observed that there is a paucity of empirical evidence to guide appropriate management of COVID 19. Collecting data and comparing outcomes is being recommended globally. In this view, it is very essential to develop guidelines for practitioners to generate evidence based data at prevention, promotion and therapeutic levels.

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AYUSH BHAWAN, B Block, GPO Complex, INA, NEW DELHI - 110023

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ANNEXURE-D

सत्यमेव जयते

Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
(EMR Division)

Guidelines on Clinical Management of COVID – 19

This document is intended for clinicians taking care of hospitalised adult and paediatric patients of COVID – 19. It is not meant to replace clinical judgment or specialist consultation but rather to strengthen clinical management of these patients and provide to up-to-date guidance. Best practices for COVID - 19 including IPC and optimized supportive care for severely ill patients are essential.This document aims to provide clinicians with updated interim guidance on timely, effective, and safe supportive management of patients with COVID - 19, particularly those with severe acute respiratory illness and critical ill

17th March 2020

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Triage: Early recognition of patients with COVID - 19

The purpose of triage is to recognize and sort all patients with COVID - 19 at first point of contact with health care system (such as the emergency department). Consider COVID - 19 as a possible etiology under certain conditions (see Table 1). Triage patients and start emergency treatments based on disease severity.

Table 1: Definitions of patients with COVID - 19

SARI	An ARI with history of fever or measured temperature ≥38 C° and cough; onset within the last ~10 days; and requiring hospitalization.
Surveillance case definitions for SARI	**1.** SARI in a person, with history of fever and cough requiring admission to hospital, with no other etiology that fully explains the clinical presentation[1] (clinicians should also be alert to the possibility of atypical presentations in patients who are immune-compromised); AND any of the following: a) A history of international travel in 14 days prior to symptom onset; or **b) the disease occurs in a health care worker who has been working in an environment where patients with severe acute respiratory infections are being cared for, without regard to place of residence or history of travel; or** c) the person develops an unusual or unexpected clinical course, especially sudden deterioration despite appropriate treatment, without regard to place of residence or history of travel, even if another etiology has been identified that fully explains the clinical presentation **2.** A person with acute respiratory illness of any degree of severity who, within 14 days before onset of illness, had any of the following exposures: a) close physical contact[2] with a confirmed case of COVID - 19 infection, while that patient was symptomatic; or b) a healthcare facility in a country where hospital-associated COVID - 19 infections have been reported;

*** see https://mohfw.gov.in/media/disease-alerts for latest case definition**

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1- Testing should be according to local guidance for management of community-acquired pneumonia. Examples of other etiologies include Streptococcus pneumoniae, Haemophilus influenza type B, Legionella pneumophila, other recognized primary bacterial pneumonias, influenza viruses, and respiratory syncytial virus.

2- CLOSE CONTACT IS DEFINED AS:

- Health care associated exposure, including providing direct care for COVID – 19 patients, working with health care workers infected with COVID – 19, visiting patients or staying in the same close environment of a COVID - 19 patients.
- Working together in close proximity or sharing the same classroom environment with a COVID - 19 patient
- Travelling together with COVID - 19 patient in any kind of conveyance.
- Living in the same household as a COVID - 19 patients.

The epidemiological link may have occurred within a 14-day period before or after the onset of illness in the case under consideration

COVID–19 may present with mild, moderate, or severe illness; the latter includes severe pneumonia, ARDS, sepsis and septic shock. Early recognition of suspected patients allows for timely initiation of IPC (see Table 2). Early identification of those with severe manifestations (see Table 2) allows for immediate optimized supportive care treatments and safe, rapid admission (or referral) to intensive care unit according to national protocols. For those with mild illness, hospitalization may not be required unless there is concern for rapid deterioration. All patients discharged for home should be instructed to return to hospital if they develop any worsening of illness.

Table 2: Clinical syndromes associated with COVID - 19 infection

Uncomplicated illness	**Patients with uncomplicated upper respiratory tract viral infection, may have non-specific symptoms such as fever, cough, sore throat, nasal congestion, malaise, headache. The elderly and immunosuppressed may present with atypical symptoms. These patients do not have any signs of dehydration, sepsis or shortness of breath.**
Mild pneumonia	Patient with pneumonia and no signs of severe pneumonia. Child with non-severe pneumonia has cough or difficulty in breathing/ fast breathing: (fast breathing - in breaths/min): <2 months, ≥60; 2–11 months, ≥50; 1–5 years, ≥40 and no signs of severe pneumonia

///

Severe pneumonia	Adolescent or adult: fever or suspected respiratory infection, plus one of the following; respiratory rate >30 breaths/min, severe respiratory distress, SpO2 <90% on room air Child with cough or difficulty in breathing, plus at least one of the following: central cyanosis or SpO2 <90%; severe respiratory distress (e.g. grunting, chest in-drawing); signs of pneumonia with any of the following danger signs: inability to breastfeed or drink, lethargy or unconsciousness, or convulsions. Other signs of pneumonia may be present: chest indrawing, fast breathing (in breaths/min): <2 months ≥60; 2–11 months ≥50; 1–5 years ≥40. The diagnosis is clinical; chest imaging can exclude complications.
Acute Respiratory Distress Syndrome	**Onset**: new or worsening respiratory symptoms within one week of known clinical insult. **Chest imaging (radiograph, CT scan, or lung ultrasound)**: bilateral opacities, not fully explained by effusions, lobar or lung collapse, or nodules. **Origin of oedema**: respiratory failure not fully explained by cardiac failure or fluid overload. Need objective assessment (e.g. echocardiography) to exclude hydrostatic cause of oedema if no risk factor present. **Oxygenation (adults)**: • Mild ARDS: 200 mmHg < PaO2/FiO2 ≤ 300 mmHg (with PEEP or CPAP ≥5 cm H_2O, or non-ventilated) • Moderate ARDS: 100 mmHg < PaO2/FiO2 ≤200 mmHg with PEEP ≥5 cm H_2O, or non-ventilated) • Severe ARDS: PaO2/FiO2 ≤ 100 mmHg with PEEP ≥5 cm H2O, or non-ventilated) • When PaO_2 is not available, SpO_2/FiO_2 ≤315 suggests ARDS (including in non-ventilated patients) Oxygenation (children; note OI = Oxygenation Index and OSI = Oxygenation Index using SpO_2) • Bilevel NIV or CPAP ≥5 cm H2O via full face mask: PaO_2/FiO_2 ≤ 300 mmHg or SpO_2/FiO_2 ≤264 • Mild ARDS (invasively ventilated): 4 ≤ OI < 8 or 5 ≤ OSI < 7.5 • Moderate ARDS (invasively ventilated): 8 ≤ OI < 16 or 7.5 ≤ OSI < 12.3 • Severe ARDS (invasively ventilated): OI ≥ 16 or OSI ≥ 12.3

Sepsis	**Adults**: life-threatening organ dysfunction caused by a dysregulated host response to suspected or proven infection, with organ dysfunction. Signs of organ dysfunction include: altered mental status, difficult or fast breathing, low oxygen saturation, reduced urine output, fast heart rate, weak pulse, cold extremities or low blood pressure, skin mottling, or laboratory evidence of coagulopathy, thrombocytopenia, acidosis, high lactate or hyperbilirubinemia. **Children**: suspected or proven infection and ≥2 SIRS criteria, of which one must be abnormal temperature or white blood cell count
Septic shock	**Adults**: persisting hypotension despite volume resuscitation, requiring vasopressors to maintain MAP ≥65 mmHg and serum lactate level < 2 mmol/L **Children**: any hypotension (SBP <5th centile or >2 SD below normal for age) or 2-3 of the following: altered mental state; bradycardia or tachycardia (HR <90 bpm or >160 bpm in infants and HR <70 bpm or >150 bpm in children); prolonged capillary refill (>2 sec) or warm vasodilation with bounding pulses; tachypnea; mottled skin or petechial or purpuric rash; increased lactate; oliguria; hyperthermia or hypothermia

A. Immediate implementation of appropriate IPC measures

IPC is a critical and integral part of clinical management of patients and should be initiated at the point of entry of the patient to hospital (typically the Emergency Department). Standard precautions should always be routinely applied in all areas of health care facilities. Standard precautions include hand hygiene; use of PPE to avoid direct contact with patients' blood, body fluids, secretions (including respiratory secretions) and non-intact skin. Standard precautions also include prevention of needle-stick or sharps injury; safe waste management; cleaning and disinfection of equipment; and cleaning of the environment.

Table 3: How to implement infection prevention and control measures for patients with suspected or confirmed COVID - 19 infection

At triage	• Give suspect patient a triple layer surgical mask and direct patient to separate area, an isolation room if available. Keep at least 1meter distance between suspected patients and other patients. Instruct all patients to cover nose and mouth during coughing or sneezing with tissue or flexed elbow for others. Perform hand hygiene after contact with respiratory secretions

Apply droplet precautions	• Droplet precautions prevent large droplet transmission of respiratory viruses. Use a triple layer surgical mask if working within 1-2 metres of the patient. Place patients in single rooms, or group together those with the same etiological diagnosis. If an etiological diagnosis is not possible, group patients with similar clinical diagnosis and based on epidemiological risk factors, with a spatial separation. When providing care in close contact with a patient with respiratory symptoms (e.g. coughing or sneezing), use eye protection (face-mask or goggles), because sprays of secretions may occur. Limit patient movement within the institution and ensure that patients wear triple layer surgical masks when outside their rooms
Apply contact precautions	• Droplet and contact precautions prevent direct or indirect transmission from contact with contaminated surfaces or equipment (i.e. contact with contaminated oxygen tubing/interfaces). Use PPE (triple layer surgical mask, eye protection, gloves and gown) when entering room and remove PPE when leaving. If possible, use either disposable or dedicated equipment (e.g. stethoscopes, blood pressure cuffs and thermometers). If equipment needs to be shared among patients, clean and disinfect between each patient use. Ensure that health care workers refrain from touching their eyes, nose, and mouth with potentially contaminated gloved or ungloved hands. Avoid contaminating environmental surfaces that are not directly related to patient care (e.g. door handles and light switches). Ensure adequate room ventilation. Avoid movement of patients or transport. Perform hand hygiene.
Apply airborne precautions when performing an aerosol generating procedure	• Ensure that healthcare workers performing aerosol-generating procedures (i.e. open suctioning of respiratory tract, intubation, bronchoscopy, cardiopulmonary resuscitation) use PPE, including gloves, long-sleeved gowns, eye protection, and fit-tested particulate respirators (N95). (The scheduled fit test should not be confused with user seal check before each use.) Whenever possible, use adequately ventilated single rooms when performing aerosol-generating procedures, meaning negative pressure rooms with minimum of 12 air changes per hour or at least 160 litres/second/patient in facilities with natural ventilation. Avoid the presence of unnecessary individuals in the room. Care for the patient in the same type of room after mechanical ventilation commences

Abbreviations: ARI, acute respiratory infection; PPE, personal protective equipment

B. Early supportive therapy and monitoring

a. Give supplemental oxygen therapy immediately to patients with SARI and respiratory distress, hypoxaemia, or shock: Initiate oxygen therapy at 5 L/min and titrate flow rates to reach target SpO_2 ≥90% in non-pregnant adults and SpO_2 ≥92-95 % in pregnant patients. Children with emergency signs (obstructed or absent breathing, severe respiratory distress, central cyanosis, shock, coma or convulsions) should receive oxygen therapy during resuscitation to target SpO_2 ≥94%; otherwise, the target SpO_2 is ≥90%. All areas where patients with SARI are cared for should be equipped with pulse oximeters, functioning oxygen systems and disposable, single-use, oxygen-delivering interfaces (nasal cannula, simple face mask, and mask with reservoir bag). Use contact precautions when handling contaminated oxygen interfaces of patients with COVID – 19.

b. Use conservative fluid management in patients with SARI when there is no evidence of shock: Patients with SARI should be treated cautiously with intravenous fluids, because aggressive fluid resuscitation may worsen oxygenation, especially in settings where there is limited availability of mechanical ventilation.

c. Give empiric antimicrobials to treat all likely pathogens causing SARI. Give antimicrobials within one hour of initial patient assessment for patients with sepsis: Although the patient may be suspected to have COVID - 19, Administer appropriate empiric antimicrobials within ONE hour of identification of sepsis. Empirical antibiotic treatment should be based on the clinical diagnosis (community-acquired pneumonia, health care-associated pneumonia [if infection was acquired in healthcare setting], or sepsis), local epidemiology and susceptibility data, and treatment guidelines. Empirical therapy includes a neuraminidase inhibitor for treatment of influenza when there is local circulation or other risk factors, including travel history or exposure to animal influenza viruses. Empirical therapy should be de-escalated on the basis of microbiology results and clinical judgment

d. Do not routinely give systemic corticosteroids for treatment of viral pneumonia or ARDS outside of clinical trials unless they are indicated for another reason: A systematic review of observational studies of corticosteroids administered to patients with SARS reported no survival benefit and possible harms (avascular necrosis, psychosis, diabetes, and delayed viral clearance). A systematic review of observational studies in influenza found a higher risk of mortality and secondary infections with corticosteroids; the evidence was

judged as very low to low quality due to confounding by indication. A subsequent study that addressed this limitation by adjusting for time-varying confounders found no effect on mortality. Finally, a recent study of patients receiving corticosteroids for MERS used a similar statistical approach and found no effect of corticosteroids on mortality but delayed lower respiratory tract (LRT) clearance of MERS-CoV. Given lack of effectiveness and possible harm, routine corticosteroids should be avoided unless they are indicated for another reason. See section F for the use of corticosteroids in sepsis.

e. Closely monitor patients with SARI for signs of clinical deterioration, such as rapidly progressive respiratory failure and sepsis, and apply supportive care interventions immediately: Application of timely, effective, and safe supportive therapies is the cornerstone of therapy for patients that develop severe manifestations of COVID – 19.
f. Understand the patient's co-morbid condition(s) to tailor the management of critical illness and appreciate the prognosis: During intensive care management of SARI, determine which chronic therapies should be continued and which therapies should be stopped temporarily.
g. Communicate early with patient and family: Communicate pro-actively with patients and families and provide support and prognostic information. Understand the patient's values and preferences regarding life-sustaining interventions.

C. Collection of specimens for laboratory diagnosis

Guidance on specimen collection, processing, transportation, including related biosafety procedures, is available on **https://mohfw.gov.in/media/disease-alerts**

Points to remember

- Collect blood cultures for bacteria that cause pneumonia and sepsis, ideally before antimicrobial therapy. DO NOT delay antimicrobial therapy to collect blood cultures
- Collect specimens of nasopharyngeal and oro – pharyngeal swab for RT - PCR. Clinicians may also collect LRT (Lower Respiratory Tract) samples when these are readily available (for example, in mechanically ventilated patients).
- Use appropriate PPE for specimen collection (droplet and contact precautions for URT specimens; airborne precautions for LRT specimens). When collecting URT samples, use viral swabs (sterile Dacron or rayon, not cotton) and viral transport media. Do not sample

the nostrils or tonsils. In a patient with suspected COVID - 19, especially with pneumonia or severe illness, a single URT sample does not exclude the diagnosis, and additional URT and LRT samples are recommended. Sputum induction should be avoided due to increased risk of increasing aerosol transmission.

- Dual infections with other respiratory viral infections have been found in SARS and MERS cases. At this stage we need detailed microbiologic studies in all suspected COVID - 19 cases. Both URT and LRT specimens can be tested for other respiratory viruses, such as influenza A and B (including zoonotic influenza A), respiratory syncytial virus, parainfluenza viruses, rhinoviruses, adenoviruses, enteroviruses (e.g. EVD68), human metapneumovirus, and endemic human coronaviruses (i.e. HKU1, OC43, NL63, and 229E). LRT specimens can also be tested for bacterial pathogens, including *Legionella pneumophila*.
- In hospitalized patients with confirmed COVID - 19 infection, repeat URT samples should be collected to demonstrate viral clearance. The frequency of specimen collection will depend on local circumstances but should be done at least every 2 to 4 days until there are two consecutive negative results (of URT samples) in a clinically recovered patient at least 24 hours apart.

D. Management of hypoxemic respiratory failure and ARDS

- Recognize severe hypoxemic respiratory failure when a patient with respiratory distress is failing standard oxygen therapy. Patients may continue to have increased work of breathing or hypoxemia even when oxygen is delivered via a face mask with reservoir bag (flow rates of 10-15 L/min, which is typically the minimum flow required to maintain bag inflation; FiO_2 0.60-0.95). Hypoxemic respiratory failure in ARDS commonly results from intrapulmonary ventilation-perfusion mismatch or shunt and usually requires mechanical ventilation.
- High – flow nasal catheter oxygenation or non – invasive mechanical ventilation: When respiratory distress and/or hypoxemia of the patient cannot be alleviated after receiving standard oxygen therapy, high – flow nasal cannula oxygen therapy or non – invasive ventilation can be considered. If conditions do not improve or even get worse within a short time (1 – 2 hours), tracheal intubation and invasive mechanical ventilation should be

used in a timely manner. Compared to standard oxygen therapy, HFNO reduces the need for intubation. Patients with hypercapnia (exacerbation of obstructive lung disease, cardiogenic pulmonary oedema), hemodynamic instability, multi-organ failure, or abnormal mental status should generally not receive HFNO, although emerging data suggest that HFNO may be safe in patients with mild-moderate and non-worsening hypercapnia[25]. Patients receiving HFNO should be in a monitored setting and cared for by experienced personnel capable of endotracheal intubation in case the patient acutely deteriorates or does not improve after a short trial (about 1 hr).

- NIV guidelines make no recommendation on use in hypoxemic respiratory failure (apart from cardiogenic pulmonary oedema and post-operative respiratory failure) or pandemic viral illness (referring to studies of SARS and pandemic influenza). Risks include delayed intubation, large tidal volumes, and injurious transpulmonary pressures. Limited data suggest a high failure rate when MERS patients received NIV. Patients receiving a trial of NIV should be in a monitored setting and cared for by experienced personnel capable of endotracheal intubation in case the patient acutely deteriorates or does not improve after a short trial (about 1 hr). Patients with hemodynamic instability, multiorgan failure, or abnormal mental status should not receive NIV.
- Recent publications suggest that newer HFNO and NIV systems with good interface fitting do not create widespread dispersion of exhaled air and therefore should be associated with low risk of airborne transmission.
- Endotracheal intubation should be performed by a trained and experienced provider using airborne precautions. Patients with ARDS, especially young children or those who are obese or pregnant, may de-saturate quickly during intubation. Pre-oxygenate with 100% FiO_2 for 5 minutes, via a face mask with reservoir bag, bag-valve mask, HFNO, or NIV. Rapid sequence intubation is appropriate after an airway assessment that identifies no signs of difficult intubation.
- Implement mechanical ventilation using lower tidal volumes (4–8 ml/kg predicted body weight, PBW) and lower inspiratory pressures (plateau pressure <30 cmH_2O). This is a strong recommendation from a clinical guideline for patients with ARDS, and is suggested for patients with sepsis-induced respiratory failure. The initial tidal volume is 6 ml/kg PBW; tidal volume up to 8 ml/kg PBW is allowed if undesirable side effects occur (e.g. dyssynchrony, pH <7.15). Hypercapnia is permitted if meeting the pH goal of 7.30-

7.45. Ventilator protocols are available. The use of deep sedation may be required to control respiratory drive and achieve tidal volume targets.

- In patients with severe ARDS, prone ventilation for >12 hours per day is recommended. Application of prone ventilation is strongly recommended for adult and paediatric patients with severe ARDS but requires sufficient human resources and expertise to be performed safely.
- Use a conservative fluid management strategy for ARDS patients without tissue hypoperfusion.
- In patients with moderate or severe ARDS, higher PEEP instead of lower PEEP is suggested. PEEP titration requires consideration of benefits (reducing atelectrauma and improving alveolar recruitment) vs. risks (end-inspiratory overdistension leading to lung injury and higher pulmonary vascular resistance). Tables are available to guide PEEP titration based on the FiO_2 required to maintain SpO_2. A related intervention of recruitment manoeuvres (RMs) is delivered as episodic periods of high continuous positive airway pressure [30–40 cm H_2O], progressive incremental increases in PEEP with constant driving pressure, or high driving pressure; considerations of benefits vs. risks are similar. Higher PEEP and RMs were both conditionally recommended in a clinical practice guideline. In patients with moderate-severe ARDS (PaO_2/FiO_2 <150), neuromuscular blockade by continuous infusion should not be routinely used.
- In settings with access to expertise in extracorporeal life support (ECLS), consider referral of patients with refractory hypoxemia despite lung protective ventilation. ECLS should only be offered in expert centres with a sufficient case volume to maintain expertise and that can apply the IPC measures required for COVID – 19 patients
- Avoid disconnecting the patient from the ventilator, which results in loss of PEEP and atelectasis. Use in-line catheters for airway suctioning and clamp endotracheal tube when disconnection is required (for example, transfer to a transport ventilator)

E. Management of septic shock

- Recognize septic shock in adults when infection is suspected or confirmed AND vasopressors are needed to maintain mean arterial pressure (MAP) ≥65 mmHg AND

lactate is < 2 mmol/L, in absence of hypovolemia. Recognize septic shock in children with any hypotension (systolic blood pressure [SBP] <5th centile or >2 SD below normal for age) or 2-3 of the following: altered mental state; tachycardia or bradycardia (HR <90 bpm or >160 bpm in infants and HR <70 bpm or >150 bpm in children); prolonged capillary refill (>2 sec) or warm vasodilation with bounding pulses; tachypnea; mottled skin or petechial or purpuric rash; increased lactate; oliguria; hyperthermia or hypothermia.

- In the absence of a lactate measurement, use MAP and clinical signs of perfusion to define shock. Standard care includes early recognition and the following treatments within 1 hour of recognition: antimicrobial therapy and fluid loading and vasopressors for hypotension. The use of central venous and arterial catheters should be based on resource availability and individual patient needs. Detailed guidelines are available for the management of septic shock in adults and children.
- In resuscitation from septic shock in adults, give at least 30 ml/kg of isotonic crystalloid in adults in the first 3 hours. In resuscitation from septic shock in children in well-resourced settings, give 20 ml/kg as a rapid bolus and up to 40-60 ml/kg in the first 1 hr. Do not use hypotonic crystalloids, starches, or gelatins for resuscitation.
- Fluid resuscitation may lead to volume overload, including respiratory failure. If there is no response to fluid loading and signs of volume overload appear (for example, jugular venous distension, crackles on lung auscultation, pulmonary oedema on imaging, or hepatomegaly in children), then reduce or discontinue fluid administration. This step is particularly important where mechanical ventilation is not available. Alternate fluid regimens are suggested when caring for children in resource-limited settings.
- Crystalloids include normal saline and Ringer's lactate. Determine need for additional fluid boluses (250-1000 ml in adults or 10-20 ml/kg in children) based on clinical response and improvement of perfusion targets. Perfusion targets include MAP (>65 mmHg or age-appropriate targets in children), urine output (>0.5 ml/kg/hr in adults, 1 ml/kg/hr in children), and improvement of skin mottling, capillary refill, level of consciousness, and lactate. Consider dynamic indices of volume responsiveness to guide volume administration beyond initial resuscitation based on local resources and experience. These indices include passive leg raises, fluid challenges with serial stroke volume measurements, or variations in systolic pressure, pulse pressure, inferior vena

cava size, or stroke volume in response to changes in intrathoracic pressure during mechanical ventilation.

- **Administer vasopressors when shock persists during or after fluid resuscitation. The initial blood pressure target is MAP ≥65 mmHg in adults and age-appropriate targets in children.**
- If central venous catheters are not available, vasopressors can be given through a peripheral IV, but use a large vein and closely monitor for signs of extravasation and local tissue necrosis. If extravasation occurs, stop infusion. Vasopressors can also be administered through intraosseous needles.
- If signs of poor perfusion and cardiac dysfunction persist despite achieving MAP target with fluids and vasopressors, consider an inotrope such as dobutamine

F. Other Therapeutic Measures:

For patients with progressive deterioration of oxygenation indicators, rapid worsening on imaging and excessive activation of the body's inflammatory response, glucocorticoids can be used for a short period of time (3 to 5 days). It is recommended that dose should not exceed the equivalent of methylprednisolone 1 – 2mg/kg/day. Note that a larger dose of glucocorticoid will delay the removal of coronavirus due to immunosuppressive effects. For pregnant severe and critical cases, pregnancy should be preferably terminated. Consultations with obstetric, neonatal, and intensive care specialists (depending on the condition of the mother) are essential. Patients often suffer from anxiety and fear and they should be supported by psychological counselling.

G. Prevention of complications

Implement the following interventions (Table 4) to prevent complications associated with critical illness. These interventions are based on Surviving Sepsis or other guidelines, and are generally limited to feasible recommendations based on high quality evidence.

Table 4: Prevention of complications

Anticipated Outcome	Interventions
Reduce days of invasive mechanical ventilation	• Use weaning protocols that include daily assessment for readiness to breathe spontaneously • Minimize continuous or intermittent sedation, targeting specific titration endpoints (light sedation unless contraindicated) or with daily interruption of continuous sedative infusions

Reduce incidence of ventilator associated pneumonia	• Oral intubation is preferable to nasal intubation in adolescents and adults • Keep patient in semi-recumbent position (head of bed elevation 30-45°) • Use a closed suctioning system; periodically drain and discard condensate in tubing • Use a new ventilator circuit for each patient; once patient is ventilated, change circuit if it is soiled or damaged but not routinely • Change heat moisture exchanger when it malfunctions, when soiled, or every 5–7 days
Reduce incidence of venous thromboembolism	• Use pharmacological prophylaxis (low molecular-weight heparin [preferred if available] or heparin 5000 units subcutaneously twice daily) in adolescents and adults without contraindications. For those with contraindications, use mechanical prophylaxis (intermittent pneumatic compression devices).
Reduce incidence of catheter related bloodstream infection	• Use a checklist with completion verified by a real-time observer as reminder of each step needed for sterile insertion and as a daily reminder to remove catheter if no longer needed
Reduce incidence of pressure ulcers	• Turn patient every two hours
Reduce incidence of stress ulcers and gastrointestinal bleeding	• Give early enteral nutrition (within 24–48 hours of admission) • Administer histamine-2 receptor blockers or proton-pump inhibitors in patients with risk factors for GI bleeding. Risk factors for gastrointestinal bleeding include mechanical ventilation for ≥48 hours, coagulopathy, renal replacement therapy, liver disease, multiple co-morbidities, and higher organ failure score
Reduce incidence of ICU-related weakness	• Actively mobilize the patient early in the course of illness when safe to do so

H. Specific COVID - 19 treatments and clinical research

There is no current evidence from RCTs to recommend any specific treatment for suspected or confirmed patients with COVID - 19. No specific anti–virals are recommended for treatment of COVID – 19 due to lack of adequate evidence from literature. The use of Lopinavir/ Ritonavir in PEP regimens for HIV (4 weeks) is also associated with significant adverse events which many a times leads to discontinuation of therapy. In light of the above, Lopinavir/ Ritonavir should ONLY be used with proper informed expressed consent on a

case to case basis for severe cases, within the under-mentioned framework along with supportive treatment as per need.

a) Administration of Lopinavir/ Ritonavir

Administration of Lopinavir/ Ritonavir to be considered in Laboratory confirmed cases of COVID – 19 when the following criteria are met:

- Symptomatic patients with any of the following:
  - i. hypoxia,
  - ii. hypotension,
  - iii. new onset organ dysfunction (one or more)
    - Increase in creatinine by 50% from baseline, GFR reduction by >25% from baseline or urine output of <0.5 ml/kg for 6 hours.
    - Reduction of GCS by 2 or more
    - Any other organ dysfunction
  - iv. High Risk Groups:
    - Age> 60 yrs
    - Diabetes Mellitus, Renal Failure, Chronic Lung disease
    - Immuno – compromised persons
- Dosage:
  - i. Lopinavir/ Ritonavir (200 mg/ 50 mg) – 2 tablets twice daily
  - ii. For patients unable to take medications by mouth: Lopinavir 400mg/ Ritonavir 100 mg – 5ml suspension twice daily
- Duration: 14 days or for 7 days after becoming asymptomatic.

b) **Support to Treating Physicians**

AIIMS, New Delhi is running a 24x7 helpline to provide support to the treating physicians on clinical management. The helpline number is 9971876591. The identified nodal doctor of the State, appointed for clinical management of COVID – 19 should only contact AIIMS Call Centre.

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ANNEXURE-E

सत्यमेव जयते

CLINICAL MANAGEMENT PROTOCOL: COVID-19

Government of India
Ministry of Health and Family Welfare
Directorate General of Health Services
(EMR Division)

Version 5
03.07.20

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1. Background

Coronaviruses are large group of viruses that cause illness in humans and animals. Rarely, animal coronaviruses can evolve and infect people and then spread between people such as has been seen with MERS and SARS. The outbreak of Novel coronavirus disease (COVID-19) was initially noticed in a seafood market in Wuhan city in Hubei Province of China in mid-December, 2019, has now spread to 214 countries/territories/areas worldwide. WHO (under International Health Regulations) has declared this outbreak as a "Public Health Emergency of International Concern" (PHEIC) on 30thJanuary 2020. WHO subsequently declared COVID-19 a pandemic on 11th March, 2020.

2. Disease Epidemiology

Current available evidence for COVID-19 suggests that the causative virus (SARS-CoV-2) has a zoonotic source closely related to bat-origin SARS-like coronavirus. It is an enveloped RNA beta coronavirus related to the Severe Acute Respiratory Syndrome (SARS) virus, and the virus has been shown to use the angiotensin-converting enzyme 2 (ACE2) receptor for cell entry.

The persons infected by the novel coronavirus are the main source of infection. Direct person-to-person transmission occurs through close contact, mainly through respiratory droplets that are released when the infected person coughs, sneezes, or talks. These droplets may also land on surfaces, where the virus remains viable. Infection can also occur if a person touches an infected surface and then touches his or her eyes, nose, or mouth.

The median incubation period is 5.1 days (range 2–14 days). The precise interval during which an individual with COVID-19 is infectious is uncertain. As per the current evidence, the period of infectivity starts 2 days prior to onset of symptoms and lasts up to 8 days. The extent and role played by pre-clinical/ asymptomatic infections in transmission still remain under investigation.

3. Patho-physiology

Most patients with COVID-19 predominantly have a respiratory tract infection associated with SARS-CoV-2 infection. However, in a small proportion of cases, they can progress to a more severe and systemic disease characterized by the Acute Respiratory Distress Syndrome (ARDS), sepsis and septic shock, multiorgan failure, including acute kidney injury and cardiac injury.

Autopsy findings in China and European countries showed endothelial damage of pulmonary vasculature, microvascular thrombosis and hemorrhage linked to extensive alveolar and interstitial inflammation that ultimately result in COVID-19 vasculopathy, pulmonary intravascular coagulopathy, hypercoagulability, ventilation perfusion

mismatch, and refractory ARDS. Hypoxemia, secondary to ARDS may also activate the coagulation cascade.

4. Case definition[1]

Suspect case

A. A patient with acute respiratory illness (fever and at least one sign/symptom of respiratory disease, e.g., cough, shortness of breath), AND a history of travel to or residence in a location reporting community transmission of COVID-19 disease during the 14 days prior to symptom onset;

OR

B. A patient with any acute respiratory illness AND having been in contact with a confirmed or probable COVID-19 case in the last 14 days prior to symptom onset;

OR

C. A patient with severe acute respiratory illness (fever and at least one sign/symptom of respiratory disease, e.g., cough, shortness of breath; AND requiring hospitalization) AND in the absence of an alternative diagnosis that fully explains the clinical presentation.

Probable case

A. A suspect case for whom testing for the COVID-19 virus is inconclusive.

OR

B. A suspect case for whom testing could not be performed for any reason.

Confirmed case

A person with laboratory confirmation of COVID-19 infection, irrespective of clinical signs and symptoms.

5. Clinical Features

COVID-19 patients reporting to various Covid treatment facilities have reported the following signs and symptoms:

- Fever
- Cough
- Fatigue
- Shortness of breath
- Expectoration
- Myalgia
- Rhinorrhea, sore throat, diarrhea

[1] As per WHO surveillance guidelines

- Loss of smell (anosmia) or loss of taste (ageusia) preceding the onset of respiratory symptoms has also been reported

Older people and immune-suppressed patients in particular may present with atypical symptoms such as fatigue, reduced alertness, reduced mobility, diarrhoea, loss of appetite, delirium, and absence of fever. Children might not have reported fever or cough as frequently as adults.

As per data from Integrated Health Information Platform (IHIP)/ Integrated Disease Surveillance Programme (IDSP) portal case investigation forms for COVID 19 (n=15,366), the details on the signs and symptoms reported are (as on 11.06.2020), fever (27%), cough (21%), sore throat (10%), breathlessness (8%), Weakness (7%), running nose (3%) and others 24%.

6. Risk factors

The major risk factors for severe disease are:

- Age more than 60 years (increasing with age).
- Underlying non-communicable diseases (NCDs): diabetes, hypertension, cardiac disease, chronic lung disease, cerebro-vascular disease, chronic kidney disease, immune-suppression and cancer

7. Clinical Severity

Table 1: Clinical severity and assessment parameters

Clinical Severity	Clinical presentation	Clinical parameters	Remarks
Mild[2]	Patients with uncomplicated upper respiratory tract infection, may have mild symptoms such as fever, cough, sore throat, nasal congestion, malaise, headache	Without evidence of breathlessness or Hypoxia (normal saturation).	(i) Managed at Covid Care Centre

[2] Revised guidelines for Home Isolation of very mild/asymptomatic COVID-19 cases (https://www.mohfw.gov.in/pdf/RevisedHomeIsolationGuidelines.pdf)

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Moderate	Pneumonia with no signs of severe disease	**Adolescent or adult** with presence of clinical features of dyspnea and or hypoxia, fever, cough, including SpO2 <94% (range 90-94%) on room air, Respiratory Rate more or equal to 24 per minute. **Child** with presence of clinical features of dyspnea and or hypoxia, fever, cough, including SpO2 <94% (range 90-94%) on room air, Respiratory Rate more or equal to 24 per minute.. Fast breathing (in breaths/min): < 2 months: ≥ 60; 2–11 months: ≥ 50; 1–5 years: ≥ 40	Managed in Dedicated Covid Health Centre (DCHC)
Severe	Severe Pneumonia	**Adolescent or adult**: with clinical signs of Pneumonia plus one of the following; respiratory rate >30 breaths/min, severe respiratory distress, SpO_2 <90% on room air. **Child** with cough or difficulty in breathing, plus at least one of the following: central cyanosis or SpO_2 <90%; severe respiratory distress (e.g. grunting, chest in- drawing); signs of pneumonia with any of the following danger signs: inability to breastfeed or drink, lethargy or unconsciousness, or convulsions. Other signs of pneumonia may be present: chest in drawing, fast breathing (in breaths/min): <2 months ≥60; 2– 11 months ≥50; 1–5 years ≥40. The diagnosis is clinical; chest imaging can exclude complications.	Managed in Dedicated Covid Hospital

	Acute Respiratory Distress Syndrome	**Onset:** new or worsening respiratory symptoms within one week of known clinical insult. **Chest imaging** (Chest X ray and portable bed side lung ultrasound): bilateral opacities, not fully explained by effusions, lobar or lung collapse, or nodules. **Origin of Pulmonary infiltrates:** respiratory failure not fully explained by cardiac failure or fluid overload. Need objective assessment (e.g. echocardiography) to exclude hydrostatic cause of infiltrates/ oedema if no risk factor present. **Oxygenation impairment in adults:** Mild ARDS: 200 mmHg < PaO2/FiO2 ≤ 300 mmHg (with PEEP or CPAP ≥5 cm H_2O) Moderate ARDS: 100 mmHg < PaO2/FiO2 ≤200 mmHg with PEEP ≥5 cm H_2O) Severe ARDS: PaO_2/FiO_2 ≤ 100 mmHg with PEEP ≥5 cm H_2O) When PaO2 is not available, SpO2/FiO2 ≤315 suggests ARDS (including in non- ventilated patients) **Oxygenation impairment in Children** Note Oxygenation Index (OI) and OSI (Oxygen Saturation Index) Use OI when available. If PaO_2 not available, wean FiO_2 to maintain SpO_2 <_97% to calculate OSI or SpO_2/FiO_2 ratio:	

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		using SpO_2) Bi-level (NIV or CPAP) ≥5 cm H_2O via full face mask: $PaO_2/FiO_2 \leq 300$ mmHg or $SpO_2/FiO_2 \leq 264$ Mild ARDS (invasively ventilated): $4 \leq OI < 8$ or $5 \leq OSI < 7.5$ Moderate ARDS (invasively ventilated): $8 \leq OI < 16$ or $7.5 \leq OSI < 12.3$ Severe ARDS (invasively ventilated): $OI \geq 16$ or $OSI \geq 12.3$	
Severe (Continued)	Sepsis	**Adults**: Acute life-threatening organ dysfunction caused by a dys-regulated host response to suspected or proven infection. Signs of organ dysfunction include: altered mental status, difficult or fast breathing, low oxygen saturation, reduced urine output, fast heart rate, weak pulse, cold extremities or low blood pressure, skin mottling, or laboratory evidence of coagulopathy, thrombocytopenia, acidosis, high lactate or hyperbilirubinemia. **Children**: suspected or proven infection and ≥2 age based Systemic Inflammatory Response Syndrome (SIRS) criteria, of which one must be abnormal temperature or white blood cell count	
	Septic Shock	**Adults**: persisting hypotension despite volume resuscitation, requiring vasopressors to maintain MAP ≥65 mmHg and serum lactate level > 2 mmol/L **Children**: any hypotension (SBP <5th centile or >2 SD below	

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		normal for age) or 2- 3 of the following: altered mental state; bradycardia or tachycardia (HR <90 bpm or >160 bpm in infants and HR <70 bpm or >150 bpm in children); prolonged capillary refill (>2 sec) or weak pulse; tachypnea; mottled or cool skin or petechial or purpuric rash; high lactate; reduced urine output ; hyperthermia or hypothermia	

8. Infection Prevention and Control Practices[3]

Infection prevention control (IPC) is a critical and integral part of clinical management of patients and should be initiated at the point of entry of the patient to hospital (typically the Emergency Department). Standard precautions should always be routinely applied in all areas of health care facilities. Standard precautions include hand hygiene; use of PPE to avoid direct contact with patients' blood, body fluids, secretions (including respiratory secretions) and non-intact skin. Standard precautions also include prevention of needle-stick or sharps injury; safe waste management; cleaning and disinfection of equipment; and cleaning of the environment.

Table 2: Infection prevention control practices

At triage	Give suspect patient a triple layer surgical mask and direct patient to separate area, an isolation room if available. Keep at least 1meter distance between suspected patients and other patients. Instruct all patients to cover nose and mouth during coughing or sneezing with tissue or flexed elbow for others. Perform hand hygiene after contact with respiratory secretions

[3] National guidelines for infection prevention and control in healthcare facilities https://www.mohfw.gov.in/pdf//National%20Guidelines%20for%20IPC%20in%20HCF%20-%20final%281%29.pdf

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Apply standard precautions	Apply standard precautions according to risk assessment for all patients, at all times, when providing any diagnostic and care services. Standard precautions include hand hygiene and the use of personal protective equipment (PPE) when risk of splashes or in contact with patients' blood, body fluids, secretions (including respiratory secretions) and non-intact skin. Standard precautions also include appropriate patient placement; prevention of needle- stick or sharps injury; safe waste management; cleaning and disinfection of equipment; and cleaning of the environment. Best practices for safely managing health care waste should be followed.
Apply droplet precautions	Droplet precautions prevent large droplet transmission of respiratory viruses. Use a triple layer surgical mask if working within 1-2 meters of the patient. Place patients in single rooms, or group together those with the same etiological diagnosis. If an etiological diagnosis is not possible, group patients with similar clinical diagnosis and based on epidemiological risk factors, with a spatial separation. When providing care in close contact with a patient with respiratory symptoms (e.g. coughing or sneezing), use eye protection (face-mask or goggles), because sprays of secretions may occur. Limit patient movement within the institution and ensure that patients wear triple layer surgical masks when outside their rooms
Apply contact precautions	Droplet and contact precautions prevent direct or indirect transmission from contact with contaminated surfaces or equipment (i.e. contact with contaminated oxygen tubing/interfaces). Use PPE (triple layer surgical mask, eye protection, gloves and gown) when entering room and remove PPE when leaving. If possible, use either disposable or dedicated equipment (e.g. stethoscopes, blood pressure cuffs and thermometers). If equipment needs to be shared among patients, clean and disinfect between each patient use. Ensure that health care workers refrain from touching their eyes, nose, and mouth with potentially contaminated gloved or ungloved hands. Avoid contaminating environmental surfaces that are not directly related to patient care (e.g. door handles and light switches). Ensure adequate room ventilation. Avoid movement of patients or transport. Perform hand hygiene.

Apply airborne precautions when performing an aerosol generating procedure	Ensure that healthcare workers performing aerosol-generating procedures (i.e. open suctioning of respiratory tract, intubation, bronchoscopy, cardiopulmonary resuscitation) use PPE, including gloves, long-sleeved gowns, eye protection, and fit-tested particulate respirators (N95). (The scheduled fit test should not be confused with user seal check before each use.) Whenever possible, use adequately ventilated single rooms when performing aerosol-generating procedures, meaning negative pressure rooms with minimum of 12 air changes per hour or at least 160 liters/second/patient in facilities with natural ventilation. Avoid the presence of unnecessary individuals in the room. Care for the patient in the same type of room after mechanical ventilation commences. Because of uncertainty around the potential for aerosolization, high-flow nasal oxygen (HFNO), NIV, including bubble CPAP, should be used with airborne precautions until further evaluation of safety can be completed. There is insufficient evidence to classify nebulizer therapy as an aerosol-generating procedure that is associated with transmission of COVID-19. More research is needed.

9. Laboratory Diagnosis

Guidance on specimen collection, processing, transportation, including related biosafety procedures, is available at:
https://www.mohfw.gov.in/pdf/5Sample%20collection_packaging%20%202019-nCoV.pdf

Sample collection

Preferred sample	Throat and nasal swab in viral transport media (VTM) and transported in cold chain.
Alternate	Nasopharyngeal swab, BAL or endotracheal aspirate which has to be mixed with the viral transport medium and transported in cold chain.

General guidelines

- Use appropriate PPE for specimen collection (droplet and contact precautions for URT specimens; airborne precautions for LRT specimens). Maintain proper infection control when collecting specimens
- Restricted entry to visitors or attendants during sample collection
- Complete the requisition form for each specimen submitted
- Proper disposal of all waste generated

Respiratory specimen collection methods:

A. Lower respiratory tract

- Bronchoalveolar lavage, tracheal aspirate, sputum
- Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container.

B. Upper respiratory tract

- Nasopharyngeal swab AND oropharyngeal swab

Oropharyngeal swab (e.g. throat swab): Tilt patient's head back 70 degrees. Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums. Use only synthetic fiber swabs with plastic shafts. Do not use calcium alginate swabs or swabs with wooden shafts. Place swabs immediately into sterile tubes containing 2-3 ml of viral transport media.

Combined nasal & throat swab: Tilt patient's head back 70 degrees. While gently rotating the swab, insert swab less than one inch into nostril (until resistance is met at turbinates). Rotate the swab several times against nasal wall and repeat in other nostril using the same swab. Place tip of the swab into sterile viral transport media tube and cut off the applicator stick. For throat swab, take a second dry polyester swab, insert into mouth, and swab the posterior pharynx and tonsillar areas (avoid the tongue). Place tip of swab into the same tube and cut off the applicator tip.

Nasopharyngeal swab: Tilt patient's head back 70 degrees. Insert flexible swab through the nares parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient. Gently, rub and roll the swab. Leave the swab in place for several seconds to absorb secretions before removing.

Clinicians may also collect lower respiratory tract samples when these are readily available (for example, in mechanically ventilated patients). In hospitalized patients in Dedicated Covid Hospitals (severe cases with confirmed COVID - 19 infection, repeat upper respiratory tract samples should be collected to demonstrate viral clearance.

Recommended Test

Real time or Conventional RT-PCR test is recommended for diagnosis. SARS-CoV-2 antibody tests are not recommended for diagnosis of current infection with COVID-19.

Dual infections with other respiratory infections (viral, bacterial and fungal) have been found in COVID-19 patients. Depending on local epidemiology and clinical symptoms, test for other potential etiologies (e.g. Influenza, other respiratory viruses, malaria, dengue fever, typhoid fever) as appropriate.

For COVID-19 patients with severe disease, also collect blood cultures, ideally prior to initiation of antimicrobial therapy

10. Management of COVID-19: symptomatic treatment

10.1. Management of Mild Cases

In the containment phase, patients with suspected or confirmed mild COVID-19 are being isolated to break the chain of transmission. Patients with mild disease may present to primary care/outpatient department, or detected during community outreach activities, such as home visits or by telemedicine.

Mild cases can be managed at Covid Care Centre, First Referral Units (FRUs), Community Health Centre (CHC), sub-district and district hospitals.

Detailed clinical history is taken including that of co-morbidities. Patient is followed up daily for temperature, vitals and Oxygen saturation (SpO_2).

Patients should be monitored for signs and symptoms of complications that should prompt urgent referral. Patients with risk factors for severe illness should be monitored closely, given the possible risk of deterioration. If they develop any worsening symptoms (such as mental confusion, difficulty breathing, persistent pain or pressure in the chest, bluish coloration of face/lips, dehydration, decreased urine output, etc.), they should be immediately admitted to a Dedicated Covid Health Centre or Dedicated Covid Hospital.

Children with mild COVID-19 should be monitored for signs and symptoms of clinical deterioration requiring urgent re-evaluation. These include difficulty in breathing/fast or shallow breathing (for infants: grunting, inability to breastfeed), blue lips or face, chest pain or pressure, new confusion, inability to awaken/not interacting when awake, inability to drink or keep down any liquids.

Mild COVID-19 cases may be given:

1. Symptomatic treatment such as antipyretic (Paracetamol) for fever and pain, anti-tussives for cough
2. Adequate nutrition and appropriate hydration to ensured.
3. Tab Hydroxychloroquine (HCQ) may be considered for any of those having high risk features for severe disease (such as age> 60 years; Hypertension, diabetes, chronic lung/kidney/ liver disease, Cerebrovascular disease and obesity) under strict medical supervision, preferably after shifting to DCHC/DCH.
4. Avoid HCQ in patients with underlying cardiac disease, history of unexplained syncope or QT prolongation (> 480 ms).

10.2. Management of Moderate Cases

Patients with suspected or confirmed moderate COVID-19 (pneumonia) is to be isolated to contain virus transmission. Patients with moderate disease may present to an emergency unit or primary care/outpatient department, or be encountered during community surveillance activities, such as active house to house search or by telemedicine.

The defining clinical assessment parameters are Respiratory Rate of more than or equal to 24 per minute and oxygen saturation (SpO_2) of less than 94% on room air (range 90-94%).

Such patients will be isolated in Dedicated Covid Health Centre (DCHC) or District hospital or Medical College hospitals.

The patient will undergo detailed clinical history including co-morbid conditions, measurement of vital signs, Oxygen saturation (SpO_2) and radiological examination of Chest X-ray, Complete Blood Count and other investigations as indicated.

Antibiotics should not be prescribed routinely unless there is clinical suspicion of a bacterial infection.

Clinical Management of Moderate cases

1. Symptomatic treatment such as antipyretic (Paracetamol) for fever and pain, anti-tussives for cough
2. Adequate hydration to be ensured
3. Oxygen Support:
   - Target SpO_2: 92-96% (88-92% in patients with COPD)
   - The device for administering oxygen (nasal prongs, mask, or masks with breathing / non-rebreathing reservoir bag) depends upon the increasing requirement of oxygen therapy. If HFNC or simple nasal cannula is used, N95 mask should be applied over it.
   - Awake proning may be used as a rescue therapy. (Protocol at Annexure-I)

Criteria to be fulfilled	Avoid proning
• Patients with oxygen requirement of >4L • Normal mental status • Able to self-prone or change position with minimal assistance	• Hemodynamic instability • Close monitoring not possible

   Patients will undergo a rotational change in position from prone to lying on each side to sitting up. Typical protocols include 30–120 minutes in prone position, followed by 30–120 minutes in left lateral decubitus, right lateral decubitus, and upright sitting position.

   - All patients should have daily 12-lead ECG
4. Anticoagulation
   - Prophylactic dose of UFH or LMWH (e.g., enoxaparin 40 mg per day SC)
     *Contraindications: End stage renal disease, active bleeding, emergency surgery

     **Consider unfractionated heparin in ESRD
5. Corticosteroids
   - Consider IV methylprednisolone 0.5 to 1 mg/kg OR Dexamethasone 0.1 to 0.2 mg/kg for 3 days (preferably within 48 hours of admission or if oxygen requirement is increasing and if inflammatory markers are increased). Review the duration of administration as per clinical response.

6. Anti-virals

   - Tab. Hydroxychloroquine (400mg) BD on 1st day followed by 200mg 1 BD for 4 days. (after ECG Assessment)
   - May consider investigational therapies such as Remdesivir (under EUA); Convalescent Plasma (Off label use) as detailed under Section 11.

7. Control of co-morbid condition
8. Follow up CRP, D-dimer & Ferritin every 48-72 hourly (if available); CBC with differential count, Absolute Lymphocyte count, KFT/LFT daily
9. Monitor for:

   - Increased work of breathing (use of accessary muscles)
   - Hemodynamic instability
   - Increase in oxygen requirement

   If any of the above occurs, shift to Dedicated Covid Hospital

Few patients with COVID-19 experience a secondary bacterial infection. Consider empiric antibiotic therapy as per local antibiogram and guidelines in older people, immune-compromised patients, and children < 5 years of age.

Close monitoring of patients with moderate COVID-19 is required for signs or symptoms of disease progression. Provision of mechanisms for follow up and transportation to Dedicated Covid Hospital should be available.

10.3. Management of Severe Cases

10.3.1 Early supportive therapy and monitoring

1. Symptomatic treatment with paracetamol and antitussives to continue
2. Oxygenation: Give supplemental oxygen therapy immediately to patients with Severe Covid and respiratory distress, hypoxaemia, or shock: Initiate oxygen therapy at 5 L/min and titrate flow rates to reach target $SpO_2 \geq 90\%$ in non-pregnant adults and $SpO_2 \geq 92\text{-}96\%$ in pregnant patients. Children with emergency signs (obstructed or absent breathing, severe respiratory distress, central cyanosis, shock, coma or convulsions) should receive oxygen therapy during resuscitation to target $SpO_2 \geq 94\%$. All areas where patients with Severe Covid are cared for should be equipped with pulse oximeters, functioning oxygen systems and disposable, single-use, oxygen-delivering interfaces (nasal cannula, simple face mask, and mask with reservoir bag). Use contact precautions when handling contaminated oxygen interfaces of patients with COVID – 19.
3. Use conservative fluid management in patients with Severe Covid when there is no evidence of shock.
4. Anticoagulation: High prophylactic dose of UFH/ LMWH (e.g. enoxaparin 40 mg BD SC) if not at high risk of bleeding.

   *Contraindications: End stage renal disease, active bleeding, emergency surgery

** Consider unfractionated heparin in ESRD

5. Corticosteroids: IV Methylprednisolone 1-2 mg/kg or Dexamethasone 0.2-0.4 mg/kg for 5-7 days
6. Investigational therapy: Tocilizumab (Off Label) Anti IL-6 therapy may be considered as detailed under Section 11.

10.3.2 Management of hypoxemic respiratory failure and ARDS

Recognize severe hypoxemic respiratory failure when a patient with respiratory distress is failing standard oxygen therapy. Patients may continue to have increased work of breathing or hypoxemia even when oxygen is delivered via a face mask with reservoir bag (flow rates of 10-15 L/min, which is typically the minimum flow required to maintain bag inflation; FiO2 0.60-0.95). Hypoxemic respiratory failure in ARDS commonly results from intrapulmonary ventilation- perfusion mismatch or shunt and usually requires mechanical ventilation.

Lung protective ventilation strategy by ARDS net protocol:

- Tidal volume 6ml/kg, RR 15-35/min, PEEP 5-15cm H2O; target plateau pressure < 30cm H2O, target SpO2 88-95% and/or PaO2 55-80mmHg

Prone ventilation to be considered when there is refractory hypoxemia; PaO2/FiO2 ratio <150 with FiO2> 0.6 with PEEP > 5cm H2O.

High – Flow Nasal Cannula oxygenation (HFNO) or non – invasive mechanical ventilation:

When respiratory distress and/or hypoxemia of the patient cannot be alleviated after receiving standard oxygen therapy, high – flow nasal cannula oxygen therapy or non – invasive ventilation can be considered. Compared to standard oxygen therapy, HFNO reduces the need for intubation. Patients with hypercapnia (exacerbation of obstructive lung disease, cardiogenic pulmonary oedema), hemodynamic instability, multi-organ failure, or abnormal mental status should generally not receive HFNO, although emerging data suggest that HFNO may be safe in patients with mild- moderate and non-worsening hypercapnia. Patients receiving HFNO should be in a monitored setting and cared for by experienced personnel capable of endotracheal intubation in case the patient acutely deteriorates or does not improve after a short trial (about 1 hr).

NIV: setting - PS 5-15 cmH2O adjusted to tidal volume of 5-7 ml/kg and PEEP 5-10 cm H2O and FiO2 @ 0.5 -1.0 titrated to target SpO2> 94%.

There have been concerns raised about generation of aerosols while using HFNO and NIV. However, recent publications suggest that newer HFNO and NIV systems with good interface fitting do not create widespread dispersion of exhaled air and therefore should be associated with low risk of airborne transmission. If conditions do not improve or even get worse within a short time (1 – 2 hours), tracheal intubation and invasive mechanical ventilation should be used in a timely manner.

- Endotracheal intubation should be performed by a trained and experienced provider using airborne precautions. Patients with ARDS, especially young children

or those who are obese or pregnant, may de-saturate quickly during intubation. Pre-oxygenate with 100% FiO2 for 5 minutes, via a face mask with reservoir bag, bag-valve mask, HFNO, or NIV. Rapid sequence intubation is appropriate after an airway assessment that identifies no signs of difficult intubation.

- Implement mechanical ventilation using lower tidal volumes (4–8 ml/kg predicted body weight, PBW) and lower inspiratory pressures (plateau pressure <30 cmH_2O). This is a strong recommendation from a clinical guideline for patients with ARDS, and is suggested for patients with sepsis-induced respiratory failure. The initial tidal volume is 6 ml/kg PBW; tidal volume up to 8 ml/kg PBW is allowed if undesirable side effects occur (e.g. dys-synchrony, pH <7.15). Hypercapnia is permitted if meeting the pH goal of 7.30-7.45. Ventilator protocols are available. The use of deep sedation may be required to control respiratory drive and achieve tidal volume targets.

- In patients with severe ARDS, prone ventilation for 16-18 hours per day is recommended but requires sufficient human resources and expertise to be performed safely. (Refer to Annexure-I)

- In patients with moderate or severe ARDS, higher PEEP instead of lower PEEP is suggested. PEEP titration requires consideration of benefits (reducing atelect trauma and improving alveolar recruitment) vs. risks (end-inspiratory over distension leading to lung injury and higher pulmonary vascular resistance). Tables are available to guide PEEP titration based on the FiO_2 required to maintain SpO_2. In patients with moderate-severe ARDS (PaO_2/FiO_2<150), neuromuscular blockade by continuous infusion should not be routinely used.

- In settings with access to expertise in extracorporeal life support (ECLS), consider referral of patients with refractory hypoxemia despite lung protective ventilation. ECLS should only be offered in expert centres with a sufficient case volume to maintain expertise and that can apply the IPC measures required for COVID – 19 patients.

- Avoid disconnecting the patient from the ventilator, which results in loss of PEEP and atelectasis. Use in-line catheters for airway suctioning and clamp endotracheal tube when disconnection is required (for example, transfer to a transport ventilator).

10.3.3 Management of septic shock

- Recognize septic shock in adults when infection is suspected or confirmed AND vasopressors are needed to maintain mean arterial pressure (MAP) ≥65 mmHg AND lactate is >2 mmol/L, in absence of hypovolemia. Recognize septic shock in children with any hypotension (systolic blood pressure [SBP] <5th centile or >2 SD below normal for age) or two of the three of the following: altered mental state; tachycardia or bradycardia (HR <90 bpm or >160 bpm in infants and HR<70 bpm or >150 bpm in children); prolonged capillary refill (>2 sec) or warm vasodilation with bounding pulses; tachypnea; mottled skin or petechial or purpuric rash; increased lactate; oliguria; hyperthermia or hypothermia.

- In the absence of a lactate measurement, use MAP and clinical signs of perfusion to define shock. Standard care includes early recognition and the following treatments within 1 hour of recognition: antimicrobial therapy and fluid loading and vasopressors for hypotension. The use of central venous and arterial catheters should be based on

resource availability and individual patient needs.

- In resuscitation from septic shock in adults, give at least 30 ml/kg of isotonic crystalloid in adults in the first 3 hours. In resuscitation from septic shock in children in well-resourced settings, give 20 ml/kg as a rapid bolus and up to 40-60 ml/kg in the first 1 hr. Do not use hypotonic crystalloids, starches, or gelatins for resuscitation.

- Fluid resuscitation may lead to volume overload, including respiratory failure. If there is no response to fluid loading and signs of volume overload appear (for example, jugular venous distension, crackles on lung auscultation, pulmonary oedema on imaging, or hepatomegaly in children), then reduce or discontinue fluid administration. This step is particularly important where mechanical ventilation is not available. Alternate fluid regimens are suggested when caring for children in resource- limited settings.

- Crystalloids include normal saline and Ringer's lactate. Determine need for additional fluid boluses (250-1000 ml in adults or 10-20 ml/kg in children) based on clinical response and improvement of perfusion targets. Perfusion targets include MAP (>65 mmHg or age- appropriate targets in children), urine output (>0.5 ml/kg/hr in adults, 1 ml/kg/hr. in children), and improvement of skin mottling, capillary refill, level of consciousness, and lactate. Consider dynamic indices of volume responsiveness to guide volume administration beyond initial resuscitation based on local resources and experience. These indices include passive leg raising test, fluid challenges with serial stroke volume measurements, or variations in systolic pressure, pulse pressure, inferior vena cava size, or stroke volume in response to changes in intrathoracic pressure during mechanical ventilation.

- Administer vasopressors when shock persists during or after fluid resuscitation. The initial blood pressure target is MAP ≥ 65 mmHg in adults and age-appropriate targets in children.

- If central venous catheters are not available, vasopressors can be given through a peripheral IV, but use a large vein and closely monitor for signs of extravasation and local tissue necrosis. If extravasation occurs, stop infusion. Vasopressors can also be administered through intraosseous needles.

- If signs of poor perfusion and cardiac dysfunction persist despite achieving MAP target with fluids and vasopressors, consider an inotrope such as dobutamine.

10.3.4. Other therapeutic measures

For patients with progressive deterioration of oxygenation indicators, rapid worsening on imaging and excessive activation of the body's inflammatory response, glucocorticoids can be used for a short period of time (3 to 5 days). It is recommended that dose should not exceed the equivalent of Methylprednisolone 1 – 2mg/kg/day OR Dexamethasone 0.2-0.4 mg/kg/day. Note that a larger dose of glucocorticoid will delay the removal of coronavirus due to immunosuppressive effects.

Prophylactic dose of UFH or LMWH (e.g., enoxaparin 40 mg per day SC) should be given for anti-coagulation. Control of co-morbid conditions should be ensured.

For pregnant severe cases, consultations with obstetric, neonatal, and intensive care specialists (depending on the condition of the mother) are essential. Patients often suffer

from anxiety and fear and they should be supported by psychological counseling.

Note – An algorithm for clinical guidance for management of COVID-19 suspect/confirmed case is placed at Annexure-II.

11. Investigational Therapies[4]

At present, use of these therapies is based on a limited available evidence. As the situation evolves, and when more data become available, the evidence will be accordingly incorporated, and recommendation upgraded. Further, use of these drugs is subjected to limited availability in the country as of now. Currently, these drugs should only be used in a defined subgroup of patients:

i. **Remdesivir** (under Emergency Use Authorization) may be considered in patients with moderate disease (those on oxygen) with none of the following contraindications:

- AST/ALT > 5 times Upper limit of normal (ULN)
- Severe renal impairment (i.e., eGFR < 30ml/min/m^2 or need for hemodialysis)
- Pregnancy or lactating females
- Children (< 12 years of age)

Dose: 200 mg IV on day 1 followed by 100 mg IV daily for 4 days (total 5 days)

ii. **Convalescent plasma** (Off Label) may be considered in patients with moderate disease who are not improving (oxygen requirement is progressively increasing) despite use of steroids. Special prerequisites while considering convalescent plasma include:

- ABO compatibility and cross matching of the donor plasma
- Neutralizing titer of donor plasma should be above the specific threshold (if the latter is not available, plasma IgG titer (against S-protein RBD) above 1:640 should be used)
- Recipient should be closely monitored for several hours post transfusion for any transfusion related adverse events
- Use should be avoided in patients with IgA deficiency or immunoglobulin allergy

Dose: Dose is variable ranging from 4 to 13 ml/kg (usually 200 ml single dose given slowly over not less than 2 hours

[4]*This document will be updated as more data emerge. The document contains some potential off label/investigational use of medications and is based on a consensus of experts along with the available evidence. An informed and shared decision making is essential before prescribing any of these therapies.*

iii. **Tocilizumab** (Off Label) may be considered in patients with moderate disease with progressively increasing oxygen requirements and in mechanically ventilated patients not improving despite use of steroids. Long term safety data in COVID 19 remains largely unknown. Special considerations before its use include:

- Presence of raised inflammatory markers (e.g., CRP, Ferritin, IL-6)
- Patients should be carefully monitored post Tocilizumab for secondary infections and neutropenia
- The drug is contraindicated in PLHIV, those with active infections (systemic bacterial/fungal), Tuberculosis, active hepatitis, ANC < 2000/mm^3 and Platelet count < 1,00,000/mm^3

Dose: 8mg/kg (maximum 800 mg at one time) given slowly in 100 ml NS over 1 hour; dose can be repeated once after 12 to 24 hours if needed

12. Repurposed or off-label therapies

Hydroxychloroquine: This drug has demonstrated in vitro activity against SARS-CoV2 and was shown to be clinically beneficial in several small single center studies though with significant limitations. Nonetheless, several large observational studies with severe methodologic limitations have shown no effect on mortality or other clinically meaningful outcomes. As such, the evidence base behind its use remains limited as with other drugs and should only be used after shared decision making with the patients while awaiting the results of ongoing studies. As is the case with other antivirals, this drug should be used as early in the disease course as possible to achieve any meaningful effects and should be avoided in patients with severe disease. An ECG should ideally be done before prescribing the drug to measure QTc interval (and HCQ avoided if QTc is >500 ms)

Dose: 400 mg BD on day 1 followed by 400mg daily for next 4 days.

13. Prevention of complications

Implement the following interventions (Table 3) to prevent complications associated with critical illness. These interventions are based on Surviving Sepsis or other guidelines, and are generally limited to feasible recommendations based on high quality evidence.

Table 3: Prevention of complications

Anticipated Outcome	Interventions
Reduce days of invasive mechanical ventilation	• Use weaning protocols that include daily assessment for readiness to breathe spontaneously • Minimize continuous or intermittent sedation, targeting specific titration endpoints (light sedation unless contraindicated) or with daily interruption of continuous sedative infusions

Reduce incidence of ventilator associated pneumonia	• Oral intubation is preferable to nasal intubation in adolescents and adults • Keep patient in semi-recumbent position (head of bed elevation 30-45º) • Use a closed suctioning system; periodically drain and discard condensate in tubing • Use a new ventilator circuit for each patient; once patient is ventilated, change circuit if it is soiled or damaged but not routinely • Change heat moisture exchanger when it malfunctions, when soiled, or every 5–7 days
Reduce incidence of venous thromboembolism	• Use pharmacological prophylaxis (low molecular-weight heparin [preferred if available] or heparin 5000 units subcutaneously twice daily) in adolescents and adults without contraindications. For those with contraindications, use mechanical prophylaxis (intermittent pneumatic compression devices).
Reduce incidence of catheter related bloodstream infection	• Use a checklist with completion verified by a real-time observer as reminder of each step needed for sterile insertion and as a daily reminder to remove catheter if no longer needed
Reduce incidence of pressure Ulcers	• Turn patient every two hours
Reduce Incidence of stress ulcers and gastrointestinal bleeding	• Give early enteral nutrition (within24-48 hours of admission) • Administer histamine-2 receptor blockers or proton-pump inhibitors in patients with risk factors for GI bleeding. Risk factors for gastrointestinal bleeding include mechanical ventilation ≥ 48 hours, coagulopathy, renal replacement therapy, liver disease, multiple co-morbidities, and higher organ failure score
Reduce incidence of ICU-related weakness	• Actively mobilize the patient early in the course of illness when safe to do so

Annexure- I

Early self-proning in awake, non-intubated patients

- Any COVID-19 patient with respiratory embarrassment severe enough to be admitted to the hospital may be considered for rotation and early self-proning.
- Care must be taken to not disrupt the flow of oxygen during patient rotation
- Typical protocols include 30–120 minutes in prone position, followed by 30–120 minutes in left lateral decubitus, right lateral decubitus, and upright sitting position *(Caputo ND, Strayer RJ, Levitan R. Academic Emergency Medicine 2020;27:375–378)*

Requirements for safe prone positioning in ARDS

- Pre-oxygenate the patient with FiO2 1.0
- Secure the endotracheal tube and arterial and central venous catheters
- Adequate number of staff to assist in the turn and to monitor the turn
- Supplies to turn (pads for bed, sheet, protection for the patient)
- Knowledge of howto perform the turn as well as how to supine the patient in case of an emergency

Contraindications to prone ventilation

- Spinal instability requires special care
- Intra cranial pressure may increase on turning
- Rapidly return to supine in case of CPR or defibrillation

When to start proning?

- P/F ratio <150 while being ventilated with FiO2 >0.6 and PEEP >5 cm H2O

When to stop proning?

- When P/F exceeds 150 on FiO2 $\geq$ 0.6 and $\geq$ 6 PEEP

What portion of the day should patients be kept prone?

- As much as possible (16-18 hours a day)
- Adult patients with severe ARDS receive prone positioning for more than 12 hours per day (strong recommendation, moderate-high confidence in effect estimates) *(ATS-ERS Guideline. Am J RespirCrit Care Med;2017;195(9):1253-1263)*

ANNEXURE II

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Clinical Guidance for management Covid-19 Suspect/confirmed cases

COVID–19 Suspect/Confirmed Case

Stratification on the basis of disease severity

Mild[1]	Moderate	Severe
(Fever and/or uncomplicated Upper Respiratory Tract Infection) without dyspnoea or hypoxemia	• Pneumonia with no signs of severe disease • RR ≥24/min **OR** SpO_2 < 94% on room air	Respiratory distress requiring mechanical ventilation (non-invasive & invasive) RR ≥30/min OR SpO_2 < 90% on room air
Admit to CCC	**Admit in DCHC / Dedicated COVID Health Centre**	**Admit in DCH / Dedicated COVID Hospital**
• Contact and droplet precautions • Strict hand hygiene • Symptomatic management with adequate hydration • Tab HCQ (400 mg BD x 1 day f/b 400 mg OD x 4 days) may be considered in patients with high-risk features[2] - preferably after shifting to DCHC/DCH • Referral to DCHC/DCH is indicated if : RR≥24 /min **OR** SpO_2 < 94% on room air	**Oxygen Support** •Target SpO_2 : 92-96% (88-92% in patients with COPD) •Preferred device for oxygenation: Non-rebreathing face mask (if HFNC or simple nasal cannula is used, N-95 or surgical mask should be applied over it) •Awake proning may be used in patients who continue to have hypoxemia despite oxygen >4L/min, if no contraindications **Anticoagulation** •Prophylactic dose of LMWH/UFH, if no contraindications (e.g. enoxaparin 40 mg daily SC)[3] **Corticosteroids** •IV Methylprednisolone 0.5-1 mg/kg or Dexamethasone 0.1-0.2 mg/kg for 3-5 days **Antivirals** •Tab HCQ (400 mg BD x 1day f/b 400 mg OD x 4 days) if no contraindications and after assessment of ECG for QT interval, CRP,D-dimer & Ferritin every 48-72 hourly (if available); CBC with differential count, absolute lymphocyte count, KFT/LFT to be done daily **Investigational Therapies[6]**	**Oxygenation** •Cautious trial of CPAP with oro-nasal mask/NIV with helmet interface/HFNC, if work of breathing is low. Consider intubation if work of breathing is high/not tolerating NIV[4] •Lung protective ventilation strategy by ARDSnet protocol •Prone ventilation to be considered when there is refractory hypoxemia **Anticoagulation** •High dose prophylactic UFH or LMWH (e.g. enoxaparin 40 mg or 0.5 mg/kg BD SC) if not at high risk of bleeding[5] **Corticosteroids** •IV Methylprednisolone 1-2 mg/kg or Dexamethasone 0.2-0.4 mg/kg for 5-7 days If sepsis/ septic shock: Manage as per existing protocol & local antibiogram Use sedation and nutrition therapy as per existing guidelines **Investigational Therapies[7]**
1 Very mild/pre-symptomatic/ asymptomatic cases can be considered for home isolation subject to fulfilment of conditions stipulated in guidelines (https: www.mohfw.gov.in/pdf/RevisedHomeIsolationGuidelines.pdf) .		

Testing: While attending suspect cases, as per above protocol based on clinical assessment, testing shall be resorted to, and if negative, manage in non-COVID facility according to clinical diagnosis

Discharge: After clinical improvement, discharge as per revised discharge policy (available at: https www.mohfw.gov.in/pdf/ReviseddischargePolicyforCOVID19.pdf)

2 High-risk patients for severe disease include:

- Age: 60 years or more
- Hypertension, DM (diabetes mellitus) & other immunocompromised states
- Cerebrovascular disease and Obesity (BMI > 25 kg / m2)
- Chronic lung / kidney / liver disease

3 LMWH: Low Molecular Weight Heparin: if no contraindication or high risk of bleeding; UFH: Unfractionated heparin

4 Higher chances of NIV failure

5 Risk of bleeding: use validated score for assessing bleeding risk (eg HAS-BLED score), **Use D-dimer and SIC score** for further risk stratification (SIC score ≥4 portends high thrombotic risk) , **Follow AHA/ESC and ISTH guidelines** in case patient is on anti-platelet agents

Investigational Therapies (Informed and shared decision making is essential before prescribing any of these therapies besides taking note of contra-indications as mentioned in the detailed guidelines)

6 *Inj Remdesivir 200 mg IV on day 1 followed by 100 mg IV daily for next 4 days (total 5 days therapy), in moderate to severe disease on oxygen or mechanical ventilation (preferably early disease), if no contraindications.
*Use of Convalescent plasma (200 ml single dose, may be repeated after 24 hrs may be considered in moderate to severe patients with persistent or increasing oxygen requirement

7 Inj Tocilizumab 8mg/kg (max. dose 800 mg once; usual dose 400 mg) may be considered (if no contraindications) in patients moderate-severe disease with progressively increasing oxygen requirements despite use of corticosteroids with raised inflammatory markers; dose can be repeated after 12 to 24 hours if no improvement occurs with the first dose

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ANNEXURE-F

Advisory on the use of hydroxy–chloroquine as prophylaxis for SARS-CoV-2 infection

The **National Task force for COVID-19** constituted by Indian Council of Medical Research recommends the use of hydroxy– chloroquine for prophylaxis of SARS-CoV-2 infection for high risk population. Copy is annexed.

The Advisory provides for placing the following high risk population under chemoprophylaxis with hydroxy chloroquine:

- Asymptomatic Healthcare Workers involved in the care of suspected or confirmed cases of COVID-19
- Asymptomatic household contacts of laboratory confirmed cases

The protocol recommended by the National Task force has been approved by the Drug Controller General of India for restricted use in emergency situations.

While following the above recommendations, States should take note of the following:

1) **The placing of healthcare workers under chemoprophylaxis should not instill a sense of false security.** They should follow all prescribed public health measures such as frequent washing of hands, respiratory etiquettes, keeping a distance of minimum 1m and use of Personal protective equipment (wherever applicable).
2) They should self-monitor their health and report to health authorities immediately in the event of them becoming symptomatic.
3) The high risk contacts of a positive case placed under chemo prophylaxis, **should remain in home quarantine while on prophylactic therapy.**
4) As recommended by the said Task Force, the drug should only be given on the prescription of a registered medical practitioner. The contraindications mentioned in the recommendations should strictly be followed.
5) Apart from the symptoms of COVID-19 (fever, cough, breathing difficulty), if the person on chemo-prophylaxis develops any other symptoms, he should immediately seek medical treatment of the medical practitioner who has prescribed the chemoprophylaxis.

It is reiterated that the intake of the above medicine should not in still sense of false security.

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ANNEXURE I

सत्यमेव जयते

प्रोफेसर (डा.) बलराम भार्गव, पदम श्री

एमडी, डीएम, एफआरसीपी (जी.), एफआरसीपी (ई.), एफएसीसी,
एफएएचए, एफएएमएस, एफएनएएस, एफएएससी, एफ.एन.ए., डी.एस.सी.

सचिव, भारत सरकार
स्वास्थ्य अनुसंधान विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय एवं
महानिदेशक, आई सी एम आर

Prof. (Dr.) Balram Bhargava, Padma Shri

MD, DM, FRCP (Glasg.), FRCP (Edin.),
FACC, FAHA, FAMS, FNASc, FASc, FNA, DSc

Secretary to the Government of India
Department of Health Research
Ministry of Health & Family Welfare &
Director-General, ICMR

भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
भारत सरकार
वी. रामलिंगस्वामी भवन, अंसारी नगर
नई दिल्ली - 110 029

Indian Council of Medical Research
Department of Health Research
Ministry of Health & Family Welfare
Government of India
V. Ramalingaswami Bhawan, Ansari Nagar
New Delhi - 110 029

D.O.No.VIR/4/2020/ECD-I
22nd March, 2020

Dear Madam

Please find attached the final recommendation of the National Taskforce for COVID-19 for the use of hydroxychloroquine as prophylaxis. This recommendation supersedes the earlier recommendation dated 21.3.2020

With regards

Yours sincerely,

Balram Bhargava

(Balram Bhargava)

Encl: As above

Smt. Preeti Sudan,
Secretary (Health & Family Welfare)
Ministry of Health & Family Welfare,
Nirman Bhawan,
New Delhi-110008.

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Recommendation for empiric use of hydroxy-chloroquine for prophylaxis of SARS-CoV-2 infection

Background:

Hydroxy-chloroquine is found to be effective against coronavirus in laboratory studies and in-vivo studies. Its use in prophylaxis is derived from available evidence of benefit as treatment and supported by pre-clinical data. The following recommendation for the use of hydroxy-chloroquine as a prophylactic agent against SARS-CoV-2 infection is based on these considerations, as well as risk-benefit consideration, under exceptional circumstances that call for the protection of high-risk individuals.

The National Taskforce for COVID-19 recommends the use of hydroxy-chloroquine for prophylaxis of SARS-CoV-2 infection for selected individuals as follows:

Eligible individuals:

- Asymptomatic healthcare workers involved in the care of suspected or confirmed cases of COVID-19
- Asymptomatic household contacts of laboratory confirmed cases

Dose:

- Asymptomatic healthcare workers involved in the care of suspected or confirmed cases of COVID-19: *400 mg twice a day on Day 1, followed by 400 mg once weekly for next 7 weeks; to be taken with meals*
- Asymptomatic household contacts of laboratory confirmed cases: *400 mg twice a day on Day 1, followed by 400 mg once weekly for next 3 weeks; to be taken with meals*

Exclusion/contraindications:

- The drug is not recommended for prophylaxis in children under 15 years of age.
- The drug is contraindicated in persons with known case of retinopathy, known hypersensitivity to hydroxychloroquine, 4-aminoquinoline compounds

Key considerations:

- The drug has to be given only on the prescription of a registered medical practitioner.
- Advised to consult with a physician for any adverse event or potential drug interaction before initiation of medication
- The prophylactic use of hydroxychloroquine to be coupled with the pharmacovigilance for adverse drug reactions through self-reporting using the Pharmacovigilance Program of India (PvPI) helpline/app.
- If anyone becomes symptomatic while on prophylaxis he/she should immediately contact the health facility, get tested as per national guidelines and follow the standard treatment protocol.
- All asymptomatic contacts of laboratory confirmed cases should remain in home quarantine as per the national guidelines, even if they are on prophylactic therapy.
- Simultaneously, proof of concept and pharmacokinetics studies be taken up expeditiously. Findings from these studies and other new evidence will guide any change in the recommendation.

ANNEXURE-G

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भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार
कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health and Family Welfare, Government of India

Date: 22/05/2020

Revised advisory on the use of Hydroxychloroquine (HCQ) as prophylaxis for SARS-CoV-2 infection (in supersession of previous advisory dated 23rd March, 2020)

1. Background

The Joint Monitoring Group under the Chairmanship of DGHS and including representatives from AIIMS, ICMR, NCDC, NDMA, WHO and experts drawn from Central Government hospitals reviewed the prophylactic use of Hydroxychloroquine (HCQ) in the context of expanding it to healthcare and other front line workers deployed in non-COVID and COVID areas, respectively.

The National Task force (NTF) for COVID-19 constituted by Indian Council of Medical Research also reviewed the use of HCQ for prophylaxis of SARS-CoV-2 infection for high risk population based on the emerging evidence on its safety and efficacy. The NTF reviewed the data on in-vitro testing of HCQ for antiviral efficacy against SARS-CoV-2, safety profile of HCQ reported to the pharmacovigilance program of India, and data on the use of HCQ for the prophylaxis of SARS-CoV-2 infection among health care workers (HCWs) and reported its findings as detailed below:

1.1 In-vitro study

At NIV, Pune, the report of the in-vitro testing of HCQ for antiviral efficacy showed reduction of infectivity /log reduction in viral RNA copy of SARs-CoV2.

1.2 Safety Profile of HCQ

The data on assessment of HCQ prophylaxis among 1323 HCWs indicated mild adverse effects such as nausea (8.9%), abdominal pain (7.3%), vomiting (1.5%), hypoglycemia (1.7%) and cardio-vascular effects (1.9%).However, as per the data from the Pharmacovigilance program of India, there have been 214 reported instances of adverse drug reactions associated with prophylactic HCQ use. Of these, 7 were serious individual case safety reports with prolongation of QT interval on ECG in 3 cases.

1.3 Studies on prophylaxis of SARS-CoV-2 infection

- A retrospective case-control analysis at ICMR has found that there is a significant dose-response relationship between the number of prophylactic doses taken and frequency of

occurrence of SARS-CoV-2 infection in symptomatic healthcare workers who were tested for SARS-CoV-2 infection.

- Another investigation from 3 central government hospitals in New Delhi indicates that amongst healthcare workers involved in COVID-19 care, those on HCQ prophylaxis were less likely to develop SARS-CoV-2 infection, compared to those who were not on it. The benefit was less pronounced in healthcare workers caring for a general patient population.
- An observational prospective study of 334 healthcare workers at AIIMS, out of which 248 took HCQ prophylaxis (median 6 weeks of follow up) in New Delhi also showed that those taking HCQ prophylaxis had lower incidence of SARS-CoV-2 infection than those not taking it.

2. Eligibility criteria for HCQ prophylaxis

The Advisory earlier issued (dated 23rd March, 2020; available at: https://www.mohfw.gov.in/pdf/AdvisoryontheuseofHydroxychloroquinasprophylaxisforSARSCoV2infection.pdf), provided placing the high risk population (asymptomatic Healthcare Workers involved in the care of suspected or confirmed cases of COVID-19 and asymptomatic household contacts of laboratory confirmed cases of COVID-19) under chemoprophylaxis with HCQ.

In light of all of the above, the Joint Monitoring Group and NTF have now recommended the prophylactic use of HCQ in the following categories:

1. All asymptomatic healthcare workers involved in containment and treatment of COVID19 and asymptomatic healthcare workers working in non-COVID hospitals/non-COVID areas of COVID hospitals/blocks
2. Asymptomatic frontline workers, such as surveillance workers deployed in containment zones and paramilitary/police personnel involved in COVID-19 related activities.
3. Asymptomatic household contacts of laboratory confirmed cases.

3. Exclusion/contraindications

- The drug is contraindicated in persons with known case of:
  1. Retinopathy,
  2. Hypersensitivity to HCQ or 4-aminoquinoline compounds
  3. G6PD deficiency
  4. Pre-existing cardiomyopathy and cardiac rhythm disorders

- The drug is not recommended for prophylaxis in children under 15 years of age and in pregnancy and lactation.

Rarely the drug causes cardiovascular side effects such as cardiomyopathy and rhythm (heart rate) disorders. In that situation the drug needs to be discontinued. The drug can rarely cause visual disturbance including blurring of vision which is usually self- limiting and improves on

discontinuation of the drug. For the above cited reasons the drug has to be given under strict medical supervision with an informed consent.

4. Dosage

S. No.	Category of personnel	Dosage
1	• Asymptomatic household contacts of laboratory confirmed cases	400 mg twice a day on Day 1, followed by 400 mg once weekly for next 3 weeks; to be taken with meals
2	• All asymptomatic healthcare workers involved in containment and treatment of COVID-19 and asymptomatic healthcare workers working in non-COVID hospitals/non-COVID areas of COVID hospitals/blocks • Asymptomatic frontline workers, such as surveillance workers deployed in containment zones and paramilitary/police personnel involved in COVID-19 related activities	400 mg twice a day on Day 1, followed by 400 mg once weekly for next 7 weeks; to be taken with meals

5. Use of HCQ prophylaxis beyond 8 weeks [in categories 4 (2) above]

In clinical practice HCQ is commonly prescribed in a daily dose of 200mg to 400mg for treatment of diseases such as Rheumatoid Arthritis and Systemic Lupus Erythematosus for prolonged treatment periods with good tolerance. With available evidence for its safety and beneficial effect as a prophylactic drug against SARS-COV-2 during the earlier recommended 8 weeks period, the experts further recommended for its use beyond 8 weeks on weekly dosage with strict monitoring of clinical and ECG parameters which would also ensure that the therapy is given under supervision.

Based on the available evidence, it has been opined that HCQ is relatively safe, when certain contraindications are avoided, and has some beneficial effect as a prophylactic option.

6. Monitoring

- An ECG (with estimation of QT interval) may be done before prescribing HCQ prophylaxis.
- An ECG should be done in case any new cardiovascular symptoms occurs (e.g., palpitations, chest pain syncope) during the course of prophylaxis.
- An ECG (with estimation of QT interval) may be done in those who are already on HCQ prophylaxis before continuing it beyond 8 weeks.
- One ECG should be done anytime during the course of prophylaxis.

7. Key considerations

While following above recommendations, it should be noted that:

1) The drug has to be given under strict medical supervision with an informed consent.
2) The drug has to be given only on the prescription of a registered medical practitioner.
3) Advised to consult with a physician for any adverse event or potential drug interaction before initiation of medication. The contraindications mentioned in the recommendations should strictly be followed.
4) Health care workers and other frontline workers on HCQ should be advised to use PPE. Front line workers should use PPEs in accordance with the guidelines issued by this Ministry (available at: https://www.mohfw.gov.in/pdf/GuidelinesonrationaluseofPersonalProtectiveEquipment.pdf and https://www.mohfw.gov.in/pdf/UpdatedAdditionalguidelinesonrationaluseofPersonalProtectiveEquipmentsettingapproachforHealthfunctionariesworkinginnonCOVID19areas.pdf) or by their respective organization.
5) They should be advised to consult their physician (within their hospital/surveillance team/security organization) for any adverse event or potential drug interaction before initiation of medication. The prophylactic use of HCQ to be coupled with the pharmacovigilance for adverse drug reactions through self-reporting using the Pharmacovigilance Program of India (PvPI) helpline/app. (available at: https://play.google.com/store/apps/details?id=com.vinfotech.suspectedadversedrugreaction&hl=en_IN)
6) If anyone becomes symptomatic while on prophylaxis, he/she should immediately contact the health facility, get tested as per national guidelines and follow the standard treatment protocol. Apart from the symptoms of COVID-19 (fever, cough, breathing difficulty), if the person on chemoprophylaxis develops any other symptoms, he should immediately seek medical treatment from the prescribing medical practitioner.
7) All asymptomatic contacts of laboratory confirmed cases should remain in home quarantine as per the National guidelines, even if they are on prophylactic therapy.
8) Simultaneously, proof of concept and pharmacokinetics studies should be continued/ taken up expeditiously. Findings from these studies and other new evidence will guide any change further in the recommendation.
9) They should follow all prescribed public health measures such as frequent washing of hands, respiratory etiquettes, keeping a distance of minimum 1meter and use of Personal protective gear (wherever applicable).

Note: It is reiterated that the intake of above medicine should not instil a sense of false security.

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ANNEXURE-H

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Case Report

Ayurvedic treatment of COVID-19/SARS-CoV-2: A case report

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Vata-kaphaja-sannipataja jwara

ABSTRACT

This is the first known case of a Coronavirus disease (COVID-19) positive patient treated entirely with Ayurveda. So far in Modern Western Medicine (MWM), no cure has been found which is specific to COVID-19. The only literature relevant to the treatment of Coronavirus disease has surfaced from Traditional Chinese Medicine (TCM). TCM which was extensively used to control the epidemic in China, also consists of herbal medicines similar to Ayurveda. In this case, the patient, who was familiar with the use of Ayurvedic medicines, fully aware that no proven cure exists in MWM, decided to entirely rely on the limited Ayurvedic medicines that he had in his possession at the time of falling ill.

Despite the patient presenting with symptoms, namely high fever, severe body pain and severe cough, along with many of the other associated symptoms of COVID-19, the progress of the disease could be arrested within a short period by being exclusively on Ayurvedic medicines. This illustrates that there is a wide scope to explore the variety of pertinent medicines present in Ayurvedic pharmacopoeia which can be used more rationally to suit every stage of the disease.

Being the first-of-its-kind it is a valuable contribution to scientific literature from the world of Ayurveda. This should encourage the healthcare policy makers to quickly use Ayurveda to bring the COVID-19 pandemic under control in India, as they seemed to have demonstrated it in China with TCM.

1. Introduction

COVID-19 is a rapidly changing and evolving situation. World Health Organisation (WHO) is constantly monitoring it and updating the information available regarding its spread, mortality, and morbidity. So far in Modern Western Medicine (MWM), no cure has been found which is specific to COVID-19. There is plenty of evidence as to how Traditional Chinese Medicine (TCM) has been put to use in China to contain COVID-19 [1–3].

Fever (*Jwara*) is well understood in Ayurveda and it occupies the first chapter in treatment (*chikitsa*) in two of the canonical texts of Ayurveda, namely *Charaka Samhita* and *Ashtanga Hrdayam*. It deals with diagnosis (*nidanam*), pathophysiology (*samprapti*), classification, management, medicines, diet and prognosis. In this case, the fever was diagnosed as per his presenting symptoms as a *Vata Kapha* predominant one [4, Nidana Sthana, 2/25], necessitating appropriate management. Subsequently, the patient tested positive for COVID-19.

From the Ayurvedic point of view, COVID-19 is a *janapadodhwamsa vikara* (epidemic disease). The concept of an epidemic is described in *Charaka Samhita: Vimana Sthana*, Chapter 3. "… even though there is dissimilarity in the physical constitution of human beings, still there are such factors which are common to all individuals and vitiation of these factors leads to the simultaneous manifestation of diseases having the same set of symptoms leading to the destruction of countries. Factors which are common for all the inhabitants of a country are air, water, location and seasons." [5, Vimana Sthana, 3/6] *Janapadodhwamsa* is a situation where the environment - air, water, land and seasons - is vitiated, causing a simultaneous manifestation of a disease among large populations (epidemic), destroying human habitations.

In India there is precedence of treating the Chikungunya virus epidemic with Ayurveda and Siddha medicines [6]. However, there is no attempt in India to directly employ Ayurvedic medicines in the treatment of Coronavirus disease. In this context we provide this case study where a patient of Coronavirus disease tested positive in New York, managed entirely with Ayurvedic medicines to get fully relieved of his symptoms.

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2. Case presentation

2.1. Patient information

The patient aged 43 years is an investment banker in New York, United States of America (USA). He is well built, with a height of 193 cms and weighing 94.3 kgs.

2.2. Present medical history

Patient on the first day of falling ill contacted his Ayurvedic *vaidya* in Chennai on the telephone, for a consultation and started on Ayurvedic medication for his complaints. He self-quarantined, on the suspicion of the possibility of a COVID-19 infection since he lives in New York. Presenting symptoms were fever associated with body pain, cough, loss of taste and smell and abdominal pain. Fever lasted for seven days. Fever is understood well in Ayurveda, and COVID-19 being one such, the patient management was started as per Ayurvedic understanding of *Jwara* (fever).

Details of the symptoms, number of days it lasted, tests performed and medicines recommended are given below in Table 1.

2.3. Past medical history

He has been under Ayurvedic treatment for seven years and has consulted for various conditions for Ayurvedic intervention including; Hypothyroidism (2013), skin issues (2014) and disturbed sleep (2015). Most recently in 2019 December, he consulted for dryness and itching of skin and intermittent cough. His long term prescription was: *Guggulutikta Ghrita* - 15 ml Bid, Kaishora Guggulu - 1 Tab Bid, Ekavimshatika Guggulu - 2 Tab Bid, Khadirarishta - 45 ml after food, Bid, *Durvadi Taila/Nalpamaradi Taila* for external us, *Anu Taila* - Nasal drops once a day.

He was on the above prescription from 27.01.2020 for a period of one month. He stopped these medicines as soon as he developed fever. Patient was not a Known Case of Diabetes Mellitus or Hypertension or any other comorbidities.

His diet prior to illness consisted of a breakfast of stewed apples and vegetable porridge, a vegetarian lunch with rice, *sambar* and vegetables, an evening snack consisting of *adai/dosa/idli*, and dinner with rice, *dal* and vegetables.

Before onset of symptoms, the patient was on a small dose of *Sudarsana Churna* 2 tablets at bedtime for a period of 3 months. He said he had started *Sudarsana Churna* on his own, since it gave him a "sense of well-being resulting in better sleep."

2.4. Ayurvedic intepretation of the Patient's condition

2.4.1. Diagnosis

In this particular case, the diagnosis was initially made, based on his symptoms and the season. Since the COVID-19 diagnosis had not yet been made, we looked at the symptoms as those of a *nija jwara* (caused by the disequilibrium of the bodily doshas), a fever with *Vata-kapha* predominance and gave appropriate medicines, diet and regimen. The final diagnosis was arrived at based on the vast literature available on COVID-19 in the public domain [7,8] and symptoms as reported by the patient. Fevers are classified according to the aggravated *doshas* (disease-causing factors), which allows us to understand all types of new and emerging fevers.

2.4.2. Pathophysiology (Samprapti)

In this *roga* (disease), the *Roga Marga* is *abhyantara* [4, Sutra Sthana, 12/44-49], as *jwara* (fever), *svasa* (respiratory distress) and *kasa* (cough), the three major symptoms of COVID-19 belong to this *roga marga*. *Abhyantara roga marga* is one of the three *roga margas* or "pathways of disease" as described in *Ashtanga Hrdayam*. There is *Pranavaha sroto dushti* [5, Vimana Sthana, 5/7] observed in this disease, as there is severe respiratory distress along with other symptoms, sometimes leading to death. The seat of affliction of this disease is primarily *Uras* (chest region).

Based on the above, Coronavirus disease can be correlated as *Agantuja Sannipataja Jwara*, which is of *Vata-Kapha* predominance [5, Chikitsa Sthana, 3/92; 3/128-129]. This *jwara* can be classified as being *agantu* (external) caused by *Bhoota Abhishanga* [5, Chikitsa Sthana, 3/111, 3/114], which aggravates all the three *doshas*. Since all the three *doshas* are aggravated it is labelled *Sannipata*. The spread and affliction caused by the virus in this *jwara* can be understood in Ayurveda under the *Bhoota abhishanga* classification. According to Ayurveda, *agantu jwara* is to be treated as a *nija jwara* caused by an imbalance of *doshas* [5, Sutra Sthana, 19/7, Chikitsa Sthana, 3/128].

2.4.3. Etiology

According to MWM, the etiology of this illness is now attributed to a novel virus belonging to the coronavirus (CoV) family. It is now named SARS-CoV-2 [9]. In Ayurveda it can be classified/correlated with a *Vata-kapha* predominant fever with all the characteristics of a *Janapadodhwamsa vikara*. It is a highly contagious disease. The methods by which contagious diseases spread from one person to another is described in *Susruta Samhita*: *Nidana Sthana*, Chapter 5:

> "Skin diseases, fever, consumption, conjunctivitis and all contagious diseases spread from person to person, by indulgence in bodily contact, by (coming into contact with another's) breath, eating with others in the same plate, sharing of bed and seat, through (contact with) clothes, ornaments, and cosmetics." [10]

2.5. Therapeutic intervention

Therapeutic intervention consisted of three components, namely, medicines, diet and regimen. The patient had self-quarantined from the first day of fever. Details of the medicines given in two stages of his condition, namely fever and convalescence are given below in Table 2.

Here it is pertinent to point out that the three medicines used in the management of COVID-19 are all classical preparations. The mode of actions of each of them as per the texts are the following: *Sudarsana Churna*: Alleviates all the three *doshas*; cures all types of fevers including *Agantuja jwara*, *Sannipata jwara* etc., *Dhanvantara Gutika*: cures *Svasa*, *Kasa*; *Vaataanulomana* (aiding the normal flow of *vayu*), *Talisadi Churna*: cures *Jwara*, *svasa*, *kasa*, *aruchi* (loss of taste); *Deepanam* (stimulates digestion).

2.6. Outcome

After reaching a peak temperature of 103 °F, the symptoms started to subside. On Day 7, the patient felt that all symptoms had subsided, except loss of taste and smell. Fever, body ache, cough had resolved and appetite also returned by Day 7. The last symptom to normalise was his sense of smell, which returned on Day 16. Resolution of fever (*Jwara Mukti Lakshanas*) were observed on Day 7 [4, Nidana Sthana, 2/79].

The patient adhered to all our instructions. There was resolution of symptoms very quickly, and there was no progression of the disease to a severe stage. There were no adverse or unanticipated events.

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Table 1
Course of the disease

Date/Day	Symptoms	Test/Result	Treatment
29.03.2020/Day 1	Severe body ache (8/10 on a scale of 1 −10), Abdominal pain (2−3/10 on a scale of 1 −10), Temp: 100 °F, Loss of taste and smell	NA	Day 1−13: *Sudarsana Churna* 4 tablets (2 gms) with room-temperature water, Tid; *Talisadi Churna* 1tsp with honey, Tid; *Dhanwantara Gutika* 2 tablets, Tid, and regulated diet.
30.03.2020/Day 2	Immediately after starting the Ayurvedic medicines, abdominal pain became very mild and manageable. Body ache persisted. Temp: 101 °F, Continued loss of taste and smell, Mild coughing	NA	Same medicines continued
31.03.2020/Day 3	Severe body ache, Peak Temp: 103 °F, Continued loss of taste and smell. Severe coughing. Cough was intermittent, dry, and he had no sputum production. All symptoms were worse in the evenings.	NA	Same medicines continued
01.04.2020/Day 4	Severe body ache, Temp: 102 °F, Continued loss of taste and smell, Severe coughing.	NA	Same medicines continued
02.04.2020/Day 5	Body ache finally got better, Temp: 100 °F. Continued loss of taste and smell, No coughing.	Home test: Completed COVID-19 Nasopharynx test: Real time RT PCR in Bio Reference Laboratories in Fulton Street, New York	Same medicines continued
03.04.2020/Day 6	No body ache, Normal temperature. Continued loss of taste and smell.	His doctor in New York verbally confirmed positive COVID19	Same medicines continued
04.04.2020/Day 7	Most symptoms disappeared other than loss of taste and smell. Appetite returned to normal.	NA	Same medicines continued
From 05.04.2020 to 12.04.2020: Days 8−15	Patient felt mostly normal, except for loss of taste and smell.	The written report for the positive test result came on 07/04/2020 (Day 10)	From 11.04.2020/Day 14−28 *Vidaryadi Ghritam* 15 ml, Bid
13.04.2020/Day 16	His sensation of smell was partially restored.	His doctor in New York said that since he had recovered there would be no need to do a follow up test. However, patient ordered a home test from the same lab. The post fever COVID 19 nasopharynx sample was taken on 13.04.2020. Lab called him later and said "Insufficient material."	Same medicine continued
28.04.2020/Day 31		Patient, wanting to interact with his family safely, gave blood sample for testing. Test given in Enco Diagnostic Laboratory, Brooklyn, New York for COVID 19 IGM and IGG, serum.	Same medicine continued
01.05.2020/Day 33		Results: SARS-CoV-2 IgG: REACTIVE SARS-CoV-2 IgG, Num: 7.084 SARS-CoV-2 IgM NON-REACTIVE	NA

Table 2
Therapeutic intervention

	Stage 1: *Jwara* Day 1−13	Stage 2: *Jwara Mukti* Day 14−30
Medicines	• *Sudarsana Churna* - [11] 4 tablets (2 gms) in room temperature water Tid; • *Talisadi Churna* - [5, Chikitsa Sthana, 8/145-148] 1tsp with honey Tid; • *Dhanwantara Gutika* - [12] 2 tablets Tid	*Vidaryadi Ghritam* — [4, Chikitsa Sthana, 3/10] 15 ml Bid
Diet	Rice porridge, *Yusha* and *Bhakta* [13]	Include milk, ghee [5, Chikitsa Sthana, 3/164-165, 3/167-168]
Regimen	Avoid sleeping during the day (*Divaswapna*) and keeping awake at night (*Ratri jagarana*)	Avoid sleeping during the day (*Divaswapna*) and keeping awake at night (*Ratri jagarana*)

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3. Patient's perspective on treatment received

"Though I was already following social distancing and safe hygiene practices, I feel I might have contracted it from one of my trips to the grocery store, despite maintaining distance in the store. On 29th March I came down with a fever. As COVID-19 was raging in New York, I was very afraid that I had contracted COVID. I quarantined myself in my office (which is in the same building as my house, but on a different floor), as my wife is pregnant with our third child.

On the 4th day, I called a doctor who came to take a test the next day. The doctor was afraid to come up to meet me. My wife took the test kit from the doctor, took a swab from my nose, placed it inside the test tube and gave it to the doctor for testing.

Because I was taking Ayurvedic medicine, I was never really worried. By Day 5 or 6 I felt progressively better, one by one my symptoms fell away.

My doctor in New York did not encourage me to go for a post-fever test since he felt I had completely recovered. However, since I wanted to interact safely with my family, I needed a reassurance from the lab test. I therefore ordered a home test from the lab on 13.04.2020. However, the swab this time was insufficient to produce a result. Two weeks later I gave a blood test for the immunoglobins.

The toughest thing about having COVID is not actually having COVID-19 infection, but you read so much about how other people's cases are very serious, and if I had not read a lot about other people who had serious cases I would not have been worried at all. Nevertheless I felt very reassured by the Ayurvedic medicine. Even though I had severe body pain and high fever and severe cough, at no point did it feel even close to life threatening. I would like to add that the body pain felt pretty bad. On the first day that I didn't have body pain I felt such a relief, and only then did I realise how bad the pain had been. Right now I am feeling fantastic thanks to Ayurvedic treatment."

4. Discussion

4.1. Limitations

Since this is a single case study, it calls for a larger sample to be studied, before we can develop a standard protocol for the treatment of COVID-19.

The physical distance between the patient and doctor made it difficult to examine and observe the patient directly.

Treatment protocol consisted only of three Ayurvedic medicines, as the patient happened to be in New York and we worked with what medicines he had on hand.

The medicines used for managing the condition had to be selected from a limited set of medicines that the patient had with him. There are a large number of Ayurvedic medicines that are currently in use for all types of *Vata-Kaphaja* and *Sannipataja jwara* which may prove to be effective for COVID-19.

4.2. Strengths

It is noticed that the patient's condition did not deteriorate. So it can be presumed that the management of COVID-19 with the given Ayurvedic medicines arrested the progress of the disease to a more serious state. Despite the patient having severe cough and fever more than 39.1 °C, the patient did not worsen and develop breathlessness.

"Median time for onset of symptoms to recovery in mild and severe cases was 2 and 3—6 weeks, respectively. Furthermore, time interval between onset and developing severe symptoms such as hypoxia was one week." [14] This patient had recovered in 7 days. Hence it can be said that the duration of the disease was presumably shorter because of the Ayurvedic medicines as it was noted where TCM was used [2]. This aspect needs to be studied further.

There are COVID-19 patients who test positive, but are asymptomatic. This case can be classified as mild to moderate in nature. There is "scarce and inconclusive evidence on symptoms that easily distinguish mild and moderate cases." [15] However, fever above 39.1 °C (102.2 °F) is not considered mild. "Many mild cases also have very few symptoms, and cough is present in less than half of the mild cases." [15] This patient exhibited many of the symptoms, including severe body pain, severe cough, anosmia, abdominal pain, and had a peak temperature of 39.5 °C (103 °F), we consider this case to be not very mild, but mild to moderate.

The regulated diet played an important supportive role in the cure. The diet was advised so that it did not further aggravate the *doshas*, it was easy to digest (*laghu*), it stimulated the digestive fire (*Agni deepanam*) and it nourished the patient [5, Chikitsa Sthana, 3/142-143, 3/163-164]. The diet recommended for the patient, namely soup made of *mung dal* and cooked parboiled rice are included in the recommended diet in management of fevers. These are two of several preparations as described in the texts, as part of a larger detailing of food preparations and their effects on *doshas* and diseases.

We report this case to show that COVID-19 is a condition where usage of Ayurvedic medicines & diet might have contributed to the case not turning critically ill.

5. Conclusion

COVID-19 is responsible for causing a large number of deaths particularly in medically and technologically advanced countries like USA. This is presumably due to the absence of a proper treatment protocol in MWM to address this condition. Therefore, we report this case to show that COVID-19 is a condition where focussed Ayurvedic treatment, if given, may prevent the deterioration of the disease into a more critical condition. This patient's presentation was not mild. However he didn't become critically ill owing to Ayurvedic intervention and regulated diet. India is in a position to use the wealth of knowledge available in the Indian Systems of Medicine, to cure this disease and control the epidemic. This is also an invaluable opportunity for demonstrating the efficacy of Ayurveda.

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Conflict of Interest

None.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jaim.2020.06.001.

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ANNEXURE-J

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Short Communication

COVID-19 pandemic: A pragmatic plan for ayurveda intervention

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ABSTRACT

World community is facing an unprecedented pandemic of novel corona virus disease (COVID-19) caused by Severe Acute Respiratory Syndrome Corona virus 2 (SARS-CoV- 2). The disease has spread globally with more than 1.43 million confirmed cases and 82,100 deaths as of April 8, 2020. Despite worldwide efforts to contain it, the pandemic is continuing to spread for want of a clinically-proven prophylaxis and therapeutic strategy. The dimensions of pandemic require an urgent harnessing of all knowledge systems available globally. Utilization of Traditional Chinese Medicine in Wuhan to treat COVID-19 cases sets the example demonstrating that traditional health care can contribute to treatment of these patients successfully. Drawing on the Ayurveda classics, contemporary scientific studies, and experiential knowledge on similar clinical settings, here we propose a pragmatic plan for intervention in India. We provide a plan for graded response, depending on the stage of infection among individuals, in a population. Notwithstanding the fact that no system of medicine has any evidence-based treatment for COVID-19 as yet, clinical interventions are required to be put in place. Therefore, pragmatic strategy proposed here for Ayurveda system of medicine requires immediate implementation. It will facilitate learning, generate evidence and shall be a way forward.

1. Background

An outbreak of pneumonia in December, 2019 in Wuhan, China, has now been determined to be caused by a novel coronavirus. It is named as Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) [1,2]. The disease has since spread to 185 countries and regions, with more than 2.06 million confirmed cases and more than 1,34,354 deaths as of April 16, 2020 [3]. Despite worldwide efforts to contain it, the pandemic is continuing to spread for want of a clinically-proven prophylaxis and therapeutic strategy [4]. Consequently, it is necessary that scientific community must draw on pluralistic knowledge systems available globally. Drawing on the original Ayurveda classics, contemporary scientific studies, and our experiential knowledge on similar clinical settings, here we propose a pragmatic plan for interventions. We provide a graded response depending on the stage of infection and proximity with disease among individuals in a population. Notwithstanding the fact that no system of medicine has any evidence-based treatment for COVID-19 as yet, clinical interventions are being done worldwide. Similar strategy is required to be implemented by Ayurveda system of medicine. Ayurveda interventions become even more relevant by the fact that there is an elaborate description of causation and management of epidemic (*Janapadodhwamsa*) in Ayurveda [5].

While the disease is almost controlled in China [6], it is still widespread in Europe and US which have emerged as the new epicentres of the COVID-19 [7,8]. There are various reasons for the containment of the disease in China, yet the evidence of role played by Traditional Chinese Medicine (TCM) cannot be overlooked [9,10]. This is now known that during the peak days of the epidemic, over 3100 TCM related workforce had been deployed to Hubei province [9]. TCM was officially included in the Chinese Guideline on diagnosis and treatment of COVID-19 [11]. This is exceptionally important to note that specific TCM wards were set up, and designated hospital were established which had used a variety of Chinese medicines utilising their own principle of syndrome differentiation in conjunction with treatment employing western medicine. Total numbers of confirmed cases treated by TCM are reported to be at least 60,107 [12].

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In coherence with the success of TCM in managing a communicable pandemic, it is logical and essential to explore how Ayurveda can help in addressing the COVID-19 challenge [13,14]. Indeed, this is the time to mainstreaming the AYUSH systems to transform Indian healthcare [15] and demonstrate the potential of AYUSH systems in addressing the challenge and restoring health [16]. An understanding of COVID-19 epidemiology and pathogenesis as learned through on-going pandemic may help us drawing a feasible plan of action. About 80% of COVID-19 cases present with mild symptoms requiring only primary medical care. Of the rest 20% cases 15% require urgent medical attention at secondary health care services. Remaining 5% are critical cases requiring an intensive care and hence require a transfer to tertiary health care units equipped with ICU [17].

Current estimated mortality of COVID-19 for overall infected population is 0.25–3.0% whereas it increases to >14% among elderly (over 80 years), 10% in associated CVD and 7% in associated diabetes. China's experience of pandemic has built the evidences that co-morbidity such as hypertension, diabetes, coronary heart diseases and cerebrovascular disease act as risk factor with increased risk of mortality [18].

In 5% cases requiring Intensive care, the disease progression is gradual, and requires about 9–10 days to progress from symptoms of Upper Respiratory Tract Infection (URTI) to Acute Respiratory Distress Syndrome (ARDS). ARDS often is followed by uncorrectable hypotensive shock, multi-organ failure and eventually death [19].

There are some risk factors that make people susceptible. People with older age, presence of co-morbidities such as diabetes, hypertension and cardiovascular disease, males, anorexia and presentation without fever are more susceptible. Reduced peripheral capillary oxygen saturation (SpO2) below 90% is also a risk indicator in apparently mild cases [20].

With this background of SARS-CoV-2 associated epidemiology and pathogenesis, a pragmatic and plausible plan of action for Ayurvedic intervention are presented (Table 1). In this context, a few important issues need to be stated at the outset. Our proposal complements the guidelines issued by Ministry of AYUSH, Government of India for boosting immunity among the masses [21]. However, it is not limited to prophylaxis alone. It addresses the therapeutic domain as well although within an integrative model of care. In that context, at a generic level, key criteria for choosing suggested Ayurveda medicines here have been safety and potential efficacy, broad-spectrum applicability, ease of availability, long-term experiential knowledge on clinical use, ease of administration, and as far as possible, affordability [22].

For the purpose of Ayurveda interventions during COVID-19 pandemic, people can be segregated into four distinct categories [23].

2. Unexposed asymptomatic group

This group will include persons who currently do not have any related symptom nor have any associated risk factor and co-morbidities. These apparently healthy people may be the most suitable for building of immunity so that infection-related pathogenesis can be countered to keep them healthy [24]. Preventive interventions here can include both pharmacological as well as non-pharmacological strategies. Among the non-pharmacological interventions healthy lifestyles, adequate physical activity, sufficient sleep, care of retainable and non-retainable urges, *sadvritta*, and avoidance and isolation from infected persons are vital [25]. Fumigation of homes, shelters and living-place by Ayurvedic herbs such as garlic (*Allium sativum*) peel, turmeric (*Curcuma longa*) powder, Carom or Ajwain (*Trachyspermum ammi*) seeds and Loban (resin of *Styrax benzoin* and *Boswellia* species) may also be a useful strategy for disinfection [26]. In addition, community based *Swarna Prashana* [27] and mass prophylaxis through *rasayana* having the predominant effects upon respiratory tract can be useful [28]. *Rasayana* may include *Brahma Rasayana, Chyavanprasha* or *Amrit Bhallataka* [29,30]. The rationale for choice of *rasayana* drugs can be traced back to *Samhita* classics of Ayurveda as well as in contemporary research [14]. *Rasayana* act as antioxidant, anti-stress, anti-inflammatory, anti-microbial, vaccine adjuvant, and confer immunity against diseases [31,32]. Further, according to Ayurveda classics, *rasayana* therapy [33], along with physical and social distancing from infected persons [34], constitute a core strategy to overcome epidemic and infectious diseases. Building immunity requires time. There may be some asymptomatic carriers who could transmit the virus to other apparently healthy people. Hence, physical and social distancing for all would be essential to avoid any transmission [34].

3. Exposed asymptomatic (quarantined)

This group comprises of people who are without apparent symptoms, but at risk due to contact history. They need to be quarantined carefully. Specific prophylaxis for this group may include *Sanjeevani vati* [35] and *Chitrakadi vati* and combination of *Guduchi (Tinospora cordifolia), Shunthi (Zingiber officinale)* and *Haridra* (*C. longa*). This choice of medicines is aimed at maintenance of *agni* as well as *aam pachana* in order to prevent the progression of pathogenesis in its initial *sanchaya-prakopa-prasara* stage [36]. *Sanjivani vati* is widely used against communicable diseases, fever due to infection and *sannipataj jvara*, cold, cough, and indigestion. It

Table 1
Proposed Ayurveda interventions in COVID-19 outbreak and their rationale[a,b].

No.	Category of people	Proposed Intervention
1.	Unexposed asymptomatic group	Common health keeping approaches of Ayurveda including healthy diet, healthy life-style, adequate sleep, physical activity, good conduct, care for retainable and non-retainable urges, and avoidance of disease causing factors (excessive cold and exposure to pollutants). In addition, *Chyavanprasha, Brahma Rasayana, Amrit Bhallataka, Sanjeevani vati, Swarna prashan.*
2.	Exposed asymptomatic (Quarantined)	*Sanjeevani vati, Chitrakatdi vati, Chyavanprasha, Brahma Rasayana*, and decoction of a combination of herbs, *Tinospora cordifolia, Zingiber officinale, Curcuma longa, Ocimum sanctum, Glycyrrhiza glabra, Adhatoda vasica, Andrographis paniculata, Swertia chirata, Moringa oleifera, Triphala and Trikatu.*
3.	With mild COVID-19 symptoms	*Pippali rasayan, Go jihvadi Quath, Kantakari Avaleha, Chitrakadi vati, Vyaghri haritaki, Dashamul kwath, Sitopaladi, Talishadi, and Yashtimadhu* etc.
4.	With moderate to severe COVID-19 symptoms	*Pippali rasayan, Laghu Vasant Malati, Sanjeevani vati, Tribhuvan Keerti rasa, Brihata Vata Chintamni rasa, Mrityunjaya rasa, Siddha Makardhvaja* etc.

[a] **Note:** The proposed interventions are supposed to be practiced without compromising the conventional advisories by government authorities including frequent hand-washing with soap till 20 s, cough and sneeze etiquette, physical distancing and universal mask usage.

[b] Dosage of individual formulations are to be judged carefully by an experienced Ayurvedic physician on the basis of *roga* and *rogi bala* with an utmost care for vulnerable population like children, pregnancy and elderly. In almost all cases hot water may be considered as preferred *anupan* (post drink) during the treatment.

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also strengthens and rejuvenates the immune system [37,38]. This group may also be provided with decoction of a combination of Ayurvedic herbs including *T. cordifolia, Z. officinale, C. longa, Ocimum sanctum, Glycyrrhiza glabra, Adhatoda vasica, Andrographis paniculata, Swertia chirata, Moringa oleifera,* Triphala and Trikatu. These herbs are proposed for the reason that these are known to be broad-spectrum antivirals and protease inhibitors [39–41].

4. With mild COVID-19 symptoms

This category relates to people found positive to SARS-CoV-2 and are having mild URTI symptoms. They are required to be carefully isolated and monitored for any progression of the disease, along with giving adequate therapy to arrest the symptoms and balancing the vitiated *doshas* to control disease progression. Formulations like *Lakshmi Vilas Rasa* [42], *Pippali rasayana* [43], *Sanjeevani vati* [35], *C. vati, Go jihvaadi Kashaya, Vyaghri haritaki, Kantakaari Avaleha, Dashamul kwath, Sitopaladi* [44], *Talishadi,* and *Yashtimadhu* may be the most suitable drugs to be used at this stage in an integrative model. Those patients showing progression of the disease may immediately require shifting to ICU.

5. With moderate to severe COVID-19 symptoms

This category may be the population where the moderate to severe symptoms are already present and the patients also belong to high risk groups. These patients require tertiary care from the beginning itself but can also be co-prescribed with Ayurveda medicines in order to reduce the impact of the pathology and to buy more time to have intensive management [45]. Recommended formulations here may include *P. rasayana* [43], *Laghu Vasant Malati, Sanjeevani vati, Tribhuvan keerti rasa* [46], *Brihata Vata Chintamni rasa, Mrityunjaya rasa,* and *Siddha makardhvaja rasa.* The key criterion for choosing *rasa aushadhi* in category 3 and 4 as noted above is the urgency of initiation of therapeutic actions. *Rasaaushadi* are shown to have better bioavailability and absorption through sublingual and oral route accounting to the nano size of their particles [47]. For example, *suvarna bhasma* has been found to get absorbed well through sublingual administration when mixed with black pepper powder and ghee [48].

Along with the above plan, Ayurveda practitioners would require training in screening of the people for associated risk factors. They should also be equipped with modern personal protection equipment and access to diagnostic facilities. Ayurveda hospitals may also be turned as the primary care setups and quarantine for the people having mild symptoms and requiring a constant monitoring. A good networking of AYUSH healthcare authorities with local health authorities may help effective utilisation of human resources in AYUSH community during the current crisis [49].

It is also important to mention a caveat here. Ayurveda doctors following the pragmatic action plan presented here should assess the prognosis and advise timely referrals to secondary or tertiary care facilities as per the need of patient. An extra and utmost care should be taken while treating COVID-19 patients/people suspected to have contracted infection of SARS-CoV-2.

This action plan, if implemented, has enormous potentials to provide learning and innovative insights. Thus, a proper documentation is crucial. Therefore, it is suggested that a proper documentation of key variables that are essential should be done on each case. These variables should include age, gender, symptoms, geography, contact history, Ayurvedic diagnosis including a *roga* and *rogi bala* examination, improvement or worsening of symptoms, Ayurvedic medicine(s) with dosage, final outcome of the management, referral to secondary/tertiary care, symptoms controlled, cured, and mortality, if any. A follow-up advice upon discharge or stop of medications should also be documented.

TCM has been employed in COVID-19 cases not for their proven effectiveness against the pathogen but rather by utilising the Chinese traditional diagnostic concept identifying the syndromes and suggesting their remedies. Similar approach is also needed to be employed in Ayurveda. Accordingly, instead of employing a western approach alone for judging the efficacy of a formulation on a western diagnosis, Ayurveda should follow its own wisdom for diagnosis and subsequent treatment choice on the basis of *roga* and *rogi bala,* as described above.

There are 3598 AYUSH hospitals available in the country including 2818 Ayurveda hospitals. Similarly, there are 25,723 AYUSH dispensaries including 15,291 Ayurveda dispensaries. There are total 7.73 lakh registered AYUSH practitioners including 4.28 lakh Ayurveda practitioners [50]. There are 8954 AYUSH drug manufacturing units (licensed pharmacies) in the country. Among these, 7718 are Ayurveda pharmacies [51]. With this infrastructure and associated human resources, implementation of the proposed action plan seems highly feasible.

6. Recommendations and the way forward

Ayurveda has enough potential and possibilities to be employed both for prevention and treatment of COVID-19. This will provide an important opportunity for learning and generating credible evidence [52]. It is pertinent to reiterate that participation of Ayurveda in addressing the COVID-19 challenge in India should not remain limited and seen as the extension of healthcare services and support to bio-medical system. Indeed, with adequate monitoring and data keeping during the implementation, important lessons and research directions are likely to emerge on the management of increasingly frequent and virulent communicable diseases. Implementation of proposed action is likely to provide evidence-based insights strengthening the scope of Ayurveda beyond preventive health care and care for non-communicable diseases. AYUSH system across the country has been put on alert for being called anytime to serve the nation. AYUSH healthcare facilities are also being readied to be converted into quarantine facilities in times of need. From this perspective, implementing the suggested intervention plan within AYUSH healthcare facilities by Ayurveda workforce may benefit the nation greatly. India is the country where the world's oldest living health care system originated and therefore it is being carefully watched by the world community for how it handles the crisis using its own resources. China has done it. And it is India's turn now to show its traditional healthcare might.

Conflict of interest

None.

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ANNEXURE-K

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Immunomodulatory and anti-oxidant properties of methanolic extract of *Adhatoda vasica* Nees leaf after particulate antigen stimulation in mice

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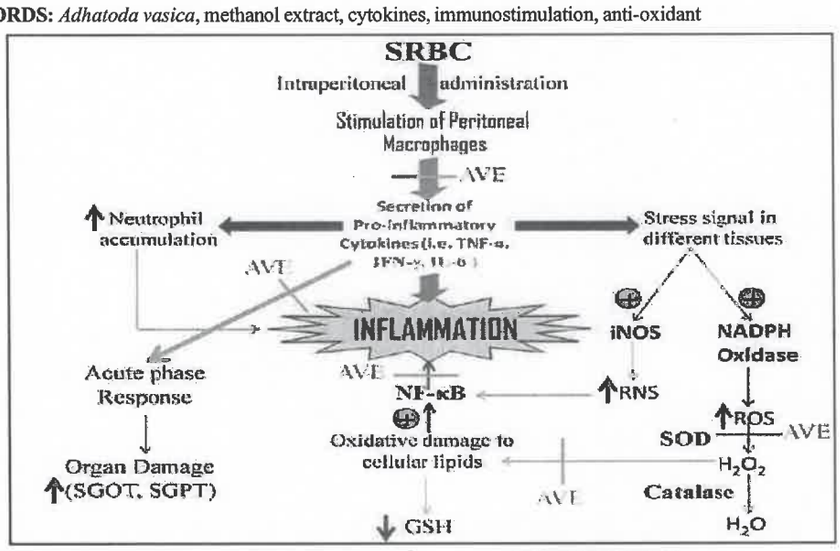
ABSTRACT

Adhatoda vasica has been used in traditional Indian medicinal system for treatment of inflammatory diseases, since several hundred years. The objective of the present study was to evaluate the immunomodulatory and antioxidant properties of the methanolic extract of the leaves of *Adhatoda vasica* in mice. The immunomodulatory properties of methanol extract of *Adhatoda vasica* (AVE) leaf at the doses of 50, 100 and 200mg/kg body weight was evaluated by determining the serum antibody titer, number of antibody producing plasma cells; delayed type hypersensitivity response, infiltration of neutrophils in spleen and serum level of cytokines after immunization with particulate antigen SRBC. The anti-oxidant properties of the extract was assessed by determination of tissue GSH, catalase and SOD enzyme activity and lipid peroxidations from different groups of mice. Oral administration of the AVE prior to SRBC challenge increased the serum antibody titer, number of plasma cells in spleen with a concomitant decrease in DTH response, MPO enzyme activity in spleen and serum level of TNF-α, IFN-γ and IL-6 in comparison to SRBC challenged mice. Increase in GSH, SOD and catalase enzyme activities and decreased lipid peroxidation as well as decreased COX-2, iNOS and NFκB expression was found in the spleen tissues examined in the AVE pre-treated mice when compared to SRBC challenge. Leaves of *Adhatoda vasica* possess potent immunostimulatory effect; free from undesired overstimulation of immune system along with its potent anti-oxidant effect which might contribute to its protective role during oxidative damage initiated by particulate antigen SRBC induced profound inflammatory response in mice.

KEYWORDS: *Adhatoda vasica*, methanol extract, cytokines, immunostimulation, anti-oxidant



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1. INTRODUCTION

Particulate antigen induced immune response lead to severe inflammatory response, followed by oxidative damage, therefore complicating and enhancing the damage in the host. Sometimes the manifestations of many diseases rely upon the modulation of the immune system in order to take over the body's own defense. Therefore, the

target becomes regulated stimulation of the immune system, so that it can reproduce only a controlled and desired response leading to clearance of the infection. In this attempt a huge number of synthetic drugs have been introduced past 3-4 decades. But now-a-days the reliability of these drugs have been questioned in their long term use, as many of them has began to exert toxicity, loss in efficacy and leading to a deadly return of the diseases to which they were applied. Therefore, search for the newer and safer immunomodulatory drugs is still going on. Nature is a sink of all the unsolvable questions for humanity, and the natural products have been proved to be safer than the conventional synthetically produced drugs, due to less toxicity and less side effects[1,2]. Therefore, to figure out the remedy using naturally available compounds has been found rational[3]. Natural sources, mostly plants possess a wide range of different bioactive molecules that are capable of giving easier remedy in many situations. A branch of the medicinal plant research is focused on the isolation of particular novel compounds with miraculous effects, and the other one is still working on the easier preparation of the natural products. The relevance for the importance of using crude plant extract rather than using an isolated compound, have been justified in the sense that plant extract is a low cost preparation and any one can avail it with ease, and it is applicable in those cases where a regulated immune response is desired, since the effect of any extract is an outcome of the interplay of a cocktail of different bio-active molecules, rather than a single compound.

Adhatoda vasica Nees is a small, evergreen subherbacious shrub seen growing in moist, deciduous, tropical region of South- Asia. The aqueous leaf extract is a common household remedy for cold and cough. The leaves of this plant were found to contain an essential oil and alkaloid vasicine, N-oxides of vasicine, vasicinone, deoxyvasicine and maiontone[4]. *Adhatoda vasica* Nees belongs to the family acanthaceae; found almost over all parts of the India and is found in profuse amounts in West Bengal. It is a medicinal herb and the leaves of *Adhatoda vasica* has been reported to possess wide spectrum medicinal properties including anti-inflammatory property, an antitussive effect, radiomodulatory influence, significant hepatoprotective effect and oils from the leaves have been found active against bacterial infections[5,8] and has been considered as an official drug in Pharmacopoeia, India, 1994. The presence of alkaloids, tannins, flavonoids, cardiac glycosides in aqueous, methanolic, diethyl ether, chloroform and hydroalcohol extracts of this plant were reported by phytochemical tests; saponins were found to be present in methanolic, aqueous and hydroalcohol extract[9,10]. However, there is lack in reports on immunomodulatory effects of such compounds isolated from *Adhatoda vasica,* excepting vasicine [1, 2, 3, 9 tetra-hydropyrolle (2, 16) quinazolin 3-ol, $C_{11}H_{12}N_2O$], a quinazoline alkaloid molecule, the most important bio-active compound from this plant with profound physiological effects[9-10]. Particular respiratory sensors and peripheral receptors for vasicine were found to be responsible for its bronchodilatory effects[11]. However, very little is known about the molecular mechanism of action of vasicine *in vivo* till date[12]. The alkaloid fraction of *A. vasica* leaf extract primarily contains vasicine and its derivative vasicinone which are having profound physiological effects but besides vasicine, the leaves also contained others alkaloids vasicinol, adhatodine, adhatonine, adhvasinone, mimosine, anisotine and hydroxypeganine, betaine, steroids and alkanes[13,14]; essential oils such as 1,2,3, trimethyl benzene; borneol, ethanonaphthalene; 1,1,4a trimethyl-5,6- trimethyl-enedecahydronaphthalene; 2, *tert* 1-butyl-1,4-dimethoxybenzene; α-caryophyllene; cycloproplejazulene; caryophyllene oxide; 2-naphthalenemethanol[15]. However, the immunomodulatory and anti-oxidant properties of the methanolic extract of *Adhatoda vasica* leaf has not been studied in detail and the underlying mechanism were also not unraveled against antigenic stimulation.

The present study was attempted to investigate the immunomodulatory role of methanolic extract of *Adhatoda vasica* leaf after particulate antigen stimulation in mice. We studied the effect of the extract (AVE) in antibody production, number of antibody producing plasma cells, delayed type hypersensitivity (DTH) response, MPO activity and the release of pro-inflammatory as well as anti-inflammatory cytokines in serum with special reference to its antioxidant properties in a murine model challenged with the particulate antigen, i.e. sheep red blood cells or SRBC. The expression of marker molecules of inflammation like NF-κB, iNOS and COX-2 were also investigated in the spleen using immunoblotting. In this study we reported the potent immunomodulatory role of methanolic extract of *Adhatoda vasica* leaf along with potent anti-oxidant activities in vivo has given protection against the inflammatory response and oxidative damage induced by particulate antigen (SRBC) challenge.

2. MATERIALS AND METHODS

2.1 Preparation of the extract

2.1.1 Plant collection

The whole plants of *Adhatoda vasica* were collected from Singur, Hooghly District, West Bengal, India. The botanical identification of the plants was confirmed taxonomically by The Botanical Survey of India, Ministry of Environment and Forest, Govt. of India, [CNH/50/2014/Tech.II/103].

2.1.2 Preparation of plant extracts

Methanolic extract of the leaf part of *Adhatoda vasica* was done according to the method described earlier[16] with some modifications. 10g of dried and finely powdered leaves were soaked into 30ml of

methanol and kept at 30°C for 12 hours on a rotary shaker. The methanol was allowed to evaporate completely, under sterile conditions and another 30ml volume of methanol was also added and kept for another 12 hours at 30°C, in a rotary shaker. It was filtered through Whatman's No.1 filter paper and the filtrate was centrifuged at 2000 rpm for 10mins. The supernatant was collected and allowed to dryness completely under sterile conditions[16].

2.2 Experimental design

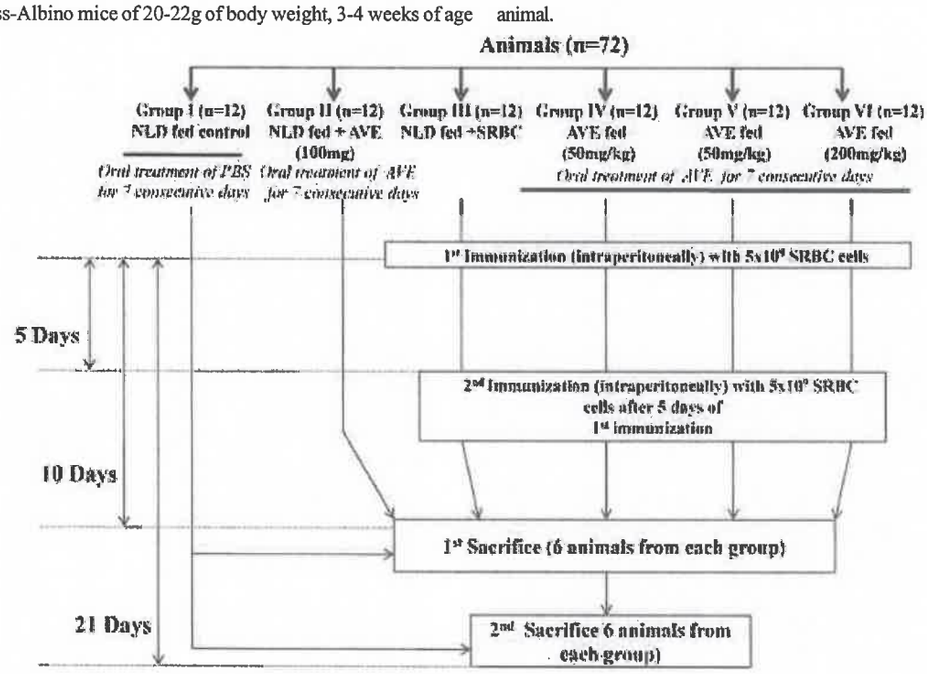
2.2.1 Experimental animals

All experiments involving animals were conducted according to the protocols that had been approved by the Institutional Animal Ethics Committee (IAEC), Department of Physiology, University of Calcutta, under the guidance of CPCSEA [Approval Number: 820/04/ac/CPCSEA , dated 05. 08.2013], Ministry of Environment and Forest, Govt. of India. Wild type male Swiss albino mice were used throughout the study. To minimize the feeling of hypoxia or discomfort before and during dissection of body and tissue collection, mice were anaesthetized with inhaling anesthetics (ether) before terminal surgery. Euthanasia was performed by general anesthesia followed by vital tissue removal using 2-3 % ether for induction and 1% for maintenance.

Male Swiss-Albino mice of 20-22g of body weight, 3-4 weeks of age were used in this study. They were provided standard rodent diet and animal house facilities, and maintained under standard laboratory conditions (temperature 25±2°C; photoperiod of 12h). Animals (total 90) were divided into six groups (group I to VI) containing 3 animals per group for assessment of DTH response (n =18) and were further divided into six groups (group I to VI) with 12 animals each for the rest of the experiments except for DTH (n = 72).

2.2.2 Dosage of plant extracts

Doses of plant extract for this study were determined from acute toxicity study. Extracts of 500, 750, 1000, 1500, 2000 and 2500 mg/Kg body weight concentrations were dissolved in sterile saline and administered orally[17]. The animals were then observed for death or any deformities or any behavioral changes up to 72 hours. The dose upto 2000 mg/ kg body weight concentration did not show any death or behavioral changes or deformities and therefore the 1/20th of this dose, i.e., 100 mg/kg was taken as the safe dose for the study as recommended from earlier study for other plant extracts[18], and a dose regimen of 50, 100 and 200 mg/kg body weight was selected for the study. These doses were further subjected for the assessment of cytotoxicity by determination of lactate dehydrogenase (LDH) activity in the liver tissue homogenate[19]. The extract at the dose of 50, 100 and 200 mg/kg body weight was administered *per orum* (p.o) for a period of one week in a daily dose schedule at a volume of 200µl per animal.



2.2.3 Preparation of SRBC for immunization

Fresh blood was collected from jugular vein of sheep being sacrificed in the local slaughter house into sterile polypropylene tubes containing sterile Alsever's solution and stored at 4°C. The blood was centrifuged to obtain cell pellet and was washed thrice with pyrogen free sterile normal saline and was adjusted to 5x10^{9}cells/ml with sterile saline[20].

2.2.4 Immunization and treatment

The animals were divided into six different groups, among which group I normal laboratory diet (NLD) fed mice received sterile PBS (pH 7.4) orally, the group II having NLD were pre-treated with AVE (100 mg/kg) was also received sterile PBS. Animals of group III were fed with NLD and challenged with SRBC suspension. Animals from group IV, V and VI were orally treated with AVE at doses of 50, 100 and 200 mg/kg body weight daily by oral administration at a volume of 200µl to each animal, for seven consecutive days. At last day of the extract treatment, animals of group III (NLD), IV, V and VI were immunized by intraperitoneal injection of 50µl of 5x10^{9}cells/ml SRBC suspension to each animal and considered as day 0 of immunization. On the 5th day after first immunization, animals from groups III, IV, V and VI were again challenged with intraperitoneal injection of 50 µl of 5x10^{9}cells/ml SRBC suspension to each animal. For analysis of MPO enzyme activity from spleen, serum cytokines and tissue antioxidants, animals were sacrificed at the 5th day after second immunization, i.e. 10th day after first immunization. Animals from each group were sacrificed at the day 5 and day 21 after second immunization, separately for the determination of antibody titer and the number of antibody producing plasma cells.

2.2.5 Time of collection of blood, preparation of serum and collection of tissue samples

After 7 days of AVE feeding (daily oral gavages) the mice were immunized with 1st dose of SRBC and after 5 days of 1st dose of SRBC, animals were again challenged with SRBC (2nd dose). Mice were sacrificed after 5 days of 2nd dose of SRBC and blood was collected for determination of antibody titre and the number of antibody producing cells by hemolytic plaque assay. Animals that have received 2nd dose of SRBC were kept in their home cage when AVE feeding was discontinued as well as no SRBC were challenged, were sacrificed on 21 days post SRBC challenge. Blood and tissue samples were collected for the determination of biochemical parameter, serum cytokines, tissue antioxidant status, western blot and also for determination of antibody titre and the number of antibody producing cells by hemolytic plaque assay. Blood sample from mice was obtained by cardiac puncture under ether anesthesia. For preparation of serum, blood was transferred into micro-centrifuge tubes and allowed to coagulate at 4°C and centrifuged at 3000 x g for 5 minutes at 4°C. The pale yellow colored supernatant was taken out carefully using micropipette and stored at -20°C for analysis. Liver, spleen and kidney tissues were collected from the mice under ether anesthesia under sterile conditions and were also stored at -20 °C for further experiments.

2.3 Bioassays

2.3.1 Assessment of creatinine, billirubin, SGOT and SGPT

2.3.1.1 Estimation of creatinine level in blood

The concentration of creatinine in blood was estimated by Folin-Wu method with some modifications. Distilled water was used to prepare the blank and standards and the creatinine was dissolved in acid solution. The creatinine level in blood was expressed as mg/100ml of blood[21].

2.3.1.2 Estimation of serum level of billirubin

The formation of pink-colored azo-billirubin by the reaction between billirubin and a diazo reagent was utilized. Finally the estimation of total billirubin was done with addition of alcohol. The total billirubin level in serum was measured as mg/100ml of serum[22].

2.3.1.3 Estimation of activity of serum glutamate oxaloacetate transaminase (SGOT) and serum glutamate pyruvate transaminase (SGPT)

100 µl of non-hemolyzed serum was mixed with 0.5 ml of SGOT and SGPT substrates and incubated with serum and will be allowed to react with 2,4-Di-nitrophenyl hydrazine (DNP solution and another incubation will be followed by addition of 0.4 (N) sodium hydroxide (NaOH) solution[23]. The intensity of the developed color was read at 540 nm. The activities were expressed as IU/ml of serum.

2.3.2 Assessment of the humoral immune response

Effect of *Adhatoda vasica* leaf extract (AVE) on parameters of humoral immune response such as circulating hemagglutinin concentration and number of plaque forming cells were assessed.

2.3.2.1 Determination of hemagglutinating antibody titer

Hemagglutinin titer was determined as described earlier[24]. Serial two-fold dilution of the serum was made in 50µl of phosphate buffered saline (PBS) (pH 7.2) using microtitre plates, equal volume of 1% SRBC suspension (5x10^{7}cells) was added to each well and incubated at room temperature (37°C) for overnight, after a proper mixing. The highest serum dilution showing visible hemagglutination was obtained as the titer value of antibody in serum.

2.3.2.2 Determination of the number of antibody producing cells

The number of antibody producing cells was determined from spleen by plaque forming cell assay. The splenic tissues from different groups of mice were washed twice in RPMI-1640 medium and a single cell suspension of 10^{6}cells/ml was prepared in the same medium. 1ml of SRBC (5 x 10^{8}cells/ml) in PBS, along with 500µl guinea-pig complement, added to the 1ml splenic cell suspension and the assay mixture was loaded in a Cunningham chamber and sealed with petroleum

jelly. The number of plaques was counted under the light microscope and expressed as PFC per 10^6 spleen cells[25].

2.3.3 Assessment of Cell-mediated immune response:

2.3.3.1 Delayed type hypersensitivity

In the separate set of experiment, the animals were sensitized with subcutaneous administration of $1x10^9$ cells of SRBC on the last day of AVE treatment. On the 5th day after sensitization, the animals were injected $1x10^8$ cells of SRBC into the foot pad and same volume of sterile normal saline was injected at the foot pad of control animals. Footpad thickness was measured at 24, 48 and 72 hours after SRBC challenge using dial caliper[26].

2.3.3.2 Assessment of Serum cytokines

Blood samples from mice of different groups were obtained by cardiac puncture under ether anesthesia at selected intervals. The serums from different groups were normalized to the protein content by the Bradford method before the assay and the levels of cytokines were determined. The serum concentrations of pro-inflammatory cytokines TNF-α, IFN-γ, IL-6, IL-12, MCP-1 and the anti-inflammatory cytokine IL-10 was determined by Sandwich ELISA method according to the manufacturer's instruction (Ray Biotech, Inc.), using the Bio-Rad ELISA Reader and was calculated based on the standard curve. Serum cytokine levels were expressed in pg/ml, following manufacturer's protocol. The values were expressed as pg/ml of serum.

2.3.3.3 Determination of myeloperoxidase activity from spleen

Myeloperoxidase (MPO) enzyme activity was analyzed as index of neutrophil infiltration in the spleen tissue, because it is closely related with the number of neutrophil present in the tissue. Spleen tissues separated from mouse, were homogenized in 10 volumes of a buffer containing 20 mM Tris–HCl (pH 7.0), Ethylene-diamine tetra-acetic acid (EDTA), sucrose and protease inhibitor cocktail, and then centrifuged at 2000 x g for 10 min at 4°C. The supernatants were sterilized by passing through a Millipore filter (0.45 lm pore size) and stored at -80°C until analysis. Protein levels in the tissue homogenates were determined by Bradford method. An aliquot of the supernatant was allowed to react with a solution of O-dianisidine dihydrochloride (0.167 mg/ml) and 0.005% H_2O_2. The rate of change in absorbance was measured spectrophotometrically at 405 nm. MPO enzyme activity has been defined as the concentration of enzyme degrading 1μM of peroxide/min at 37°C and was expressed as change in absorbance/min/mg of tissue protein[27].

2.3.4 Assessment of the antioxidant activities

The antioxidant activities were determined from the different tissues, i.e., liver, kidney and spleen.

2.3.4.1 Preparation of tissue homogenates

For assessment of the antioxidant activities the tissue homogenates were prepared from different groups of mice. The liver, spleen and brain tissues were separately homogenized in 10 volumes of 50 mM phosphate buffer (pH 7.4) on ice for 30 s using a power driven polytron homogenizer. The homogenate was transferred into micro-centrifuge tubes and centrifuged at 9000 x g at 4°C for 20 min. The supernatant was stored at -20°C and used to measure activity of antioxidant enzymes and the amount of protein present[28-29].

2.3.4.2 Estimation of tissue protein

Protein content of tissue homogenates and supernatants were determined by using the dye-binding technique, according to Bradford. In this colorimetric assay Coomassie brilliant blue (G-250) was used to bind to the proteins at an acidic pH and the change in absorbance was measured[30].

2.3.4.3 Assessment of the reduced glutathione (GSH) level

Reduced glutathione concentration was estimated as acid soluble sulfhydryl content, by its reaction with DTNB (Elman's reagent), following the method of Sedlak and Lindsay with some modifications and was measured spectrophotometrically at 412nm. Values were expressed as μ moles of GSH per mg tissue protein[31].

2.3.4.4 Measurement of Lipid peroxidation level

Tissue was homogenized on ice cold 0.9% saline (pH 7.0) with a Potter Elvejhem all glass homogenizer (Belco Glass Inc., Vineland, NJ, USA) for 30s and the level of lipid peroxidation products in was determined as thio-barbituric reactive substances (TBARs) and the values were expressed as n moles of TBARs per mg of tissue protein[29].

2.3.4.5 Assessment of the SOD activity

Tissue homogenate (100 μl) was mixed with 1.5 ml of a Tris–EDTA–HCl buffer (pH 8.5), then 100 μl of 7.2 mM pyrogallol was added and the reaction mixture was incubated at 25 °C for 10 min. The reaction was terminated by addition of 50 μl of 1 M HCl and measured at 420 nm. One unit was determined as the amount of enzyme that inhibited the oxidation of pyrogallol by 50%. The activity was expressed as U/mg protein[32].

2.3.4.6 Assessment of the catalase activity

Decomposition of hydrogen peroxide (H_2O_2) due to catalase activity was assayed by the decrease in absorbance of H_2O_2 at 240 nm. Catalase activity in the cell free homogenate was determined spectrophotometrically by measuring the decrease in H_2O_2 concentration at 240 nm. At time zero, 1.8 ml of each homogenate was mixed with 0.2 ml of a phosphate buffer containing 10m mole H_2O_2. One ml of the mixture was immediately added to a cuvette and placed into a spectrophotometer. Catalase activity was observed via degradation of H_2O_2 as

determined by a decrease in UV light absorbance over time. Measurement of absorbance was taken at 15 second interval after addition of the homogenate to hydrogen peroxide buffer. Units of catalase activity present in 1 ml of homogenate were calculated and expressed as µmoles H_2O_2 min/mg of tissue protein[32].

2.3.5 Detection of cyclooxygenase-2 (COX-2), NF-κBp65 and inducible nitric oxide synthase (iNOS) expression from spleen

Western blot analysis of spleen COX-2, NF-κB and iNOS expression was performed by standard methods. Briefly, whole tissue collected from mice were lysed with RIPA-NP40 and 60 µg of the tissue lysates were separated on an 10% sodium dodecyl-sulphate (SDS)-polyacrylamide gel and blotted onto nitrocellulose membrane. Protein concentrations were normalized to the protein content by Bradford method before the assay. Proteins were denatured at 100 °C for 5 min in loading buffer (60 mM Tris, 2.5% sodium dodecyl sulphate, 10% glycerol, 5% mercaptoethanol, 0.01% bromophenol blue). Aliquots containing an equal amount of total proteins from each sample were separated by SDS-PAGE (10% gel) and transferred onto BioTrace, PVDF, transfer membranes (PALL; Gelman Laboratory; 100 V, 1.0 h, 4 °C). After blocking for 2 h at 4 °C in TBST (20 mM Tris-HCl, 150 mM NaCl, 0.1% Tween 20) containing 5% non-fat milk, membranes were washed three times in TBST and probed overnight at 4 °C with appropriate primary antibodies[28] (anti-iNOS; Biorbyt, Cambridgeshire, UK; anti-NF-κB [p65] from Abcam, Cambridge, UK[33] and anti COX-2 (1: 1000) from Chemicon, Temecula, CA, USA)[34] in TBST containing 1% bovine serum albumin. Blots were washed three times in TBST, incubated for 2 h with appropriate HRP-conjugated secondary antibodies, developed with the Super Signal chemiluminescent substrate (Super Signal West Pico Chemiluminescent Substrate; Thermo Scientific) and exposed to X-Omat BT films (Kodak, Windsor, CO, USA). Bands were quantified using QUANTITY ONE software (Bio-Rad, Inc., Hercules, CA, USA).

2.4. Statistical analysis

One-way model 1 ANOVA (Analysis of Variance) was performed between the groups. In ANOVA observed variance is partitioned into components due to different explanatory variables. A level of $P < 0.05$ was considered significant. Significant differences of the means between the groups were performed by One-Way ANOVA. Scheffe's F-test had been done as post hoc test for multiple comparisons of means of different groups when significant F-value was found.

3. RESULTS

3.1 Effect on the serum GOT, GPT, billirubin and creatinine levels

The blood creatinine level that was significantly increased with SRBC challenge in NLD fed mice, when compared to control (NLD + sterile PBS). However, oral treatment of mice with AVE at the dose of 100mg/kg body weight before SRBC challenge significantly ($P<0.05$) reduced the blood creatinine level in comparison to NLD-fed SRBC challenged mice from. AVE pre-treatment alone did not alter the creatinine level in blood significantly in comparison to NLD-fed control mice (Table 1). The significant elevation in the serum billirubin concentration with the SRBC challenge to NLD fed mice was found to be attenuated significantly in the AVE pre-treated mice at the dose of 100mg/kg body wt. before SRBC challenge ($P<0.05$), The serum billirubin level in NLD fed control mice was found to be almost same as in mice pre-treated with AVE without any SRBC challenge (Table 1). The level of SGOT in serum was increased significantly with SRBC challenge in the NLD fed mice. SGPT in serum was also increased significantly with SRBC challenge in the NLD fed mice. AVE pre-treatment at the dose of 100mg/kg body wt. was found to attenuate this increase in SGOT and SGPT significantly ($P<0.05$). No significant change in SGOT and SGPT was found in the NLD-fed control mice when compared to the AVE pre-treated group receiving same dose without SRBC challenge (Table 1).

Table 1: Effect of AVE on the organ function as assessed from the level of serum billirubin, blood creatinine, SGOT and SGPT

Groups	Serum Billirubin (mg%)	Blood Creatinine (mg%)	SGOT (IU/ml)	SGPT (IU/ml)
NLD (Control)	8.13 ± 0.75	0.49 ± 0.03	16.69 ± 1.54	8.39 ± 0.82
AVE (50mg/kg)	7.89 ± 0.63#	0.47 ± 0.02	16.27 ± 1.26	8.23 ± 0.72
AVE (100mg/kg)	7.93 ± 0.42#	0.42 ± 0.05	15.83 ± 1.31	8.76 ± 0.62
AVE (200mg/kg)	8.20 ± 0.59#	0.42 ± 0.04	16.13 ± 1.23	8.34 ± 0.79
NLD + SRBC	12.21 ± 0.9*	0.78 ± 0.05*	21.53 ± 1.89*	12.83 ± 0.82*
AVE (50mg/kg) + SRBC	9.79 ± 0.42*#^	0.59 ± 0.04*#^	18.65 ± 1.41	10.23 ± 1.09#
AVE (100mg/kg) + SRBC	8.27 ± 0.57#	0.42 ± 0.03*#	16.58 ± 1.48#	8.71 ± 0.79#
AVE (200mg/kg) + SRBC	9.21 ± 0.63#	0.48 ± 0.04#	17.19 ± 1.51#	9.04 ± 0.78#

The results in this table represent the serum GOT, GPT, billirubin and blood creatinine levels (Mean ± SD) in the NLD and AVE fed mice challenged with SRBC of three independent experiments (P<0.05). * indicates significant (P<0.05) difference in comparison to NLD (control), # indicates significant difference in comparison to SRBC challenged group and ^indicates significant difference between AVE pre-treated and AVE pre-treated mice challenged with SRBC (P<0.05).

3.2 Effect of AVE on the antibody titer

Production of anti-SRBC antibody (IgG and IgM) as the circulating antibody titre was found to be increased in AVE pre-treatment prior to SRBC challenge. Almost 4 times increase in antibody production was found with pre-treatment of 100 mg/kg dose of AVE. No visible he-magglutination was observed in case of control animals (Table 2).

Table-2: Effect of AVE pre-treatment on the serum antibody titre

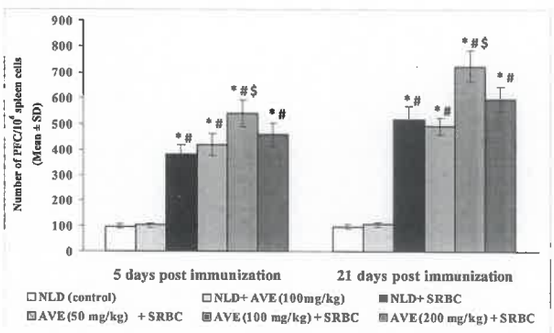
Groups	Serum antibody titre	
	5th day post immunization	21st day post immunization
NLD (Control)	-	-
NLD + AVE (100mg/kg)	-	-
NLD + SRBC	1:256	1:512
AVE (50mg/kg) + SRBC	1:256	1:1024
AVE (100mg/kg) + SRBC	1:512	1:2048
AVE (200mg/kg) + SRBC	1:512	1:1024

Serum obtained from the NLD and AVE fed mice after completion of SRBC immunization was serially diluted in a series of tubes to which SRBC was added as antigen. The last tube showing visible agglutination will reflect the antibody titre which can also serve as a useful semiquantitative measure of the concentration of agglutinating antibodies.

3.3 Effect of AVE on the number antibody producing cells

A significant increase ($P<0.05$) in the number of antibody producing cells in spleen of AVE pre-treated mice upto $540 \pm 51.43/10^6$ spleen cells and $724 \pm 62.1/10^6$ spleen cells was observed in comparison to the number of spleen cells from NLD fed mice, challenged with SRBC, i.e., $380 \pm 36.89/ 10^6$ spleen cells and $520 \pm 51.3/ 10^6$ spleen cells, respectively at 5th and 21st days post immunization (Fig. 1).

Fig-1: Effects of AVE against SRBC immunization–induced humoral immune response

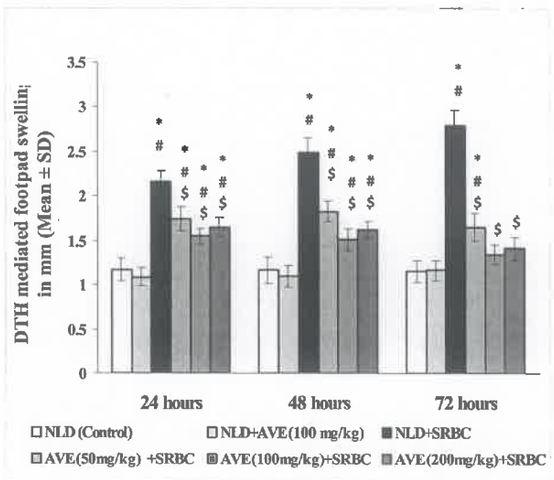


NLD and AVE fed mice were immunized with SRBC. Plaques were counted under a low power microscope. The number of plaques is expressed as Mean ± SD for 6 mice per group. Experiments were completed in triplicate. *represents significant difference (P<0.05) in comparison to the NLD fed control group, #represents significant difference (P<0.05) in comparison to the NLD and AVE (100mg) fed group without SRBC challenge, $ represents significant difference (P<0.05) in comparison to the NLD fed SRBC challenged group.

3.4 Effect of AVE on the delayed type hypersensitivity (DTH) response

The effect of AVE pre-treatment on delayed-type hypersensitivity response mediated swelling of the footpad (Fig. 2). Pre-treatment with AVE at different doses significantly ($P<0.05$) decreased the DTH response mediated swelling of paw diameter in comparison to NLD group challenged with SRBC (Fig. 2)

Fig-2: Effects of AVE against SRBC immunization–induced of Delayed type hypersensitivity (DTH) reaction

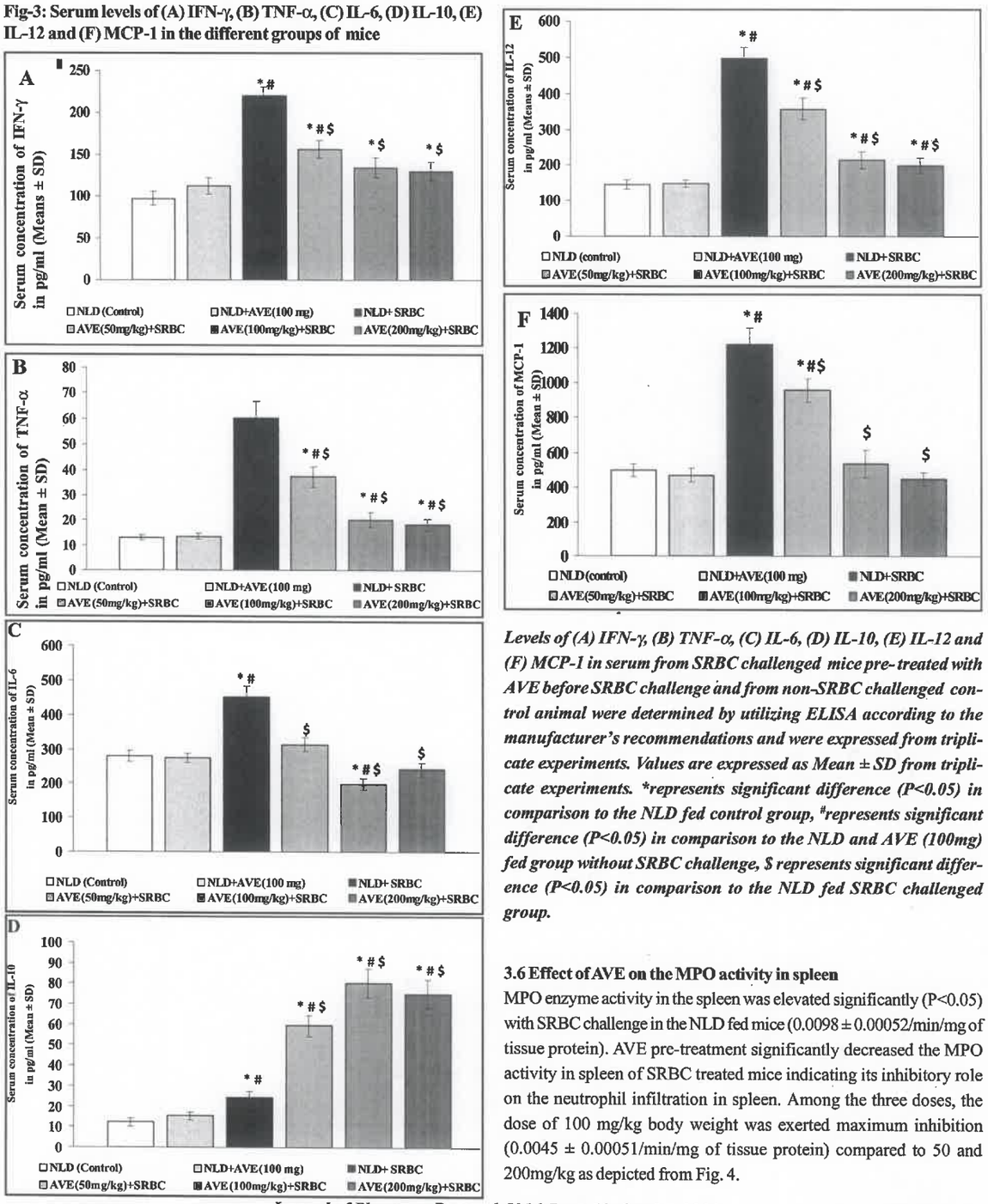


Cell mediated immune response was assessed by foot pad reaction. Swelling of foot pad was measured in both NLD and AVE fed mice that were challenged with SRBC. The results in this figure represent the mean diameter (in mm) ± SD of swollen foot pad in SRBC challenged mice of triplicate experiments for 6 mice per groups. *represents significant difference (P<0.05) in comparison to the NLD fed control group, #represents significant difference (P<0.05) in comparison to the NLD and AVE (100mg) fed group without SRBC challenge, $ represents significant difference (P<0.05) in comparison to the NLD fed SRBC challenged group.

3.5 Effect on the pro-inflammatory and anti-inflammatory cytokines

The elevated concentration of the pro-inflammatory cytokines IFN-γ (Fig 3A), TNF-α (Fig 3B), IL-6 (Fig.3C), IL-12 (Fig. 3E) and MCP-1 (Fig. 3F) after SRBC challenge to NLD fed mice in serum was found to be significantly ($P<0.05$) attenuated in the animals pre-treated with AVE before SRBC challenge, in a dose dependent manner. The serum level of anti-inflammatory cytokine IL-10 (Fig. 3D) was also found to increase significantly ($P<0.05$) in the AVE treated group, also in a dose dependent manner.

Fig-3: Serum levels of (A) IFN-γ, (B) TNF-α, (C) IL-6, (D) IL-10, (E) IL-12 and (F) MCP-1 in the different groups of mice

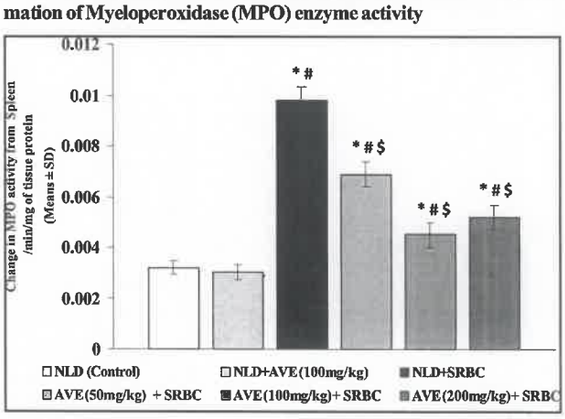


Levels of (A) IFN-γ, (B) TNF-α, (C) IL-6, (D) IL-10, (E) IL-12 and (F) MCP-1 in serum from SRBC challenged mice pre-treated with AVE before SRBC challenge and from non-SRBC challenged control animal were determined by utilizing ELISA according to the manufacturer's recommendations and were expressed from triplicate experiments. Values are expressed as Mean ± SD from triplicate experiments. *represents significant difference (P<0.05) in comparison to the NLD fed control group, #represents significant difference (P<0.05) in comparison to the NLD and AVE (100mg) fed group without SRBC challenge, $ represents significant difference (P<0.05) in comparison to the NLD fed SRBC challenged group.

3.6 Effect of AVE on the MPO activity in spleen

MPO enzyme activity in the spleen was elevated significantly (P<0.05) with SRBC challenge in the NLD fed mice (0.0098 ± 0.00052/min/mg of tissue protein). AVE pre-treatment significantly decreased the MPO activity in spleen of SRBC treated mice indicating its inhibitory role on the neutrophil infiltration in spleen. Among the three doses, the dose of 100 mg/kg body weight was exerted maximum inhibition (0.0045 ± 0.00051/min/mg of tissue protein) compared to 50 and 200mg/kg as depicted from Fig. 4.

Fig-4: Neutrophil accumulation in the spleen as determined by estimation of Myeloperoxidase (MPO) enzyme activity



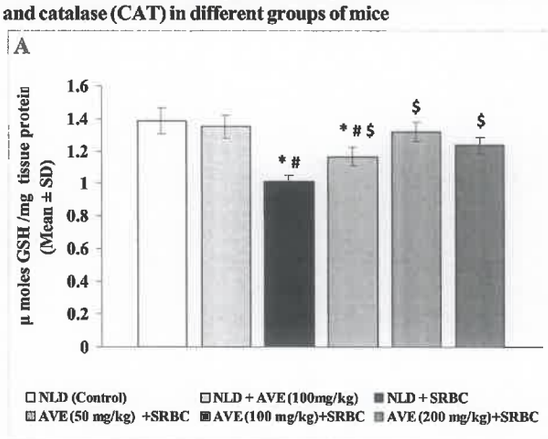
MPO activity was analyzed as index of neutrophil infiltration in the spleen tissue. The rate of change in absorbance was measured spectrophotometrically at 405 nm. MPO activity has been defined as the concentration of enzyme degrading 1 µmol of peroxide/min at 37°C and was expressed as change in absorbance/min.mg of protein. The results were reproduced in three repeated experiments. Data are expressed as mean ± SD of six mice per group. All the values are significant in the population mean (P = 0.05). *represents significant difference (P<0.05) in comparison to the NLD fed control group, #represents significant difference (P<0.05) in comparison to the NLD and AVE (100mg) fed group without SRBC challenge, $ represents significant difference (P<0.05) in comparison to the NLD fed SRBC challenged group.

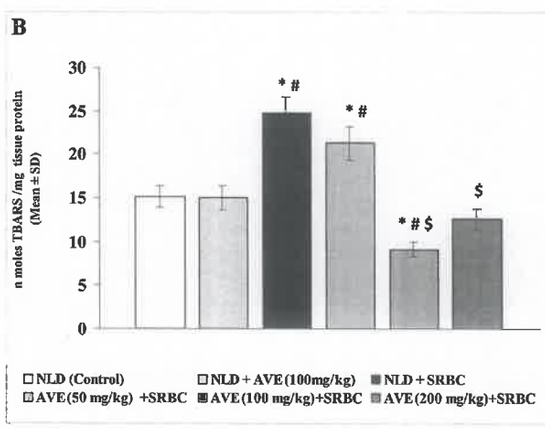
3.7 Effects of AVE against SRBC challenge–induced oxidative stress in liver, kidney and spleen and tissues of mice and its relation with progression of immune response

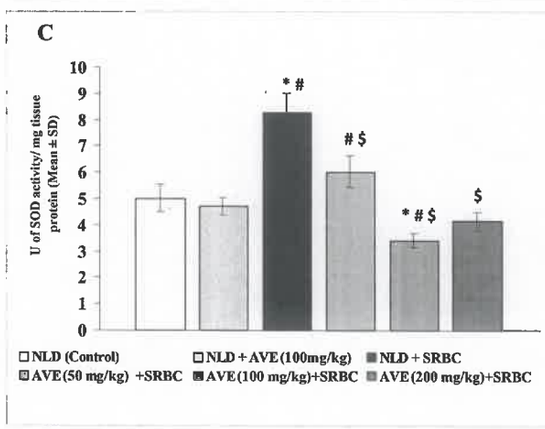
3.7.1 Effect of AVE on GSH levels in liver, kidney and spleen tissues of mice

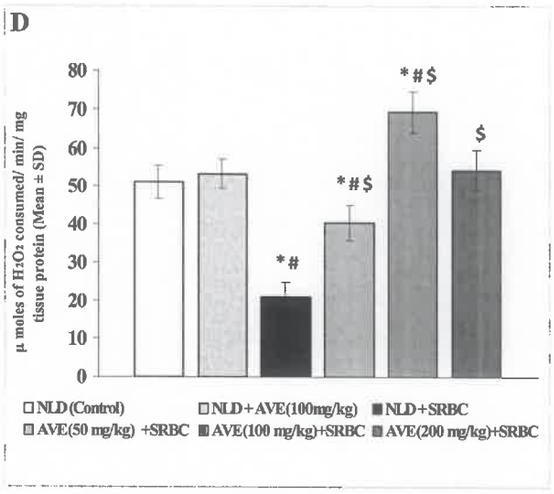
That oxidative stress is induced following SRBC challenge is also evident from our finding that the level of reduced glutathione (GSH) was found to be decreased in all the tissues tested in mice. However, when the mice were fed with AVE, the tissue glutathione level in most of the cases was found to be restored to near control values (Liver – Fig. 5A, Kidney – Fig. 6A and Spleen – Fig. 7A). These results indicate that the AVE is capable of ameliorating the oxidative stress induced in these organs due to SRBC challenge. Thus pre-treatment of mice with all the three doses of AVE restored the decline in GSH level in hepatic tissues after SRBC challenge significantly in a dose dependent manner, with the dose 100mg/kg having maximum effect (Fig. 5A). The decline in GSH during SRBC challenge in the kidney (Fig. 6A) and spleen (Fig. 7A) tissues was also restored significantly (P<0.05) with the pre-treatment of AVE before SRBC immunization in a dose dependent manner with the maximum effect observed at 100mg/kg b.w. dose.

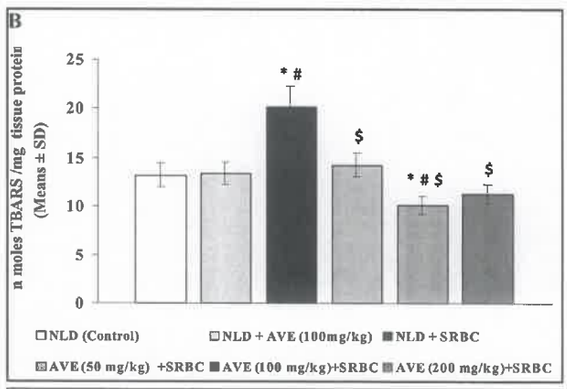
Fig-5: Alteration in mouse hepatic antioxidant status like reduced glutathione level (GSH), lipid peroxidation level (LPO) and the activities of antioxidant enzymes like superoxide dismutase (SOD) and catalase (CAT) in different groups of mice

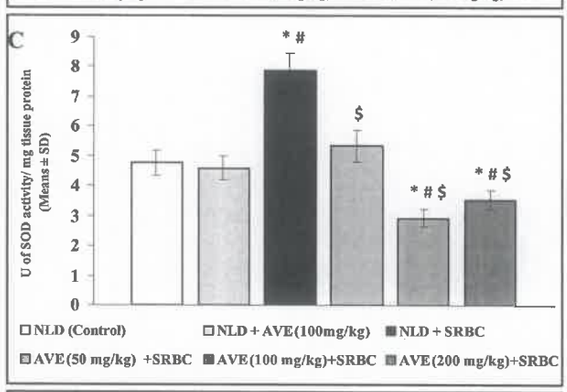






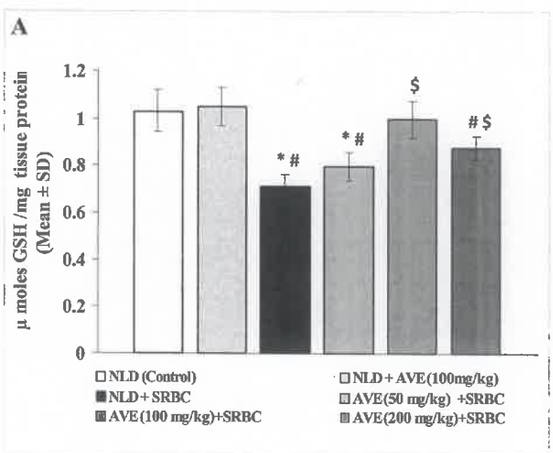


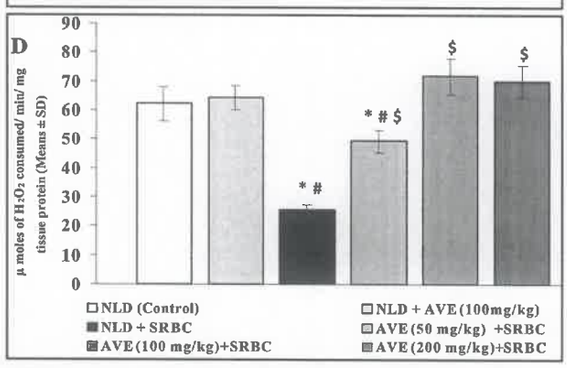




*Alterations in the level of (A) GSH (in μ moles/mg of tissue proteins), (B) LPO (expressed in n moles/mg of tissue protein), (C) SOD (U/mg of tissue protein) and (D) Catalase activity (expressed as μ moles of H_2O_2 consumed/min/mg of tissue protein) in hepatic tissues of the different groups of mice were performed as mentioned in the methods section. Values are expressed as Mean ± SD and are significant (P<0.05) for 6 mice per groups. *represents significant difference (P<0.05) in comparison to the NLD fed control group, #represents significant difference (P<0.05) in comparison to the NLD and AVE (100mg) fed group without SRBC challenge, $ represents significant difference (P<0.05) in comparison to the NLD fed SRBC challenged group.*

Fig-6: Alteration in mouse renal antioxidant status like reduced glutathione level (GSH), lipid peroxidation level (LPO) and the activities of antioxidant enzymes like superoxide dismutase (SOD) and catalase (CAT) in different groups of mice



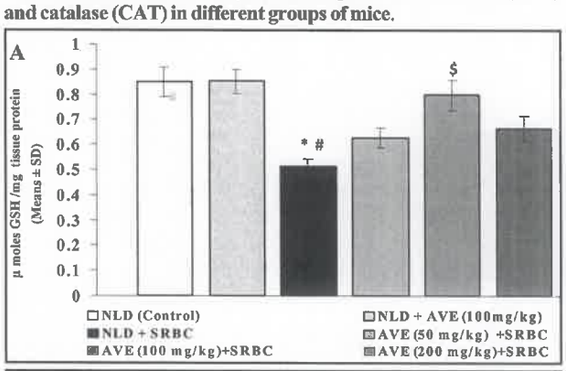


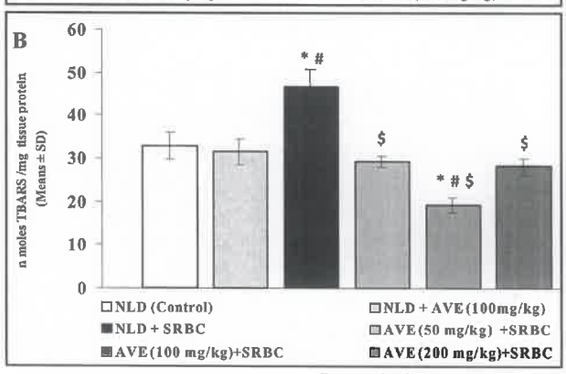
*Alterations in the level of (A) GSH (in μ moles/mg of tissue proteins), (B) LPO (expressed in n moles/mg of tissue protein), (C) SOD (U/mg of tissue protein) and (D) Catalase activity (expressed as μ moles of H_2O_2 consumed/ min/mg of tissue protein) in kidney tissues of the different groups of mice were performed as mentioned in the methods section. Values are expressed as Mean ± SD and are significant (P<0.05) for 6 mice per groups. *represents significant difference (P<0.05) in comparison to the NLD fed control group, #represents significant difference (P<0.05) in comparison to the NLD and AVE (100mg) fed group without SRBC challenge, $ represents significant difference (P<0.05) in comparison to the NLD fed SRBC challenged group.*

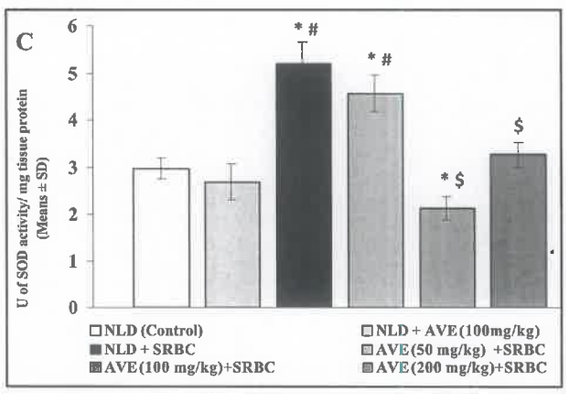
3.7.2 Effect of AVE on the level of lipid peroxidation in liver, kidney and spleen tissues of mice

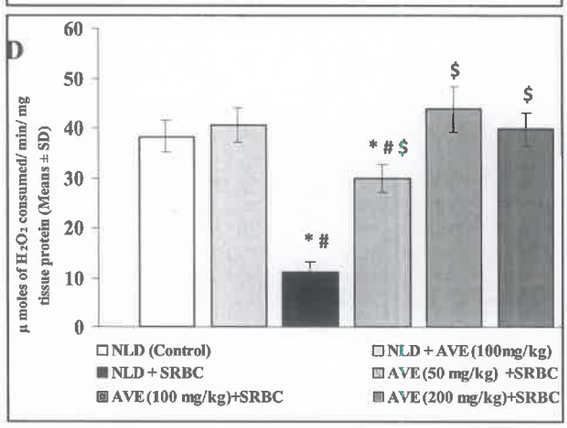
The oxidative damage on the membrane lipids was measured as the level of TBARS in the tissues tested in mice. Treatment of mice with SRBC caused elevation of LPO in all the tissues tested, viz., liver (Fig. 5A), kidneys (Fig. 6A) and spleen (Fig. 7A). However, this elevation in LPO was found to be significantly ameliorated when the mice were treated with AVE indicating efficacy of the AVE in the abatement of the oxidative stress induced in the tissue due to the SRBC challenge. The hepatic TBARs level was found to increase significantly ($P<0.05$) in the NLD fed and SRBC treated mice to 24.70 ± 1.87 n moles/ mg of tissue protein than the control mice (15.12 ± 1.23 n moles/mg tissue protein), but AVE pre-treatment significantly decreased the hepatic TBARs level (Fig 5.B)at all the three doses with maximum decrease was found at the dose of 100mg/kg body weight to 9.13 ± 0.83 n moles/mg tissue protein, when compared with NLD fed control mice and SRBC challenged mice (Fig. 5B). In kidney (Fig. 6B) as well as in spleen (Fig. 7B) TBARs level was found in significantly ($P<0.05$) decreased amount with AVE pre-treatment in comparison to the SRBC challenged mice. Among the three doses (50, 100 and 200mg/kg b.w.), 100 mg/ kg b.w. dose was found to be the most effective dose in the tissues tested in mice.

Fig-7: Alteration in mouse splenic antioxidant status like reduced glutathione level (GSH), lipid peroxidation level (LPO) and the activities of antioxidant enzymes like superoxide dismutase (SOD) and catalase (CAT) in different groups of mice.









Alterations in the level of (A) GSH (in μ moles/mg of tissue proteins), (B) LPO (expressed in n moles/mg of tissue protein), (C) SOD (U/mg of tissue protein) and (D) Catalase activity (expressed as μ moles of H_2O_2 consumed/min/mg of tissue protein) in spleen tissues of the different groups of mice were performed as mentioned in the methods section. Values are expressed as Mean ± SD and are significant ($P<0.05$) for 6 mice per groups. *represents significant difference ($P<0.05$) in comparison to the NLD fed control group, #represents significant difference ($P<0.05$) in comparison to the NLD and AVE (100mg) fed group without SRBC challenge, $ represents significant difference ($P<0.05$) in comparison to the NLD fed SRBC challenged group.

3.7.3 Effect of AVE on SOD activity in liver, kidney and spleen tissues of mice

Similarly, we have examined the activities of the key antioxidant enzymes like SOD and CAT in all the three tissues tested. The results indicate that SOD activity in SRBC-infected group increased significantly in liver (Fig. 5C), kidney (Fig. 6C) and spleen tissues (Fig. 7C). However, the SOD activity was decreased in SRBC challenged mice and almost restored to control after treatment with AVE before SRBC challenge in liver (Fig. 5C), kidney (Fig. 6C), and spleen (Fig. 7C) tissues at the dose of 50mg/kg dose of AVE treatment.

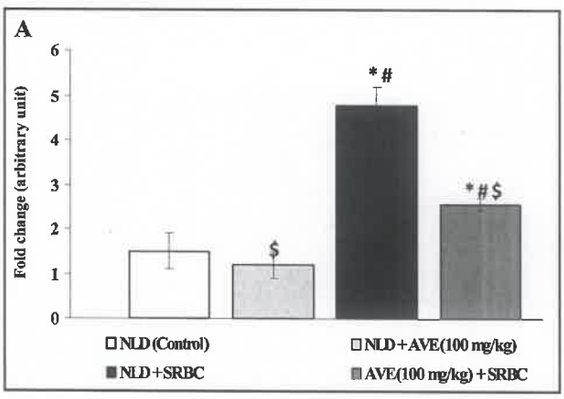
3.7.4 Effect of AVE on catalase activity in liver, kidney and spleen tissues of mice

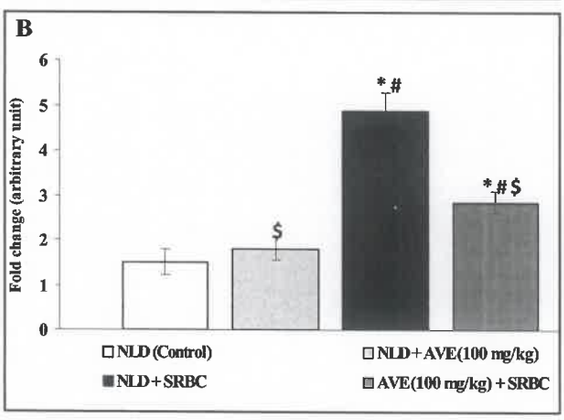
The activity of CAT, another important antioxidant enzyme, was found to be decreased in liver (Fig. 5D), kidney (Fig. 6D) and spleen tissues (Fig. 7D) following challenge with SRBC. However, the CAT activity was found to be significantly increased in liver (Fig. 5D), kidney (Fig. 6D) and spleen (Fig. 7D) tissues in the AVE pre-treated mice before SRBC challenge and restored over the control level at 100mg/kg dose. This may be an adaptive response.

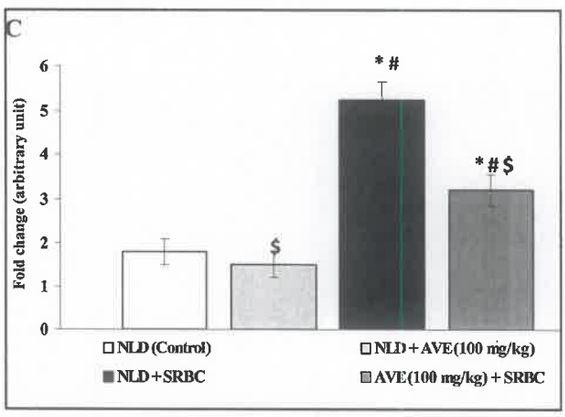
3.8 Effect of AVE treatment on splenic tissue COX-2, NF-κB and iNOS level in the SRBC challenged mice

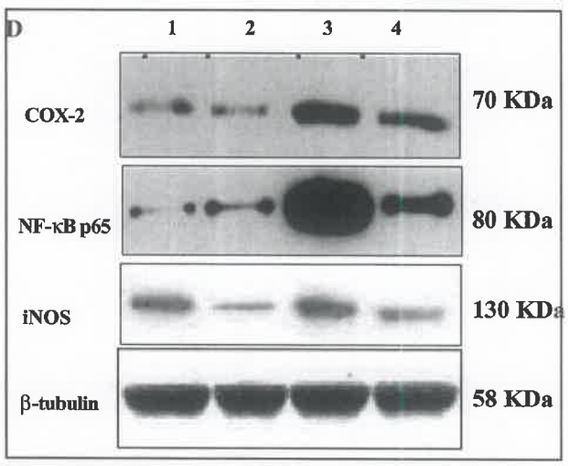
Immunoblot analysis of splenic tissue homogenate showed that COX-2, NFκB and iNOS level was significantly increased at 21 days post-immunization with SRBC (Fig.8 lane 3). After treatment with AVE for 7 days, COX-2, NFκB and iNOS level was found to be significantly decreased (Fig. 8 lane 4) with respect to NLD fed –SRBC challenged mice.

Fig-8: Effect of AVE treatment on splenic tissue Cyclooxygenase-2 (COX-2), NF-κB and iNOS level in the SRBC challenged mice









Spleen tissue homogenates were prepared for the analysis of COX-2, NF-κB and iNOS expression (Fig.8A) by Western blot as described previously. All the samples were probed with b-tubulin to show equal protein loading Expression of COX-2 (Fig.8B), NF-κB (Fig.8C) and iNOS (Fig.8D) was measured in terms of fold change over control. Results shown are representative of three independent experiments. *Significant difference in comparison to SRBC non-treated control mice. #significant difference in comparison to AVE pre-treated plus SRBC challenged mice Vs SRBC alone group.

4. DISCUSSION

Modulation of immune system however is required to maintain a balance between stimulation and suppression of immune system; in many diseased states this immunomodulation can take part in deleterious outcome, i.e. greater susceptibility to infectious agents and pathogens and also the inflammatory damage to host itself[55]. Intraperitoneal administration of SRBC, as particulate antigen in mice, immediately elicits profound immune activation as well as inflamma-

tory response[36-37] and peritoneal macrophages accumulate in an attempt to clear the pathogen and secrete pro-inflammatory cytokines like TNF-α, IFN-γ, and IL-6 upon their activation, leading to increased concentration of these cytokines in serum. However, the pro-inflammatory cytokines produced in this way, can have severe damage to different organs, i.e. liver acute phase response and severe oxidative stress.

To determine the importance of AVE on the effects of metabolic activity and immune system we investigated changes in few biochemical and immunological parameters in NLD or AVE fed mice after SRBC challenge. Increase in serum hemagglutinating antibody titre revealed the stimulatory role of AVE on humoral immune system in mice. Agglutinin titre finds frequent clinical use in diagnosis usually when the patient is well in the road to recovery. A substantial rise in the titre of specific agglutinating antibodies during the time of patient's illness is a good evidence of the identity of the pathogen. When the serum against AVE fed SRBC immunized mice was added to SRBC, hemagglutination was obtained at lowest antibody concentration, whereas serum from NLD fed and SRBC immunized mice showed early agglutination or required more antibody to agglutinate the same amount of antigen. Changes in titre upon AVE pretreatment followed by SRBC indicate that AVE may somehow alter the functions of peritoneal or splenic macrophages (phagocytosis, killing and chemotaxis) and it reflects potent antibody production. These findings indicate that diverse mechanisms exist for the processing of these antigens (SRBC) and AVE may be a useful tool to study this diversity.

Spleen, being the most important secondary lymphoid organ with immense contribution in humoral immunity was studied for its role in generation of antibody secreting plasma cells by PFC assay and the result showed a significant increase in the number of antibody producing plasma cells with AVE pre-treatment. Taken together, these results indicated that immunomodulation by AVE pre-treatment was achieved through the activation of the humoral arm of immune system during SRBC challenge. Ours study investigated the influence of AVE on the humoral immune response to SRBC in Swiss albino mice. Although in the direct hemolytic plaque assay we have measured predominantly IgM producing plasma cells, the high antibody titre may be due to presence of both IgM and IgG. Therefore, detection of IgG secreting plasma cells, which can also be measured by indirect plaque assay, will be helpful. These changes may be due to AVE induced selective alteration in the circulation pattern of certain population of lymphocytes. Thereby, during AVE treatment, immunostimulatory effect of AVE might be potent; as a result we observed immunopotentiation in the immune response.

In contrast to this, AVE pre-treatment significantly suppressed the delayed type hypersensitive (DTH) response as evident from the decreased paw diameter in AVE-pre-treated mice. DTH response is a type IV hypersensitivity reaction which includes the influx of non-specific inflammatory cells, i.e., macrophages, neutrophils through increased production of IFN-γ, IL-2 etc. and other chemokines, causing sensitization and differentiation of resting T-cells into active form[38]. Since we obtained reduced DTH response during AVE treatment before SRBC challenge, indicating reduced recruitment of antigen specific cells into the area of lesion, reduced cytokine levels may also be responsible for the recruitment of cells to the site of inflammation. Interestingly, the IFN-γ level was significantly decreased in the AVE pretreated mice. However, we have not tested the IL-2 level in our case.

Among the oxidative stress sensitive generated molecules, cytokines are pivotal ROS mediators that act in synergistic or additive manner. Therefore, ROS and cytokines might be integrated in SRBC challenged mice and are engaging in cross-talking in almost every organ like liver, spleen and kidney. In this study, IFN-γ, TNF-α, IL-6 and IL-12 production was increased initially within 9 days SRBC post-immunization and decreased thereafter following treatment with AVE before SRBC challenge. We found that severity of immune response is associated with altered balance of inflammatory cytokines, and conversely, altering the balance of inflammatory cytokines as shown in AVE treatment has a significant impact on the severity of immune response.

Of several immune response-related molecular pathways with anti-inflammatory actions, we chose to focus on IL-10 as a representative of cytokine in this class. In serum, which reflects the primary site of inflammation in this model, IL- 10 continues to increase even at 21 days post immunization after treatment of mice with AVE. This increment in IL-10 level dictates the resolution of inflammation and may be a positive prognostic indicator for recovery of exaggerated immune response due to the AVE treatment. IL-10 inhibits the production of reactive oxygen and reactive nitrogen intermediates when monocyte/macrophages are activated by IFN-γ and therefore may be important in determining the outcome of immune response. Previous observations have demonstrated a protective role for IL-10 in animal models found it to inhibit the production of ROS and reactive nitrogen intermediates when monocyte/macrophages are activated by IFN-γ[39]. Thus the suppressive effects of IL-10 on host responses might be predominantly mediated by AVE treatment.

It may be suggested that non-phagocytosed, spleen-tissue-infiltrated SRBC activate macrophages and monocytes to release TNF-α, IFN-γ and IL-6 which enter the circulation and trigger a general inflammatory response. Moreover, we found elevated MCP-1 in the serum of SRBC challenged mice, indicating recruitment of monocytes to the

spleen tissue to regulate inflammation. Monocyte chemotactic protein -1 (MCP-1) is reported to be the key molecule in terms of chemotaxis and activation of macrophages[40]. We hypothesized that intraperitoneal administration of SRBC to Swiss albino mice are an important source of endogenous MCP-1 produced during SRBC challenge leading to peritonitis and its production is regulated via AVE treatment. Furthermore, we thought that SRBC challenge can serve as an important stimulus for MCP-1 production by peritoneal macrophages and also regulates the recruitment of monocytes/macrophages towards spleen, though this production is also dependent directly or indirectly on other cytokines, reactive oxygen species (ROS) and nitric oxide (NO). Therefore, reduced MCP-1 in the serum of AVE treated mice might have regulated the infiltration of monocytes/macrophages into the spleen for the abatement of exaggerated inflammatory response induced by SRBC. However, to get more insight into the role of AVE on the immunomodulation during SRBC mediated immunological stress assessment of serum level of cytokines such as IL-4, IL-5 would have been better justification.

The inhibitory effect of AVE on the non-specific immune response also dictated anti-inflammatory potential of the AVE. AVE pre-treatment also decreased the splenic MPO level, which indicated decreased neutrophil infiltration as well as granule release and this decrease in MPO level may indicate the protective role of AVE, since hyperactivity of MPO can also lead to severe undesired immunosuppression[41-42]. Together, these observations give an indication about the modulatory effect of AVE on the cell-mediated immune response towards protection against particulate antigen (SRBC) induced immune response.

SRBC–induced GSH depletion may be associated with augmentation of an oxidative stress-mediated production of pro-inflammatory cytokines particularly TNF-α and IFN-γ because GSH is reported to play an important role in the polarization of TH1/TH2 balance[43]. Alteration in the activities of antioxidant enzymes in different tissues tested in our case may be due to the differences in the infiltrated SRBC and it is reported that the capacity of antioxidant enzyme induction to ROS is different from species to species[44]. This AVE mediated alteration may also be due to the adaptive responses wherein tissues maintain their metabolic status with minimum damage despite the presence of chronic oxidative stress. Reduction in oxidative stress due to AVE treatment may also reduce the ROS burden in the tissues tested which may have protective action on the mitochondrial membrane thereby preventing the cytochrome-C leakage[45]. This may facilitate tissue repair mechanisms to override upon the destructive mechanisms due to oxidative stress following SRBC challenge in our experimental murine model. In our studies, AVE pre-treatment seemed to stimulate glutathione biosynthesis in mouse liver, kidney, and spleen. There were previous reports that antioxidant(s) stimulate glutathione biosynthesis in the mouse tissues[46]. The results indicate that the AVE treatment has the ability to provide protection against oxidative stress in mouse tissues following challenge with SRBC.

Generation of oxidative stress following intraperitoneal administration of the mice with SRBC was further confirmed by studying the activities of the two key antioxidant enzymes of liver, kidneys and the spleen tissues. The increased activity of SOD and decreased catalase activity was found in all the tissues studied. The increase in SOD and decrease in catalase activity at all tissues studied may be an adaptive response of the tissue against the elevated levels of superoxide anion free radicals and hydrogen peroxide generated within the tissue following SRBC challenge in mice. However, in case of mice that were pre-treated with AVE, enzymatic activity of catalase was found near normal as compared, whereas decreased SOD activity indicating that the treatment with AVE was effective in combating oxidative stress following SRBC challenge.

Pre-treatment with AVE showed an overall protective effect against the oxidative damage, initiated during inflammatory response after intraperitoneal injection of SRBC, which is largely due to the stress response mediated by pro-inflammatory cytokines. The stress signal mediated by the pro-inflammatory cytokines involves increased phosphorylation of NF-κB, which in turn can induce the synthesis of iNOS as well as NADPH oxidase[47-48]. NADPH oxidase is a multimeric component of mitochondrial electron transport chain. Upon activation NADPH oxidase generates superoxide anions, which is converted to H_2O_2 in a reaction catalyzed by SOD, and further degraded to H_2O through reactions catalyzed by catalase or glutathione peroxidase, thereby resulting in huge consumption of reduced glutathione (GSH) level in different organs and that in turn increased the level of lipid peroxidations. Scavenging of the free radicals and reactive oxygen species (ROS) by important phytochemicals with antioxidant properties present in *Adhatoda vasica* leaf might have been contributed to the AVE pre-treatment mediated restoration of GSH level and decreased lipid peroxidation in different tissues. Generation of lipid peroxides lead to the activation of NF-κB, a key signaling molecule[49-51], which mediates inflammatory response through activation of macrophages and functional T-cells[52]. This decrease in GSH consumption in turn decreased the oxidation of membrane lipids and thus generation of lipid peroxides. Since lipid peroxides are important for NF-κB activation, inhibitory effect on lipid peroxidation might have been contributed to the decreased NF-κBp65 level in spleen with AVE pre-treatment, as indicated from the immunoblot data. However, this decreased signaling via NF-κB; the fact, further supported by decreased release of pro-inflammatory cytokines like

TNF-α and IFN-γ, mediators of the downstream signaling pathway activated by NF-κB.

Immunoblot analysis of spleen tissue homogenate showed that COX-2 level was significantly increased at 9 days post immunization in case of the SRBC which was decreased with pretreatment of AVE. Similar reduction in prostaglandin, nitric oxide, TNF-α, and IL-6 levels has been previously reported in murine macrophages[53]. Given its constitutively expressed nature and predominant role in prostaglandin synthesis during inflammation, potential strategies of inhibiting COX-2[54] can be targeted. These data collectively support that AVE treatment mediated COX-2 inhibition or strategies that disrupt prostaglandin signaling pathways as useful adjunctive therapies in treating persistent inflammation.

Inducible isoform of nitric oxide synthase (iNOS) has also found to be increased in the spleen of SRBC challenged mice. It has been reported that the expression of COX-2 mRNA was significantly suppressed by amino guanidine, a selective iNOS inhibitor, in lung tissue of rats[55]. Treatment of mice with AVE before SRBC challenge downregulated the expression of iNOS in the spleen. The expression of COX-2 is also partly regulated by the nitric oxide (NO), because it has been reported that exacerbation of the inflammatory response is largely due to the production of several inflammatory mediators, like TNF, interleukins, prostaglandins (PG), and NO[56]. Although decreased NO production as well as prostaglandin production in the spleen or serum of AVE pretreated mice could be expected which might add evidence to the fact that the AVE treatment will be efficacious for the treatment of inflammation, however, we have not tested this so far. Thus, elucidating these complex interactions may allow for the development of more rational pharmacological approaches to the AVE treatment and prevention of the exaggerated immune response or inflammation in which they play a role.

Western blot analysis of nuclear proteins showed that SRBC-induced NF-κB activation in the spleen of Swiss albino mice. However, pre-treatment with AVE before SRBC challenge decreased expression of the NF-κB (Fig. 8) when compared to the SRBC challenged mice. In the signal transduction pathway, the NF-κB pathway is closely related to the inflammatory response. Nuclear factor-κB is the generic name for a family of dimers formed by a several proteins: NF-κB 1 (also known as p50/p105), NF-κB 2 (also known as p52/p100) and REL, RELA (also known as p65/ NF-κB3) and RELB. The different heterodimers bind to specific promoters to initiate transcription of a wide range of genes that influence the inflammatory response as well as cell death and survival and tissue repair. The most common NF-κB dimer comprises a p65 and p50 heterodimer. IκBα binds NF-κB in the cytoplasm to block its nuclear translocation. A variety of stimuli lead to phosphorylation of critical serine residues on IκBα, targeting it for ubiquitination and degradation by the proteasome, thus allowing NF-κB to enter the nucleus and mediate transcription. This study indicates that nuclear expression of NF-κB in was increased in the spleen response to SRBC challenge and was inhibited by administration AVE before stimulation. These data support the hypothesis that SRBC induces inflammatory reactions through activation of NF-κB signalling pathways. In this model activation of NF-κB transcriptional factors may explain the regulatory action of splenic macrophages, during AVE treatment. We observed reduced activation of NF-κB during AVE treatment. Furthermore, it can be suggested that the decreased production of TNF-α, IFN-γ, IL-6 and IL-12 by SRBC–stimulated splenic macrophage associated with AVE treatment is mediated by reduced induction of NF-κB transfer due to AVE treatment before SRBC challenge.

Although, herein we reported that mice orally treated with AVE at dose of 100 mg/kg body weight for seven consecutive days and subsequent challenge of these AVE-fed mice with two bolus of SRBC (when AVE feeding was stopped) showed improvement in both the cell mediated, humoral as well as anti-inflammatory responses, but further studies are needed by continuing the AVE treatment during SRBC challenge. It might be expected that continuous feeding with AVE during SRBC challenge the outcome of improvement could be attained even at lower dose, i.e. at 50mg/kg daily dose. Since, it has been out of scope of this study to single out the most effective bioactive compound present in the extract responsible for its immunostimulatory potential and anti-oxidant activity; and the effect shown by the extract in present study is an outcome of cumulative effect of a cocktail of different bioactive molecules present in the methanolic extract of *Adhatoda vasica* leaf, further studies are required to explore more information on the complex signaling induced by the extract and active principle present in it.

CONCLUSION

The present study has validated the scientific rationale of the use of *Adhatoda vasica* leaf as immunomodulatory drug in traditional medicinal system. The long-term potentiating effect of the *Adhatoda vasica* leaf on humoral immune system, with simultaneous inhibitory potential on inflammatory response and potent antioxidant potential draws severe attention for further study of active principle in it, which would be helpful in designing newer and advanced therapeutics from this plant in future.

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analyses. R.A. undertook the statistical analysis; B.B. and R.A. wrote the manuscript.

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ANNEXURE-L

Adhatoda Vasica ameliorates cellular hypoxia dependent mitochondrial dysfunction in acute and severe asthmatic mice.

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Keywords

Severe asthma, steroid resistance, hypoxia, Ayurveda, *Adhatoda Vasica*.

Abstract

Severe asthma is chronic airway disease, exhibit poor response to conventional asthma therapies. Growing evidence suggests that elevated hypoxia increases the severity of asthmatic inflammation among patient and model systems. In this study, we elucidate the therapeutic effect and mechanistic basis of *Adhatoda Vasica* (AV) aqueous extract on acute allergic as well as severe asthma subtypes, at physiological, histopathological and molecular levels using mouse models. We observed, oral administration of AV extract not only attenuates the increased airway resistance and inflammation in acute allergic asthmatic mice but also alleviates the molecular signatures of steroid (dexamethasone) resistance like IL-17A, KC and HIF-1α (hypoxia inducible factor-1alpha) in severe asthmatic mice. The reversal of pathophysiological features after AV treatment is associated with inhibition of elevated HIF-1α levels by restoring the expression of its negative regulator-PHD2 (prolyl hydroxylase domain-2). This was further confirmed in acute and severe

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asthma model developed by augmented hypoxic response. Further, AV treatment reverses cellular hypoxia- induced mitochondrial dysfunction in human bronchial epithelial cells - evident from bioenergetic profiles and morphological analysis of mitochondria. Involvement of hypoxia and mitochondrial dysfunction in asthma severity is being increasingly realised. Extract of AV although widely used in *Ayurveda* practice for the treatment of diverse respiratory ailments, including asthma, its molecular basis of action and effect on severe asthma subtype is still unclear. This study, demonstrates therapeutic mechanism of *Adhatoda Vasica* through hypoxia-induced mitochondrial dysfunction and highlights its potential in the treatment of severe steroid-resistant asthma.

Significance Statement

Severe asthma is a global health concern found to be unresponsive to current treatment modalities involving corticosteroids. Recent findings suggest that elevated hypoxia has a critical role in severity of asthma. Here, we report therapeutic treatment with aqueous extract of *Adhatoda Vasica* (AV), an ayurvedic medicine, is effective in attenuation of severe steroid-insensitive asthmatic features in mice. The observed anti-asthmatic effects of AV was through inhibition of hypoxic response, both *in vivo and in vitro*. AV also reverses mitochondrial dysfunction, a key consequence associated with hypoxia, and asthma. This study not only highlights the translational potential of AV for the treatment of severe asthma but also provides opportunities for its usage in other disease conditions where hypoxia is pertinent.

Introduction

Asthma is a complex and heterogeneous disease that involves recurrent, partially reversible bronchial obstruction. Airway inflammation and airway remodelling is central to disease pathophysiology and is related to airway dysfunction (1, 2). With ~300 million people affected and 250,000 annual deaths, asthma significantly contributes to the global health burden (3). Initially, it was considered to be primarily an allergic, eosinophilic Th2 biased disease with involvement of its cytokines (IL-4, IL-5 and IL-13) in the inflammatory cascade leading to allergic exacerbations (4). However, there are non-Th2 asthma patho- phenotypes, where cells like Th17, Th1 and their respective cytokines play a major role in disease pathogenesis and severity (5, 6). Corticosteroids that modulate Th2 cytokines and associated inflammation continue to be the mainstay therapy for the treatment of Th2 dependent allergic asthma (6, 8). The non-Th2 severe asthma cases however are steroid non-responsive with increased risk of exacerbations and morbidity (5, 6). Although

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severe asthma accounts for 10-15% of all patients, they consume much more higher cost in healthcare management than acute asthma (3).

Elevated hypoxic response has been reported in more than 90% of severe asthma exacerbations with increased asthma severity and inflammation (7–10). This exaggerated hypoxic response is highly proinflammatory and primarily mediated through inhibition of the oxygen sensor, PHD2 resulting in elevation on HIF-1α (11–14). In addition, neutrophil survival and IL-17-producing CD4+ T helper cell (Th17) levels are known to be induced by HIF-1α (15, 16). High levels of both IL-17 and neutrophils are observed in severe steroid-resistant human asthmatics and mouse models (10, 17–21). A subset of severe asthmatics respond poorly to glucocorticoid treatment, even at a higher dose (3). Modulation of hypoxia signalling or HIF-1α could thus be a promising target to combat the hypoxia-induced severe asthmatic changes. Unfortunately, there is no clinical inhibitor currently available in market that targets HIF-1α.

Plant-derived medicines that have been traditionally used to prevent and treat a large number of diseases are a continuous source of novel drug leads. In India, *Ayurveda* is an ancient system of medicine which offers a translational framework to connect physio-pathology with therapeutics in a stratified manner. The actions of drugs are described on the basis of their effect on biological axes governed by three physiological entities doshas namely *Vata*, *Pitta* and *Kapha* (22) that not only govern homeostasis in individuals but the same when perturbed from their threshold levels, result in disease conditions. Previously we have shown inter-individual variability in genetic as well as expression level in PHD2 between constitution types that differ in *Pitta* (P) and *Kapha* (K) (23, 24). Modulation of this axis revealed hypoxia to be an important modifier of asthma severity (11). We hypothesised that herbal medicines that are reported for the treatment of asthma through balancing of P-K perturbations may have hypoxic modulatory activity. This could then be harnessed to reverse the severe asthma patho-phenotype.

In this study, we have tested the effect of *Adhatoda Vasica* (AV), commonly known as Malabar nut, an ayurvedic medicine indigenously used to treat various aspects of asthma. AV is from *Acanthaceae* family, a dense shrub founds in all parts of India. It has a bitter and astringent taste with *Pitta-Kapha* balancing action, and described for the treatment of asthma and respiratory conditions. Vasicine and vasicinone from AV have been shown to have strong bronchodilatory and anti-inflammatory effects (25–27). In this study, we demonstrated that oral administration of aqueous extract of AV to the Ova-induced allergic mice reduces the cardinal features of asthma both at phenotypic as well as a molecular level. We also provide evidence for the mechanism of action of AV in asthma through modulation of the cellular hypoxic response. We observed that AV treatment to the asthmatic mice inhibits the increased hypoxic response by downregulating HIF-1α. Decline in HIF-1α also improved mitochondrial morphofunction. We further demonstrate that

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AV has therapeutic effect even in severe asthma condition that is augmented in mice by elevated hypoxic response and is non-responsive to steroids.

Results

AV attenuates airway pathophysiology of acute allergic lung inflammation in mouse model: We first measured the therapeutic effects of AV extract (fig. S1A) on the pathophysiological features observed in mouse models of acute allergic airway inflammation. A schematic showing the timeline of model development and drug/vehicle treatments is shown in fig. 1A. Mice sensitized and challenged with OVA exhibited increased airway resistance and eosinophilic infiltration into the lungs, mucus metaplasia, and airway remodelling which were reversed by dexamethasone or AV treatment (fig. 1). However, the beneficial effects of AV were found to be non-linear in the range of doses tested (fig. S1). While 130 mg/Kg (AV-D2) dose was found to reverse all the aforementioned pathophysiological features, considerable variability was observed in lower and higher doses (fig. 1, S1). For instance, OVA-induced increase in airway resistance was found to be reduced by all except the highest AV dose (fig. S1B). But, histological assessment of fixed lung sections showed that AV-D2 is more effective in reducing lung inflammation (fig. 1C, F and S1C, F), mucus metaplasia (fig. 1D, G and S1D, G), and sub-epithelial collagen deposition (fig. 1E, H and S1E, H), compare to other doses. Assessment of eosinophils in BAL fluid and TGF-β levels in lung homogenate substantiate efficacy of AV-D2 compared to other doses (fig. 1I, J and S1I, J). In contrast, all the AV doses considered were found to significantly reduce the lung levels of Th2 cytokines, IL-4, IL-5 and IL-13 (fig. 1K and Table S3). Taken together, AV-D2 is more effective, compared to other doses, in the remission of OVA-induced pathological features.

Increased cellular hypoxia (HIF-1α) levels in are reduced after AV treatment both *in vivo* and *in vitro*

An earlier study by our group has shown that the differential severity of airway inflammation in allergic asthma could be modulated by prolyl hydroxylase 2 (PHD2), an inhibitor of HIF-1α which govern the hypoxia axis (11). Exaggerated hypoxic response causes increase in disease severity in acute Ova allergic mice (10, 11). We wanted to explore whether AV treatment could modulate the hypoxia response in Ova challenged mice. We observed elevated levels of HIF-1α in Ova allergic mice compared to Sham mice (fig. 2A, B and C). While dexamethasone treatment failed to restore the OVA-induced increase in HIF-1α levels, AV-D2 completely reversed the HIF-1α levels (fig. 2A, B and C). We observed a non-linear effect of increasing doses of AV on the HIF-1α levels similar to those observed in the previous results (fig. S2A, B). In fact, a strong positive correlation (R_2 = 0.63) was found between airway inflammation score and HIF-1α levels in D0, D2, and D4 doses of AV (fig. S2C). Further, AV also restored the *PHD2* mRNA levels which was

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reduced in Ova mice lungs (S2D). In order to confirm the inhibitory effect of AV on HIF-1α as observed in Ova allergic mice, we tested its effect on chemically induced hypoxia in human bronchial epithelial cells (BEAS2B). To induce cellular hypoxia, dimethyloxaloylglycine (DMOG), an inhibitor of PHD and FIH, was used. We observed that *in vitro* treatment of AV (10μg/ml) was capable of attenuating the DMOG induced increase in HIF-1α levels in BEAS2B cells (fig. 2D, S2E). This result confirms the inhibitory effect of AV on HIF-1α levels in cellular hypoxia conditions like asthma. This result confirms the inhibitory effect of AV on HIF-1α levels in cellular hypoxia conditions like asthma and indicates this could be its most important therapeutic effect.

Hypoxia induced mitochondrial dysfunction is rescued by AV treatment

Hypoxia induced mitochondrial dysfunction in asthma has been reported earlier (28, 29). Therefore, we determined the effect of AV on mitochondrial health, since it was observed that AV treatment reduces the increased hypoxia/HIF-1α levels, both *in vitro* as well as *in vivo* conditions. Induction of cellular hypoxia in human bronchial epithelial cells (BEAS2B) by DMOG led to an overall decrease in OCR (fig. 2E) as well as mitochondrial basal respiration, ATP production and maximum respiration. We observed similar results using adenocarcinomic human alveolar basal epithelial cells (A549), where we see AV has potential to improve mitochondrial health in both the cells, when compared to vehicle group as well as in cellular hypoxic environment (fig. 2E and S3A). We next examined effect of cellular hypoxia stress on mitochondrial morphology in BEAS2B cells transfected with mitochondria- targeted green fluorescent protein (mito-GFP). To assess the alterations in mitochondria morphology, previously reported parameters such as number of individual mitochondria, area, elongation, number of networks, and mean branch length of networks were determined. Healthy mitochondria are elongated and exhibit branched chain (network) morphology. In control (vehicle group), the scores for all the aforementioned morphological parameters were found to be higher than in the DMOG treated cells (fig. 2F, G and S2F-I). AV treatment was found to restore morphological defects induced by DMOG treatment (fig. 2F, G and S2F-I) In contrast, Dex treatment alone was found to be ineffective in restoring the DMOG induced morphological alteration in mitochondria (fig. 2F, G and S2F-I), but combination of Dex with AV was observed to be beneficial in significantly improving majority of the morphological parameters measured (fig. 2F, G and S2F-I). This suggests AV treatment may be helpful in conditions where hypoxia stress is prominent through its ability to restore mitochondrial morphofunction. To further validate the effect of AV on mitochondrial morphology, we labeled the mitochondria with mitochondria specific TOM20 (mitochondrial import receptor subunit) antibody in BEAS2B cells treated with DMOG or vehicle. We observed significant impact in improving mitochondrial morphofunction (fig. S3B) after hypoxic stress. Noteworthy, this alteration in mitochondrial parameters after cellular hypoxia was not restored with Dex treatment (fig. S3C-F). However,

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combination of Dex with AV treatment in cellular hypoxic stress is able to restore some of the changes in morphological aspects of mitochondria as shown in fig. S3C-F.These results establish that AV targets hypoxia-oxo/nitrative stress-mitochondrial dysfunction axis to attenuate the airway pathology during asthma.

Severe airway inflammation resistant to steroid is resolved with AV treatment

DHB induced severe asthma model

Increased hypoxic response has been associated with increased Th17 cell proliferation as well as neutrophil levels in human asthmatics and murine models leading to steroid resistant phenotype (9–11, 15–20). Earlier, we showed that chemical as well as siRNA-mediated inhibition of prolyl-hydroxylase 2 (PHD-2) in allergic mice led to increased hypoxic response and was associated with severity of the disease (11). In this study, we used the same model of severe asthma to identify their steroid sensitivity (fig. 3A). We found that chemical inhibition of prolyl-hydroxylase (PHD) level in Ova-allergic mice by DHB (10mg/kg,) treatment led to severe increase in airway hyper-responsiveness (AHR) compared to mice challenged with OVA alone and this increased AHR was resistant to Dex treatment (fig. 3B). Therapeutic treatment of AV (130mg/kg, AV-D2) to such DHB+Ova mice led to significant reduction in airway resistance as compared to Ova+DHB and Ova+DHB+Dex mice group (fig. 3B). Similarly, DHB treatment also led to severe increase in airway inflammation (AI) and mucus metaplasia in mice (fig. 3C, G) which was confirmed by quantitative scoring and morphometry of mouse lung sections (fig. S4A, B). This increased AI and mucus metaplasia was resistant to Dex treatment but AV was able to rescue these features (fig. 3C, G and S4A, B). DHB treatment to Ova mice also leads to significant increase in IL-13 levels, which was significantly reduced after AV-D2 treatment and was unaffected by Dex treatment in Ova+DHB mice (fig.S4C). To confirm whether the observed steroid insensitive effect in mice was because of increase in hypoxia and/or HIF-1αlevel, we determined the effect of DHB on HIF-1αprotein levels. We observed that DHB treatment to Ova-allergic mice led to significant increase in lung HIF-1αlevels compared to Ova mice (fig. 3D) which was significantly reduced with AV treatment but not by Dex treatment (fig. 3D). In addition, cellular hypoxia induced by DHB treatment leads to significant increase in steroid non-responsive and steroid resistant asthma associated cytokines namely IL-17A (fig.3E), KC (fig.3F, mouse homologue of IL-8), IFN-γ and TNF-α(fig. S4D, E), compared to Ova mice group. These increased cytokine levels were also significantly reduced with AV treatment whereas Dex treatment (fig. 3 D-F and S4D, E) couldn't reduce them. In addition, there was also a significant difference in therapeutic effect accounted by AV-D2 treatment on DHB induced severe airway inflammation when compared with the Dex-treated severe asthmatic mice

(Ova+DHB+Dex). These results indicate that therapeutic treatment of AV to severe allergic mice reduces airway inflammation and associated cytokine levels through modulation of HIF-1αlevels.

PHD2 siRNA induced severe asthma model

In order to test whether AV alleviates the steroids resistance under high cellular hypoxia in the severe asthma through specific inhibition of PHD2 in lung, we administered siRNA through intranasal route in Ova allergic mice (fig. 4A). Down-regulation of PHD2 level was confirmed by measurements of its protein levels (fig. 4B). Interestingly AV treatment increases the PHD2 protein levels significantly compared to only PHD2 siRNA administered allergic mice (fig. 4B).Consequently, a significant increase in HIF-1α was also observed in PHD2 siRNA treated Ova mice compared to scrambled (Scrm)siRNA+Ova mice group and increased HIF-1α was significantly downregulated by AV treatment but not by Dex (fig. 4C). PHD2 siRNA recapitulated the severely increased airway resistance, which was significantly reduced after AV (130mg/kg, AV-D2) treatment but not by Dex treatment (fig. 4D). PHD2 siRNA treatment to Ova mice also increased the airway inflammation (AI), mucus metaplasia as well as IL-17A levels significantly compared to Scrm siRNA treated Ova mice (fig. 4E, F and S5A, B and F). These increased levels of AI and IL-17A was significantly reduced in AV but not in Dex treatment (fig. 4E, F and S5A, B). In addition, PHD2 siRNA treatment also increases the pro-inflammatory and steroid resistant related cytokines like IL-13, KC and IL-6 levels (fig. S5C-E). Oral administration of AV-D2 to such a severe asthmatic mice reduces these elevated levels of cytokines but not by Dex treatment (fig. S5C-E). This confirms that the observed severe asthmatic features in mice is because of increase in cellular hypoxic response in allergic mouse lung and it could be attenuated by AV administration. This effect could be possibly increasing lung PHD2 levels. These results indicate that AV reduces the severe steroid resistant airway inflammation in mice with exaggerated hypoxic response.

Discussion

Plant derived medicines, like phytoextracts, form an integral component of indigenous medical systems and have been successfully used to prevent and treat various diseases (30–32). In this study, we use aqueous extract of the plant *Adhatoda Vasica* (AV) which was prepared as per descriptions in *Ayurvedic* texts to understand its effect and possible mode of action against asthma (33–35). AV is one of the primary medicinal herbs in *Ayurveda* for the treatment of cough, bronchitis, asthma and various respiratory ailments (27). A number of active constituents have been isolated from AV herb, among which vasicine and vasicinone are the primary alkaloids and known to have strong bronchodilatory effects (25, 27). Semisynthetic derivatives of vasicine, bromohexine and ambroxol, are also widely used either alone or in combination with expectorant and mucolytic agents. (36). We observed, therapeutic administration of AV has a strong inhibitory action against increased airway resistance and airway inflammation observed in Ova challenged allergic mice (fig.

1). Though the therapeutic effects on the cardinal features of asthma like airway hyperresponsiveness (AHR) and airway inflammation (AI) was observed nearly at all four doses, of AV, the D2 dose was found to be most effective across all parameters with least variability within the group. Its effect on cytokine levels was dose-independent and all the doses were more or less equally effective in reducing Th2 and Th17 cytokines (table S3 and fig. S1F). However, AV demonstrated a "U-shape curve effect" observable at the level of airway physiology as evident in AHR (fig. S1C.) as well as AI (fig. 1F) and, in airway remodelling (fig. S1D, E) mediated by increased TGF-β1 in allergic mice (fig. 1H). This U shaped curve effect was mirrored in HIF-1α levels indicating the role of AV as a modulator of hypoxic response (fig. 2A).

A modifying role of elevated hypoxic response in acute allergic asthma primarily mediated through hypoxia inducible factor-1α (HIF-1α) has been shown by our group earlier(11). Mild or low level of cellular hypoxia mediated by PHD2 inhibition produces the protective effect in allergic asthma whereas, high hypoxia level induces exaggerated pro-inflammatory and pro-asthmatic effects in allergic mice (11). Levels of IL-17A (a Th17 cytokine) and neutrophils are known to positively regulated by HIF-1α and both IL-17A and neutrophils are high in severe steroid resistant human asthmatics and mouse models (9–11, 15–20).

We therefore examined the effect of PHD inhibition and hypoxia response for steroid sensitivity as well the effects of AV on hypoxia induced severe asthma model. Here, we show that chemical as well as siRNA mediated induction of HIF-1α in allergic mice increases the asthma severity (fig. 3, 4). We also show that AV treatment is able to rescue all the severe asthma phenotypes including its effect on molecular markers like IL17, KC which were found to be non-responsive to the steroids (Dex) (fig. 3, 4, S4 and S5). This could be because of inhibitory effect of AV on increased HIF-1α levels or by restoration of decreased PHD2 levels in allergic severe asthmatic mice (fig. 4B, S2C). The inhibitory effect of AV on HIF-1α in cellular hypoxic condition is also validated by *in vitro* experiments (fig. 2D, S2D).

One of the axes associated with severe inflammation is hypoxia-oxo-nitrative stress-mitochondrial dysfunction in asthma (28, 29, 37, 38). Indeed, increased cellular hypoxic response have been shown to cause mitochondrial dysfunction and oxidative stress, both of which have larger role in pathogenesis of asthma (28, 38). Coupled with our *in vitro* results we thought it would be worthwhile to check if AV could improve the consequences of hypoxia such as mitochondrial dysfunction and thereby modulate the outcomes of the disease. Hypoxia induced mitochondrial dysfunction was assessed *in vitro* in cultured lung epithelial cells treated with DMOG. Our results reveal that AV treatment to lung epithelial cells in hypoxic conditions was able to improve the mitochondrial dysfunction revealed through mitochondrial morphological analysis and increased OCR (fig. 2E-G, S2E-I and S3). AV treatment restored the thread like shape and mitochondrial network morphology caused by cellular hypoxic stress (fig. 2E-G, S2E-I and S3). The beneficial effects of AV on

mitochondrial respiration could be either through direct attenuation of cellular hypoxic state or indirectly through increase in mitochondrial biogenesis (37). It would be interesting to test the effect of AV in corticosteroid insensitive obese-asthma phenotype, where the mitochondrial dysfunction and hypoxia co-exist (29).

Inter-individual variability in baseline levels of HIF-1α and/ or PHD2 may predispose individuals to severe hypoxia response in respiratory disorders. Previously, we observed genetic variation in *PHD2* in healthy individuals linked to *Ayurveda* constitution types was different between natives of high altitude and sojourners who suffered from HAPE (24). Subsequently we showed the significance of PHD2 in asthma, where chemical inhibition of PHD2 modulated hypoxic response in asthma and increases disease severity (11). *Ayurveda*, an Indian system of medicine, describes inter-individual variability in health and disease through common organising principle of *Tridosha*, i.e. *Vata Pitta* and *Kapha*. *Tridosha* are three physiological entities which govern the functioning and homeostasis of the system, which have been shown to have the molecular correlation (22, 23, 39–42). The drugs prescribed in *Ayurveda* are also classified on the basis of their effect on *Tridosha* (43). The herbal medicine *Adhatoda Vasica* tested in this study is described to be *Pitta- Kapha* balancing herb and used for treatment of asthma and other respiratory conditions (43). Effect of AV on asthma not only lead to identification of novel inhibitor of HIF-1α, that could be useful in treatment of severe asthma, but also explains/validates the molecular correlate of *Pitta- Kapha* axis identified through the inter-individual variability between *Pitta- Kapha* constitution types using *Ayurgenomics* approach.

Taken together, we demonstrate for the first time that the inhibition of increased HIF-1α is an important therapeutic mechanism of *Adhatoda Vasica* effects. It is also observed that the effect of AV is not limited to acute asthma, but also beneficial in severe asthma model where steroids are ineffective. In addition, AV also showed a promising effect against mitochondrial dysfunction in elevated cellular hypoxia state. As we described, the extract (fig. S1A and table S1) used in this study is a mixture of various quinazoline alkaloids (Vasicine, Vasicinone, Adhavasicinone etc.), it is possible that AV may be acting on molecular targets or processes other than HIF-1α, for the observed anti-asthmatic effects. Nevertheless, results of our study highlights an important molecular mechanism that could explain the clinical efficacy of aqueous AV extract reported in human asthmatic patients (33, 34). Also, anti-inflammatory effects of AV observed in acute asthma models indicate that AV could be an alternative to steroids which has multiple local and systemic side effects. This study demonstrates the potential of AV treatment specifically in severe steroid resistant asthmatics and in conditions where restoration of mitochondrial dysfunction is pertinent. The therapeutic observation of AV extract on cellular, histological (tissue level) and physiological (phenotype level) parameters involved in pathophysiology reflects the importance of retaining the multi compound nature of the extract as practised in *Ayurveda*.

Materials and Methods

AV was prepared according to the classical method described for *rasakriya* (decoction-condensation- drying) in *Caraka Samhita* (33, 44). The detailed quality and chemical fingerprinting study were carried out by LC-MS at CSIR-CDRI, Lucknow, India (fig. S1A, B and table S1, S2). Acute allergic asthma was developed in mice using Ova sensitization by intraperitoneal injection from a 1-3 week. After a 1week gap mice were challenged with Ova using an aerosol nebulizer for 7 days. AV (13-260mg/kg, orally), and Dex (0.75mg/kg, orally) was given for 4 days from the 24th-day protocol. On the 28th-day, mice were cannulated to determine airway resistance in response to methacholine and sacrificed by phenobarbital anesthesia. Severe asthma model was developed by intraperitoneal injection of DHB (10 mg/kg), and intranasal PHD2 siRNA (90 µg) treatment to induce a hypoxic response in Ova-sensitized and challenged mice. Lungs were removed, fixed in formalin, embedded in paraffin, and sectioned at 5µm. Staining of hematoxylin and eosin, periodic acid-Schiff, and Masson Trichrome was used to assess the lung inflammation, mucus hypersecretion, and sub-epithelial fibrosis, respectively. Quantitative real-time reverse transcription PCR (RT-PCR) was used to quantify PHD2 mRNA expression. Lung tissue lysate was used for cytokines and western blot assay. Cellular hypoxia model was developed using DMOG (1mM; 32 hours), in BEAS2B and A549 lung epithelial cells. AV(10µg/ml), and Dex (10µM/ml) were added to culture after 8 hours of DMOG induction and kept for next 24 hours. The cell lysate was used to detect HIF-1α protein. Seahorse assay was carried out using a 24-well plate with BEAS-2B, and A549 cell culture in presence of DMOG. GFP-mito or immunofluorescence was used to detect mitochondria and its morphological characteristics. Data were analyzed by one- or two-way analysis of variance (ANOVA), Student's t-test, and correlation analysis. Mitochondrial quantitative analysis was performed by using image J. The difference was considered to be statistically significant when $P< 0.05$.

Details of methods and experimental protocol is provided in supplementary materials and methods.

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Author Contributions

A.G. designed and performed the experiment, analysed the results and wrote the paper. A.G., L.P., and K.K. performed the experiment, analysed the results. V.J. and V.P.S. contributed to animal model experiments. N.K.B. contributed in seahorse experiment and quantification of flurosense labeled mitochondrial images. S.S. & M.K. contributed in imaging experiment. B.P. conceptualized the study, provided AV, quality control information, discussion, designed the experiment, analysed the results and wrote the paper. M.M. and A.A. designed experiments, analysed and discussed the results and wrote the paper. All the authors reviewed and approved the final version of the manuscript.

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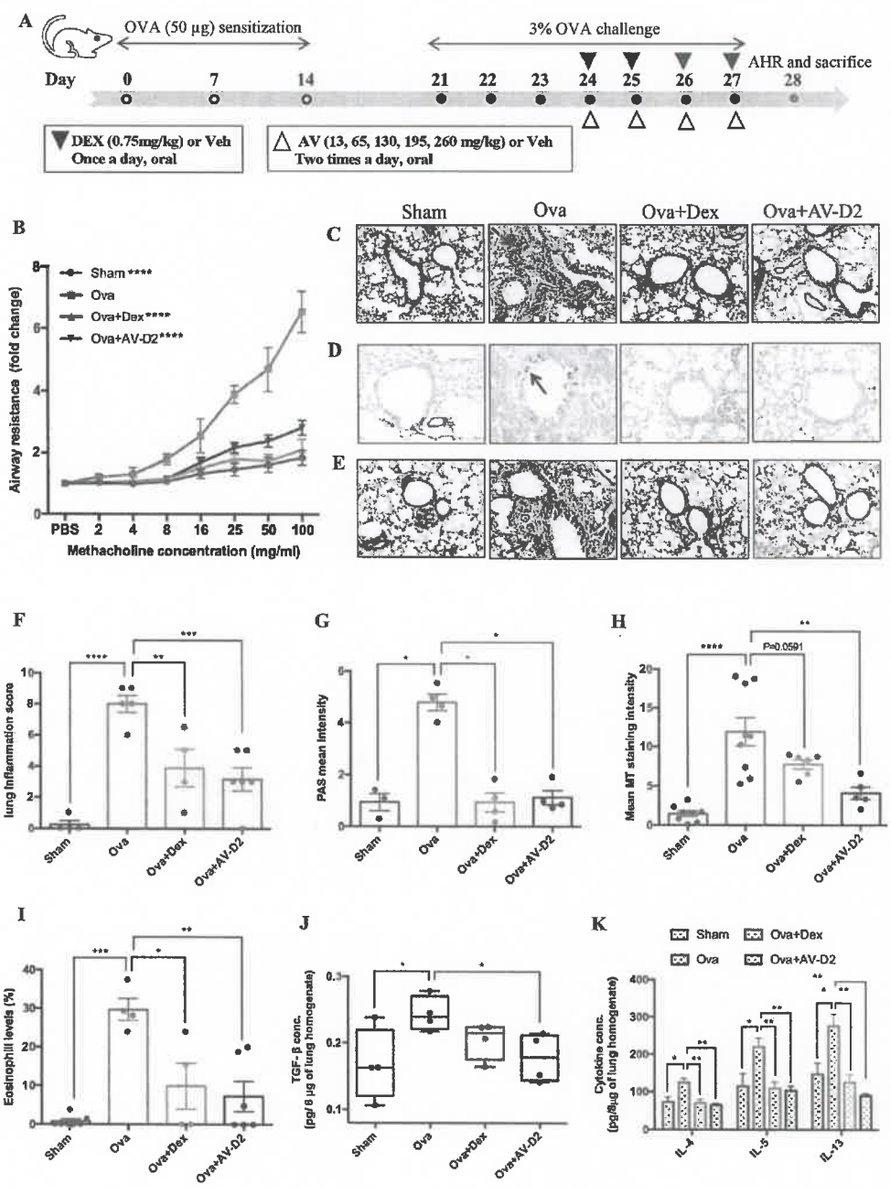

Fig. 1. AV treatment alleviates the asthmatic features in mice model of acute asthma. (A) Schematic representation showing the timelines for mice model development and drug treatments. Male BALB/c mice were sensitised and challenged using Ova-allergen and AV or Dex was administered to Ova-allergic mice from day 24 to 27 as described in materials and methods. **(B)** Flexivent analysis of airway resistance after methacholine treatment in AV or Dex treated Ova allergic mice compared with Ova alone mice. **(C to E)** Representative photomicrographs of fixed mouse lung tissue sections stained with (C) H&E (10X magnification), (D) PAS (20X magnification), and (E) MT (10X magnification) for the analysis of cellular infiltration of inflammatory cell, mucin and collagen levels, respectively. Black arrow indicates positive staining in respect to particular stain. **(F)** Quantification of peribronchial and perivascular inflammation of mouse lung tissues stained with H&E in using inflammation grade scoring system. **(G and H)** Densitometric analysis of mouse lung tissues stained with PAS and MT to measure mucus metaplasia and collagen deposition using ImageJ. **(I)** Eosinophil abundance in mouse BAL fluid. **(J and K)** ELISA for TGF-β1 and Th2 cytokines in mice lung homogenate. Data are shown as mean ±SEM of three to seven mice per group and representative from three independent experiments. Significance denoted by **P* ≤0.05, ***P*≤0.01, ****P*≤0.001 and *****P*≤0.000; by two way ANOVA (B) and ordinary one way ANOVA (F to K). **Ova-** chicken egg albumin, **Sham**- vehicle (PBS), **Dex**- Dexamethasone (0.75mg/kg), AV-**D2**- *Adhatoda Vasica* extract (130 mg/kg)

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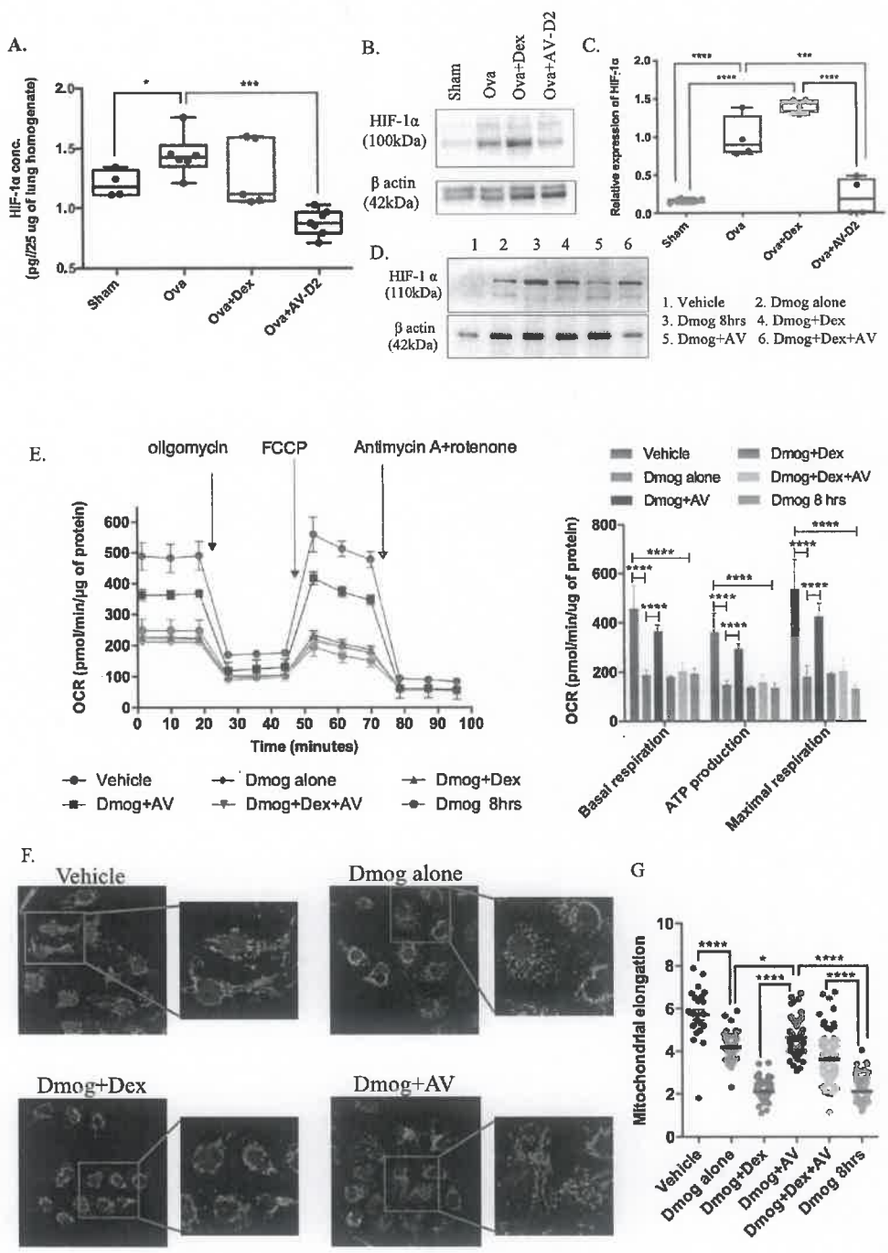

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Fig. 2. AV treatment rescues hypoxia induced HIF-1α and related mitochondrial dysfunction. (A to C) HIF-1α levels measured in lung homogenate of acute asthmatic mice by (A) ELISA and (B) Western blot analysis, (C) compiled with densitometric comparison for western blot. Data are shown as mean ±SEM of four to seven mice per group and representative of three independent experiments. **(D)** Representative western blot for HIF-1α abundance in BEAS2B cell lysate. (**E to G**) Effect of AV on cellular hypoxia induced mitochondrial dysfunction. (E) Left: representative OCR graph showing effect of cellular hypoxia on mitochondrial bioenergetics profile in presence of AV or Dex treatment. Right: mitochondrial bioenergetics profile measured at Basal respiration, ATP production and at Maximum respiration level in presence of ETC inhibitors. Cellular hypoxia-induced changes in mitochondrial morphology. (F) Representative confocal images showing the mitochondria in BEAS2B cells transfected with mitochondria targeted-GFP (mito-GFP) and nucleus stained with blue (DAPI). Boxed areas of image are shown with magnification to represent the morphological status of mitochondria typical to the treatment or specific condition. (G) Dot plot showing mitochondrial elongation parameter. Data are shown as mean ±SEM of thirty or more cells per group and representative of at least two independent experiments. Significance denoted by $*P \leq 0.05$, $**P \leq 0.01$, $***P \leq 0.001$ and $****P \leq 0.0001$; by Unpaired t test with Welch's correction (A), ordinary one way ANOVA (B), two way ANOVA with Tukey's multiple correction test (E), ordinary one way ANOVA with Tukey's multiple correction test (G). **Ova-** chicken egg albumin, **Sham-** vehicle (PBS), **Dex-** Dexamethasone (0.75mg/kg), **AV-D2-** *Adhatoda Vasica* extract (130 mg/kg), **BEAS-2B-** normal human bronchial epithelium cells, **OCR-** oxygen consumption rate, **DMOG-** dimethyloxaloylglycine, **DMOG+AV-** DMOG+10µg/ml. *Adhatoda Vasica* extract, **DMOG+Dex-** DMOG+10nM of Dexamethasone, **DMOG+Dex+AV-**DMOG+10nM of Dexamethasone+10µg/ml. *Adhatoda Vasica* extract, **DMOG 8hrs-** DMOG treatment for 8 hours.

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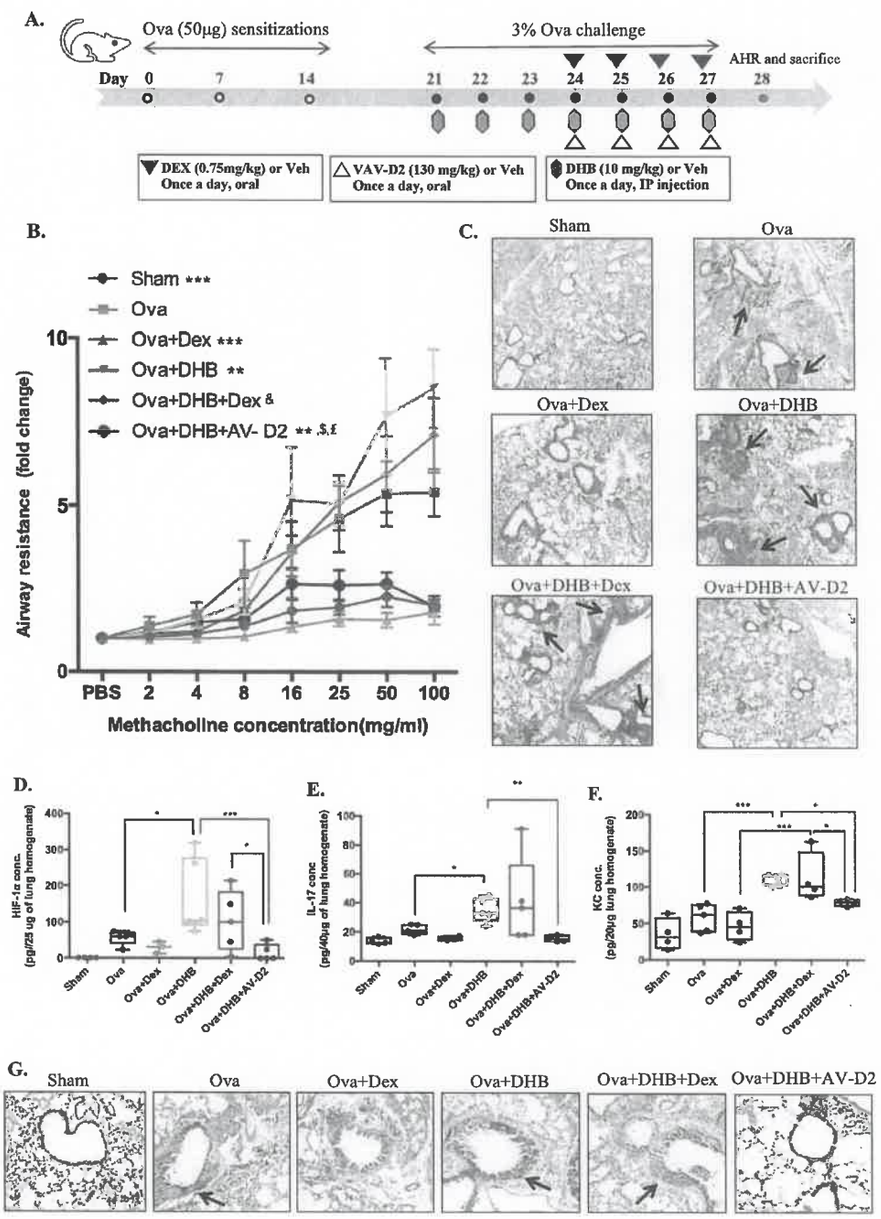

Fig. 3. AV treatment resolves the severe steroid resistant airway pathological features induced by chemical inhibition of PHD in mice model of asthma. (A) Schematic representation of experimental protocol used to induce severe asthma in mice using DHB as described in materials and methods. **(B)** Flexivent analysis of airway resistance after methacholine treatment for DHB induced severe asthma mouse model. (**C)** Representative photomicrographs (4X magnification) of mouse lung tissues stained with H&E **(D to F)** ELISA analysis for HIF-1α (D), IL-17 (E) and KC (F) abundance in mouse lung tissue homogenate. **(G)** Representative photomicrographs of mouse lung tissues stained with PAS. Arrow indicates positive staining for mucin. Data are shown as mean ±SEM of three to five mice per group and representative of two independent experiment. Significance denoted by *$P \leq 0.05$, **$P \leq 0.01$, ***$P \leq 0.001$ and ****$P \leq 0.0001$ compared with Ova group, & denotes $P \leq 0.0001$ compared to Ova+Dex group, $ and £ denotes $P \leq 0.0001$compared to Ova+DHB group and Ova+DHB+Dex group respectively; assessed by two way ANOVA with Tukey's multiple correction test (B), ordinary one way ANOVA (D and F), Unpaired t test with Welch's correction (E). **Ova-** chicken egg albumin, **Sham**- vehicle (PBS), **DHB**- ethyl, 3,4 -dihydroxy benzoic acid (10mg/kg), **Dex**- Dexamethasone (0.75mg/kg), **AV-D2**- *Adhatoda Vasica* extract (130mg/kg).

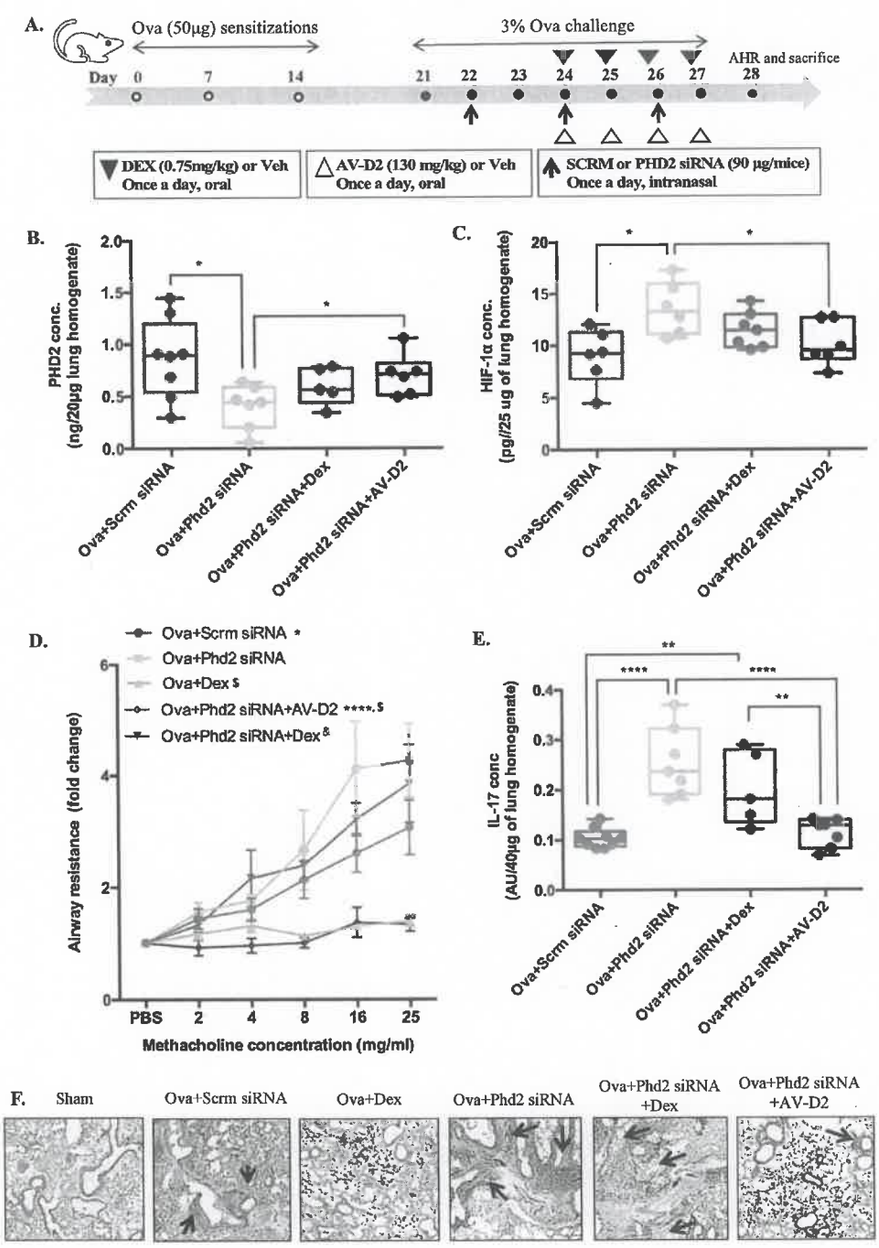

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Fig. 4. AV treatment rescues the *PHD2* siRNA induced severe steroid insensitive asthmatic features in mouse model of asthma. A) Schematic representation of experimental protocol used to induce severe asthma in mice using *PHD2* siRNA as described in materials and methods. **(B and C)** ELISA analysis for PHD2 (B) and HIF-1α (C) levels in mouse lung tissue homogenate. **(D)** Flexivent analysis of airway resistance after methacholine treatment in *PHD2* siRNA mediated severe asthma mouse model. **D)** ELISA analysis for IL-17 abundance in mouse lung tissue homogenate. **(E)** Representative photomicrographs (4X magnification) of mouse lung tissues stained with H&E. Black arrow indicates airway inflammation. Data are shown as mean ±SEM of five to nine mice per group and representative of two independent experiment. Significance denoted by **P* ≤0.05, and *****P*≤0.0001compared with Ova+PHD2 siRNA mice, £ denotes *P* ≤0.05 compared to Ova+Scrm siRNA group, $ indicates *P*≤0.01 compared with Ova+PHD2 siRNA+Dex group and & denotes *P*≤0.0001compared with Ova+Dex group; assessed by assessed by Unpaired t test with Welch's correction (B and C), two way ANOVA with Tukey's multiple correction test (D), and ordinary one way ANOVA (E). **Ova-** chicken egg albumin, **Sham**- vehicle (PBS), **Scrm siRNA**- Scrambled siRNA-90μg/mice, **PHD2 siRNA-** mouse specific PHD2 siRNA 90μg/mice., **Dex**- Dexamethasone (0.75mg/kg), **AV-D2**- *Adhatoda Vasica* extract (130mg/kg).

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Supplementary Information for

Adhatoda Vasica ameliorates cellular hypoxia dependent mitochondrial dysfunction in acute and severe asthmatic mice

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Supplementary Information Text

Materials and Methods

Preparation of plant extract and LC-MS fingerprinting: *Adhatoda Vasica* (AV) was collected from Delhi-NCR region, India in the flowering season (November to March). Water extract of plant (leaves, twigs and flowers) was prepared according to classical method described for rasakriya in *Caraka Samhita* (1). The process for the formulation involved preparation of decoction condensation and drying as described in earlier study (2). Chemical fingerprinting of prepared AV extract was carried out by LC-MS at CSIR-CDRI, Lucknow, India; in two independent experiment. Briefly, Liquid chromatography-electrospray ionization-mass spectrometry of AV extract was recorded in positive- and negative- ion modes using an Agilent 6520 QTOF-MS/MS system coupled with an Agilent 1200 HPLC (Agilent technologies, USA) via an ESI interface **(Table S1 and S2)**. HPLC separation was carried out on a Supelco Discovery HS C18 column (15 cm×4.6 mm, 3µm) operated at 25°C. The mobile phase, which consisted of a 0.1% formic acid aqueous solution and acetonitrile. The analyses were performed on an Agilent 1200 HPLC system consisted of a quaternary pump (G1311A), online vacuum degasser (G1322A), auto sampler (G1329A), thermostatted column compartment (G1316C) and diode-array detector (G1315D). In the ESI source, nitrogen was used as drying and collision gas in both positive and negative ion mode. Detection was carried out within a mass range of m/z 50-2000 and resolving power above 15000 (FWHM). The chromatographic and mass spectrometric analyses were performed by using Mass Hunter software version B.04.00 build 4.0.479.0 (Agilent Technology, USA).

Animals

All animals were maintained as per the guidelines of the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA). The BALB/c male mice (8-10 weeks old) were obtained from Central Drug Research Institute, Lucknow, India and were acclimatized to animal house environment one week prior to starting the experiments at CSIR-Institute of Genomics and Integrative Biology (IGIB), Delhi, India; as per the protocols approved by Institutional Animal Ethics

Committee of CSIR-IGIB, Delhi, India. All the surgical procedures were performed under sodium pentobarbital anesthesia and maximum efforts were taken for minimum suffering of animals.

Grouping of mice

Mice were divided into two groups, acute and severe as per allergen challenge and treatment protocol. In both groups, there were three main sub-groups (n = 4-7): Sham (mice that were PBS sensitized, PBS challenged), Ova (mice that were Ova [grade V chicken egg Ovalbumin, Sigma] sensitized, Ova challenged and treated with vehicle, 50 % ethanol and distill water), Ova+Dex (allergic mice treated with Dexamethasone [0.75mg/kg], dissolved in 50% ethanol, by orally). In acute model, in addition to the above groups, mice were divided into five different Ova+AV groups (allergic mice treated with *Adhatoda* extract [AV, 13mg/kg, 65mg/kg, 130mg/kg, 195mg/kg and 260mg/kg], dissolved in distil water, oral). For severe model, Ova sensitized and challenged mice were further sub-divided according to treatment: Ova+DHB (allergic mice treated with ethyl 3,4-dihydroxybenzoic acid [DHB, 10 mg/kg], dissolved in 50% ethanol, intraperitoneal injection) or Ova+ scrambled siRNA (mice that were Ova sensitized, Ova challenged and administered with intranasal scrambled siRNA[90 µg]) and Ova+PHD2 siRNA (allergic mice treated with intranasal prolyl hydroxylase domain 2 siRNA and treated with vehicle), Ova+DHB+Dex (allergic mice treated with DHB [10 mg/kg] and administered with Dexamethasone [0.75mg/kg]) or Ova+PHD2+Dex (allergic mice treated with intranasal PHD2 siRNA [90 µg] and administered with Dexamethasone [0.75mg/kg]), Ova+DHB+AV (allergic mice treated with DHB [10 mg/kg] and administered with AV [130 mg/kg] or Ova+PHD2+AV(allergic mice treated with intranasal PHD2 siRNA [90 µg] and administered with AV [130 mg/kg]).

Sensitization, Challenge, and Treatment of Mice

In all models, mice were sensitized on days 0, 7, and 14 with 50 mg Ova (Sigma, Missouri, USA) adsorbed in 4 mg alum or 4 mg alum alone and were challenged from day 21 to 27 with 3% Ova in PBS or PBS alone consecutively, as described earlier. Acute Ova model effect was determined by three independent experiments and both severe model effect was determined by two independent experiments. Dexamethasone (sigma) was dissolved in 50% ethanol and was administered orally (0.75mg/kg) to mice from fourth day of challenge (24th day) till the last day of challenge (27$_{th}$ day), once a day. Similarly, AV (dissolved in distilled water, was given orally (13mg/kg, 65mg/kg, 130mg/kg, 195mg/kg and 260mg/kg and denoted hereafter as AV-D0, AV-D1, AV-D2, AV-D3 and AV-D4, respectively) by gavage from day 24 to 27, once a day. DHB (TCI, Tamilnadu, India) was administered from day 21 to 27 by intraperitoneal injection (10 mg/kg) in 200µl volume of 50% ethanol, was given 2 hours before the Ova challenge. For PHD2 siRNA model, scrambled (Sigma) or PHD2 siRNA (Sigma) was dissolved in ultrapure DNAse and RNAse free water with in vivo-jetPEI as the transfection reagent (Polyplus), was administered intranasally in 90µg concentration to isoflurane-anesthetized mice 2 hours prior to Ova challenge, on day 23, 25 and 27.

Measurement of airway hyperresponsiveness, bronchoalveolar lavage fluid collection, sera separation and histopathology

Airway hyperresponsiveness (AHR) in response to methacholine (Mch, Sigma) was determined in pentobarbital anesthetized mice using flexivent system (Scireq, Canada), as described previously. The results were expressed in the fold change of airway resistance with increasing concentrations of Mch, considering the PBS aerosol induced airway resistance as baseline values. After the AHR measurement, bronchoalveolar lavage fluid (BAL) was collected by instilling 1 ml PBS into the tracheotomised airway and recovered BAL fluids were processed to get cell pellet that will be stained with Leishman stain to determine differential cell count as well as total cell count, as described previously. Blood was withdrawn by cardiac puncture, and serum was separated by centrifugation at 1500 ×g for 10 min and was kept at −70 °C till the measurements of IgE. Lungs were removed and fixed with 10% formalin (3, 4). Fixed lungs were further processed and embedded with paraffin. 5-mm paraffin embedded lung sections then stained with haematoxylin and eosin, periodic acid-Schiff, and Masson Trichrome staining to assess the lung inflammation, mucus hypersecretion and sub-epithelial fibrosis, respectively. Microphotographs were taken by Nikon microscope with camera (Model YS-100). The inflammation scoring was performed as per inflammation grade system by experimentally blind experts to find out the perivascular (PV), peribronchial (PB) lung inflammation to calculate the lung inflammation score (3, 5, 6).

Measurement of Interleukin IL-4, IL-5, IL-13, IL-17, TGF-β1, IFN-γ, PHD2 and HIF-1α

Lung tissue homogenates were used for sandwich ELISA. IL-4, IL-5, TGF-β1, IFN-γ (BD Biosciences), IL-13 (R &D), Il-17 (ebioscience), PHD2 and HIF-1α (USCN), were measured as per manufacturer's instructions and results were expressed in picograms.

Western Blotting

For western blot lung tissue lysate was used. Proteins was separated on 8-10 % sodium dodecyl sulphate-polyacrylamide gel electrophoresis (SDS-PAGE), transferred onto polyvinylidene fluoride (PVDF) membranes (Millipore Corp, USA). Transferred membrane were blocked with blocking buffer (5% or 10% bovine serum albumin "BSA" in phosphate buffered saline with tween 20) or with non-animal protein blocker (NAP, G biosciences). Incubated with primary antibody (abcam, USA or ebiotech, USA) in 1:1000 dilution, followed by HRP conjugated secondary antibody and detected with DAB-H_2O_2 (Sigma, USA) or by chemiluminescence (ECL) method. α-tubulin (Sigma, St. Louis, MO, USA) or β-actin was used as a loading control. Signals were detected by spot densitometry (Image J software).

Transfection, Immunofluorescence and imaging

Human bronchial epithelial cells (BEAS2B) were seeded on glass bottomed dish in 6-well plate and cultured in bronchial epithelial cell growth medium. Cells were transfected with GFP-Mito(mito-GFP) was purchased from addagene as per manufactures instruction. This was generous gift from Dr. Shital (CSIR-IGIB, Delhi). Similarly for immunofluorescence, after appropriate induction, cells

were fixed with 2% paraformaldehyde and permeabilized with 0.1% Triton-X100 (Sigma). Blocking was done with 1.5% BSA. These cells then were labeled with TOM 20 primary antibody (Santacruz), followed by Alexa Fluor 488 (Invitrogen) conjugated secondary antibodies. DAPI (Invitrogen) was used for nuclear staining.

The fluorescent images were collected using point scanning laser confocal microscope system (Nikon A1R-HD, Japan; Leica TCS SP8, Germany) with 60X, 1.4N oil immersion objective lens. The imaging software NIS element AR 5.11.01 and LAX3.1.5 was used to process the raw recorded image data. Modified version of the mitochondrial morphology plugin of ImageJ was used for automated mitochondrial morphometric analysis (7–9).

***In Vitro* Culture of Human Bronchial and Alveolar Epithelial cells**

Human bronchial epithelial cells (BEAS 2B) and adenocarcinomic human alveolar basal epithelial cell line (A549) was obtained from ATCC and cultured in DMEM high glucose medium (obtained from Sigma). For the induction of cellular hypoxia stress cells were treated with DMOG (1 mM/ml, Dimethyloxallyl Glycine, Cayman, 71210) or vehicle (DMSO and distill water) as control. After 8 hours of DMOG treatment, cells were treated with AV extract (10μg/ml), and Dex (10μM/ml). After 24 hrs o treatment, cells were harvested and the levels of HIF-1α was determined in cell lysates (USCN life Science, China) by western blot.

Seahorse assay experiment

Cells were seeded in a 24-well plate of the seahorse format (sup fig), with a seeding density 40000 and 60000 cells per well per 100 µl media for BEAS-2B and A549 respectively. The wells A1, B4, C3 and D6 served as blank and were left without any cells; only media was added to these wells. After 5 hours, when the cells adhered and almost attained morphology, additional 900µl media was added to each well. For the seahorse experiment, following groups were set up: Vehicle (DMSO and distil water), DMOG alone , a DMOG (1mM; 8 hours), AV extract (24 hours), DMOG+Dex (10μM/ml of Dex was added to cells after 8 hours of DMOG treatment and incubated for further 24 hours), DMOG + AV extract (AV extract is added to cells after 8 hours of DMOG treatment and incubated for further 24 hours), and DMOG+Dex+AV. The next day, in fresh media, 1mM DMOG and corresponding volume of DMSO was added to the designated wells. After 8 hours, AV extract (10μg/ml) was added to the respective wells. After 24 hours of AV extract induction, seahorse experiment was initiated to test mitochondrial function and it was determined by XF Cell Mito Stress Test assay using manufacturer's instructions. A day prior to the seahorse experiment, a sensor cartridge was hydrated in Seahorse XF Calibrant at 37°C in a non-CO_2 incubator overnight. On the day of the experiment, assay medium was prepared by adding 1mM pyruvate, 2mM glutamine and 10mM glucose to the basal medium. The pH of the medium was adjusted using 0.1N NaOH and warmed to 37°C until use. After the 24 hours incubation of cells with AV extract, the cell culture media was replaced with the prepared assay medium for 1 hour. After this, the wells were washed thrice with the assay medium. Meanwhile, antibiotics were prepared and added to respective ports

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in a constant volume mode. Following were the final concentrations at which the inhibitors was used: Oligomycin 1µM, FCCP 2µM, Rotenone 0.5 µM. Once the plate containing cells is ready and the ports have been loaded with the inhibitors, it was placed in the seahorse instrument and run. After the run, the data was normalised with protein content in each well and analysed further on.

Statistical analysis

All data represents mean ± SEM; n= 3-7 each group; *p <0.05, **p <0.01, ***p <0.001. p-value > 0.05 is considered non-significant (NS). Statistical significance of the differences between paired groups was determined with a two-tailed Student's t test. One-way or two way analysis of variance was used to compare multiple groups and was evaluated further with a nonparametric Mann-Whitney rank-sum test or Kruskal - wallis test wherever appropriate.

Fig. S1. Non-linear effect (U shape curve effect) of AV on physiological parameters of acute asthma. (A) LC-MS analysis of aqueous extract of *Adhatoda Vasica* using (+)-ESI-MS for identification of Quinazoline alkaloids. **(B and F)** AV shows U shape curve effect on increased airway resistance in Ova allergic mice in dose dependent manner from D0 to D4. **(C to E)** Representative photomicrographs of mouse lung tissues stained with (C) H&E (4X magnification), (D) PAS (10X magnification), and (E) MT (10X magnification) staining respectively. Black arrow indicates positive staining in respect to particular stain. **(G)** Quantification of peribronchial and perivascular inflammation of lung tissues stained with H&E in using inflammation grade scoring system. **(H and I)** Densitometric analysis of mouse lung tissues stained with PAS and MT to measure mucus metaplasia and collagen deposition respectively using ImageJ. **(J)** Eosinophil abundance in mouse BAL fluid. **(K)** ELISA analysis for TGF-β1 levels in mice lung homogenate. Data are shown as mean ±SEM of three to seven mice per group and representative from at least two independent experiments. Significance denoted by $*P \leq 0.05$, $**P \leq 0.01$, $***P \leq 0.001$ and $****P \leq 0.000$; by two way ANOVA (B) and ordinary one way ANOVA (G to K). **Ova-** chicken egg albumin, **Sham**- vehicle (PBS), **Dex**- Dexamethasone (0.75mg/kg), **AV-***Adhatoda Vasica* extract, **D0**- AV 0.130mg/kg, **D1**- AV 65mg/kg, **D2**- AV 130 mg/kg, **D3**- AV 195 mg/kg and **D4**- AV 260mg/kg.

Figure S2: AV restores the HIF-1α induced increased airway inflammation in mitochondria dependent manner. (A) ELISA analysis for HIF-1α levels in mice lung tissue homogenate (n = 3 to 7). **(B)** Representative western blot for HIF-1α abundance in lung tissue lysate of Ova allergic mice treated with Dex or AV in dose dependent manner. **(C)** Correlation analysis of airway

peribronchial inflammation with HIF-1α levels in mice lung after AV-D0, D2, and D4 treatment. **(D)** qPCR for *PHD2* mRNA levels in mice lung RNA samples. Data are shown as mean ±SEM (A to D). **(E)** Western blot for HIF-1α abundance in BEAS2B cell lysate. **(F to I)** Morphological analysis of mitochondria of BEAS2B cells transfected with mitochondria targeted-GFP (mito-GFP) for assessment of mitochondrial network (F), mean branch length (G), area (H), its individual number (I). Data are shown as mean ±SEM of thirty or more cells per group and representative of two independent experiments (E to I). Significance denoted by **P* ≤0.05, ***P*≤0.01, and ****P*≤0.001; by ordinary one way ANOVA (A), Unpaired t test with Welch's correction (D), ordinary one way ANOVA with Tukey's multiple correction test (F to I). **Sham**- vehicle (PBS), **Dex**- Dexamethasone (0.75mg/kg), **AV-***Adhatoda Vasica* extract, **AV-D0**- AV 0.130mg/kg, **AV-D1**- AV 65mg/kg, **AV-D2**- AV 130 mg/kg, **AV-D3**- AV 195 mg/kg and **AV-D4**- AV 260mg/kg, **Veh-** Vehicle (sterile distill water +DMSO), **BEAS-2B**- normal human bronchial epithelium cells, **DMOG**- dimethyloxaloylglycine, **DMOG+AV**- DMOG+10µg/ml. of AV, **DMOG+Dex**- DMOG+10nM of Dex, **DMOG+Dex+AV**- DMOG+10nM of Dex+10 µg/ml of AV, **DMOG 8hrs**- DMOG treatment for 8 hours.

Figure S3: AV treatment rescues cellular hypoxia induced mitochondrial dysfunction in adenocarcinomic human alveolar basal epithelial cells. (A) Representative OCR levels linked with Basal respiration, ATP production and at Maximum respiration indicated by fold change value as compare to vehicle (sterile distil water) group in adenocarcinomic human alveolar basal epithelial cells (A549). Significance denoted by $ indicates *P*≤0.0001 compared to Veh group and ***P*≤0.01 and *****P*≤0.0001 compared DMOG group. **(B)** Representative confocal images of cells labelled with mitochondria specific TOM20 show in green, with nuclear stain (DAPI) in blue. Boxed areas in the image are magnified to show typical changes in mitochondria after each treatment and condition. **(C to F)** Dot plot showing statistical score of mitochondrial elongation (C), mitochondrial network (D), area (E) and its individual numbers per cell (F). Data are shown as mean ±SEM of thirty or more cells per group. Significance denoted by **P* ≤0.05, ***P*≤0.01, ****P*≤0.001 and *****P*≤0.0001, by two way ANOVA with Tukey's multiple correction test (A), ordinary one way ANOVA with Tukey's multiple correction test (C to F). **OCR-** oxygen consumption rate, **DMOG**- dimethyloxaloylglycine, **DMOG+AV**- DMOG+10µg/ml. *Adhatoda Vasica* extract, **DMOG+Dex**- DMOG+10nM of Dexamethasone, **DMOG+Dex+AV**-DMOG+10nM of Dexamethasone+10µg/ml. *Adhatoda Vasica* extract, **DMOG 8hrs**- DMOG treatment for 8 hours.

Figure S4: AV resolves the chemically induced severe corticosteroid insensitive airway inflammation. (A) Quantification of Peribronchial and Perivascular inflammation of lung tissues stained with H&E by inflammation scoring grade method. **(B.)** Densitometric analysis of mouse lung tissues stained with PAS to measure goblet hyperplasia in severe asthmatic mice using

ImageJ **(C to E)** ELISA for IL-13, TNF-α and IFN-γ cytokine levels measured in lung tissue lysate of severe asthmatic mice. Data are shown as mean ±SEM of three to five mice per group and representative of two independent experiment.. Significance denoted by $*P \leq 0.05$, $**P \leq 0.01$, $***P \leq 0.001$ and $***P \leq 0.001$; by ordinary one way ANOVA. **Ova-** chicken egg albumin, **Sham-** vehicle (PBS), **DHB-** ethyl, 3,4 -dihydroxy benzoic acid (10mg/kg), **Dex-** Dexamethasone (0.75mg/kg), **AV-D2-** *Adhatoda Vasica* extract (130mg/kg).

Figure S5: AV resolves the *PHD2* siRNA induced severe corticosteroid insensitive airway inflammation. (A) Quantification of Peribronchial inflammation of lung tissues stained with H&E by inflammation scoring grade method. **(B)** Densitometric analysis of mouse lung tissues stained with PAS to mucus metaplasia in severe asthmatic mice using ImageJ. **(C to E)** ELISA analysis of IL-13 (C), KC (D) and IL-6 (E) cytokine levels in lung tissue lysate of severe asthmatic mice. **(F)** Representative photomicrographs of mouse lung tissues stained with PAS to check mucin levels. Arrow indicates positive staining for mucin. Data are shown as mean ±SEM of five to eight mice per group and representative of two independent experiments. Significance indicated by $*P \leq 0.05$, $**P \leq 0.01$, $***P \leq 0.001$ and $***P \leq 0.001$; by ordinary one way ANOVA. **Ova-** chicken egg albumin, **Sham-** vehicle (PBS), **Scrm siRNA-** scrambled siRNA- 90 μg/mice, **PHD2 siRNA-** mouse specific PHD2 siRNA 90μg/mice., **Dex-** Dexamethasone (0.75mg/kg), **AV-D2-***Adhatoda Vasica* extract (130mg/kg)

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Table S1- Liquid chromatography–electrospray ionization–mass spectroscopy of AV extract in positive-ion mode. Identification of Quinazoline alkaloids from the water extract of *Adhatoda Vasica*, separated by mobile phase consist of 0.1% formic acid aqueous solution and acetonitrile. The various peaks obtained (fig. S1A) were analyzed at different time intervals under a gradient program using (+)-ESI-MS.

Sr. No.	RT (in min)	Molecular Formula	$[M+H]^+$ *m/z* (calc)	$[M+H]^+$ *m/z* (exp)	Error (Δppm)	Identification
1	2.4	$C_5H_{14}NO^+$	104.1073	104.1073	0	Choline
2	2.9	$C_5H_{11}NO_2$	118.0864	118.0864	0	Betaine
3	8	$C_{11}H_{12}N_2O_2$	205.0972	205.0974	0.98	Vasicinol/ 5-hydroxy vasicine
4	8.2	$C_{12}H_{12}N_2O_3$	233.0921	233.0921	0	Adhavasicinone
5	10	$C_{11}H_{12}N_2O_2$	205.0972	205.0974	0.98	Vasicinol/ 5-hydroxy vasicine
6	10.4	$C_{12}H_{12}N_2O_2$	217.0972	217.0969	-1.38	Linarinic acid
7	10.9	$C_{11}H_{12}N_2O$	189.1022	189.1022	0	Vasicine
8	13.3	$C_{11}H_{10}N_2O_3$	219.0764	219.0766	0.91	Vasicinolone
9	13.7	$C_{12}H_{14}N_2O_2$	219.1128	219.1131	1.37	5-methoxy vasicine
10	15.7	$C_{17}H_{22}N_2O_6$	351.1551	351.1548	-0.85	Vasicine glycoside
11	15.7	$C_{11}H_{10}N_2O_2$	203.0815	203.0812	-1.48	Vasicinone

Table S2- Liquid chromatography–electrospray ionization–mass spectroscopy of AV extract in negative-ion mode. Identification of flavonoids C- and O- glycosides from the water extract of

Adhatoda Vasica, separated by mobile phase consist of 0.1% formic acid aqueous solution and acetonitrile. The various peaks obtained (fig. S1B) were analyzed at different time intervals under a gradient program using (-)-ESI-MS.

Sr. No	RT (minute)	Molecular Formula	$[M-H]^-$ m/z (calc)	$[M-H]^-$ m/z (exp)	Error (Δppm)	Identification
1	14.8, 17.9	$C_{27}H_{30}O_{16}$	609.1461	609.1464	0.49	Luteolin-6,8-di-C-glucoside/ Quercetin-3-O-rutinoside
2	15.3, 15.8	$C_{26}H_{28}O_{15}$	579.1355	579.1354	-0.17	Luteolin-6-C-glucoside-8-C-arabinoside/ Luteolin-6-C-arabinoside 8-C-glucoside
3	15.5, 18.8	$C_{27}H_{30}O_{15}$	593.1512	593.151	-0.34	Kaempferol-3-O-rutinoside/ Apigenin-6,8-di-C-glucoside
4	15.8, 16.2, 16.5, 16.8, 17.3	$C_{26}H_{28}O_{14}$	563.1406	563.1401	-0.89	Apigenin-6-C-glucoside-8-C-arabinoside/ Apigenin-6-C-arabinoside 8-C-glucoside/ Apigenin-6-C-arabinoside 7-O-glucoside
5	16.6	$C_{25}H_{26}O_{14}$	549.125	549.1253	0.55	Luteolin-6,8-di-C-arabinoside
6	16.7	$C_{21}H_{20}O_{11}$	447.0933	447.0928	-1.12	Luteolin-8-C-glucoside/ Luteolin-6-C-glucoside/ Kaempferol-3-O-glucoside
7	16.8, 17.2, 17.5, 18.1, 18.5	$C_{25}H_{26}O_{13}$	533.1301	533.1303	0.38	Apigenin-6,8-di-C-arabinoside
8	18.1, 18.3	$C_{21}H_{20}O_{10}$	431.0984	431.0983	-0.23	Apigenin-6-C-glucoside/ Apigenin-8-C-glucoside
9	18.6, 19.3	$C_{20}H_{18}O_{10}$	417.0827	417.0831	0.96	Luteolin-8-C-arabinoside/ Luteolin-6-C-arabinoside
10	18.7	$C_{21}H_{20}O_{12}$	463.0882	463.0881	-0.22	Quercetin-3-O-glucoside
11	19.7, 20.1	$C_{20}H_{18}O_9$	401.0878	401.0873	-1.25	Apigenin-8-C-arabinoside/ Apigenin-6-C-arabinoside

Table S3.AV attenuates increased Th2 cytokines levels. Levels of IL-4, 5 and 13 levels in lung homogenate measured by ELISA in acute asthmatic mouse. Data are shown as mean, ± SEM. *P ≤0.05, **P≤0.01 and ***P≤0.001 compared Ova mice group (n = 4-7 per group).

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MICE GROUP	IL-4 LEVELS	IL-5 LEVELS	IL-13 LEVELS
SHAM	72.75(±13.56)*	115.08(±34.05)*	147.04(±29.73)*
OVA	124.02(±11.45)	220.33(±23.64)	275.89(±31.69)
OVA+DEX	70.04(±9.77)**	108.73(±16.62)**	124.60(±22.12)**
OVA+D0	48.26(±9.74)**	123.15(±24.48)*	114.79(±20.50)**
OVA+D1	43.64(±10.69)**	103.12(±27.12)*	87.37(±18.69)**
OVA+D2	64.65(±3.89)**	102.37(±13.25)**	89.56(±5.98)**
OVA+D3	74.76(±13.19)**	128.54(±14.35)*	104.20(±14.07)**
OVA+D4	63.29(±7.35)**	128.54(±19.09)*	73.93(±21.42)***

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ANNEXURE-M

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IMMUNOSUPPRESSIVE ACTIVITY OF SAPONIN FROM THE LEAVES OF *ADHATODA VASICA* USING FLOW CYTOMETRY

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ABSTRACT

Immunosuppressive activity of saponin extracted from the leaves of *Adhatoda vasica* were observed in human whole blood using hepatitis vaccine antigen to estimate the monocytes, lymphocytes and granulocytes count. In addition, the effect of saponin along with hepatitis vaccine antigen was observed in Swiss mice and evaluated the peritoneal macrophages activation and estimates the T cell surface marker i.e. CD3. The results showed that the saponin showed a significant decrease in the number of monocytes and granulocytes count in human whole blood and also showed the sudden decline in the level of peritoneal macrophage activation and T cell surface marker i.e. CD3 as compared to control. No mortality was occurred in all the tested drug samples. Overall, the saponin showed immunosuppressive effect on the cell mediated immune (T cell surface markers) response and macrophage activation in mice.

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1. INTRODUCTION

Saponins are the glycosides of twenty seven carbon atom steroids or thirty carbon atom triterpenes in plants. These saponin are found in various parts of the plant especially leaves, stems, roots, bulbs, flowers and fruits [1, 2]. These are characterized through their bitter taste and their ability to showed hemolytic activity in human red blood cells. These saponins are commonly used in Ayurvedic medicine as a treatment for eczema, psoriasis and for removing freckles. Saponins are believed to be useful in the human diet for controlling cholesterol [1, 2, 3, 4]. Digitalis - type saponins strengthen the heart muscle causing the heart to pump more efficiently [5, 6]. Saponins also inhibit cancer tumor growth in animal model studies, particularly, lung and blood cancers, without killing normal cells. Saponins are the plant's immune system acting as an antibiotic to protect the plant against microbes and fungus [7, 8, 9, 10]. To achieve this objective, our group focused on saponins isolated from the medicinal plants for determining its various immunopharmacological activities. According to Ayurveda, one of the highly reputed medicinal plant i.e. *Adhatoda vasica* (adulsa, or malabar nut tree, family Acanthaceae) is small evergreen, sub-herbaceous bush which grows commonly in India, Sri Lanka, Burma and Malaysia [11]. This plant is generally used for the treatment of various diseases e.g. bronchitis, asthma, malaria, dysentery and diarrhea [12, 13]. In addition, it also showed potent anti-inflammatory activity, analgesic, antioxidant, hepatoprotective, sedative, antispasmodic, antihelmintic properties, antimicrobial activity, antidiabetic activity, wound healing effect, Infertility, anti-ulcer, antibacterial and anti-fungal activity [11, 12, 13, 14]. So far, the immunomodulatory activities of saponin extracted from *Adhatoda vasica* have not been studied *in vivo*. Crude saponin fractions isolated from the leaves of various medicinal plants and these were subjected to an immunological screening. In this article, our group focused on the immunomodulatory effect of saponin extracted from *Adhatoda vasica* using flow cytometry.

2. MATERIALS AND METHODS

2.1 Plant collection

Leaves of *Adhatoda vasica* were collected in January 2015 from the garden of Vidya Pratishthan's, Baramati, Maharashtra, India. The leaves were sun dried and make a powder for the isolation of crude saponin was analyzed.

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2.2. Phytochemical Screening and extraction of saponin

The procedure was carried out for the separation of saponins e.g. foaming assay from the aqueous extract of *Adhatoda vasica*. To prepare the aqueous extract, the dried plant materials (10 g) of *Adhatoda vasica* were prepared in phosphate buffered saline (20 ml). After preparing the aqueous extract, this was extracted thrice with diethyl ether (10 ml). The diethyl ether layer was discarded and the retained aqueous layer extracted at the bottom further with 30 ml n-butanol (four times). The n-butanol extracts were bulked together and washed four times using 5 ml of five percent NaCl. The washed extract was concentrated at < 70 °C in an oven and air dried at room temperature to yield 500 mg of crude saponin residue. Residue was screened for saponin using the foaming test. Powder is dissolved in phosphate buffered saline, filtered through a Whatman filter paper [15].

2.3. Human blood samples and estimation of blood counts through flow cytometry

Human Blood samples were received for immunological studies from Mangal Pathology lab, Baramati region, District Pune Maharashtra especially for the estimation of blood counts i.e. lymphocytes, monocytes and granulocytes count using flow cytometry. Briefly, 100 µl of human whole blood is taken into the falcon tube and add serial dilutions of test candidate i.e. *Adhatoda vasica*. Incubate the samples for 2h at 37°C, 5% carbon dioxide incubator for 2 h. After incubation, lyse the cells with red cell lysis buffer and then washed the samples 2-3 times with phosphate buffered saline and then analyzed the cells using forward and side scatter through flow cytometer [16, 17].

2.4. Animal studies

The animal experiment i.e. mouse model based studies will be done as per the ethical guidelines. Animals were immunized on day 0 and 7 with hepatitis vaccine antigen (20 µg) and drugs continuously given from day 0 to day 10. On day 10, collect the whole blood from retro-orbital plexus and peritoneal macrophages from the abdominal cavity of mouse for the estimation of CD3 surface marker and macrophages activation.

For CD3 estimation, mice whole blood (100 µl) were placed in falcon tube and then stained with CD3 surface marker. Incubate the samples for 30 minutes in dark. After incubation, lysed and washed the cells with phosphate buffered saline and then analyzed the cells through flow cytometer [18].

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For peritoneal macrophages, mice were injected with 10 ml of ice cold phosphate buffered saline containing fetal bovine serum. The abdomen was gently massaged and collects all these cells from the peritoneal cavity and then transferred the cells into 6 well plates. Incubate the cells for 24 h at 37°C. After 24h incubation, analyzed the cells using forward and side scatter through flow cytometric analysis [18].

2.5. Statistical analysis

Values are expressed as Mean ± S.E. The difference between the control and treated is determined through Bonferroni multiple comparison test.

3. RESULTS

3.1. Effect of *Adhatoda vasica* on human whole blood

The effect of variable doses of saponin extracted from *Adhatoda vasica* on human whole blood as shown in **Fig.1.**The results showed that the saponin at higher doses with hepatitis B vaccine antigen showed inhibitory activity in monocytes and granulocytes count as compared to control. In addition, lymphocyte count increases at higher doses.

3.2. Effect of saponins on T cell surface marker (CD3, CD4 and CD8)

The effects of variable doses of saponin on T cell surface marker i.e. CD3. in mice are shown in **Fig. 2.** The results showed that the saponin along with hepatitis vaccine antigen significantly decreased the T cell surface marker i.e. CD3 as compared to the control group. Although the proportions of CD3+ T cells in the whole blood from the mice treated with 10 mg/ml of *Adhatoda vasica* were higher than those from the control group.

3.3. Effect of saponins on peritoneal macrophages activation

The effects of variable doses of saponin along with hepatitis vaccine antigen are shown in **Fig. 3.** At higher doses, there is decline in peritoneal macrophages activation as compared to control group. Although, the proportion of peritoneal macrophages in mice at lower dose i.e. 10 mg/ml is still higher as compared to control group using forward and side scatter. In this case, both forward and side scatter count increased in the same fashion. It means that saponin extracted from *Adhatoda vasica* showed immunosuppressive activity.

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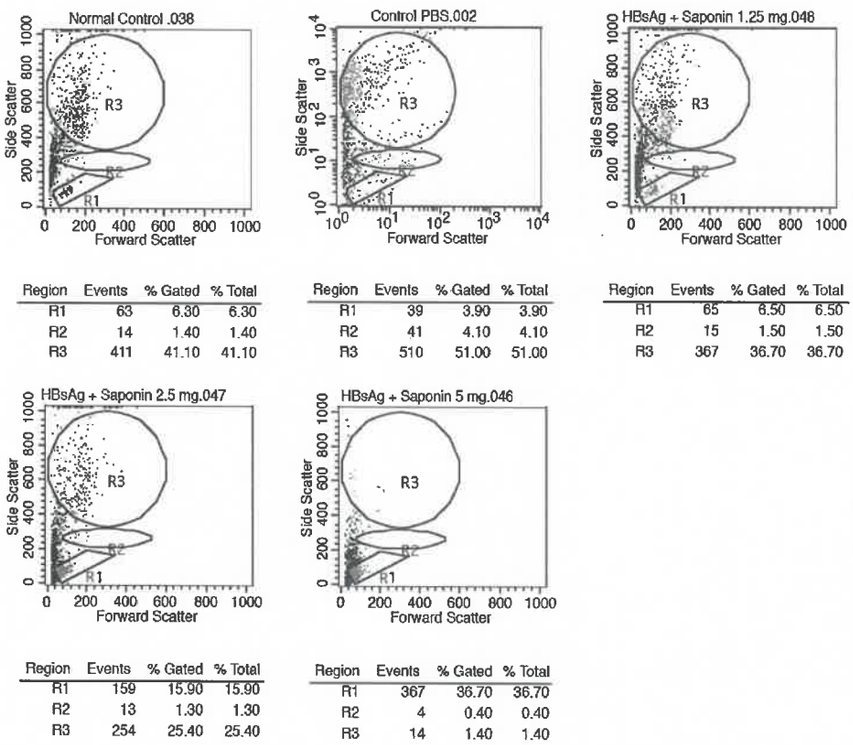

Region	Events	% Gated	% Total
R1	63	6.30	6.30
R2	14	1.40	1.40
R3	411	41.10	41.10

Region	Events	% Gated	% Total
R1	39	3.90	3.90
R2	41	4.10	4.10
R3	510	51.00	51.00

Region	Events	% Gated	% Total
R1	65	6.50	6.50
R2	15	1.50	1.50
R3	367	36.70	36.70

Region	Events	% Gated	% Total
R1	159	15.90	15.90
R2	13	1.30	1.30
R3	254	25.40	25.40

Region	Events	% Gated	% Total
R1	367	36.70	36.70
R2	4	0.40	0.40
R3	14	1.40	1.40

Fig.1. Flow cytometric analysis of saponins extracted from *Adhatoda vasica* on lymphocytes, monocytes and granulocytes count. EDTA human whole blood were treated with variable doses of saponin and then lysed and wash the cells with phosphate buffered saline and analyzed through flow cytometer. Values are expressed in Mean ± S.E. of fifty four human whole blood samples.

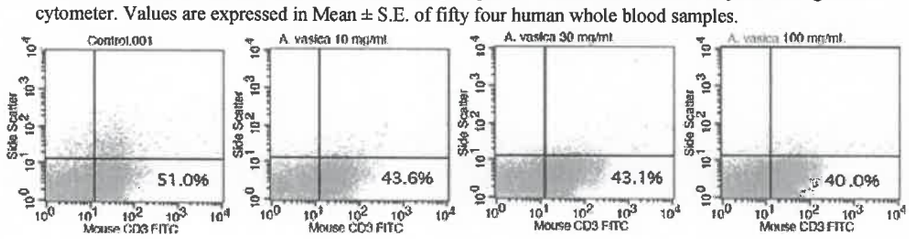

Fig.2. Flow cytometric analysis of saponins on CD3 T cell surface marker. Swiss mice were treated orally with variable concentration of saponins with hepatitis B surface antigen from day 0 and day 7. On day 10, whole blood were collected from retro-orbital plexus of mice and stained with CD3 FITC surface marker. After 30 minutes incubation with monoclonal antibody, cells were lysed and washed the cells with phosphate buffered saline and analyzed through flow cytometer (FACS Calibur).

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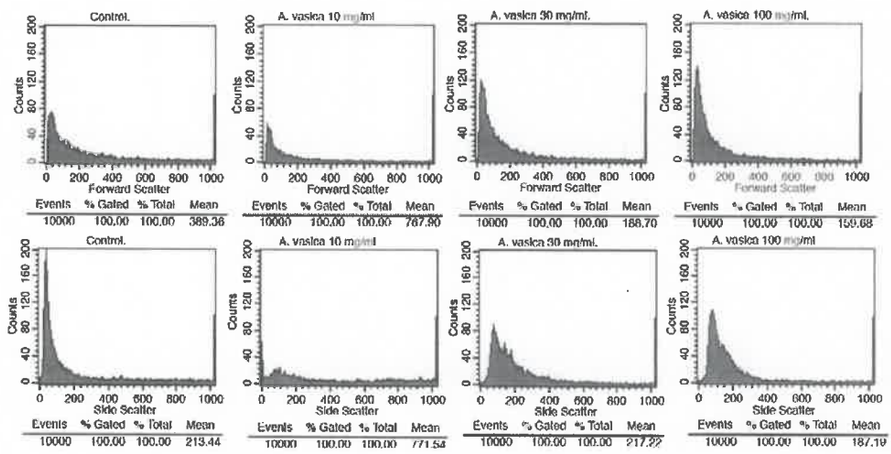

Fig.3. Flow cytometric analysis of saponins extracted from *Adhatoda vasica* on peritoneal macrophages. Mouse peritoneal cells were collected on day 16. Mouse peritoneal cells (2 x 10^6 cells/ml) dissolved in phosphate buffered saline containing 10 % FCS (heat inactivated). 500 µl cell suspensions containing 2 x 10^6 cells/ml of treated mice of variable doses of saponins (10 – 100 mg/ml) were added in each 6 well plate and then add again exposure of saponins. Samples were incubated for 24 h at 37°C in CO2 incubator and then analyzed the forward and side scatter using flow cytometer. Experiment repeatedly three times.

4. DISCUSSION

Suppression or decline in the level of immune response through medicinal plant products as a possible therapeutic measure has become a subject of scientific investigation. Due to these synthetic based immunosuppressants which are available in the market showed serious adverse effects among which nephrotoxicity, hepatotoxicity, induction of diabetes, induction of hypertension and neurotoxicity are most notorious for cyclosporine and tacrolimus [19, 20, 21]. As a consequence, there continues to be a high demand for new immunosuppressants. In an effort to search for new immunosuppressants from medicinal plants which is clinically useful and safe product that could suppress immune response and may have future use for the local people. This study reported the effect of saponins extracted from *Adhatoda vasica* on human whole blood and also observed the T cell marker i.e. CD3 and peritoneal macrophages activation in mice intraperitoneally immunized with hepatitis B vaccine antigen.

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The study of the immunomodulatory effects of various medicinal plants on animal and human model based studies is a matter of interest for many researchers. Several studies have previously been published and demonstrated the immunomodulating either immunostimulatory or immunosuppressive effects of medicinal plants on humoral and cell mediated immune response. This study focused on the influence of medicinal plant that has shown inhibitory activity of monocytes on human whole blood and also showed the decline in the level of T cell count i.e. CD3 marker and peritoneal macrophages activation in mice. The results obtained from this study which is indicated that saponins extracted from *Adhatoda vasica* showed immunosuppressive effect on human whole blood and animal model studies with a dosage-dependent relationship. In the experiments undertaken to study the effect of saponin on human whole blood along with hepatitis vaccine antigen were observed and it showed that with the administration of increasing doses of saponins, there is decline in the level of monocytes and granulocytes count as compared to control. The capacity to elicit a decline in T cell immunity can be shown by the CD3 (total T cell count) surface marker. The results indicated that saponin could significantly inhibit the potential of T cells in hepatitis vaccine immunized mice. The results of cell mediated response (decline in monocytes level and CD3 count) and macrophage activation after immunization with T-dependent antigen suggest that the activity of saponin could be mediated through the immunosuppressive effect on T lymphocytes and macrophages [23, 24]. Macrophages reside within the peritoneal cavity of mice and these were originated from specific white blood cells called monocytes which are present in the blood. Monocytes and macrophages are phagocytes, acting in either or innate as well as cell-mediated immunity of vertebrate animals. The results showed that there is significant decrease in level of macrophages at higher doses as compared to control.

CONCLUSION

In the present study, the immunosuppressant activity of *Adhatoda vasica*, an important plant in indigenous medicinal practice was explored. Administration of *Adhatoda vasica* was found to decrease in the level of monocytes in human whole blood and also confirmed through in mice where there is decline in CD3 count and macrophage activation.

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In-Vitro Thrombolytic and Anti-inflammatory Activity of *Swertia chirata* Ethanolic Extract.

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Ethanol extract of *Swertia chirata* was assessed for its thrombolytic, anti-inflammatory activity and phytochemical screening. *In vitro* anti-inflammatory activity was evaluated using albumin denaturation. Aspirin was used as a standard drug for the study of anti-inflammatory activity. The ethanol extract of *Swertia chirata* showed mean inhibition of protein denaturation 45.31±0.000576 whereas, for control group it was found to be 50.00±0.00177. In thrombolytic activity using *in vitro* clot lysis assay method, the crude ethanol extract was found to have significant, thrombolytic test showed a maximum effect of 40.38% while the standard streptokinase showed 69.35.

Keyword: Swertia chirata, Thrombolytic, Anti-inflammatory.

1. Introduction

Medicinal plants have always been considered a healthy source of life for all people. Therapeutically properties of medical plants are very useful in healing various diseases and the advantage of these medicinal plants is being 100% natural.

Nowadays people are being bombarded with thousands of unhealthy products, the level of sensibility in front of diseases is very high and that's why the use of medicinal plants can represent the best solution. Since antiquity, man has used plants to treat common infectious diseases and even long before mankind discovered the existence of microbes; the idea that certain plants had healing potential was well accepted[1]. A medicinal plant is any plant which, in one or more of its organs, contains substances that can be used for therapeutic purpose or which are precursors for the synthesis of useful drugs. A number of plants have been used in traditional medicine for many years due to their antimicrobial properties[2]. Specifically, the medicinal value of these plants lies in some chemical substances that produce a definite physiological action on the human or animal body[3]. The most important of these bioactive constituents which are mainly secondary metabolites are alkaloids, flavonoids, tannins and phenolic compounds. These phytochemicals are toxic to microbial cells.

Inflammation is considered as a primary physiologic defense mechanism that helps body to protect itself against infection, burn, toxic chemicals, allergens or other noxious stimuli. An uncontrolled and persistent inflammation may act

as an etiologic factor for many of these chronic illnesses. Although it is a defense mechanism, the complex events and mediators involved the inflammatory reaction can induce, maintain or aggravate many diseases. Currently used synthetic anti-inflammatory drugs are associated with some severe side effects. Therefore, the development of potent anti-inflammatory drugs with fewer side effects is necessary from medicinal plants origin.

A blood clot (thrombus) developed in the circulatory system due to failure of hemostasis causes vascular blockage and while recovering leads to serious consequences in atherothrombotic diseases such as myocardial or cerebral infarction, at times leading to death.[5] Thrombolytic agents that include tissue plasminogen activator (t-PA), Urokinase (UK), streptokinase (SK) etc. are used all over the world for the treatment of these diseases. In India, though SK and UK are widely used due to lower cost,[6,7] as compared to other thrombolytic drugs, their use is associated with hyper risk of hemorrhage[8] severe anaphylactic reaction and lacks specificity. Moreover, as a result of immunogenicity multiple treatments with SK in a given patient are restricted[9]. Because of the shortcomings of the available thrombolytic drugs, attempts are underway to develop improved recombinant variants of these drugs[10 – 14].

Herbal products are often perceived as safe because they are "natural".[15] In India, in recent years, there is increased research on traditional ayurvedic herbal medicines on the basis of their known effectiveness in the treatment of ailments for which they have been traditionally applied.
Considerable efforts have been directed towards the discovery and development of natural products from various plant and animal sources which have antiplatelet[16, 17], anticoagulant,[18, 19] antithrombotic [20], and thrombolytic activity. Epidemiologic studies have provided evidence that foods with experimentally proved antithrombotic effect could reduce risk of thrombosis. Herbs showing thrombolytic activity have been studied and some significant observations have been reported[21].

The aim of present study was to screen extracts of *Swertia chirata* for its clot lysis property (thrombolytic activity) and anti-inflammatory activity by using an *in-vitro* procedure. Plant-derived drugs remain an important resource, especially in developing countries, to combat serious diseases. Approximately 60–80% of the world's population still relies on traditional medicines for the treatment of common illnesses. Medicinal plants have a long-standing history in many locations in Bangladesh and continue to provide useful and applicable tools for treating ailments. Nevertheless, little scientific research was done to investigate the plants *Swertia chirata.*

The activities have been selected because of their great medicinal relevance. Within the recent years, Heart diseases have increased to a great extent and side effects of synthetic drug becomes an ever-increasing therapeutic problem [4] Because natural products of higher plants may give a new source of thrombolytic agents, as well as anti-inflammatory agents, many research groups are now engaged in medicinal plants research.

2. Materials and methods

2.1 Plant Material

The plant *Swertia chirata* was selected based on variety of its medicinal value. The *Swertia chirata* was collected at their fully mature form, from local market (Khatunghang, Chittagong). It was then separated, cleaned from impurities.

2.2 Extraction & Preparation of the plant sample

The plant *Swertia chirata* was then subjected for shade dry at temperature not exceeding 50 °C. Then they were ground into coarse powder with help of a grinder. The dry powder was then subjected to cold extraction with ethanol and then fractionation by Chloroform and Petroleum ether.

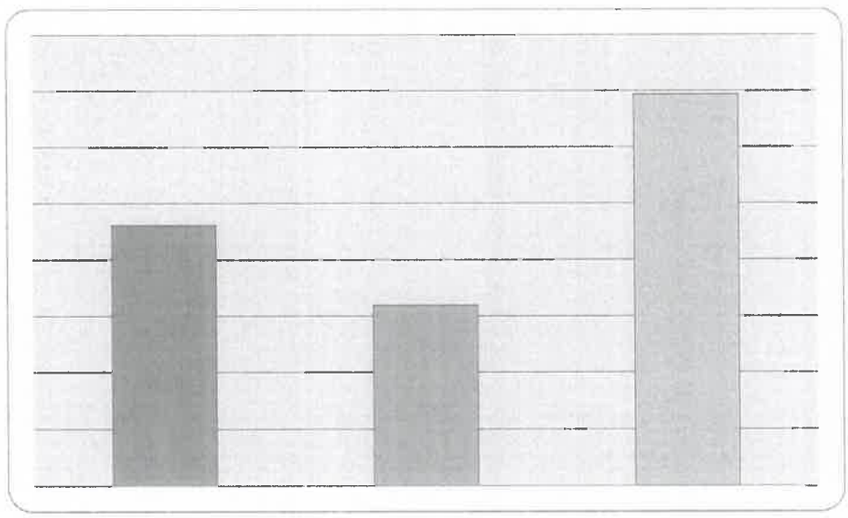

Fig 1: Percent clot lysis of Ethanol extract, Chloroform fraction of *Swertia chirata* and Standard Streptokinase.

2.3 In vitro Thrombolysis Activity

Phosphate buffered saline (PBS) (5 ml) was added to the commercially available lyophilized streptokinase vial (15, 00,000 I.U.) and mixed properly. This suspension was used as a stock from which appropriate dilutions were made to observe the thrombolytic activity. Experiments for clot lysis were carried as reported.[22] In brief; 2 ml venous blood drawn from healthy volunteers was distributed in three different pre weighed sterile micro centrifuge tube (0.5 ml/tube) and incubated at 37 °C for 45 minutes. After clot formation, serum was completely removed (aspirated out without disturbing the clot formed) and each tube having clot was again weighed to determine the clot weight (clot weight = weight of clot containing tube – weight of tube alone). To each micro centrifuge tube containing pre-weighed clot, 100 µl of ethanol extract (10 mg/ml) of was added. As a positive control, 100 µl of streptokinase and as a negative non-thrombolytic control, 100 µl of distilled water were separately added to the control tubes numbered. All the tubes were then incubated at 37 °C for 90 minutes and observed for clot lysis. After incubation, fluid released was removed and tubes were again weighed to observe the difference weight after clot disruption. Difference obtained in weight taken before and after clot lysis was expressed as constant oxygen supply for 48 hours.

2.4 *In-vitro* Anti-inflammatory activity

The ethanol extract of *Swertia chirata* was screened for anti-inflammatory activity using inhibition of albumin denaturation technique which was studied according to Mizushima and Kobayashi with slight modification.[23, 24, 25] The standard drug and extract were dissolved in minimum quantity of dimethylformamide (DMF) and diluted with phosphate buffer (0.2 M, pH 7.4). Final concentration of DMF in all solution was less than 2.5%. Test solution (1ml) containing different concentrations of drug was mixed with 1 ml of 1mM albumin solution in phosphate buffer and incubated at 27±1 °C in BOD incubator for 15 min. Denaturation was induced by keeping the reaction mixture at 60±1 °C in water bath for 10 min. After cooling, the turbidity was measured at 660 nm. Percentage of inhibition of denaturation was calculated from control where no drug was added. Each experiment was done in triplicate and average is taken. The Acetyl Salicylic Acid was used as standard drug. The percentage inhibition of denaturation was calculated by using following formula.

$$\% \text{ of Inhibition} = 100 \text{ X } \{ \text{ Vt / Vc} - 1 \}$$

Where,
Vt = Mean absorbance of test sample.
Vc = Mean absorbance of control

3. Results

3.1 Result of Thrombolytic Activity

In thrombolytic activity using *in vitro* clot lysis assay method, the crude ethanol extract and chloroform fraction showed average clot lysis of 46.096% and 31.87% while the standard streptokinase showed 69.35% which is shown in Figure-1. The percentage of clot lysis was found to be significant when compared with the vehicle control.

3.2 Result of Anti-inflammatory activity

Anti-inflammatory activity was measured by measuring the absorbance of treatment groups and converting it into total inhibition of protein denaturation. The statistical data were obtained significant below the P-value<0.5 ($p<0.001$). Percent inhibition of protein denaturation was calculated as follows:

$$\%\text{Inhibition} = (\text{Abs}_{\text{control}} - \text{Abs}_{\text{sample}})/\text{Abs}_{\text{control}} \times 100.$$

In the present study for *in-vitro* anti-inflammatory test, the 1000 mg/kg of crude ethanol extract of *Swertia chirata* showed mean inhibition of protein denaturation 45.31±0.000576 and whereas for Acetyl Salicylic Acid, it was found to be 50.00±0.00177.

Table 1: *In- vitro* of anti-inflammatory activity of *Swertia chirata*

Observation	Mean Absorbance ±SD	%MIPD	Total Inhibition of Protein Denaturation (%MIPD±SEM)
ETHANOL (Vehicle Control)	0.064±0.00416	0	0.00±0.00294
ASA (Positive control)	0.032±0.00416	50	50.00±0.00177
EESC 1000mg/kg	0.035±0.00416	45.31	45.31±0.000576

ASA= Acetyl Salicylic acid,
MIPD= Mean inhibition of Protein denaturation,
EESC= Ethanol Extract of *Swertia chirata.*
SEM= Standard error of mean,
Total inhibition of protein denaturation= %MIPD±SEM,[a]p<0.001

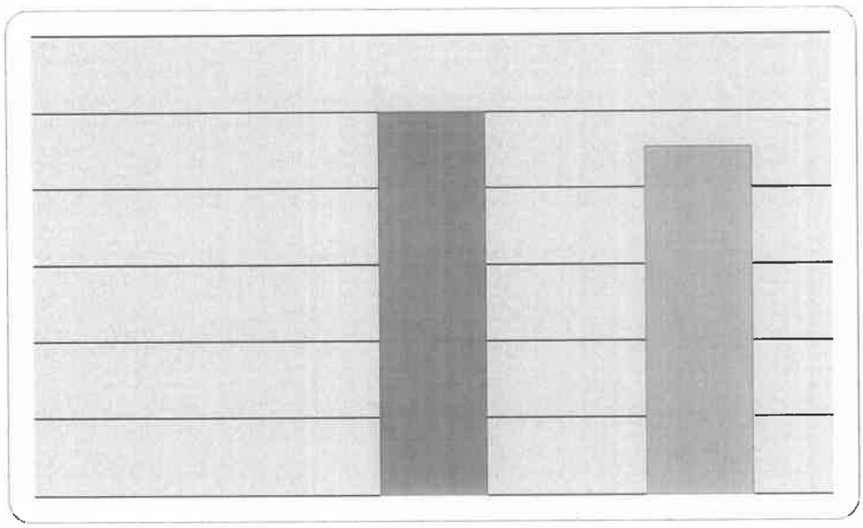

Fig 2: % MIPD of Ethanol, ASA and EESC.

4. Discussion and conclusion

The result of this work showed that the extract of *Swertia chirata* had mild to moderate ani-inflammatory activity (Table 1). The results of clot lysis was indicated that test samples showed different thrombolytic activity e at different concentration. The clot lysis of *Swertia chirata* was found to be increased with the increase with the concentration of the sample. The significant average percent of clot lysis (46.096%) of ethanol extract of *Swertia chirata* was found. Therefore, it is evident that the test sample and ethanol extract were thrombolytic and possess anti-inflammatory activity as well as biologically active.

In conclusion, it can be claimed that *Swertia chirata* possesses significant anti-inflammatory activity as well as thrombolytic activity. In addition, positive result in thrombolytic activity test led us to the interference that the plant extract may contain bioactive compounds, which may aid ongoing cardiovascular drug discovery from the floristic resources. Hence, further studies are suggested to be undertaken to pin point the exact compounds and to better, understand its actions scientifically.

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ANNEXURE- P

FULL LENGTH | Iranian Biomedical Journal 21(6): 400-405 November 2017

Cheminformatics-Based Anticoagulant Study of Traditionally Used Medicinal Plants

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ABSTRACT

Background: Medicinal plants, as a complementary medicine, have been used to treat various diseases since ancient times. These plants have numerous beneficial applications and are the source of certain conventional drugs. In diseases such as stroke and ischemia, which are caused by several factors, abnormal coagulation is an important causative factor. Accordingly, novel and effective therapies such as herbal remedies should be practiced to prevent such lethal diseases. **Methods:** Using the available databases such as Google Scholar and PubMed, the previously reported anticoagulant compounds and plants possessing anticoagulant activity were identified and collected in two separate lists. Next, the fast and cost-effective cheminformatics methods incorporated in PubChem were applied to detect some compounds similar to reported anticoagulants. Subsequently, 15 native medical plants of Iran containing the potential anticoagulants were selected. The selected plants were purchased and chopped, and the potential compounds were extracted by ethanol. Then three concentrations of extracts (1, 10, and 100 µg per ml) were made. Finally, anticoagulant effect of the selected plants was evaluated by *in vitro* prothrombin time and activated partial thromboplastin time coagulation tests. **Results:** Among the 15 selected medicinal plants, three plants, including *Terminalia bellirica* (P=0.0019), *Astragalus arbusculinus* (P=0.0021), and *Origanum vulgare* (P=0.0014) showed a more promising anticoagulant effect in comparison to the control. **Conclusion:** The anticoagulant activity was identified for the first time in these three plants. Further *in vivo* study and mechanism of action assay are required to be performed on these three plants, which could be suitable candidates for use as natural anticoagulant medicines. ***DOI:*** **10.18869/acadpub.ibj.21.6.400**

Keywords: Cheminformatics, Cardiovascular diseases, Medicinal plants

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INTRODUCTION

Plants are a great source of ingredients with numerous beneficial uses, including therapeutic and pharmaceutical applications, which are in use since ancient times. Although they are known safe and show many therapeutic effects in a vast range of illnesses, they may have harmful effects due to a great amount of compounds, which some are unknown and some are toxic[1]. Nevertheless, medicinal plants are the only available option to treat diseases in some regions[2]. The modern drugs have more usages than herbal medicines in the community, but in most cases, they have more adverse side effects, especially those made from chemical materials; for example, bleeding complications in warfarin use[3]. Therefore, the use of

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medicinal plants may be a better choice due to negligible harmful effects[4]. It should be noted that those who use their medicine along with medicinal plants should be cautious due to the increased effect of the medicine. There are several reports regarding the harms of concurrent use of medicinal plants and modern drugs[5,6], and it should be taken seriously.

Heart attack and stroke are the most important causes of death worldwide. In individuals with high blood pressure, hyperlipidemia, and relevant disorders, there is an increased risk of heart attack and stroke, which have irrecoverable consequences. The blood coagulation system is a necessary process to stop excessive bleeding and to prevent hemostasis imbalance[7,8]. Despite the high importance of the normal coagulation, any incorrect blood clot, especially in vital organs such as brain, heart, and liver, will cause serious injuries, and in acute incidences, it will lead to death. For instance, the number of deaths caused by heart attack and strokes has increased in Iran recently[9]. Hence, finding safe and effective therapeutic approaches to prevent and treat such diseases, particularly with the use of medicinal plants, which are safer, cheaper, and more available, is an important goal that we are seeking to achieve with the help of novel and fast cheminformatics methods[10] in the present study.

MATERIALS AND METHODS

Gathering information regarding anticoagulant compounds and plants

To gather a list of all the known anticoagulant compounds and plants, databases such as Google Scholar and PubMed were searched with appropriate keywords, which are listed in our previous work[11]. Accordingly, we prepared two separate lists from anticoagulant compounds and plants reported previously[11].

Cheminformatics step: finding similar compounds and substances

To find similar compounds to the reported anticoagulant compounds, similarity search was carried out according to the name or the chemical structure of the identified anticoagulant compounds in the PubChem structure search engine. The PubChem similarity search uses Tanimoto calculation and the PubChem constructed binary fingerprint to discover related structures according to the specified threshold of similarity. In this respect, the specified threshold of similarity was set at 90%[12]. Afterward, the similar compounds found by PubChem were used to select suitable medicinal plants to evaluate their anticoagulant effect.

Selecting, purchasing, and extracting the candidate plants

The selection of candidate plants was based on their similarity in having one of the similar anticoagulant compounds resulted from step 2.2, and their anticoagulant effect was not reported previously. According to these principles, 15 medicinal plants of Iran were selected to be evaluated for their anticoagulant effect. Then the selected anticoagulant plants were purchased from Omidvar, a specialized plant shop (Grand Bazaar, Tehran, Iran). Subsequently, the identity of the purchased plants was checked by an expert botanist, and a voucher specimen was appointed to each plant in the herbarium of Bioinformatics and Drug Design Unit, Pasteur Institute of Iran, Tehran (Table 1). Plants were chopped individually for the extraction procedure. Extraction was completed by the percolation technique in which 100 grams of plant powder were dissolved in 300 ml of 80% ethanol and retained in a sealed dish for 24 hours. This process was done three times at room temperature (25°C) to extract all the active ingredients of the plants. Each plant extract was then condensed by an evaporator device in which, using a vacuum at temperatures below 50°C, all ethanol evaporated, and then the resulting extract was refrigerated at 4°C[13]. To provide a stock of extracts, 10 mg of the condensed extract of each plant was dissolved in one ml DMSO (Merck, Germany). Eventually, from each plant extract, three concentrations (1, 10, and 100 µg per ml) were prepared in DMSO for use in the blood coagulation test[14].

In vitro coagulation test

The *in vitro* coagulation tests, prothrombin time (PT) and activated partial thromboplastin time (APTT), were carried out by a practiced lab technician. Initially, 5 ml of blood from seven normal candidates with identical blood group was collected and mixed together and then transferred to a tube containing sodium citrate 3.8%, as the anticoagulant. Next, the blood samples were centrifuged at 2016 ×g for 10 minutes to acquire required platelet-rich plasma (PRP). In PT test, 100 µl of PRP was mixed with 20 µl of each concentration of the plant extract and incubated at 37°C for 5 minutes. Lastly, 200 µl of PT assay reagent (Liquplastin, Bahar Afshan, Iran), preincubated at 37°C, was added to the mixture, and the PT clotting time was recorded. For APTT test, 100 µl of PRP were mixed with 20 µl of each concentration of the plant extract and incubated at 37°C for 5 min. Then 100 µl of APTT assay reagent

Table 1. The 15 selected medicinal plants with the help of cheminformatics approaches

No.	Voucher specimen	Plant	Used part of the plant	Place of cultivation	Major chemical compounds (%)
1	P148-16	*Dracocephalum moldavica*	Flower and leaves	Varamin, Iran	Acacetin (16), Diosmetin (10), salvigenin (6)[16]
2	P148-17	*Vachellia nilotica*	Seed	Isfahan, Iran	Rutin (28.5), Apigenin(10.5), Luteolin (9), Vanillic acid (0.36), Ellagic acid (0.57)[17]
3	P148-18	*Dianthus caryophyllus* L.	Dried bud	Mahalat, Iran	Hexadecanoic acid (28.7), Benzyl benzoate (12.6), Eugenol (18.22)[18]
4	P148-19	*Elettaria cardamomum* L.	Seed	India	Terpenyl acetate (64.5), Cineole (11.8), Terpineol (5.51), Limonene (2.23)[19]
5	P148-20	*Zea mays* L.	Seed	Ardabil, Iran	N/A
6	P148-21	*Marrubium vulgare* L.	Flower and leaves	Mazandaran, Iran	Eudesmol (11.93), Germacrene (9.37), Citronellyl formate (9.50), Citronellol (9.90)[20]
7	P148-22	*Rumex acetosella* L.	Flower and leaves	Isfahan, Iran	N/A
8	P148-23	*Terminalia bellirica* Roxb.	Fruit	Indonesia	Tannins (40%: Gallic acid, Sitosterol, Ellagic acid)[21]
9	P148-24	*Acacia senegal* L.	Resin	India	Arabinogalactan, diferulic acid[22]
10	P148-25	*Astragalus arbusculinus*	Resin	Shiraz, Iran	N/A
11	P148-26	*Centaurea depressa*	Flower	Ardabil, Iran	Piperitone (35.2), Elemol (14.1), β-Eudesmol (6.9), Spathulenol (5), Caryophyllene oxide (4.0), Hexadecanoic acid (4)[23]
12	P148-27	*Origanum vulgare* L.	Flower and leaves	Yazd, Iran	Caryophyllene (14.4), Spathulenol (11.6), Germacrene (8.1), α-Caryophyllene (2.7)[24]
13	P148-28	*Styrax officinalis* L.	Resin	Shiraz, Iran	2-Hexenal (20.7), Hexanol (5.8), Octanol (8.1), Geraniol (10.4)[25]
14	P148-29	*Juniperus sabina* L.	Seed	Isfahan, Iran	Sabinene (50.31), Elemol (5.74), Limonene (7.50), Terpinene (3.62), α-Pinene (7.97), β-Pinene (3.71), Terpinen-4-ol (3.79)[26]
15	P148-30	*Solanum melongena* L.	Seed	Tehran, Iran	Chlorogenic acid, Caffeic acid, Nasunin[27]

N/A, not available (according to literature review)

(Liqucephal, Bahar Afshan, Iran) was added and incubated for 1 minute. Finally, 100 µl $CaCl_2$, preincubated at 37°C, was added, and the APTT clotting time was recorded[15]. Furthermore, heparin (Alborz Darou, Iran; in three concentrations of 0.01, 0.1, and 1 IU) and *Glycyrrhiza glabra* L. in three concentrations (similar to plant extracts) were used as positive controls along with DMSO as the negative control.

Statistical analysis

The resulting data are shown as the means ± standard deviation of three independent experiments. The statistical significance between control and treatment groups was determined by a paired student *t*-test and among multiple groups by one way analysis of variance (ANOVA), followed by Dunnett's test. The significance level was set at $P<0.05$.

RESULTS

Search results for anticoagulant compounds and plants

According to search results, 27 anticoagulant compounds and 58 anticoagulant plants were identified, which are represented in our previous work[11].

Results of cheminformatics approaches

In the results of similarity search, around 1,000 compounds similar to the anticoagulant compounds were found. Among the similar compounds, 15 medicinal plants of Iran, which comprised of the similar compounds and also their anticoagulant effect was not reported previously, were selected for coagulation test. These plants, their voucher specimen, place of cultivation, their major chemical compounds and the part used are listed in Table 1.

Results of *in vitro* coagulation tests

Based on coagulation test, three plants, including *Terminalia bellirica* (P=0.0019), *Astragalus arbusculinus* (P=0.0021), and *Origanum vulgare* (P=0.0014) with highest concentration (100 µg/ml) were found. Also, *Origanum vulgare* (P=0.0033) in concentration of 10 µg/ml presented a noteworthy anticoagulant effect on APTT test compared to negative control DMSO (Fig. 1). However, none of the plant extracts showed any effect on the PT test similar to our previous work[11]. In addition, two control positive samples, including *Glycyrrhiza glabra* (P=0.0142, 100 µg/ml) and heparin (P=0.0004, 0.01 IU and P=0.0002, 0.1 IU), showed a notable effect on APTT test compared to the negative control (Table 2, Fig. 1).

DISCUSSION

In the present study, the main objective was to evaluate the efficacy of cheminformatics approach in

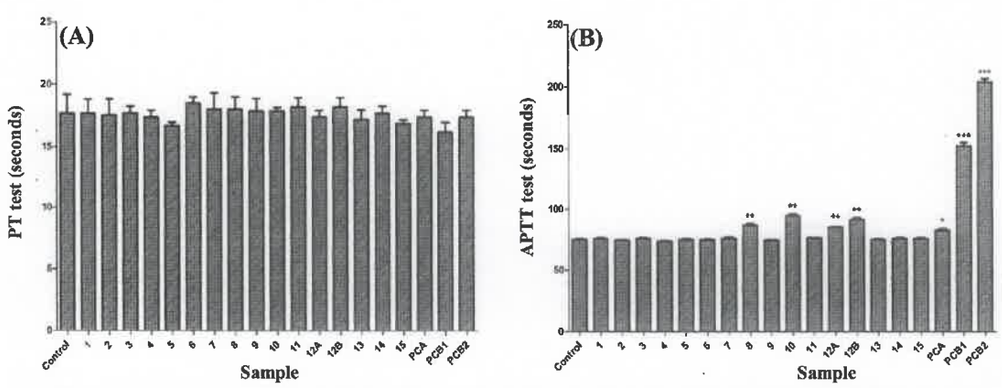

Fig. 1. The effect of 15 selected medicinal plants on prothrombin time (**A**) and activated partial thromboplastin time (**B**) analyzed by one way analysis of variance (ANOVA) and Dunnett's post-test. Samples: DMSO (Control), *Dracocephalum moldavica* (1), *Vachellia nilotica* (2), *Dianthus caryophyllus* (3), *Elettaria cardamomum* (4), *Zea mays* (5), *Marrubium vulgare* (6), *Rumex acetosella* (7), *Terminalia bellirica* (8), *Acacia senegal* (9), *Astragalus arbusculinus* (10), *Centaurea depressa* (11), *Origanum vulgare* (10 µg/ml; 12A), *Origanum vulgare* (100 µg/ml; 12B), *Styrax officinalis* (13), *Juniperus sabina* (14), *Solanum melongena* (15), *Glycyrrhiza glabra* (PCA) in concentration of 100 µg per ml, and heparin in concentrations of 0.01 IU (PCB1) and 0.1 IU (PCB2). *$P<0.05$, **$P<0.01$, and *** $P<0.001$ as compared to the control (standard *t*-test; means±standard deviation; n=3).

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Table 2. Results of *in vitro* coagulation test

Sample[a]	Dose (µg/ml)	APTT (Seconds)	PT (Seconds)
Control	DMSO	75.30±0.57	17.66±1.53
Dracocephalum moldavica	100	76.00±1.00	17.66±1.15
Vachellia nilotica	100	74.60±0.57	17.50±1.32
Dianthus caryophyllus	100	76.16±0.76	17.60±0.57
Elettaria cardamomum	100	73.83±0.76	17.30±0.57
Zea mays	100	75.00±1.00	16.66±0.28
Marrubium vulgare	100	75.00±0.50	18.50±0.50
Rumex acetosella	100	76.16±1.04	18.00±1.32
Terminalia bellirica	100	86.83±1.25**	18.00±1.00
Acacia Senegal	100	74.60±0.57	17.83±1.04
Astragalus arbusculinus	100	94.60±1.52**	17.83±0.28
Centaurea depressa	100	76.50±0.50	18.16±0.76
Origanum vulgare	10	85.30±0.57**	17.33±0.57
Origanum vulgare	100	91.50±1.50**	18.16±0.76
Styrax officinalis	100	75.30±0.57	17.16±0.76
Juniperus sabina	100	76.16±0.76	17.66±0.57
Solanum melongena	100	75.83±1.04	16.83±0.28
Glycyrrhiza glabra[b]	100	82.66±1.53*	17.30±0.57
Heparin[b]	0.01 IU	152.66±2.51***	15.50±0.50
Heparin[b]	0.1 IU	204.00±2.64***	17.33±0.57
Heparin[b]	1 IU	NC[c]	NC[c]

[a]Each value represents the means±standard deviation (n=3). [b]Positive control; [c]No clotting; *P<0.05, **P<0.01, and ***P<0.001 as compared to the control (standard t-test).

drug design and to study the anticoagulant effect of selected candidate plants, as well as to anticipate the possible additive effect of medicinal plants in case of concomitant use of anticoagulant medication. Therefore, we successfully identified an anticoagulant influence in three out of 15 evaluated plants. Hence, following our previous work[11], we evaluated the anticoagulant effect of 30 different native medicinal plants of Iran, which eight of which showed a significant *in vitro* anticoagulant effect. According to our results, in the continuation of the previous study[11], we confirmed the usefulness and cost-effectiveness of the cheminformatics methods to predict and to discover potential new therapeutic compounds and plant materials. Also, we could effectively show the suitability of PT and APTT coagulation tests to evaluate the effect of plant extracts on the coagulation system *in vitro*.

The three medicinal plants with recognized anticoagulant effect, including *Terminalia bellirica*, *Astragalus arbusculinus*, and *Origanum vulgare*, are suitable candidates to be considered as candidate herbal medicines in the prevention and treatment of cardiovascular diseases, such as heart attacks and strokes. However, more evidence like *in vivo* study is required to understand the safety and the real effect of these plants. Regarding the effect of heparin, concomitant use of those plants with positive *in vitro* anticoagulant effect and anticoagulant drugs (e.g. heparin) will have an increased effect on coagulation[6]. Therefore, caution should be taken by patients who consume anticoagulant drugs and medicinal plants simultaneously, due to high risk of excessive bleeding and other unknown effects. Moreover, determining the active ingredients of the plants in order to produce plant-based anticoagulant compounds and medicines would be helpful.

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REVIEW
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Anti-infective Properties of the Golden Spice Curcumin

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The search for novel anti-infectives is one of the most important challenges in natural product research, as diseases caused by bacteria, viruses, and fungi are influencing the human society all over the world. Natural compounds are a continuing source of novel anti-infectives. Accordingly, curcumin, has been used for centuries in Asian traditional medicine to treat various disorders. Numerous studies have shown that curcumin possesses a wide spectrum of biological and pharmacological properties, acting, for example, as anti-inflammatory, anti-angiogenic and anti-neoplastic, while no toxicity is associated with the compound. Recently, curcumin's antiviral and antibacterial activity was investigated, and it was shown to act against various important human pathogens like the influenza virus, hepatitis C virus, HIV and strains of *Staphylococcus*, *Streptococcus,* and *Pseudomonas*. Despite the potency, curcumin has not yet been approved as a therapeutic antiviral agent. This review summarizes the current knowledge and future perspectives of the antiviral, antibacterial, and antifungal effects of curcumin.

Keywords: curcumin, natural products, nutraceutical, anti-infective properties, virus, bacteria, fungi

INTRODUCTION

Infectious diseases are ailments caused by pathogenic viruses and microorganisms such as bacteria and fungi. Infections can spread directly from person to person and from animal to human, or indirectly via contaminated water and food. This can result in small local outbreaks and epidemics, like the plague, syphilis and SARS, or pandemics affecting several countries, of which the flu is one of the best-known examples. In times of globalization and climate change, infectious diseases are spreading more rapidly than ever before, and new ones continue to emerge. Even though they are a global health burden, inhabitants of developing countries especially suffer from infections. Accordingly in 2010, worldwide, roughly one quarter of deaths was due to infectious diseases, while in low-income countries, nearly 60% of fatalities could be attributed to them (Dye, 2015). This is primarily because in these regions often hygienic measures are insufficient, diagnostic tools are lacking and therapeutic options are not available.

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Existing medications are categorized into antivirals used to combat viral diseases, antibiotics contradicting bacterial infections and antifungals inhibiting the growth of fungi. In addition, multiple vaccines preventing viral and bacterial diseases exist, which has already led to the successful eradication of smallpox. However, countermeasures are available only for a limited number of pathogens, not including all potentially lethal and pandemic agents, as e.g., Ebola virus, and resistance to current therapies is increasing. Thus, new therapeutic options are urgently needed. Natural compounds are a continuing source of new drugs. From 1940 to 2014, 49% of all small molecules approved by the US Food and Drug Administration (FDA) were natural products or derivates directly linked to them (Newman and Cragg, 2016). One plant that has been extensively studied on that score is turmeric.

Turmeric (*Curcuma longa* L.) belongs to the family of ginger (Zingiberaceae) and natively grows in India and Southeast Asia. The plants rhizomes contain several secondary metabolites including curcuminoids, sesquiterpenes, and steroids (Omosa et al., 2017); with the curcuminoid curcumin being the principal component of the yellow pigment and the major bioactive substance. Chemically, curcumin is a diferuloylmethane, a diarylheptanoid belonging to the class of natural phenols. Its chemical structure has been described already in 1910 as a symmetric molecule of two phenol rings connected by α,β-unsaturated carbonyl groups (Miłobędzka et al., 1910) (see **Figure 1**).

In Europe, curcumin is widely used as a dye to color products in a bright to golden yellow. Historically, it was utilized mostly for leather and fabric, while nowadays, it functions as a food coloring. In the European Union the molecule is approved as a food additive and can be found labeled as E100 in the ingredient list of many groceries, including baked goods, sweets, spreads, or cheese. In the Asian society, ground turmeric has been used as a spice for centuries. It also plays a role in traditional Chinese and Indian medicine, where it is used to treat different maladies such as dermatologic ailments, infections, liver complaints, and depression. The use of curcumin is not associated with toxicity, and the FDA categorized it as "Generally Recognized As Safe." Thus, the medical properties of the natural product have been widely investigated. Today, a literature search at pubmed.gov finds over 11,000 publications, while a quest at clinicaltrials.gov reveals 179 clinical studies using curcumin. Most studies analyzed curcumin's anti-cancer effect and it has been shown to inhibit tumor cell proliferation, invasion and metastatic dissemination (as reviewed, e.g., Bachmeier et al., 2018). Besides this, curcumin has been documented to act, e.g., anti-inflammatory and anti-infective (as reviewed, e.g., Hatcher et al., 2008) and due to its wide spectrum of biological and pharmacological properties it is often called "cure-cumin."

In this review, we will give an up-to-date overview of the anti-infective properties of curcumin. At first, we will summarize the antiviral effect of the molecule against different virus families. We will then reflect the antibacterial and the antifungal activities of the compound. Finally, we will discuss the obstacles and the future perspectives regarding the use of curcumin as a therapeutic drug.

ANTIVIRAL ACTIVITIES OF CURCUMIN

Due to the lack of preventive and therapeutic options for many viral infections, numerous studies have been conducted to investigate the antiviral potential of natural compounds. Accordingly, antiviral effects haven been shown, e.g., for components of green tea (as reviewed, e.g., Steinmann et al., 2013), cinnamon (Connell et al., 2016) and many herbs. For curcumin, an antiviral activity was observed against several different viruses including hepatitis viruses, influenza viruses and emerging arboviruses like the Zika virus (ZIKV) or chikungunya virus (CHIKV). Interestingly, it has also been reported that the molecule inhibits human immunodeficiency virus (HIV), herpes simplex virus 2 (HSV-2) and human papillomavirus (HPV), indicating that curcumin reduces the spread of sexually transmitted diseases. In this section and in **Table 1** we will summarize the current understanding of the antiviral aspects of curcumin and possible mechanisms underlying its inhibitory effects.

Curcumin Inhibits Human Immunodeficiency Virus

The HIV is a lentivirus which belongs to the family of *Retroviridae*. HIV is the causative agent of the acquired immunodeficiency syndrome, better known as AIDS, and since its first report in 1981 it has become one of the major global public health issues: worldwide, more than 35 million people are infected with HIV, and in 2017 approximately 0.95 million people died of its consequences (WHO, 2018). Still, to date no preventive vaccine or effective cure exists for HIV.

Several studies have reported that curcumin exhibits an anti-HIV activity by directly targeting viral proteins. Already in 1993, Sui et al. reported a modest inhibition of the HIV-1 and HIV-2 proteases by curcumin. The authors found that the molecule binds to multiple sites of the enzyme, with micro molar concentrations leading to a suppression of enzymatic activity. A curcumin-boron complex showed an improved inhibitory effect, which is due to the complex's binding to additional sites within the substrate-binding cavity of the protease. In line with this, *in silico* modeling studies confirmed that curcumin fits well to the protease active site (Vajragupta et al., 2005). Besides the protease also the HIV integrase is an interesting drug target, because the enzyme is responsible for the integration of the viral genome into the host DNA. It has been shown that curcumin is a potent HIV integrase inhibitor, as it is able to bind acidic residues in the integrases catalytic core domain, preventing it from binding its substrates (Mazumder et al., 1995). Computational docking studies revealed that specifically the keto-enol and terminal o-hydroxyl group of curcumin exhibit tight linkage to the integrases binding site formed by residues Asp64, His67, Thr66, Glu92, Thr93, Asp116, Ser119, Asn120, and Lys159 (Vajragupta et al., 2005). Another HIV protein targeted by curcumin is the trans-activator of transcription (tat),

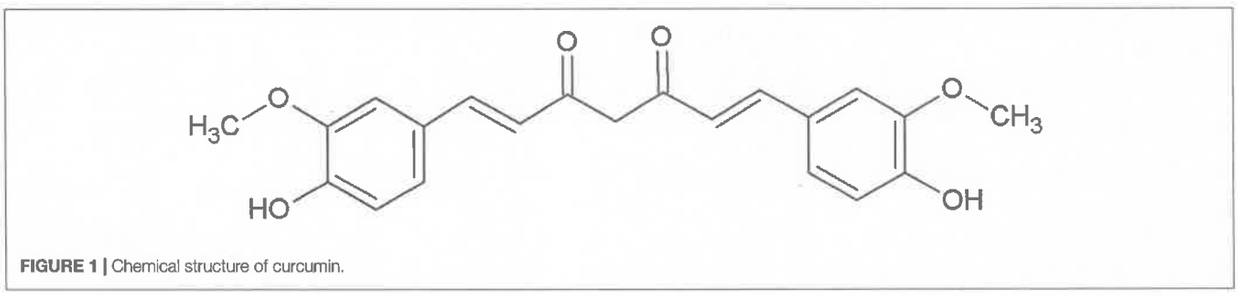

FIGURE 1 | Chemical structure of curcumin.

TABLE 1 | Antiviral activity of curcumin against several different viruses.

Virus	Family	Antiviral activity	References
CHIKV	*Togaviridae*	Entry inhibitor	Rhein et al., 2016
DENV	*Flaviviridae*	Entry inhibitor Particle production inhibition	Chen et al., 2013 Padilla-S et al., 2014
HBV	*Hepadnaviridae*	Replication inhibitor cccDNA inhibitor	Kim et al., 2009, 2011; Rechtman et al., 2010 Wei et al., 2017
HCV	*Flaviviridae*	Entry inhibitor	Anggakusuma et al., 2014
HIV	*Retroviridae*	Protease inhibitor Integrase inhibitor Tat protein inhibitor	Sui et al., 1993 Mazumder et al., 1995 Barthelemy et al., 1998; Balasubramanyam et al., 2004; Ali and Banerjea, 2016
HPV	*Papilomaviridae*	Gene expression inhibition	Maher et al., 2011; Mishra et al., 2015
HSV	*Herpesviridae*	Gene expression inhibition	Kutluay et al., 2008
IAV	*Orthomyxoviridae*	Entry inhibitor	Chen et al., 2010; Ou et al., 2013
JEV	*Flaviviridae*	Entry inhibitor Particle production inhibition	Chen et al., 2013 Padilla-S et al., 2014
MNV	*Caliciviridae*	Entry inhibitor	Yang M. et al., 2016
RSV	*Pneumoviridae*	Entry inhibitor Replication and budding inhibition	Yang X.X. et al., 2016; Yang et al., 2017 Obata et al., 2013
RVFV	*Phenuiviridae*	Replication inhibitor	Narayanan et al., 2012
ZIKV	*Flaviviridae*	Entry inhibitor	Mounce et al., 2017

a viral transcription regulator. Upon infection, tat is secreted and taken up by uninfected cells, which promotes the growth of HIV-induced tumors and the apoptosis of T-cells, fostering the development of AIDS (Ensoli et al., 1990; Westendorp et al., 1995; Campbell et al., 2004). Thus, inhibiting tat would prevent efficient viral gene transcription as well as disease progress. Interestingly, tat is known to be an intrinsically disordered protein (Shojania and O'Neil, 2010) and curcumin is known to induce the degradation of proteins with partially intrinsically disordered regions, like p53 (Tsvetkov et al., 2005). Accordingly, in tat-transduced HEK293T cells the tat protein level decreased upon incubation with curcumin in a dose-dependent manner that can be blocked by proteasome inhibitors, indicating that curcumin causes proteasomal degradation of tat (Ali and Banerjea, 2016). Moreover, it has been reported that curcumin inhibits HIV proliferation by inhibiting tat acetylation in SupT1 cells (Balasubramanyam et al., 2004) and that curcumin efficiently inhibits tat-induced transactivation of HIV-1 long terminal repeats in HeLa cells (Barthelemy et al., 1998).

In addition to targeting viral proteins, curcumin has also been described to indirectly inhibit HIV or the progression of AIDS by reducing HIV-induced cancer, inflammation and others. Despite this, a clinical study conducted in the 1990s could not find a decreased viral load or increased T-cell count in 40 HIV-patients treated with the molecule for 8 weeks (Gilden and Smart, 1996; James, 1996). Recently, new curcumin derivates or formulations with increased bioavailability and stability were developed against HIV (Kumari et al., 2015; Lin et al., 2017; Sharma et al., 2017; Zhao et al., 2017) and it has been shown that curcumin pretreatment of human genital epithelial cells blocks the infection-mediated induction of chemokines associated with the recruitment of HIV-target cells (Ferreira et al., 2015). Clinical assessment will show, whether these new curcumin variants and mechanisms of protection are effective in humans. Concluding, the attempt to use curcumin as an anti-HIV drug is still ongoing.

Curcumin Inhibits Hepatitis Viruses

Viral hepatitis is one of the major causes of chronic liver disease, leading to more deaths than those caused by HIV, according to the World Health Organization (WHO) (WHO, 2017). In 2015 worldwide 256 million people were chronically infected with the hepatitis B virus (HBV; *Hepadnaviridae*) (WHO, 2017) and 71 million people suffered from chronic hepatitis C virus (HCV; *Flaviviridae*) infections (WHO, 2017). In addition, sporadic hepatitis A virus (*Picornaviridae*) and hepatitis E virus (*Hepeviridae*) outbreaks occur, affecting approximately 14 and 20 million people every year, respectively (Rein et al., 2012; Percivalle et al., 2016). To date, a globally licensed vaccine is only present for HBV, while curative medications are only available for HCV. Besides developing new therapeutic options, also raising the awareness of transmission risks and reducing virus spread are important steps in controlling these infections (as reviewed, e.g., Pfaender et al., 2016).

The antiviral effect of curcumin against hepatitis viruses has been investigated by several groups. First hints that curcumin acts on HBV were given by studies suggesting that aqueous extracts of *Curcuma longa* inhibited the production of HBV particles and

operated beneficial on the development of HBx protein-induced hepatocellular carcinoma (Kim et al., 2009, 2011). Further research revealed that indeed curcumin inhibits HBV gene expression and replication by down-regulating PGC-1a, a protein co-activating HBV transcription (Rechtman et al., 2010). A recent study even indicated that curcumin reduces the presence of covalently closed circular HBV DNA (cccDNA) *in vitro* (Wei et al., 2017), a holy grail in the cure of chronic HBV.

Curcumin was also found to be effective against HCV without cytotoxicity. Anggakusuma et al. (2014) showed that curcumin inhibits the entry of all HCV genotypes into hepatoma cells and primary human hepatocytes. The authors found that curcumin, especially its α,β-unsaturated ketones, affects the fluidity of the viral envelope and by this impairs its binding and fusion with the plasma membrane during cell entry and cell-to-cell spread. These findings are supported by earlier studies, which illustrated that curcumin changes the lipid bilayer properties of membranes, making them less stiff and leading to the disruption of liposomes (Ingolfsson et al., 2007; Chen et al., 2013). Besides entry, also later steps in the HCV life cycle have been reported to be impaired by curcumin. Accordingly, several studies showed that curcumin reduces HCV replication, but the exact mode of action is still unclear (Kim et al., 2010; Chen et al., 2012). Combination studies demonstrated that curcumin even acts synergistic with (clinically used) HCV inhibitors as interferon-α, Boceprevir and Cyclosporin (Kim et al., 2010; Anggakusuma et al., 2014) however, it's low bioavailability leads to no therapeutic effect *in vivo* (Anggakusuma et al., 2014).

Curcumin Inhibits Influenza A Virus

Influenza viruses belong to the family *Orthomyxoviridae* and can be divided into three types: A, B, and C. The influenza A virus (IAV) mainly infects birds, but it can cause severe pandemics in domestic poultry and in humans, even though this happens rarely. Currently two classes of drugs are FDA-approved for the treatment of influenza: matrix protein 2 (M2) inhibitors (amantadine, rimantadine) and neuraminidase inhibitors (oseltamivir, zanamivir, and peramivir). However, the emergence of drug-resistant viruses continuously increases, thus the use of M2-inhibitors is not recommended anymore. Therefore, new antiviral targets with novel inhibition mechanisms are urgently needed.

Several studies tested the effect of curcumin on different IAV types *in vitro* and found it to inhibit virus uptake, replication and particle production (Chen et al., 2010; Dai et al., 2018; Han et al., 2018). Experimental work and structure-relationship modeling suggested that the inhibition was due to the molecule interfering with binding of the viral glycoprotein hemagglutinin (HA) to its cellular receptor (Chen et al., 2010; Ou et al., 2013). A subsequent study confirmed this effect and explained it by curcumin's ability to modulate the features of lipid bilayers (Chen et al., 2013). Interestingly, curcumin's structural analog monoacetyl-curcumin seems not to act on HA binding, but on Akt phosphorylation required for IAV propagation (Richart et al., 2018). The compound alone was as effective in dampening IAV infection as pure curcumin and a synergistic effect of the two analogs was observed.

Besides acting directly antiviral, recent *in vivo* studies showed that curcumin treatment reduces lung inflammation due to IAV infection in mice and increases the immune response toward IAV in turkeys (Umar et al., 2016; Han et al., 2018). Thus, curcumin treatment could be an alternative strategy to combat IAV infections and its sequelae.

Curcumin Inhibits Herpesviruses

The family of *Herpesviridae* consists of many DNA viruses causing persistent, latent infections with no curative therapy present to date. Several members of the family show a very high prevalence in humans worldwide.

The most famous herpesvirus is probably the herpes simplex virus, which is categorized into two types: HSV-1, commonly associated with orofacial ulcer and HSV-2, which mainly causes genital ulcers. In 2012, the WHO estimated the global incidence of HSV-1 and HSV-2 infections to be 67 and 11%, respectively (Looker et al., 2015). Several studies found that low micro molar, not cytotoxic amounts of curcumin dampened HSV-1 and HSV-2 infectivity *in vitro* and *in vivo* (Bourne et al., 1999; Kutluay et al., 2008; Zandi et al., 2010). For HSV-1 this is associated with a considerably decreased expression of viral immediate early (IE) genes, which is due to a reduced RNA polymerase II recruitment to IE gene promoters (Kutluay et al., 2008). Intriguingly, similar to HIV, the pretreatment of human genital epithelial cells with the substance reduced the shedding of HSV-2 from these cells, a mechanism that might help to stop the spread of the sexually transmitted disease (Ferreira et al., 2015). Another highly prevalent *Herpesviridae* member is the human cytomegalovirus (HCMV). As shown for HSV-1, curcumin leads to a decreased IE gene expression during HCMV infections (Lv et al., 2014). This is probably caused by curcumin downregulating the cellular heat shock protein 90, a protein needed for HCMV IE gene expression (Lv et al., 2015).

Besides HSV and HCMV, curcumin has also been suggested to influence Epstein–Barr virus (EBV) infections. However, its effect is unclear, as one study reported the molecule to inhibit the reactivation of EBV (Hergenhahn et al., 2002), while another study showed that curcuminoids enhance lytic reactivation of the virus in nasopharyngeal and gastric carcinomas (Ramayanti et al., 2018).

Curcumin Inhibits Human Papillomavirus

The *Papilomaviridae* family includes small, non-enveloped DNA viruses of which more than 150 different genotypes have been identified in humans. Human papillomaviruses cause persistent cutaneous or mucosal infections, and the infection with at least 13 HPV types is associated with the development of multiple types of cancer. Especially the incidence of cervical cancer, the fourth-most common cancer in women, is tightly linked to HPV infection (WHO, 2014) and in over 60% of the cases the high-risk HPV types 16 and 18 are detected (Clifford et al., 2003).

The effect of curcumin on HPV infection and HPV-associated tumor growth has been extensively studied (as reviewed, e.g., Teymouri et al., 2017). Already in 1990 the group of Howley could show that the viral oncoprotein E6 of HVP-16 and 18

complexes with the tumor suppressor protein p53 (Scheffner et al., 1990), targeting it for proteasomal degradation (Scheffner et al., 1990). *In silico* modeling suggested that curcumin binds to the p53 interaction site of E6, by this prohibiting it from binding p53 (Mamgain et al., 2015). In addition, *in vitro* studies showed that curcumin inhibited E6 and E7 expression and by this rescued p53 levels (Maher et al., 2011; Mishra et al., 2015). Several groups then developed creams and capsules containing curcumin for the local application to prevent or treat HPV infections, by this circumventing curcumin's low bioavailability problem. These creams indeed suppressed the growth of HPV-positive cells and cervical tumors and even induced apoptosis of cervical cancer cells *in vitro* and *in vivo* (Singh and Singh, 2009; Debata et al., 2013; Mukherjee et al., 2017). Clinical studies confirmed that a topical, cervical application of curcumin had no toxic effect on healthy women and indicated that it led to an increased HPV clearance rate (Basu et al., 2013; Gattoc et al., 2017). Thus, curcumin formulations could potentially be used to prevent sexually-transmitted HPV infections or to treat cervical dysplasia caused by the virus.

Curcumin Inhibits Respiratory Syncytial Virus

The human respiratory syncytial virus (RSV) causes respiratory tract infections and is one of the leading causes of morbidity and mortality in children under 5 years of age. In 2015, it has been estimated to have caused 33.1 million episodes of acute lower respiratory infection and an overall mortality of 118.200 deaths globally (Shi et al., 2017). To date, the broad-spectrum antiviral ribavirin is the only approved countermeasure for severe RSV infection, but clinical trials could not proof its efficacy (Law et al., 1997; Long et al., 1997). Due to the lack of effective RSV treatment and vaccine, there is an urgent need for novel antivirals.

The use of curcumin against RSV infections revealed that it prevented RSV replication and budding from human nasal epithelial cells and at the same time increased the epithelial barrier function, while it did not affect RSV in lung cells (Obata et al., 2013). To enable a local application of curcumin, Yang and coworkers just recently developed two different types of nanomaterials loaded with the compound, which showed good biocompatibility and abrogated RSV infection (Yang X.X. et al., 2016; Yang et al., 2017). The nanoparticles seemed to directly bind RSV, inhibiting virus–host interactions and leading to a significant decrease of infected cells. Future studies will show, whether the use of curcumin loaded nanoparticles is applicable and effective *in vivo*.

Curcumin Inhibits Noroviruses

Noroviruses are members of the *Caliciviridae* family, which commonly cause acute gastroenteritis in developed as well as in developing countries. The WHO ranks human noroviruses (NoV) as the number one cause of foodborne illness and the number four cause of foodborne deaths globally (WHO, 2015). Today, the treatment of NoV infections is only symptomatic, and the focus is more on preventing the disease and its expansion. While incubation of murine norovirus (MNV) with curcumin was found to significantly neutralize subsequent infections of a mouse macrophage cell line in a time- and dose-dependent manner, it had no effect on a NoV-replicon carrying hepatoma cell line (Yang M. et al., 2016). This indicates, that curcumin acts on early steps in the viral life cycle before replication. Further studies are needed to clarify whether curcumin could be used as an anti-NoV therapy option. Different studies analyzed the potential of photodynamic therapy (PDT) with curcumin as a photosensitizer to prevent NoV transmission through contaminated foods. PDT is a technique often used in cancer studies, which uses light in combination with a photosensitizing molecule to elicit cell death due to the production of reactive oxygen species (ROSs). It was shown that the use of curcumin together with LED light significantly reduced MNV titers in buffer and in oysters (Wu et al., 2015; Randazzo et al., 2016), probably by destroying genome integrity and viral capsid protein stability (Wu et al., 2015). It still needs to be elucidated whether this also works for NoV and whether curcumin-PDT might be a novel approach to avoid norovirus transmission in the food-industry.

Curcumin Inhibits Arboviruses

The group of arboviruses comprises different viruses which are transmitted by arthropod vectors like ticks and mosquitos. Nowadays arboviruses are rapidly re-emerging worldwide, as arthropod habitats are expanding due to climate change and the increase of global traffic. For most arboviruses, except Japanese encephalitis virus (JEV; *Flaviviridae*) and yellow fever virus (*Flaviviridae*), no vaccines are available and there is a lack of specific preventing or curing treatment for all of them.

Recently, two studies revealed that curcumin blocks the entry of CHIKV (*Tongaviridae*) by inhibiting its binding to host cells (Rhein et al., 2016; Mounce et al., 2017). Incubation of cells with the natural compound also significantly dampened infection with Dengue virus (DENV; *Flaviviridae*), JEV and ZIKV (*Flaviviridae*) via the same mechanism (Chen et al., 2013; Mounce et al., 2017). Similar as for HCV and IAV, this might be due to curcumin's influence on membrane properties (Ingolfsson et al., 2007; Chen et al., 2013). In addition to inhibiting virus entry, curcumin treatment of cells already infected with DENV or JEV resulted in the intracellular accumulation of viral proteins and a reduction of viral particle production (Dutta et al., 2009; Padilla-S et al., 2014). Also Rift Valley fever virus (RVFV; *Phenuiviridae*) has been shown to be inhibited by curcumin: Narayanan et al. (2012) observed that the molecule inhibits IKK-mediated phosphorylation of the viral NSs protein, resulting in reduced viral replication. Notably, this did not only hold true *in vitro*, but also mice subcutaneously treated with curcumin showed an increased survival (60% compared to untreated animals) and a decreased hepatic viral load (90% compared to controls).

Interestingly, curcumin seems to not only act antiviral on several arboviruses, but might also be useful for reducing the spread of arthropod vectors: dietary uptake of essential oils from turmeric led to modest lethality in larvae and pupae of *Aedes aegypti*, the mosquito transmitting, e.g., CHIKV, DENV, YFV, and ZIKV (Kalaivani et al., 2012).

ANTIBACTERIAL ACTIVITIES OF CURCUMIN

Bacterial infections can cause a number of human diseases, including relatively harmless self-limiting ailments and potentially lethal medical conditions if left untreated. Potent antibiotics are available against many bacteria. Nevertheless, due to the extensive use of the drugs, antibiotic resistance is on the rise, making formerly easy to eliminate pathogens untreatable. As for other infectious agents globalization has contributed to the expansion of (resistant) strains. In response to this, in 2017 the WHO published a list of 12 bacterial strains against which new drugs are critically needed (Tacconelli et al., 2018). Among them are strains of *Staphylococcus, Streptococcus, Helicobacter* and *Pseudomonas*, which all have been shown to be inhibited by curcumin. In the following chapter, we will summarize today's research status of curcumin's activity against Gram-positive and Gram-negative bacteria, as also given in **Table 2**.

TABLE 2 | Antibacterial activity of curcumin.

Bacteria	Antibacterial activity	References
Staphylococcus aureus	Growth inhibition Sortase A inhibitor	Bhawana et al., 2011; Krausz et al., 2015; Park et al., 2005
Staphylococcus epidermidis	Growth inhibition Biofilm formation inhibition	Tajbakhsh et al., 2008; Liu and Huang, 2012; Hegge et al., 2012
Streptococcus mutans	Adhesion inhibition Biofilm formation inhibition Sortase A inhibitor	Song et al., 2012 Li et al., 2018 Hu et al., 2013
Streptococcus pyogenes	Growth inhibition	Betts et al., 2016
Bacillus subtilis	Growth inhibition FtsZ inhibitor	Rai et al., 2008; Wang et al., 2009; Bhawana et al., 2011; Jaiswal and Mishra, 2018 Rai et al., 2008
Bacillus cereus	Growth inhibition	Rai et al., 2008; Wang et al., 2009; Bhawana et al., 2011; Jaiswal and Mishra, 2018
Listeria innocua	Growth inhibition	de Oliveira et al., 2018
Escherichia coli	Growth inhibition Biofilm formation inhibition	Wang et al., 2009; Bhawana et al., 2011; Jaiswal and Mishra, 2018
Salmonella enteritica serotype Typhimurium	Growth inhibition	Tonnesen et al., 1987; Dahl et al., 1989
Helicobacter pylori	Growth inhibition	De et al., 2009
Pseudomonas aeruginosa	Growth inhibition Biofilm formation inhibition	Bhawana et al., 2011; Krausz et al., 2015; Jaiswal and Mishra, 2018

Curcumin Inhibits Staphylococci

Staphylococcus aureus is known to be among the most common pathogens causing both community and hospital acquired infections and it is the most important causative agent of bloodstream bacterial infections worldwide (Biedenbach et al., 2004).

Infections with methicillin-resistant *S. aureus* (MRSA), a type of *Staphylococcus* being resistant to certain antibiotics as β-lactams, are more difficult to treat. This resistance is based on the lowered β-lactam affinity of penicillin binding proteins encoded by mecA. Thus, infections with MRSA are characterized by a high mortality rate and increased health care costs (Cosgrove et al., 2003). MRSA was first reported in 1961, only 2 years after the introduction of methicillin against penicillin-resistant *S. aureus* (Jevons, 1961). Today, *S. aureus* including MRSA is endemic and among the deadliest pathogens (Klevens et al., 2007).

The activity of curcumin against staphylococci has been assessed in several studies. *In vitro* data revealed antimicrobial activity of curcumin against both, MRSA and methicillin-sensitive *S. aureus* (MSSA), with determined minimum inhibitory concentrations (MICs) in the micro molar range (Tajbakhsh et al., 2008; Mun et al., 2013; Teow and Ali, 2015; Jaiswal and Mishra, 2018). Furthermore, a synergistic effect of curcumin and different antibiotics (oxacillin, ampicillin, ciprofloxacin, gentamicin, amikacin, polymyxin B, and norfloxacin) was detected in a strain dependent manner, while no antagonistic effects were observed (Mun et al., 2013; Teow and Ali, 2015; Betts et al., 2016). The synergistic effects might possibly occur due to the capability of curcumin to bind bacterial enzymes, reducing lysis and hydrolyzation of antibiotics (Zhou et al., 2011; Teow and Ali, 2015).

Curcumin is known to be a relatively instable molecule with a particle size of 500–800 nm, impairing cellular uptake and resulting in low bioavailability (Wang et al., 2009; Bhawana et al., 2011). Various methods to improve its stability and bioavailability were investigated. Wang and colleagues used a capsulation technique to stabilize curcumin. They described a MIC of microencapsulated curcumin of 62.5 μg/ml against *S. aureus*, which is much lower compared to pure curcumin (Wang et al., 2009). Another approach is the construction of nanoparticles loaded with curcumin. Most recently, Jaiswal and Mishra compared the MICs of curcumin and curcumin-silver nanoparticles, revealing treatment with curcumin-silver nanoparticles being more effective against *S. aureus* (MIC = 5 μg/ml) (Jaiswal and Mishra, 2018). Nanocurcumin was previously shown to have a stronger antimicrobial activity due to a reduced particle size of 2–40 nm and an enhanced solubility in water (Bhawana et al., 2011). Accordingly, Bhawana et al. (2011) revealed a MIC of 150 mg/L of pure curcumin in DMSO and a MIC of 100 mg/L of nanocurcumin in water against *S. aureus*. In their *in vitro* study, curcumin nanoparticles exhibited antimicrobial effects against MRSA after 8 h. Colony forming unit quantification displayed a reduction of 97% in viable MRSA. Additionally, in an *in vivo* skin infection model, Krausz and colleagues investigated the antibacterial efficacy of curcumin encapsulated nanoparticles against MRSA. They stated that those nanoparticles

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reduce bacterial load and enhance wound healing in the mice (Krausz et al., 2015).

Photodynamic therapy has been shown to be a promising alternative therapy of infections with resistant pathogens and has been widely studied in the context of bacterial biofilm formation. In 2013, the phototoxic effect of curcumin against MRSA and MSSA was evaluated in an *in vitro* study (Ribeiro et al., 2013). Blue LED light in combination with curcumin resulted in total elimination of MSSA when curcumin was applied in concentrations of 5, 10 and 20 μM, whereas lower doses resulted in a dose-dependent decreased bacterial viability. In contrast, MRSA was only eliminated by 20 μM curcumin plus illumination, while lower concentrations still significantly reduced MRSA viability. This *in vitro* detected photokilling effect of curcumin was validated in mice by Ye et al. (2014) in a study where they analyzed the inhibitory effect of upconverted nanoparticles conjugated with curcumin (UCNPs-CCM) on MRSA-induced pneumonia. The UCNPs-CCM improved the stability and bioavailability of curcumin, ensuring better effects *in vivo* and resulting in significantly decreased bacterial counts in lungs of mice treated with UCNPs-CCM plus irradiation. The authors explained this by the fact that after irradiation, UCNPs-CCM lead to ROS production, destroying the bacterial cell membrane.

Park et al. (2005) reported an inhibitory activity of curcumin against sortase A, which is a bacterial surface protein anchoring transpeptidase. They investigated the activity of curcumin and other curcuminoids against *S. aureus* and detected an IC_{50} of 13.8 μg/ml of curcumin against sortase A, with curcumin being the most potent inhibitor among the tested curcuminoids. However, no inhibitory effect of curcumin against bacterial growth with a MIC > 200 μg/ml against *S. aureus* was observed. Inhibition of sortase A leads to a reduction of pathogenesis as shown for murine arthritis. Bacterial strains lacking sortase A are impaired in the ability to cause acute infections (Mazmanian et al., 2000; Jonsson et al., 2003). Agents targeting sortase A are thus not affecting the microbial viability but pathogenicity (Park et al., 2005).

In addition, dieacetylcurcumin, a synthetic derivative of curcumin in which two phenolic hydroxyl groups are replaced by acetyl groups, has been shown to be effective against MRSA and MSSA adhesion as well as against mature biofilm (Sardi et al., 2017).

Staphylococcus epidermidis is a skin commensal. Its capability of forming a biofilm on indwelling medical devices makes *S. epidermidis* a significant nosocomial pathogen. Multiple drug resistances in *S. epidermidis* have spread over the last years and the need for new agents with antimicrobial activity increased. Curcumin was shown to abrogate *S. epidermidis* growth with MICs of 10.5 to 46.9 μg/ml (Tajbakhsh et al., 2008; Liu and Huang, 2012). Aqueous extracts from *Curcuma longa* roots were also shown to act antibacterial (Niamsa and Sittiwet, 2009). Phototoxic activity of curcumin nanocarriers against *S. epidermidis* biofilms and suspensions was documented by Hegge et al. (2012): 10 μM curcumin combined with light reduced the viable cells in suspension to zero. The authors also showed that a fresh solution of supersaturated curcumin with light and without a nanocarrier kills all bacterial cells (Hegge et al., 2012).

Even though the effect of curcumin against *Staphylococci* looks promising, it has been shown that the presence of human serum albumins impedes the molecules antibacterial activity by binding it; thus hindering the molecules traverse through the bacterial membrane (Teow and Ali, 2017). *In vivo* studies or tests using human plasma or whole blood are thus needed to validate curcumin's activity against staphylococci infections in patients.

Curcumin Inhibits Streptococci

Streptococcus species are frequently found as the source of meningitis, pneumonia, and endocarditis. *S. mutans* is known for its ability to form biofilms in oral niches (Wen and Burne, 2002). However, there are also non-pathogenic *Streptococcus* species which belong to the human microbiome.

Song et al. (2012) described a suppressing activity of curcumin against the adherence of *S. mutans* to human tooth surfaces. They furthermore defined a MIC of 128 μg/ml against *S. mutans*, concentrations below the MIC diminished the adherence on both, glass surfaces as well as on human tooth. On basis of their results, the authors suggested the use of curcumin as a food-based antimicrobial agent. Also Li et al. (2018) found reduced *S. mutans* biofilm with lower extracellular polysaccharide production after treatment with curcumin in an oral habitat. In addition to pure curcumin, some studies also investigated curcumin-loaded polysaccharide nanoparticles on their antibiofilm activities against *S. mutans* in a dental model. Here, chitosan nanoparticles were revealed as the most effective form with over 75% reduction of the MIC compared to free curcumin (Maghsoudi et al., 2017). Furthermore, curcumin-PDT was shown to be effective against *S. mutans in vitro* (Lee et al., 2017).

Sortase A, which has been shown to be inhibited by curcumin in *S. aureus* (Park et al., 2005), is also a relevant enzyme in *S. mutans*, being responsible for covalent attachment of the major cell-surface adhesin to the cell wall, thus playing a role in biofilm formation. Intriguingly, curcumin is effective against sortase A activity and biofilm formation in *S. mutans* (Hu et al., 2013). Curcumin was also shown to act antibiostatic against *S. pyogenes* and even a synergistic effect was detected in combination with polymyxin B (Betts et al., 2016).

Curcumin Inhibits Other Gram-Positive Bacteria

Besides *Staphylococcus* and *Streptococcus*, also other Gram-positive bacteria can be pathogenic in humans. *Bacillus* spp. are found in the human gastrointestinal tract. Free and microencapsulated curcumin showed antibiostatic activity against *B. subtilis* and *B. cereus* (Rai et al., 2008; Wang et al., 2009; Bhawana et al., 2011; Jaiswal and Mishra, 2018). While these studies found different MICs of free curcumin against *B. subtilis*, all of them showed a reduced MIC when nanocurcumin formulations were used instead (Bhawana et al., 2011; Jaiswal and Mishra, 2018). As described for *B. subtilis*, curcumin blocks

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the assembly and stability of FtsZ, a prokaryotic homolog of the eukaryotic cytoskeletal protein tubulin, orchestrating cell division (Rai et al., 2008). The perturbation of FtsZ functions leads to lacking bacterial proliferation, making it a suitable target for novel antimicrobial agents (Stokes et al., 2005; Kaur et,al., 2010).

Another Gram-positive bacteria being a human pathogen is foodborne *Listeria*. *L. innocua* was analyzed on its susceptibility toward UVA-light exposed curcumin and a synergistic effect was detected, even when curcumin was applied in low concentrations (de Oliveira et al., 2018).

Gram-positive bacteria are considered to be less resistant against bioactive molecules and PDT than Gram-negative bacteria. This is mainly due to their outer cell wall architecture, displaying a high degree of permeability for bioactive compounds with molecular weights up to 60,000 g/mol, such as curcumin (Jori et al., 2006). Thus, Gram-negative bacteria are supposed to be more resistant against both, curcumin treatment and PDT as the outer membrane can act as a barrier for the molecules (de Oliveira et al., 2018).

Curcumin Inhibits Gram-Negative Bacteria

Gram-negative bacteria are a large group of microorganisms, of which some can cause infections in humans. The model organism of Gram-negative bacteria is *Escherichia coli*. Shiga toxin (Stx) or Stx-like toxin producing *E. coli* is known to be an important foodborne pathogen, causing a hemolytic-uremic syndrome. In 2011, Stx-producing enterohemorrhagic *E. coli* (EHEC; serotype O104:H4) caused an outbreak in Germany affecting 3816 patients (Frank et al., 2011). Various studies demonstrated that curcumin is active against *E. coli* and the formation of its biofilms, while both effects are enhanced by curcumin nanoparticles (Wang et al., 2009; Bhawana et al., 2011; Jaiswal and Mishra, 2018). The substances activity against *E. coli* might be due to curcumin shutting of the DNA-damage response, also known as the SOS response, a complex system of genes activated, e.g., upon UV-induced mutagenesis (Oda, 1995). Another process responsible is the binding of curcumin to the bacterial FtsZ protein, decreasing cell proliferation, an effect shown for *B. subtilis* as well as for *E. coli* (Kaur et al., 2010). In addition to acting directly antibacterial, phototoxic effects of curcumin were detected against *E. coli* and the *Salmonella enterica* serotype Typhimurium already in the 1980s (Tønnesen et al., 1987; Dahl et al., 1989). Most recently, de Oliveira et al. (2018) also observed an antibacterial effect of UVA light-exposed curcumin against *E. coli* O157:H7, a mechanism which could be used to reduce cross-contamination from wash water to fresh produce.

Another important Gram-negative bacteria species is *Helicobacter pylori*, which is characterized by its ability to establish infections in the human stomach and persist there for several years. More than a half of all people worldwide are carrying *H. pylori*, causing peptic ulcer disease, gastritis and gastric cancer (Covacci et al., 1999). Because of the emergence of antibiotic resistant *H. pylori*, the need for alternative therapeutic agents is high. Curcumin was shown to be highly effective against *H. pylori* infections *in vivo* and *in vitro* (Mahady et al., 2002; De et al., 2009). De et al. (2009) showed complete eradication of *H. pylori* infection in a mouse model and even reported restoration of *H. pylori* -induced gastric damage.

Also *Pseudomonas aeruginosa*, a prominent example of a frequently multi-drug resistant organism, is a representative Gram-negative bacterium. With its ability to survive under tough environmental conditions, e.g., in antibacterial hand soaps, it marks a big issue in hospital settings (Lanini et al., 2011). *P. aeruginosa* growth is only slightly influenced by treatment with pure curcumin in a strain dependent manner (Betts et al., 2016; Jaiswal and Mishra, 2018). This effect can be boosted by the antibiotic agent polymyxin B, which alone also did not show activity against *P. aeruginosa*, but in combination with curcumin a significant synergism was detected (Betts et al., 2016). In contrast to free curcumin, curcumin-silver nanoparticles exhibit strong activity against *P. aeruginosa* and anti-biofilm activity was reported for both, pure curcumin and nanoparticles, with higher effects shown by the latter (Jaiswal and Mishra, 2018). In addition, *P. aeruginosa* growth was strongly inhibited after incubation with nano-encapsulated curcumin (Bhawana et al., 2011; Krausz et al., 2015). However, a higher activity of those nanoparticles was detected against MRSA (97% inhibition) than against *P. aeruginosa* (59% inhibition), indicating that curcumin's effect on *P. aeruginosa* is not so strong (Krausz et al., 2015). Still, in a study on curcumin's effects on *P. aeruginosa* virulence, a MIC of 30 μg/ml was detected, while concentrations less than the MIC still resulted in inhibition of biofilm initiation (Rudrappa and Bais, 2008). The production of virulence factors as pyocyanin was reduced and the quorum sensing system, especially acyl homoserine lactone, was also affected by curcumin. In *in vivo* models, the authors also detected that the natural compound acted preventive against *P. aeruginosa* infections of *C. elegans*: the nematode survival increased to 28% in comparison to 0% for untreated worms.

The emerging nosocomial pathogen *Stenotrophomonas maltophilia* is intrinsically resistant to β-lactams and other antibiotics with a broad spectrum (Brooke, 2012). The activity of curcumin against *S. maltophilia* was demonstrated in two *in vitro* studies (Betts et al., 2016; Yu et al., 2016). Similar as for *P. aeruginosa*, synergistic effects in combination with polymyxin B were observed (Betts et al., 2016).

ANTIFUNGAL ACTIVITIES OF CURCUMIN

Millions of fungal species can be found worldwide, but only few are human pathogens (Köhler et al., 2014; Hawksworth and Lücking, 2017). Still, fungal infections of the skin and mucosa are common, though most of them are harmless when treated. However, especially immunosuppressed individuals, such as HIV infected, cancer or organ transplant patients, are at risk of developing severe forms of infections. As with modern medicine the number of immunocompromised people increases, fungal diseases are emerging and some evolved from a rare disorder

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to a leading cause of illness, as observed, e.g., for cryptococcal meningitis during the HIV epidemic in Africa (Warkentien and Crum-Cianflone, 2010). In addition, global warming might contribute to a raising prevalence of fungal infections, as the geographic range of pathogenic species is increasing and they might adapt to higher temperatures, promoting their growth at body temperature (Garcia-Solache and Casadevall, 2010).

There are different types of drugs available to treat a number of fungal diseases, among them are amphotericin B, triazoles, and echinocandins (Pappas et al., 2016). Even though they are effective, severe side effects can occur and emergence of drug resistance has been observed (Klotz et al., 2016; Seufert et al., 2018). New medications are needed, especially cost-effective versions for the use in resource-limited developing countries. Turmeric has been used as a food preservative for centuries and curcumin is known to abrogate production of fungal toxins (Ferreira et al., 2013). Consequently, many studies demonstrated an antifungal effect of turmeric extracts and curcumin. In this chapter, we will recapitulate the current knowledge on curcumin's potential to restrain the most common human pathogenic fungi. These findings are also summarized in **Table 3**.

Curcumin Inhibits *Candida* spp.

Candida spp., a genus of yeast, is a commensal fungus usually found on the skin and on the mucosa of the gastrointestinal tract and mouth. It is the most common cause of fungal infections in humans, as it can elicit opportunistic infections known as candidiasis. This can affect different parts of the body, but the most frequent forms are oropharyngeal or vulvovaginal candidiasis. *Candida* spp. can become invasive and lead to systemic infections of the blood, candidemia, or to deep-seated tissue candidiasis. It still is the most common fungal disease among hospitalized patients in the developed world, causing more than 50,000 deaths per year (Kullberg and Arendrup, 2015).

A prerequisite for candidiasis is the adhesion of *Candida* to human cell surfaces. Intriguingly, curcumin has been shown to block the adhesion of *Candida* spp. to buccal epithelial cells (Martins et al., 2009) and the development of *C. albicans* biofilms by downregulating adhesin and filamentation-associated genes (Shahzad et al., 2014). In general, curcumin exhibits antifungal activity against planktonic forms of standard and at least 10 clinical *Candida* strains (Neelofar et al., 2011). Sharma et al. (2010b, 2012) explained this by curcumin-induced modifications of the fungus membrane lipid composition, which eventually leads to the production of ROS, triggering early apoptosis. Furthermore, Kumar et al. (2014) showed that curcumin downregulates cell wall integrity pathway genes, causing cell wall damage and membrane permeabilization in *C. albicans*.

Upon infection, candidiasis due to *C. albicans* is often treated with the antifungal drug fluconazole (Pappas et al., 2016). Several studies showed that curcumin is far more potent than fluconazole (Martins et al., 2009), acts synergistic with the drug (Sharma et al., 2010a) and even restores sensitivity to it in resistant *C. albicans* clinical isolates (Garcia-Gomes et al., 2012). This might be due to curcumin's ability to modulate the activity of ABC and MDR transporters, which facilitate the active efflux of multiple drugs in resistant strains (Sharma et al., 2009; Garcia-Gomes et al., 2012).

Due to the development of drug resistance, alternative therapy options are needed. In this context, several studies examined curcumin's potential as a sensitizer for photodynamic inactivation of fungi and found that, *in vitro*, it indeed inactivated or at least inhibited the growth of different *Candida* strains and isolates (Dovigo et al., 2011; Andrade et al., 2013; Sanitá et al., 2018). Dovigo et al. (2013) also used curcumin as a photosensitizer in a murine model of oral candidiasis, where it drastically reduced colony counts. Curcumin's photosensitizing activity might be explained by a genotoxic effect, as the compound seems to prevent repair of DNA damage caused by light (Carmello et al., 2015), similar as observed for *E. coli* (Oda, 1995). Another non-invasive treatment option is the local application of curcumin containing formulations. A recent study used a cream containing 1.0% curcumin to treat vulvovaginal candidiasis in a rat model (Fernandes et al., 2018). The authors observed a reduction of fungal burden and inflammatory infiltration due to the cream. Therefore, curcumin formulations could be a promising alternative to combat candidiasis.

TABLE 3 | Antifungal activity of curcumin.

Fungi	Antifungal activity	References
Candida spp.	Growth inhibition Adhesion inhibition Gene expression inhibition Triggering early apoptosis	Martins et al., 2009; Shahzad et al., 2014 Sharma et al., 2010b, 2012
Cryptococcus spp.	Growth inhibition	Hu et al., 2017
Aspergillus spp.	Growth inhibition Aflatoxin production inhibition	Al-Asmari et al., 2017 Ferreira et al., 2013
Dermatophytes	Growth inhibition	Brasch et al., 2017, 2018

Curcumin Inhibits *Cryptococcus* spp.

Cryptococcus is a widespread encapsulated yeast, and some of its species, including *C. neoformans*, *C. gattii* and *C. bacillispores*, are the causative agents of the most common invasive fungal infections in humans, called cryptococcosis. Cryptococcal infections affect mainly immunocompromised patients and show high mortality and morbidity rates. As treatment options are limited and resistance emerges, new therapeutic options are needed.

A recent study found that in *C. neoformans*, curcumin accumulates in the endoplasmic reticulum, causing a growth-reduction (Hu et al., 2017). The authors showed that this is probably due to curcumin's iron-chelator activity. In line with this, another study found that, in mice, curcumin alone or in combination with fluconazole significantly reduces pulmonary damage and fungal burden of *C. gattii* infections (da Silva et al., 2016). Further research is needed to reveal the exact mechanisms of action and to show whether curcumin holds the potential to be a new drug option to cure cryptococcosis.

Curcumin Inhibits *Aspergillus* spp.

The genus *Aspergillus* contains over a 100 mold species, of which *A. fumigatus* causes the most invasive infections in humans (Schmitt et al., 1990). Aspergillosis is a group of

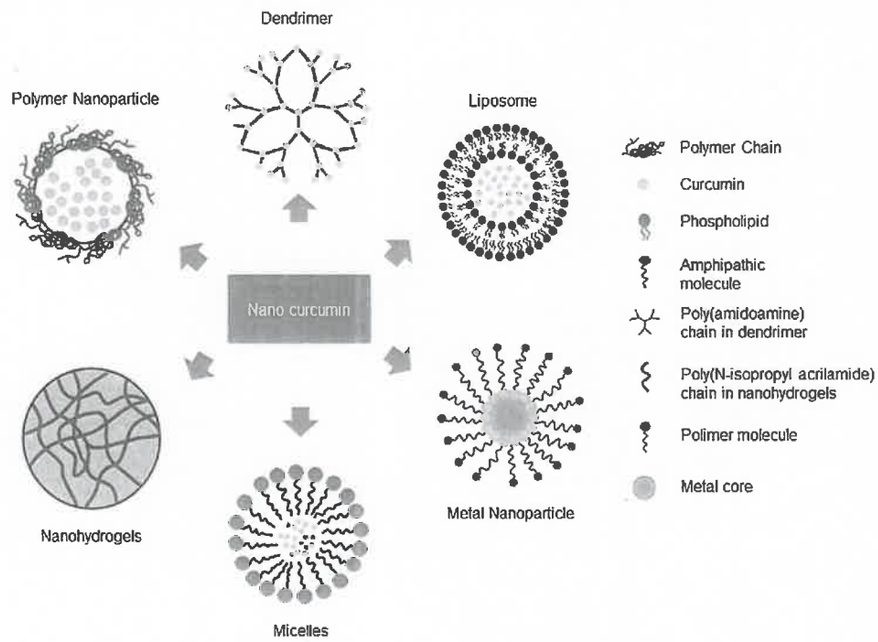

FIGURE 2 | Nanocarrier systems encapsulating curcumin. Different nanoformulation strategies have been reported to improve the bioavailability and therapeutic efficacy of curcumin based on their chemical composition.

diseases, including, for example, non-invasive infections of the respiratory tract, the ears or the eyes. After major surgery or upon immunosuppression, patients sometimes develop severe invasive and potentially lethal forms of aspergillosis (Zilberberg et al., 2018). Besides causing ailment, *Aspergillus* is known for contaminating improperly stored food. As some strains produce aflatoxins, consumption of spoiled food often leads to poisoning, which in turn can cause hepatic injury (Probst et al., 2007; Yard et al., 2013).

Several studies showed that *Aspergillus* isolates were not affected by curcumin essential oil (Tantaoui-Elaraki and Beraoud, 1994) and that pure curcumin only reduced fungal growth in very high concentrations of over 256 mg/L (Martins et al., 2009). However, even though the natural compound does not directly act antifungal on *Aspergillus*, it was shown to reduce aflatoxin production: already 0.1% curcumin abrogated the production of the toxin in *A. flavus* (Ferreira et al., 2013). In addition, curcumin seems to act beneficial on aflatoxin-induced liver and kidney injury in mice and chicken (Verma et al., 2008; Zhang et al., 2016), probably by reducing aflatoxin-mediated oxidative stress in a dose-dependent manner (Wang et al., 2018).

Recent studies also examined curcumin's photosensitizing ability in PDT of *Aspergillus* infections. Similar as for other fungi, curcumin significantly inhibited the growth of cells and spores of *A. flavus* and *A. niger* (Al-Asmari et al., 2017).

TABLE 4 | Formulations of curcumin to improve its bioavailability.

Formulation	Effect	References
Polymer nanoparticle	Improved stability and solubility, enhanced antibacterial effect	Pietra et al., 2017; Trigo Gutierrez et al., 2017
Liposome	Increased bioavailability	Chen et al., 2009
Micelle	Solubility and antibacterial activity	Liu and Huang, 2012
Dendrimer	Improved solubility	Falconieri et al., 2016
Nanogel	Improved solubility and bioavailability	Reeves et al., 2015
Metal nanoparticle	Improved stability and solubility	Sindhu et al., 2014

Curcumin Inhibits Dermatophytes

Dermatophytes is a group of fungi consisting of over 40 species in the genera of *Microsporum*, *Epidermophyton*, and *Trichophyton*. All of them commonly cause skin infections, called tinea or dermatophytosis, like athlete's foot (tinea pedis).

Early studies indicated that *Curcuma longa* L. oils, but not curcumin itself, act against dermatophytosis caused by *Trichophyton* in guinea pigs (Apisariyakul et al., 1995). In contrast, another study found that volatile oils extracted from turmeric, consisting of at least 10% curcumin, dampened the growth of 29 clinical dermatophytes strains *in vitro* using an agar disk diffusion method (Wuthi-udomlert et al., 2000). Recent studies investigated curcumin's potential as a photosensitizer in dermatophytosis treatment. Brasch et al. (2017, 2018) found that curcumin plus visible light significantly inhibited the conidia- and mycelial-derived growth of different dermatophytes

species for at least 96 h. Thus, the development of a PDT with curcumin against dermatophytosis could be a promising novel therapeutic option.

OBSTACLES AND FUTURE PERSPECTIVE OF CURCUMIN AS AN ANTI-INFECTIVE AGENT

Comprehensive clinical trials evaluated the safety, pharmacokinetics and effectiveness of curcumin against different diseases (as reviewed, e.g., Goel et al., 2008). Despite its excellent tolerability with no or minimal toxicity even at high oral doses of up to 12 g/day, its poor bioavailability leads to only low serum concentrations, limiting the exploitation of its potentially valuable therapeutic effects (Cheng et al., 2001; Lao et al., 2006). Curcumin's low bioavailability can be explained by its insolubility in water at neutral pH and the facts that it degrades or crystallizes in alkaline and acidic solutions, respectively (Tønnesen and Karlsen, 1985; Kharat et al., 2017). In human blood curcumin is more stable with a half-life of approximately 8 h (Wang et al., 1997). However, the major part of orally administered curcumin never reaches the blood, as it is poorly absorbed from the intestine and directly discharged again (Holder et al., 1978; Wahlström and Blennow, 1978). In addition, curcumin taken up into the blood is rapidly metabolized, conjugated in the liver and excreted in the feces (Holder et al., 1978; Ravindranath and Chandrasekhara, 1981–1982), therefore it has limited systemic bioavailability.

To overcome these drawbacks, several nanoparticle-based approaches have been developed. In general, there are two proposed nanoforms for curcumin: nanocrystals, and nanocarriers. Nanocrystals are particles with nanometer-range size, which have been engineered as a pharmacological tool for drugs with limited solubility. Due to their small size, the molecules surface area and solubility are increased, leading to an enhanced dissolution rate and bioavailability, as e.g., shown for curcumin combined with different stabilizing agents (Rachmawati et al., 2013). However, nanocrystals do not solve the problems of the pre-systemic degradation and rapid systemic metabolism of curcumin. Thus, different nanocarrier systems encapsulating the natural compound have been developed. These include, among others, curcumin incorporated within polymer nanoparticles or nanovesicles such as liposomes or micelles; matrix-based formulations such as hydrogels and nanoemulsions. Exemplarily, some nanocarrier-curcumin systems are depicted in **Figure 2**. Their advantages compared to pure curcumin are given in **Table 4**. Curcumin-loaded nanocarrier systems do not only show enhanced solubility, uptake and bioavailability compared to the pure substance, but they also protect it from external and internal degradation or early metabolism. But still, after entering the body, the carriers are rapidly taken up by the liver and spleen, leading to a relatively short circulation time. Moreover, e.g., nanoemulsions also contain multiple surfactants, which can lead to toxicity. However, due to the great potential benefit in therapy, the development and refining of curcumin-nanocarrier formulations for the treatment of various diseases is still ongoing.

CONCLUSION

Numerous *in vitro* and *in vivo* studies have shown that curcumin is active against different viruses, bacteria and fungi, including even highly pathogenic, emerging and multi-drug-resistant strains. The underlying mechanism seems to be complex and to differ from organism to organism, thus it has not always been elucidated. As curcumin is not toxic even at high oral doses and as it is already approved and widely used in the food industry, its broad-spectrum anti-infective activity makes it a promising drug candidate. Unfortunately, the molecule's poor solubility, low bioavailability, and rapid metabolism hamper its use in clinical settings and resulted in no observable therapeutic effects in many clinical trials. However, it should be kept in mind that most clinical trials were analyzing systemic applications of curcumin and were focused on general safety aspects or on the treatment of cancer; studies of curcumin's systemic activity against infectious diseases in humans are largely missing. Nevertheless, clinical assessment showed that the topical oral or cervical application of curcumin had no toxic effect and led to the disaggregation of oral plaque (Leite et al., 2014) and to an enhanced HPV clearance (Basu et al., 2013; Gattoc et al., 2017), respectively. This suggests that at least the local treatment with curcumin is effective against bacteria and viruses in humans. The development of curcumin formulations in various nanocarrier systems could help to overcome the obstacles experienced in systemic curcumin application, paving the way to new (infectious disease) clinical trials with the natural product.

Concluding, further research is required to fully understand curcumin's mode of action and to improve formulations to make it usable as a drug. Clinical trials will then show whether its effect seen in the lab will hold true in patients.

AUTHOR CONTRIBUTIONS

DP, JB, and ES contributed to Antiviral section. LK and JS contributed to Antibacterial and Antifungal section. HR contributed to Obstacles and Future Perspective of Curcumin as an Anti-Infective Agent section.

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Conflict of Interest Statement: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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MORE MARKET STATS

Delhi institute cures COVID-19 patients with Ayurvedic treatment protocol, records zero deaths

By: PTI
Published: July 28, 2020 9:18 PM

"Patients were discharged at good health showing hundred percent recoveries without complications during the treatment period with SPO2 more than 90 per cent. No aggravation of symptoms was observed. It is also observed that there has been zero per cent mortality till now in admitted patients," a statement by the AYUSH ministry said.

Majority of the patients admitted in CHC were administered stand-alone Ayurveda treatment protocol, including diet and Yoga. (Courtesy: Reuters; Representational image)

Minister of State for AYUSH Shripad Yesso Naik on Tuesday visited the COVID-19 Health Centre at the All India Institute of Ayurveda (AIIA) in Sarita Vihar to review arrangements for treatment of coronavirus-infected patients.

Ayurveda, the traditional medicine system of India, has a huge potential in preventive and curative healthcare of this pandemic, the minister said during the visit.

WHO calls for widespread flu vaccinations this year

Airborne viruses may spread on dust, non-respiratory particles: Study

Uttar Pradesh: 70 COVID-19 deaths in one day, worst ever

Yoga.

"Patients were discharged at good health showing hundred percent recoveries without complications during the treatment period with SPO2 more than 90 per cent. No aggravation of symptoms was observed. It is also observed that there has been zero per cent mortality till now in admitted patients," a statement by the AYUSH ministry said. All were tested negative before discharge, it added.

The minister interacted with doctors and enquired about the wellbeing of the patients at the centre. He sought their feedback on the facilities available and the results of treatment by Ayurvedic medicines, the statement said.

"The minister expressed satisfaction with the services provided by AIIA in wake of COVID-19 pandemic. He said that the spirit, enthusiasm, courage and efforts of the whole team of AIIA in providing care to the COVID-positive patients on the basis of principles of Ayurveda is praiseworthy.

"AIIA is playing an exemplary role in providing holistic care through individualized Ayurveda Medicine, diet, Yoga and relaxation techniques to COVID 19 patients across India," the statement said.

The minister further said all the patients at CHC developed a positive approach towards life and were very satisfied with the transformation within them.

This will help them not only in overcoming the disease but also in other phases of their lives, he said. The minister congratulated the whole team of AIIA for its exemplary role in treating COVID-19 patients through holistic Ayurveda care, the statement said.

The minister also visited the free COVID-19 testing centre at the facility.

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ANNEXURE-S

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Letter to the Editor

Traditional Chinese medicine for COVID-19 treatment

1. Summary

The current 2019-nCoV outbreak is moving rapidly [1], the cumulative number of confirmed cases in mainland China has reached 80151, with 47,204 (58.89 %) cured cases and 2943 (3.67 %) deaths as of 2-Mar-2020, and no specific drug has been discovered for Coronavirus Disease 2019 (COVID-19). However, a number of clinical practice results showed that traditional Chinese medicine (TCM) plays significant role in the treatment of COVID-19, bringing new hope for the prevention and control of COVID-19.

TCM has a long history and played an indispensable role in the prevention and treatment of several epidemic diseases. During the SARS epidemic in 2003, the intervention of TCM has also achieved remarkable therapeutic effect. During the treatment period of COVID-19, more than 3100 medical staff of TCM were dispatched to Hubei province, and TCM scheme was included in the guideline on diagnosis and treatment of COVID-19 [2], and TCM experts fully participate in the whole rescue process. The decoction, Chinese patent medicine, acupuncture and other characteristic therapy of TCM was comprehensively employed, mainly treated based on syndrome differentiation. Specific TCM wards were set up, and established the designated hospital, moreover, TCM team participates in treatment collectively. Currently, the total number of confirmed cases treated by TCM has reached 60,107 [3]. In 102 cases of mild symptoms treated with TCM, the clinical symptom disappearance time was shortened by 2 days, the recovery time of body temperature was shortened by 1.7 days, the average length of stay in hospital was shortened by 2.2 days, the improvement rate of CT image was increased by 22 %, the clinical cure rate was increased by 33 %, 27.4 % reduction in the rate of common to severe cases and 70 % increase in lymphocyte.[3] In addition, in the treatment of severe patients with TCM, the average length of stay in hospital and the time of nucleic acid turning negative has been shortened by more than 2 days.

From current treatment results, TCM based on an over-all symptoms of 2019-nCoV pneumonia patients, has suggested to prescribe prescription that are likely to be effective, such as *qingfei paidu* decoction (QPD), *gancaoganjiang* decoction, *sheganmahuang* decoction, *qingfei touxie fuzheng recipe, etc*. QPD which consisted of *Ephedrae Herba, Glycyrrhizae Radix et Rhizoma Praeprata cum Melle, Armeniacae Semen Amarum, Gypsum Fibrosum, Cinnamomi Ramulus, Alismatis Rhizoma, Polyporus, Atractylodis Macrocephalae Rhizoma, Poria, Bupleuri Radix, Scutellariae Radix, Pinelliae Rhizoma Praepratum cum Zingibere et Alumine, Zingiberis Rhizoma Recens, Asteris Radix et Rhizoma, Farfarae Flos, Belamcandae Rhizoma, Asari Radix et Rhizoma, Dioscoreae Rhizoma, Aurantii Fructus Immaturus, Citri Reticulatae Pericarpium, and Pogostemonis Herba*, has been promoted as a general prescription in the diagnosis and treatment plan of COVID-19 in China [2]. Among the 701 confirmed cases treated by QPD, 130 cases were cured and discharged, clinical symptoms of 51 cases disappeared, 268 cases of symptoms improved, and 212 cases of stable symptoms without aggravation [3]. The effective cure rate of QPD against COVID-19 is over 90 %. According to the theory of TCM, the target organ location of COVID-19 is the lung, and the etiology attribute is "damp and toxin plague". The network pharmacology analysis showed that QPD has an overall regulatory effect *via* multi-component and multi-target. The primary site of pharmacological action is the lung, as 16 herbs to lung meridian, which indicated that the decoction is mainly specific for lung diseases. In addition, it can play the role of dehumidification through the rise and fall of the spleen and stomach, and exhibited the protection for heart, kidney and other organs. Among the potential targets screen, most of them co-expressed with ACE-2, the receptor of COVID-19, indicating the potential improvement of COVID-19. It can inhibit the replication of COVID-19 by acting on multiple ribosomal proteins. COVID-19 can lead to strong immune response and inflammatory storm [4]. Functional enrichment analysis showed that QPD could inhibit and alleviate excessive immune response and eliminate inflammation by regulating immune related pathway and cytokine action related pathway [5]. Furthermore, through the prediction of molecular docking, it was found that patchouli alcohol, ergosterol and shionone in the formula had better anti−COVID-19 effect, which provided new molecule structures for new drug development [6].

Here, we take one highly suspected COVID-19 patient treated with TCM as a case example to show its effectiveness [7]. The male patient was on a business trip in *Wuhan* for several days before the onset of the disease. During the admission period, fever and cough were repeated, and respiratory rales of both lungs were not obvious. Western medicine was used firstly, including orally take oseltamivir phosphate capsule, intravenous infusion of ganciclovir, aerosol inhalation of recombinant human interferon a1b, *etc*. Although the nucleic acid test was negative, the results of chest CT showed that the fusion of two lung ground glass shadows was enlarged and the density was increased, which was more advanced than that of admission (Fig. 1a-1c). As the serious illness, combined with the patient's performance of damp-heat syndrome, and the heat is more serious than damp, QPD was added for treatment. On the night of administration, the body temperature dropped to 36.2 °C, and then tended to be normal. After 6 days of treatment, chest CT was better than before, tracheobronchial shadow was normal, and inflammation was obviously absorbed (Fig. 1d). The patient had no fever or asthenia, coughing occasionally, and the rales of two lungs were weaker than before. After discharge, continue to take 7 doses of the prescription, occasionally cough, no special discomfort was found. The clinical symptoms and imaging examination of the patients improved significantly after the treatment, reflecting the advantages of TCM.

TCM has own characteristics such as holistic concept, balance of *Yin* and *Yang*, syndrome differentiation and treatment, strengthening the

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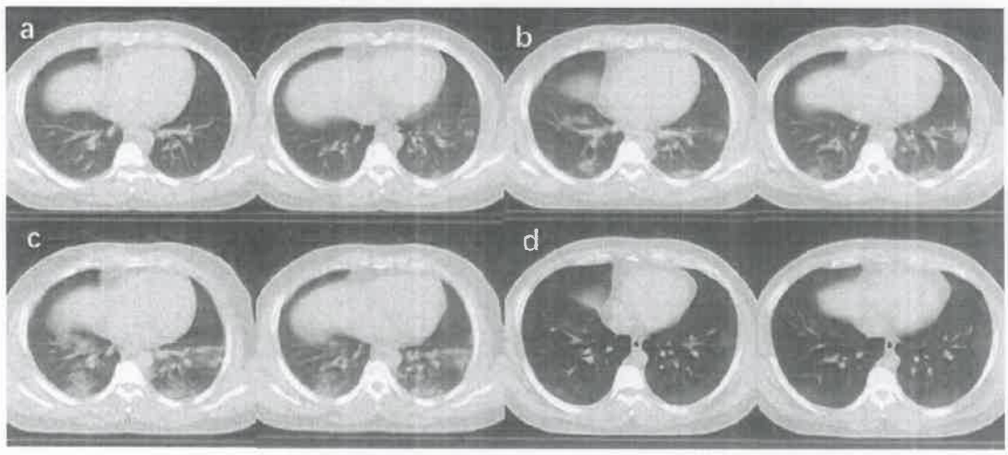

Fig. 1. Comparison of chest CT results of patients. (a), chest CT on January 24; (b), chest CT on January 28; (c), chest CT on January 30; (d), chest CT on February 4.

body resistance to eliminate pathogenic factors. TCM has thousands of years of experience in regulating the body and enhancing the resistance to epidemic diseases, with unique insights and prevention and control experience. For mild and common patients, the early intervention of TCM can effectively prevent the disease from transforming into severe and critical disease. In the severe cases, TCM has won time for rescuing them by improving symptoms (http://www.scio.gov.cn/xwfbh/xwbfbh/wqfbh/42311/42560/index.htm). Treatment practice of COVID-19 showed that early intervention of TCM is important way to improve cure rate, shorten the course of disease, delay disease progression and reduce mortality rate. Furthermore, the reason why TCM works is not only to inhibit the virus, but might block the infection, regulate the immune response, cut off the inflammatory storm, and promote the repair of the body. Moreover, the prevention and control measures of COVID-19 fully reflect the ideology of "preventive treatment of disease". Apart from the epidemic diseases recorded in the Han Dynasty should be isolated, the preventive measures of TCM also include psychology, sports, diet, medication, *etc.*

In the next prevention and control work of COVID-19, it should give full play to the advantages of TCM in syndrome differentiation and the whole therapeutic effect, reduce the complications as well as death rate. Besides, the scientific research should also be carried out on the TCM with definite curative effective of COVID-19, to comprehensively evaluating its action mechanism and in-depth understanding COVID-19.

Declaration of Competing Interest

There are no conflicts to declare.

Acknowledgments

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.phrs.2020.104743.

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ANNEXURE-T

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology

Pharmacovigilance Memorandum

Date:	May 19, 2020
Reviewers:	Kim Swank, PharmD, Safety Evaluator Division of Pharmacovigilance II Kate McCartan, MD, Medical Officer Division of Pharmacovigilance II
Acting Team Leader:	Rachna Kapoor, PharmD, MBA Division of Pharmacovigilance II
Acting Cross Discipline Safety Lead:	Neha Gada, PharmD, BCPS Office of Pharmacovigilance and Epidemiology
Deputy Division Director:	Ida-Lina Diak, PharmD, MS Division of Pharmacovigilance II
Product Names:	Hydroxychloroquine and Chloroquine
Subject:	All adverse events in the setting of COVID-19
Application Type/Number:	NDA 009768, ANDA multiple
Applicant:	Concordia, Teva, Sandoz, Watson Labs, Mylan, Zydus, Hikma, IPCA Labs, Alkaloida, APPCO, Lupin, Amneal, Laurus Labs, Accord Healthcare, Natco
OSE RCM #:	2020-1000
TSI #:	2150

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1 INTRODUCTION

The purpose of this review is for the Division of Pharmacovigilance II (DPV II) to provide the Division of Antiviral (DAV) Drug Products a high-level overview of the postmarketing safety data related to the use of hydroxychloroquine and chloroquine in the setting of coronavirus disease 2019 (COVID-19). The data reviewed for this evaluation were from the FDA Adverse Event Reporting System (FAERS) database, published medical literature, American Association of Poison Control Centers National Poison Data System (AAPPC-NPDS), and other safety reports forwarded from DAV.[a]

1.1 BACKGROUND

On March 28, 2020, FDA authorized the emergency use of hydroxychloroquine and chloroquine supplied from the Strategic National Stockpile to treat adults and adolescents who weigh 50 kg or more and are hospitalized with COVID-19 for whom a clinical trial is not available, or participation is not feasible.

On April 13, 2020, the Division of Anti-infective (DAI) products opened a priority Tracked Safety Issue (TSI) 2150 to assess the risk of cardiac toxicity with hydroxychloroquine and chloroquine with or without azithromycin when used for the treatment of COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection.

On April 24, 2020, FDA issued a Drug Safety Communication (DSC) cautioning against the use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of arrhythmias. The DSC described reports of serious cardiac events, including QT prolongation, in patients receiving hydroxychloroquine or chloroquine, often in combination with azithromycin and other QT prolonging medicines, for the prevention or treatment of COVID-19.[1]

On May 6, 2020, DAV consulted the Office of Surveillance and Epidemiology (OSE) to review clinical trials, observational studies, and postmarketing surveillance data published or available after the March 28, 2020 EUA for hydroxychloroquine and chloroquine in the setting of COVID-19 and comment on implications of these data regarding known and potential risks of the authorized use. DPV's analysis focused on the available safety data reporting the use of hydroxychloroquine or chloroquine for the treatment or prevention of COVID-19 in any setting.

On May 6, 2020, the Division of Applied Regulatory Science (DARS) and DPV opened a Newly Identified Safety Signal (Safety Signal ID 1004045) in the pre-evaluation stage to track an emerging signal of methemoglobinemia with hydroxychloroquine in the setting of COVID-19.

On May 12, 2020, the DPV and the DARS met with the Office of New Drugs (OND), specifically, DAI, DAV, and the Division of Rheumatology and Transplant Medicine (DRTM),

[a] DPV reviewed these safety reports that were forwarded from DAV prior to their entry into FAERS; therefore, these cases were not yet assigned a FAERS Case ID at the time of this memo.

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to discuss emerging safety data from the National Poison Data System, with hydroxychloroquine and methemoglobinemia in the setting of COVID-19.

2 METHODS AND MATERIALS

2.1 CASE SELECTION CRITERIA

Reports retrieved from the search strategies described in Tables 1-3 were screened for cases of adverse events associated with hydroxychloroquine or chloroquine used for the prevention or treatment of COVID-19.

2.2 FAERS SEARCH STRATEGY

DPV II searched the FAERS database with the strategy described in Table 1.

Table 1. FAERS Search Strategy*	
Date of search	Recurring daily searches†
Time period of search	December 1, 2019 – May 6, 2020
Search type	Drug Safety Analytics Dashboard (DSAD)
Product terms	**Product Active Moiety (PAM):** hydroxychloroquine, chloroquine
MedDRA search terms (Version 23.0)	**Preferred Terms (PTs)**: *Asymptomatic COVID-19, COVID-19, COVID-19 pneumonia, Suspected COVID-19, SARS-CoV-2 carrier, Exposure to SARS-CoV-2, Occupational exposure to SARS-CoV-2, SARS-CoV-2 test, SARS-CoV-2 test false negative, SARS-CoV-2 test positive, COVID-19 prophylaxis, COVID-19 treatment, Coronavirus test positive, Coronavirus infection*
Other criteria (text string search)	**Reported Reason for Use:** Coronavirus infection, Corona virus infection, Coronavirus test positive **Reporter Narrative:** Coronavirus, Corona virus, Novel coronavirus, ncov, 2019-ncov, 2019 ncov, Hubei, Wuhan, COVID, SARS-COV-2, SARS COV 2, T705, T-705, Emergency use authorization, EUA **Medical History Comments:** SARS-COV-2, SARS COV2, ncov, 2019-ncov, Corona virus, Coronavirus, COVID
* See Appendix A for a description of the FAERS database. † Searches recurring daily Tuesday through Friday with a 1-day prior completion date and on Monday with a 3-day prior completion date.	

2.3 LITERATURE CASE SEARCH STRATEGY

DPV II searched the medical literature with the search strategy described in Table 2.

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Table 2. Literature Case Search Strategy	
Date of search	Recurring daily searches
Database	Embase
Search terms	Drug search for "hydroxychloroquine" and "chloroquine"
Time period of search	January 1, 2020 – May 6, 2020

In addition, weekly PubMed and EMBASE Early Alerts for COVID-19 and safety-related articles were reviewed (March 15, 2020 – April 30, 2020).

2.4 AAPCC-NPDS Search Strategy

In an effort to identify exposures to hydroxychloroquine or chloroquine, DPV set up a case-based definition with daily alerts in the NPDS database using the search strategy described in Table 3.

Exposure calls received by Poison Control Centers (PCCs) are managed by healthcare professionals with specialized toxicology training needed to assess, triage to the most appropriate level of care, provide recommendations, and follow up on toxic emergencies.

Table 3. NPDS Search Strategy*	
Date of Search	March 27, 2020 through May 6, 2020
Type of Search	Prospective case-based definition (toxicosurveillance) Anomaly IDs 2258 and 2266 with daily alerts†
Search Restrictions	Call type: Exposure Case status: Open, Closed Species: Human Product Type: Contains at least one Single Substance Only: No
Product Codes‡	All chloroquine and hydroxychloroquine products Complete list of product codes: (b) (4) [redacted]
Reason for Exposure	All excluding Intentional – Suspected suicide and Unintentional Therapeutic error†
Outcomes	All outcomes

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*See **Appendix B** for a description of the NPDS database
†Anomaly ID 2258 was used from March 27, 2020 to April 14, 2020 (all outcomes included). Anomaly ID was used from April 15, 2020 to May 6, 2020 (modified alert to exclude reason for exposure of "Intentional – Suspected suicide" and "Unintentional Therapeutic error").
‡These product codes must be redacted for public release.
AAPCC = American Association of Poison Control Centers

2.5 OTHER SAFETY REPORTS

DPV II reviewed hydroxychloroquine safety reports forwarded from DAV through April 24, 2020.

3 RESULTS

Table 4 provides the total number of cases identified from each source that met the selection criteria (see Section 2) and describes characteristics of these cases. The most frequently reported preferred terms (PTs) can be found in Appendix C. The majority of PTs are either 1) known and labeled adverse events for hydroxychloroquine or chloroquine, 2) known and labeled adverse events for concomitant medications, or 3) known effects of COVID-19 (e.g., respiratory failure, liver impairment, pulmonary embolism). **Table 5** describes cases that reported serious adverse events with the use of hydroxychloroquine or chloroquine in the setting of COVID-19. Cases in **Table 5** were assessed for a causal association with hydroxychloroquine or chloroquine using elements from a modified World Health Organization (WHO) – Uppsala Monitoring Centre (UMC) Causality Categories described in Appendix D.[2] We categorized the cases as probable, possible, unlikely, or unassessable based on the strength of the evidence for a causal association. We excluded cases we classified as unlikely or unassessable from further analysis. **Table 6** describes the most frequently reported dosages in patients receiving hydroxychloroquine or chloroquine in the setting of COVID-19.

Table 4. All Hydroxychloroquine and Chloroquine Cases Reporting Adverse Events in the Setting of COVID-19 from December 1, 2019 – May 6, 2020 (n=385)

	Hydroxychloroquine (n=347)	Chloroquine (n=38)
Source*		
FAERS	291	21
Literature	25	13
NPDS	20	3
Other Safety Reports	11	1
Sex	(n=331)	(n=37)
Male	230	22
Female	101	15
Age (years)	(n=324)	(n=24)
Range	18-96	34-83
Median	63.5	61
Mean	61.8	57.9
Country of Origin		
US	97	5
Foreign	250	33

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Table 4. All Hydroxychloroquine and Chloroquine Cases Reporting Adverse Events in the Setting of COVID-19 from December 1, 2019 – May 6, 2020 (n=385)		
	Hydroxychloroquine (n=347)	**Chloroquine (n=38)**
Fatal Cases	77	10

* FAERS – includes any case identified in either FAERS alone OR both FAERS and the literature. Literature – includes cases only identified in the literature. Other safety reports– includes cases that were forwarded by DAV and were not yet entered into FAERS at the time of this memo.

Table 5. Possibly/Probably Associated Hydroxychloroquine and Chloroquine Cases Reporting Serious Adverse Events in the Setting of COVID-19 from December 1, 2019 – May 6, 2020 (n=211) *		
	Hydroxychloroquine	**Chloroquine**
Serious Cardiac AEs*	**(n=90)**	**(n=19)**
Labeled Cardiac AEs*	(n=85)	(n=19)
QT prolongation	62	18
VA, VF, VT	11	3
Bradycardia	7	1
Tachyarrhythmia	4	0
Tachycardia (excluding VT, tachyarrhythmia)	4	0
TdP	4	0
AV block	3	1
Arrhythmia (excluding VA, VF, VT, tachyarrhythmia)	3	0
QRS prolonged	2	1
Cardiovascular collapse (in overdose)	1	0
Unlabeled Cardiac AEs*	(n=5)	(n=0)
Atrial fibrillation/atrial flutter	4	0
Myocardial infarction	1	0
Concomitant Treatments of Interest‡	(n=76)	(n=16)
Azithromycin	55	12
LPV/r	5	0
Azithromycin + LPV/r	7	1
Other QT prolonging drugs	24	3
Fatal Cardiac Cases§	17	8
Serious Non-Cardiac AEs of Interest*	**(n=101)**	**(n=12)**
Labeled Non-Cardiac AEs*	(n=86)	(n=11)
Psychiatric Disorders	(n=3)	(n=4)*
Hallucinations/psychosis	3	2
Other neuropsychiatric changes (mania, abnormal behavior)	0	3
Blood and Lymphatic System Disorders	(n=17)*	(n=0)
Hemolytic anemia/G6PD deficiency related issues	5	0
Pancytopenia/thrombocytopenia/anemia/leukopenia	12	0
Agranulocytosis	1	0
Hepatobiliary Disorders	(n=63)	(n=4)
Hepatitis/increased liver enzymes/hyperbilirubinemia	60	4
Hepatic failure	3	0
Nervous System Disorders	(n=0)	(n=2)
Seizure	0	2
Musculoskeletal and connective tissue disorders	(n=3)	(n=0)
Rhabdomyolysis	3	0
Immune System Disorders	(n=1)	(n=0)
	1	0

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Table 5. Possibly/Probably Associated Hydroxychloroquine and Chloroquine Cases Reporting Serious Adverse Events in the Setting of COVID-19 from December 1, 2019 – May 6, 2020 (n=211) *

	Hydroxychloroquine	Chloroquine
Exacerbation of psoriasis	(n=0)	(n=1)
Eye disorders	0	1
Visual impairment		
Unlabeled Non-Cardiac AEs*	(n=18)	(n=2)
Acute kidney injury/Renal failure	5	1
Methemoglobinemia	4	0
Hypokalemia	4	1
Hyponatremia	2	0
Oropharyngeal edema	1	0
Anuria	1	0
Hyperglycemia	1	0
Hypoacusis	1	0

* A case may have more than one AE. Some cases reported both a cardiac and non-cardiac AE. The FDA reviewer assessed the reported AEs were probably/possibly associated with HCQ or CQ use.

‡ A case may have more than one concomitant treatment.

§ Fatal cardiac cases are considered those cases reporting death and a cardiac AE. Cases were not individually evaluated to determine if the cardiac AE was the cause of death.

Abbreviations: AE = adverse event, CQ = chloroquine, HCQ = hydroxychloroquine, LPV/r = lopinavir/ritonavir, VA = ventricular arrhythmia, VF = ventricular fibrillation, VT = ventricular tachycardia, TdP = Torsades de Pointes, AV = atrioventricular

Key Findings:

- The majority of the cases (69%) involved males with a median age in the early 60s.
- Of the 385 cases reporting use of hydroxychloroquine or chloroquine in the setting of COVID-19, 377 cases reported use for treatment and 8 cases reported use for prophylaxis.
- 28% of the cases were from the U.S. Of the 97 U.S. cases for hydroxychloroquine, 5 reported use of hydroxychloroquine through the EUA.
- Eleven cases reported both a cardiac and non-cardiac AE.
- Of all serious adverse events (cardiac and non-cardiac), QT prolongation was the most commonly reported adverse event for both hydroxychloroquine and chloroquine.
- Of the 109 hydroxychloroquine and chloroquine cases with a serious cardiac adverse event:
    - 80 (73%) reported QT prolongation.
    - 4 (4%) reported Torsades de Pointes (TdP)
    - 92 (84%) reported concomitant use of at least one other medication that prolongs the QT interval. 75 (69%) reported concomitant use of azithromycin.
    - 14 (13%) reported ventricular arrhythmia, ventricular tachycardia or ventricular fibrillation.
    - 25 (23%) had a fatal outcome. Fatal cardiac cases were considered those cases reporting death and a cardiac AE.
        - 9/25 had a cardiac event that was assessed to have possibly or probably contributed to death.
        - 22/25 reported use of a concomitant QT-prolonging medication.

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- Of the 113 hydroxychloroquine and chloroquine cases with a serious non-cardiac adverse event of interest:
  - Hepatitis/increased liver enzymes/hyperbilirubinemia was the most commonly reported adverse event (59% of cases). These are labeled events for hydroxychloroquine and chloroquine.
  - The most commonly reported unlabeled adverse event was acute kidney injury/renal failure (5%).
  - Methemoglobinemia was reported in 4 cases (4%), two of these cases were fatal. Methemoglobinemia is currently not labeled for hydroxychloroquine or chloroquine.

Table 6. Hydroxychloroquine/ Chloroquine Dosage	
Reported Dosage	(n=256)
1200 mg/day, then 400 mg/day	3
1000 mg/day	4
800 mg/day x 1, then 400 mg/day	33
800 mg/day	16
600 mg/day	39
400 mg/day	109
250 mg/day	2
200 mg/day	11
800 mg*	4
600 mg*	3
400 mg*	9
200 mg*	6
1 teaspoon of powder	2
Miscellaneous†	15
*** Frequency was not reported** **† One case each reported doses ranging from 100 mg to 2200 mg**	

Key Findings:

- The most frequently reported dose was 400 mg/day (43%), which is consistent with FDA-approved dosing for labeled indications.
- Of the 256 cases that reported hydroxychloroquine or chloroquine doses, 6 were for prophylaxis and 250 for treatment.

4 REVIEWER'S COMMENTS

In addition to the key findings listed in Section 3, two emerging safety signals were identified:

- **Cardiac toxicity with hydroxychloroquine and chloroquine:** Hydroxychloroquine and chloroquine are labeled for several cardiotoxic events including QT prolongation, ventricular arrhythmias, TdP, and conduction disorders. Both labels advise caution with use of hydroxychloroquine or chloroquine with other drugs that have the potential to prolong the QT interval.[3,4] In our evaluation of hydroxychloroquine and chloroquine use in the setting of prevention or treatment of COVID-19, QT prolongation was the most

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frequently reported serious adverse event for both hydroxychloroquine and chloroquine. Notably, 84% of hydroxychloroquine and chloroquine cases reporting a serious cardiac adverse event also reported concomitant use of at least one other QT prolonging medication; 69% of the cases with a serious adverse cardiac event reported concomitant azithromycin use, with or without other QT prolonging medications. Fourteen cases were identified with ventricular arrhythmia, ventricular tachycardia or ventricular fibrillation; seven of these had a fatal outcome. Two of the ventricular arrhythmia cases also reported TdP, one of which was fatal. Two additional cases reported TdP, neither of these were fatal. On April 13, 2020, a priority TSI was opened for cardiac toxicity with use of hydroxychloroquine and chloroquine in the setting of COVID-19. Additionally, the DSC emphasized the potential for hydroxychloroquine and chloroquine to prolong the QT interval and interact with other QT prolonging medications as well as to cause potentially fatal heart rhythms, such as ventricular tachycardia. DPV II will continue to actively monitor for cases in the available data sources for this emerging safety signal.

- **Methemoglobinemia with hydroxychloroquine:** Hemolysis in individuals with G6PD deficiency is labeled for hydroxychloroquine; however, the adverse event methemoglobinemia is not specifically described. Four cases of methemoglobinemia occurring with hydroxychloroquine use in the treatment of COVID-19 were identified in the NPDS database. All patients had evidence of hemolysis; two of these patients were confirmed not to have G6PD deficiency. Cases of methemoglobinemia with hydroxychloroquine use in the treatment of COVID-19 have not been identified in either the FAERS or literature searches. During the May 12, 2020 meeting, DPV, DARS, DAI, DAV and DRTM agreed that continued surveillance is most appropriate at this time given the small number of methemoglobinemia cases and limited information in the context of years of experience with hydroxychloroquine in the autoimmune disease population. Data with enough details to ascertain if methemoglobinemia is only observed in patients who are critically ill or if it also occurs in patients taking hydroxychloroquine in the setting of moderate COVID-19 disease are needed. In addition, DPV and OND agreed to include cases of hemolysis in ongoing surveillance. DPV, DARS, and OND plan to reassess this emerging signal if more compelling data become available.

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5 REFERENCES

[1] U.S. Food and Drug Administration. Drug Safety Communication: FDA cautions against use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems. Available at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or. Accessed on May 12, 2020.
[2] The Use of the WHO-UMC System for Standardized Case Causality Assessment. The Uppsala Monitoring Centre. Available at: https://www.who.int/medicines/areas/quality_safety/safety_efficacy/WHOcausality_assessment.pdf. Accessed May 12, 2020.
[3] Plaquenil (hydroxychloroquine sulfate) [package insert]. Concordia Pharmaceuticals, Inc. St. Michael, Barbados. January 2019.
[4] Chloroquine phosphate [package insert]. NATCO Pharma Limited. Kother, India. February 2018.

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6 APPENDICES

6.1 APPENDIX A. FDA ADVERSE EVENT REPORTING SYSTEM (FAERS)

FDA Adverse Event Reporting System (FAERS)

FAERS is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support FDA's postmarketing safety surveillance program for drug and therapeutic biological products. The informatic structure of the database adheres to the international safety reporting guidance issued by the International Council on Harmonisation. Adverse events and medication errors are coded to terms in the Medical Dictionary for Regulatory Activities terminology. The suspect products are coded to valid tradenames or active ingredients in the FAERS Product Dictionary.

FAERS data have limitations. First, there is no certainty that the reported event was actually due to the product. FDA does not require that a causal relationship between a product and event be proven, and reports do not always contain enough detail to properly evaluate an event. Further, FDA does not receive reports for every adverse event or medication error that occurs with a product. Many factors can influence whether or not an event will be reported, such as the time a product has been marketed and publicity about an event. Therefore, FAERS data cannot be used to calculate the incidence of an adverse event or medication error in the U.S. population.

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6.2 APPENDIX B. NATIONAL POISON DATA SYSTEM (NPDS)

The National Poison Data System (NPDS) is a database managed by the American Association of Poison Control Centers (AAPCC) and derived from a nationwide network of Poison Control Centers (PCCs) that receives calls from individuals, healthcare professionals, and other interested persons regarding exposures to prescription drugs, over-the-counter medications as well as unapproved products. Within NPDS, calls for exposures may result in documentation of an event, provision of information, or advice regarding medical management, and AAPCC staff managing these calls undergo training in the efforts to standardize documentation across centers.

Documentation of calls includes detail on the drug(s), patient characteristics, route of exposure, reported reasons for exposure, level of care received (e.g. admitted to critical care unit vs. treated and released), medical outcomes (e.g., death, no effect) and other more curated variables, such as "relatedness" of the reported exposure to the outcomes of interest. Reasons for use are categorized into groups by AAPCC, and include such categories as "intentional", "unintentional," the former encompassing the subgroups of intentional misuse, abuse, suspected suicide or unknown intent.

PCC call data should not be interpreted as representing the complete incidence of national exposures or cases of misuse/abuse related to any substance. These data only capture events if the exposure resulted in a call to a PCC. PCC data rely on information electively shared by patients and healthcare personnel, and most substance classification is based on history alone and does not involve any biologic confirmation. Reported exposures may be unconfirmed ingestions, i.e., the product may not have been ingested at all by the patient. Drug exposures resulting in unattended or out-of-hospital death are unlikely to generate a call to a PCC, and therefore, fatal poisonings are expected to be substantially under-reported in PCC call data. Follow-up and medical outcomes are not available for all calls. It is possible that changes in PCC rates in part reflect changes in public and professional awareness of the risks associated with specific drugs, and awareness of the abuse potential of a drug among call center personnel could also increase the likelihood of an exposure being coded as intentional abuse. Call rates may also be influenced by general changes in use of PCCs over time. AAPCC is not able to completely verify the accuracy of every report made to member centers.

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6.3 Appendix C. Most Frequently Reported MedDRA Preferred Terms (PTs) for FAERS Reports for Hydroxychloroquine and Chloroquine from December 1, 2019 – May 6, 2020 (N=312)

Table 1. Most Frequently Reported MedDRA Preferred Terms (PTs) Reporting ≥ 2% of Total

Event-Preferred Terms (PTs)	Percent of Total
OFF LABEL USE	41.22
ELECTROCARDIOGRAM QT PROLONGED	20
CORONAVIRUS INFECTION	11.84
HEPATITIS	11.02
PRODUCT USE IN UNAPPROVED INDICATION	11.02
CONDITION AGGRAVATED	8.98
DRUG INTERACTION	8.57
ACUTE RESPIRATORY DISTRESS SYNDROME	4.49
TRANSAMINASES INCREASED	4.08
ACUTE KIDNEY INJURY	3.67
DEATH	3.67
CARDIO-RESPIRATORY ARREST	3.27
HEPATITIS ACUTE	3.27
HEPATOCELLULAR INJURY	3.27
PNEUMONIA	3.27
PYREXIA	2.86
CARDIAC ARREST	2.45
DIARRHOEA	2.45
DYSPNOEA	2.45
ACUTE RESPIRATORY FAILURE	2.04
BRADYCARDIA	2.04
CORONAVIRUS TEST POSITIVE	2.04
HYPERBILIRUBINAEMIA	2.04
INTENTIONAL PRODUCT USE ISSUE	2.04
MALAISE	2.04
MULTIPLE ORGAN DYSFUNCTION SYNDROME	2.04
VENTRICULAR FIBRILLATION	2.04
VENTRICULAR TACHYCARDIA	2.04

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6.4 APPENDIX D. WHO-UMC CAUSALITY ASSESSMENT CATEGORIES

Categorization[b]	Assessment Criteria*
Certain	• Event or laboratory test abnormality, with plausible time relationship to drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically (i.e., an objective and specific medical disorder or a recognized pharmacological phenomenon) • Rechallenge satisfactory, if necessary
Probable/ Likely	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Rechallenge not required
Possible	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drug withdrawal may be lacking or unclear
Unlikely	• Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanations
Unassessable	• Cannot be assessed because information is insufficient or contradictory

*All points should be reasonably complied with

[b] The Use of the WHO-UMC System for Standardised Case Causality Assessment. The Uppsala Monitoring Centre. Available at: https://www.who.int/medicines/areas/quality_safety/safety_efficacy/WHOcausality_assessment.pdf. Accessed November 18, 2019

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This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

KIMBERLEY A SWANK
05/19/2020 02:25:35 PM

KATE L MCCARTAN
05/19/2020 02:27:38 PM

RACHNA KAPOOR
05/19/2020 02:33:11 PM

NEHA GADA
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IDA-LINA DIAK
05/19/2020 02:46:07 PM

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ANNEXURE-U

U.S. FOOD & DRUG ADMINISTRATION

June 15, 2020

Gary L. Disbrow Ph.D.
Deputy Assistant Secretary
Director, Medical Countermeasure Programs
Biomedical Advanced Research and Development Authority (BARDA)
Office of Assistant Secretary for Preparedness and Response (ASPR)
U.S. Department of Health and Human Services (HHS)
330 Independence Ave, S.W., Room 640G
Washington, D.C. 20201

Dear Dr. Disbrow:

This letter is in response to your request, dated today, that the Food and Drug Administration (FDA) revoke the Emergency Use Authorization (EUA) for emergency use of oral formulations of chloroquine phosphate (CQ) and hydroxychloroquine sulfate (HCQ) to be distributed from the Strategic National Stockpile (SNS) issued on March 28, 2020. Like BARDA's earlier request to FDA to issue the EUA, BARDA's request to revoke the EUA is part of a collaborative, USG-interagency effort to rapidly respond to this continuously evolving public health emergency. Today's request to revoke is based on new information, including clinical trial data results, that have led BARDA to conclude that this drug may not be effective to treat COVID-19 [Coronavirus Disease 2019] and that the drug's potential benefits for such use do not outweigh its known and potential risks.

The authorization of a product for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revised or revoked when the criteria under section 564(b)(1) of the Act no longer exist, the criteria under section 564(c) of the Act for issuance of such authorization are no longer met, or other circumstances make such revision or revocation appropriate to protect the public health or safety.

FDA has determined that the criteria under section 564(c) of the Act for issuance of the EUA referenced above are no longer met. Under section 564(c)(2) of the Act, an EUA may be issued only if FDA concludes "that, based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) the product may be effective in diagnosing, treating, or preventing—(i) such disease or condition [….]; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product […]."

As explained in the attached memorandum, based on a review of new information and a reevaluation of information available at the time the EUA was issued, FDA now concludes that these criteria are no longer met. The bases for this decision include the following:

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- We now believe that the suggested dosing regimens for CQ and HCQ as detailed in the Fact Sheets are unlikely to produce an antiviral effect.
- Earlier observations of decreased viral shedding with HCQ or CQ treatment have not been consistently replicated and recent data from a randomized controlled trial assessing probability of negative conversion showed no difference between HCQ and standard of care alone.
- Current U.S. treatment guidelines do not recommend the use of CQ or HCQ in hospitalized patients with COVID-19 outside of a clinical trial, and the NIH guidelines now recommend against such use outside of a clinical trial.
- Recent data from a large randomized controlled trial showed no evidence of benefit for mortality or other outcomes such as hospital length of stay or need for mechanical ventilation of HCQ treatment in hospitalized patients with COVID-19.

FDA has concluded that, based on this new information and other information discussed in the attached memorandum, it is no longer reasonable to believe that oral formulations of HCQ and CQ may be effective in treating COVID-19, nor is it reasonable to believe that the known and potential benefits of these products outweigh their known and potential risks. Accordingly, FDA revokes the EUA for emergency use of HCQ and CQ to treat COVID-19, pursuant to section 564(g)(2) of the Act. As of the date of this letter, the oral formulations of HCQ and CQ are no longer authorized by FDA to treat COVID-19.

While HCQ that has been distributed from SNS is no longer authorized under the EUA for the authorized use to treat hospitalized patients for COVID-19, FDA-approved HCQ can be distributed in interstate commerce. The CQ products covered by the EUA are not approved by FDA for any indication and therefore cannot be legally introduced into interstate commerce. In addition, under section 564(f)(2) of the Act, HCQ and CQ that were distributed from the SNS under this EUA remain authorized for emergency use to continue to treat any hospitalized patient to whom the authorized product has already been administered during the COVID-19 public health emergency, to the extent found necessary by such patient's attending physician.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Attachment: Memorandum Explaining Basis for Revocation of Emergency Use Authorization for Emergency Use of Chloroquine Phosphate and Hydroxychloroquine Sulfate

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U.S. FOOD & DRUG ADMINISTRATION

Memorandum Explaining Basis for Revocation of Emergency Use Authorization for Emergency Use of Chloroquine Phosphate and Hydroxychloroquine Sulfate

On March 28, 2020, the Biomedical Advanced Research and Development Authority (BARDA) requested and the U.S. Food and Drug Administration (FDA or The Agency) issued an Emergency Use Authorization (EUA) for emergency use of oral formulations of chloroquine phosphate (CQ) and hydroxychloroquine sulfate (HCQ) for the treatment of 2019 coronavirus disease (COVID-19). Based on information available to FDA at the time, the Agency determined that CQ and HCQ may be effective in treating COVID-19 and that the known and potential benefits of CQ and HCQ outweigh the known and potential risks for this use. The Agency limited the use of the authorized products to adults and adolescents who weigh 50 kg or more and are hospitalized with COVID-19 when participation in a clinical trial is not available, or participation is not feasible.[1]

Since that time, emerging data and published literature have raised new questions on whether CQ and HCQ may be effective in treating COVID-19 and whether CQ and HCQ's known and potential benefits outweigh the known and potential risks associated with their authorized use. As part of the Agency's ongoing review of the appropriateness of the EUA, FDA scientific staff conducted reviews of these new data and also conducted new analyses of information known at the time of initial authorization.

A summary of this information includes the following:

- The suggested dosing regimens for CQ and HCQ as detailed in the Fact Sheets are unlikely to produce an antiviral effect.
- Earlier reports of decreased viral shedding with CQ or HCQ treatment have not been consistently replicated and recent data from a randomized controlled trial assessing probability of negative conversion showed no difference between HCQ and standard of care alone.
- Current U.S. treatment guidelines do not recommend the use of CQ or HCQ in hospitalized patients with COVID-19 outside of a clinical trial, and the NIH guidelines now recommend against such use outside of a clinical trial.
- Recent data from a large randomized controlled trial showed no evidence of benefit for mortality or other outcomes such as hospital length of stay or need for mechanical ventilation of HCQ treatment in hospitalized patients with COVID-19.

[1] Letter of Authorization, March 28, 2020. *Available at: https://www.fda.gov/media/136534/download* ***Accessed*** *June 9, 2020.*

Based on the above, the Agency has concluded that it is unlikely that CQ and HCQ may be effective in treating COVID-19. Further, in light of ongoing reports of serious cardiac adverse events and several newly reported cases of methemoglobinemia in COVID-19 patients, the Agency has concluded that the known and potential benefits of CQ and HCQ do not outweigh the known and potential risks for the authorized uses. Therefore, the Agency believes that the criteria[2] for issuance of an authorization are no longer met and is revoking[3] EUA 039.[4]

Authorization of EUA 039

The information available at the time the EUA was issued regarding potential benefit included several components.[5] First, CQ and HCQ are antimalarial drugs that were reported to have in vitro activity against SARS-CoV-2 at drug concentrations achievable by doses considered safe in humans.[6,7,8] A brief clinical report on 100 COVID-19 patients in China reported clinical improvement and superior viral clearance with CQ treatment versus an unspecified control.[9] Additionally, a clinical survey by French researchers involving 20 COVID-19 patients reported that HCQ alone and in combination with azithromycin was associated with viral load reduction over 6 days. In the French report, the viral load changes were statistically significant compared to a nonrandomized control group and were more pronounced in patients who received the combination.[10] Based on experience with other viral illnesses, it was reasonable to believe that reduction in viral load may be predictive of clinical benefit.

At the time, a number of national treatment guidelines had been reported as incorporating recommendations regarding the use of CQ or HCQ in the setting of COVID-19, including guidelines used in China and Korea. Expert assessments associated with a number of U.S. medical institutions also included discussion on the use of these drugs in clinical care. Regarding the known and potential risks, the safety profiles of CQ and HCQ were well established as these are approved and commonly used anti-malarial drugs and, in the case of HCQ, approved for rheumatoid arthritis and systemic lupus erythematosus as well. The suggested dosing for CQ and HCQ under the EUA was within the range of that recommended in the approved labeling for these products. In general, the drugs are well-tolerated for their approved uses, though known

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[2] *See* Section 564(c) of the Federal Food, Drug & Cosmetic Act (FD&C Act).
[3] FDA notes that the Agency has consulted with BARDA on this matter. On June 15, 2020, BARDA requested that FDA revoke this EUA.
[4] *See* Section 564(g)(2) of the FD&C Act.
[5] *See* FDA Decision Memo for EUA 039, Submitted March 28, 2020.
[6] Wang M, Cao R, Zhang L, et al. Remdesivir and chloroquine effectively inhibit the recently emerged novel coronavirus (2019-nCoV) in vitro. Cell Res 2020; 30: 269-71.
[7] Liu J, Cao R, Xu M, et al. Hydroxychloroquine, a less toxic derivative of chloroquine, is effective in inhibiting SARS-CoV02 infection in vitro. Cell Discov 2020; doi: 10.1038/s41421-020-0156-0. [epub ahead of print]
[8] Yao X, Ye F, Zhang M, et al. In vitro activity and projection of optimized dosing design of hydroxychloroquine for the treatment of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Clin Infect Dis 2020; doi: 10.1093/cid/ciaa237. [Epub ahead of print]
[9] Gao J, Tian Z, Yang X. Breakthrough: Chloroquine phosphate has shown apparent efficacy in treatment of COVID-19 associated pneumonia in clinical studies. Biosci Trends. 2020. DOI: 10.5582/bst.2020.01047. [Epub ahead of print]
[10] Gautret P, Lagier JC, Parola P, et al. Hydroxychloroquine and azithromycin as a treatment of COVID-19: Results of an open-label non-randomized clinical trial. Int J Antimicrob Agents. 2020. doi: 10.1016/j.ijantimicag.2020.105949. [Epub ahead of print]

adverse reactions may include QTc prolongation and ocular, neuropsychiatric, cardiac, and hematologic toxicity.

Hospitalized patients were likely to have greater prospect of benefit (compared to ambulatory patients with mild illness) and could be more closely monitored for potential toxicity, although it was recognized that enrollment in a clinical trial would be the best option when using these drugs so that data on safety and effectiveness could be obtained.

FDA therefore concluded, based on the totality of scientific evidence available to FDA at the time, that it was reasonable to believe that CQ and HCQ may be effective in treating COVID-19, and that, when used under the conditions described in the authorization, the known and potential benefits of CQ and HCQ when used to treat COVID-19 outweigh the known and potential risks of such products. The EUA was authorized at a time when there was widespread use of these drugs by physicians to treat COVID-19 patients, and when such use had presented challenges with ensuring adequate drug availability for patients being treated with these drugs for approved uses as well as adequate drug availability to conduct clinical trials.

Similarity of CQ and HCQ and Rationale for Inclusion of Both Products in EUA 039

CQ and HCQ belong to a class of drugs known as 4-aminoquinolines and both occur as enantiomers (R and S isomers). Desethylchloroquine is an immediate downstream product of CYP-mediated dealkylation of both drugs, whereas desethylhydroxychloroquine is a metabolite of only HCQ. Bisdesethylchloroquine is a downstream metabolite of both drugs.[11] HCQ is administered as a sulfate, whereas CQ is administered as a phosphate salt. Both drugs are usually absorbed in the upper intestinal tract. Some studies have reported differences in the pharmacokinetics of CQ and HCQ in humans; however, these differences can be explained by differences in either the analytical methods applied, the sample source used (that is, plasma versus whole blood), or renal clearance of these drugs.[12] Important to the pharmacokinetics, pharmacodynamics, and toxic properties of these drugs is their ability to accumulate in acidic compartments such as lysosomes, as well as inflamed (acidic) tissues. The large volume of distribution and long half-lives of these drugs can explain some of their clinical characteristics, such as their slow onset of action and prolonged effects after drug discontinuation. Both drugs are approved for the treatment of malaria with similar dosing and both have similar adverse

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[11] Costedoat- Chalumeau, N., Isenberg, D. & Petri, M. Letter in response to the 2019 update of the EULAR recommendations for the management of systemic lupus erythematosus by Fanouriakis et al. *Ann. Rheum.Dis.* https://doi.org/10.1136/annrheumdis-2019- 215573 (2019).
McChesney, E. W. Animal toxicity and pharmacokinetics of hydroxychloroquine sulfate. *Am. J. Med.* **75**, 11–18 (1983).

[12] Tett, S. E. et al. Bioavailability of hydroxychloroquine tablets in healthy volunteers. *Br. J. Clin. Pharmacol.* **27**, 771–779 (1989).
Furst, D. E. Pharmacokinetics of hydroxychloroquine and chloroquine during treatment of rheumatic diseases. *Lupus* **5**, S11–S15 (1996).
Cutler, D. J., MacIntyre, A. C. & Tett, S. E. Pharmacokinetics and cellular uptake of 4-aminoquinoline antimalarials. *Agents Actions Suppl.* **24**, 142–157 (1988).
McChesney, E. W. Animal toxicity and pharmacokinetics of hydroxychloroquine sulfate. *Am. J. Med.* **75**, 11–18 (1983).

effects such as QT prolongation.[13] While only HCQ has an approved indication for chronic discoid lupus erythematosus and systemic lupus erythematosus in adults and the treatment of acute and chronic rheumatoid arthritis in adults, this is based on NDA submissions to the Agency. Both drugs have been used to treat rheumatologic diseases for many years.[14] Thus, for the purposes of EUA 039 and consideration of data regarding the use of these products for COVID-19, it is reasonable to assume that data regarding one product are applicable to the other.

Review of New Information Relevant to Assessing Whether CQ and HCQ May be Effective in Treating COVID-19

Clinical Pharmacology Assessment Regarding Dosing

Agency clinical pharmacology reviewers have re-assessed the publications relied upon at the time of EUA authorization regarding significantly higher lung concentration relative to the in vitro EC_{50} value as the rationale to support CQ and HCQ as potentially efficacious against SARS-CoV-2 at the dosage suggested in the EUA. The FDA clinical pharmacology reviewers cite limitations with these studies[15] including that the in vitro antiviral EC_{50} values reported in the literature were extracellular drug concentrations present in cell culture media and should be compared with in vivo free drug concentration in the plasma (likely to be equal to free extracellular tissue concentration). Under the assumption that in vivo cellular accumulation is similar to that from the in vitro cell-based assays, the calculated free lung concentrations that would result from the EUA suggested dosing regimens are well below the in vitro EC_{50}/EC_{90} values, making the antiviral effect against SARS-CoV-2 not likely achievable with the dosing regimens recommended in the EUA. The substantial increase in dosing that would be needed to increase the likelihood of an antiviral effect would not be acceptable due to toxicity concerns. The reviewers include the caveat that if these drugs have immunomodulatory effects that could be beneficial in patients with COVID-19, those effects would not be predicated on achieving concentrations that exceed the EC_{50} value.

Although many published papers predict adequate antiviral effect, the majority of these papers refer to the methods and findings of the publication with the limitations described above. In addition, conclusions in the most recent publication regarding in vitro activity of HCQ and achievable concentrations at the site of action are consistent with the FDA assessment.[16] Results of analyses made available since the EUA was issued lead to the conclusion that it is unlikely that the dosing regimens in the EUA would be able to have an antiviral effect.

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[13] *See* FDA Decision Memo for EUA 039, Submitted March 28, 2020.

[14] Schrezenmeir E, Dorner T. Mechanisms of action of hydroxychloroquine and chloroquine: implications for rheumatology. Nature Reviews Rheumatology 2020. 16:155-60.

[15] Office of Clinical Pharmacology Consult Review, EUA 039, Submitted May 15, 2020.

[16] Maharaj AR, Wu H, Hornik CP, et al. Simulated Assessment of Pharmacokinetically Guided Dosing for Investigational Treatments of Pediatric Patients With Coronavirus Disease 2019. JAMA Pediatr. 2020. doi:10.1001/jamapediatrics.2020.2422.

Published Literature Regarding Viral Shedding

The Agency has reviewed additional published literature becoming available since the EUA was issued regarding the effects of CQ or HCQ on viral RNA shedding (see TABLE 1). The highest quality data are those published by Tang et al. from a randomized open-label trial comparing HCQ with standard of care alone in 150 hospitalized patients with COVID-19. The proportion with conversion of RT-PCR specimens obtained from the upper or lower respiratory tract to negative by day 28 was similar in both groups at multiple timepoints. Other published studies, which include an extremely small randomized trial as well as several observational comparisons, were inconsistent with respect to reporting a difference in viral RNA shedding comparing HCQ- or CQ- treated patients with others who were not treated with either of these medications. These publications are summarized in TABLE 1 below.

TABLE 1: Publications Relevant to Viral Shedding[17]

Article (design)	Comparison groups (n)	Viral shedding outcomes
Tang W, et al *BMJ* (randomized, open-label, stopped early)	HCQ 1200 mg/day x 3 d then 800 mg/day to complete 2-3 weeks plus standard of care (75) SOC alone (75)	53 HCQ and 56 SOC PCR(-) "well before" day 28 endpoint; K-M "probability of negative conversion" by 28 days reported as "similar"; median time to (-) 8 and 7 days respectively; proportion (-) "similar" at multiple time points
Huang M, et al *J Mol Cell Biol* (randomized, 2 antiviral arms)	CQ 500 mg bid x 10 d (10) Lopinavir/ritonavir (12)	All CQ patients PCR(-) by day 13, 11 of 12 L/r patients PCR(-) by day 14; authors say CQ PCR(-) % "slightly higher" on some days
Chen X, et al medRxiv preprint (retrospective, observational)	Retrospective analysis of multiple interventions (CQ in 25 of 284 on page 7, 28 on page 9; also steroids, L/r, arbidol, oseltamivir)	CQ (and other antivirals) not associated with improvement in viral clearance; median 6 days from admission in 121 on no antivirals, 7 days in 17 patients receiving CQ without other antivirals
Mallat J, et al medRxiv preprint (retrospective, observational)	HCQ 400 mg/day (21) Non-HCQ (13)	Median time to (-) PCR 17 days HCQ, 10 days non-HCQ; 14/23 HCQ, 10/11 controls (-) day 14
Huang M, et al medRxiv preprint (prospective, observational)	CQ Phosphate 500 mg (300 mg base) once or twice daily until (-) (233 but analyzed only 197 who "completed") Historical controls (192 "collected"; 176 analyzed)	Median time to (-) PCR 3 days CQ, 9 days controls; 91% and 94-96% CQ, 57% and 80% controls (-) at days 10 and 14; 3 CQ patients "re-positive" after discharge

[17] Citations for articles mentioned in table:
Tang W et al. *BMJ*. May 14, 2020;369:m1849. doi:10.1136/bmj.m1849
Huang M et al. *J Mol Cell Biol*. May 18, 2020;12(4):322-325. doi:10.1093/jmcb/mjaa014
Chen X et al. medRxiv 2020.04.09.20058941; doi: https://doi.org/10.1101/2020.04.09.20058941
Mallat J et al. medRxiv 2020.04.27.20082180; doi: https://doi.org/10.1101/2020.04.27.20082180
Huang M et al. medRxiv 2020.04.26.20081059; doi: https://doi.org/10.1101/2020.04.26.20081059
Shabrawishi M et al. medRxiv 2020.05.08.20095679; doi: https://doi.org/10.1101/2020.05.08.20095679
Kim M et al. medRxiv 2020.05.13.20094193; doi: https://doi.org/10.1101/2020.05.13.20094193
Hraiech S et al. *Ann Intensive Care*. May 24, 2020;10(1):63. doi: https://doi.org/10.1186/s13613-020-00678-4

Article (design)	Comparison groups (n)	Viral shedding outcomes
Shabrawishi M, et al medRxiv preprint (retrospective, observational)	HCQ (any dose) ± AZI/other AV (45) Supportive care (48) (excluded those transferred to ICU or isolation facility while still PCR(+))	No significant difference in time to first (-) PCR or proportion (-) by 5 or 12 days (median 3 days from treatment start, 33 by 5 days and 38 by 12 days in each group)
Kim M, et al medRxiv preprint (retrospective, observational)	HCQ 200 mg bid + antibiotics (22) Lopinavir/ritonavir + antibiotics (35) Conservative treatment (40)	Hazard ratio for time to viral clearance 0.49 for HCQ/antibiotics (mean 15.3 days) versus L/r plus antibiotics (mean 19.1 days), 0.44 for HCQ/antibiotics versus conservative treatment (20.7 days)
Hraiech S, et al *Ann Intensive Care* (retrospective, observational)	HCQ 600 mg/day + AZI (17) Lopinavir/ritonavir (13) No antivirals (15)	At day 6 of treatment, PCR(-) in 3 HCQ/AZI, 5 L/r, 2 no-antivirals

In summary, although there were two positive reports observing an impact on viral shedding available at the time the EUA was issued, this observation has not been consistently replicated. The largest randomized controlled trial assessing probability of negative conversion (Tang et al.) showed no difference: the proportion of patients with detectible shedding of viral RNA was very similar over time in the group that received HCQ when compared to the group that did not. At the time the EUA was issued, it was reasonable to assume that an impact on viral shedding would be associated with a clinical benefit for patients. However, neither a favorable impact of CQ or HCQ on viral shedding nor an established clinical benefit of a decrease in viral shedding has been borne out by data and reports available since the EUA was issued.

U.S. National Treatment Guidelines

At the time EUA 039 was authorized, a number of countries initially impacted by COVID-19 had recommended treatment of patients with COVID-19 with CQ or HCQ in their national treatment guidelines.[18] However, there were no national treatment guidelines available in the U.S. This is no longer the case. On April 11, 2020, The *Infectious Diseases Society of America Guidelines on the Treatment and Management of Patients with COVID-19* published recommendations on CQ and HCQ in the context of a clinical trial among patients admitted to hospital with COVID-19, describing the evidence supporting its use as "very low."[19] The *NIH COVID-19 Treatment Guidelines,* which were initially published on April 21, 2020, were updated on June 11, 2020,[20] to recommend against the use of CQ and HCQ for the treatment of COVID-19, except in a clinical trial. *The Johns Hopkins ABX Guide* updated June 3, 2020, states,[21] "CQ or HCQ: the overall feeling is that safety is an issue especially in more severely ill patients; however, it remains without high-quality data to argue for or against its use." In summary, U.S. treatment guidelines are now available and do not recommend the use of HCQ or CQ in hospitalized patients with COVID-19 outside of a clinical trial.

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[18] *See* FDA Decision Memo for EUA 039, Submitted March 28, 2020.
[19] *Available at:* https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/#toc-1
[20] *Available at:* https://www.covid19treatmentguidelines.nih.gov/
[21] *Available at:* https://www.hopkinsguides.com/hopkins/view/Johns_Hopkins_ABX_Guide/540747/all/Coronavirus_COVID_19__SARS_CoV_2_

Randomized Evaluation of COVID-19 Therapy RECOVERY Trial (NCT04381936)

The RECOVERY trial is being sponsored by Oxford University in the United Kingdom in collaboration with several foundations and British government agencies. It is designed as an adaptive platform trial in hospitalized patients with COVID-19 to assess the effectiveness of trial treatments in reducing all-cause mortality within 28 days. Treatment arms include: usual care; or usual care combined with corticosteroid therapy, lopinavir/ritonavir, azithromycin, or HCQ. Additional randomizations are included between convalescent plasma and placebo and between tocilizumab and placebo for eligible patients.

Over 11,000 patients have been enrolled so far, of an estimated target enrollment of 12,000. On June 5, 2020, the chief investigators announced closure of the HCQ arm due to lack of benefit.[22] With 1542 patients randomized to HCQ and 3132 to the usual care comparator, mortality was reported as 25.7% and 23.5% respectively (hazard ratio 1.11, 95% CI 0.98-1.26, p=0.10).[23] The difference in mortality rates trends in favor of the usual care comparator. No evidence of benefit was reported for other outcomes such as hospital length of stay or need for mechanical ventilation. These were noted as preliminary results with follow-up complete for just over 80% of participants; the investigators announced "These data convincingly rule out any meaningful mortality benefit of hydroxychloroquine in patients hospitalised with COVID-19. Full results will be made available as soon as possible." While the HCQ findings in the RECOVERY trial were based on a randomized but open label design, the endpoint of mortality is generally less susceptible than other more subjectively assessed endpoints to biases that may be of concern with such a design.

Only randomized controlled trials can answer the question of whether HCQ or CQ is of clinical benefit in hospitalized patients with COVID-19, and the RECOVERY Trial results offer persuasive evidence of a lack of benefit of HCQ in the treatment of hospitalized patients with COVID-19.

There are additional trials ongoing in hospitalized patients.[24] It is important to note that the criteria for issuance of an EUA are more stringent than the conditions justifying equipoise to

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[22] *See:* https://www.recoverytrial.net/news/statement-from-the-chief-investigators-of-the-randomised-evaluation-of-covid-19-therapy-recovery-trial-on-hydroxychloroquine-5-june-2020-no-clinical-benefit-from-use-of-hydroxychloroquine-in-hospitalised-patients-with-covid-19

[23] Preliminary results from the RECOVERY trial were provided to FDA by the chief investigators. See letter from P. Horby and M. Landray, University of Oxford, to J. Woodcock, Director, CDER (June 10, 2020). Archived in the Document Archiving Reporting and Regulatory Tracking System for EUA 039.

[24] Some examples of ongoing trials include:
Outcomes Related to COVID-19 Treated with Hydroxychloroquine Among In-Patients with Symptomatic Disease (ORCHID) Study (NCT04332991): This trial is being conducted by the Prevention and Early Treatment of Acute Lung Injury (PETAL) Clinical Trials Network of the National Heart, Lung, and Blood Institute (NHLBI), part of the National Institutes of Health. ORCHID is a multicenter, blinded, placebo-controlled, randomized clinical trial evaluating HCQ for the treatment of adults hospitalized with COVID-19. The primary aim is to compare the effect of HCQ versus placebo on clinical outcomes, measured using the COVID Ordinal Outcomes Scale at Day 15. The current planned sample size is 510. Over 400 participants have been enrolled to date. The trial has undergone recent DMC review and the DMC recommended continuation of the trial.

continue a clinical trial. In addition to trials in hospitalized patients, numerous clinical trials have been in progress studying treatment of outpatients with COVID-19 or use of HCQ or CQ for pre- or post-exposure prophylaxis. One such trial conducted under U.S. IND recently published results showing no significant difference in development of symptomatic illness compatible with COVID-19 between HCQ and placebo recipients for post-exposure prophylaxis, though with limitations that outcomes were largely self-reported with little opportunity for laboratory confirmation.[25]

Review of New Information on Known and Potential Risks of the Products

Office of Surveillance and Epidemiology Review of Adverse Events Associated with CQ or HCQ Use for COVID-19[26]

The FAERS database and literature were searched for adverse events associated with CQ or HCQ use for COVID-19, as well as the American Association of Poison Control Centers (AAPCC) National Poison Data System (NPDS) for calls associated with CQ OR HCQ exposure.

As of May 6, 2020, key findings were as follows: A total of 347 HCQ and 38 CQ cases were identified. The majority of the cases (69%) involved males with a median age in the early 60s. Five cases reported HCQ use through the EUA. Of all serious adverse events (cardiac and non-cardiac), QT prolongation was the most commonly reported adverse event for both HCQ and CQ.

There were 109 cases with serious cardiac AEs, some reporting one or more of the following: 80 (73%) reported QT prolongation, 4 (4%) reported Torsades de Pointes, 14 (13%) reported ventricular arrhythmia, ventricular tachycardia or ventricular fibrillation, and 25 (23%) had a fatal outcome. Among the 109 cases, 92 (84%) reported concomitant use of at least one other medication that prolongs the QT interval and 75 (69%) reported concomitant use of azithromycin.

There were 113 cases with serious non-cardiac AEs. Hepatitis/increased liver enzymes/hyperbilirubinemia were the most commonly reported adverse event (59%). These are

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Solidarity Clinical Trial for COVID-19 Treatments: This is a collaborative trial facilitated by the World Health Organization enrolling adults with COVID-19 admitted to hospital. Patients are randomized to local standard of care or local standard of care plus one of remdesivir, hydroxychloroquine, lopinavir with ritonavir, or lopinavir with ritonavir plus interferon beta-1a. National arms of this trial, such as those from Canada (NCT04330690) and Norway (NCT04321616), may be listed separately in ClinicalTrials.gov. The primary endpoint is in-hospital mortality. As of 3 June 2020, more than 3500 patients have been recruited in 35 countries, with over 400 hospitals actively recruiting patients.

[25] Boulware DR, Pullen MF, Bangdiwala AS, et al. A Randomized Trial of Hydroxychloroquine as Postexposure Prophylaxis for Covid-19 [published online ahead of print, 2020 Jun 3]. *N Engl J Med.* 2020;10.1056/NEJMoa2016638. doi:10.1056/NEJMoa2016638;
Cohen MS. Hydroxychloroquine for the Prevention of Covid-19 - Searching for Evidence [published online ahead of print, 2020 Jun 3]. *N Engl J Med.* 2020;10.1056/NEJMe2020388. doi:10.1056/NEJMe2020388

[26] Office of Surveillance and Epidemiology Pharmacovigilance Memorandum, EUA 039, Submitted May 19, 2020.

labeled events for HCQ and CQ. The most commonly reported unlabeled adverse event was acute kidney injury/renal failure (5%). Of note, acute kidney injury has been associated with COVID-19. Methemoglobinemia was reported in 4 cases (4%); two of these cases were fatal (methemoglobinemia is currently not in the labels for HCQ or CQ).

The reviewers were unable to assess the rates of these AEs using FAERS data, NPDS data, and literature alone because the total number of persons exposed to either product is unknown. The cardiac adverse events identified are serious risks associated with death in some patients. On April 24, 2020, FDA issued a Drug Safety Communication cautioning against the use of HCQ and CQ for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems.[27] The EUA 039 Health Care Provider Fact Sheets recommend use with caution in patients at increased risk for ventricular arrhythmia, performing a baseline electrocardiogram, and monitoring the electrocardiogram during treatment. While this monitoring can reduce the risk of harm, the risk of cardiac adverse events under the EUA 039 authorized use remains. Methemoglobinemia is an adverse event which was not included in labeling for either products and is now reported in the setting of COVID-19. A recent case series described 3 cases of methemoglobinemia occurring in critically ill COVID-19 patients from a single institution.[28]

Additional Information Reviewed

Outcome Data Reported to BARDA

The Health Care Provider Fact Sheets for EUA 39 state that the prescribing health care provider and/or the provider's designee are/is responsible for submitting patient outcomes via an on-line reporting form.[29] However, few reports have been submitted to date. As of May 22, 2020, the Strategic National Stockpile reports dispensing approximately 2.4 million HCQ 7-day treatment courses to State and local health authorities. The approximate number of treatment courses dispensed to hospitals by State and local health authorities is not available at this time. As of May 26, 2020, outcome data for 1763 patients receiving HCQ (1762) or CQ (1) through the EUA have been reported to BARDA (see TABLE 2).

TABLE 2: Outcome Data Reported to BARDA for 1762 Patients as of May 26, 2020

Baseline Characteristics

- The mean (SD) age was 62.6 (15.50) years
- Sex: 35% male, 23.3% female, 41.7% missing
- Baseline severity of illness: 5% mild, 33% moderate, 45% severe, 17% critical
- Comorbidities: 6% had cardiovascular disease, 23% had HTN, and 20% had DM

[27] *Available at:* https://www.fda.gov/drugs/drug-safety-and-availability/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or

[28] Naymagon L, Berwick S, Kessler A, Lancman G, Gidwani U, Troy K. The emergence of methemoglobinemia amidst the COVID-19 pandemic. American Journal of Hematology epub ahead of print 15 May 2020. https://doi.org/10.1002/ajh.25868

[29] *See:* Mandatory Patient Outcome Reporting Survey - EUA for Chloroquine Phosphate and Hydroxychloroquine Sulfate. Available at: https://euachloroquine-hydroxychloroquine-outcome.ppdi.com/.

Clinical Characteristics

- The mean (SD) number of days patients received a dose was 4.1 (2.24), maximum number of days was 23
- The mean (SD) number of days hospitalized was 9.7 (12.12)
- 68.3% of patients were discharged and 31.7% of patients were deceased
- Ventricular arrhythmias were reported in 6 (0.34%) subjects
- Other cardiac AEs were reported in 30 (1.70%) subjects

Treatment Outcomes and Characteristics

- The mean number of days of dosing was the same in the discharged and deceased groups
- The rate of ventricular arrhythmia was similar in the discharged and deceased groups
- Other cardiac AEs were reported in 17 (1.41%) of discharged patients and 12 (2.33%) of deceased patients

Data interpretation is limited due to the low number of patients with a reported outcome and the absence of a comparison group.

Office of Surveillance and Epidemiology Memorandum – Literature Review on CQ and HCQ Use in the COVID-19 Population[30]

The CDC Stephen B. Thacker Library of COVID-19 research articles was searched for articles that contain "hydroxychloroquine" or "chloroquine" in the title or abstract and at a minimum had the following design features: conducted in a population with confirmed COVID-19 infection, reported quantitative estimates of treatment effectiveness or safety associated with HCQ or CQ use, and included a reference group that was not treated with HCQ or CQ. The search identified 317 articles. After excluding non-observational studies (e.g., RCTs) and studies not designed to evaluate HCQ or CQ treatment outcomes in the COVID-19 population, there were 10 observational studies eligible for review and one additional study that had been shared with FDA in manuscript proof format. All 11 studies were cohort studies conducted in hospitalized COVID-19 populations. All 11 studies reported findings on HCQ or CQ treatment effectiveness.

FDA reviewers concluded that the findings on the effectiveness endpoints were inconsistent across all reviewed studies. Most of the point estimates reported were imprecise, with confidence intervals that crossed the null.

Only one study evaluated cardiac safety associated with HCQ treatment (Rosenberg et al[31]). This study was a retrospective multicenter cohort study of patients with laboratory-confirmed COVID-19 admitted to one of 25 participating New York metropolitan region hospitals. The primary effectiveness outcome was in-hospital mortality. After adjustment for demographic characteristics, hospital, preexisting conditions and illness severity, no significant differences in mortality were found between patients receiving HCQ + azithromycin, HCQ alone or azithromycin alone compared with neither drug. The secondary cardiac safety outcomes were cardiac arrest and abnormal ECG findings (based on chart review). Compared to patients who received neither HCQ nor azithromycin, risks of cardiac arrest were higher among patients

[30] Office of Surveillance and Epidemiology Memorandum - Literature review on hydroxychloroquine or chloroquine use in COVID-19 population, EUA 039, Submitted May 28, 2020.
[31] Rosenberg ES, Dufort EM, Udo T, et al. Association of Treatment with Hydroxychloroquine or Azithromycin With In-Hospital Mortality in Patients With COVID-19 in New York State [published online ahead of print, 2020 May 11]. *JAMA*. 2020;e208630. doi:10.1001/jama.2020.8630

receiving HCQ + azithromycin, and those receiving HCQ alone, although the risk estimates were not statistically significant for the monotherapy group. FDA reviewers concluded that this study is limited by potential for residual confounding and bias due to outcome misclassification, and overall, the available observational data are of insufficient quality to inform the effectiveness or safety of HCQ or CQ use in the COVID-19 population.

In an Addendum included in the Memorandum, reviewers additionally evaluated a large observational study of HCQ and CQ with or without a macrolide for the treatment of patients hospitalized with COVID-19, based on data from a multinational registry (Mehra et al[32]). This publication was subsequently withdrawn by the authors[33] and will not be included in this Memorandum.

Conclusion

Since FDA initially authorized CQ and HCQ for emergency use on March 28, 2020, new scientific and clinical data, as well as published literature, have raised questions regarding whether CQ and HCQ may be effective in treating COVID-19 and whether CQ and HCQ's known and potential benefits outweigh the known and potential risks associated with their authorized use. FDA has reviewed this information and data as part of its ongoing assessment of whether an EUA remains appropriate.

Based on its review, the Agency has determined the following:

- The suggested dosing regimens for CQ and HCQ as detailed in the Fact Sheets are unlikely to produce an antiviral effect.
- Earlier reports of decreased viral shedding with HCQ or CQ treatment have not been consistently replicated and recent data from a randomized controlled trial assessing probability of negative conversion showed no difference between HCQ and standard of care alone.
- Current U.S. treatment guidelines do not recommend the use of HCQ or CQ in hospitalized patients with COVID-19 outside of a clinical trial, and the NIH guidelines now recommend against such use outside of a clinical trial.
- Recent data from a large randomized controlled trial showed no evidence of benefit for mortality or other outcomes such as hospital length of stay or need for mechanical ventilation of HCQ treatment in hospitalized patients with COVID-19.

Therefore, based on the totality of scientific evidence available, it is no longer reasonable to believe that CQ and HCQ may be effective in treating COVID-19 for the authorized uses detailed in EUA 039. Further, in considering the known safety profile for both CQ and HCQ and

[32] Mehra MR, Desai SS, Ruschitzka F, Patel AN. Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis [published online ahead of print, 2020 May 22] 6

[33] Mandeep R Mehra, Frank Ruschitzka, Amit N Patel. Retraction—Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis *The Lancet* Published: June 5, 2020 *Available at:* https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31324-6/fulltext

the ongoing reports of serious cardiac adverse events, in addition to several new reports of methemoglobinemia in COVID-19 patients, it is no longer reasonable to believe that the known and potential benefits of CQ and HCQ outweigh the known and potential risks associated with the authorized use.

BARDA has received few reports from healthcare providers and/or provider designees detailing outcome data as requested in the EUA. Interpretation of these data is limited due to the low number of patients with a reported outcome and the absence of a comparison group. A review of recent published literature describing observational studies does not provide informative findings given residual confounding and other methodological issues.

Based on the above, FDA concludes that the criteria for Emergency Use Authorization as outlined in Section 564(c)(2) of the FD&C Act are no longer met and is revoking EUA 039 for CQ and HCQ for the treatment of COVID-19.

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ANNEXURE-V

THE
SUPREME COURT CASES

(2018) 5 SCC

(2018) 5 Supreme Court Cases 1

(BEFORE DIPAK MISRA, C.J. AND DR A.K. SIKRI, A.M. KHANWILKAR, DR D.Y. CHANDRACHUD AND ASHOK BHUSHAN, JJ.)

COMMON CAUSE (A REGISTERED SOCIETY) .. Petitioner;

Versus

UNION OF INDIA AND ANOTHER .. Respondents.

Writ Petition (C) No. 215 of 2005†, decided on March 9, 2018

A. Constitution of India — Art. 21 — Euthanasia — Passive euthanasia — Patients who are terminally ill or in permanent vegetative state or brain dead state without any hope for revival — Smoothening natural process of dying of such patients by withholding or withdrawing life prolonging medical support or treatment in accordance with express or implied will of such patients i.e. voluntary and non-voluntary passive euthanasia, held, permissible — Such patients, if adult and while in conscious mind, can also execute living will in form of "Advance Directive" directing not to prolong their life by medical treatment — Procedure for effectuating voluntary and non-voluntary passive euthanasia, when (a) there is an Advance Directive; and (b) when there is no Advance Directive — Detailed Safeguards and Guidelines laid down, to be in force till legislation is enacted to cover the field (*see* Shortnote *T*, from p. 37 below) — Their right to live with dignity till end of their natural span of life without intervention of medical life-sustaining measures is based on right to life, liberty, human dignity and privacy inherent under Art. 21 of the Constitution, as also Common Law right of autonomy and self-determination and right to refuse medical treatment — Judgments in *Gian Kaur*, (1996) 2 SCC 648 and *Aruna Ramachandra Shanbaug*, (2011) 4 SCC 454 analysed, explained and commented upon — Human and Civil Rights — Right to Die/ Euthanasia — Common Law

† Under Article 32 of the Constitution of India

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In *P. Rathinam*, (1994) 3 SCC 394, the writ petitioners had assailed the constitutional validity of Section 309 of the Penal Code, 1860 (IPC) contending that the same is violative of Articles 14 and 21 of the Constitution. The Supreme Court declared Section 309 IPC ultra vires and held that it deserved to be effaced from the statute book to humanise our penal laws. In *Gian Kaur*, (1996) 2 SCC 648, the appellants' conviction under Section 306 IPC was assailed on the ground of it being unconstitutional by relying upon *P. Rathinam case*. The Constitution Bench in *Gian Kaur case* considered the correctness of *P. Rathinam decision* and opined that the "right to live with human dignity" cannot be construed to include within its ambit the right to terminate natural life, at least before the commencement of the process of certain natural death. It then examined the question of validity of Section 306 IPC and held that Section 306 is constitutional. Although the controversy relating to attempt to suicide or abetment of suicide was put to rest, yet the issue of euthanasia remained alive. It arose for consideration almost after a span of eleven years in *Aruna Ramachandra Shanbaug*, (2011) 4 SCC 454. A writ petition was filed by the next friend of the petitioner pleading, inter alia, that the petitioner was suffering immensely because of an incident that took place thirty-six years back on 27-11-1973 and was in a persistent vegetative state (PVS) and in no state of awareness and her brain was virtually dead. The prayer of the next friend was that the respondent be directed to stop feeding the petitioner and to allow her to die peacefully. The Court noticed that there was some variance in the allegation made in the writ petition and the counter-affidavit filed by the Professor and Head of the hospital where the petitioner was availing treatment. The Court appointed a team of three very distinguished doctors to examine the petitioner thoroughly and to submit a report about her physical and mental condition. The team submitted a joint report. But after perusing the reports, and addressing the legal issues, namely, active and passive euthanasia, the Court rejected the prayer of the writ petitioner.

The aforesaid matter was decided when the present writ petition was pending for consideration. The instant writ petition preferred under Article 32 of the Constitution of India by the petitioner, a registered society, seeks to declare "right to die with dignity" as a fundamental right within the fold of "right to live with dignity" guaranteed under Article 21 of the Constitution; to issue directions to the respondents to adopt suitable procedure in consultation with the State Governments, where necessary; to ensure that persons of deteriorated health or terminally-ill patients should be able to execute a document titled "My Living Will and Attorney Authorisation" which can be presented to the hospital for appropriate action in the event of the executant being admitted to the hospital with serious illness which may threaten termination of the life of the executant; to appoint a committee of experts including doctors, social scientists and lawyers to study into the aspect of issuing guidelines as to the "Living Wills"; and to issue such further appropriate directions and guidelines as may be necessary.

The present petition was, thereafter, listed before a three-Judge Bench which noted the submissions advanced on behalf of the petitioner and also that of the Additional Solicitor General on behalf of the Union of India. Reliance was placed on the decision in *Aruna Shanbaug case*. The three-Judge Bench reproduced paras 24 and 25 from *Gian Kaur case* and noted that the Constitution Bench did not express any binding view on the subject of euthanasia, rather it reiterated that the legislature would be the appropriate authority to bring the change. The three-

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Judge Bench expressed the view that the opinion of the House of Lords in *Airedale N.H.S. Trust*, 1993 AC 789 has not been approved in *Gian Kaur case* and to that extent, the observation in *Aruna Shanbaug case* is incorrect. After so stating, the three-Judge Bench opined that *Aruna Shanbaug case* upholds the authority of passive euthanasia and lays down an elaborate procedure for executing the same on the wrong premise that the Constitution Bench in *Gian Kaur case* had upheld the same. Thereafter, considering the important question of law involved which needs to be reflected in the light of social, legal, medical and constitutional perspectives, in order to have a clear enunciation of law, it referred the matter for consideration by the Constitution Bench of the Supreme Court for the benefit of humanity as a whole. The three-Judge Bench further observed that it was refraining from framing any specific questions for consideration by the Constitution Bench as it would like the Constitution Bench to go into all the aspects of the matter and lay down exhaustive guidelines. That is how the matter has been placed before the present Bench.

This Constitution Bench of the Supreme Court unanimously held that passive euthanasia is permissible and "Advance Directive" can be executed by the patient.

B. **Constitution of India — Art. 21 — Euthanasia — Meaning — Intentional premature termination of life of another person at his/her request to cause "good death"**

— Euthanasia — Types — Active, passive, voluntary, non-voluntary and involuntary

— Active euthanasia — Causing death of a person with his/her consent by direct medical intervention — Some positive act on part of person causing death necessary

— Passive euthanasia — Withholding or withdrawing life prolonging medical treatment in accordance with express or implied will of terminally ill, permanent vegetative state (PVS)/brain dead patient resulting in his/her death

— Voluntary euthanasia — Terminating life at request of patient — Request may be made prior to development of illness or during course of illness

— Non-voluntary euthanasia — Terminating life without patient's consent — It may be for patient's good on proxy request when not in position to express own views; an alternative to non-treatment

— Involuntary euthanasia — Terminating life against patient's will — Human and Civil Rights — Right to Die/Euthanasia

C. **Constitution of India — Art. 21 — Passive euthanasia — Complex issue — Requires consideration of moral, ethical, religious, philosophical, social, economic, penal and constitutional aspects**

— Passive euthanasia — Withholding or withdrawal of life prolonging medical support in accordance with express or implied will of patient who is terminally ill, in PVS or brain dead state and consequent acceleration of

natural process of dying which has already commenced — Held, permissible — Distinction between active and passive euthanasia and withholding and withdrawal of medical treatment, considered — Human and Civil Rights — Right to Die/Euthanasia

D. Constitution of India — Arts. 32 and 136 — Function of Supreme Court — To ascertain and build law — Court should not act as moral or ethical arbiter — But it should consider interest of disadvantaged and vulnerable people

Held :

Per Dipak Misra, C.J. and Khanwilkar, J.

Euthanasia — Concept

Euthanasia is basically an intentional premature termination of another person's life either by direct intervention (active euthanasia) or by withholding life-prolonging measures and resources (passive euthanasia) either at the express or implied request of that person (voluntary euthanasia) or in the absence of such approval/consent (non-voluntary euthanasia). (Para 46)

There is an inherent difference between active euthanasia and passive euthanasia as the former entails a positive affirmative act, while the latter relates to withdrawal of life-support measures or withholding of medical treatment meant for artificially prolonging life. In active euthanasia, a specific overt act is done to end the patient's life whereas in passive euthanasia, something is not done which is necessary for preserving a patient's life. Passive euthanasia fundamentally connotes absence of any overt act either by the patient or by the doctors. It also does not involve any kind of overt act on the part of the family members. It is avoidance of unnecessary intrusion in the physical frame of a person, for the inaction is meant for smooth exit from life. It is paramount for an individual to protect his dignity as an inseparable part of the right to life which engulfs the dignified process of dying sans pain, sans suffering and, most importantly, sans indignity. It is due to this difference that most of the countries across the world have legalised passive euthanasia either by legislation or by judicial interpretation with certain conditions and safeguards. (Paras 202.5, 202.6 and 178)

It is perhaps due to the distinction evolved between these two forms of euthanasia, which has gained moral and legal sanctity all over, that most of the countries today have legalised passive euthanasia either by way of legislations or through judicial interpretation but there remains uncertainty whether active euthanasia should be granted legal status. (Para 52)

The society at large may feel that a patient should be treated till he breathes his last breath and the treating physicians may feel that they are bound by their Hippocratic oath which requires them to provide treatment and save life and not to put an end to life by not treating the patient. The members of the family may remain in a constant state of hesitation being apprehensive of many a social factor which include immediate claim of inheritance, social stigma and, sometimes, the individual guilt. The Hippocratic oath taken by a doctor may make him feel that there has been a failure on his part and sometimes also make him feel scared of various laws. There can be allegations against him for negligence or criminal culpability. (Para 176)

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In this regard, two aspects are to be borne in mind. First, withdrawal of treatment in an irreversible situation is different from not treating or attending to a patient and second, once passive euthanasia is recognised in law regard being had to the right to die with dignity when life is ebbing out and when the prolongation is done sans purpose, neither the social morality nor the doctors' dilemma or fear will have any place. It is because the sustenance of dignity and self-respect of an individual is inhered in the right of an individual pertaining to life and liberty and there is necessity for this protection. And once the said right comes within the shelter of Article 21 of the Constitution, the social perception and the apprehension of the physician or treating doctor regarding facing litigation should be treated as secondary because the primacy of the right of an individual in this regard has to be kept on a high pedestal. (Para 177)

There are philosophers, thinkers and also scientists who feel that life is not confined to the physical frame and biological characteristics. However, the legal fulcrum has to be how Article 21 of the Constitution is understood. If a man is allowed to or, for that matter, forced to undergo pain, suffering and state of indignity because of unwarranted medical support, the meaning of dignity is lost and the search for meaning of life is in vain. (Para 179)

Aruna Shanbaug case has discussed about these two categories of euthanasia —active and passive. The main idea behind the distinction between the two, as observed by the Bench, is that in passive euthanasia, the doctors are not actively killing the patient, they are merely not saving him and only accelerating the conclusion of the process of natural death which has already commenced. (Paras 46 and 47)

Aruna Ramachandra Shanbaug v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294, *affirmed on this point*

The Court in *Aruna Shanbaug case* had drawn further distinction between voluntary euthanasia and non-voluntary euthanasia in the sense that voluntary euthanasia is where the consent is taken from the patient and non-voluntary euthanasia is where the consent is unavailable, for instances when the patient is in coma or is otherwise unable to give consent. Describing further about active euthanasia, the Division Bench had observed that the said type of euthanasia involves taking specific steps to cause the patient's death such as injecting the patient with some lethal substance i.e. sodium pentothal which causes, in a person, a state of deep sleep in a few seconds and the person instantly dies in that state. The Court further categorised passive euthanasia into voluntary passive euthanasia and non-voluntary passive euthanasia. The voluntary passive euthanasia has been described as a situation where a person who is capable of deciding for himself decides that he would prefer to die because of various reasons whereas non-voluntary passive euthanasia has been described to mean that a person is not in a position to decide for himself e.g. if he is in coma or PVS. (Paras 46 and 48)

Aruna Ramachandra Shanbaug v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294, *affirmed on this point*

Airedale N.H.S. Trust v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL); *Vacco* v. *Quill*, 1997 SCC OnLine US SC 80 : 138 L Ed 2d 834 : 521 US 793 (1997); *Rodriguez* v. *Attorney General of Canada*, 1993 SCC OnLine Can SC 97 : (1993) 3 SCR 519 : 85 CCC 3d 15; *Conroy, In re*, 98 NJ 321 : 486 A 2d 1209 (NJ 1985), *considered*

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After the judgment of *Aruna Shanbaug case* was delivered, the Law Commission of India submitted its 241st Report which dealt with "Passive Euthanasia — A Relook". The Report supports the view of several authorities especially Lord Browne-Wilkinson (in *Airedale case*) and Justice Cardozo that in case of any forced medical intervention on the body of a patient, the surgeon/doctor is guilty of "assault" or "battery". The Report also laid emphasis on the opinion of Lord Goff placing right of self-determination on a higher pedestal. (Paras 127 and 131)

Airedale N.H.S. Trust v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL); *F. (Mental Patient: Sterilisation), In re*, (1990) 2 AC 1 : (1989) 2 WLR 1025 : (1989) 2 All ER 545 (HL); *R. (Pretty)* v. *Director of Public Prosecutions*, (2002) 1 AC 800 : (2001) 3 WLR 1598 : (2002) 1 All ER 1 : 2001 UKHL 61 (HL); *B. (Consent to Treatment: Capacity), In re*, (2002) 1 FLR 1090 sub nom *B. (Adult: Refusal of Medical Treatment), In re*, (2002) 2 All ER 449; *R. (Nicklinson)* v. *Ministry of Justice*, 2015 AC 657 : (2014) 3 WLR 200 : 2014 UKSC 38; *Cruzan* v. *Missouri Department of Health*, 1990 SCC OnLine US SC 123 : 111 L Ed 2d 224 : 110 S Ct 2841 : 497 US 261 (1990); *Vacco* v. *Quill*, 1997 SCC OnLine US SC 80 : 138 L Ed 2d 834 : 521 US 793 (1997); *Hunter and New England Area Health Service* v. *A.*, 2009 NSWSC 761; *Brightwater Care Group (Inc.)* v. *Rossiter*, 2009 WASC 229 : 40 WAR 84; *Australian Capital Territory* v. *JT*, 2009 ACTSC 105; *Vikas Yadav* v. *State of U.P.*, (2016) 9 SCC 541 : (2016) 3 SCC (Cri) 621, *considered*

Bolam v. *Friern Hospital Management Committee*, (1957) 1 WLR 582 : (1957) 2 All ER 118 (QB); *Quinlan, In re*, 355 A 2d 647 : 70 NJ 10 (NJ 1976); *Garger* v. *New Jersey*, 429 US 922 (1976); *Supt. of Belchertown State School* v. *Saikewicz*, 373 Mass 728 : 370 NE 2d 417 (1977); *B. (A Minor) (Wardship: Medical Treatment), In re*, (1981) 1 WLR 1421 : (1990) 3 All ER 927 (CA); *J. (A Minor) (Wardship: Medical Treatment), In re*, 1991 Fam 33 (CA) : (1991) 2 WLR 140 : (1990) 3 All ER 930; *Pretty* v. *United Kingdom*, (2002) 35 EHRR 1 : 2002 ECHR 423; *Haas* v. *Switzerland*, (2011) 53 EHRR 33 : 2011 ECHR 2422; *Quill* v. *Vacco*, 80 F 3d 716 (2d Cir 1996); *Auckland Area Health Board* v. *Attorney General*, (1993) 1 NZLR 235 (HC); *Messiha* v. *South East Health*, 2004 NSWSC 1061; *Brightwater Care Group (Inc.)* v. *Rossiter*, 2009 WASC 229 : 40 WAR 84; *Australian Capital Territory* v. *JT*, 2009 ACTSC 105, *cited*

In *Aruna Shanbaug case* at para 101 the two-Judge Bench noted that *Gian Kaur case* has approved the decision of the House of Lords in *Airedale case* and observed that euthanasia could be made lawful only by legislation. This perception is not correct. The Constitution Bench of the Supreme Court in *Gian Kaur case* has not decried euthanasia as a concept. On the contrary, it gives an indication that in such situations, it is the acceleration of the process of dying which may constitute a part of right to life with dignity so that the period of suffering is reduced. It is understood and appreciated that there is a distinction between a positive or overt act to put an end to life by the person living his life and termination of life so that an individual does not remain in a vegetative state or, for that matter, when the death is certain because of terminal illness and he remains alive with the artificially assisted medical system. While dealing with the attempt to commit suicide, the Court clearly held that when a man commits suicide, he has to undertake certain positive overt acts and the genesis of those acts cannot be tested to or be included within the protection of the expression "right to life" under Article 21 of the Constitution. It was also observed that a dignified procedure of death may include the right of a dying man to also die with dignity when the life is ebbing out. (Paras 45, 44.2, 44.3, 202.3 and 202.4)

A careful and precise perusal of the judgment in *Gian Kaur case* reflects the right of a dying man to die with dignity when life is ebbing out, and in the case of a terminally-ill patient or a person in PVS, where there is no hope of recovery, accelerating the process of death for reducing the period of suffering constitutes a right to live with dignity. This is how the pronouncement in *Gian Kaur case* has to be understood. It is also not the ratio of the authority in *Gian Kaur case* that euthanasia has to be introduced only by a legislation. What has been stated in para 41 of *Gian Kaur case* is what has been understood to have been held in *Airedale case*. The Court has neither expressed any independent opinion nor has it approved the said part or the ratio as stated in *Airedale case*. There has been only a reference to *Airedale case* and the view expressed therein as regards legislation. Therefore, the perception in *Aruna Shanbaug case* that the Constitution Bench has approved the decision in *Airedale case* is not correct. It is also quite clear that *Gian Kaur case* does not lay down that passive euthanasia can only be thought of or given effect to by legislation. Appositely understood, it opens an expansive sphere of Article 21 of the Constitution and it cannot thus be treated as a binding precedent for the purpose of laying down the principle that passive euthanasia can be made lawful "only by legislation". *Gian Kaur case* has neither given any definite opinion with regard to euthanasia nor has it stated that the same can be conceived of only by a legislation. However, the view of *Aruna Shanbaug case* that euthanasia could be made lawful only by legislation, which has not been accepted by the referral Bench, makes no difference to the present analysis. (Paras 44.4, 45, 202.1 and 202.2)

Gian Kaur v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374, *explained*

Aruna Ramachandra Shanbaug v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294, *overruled on this point*

Airedale N.H.S. Trust v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL), *referred to*

Compassion in Dying v. *Washington*, 49 F 3d 586 (9th Cir 1995); *Compassion in Dying* v. *Washington*, 850 F Supp 1454 (WD Wash 1994); *R.* v. *Cox*, 18-9-1992 (unreported); *Vikram Deo Singh Tomar* v. *State of Bihar*, 1988 Supp SCC 734 : 1989 SCC (Cri) 66; *J. (A Minor) (Wardship: Medical Treatment), In re*, 1991 Fam 33 (CA) : (1991) 2 WLR 140 : (1990) 3 All ER 930; *Washington* v. *Glucksberg*, 1997 SCC OnLine US SC 79 : 138 L Ed 2d 772 : 521 US 702 (1997); *Vacco* v. *Quill*, 1997 SCC OnLine US SC 80 : 138 L Ed 2d 834 : 521 US 793 (1997); *Charan Lal Sahu* v. *Union of India*, (1990) 1 SCC 613; *State of Kerala* v. *N.M. Thomas*, (1976) 2 SCC 310 : 1976 SCC (L&S) 227; *Common Cause* v. *Union of India*, (2014) 5 SCC 338 : (2014) 2 SCC (Cri) 557, *cited*

Per Sikri, J. (concurring)

The word euthanasia appears to have come into usage in the early 17th century and was used in the sense of "*easy death*". The term is derived from the Greek "*euthanatos*", with "*eu*" meaning well, and "*thanatos*" meaning death. In ancient Greece and Rome, citizens were entitled to a good death to end the suffering of a terminal illness. The above Greek definition of euthanasia apart, it is a loaded term. People have been grappling with it for ages. Devised for service in a rhetoric of persuasion, the term "*euthanasia*" has no generally accepted and philosophically warranted core meaning. It is also defined as: *killing at the request of the person killed*. The popular conception which is widely accepted is that some sorts of life are not worth living; life in such a state demeans the patient's dignity, and maintaining it (otherwise than at the patient's express request) insults that dignity; proper respect for the patient and the patient's best interests requires that that life be

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brought to an end. In this thought process, the basic Greek ideology that it signifies "*an easy and gentle death*" still remains valid. (Paras 216 and 217)

Michael Manning: *Euthanasia and Physician-Assisted Suicide* (Paulist Press, 1998), *referred to*

In common parlance euthanasia can be of three types, namely, voluntary, non-voluntary and involuntary euthanasia. The terms can be described as under:

Voluntary euthanasia—People concerned to legalise the termination of life on medical grounds have always concentrated on voluntary euthanasia (this implies that the patient specifically requests that his life be ended). It is generally agreed that the request must come from someone who is either (*a*) in intolerable pain, or (*b*) who is suffering from an illness which is agreed as being terminal. It may be prior to the development of the illness in question or during its course. In either case it must not result from any pressure from relatives or those who have the patients in their care. Both active and passive euthanasia can be termed as forms of voluntary euthanasia. These definitions of voluntary, non-voluntary and involuntary euthanasia correspond to those employed by the House of Lords Select Committee on Medical Ethics (Walton Committee). (Para 218.1)

Non-voluntary euthanasia—Seen by some as subvariety of voluntary euthanasia. This involves the death, ostensibly for his own good, of someone who cannot express any views on the matter and who must, therefore, use some sort of proxy request that his/her life be ended. This form of euthanasia is that which most intimately concerns the medical profession. Selective non-treatment of the newborn or the doctor may be presented with demented and otherwise senilely incompetent patients. In practice, non-voluntary euthanasia presents only as an arguable alternative to non-treatment. (Para 218.2)

Involuntary euthanasia—It involves ending the patient's life in the absence of either a personal or proxy invitation to do so. The motive "the relief from suffering" may be the same as voluntary euthanasia—but its only justification — "a paternalistic decision as to what is best for the victim of the disease". In extreme cases, it could be against the patient's wishes or could be just for social convenience. It is examples of the latter which serve as warnings as to those who would invest the medical professional with more or unfettered powers over life and death. (Para 218.3)

"Euthanasia and Its Legality and Legitimacy from Indian and International Human Right Instruments Perspectives" in *Human Rights & Social Justice* by Muzafer Assadi, *referred to*

Contrary to the above, in legal parlance, euthanasia has since come to be recognised as of two distinct types: the first is active euthanasia, where death is caused by the administration of a lethal injection or drugs. Active euthanasia also includes physician-assisted suicide, where the injection or drugs are supplied by the physician, but the act of administration is undertaken by the patient himself. Active euthanasia is not permissible in most countries. (Para 219)

Passive euthanasia occurs when medical practitioners do not provide life-sustaining treatment (i.e. treatment necessary to keep a patient alive) or remove patients from life-sustaining treatment. This could include disconnecting life support machines or feeding tubes or not carrying out life-saving operations or providing life-extending drugs. In such cases, the omission by the medical

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practitioner is not treated as the cause of death; instead, the patient is understood to have died because of his underlying condition. (Para 219)

In *Aruna Ramachandra Shanbaug case*, the Court recognised these two types of euthanasia i.e. active and passive. It also noted that active euthanasia is impermissible, which was so held by the Constitution Bench in *Gian Kaur case*. Therefore, without going into further debate on differential that is assigned to the term "euthanasia", ethically, philosophically, medically, etc., discussion should be confined to the aforesaid legal meaning assigned to active and passive euthanasia. Thus, insofar as active euthanasia is concerned, this has to be treated as legally impermissible, at least for the time being. It is more so, as there is absence of any statutory law permitting active euthanasia. If at all, legal provisions in the form of Sections 306 and 307 IPC, etc. point towards its criminality. The discussion henceforth, therefore, would confine to passive euthanasia. (Para 220)

Gian Kaur v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374, *relied on*

Aruna Ramachandra Shanbaug v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294, *affirmed on this point*

Per Chandrachud, J. (concurring)

Central to the debate are notions such as "involuntary", "non-voluntary" and "voluntary". Also "active" and "passive" are used, particularly in combination with "voluntary" euthanasia. In general, the following might be said:

(*i*) involuntary euthanasia refers to the termination of life against the will of the person killed;

(*ii*) non-voluntary euthanasia refers to the termination of life without the consent or opposition of the person killed;

(*iii*) voluntary euthanasia refers to the termination of life at the request of the person killed;

(*iv*) active euthanasia refers to a positive contribution to the acceleration of death;

(*v*) passive euthanasia refers to the omission of steps which might otherwise sustain life. (Para 384)

What is relatively straightforward is that involuntary euthanasia is illegal and amounts to murder. However, the boundaries between active and passive euthanasia are blurred since it is quite possible to argue that an omission amounts to a positive act. (Para 384)

Consent postulates that the individual is in a mental condition which enables her to choose and to decide on a course of action and convey this decision. Its voluntary nature is premised on its consensual character. Euthanasia becomes non-voluntary where the individual has lost those faculties of mind which enable her to freely decide on the course of action or lost the ability to communicate the chosen course of action. (Para 385)

Passive euthanasia—whether in the form of withholding or withdrawing treatment—has the effect of removing, or as the case may be, not providing supportive treatment. Its effect is to allow the individual to continue to exist until the end of the natural span of life. On the other hand, active euthanasia involves hastening of death: the lifespan of the individual is curtailed by a specific act

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designed to bring an end to life. Active euthanasia would on the state of the penal law as it stands constitute an offence. Hence, it is only Parliament which can in its legislative wisdom decide whether active euthanasia should be permitted. Passive euthanasia on the other hand would not implicate a criminal offence since the decision to withhold or withdraw artificial life support after taking into account the best interest of the patient would not constitute an illegal omission prohibited by law. (Para 450)

R. (Conway) v. *Secy. of State for Justice*, (2018) 2 WLR 322 : 2017 EWHC 2447 (Admin), *considered*

R. (Countryside Alliance) v. *Attorney General*, 2008 AC 719 : (2007) 3 WLR 922 (HL); *AXA General Insurance Ltd.* v. *HM Advocate*, (2012) 1 AC 868 : (2011) 3 WLR 871 (SC), *cited*

The distinctions between active and passive euthanasia are based on the manner in which death is brought about. They closely relate to the understanding and consequences of the legal concepts of act and omission. The expression "passive" has been used to denote the withdrawal or withholding of medical treatment. Implicit in this definition is the assumption that both the withdrawal of or withholding treatment stand on the same ethical or moral platform. There is a qualitative difference between a positive medical intervention (such as a lethal injection) which terminates life and a decision to not put a patient on artificial life support, which will not artificially prolong life. The former brings a premature extinction of life. The latter does not delay the end of life beyond its natural end point. Even though euthanasia is grounded in compassion and to relieve the patient of suffering, only certain types of deaths can be lawful. If active euthanasia amounts to "killing", the operation of criminal law can lead to medical practitioners being exposed to the indignity of criminal prosecutions and punishments. While passive euthanasia can appear to save the dignity of medical practitioners, it is perhaps at the expense of the patient's dignity. (Paras 385, 386, 388 and 390)

Hazel Biggs: "Euthanasia, Death with Dignity and the Law" (Hart Publishing, 2001), at pp. 12, 162; James Rachels: "Active and Passive Euthanasia", New England Journal of Medicine (9-1-1975), at pp. 78-80; James Rachels: *End of Life: Euthanasia and Morality* (Oxford University Press, 1986); Bruce R. Reichenbach: "Euthanasia and the Active-Passive Distinction", *Bioethics* (January 1987), Vol. 1, at pp. 51-73; James Rachels: *End of Life: Euthanasia and Morality* (Oxford University Press, 1986), at pp. 101-20; Len Doyal and Lesley Doyal: "Why Active Euthanasia and Physician-Assisted Suicide should be Legalised if Death is in a Patient's Best Interest Then Death Constitutes a Moral Good", British Medical Journal (2001), at pp. 1079-80; Rohini Shukla: "Passive Euthanasia in India: A Critique", Indian Journal of Medical Ethics (Jan-Mar 2016), pp. 35-38; Aparna Chandra and Mrinal Satish: "Misadventures of the Supreme Court in *Aruna Shanbaug* v. *Union of India*", *Law and Other Things* (13-3-2011) <http://lawandotherthings.com/2011/03/misadventures-of-supreme-court-in-aruna/>; Ratna Kapur: "The Spectre of Aruna Shanbaug", *The Wire* (18-5-2015) <https://thewire.in/2005/the-spectre-of-aruna-shanbaug/>, *referred to*

But, if the decision to proceed with euthanasia is the right one based on compassion and the humanitarian impulse to reduce pain and suffering, then the method used is not in itself important. Moreover, it is argued that passive euthanasia often involves more suffering since simply withholding treatment means that the patient may take longer to die and thus suffer more. Passive euthanasia may become questionable where the withholding or withdrawal of medical intervention may lead to a condition of pain and suffering, often a lingering and cruel death. The avoidance of suffering, which is the object and purpose of euthanasia, may hence

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not be the result of passive euthanasia and the converse may result. Besides raising troubling moral questions—especially where it is non-voluntary, it questions the efficacy of passive euthanasia. Moreover, it raises a troubling issue of the validity of the active-passive divide. (Paras 388 and 450)

Aruna Shanbaug judgment has been criticised in an article by Rohini Shukla in Indian Journal of Medical Ethics (2016) on the ground that it does not distinguish between the terms "withholding and withdrawing and uses them interchangeably". Throughout the above judgment, the words "withholding" and "withdrawing" are used interchangeably. However, the difference between the two is relevant to the distinction between what is "active" and "passive" as act and omission. Withholding life support implies that crucial medical intervention is restrained or is not provided—an act of omission on the part of the doctor. Withdrawing life support implies suspending medical intervention that was already in use to sustain the patient's life—an act of commission. If the basis of distinction between active and passive euthanasia is that in passive euthanasia the doctor only passively commits acts of omission, while in active euthanasia the doctor commits acts of commission then withdrawing medical treatment is an act of commission and therefore amounts to active euthanasia. In both these cases, the doctor is aware that his/her commissions or omissions will in all likelihood lead to the patient's death. However, in passive euthanasia death may not be the only consequence and the suffering that passive euthanasia often entails such as suffocation to death or starvation till death, raises the question of whether passive euthanasia, in such circumstances, militates against the idea of death with dignity—the very basis of legalising euthanasia. Shukla's criticism needs careful attention since it raises profound questions about the doctor-patient relationship and the efficacy of the distinction in the context of death with dignity. Where there is a duty to care, the distinction between an act and an omission may have questionable relevance. Acts and omissions are not disjunctive or isolated events. Treatment of the human body involves a continuous association between the caregiver and receiver. The expert caregiver is involved in a continuous process where medical knowledge and the condition of the patient as well as the circumstances require the doctor to evaluate choices—choices on the nature and extent of medical intervention, the wisdom about a course of action and about what should or should not be done. If the divide between active-passive is questioned, should both forms be disallowed or, in converse should both be allowed? More significantly, are both equally amenable to judicially manageable standards? (Paras 391 and 392)

Since the judgment legalised passive euthanasia, withdrawing medical support was the only option in *Aruna Shanbaug case* and if this had been done, she would have in all likelihood suffocated to death. Question is whether this could be the best possible death in consonance with the right to live with dignity (which extends to dignity when death approaches) and the extent to which it upholds the principle of prioritising the patient's autonomy and dignity over mere prolongation of life. Had the Court taken into account these consequences of passive euthanasia for the patient, it would be apparent that passive euthanasia is not a simple panacea for an individual faced with end of life suffering. (Para 394)

Aruna Ramachandra Shanbaug v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294, *disapproved on this point*

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The second and more critical flaw in *Aruna Shanbaug* judgment was the unjustified emphasis on doctor's agency in administering different types of euthanasia which led to ignoring the patient's autonomy and suffering. Respecting patient autonomy and reducing suffering are fundamental ethical values ascribed to euthanasia. It is also the foremost principle of bioethics. The effects of euthanasia on everyone (particularly her caregivers) were given greater importance than the patient's own wishes. (Para 395)

Aruna Ramachandra Shanbaug v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294, *disapproved on this point*

Roop Gurusahani and Raj Kumar Mani: "India: Not a Country to Die in", Indian Journal of Medical Ethics (Jan-Mar 2016), at pp. 30-35, *referred to*

Even while there are pertinent questions regarding the moral validity of the active-passive distinction, there appears to be a significant difference between active and passive euthanasia when viewed from the lens of the patient's consent. Consent gives an individual the ability to choose whether or not to accept the treatment that is offered. But consent does not confer on a patient the right to demand that a particular form of treatment be administered, even in the quest for death with dignity. Voluntary passive euthanasia, where death results from selective non-treatment because consent is withheld, is therefore legally permissible while voluntary active euthanasia is prohibited. Moreover, passive euthanasia is conceived with a purpose of not prolonging the life of the patient by artificial medical intervention. Both in the case of a withdrawal of artificial support as well as in non-intervention, passive euthanasia allows for life to ebb away and to end in the natural course. In contrast, active euthanasia results in the consequence of shortening life by a positive act of medical intervention. It is perhaps this distinction which necessitates legislative authorisation for active euthanasia, as differentiated from the passive. (Para 398)

The question of legality of these two forms of euthanasia has significant consequences. Death when it is according to the wishes and in the caregiver of the patient must be viewed as a moral good. The fact that active euthanasia is an illegal act (absent legislative authorisation) also prevents many professional and emotional carers from performing it even if they perceive it as a compassionate and otherwise appropriate response in line with the patient's wishes and caregiver, thereby prolonging the patient's suffering and indignity. These complex issues cannot be addressed when active euthanasia is not legalised and regulated. The meeting point between bioethics and law does not lie on a straight course. (Para 399)

The decision by a treating doctor to *withhold* or *withdraw* medical intervention in the case of a patient in the terminal stage of illness or in a persistently vegetative state or the like where artificial intervention will merely prolong the suffering and agony of the patient is protected by the law. Where the doctor has acted in such a case in the best interest of the patient and in bona fide discharge of the duty of care, the law will protect the reasonable exercise of a professional decision. (Para 521)

"The Dilemmas of Euthanasia", *Bio-Science* (August 1973), Vol. 23, No. 8, at p. 459; Margaret A. Somerville: "Legalising euthanasia: Why Now?", The Australian Quarterly (Spring 1996), Vol. 68, No. 3, at p. 1; Christopher N. Manning: "Live and Let Die: Physician-Assisted Suicide and the Right to Die", Harvard Journal of Law and Technology (1996), Vol. 9, No. 2, at p. 513; Alan Norrie: "Legal Form and Moral Judgement: Euthanasia and Assisted Suicide" in R.A. Duff, et al (ed), *The Structures of the Criminal Law* (Oxford

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University Press, 2011), at p. 134; Elizabeth Wicks: *The Right to Life and Conflicting Interests* (Oxford University Press, 2010), at p. 199; Elizabeth M. Andal Sorrentino: "The Right to Die?", Journal of Health and Human Resources Administration (Spring, 1986), Vol. 8, No. 4, p. 361; Atul Gawande: *Being Mortal: Medicine and What Matters in the End* (Hamish Hamilton, 2014), at p. 260; Henry Marsh: *Admissions: A Life in Brain Surgery*, (Weidenfeld & Nicolson, 2017), at pp. 265-66; Randy Pausch and Jeffrey Zaslow: *The Last Lecture*, (Hodder & Stoughton, 2008), at p. 17, *referred to*

The decision in *Aruna Shanbaug case* has proceeded on the hypothesis that the Constitution Bench in *Gian Kaur case* had "quoted with approval" the decision of the House of Lords in *Airedale case*. This hypothesis is incorrect. There was only a passing reference to the decision of the House of Lords. The decision in *Gian Kaur case* referred to the distinction made in *Airedale case* between cases in which a physician decides not to provide or to continue to provide treatment which would prolong life and cases in which a physician decides to actively bring an end to the life of the patient by administering a lethal drug. The Court in *Airedale case* observed that actively causing the death of the patient could be made lawful only by legislation. It was this aspect which was emphasised by the judgment in *Gian Kaur case*. Hence, the position adopted in *Aruna Shanbaug case*, that the Constitution Bench in *Gian Kaur case* quoted *Airedale case* with approval (as the basis of allowing passive euthanasia) is seriously problematic. (Para 376)

Ratna Kapur: "The Spectre of Aruna Shanbaug", *The Wire* (18-5-2015) <https://thewire.in/2005/the-spectre-of-aruna-shanbaug/>, *referred to*

Per Ashok Bhushan, J. (concurring)

Euthanasia is derived from the Greek word *euthanatos*; *eu* means well or good and *thanatos* means death. (Para 597)

In ancient Greek society, euthanasia as "good death" was associated with the drinking of "Hemlock". In last few centuries, euthanasia increasingly came to connote specific measures taken by physicians to hasten the death. The primary meaning, as has now been ascribed to the word is compassionate murder. In the last century, the thought has gained acceptance that euthanasia is to be distinguished from withdrawal of life saving treatments which may also result in death. Withdrawing medical treatment in a way hasten the death in case of terminal illness or persistent vegetative state (PVS) but is not to be treated as compassionate murder. Advancement in the medical science on account of which life can be prolonged by artificial devices are the developments of only last century. (Para 599)

Airedale N.H.S. Trust v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL), *relied on*

The withdrawal of medical treatment of terminally ill persons is a complex ethical, moral and social issue with which many countries have wrestled with their attempt to introduce a legal framework for end of life decision-making. In absence of a comprehensive legal framework on the subject the issue has to be dealt with great caution. (Para 557)

The act of withdrawal from live-saving devices is an independent right which can lawfully be exercised by informed decision. Withdrawal of medical assistance or withdrawal of medical devices which artificially prolong the life cannot be regarded as an act to achieve a good death. Artificial devices to prolong the life are implanted, when a person is likely to die due to different causes in his body.

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Lifesaving treatment and devices are put by physicians to prolong the life of a person. (Paras 609 and 603)

Withdrawal of life-saving devices, leads to natural death which is arrested for the time being due to above device and the act of withdrawal put the life on the natural track. Decision to withdraw life-saving devices is not an act to cause good death of the person rather, decision to withdraw or not to initiate life-supporting measures is a decision when treatment becomes futile and unnecessary. Practice of euthanasia in this country is prohibited and for medical practitioners it is already ordained to be unethical conduct. (Para 606)

K.S. Puttaswamy v. *Union of India*, (2017) 10 SCC 1, *relied on*

A critically ill patient who is mentally competent to take a decision, decides not to take support of life prolonging measures, and respecting his wisdom if he is not put on such devices like ventilator, etc. it is not at all euthanasia. Large number of persons in advance age of life decide not to take medical treatment and embrace death in its natural way; their death cannot be termed as euthanasia. The decision not to take lifesaving medical treatment by a patient, who is competent to express his opinion cannot be termed as euthanasia, but a decision to withdraw lifesaving treatment by a patient who is competent to take decision as well as with regard to a patient who is not competent to take decision can be termed as passive euthanasia. On the strength of the precedents in this country and weight of precedents of other countries, such action of withdrawing lifesaving device is legal. Thus, such acts, which are commonly expressed as passive euthanasia is lawful and legally permissible in this country. (Para 607)

Court is not a legislative body nor is entitled or competent to act as a moral or ethical arbiter. The task of the Supreme Court is not to weigh or evaluate or reflect different beliefs and views or give effect to its own but to ascertain and build the law of land as it is now understood by all. Message which need to be sent to vulnerable and disadvantaged people should not, however, obliviously to encourage them to seek death but should assure them of care and support in life. (Para 608)

Nancy B. v. *Hotel Dieu de Quebec*, (1992) 86 DLR (4th) 385 (Que SC); *T. (Adult: Refusal of Treatment), In re*, 1993 Fam 95 : (1992) 3 WLR 782 : (1992) 4 All ER 649 (CA); *B. (Adult: Refusal of Medical Treatment), In re*, (2002) 2 All ER 449; *S.* v. *McC. (Orse. S.) and M. (D.S. Intervener)*, 1972 AC 24 : (1970) 3 WLR 366 (HL); *R. (Pretty)* v. *Director of Public Prosecutions*, (2002) 1 AC 800 : (2001) 3 WLR 1598 : (2002) 1 All ER 1 : 2001 UKHL 61 (HL); *Schloendorff* v. *Society of New York Hospital*, 105 NE 92 : 211 NY 125 (1914); *Cruzan* v. *Missouri Department of Health*, 1990 SCC OnLine US SC 123 : 111 L Ed 2d 224 : 110 S Ct 2841 : 497 US 261 (1990); *Compassion in Dying* v. *Washington*, 79 F 3d 790 (1996); *Vacco* v. *Quill*, 1997 SCC OnLine US SC 80 : 138 L Ed 2d 834 : 521 US 793 (1997); *Washington* v. *Glucksberg*, 1997 SCC OnLine US SC 79 : 138 L Ed 2d 772 : 521 US 702 (1997); *Rodriguez* v. *Attorney General of Canada*, 1993 SCC OnLine Can SC 97 : (1993) 3 SCR 519 : 85 CCC 3d 15; *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374, *referred to*

Pratt v. *Davis*, 224 Ill 300 : 79 NE 562 (1906); *Mohr* v. *Williams*, 95 Minn 261 : 104 NW 12 (1905); *Union Pacific Rly. Co.* v. *Botsford*, 1891 SCC OnLine US SC 217 : 35 L Ed 734 : 11 S Ct 1000 : 141 US 250 (1891); *Conroy, In re*, 98 NJ 321 : 486 A 2d 1209 (NJ 1985); *Quill* v. *Vacco*, 80 F 3d 716 (2d Cir 1996); *Stanford* v. *Kentucky*, 1989 SCC OnLine US SC 151 : 106 L Ed 2d 306 : 109 S Ct 2969 : 492 US 361 (1989), *cited*

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E. **Constitution of India — Art. 21 — Constitutional value of euthanasia — Considered having regard to theological, philosophical and constitutional models**

— Life, liberty and dignity — Human dignity in euthanasia — Though right to life does not include right to die (*Gian Kaur case*), but right to live with dignity protected under Art. 21 includes right to live with dignity up to end of natural life by smoothening process of dying — Dignity in death has a sense of realism that permeates right to life — Right to dignity is neither lost in process of dying nor when death occurs — Individual cannot be deprived of his/her dignity till end of his/her life — Right to die with dignity being legal, neither morality, not doctor's dilemma, nor patient's fear will have any place — There is constitutional expectation of providing dignity in death which is protected under Art. 21 and is enforceable against the State

— Life, liberty and dignity — Human dignity is an inextricable facet of right to life — It is intrinsic in preserving sanctity and quality of life — Liberty, autonomy and self-determination are its essential attributes

— Life and liberty — Connotation and amplitude — Both are interlinked concepts — Together they constitute right of core significance

— Liberty — Of personal sovereignty over body and mind falls under Art. 21

— Life and natural death — Life is not mere biological existence — It relates to quality of life — Prolongation of life by means of modern medical technology of a patient who is terminally ill, in PVS or brain dead state — In certain circumstances it renders life to mere biological existence — Thus notion of life is reshaped

— Right to privacy — It is constitutional core of dignity — Comprehends right to take decisions relating to own bodily integrity and death by refusing medical treatment — Every person has a right to make essential choices which affect course of life — Patient's right to refuse life prolonging medical treatment or terminate his/her life, is a freedom which falls within ambit of privacy — Continuing treatment against wishes of patient violative of his/her bodily privacy — Patient must have freedom to decide whether to continue living when quality of life deteriorates

— Right to health — A facet of Art. 21

— Sanctity of life — Meaning and limits — Concepts of sacred value and inviolability of human life considered in context of religion, morality and ethics, as also right to life, autonomy and quality of life — Quality of life needs to be protected — When a person is only alive in most rudimentary sense without having any capacity to experience pleasure or pain, life loses its value — Rule against killing applies where person has life in qualitative sense not where person living merely in vegetative sense — Human and Civil Rights — Right to Die/Euthanasia

F. **Constitution of India — Pt. III — Fundamental Rights — Liberal, dynamic and expansive interpretation needed**

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G. Jurisprudence — Law and morality — Normally moral basis of law is not required to be examined by court in its interpretative process — But moral aspect gains significance when some legal norms are jurisprudentially expounded by courts or developed as common law principles — Common Law

Held :

Per Dipak Misra, C.J. and Khanwilkar, J.

Life and liberty

Under Article 21 of the Constitution word "liberty" is the sense and realisation of choice of the attributes associated with the said choice; and the term "life" is the aspiration to possess the same in a dignified manner. The two are intrinsically interlinked. Liberty impels an individual to change and life welcomes the change and the movement. Life does not intend to live sans liberty as it would be, in all possibility, a meaningless survival. (Para 142)

The language employed in the constitutional provision should be liberally construed, for such provision can never remain static. It is because staticity would mar the core which is not the intent. The interpretation of the Constitution, especially fundamental rights, has to be dynamic and it is only such interpretative dynamism that breathes life into the written words. As far as Article 21 is concerned, it is imperative to mention that dynamism can, of course, infuse life into life and liberty as used in the said Article. The word "liberty" is the sense and realisation of choice of the attributes associated with the said choice; and the term "life" is the aspiration to possess the same in a dignified manner. The two are intrinsically interlinked. Liberty impels an individual to change and life welcomes the change and the movement. Life does not intend to live sans liberty as it would be, in all possibility, a meaningless survival. (Paras 153, 149 and 142)

There is no doubt that no fundamental right is absolute, but any restraint imposed on liberty has to be reasonable. The concept of liberty perceives a hazard when it feels it is likely to become hollow. This necessarily means that there would be liberty available to individuals subject to permissible legal restraint and it should be made clear that in that restraint, free ideas cannot be imprisoned by some kind of unknown terror. Liberty cannot be a slave because it constitutes the essential marrow of life and that is how the conception of liberty is intended to be understood when it is read in association with the term "life" as used in Article 21 of the Constitution. Life as envisaged under Article 21 has been very broadly understood by the Supreme Court. (Paras 142, 144 and 145)

The fundamental rights in their connotative expanse are bound to engulf certain rights which really flow from the same. Liberty allows freedom of speech, association and dissemination without which the society may face hurdles in attaining the requisite maturity. History is replete with narratives how the thoughts of individuals, though not accepted by the contemporaneous society, later on gained not only acceptance but also respect. There is a danger in discouraging free thinking and curtailing the power of imagination. (Paras 151 and 143)

Adkins v. *Children's Hospital of the District of Columbia*, 1923 SCC OnLine US SC 105 : 67 L Ed 785 : 261 US 525 (1923); *Maneka Gandhi* v. *Union of India*, (1978) 1 SCC 248; *M. Nagaraj* v. *Union of India*, (2006) 8 SCC 212 : (2007) 1 SCC (L&S) 1013, *relied on*

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Port of Bombay v. *Dilipkumar Raghavendranath Nadkarni*, (1983) 1 SCC 124 : 1983 SCC (L&S) 61; *State of A.P.* v. *Challa Ramkrishna Reddy*, (2000) 5 SCC 712; *Central Inland Water Transport Corpn. Ltd.* v. *Brojo Nath Ganguly*, (1986) 3 SCC 156 : 1986 SCC (L&S) 429; *V.C. Rangadurai* v. *D. Gopalan*, (1979) 1 SCC 308, *affirmed on this point*

P. Rathinam v. *Union of India*, (1994) 3 SCC 394 : 1994 SCC (Cri) 740; *State of H.P.* v. *Umed Ram Sharma*, (1986) 2 SCC 68; *Maruti Shripati Dubal* v. *State of Maharashtra*, 1986 SCC OnLine Bom 278 : 1987 Cri LJ 743 : (1986) 88 Bom LR 589; *Rustom Cowasjee Cooper* v. *Union of India*, (1970) 2 SCC 298; *Carter* v. *Attorney General of Canada*, 2015 SCC OnLine Can SC 1 : 2015 SCC 5, *referred to*

Earl of Oxford, In re, 1625 Jones, W. 97 : (1626) 82 ER 51 (HL), *cited*

Dignity

Right to life and liberty as envisaged under Article 21 of the Constitution is meaningless unless it encompasses within its sphere individual dignity. With the passage of time, the Supreme Court has expanded the spectrum of Article 21 to include within it the right to live with dignity as component of right to life and liberty. (Para 202.9)

The nine-Judge Bench of the Supreme Court in *Puttaswamy case* has reaffirmed that human dignity is a component of Article 21. Life without dignity is like a sound that is not heard. Dignity speaks, it has its sound, it is natural and human. It is a combination of thought and feeling, and it deserves respect even when the person is dead and described as a "body". Dignity does not recognise or accept any nexus with the status or station in life. The singular principle that it pleasantly gets beholden to is the integral human right of a person. Law gladly takes cognizance of the fact that dignity is the most sacred possession of a man. And the said possession neither loses its sanctity in the process of dying nor evaporates when death occurs. The concept is based on non-prolongation of life where there is no cure for the state the patient is in and he, under no circumstances, would have liked to have such a degrading state needs consideration. The words "no cure" have to be understood to convey that the patient remains in the same state of pain and suffering or the dying process is delayed by means of taking recourse to modern medical technology. It is a state where the treating physicians and the family members know fully well that the treatment is administered only to procrastinate the continuum of breath of the individual and the patient is not even aware that he is breathing. Life is measured by artificial heartbeats and the patient has to go through this undignified state which is imposed on him. The dignity of life is denied to him as there is no other choice but to suffer an avoidable protracted treatment thereby thus indubitably casting a cloud and creating a dent in his right to live with dignity and face death with dignity, which is a preserved concept of bodily autonomy and right to privacy. In such a stage, he has no old memories or any future hopes but he is in a state of misery which nobody ever desires to have. Some may also silently think that death, the inevitable factum of life, cannot be invited. To meet such situations, the Court has a duty to interpret Article 21 in a further dynamic manner and it has to be stated without any trace of doubt that the right to life with dignity has to include the smoothening of the process of dying when the person is in a vegetative state or is living exclusively by the administration of artificial aid that prolongs the life by arresting the dignified and inevitable process of dying. Here, the issue of choice also comes in. Thus analysed, such a right would come within the ambit of Article 21 of the Constitution. (Paras 156, 160 and 166)

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It has to be stated without any trace of doubt that the right to live with dignity also includes the smoothening of the process of dying in case of a terminally-ill patient or a person in PVS with no hope of recovery. (Para 202.10)

K.S. Puttaswamy v. *Union of India*, (2017) 10 SCC 1; *Christine Goodwin* v. *United Kingdom*, 2002 ECHR 588; *S.* v. *Makwanyane*, 1995 SCC OnLine ZACC 2 : (1995) 3 SA 391, *relied on*

Kharak Singh v. *State of U.P.*, (1964) 1 SCR 332 : AIR 1963 SC 1295 : (1963) 2 Cri LJ 329; *Gobind* v. *State of M.P.*, (1975) 2 SCC 148 : 1975 SCC (Cri) 468; *PUCL* v. *Union of India*, (1997) 1 SCC 301; *Cruzan* v. *Missouri Department of Health*, 1990 SCC OnLine US SC 123 : 111 L Ed 2d 224 : 110 S Ct 2841 : 497 US 261 (1990), *referred to*

In *Gian Kaur case* the Court expounded that the word "life" in Article 21 has been construed as life with human dignity and it takes within its ambit the "right to die with dignity" being part of the "right to live with dignity". Further, the "right to live with human dignity" would mean existence of such a right up to the end of natural life which would include the right to live a dignified life up to the point of death including the dignified procedure of death. A dying man who is terminally ill or in a persistent vegetative state can make a choice of premature extinction of his life as being a facet of Article 21 of the Constitution. If that choice is guaranteed being part of Article 21, there is no necessity of any legislation for effectuating that fundamental right and more so his natural human right. Indeed, that right cannot be an absolute right but subject to regulatory measures to be prescribed by a suitable legislation which, however, must be reasonable restrictions and in the interests of the general public. As part of the right to die with dignity in case of a dying man who is terminally ill or in a persistent vegetative state, only passive euthanasia would come within the ambit of Article 21 and not the one which would fall within the description of active euthanasia in which positive steps are taken either by the treating physician or some other person. That is because the right to die with dignity is an intrinsic facet of Article 21. (Paras 164 and 165)

Gian Kaur v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374, *relied on*

Mehmood Nayyar Azam v. *State of Chhattisgarh*, (2012) 8 SCC 1 : (2012) 4 SCC (Civ) 34 : (2012) 3 SCC (Cri) 733 : (2012) 2 SCC (L&S) 449; *Vikas Yadav* v. *State of U.P.*, (2016) 9 SCC 541 : (2016) 3 SCC (Cri) 621; *Francis Coralie Mullin* v. *State (UT of Delhi)*, (1981) 1 SCC 608 : 1981 SCC (Cri) 212; *National Legal Services Authority* v. *Union of India*, (2014) 5 SCC 438; *Shabnam* v. *Union of India*, (2015) 6 SCC 702 : (2015) 3 SCC (Cri) 355, *affirmed*

Vikas Yadav v. *State of U.P.*, 2015 SCC OnLine Del 7129, *held, affirmed on this point*

Sushila Rao: "India and Euthanasia: The Poignant Case of Aruna Shanbaug", Oxford Medical Law Review, Vol. 19, Issue 4 (1-12-2011), at pp. 646-656; "Humanization and Decriminalization of Attempt to Suicide", Law Commission of India (Report No. 210, 2008); Rajeev Ranjan, et al, "(De-) Criminalization of Attempted Suicide in India: A Review", Industrial Psychiatry Journal (2014), Vol. 23, Issue 1, at pp. 4-9; D. Benatar, "Should There be a Legal Right to Die?" *Current Oncology* (2010), Vol. 17, Issue 5, at pp. 2-3; Richard Delgado: "Euthanasia Reconsidered—The Choice of Death as an Aspect of the Right of Privacy", Arizona Law Review (1975), Vol. 17, at p. 474., *referred to*

Per Sikri, J. (concurring)

Life, liberty, dignity, privacy

Euthanasia is a complexed and complicated issue. Article 21 of the Constitution has been interpreted by the Court in most expansive terms, particularly when it comes to the meaning that is assigned to "right to life". Right to life has

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been treated as more than "mere animal existence". Article 21 recognises right to live with human dignity. The legal position which stands as of today is that right to life does not include right to die. Although "right to life" under Article 21 does not include "*right to die*", but "right to live with dignity" includes "*right to die with dignity*". (Paras 236, 238, 241 and 330)

Kharak Singh v. *State of U.P.*, (1964) 1 SCR 332 : AIR 1963 SC 1295 : (1963) 2 Cri LJ 329; *K.S. Puttaswamy* v. *Union of India*, (2017) 10 SCC 1; *Rustom Cavasjee Cooper* v. *Union of India*, (1970) 1 SCC 248; *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374; *State* v. *Sanjay Kumar Bhatia*, 1985 SCC OnLine Del 134 : 1985 Cri LJ 931; *Maruti Shripati Dubal* v. *State of Maharashtra*, 1986 SCC OnLine Bom 278 : 1987 Cri LJ 743; *Chenna Jagadeeswar* v. *State of A.P.*, 1987 SCC OnLine AP 263 : 1988 Cri LJ 549; *P. Rathinam* v. *Union of India*, (1994) 3 SCC 394 : 1994 SCC (Cri) 740; *CESC Ltd.* v. *Subhash Chandra Bose*, (1992) 1 SCC 441 : 1992 SCC (L&S) 313; *Prem Shankar Shukla* v. *State (UT of Delhi)*, (1980) 3 SCC 526 : 1980 SCC (Cri) 815; *Francis Coralie Mullin* v. *State (UT of Delhi)*, (1981) 1 SCC 608 : 1981 SCC (Cri) 212; *Bandhua Mukti Morcha* v. *Union of India*, (1984) 3 SCC 161 : 1984 SCC (L&S) 389; *Khedat Mazdoor Chetna Sangath* v. *State of M.P.*, (1994) 6 SCC 260 : 1994 SCC (Cri) 1643; *M. Nagaraj* v. *Union of India*, (2006) 8 SCC 212 : (2007) 1 SCC (L&S) 1013; *Maharashtra University of Health Sciences* v. *Satchikitsa Prasarak Mandal*, (2010) 3 SCC 786 : (2010) 1 SCC (L&S) 894; *Selvi* v. *State of Karnataka*, (2010) 7 SCC 263 : (2010) 3 SCC (Cri) 1; *Mehmood Nayyar Azam* v. *State of Chhattisgarh*, (2012) 8 SCC 1 : (2012) 4 SCC (Civ) 34 : (2012) 3 SCC (Cri) 733 : (2012) 2 SCC (L&S) 449; *Shabnam* v. *Union of India*, (2015) 6 SCC 702 : (2015) 3 SCC (Cri) 355; *Jeeja Ghosh* v. *Union of India*, (2016) 7 SCC 761 : (2016) 3 SCC (Civ) 551, *referred to*

Ronald Dworkin: *Taking Rights Seriously* (A&C Black, 2013) 239; Ronald Dworkin: *Is Democracy Possible Here? Principles for a New Political Debate* (Princeton University Press, 2006); Harvard University Press, 2011; Kenneth W. Simons: "Dworkin's Two Principle of Dignity: An Unsatisfactory Non-consequentialist Account of Interpersonal Moral Duties", 90 Boston Law Rev. 715 (2010); Aharon Barak: *Human Dignity: The Constitutional Value and the Constitutional Right*, *referred to*

As the process of dying is an inevitable consequence of life, the right to life necessarily implies the right to have nature take its course and to die a natural death. It also encompasses a right, unless the individual so wishes, not to have life artificially maintained by the provision of nourishment by abnormal artificial means which have no curative effect and which are intended merely to prolong life. According to John Finnis, there is no real and morally relevant distinction between active euthanasia and passive euthanasia inasmuch as one employs the method of deliberate omissions (or forbearances or abstentions) in order to terminate life (passive euthanasia) and other employs "a deliberate intervention" for the same purpose (active euthanasia). In this sense, in both the cases, it is an intentional act whether by omission or by intervention, to put an end to somebody's life and, therefore, morally wrong. (Para 269)

Sushila Rao: *Economic and Political Weekly*, Vol. 46, No. 18 (30-4-2011-6-5-2011), pp. 13-16; John Finnis: *Human Rights and Common Good: Collected Essays*, Vol. III; S.D. Sharma: *Administration of Justice in Ancient Bharat*, (1988); Toman E. Hill: "Humanity as an End in itself" (1980) 91 Ethics 84; Jeremy Waldron: "How Law Protects Dignity", *referred to*

In *K.S. Puttaswamy*, (2017) 10 SCC 1, the Constitution Bench has recognised the dignity of existence. Liberty and autonomy are regarded as the essential attributes of a life with dignity. In this manner, sanctity of life also stands acknowledged, as part of Article 21 of the Constitution. That apart, while holding the right of privacy as an intrinsic part of right to life and liberty in Article 21, various facets thereof are discussed by the learned Judges in their separate opinions.

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A common theme which flows in all these opinions is that that privacy recognises the autonomy of the individual; every person has right to make essential choices which affect the course of life; he has to be given full liberty and freedom in order to achieve his desired goals of life; and the concept of privacy is contained not merely in personal liberty, but also in the dignity of the individual. Chelameswar, J. in *K.S. Puttaswamy case*, observed: "Forced feeding of certain persons by the State raises concerns of privacy. An individual's right to refuse life prolonging medical treatment or terminate his life is another freedom which falls within the zone of privacy." Liberty by itself, which is a facet of Article 21 of the Constitution, duly recognised in *K.S. Puttaswamy case*, ensures and guarantees such a choice to the individual. In fact, the entire structure of civil liberties presupposes that freedom is worth fostering. The very notion of liberty is considered as good for the society. It is also recognised that there are some rights, encompassing liberty, which are needed in order to protect freedom. (Paras 300 and 301)

K.S. Puttaswamy v. *Union of India*, (2017) 10 SCC 1, *relied on*

David Feldman: *Civil Liberties & Human Rights in England & Wales*; Arval A. Morris: "Voluntary Euthanasia", Washington Law Review (1970), Vol. 45, at p. 240, *referred to*

Right to health is a part of Article 21 of the Constitution. At the same time, it is also a harsh reality that everybody is not able to enjoy that right because of poverty, etc. The State is not in a position to translate into reality this right to health for all citizens. Thus, when citizens are not guaranteed the right to health, can they be denied right to die in dignity? (Para 304)

National Legal Services Authority v. *Union of India*, (2014) 5 SCC 438, *affirmed*

Anuj Garg v. *Hotel Assn. of India*, (2008) 3 SCC 1, *cited*

Dignity is, thus, the core value of life and dying in dignity stands recognised in *Gian Kaur case*. It becomes a part of right of self-determination. Passive euthanasia and death with dignity are inextricably linked, which can be summed up with the following pointers: (Paras 308 and 311)

The opportunity to die unencumbered by the intrusion of medical technology and before experiencing loss of independence and control, appears to many to extend the promise of a dignified death. When medical technology intervenes to prolong dying like this it does not do so unobtrusively; Today many patients insist on more than just a right to healthcare in general. They seek a right to choose specific types of treatment, able to retain control throughout the entire span of their lives and to exercise autonomy in all medical decisions concerning their welfare and treatment; A dreadful, painful death on a rational but incapacitated terminally-ill patient are an affront to human dignity. (Paras 311.1 to 311.3)

Gian Kaur v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374, *relied on*

A. Kolnai: "Dignity", in R.S. Dillon (Ed.) *Dignity, Character, and Self-Respect* (London, Routledge, 1995) 53-75, at pp. 55, 56; R.S. Downie: K.S. Calman, *Healthy Respect: Ethics in Health Care* (Oxford, Oxford University Press, 1994) at 51-53, *referred to*

At least the case for passive euthanasia is made out. Certain moral dilemma as to what is the exact stage when such a decision to withdraw medical support, would still remain. At times, a physician would be filled with profound ethical uncertainties when a person is suffering unbearable pain and agony, the question would be as to whether such suffering has reached the stage where it is incurable and, therefore, decision should be taken to allow such person to pass away in peace

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and dignity of hastening the process of death or the situation may be reversible, though chances thereof are far remote. (Para 312)

Dr R.R. Kishore: "End of Life Issues and the Moral Certainty : A Discovery through Hinduism" Eubios Journal of Asian and International Bioethics, Vol. 13(6), Nov. 2003 at pp. 210-13, *referred to*

While discussing a particular norm of law, the law per se is to be applied and, generally speaking, it is not the function of the courts to look into the moral basis of law. At the same time, some legal norms, particularly those which are jurisprudentially expounded by the courts or developed as common law principles, would have moral backing behind them. In that sense moral aspects of an issue may assume relevance. This relevancy and rationale is quite evident in the discussion about euthanasia. In fact, the very concept of dignity of life is substantially backed by moral overtones. Though western thinking is that the concept of human dignity has 2500 years' history, in many eastern civilisations including India human dignity as core human value was recognised thousands of years ago. (Para 260)

S.D. Sharma: *Administration of Justice in Ancient Bharat*, (1988); Thomas Aquinas (1225-1274): *Summa Theologia*, *referred to*

The issue is not purely a legal one. It has moral and philosophical overtones. It has even religious overtones. Insofar as concept of human dignity is concerned, it dates back to thousands of years. Historically, human dignity, as a concept, found its origin in different religions which is held to be an important component of their theological approach. Later, it was also influenced by the views of philosophers who developed human dignity in their contemplations. Jurisprudentially, three types of models for determining the content of the constitutional value of human dignity are recognised. These are: (*i*) Theological Model, (*ii*) Philosophical Model, and (*iii*) Constitutional Model. Legal scholars were called upon to determine the theological basis of human dignity as a constitutional value and as a constitutional right. Philosophers also came out with their views justifying human dignity as core human value. Legal understanding is influenced by theological and philosophical views, though these two are not identical. (Paras 245 and 277)

Lochner v. *New York*, 1905 SCC OnLine US SC 100 : 49 L Ed 937 : 198 US 45 (1905), *referred to*

Philosophers believe that we have to control switch that can end it all, on request. In medical/legal parlance, it is called euthanasia: "*an easy and gentle death*". Philosophically, this debate is about our right, when terminally ill, to choose how to die. It is about the right to control how much we have to suffer and when and how we die. It is about having some control over our dying process in a system that can aggressively prolong life with invasive technology. Traditional religions are echoed in the modern Western understanding of euthanasia, as a means of achieving death with dignity, which focuses on avoiding dependence and loss of control. Choosing to deliberately end one's life allows control over the time, place and method of one's dying and explains why euthanasia appears to offer death with dignity. Rather than active euthanasia these ancient religions advocate calm, control and compassion as a means of achieving dignity. It is well known that medical scientists are intensely busy in finding the ways to become ageless and immortal, but till date have remained unsuccessful in achieving this dream. (Paras 256 and 259)

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Charles I. Lugosi: "Natural Disaster, Unnatural Deaths: The Killings on the Life Care Floors at Tenet's Memorial Centre after Hurricane Katrina", *Issues in Law and Medicine*, Vol. 23, Summer, 2007; John Keown: *Euthanasia, Ethics and Public Policy* (Cambridge: Cambridge University Press, 2002) p. 37; T.N. Madan: "Dying with Dignity" (1992) 35(4) *Social Science and Medicine* 425-32; T.N. Madan: "Living and Dying" in *Non-Renunciation: Themes and Interpretations of the Hindu Culture* (New Delhi, Oxford University Press, 1987); J. Parry: *Death and the Regeneration of Life* (Cambridge, Cambridge University Press, 1982); Justice Holmes: "The Path of the Law", 10 Harvard Law Review 457-78, at p. 459 (1897); Lon L. Fuller: "The Morality of Law" (Revised Edn.), Yale University Press, *referred to*

The philosophy of euthanasia, coupled with its morality aspect, brings out the conflicting views. Though philosophical as well as religious overtones may indicate that a person does not have right to take his life, it is still recognised that a human being is justified in his expectation to have a peaceful and dignified death. Opposition to euthanasia, on moral grounds, proceeds primarily on the basis that neither the person concerned has a right to take his own life, which is God's creation, nor anybody else has this right. However, while opposing euthanasia, no segregated discussion on active and passive euthanasia is made. It also does not take into consideration permissibility of passive euthanasia under certain specific circumstances. (Para 274)

Per Chandrachud, J. (concurring)

Dignity

Under our Constitution, the inherent value which sanctifies life is the dignity of existence. Recognising human dignity is intrinsic to preserving the sanctity of life. Life is truly sanctified when it is lived with dignity. There exists a close relationship between dignity and the quality of life. For, it is only when life can be lived with a true sense of quality that the dignity of human existence is fully realised. Hence, there should be no antagonism between the sanctity of human life on the one hand and the dignity and quality of life on the other hand. Quality of life ensures dignity of living and dignity is but a process in realising the sanctity of life. (Para 437)

The right to a dignified existence, the liberty to make decisions and choices and the autonomy of the individual are central to the quest to live a meaningful life. Liberty, dignity and autonomy are essential to the pursuit of happiness and to find meaning in human existence. Human dignity is an essential element of a meaningful existence. A life of dignity comprehends all stages of living including the final stage which leads to the end of life. Liberty and autonomy are essential attributes of a life of substance. It is liberty which enables an individual to decide upon those matters which are central to the pursuit of a meaningful existence. The expectation that the individual should not be deprived of his or her dignity in the final stage of life gives expression to the central expectation of a fading life: control over pain and suffering and the ability to determine the treatment which the individual should receive. When society assures to each individual a protection against being subjected to degrading treatment in the process of dying, it seeks to assure basic human dignity. Dignity ensures the sanctity of life. The recognition afforded to the autonomy of the individual in matters relating to end-of-life decisions is ultimately a step towards ensuring that life does not despair of dignity as it ebbs away. (Paras 516 and 438)

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The entitlement of each individual to a dignified existence necessitates constitutional recognition of the principle that an individual possessed of a free and competent mental state is entitled to decide whether or not to accept medical treatment. The right of such an individual to refuse medical treatment is unconditional. Neither the law nor the Constitution compel an individual who is competent and able to take decisions, to disclose the reasons for refusing medical treatment nor is such a refusal subject to the supervisory control of an outside entity. (Para 517)

Dignity is the core value of life and personal liberty which infuses every stage of human existence. Dignity in the process of dying as well as dignity in death reflects a long yearning through the ages that the passage away from life should be bereft of suffering. These individual yearnings are enhanced by the experiences of sharing, observing and feeling with others: the loss of a parent, spouse, friend or an acquaintance to the cycle of life. Dignity in death has a sense of realism that permeates the right to life. It has a basic connect with the autonomy of the individual and the right to self-determination. Loss of control over the body and the mind are portents of the deprivation of liberty. As the end of life approaches, a loss of control over human faculties denudes life of its meaning. Terminal illness hastens the loss of faculties. Control over essential decisions about how an individual should be treated at the end of life is hence an essential attribute of the right to life. Corresponding to the right is a legitimate expectation that the State must protect it and provide a just legal order in which the right is not denied. In matters as fundamental as death and the process of dying, each individual is entitled to a reasonable expectation of the protection of his or her autonomy by a legal order founded on the rule of law. A constitutional expectation of providing dignity in death is protected by Article 21 and is enforceable against the State. (Para 439)

Constitutional recognition of the dignity of existence as an inseparable element of the right to life necessarily means that dignity attaches throughout the life of the individual. Every individual has a constitutionally protected expectation that the dignity which attaches to life must subsist even in the culminating phase of human existence. Dignity of life must encompass dignity in the stages of living which lead up to the end of life. Dignity in the process of dying is as much a part of the right to life under Article 21. To deprive an individual of dignity towards the end of life is to deprive the individual of a meaningful existence. Hence, the Constitution protects the legitimate expectation of every person to lead a life of dignity until death occurs. (Para 518)

K.S. Puttaswamy v. *Union of India*, (2017) 10 SCC 1; *Maneka Gandhi* v. *Union of India*, (1978) 1 SCC 248, *relied on*

Ronald Dworkin: *Life's Dominion* (London: HarperCollins, 1993); Deryck Beyleveld and Roger Brownsword: "Human Dignity, Human Rights, and Human Genetics", Modern Law Review (1998), Vol. 61, at pp. 665-66; Christopher O. Tollefsen: "Capital Punishment, Sanctity of Life, and Human Dignity", *Public Discourse* (16-9-2011), <http://www.thepublic discourse.com/2011/09/3985/>; Stefania Negri: "Ending Life and Death" in A. den Exter (eds.), European Health Law, MAKLU Press (2017), at p. 241; Arval A. Morris: "Voluntary Euthanasia", Washington Law Review (1970), Vol. 45, at p. 240, 247, 251-252; Sebastian Muders: *Autonomy and the Value of Life as Elements of Human Dignity* (Oxford University Press, 2017); Lawrence O. Gostin: "The Constitutional Right to Die: Ethical Considerations", St John's Journal of Legal Commentary (1997), Vol. 12, at pp. 602-603; L.W. Sumner: "Dignity through Thick and Thin", in Sebastian Muders, *Human Dignity*

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and Assisted Death (Oxford University Press, 2017); Aneeta A. Minocha, Arima Mishra and Vivek R. Minocha: "Euthanasia: A Social Science Perspective", Economic & Political Weekly (3-12-2011), at pp. 25-28, *referred to*

Privacy

The right to privacy was held to be an intrinsic part of the right to life and liberty under Article 21 and protected under Part III of the Constitution. The protective mantle of privacy covers certain decisions that fundamentally affect the human life cycle. It protects the most personal and intimate decisions of individuals that affect their life and development. Thus, choices and decisions on matters such as procreation, contraception and marriage have been held to be protected. While death is an inevitable end in the trajectory of the cycle of human life of individuals are often faced with choices and decisions relating to death. Decisions relating to death, like those relating to birth, sex, and marriage, are protected by the Constitution by virtue of the right of privacy. The right to privacy resides in the right to liberty and in the respect of autonomy. The right to privacy protects autonomy in making decisions related to the intimate domain of death as well as bodily integrity. Few moments could be of as much importance as the intimate and private decisions that we are faced regarding death. Continuing treatment against the wishes of a patient is not only a violation of the principle of informed consent, but also of bodily privacy and bodily integrity that have been recognised as a facet of privacy by the Supreme Court. (Paras 440 and 441)

K.S. Puttaswamy v. *Union of India*, (2017) 10 SCC 1, *relied on*

Just as people value having control over decisions during their lives such as where to live, which occupation to pursue, whom to marry, and whether to have children, so people value having control over whether to continue living when the quality of life deteriorates. The protection of these rights by the legal order is as much an emanation of the right to privacy which shares a functional relationship with the fundamental right to life and personal liberty guaranteed by the Constitution. Privacy recognises that the body and mind are inviolable. An essential attribute of this inviolability is the ability of the individual to refuse medical treatment. The right to privacy envisages safeguarding the integrity of individual choice in the intimate sphere of decisions relating to death. However, since privacy is not an absolute right and is subject to restrictions, the restrictions must fulfil the requirements as laid down by this Court in *Puttaswamy case*. (Paras 442, 446 and 447)

Haas v. *Switzerland*, (2011) 53 EHRR 33, *referred to*

Richard Delgado: "Euthanasia Reconsidered—The Choice of Death as an Aspect of the Right of Privacy", Arizona Law Review (1975), Vol. 17, at p. 474; T.L. Beauchamp: "The Right to Privacy and the Right to Die", *Social Philosophy and Policy* (2000), Vol. 17, at p. 276; D. Benatar: "Should There be a Legal Right to Die?" *Current Oncology* (2010), Vol. 17, Issue 5, at pp. 2-3; Peter J. Riga: "Privacy and the Right to Die", *The Catholic Lawyer* (2017) Vol. 26: No. 2, Article 2, *referred to*

Sanctity of life

The "sanctity of life" principle has historically been the single most basic and normative concept in ethics and the law. The phrase has emerged as a key principle in contemporary bioethics, especially in debates about end-of-life issues. The traditional and standard view is that life is invaluable. It has persisted as an

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idea in various cultures through the centuries. A sacred value has been prioritised for human life. This "rhetoric of the value in human life" has been highlighted in various traditions. The protection of the right to life derives from "the idea that all human life is of equal value"—the idea being drawn from religion, philosophy and science. The principle or doctrine of the "sanctity of life", sometimes also referred to as the "inviolability of human life", is based on "overarching moral considerations", the first of which has been stated as: "Human life is sacred, that is inviolable, so one should never aim to cause an innocent person's death by act or omission." (Paras 400 to 402)

Elizabeth Wicks: The Right to Life and Conflicting Interests (Oxford University Press, 2010); Anne J. Davis: "Dilemmas in Practice: To Make Live or Let Die", The American Journal of Nursing (March 1981), Vol. 81, No. 3, at p. 582; Heike Baranzke: ""Sanctity-of-Life"—A Bioethical Principle for a Right to Life?", *Ethic Theory Moral Practice* (2012), Vol. 15, Issue 3, at p. 295; P.G. Lauren: *The Evolution of International Human Rights: Visions Seen* (University of Pennsylvania Press, 2003, 2nd Edn.), at p. 12; John Keown: *The Law and Ethics of Medicine: Essays on the Inviolability of Human Life* (Oxford University Press, 2012), at p. 3; John Locke: *Two Treatises of Government* (ed. P. Laslett) (Cambridge University Press, 1988); Ronald Dworkin, *Life's Dominion: An Argument about Abortion and Euthanasia* (HarperCollins, 1993), at pp. 73-74; John Finnis: *Human Rights and Common Good* (Oxford University Press, 2011), at p. 221, *referred to*

The principle of the sanctity of life considers autonomy as a "valuable capacity, and part of human dignity". However, autonomy's contribution to dignity is "conditional, not absolute". The issue of the sacred value of life is potentially a conflicting interest between a right to life and autonomy. The disagreement between "sanctity of life" and the "quality of life" is another conflict. Therefore, intractable questions about morality and ethics arise. What is the core of life that might be protected by law? Will a poor quality of life (in the shadow of the imminence of death) impact upon the value of that life to such an extent that it reduces the protection for that life offered by the sanctity of life doctrine? Are there limits to the principle of sanctity? (Paras 409 to 411)

Elizabeth Wicks: The Right to Life and Conflicting Interests (Oxford University Press, 2010), at pp. 176-77; Alan Norrie: "Legal Form and Moral Judgement: Euthanasia and Assisted Suicide" in R.A. Duff, et al (ed), *The Structures of the Criminal Law* (Oxford University Press, 2011), at pp. 141-142, *referred to*

The doctrine of "sanctity of life" must be accepted or rejected on its merits, by religious and non-religious people alike. The value of life is not the value that it has for God or the value that it may have from any religious perspective. The truth of moral judgments and exercising reason to decide what is right and wrong does not depend on the truth of theological claims. The value of life is the value that it has for the human beings who are subjects of lives. Thus, the value of life must be understood from the perspective of the person who will be harmed by the loss, the subject of life. The rule against killing protects individuals that have lives and not merely individuals who are alive. When an individual is alive only to the extent of being conscious in the most rudimentary sense, the capacity to experience pleasure and pain (if any) does not necessarily have value if that is the only capacity one has. These sensations will not be endowed with any significance by the one experiencing them since they do not arise from any human activities or projects and they will not be connected with any coherent view of the world. The quality of life approach has its basis in the way life is being lived. "An overriding concern",

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"is the conditions under which people live rather than whether they live". This does not mean that someone "who chooses to end their life through euthanasia" does not value their lives as much as others. (Paras 414 and 419)

The sanctity of life principle appears in declarations on human rights as the "right to life". Under the Indian Constitution, right to life has been provided under Article 21. The sanctity of human life is the arterial vein which animates the values, spirit and cellular structure of the Constitution. The Constitution recognises the value of life as its indestructible component. The survival of the sanctity principle is founded upon the guarantees of dignity, autonomy and liberty. The sanctity of human life lies in its intrinsic value. It inheres in nature and is recognised by natural law. But human lives also have instrumental functions. Our lives enable us to fulfil our needs and aspirations. The intrinsic worth of life is not conditional on what it seeks to or is capable to achieve. Life is valuable because it *is*. The Indian Constitution protects the right to life as the supreme right, which is inalienable and inviolable even in times of Emergency. It clearly recognises that every human being has the inherent right to life, which is protected by law, and that "No person shall be deprived of his life … except according to procedure established by law". It, thus, envisages only very limited circumstances where a person can be deprived of life. (Paras 428 and 515)

Parmanand Katara v. *Union of India*, (1989) 4 SCC 286 : 1989 SCC (Cri) 721, *affirmed*

Alexandra Mullock: *End-of-Life Law and Assisted Dying in the 21st Century: Time for Cautious Revolution?* (PhD Thesis, University of Manchester, 2011), at pp. 24-25; Luis Kutner: "Euthanasia: Due Process for Death with Dignity; The Living Will", Indiana Law Journal (Winter 1979), Vol. 54, Issue, 2, at p. 225; Sushila Rao: "The Moral Basis for a Right to Die", *Economic & Political Weekly* (30-4-2011), at p. 14; John Keown: "The Legal Revolution: From "Sanctity of Life" to "Quality of Life" and "Autonomy", Journal of Contemporary Health Law & Policy (1998), Vol. 14, Issue 2, at p. 281; Sushila Rao: "The Moral Basis for a Right to Die", Economic & Political Weekly (30-4-2011), at p. 14; Elizabeth Wicks: The Right to Life and Conflicting Interests (Oxford University Press, 2010), at pp. 102-149; Margaret A. Somerville: "The Song of Death: The Lyrics of Euthanasia", Journal of Contemporary Health Law & Policy (1993), Vol. 9, Issue 1, at p. 67; James Rachels: *End of Life: Euthanasia and Morality* (Oxford University Press, 1986), at p. 26; Roger S. Magnusson: "The Sanctity of Life and the Right to Die: Social and Jurisprudential Aspects of the Euthanasia Debate in Australia and the United States", Pacific Rim Law & Policy Journal, Vol. 6, No. I, at p. 40; Peter Singer: "Sanctity of Life or Quality of Life", *Pediatrics* (1983), Vol. 72, Issue 1, at pp. 128-129; Sanctity of Life Versus Quality of Life", *Los Angeles Times* (7-6-2015), <http://www.latimes.com/opinion/readersreact/la-le-0607-sunday-assisted-suicide-20150607- story.html>; Jessica Stern: Euthanasia and the Terminally Ill (2013) <https://fsu.digital.flvc.org/islandora/object/fsu: 209909/datastream/PDF/view>; John Breck: "Euthanasia and the Quality of Life Debate", *Christian Bioethics* (1995), Vol. 1, No. 3, at pp. 322-337; Michael A. Weingarten: "On the Sanctity of Life", British Journal of General Practice (April 2007), Vol. 57(537), at p. 333; Alan Norrie: "Legal Form and Moral Judgement: Euthanasia and Assisted Suicide" in R.A. Duff, et al (ed), *The Structures of the Criminal Law* (Oxford University Press, 2011), at p. 143; Stefania Negri: "Universal Human Rights and End-of-Life Care" in S. Negri et al. (Eds.), Advance Care Decision Making in Germany and Italy: A Comparative, European and International Law Perspective, Springer (2013), at p. 18, *referred to*

Life and natural death

The word "natural" implies that "the only acceptable death is one that occurs from natural causes". Life is only "sacred insofar as it ends by natural means".

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Medical advancements, however, have brought uncertainty about the definition of death — "what constitutes death, in particular a "natural" death". Medical advances have "complicated the question of when life ends". There exists no natural death where artificial technology is concerned. (Paras 421 and 422)

Modern medicine has found ways to prolong life and to delay death. But, it does not imply that modern medicine "necessarily prolongs our living a full and robust life because in some cases it serves only to prolong mere biological existence during the act of dying". This may, in certain situations result in a mere "prolongation of a heartbeat that activates the husk of a mindless, degenerating body that sustains an unknowing and pitiable life—one without vitality, health or any opportunity for normal existence—an inevitable stage in the process of dying". Prolonging life in a vegetative state by artificial means or allowing pain and suffering in a terminal state would lead to questioning the belief that any kind of life is so sanctified as to be preferred absolutely over death. (Para 423)

Modern technology has in a fundamental manner reshaped the notion of life. As technology continuously evolves into more complex planes, it becomes even more necessary to re-evaluate its relationship with the meaning and quality of life. (Para 427)

Great Ormond Street Hospital v. *Yates*, 2017 EWHC 1909 : (2017) 4 WLR 131 (Fam), *referred to*

Alecia Pasdera: The Rhetoric of the Physician-Assisted Suicide Movement: Choosing Death Over Life (2014), available at *https:// ou.monmouthcollege.edu/_resources/pdf/academics/mjur/2014/Rhetoric-of-the-Physician- Assisted-Suicide-Movement-Choosing-Death-Over-Life.pdf*, at p. 68; Sushila Rao: "The Moral Basis for a Right to Die", Economic & Political Weekly (30-4-2011), at p. 15; Arval A. Morris: "Voluntary Euthanasia", Washington Law Review (1970), Vol. 45, at p. 240; Elizabeth M. Andal Sorrentino: "The Right to Die?", Journal of Health and Human Resources Administration (Spring, 1986), Vol. 8, No. 4, at pp. 361-373; Peter Singer: "The Sanctity of Life", *Foreign Policy* (20-10-2009) <http:// foreignpolicy.com/2009/10/20/the-sanctity-of-life/>; Lady Justice Arden, Law of Medicine and the Individual: Current Issues, What does Patient Autonomy Mean for the Courts?, (Justice K.T. Desai Memorial Lecture 2017), *referred to*

Per Ashok Bhushan, J. (concurring)

In recent times, three principles had gained acceptance throughout the world and they are:

(*1*) Sanctity of life,

(2) Right of self-determination,

(*3*) Dignity of the individual human being. (Para 600)

The sanctity of life is one thought which is philosophically, religiously and mythologically accepted by the large number of population of the world practising different faiths and religions. Sanctity of life entails its inviolability by an outsider. Sanctity of life is the concern of State. (Para 601)

Right of self-determination also encompasses in it bodily integrity. Without consent of an adult person, who is in fit state of mind, even a surgeon is not authorised to violate the body. Sanctity of the human life is the most fundamental of the human social values. The acceptance of human rights and development of its meaning in recent times has fully recognised the dignity of the individual human being. All the above three principles enable an adult human being of conscious

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mind to take decision regarding extent and manner of taking medical treatment. An adult human being of conscious mind is fully entitled to refuse medical treatment or to decide not to take medical treatment and may decide to embrace the death in natural way. Euthanasia as the meaning of the word suggest is an act which leads to a good death. Some positive act is necessary to characterise the action as euthanasia. Euthanasia is also commonly called "assisted suicide" due to the above reasons. (Para 602)

H. **Common Law — Right of self-determination and individual autonomy — Right to choose how one should live his/her own life — Right to self-determination encompasses in it bodily integrity — Every adult person having capacity to decide has right to choose his/her own way of life which includes right to decide whether to have medical treatment or to refuse the same — Wishes of patient should be given effect to even if considered to be against his/her best interest — Principle of sanctity of life should yield to that of self-determination — Constitution of India, Art. 21**

I. **Medical Jurisprudence — Euthanasia — Right to refuse medical treatment — Refusal by terminally ill or PVS patient to take medical treatment neither amounts to euthanasia nor suicide — By refusal patient allows disease to take its natural course — Constitution of India — Art. 21 — Human and Civil Rights — Right to Die/Euthanasia — Common Law — Penal Code, 1860, S. 309**

J. **Medical Jurisprudence — Euthanasia — Right to refuse medical treatment — Based on right to self-determination and autonomy — Competence to accept or refuse treatment — There is presumption of capacity to consent to or refuse medical treatment unless same is rebutted — Patient from whom consent is obtained by medical practitioner should have full information including risk and benefits involved in giving consent — Situation in which medical treatment can be given without consent — "Emergency principle" and "principle of necessity" — Applicability — Constitution of India — Art. 21 — Human and Civil Rights — Right to Die/Euthanasia — Common Law**

Held :

Per Dipak Misra, C.J. and Khanwilkar, J.

The liberal concept of autonomy focuses on choice and likewise, self-determination is understood as exercised through the process of choosing. The respect for an individual human being and in particular for his right to choose how he should live his own life is individual autonomy or the right of self-determination. It is the right against non-interference by others, which gives a competent person who has come of age the right to make decisions concerning his or her own life and body without any control or interference of others. (Para 168)

Lambert v. *France*, 2015 ECHR 185, *considered*

In the context of health and medical care decisions, a person's exercise of self-determination and autonomy involves the exercise of his right to decide whether and to what extent he/she is willing to submit himself/herself to medical procedures and treatments, choosing amongst the available alternative treatments or, for that

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matter, opting for no treatment at all which, as per his or her own understanding, is in consonance with his or her own individual aspirations and values. Thus all adults with the capacity to consent have the Common Law right to refuse medical treatment and the right of self-determination. Doctors would be bound by the choice of self-determination made by the patient who is terminally ill and undergoing a prolonged medical treatment or is surviving on life support, subject to being satisfied that the illness of the patient is incurable and there is no hope of his being cured. Any other consideration cannot pass off as being in the best interests of the patient. (Paras 169, 174 and 175)

Reeves v. *Commr. of Police of the Metropolis*, (2000) 1 AC 360 : (1993) 3 WLR 363 (HL); *Jobes, In re*, 108 NJ 394 (1987); *Reibl* v. *Hughes*, 1980 SCC OnLine Can SC 88 : (1980) 2 SCR 880; *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL), *relied on*

Aruna Ramachandra Shanbaug v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294, *affirmed on this point*

Rawls, John, *Political Liberalism*, 32, 33 (New York: Columbia University Press, 1993), *relied on*

The recognition of the freedom of competent adults to make choices about their medical care necessarily encompasses recognition of the right to make choices since individual free choice and self-determination are themselves fundamental constituents of life. In the 21st Century, with the advancement of technology in medical care, it has become possible, with the help of support machines, to prolong the death of patients for months and even years in some cases. At this juncture, the right to refuse medical treatment comes into the picture. A patient (terminally ill or in a persistent vegetative state) exercising the right to refuse treatment may ardently wish to live but, at the same time, he may wish to be free from any medical surgery, drugs or treatment of any kind so as to avoid protracted physical suffering. Any such person who has come of age and is of sound mind has a right to refuse medical treatment. This right stands on a different pedestal as compared to suicide, physician-assisted suicide or even euthanasia. When a terminally-ill patient refuses to take medical treatment, it can neither be termed as euthanasia nor as suicide. Albeit, both suicide and refusal to take treatment in case of terminal ailment shall result in the same consequences, that is, death, yet refusal to take treatment by itself cannot amount to suicide. In case of suicide, there has to be a self-initiated positive action with a specific intention to cause one's own death. On the other hand, a patient's right to refuse treatment lacks his specific intention to die, rather it protects the patient from unwanted medical treatment. A patient refusing medical treatment merely allows the disease to take its natural course and if, in this process, death occurs, the cause for it would primarily be the underlying disease and not any self-initiated act. (Paras 135 and 136)

There is a presumption of capacity whereby an adult is presumed to have the capacity to consent to or to refuse medical treatment unless and until that presumption is rebutted in deciding whether a person has the capacity to make a particular decision. The ultimate question is whether that person suffers from some impairment or disturbance of mental functioning so as to render him or her incapable of making the decision. The consent may be vitiated if the individual concerned may not have been competent in law to give or refuse that consent; or even if the individual was competent in law, the decision has been obtained by

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undue influence or some other vitiating means; or the apparent consent or refusal does not extend to the particular situation; or the terms of the consent or refusal are ambiguous or uncertain; or if the consent or refusal is based on incorrect information or incorrect assumption. In circumstances where it is practicable for a medical practitioner to obtain consent to treatment, then, for the consent to be valid, it must be based on full information, including as to its risks and benefits. (Para 139)

Where it is not practicable for a medical practitioner to obtain consent for treatment and where the patient's life is in danger if appropriate treatment is not given, then the treatment may be administered without consent. This is justified by what is sometimes called the "emergency principle" or "principle of necessity". Usually, the medical practitioner treats the patient in accordance with his clinical judgment of what is in the patient's best interests. For the principle of necessity to apply, two conditions must be met:

(*a*) There must be "a necessity to act when it is not practicable to communicate with the assisted person"; and

(*b*) "the action taken must be such as a reasonable person would in all the circumstances take, acting in the best interests of the assisted person".

However, the principle of necessity cannot be relied upon to justify a particular form of medical treatment where the patient has given an advance care directive specifying that he/she does not wish to be so treated and where there is no reasonable basis for doubting the validity and applicability of that directive. (Para 140)

An inquiry into Common Law jurisdictions reveals that all adults with capacity to consent have the right of self-determination and autonomy. The said rights pave the way for the right to refuse medical treatment which has acclaimed universal recognition. A competent person who has come of age has the right to refuse specific treatment or all treatment or opt for an alternative treatment, even if such decision entails a risk of death. The "Emergency Principle" or the "Principle of Necessity" has to be given effect to only when it is not practicable to obtain the patient's consent for treatment and his/her life is in danger. But where a patient has already made a valid Advance Directive which is free from reasonable doubt and specifying that he/she does not wish to be treated, then such directive has to be given effect to. (Para 202.8)

F. v. *R.*, (1983) 33 SASR 189; *Rogers* v. *Whitaker*, 1992 HCA 58 : (1992) 175 CLR 479; *Department of Health and Community Services* v. *JWB and SMB*, (1992) 66 AJLR 300 : (1992) 175 CLR 218; *Rodriguez* v. *Attorney General of Canada*, 1993 SCC OnLine Can SC 97 : (1993) 3 SCR 519 : 85 CCC 3d 15; *F. (Mental Patient: Sterilisation), In re*, (1990) 2 AC 1 : (1989) 2 WLR 1025 : (1989) 2 All ER 545 (HL), *relied on*

Schloendorff v. *Society of New York Hospital*, 105 NE 92 : 211 NY 125 (1914); *Malette* v. *Shulman*, (1990) 67 DLR (4th) 321 : 72 OR (2d) 417 (CA); *MB (Medical Treatment), In re*, 1997 EWCA Civ 3093 : (1997) 2 FLR 426, *approved*

Per Sikri, J. (concurring)

In the context of euthanasia, "personal autonomy" of an individual, as a part of human dignity, can be pressed into service. In addition to personal autonomy, other facets of human dignity, namely, "self-expression" and "right to determine"

also support the argument that it is the choice of the patient to receive or not to receive treatment. (Paras 305 and 306)

Ronald Dworkin, *Life's Dominion* (2nd Edn., Vintage Books, New York 1944) 239; Ronald Dworkin, *Life's Dominion* (London, Harper-Collins, 1993) at p. 166, *referred to*

It is a common law right of people, of any civilised country, to refuse unwanted medical treatment and no person can force him/her to take any medical treatment which the person does not desire to continue with. (Para 329)

Aruna Ramachandra Shanbaug v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294, *affirmed on this point*

Schloendorff v. *Society of New York Hospital*, 105 NE 92 : 211 NY 125 (1914); *Sidaway* v. *Board of Governors of the Bethlem Royal Hospital*, 1985 AC 871 : (1985) 2 WLR 480 : (1985) 1 All ER 643 (HL); *Nancy B.* v. *Hotel Dieu de Quebec*, (1992) 86 DLR (4th) 385 (Que SC); *T. (Adult: Refusal of Treatment), In re*, 1993 Fam 95 : (1992) 3 WLR 782 : (1992) 4 All ER 649 (CA); *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL), *cited*

Per Chandrachud, J. (concurring)

Respecting patient autonomy and reducing suffering are fundamental ethical values ascribed to euthanasia. Dignity has basic connect with autonomy of the individual and right to self-determination. In matters as fundamental as death and the process of dying, each individual is entitled to a reasonable expectation of protection of his or her autonomy by a legal order founded on rule of law. (Paras 53 and 97)

Recognition of the right to accept or refuse medical treatment is founded upon autonomy. The *Stanford Encyclopaedia of Philosophy* postulates that there is "a rough consensus in medical ethics on the requirement of respect for patient autonomy". However, a patient may not always have the opportunity to grant or withhold consent to medical treatment. An unforeseen event may deprive the individual of the ability to indicate a desire to either receive or not to have medical treatment. (Para 470)

Luis Kutner: "Due Process of Euthanasia: The Living Will, A Proposal", Indiana Law Journal (1969), Vol. 44, Issue 4, at pp. 539, 551; "Advance Directives and Substitute Decision-Making", *Stanford Encyclopaedia of Philosophy* (24-3-2009) <https://plato.standford.edu/entries/advance-directives/>; Luis Kutner: "Euthanasia: Due Process for Death with Dignity; The Living Will", Indiana Law Journal (Winter 1979), Vol. 54, Issue, 2, at p. 226, *referred to*

Per Ashok Bhushan, J. (concurring)

Right of self-determination encompasses in it bodily integrity. The rights of bodily integrity and self-determination are the rights which belong to every human being. When an adult person having mental capacity to take a decision can exercise his right not to take treatment or withdraw from treatment, the above right cannot be negated for a person who is not able to take an informed decision due to terminal illness or being in a persistent vegetative state (PVS). Without consent of an adult person, who is in a fit state of mind, even a surgeon is not authorised to violate the body. (Paras 611 and 602)

K. **Constitution of India — Art. 21 — Passive euthanasia — Economic considerations may be an instrument of cost curtailment in view of high cost factor involved in modern medical treatment, lack of capacity to afford health**

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services and limited availability of medical facilities — In such circumstances, economic considerations would support passive euthanasia — Utilitarian principle of evaluating policies in virtue of their effect on individual welfare or utility considered — Human and Civil Rights — Right to Die/Euthanasia — Economic Theory, Law and Economics — Economic analysis of law — When warranted

Held :

Per Sikri, J.

The matter of euthanasia can be considered in the context of economic principles also. This aspect can be dealt with in two ways: First, because of rampant poverty where majority of the persons are not able to afford health services, should they be forced to spend on medical treatment beyond their means and in the process compelling them to sell their house property, household things and other assets which may be means of livelihood. Secondly, when there are limited medical facilities available, should a major part thereof be consumed on those patients who have no chances of recovery? (Paras 321 to 321.2)

Some of the apprehensions expressed in ethical debates about euthanasia can be answered when the ethical debate about euthanasia is not divorced from an economic consideration of cost and benefits of euthanasia to society. Under certain circumstances i.e. when the patient is in PVS or brain dead/clinically dead, at least passive euthanasia would even be ethically acceptable, on the application of doctrine of dignity. In such a situation, the economic considerations would strengthen the conclusion in favour of passive euthanasia. (Paras 323 and 324)

Shivashakti Sugars Ltd. v. *Shree Renuka Sugar Ltd.*, (2017) 7 SCC 729 : (2017) 4 SCC (Civ) 234, *explained*

"Health Care Rationing: Can We Afford to Ignore Euthanasia?", Health Services Management Research 1997; 10; 32-41; Mooney G.: *The Valuation of Human Life*, London: Macmillan Press, 1977; *Economics and Euthanasia* by Stephen Heasell, Department of Economics and Politics, Nottingham Trent University, and David Paton, Nottingham University Business School, *referred to*

At times, for deciding legal issues, economic analysis of law assumes importance. It is advocated that one of the main reasons which should prompt philosophers of law to undertake economic analysis seriously is that the most basic notion in the analysis—efficiency or Pareto optimality—was originally introduced to help solve a serious objection to widely held moral theory, utilitarianism. Utilitarians hold that the principle of utility is the criterion of the right conduct. If one has to evaluate policies in virtue of their effect on individual welfare or utility, one norm of utility has to be compared with that of another. This economic principle has been applied in a limited sense only as a supporting consideration with the aim to promote efficiency. (Para 325)

Jeffrie G. Murphy & Jules L. Coleman: *Philosophy of Law (An Introduction to Jurisprudence)*, *referred to*

Per Chandrachud, J. (concurring)

One of the limitations of contemporary debates on euthanasia is that they do not take into consideration "certain socio-economic concerns that must necessarily be factored into any discourse". Cost of treatment is a critical factor in influencing the medical decision. "Sometimes patients are 'transferred' to smaller (read

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cheaper) institutions or even their homes, with the tacit understanding that this will hasten the inevitable." "In the absence of adequate medical insurance, specialised treatments like ventilator support, kidney dialysis, and expensive life-saving drugs administered in private hospitals can turn middle-class families into virtual paupers. Poorly equipped government hospitals simply do not have enough life-support machines compared to the number of patients who need them." The inadequacies of the range and reach of Indian Health Care may lead to a situation where euthanasia/active euthanasia may become "an instrument of cost containment". Wealth, poverty, and class structure have a profound effect on the choices people make. (Paras 448 and 449)

S. Nagral: "Euthanasia: Cost Factor is a Worry", *The Times of India* (19-6-2011) <http://www.timesofindia.com/home/sunday/Euthanasia-cost-factor-is-a-worry/articleshow/7690155.cms>; Sushila Rao: "India and Euthanasia: The Poignant Case of Aruna Shanbaug", Oxford Medical Law Review, Vol. 19, Issue 4 (1-12-2011), at pp. 654-655; Alan Norrie: "Legal Form and Moral Judgement: Euthanasia and Assisted Suicide" in R.A. Duff, et al (ed), *The Structures of the Criminal Law* (Oxford University Press, 2011), at p. 144, *referred to*

L. **Constitution of India — Art. 21 — Passive euthanasia — Withholding or withdrawing life prolonging treatment of patient — By allowing the same to a person who is terminally ill, in PVS or brain dead state and thereby hastening process of natural death with dignity in compliance with wishes of the patient, medical practitioner would not be guilty of any penal provision under Penal Code — Contrasted with position obtaining in respect of active euthanasia under prevailing law — Penal Code, 1860 — Ss. 43, 76, 79, 81, 88, 92, 107, 300, 306 and 399 — Human and Civil Rights — Right to Die/ Euthanasia**

M. **Penal Code, 1860 — Ss. 299 and 300 — "Cause death" — Decision not to prolong life of a terminally ill/permanent vegetative state patient by medical treatment does not involve intention to cause death**

N. **Penal Code, 1860 — Ss. 43 and 32 — Illegality — Act or Omission which is prohibited by law — When omission to do something is unlawful, individual is legally bound to do it**

O. **Penal Code, 1860 — S. 81 — Protection to act done with knowledge that it is likely to cause harm — Available when act done without criminal intent to cause harm, in good faith and for preventing other harm**

P. **Penal Code, 1860 — S. 92 — Act done in good faith for benefit of another person, even if causes unintended harm to that person protected under S. 92 — Such act would be protected even if it was not possible to obtain consent of that person**

Q. **Penal Code, 1860 — Ss. 107, 305, 306 — To constitute abetment, there must be course of conduct or action of intentionally aiding or facilitating another person to end life**

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R. **Interpretation of Statutes — Particular Statutes or Provisions — Penal statutes or provisions — Interpretation in background of constitutional principles — Where penal statute bears significant relationship to fundamental constitutional principles of liberty, dignity and autonomy on which question in issue is based, Court, while analysing penal provisions, should give effect to constitutional principles**

Held :

Per Chandrachud, J.

The constitutionally recognised right to life is subject to the procedure established by law. The procedure for regulation or deprivation must, it is well-settled, be fair, just and reasonable. Criminal law imposes restraints and penal exactions which regulate the deprivation of life, or as the case may be, personal liberty. The intentional taking away of the life of another is made culpable by the Penal Code. Active euthanasia falls within the express prohibitions of the law and is unlawful. (Para 519)

The legality of and constitutional protection which is afforded to passive euthanasia cannot be read in isolation from the provisions of the Penal Code. Physicians are apprehensive about their civil or criminal liability when called upon to decide whether to limit life-supporting treatment. Undoubtedly, constitutional positions are not controlled by statutory provisions, because the Constitution rises above and controls legislative mandates. But, in the present reference where no statutory provision is called into question, it is necessary for the Court to analyse the relationship between what the statute penalises and what the Constitution protects. The task of interpretation is to allow for their co-existence while interpreting the statute to give effect to constitutional principle. This is particularly so in an area such as the present where criminal law may bear a significant relationship to the fundamental constitutional principles of liberty, dignity and autonomy. (Para 452)

S. Balakrishnan and R.K. Mani, "The Constitutional and Legal Provisions in Indian Law for Limiting Life Support", Indian Journal of Critical Care Medicine (2005), Vol. 9, Issue 2, at p. 108, *referred to*

A distinction arises between active and passive euthanasia from the provisions of the Penal Code. Active euthanasia involves an intention to cause the death of the patient. Mens rea requires a guilty mind; essentially an intent to cause harm or injury. Passive euthanasia does not embody an intent to cause death. A doctor may withhold life support to ensure that the life of a patient who is in the terminal stage of an incurable illness or in a permanent vegetative state, is not prolonged artificially. The decision to do so is not founded upon an intent to cause death but to allow the life of the patient to continue till and cease at the end of its natural term. Placing such a person on life support would have been an intervention in the natural process of death. A decision not to prolong life by artificial means does not carry an intention to cause death. The crucial element in Section 299 is provided by the expression "causes death". In a case involving passive euthanasia, the affliction of the patient is not brought about either by an act or omission of the doctor. There is neither an animus nor an intent to cause death. The creation of the condition of the patient is outside the volition of the doctor and has come about without a

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covert or overt act by the doctor. The decision to withhold medical intervention is not intended to cause death but to prevent pain, suffering and indignity to a human being who is in the end stage of a terminal illness or of a vegetative state with no reasonable prospect of cure. Placing a patient on artificial life support would, in such a situation, merely prolong the agony of the patient. Hence, a decision by the doctor based on what is in the best interest of the patient precludes an intent to cause death. Similarly, withdrawal of artificial life support is not motivated by an intent to cause death. What a withdrawal of life support does is not to artificially prolong life. The end of life is brought about by the inherent condition of the patient. Thus, both in a case of a withdrawal of life supporting intervention and withholding it, the law protects a bona fide assessment of a medical professional. There being no intent to cause death, the act does not constitute either culpable homicide or murder. (Para 462)

Section 32 of the Penal Code places acts and omissions on the same plane. An *illegal* omission (unless a contrary intent appears in the Code) is proscribed when the act is unlawful. Further, Section 43 comprehends within the meaning of illegality, that (*i*) which is an offence; or (*ii*) which is prohibited by law; or (*iii*) which furnishes a ground for a civil action. Omissions and acts are mirror images. When it is unlawful to *omit* to do something, the individual is legally *bound* to do it. This raises the question of whether an omission to provide life-sustaining treatment constitutes an illegal omission. (Paras 453 and 454)

"Doctrine of Double Effect", *Stanford Encyclopedia of Philosophy* (28-7-2004) <https://plato.stanford.edu/entries/double-effect/>, *referred to*

Section 81 protects acts which are done without a criminal intent to cause harm, in good faith, to prevent or avoid other harm to person or property. The law protects the action though it was done with the knowledge that it was likely to cause harm if a threefold requirement is fulfilled. It comprehends an absence of criminal intent to cause harm, the presence of good faith and the purpose of preventing other harm. Knowledge of the likelihood of harm is not culpable when a criminal intent to cause harm is absent and there exists an element of good faith to prevent or avoid other harm. (Para 455)

The doctor does not inflict a bodily injury. The condition of a patient is on account of a factor independent of the doctor and is not an outcome of his or her actions. Death emanates from the pre-existing medical condition of the patient which enables life to chart a natural course to its inexorable end. The law protects a decision which has been made in good faith by a medical professional not to prolong the indignity of a life placed on artificial support in a situation where medical knowledge indicates a point of no return. Neither the act nor the omission is done with the knowledge that it is likely to cause death. This is for the reason that the likelihood of death is not occasioned by the act or omission but by the medical condition of the patient. When a doctor takes a considered decision in the case of a patient in a terminal stage of illness or in a permanently vegetative state, not to provide artificial life support, the law does not attribute to the doctor the knowledge that it is likely to cause death. (Para 463)

Withdrawing life support to a person in a permanently vegetative state or in a terminal stage of illness is not "prohibited by law" within the meaning of Section 43

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IPC Such an act would also not fall outside the purview of Section 92 for the reason that there is no intentional causing of death or attempt to cause death. Where a decision to withdraw artificial life support is made in the caregiver of the patient, it fulfils the duty of care required from a doctor towards the patient. Where a doctor has acted in fulfilment of a duty of care owed to the patient, the medical judgment underlying the decision protects it from a charge of illegality. Such a decision is not founded on an intention to cause death or on the knowledge that it is likely to cause death. An act done in pursuance of the duty of care owed by the doctor to a patient is not prohibited by law. (Para 464)

Section 92 protects an individual from a consequence which arises from the doing of an act for the benefit of another in good faith, though a harm is caused to the other. What was done is protected because it was done in good faith. Good faith is distinguished from an evil design. When a person does something to protect another from a harm or injury, the law protects what was done in good faith, treating the harm that may result as a consequence unintended by the doer of the act. This protection is afforded by the law even in the absence of consent when the circumstances are such that it is impossible for the person for whose benefit the act was done to consent to it. This may arise where the imminence of the apprehended danger makes it impossible to obtain consent. Another eventuality is where the individual is incapable of consenting (by being incapacitated in mind) and there is no person in the position of a guardian or person in lawful charge from whom consent can be obtained in time to perform the act for the benefit of that person. However, the first proviso to Section 92 makes it clear that the exception does not extend to the *intentional* causing of death or attempt to cause death to the individual, howsoever it may be for the benefit of the other. Absence of intent to cause death is the crucial element in the protection extended by Section 92. (Para 456)

For abetting an offence, the person abetting must have intentionally aided the commission of the crime. Abetment requires an instigation to commit or intentionally aiding the commission of a crime. It presupposes a course of conduct or action which (in the context of the present discussion) facilitates another to end life. Hence abetment of suicide is an offence expressly punishable under Sections 305 and 306 IPC. (Para 458)

In 2006, the Law Commission of India submitted its 196th Report titled "Medical Treatment to Terminally-Ill Patients (Protection of Patients and Medical Practitioners)". The Report by Justice M. Jagannadha Rao as Chairperson contains a succinct elucidation of legal principles governing criminal law on the subject. Some of them are explained below: (Para 466)

While a doctor has a duty of care, a doctor who obeys the instructions of a competent patient to withhold or withdraw medical treatment does not commit a breach of professional duty and the omission to treat will not be an offence; (Para 466.1)

And a decision to not receive medical treatment does not constitute an attempt to commit suicide within the meaning of Section 309 of the Penal Code; (Para 466.2)

Once a competent patient has decided not to accept medical intervention, and to allow nature to take its course, the action of the treating doctor in abiding by those

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wishes is not an offence, nor would it amount to an abetment under Section 306. Under Section 107, an omission has to be illegal to constitute an abetment. A doctor bound by the instructions of a patient to withhold or withdraw medical treatment is not guilty of an illegal act or an abetment. The doctor is bound by the decision of the patient to refuse medical intervention; (Para 466.3)

The act of withholding or withdrawing a life support system in the case of a competent patient who has refused medical treatment and, in the case of an incompetent person where the action is in the best interest of the patient would be protected by good faith protections available under Sections 76, 79, 81 or, as the case may be, by Section 88, even if it is construed that the doctor had knowledge of the likelihood of death. (Para 466.4)

Introducing a structural safeguard, in the form of a Medical Board of experts can be contemplated to further such an objective. The Transplantation of Human Organs and Tissues Act, 1994 provides for the constitution of Authorisation Committees under Section 9(4). The Authorisation Committees are contemplated at the State and district levels and a hospital board. Once the process of decision-making has been arrived at by fulfilling a mandated safeguard (the prior approval of a committee), the decision to withdraw life support should not constitute an illegal act or omission. The setting up of a broad-based board is precisely with a view to lend assurance that the duty of care owed by the doctor to the patient has been fulfilled. Once due safeguards have been fulfilled, the doctor is protected against the attribution of a culpable intent or knowledge. It will hence fall outside the definition of culpable homicide (Section 299), murder (Section 300) or causing death by a rash or negligent act (Section 304-A). (Para 467)

Schloendorff v. *Society of New York Hospital*, 105 NE 92 : 211 NY 125 (1914), *referred to*

S. Constitution of India — Art. 21 — Euthanasia — Passive Euthanasia (Voluntary and Non-Voluntary) — Procedure for effectuating when (a) there is an Advance Directive; and (b) when there is no Advance Directive — Detailed Safeguards and Guidelines laid down, to be in force till legislation is enacted to cover the field — Living will — Advance Directive — Adult terminally ill patient, while possessed of mental capacity to take informed decision relating to own healthcare and treatment, has right to execute Advance Directive document expressing his/her will of not to be treated with life prolonging medical supportive measures till end of his/her natural life in case of his/her future mental impairment, PVS or brain dead/clinically dead state — Object and reason for recognising Advance Directive, stated — Meaning of terminal condition, persistently unconscious condition and end-stage condition, explained — Concept of Advance Directive based on fundamental right to liberty to live with dignity till end of natural life, right to privacy and common law rights of individual autonomy, self-determination and concept of sanctity of life

Held :

Per Dipak Misra, C.J. and Khanwilkar, J.

In order to overcome the difficulty faced in case of patients who are unable to express their wishes at the time of taking the decision, the concept of Advance Medical Directives emerged in various countries. Advance Directives for

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healthcare go by various names in different countries though the objective by and large is the same, that is, to specify an individual's healthcare decisions and to identify persons who will take those decisions for the said individual in the event he is unable to communicate his wishes to the doctor. (Paras 184 and 185)

A living will, on the other hand, is a document prescribing a person's wishes regarding the medical treatment the person would want if he was unable to share his wishes with the healthcare provider. (Para 186)

Another type of Advance Medical Directive is medical power of attorney. It is a document which allows an individual (principal) to appoint a trusted person (agent) to take healthcare decisions when the principal is not able to take such decisions. The agent appointed to deal with such issues can interpret the principal's decisions based on their mutual knowledge and understanding. (Para 187)

A failure to legally recognise Advance Medical Directives may amount to non-facilitation of the right to smoothen the dying process and the right to live with dignity. Further, a study of the position in other jurisdictions shows that Advance Directives have gained lawful recognition in several jurisdictions by way of legislation and in certain countries through judicial pronouncements. Though the sanctity of life has to be kept on the high pedestal yet in cases of terminally ill persons or PVS patients where there is no hope for revival, priority shall be given to the Advance Directive and the right of self-determination. (Paras 202.11 and 202.12)

Advance Medical Directive would serve as a fruitful means to facilitate the fructification of the sacrosanct right to life with dignity. The said directive will dispel many a doubt at the relevant time of need during the course of treatment of the patient. That apart, it will strengthen the mind of the treating doctors as they will be in a position to ensure, after being satisfied, that they are acting in a lawful manner. However, Advance Medical Directive cannot operate in abstraction. There has to be safeguards. They need to be spelt out. They are enumerated as follows: (Para 198)

Who can execute the Advance Directive and how?

The Advance Directive can be executed only by an adult who is of a sound and healthy state of mind and in a position to communicate, relate and comprehend the purpose and consequences of executing the document. It must be voluntarily executed and without any coercion or inducement or compulsion and after having full knowledge or information. It should have characteristics of an informed consent given without any undue influence or constraint. It shall be in writing clearly stating as to when medical treatment may be withdrawn or no specific medical treatment shall be given which will only have the effect of delaying the process of death that may otherwise cause him/her pain, anguish and suffering and further put him/her in a state of indignity. (Paras 198.1, 198.1.1, 198.1.2, 198.3 and 198.1.4)

What should it contain?

It should clearly indicate the decision relating to the circumstances in which withholding or withdrawal of medical treatment can be resorted to. It should be in

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specific terms and the instructions must be absolutely clear and unambiguous. It should mention that the executor may revoke the instructions/authority at any time. It should disclose that the executor has understood the consequences of executing such a document. It should specify the name of a guardian or close relative who, in the event of the executor becoming incapable of taking decision at the relevant time, will be authorised to give consent to refuse or withdraw medical treatment in a manner consistent with the Advance Directive. In the event that there is more than one valid Advance Directive, none of which have been revoked, the most recently signed Advance Directive will be considered as the last expression of the patient's wishes and will be given effect to. (Para 198.2)

How should it be recorded and preserved?

The document should be signed by the executor in the presence of two attesting witnesses, preferably independent, and countersigned by the jurisdictional Judicial Magistrate of First Class (JMFC) so designated by the District Judge concerned. The witnesses and the jurisdictional JMFC shall record their satisfaction that the document has been executed voluntarily and without any coercion or inducement or compulsion and with full understanding of all the relevant information and consequences. The JMFC shall preserve one copy of the document in his office, in addition to keeping it in digital format. The JMFC shall forward one copy of the document to the Registry of the jurisdictional District Court for being preserved. Additionally, the Registry of the District Judge shall retain the document in digital format. The JMFC shall cause to inform the immediate family members of the executor, if not present at the time of execution, and make them aware about the execution of the document. A copy shall be handed over to the competent officer of the local Government or the Municipal Corporation or Municipality or Panchayat, as the case may be. The aforesaid authorities shall nominate a competent official in that regard who shall be the custodian of the said document. The JMFC shall cause to hand over copy of the Advance Directive to the family physician, if any. (Para 198.3)

When and by whom can it be given effect to?

In the event the executor becomes terminally ill and is undergoing prolonged medical treatment with no hope of recovery and cure of the ailment, the treating physician, when made aware about the Advance Directive, shall ascertain the genuineness and authenticity thereof from the jurisdictional JMFC before acting upon the same. (Para 198.4.1)

The instructions in the document must be given due weight by the doctors. However, it should be given effect to only after being fully satisfied that the executor is terminally ill and is undergoing prolonged treatment or is surviving on life support and that the illness of the executor is incurable or there is no hope of him/her being cured. (Para 198.4.2)

If the physician treating the patient (executor of the document) is satisfied that the instructions given in the document need to be acted upon, he shall inform the executor or his guardian/close relative, as the case may be, about the nature of illness, the availability of medical care and consequences of alternative forms of treatment and the consequences of remaining untreated. He must also ensure that he beliefs on reasonable grounds that the person in question understands the information provided, has cogitated over the options and has come to a firm

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view that the option of withdrawal or refusal of medical treatment is the best choice. (Para 198.4.3)

The physician/hospital where the executor has been admitted for medical treatment shall then constitute a Medical Board consisting of the Head of the treating department and at least three experts from the fields of general medicine, cardiology, neurology, nephrology, psychiatry or oncology with experience in critical care and with overall standing in the medical profession of at least twenty years who, in turn, shall visit the patient in the presence of his guardian/close relative and form an opinion whether to certify or not to certify carrying out the instructions of withdrawal or refusal of further medical treatment. This decision shall be regarded as a preliminary opinion. (Para 198.4.4)

In the event the Hospital Medical Board certifies that the instructions contained in the Advance Directive ought to be carried out, the physician/hospital shall forthwith inform the jurisdictional Collector about the proposal. The jurisdictional Collector shall then immediately constitute a Medical Board comprising the Chief District Medical Officer of the district concerned as the Chairman and three expert doctors from the fields of general medicine, cardiology, neurology, nephrology, psychiatry or oncology with experience in critical care and with overall standing in the medical profession of at least twenty years (who were not members of the previous Medical Board of the hospital). They shall jointly visit the hospital where the patient is admitted and if they concur with the initial decision of the Medical Board of the hospital, they may endorse the certificate to carry out the instructions given in the Advance Directive. (Para 198.4.5)

The Board constituted by the Collector must beforehand ascertain the wishes of the executor if he is in a position to communicate and is capable of understanding the consequences of withdrawal of medical treatment. In the event the executor is incapable of taking decision or develops impaired decision-making capacity, then the consent of the guardian nominated by the executor in the Advance Directive should be obtained regarding refusal or withdrawal of medical treatment to the executor to the extent of and consistent with the clear instructions given in the Advance Directive. (Para 198.4.6)

The Chairman of the Medical Board nominated by the Collector, that is, the Chief District Medical Officer, shall convey the decision of the Board to the jurisdictional JMFC before giving effect to the decision to withdraw the medical treatment administered to the executor. The JMFC shall visit the patient at the earliest and, after examining all aspects, authorise the implementation of the decision of the Board. (Para 198.4.7)

It will be open to the executor to revoke the document at any stage before it is acted upon and implemented. (Para 198.4.8)

What if permission is refused by Medical Board?

If permission to withdraw medical treatment is refused by the Medical Board, it would be open to the executor of the Advance Directive or his family members or even the treating doctor or the hospital staff to approach the High Court by way of writ petition under Article 226 of the Constitution. If such application is filed before the High Court, the Chief Justice of the said High Court shall constitute a Division Bench to decide upon grant of approval or to refuse the same. The High Court will

be free to constitute an independent committee consisting of three doctors from the fields of general medicine, cardiology, neurology, nephrology, psychiatry or oncology with experience in critical care and with overall standing in the medical profession of at least twenty years. (Para 198.5.1)

The High Court shall hear the application expeditiously after affording opportunity to the State counsel. It would be open to the High Court to constitute Medical Board in terms of its order to examine the patient and submit report about the feasibility of acting upon the instructions contained in the Advance Directive. (Para 198.5.2)

Needless to say that the High Court shall render its decision at the earliest as such matters cannot brook any delay and it shall ascribe reasons specifically keeping in mind the principles of "best interests of the patient". (Para 198.5.3)

Revocation or inapplicability of Advance Directives.

An individual may withdraw or alter the Advance Directive at any time when he/she has the capacity to do so and by following the same procedure as provided for recording of Advance Directive. Withdrawal or revocation of an Advance Directive must be in writing. (Para 198.6.1)

An Advance Directive shall not be applicable to the treatment in question if there are reasonable grounds for believing that circumstances exist which the person making the directive did not anticipate at the time of the Advance Directive and which would have affected his decision had he anticipated them. (Para 198.6.2)

If the Advance Directive is not clear and ambiguous, the Medical Boards concerned shall not give effect to the same and, in that event, the guidelines meant for patients without Advance Directive shall be made applicable. (Para 198.6.3)

Where the Hospital Medical Board takes a decision not to follow an Advance Directive while treating a person, then it shall make an application to the Medical Board constituted by the Collector for consideration and appropriate direction on the Advance Directive. (Para 198.6.4)

Cases where there is no Advance Directive

It is necessary to make it clear that there will be cases where there is no Advance Directive. The said class of persons cannot be alienated. In cases where there is no Advance Directive, the procedure and safeguards are to be same as applied to cases where Advance Directives are in existence and in addition there to, the following procedure shall be followed: (Para 199)

In cases where the patient is terminally ill and undergoing prolonged treatment in respect of ailment which is incurable or where there is no hope of being cured, the physician may inform the hospital which, in turn, shall constitute a Hospital Medical Board in the manner indicated earlier. The Hospital Medical Board shall discuss with the family physician and the family members and record the minutes of the discussion in writing. During the discussion, the family members shall be apprised of the pros and cons of withdrawal or refusal of further medical treatment to the patient and if they give consent in writing, then the Hospital Medical Board may certify the course of action to be taken. Their decision will be regarded as a preliminary opinion. (Para 199.1)

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In the event the Hospital Medical Board certifies the option of withdrawal or refusal of further medical treatment, the hospital shall immediately inform the jurisdictional Collector. The jurisdictional Collector shall then constitute a Medical Board comprising the Chief District Medical Officer as the Chairman and three experts from the fields of general medicine, cardiology, neurology, nephrology, psychiatry or oncology with experience in critical care and with overall standing in the medical profession of at least twenty years. The Medical Board constituted by the Collector shall visit the hospital for physical examination of the patient and, after studying the medical papers, may concur with the opinion of the Hospital Medical Board. In that event, intimation shall be given by the Chairman of the Collector nominated Medical Board to the JMFC and the family members of the patient. (Para 199.2)

The JMFC shall visit the patient at the earliest and verify the medical reports, examine the condition of the patient, discuss with the family members of the patient and, if satisfied in all respects, may endorse the decision of the Collector nominated Medical Board to withdraw or refuse further medical treatment to the terminally-ill patient. (Para 199.3)

There may be cases where the Board may not take a decision to the effect of withdrawing medical treatment of the patient or the Collector nominated Medical Board may not concur with the opinion of the hospital Medical Board. In such a situation, the nominee of the patient or the family member or the treating doctor or the hospital staff can seek permission from the High Court to withdraw life support by way of writ petition under Article 226 of the Constitution in which case the Chief Justice of the said High Court shall constitute a Division Bench which shall decide to grant approval or not. The High Court may constitute an independent committee to depute three doctors from the fields of general medicine, cardiology, neurology, nephrology, psychiatry or oncology with experience in critical care and with overall standing in the medical profession of at least twenty years after consulting the competent medical practitioners. It shall also afford an opportunity to the State counsel. The High Court in such cases shall render its decision at the earliest since such matters cannot brook any delay. Needless to say, the High Court shall ascribe reasons specifically keeping in mind the principle of "best interests of the patient". (Para 199.4)

It is appropriate to cover a vital aspect to the effect the life support is withdrawn, the same shall also be intimated by the Magistrate to the High Court. It shall be kept in a digital format by the Registry of the High Court apart from keeping the hard copy which shall be destroyed after the expiry of three years from the death of the patient. (Para 200)

When passive euthanasia as a situational palliative measure becomes applicable, the best interest of the patient shall override the State interest. (Para 202.14)

The principles relating to the procedure for execution of Advance Directive and the guidelines to give effect to passive euthanasia in both circumstances, namely, where there are Advance Directives and where there are none, have been laid down in exercise of the power under Article 142 of the Constitution and the law stated in

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Vishaka, (1997) 6 SCC 241. The directive and guidelines shall remain in force till Parliament brings a legislation in the field. (Para 203)

Vishaka v. *State of Rajasthan*, (1997) 6 SCC 241 : 1997 SCC (Cri) 932, *referred to*

Per Sikri, J. (concurring)

The petitioner wants that citizens should have right to decide in advance not to accept any kind of treatment at a stage when they are terminally ill. Expressing this in advance in a document is known as "living will" or "Advance Directive", whereby the aforesaid self-determination of the person is to be acted upon when he reaches PVS or is brain dead/clinically dead. Such an advance authority is akin to well-recognised common law right to refuse medical treatment. (Paras 328 and 333)

Gian Kaur v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374; *Cruzan* v. *Missouri Department of Health*, 1990 SCC OnLine US SC 123 : 111 L Ed 2d 224 : 110 S Ct 2841 : 497 US 261 (1990); *K.S. Puttaswamy* v. *Union of India*, (2017) 10 SCC 1, *relied on*

Aruna Ramachandra Shanbaug v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294, *affirmed on this point*

T. (Adult: Refusal of Treatment), In re, 1993 Fam 95 : (1992) 3 WLR 782 : (1992) 4 All ER 649 (CA); *B. (Adult: Refusal of Medical Treatment), In re*, (2002) 2 All ER 449; *Malette* v. *Shulman*, (1990) 67 DLR (4th) 321 : 72 OR (2d) 417 (CA), *approved*

Schloendorff v. *Society of New York Hospital*, 105 NE 92 : 211 NY 125 (1914); *Sidaway* v. *Board of Governors of the Bethlem Royal Hospital*, 1985 AC 871 : (1985) 2 WLR 480 : (1985) 1 All ER 643 (HL); *Nancy B.* v. *Hotel Dieu de Quebec*, (1992) 86 DLR (4th) 385 (Que SC); *T. (Adult: Refusal of Treatment), In re*, 1993 Fam 95 : (1992) 3 WLR 782 : (1992) 4 All ER 649 (CA); *Skinner* v. *Oklahoma*, 1942 SCC OnLine US SC 125 : 86 L Ed 1655 : 316 US 535 (1942); *Williams* v. *Fears*, 1900 SCC OnLine US SC 211 : 45 L Ed 186 : 179 US 270 (1900), *cited*

Advance Directives are instruments through which persons express their wishes at a prior point in time, when they are capable of making an informed decision, regarding their medical treatment in the future, when they are not in a position to make an informed decision, by reason of being unconscious or in a PVS or in a coma. A medical power of attorney is an instrument through which persons nominate representatives to make decisions regarding their medical treatment at a point in time when the persons executing the instrument are unable to make informed decisions themselves. Clause 11 of the draft Treatment of Terminally-ill Patients (Protection of Patients and Medical Practitioners) Bill, 2016 states that Advance Directives or medical power of attorney shall be void and of no effect and shall not be binding on any medical practitioner. This blanket ban, including the failure even to give some weight to Advance Directives while making a decision about the withholding or withdrawal of life-sustaining treatment is disproportionate. It does not constitute a fair, just or reasonable procedure, which is a requirement for the imposition of a restriction on the right to life (in this case, expressed as the right to die with dignity) under Article 21. (Para 335)

On the one hand autonomy of an individual gives him right to choose his destiny and, therefore, he may decide beforehand, in the form of Advance Directive, at what stage of his physical condition he would not like to have medical treatment, and on the other hand, there are dangers of misuse thereof as well. But possibility of misuse cannot be held to be a valid ground for rejecting Advance Directive, as opined by the Law Commission of India as well in its 196th and

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241st Reports. Instead, attempt can be made to provide safeguards for exercise of such Advance Directive. Section 5 of the Mental Health Ccare Act, 2017 and Section 3 of the Transplantation of Human Organs and Tissues Act, 1994 provide such safeguards. (Paras 336 and 337)

All the suggestions of the counsel and various aspects of Advance Directives have been elaborately considered and detailed directions are given by the Hon'ble the Chief Justice in his judgment, with which I duly concur. (Para 341)

Per Chandrachud, J. (concurring)

A patient, in a sound state of mind, possesses the ability to make decisions and choices and can legitimately refuse medical intervention. Advance Directives have evolved conceptually to deal with cases where a patient who subsequently faces a loss of the mental faculty to decide has left instructions, when he or she was possessed of decision-making capacity, on how future medical decisions should be made. Advance Directives are thus documents a person completes while still in possession of decisional capacity about how treatment decisions should be made in the event she or he loses decision-making capacity in future. They cover three conditions: (*i*) a terminal condition; (*ii*) a persistently unconscious condition; and (*iii*) an end-stage condition. The Advance Directive is an indicator to medical professionals of the underlying desire of the person executing it. (Paras 468, 472, 474 and 486)

"Advance Directives and Substitute Decision-Making", *Stanford Encyclopaedia of Philosophy* (24-3-2009) <https://plato.standford.edu/entries/advance-directives/>; Hazel Biggs: "Euthanasia, Death with Dignity and the Law" (Hart Publishing, 2001), at p. 115; James C. Turner: "Living Wills — Need for Legal Recognition", West Virginia Law Review (1976), Vol. 78, Issue 3, at p. 370, *referred to*

An individual who is in a sound and competent state of mind is entitled by means of an Advance Directive in writing, to specify the nature of medical intervention which may not be adopted in future, should he or she cease to possess the mental ability to decide. Such an Advance Directive is entitled to deference by the treating doctor. The treating doctor who, in a good faith exercise of professional medical judgment abides by an Advance Directive is protected against the burden of criminal liability. (Para 520)

A *terminal condition* is an incurable or irreversible condition which even with the administration of life-sustaining treatment will result in death in the foreseeable future. A *persistently unconscious* condition is an irreversible condition, in which thought and awareness of self and environment are absent. An *end-stage condition* is a condition caused by injury, disease or illness which results in severe and permanent deterioration indicated by incompetency and complete physical dependency for which treatment of the irreversible condition would be medically ineffective. (Para 475)

The reason for recognising an Advance Directive is based on individual autonomy. As an autonomous person, every individual has a constitutionally recognised right to refuse medical treatment. The right not to accept medical treatment is essential to liberty. Medical treatment cannot be thrust upon an individual, however, it may have been conceived in the interest of the individual. The reasons which may lead a person in a sound state of mind to refuse

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medical treatment are inscrutable. Those decisions are not subject to scrutiny and have to be respected by the law as an essential attribute of the right of the individual to have control over the body. The State cannot compel an unwilling individual to receive medical treatment. While an individual cannot compel a medical professional to provide a *particular* treatment (this being in the realm of professional medical judgment), it is equally true that the individual cannot be compelled to undergo medical intervention. The principle of sanctity of life thus recognises the fundamental liberty of every person to control his or her body and as its incident, to decline medical treatment. The ability to take such a decision is an essential element of the privacy of the being. Privacy also ensures that a decision as personal as whether or not to accept medical treatment lies exclusively with the individual as an autonomous being. The reasons which impel an individual to do so are part of the privacy of the individual. The mental processes which lead to decision-making are equally part of the constitutionally protected right to privacy. (Para 476)

Advance Directives are founded on the principle that an individual whose state of mind is not clouded by an affliction which prevents him or her from taking decisions is entitled to decide whether to accept or not accept medical intervention. If a decision can be made for the present, when the individual is in a sound state of mind, such a person should be allowed to decide the course of action which should be followed in the future if he or she were to be in a situation which affects the ability to take decisions. If a decision on whether or not to receive medical treatment is valid for the present such a decision must be equally valid when it is intended to operate in the future. Advance Directives are, in other words, grounded in a recognition by the law of the importance of consent as an essential attribute of personal liberty. It is the consensual nature of the act underlying the Advance Directive which imparts sanctity to it in future in the same manner as a decision in the present on whether or not to accept medical treatment. (Para 477)

When a patient is brought for medical treatment in a state of mind in which he or she is deprived of the mental capacity to make informed choices, the medical professional needs to determine the line of treatment. One line of enquiry, which seeks to protect patient autonomy is how the individual would have made a decision if he or she had decision-making capacity. This is called the substituted judgment standard. An Advance Medical Directive is construed as a facilitative mechanism in the application of the substituted judgment standard, if it provides to the physician a communication by the patient (when she or he was in a fit state of mind) of the desire for or restraint on being provided medical treatment in future. (Para 478)

Conceptually, there is a second standard, which is the caregiver standard. This is founded on the principle of beneficence. The second standard seeks to apply an objective notion of a line of treatment which a reasonable individual would desire in the circumstances. The difference between these two standards is that the first seeks to reconstruct the subjective point of view of the patient. The second allows for "a more generic view of interests", without having to rely on the "idiosyncratic values and preference of the patient in question". An autonomous decision suited to an earlier identity may not always be a valid rationale for determining the course of action in respect of a new identity which a patient acquires in the course of illness. (Paras 479, 480 and 483)

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The relationship between a doctor and her patient with an evolving mental condition needs a balance between the *desires* of the patient in a different mental state and the *needs* of the patient in the present condition. Neither can be ignored in preference to the other. The first recognises the patient as an autonomous individual whose desires and choices must be respected by law and medicine. The desire not to be subject to endless medical intervention, when one's condition of mind or body have reached an irreversible state is a profound reflection of the value to be left alone. Constitutional jurisprudence protects it as part of the right to privacy. On the other hand, the need to procure the dignity of the individual in a deteriorating and irreversible state of body or mind is as crucial to the value of existence. The doctor must respect the former while being committed as a professional to protect the latter. (Para 484)

Human experience suggests that there is a chasm of imponderables which divide the present from the future. Such a divide may have a bearing on whether and if so, the extent to which an Advance Directive should bind in the future. The sanctity of an Advance Directive is founded upon the expression of the will of an individual who is in a sound state of mind when the directive is executed. Underlying the consensual character of the declaration is the notion of the consent being informed. Undoubtedly, the reasons which have weighed with an individual in executing the Advance Directive cannot be scrutinised (in the absence of situations such as fraud or coercion which implicate the very basis of the consent). However, an individual who expresses the desire not to be subjected to a particular line of treatment in the future, should she or he be ailing in the future, does so on an assessment of treatment options available when the directive is executed. Advances in medical knowledge between the date of the execution of the document and an uncertain future date when the individual may possibly confront treatment for the disease may have led to a re-evaluation by the person of the basis on which a desire was expressed several years earlier. Another fundamental issue is whether the individual can by means of an Advance Directive compel the withholding of basic care such as hydration and nourishment in the future. Protecting the individual from pain and suffering as well as the indignity of debility may similarly raise important issues. Advance Directives may hence conceivably raise ethical issues of the extent to which the perception of the individual who executes it must prevail in priority to the best interest of the patient. The Advance Directive is an indicator to medical professionals of the underlying desire of the person executing it. (Paras 485 and 486)

In a society such as ours where family ties have an important place in social existence, Advance Directives also provide a sense of solace to the family. Decisions such as whether to withhold or withdraw artificial life saving treatment are difficult for families to take. Advance Directives provide moral authority for the family of the patient that the decision which has been taken to withdraw or withhold artificial life support is in accord with the stated desire of the patient expressed earlier. The Court is above all, engaged in the task of expounding the Constitution. In doing so, the Court have been confronted with the enormous task of finding substance and balance in the relationship between life, morality and the experience of dying. The reason which has impelled the Court to recognise passive euthanasia and Advance Directives is that both bear a close association to the human urge to live with dignity. Age brings isolation. Physical and mental debility bring a loss of self-worth. Pain and suffering are accompanied by a sense of being helpless. The loss of control is compounded when medical intervention takes over

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life. Human values are then lost to technology. More significant than the affliction of ageing and disease is the fear of our human persona being lost in the anonymity of an intensive care ward. It is hence necessary for this Court to recognise that our dignity as citizens continues to be safeguarded by the Constitution even when life is seemingly lost and questions about our own mortality confront us in the twilight of existence. (Paras 487 and 514)

The recognition of Advance Directives as part of a regime of constitutional jurisprudence is an essential attribute of the right to life and personal liberty under Article 21. That right comprehends dignity as its essential foundation. Quality of life is integral to dignity. As an essential aspect of dignity and the preservation of autonomy of choice and decision-making, each individual must have the right on whether or not to accept medical intervention. Such a choice expressed at a point in time when the individual is in a sound and competent state of mind should have sanctity in the future if the individual were to cease to have the mental capability to take decisions and make choices. Yet, a balance between the application of the substituted judgment standard and the best interest standard is necessary as a matter of public interest. This can be achieved by allowing a supervisory role to an expert body with whom shall rest oversight in regard to whether a patient in the terminal stage of an illness or in a permanent vegetative state should be withheld or withdrawn from artificial life support. (Para 488)

In the context of mental illness, Parliament has now expressly recognised the validity of Advance Directives and delineated the role of nominated representatives in being associated with healthcare and treatment decisions. (Para 506)

A comparative analysis of Advance Directives in various jurisdictions indicates some common components. They include the patient's views and wishes regarding: (*i*) Cardio-pulmonary resuscitation (CPR) — treatment that attempts to start breathing and blood flow in people who have stopped breathing or whose heart has stopped beating; (*ii*) Breathing tubes; (*iii*) Feeding/hydration; (*iv*) Dialysis; (*v*) Pain killers; (*vi*) Antibiotics; (*vii*) Directions for organ donation; and (*viii*) Appointment of proxy/healthcare agent/surrogate, etc. (Para 507)

Certain precepts can be deduced from the existing global framework on Advance Directives. These include the following: (Para 508)

Advance Directives reflect the right of an adult with capacity to make a decision to refuse specific treatment at a point in the future when they lack capacity. A person can be said to lack capacity when "in relation to a matter if at the material time he is unable to make a decision for himself in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain". He/she must be deemed to have capacity to make decisions regarding his treatment if such person has ability to— (*a*) understand the information that is relevant to take a decision on the treatment or admission or personal assistance; or (*b*) appreciate any reasonably foreseeable consequence of a decision or lack of decision on the treatment or admission or personal assistance; or (*c*) communicate such decision by means of speech, expression, gesture or any other means. (Para 508.1)

For a legally valid advance decision to refuse treatment, an Advance Directive must fulfil a basic criteria, which should include that—a directive must be made by a person after he has reached 18 years of age; the person must be mentally competent when the directive is made; the directive must specify—in medical or

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layman's terms—the treatment refused; and, it can specify the circumstances in which the refusal is to apply. (Para 508.2)

At any time before reaching the comatose state, an individual can revoke the directive. In other words, an individual may withdraw or alter an advance decision at any time when he/she has capacity to do so. Such withdrawal (including a partial withdrawal) need not be in writing. A directive must be revoked if the statements or actions subsequent to the written document indicate contrary consent. (Para 508.3)

An advance decision will not be applicable to the treatment in question if — (*a*) at the material time, the person, who made it, did not have the capacity to give or refuse consent to it; (*b*) the treatment is not the treatment specified in the advance decision; (*c*) any circumstances specified in the advance decision are absent; or (*d*) there are reasonable grounds for believing that circumstances exist which the person making the directive did not anticipate at the time of the advance decision and which would have affected his decision had he anticipated them. (Para 508.4)

If a person intends specifically to refuse life-sustaining procedures, he/she must — clearly indicate that it is to apply even if life is at risk and death will predictably result; put the decision in writing; and, ensure it is signed and witnessed. (Para 508.5)

In the event that there is more than one valid Advance Directive, none of which have been revoked, the most recently signed Advance Directive will be considered as the last expression of the patient's wishes and will be given effect to. (Para 508.6)

A person will not incur any liability for the consequences of withholding or withdrawing a treatment from an individual, if he, at the material time, reasonably beliefs that a valid advance decision applicable to the treatment, made by that individual, exists. (Para 508.7)

An Advance Directive must clearly contain the following:

(*a*) full details of its maker, including date of birth, home address and any distinguishing features;

(*b*) the name and address of a general practitioner and whether they have a copy;

(*c*) a statement that the document should be used if the maker lacks capacity to make treatment decisions;

(*d*) a clear statement of the decision, the treatment to be refused and the circumstances in which the decision will apply;

(*e*) the date the document was written (or reviewed); and,

(*f*) the person's signature and the signature of a witness. (Para 508.8)

Advance Directives also have limitations. Individuals may not fully understand treatment options or recognise the consequences of certain choices in the future. Sometimes, people change their minds after expressing Advance Directives and forget to inform others. Another issue with Advance Directives is that vague statements can make it difficult to understand the course of action when a situation arises. For example, general statements rejecting "heroic treatments" are vague and do not indicate whether you want a particular treatment for a specific situation

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(such as antibiotics for pneumonia after a severe stroke). On the other hand, very specific directives for future care may not be useful when situations change in unexpected ways. New medical therapies may also have become available since an Advance Directive was given. Thus, Advance Directives should be reviewed and revised regularly if feelings about certain issues change, so that current wishes and decisions are always legally documented. (Para 509)

An important facet which a regime of advanced care directives must factor in, is the existence of variables which affect the process. These include, in our society, institutional aspects such as the paucity of access to publicly funded medicare, declining standards of professional ethics and the inadequacy of institutional responses to the lack of professional accountability in the medical profession. (Para 510)

A report submitted in October 2017 by the American Bar Association's Commission on Law and Ageing to the US Department of Health Services, dwelt on several variables which bear upon Advance Directives. (Para 511)

There are variables which "profoundly affect the experience of dying" even in a developed society. They provide a sobering reflection of the gulf which separates the needs of patients and the availability of services to the poor, in a society like ours with large impoverished strata. Patient autonomy may mean little to the impoverished citizen. For marginalised groups in urban and rural India, even basic medical care is a distant reality. Advance Directives postulate the availability of medical care. For, it is on the hypothesis of such care being available that the right to choose or refuse treatment is based. The stark reality in our society is that medical facilities are woefully inadequate. Primary medical care is a luxury in many places. Public hospitals are overwhelmed by the gap between the demand for medical care and its supply. Advance Directives may have little significance to large segments of Indian society which are denied access to basic care. Advance Directives also require an awareness of rights. The stark reality is that the average Indian is deprived of even basic medical facilities in an environment where absence of rudimentary care is the norm. Moreover, absolute notions of patient autonomy need to be evaluated in the context of the Indian social structure where bonds of family, religion and caste predominate. The immediate family and in many situations, the larger unit of the extended family are caregivers. In the absence of a social security net, universal medical coverage and compulsory insurance, it is the family to which a patient turns to in distress. Families become the caregivers, willingly or as a result of social conditioning, especially in the absence of resources and alternative institutional facilities. The views of the family which are drawn by close bonds of kinship have to be factored into the process. At the other end of the spectrum, rising costs of medical care in the urban areas threaten to ruin the finances of a family when a member is struck by a serious illness. To them, Advance Directives may provide a measure of assurance when a crucial decision as to whether to prolong artificial support in an irreversible medical situation is to be taken. The fact that the patient had expressed a desire in the form of an Advance Directive obviates a sense of moral guilt on the part of the caregivers, when the family accepts the doctors' wisdom to withdraw or withhold artificial support. Another important variable which a regime of Advance Directives must

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bear in mind is the danger of misuse. The regime of Advance Directives which is intended to secure patient autonomy must contain safeguards against the greed of avaricious relatives colluding with willing medical professionals. The safeguards must be robust to obviate the dangers. The complexities of culture and of the social strata adverted to above only emphasise the wide diversity that prevails within the country. Our solution must take into account the diversity across the country. It is with the above background in view that a safeguard in the form of broad-based committees to oversee the process have been introduced. (Para 512)

The directions in regard to the regime of Advance Directives have been issued in exercise of the power conferred by Article 142 of the Constitution and shall continue to hold the field until a suitable legislation is enacted by Parliament to govern the area. (Para 524)

I agree with the directions proposed in the judgment of the learned Chief Justice. The reference shall stand disposed of in the above terms. (Para 525)

T. (Adult: Refusal of Treatment), In re, (1942) 4 All ER 649; *C. (Adult: Refusal of Treatment), In re*, (1994) 1 WLR 290 : (1994) 1 All ER 819; *St. George's Health Care N.H.S. Trust* v. *S.*, 1999 Fam 26 : (1998) 3 WLR 936 (CA); *B. (Adult: Refusal of Medical Treatment), In re*, (2002) 2 All ER 449; *M. (Adult Patient), In re*, (2012) 1 WLR 1653 : 2011 EWHC 2443 (Fam); *Aintree University Hospitals NHS Foundation Trust* v. *James*, 2013 UK SC 67; *AK (Adult Patient) (Medical Treatment: Consent), In re*, (2001) 1 FLR 129; *HE* v. *A Hospital N.H.S. Trust*, (2003) 2 FLR 408, *referred to*

A.S. Kessel and J. Meran: "Advance Directives in the UK: Legal, Ethical, and Practical Considerations for Doctors", British Journal of General Practice (1998), at p. 1263; "Are Advance Directives Legally Binding or Simply the Starting Point for Discussion on patients' Best Interests?", BMJ (28-11-2009), Vol. 339, p. 1231; Elizabeth Wicks, *The State and the Body: Legal Regulation of Bodily Autonomy*, (Hart Publishing, 2016), at p. 69; Alexander Ruck Keene, "Advance Decisions: Getting it Right?" <http://www.39essex.com/docs/articles/advance_decisions_paper_ark_december_2012.pdf>; Luis Kutner, "Euthanasia: Due Process for Death with Dignity; The Living Will", Indiana Law Journal (Winter 1979), Vol. 54, Issue, 2, at p. 228; "Advance Directives and Advance Care Planning: Legal and Policy Issues", US Department of Health and Human Services (October 2007) <https://aspe.hhs.gov/system/files/pdf/75366/adacplpi.pdf> at p. 1, *referred to*

Per Ashok Bhushan, J. (concurring)

The question is who is competent to take decision in case of terminally ill or PVS patient, who is not able to take decision. In case of a person who is suffering from a disease and is taking medical treatment, there are three stakeholders; the person himself, his family members and doctor treating the patient. In cases of incompetent patients who are unable to take an informed decision, it is in the best interests of the patient that the decision be taken by the competent medical experts and that such decision be implemented after providing a cooling period at least of one month to enable aggrieved person to approach the court of law. The best interest of the patient as determined by medical experts shall meet the ends of justice. The medical team by taking decision shall also take into consideration the opinion of the blood relations of the patient and other relevant facts and circumstances. (Paras 611 and 612)

The concept of Advance Medical Directive is also called living will is of recent origin, which gained recognition in latter part of the 20th century. Advance Medical Directives are not exclusively associated with end-of-life decisions. However, it

is vital to ensure that form of an Advance Medical Directive reflects the needs of its author and is sufficiently authoritative and practical to enable its provisions to be upheld. In most of the western countries Advance Medical Directives have taken a legalistic form incorporating a formal declaration to be signed by competent witnesses. The laws also make provisions for updating confirmation of its applicability and revocation. Protecting the individual autonomy is obviously the primary purpose of an Advance Medical Directive. The right to decide one's own fate presupposes a capacity to do so. The answer as to when a particular Advance Medical Directive becomes operative usually depends upon an assent of when its author is no longer competent to participate in medical decision-making. (Paras 614 and 615)

An Advance Medical Directive is an individual's advance exercise of his autonomy on the subject of extent of medical intervention that he wishes to allow upon his own body at a future date, when he may not be in a position to specify his wishes. The purpose and object of Advance Medical Directive is to express the choice of a person regarding medical treatment in an event when he loses capacity to take a decision. Use and operation of Advance Medical Directive is to confine only to a case when person becomes incapacitated to take an informed decision regarding his medical treatment. So long as an individual can take an informed decision regarding his medical treatment, there is no occasion to look into Advance Medical Directives. A person has unfettered right to change or cancel his Advance Medical Directives looking to the need of time and advancement in medical science. Hence, a person cannot be tied up or bound by his instructions given at an earlier point of time. (Para 616)

The concept of Advance Medical Directive originated largely as a response to development in medicines. Many people living depending on machines cause great financial distress to the family with the cost of long-term medical treatment. Advance Medical Directive was developed as a means to restrict the kinds of medical intervention in event when one becomes incapacitated. The foundation for seeking direction regarding Advance Medical Directive is extension of the right to refuse medical treatment and the right to die with dignity. When a competent patient has right to take a decision regarding medical treatment, with regard to medical procedure entailing right to die with dignity, the said right cannot be denied to those patients, who have become incompetent to take an informed decision at the relevant time. The concept of Advance Medical Directive has gained ground to give effect to the rights of those patients, who at a particular time are not able to take an informed decision. (Para 617)

Another concept which has been accepted in several countries is recognition of instrument through which a person nominates a representative to make decision regarding their medical treatment at a point of time when the person executing the instrument is unable to make an informed decision. This is called attorney authorisation leading to medical treatment. (Para 618)

The right to execute an Advance Medical Directive is nothing but a step towards protection of the aforesaid right by an individual, in event he becomes incompetent to take an informed decision, in particular stage of life. It has to be recognised by all including the States that a person has right to execute an

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Advance Medical Directive to be utilised to know his decision regarding manner and extent of medical treatment given to his body, in case he is incapacitated to take an informed decision. Such right by an individual does not depend on any recognition or legislation by a State and such rights can be exercised by an individual in recognition and in affirmation of his right of bodily integrity and self-determination which are duly protected under Article 21 of the Constitution. The procedure and manner of such expression of such right is a question which needs to be addressed to protect the vulnerable, infirm and old from any misuse. It is the duty of the State to protect its subjects specially those who are infirm, old and need medical care. The duty of doctor to extend medical care to the patients, who comes to them in no manner diminishes in any manner by recognition of concept that an individual is entitled to execute an Advance Medical Directive. The physicians and medical practitioners treating a person, who is incompetent to express an informed decision have to act in a manner so as to give effect to the express wishes of an individual. (Para 624)

The directions and safeguards which have been enumerated by the Hon'ble Chief Justice in his judgment shall be sufficient to safeguard the interests of the patients, doctors and society till the appropriate legislation is framed and enforced. (Para 627)

The conclusion is that a person with competent medical facility is entitled to execute an Advance Medical Directive subject to various safeguards as noted above. (Para 628)

T. **Jurisprudence — Decision-making process of court — Kinds of cases which come up before Supreme Court for adjudication viz. easy cases, intermediate cases and hard cases — In hard cases there are multiple lawful situations in which Court is required to exercise discretion in larger public interest — This has to be done within framework of limitations, procedural as well as substantive — After considering all alternatives, Court has freedom of "sovereign prerogative choice"**

Held :

Per Sikri, J.

The courts, in dispensation of their judicial duties of deciding cases, come across all types of problems which are brought before them. These cases may be broadly classified into three categories: (*i*) the easy cases, (*ii*) the intermediate cases, and (*iii*) the hard cases. The meaning of certain legal norms, when applied with respect to a given system of facts, is so simple and clear that their application involves no judicial discretion. These are termed as the "*easy cases*". This may even apply to "*intermediate cases*". These would be those cases where both sides appear to have a legitimate legal argument supporting their position and a conscious act of interpretation is noted, before a Judge can conclude which side is right in law and there is only one lawful situation. However, when it comes to the hard cases, the court is faced with number of possibilities, all of which appear to be lawful within the context of the system. In these cases, judicial discretion exists as the choice is not between lawful and unlawful, but between lawful and lawful. A number of lawful solutions exist. In this scenario, the court is supposed to ultimately choose that solution which is in larger public interest. In other words, there are

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limitations that find the court with respect to the manner in which it chooses among possibilities (procedural limitations) and with respect to the considerations it takes into account in the choice (substantive limitations). Thus, discretion when applied to a court of justice means sound discretion guided by law. Thus, though the judicial discretion is with the court, the same is limited and not absolute. The court is not entitled to weigh any factor as it likes. It has to act within the framework of the limitations, and after they have been exhausted, there is a freedom of choice which can also be described as "*sovereign prerogative of choice*". (Paras 206 and 207)

"The Role of Judiciary and HIV Law"—Michael Kirby, in D.C. Jayasuriya (Ed.), *HIV Law, Ethics and Human Rights*; Dworkin, "Judicial Discretion", 6 J of Phil 624 (1963); *Aharon Barak: Judicial Discretion*, Yale University Press; B. Cardozo: *The Growth of the Law* 144 (1924), at 60-61; Justice O. Holmes: *Collected Legal Papers*, 239 (1921), *referred to*

U. **Human and Civil Rights — Universal Declaration of Human Rights, 1948 — Interpretation — Must keep pace with changing society — Needs of present have to be addressed through interpretative process accordingly unless same falls outside framework of the Constitution**

V. **Jurisprudence — Normative and analytical jurisprudence — When Court dealing with new concept and developing new legal norm, analytical and normative jurisprudence have significance**

Held :

Per Sikri, J.

Whenever the Court is entering into a new territory and is developing a new legal norm, discussion on normative jurisprudence assumes greater significance as the Court is called upon to decide what the legal norm should be. At the same time, this normative jurisprudence discourse has to be preceded by analytical jurisprudence, which is necessary for the Court to underline existing nature of law. That would facilitate knowing legal framework of what is the current scenario and, in turn, help in finding the correct answers. (Para 245)

W. **Jurisprudence — Law and social dynamism — Law must take cognizance of changing social ideology and developments and see how much strength and sanction can be drawn from the Constitution to convert the same into reality — Present immediate needs required to be addressed by Court through interpretative process**

Held :

Per Dipak Misra, C.J. and Khanwilkar, J.

The law must take cognizance of the changing society and march in consonance with the developing concepts. The need of the present has to be served with the interpretative process of law. However, it is to be seen how much strength and sanction can be drawn from the Constitution to consummate the changing ideology and convert it into a reality. The immediate needs are required to be addressed through the process of interpretation by the Court unless the same totally fall outside the constitutional framework or the constitutional interpretation fails to recognise such dynamism. (Para 166)

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92. (1970) 2 SCC 298, *Rustom Cowasjee Cooper* v. *Union of India* 66*c-d*
93. (1970) 1 SCC 248, *Rustom Cavasjee Cooper* v. *Union of India* 150*b-c*
94. (1964) 1 SCR 332 : AIR 1963 SC 1295 : (1963) 2 Cri LJ 329, *Kharak Singh* v. *State of U.P.* 63*a*, 149*e*, 149*f-g*
95. (1957) 1 WLR 582 : (1957) 2 All ER 118 (QB), *Bolam* v. *Friern Hospital Management Committee* 86*a-b*, 90*b*
96. 1942 SCC OnLine US SC 125 : 86 L Ed 1655 : 316 US 535 (1942), *Skinner* v. *Oklahoma* 187*c-d*
97. (1942) 4 All ER 649, *T. (Adult: Refusal of Treatment), In re* 257*f*
98. 1923 SCC OnLine US SC 105 : 67 L Ed 785 : 261 US 525 (1923), *Adkins* v. *Children's Hospital of the District of Columbia* 112*f*
99. 105 NE 92 : 211 NY 125 (1914), *Schloendorff* v. *Society of New York Hospital* 109*d*, 123*d-e*, 181*c*, 185*c-d*, 248*f-g*, 289*d*, 290*c-d*
100. 224 Ill 300 : 79 NE 562 (1906), *Pratt* v. *Davis* 289*e*
101. 1905 SCC OnLine US SC 100 : 49 L Ed 937 : 198 US 45 (1905), *Lochner* v. *New York* 164*a*
102. 95 Minn 261 : 104 NW 12 (1905), *Mohr* v. *Williams* 289*e*
103. 1900 SCC OnLine US SC 211 : 45 L Ed 186 : 179 US 270 (1900), *Williams* v. *Fears* 188*a*
104. 1891 SCC OnLine US SC 217 : 35 L Ed 734 : 11 S Ct 1000 : 141 US 250 (1891), *Union Pacific Rly. Co.* v. *Botsford* 290*a-b*
105. 1625 Jones, W. 97 : (1626) 82 ER 51 (HL), *Earl of Oxford, In re* 114*c-d*

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The Judgments* of the Court were delivered by

DIPAK MISRA, C.J. *(for himself and Khanwilkar, J.; Sikri, J., Chandrachud, J. and Ashok Bhushan, J., concurring)*—

INDEX TO JUDGMENT

* **Ed.**: Dipak Misra, C.J. delivered the judgment of the Court for himself and Khanwilkar, J. Sikri, J., Chandrachud, J. and Ashok Bhushan, J. rendered separated concurring judgments.

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A. *Prologue*

1. Life and death as concepts have invited many a thinker, philosopher, writer and physician to define or describe them. Sometimes attempts have been made or efforts have been undertaken to gloriously paint the pictures of both in many a colour and shade. Swami Vivekananda expects one to understand that life is the lamp that is constantly burning out and further suggests that if one wants to have life, one has to die every moment for it. John Dryden, an illustrious English author, considers life a cheat and says that men favour the deceit. No one considers that the goal of life is the grave. Léon Montenaeken would like to describe life as short, a little hoping, a little dreaming and then good night. The famous poet Dylan Thomas would state "do not go gentle into that good night". One may like to compare life with constant restless moment spent in fear of extinction of a valued vapour; and another may sincerely believe that it is beyond any conceivable metaphor. A metaphysical poet like John Donne, in his inimitable manner, says:

> "One short sleep past, we wake eternally, And death shall be no more; Death, thou shalt die."

2. Some would say with profound wisdom that life is to be lived only for pleasure and others with equal wise pragmatism would proclaim that life is meant for the realisation of divinity within one because that is where one feels the "self", the individuality and one's own real identity. Dharmaraj Yudhisthira may express that though man sees that death takes place every moment, yet he feels that the silence of death would not disturb him and nothing could be more surprising than the said thought. Yet others feel that one should never be concerned about the uncertain death and live life embracing hedonism till death comes. Charvaka, an ancient philosopher, frowns at the conception of re-birth and commends for living life to the fullest. Thus, death is complicated and life is a phenomenon which possibly intends to keep away from negatives that try to attack the virtue and vigour of life from any arena. In spite of all the statements, references and utterances, be it mystical, philosophical or psychological, the fact remains, at least on the basis of conceptual majority, that people love to live — whether at eighty or eighteen — and do not, in actuality, intend to treat life like an "autumn leaf". As Alfred Tennyson says:

> "No life that breathes with human breath has ever truly longed for death."

3. The perception is not always the same at every stage. There comes a phase in life when the spring of life is frozen, the rain of circulation becomes dry, the movement of body becomes motionless, the rainbow of life becomes colourless and the word "life" which one calls a dance in space and time

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becomes still and blurred and the inevitable death comes near to hold it as an octopus gripping firmly with its tentacles so that the person "shall rise up never". The ancient Greek philosopher, Epicurus, has said, although in a different context:

> "Why should I fear death?
> If I am, then death is not.
> If death is, then I am not.
> Why should I fear that which
> can only exist when I do not?"

But there is a fallacy in the said proposition. It is because mere existence does not amount to presence. And sometimes there is a feebleness of feeling of presence in semi-reality state when the idea of conceptual identity is lost, quality of life is sunk and the sanctity of life is destroyed and such destruction is denial of real living. Ernest Hemingway, in his book *The Old Man and the Sea*, expounds the idea that man can be destroyed, but cannot be defeated. In a certain context, it can be said, life sans dignity is an unacceptable defeat and life that meets death with dignity is a value to be aspired for and a moment for celebration.

4. The question that emerges is whether a person should be allowed to remain in such a stage of incurable passivity suffering from pain and anguish in the name of Hippocratic oath or, for that matter, regarding the suffering as only a state of mind and a relative perception or treating the utterance of death as a "word infinitely terrible" to be a rhetoric without any meaning. In contradistinction to the same, the question that arises is should he not be allowed to cross the doors of life and enter, painlessly and with dignity, into the dark tunnel of death whereafter it is said that there is resplendence. In delineation of such an issue, there emerges the question in law — Should he or she be given such treatment which has come into existence with the passage of time and progress of medical technology so that he/she exists possibly not realising what happens around him/her or should his/her individual dignity be sustained with concern by smoothening the process of dying.

5. The legal question does not singularly remain in the set framework of law or, for that matter, morality or dilemma of the doctors but also encapsulates social values and the family mindset to make a resolute decision which ultimately is a cause of concern for all. There is also another perspective to it. A family may not desire to go ahead with the process of treatment but is compelled to do so under social pressure especially in a different milieu, and in the case of an individual, there remains a fear of being branded that he/she, in spite of being able to provide the necessary treatment to the patient, has chosen not to do so. The social psyche constantly makes him/her feel guilty. The collective puts him at the crossroads between socially carved out "meaningful guilt" and his constant sense of rationality and individual responsibility. There has to be a legalistic approach which is essential to clear the maze and instil

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awareness that gradually melts the idea of "meaningful guilt" and ushers in an act of "affirmative human purpose" that puts humanness on a high pedestal.

6. There is yet another aspect. In an action of this nature, there can be abuse by the beneficiaries who desire that the patient's heart should stop so that his property is inherited in promptitude and in such a situation, the treating physicians are also scared of collusion that may invite the wrath of criminal law as well as social stigma. The medical, social and ethical apprehensions further cloud their mind to take a decision. The apprehension, the cultural stigma, the social reprehension, the allegation of conspiracy, the ethical dilemma and eventually the shadow between the individual desire and the collective expression distances the reality and it is here that the law has to have an entry to alleviate the agony of the individual and dispel the collective attributes and perceptions so that the imbroglio is clear. Therefore, the heart of the matter is whether the law permits for accelerating the process of dying sans suffering when life is on the path of inevitable decay and if so, at what stage and to what extent. The said issue warrants delineation from various perspectives.

B. ***Contentions in the writ petition***

7. The instant writ petition preferred under Article 32 of the Constitution of India by the petitioner, a registered society, seeks to declare "right to die with dignity" as a fundamental right within the fold of "right to live with dignity" guaranteed under Article 21 of the Constitution; to issue directions to the respondents to adopt suitable procedure in consultation with the State Governments, where necessary; to ensure that persons of deteriorated health or terminally-ill patients should be able to execute a document titled "My Living Will and Attorney Authorisation" which can be presented to the hospital for appropriate action in the event of the executant being admitted to the hospital with serious illness which may threaten termination of the life of the executant; to appoint a committee of experts including doctors, social scientists and lawyers to study into the aspect of issuing guidelines as to the "Living Wills"; and to issue such further appropriate directions and guidelines as may be necessary.

8. It is asserted that every individual is entitled to take his/her decision about the continuance or discontinuance of life when the process of death has already commenced and he/she has reached an irreversible permanent progressive state where death is not far away. It is contended that each individual has an inherent right to die with dignity which is an inextricable facet of Article 21 of the Constitution. That apart, it is set forth that right to die sans pain and suffering is fundamental to one's bodily autonomy and such integrity does not remotely accept any effort that puts the individual on life support without any ray of hope and on the contrary, the whole regime of treatment continues in spite of all being aware that it is a Sisyphean endeavour, an effort to light a bulb without the filament or to expect a situation to be in an apple-pie order when it is actually in a state of chaos.

9. It is put forth that the concept of sustenance of individual autonomy inheres in the right of privacy and also comes within the fundamental

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conception of liberty. To sustain the stand of privacy, reliance has been placed on the decisions in *Kharak Singh* v. *State of U.P.*[1], *Gobind* v. *State of M.P.*[2] and *PUCL* v. *Union of India*[3]. Inspiration has also been drawn from the decision of the United States in *Cruzan* v. *Missouri Department of Health*[4]. It is averred that due to the advancement of modern medical technology pertaining to medical science and respiration, a situation has been created where the dying process of the patient is unnecessarily prolonged causing distress and agony to the patient as well as to the near and dear ones and, consequently, the patient is in a persistent vegetative state thereby allowing free intrusion. It is also contended that the petitioner Society is not claiming that the right to die is a part of the right to life but asserting the claim that the right to die with dignity is an inseparable and inextricable facet of the right to live with dignity. The execution of a living will or issuance of Advance Directive has become a necessity in today's time keeping in view the prolongation of treatment in spite of irreversible prognosis and owing to penal laws in the field that creates a dilemma in the minds of doctors to take aid of the modern techniques in a case or not. A comparison has been made between the fundamental rights of an individual and the State interest focusing on sanctity as well as quality of life. References have been made to the laws in various countries, namely, the United Kingdom, the United States of America, Australia, Denmark, Singapore, Canada, etc. The autonomy of the patient has been laid stress upon to highlight the right to die with dignity without pain and suffering which may otherwise be prolonged because of artificial continuance of life through methods that are really not of any assistance for cure or improvement of living conditions.

C. *Stand in the counter-affidavit and the applications for intervention*

10. A counter-affidavit has been filed by the Union of India contending, inter alia, that serious thought has been given to regulate the provisions of euthanasia. A Private Member's Bill and the 241st Report of the Law Commission of India have been referred to. It has been set forth that the Law Commission had submitted a Report on the Medical Treatment of Terminally-Ill Patients (Protection of Patients and Medical Practitioners) Bill, 2006 but the Ministry of Health and Family Welfare was not in favour of the enactment due to the following reasons:

> "(*a*) Hippocratic oath is against intentional/voluntary killings of patient.
>
> (*b*) Progression of medical science to relieve pain, suffering, rehabilitation and treatment of so-called diseases will suffer a setback.
>
> (*c*) An individual may wish to die at certain point of time, his/her wish may not be persistent and only a fleeting desire out of transient depression.

1 (1964) 1 SCR 332 : AIR 1963 SC 1295 : (1963) 2 Cri LJ 329
2 (1975) 2 SCC 148 : 1975 SCC (Cri) 468
3 (1997) 1 SCC 301
4 1990 SCC OnLine US SC 123 : 111 L Ed 2d 224 : 110 S Ct 2841 : 497 US 261 (1990)

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(*d*) Suffering is a state of mind and a perception, which varies from individual to individual and depends on various environmental and social factors.

(*e*) Continuous advancement in medical science has made possible good pain management in patients of cancer and other terminal illness. Similarly, rehabilitation helps many spinal injury patients in leading near normal life and euthanasia may not be required.

(*f*) Wish of euthanasia by a mentally ill patient/in depression may be treatable by good psychiatric care.

(*g*) It will be difficult to quantify suffering, which may always be subject to changing social pressures and norms.

(*h*) Can doctors claim to have knowledge and experience to say that the disease is incurable and patient is permanently invalid?

(*i*) Defining of bed-ridden and requiring regular assistance is again not always medically possible.

(*j*) There might be psychological pressure and trauma to the medical officers who would be required to conduct euthanasia."

11. The counter-affidavit further states that after the judgment was delivered by this Court in *Aruna Ramachandra Shanbaug* v. *Union of India*[5], the Ministry of Law and Justice opined that the directions given by this Court have to be followed in such cases and the said directions should be treated as law. The Law Commission in its 241st Report titled "Passive Euthanasia — A Relook" again proposed for making a legislation on "Passive Euthanasia" and also prepared a draft Bill titled the Medical Treatment of Terminally-Ill Patients (Protection of Patients and Medical Practitioners) Bill. The said Bill was referred to the technical wing of the Ministry of Health and Family Welfare (Directorate General of Health Services—Dte. GHS) for examination in June 2014. It is the case of the Union of India that two meetings were held under the chairmanship of Special Director General of Health Service which was attended by various experts. A further meeting was held under the chairmanship of Secretary, Ministry of Health and Family Welfare, on 22-5-2015 to examine the Bill. Thereafter, various meetings have been held by experts and the expert committee had proposed formulation of legislation on passive euthanasia.

12. Counter-affidavits have been filed by various States. We need not refer to the same in detail. Suffice it to mention that in certain affidavits, emphasis has been laid on Articles 37, 39 and 47 which require the States to take appropriate steps as envisaged in the said Articles for apposite governance. That apart, it has been pronouncedly stated that the right to life does not include the right to die and, in any case, the right to live with dignity guaranteed under Article 21 of the Constitution means availability of food, shelter and health and does not include the right to die with dignity. It is asseverated that saving the life is the primary duty of the State and, therefore, there is necessity for healthcare. It is also contended that the introduction of the right to die with dignity as a facet of

5 (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

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the right under Article 21 will create a right that the said constitutional provision does not envisage and further it may have the potential effect to destroy the said basic right.

13. An application for intervention has been filed by the "Society for the Right to Die with Dignity" whose prayer for intervention has been allowed. The affidavit filed by the said Society supports the concept of euthanasia because it is a relief from irrecoverable suffering of which pain is a factor. It has cited many an example from various texts to support passive euthanasia and suggested certain criteria to be followed. It has also supported the idea of introduction of living will and durable power of attorney documents and has filed a sample of living will or advance health directive or advance declaration provided by Luis Kutner. Emphasis has been laid on peaceful exit from life and the freedom of choice not to live and particularly so under distressing conditions and ill-health which lead to an irrecoverable state. The management of terminally-ill patients has been put at the centre stage. It has been highlighted that determination of the seemly criteria will keep the element of misuse by the family members or the treating physician or, for that matter, any interested person at bay and also remove the confusion.

14. We have heard Mr Prashant Bhushan, learned counsel for the petitioner. Mr P.S. Narasimha, learned Additional Solicitor General for the Union of India, Mr Arvind P. Datar learned Senior Counsel and Mr Devansh A. Mohta, learned counsel who have supported the cause put forth in the writ petition.

D. *Background of the writ petition*

15. Before we engage ourselves with the right claimed, it is requisite to state that the present litigation has a history and while narrating the same, the assertions made in the writ petition and the contentions which have been raised during the course of hearing, to which we shall refer in due course, are to be kept in mind.

D.1 *P. Rathinam case*[6] — *The question of unconstitutionality of Section 309 of the Penal Code*

16. Presently, it is necessary to travel backwards in time, though not very far. Two individuals, namely, P. Rathinam and Nagbhushan Patnaik, filed two writ petitions under Article 32 of the Constitution which were decided by a two-Judge Bench in *P. Rathinam* v. *Union of India*[6]. The writ petitions assailed the constitutional validity of Section 309 of the Penal Code, 1860 (IPC) contending that the same is violative of Articles 14 and 21 of the Constitution. The Court posed 16 questions. The relevant ones read thus: (SCC p. 407, para 24)

> "(*1*) Has Article 21 any positive content or is it merely negative in its reach?
>
> (*2*) Has a person residing in India a right to die?
>
> * * *
>
> (*12*) Is suicide against public policy?

6 *P. Rathinam* v. *Union of India*, (1994) 3 SCC 394 : 1994 SCC (Cri) 740

(*13*) Does commission of suicide damage the monopolistic power of the State to take life?

(*14*) Is apprehension of "constitutional cannibalism" justified?

(*15*) Recommendation of the Law Commission of India and follow-up steps taken, if any.

(*16*) Global view. What is the legal position in other leading countries of the world regarding the matter at hand?"

17. Answering Question (1), the Court, after referring to various authorities under Article 21, took note of the authority in *State of H.P.* v. *Umed Ram Sharma*[7] wherein it has been observed that the right to life embraces not only physical existence but also the quality of life as understood in its richness and fullness within the ambit of the Constitution. In the said case, the Court had held that for residents of hilly areas, access to road was access to life itself and so, necessity of road communication in a reasonable condition was treated as a constitutional imperative. *P. Rathinam*[6] perceived the elevated positive content in the said ruling. Answering Question (2), the Court referred to the decision of the Bombay High Court in *Maruti Shripati Dubal* v. *State of Maharashtra*[8] that placed reliance on *Rustom Cowasjee Cooper* v. *Union of India*[9] wherein it had been held that what is true of one fundamental right is also true of another fundamental right and on the said premise, the Bombay High Court had opined that it cannot be seriously disputed that fundamental rights have their positive as well as negative aspects. Citing an example, it had stated that freedom of speech and expression includes freedom not to speak and similarly, the freedom of association and movement includes freedom not to join any association or move anywhere and, accordingly, it stated that logically it must follow that the right to live would include the right not to live i.e. right to die or to terminate one's life.

18. After so stating, this Court in *P. Rathinam case*[6] approved the view taken by the Bombay High Court in *Maruti Shripati Dubal*[8] and meeting the criticism of that judgment from certain quarters, the two-Judge Bench opined that the criticism was only partially correct because the negative aspect may not be inferable on the analogy of the rights conferred by different clauses of Article 19 and one may refuse to live if his life, according to the person concerned, is not worth living. One may rightly think that having achieved all worldly pleasures or happiness, he has something to achieve beyond this life. This desire for communion with God may rightly lead even a healthy mind to think that he would forego his right to live and would rather choose not to live. In any case, a person cannot be forced to enjoy the right to life to his detriment, disadvantage

7 (1986) 2 SCC 68 : AIR 1986 SC 847
6 *P. Rathinam* v. *Union of India*, (1994) 3 SCC 394 : 1994 SCC (Cri) 740
8 1986 SCC OnLine Bom 278 : 1987 Cri LJ 743 : (1986) 88 Bom LR 589
9 (1970) 2 SCC 298 : AIR 1970 SC 1318

or disliking. Eventually, it concluded that the right to live of which Article 21 speaks of can be said to bring in its trail the right not to live a forced life.

19. Answering all the questions, the Court in *P. Rathinam case*[6] declared Section 309 IPC ultra vires and held that it deserved to be effaced from the statute book to humanise our penal laws.

D.2 *Gian Kaur case*[10] — *The question of unconstitutionality of Section 306 of the Penal Code*

20. The dictum laid down by the two-Judge Bench in *P. Rathinam*[6] did not remain a precedent for long. In *Gian Kaur* v. *State of Punjab*[10], the Constitution Bench considered the correctness of the decision rendered in *P. Rathinam*[6]. In the said case, the appellants were convicted by the trial court under Section 306 IPC and the conviction was assailed on the ground that Section 306 IPC is unconstitutional and to sustain the said argument, reliance was placed on the authority in *P. Rathinam*[6] wherein Section 309 IPC was held to be unconstitutional being violative of Article 21 of the Constitution. It was urged that once Section 309 IPC had been held to be unconstitutional, any person abetting the commission of suicide by another is merely assisting in the enforcement of the fundamental right under Article 21 and, therefore, Section 306 IPC penalising abetment of suicide is equally violative of Article 21. The two-Judge Bench before which these arguments were advanced in appeal referred the matter to a Constitution Bench for deciding the same. In the course of arguments, one of the Amici Curiae, Mr F.S. Nariman, learned Senior Counsel, had submitted that the debate on euthanasia is not relevant for deciding the question of constitutional validity of Section 309 and Article 21 cannot be construed to include within it the so-called "right to die" since Article 21 guarantees protection of life and liberty and not its extinction. The Constitution Bench, after noting the submissions, stated: (*Gian Kaur case*[10], SCC p. 658, para 17)

> "*17.* ... We, therefore, proceed now to consider the question of constitutional validity with reference to Articles 14 and 21 of the Constitution. Any further reference to the global debate on the desirability of retaining a penal provision to punish attempted suicide is unnecessary for the purpose of this decision. Undue emphasis on that aspect and particularly the reference to euthanasia cases tends to befog the real issue of the constitutionality of the provision and the crux of the matter which is determinative of the issue."

21. Thereafter, the Constitution Bench in *Gian Kaur*[10] scrutinised the reasons given in *P. Rathinam*[6] and opined that the Court in the said case took the view that if a person has a right to live, he also has a right not to live. The

6 *P. Rathinam* v. *Union of India*, (1994) 3 SCC 394 : 1994 SCC (Cri) 740
10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374

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Court in *Gian Kaur*[10] observed that the Court in *P. Rathinam*[6], while taking such a view, relied on the decisions which relate to other fundamental rights dealing with different situations and those decisions merely hold that the right to do an act also includes the right not to do an act in that manner. The larger Bench further observed that in all those decisions, it was the negative aspect of the right that was involved for which no positive or overt act was to be done. The Constitution Bench categorically stated that this difference has to be borne in mind while making the comparison for the application of this principle.

22. Delving into the facet of committing suicide, the larger Bench in *Gian Kaur*[10] observed that when a man commits suicide, he has to undertake certain positive overt acts and the genesis of those acts cannot be traced to or be included within the protection of the "right to life" under Article 21. It also held that the significant aspect of "sanctity of life" should not be overlooked. The Court further opined that by no stretch of imagination, extinction of life can be read to be included in protection of life because Article 21, in its ambit and sweep, cannot include within it the right to die as a part of fundamental right guaranteed therein. The Constitution Bench ruled:

> "22. ... "Right to life" is a natural right embodied in Article 21 but suicide is an unnatural termination or extinction of life and, therefore, incompatible and inconsistent with the concept of "right to life". With respect and in all humility, we find no similarity in the nature of the other rights, such as the right to "freedom of speech", etc. to provide a comparable basis to hold that the "right to life" also includes the "right to die". With respect, the comparison is inapposite, for the reason indicated in the context of Article 21. The decisions relating to other fundamental rights wherein the absence of compulsion to exercise a right was held to be included within the exercise of that right, are not available to support the view taken in *P. Rathinam*[6] qua Article 21."

23. Adverting to the concept of euthanasia, the Court in *Gian Kaur*[10] observed that protagonism of euthanasia on the view that existence in persistent vegetative state (PVS) is not a benefit to the patient of terminal illness being unrelated to the principle of "sanctity of life" or the "right to live with dignity" is of no assistance to determine the scope of Article 21 for deciding whether the guarantee of "right to life" therein includes the "right to die". The "right to life" including the right to live with human dignity would mean the existence of such a right up to the end of natural life. The Constitution Bench further explained that the said conception also includes the right to a dignified life up to the point of death including a dignified procedure of death or, in other words, it may include the right of a dying man to also die with dignity when his life is ebbing out. It has been clarified that the right to die with dignity at the end of life is not to be confused or equated with the "right to die" an unnatural

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374
6 *P. Rathinam* v. *Union of India*, (1994) 3 SCC 394 : 1994 SCC (Cri) 740

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death curtailing the natural span of life. Thereafter, the Court proceeded to state: (SCC pp. 660-61, para 25)

> "25. A question may arise, *in the context of a dying man who is terminally ill or in a persistent vegetative state that he may be permitted to terminate it by a premature extinction of his life in those circumstances. This category of cases may fall within the ambit of the "right to die" with dignity as a part of right to live with dignity, when death due to termination of natural life is certain and imminent and the process of natural death has commenced.* These are not cases of extinguishing life but only of accelerating conclusion of the process of natural death which has already commenced. The debate even in such cases to permit physician-assisted termination of life is inconclusive. It is sufficient to reiterate that the argument to support the view of permitting termination of life in such cases to reduce the period of suffering during the process of certain natural death is not available to interpret Article 21 to include therein the right to curtail the natural span of life." (emphasis supplied)

24. In view of the aforesaid analysis and taking into consideration various other aspects, the Constitution Bench in *Gian Kaur*[10] declared Section 309 IPC as constitutional.

25. The Court in *Gian Kaur*[10] held that the "right to live with human dignity" cannot be construed to include within its ambit the right to terminate natural life, at least before the commencement of the process of certain natural death. It then examined the question of validity of Section 306 IPC. It accepted the submission that Section 306 is constitutional. While adverting to the decision in *Airedale N.H.S. Trust* v. *Bland*[11], the Court at the outset made it clear that it was not called upon to deal with the issue of physician-assisted suicide or euthanasia cases. The decision in *Airedale case*[11], was relating to the withdrawal of artificial measures for continuance of life by a physician. In the context of existence in the persistent vegetative state of no benefit to the patient, the principle of sanctity of life, which is the concern of the State, was stated to be not an absolute one. To bring home the distinction between active and passive euthanasia, an illustration was noted in the context of administering lethal drug actively to bring the patient's life to an end. The significant dictum in that decision has been extracted in *Gian Kaur*[10] wherein it is observed that it is not lawful for a doctor to administer a drug to his patient to bring about his death even though that course is promoted by a humanitarian desire to end his suffering and however great that suffering may be. Further, to act so is to cross the Rubicon which runs between the care of the living patient on one hand and euthanasia—actively causing his death to avoid or to end his suffering on the

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374
11 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

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other hand. It has been noticed in *Airedale*[11] that euthanasia is not lawful at Common Law. In the light of the demand of responsible members of the society who believe that euthanasia should be made lawful, it has been observed in that decision that the same can be achieved by legislation. The Constitution Bench has merely noted this aspect in para 41 with reference to the dictum in *Airedale case*[11].

26. Proceeding to deal with physician-assisted suicide, the Constitution Bench observed: (*Gian Kaur case*[10], SCC p. 666, para 42)

> "*42.* The decision of the United States Court of Appeals for the Ninth Circuit in *Compassion in Dying* v. *Washington*[12], which reversed the decision of United States District Court, W.D. Washington reported in *Compassion in Dying* v. *Washington*[13], has also relevance. The constitutional validity of the State statute that banned physician-assisted suicide by mentally competent, terminally ill adults was in question. The District Court held unconstitutional the provision punishing for promoting a suicide attempt. On appeal, that judgment was reversed and the constitutional validity of the provision was upheld."

And again: (SCC p. 666, para 43)

> "*43.* This caution even in cases of physician-assisted suicide is sufficient to indicate that assisted suicides outside that category have no rational basis to claim exclusion of the fundamental principles of sanctity of life. The reasons assigned for attacking a provision which penalises attempted suicide are not available to the abettor of suicide or attempted suicide. Abetment of suicide or attempted suicide is a distinct offence which is found enacted even in the law of the countries where attempted suicide is not made punishable. Section 306 IPC enacts a distinct offence which can survive independent of Section 309 in the IPC. The learned Attorney General as well as both the learned Amici Curiae rightly supported the constitutional validity of Section 306 IPC."

Eventually, the Court in *Gian Kaur*[10], apart from overruling *P. Rathinam*[6], upheld the constitutional validity of Section 309 IPC.

D.3 *The approach in Aruna Shanbaug*[5] *qua passive euthanasia vis-à-vis India*

27. Although the controversy relating to attempt to suicide or abetment of suicide was put to rest, yet the issue of euthanasia remained alive. It arose for consideration almost after a span of eleven years in *Aruna Shanbaug*[5]. A writ petition was filed by the next friend of the petitioner pleading, inter alia,

11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)
10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374
12 49 F 3d 586 (9th Cir 1995)
13 850 F Supp 1454 (WD Wash 1994)
6 *P. Rathinam* v. *Union of India*, (1994) 3 SCC 394 : 1994 SCC (Cri) 740
5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

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that the petitioner was suffering immensely because of an incident that took place thirty-six years back on 27-11-1973 and was in a persistent vegetative state (PVS) and in no state of awareness and her brain was virtually dead. The prayer of the next friend was that the respondent be directed to stop feeding the petitioner and to allow her to die peacefully. The Court noticed that there was some variance in the allegation made in the writ petition and the counter-affidavit filed by the Professor and Head of the hospital where the petitioner was availing treatment. The Court appointed a team of three very distinguished doctors to examine the petitioner thoroughly and to submit a report about her physical and mental condition. The team submitted a joint report. The Court asked the team of doctors to submit a supplementary report by which the meaning of the technical terms in the first report could be explained. Various other aspects were also made clear. It is also worth noting that the KEM Hospital where the petitioner was admitted was appointed as the next friend by the Court because of its services rendered to the petitioner and the emotional bonding and attachment with the petitioner.

28. In *Aruna Shanbaug*[5], after referring to the authority in *Vikram Deo Singh Tomar* v. *State of Bihar*[14], this Court reproduced paras 24 and 25 from *Gian Kaur case*[10] and opined that the said paragraphs simply mean that the view taken in *Rathinam case*[6] to the effect that the "right to life" includes the "right to die" is not correct and para 25 specifically mentions that the debate even in such cases to permit physician-assisted termination of life is inconclusive. The Court further observed that it was held in *Gian Kaur*[10] that there is no "right to die" under Article 21 of the Constitution and the right to life includes the right to live with human dignity but in the case of a dying person who is terminally ill or in permanent vegetative state, he may be allowed a premature extinction of his life and it would not amount to a crime. Thereafter, the Court took note of the submissions of the learned Amicus Curiae to the effect that the decision to withdraw life support is taken in the best interests of the patient by a body of medical persons. The Court observed that it is not the function of the Court to evaluate the situation and form an opinion on its own. The Court further noted that in England, the *parens patriae* jurisdiction over adult mentally incompetent persons was abolished by statute and the Court has no power now to give its consent and in such a situation, the Court only gives a declaration that the proposed omission by doctors is not unlawful.

29. After so stating, the Court in *Aruna Shanbaug*[5] addressed the legal issues, namely, active and passive euthanasia. It noted the legislations prevalent in Netherlands, Switzerland, Belgium, UK, Spain, Austria, Italy, Germany, France and the United States of America. It also noted that active euthanasia is illegal in all States in USA, but physician-assisted death is legal in the

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294
14 1988 Supp SCC 734 : 1989 SCC (Cri) 66 : AIR 1988 SC 1782
10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374
6 *P. Rathinam* v. *Union of India*, (1994) 3 SCC 394 : 1994 SCC (Cri) 740

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States of Oregon, Washington and Montana. The Court also referred to the legal position in Canada. Dealing with passive euthanasia, the two-Judge Bench opined that passive euthanasia is usually defined as withdrawing medical treatment with a deliberate intention of causing the patient's death. An example was cited by stating that if a patient requires kidney dialysis to survive, not giving dialysis although the machine is available is passive euthanasia and similarly, withdrawing the machine where a patient is in coma or on heart-lung machine support will ordinarily result in passive euthanasia. The Court also put non-administration of life saving medicines like antibiotics in certain situations on the same platform of passive euthanasia. Denying food to a person in coma or PVS has also been treated to come within the ambit of passive euthanasia. The Court copiously referred to the decision in *Airedale*[11].

30. In *Airedale case*[11], as has been noted in *Aruna Shanbaug*[5], Lord Goff observed that discontinuance of artificial feeding in such cases is not equivalent to cutting a mountaineer's rope or severing the airpipe of a deep sea diver. The real question has to be not whether the doctor should take a course in which he will actively kill his patient but whether he should continue to provide his patient with medical treatment or care which, if continued, will prolong his life. Lord Browne-Wilkinson was of the view that removing the nasogastric tube in the case of Anthony Bland cannot be regarded as a positive act causing death. The tube by itself, without the food being supplied through it, does nothing. Its non-removal by itself does not cause death since by itself, it does not sustain life. The learned Judge observed that removal of the tube would not constitute the actus reus of murder since such an act by itself would not cause death.

31. Lord Mustill observed: (*Airedale case*[11], AC p. 896 C-E)

> "Threaded through the technical arguments addressed to the House were the strands of a much wider position, that it is in the best interests of the community at large that *Anthony Bland's life should now end.* The doctors *have done all they can. Nothing will be gained by going on* and much will be lost. The *distress of the family will get steadily worse.* The strain on the *devotion of a medical staff charged with the care* of a patient whose condition will never improve, who may live for years and who does not even recognise that he is being cared for, will continue to mount. The large resources of skill, *labour and money now being devoted to Anthony Bland* might in the opinion of many be more fruitfully employed in improving the condition of other patients, who if treated may have useful, healthy and enjoyable lives for years to come." (*Aruna Shanbaug case*[5], SCC p. 507, para 82) (emphasis supplied in *Aruna Shanbaug*[5])

11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

32. The two-Judge Bench in *Aruna Shanbaug*[5] further observed that the decision in *Airedale*[11] by the House of Lords has been followed in a number of cases in UK and the law is now fairly well settled that in the case of incompetent patients, if the doctors act on the basis of notified medical opinion and withdraw the artificial life support system in the patient's best interest, the said act cannot be regarded as a crime. The learned Judges posed the question as to who is to decide what is that patient's best interest where he is in a PVS and, in that regard, opined that it is ultimately for the Court to decide, as *parens patriae*, as to what is in the best interest of the patient, though the wishes of close relatives and next friend and the opinion of medical practitioners should be given due weight in coming to its decision. For the said purpose, reference was made to the opinion of Balcombe, J. in *J. (A Minor) (Wardship: Medical Treatment), In re*[15] whereby it has been stated that the Court as representative of the Sovereign and as *parens patriae* will adopt the same standard which a reasonable and responsible parent would do.

33. The two-Judge Bench in *Aruna Shanbaug*[5] referred to the decisions of the Supreme Court of United States in *Washington* v. *Glucksberg*[16] and *Vacco* v. *Quill*[17] which addressed the issue whether there was a federal constitutional road to assisted suicide. Analysing the said decisions and others, the Court observed that the informed consent doctrine has become firmly entrenched in American Tort Law and, as a logical corollary, lays foundation for the doctrine that the patient who generally possesses the right to consent has the right to refuse treatment.

34. In the ultimate analysis, the Court in *Aruna Shanbaug*[5] opined that the *Airedale case*[11] is more apposite to be followed. Thereafter, the Court adverted to the law in India and ruled that in *Gian Kaur case*[10], this Court had approved the decision of the House of Lords in *Airedale*[11] and observed that euthanasia could be made lawful only by legislation. After so stating, the learned Judges opined: (*Aruna Shanbaug case*[5], SCC pp. 512-13, para 104)

> "*104.* It may be noted that in *Gian Kaur case*[10] although the Supreme Court has quoted with approval the view of the House of Lords in *Airedale case*[11], it has not clarified who can decide whether life support should be discontinued in the case of an incompetent person e.g. a person in coma or PVS. This vexed question has been arising often in India because there are

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294
11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)
15 1991 Fam 33 (CA) : (1991) 2 WLR 140 : (1990) 3 All ER 930
16 1997 SCC OnLine US SC 79 : 138 L Ed 2d 772 : 521 US 702 (1997)
17 1997 SCC OnLine US SC 80 : 138 L Ed 2d 834 : 521 US 793 (1997)
10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374

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a large number of cases where persons go into coma (due to an accident or some other reason) or for some other reason are unable to give consent, and then the question arises as to who should give consent for withdrawal of life support. This is an extremely important question in India because of the unfortunate low level of ethical standards to which our society has descended, its raw and widespread commercialisation, and the rampant corruption, and hence, the Court has to be very cautious that unscrupulous persons who wish to inherit the property of someone may not get him eliminated by some crooked method."

35. After so stating, the two-Judge Bench dwelled upon the concept of brain dead and various other aspects which included withdrawal of life support of a patient in PVS and, in that context, ruled thus: (*Aruna Shanbaug case*[5], SCC pp. 519-20, para 125)

"*125.* In our opinion, if we leave it solely to the patient's relatives or to the doctors or next friend to decide whether to withdraw the life support of an incompetent person there is always a risk in our country that this may be misused by some unscrupulous persons who wish to inherit or otherwise grab the property of the patient. Considering the low ethical levels prevailing in our society today and the rampant commercialisation and corruption, we cannot rule out the possibility that unscrupulous persons with the help of some unscrupulous doctors may fabricate material to show that it is a terminal case with no chance of recovery. There are doctors and doctors. While many doctors are upright, there are others who can do anything for money (*see* George Bernard Shaw's play *The Doctor's Dilemma*). The commercialisation of our society has crossed all limits. Hence we have to guard against the potential of misuse (*see* Robin Cook's novel *Coma*). In our opinion, while giving great weight to the wishes of the parents, spouse, or other close relatives or next friend of the incompetent patient and also giving due weight to the opinion of the attending doctors, we cannot leave it entirely to their discretion whether to discontinue the life support or not. We agree with the decision of Lord Keith in *Airedale case*[11] that the approval of the High Court should be taken in this connection. This is in the interest of the protection of the patient, protection of the doctors, relatives and next friend, and for reassurance of the patient's family as well as the public. This is also in consonance with the doctrine of parens patriae which is a well-known principle of law."

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

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36. After so laying down, the Court in *Aruna Shanbaug*[5] referred to the authorities in *Charan Lal Sahu* v. *Union of India*[18] and *State of Kerala* v. *N.M. Thomas*[19] and further opined that the High Court can grant approval for withdrawing life support of an incompetent person under Article 226 of the Constitution because Article 226 gives abundant power to the High Court to pass suitable orders on the application filed by the near relatives or next friend or the doctors/hospital staff praying for permission to withdraw the life support of an incompetent person. Dealing with the procedure to be adopted by the High Court when such application is filed, the Court ruled that when such an application is filed, the Chief Justice of the High Court should forthwith constitute a Bench of at least two Judges who should decide to grant approval or not and before doing so, the Bench should seek the opinion of a committee of three reputed doctors to be nominated by the Bench after consulting such medical authorities/medical practitioners as it may deem fit. Amongst the three doctors, as directed, one should be a Neurologist, one should be a Psychiatrist and the third a Physician. The Court further directed: (*Aruna Shanbaug case*[5], SCC pp. 522-23, paras 134-136)

> "*134.* ... The committee of three doctors nominated by the Bench should carefully examine the patient and also consult the record of the patient as well as take the views of the hospital staff and submit its report to the High Court Bench. Simultaneously with appointing the committee of doctors, the High Court Bench shall also issue notice to the State and close relatives e.g. parents, spouse, brothers/sisters, etc. of the patient, and in their absence his/her next friend, and supply a copy of the report of the doctor's committee to them as soon as it is available. After hearing them, the High Court Bench should give its verdict.
>
> *135.* The above procedure should be followed all over India until Parliament makes legislation on this subject.
>
> *136.* The High Court should give its decision speedily at the earliest, since delay in the matter may result in causing great mental agony to the relatives and persons close to the patient. The High Court should give its decision assigning specific reasons in accordance with the principle of "best interest of the patient" laid down by the House of Lords in *Airedale case*[11]. The views of the near relatives and committee of doctors should be given due weight by the High Court before pronouncing a final verdict which shall not be summary in nature."

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294
18 (1990) 1 SCC 613
19 (1976) 2 SCC 310 : 1976 SCC (L&S) 227
11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

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37. We must note here that the two-Judge Bench in *Aruna Shanbaug*[5] declined to grant the permission after perusing the medical reports. For the sake of completeness, we think it apt to reproduce the reasoning: (SCC p. 518, para 122)

> "*122.* From the above examination by the team of doctors, it cannot be said that Aruna Shanbaug is dead. Whatever the condition of her cortex, her brainstem is certainly alive. She does not need a heart-lung machine. She breathes on her own without the help of a respirator. She digests food, and her body performs other involuntary functions without any help. From the CD (which we had screened in the courtroom on 2-3-2011 in the presence of the counsel and others) it appears that she can certainly not be called dead. She was making some sounds, blinking, eating food put in her mouth, and even licking with her tongue morsels on her mouth. However, there appears little possibility of her coming out of PVS in which she is in. In all probability, she will continue to be in the state in which she is in till her death."

D.4 ***The Reference***

38. The aforesaid matter was decided when the present writ petition was pending for consideration. The present petition was, thereafter, listed before a three-Judge Bench which noted[20] the submissions advanced on behalf of the petitioner and also that of the learned Additional Solicitor General on behalf of the Union of India. Reliance was placed on the decision in *Aruna Shanbaug*[5]. The three-Judge Bench reproduced paras 24 and 25 from *Gian Kaur*[10] and noted that the Constitution Bench did not express any binding view on the subject of euthanasia, rather it reiterated that the legislature would be the appropriate authority to bring the change.

39. After so holding, it referred to the understanding of *Gian Kaur*[10] in *Aruna Shanbaug*[5] by the two-Judge Bench and reproduced paras 21 and 101 from the said judgment: (*Common Cause case*[20], SCC p. 343, para 12)

> "*12. ... '21.* We have carefully considered paras 24 and 25 in *Gian Kaur case*[10] and we are of the opinion that all that has been said therein is that the view in *Rathinam case*[6] that the right to life includes the right to die is not correct. We cannot construe *Gian Kaur case*[10] to mean anything beyond that. *In fact, it has been specifically mentioned in para 25 of the aforesaid decision that "the debate even in such cases to permit physician-assisted termination of life is inconclusive". Thus it is obvious that no final view*

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294
20 *Common Cause* v. *Union of India*, (2014) 5 SCC 338 : (2014) 2 SCC (Cri) 557
10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374
6 *P. Rathinam* v. *Union of India*, (1994) 3 SCC 394 : 1994 SCC (Cri) 740

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was expressed in the decision in Gian Kaur case[10] *beyond what we have mentioned above.*' (*Aruna Shanbaug case*[5], SCC p. 487)

* * *

'*101.* The Constitution Bench of the Supreme Court in *Gian Kaur* v. *State of Punjab*[10] held that both euthanasia and assisted suicide are not lawful in India. That decision overruled the earlier two-Judge Bench decision of the Supreme Court in *P. Rathinam* v. *Union of India*[6]. The Court held that the right to life under Article 21 of the Constitution does not include the right to die (vide SCC para 33). *In Gian Kaur case*[10] *the Supreme Court approved of the decision of the House of Lords in Airedale case*[11] *and observed that euthanasia could be made lawful only by legislation.*' (*Aruna Shanbaug case*[5], SCC p. 512)" (emphasis in original)

40. Commenting on the said analysis, the three-Judge Bench went on to say: (*Common Cause case*[20], SCC pp. 343-44, para 13)

"*13.* Insofar as the above paragraphs are concerned, *Aruna Shanbaug*[5] aptly interpreted the decision of the Constitution Bench in *Gian Kaur*[10] and came to the conclusion that euthanasia can be allowed in India only through a valid legislation. However, it is factually wrong to observe that in *Gian Kaur*[10], the Constitution Bench approved the decision of the House of Lords in *Airedale N.H.S. Trust* v. *Bland*[11]. Para 40 of *Gian Kaur*[10], clearly states that: (SCC p. 665)

> '*40. ... Even though it is not necessary to deal with physician-assisted suicide or euthanasia cases, a brief reference to this decision cited at the Bar may be made.*'

Thus, it was a mere reference in the verdict and it cannot be construed to mean that the Constitution Bench in *Gian Kaur*[10] approved the opinion of the House of Lords rendered in *Airedale*[11]. To this extent, the observation in para 101 of *Aruna Shanbaug*[5] is incorrect." (emphasis in original)

41. From the aforesaid, it is clear that the three-Judge Bench expressed the view that the opinion of the House of Lords in *Airedale*[11] has not been approved in *Gian Kaur*[10] and to that extent, the observation in *Aruna Shanbaug*[5] is incorrect. After so stating, the three-Judge Bench opined that *Aruna Shanbaug*[5] upholds the authority of passive euthanasia and lays down an elaborate procedure for executing the same on the wrong premise that the Constitution Bench in *Gian Kaur*[10] had upheld the same. Thereafter, considering the important question of law involved which needs to be reflected in the light of social, legal, medical and constitutional perspectives, in order to have a clear enunciation of law, it referred the matter for consideration by

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374
5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294
6 (1994) 3 SCC 394 : 1994 SCC (Cri) 740
11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)
20 *Common Cause* v. *Union of India*, (2014) 5 SCC 338 : (2014) 2 SCC (Cri) 557

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the Constitution Bench of this Court for the benefit of humanity as a whole. The three-Judge Bench further observed that it was refraining from framing any specific questions for consideration by the Constitution Bench as it would like the Constitution Bench to go into all the aspects of the matter and lay down exhaustive guidelines. That is how the matter has been placed before us.

E. *Our analysis of Gian Kaur*[10]

42. It is the first and foremost duty to understand what has been stated by the Constitution Bench in *Gian Kaur case*[10]. It has referred to the decision in *Airedale*[11] that has been recapitulated in *Aruna Shanbaug case*[5] which was a case relating to withdrawal of artificial measures of continuance of life by the physician. It is relevant to mention here that the Constitution Bench in *Gian Kaur*[10] categorically noted that it was not necessary to deal with physician-assisted suicide or euthanasia cases though a brief reference to the decisions cited at the Bar was required to be made. The Constitution Bench noted that *Airedale*[11] held that in the context of existence in the persistent vegetative state of no benefit to the patient, the principle of sanctity of life, which is the concern of the State, was not an absolute one. The larger Bench further noticed that in *Airedale*[11], it had been stated that in such cases also, the existing crucial distinction between cases in which a physician decides not to provide or to continue to provide, for his patient, treatment or care which could or might prolong his life, and those in which he decides, for example, by administering a lethal drug actively to bring his patient's life to an end, was indicated. Thereafter, while again referring to *Airedale case*[11], the larger Bench observed that it was a case relating to withdrawal of artificial measures for continuance of life by the physician.

43. After so stating, the Court in *Gian Kaur*[10] reproduced the following passage from the opinion of Lord Goff of Chieveley: (SCC p. 665, para 40)

> "*40.* ... '... But it is not lawful for a doctor to administer a drug to his patient to bring about his death, even though that course is prompted by a humanitarian desire to end his suffering, however great that suffering may be (see *R.* v. *Cox*[21]). So to act is to cross the Rubicon which runs between on the one hand the care of the living patient and on the other hand euthanasia—actively causing his death to avoid or to end his suffering. *Euthanasia is not lawful at common law. It is of course well known that there are many responsible members of our society who believe that euthanasia should be made lawful; but that result could, I believe, only be achieved by legislation which expresses the democratic will that so fundamental a change should be made in our law, and can, if enacted, ensure that such legalised killing can only be carried out subject to appropriate supervision and control.*' (*Airedale case*[11], AC p. 865 E-G)" (*emphasis supplied in Gian Kaur*[10])

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374

11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

21 18-9-1992, Ognall, J. (unreported).

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After reproducing the said passage, the Court opined thus: (*Gian Kaur*[10], SCC p. 665, para 41)

> "*41.* The desirability of bringing about such a change was considered to be the function of the legislature by enacting a suitable law providing therein adequate safeguards to prevent any possible abuse."

44. At this stage, it is necessary to clear the maze whether the Constitution Bench in *Gian Kaur*[10] had accepted what has been held in *Airedale*[11].

44.1. On a careful and anxious reading of *Gian Kaur*[10], it is noticeable that there has been narration, reference and notice of the view taken in *Airedale case*[11]. It is also worth noting that the Court was concerned with the constitutional validity of Section 309 IPC that deals with attempt to commit suicide and Section 306 IPC that provides for abetment to commit suicide. As noted earlier, the Constitution Bench, while distinguishing the case of a dying man who is terminally ill or in a persistent vegetative state and his termination or premature extinction of life, observed that the said category of cases may fall within the ambit of right to die with dignity as a part of right to life with dignity when death due to termination of natural life is inevitable and imminent and the process of natural death has commenced. The Constitution Bench further opined that the said cases do not amount to extinguishing the life but only amount to accelerating the process of natural death which has already commenced and, thereafter, the Constitution Bench stated that the debate with regard to physician-assisted suicide remains inconclusive. The larger Bench has reiterated that the cases pertaining to premature extinction of life during the process of certain natural death of patients who are terminally ill or in persistent vegetative state were of assistance to interpret Article 21 of the Constitution to include therein the right to curtail the natural span of life.

44.2. On a seemly understanding of the judgment in *Gian Kaur*[10], we do not find that it has decried euthanasia as a concept. On the contrary, it gives an indication that in such situations, it is the acceleration of the process of dying which may constitute a part of right to life with dignity so that the period of suffering is reduced. We are absolutely conscious that a judgment is not to be construed as a statute but our effort is to understand what has been really expressed in *Gian Kaur*[10]. Be it clarified, it is understood and appreciated that there is a distinction between a positive or overt act to put an end to life by the person living his life and termination of life so that an individual does not remain in a vegetative state or, for that matter, when the death is certain because of terminal illness and he remains alive with the artificially assisted medical system.

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374
11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

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44.3. In *Gian Kaur*[10], while dealing with the attempt to commit suicide, the Court clearly held that when a man commits suicide, he has to undertake certain positive overt acts and the genesis of those acts cannot be tested to or be included within the protection of the expression "right to life" under Article 21 of the Constitution. It was also observed that a dignified procedure of death may include the right of a dying man to also die with dignity when the life is ebbing out.

44.4. This is how the pronouncement in *Gian Kaur*[10] has to be understood. It is also not the ratio of the authority in *Gian Kaur*[10] that euthanasia has to be introduced only by a legislation. What has been stated in para 41 of *Gian Kaur*[10] is what has been understood to have been held in *Airedale case*[11]. The Court has neither expressed any independent opinion nor has it approved the said part or the ratio as stated in *Airedale*[11]. There has been only a reference to *Airedale case*[11] and the view expressed therein as regards legislation. Therefore, the perception in *Aruna Shanbaug*[5] that the Constitution Bench has approved the decision in *Airedale*[11] is not correct. It is also quite clear that *Gian Kaur*[10] does not lay down that passive euthanasia can only be thought of or given effect to by legislation. Appositely understood, it opens an expansive sphere of Article 21 of the Constitution. Therefore, it can be held without any hesitation that *Gian Kaur*[10] has neither given any definite opinion with regard to euthanasia nor has it stated that the same can be conceived of only by a legislation.

F. *Our analysis of Aruna Shanbaug*[5] *qua legislation*

45. Having said this, we shall focus in detail what has been stated in *Aruna Shanbaug*[5]. In para 101 which has been reproduced hereinbefore, the two-Judge Bench noted that *Gian Kaur*[10] has approved the decision of the House of Lords in *Airedale*[11] and observed that euthanasia could be made lawful only by legislation. This perception, according to us, is not correct. As already stated, *Gian Kaur*[10] does not lay down that passive euthanasia could be made lawful only by legislation. In para 41 of the said judgment, the Constitution Bench was only adverting to what has been stated by Lord Goff of Chieveley in *Airedale case*[11]. However, this expression of view of *Aruna Shanbaug*[5] which has not been accepted by the referral Bench makes no difference to our present analysis. We unequivocally express the opinion that *Gian Kaur*[10] is not a binding precedent for the purpose of laying down the principle that passive euthanasia can be made lawful "only by legislation".

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374
11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)
5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

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G. *The distinction between active and passive euthanasia*

46. As a first step, it is imperative to understand the concept of euthanasia before we enter into the arena of analysis of the expanded right of Article 21 in *Gian Kaur*[10] and the understanding of the same. Euthanasia is basically an intentional premature termination of another person's life either by direct intervention (active euthanasia) or by withholding life-prolonging measures and resources (passive euthanasia) either at the express or implied request of that person (voluntary euthanasia) or in the absence of such approval/consent (non-voluntary euthanasia). *Aruna Shanbaug*[5] has discussed about two categories of euthanasia—active and passive. While dealing with active euthanasia, also known as "positive euthanasia" or "aggressive euthanasia", it has been stated that the said type of euthanasia entails a positive act or affirmative action or act of commission entailing the use of lethal substances or forces to cause the intentional death of a person by direct intervention e.g. a lethal injection given to a person with terminal cancer who is in terrible agony. Passive euthanasia, on the other hand, also called "negative euthanasia" or "non-aggressive euthanasia", entails withdrawing of life-support measures or withholding of medical treatment for continuance of life e.g. withholding of antibiotics in case of a patient where death is likely to occur as a result of not giving the said antibiotics or removal of the heart-lung machine from a patient in coma. The two-Judge Bench has also observed that the legal position across the world seems to be that while active euthanasia is illegal unless there is a legislation permitting it, passive euthanasia is legal even without legislation, provided certain conditions and safeguards are maintained. The Court has drawn further distinction between voluntary euthanasia and non-voluntary euthanasia in the sense that voluntary euthanasia is where the consent is taken from the patient and non-voluntary euthanasia is where the consent is unavailable, for instances when the patient is in coma or is otherwise unable to give consent. Describing further about active euthanasia, the Division Bench has observed that the said type of euthanasia involves taking specific steps to cause the patient's death such as injecting the patient with some lethal substance i.e. sodium pentothal which causes, in a person, a state of deep sleep in a few seconds and the person instantly dies in that state.

47. That apart, the Court in *Aruna Shanbaug*[5] has drawn a distinction between euthanasia and physician-assisted dying and noted that the difference lies in the fact as to who administers the lethal medication. It has been observed that in euthanasia, a physician or third party administers it while in physician-assisted suicide, it is the patient who does it though on the advice of the doctor. Elaborating further, the two-Judge Bench has opined that the predominant difference between "active" and "passive" euthanasia is that in the former, a specific act is done to end the patient's life while the latter covers a situation where something is not done which is necessary in preserving the

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374
5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

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patient's life. The main idea behind the distinction, as observed by the Bench, is that in passive euthanasia, the doctors are not actively killing the patient, they are merely not saving him and only accelerating the conclusion of the process of natural death which has already commenced.

48. The two-Judge Bench in *Aruna Shanbaug*[5], thereafter, elaborated on passive euthanasia and gave more examples of cases within the ambit of passive euthanasia. The learned Judges further categorised passive euthanasia into voluntary passive euthanasia and non-voluntary passive euthanasia. The learned Judges described voluntary passive euthanasia as a situation where a person who is capable of deciding for himself decides that he would prefer to die because of various reasons whereas non-voluntary passive euthanasia has been described to mean that a person is not in a position to decide for himself e.g. if he is in coma or PVS.

49. While scrutinising the distinction between active and passive euthanasia, the paramount aspect is "foreseeing the hastening of death". The said view has been propagated in several decisions all over the world. The Supreme Court of Canada, in *Rodriguez* v. *Attorney General of Canada*[22], drew the distinction between these two forms of euthanasia on the basis of intention. Echoing a similar view, the Supreme Court of the United States affirmed the said distinction on the basis of "intention" in *Vacco*[17] wherein Rehnquist, C.J. observed that the said distinction coheres with the fundamental legal principles of causation and intention. In case when the death of a patient occurs due to removal of life-supporting measures, the patient dies due to an underlying fatal disease without any intervening act on the part of the doctor or medical practitioner, whereas in the cases coming within the purview of active euthanasia, for example, when the patient ingests lethal medication, he is killed by that medication.

50. This distinction on the basis of "intention" further finds support in the explanation provided in *Conroy, In re*[23] wherein the Court made an observation that people who refuse life-sustaining medical treatment may not harbour a specific intent to die, rather they may fervently wish to live but do so free of unwanted medical technology, surgery or drugs and without protracted suffering.

51. Another distinction on the basis of "action and non-action" was advanced in the *Airedale case*[11]. Drawing a crucial distinction between the two forms of euthanasia, Lord Goff observed that passive euthanasia includes cases in which a doctor decides not to provide, or to continue to provide, for his patient, treatment or care which could prolong his life and active euthanasia involves actively ending a patient's life, for example, by administering a lethal

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294
22 1993 SCC OnLine Can SC 97 : (1993) 3 SCR 519 : 85 CCC 3d 15
17 *Vacco* v. *Quill*, 1997 SCC OnLine US SC 80 : 138 L Ed 2d 834 : 521 US 793 (1997)
23 98 NJ 321 : 486 A 2d 1209 (NJ 1985)
11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

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drug. As per the observations made by Lord Goff, the former can be considered lawful either because the doctor intends to give effect to his patient's wishes by withholding the treatment or care, or even in certain circumstances in which the patient is incapacitated from giving his consent. However, active euthanasia, even voluntary, is impermissible despite being prompted by the humanitarian desire to end the suffering of the patient.

52. It is perhaps due to the distinction evolved between these two forms of euthanasia, which has gained moral and legal sanctity all over, that most of the countries today have legalised passive euthanasia either by way of legislations or through judicial interpretation but there remains uncertainty whether active euthanasia should be granted legal status.

H. *Euthanasia*: *International position*

H.1 *UK decisions*

H.1.1 *Airedale case*[11]

53. In the obtaining situation, we shall now advert to the opinions stated in *Airedale case*[11]. In the said case, one Anthony Bland, a supporter of Liverpool Football Club, who had gone to Hillsborough Ground, suffered severe injuries as a result of which supply to his brain was interrupted. Eventually, he suffered an irreversible damage to the brain as a consequence of which he got into a condition of persistent vegetative state (PVS). He became incapable of voluntary movement and could feel no pain. He was not in a position to feel or communicate. To keep him alive, artificial means were taken recourse to. In such a state of affairs, the treating doctors and the parents of Bland felt that no fruitful purpose would be served by continuing the medical aid. As there were doubts with regard to stoppage of medical care which may incur a criminal liability, a declaration from the British High Court was sought to resolve the doubts. The Family Division of the High Court granted the declaration which was affirmed by the Court of Appeal. The matter travelled to the House of Lords.

54. Lord Keith of Kinkel opined that regard should be had to the whole artificial regime which kept Anthony Bland alive and it was incorrect to direct attention exclusively to the fact that nourishment was being provided. In his view, the administration of nourishment by the means adopted involved the application of a medical technique.

55. Lord Keith observed that in general, it would not be lawful for a medical practitioner who assumed responsibility for the care of an unconscious patient simply to give up treatment in circumstances where continuance of it would confer some benefit on the patient. On the other hand, a medical practitioner is under no duty to continue to treat such a patient where a large body of informed and responsible medical opinion is to the effect that no benefit at all would be conferred by continuance of treatment. Existence in a vegetative state with no prospect of recovery is, by that opinion, regarded as not being a benefit, and

11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

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that, if not unarguably correct, at least forms a proper basis for the decision to discontinue treatment and care. He was of the further opinion that since existence in PVS is not a benefit to the patient, the principle of sanctity of life is no longer an absolute one. It does not compel a medical practitioner to treat a patient, who will die if not treated, contrary to the express wishes of the patient. It does not compel the temporary keeping alive of patients who are terminally ill where to do so would merely prolong their suffering. On the other hand, it forbids the taking of active measures to cut short the life of a terminally-ill patient.

56. Lord Keith further stated that it does no violence to the principle of sanctity of life to hold that it is lawful to cease to give medical treatment and care to a PVS patient who has been in that state for over three years considering that to do so involves invasive manipulation of the patient's body to which he has not consented and which confers no benefit upon him. He also observed that the decision whether or not the continued treatment and care of a PVS patient confers any benefit on him is essentially one for the practitioners in charge.

57. Lord Goff of Chieveley also held that the principle of sanctity of life is not an absolute one and there is no absolute rule that the patient's life must be prolonged by such treatment or care, if available, regardless of the circumstances.

58. Lord Goff observed that though he agreed that the doctor's conduct in discontinuing life support can properly be categorised as an omission, yet discontinuation of life support is, for the present purposes, no different from not initiating life support in the first place as in such a case, the doctor is simply allowing his patient to die in the sense that he is desisting from taking a step which might, in certain circumstances, prevent his patient from dying as a result of his pre-existing condition; and as a matter of general principle, an omission such as this will not be unlawful unless it constitutes a breach of duty to the patient.

59. The learned Law Lord further observed that the doctor's conduct is to be differentiated from that of, for example, an interloper who maliciously switches off a life support machine in the sense that although the interloper performs the same act as the doctor who discontinues life support, yet the doctor, in discontinuing life support, is simply allowing his patient to die of his pre-existing condition, whereas the interloper is actively intervening to stop the doctor from prolonging the patient's life, and such conduct cannot possibly be categorised as an omission. This distinction as per Lord Goff appears to be useful in the context as it can be invoked to explain how discontinuance of life support can be differentiated from ending a patient's life by a lethal injection. Lord Goff stated that the reason for this difference is that the law considers discontinuance of life support to be consistent with the doctor's duty to care for his patient, but it does not, for reasons of policy, consider that it forms any part of his duty to give his patient a lethal injection to put the patient out of his agony.

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60. Emphasising on the patient's best interest principle, Lord Goff referred to *F. (Mental Patient: Sterilisation), In re*[24] wherein the House of Lords stated the legal principles governing the treatment of a patient who, for the reason that he was of unsound mind or that he had been rendered unconscious by accident or by illness, was incapable of stating whether or not he consented to the treatment or care. In such circumstances, a doctor may lawfully treat such a patient if he acts in his best interests, and indeed, if the patient is already in his care, he is under a duty so to treat him.

61. Drawing an analogy, Lord Goff opined that a decision by a doctor whether or not to initiate or to continue to provide treatment or care which could or might have the effect of prolonging such a patient's life should also be governed by the same fundamental principle of the patient's best interest. The learned Law Lord further stated that the doctor who is caring for such a patient cannot be put under an absolute obligation to prolong his life by any means available to the doctor, regardless of the quality of the patient's life. Common humanity requires otherwise as do medical ethics and good medical practice accepted in the United Kingdom and overseas. Lord Goff said that the doctor's decision to take or not to take any step must be made in the best interests of the patient (subject to his patient's ability to give or withhold his consent).

62. Lord Goff further stated that in such cases, the question is not whether it is in the best interests of the patient that he should die, rather the correct question for consideration is whether it is in the best interests of the patient that his life should be prolonged by the continuance of such form of medical treatment or care. In Lord Goff's view, the correct formulation of the question is of particular importance in such cases as the patient is totally unconscious and there is no hope whatsoever of any amelioration of his condition. Lord Goff opined that if the question is asked whether it is in the best interests of the patient to continue the treatment which has the effect of artificially prolonging his life, that question can sensibly be answered to the effect that the patient's best interests no longer require such a treatment to be continued.

63. Lord Goff opined that medical treatment is neither appropriate nor requisite simply to prolong a patient's life when such treatment has no therapeutic purpose of any kind and such treatment is futile because the patient is unconscious and there is no prospect of any improvement in his condition. Thereafter, the learned Law Lord observed that regard should also be had to the invasive character of the treatment and to the indignity to which a patient is subjected by prolonging his life by artificial means which, in turn, causes considerable distress to his family. In such cases, Lord Goff said that it is the futility of the treatment which justifies its termination and in such circumstances, a doctor is not required to initiate or to continue life-prolonging treatment or care keeping in mind the best interests of the patient.

24 (1990) 2 AC 1 : (1989) 2 WLR 1025 : (1989) 2 All ER 545 (HL)

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64. Lord Goff, referring to *F. (Mental Patient: Sterilisation), In re*[24], said that it was stated therein that where a doctor provides treatment to a person who is incapacitated from saying whether or not he consents to it, the doctor must, when deciding on the form of treatment, act in accordance with a responsible and competent body of relevant professional opinion on the principles set down in *Bolam* v. *Friern Hospital Management Committee*[25]. Lord Goff opined that this principle must equally be applicable to decisions to initiate or to discontinue life support as it is to other forms of treatment. He also referred to a Discussion Paper on Treatment of Patients in Persistent Vegetative State issued in September 1992 by the Medical Ethics Committee of the British Medical Association pertaining to four safeguards in particular which, in the Committee's opinion, should be observed before discontinuing life support for such patients, which were: (*1*) every effort should be made at rehabilitation for at least six months after the injury; (*2*) the diagnosis of irreversible PVS should not be considered confirmed until at least 12 months after the injury with the effect that any decision to withhold life-prolonging treatment will be delayed for that period; (*3*) the diagnosis should be agreed by two other independent doctors; and (*4*) generally, the wishes of the patient's immediate family will be given great weight.

65. According to him, the views expressed by the Committee on the subject of consultation with the relatives of PVS patients are consistent with the opinion expressed by the House of Lords in *F. (Mental Patient: Sterilisation), In re*[24] that it is good practice for the doctor to consult relatives. Lord Goff observed that the Committee was firmly of the opinion that the relatives' views would not be determinative of the treatment inasmuch as if that would have been the case, the relatives would be able to dictate to the doctors what is in the best interests of the patient which cannot be right. Even so, a decision to withhold life-prolonging treatment such as artificial feeding must require close cooperation with those close to the patient and it is recognised that, in practice, their views and the opinions of doctors will coincide in many cases.

66. Thereafter, Lord Goff referred to American cases, namely, *Quinlan, In re*[26] and *Supt. of Belchertown State School* v. *Saikewicz*[27] wherein the American Courts adopted what is called the substituted judgment test which involves a detailed inquiry into the patient's views and preferences. As per the substituted judgment test, when the patient is incapacitated from expressing any view on the question whether life-prolonging treatment should be withheld, an attempt is made to determine what decision the patient himself would have made had he been able to do so. In later American cases concerning PVS patients, it has been held that in the absence of clear and convincing evidence of the patient's wishes, the surrogate decision-maker has to implement as far as possible the decision which the incompetent patient would have made if he was competent.

24 (1990) 2 AC 1 : (1989) 2 WLR 1025 : (1989) 2 All ER 545 (HL)
25 (1957) 1 WLR 582 : (1957) 2 All ER 118 (QB)
26 355 A 2d 647 : 70 NJ 10 (NJ 1976), cert. denied sub nom *Garger* v. *New Jersey*, 429 US 922 (1976)
27 373 Mass 728 : 370 NE 2d 417 (1977)

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67. However, Lord Goff acknowledged that any such test (substituted judgment test) does not form part of English law in relation to incompetent adults on whose behalf nobody has power to give consent to medical treatment. In contrast, England followed a straightforward test based on the best interests of the patient coined by the House of Lords in *F. (Mental Patient: Sterilisation), In re*[24]. He opined that the same test (patient's best interest) should be applied in the case of PVS patients where the question is whether life-prolonging treatment should be withheld. The learned Law Lord further observed that consistent with the best interests test, anything relevant to the application of the test may also be taken into account and if the personality of the patient is relevant to the application of the test (as it may be in cases where the various relevant factors have to be weighed), it may be taken into account as was done in *J. (A Minor) (Wardship: Medical Treatment), In re*[15]. But where the question is whether life support should be withheld from a PVS patient, it is difficult to see how the personality of the patient can be relevant, though it may be of comfort to his relatives if they believe, as in the present case, and indeed may well be so in many other cases, that the patient would not have wished his life to be artificially prolonged if he was totally unconscious and there was no hope of improvement in his condition.

68. As regards the extent to which doctors should, as a matter of practice, seek the guidance of the court by way of an application for declaratory relief before withholding life-prolonging treatment from a PVS patient, Lord Goff took note of the judgment of Sir Stephen Brown P., the President of the Family Division, wherein he held that the opinion of the court should be sought in all cases of similar nature. Lord Goff also noted that Sir Thomas Bingham, M.R. in the Court of Appeal expressed his agreement with Sir Stephen Brown P. in the following words: (*Airedale case*[11], AC pp. 815 H-816 A)

> "... This was in my respectful view a wise ruling, directed to the protection of patients, the protection of doctors, the reassurance of patients' families and the reassurance of the public. The practice proposed seems to me desirable. It may very well be that with the passage of time a body of experience and practice will build up which will obviate the need for application in every case, but for the time being I am satisfied that the practice which the President described should be followed."

69. It is worthy to mention that Lord Goff was of the view that there was a considerable cost involved in obtaining guidance from the court in cases of such nature. He took note of the suggestions forwarded by Mr Francis, the counsel for the respondents, to the effect that reference to the court was required in certain specific cases i.e. (*1*) where there was known to be a medical disagreement as to the diagnosis or prognosis, and (2) problems had arisen with the patient's relatives'/disagreement by the next of kin with the medical

24 (1990) 2 AC 1 : (1989) 2 WLR 1025 : (1989) 2 All ER 545 (HL)
15 1991 Fam 33 (CA) : (1991) 2 WLR 140 : (1990) 3 All ER 930
11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

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recommendation; actual or apparent conflict of interest between the next of kin and the patient; dispute between members of the patient's family; or absence of any next of kin to give consent. Lord Goff said that the President of the Family Division should be able to relax the present requirement so as to limit applications for declarations only to those cases in which there is a special need for the procedure to be invoked.

70. Lord Mustill observed that an argument had been advanced that it was in the best interest of the community at large that Anthony Bland's life should end. The doctors had done all they could have done. It was a lose-lose situation as nothing would be gained by continuing Bland's treatment and much would be lost. The distress of Bland's family members would steadily get worse and so would be the strain of the medical staff charged with the care of Bland despite the fact that Bland's condition would never improve and he would never recognise that he was being cared for. Further, the learned Law Lord observed that large resources in terms of skill, labour and money had been applied for maintaining Bland in his present condition which, in the opinion of many, could be fruitfully employed in improving the conditions of other patients who, if treated, may have useful, healthy and enjoyable lives for years to come.

71. Lord Lowry, agreeing with the reasoning of Lord Goff of Chieveley with whom the other learned Law Lords were also in general agreement, dismissed the appeal. In coming to this conclusion, Lord Lowry opined that the court, in reaching a decision according to law, ought to give weight to informed medical opinion both on the point whether to continue the artificial feeding regime of a patient in PVS and also on the question of what is in the best interests of a patient. Lord Lowry rejected the idea that informed medical opinion in these respects was merely a disguise which, if accepted, would legalise euthanasia. Lord Lowry also rejected the Official Solicitor's argument that the doctors were under a "duty to feed" their patients in PVS as in the instant case, the doctors overwhelmingly held the opposite view which had been upheld by the courts below. The doctors considered that it was in the patient's best interests that they should stop feeding him. Lord Lowry observed that the learned Law Lords had gone further by saying that the doctors are not entitled to feed a patient in PVS without his consent which cannot be obtained.

72. Lord Lowry further opined that there is no proposed guilty act in stopping the artificial feeding regime inasmuch as if it is not in the interests of an insentient patient to continue the life-supporting care and treatment, the doctor would be acting unlawfully if he continued the care and treatment and would perform no guilty act by discontinuing it. There is a gap between the old law on the one hand and new medicine and new ethics on the other. It is important, particularly in the area of criminal law which governs conduct, that the society's notions of what the law is and what is right should coincide. One role of the legislator, as per Lord Lowry, is to detect any disparity between these notions and to take appropriate action to close the gap.

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73. Lord Browne-Wilkinson observed that the ability to sustain life artificially is a relatively recent phenomenon. Existing law may not provide an acceptable answer to the new legal questions which it raises.

74. In the opinion of the learned Law Lord, there exists no doubt that it is for Parliament and not the courts to decide the broader issues raised by cases of such nature. He observed that recent developments in medical science have fundamentally changed the meaning of death. In medicine, the cessation of breathing or of heartbeat is no longer death because by the use of a ventilator, lungs which in the unaided course of nature stop breathing can be made to breathe artificially thereby sustaining the heartbeat. Thus, people like Anthony Bland, who would have previously died through inability to swallow food, can be kept alive by artificial feeding. This has led the medical profession, in Lord Browne-Wilkinson's view, to redefine death in terms of brain stem death i.e. the death of that part of the brain without which the body cannot function at all without assistance. He further said that if the Judges seek to develop new law to regulate the new circumstances, the law so laid down will reflect the Judges' views on the underlying ethical questions, questions on which there is a legitimate division of opinion. He proceeded to state that where a case raises wholly new moral and social issues, it is neither for the Judges to develop new principles of law nor would it be legitimate for the Judges to arrive at a conclusion as to what is for the benefit of one individual whose life is in issue.

75. For the said reasons, the learned Law Lord observed that it is imperative that the moral, social and legal issues raised by the case at hand should be considered by Parliament and only if Parliament fails to act, the Judge-made law will, by necessity, provide a legal answer to each new question as and when it arises.

76. The function of the court, in Lord Browne-Wilkinson's view, in such circumstances is to determine a particular case in accordance with the existing law and not to develop new law laying down a new regimen. He held that it is for Parliament to address the wider problems which such a case raises and lay down principles of law generally applicable to the withdrawal of life-support systems. He explained why the removal of the nasogastric tube in the present case could not be regarded as a positive act causing death since the tube itself, without the food being supplied through it, does nothing. The removal of the tube by itself does not cause death since it does not sustain life by itself. Therefore, the removal of the tube would not constitute the *actus reus* of murder since such positive act would not be the cause of death.

77. Thus, Lord Browne-Wilkinson observed that in case of an adult who is mentally competent, the artificial feeding regime would be unlawful unless the patient consented to it as a mentally competent patient can, at any time, put an end to life-support systems by refusing his consent to their continuation. He also observed that the House of Lords in *F. (Mental Patient: Sterilisation), In re*[24] developed the principle based on the concept of necessity under which a doctor can lawfully treat a patient who cannot consent to such treatment if

24 (1990) 2 AC 1 : (1989) 2 WLR 1025 : (1989) 2 All ER 545 (HL)

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it is in the best interests of the patient to receive such treatment. The learned Law Lord opined that the correct answer to the case at hand depends on the extent of the right to lawfully continue to invade the bodily integrity of Anthony Bland without his consent. To determine the extent of the said right, Lord Browne-Wilkinson observed that it can be deduced from *F. (Mental Patient: Sterilisation), In re*[24] wherein both Lord Brandon of Oakbrook and Lord Goff made it clear that the right to administer invasive medical care is wholly dependent upon such care being in the best interests of the patient and moreover, a doctor's decision whether to continue invasive care is in the best interests of the patient has to be assessed with reference to the test laid down in *Bolam*[25].

78. Lord Browne-Wilkinson held that if there comes a stage where a responsible doctor comes to the reasonable conclusion (which accords with the views of a responsible body of medical opinion) that further continuance of an intrusive life support system is not in the best interests of the patient, the doctor can no longer lawfully continue that life support system as to do so would constitute the crime of battery and the tort of trespass.

79. In Lord Browne-Wilkinson's view, the correct legal question in such cases is not whether the court thinks it is in the best interests of the patient in PVS to continue to receive intrusive medical care but whether the doctor responsible has arrived at a reasonable and bona fide belief that it is not in the best interests of the patient to continue to receive artificial medical regime.

80. Accordingly, Lord Browne-Wilkinson observed that on an application to the court for a declaration that the discontinuance of medical care will be lawful, the sole concern of the courts is to be satisfied that the doctor's decision to discontinue is in accordance with a respectable body of medical opinion and that it is reasonable. Adverting to various passages, Lord Browne-Wilkinson dismissed the appeal.

81. It is pertinent to mention here that in adopting the "best interests" principle in *Airedale*[11], the House of Lords followed its earlier decision in *F. (Mental Patient: Sterilisation), In re*[24] and in adopting the omission/commission distinction, it followed the approach of the Court of Appeal in *B. (A Minor) (Wardship: Medical Treatment), In re*[28] and *J. (A Minor) (Wardship: Medical Treatment), In re*[15] which raised the question of medical treatment for severely disabled children. In the context of cases where the patients are unable to communicate their wishes, it is pertinent to mention the observations made by Lord Goff in the *Airedale case*[11]. As observed by Lord Goff, the correct question in cases of this kind would be "whether it is in his best interests that treatment which has the effect of artificially prolonging his life should be continued". Thus, it was settled in *Airedale*[11] that it was lawful for the doctors

24 (1990) 2 AC 1 : (1989) 2 WLR 1025 : (1989) 2 All ER 545 (HL)
25 *Bolam* v. *Friern Hospital Management Committee*, (1957) 1 WLR 582 : (1957) 2 All ER 118 (QB)
11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)
28 (1981) 1 WLR 1421 : (1990) 3 All ER 927 (CA)
15 1991 Fam 33 (CA) : (1991) 2 WLR 140 : (1990) 3 All ER 930

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to discontinue treatment if the patient refuses such treatment. And in case the patient is not in a situation permitting him to communicate his wishes, then it becomes the responsibility of the doctor to act in the "best interest" of the patient.

H.1.2 ***Later cases***

82. With reference to the ongoing debate pertaining to assisted dying, Lord Steyn in *R. (Pretty)* v. *Director of Public Prosecutions*[29] explained that on one hand is the view which finds support in the Roman Catholic Church, Islam and other religions that human life is sacred and the corollary is that euthanasia and assisted suicide are always wrong, while on the other hand, as observed by Lord Steyn, is the belief defended by millions that the personal autonomy of individuals is predominant and it is the moral right of individuals to have a say over the time and manner of their death. Taking note of the imminent risk in legalising assisted dying, Lord Steyn took note of the utilitarian argument that the terminally-ill patients and those suffering great pain from incurable illnesses are often vulnerable and not all families, whose interests are at stake, are wholly unselfish and loving and there exists the probability of abuse in the sense that such people may be persuaded that they want to die or that they ought to want to die. Further, Lord Steyn observed that there is also the view that if the genuine wish of a terminally-ill patient to die is expressed by the patient, then they should not be forced against their will to endure a life that they no longer wish to endure. Without expressing any view on the unending arguments on either side, Lord Steyn noted that these wide-ranging arguments are ancient questions on which millions have taken diametrically opposite views and still continue to do.

83. In *B. (Consent to Treatment: Capacity), In re*[30], the primacy of patient autonomy, that is, the competent patient's right to decide for herself whether to submit to medical treatment over other imperatives, such as her best interests objectively considered, was recognised thereby confirming the right of the competent patient to refuse medical treatment even if the result is death and thus, a competent, ventilator-dependent patient sought and won the right to have her ventilator turned off.

84. Taking a slightly divergent view from *Airedale*[11], Lord Neuberger in *R. (Nicklinson)* v. *Ministry of Justice*[31] observed that the difference between administering fatal drug to a person and setting up a machine so that the person can administer the drug to himself is not merely a legal distinction but also a moral one and, indeed, authorising a third party to switch off a person's life support machine, as in *Airedale*[11], is a more drastic interference and a more extreme moral step than authorising a third party to set up a lethal drug delivery system to enable a person, only if he wishes, to activate the system to administer

29 (2002) 1 AC 800 : (2001) 3 WLR 1598 : (2002) 1 All ER 1 : 2001 UKHL 61 (HL)
30 (2002) 1 FLR 1090 sub nom *B. (Adult: Refusal of Medical Treatment), In re*, (2002) 2 All ER 449
11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)
31 2015 AC 657 : (2014) 3 WLR 200 : 2014 UKSC 38

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a lethal drug. Elaborating further on this theory, the Law Lord explained that in those cases which are classified as "omission", for instance, switching off a life support machine as in *Airedale*[11] and *B. (Consent to Treatment: Capacity), In re*[30], the act which immediately causes death is that of a third party which may be wrong whereas if the final act is that of a person who himself carries it out pursuant to a voluntary, clear, settled and informed decision, that may be the permissible side of the line as in the latter case, the person concerned had not been "killed" by anyone but had autonomously exercised his right to end his life. The Law Lord, however, immediately clarified that it is not intended to cast any doubt on the correctness of the decisions in *Airedale*[11] and *B. (Consent to Treatment: Capacity), In re*[30].

85. Suffice it to say, he concurred with the view in *Airedale case*[11] which he referred to as *Bland case*[11]. Lord Mance agreed with Lord Neuberger and Lord Sumption. In his opinion, he referred to *Airedale case*[11] and thereafter pointed out that a blanket prohibition was unnecessary and stated in his observations that persons in tragic position represent a distinct and relatively small group, and that by devising a mechanism enabling careful prior review (possibly involving the court as well as medical opinion), the vulnerable can be distinguished from those capable of forming a free and informed decision to commit suicide. Lord Mance acknowledged that the law and courts are deeply engaged in the issues of life and death and made a reference to the observations of Lord Neuberger.

86. We may note with profit that the prayer of Mr Nicklinson and Mr Lamb were rejected by the Court of Appeal.

87. Lord Mance referred to the expression by Rehnquist, C.J. in *Washington*[16] in a slightly different context that there is "an earnest and profound debate about the morality, legality, and practicality of … assisted suicide" and "our holding permits this debate to continue as it should in a democratic society".

88. Lord Wilson concurred with the judgment rendered by Lord Neuberger, referred to *Airedale case*[11] and said: [*R. (Nicklinson) case*[31], AC p. 820, para 199]

> "*199.* … As Hoffmann, L.J. suggested in his classic judgment in the Court of Appeal in *Airedale N.H.S. Trust* v. *Bland*[11], AC at p. 826, a law will forfeit necessary support if it pays no attention to the ethical dimension of its decisions. In para 209 below, Lord Sumption, JSC quotes Hoffmann, L.J.'s articulation of that principle but it is worth remembering that Hoffmann, L.J. then proceeded to identify two other ethical principles, namely those of individual autonomy and of respect for human dignity, which can run the other way."

11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)
30 (2002) 1 FLR 1090 sub nom *B. (Adult: Refusal of Medical Treatment), In re*, (2002) 2 All ER 449
16 *Washington* v. *Glucksberg*, 1997 SCC OnLine US SC 79 : 138 L Ed 2d 772 : 521 US 702 (1997)
31 *R. (Nicklinson)* v. *Ministry of Justice*, 2015 AC 657 : (2014) 3 WLR 200 : 2014 UKSC 38

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And further: (AC pp. 820-21, paras 199 & 200)

> "*199.* ... In *Pretty case*[32], at para 65, the ECHR was later to describe those principles as of the very essence of the ECHR. It was in the light (among other things) of the force of those two principles that in *Bland case*[11] the House of Lords ruled that it was lawful in certain circumstances for a doctor not to continue to provide life-sustaining treatment to a person in a persistent vegetative state....
>
> *200.* I agree with the observation of Lord Neuberger, PSC at para 94 that, in sanctioning a course leading to the death of a person about which he was unable to have a voice, the decision in *Bland case*[11] was arguably more extreme than any step which might be taken towards enabling a person of full capacity to exercise what must, at any rate now, in the light of the effect given to Article 8 of the ECHR in *Haas case*[33] at para 51, cited at para 29 above, be regarded as a positive legal *right* to commit suicide. Lord Sumption, JSC suggests in paras 212-213 below that it remains morally wrong and contrary to public policy for a person to commit suicide. Blackstone, in his *Commentaries on the Laws of England*, Book 4, Chapter 14, wrote that suicide was also a spiritual offence "in evading the prerogative of the Almighty, and rushing into his immediate presence uncalled for". If expressed in modern religious terms, that view would still command substantial support and a moral argument against committing suicide could convincingly be cast in entirely non-religious terms. Whether, however, it can be elevated into an overall conclusion about moral wrong and public policy is much more difficult." (emphasis in original)

89. Lord Sumption commenced the judgment stating that English Judges tend to avoid addressing the moral foundations of law. It is not their function to lay down principles of morality and the attempt leads to large generalisations which are commonly thought to be unhelpful. He further observed that in some cases, however, it is unavoidable and this is one of them. He referred to the opinion of Hoffmann, L.J. in *Airedale case*[11] and the concept of sanctity of life and, eventually, reproduced a passage from Hoffmann, L.J. and opined: [*R. (Nicklinson) case*[31], AC pp. 826-27, para 215]

> "*215.* Why should this be so? There are at least three reasons why the moral position of the suicide (whom I will call "the patient" from this point on, although the term may not always be apt) is different from that of a third party who helps him to kill himself. In the first place, the moral quality of their decisions is different. A desire to die can only result from an overpowering negative impulse arising from perceived incapacity, failure or pain. This is an extreme state which is unlikely to be shared

32 *Pretty* v. *United Kingdom*, (2002) 35 EHRR 1 : 2002 ECHR 423
11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)
33 *Haas* v. *Switzerland*, (2011) 53 EHRR 33 : 2011 ECHR 2422
31 *R. (Nicklinson)* v. *Ministry of Justice*, 2015 AC 657 : (2014) 3 WLR 200 : 2014 UKSC 38

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by the third party who assists. Even if the assister is moved by pure compassion, he inevitably has a greater degree of detachment. This must in particular be true of professionals such as doctors, from whom a high degree of professional objectivity is expected, even in situations of great emotional difficulty. Secondly, whatever right a person may have to put an end to his own life depends on the principle of autonomy, which leaves the disposal of his life to him. The right of a third party to assist cannot depend on that principle. It is essentially based on the mitigating effect of his compassionate motive. Yet not everyone seeking to end his life is equally deserving of compassion. The choice made by a person to kill himself is morally the same whether he does it because he is old or terminally ill, or because he is young and healthy but fed up with life. In both cases his desire to commit suicide may be equally justified by his autonomy. But the choice made by a third party who intervenes to help him is very different. The element of compassion is much stronger in the former category than in the latter. Third, the involvement of a third party raises the problem of the effect on other vulnerable people, which the unaided suicide does not. If it is lawful for a third party to encourage or assist the suicide of a person who has chosen death with a clear head, free of external pressures, the potential arises for him to encourage or assist others who are in a less good position to decide. Again, this is a more significant factor in the case of professionals, such as doctors or carers, who encounter these dilemmas regularly, than it is in the case of, say, family members confronting them for what will probably be the only time in their lives."

90. Dealing with the appeal by Nicklinson, Lord Sumption referred to the view of the Canadian Supreme Court in *Rodriguez*[22] and opined: [*R. (Nicklinson) case*[31], AC pp. 835-36, para 234]

> "*234.* ... the issue is an inherently legislative issue for Parliament, as the representative body in our Constitution, to decide. The question what procedures might be available for mitigating the indirect consequences of legalising assisted suicide, what risks such procedures would entail, and whether those risks are acceptable, are not matters which under our Constitution a court should decide."

91. Dealing with Martin's appeal, Lord Sumption dismissed the same. While doing so, he said: [*R. (Nicklinson) case*[31], AC p. 846, para 256]

> "*256.* This state of English law and criminal practice does not of course resolve all of the problems arising from the pain and indignity of the death which was endured by Tony Nicklinson and is now faced by Mr Lamb and Martin. But it is worth reiterating these well-established propositions, because it is clear that many medical professionals are frightened by the law and take an unduly narrow view of what can lawfully be done to relieve

22 *Rodriguez* v. *Attorney General of Canada*, 1993 SCC OnLine Can SC 97 : (1993) 3 SCR 519 : 85 CCC 3d 15

31 *R. (Nicklinson)* v. *Ministry of Justice*, 2015 AC 657 : (2014) 3 WLR 200 : 2014 UKSC 38

the suffering of the terminally ill under the law as it presently stands. Much needless suffering may be occurring as a result. It is right to add that there is a tendency for those who would like to see the existing law changed, to overstate its difficulties. This was particularly evident in the submissions of dignity and choice in dying. It would be unfortunate if this were to narrow yet further the options open to those approaching death, by leading them to believe that the current law and practice is less humane and flexible than it really is."

92. Lord Hughes agreed with the reasoning of Lord Sumption and dismissed the private appeals and allowed the appeals preferred by the Director of Public Prosecutions. Lord Clarke concurred with the reasoning given by Lord Sumption, Lord Reed and Lord Hughes. Lord Reed agreed with the view with regard to the dismissal of the appeals but observed some aspects with regard to the issue of compatibility.

93. Lady Hale entirely agreed with the judgment of Lord Neuberger. Lord Kerr in his opinion stated: [*R. (Nicklinson) case*[31], AC p. 873, para 358]

"*358.* I agree with Lord Neuberger, PSC that if the store put on the sanctity of life cannot justify a ban on suicide by the able-bodied, it is difficult to see how it can justify prohibiting a physically incapable person from seeking assistance to bring about the end of their life. As one of the witnesses for one of the interveners, the British Humanist Association, Professor Blackburn, said, there is "no defensible moral principle" in denying the [appellants] the means of achieving what, under Article 8 and by all the requirements of compassion and humanity, they should be entitled to do. To insist that these unfortunate individuals should continue to endure the misery that is their lot is not to champion the sanctity of life; it is to coerce them to endure unspeakable suffering."

And again: (AC p. 873, para 360)

"*360.* If one may describe the actual administration of the fatal dose as active assistance and the setting up of a system which can be activated by the assisted person as passive assistance, what is the moral objection to a person actively assisting someone's death, if passive assistance is acceptable? Why should active assistance give rise to moral corruption on the part of the assister (or, for that matter, society as a whole), but passive assistance not? In both cases the assister's aid to the person who wishes to die is based on the same conscientious and moral foundation. That it is that they are doing what the person they assist cannot do; providing them with the means to bring about their wished-for death. I cannot detect the moral distinction between the individual who brings a fatal dose to their beloved's lips from the person who sets up a system that allows their beloved to activate the release of the fatal dose by the blink of an eye."

31 *R. (Nicklinson)* v. *Ministry of Justice*, 2015 AC 657 : (2014) 3 WLR 200 : 2014 UKSC 38

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Eventually, Lady Hale dismissed the appeal and allowed the appeals of the Director of Public Prosecutions.

H.2 ***The legal position in the United States***

94. In the United States of America, active euthanasia is illegal but physician-assisted death is legal in the States of Oregon, Washington and Montana. A distinction has been drawn between euthanasia and physician-assisted suicide. In both Oregon and Washington, only self-assisted dying is permitted. Doctor-administered/assisted dying and any form of assistance to help a person commit suicide outside the provisions of the legislation remains a criminal offence.

95. As far as the United States of America is concerned, we think it appropriate to refer to *Cruzan*[4]. The said case involved a 30 year old Missouri woman who was lingering in a permanent vegetative state as a result of a car accident. Missouri requires "clear and convincing evidence" of patients' preferences and the Missouri Supreme Court, reversing the decision of the State trial court, rejected the parents' request to impose a duty on their daughter's physician to end life-support. The United States Supreme Court upheld that States can require "clear and convincing evidence" of a patient's desire in order to oblige physicians to respect this desire. Since Nancy Cruzan had not clearly expressed her desire to terminate life support in such a situation, physicians were not obliged to follow the parents' request.

96. Rehnquist, C.J. in his opinion, stated: (*Cruzan case*[4], SCC OnLine US SC para 6)

> "*6.* ... 'Every human being of adult years and sound mind has a right to determine what shall be done with his own body, and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages.' "

He further proceeded to state: (SCC OnLine US SC para 7)

> "*7.* The logical corollary of the doctrine of informed consent is that the patient generally possesses the right not to consent, that is, to refuse treatment. Until about 15 years ago and the seminal decision in *Quinlan, In re*[26] the number of right-to-refuse-treatment decisions were relatively few. Most of the earlier cases involved patients who refused medical treatment forbidden by their religious beliefs, thus implicating First Amendment rights as well as common law rights of self-determination. More recently, however, with the advance of medical technology capable of sustaining life well past the point where natural forces would have brought certain death in earlier times, cases involving the right to refuse life-sustaining treatment have burgeoned."

4 *Cruzan* v. *Missouri Department of Health*, 1990 SCC OnLine US SC 123 : 111 L Ed 2d 224 : 110 S Ct 2841 : 497 US 261 (1990)

26 355 A 2d 647 : 70 NJ 10 (NJ 1976), cert. denied sub nom *Garger* v. *New Jersey*, 429 US 922 (1976)

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97. Meeting the submissions on behalf of the petitioner, the learned Chief Justice opined: (*Cruzan case*[4], SCC OnLine US SC para 23)

> "*23.* The difficulty with petitioners' claim is that, in a sense, it begs the question: an incompetent person is not able to make an informed and voluntary choice to exercise a hypothetical right to refuse treatment or any other right. Such a "right" must be exercised for her, if at all, by some sort of surrogate. Here, Missouri has in effect recognized that under certain circumstances a surrogate may act for the patient in electing to have hydration and nutrition withdrawn in such a way as to cause death, but it has established a procedural safeguard to assure that the action of the surrogate conforms as best it may to the wishes expressed by the patient while competent. Missouri requires that evidence of the incompetent's wishes as to the withdrawal of treatment be proved by clear and convincing evidence. The question, then, is whether the United States Constitution forbids the establishment of this procedural requirement by the State. We hold that it does not."

98. The learned Chief Justice came to hold that there was no clear and convincing evidence to prove that the patient's desire was not to have hydration and nutrition. In the ultimate analysis, it was stated: (*Cruzan case*[4], SCC OnLine US SC para 32)

> "*32.* No doubt is engendered by anything in this record but that Nancy Cruzan's mother and father are loving and caring parents. If the State were required by the United States Constitution to repose a right of "substituted judgment" with anyone, the Cruzans would surely qualify. But we do not think the Due Process Clause requires the State to repose judgment on these matters with anyone but the patient herself. Close family members may have a strong feeling—a feeling not at all ignoble or unworthy, but not entirely disinterested, either—that they do not wish to witness the continuation of the life of a loved one which they regard as hopeless, meaningless, and even degrading. But there is no automatic assurance that the view of close family members will necessarily be the same as the patient's would have been had she been confronted with the prospect of her situation while competent. All of the reasons previously discussed for allowing Missouri to require clear and convincing evidence of the patient's wishes lead us to conclude that the State may choose to defer only to those wishes, rather than confide the decision to close family members."

The aforesaid decision has emphasised on "bodily integrity" and "informed consent".

4 *Cruzan* v. *Missouri Department of Health*, 1990 SCC OnLine US SC 123 : 111 L Ed 2d 224 : 110 S Ct 2841 : 497 US 261 (1990)

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99. The question that was presented before the Court was whether New York's prohibition on assisted suicide violates the Equal Protection Clause of the Fourteenth Amendment. The Court held that it did not and in the course of the discussion, Rehnquist, C.J. held: (*Vacco case*[17], SCC OnLine US SC)

> "The Court of Appeals, however, concluded that some terminally ill people—those who are on life-support systems—are treated differently from those who are not, in that the former may "hasten death" by ending treatment, but the latter may not "hasten death" through physician-assisted suicide. (*Quill* v. *Vacco*[34], F 3d at p. 729.) This conclusion depends on the submission that ending or refusing life saving medical treatment "is nothing more nor less than assisted suicide". *Ibid.* Unlike the Court of Appeals, we think the distinction between assisting suicide and withdrawing life-sustaining treatment, a distinction widely recognized and endorsed in the medical profession and in our legal traditions, is both important and logical; it is certainly rational."

Dealing with the conclusion in *Cruzan*[4], it was held: (*Vacco case*[17], SCC OnLine US SC)

> "This Court has also recognized, at least implicitly, the distinction between letting a patient die and making that patient die. In *Cruzan* v. *Missouri Department of Health*[4], SCC OnLine US SC para 18 : US p. 278, we concluded that "[t]he principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from our prior decisions", and we assumed the existence of such a right for purposes of that case, *id.*, at p. 279. But our assumption of a right to refuse treatment was grounded not, as the Court of Appeals supposed, on the proposition that patients have a general and abstract "right to hasten death", *Quill* v. *Vacco*[34], F 3d at pp. 727-28, but on well-established, traditional rights to bodily integrity and freedom from unwanted touching, *Cruzan*[4], US at pp. 278-79; *id.*, at pp. 287-88 (O'Connor, J., concurring). In fact, we observed that "the majority of States in this country have laws imposing criminal penalties on one who assists another to commit suicide". *Id.*, SCC OnLine US SC para 24 : US at p. 280. *Cruzan*[4] therefore provides no support for the notion that refusing life-sustaining medical treatment is "nothing more nor less than suicide."

100. From the aforesaid passages, it is crystal clear that the US Supreme Court has recognised that there is a distinction, in the context of the prevalent law, between letting a patient die and making that patient die. Right to refuse treatment is not grounded on the proposition that the patients have general and abstract right to hasten death. The learned Chief Justice has also endorsed the view of the American Medical Association emphasising the fundamental

17 *Vacco* v. *Quill*, 1997 SCC OnLine US SC 80 : 138 L Ed 2d 834 : 521 US 793 (1997)
34 80 F 3d 716 (2d Cir 1996)
4 *Cruzan* v. *Missouri Department of Health*, 1990 SCC OnLine US SC 123 : 111 L Ed 2d 224 : 110 S Ct 2841 : 497 US 261 (1990)

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difference between refusing life-sustaining treatment and demanding a life-ending treatment.

101. In *Vacco*[34], while ruling that a New York ban on physician-assisted suicide was constitutional, the Supreme Court of the United States applied the standard of intent to the matter finding that a doctor who withdraws life support at the request of his patient intends only to respect his patient's wishes. This, the Court said, is in sharp contrast to a doctor who honours a patient's request to end life which necessarily requires more than an intent to respect the patient's wishes i.e. it requires the intent to kill the patient. A major difference, the Court determined, in the two scenarios is that the former may cause the patient to die from underlying causes while the latter will cause the patient to die. The Court noted that the law plainly recognised the difference between "killing" and "letting die". It also recognised that the State of New York had, as a matter of policy, a compelling interest in forbidding assisted suicide, while allowing a patient to refuse life support was simply an act of protecting a Common Law right which was the right to retain bodily integrity and preserve individual autonomy since the prevention of "unwanted touching" was, in the opinion of the Court, a very legitimate right to protect.

H.3 ***Australian jurisdiction***

102. Moving to Australian jurisdiction, in *Hunter and New England Area Health Service* v. *A.*[35], the Supreme Court of New South Wales considered the validity of a Common Law Advance Directive (there being no legislative provisions for such directives in NSW) given by Mr *A* refusing kidney dialysis. One year after making the directive, Mr *A* was admitted to a hospital emergency department in a critical state with decreased level of consciousness. His condition deteriorated to the point that he was being kept alive by mechanical ventilation and kidney dialysis. The hospital sought a judicial declaration to determine the validity of his Advance Directive. The Court, speaking through McDougall, J. confirmed the directive and held that the hospital must respect the Advance Directive. Applying the Common Law principle, the Court observed:

> "A person may make an 'advance care directive': a statement that the person does not wish to receive medical treatment, or medical treatment of specified kinds. If an advance care directive is made by a capable adult, and it is clear and unambiguous, and extends to the situation at hand, it must be respected. It would be a battery to administer medical treatment to the person of a kind prohibited by the advance care directive."

103. In *Brightwater Care Group (Inc.)* v. *Rossiter*[36], the Court was concerned with an anticipatory refusal of treatment by Mr Rossiter, a man with quadriplegia who was unable to undertake any basic human function including taking nutrition or hydration orally. Mr Rossiter was not terminally ill, dying

34 *Quill* v. *Vacco*, 80 F 3d 716 (2d Cir 1996)
35 2009 NSWSC 761
36 2009 WASC 229 : 40 WAR 84

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or in a vegetative state and had full mental capacity. He had "clearly and unequivocally" indicated that he did not wish to continue to receive medical treatment which, if discontinued, would inevitably lead to his death. Martin, C.J., considering the facts and the Common Law principle, held:

> "At common law, the answers to the questions posed by this case are clear and straightforward. They are to the effect that Mr Rossiter has the right to determine whether or not he will continue to receive the services and treatment provided by Brightwater and, at common law, Brightwater would be acting unlawfully by continuing to provide treatment, [namely, the administration of nutrition and hydration via a tube inserted into his stomach] contrary to Mr Rossiter's wishes."

104. In *Australian Capital Territory* v. *JT*[37], an application to stop medical treatment, other than palliative care, was rejected. The man receiving treatment suffered from paranoid schizophrenia and was, therefore, held not mentally capable of making a decision regarding his treatment. Higgins, C.J. found that it would be unlawful for the service providers to stop providing treatment. The Chief Justice distinguished this situation from *Rossiter*[36] as the patient lacked "both understanding of the proposed conduct and the capacity to give informed consent to it". It is clear that mental capacity is the determining factor in cases relating to self-determination. Since the right of self-determination requires the ability to make an informed choice about the future, the requirement of mental capacity would be an obvious prerequisite. Higgins, C.J. undertook a detailed analysis and rightly distinguished *Auckland Area Health Board* v. *Attorney General*[38] in which a Court similarly bound to apply the human right to life and the prohibition on cruel and degrading treatment found that futile treatment could be withdrawn from a patient in a persistent vegetative state. He agreed with Howie, J. in *Messiha* v. *South East Health*[39] that futility of treatment could only be determined by consideration of the best interests of the patient and not by reference to the convenience of medical cares or their institutions.

105. The above decision basically considered the circumstances in which technically futile treatment may be withdrawn from patients at their direct or indirect request or in their best interests.

H.4 *Legal position in Canada*

106. In Canada, physician-assisted suicide is illegal as per Section 241(*b*) of the Criminal Code of Canada. The Supreme Court of Canada in *Rodriguez*[22] has drawn a distinction between "intentional actor" and "merely foreseeing". Delivering the judgment on behalf of the majority, Sopinka, J. rejected the argument that assisted suicide was similar to the withdrawal of life-preserving treatment at the patient's request. He also rejected the argument that the

37 2009 ACTSC 105
36 *Brightwater Care Group (Inc.)* v. *Rossiter*, 2009 WASC 229 : 40 WAR 84
38 (1993) 1 NZLR 235 (HC)
39 2004 NSWSC 1061
22 *Rodriguez* v. *Attorney General of Canada*, 1993 SCC OnLine Can SC 97 : (1993) 3 SCR 519 : 85 CCC 3d 15

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distinction between assisted suicide and accepted medical treatment was even more attenuated in the case of palliative treatment which was known to hasten death. He observed: (SCC OnLine Can SC)

> "... the distinction drawn here is one based upon intention—in the case of palliative care the intention is to ease pain, which has the effect of hastening death, while in the case of assisted suicide, the intention is undeniably to cause death."

He added: (SCC OnLine Can SC)

> "... In my view, distinctions based upon intent are important, and in fact form the basis of our criminal law. While factually the distinction may, at times, be difficult to draw, legally it is clear."

107. The Supreme Court of Canada in *Carter* v. *Attorney General of Canada*[40] held that the prohibition on physician-assisted death in Canada [in Sections 14 and 241(*b*) of the Canadian Criminal Code] unjustifiably infringed the right to life, liberty and security of the person in Article 7 of the Charter of Rights and Freedoms in the Canadian Constitution.

108. The Supreme Court declared the infringing provisions of the Criminal Code void insofar as they prohibit physician-assisted death for a competent adult person who (*1*) clearly consents to the termination of life; and (*2*) has a grievous and irremediable medical condition (including an illness, disease or disability) that causes enduring suffering that is intolerable to the individual in the circumstances of his or her condition. "Irremediable", it should be added, does not require the patient to undertake treatments that are not acceptable to the individual.

109. After the Supreme Court's decision, the Canadian Government appointed a Special Joint Committee on Physician-Assisted Dying to "make recommendations on the framework of a federal response on physician-assisted dying in consonance with the Constitution, the Charter of Rights and Freedoms, and the priorities of Canadians". The Special Joint Committee released its report in February 2016 recommending a legislative framework which would regulate "medical assistance in dying" by imposing both substantive and procedural safeguards, namely:

> *Substantive safeguards*:
>
> (*i*) A grievous and irremediable medical condition (including an illness, disease or disability) is required;
>
> (*ii*) Enduring suffering that is intolerable to the individual in the circumstances of his or her condition is required;
>
> (*iii*) Informed consent is required;
>
> (*iv*) Capacity to make the decision is required at the time of either the advance or contemporaneous request; and

40 2015 SCC OnLine Can SC 1 : 2015 SCC 5

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(*v*) Eligible individuals must be insured persons eligible for publicly funded healthcare services in Canada.

Procedural safeguards:

(*i*) Two independent doctors must conclude that a person is eligible;

(*ii*) A request must be in writing and witnessed by two independent witnesses;

(*iii*) A waiting period is required based, in part, on the rapidity of progression and nature of the patient's medical condition as determined by the patient's attending physician;

(*iv*) Annual report analysing medical assistance in dying cases are to be tabled in Parliament;

and

(*v*) Support and services, including culturally and spiritually appropriate end-of-life care services for indigenous patients, should be improved to ensure that requests are based on free choice, particularly for vulnerable people.

110. It should be noted that physician-assisted dying has already been legalised in the province of Quebec. Quebec passed an Act respecting end-of-life care (the Quebec Act) in June 2014 with most of the Act coming into force on 10-12-2015. The Quebec Act provides a "framework for end-of-life care" which includes "continuous palliative sedation" and "medical aid in dying" defined as "administration by a physician of medications or substances to an end-of-life patient, at the patient's request, in order to relieve their suffering by hastening death". In order to be able to access medical aid in dying under the Quebec Act, a patient must:

(*1*) be an insured person within the meaning of the Health Insurance Act (Chapter A-29);

(*2*) be of full age and capable of giving consent to care;

(*3*) be at the end of life;

(*4*) suffer from a serious and incurable illness;

(*5*) be in an advanced state of irreversible decline in capability; and

(*6*) experience constant and unbearable physical or psychological suffering

(*7*) which cannot be relieved in a manner the patient deems tolerable.

111. The request for medical aid in dying must be signed by two physicians. The Quebec Act also established a Commission on end-of-life care to provide oversight and advice to the Minister of Health and Social Services on the implementation of the legislation regarding end-of-life care.

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H.5 ***Other jurisdictions***

112. Presently, we think it appropriate to deal with certain legislations in other countries and the decisions in other jurisdictions. In *Aruna Shanbaug*[5], the Court has in detail referred to the legislations in Netherlands i.e. the Termination of Life on Request and Assisted Suicide (Review Procedures) Act, 2002 that regulates euthanasia. The provisions of the said Act lay down that euthanasia and physician-assisted suicide are not punishable if the attending physician acts in accordance with the criteria of due care. As the two-Judge Bench has summarised, this criteria concern the patient's request, the patient's suffering (unbearable and hopeless), the information provided to the patient, the presence of reasonable alternatives, consultation of another physician and the applied method of ending life. To demonstrate their compliance, the Act requires physicians to report euthanasia to a Review Committee. It has been observed that the said Act legalises euthanasia and physician-assisted suicide in very specific cases under three specific conditions and euthanasia remains a criminal offence in cases not meeting the laid-down specific conditions with the exception of several situations that are not subject to restrictions of law at all because they are considered normal medical practice. The three conditions are: stopping or not starting a medically useless (futile) treatment, stopping or not starting a treatment at the patient's request and speeding up death as a side-effect of treatment necessary for alleviating serious suffering.

113. Reference has been made to the Swiss Criminal Code where active euthanasia has been regarded as illegal. Belgium has legalised the practice of euthanasia with the enactment of the Belgium Act on Euthanasia of 28-5-2002 and the patients can wish to end their life if they are under constant and unbearable physical or psychological pain resulting from an accident or an incurable illness. The Act allows adults who are in a "futile medical condition of constant and unbearable physical or mental suffering that cannot be alleviated" to request voluntary euthanasia. Doctors who practise euthanasia commit no offence if the prescribed conditions and procedure is followed and the patient has the legal capacity and the request is made voluntarily and repeatedly with no external pressure.

114. Luxembourg too has legalised euthanasia with the passing of the Law of 16-3-2009 on Euthanasia and Assisted Suicide (Lux.). The law permits euthanasia and assisted suicide in relation to those with incurable conditions with the requirements including repeated requests and the consent of two doctors and an expert panel.

115. The position in Germany is that active assisted suicide is illegal. However, this is not the case for passive assisted suicide. Thus, in Germany, if doctors stop life-prolonging measures, for instance, on the written wishes of a patient, it is not considered as a criminal offence. That apart, it is legal for doctors in Germany to administer painkillers to a dying patient to ease pain.

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

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The said painkillers, in turn, cause low breathing that may lead to respiratory arrest and, ultimately, death.

H.6 ***International considerations and decisions of the European Court of Human Rights (ECHR)***

116. Certain relevant obligations when discussing voluntary euthanasia are contained in the *International Covenant on Civil and Political Rights* (ICCPR). The following rights in the ICCPR have been considered by the practice of voluntary euthanasia:

(*i*) Right to life (Article 6)

(*ii*) Freedom from cruel, inhuman or degrading treatment (Article 7)

(*iii*) Right to respect for private life (Article 17)

(*iv*) Freedom of thought, conscience and religion (Article 18).

117. Right to life under Article 6(1) of the ICCPR provides that every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life. The second sentence of Article 6(1) imposes a positive obligation on the States to provide legal protection of the right to life. However, the subsequent reference to life not being "arbitrarily deprived" operates to limit the scope of the right (and therefore the States' duty to ensure the right). Comments from the UN Human Rights Committee suggest that laws allowing for voluntary euthanasia are not necessarily incompatible with the States' obligation to protect the right to life.

118. The UN Human Rights Committee has emphasised that laws allowing for euthanasia must provide effective procedural safeguards against abuse if they are to be compatible with the State's obligation to protect the right to life. In 2002, the UN Committee considered the euthanasia law introduced in the Netherlands. The Committee stated that:

> "where a State party seeks to relax legal protection with respect to an act deliberately intended to put an end to human life, the Committee beliefs that the Covenant obliges it to apply the most rigorous scrutiny to determine whether the State party's obligations to ensure the right to life are being complied with (Articles 2 and 6 of the Covenant)."

119. The European Court of Human Rights (ECHR) has adopted a similar position to the UN Human Rights Committee when considering euthanasia laws and the right to life in Article 2 of the European Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention). According to the ECHR, the right to life in Article 2 cannot be interpreted as conferring a right to die or a right to self-determination in terms of choosing death rather than life. However, the ECHR has held that a State's obligation to protect life under that Article does not preclude it from legalising voluntary euthanasia, provided adequate safeguards are put in place and adhered to. In *Pretty* v. *United Kingdom*[32], the ECHR ruled that the decision

32 (2002) 35 EHRR 1 : 2002 ECHR 423

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of the applicant to avoid what she considered would be an undignified and distressing end to her life was part of the private sphere covered by the scope of Article 8 of the Convention. The Court affirmed that the right of an individual to decide how and when to end her life, provided that the said individual was in a position to make up her own mind in that respect and to take the appropriate action, was one aspect of the right to respect for private life under Article 8 of the Convention. The Court, thus, recognised, with conditions, a sort of right to self-determination as to one's own death, but the existence of this right is subject to two conditions, one linked to the free will of the person concerned and the other relating to the capacity to take appropriate action. However, respect for the right to life compels the national authorities to prevent a person from putting an end to life if such a decision is not taken freely and with full knowledge.

120. In *Haas* v. *Switzerland*[33], the ECHR explained that Article 2:

> "creates for the authorities a duty to protect vulnerable persons, even against actions by which they endanger their own lives... this latter Article obliges the national authorities to prevent an individual from taking his or her own life if the decision has not been taken freely and with full understanding of what is involved".

Accordingly, the ECHR concluded that:

> "the right to life guaranteed by Article 2 of the Convention obliges States to establish a procedure capable of ensuring that a decision to end one's life does indeed correspond to the free will of the individual concerned".

121. In a recent decision regarding end of life issues, *Lambert* v. *France*[41], the ECHR considered whether the decision to withdraw artificial nutrition and hydration of Vincent Lambert violated the right to life in Article 2. Vincent Lambert was involved in a serious road accident which left him tetraplegic and with permanent brain damage. He was assessed in expert medical reports as being in a chronic vegetative state that required artificial nutrition and hydration to be administered via a gastric tube.

122. Mr Lambert's parents applied to the ECHR alleging that the decision to withdraw his artificial nutrition and hydration breached, inter alia, the State's obligations under Article 2 of the European Convention. The ECHR highlighted that Article 2 imposes on the States both a negative obligation (to refrain from the "intentional" taking of life) and a positive obligation (to "take appropriate steps to safeguard the lives of those within its jurisdiction"). The Court held that the decision of a doctor to discontinue life-sustaining treatment (or "therapeutic abstention") did not involve the State's negative obligation under Article 2 and, therefore, the only question for the Court under Article 2 was whether it was consistent with the State's positive obligation.

33 (2011) 53 EHRR 33 : 2011 ECHR 2422
41 2015 ECHR 185

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123. The ECHR emphasised that "the Convention has to be read as a whole", and, therefore:

> "in a case such as the present one reference should be made, in examining a possible violation of Article 2, to Article 8 of the Convention and to the right to respect for private life and the notion of personal autonomy which it encompasses".

124. The Court noted that there was a consensus among European member States "as to the paramount importance of the patient's wishes in the decision-making process, however those wishes are expressed". It identified that in dealing with end-of-life situations, States have some discretion in terms of striking a balance between the protection of the patients' right to life and the protection of the right to respect their private life and their personal autonomy. The Court considered that the provisions of the Law of 22-4-2005 "on patients' rights and the end of life" promulgated in France making changes in the French Code of Public Health, as interpreted by the *Conseil d'État*, constituted a legal framework which was sufficiently clear to regulate with precision the decisions taken by doctors in situations such as in Mr Lambert's case. The Court found the legislative framework laid down by domestic law, as interpreted by the *Conseil d'État*, and the decision-making process which had been conducted in meticulous fashion, to be compatible with the requirements of the State's positive obligation under Article 2. With respect to negative obligations, the ECHR observed that the "therapeutic abstention" (that is, withdrawal and withholding of medical treatment) lacks the intention to end the patient's life and rather, a doctor discontinuing medical treatment from his or her patient merely intends to "allow death to resume its natural course and to relieve suffering". Therefore, as long as therapeutic abstention as authorised by the French Public Health Code is not about taking life intentionally, the ECHR opined that France had not violated its negative obligation to "refrain from the intentional taking of life".

125. When considering the State's positive obligations to protect human life, the ECHR noted that the regulatory framework developed in the Public Health Code and the decision of the *Conseil d'État* established several "important safeguards" with respect to therapeutic abstention and the regulation is, therefore, "apt to ensure the protection of patients' lives".

126. All this compelled the ECHR to conclude that there was no violation of the State's positive obligation to protect human life which, together with the absence of violation of negative obligations, resulted in the conclusion that "there would be no violation of Article 2 of the Convention in the event of implementation of the Conseil d'État judgment". Thus, the ECHR in the *Lambert*[41] case struck the balance between the sanctity of life on the one hand and the notions of quality of life and individual autonomy on the other.

41 *Lambert* v. *France*, 2015 ECHR 185

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I. *The 241st Report of the Law Commission of India on passive euthanasia*

127. After the judgment of *Aruna Shanbaug*[5] was delivered, the Law Commission of India submitted its 241st Report which dealt with "Passive Euthanasia — A Relook". The Report in its introduction has dealt with the origin of the concept of euthanasia. It states that the word "euthanasia" is derived from the Greek words "eu" and "thanatos" which literally mean "good death" and is otherwise described as "mercy killing". The word euthanasia, as pointed out in the Report, was used by Francis Bacon in the 17th century to refer to an easy, painless and happy death as it is the duty and responsibility of the physician to alleviate the physical suffering of the body of the patient. A reference has also been made in the Report to the meaning given to the term by the House of Lords. The Select Committee on "Medical Ethics" in England defined euthanasia as "a deliberate intervention undertaken with the express intention of ending a life to relieve intractable suffering". Impressing upon the voluntary nature of euthanasia, the Report has rightly highlighted the clarification as provided by the European Association of Palliative Care (EAPC) Ethics Task Force in a discussion on Euthanasia in 2003 to the effect that "medicalised killing of a person without the person's consent, whether non-voluntary (where the person is unable to consent) or involuntary (against the person's will) is not euthanasia: it is a murder".

128. The Commission in its Report referred to the observations made by the then Chairman of the Law Commission in his letter dated 28-8-2006 addressed to the Hon'ble Minister which was extracted. It is pertinent to reproduce the same:

> "2.4. … 'A hundred years ago, when medicine and medical technology had not invented the artificial methods of keeping a terminally-ill patient alive by medical treatment, including by means of ventilators and artificial feeding, such patients were meeting their death on account of natural causes. Today, it is accepted, a terminally ill person has a common law right to refuse modern medical procedures and allow nature to take its own course, as was done in good old times. It is well-settled law in all countries that a terminally-ill patient who is conscious and is competent, can take an "informed decision" to die a natural death and direct that he or she be not given medical treatment which may merely prolong life. There are currently a large number of such patients who have reached a stage in their illness when according to well-informed body of medical opinion, there are no chances of recovery. But modern medicine and technology may yet enable such patients to prolong life to no purpose and during such prolongation, patients could go through extreme pain and suffering. Several such patients prefer palliative care for reducing pain and suffering and do not want medical treatment which will merely prolong life or postpone death.' "

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

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129. The Report rightly points out that a rational and humanitarian outlook should have primacy in such a complex matter. Recognising that passive euthanasia, both in the case of competent and incompetent patients, is being allowed in most of the countries subject to the doctor acting in the best interests of the patient, the Report summarised the broad principles of medical ethics which shall be observed by the doctor in taking the decision. The said principles as obtained in the Report are the patient's autonomy (or the right to self-determination) and beneficence which means following a course of action that is best for the patient uninfluenced by personal convictions, motives or other considerations. The Report also refers to the observations made by Lord Keith in *Airedale case*[11] providing for a course to safeguard the patient's best interest. As per the said course, which has also been approved by this Court, the hospital/medical practitioner should apply to the Family Division of the High Court for endorsing or reversing the decision taken by the medical practitioners in charge to discontinue the treatment of a PVS patient. With respect to the ongoing debates on "legalising euthanasia", the Report reiterates the observations made in *Airedale*[11] that euthanasia (other than passive euthanasia) can be legalised by means of legislation only.

130. The Report, in upholding the principle of the patient's autonomy, went on to state:

> "11.2. ... the patient (competent) has a right to refuse medical treatment resulting in temporary prolongation of life. The patient's life is at the brink of extinction. There is no slightest hope of recovery. The patient undergoing terrible suffering and worst mental agony does not want his life to be prolonged by artificial means. She/he would not like to spend for his treatment which is practically worthless. She/he cares for his bodily integrity rather than bodily suffering. She/he would not like to live like a "cabbage" in an intensive care unit for some days or months till the inevitable death occurs. He would like to have the right of privacy protected which implies protection from interference and bodily invasion. As observed in *Gian Kaur case*[10], the natural process of his death has already commenced and he would like to die with peace and dignity. No law can inhibit him from opting such course. This is not a situation comparable to suicide, keeping aside the viewpoint in favour of decriminalising the attempt to suicide. The doctor or relatives cannot compel him to have invasive medical treatment by artificial means or treatment."

11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374

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131. The Report supports the view of several authorities especially Lord Browne-Wilkinson (in *Airedale case*[11]) and Justice Cardozo that in case of any forced medical intervention on the body of a patient, the surgeon/doctor is guilty of "assault" or "battery". The Report also laid emphasis on the opinion of Lord Goff placing the right of self-determination on a high pedestal. The said relevant observations of Lord Goff, as also cited in the Report, are as follows:

> "11.2. ... '... I wish to add that, in cases of this kind, there is no question of the patient having committed suicide, nor therefore of the doctor having aided or abetted him in doing so. It is simply that the patient has, as he is entitled to do, declined to consent to treatment which might or would have the effect of prolonging his life, and the doctor has, in accordance with his duty, complied with his patient's wishes.' (*Airedale case*[11], AC p. 864 G)"

132. We have referred to the Report of the Law Commission post *Aruna Shanbaug*[5] only to highlight that there has been affirmative thought in this regard. We have also been apprised by Mr Narasimha, learned Additional Solicitor General appearing for the Union of India, that there is going to be a law with regard to passive euthanasia.

J. *Right to refuse treatment*

133. Deliberating on the issue of right to refuse treatment, Cardozo, J. in *Schloendorff* v. *Society of New York Hospital*[42] observed:

> "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs the operation without his patient's consent commits an assault for which he is liable in damages."

134. In a somewhat different context, King, C.J. in *F.* v. *R.*[43] identified "the paramount consideration that a person is entitled to make his own decisions about his life". The said statement was cited with approval by Mason, C.J., Brennan, Dawson, Toohey and McHugh, JJ. in *Rogers* v. *Whitaker*[44]. Justice Cardozo's statement has been cited and applied in many cases. Thus, in *Malette* v. *Shulman*[45], Robins, J.A., speaking with the concurrence of Catzman and Canthy, JJ.A., said:

> "A competent adult is generally entitled to reject a specific treatment or all treatment, or to select an alternative form of treatment even if the decision may entail risks as serious as death and may appear mistaken in

11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)
5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294
42 105 NE 92 : 211 NY 125 (1914)
43 (1983) 33 SASR 189 at p. 193
44 1992 HCA 58 : (1992) 175 CLR 479 at p. 487
45 (1990) 67 DLR (4th) 321 : 72 OR (2d) 417 (CA)

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the eyes of the medical profession or of the community.... it is the patient who has the final say on whether to undergo the treatment."

135. The recognition of the freedom of competent adults to make choices about their medical care necessarily encompasses recognition of the right to make choices since individual free choice and self-determination are themselves fundamental constituents of life. Robins, J.A. further clarified in *Malette*[45] at p. 334:

> "To deny individuals freedom of choice with respect to their healthcare can only lessen and not enhance the value of life."

136. In the 21st century, with the advancement of technology in medical care, it has become possible, with the help of support machines, to prolong the death of patients for months and even years in some cases. At this juncture, the right to refuse medical treatment comes into the picture. A patient (terminally ill or in a persistent vegetative state) exercising the right to refuse treatment may ardently wish to live but, at the same time, he may wish to be free from any medical surgery, drugs or treatment of any kind so as to avoid protracted physical suffering. Any such person who has come of age and is of sound mind has a right to refuse medical treatment. This right stands on a different pedestal as compared to suicide, physician-assisted suicide or even euthanasia. When a terminally-ill patient refuses to take medical treatment, it can neither be termed as euthanasia nor as suicide. Albeit, both suicide and refusal to take treatment in case of terminal ailment shall result in the same consequences, that is, death, yet refusal to take treatment by itself cannot amount to suicide. In case of suicide, there has to be a self-initiated positive action with a specific intention to cause one's own death. On the other hand, a patient's right to refuse treatment lacks his specific intention to die, rather it protects the patient from unwanted medical treatment. A patient refusing medical treatment merely allows the disease to take its natural course and if, in this process, death occurs, the cause for it would primarily be the underlying disease and not any self-initiated act.

137. In *Rodriguez*[22], Sopinka, J. speaking for the Supreme Court of Canada, held: (SCC OnLine Can SC)

> "Canadian Courts have recognized a common law right of patients to refuse consent to medical treatment or to demand that the treatment, once commenced, be withdrawn or discontinued.... This right has been specially recognized to exist even if the withdrawal from or refusal of treatment may result in death...."

138. In *Department of Health and Community Services* v. *JWB and SMB*[46], the High Court of Australia acknowledged the fundamental right of personal inviolability. McHugh, J. observed that the voluntary decision of an adult person of sound mind as to what should be done to his or her body must

45 *Malette* v. *Shulman*, (1990) 67 DLR (4th) 321 : 72 OR (2d) 417 (CA)
22 *Rodriguez* v. *Attorney General of Canada*, 1993 SCC OnLine Can SC 97 : (1993) 3 SCR 519 : 85 CCC 3d 15
46 (1992) 66 AJLR 300 : (1992) 175 CLR 218

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be respected. It was further observed that under the doctrine of trespass, the Common Law respects and protects the autonomy of adult persons and also accepts the right to self-determination in respect of his or her body which can be altered only with the consent of the person concerned.

139. There is a presumption of capacity whereby an adult is presumed to have the capacity to consent to or to refuse medical treatment unless and until that presumption is rebutted. Butler-Sloss, L.J. in *MB (Medical Treatment), In re*[47], stated that in deciding whether a person has the capacity to make a particular decision, the ultimate question is whether that person suffers from some impairment or disturbance of mental functioning so as to render him or her incapable of making the decision. The consent may be vitiated if the individual concerned may not have been competent in law to give or refuse that consent; or even if the individual was competent in law, the decision has been obtained by undue influence or some other vitiating means; or the apparent consent or refusal does not extend to the particular situation; or the terms of the consent or refusal are ambiguous or uncertain; or if the consent or refusal is based on incorrect information or incorrect assumption. In circumstances where it is practicable for a medical practitioner to obtain consent to treatment, then, for the consent to be valid, it must be based on full information, including as to its risks and benefits.

140. Where it is not practicable for a medical practitioner to obtain consent for treatment and where the patient's life is in danger if appropriate treatment is not given, then the treatment may be administered without consent. This is justified by what is sometimes called the "emergency principle" or "principle of necessity". Usually, the medical practitioner treats the patient in accordance with his clinical judgment of what is in the patient's best interests. Lord Goff of Chieveley has rightly pointed out in *F. (Mental Patient: Sterilisation), In re*[24] that for the principle of necessity to apply, two conditions must be met:

> (*a*) There must be "a necessity to act when it is not practicable to communicate with the assisted person"; and
>
> (*b*) "the action taken must be such as a reasonable person would in all the circumstances take, acting in the best interests of the assisted person". (AC p. 75 H)

However, Lord Goff pointed out that the principle of necessity does not apply where the proposed action is contrary to the known wishes of the assisted person to the extent that he/she is capable of rationally forming such a wish. It follows that the principle of necessity cannot be relied upon to justify a particular form of medical treatment where the patient has given an advance care directive specifying that he/she does not wish to be so treated and where there is no reasonable basis for doubting the validity and applicability of that directive.

47 1997 EWCA Civ 3093 : (1997) 2 FLR 426
24 (1990) 2 AC 1 : (1989) 2 WLR 1025 : (1989) 2 All ER 545 (HL)

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K. ***Passive euthanasia in the context of Article 21 of the Constitution***

141. We have to restrict our deliberation to the issue whether euthanasia can come within the ambit and sweep of Article 21. Article 21 reads as follows: a

> "**21.** ***Protection of life and personal liberty.***—No person shall be deprived of his life or personal liberty except according to procedure established by law."

142. The word "liberty" is the sense and realisation of choice of the attributes associated with the said choice; and the term "life" is the aspiration b to possess the same in a dignified manner. The two are intrinsically interlinked. Liberty impels an individual to change and life welcomes the change and the movement. Life does not intend to live sans liberty as it would be, in all possibility, a meaningless survival. There is no doubt that no fundamental right is absolute, but any restraint imposed on liberty has to be reasonable. Individual liberty aids in developing one's growth of mind and assert individuality. She/he c may not be in a position to rule others but individually, she/he has the authority over the body and mind. The liberty of personal sovereignty over body and mind strengthens the faculties in a person. It helps in their cultivation. Roscoe Pound, in one of his lectures, has aptly said:

> "... although we think socially, we must still think of individual interests, and of that greatest of all claims which a human being may make, d the claim to assert his individuality, to exercise freely the will and the reason which God has given him. We must emphasize the social interest in the moral and social life of the individual, but we must remember that it is the life of a free-willing being."

143. Liberty allows freedom of speech, association and dissemination e without which the society may face hurdles in attaining the requisite maturity. History is replete with narratives how the thoughts of individuals, though not accepted by the contemporaneous society, later on gained not only acceptance but also respect. One may not agree with Kantian rigorism, but one must appreciate that without the said doctrine, there could not have been dissemination of further humanistic principles. There is a danger in f discouraging free thinking and curtailing the power of imagination. Holmes in *Adkins* v. *Children's Hospital of the District of Columbia*[48] has observed: (SCC OnLine US SC para 66)

> "*66.* ... It is merely an example of doing what you want to do, embodied in the word "liberty"."

144. The concept of liberty perceives a hazard when it feels it is likely to g become hollow. This necessarily means that there would be liberty available to individuals subject to permissible legal restraint and it should be made clear that in that restraint, free ideas cannot be imprisoned by some kind of unknown terror. Liberty cannot be a slave because it constitutes the essential marrow of life and that is how we intend to understand the conception of liberty when h

48 1923 SCC OnLine US SC 105 : 67 L Ed 785 : 261 US 525 at p. 568 (1923)

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we read it in association with the term "life" as used in Article 21 of the Constitution. The great American playwright Tennessee Williams has said:

"To be free is to have achieved your life."

145. Life as envisaged under Article 21 has been very broadly understood by this Court. In *Port of Bombay* v. *Dilipkumar Raghavendranath Nadkarni*[49], the Court has held that the expression "life" does not merely connote animal existence or a continued drudgery through life. The expression "life" has a much wider meaning and, therefore, where the outcome of a departmental enquiry is likely to adversely affect the reputation or livelihood of a person, some of the finer graces of human civilisation which make life worth living would be jeopardised and the same can be put in jeopardy only by law which inheres fair procedures.

146. In *Maneka Gandhi* v. *Union of India*[50], Krishna Iyer, J., in his own inimitable style, states that among the great guaranteed rights, life and liberty are the first among equals carrying a universal connotation cardinal to a decent human order and protected by constitutional armour. Once liberty under Article 21 is viewed in a truncated manner, several other freedoms fade out automatically. To sum up, personal liberty makes for the worth of the human person. Travel makes liberty worthwhile. "Life" is a terrestrial opportunity for unfolding personality, rising to higher status, moving to fresh woods and reaching out to reality which makes our earthly journey a true fulfilment — not a tale told by an idiot full of sound and fury signifying nothing, but a fine frenzy rolling between heaven and earth. The spirit of Man is at the root of Article 21. In the absence of liberty, other freedoms are frozen.

147. In *State of A.P.* v. *Challa Ramkrishna Reddy*[51], this Court held that right to life is one of the basic human rights and it is guaranteed to every person by Article 21 of the Constitution and not even the State has the authority to violate that right. A prisoner, whether a convict or undertrial or a detenu, does not cease to be a human being. Even when lodged in jail, he continues to enjoy all his fundamental rights including the right to life guaranteed to him under the Constitution. The Court further ruled that on being convicted of crime and deprived of their liberty in accordance with the procedure established by law, prisoners still retain the residue of constitutional rights.

148. Having said so, we are required to advert to the issue whether passive euthanasia can only be conceived of through legislation or this Court can, for the present, provide for the same. We have already explained that the ratio laid down in *Gian Kaur*[10] does not convey that the introduction of passive euthanasia can only be by legislation. In *Aruna Shanbaug*[5], the two-Judge

49 (1983) 1 SCC 124 : 1983 SCC (L&S) 61
50 (1978) 1 SCC 248
51 (2000) 5 SCC 712 : AIR 2000 SC 2083
10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374
5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

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Bench has placed reliance on the Constitution Bench judgment in *Gian Kaur*[10] to lay down the guidelines. If, eventually, we arrive at the conclusion that passive euthanasia comes within the sweep of Article 21 of the Constitution, we have no iota of doubt that this Court can lay down the guidelines.

149. We may clearly state here that the interpretation of the Constitution, especially fundamental rights, has to be dynamic and it is only such interpretative dynamism that breathes life into the written words. As far as Article 21 is concerned, it is imperative to mention that dynamism can, of course, infuse life into life and liberty as used in the said Article.

150. In this regard, we may reproduce a couple of paragraphs from *Central Inland Water Transport Corpn. Ltd.* v. *Brojo Nath Ganguly*[52]. They read as under: (SCC p. 178, paras 25 & 26)

> "*25.* The story of mankind is punctuated by progress and retrogression. Empires have risen and crashed into the dust of history. Civilisations have nourished, reached their peak and passed away. In the year 1625, Carew, C.J., while delivering the opinion of the House of Lords in *Earl of Oxford, In re*[53] in a dispute relating to the descent of that Earldom, said: (ER p. 53)
>
> > '... and yet time hath his revolution, there must be a period and an end of all temporal things, finis rerum, an end of names and dignities, and whatsoever is terrene....'
>
> The cycle of change and experiment, rise and fall, growth and decay, and of progress and retrogression recurs endlessly in the history of man and the history of civilisation. T.S. Eliot in the First Chorus from "*The Rock*" said:
>
> > 'O perpetual revolution of configured stars,
> > O perpetual recurrence of determined seasons,
> > O world of spring and autumn, birth and dying;
> > The endless cycle of idea and action,
> > Endless invention, endless experiment.'
>
> *26.* The law exists to serve the needs of the society which is governed by it. If the law is to play its allotted role of serving the needs of the society, it must reflect the ideas and ideologies of that society. It must keep time with the heartbeats of the society and with the needs and aspirations of the people. As the society changes, the law cannot remain immutable. The early nineteenth century essayist and wit, Sydney Smith, said: "When I hear any man talk of an unalterable law, I am convinced that he is an unalterable fool." *The law must, therefore, in a changing society march in tune with the changed ideas and ideologies.*" (emphasis supplied)

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374
52 (1986) 3 SCC 156 : 1986 SCC (L&S) 429
53 1625 Jones, W. 97 : (1626) 82 ER 51 (HL)

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151. We approve the view in the aforesaid passages. Having approved the aforesaid principle, we are obliged to state that the fundamental rights in their connotative expanse are bound to engulf certain rights which really flow from the same. In *M. Nagaraj* v. *Union of India*[54], the Constitution Bench has ruled: (SCC pp. 240-41, para 19)

> "*19.* The Constitution is not an ephemeral legal document embodying a set of legal rules for the passing hour. It sets out principles for an expanding future and is intended to endure for ages to come and consequently to be adapted to the various crises of human affairs. Therefore, a purposive rather than a strict literal approach to the interpretation should be adopted. A constitutional provision must be construed not in a narrow and constricted sense but in a wide and liberal manner so as to anticipate and take account of changing conditions and purposes so that a constitutional provision does not get fossilised but remains flexible enough to meet the newly emerging problems and challenges."

And again: (SCC p. 244, para 29)

> "*29.* ... constitutionalism is about limits and aspirations. According to Justice Brennan, interpretation of the Constitution as a written text is concerned with aspirations and fundamental principles. In his article titled "Challenge to the Living Constitution" by Herman Belz, the author says that the Constitution embodies aspiration to social justice, brotherhood and human dignity. It is a text which contains fundamental principles. ..."

152. In this context, we may make a reference to a three-Judge Bench decision in *V.C. Rangadurai* v. *D. Gopalan*[55] wherein the majority, while dealing with Section 35(3) of the Advocates Act, 1961, stated: (SCC p. 312, para 8)

> "*8.* ... we may note that words grow in content with time and circumstance, that phrases are flexible in semantics, that the printed text is a set of vessels into which the court may pour appropriate judicial meaning. That statute is sick which is allergic to change in sense which the times demand and the text does not countermand. That court is superficial which stops with the cognitive and declines the creative function of construction. So, we take the view that "quarrying" more meaning is permissible out of Section 35(3) and the appeal provisions, in the brooding background of social justice, sanctified by Article 38, and of free legal aid enshrined by Article 39-A of the Constitution."

The learned Judges went on to say: (SCC p. 313, para 11)

> "*11.* ... Judicial "Legisputation" to borrow a telling phrase of J. Cohen [*The Interpretation and Application of Statutes*, Read Dickerson, p. 238], is not legislation but application of a given legislation to new or unforeseen

54 (2006) 8 SCC 212 : (2007) 1 SCC (L&S) 1013
55 (1979) 1 SCC 308

needs and situations broadly falling within the statutory provision. In that sense, "interpretation is inescapably a kind of legislation" *Ibid.*, p. 238. This is not legislation stricto sensu but application, and is within the court's province."

153. The aforesaid authorities clearly show the power that falls within the province of the Court. The language employed in the constitutional provision should be liberally construed, for such provision can never remain static. It is because staticity would mar the core which is not the intent.

K.1 ***Individual dignity as a facet of Article 21***

154. Dignity of an individual has been internationally recognised as an important facet of human rights in the year 1948 itself with the enactment of the Universal Declaration of Human Rights. Human dignity not only finds place in the Preamble of this important document but also in Article 1 of the same. It is well known that the principles set out in UDHR are of paramount importance and are given utmost weightage while interpreting human rights all over the world. The first and foremost responsibility fixed upon the State is the protection of human dignity without which any other right would fall apart. Justice Brennan in his book *The Constitution of the United States: Contemporary Ratification* has referred to the Constitution as "a sparkling vision of the supremacy of the human dignity of every individual".

155. In fact, in *Christine Goodwin* v. *United Kingdom*[56] the European Court of Human Rights, speaking in the context of the Convention for the Protection of Human Rights and Fundamental Freedoms, has gone to the extent of stating that "the very essence of the Convention is respect for human dignity and human freedom". In the South African case of *S.* v. *Makwanyane*[57] O'Regan, J. stated in the Constitutional Court that "without dignity, human life is substantially diminished".

156. Having noted the aforesaid, it is worthy to note that our Court has expanded the spectrum of Article 21. In the latest nine-Judge Bench decision in *K.S. Puttaswamy* v. *Union of India*[58], dignity has been reaffirmed to be a component under the said fundamental right. Human dignity is beyond definition. It may at times defy description. To some, it may seem to be in the world of abstraction and some may even perversely treat it as an attribute of egotism or accentuated eccentricity. This feeling may come from the roots of absolute cynicism. But what really matters is that life without dignity is like a sound that is not heard. Dignity speaks, it has its sound, it is natural and human. It is a combination of thought and feeling, and, as stated earlier, it deserves respect even when the person is dead and described as a "body". That is why,

56 2002 ECHR 588
57 1995 SCC OnLine ZACC 2 : (1995) 3 SA 391
58 (2017) 10 SCC 1

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the Constitution Bench in *M. Nagaraj*[54] lays down: (*M. Nagaraj case*[54], SCC p. 244, para 26)

> "26. ... *It is the duty of the State not only to protect the human dignity but to facilitate it by taking positive steps in that direction. No exact definition of human dignity exists. It refers to the intrinsic value of every human being, which is to be respected. It cannot be taken away. It cannot give* (sic be given). *It simply is. Every human being has dignity by virtue of his existence.* ... (*K.S. Puttaswamy case*[58], SCC p. 405, para 113)" (emphasis supplied in *K.S. Puttaswamy*[58])

157. The concept and value of dignity requires further elaboration since we are treating it as an inextricable facet of right to life that respects all human rights that a person enjoys. Life is basically self-assertion. In the life of a person, conflict and dilemma are expected to be normal phenomena. Oliver Wendell Holmes, in one of his addresses, quoted a line from a Latin poet who had uttered the message, "Death plucks my ear and says, Live—I am coming". That is the significance of living. But when a patient really does not know if he/she is living till death visits him/her and there is constant suffering without any hope of living, should one be allowed to wait? Should she/he be cursed to die as life gradually ebbs out from her/his being? Should she/he live because of innovative medical technology or, for that matter, should he/she continue to live with the support system as people around him/her think that science in its progressive invention may bring about an innovative method of cure? To put it differently, should he/she be "Guinea pig" for some kind of experiment? The answer has to be an emphatic "No" because such futile waiting mars the pristine concept of life, corrodes the essence of dignity and erodes the fact of eventual choice which is pivotal to privacy.

158. Recently, in *K.S. Puttaswamy*[58], one of us (Dr Chandrachud, J.), while speaking about life and dignity, has observed: (SCC pp. 406-407, paras 118 & 119)

> "*118.* Life is precious in itself. But life is worth living because of the freedoms which enable each individual to live life as it should be lived. The best decisions on how life should be lived are entrusted to the individual. They are continuously shaped by the social milieu in which individuals exist. The duty of the State is to safeguard the ability to take decisions—the autonomy of the individual—and not to dictate those decisions. "Life" within the meaning of Article 21 is not confined to the integrity of the physical body. The right comprehends one's being in its fullest sense. That which facilitates the fulfilment of life is as much within the protection of the guarantee of life.
>
> *119.* To live is to live with dignity. The draftsmen of the Constitution defined their vision of the society in which constitutional values would be

54 *M. Nagaraj* v. *Union of India*, (2006) 8 SCC 212 : (2007) 1 SCC (L&S) 1013
58 *K.S. Puttaswamy* v. *Union of India*, (2017) 10 SCC 1

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attained by emphasising, among other freedoms, liberty and dignity. So fundamental is dignity that it permeates the core of the rights guaranteed to the individual by Part III. Dignity is the core which unites the fundamental rights because the fundamental rights seek to achieve for each individual the dignity of existence. Privacy with its attendant values assures dignity to the individual and it is only when life can be enjoyed with dignity can liberty be of true substance. Privacy ensures the fulfilment of dignity and is a core value which the protection of life and liberty is intended to achieve."

159. In *Mehmood Nayyar Azam* v. *State of Chhattisgarh*[59], a two-Judge Bench held thus: (SCC p. 6, para 1)

"*1.* ... Albert Schweitzer*, highlighting on Glory of Life, pronounced with conviction and humility, "the reverence of life offers me my fundamental principle on morality". The aforesaid expression may appear to be an individualistic expression of a great personality, but, when it is understood in the complete sense, it really denotes, in its conceptual essentiality, and connotes, in its macrocosm, the fundamental perception of a thinker about the respect that life commands. The reverence of life is insegregably associated with the dignity of a human being who is basically divine, not servile. A human personality is endowed with potential infinity and it blossoms when dignity is sustained. The sustenance of such dignity has to be the superlative concern of every sensitive soul. The essence of dignity can never be treated as a momentary spark of light or, for that matter, "a brief candle", or "a hollow bubble". The spark of life gets more resplendent when man is treated with dignity sans humiliation, for every man is expected to lead an honourable life which is a splendid gift of "creative intelligence"."

160. The aforesaid authority emphasises the seminal value of life that is inherent in the concept of life. Dignity does not recognise or accept any nexus with the status or station in life. The singular principle that it pleasantly gets beholden to is the integral human right of a person. Law gladly takes cognizance of the fact that dignity is the most sacred possession of a man. And the said possession neither loses its sanctity in the process of dying nor evaporates when death occurs. In this context, reference to a passage from *Vikas Yadav* v. *State of U.P.*[60] is noteworthy. The two-Judge Bench of this Court, while dealing with the imposition of a fixed term sentence under Section 302 IPC, took note of the fact that the High Court had observed[61] the magnitude of vengeance of the accused and the extent to which they had gone to destroy the body of the deceased. Keeping in view the findings of the High Court, this Court stated: (*Vikas Yadav case*[60], SCC p. 593, para 77)

59 (2012) 8 SCC 1 : (2012) 4 SCC (Civ) 34 : (2012) 3 SCC (Cri) 733 : (2012) 2 SCC (L&S) 449
* Ed.: Albert Schweitzer was awarded the Noble Prize for Peace in 1952.
60 (2016) 9 SCC 541 : (2016) 3 SCC (Cri) 621
61 *Vikas Yadav* v. *State of U.P.*, 2015 SCC OnLine Del 7129

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"77. ... From the evidence brought on record as well as the analysis made by the High Court, it is demonstrable about the criminal proclivity of the accused persons, for they have neither the respect for human life nor did they have any concern for the dignity of a dead person. They had deliberately comatosed the feeling that even in death a person has dignity and when one is dead deserves to be treated with dignity. That is the basic human right. The brutality that has been displayed by the accused persons clearly exposes the depraved state of mind."

The aforesaid passage shows the pedestal on which the Court has placed the dignity of an individual.

161. Reiterating that dignity is the most fundamental aspect of right to life, it has been held in the celebrated case of *Francis Coralie Mullin* v. *State (UT of Delhi)*[62]: (SCC pp. 618-19, para 8)

"8. ... We think that the right to life includes the right to live with human dignity and all that goes along with it, namely, the bare necessaries of life such as adequate nutrition, clothing and shelter and facilities for reading, writing and expressing one-self in diverse forms, freely moving about and mixing and commingling with fellow human beings. Of course, the magnitude and content of the components of this right would depend upon the extent of the economic development of the country, but it must, in any view of the matter, include the right to the basic necessities of life and also the right to carry on such functions and activities as constitute the bare minimum expression of the human-self. Every act which offends against or impairs human dignity would constitute deprivation pro tanto of this right to live and it would have to be in accordance with reasonable, fair and just procedure established by law which stands the test of other fundamental rights. Now obviously, any form of torture or cruel, inhuman or degrading treatment would be offensive to human dignity and constitute an inroad into this right to live and it would, on this view, be prohibited by Article 21 unless it is in accordance with procedure prescribed by law, but no law which authorises and no procedure which leads to such torture or cruel, inhuman or degrading treatment can ever stand the test of reasonableness and non-arbitrariness: it would plainly be unconstitutional and void as being violative of Articles 14 and 21. It would thus be seen that there is implicit in Article 21 the right to protection against torture or cruel, inhuman or degrading treatment which is enunciated in Article 5 of the Universal Declaration of Human Rights and guaranteed by Article 7 of the International Covenant on Civil and Political Rights."

162. In *National Legal Services Authority* v. *Union of India*[63], the Apex Court has held that there is a growing recognition that the true measure of development of a nation is not economic growth; it is human dignity.

62 (1981) 1 SCC 608 : 1981 SCC (Cri) 212
63 (2014) 5 SCC 438

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163. In *Shabnam* v. *Union of India*[64], it has been further held that: (SCC p. 713, para 14)

> "*14*. This right to human dignity has many elements. First and foremost, human dignity is the dignity of each human being "*as a human being*". Another element, which needs to be highlighted, in the context of the present case, is that human dignity is infringed if a person's life, physical or mental welfare is armed. It is in this sense torture, humiliation, forced labour, etc. all infringe on human dignity." (emphasis in original)

164. In *Gian Kaur*[10], the Constitution Bench indicates acceleration of the conclusion of the process of death which has commenced and this indication, as observed by us, allows room for expansion. In the said case, the Court was primarily concerned with the question of constitutional validity of Sections 306 and 309 IPC. The Court was conscious of the fact that the debate on euthanasia was not relevant for deciding the question under consideration. The Court, however, in no uncertain terms expounded that the word "life" in Article 21 has been construed as life with human dignity and it takes within its ambit the "right to die with dignity" being part of the "right to live with dignity". Further, the "right to live with human dignity" would mean existence of such a right up to the end of natural life which would include the right to live a dignified life up to the point of death including the dignified procedure of death. While adverting to the situation of a dying man who is terminally ill or in a persistent vegetative state where he may be permitted to terminate it by a premature extinction of his life, the Court observed that the said category of cases may fall within the ambit of "right to die with dignity" as part of the right to live with dignity when death due to the termination of natural life is certain and imminent and the process of natural death has commenced, for these are not cases of extinguishing life but only of accelerating the conclusion of the process of natural death which has already commenced. The sequitur of this exposition is that there is little doubt that a dying man who is terminally ill or in a persistent vegetative state can make a choice of premature extinction of his life as being a facet of Article 21 of the Constitution. If that choice is guaranteed being part of Article 21, there is no necessity of any legislation for effectuating that fundamental right and more so his natural human right. Indeed, that right cannot be an absolute right but subject to regulatory measures to be prescribed by a suitable legislation which, however, must be reasonable restrictions and in the interests of the general public.

165. In the context of the issue under consideration, we must make it clear that as part of the right to die with dignity in case of a dying man who is terminally ill or in a persistent vegetative state, only passive euthanasia would come within the ambit of Article 21 and not the one which would fall within the description of active euthanasia in which positive steps are taken either by the treating physician or some other person. That is because the right to die with dignity is an intrinsic facet of Article 21. The concept that has been touched

64 (2015) 6 SCC 702 : (2015) 3 SCC (Cri) 355
10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374

deserves to be concretised, the thought has to be realised. It has to be viewed from various angles, namely, legal permissibility, social and ethical ethos and medical values.

166. The purpose of saying so is only to highlight that the law must take cognizance of the changing society and march in consonance with the developing concepts. The need of the present has to be served with the interpretative process of law. However, it is to be seen how much strength and sanction can be drawn from the Constitution to consummate the changing ideology and convert it into a reality. The immediate needs are required to be addressed through the process of interpretation by the Court unless the same totally falls outside the constitutional framework or the constitutional interpretation fails to recognise such dynamism. The Constitution Bench in *Gian Kaur*[10], as stated earlier, distinguishes attempt to suicide and abetment of suicide from acceleration of the process of natural death which has commenced. The authorities, we have noted from other jurisdictions, have observed the distinctions between the administration of lethal injection or certain medicines to cause painless death and non-administration of certain treatment which can prolong the life in cases where the process of dying that has commenced is not reversible or withdrawal of the treatment that has been given to the patient because of the absolute absence of possibility of saving the life. To explicate, the first part relates to an overt act whereas the second one would come within the sphere of informed consent and authorised omission. The omission of such a nature will not invite any criminal liability if such action is guided by certain safeguards. The concept is based on non-prolongation of life where there is no cure for the state the patient is in and he, under no circumstances, would have liked to have such a degrading state. The words "no cure" have to be understood to convey that the patient remains in the same state of pain and suffering or the dying process is delayed by means of taking recourse to modern medical technology. It is a state where the treating physicians and the family members know fully well that the treatment is administered only to procrastinate the continuum of breath of the individual and the patient is not even aware that he is breathing. Life is measured by artificial heartbeats and the patient has to go through this undignified state which is imposed on him. The dignity of life is denied to him as there is no other choice but to suffer an avoidable protracted treatment thereby thus indubitably casting a cloud and creating a dent in his right to live with dignity and face death with dignity, which is a preserved concept of bodily autonomy and right to privacy. In such a stage, he has no old memories or any future hopes but he is in a state of misery which nobody ever desires to have. Some may also silently think that death, the inevitable factum of life, cannot be invited. To meet such situations, the Court has a duty to interpret Article 21 in a further dynamic manner and it has to be stated without any trace of doubt that the right to life with dignity has to include the smoothening of the process of dying when the person is in a vegetative state or is living exclusively by the administration of artificial aid that prolongs the life by arresting the

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374

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dignified and inevitable process of dying. Here, the issue of choice also comes in. Thus analysed, we are disposed to think that such a right would come within the ambit of Article 21 of the Constitution.

L. *Right of self-determination and individual autonomy*

167. Having dealt with the right to acceleration of the process of dying a natural death which is arrested with the aid of modern innovative technology as a part of Article 21 of the Constitution, it is necessary to address the issues of right of self-determination and individual autonomy.

168. John Rawls says that the liberal concept of autonomy focuses on choice and likewise, self-determination is understood as exercised through the process of choosing[65]. The respect for an individual human being and in particular for his right to choose how he should live his own life is individual autonomy or the right of self-determination. It is the right against non-interference by others, which gives a competent person who has come of age the right to make decisions concerning his or her own life and body without any control or interference of others. Lord Hoffman, in *Reeves* v. *Commr. of Police of the Metropolis*[66] has stated: (AC p. 369 B)

> "... Autonomy means that every individual is sovereign over himself and cannot be denied the right to certain kinds of behaviour, even if intended to cause his own death."

169. In the context of health and medical care decisions, a person's exercise of self-determination and autonomy involves the exercise of his right to decide whether and to what extent he/she is willing to submit himself/herself to medical procedures and treatments, choosing amongst the available alternative treatments or, for that matter, opting for no treatment at all which, as per his or her own understanding, is in consonance with his or her own individual aspirations and values.

170. In *Airedale*[11], Lord Goff has expressed that it is established that the principle of self-determination requires that respect must be given to the wishes of the patient so that if an adult patient of sound mind refuses, however unreasonably, to consent to treatment or care by which his/her life would or might be prolonged, the doctors responsible for his/her care must give effect to his/her wishes, even though they do not consider it to be in his/her best interests to do so and to this extent, the principle of sanctity of human life must yield to the principle of self-determination. Lord Goff further says that the doctor's duty to act in the best interests of his patient must likewise be qualified with the patient's right of self-determination. Therefore, as far as the United Kingdom is concerned, it is generally clear that whenever there is a conflict between a capable adult's exercise of the right of self-determination and the State's

65 Rawls, John, *Political Liberalism*, 32, 33 (New York: Columbia University Press, 1993).
66 (2000) 1 AC 360 : (1993) 3 WLR 363 (HL)
11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

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interest in preserving human life by treating it as sanctimonious, the right of the individual must prevail.

171. In the United States, the aspect of self-determination and individual autonomy is concretised in law as all fifty States along with the District of Columbia, the capital, which is commonly referred as Washington D.C., have passed legislations upholding different forms of Advance Directives. In the United States, even before the enactment of the said laws, a terminally ill person was free to assert the right to die as an ancillary right to the constitutionally protected right to privacy. In *Quinlan, In re*[26], where a 21 year old girl in chronic PVS was on ventilator support, the Court, while weighing Quinlan's right to privacy qua the State's interest in preserving human life, found that as the degree of bodily invasion increases and the prognosis for the patient's recovery dims, the patient's right to privacy increases and the State's interest weakens. The Supreme Court of New Jersey finally ruled that the unwritten constitutional right of privacy was broad enough to encompass a patient's decision to decline medical treatment in certain circumstances. Again, in *Jobes, In re*[67], which was also a case concerned with a PVS patient, the Court, following the decision in *Quinlan, In re*[26], upheld the principle of self-determination and autonomy of an incompetent person.

172. The Canadian Criminal Code asserts and protects the sanctity of life in a number of ways which directly confront the autonomy of the terminally ill in their medical decision making. However, the Supreme Court of Canada in *Reibl* v. *Hughes*[68] approved an oft-quoted statement of Cardozo, J. in *Schloendorff*[42] that "every human being of adult years and sound mind has a right to determine what shall be done with his own body" and Laskin, C.J. in *Reibl*[68] has further added that battery would lie where surgery or treatment was performed without consent or where apart from emergency situations, surgery or medical treatment was given beyond that to which there was consent. Thus, the Supreme Court of Canada suggested that competent adults have the right to make their own medical decisions even if such decisions are unwise.

173. In *Aruna Shanbaug*[5], this Court has observed that autonomy means the right to self-determination where the informed patient has a right to choose the manner of his treatment. To be autonomous the patient should be competent to make decisions and choices. In the event that he is incompetent to make choices, his wishes expressed in advance in the form of a Living Will, or the wishes of surrogates acting on his behalf ("substituted judgment") are to be respected. The surrogate is expected to represent what the patient may have decided had he/she been competent or to act in the patient's best interest. It is expected that a surrogate acting in the patient's best interest follows a course

26 355 A 2d 647 : 70 NJ 10 (NJ 1976), cert. denied sub nom *Garger* v. *New Jersey*, 429 US 922 (1976)
67 108 NJ 394 (1987)
68 1980 SCC OnLine Can SC 88 : (1980) 2 SCR 880 at pp. 890-91
42 *Schloendorff* v. *Society of New York Hospital*, 105 NE 92 : 211 NY 125 (1914)
5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

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of action because it is best for the patient, and is not influenced by personal convictions, motives or other considerations.

174. Thus, enquiring into Common Law and statutory rights of terminally ill persons in other jurisdictions would indicate that all adults with the capacity to consent have the Common Law right to refuse medical treatment and the right of self-determination.

175. We may, however, add a word of caution that doctors would be bound by the choice of self-determination made by the patient who is terminally ill and undergoing a prolonged medical treatment or is surviving on life support, subject to being satisfied that the illness of the patient is incurable and there is no hope of his being cured. Any other consideration cannot pass off as being in the best interests of the patient.

M. ***Social morality, medical ethicality and State interest***

176. Having dwelt upon the issue of self-determination, we may presently delve into three aspects, namely, social morality, medical ethicality and the State interest. The aforesaid concepts have to be addressed in the constitutional backdrop. We may clearly note that the society at large may feel that a patient should be treated till he breathes his last breath and the treating physicians may feel that they are bound by their Hippocratic oath which requires them to provide treatment and save life and not to put an end to life by not treating the patient. The members of the family may remain in a constant state of hesitation being apprehensive of many a social factor which include immediate claim of inheritance, social stigma and, sometimes, the individual guilt. The Hippocratic oath taken by a doctor may make him feel that there has been a failure on his part and sometimes also make him feel scared of various laws. There can be allegations against him for negligence or criminal culpability.

177. In this regard, two aspects are to be borne in mind. First, withdrawal of treatment in an irreversible situation is different from not treating or attending to a patient and second, once passive euthanasia is recognised in law regard being had to the right to die with dignity when life is ebbing out and when the prolongation is done sans purpose, neither the social morality nor the doctors' dilemma or fear will have any place. It is because the sustenance of dignity and self-respect of an individual is inhered in the right of an individual pertaining to life and liberty and there is necessity for this protection. And once the said right comes within the shelter of Article 21 of the Constitution, the social perception and the apprehension of the physician or treating doctor regarding facing litigation should be treated as secondary because the primacy of the right of an individual in this regard has to be kept on a high pedestal.

178. It is to be borne in mind that passive euthanasia fundamentally connotes absence of any overt act either by the patient or by the doctors. It also does not involve any kind of overt act on the part of the family members. It is avoidance of unnecessary intrusion in the physical frame of a person, for the inaction is meant for smooth exit from life. It is paramount for an individual to protect his dignity as an inseparable part of the right to life which engulfs

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the dignified process of dying sans pain, sans suffering and, most importantly, sans indignity.

179. There are philosophers, thinkers and also scientists who feel that life is not confined to the physical frame and biological characteristics. But there is no denial of the fact that life in its connotative expanse intends to search for its meaning and find the solution of the riddle of existence for which some lean on atheism and some vouchsafe for faith and yet some stand by the ideas of an agnostic. However, the legal fulcrum has to be how Article 21 of the Constitution is understood. If a man is allowed to or, for that matter, forced to undergo pain, suffering and state of indignity because of unwarranted medical support, the meaning of dignity is lost and the search for meaning of life is in vain.

N. *Submissions of the States*

180. In this context, we may reflect on the submissions advanced on behalf of certain States. As stated earlier, there is a categorical assertion that protection of human life is paramount and it is obligatory on behalf of the States to provide treatment and to see that no one dies because of lack of treatment and to realise the principles enshrined in Part IV of the Constitution. Emphasis has been laid on the State interest and the process of abuse that can take place in treating passive euthanasia as permissible in law. To eliminate the possibility of abuse, safeguards can be taken and guidelines can be framed. But on the plea of possibility of abuse, the dignity in the process of dying being a facet of Article 21 should not be curbed.

181. Mr Datar, learned Senior Counsel in the course of arguments, has advanced submissions in support of passive euthanasia and also given suggestions spelling out the guidelines for Advance Directive and also implementation of the same when the patient is hospitalised. The said aspect shall be taken into consideration while giving effect to the Advance Directive and also taking steps for withdrawal of medical support.

O. *Submissions of Intervenor (Society for the Right to Die with Dignity)*

182. Mr Mohta, learned counsel appearing for the intervenor, that is, Society for the Right to Die with Dignity, has drawn our attention to certain articles and submitted that from the days of Plato to the time of Sir Thomas More and other thinkers, painless and peaceful death has been advocated. He would also submit that ancient wisdom of India taught people not to fear death but to aspire for deathlessness and conceive it as "Mahaprasthana". It is his submission that in the modern State, the State interest should not overweigh the individual interest in the sphere of a desire to die a peaceful death which basically conveys refusal of treatment when the condition of the individual suffering from a disease is irreversible. The freedom of choice in this sphere, as Mr Mohta would put it, serves the cause of humanitarian approach which is not the process to put an end to life by taking a positive action but to allow a dying patient to die peaceably instead of prolonging the process of dying without purpose that creates a dent in his dignity.

183. The aforesaid argument, we have no hesitation to say, has force. It is so because it is in accord with the constitutional precept and fosters the cherished value of dignity of an individual. It saves a helpless person from uncalled for and unnecessary treatment when he is considered as merely a creature whose breath is felt or measured because of advanced medical technology. His "being" exclusively rests on the mercy of the technology which can prolong the condition for some period. The said prolongation is definitely not in his interest. On the contrary, it tantamounts to destruction of his dignity which is the core value of life. In our considered opinion, in such a situation, an individual interest has to be given priority over the State interest.

P. ***Advance Directive/Advance Care Directive/Advance Medical Directive***

184. In order to overcome the difficulty faced in case of patients who are unable to express their wishes at the time of taking the decision, the concept of Advance Medical Directives emerged in various countries. The proponents of Advance Medical Directives contend that the concept of patient autonomy for incompetent patients can be given effect to, by giving room to new methods by which incompetent patients can beforehand communicate their choices which are made while they are competent. Further, it may be argued that failure to recognise Advance Medical Directives would amount to non-facilitation of the right to have a smoothened dying process. That apart, it accepts the position that a competent person can express her/his choice to refuse treatment at the time when the decision is required to be made.

185. Advance Directives for healthcare go by various names in different countries though the objective by and large is the same, that is, to specify an individual's healthcare decisions and to identify persons who will take those decisions for the said individual in the event he is unable to communicate his wishes to the doctor.

186. *Black's Law Dictionary* defines an Advance Medical Directive as, "a legal document explaining one's wishes about medical treatment if one becomes incompetent or unable to communicate". A living will, on the other hand, is a document prescribing a person's wishes regarding the medical treatment the person would want if he was unable to share his wishes with the healthcare provider.

187. Another type of Advance Medical Directive is medical power of attorney. It is a document which allows an individual (principal) to appoint a trusted person (agent) to take healthcare decisions when the principal is not able to take such decisions. The agent appointed to deal with such issues can interpret the principal's decisions based on their mutual knowledge and understanding.

188. Advance Directives have gained lawful recognition in several jurisdictions by way of legislation and in certain countries through judicial pronouncements. In vast majority of the States in USA, it is mandatory for the doctors to give effect to the wishes of the patients as declared by them in their Advance Directives. California was the first State to legally sanction living will. The United States Congress in 1990, with the objective of protecting the

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fundamental principles of self-autonomy and self-determination, enacted the Patient Self-Determination Act (PSDA) which acknowledged the rights of the patient to either refuse or accept treatment. Following this, all 50 States enacted legislations adopting Advance Directives. Apart from this, several States of USA also permit the patients to appoint a healthcare proxy which becomes effective only when the patient is unable to make decisions.

189. In order to deal with the technicalities and intricacies associated with an instrument as complex as an Advance Directive, several derivatives/versions have evolved over time. The National Right to Life Committee (NRLC) in the United States came up with a version of a living will which was called "Will to Live" which is a safeguard of the lives of patients who wish to continue treatment and not refuse life-sustaining treatment. This form of active declaration gains importance in cases where the will of the patient cannot be deciphered with certainty and the courts order withdrawal of life-supporting treatment where they deem the life of the patient as not worthwhile.

190. Yet another measure for finding and accessing the patient's Advance Directive was the setting up of the US Living Will Registry. As per this model, it was obligatory on the part of the hospital administration to ask a patient, who would be admitted, if he/she had an Advance Directive and store the same on their medical file. A special power to the Advance Directives introduced by Virginia was the "Ulysses Clause" which accords protection in situations when the patient goes into relapse in his/her condition, that is, schizophrenia and refuses treatment which they would not refuse if not for the said relapse.

191. A new type of Advance Directive is the "Do Not Resuscitate Order" (DNRO) in Florida which is a form of patient identification device developed by the Department of Health to identify people who do not wish to be resuscitated in the event of respiratory or cardiac arrest. In Florida State of United States, where an unconscious patient with the phrase "Do Not Resuscitate" tattooed on his chest was brought in paramedics, the doctors were left in a conundrum whether the message was not to provide any medical treatment to the patient and ultimately, the doctors opted not to perform any medical procedure and the patient, thereafter, died. This case highlights the dynamics involved in the concept of Advance Directives due to the intricacies surrounding the concept.

192. The Mental Capacity Act governs the law relating to Advance Directives in UK Specific guidelines as to the manner in which the Advance Directive should be drafted and the necessary conditions that need to be fulfilled in order to give effect to the directives have been categorically laid out in the said piece of legislation. A few specific requirements in case of refusal of life-sustaining treatment is the verification of the decision-maker that the refusal operates even if life is at risk and that the directive should be in the written form and signed and witnessed. However, an Advance Directive refusing food and water has not been recognised under this statute. Further, the Act recognises the rights of the patient to appoint a healthcare proxy who is referred to as "lasting power of attorney". In order for the proxy decision-maker so appointed

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to be competent to consent or refuse life-sustaining treatment of the decision-maker, an express provision delegating the said authority should be a part of the Advance Directive. In general, as per the settled law vide the decision in *Airedale*[11], life-sustaining treatment including artificial nutrition and hydration can be withdrawn if the patient consents to it and in case of incompetent patients, if it is in their best interest to do so.

193. Australia too, by way of legislation, has well-established principles governing Advance Health Directives. Except Tasmania, all States have a provision for Advance Directives. The Advance Directives as postulated by the different legislations in each State in Australia differ in nature and their binding effect but the objective of every type remains the same, that is, preservation of the patient's autonomy. There are several circumstances when the advance healthcare directives or certain provisions contained therein become inoperative.

194. In Queensland, the directive becomes inoperative if the medical health practitioner is of the opinion that giving effect to the directive is inconsistent with good medical practice or in case of a change in circumstances, including new advances in medicine, medical practice and technology, to the extent that giving effect to the directive is inappropriate.

195. In the State of Victoria, an Advance Directive ceases to apply due to a change in the condition of the patient to the extent that the condition in relation to which the Advance Directive was given no longer exists. Further, South Australia permits a medical practitioner to refuse to comply with a certain provision in an Advance Directive in case he/she has enough reason to believe that the patient did not intend the provision to apply in certain conditions or the provision would not reflect the present wishes of the patient. In Western Australia, the occurrence of a change in circumstances which either the decision-maker could have never anticipated at the time of making the directive or which could have the effect on a reasonable person in the position of the decision-maker to change his/her mind regarding the treatment decision would invalidate the said treatment decision in the directive. In Northern Territory, an advance consent direction is disregarded in case giving effect to it would result in such unacceptable pain and suffering to the patient or would be so unjustifiable and rather it is more reasonable to override the wishes of the patient. Furthermore, if the medical practitioner is of the opinion that the patient would have never intended the advance consent direction to apply in the circumstances, then the advance consent direction need not be complied with.

196. Canada does not have a federal legislation exclusively to regulate Advance Directives. Rather, there are eleven different provincial approaches governing the law on passive euthanasia and Advance Directives in Canada. The provinces of Alberta, Saskatchewan, Manitoba, Prince Edward Island, Newfoundland and Labrador and Northwest Territories have a provision for both proxy and instructional directives, whereas, the States of British

11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

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Columbia, Ontario, Quebec and Yukon provide only for appointment of a proxy while simultaneously recognising the binding nature of previously given instructions. The respective legislations of the provinces/territories differ from one another on several criteria, for instance, minimum age requirement and other formalities to be complied with, such as written nature of the Advance Directive, etc. Furthermore, some of the provinces mandate a prior consultation with a lawyer. Wishes orally expressed have also been recognised by some provinces.

197. Having dealt with the principles in vogue across the globe, we may presently proceed to deal with the issue of Advance Medical Directive which should be ideal in our country. Be it noted, though the learned counsel for the petitioner has used the words "living will", yet we do not intend to use the said terminology. We have already stated that safeguards and guidelines are required to be provided. First, we shall analyse the issue of legal permissibility of the Advance Medical Directive. In other jurisdictions, the concepts of "living will" and involvement of attorney are stipulated. There is no legal framework in our country as regards the Advance Medical Directive but we are obliged to protect the right of the citizens as enshrined under Article 21 of the Constitution. It is our constitutional obligation. As noticed earlier, the two-Judge Bench in *Aruna Shanbaug*[5] has provided for approaching the High Court under Article 226 of the Constitution. The directions and guidelines to be given in this judgment would be comprehensive and would also cover the situation dealt with *Aruna Shanbaug case*[5].

198. In our considered opinion, Advance Medical Directive would serve as a fruitful means to facilitate the fructification of the sacrosanct right to life with dignity. The said directive, we think, will dispel many a doubt at the relevant time of need during the course of treatment of the patient. That apart, it will strengthen the mind of the treating doctors as they will be in a position to ensure, after being satisfied, that they are acting in a lawful manner. We may hasten to add that Advance Medical Directive cannot operate in abstraction. There has to be safeguards. They need to be spelt out. We enumerate them as follows:

198.1. ***Who can execute the Advance Directive and how?***

198.1.1. The Advance Directive can be executed only by an adult who is of a sound and healthy state of mind and in a position to communicate, relate and comprehend the purpose and consequences of executing the document.

198.1.2. It must be voluntarily executed and without any coercion or inducement or compulsion and after having full knowledge or information.

198.1.3. It should have characteristics of an informed consent given without any undue influence or constraint.

198.1.4. It shall be in writing clearly stating as to when medical treatment may be withdrawn or no specific medical treatment shall be given which will only have the effect of delaying the process of death that may otherwise

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

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cause him/her pain, anguish and suffering and further put him/her in a state of indignity.

198.2. ***What should it contain?***

198.2.1. It should clearly indicate the decision relating to the circumstances in which withholding or withdrawal of medical treatment can be resorted to.

198.2.2. It should be in specific terms and the instructions must be absolutely clear and unambiguous.

198.2.3. It should mention that the executor may revoke the instructions/ authority at any time.

198.2.4. It should disclose that the executor has understood the consequences of executing such a document.

198.2.5. It should specify the name of a guardian or close relative who, in the event of the executor becoming incapable of taking decision at the relevant time, will be authorised to give consent to refuse or withdraw medical treatment in a manner consistent with the Advance Directive.

198.2.6. In the event that there is more than one valid Advance Directive, none of which have been revoked, the most recently signed Advance Directive will be considered as the last expression of the patient's wishes and will be given effect to.

198.3. ***How should it be recorded and preserved?***

198.3.1. The document should be signed by the executor in the presence of two attesting witnesses, preferably independent, and countersigned by the jurisdictional Judicial Magistrate of First Class (JMFC) so designated by the District Judge concerned.

198.3.2. The witnesses and the jurisdictional JMFC shall record their satisfaction that the document has been executed voluntarily and without any coercion or inducement or compulsion and with full understanding of all the relevant information and consequences.

198.3.3. The JMFC shall preserve one copy of the document in his office, in addition to keeping it in digital format.

198.3.4. The JMFC shall forward one copy of the document to the Registry of the jurisdictional District Court for being preserved. Additionally, the Registry of the District Judge shall retain the document in digital format.

198.3.5. The JMFC shall cause to inform the immediate family members of the executor, if not present at the time of execution, and make them aware about the execution of the document.

198.3.6. A copy shall be handed over to the competent officer of the local Government or the Municipal Corporation or Municipality or Panchayat, as the case may be. The aforesaid authorities shall nominate a competent official in that regard who shall be the custodian of the said document.

198.3.7. The JMFC shall cause to hand over copy of the Advance Directive to the family physician, if any.

198.4. ***When and by whom can it be given effect to?***

198.4.1. In the event the executor becomes terminally ill and is undergoing prolonged medical treatment with no hope of recovery and cure of the ailment, the treating physician, when made aware about the Advance Directive, shall ascertain the genuineness and authenticity thereof from the jurisdictional JMFC before acting upon the same.

198.4.2. The instructions in the document must be given due weight by the doctors. However, it should be given effect to only after being fully satisfied that the executor is terminally ill and is undergoing prolonged treatment or is surviving on life support and that the illness of the executor is incurable or there is no hope of him/her being cured.

198.4.3. If the physician treating the patient (executor of the document) is satisfied that the instructions given in the document need to be acted upon, he shall inform the executor or his guardian/close relative, as the case may be, about the nature of illness, the availability of medical care and consequences of alternative forms of treatment and the consequences of remaining untreated. He must also ensure that he beliefs on reasonable grounds that the person in question understands the information provided, has cogitated over the options and has come to a firm view that the option of withdrawal or refusal of medical treatment is the best choice.

198.4.4. The physician/hospital where the executor has been admitted for medical treatment shall then constitute a Medical Board consisting of the Head of the treating department and at least three experts from the fields of general medicine, cardiology, neurology, nephrology, psychiatry or oncology with experience in critical care and with overall standing in the medical profession of at least twenty years who, in turn, shall visit the patient in the presence of his guardian/close relative and form an opinion whether to certify or not to certify carrying out the instructions of withdrawal or refusal of further medical treatment. This decision shall be regarded as a preliminary opinion.

198.4.5. In the event the Hospital Medical Board certifies that the instructions contained in the Advance Directive ought to be carried out, the physician/hospital shall forthwith inform the jurisdictional Collector about the proposal. The jurisdictional Collector shall then immediately constitute a Medical Board comprising the Chief District Medical Officer of the district concerned as the Chairman and three expert doctors from the fields of general medicine, cardiology, neurology, nephrology, psychiatry or oncology with experience in critical care and with overall standing in the medical profession of at least twenty years (who were not members of the previous Medical Board of the hospital). They shall jointly visit the hospital where the patient is admitted and if they concur with the initial decision of the Medical Board of the hospital, they may endorse the certificate to carry out the instructions given in the Advance Directive.

198.4.6. The Board constituted by the Collector must beforehand ascertain the wishes of the executor if he is in a position to communicate and is capable of understanding the consequences of withdrawal of medical treatment. In

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the event the executor is incapable of taking decision or develops impaired decision-making capacity, then the consent of the guardian nominated by the executor in the Advance Directive should be obtained regarding refusal or withdrawal of medical treatment to the executor to the extent of and consistent with the clear instructions given in the Advance Directive.

198.4.7. The Chairman of the Medical Board nominated by the Collector, that is, the Chief District Medical Officer, shall convey the decision of the Board to the jurisdictional JMFC before giving effect to the decision to withdraw the medical treatment administered to the executor. The JMFC shall visit the patient at the earliest and, after examining all aspects, authorise the implementation of the decision of the Board.

198.4.8. It will be open to the executor to revoke the document at any stage before it is acted upon and implemented.

198.5. ***What if permission is refused by the Medical Board?***

198.5.1. If permission to withdraw medical treatment is refused by the Medical Board, it would be open to the executor of the Advance Directive or his family members or even the treating doctor or the hospital staff to approach the High Court by way of writ petition under Article 226 of the Constitution. If such application is filed before the High Court, the Chief Justice of the said High Court shall constitute a Division Bench to decide upon grant of approval or to refuse the same. The High Court will be free to constitute an independent committee consisting of three doctors from the fields of general medicine, cardiology, neurology, nephrology, psychiatry or oncology with experience in critical care and with overall standing in the medical profession of at least twenty years.

198.5.2. The High Court shall hear the application expeditiously after affording opportunity to the State counsel. It would be open to the High Court to constitute Medical Board in terms of its order to examine the patient and submit report about the feasibility of acting upon the instructions contained in the Advance Directive.

198.5.3. Needless to say that the High Court shall render its decision at the earliest as such matters cannot brook any delay and it shall ascribe reasons specifically keeping in mind the principles of "best interests of the patient".

198.6. ***Revocation or inapplicability of Advance Directive***

198.6.1. An individual may withdraw or alter the Advance Directive at any time when he/she has the capacity to do so and by following the same procedure as provided for recording of Advance Directive. Withdrawal or revocation of an Advance Directive must be in writing.

198.6.2. An Advance Directive shall not be applicable to the treatment in question if there are reasonable grounds for believing that circumstances exist which the person making the directive did not anticipate at the time of the Advance Directive and which would have affected his decision had he anticipated them.

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198.6.3. If the Advance Directive is not clear and ambiguous, the Medical Boards concerned shall not give effect to the same and, in that event, the guidelines meant for patients without Advance Directive shall be made applicable.

198.6.4. Where the Hospital Medical Board takes a decision not to follow an Advance Directive while treating a person, then it shall make an application to the Medical Board constituted by the Collector for consideration and appropriate direction on the Advance Directive.

199. It is necessary to make it clear that there will be cases where there is no Advance Directive. The said class of persons cannot be alienated. In cases where there is no Advance Directive, the procedure and safeguards are to be same as applied to cases where Advance Directives are in existence and in addition there to, the following procedure shall be followed:

199.1. In cases where the patient is terminally ill and undergoing prolonged treatment in respect of ailment which is incurable or where there is no hope of being cured, the physician may inform the hospital which, in turn, shall constitute a Hospital Medical Board in the manner indicated earlier. The Hospital Medical Board shall discuss with the family physician and the family members and record the minutes of the discussion in writing. During the discussion, the family members shall be apprised of the pros and cons of withdrawal or refusal of further medical treatment to the patient and if they give consent in writing, then the Hospital Medical Board may certify the course of action to be taken. Their decision will be regarded as a preliminary opinion.

199.2. In the event the Hospital Medical Board certifies the option of withdrawal or refusal of further medical treatment, the hospital shall immediately inform the jurisdictional Collector. The jurisdictional Collector shall then constitute a Medical Board comprising the Chief District Medical Officer as the Chairman and three experts from the fields of general medicine, cardiology, neurology, nephrology, psychiatry or oncology with experience in critical care and with overall standing in the medical profession of at least twenty years. The Medical Board constituted by the Collector shall visit the hospital for physical examination of the patient and, after studying the medical papers, may concur with the opinion of the Hospital Medical Board. In that event, intimation shall be given by the Chairman of the Collector nominated Medical Board to the JMFC and the family members of the patient.

199.3. The JMFC shall visit the patient at the earliest and verify the medical reports, examine the condition of the patient, discuss with the family members of the patient and, if satisfied in all respects, may endorse the decision of the Collector nominated Medical Board to withdraw or refuse further medical treatment to the terminally-ill patient.

199.4. There may be cases where the Board may not take a decision to the effect of withdrawing medical treatment of the patient or the Collector nominated Medical Board may not concur with the opinion of the hospital Medical Board. In such a situation, the nominee of the patient or the family member or the treating doctor or the hospital staff can seek permission from

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the High Court to withdraw life support by way of writ petition under Article 226 of the Constitution in which case the Chief Justice of the said High Court shall constitute a Division Bench which shall decide to grant approval or not. The High Court may constitute an independent committee to depute three doctors from the fields of general medicine, cardiology, neurology, nephrology, psychiatry or oncology with experience in critical care and with overall standing in the medical profession of at least twenty years after consulting the competent medical practitioners. It shall also afford an opportunity to the State counsel. The High Court in such cases shall render its decision at the earliest since such matters cannot brook any delay. Needless to say, the High Court shall ascribe reasons specifically keeping in mind the principle of "best interests of the patient".

200. Having said this, we think it appropriate to cover a vital aspect to the effect the life support is withdrawn, the same shall also be intimated by the Magistrate to the High Court. It shall be kept in a digital format by the Registry of the High Court apart from keeping the hard copy which shall be destroyed after the expiry of three years from the death of the patient.

201. Our directions with regard to the Advance Directives and the safeguards as mentioned hereinabove shall remain in force till Parliament makes legislation on this subject.

Q. *Conclusions in seriatim*

202. In view of the aforesaid analysis, we record our conclusions in seriatim:

202.1. A careful and precise perusal of the judgment in *Gian Kaur case*[10] reflects the right of a dying man to die with dignity when life is ebbing out, and in the case of a terminally-ill patient or a person in PVS, where there is no hope of recovery, accelerating the process of death for reducing the period of suffering constitutes a right to live with dignity.

202.2. The Constitution Bench in *Gian Kaur*[10] has not approved the decision in *Airedale*[11] inasmuch as the Court has only made a brief reference to the *Airedale case*[11].

202.3. It is not the ratio of *Gian Kaur*[10] that passive euthanasia can be introduced only by legislation.

202.4. The two-Judge Bench in *Aruna Shanbaug*[5] has erred in holding that this Court in *Gian Kaur*[10] has approved the decision in *Airedale case*[11] and that euthanasia could be made lawful only by legislation.

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374
11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)
5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

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202.5. There is an inherent difference between active euthanasia and passive euthanasia as the former entails a positive affirmative act, while the latter relates to withdrawal of life-support measures or withholding of medical treatment meant for artificially prolonging life.

202.6. In active euthanasia, a specific overt act is done to end the patient's life whereas in passive euthanasia, something is not done which is necessary for preserving a patient's life. It is due to this difference that most of the countries across the world have legalised passive euthanasia either by legislation or by judicial interpretation with certain conditions and safeguards.

202.7. Post *Aruna Shanbaug*[5], the 241st Report of the Law Commission of India on Passive Euthanasia has also recognised passive euthanasia, but no law has been enacted.

202.8. An inquiry into Common Law jurisdictions reveals that all adults with capacity to consent have the right of self-determination and autonomy. The said rights pave the way for the right to refuse medical treatment which has acclaimed universal recognition. A competent person who has come of age has the right to refuse specific treatment or all treatment or opt for an alternative treatment, even if such decision entails a risk of death. The "Emergency Principle" or the "Principle of Necessity" has to be given effect to only when it is not practicable to obtain the patient's consent for treatment and his/her life is in danger. But where a patient has already made a valid Advance Directive which is free from reasonable doubt and specifying that he/she does not wish to be treated, then such directive has to be given effect to.

202.9. Right to life and liberty as envisaged under Article 21 of the Constitution is meaningless unless it encompasses within its sphere individual dignity. With the passage of time, this Court has expanded the spectrum of Article 21 to include within it the right to live with dignity as component of right to life and liberty.

202.10. It has to be stated without any trace of doubt that the right to live with dignity also includes the smoothening of the process of dying in case of a terminally-ill patient or a person in PVS with no hope of recovery.

202.11. A failure to legally recognise Advance Medical Directives may amount to non-facilitation of the right to smoothen the dying process and the right to live with dignity. Further, a study of the position in other jurisdictions shows that Advance Directives have gained lawful recognition in several jurisdictions by way of legislation and in certain countries through judicial pronouncements.

202.12. Though the sanctity of life has to be kept on the high pedestal yet in cases of terminally ill persons or PVS patients where there is no hope for revival, priority shall be given to the Advance Directive and the right of self-determination.

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

202.13. In the absence of Advance Directive, the procedure provided for the said category hereinbefore shall be applicable.

202.14. When passive euthanasia as a situational palliative measure becomes applicable, the best interest of the patient shall override the State interest.

203. We have laid down the principles relating to the procedure for execution of Advance Directive and provided the guidelines to give effect to passive euthanasia in both circumstances, namely, where there are Advance Directives and where there are none, in exercise of the power under Article 142 of the Constitution and the law stated in *Vishaka* v. *State of Rajasthan*[69]. The directive and guidelines shall remain in force till Parliament brings a legislation in the field.

204. The writ petition is, accordingly, disposed of. There shall be no order as to costs.

DR A.K. SIKRI, J. (*concurring*)— Michael Kirby, a former Judge of the Australian High Court, while discussing about the role of judiciary in the context of HIV law[70], talks about the consciousness with which the judiciary is supposed to perform its role. In this hue, while discussing about the responsibility of leadership which the society imposes upon Judges, he remarks:

> "*Nowhere more is that responsibility tested than when a completely new and unexpected problem presents itself to society. All the judges' instincts for legality, fairness and reasonableness must then be summoned up, to help lead society towards an informed, intelligent and just solution to the problem.*"

The problem at hand, just solution whereof is imminently needed, is that of euthanasia. This Court is required to summon up instincts for legality, fairness and reasonableness in order to find just solution to the problem. In this process, the Court is duty-bound to look into the relevant provisions of the Constitution of India, particularly those pertaining to the fundamental rights, and to discharge the task of expounding those basic human rights enshrined in the Chapter relating to Fundamental Rights. The issue of euthanasia, with the seminal importance that is attached to it, has thrown the challenge of exposition, development and obligation of the constitutional morality and exhorts the Court to play its creative role so that a balanced approach to an otherwise thorny and highly debatable subject-matter is found.

206. The courts, in dispensation of their judicial duties of deciding cases, come across all types of problems which are brought before them. These cases may be broadly classified into three categories: (*i*) the easy cases, (*ii*) the

69 (1997) 6 SCC 241 : 1997 SCC (Cri) 932

70 "The Role of Judiciary and HIV Law"—Michael Kirby, published in the book titled *HIV Law, Ethics and Human Rights*, edited by D.C. Jayasuriya.

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intermediate cases, and (*iii*) the hard cases. Professor Ronald Dworkin[71] has argued that each legal problem has one lawful solution and even in the hard cases, the Judge is never free to choose among alternatives that are all inside the bounds of law. This may not be entirely correct inasmuch as judicial discretion does exist. This is true, at least, in solving "*hard cases*"[72]. It is found that meaning of certain legal norms, when applied with respect to a given system of facts, is so simple and clear that their application involves no judicial discretion. These are termed as the "*easy cases*". This may even apply to "*intermediate cases*". These would be those cases where both sides appear to have a legitimate legal argument supporting their position and a conscious act of interpretation is noted, before a Judge can conclude which side is right in law and there is only one lawful situation. However, when it comes to the hard cases, the court is faced with number of possibilities, all of which appear to be lawful within the context of the system. In these cases, judicial discretion exists as the choice is not between lawful and unlawful, but between lawful and lawful. A number of lawful solutions exist. In this scenario, the court is supposed to ultimately choose that solution which is in larger public interest. In other words, there are limitations that find the Court with respect to the manner in which it choses among possibilities (procedural limitations) and with respect to the considerations it takes into account in the choice (substantive limitations). Thus, discretion when applied to a court of justice means sound discretion guided by law. It must be governed by legal rules. To quote Justice Cardozo:

> "Given freedom of choice, how shall the choice be guided? Complete freedom—unfettered and undirected—there never is. A thousand limitations—the product some of statute, some of precedent, some of vague tradition or of an immemorial technique—encompass and hedge us even when we think of ourselves as ranging freely and at large. The inscrutable force of professional opinion presses upon us like the atmosphere, though we are heedless of its weight. Narrow at best is any freedom that is allotted to us."[72a]

207. Thus, though the judicial discretion is with the court, the same is limited and not absolute. The court is not entitled to weigh any factor as it likes. It has to act within the framework of the limitations, and after they have been exhausted, there is a freedom of choice which can also be described as "*sovereign prerogative of choice*"[73]. Instant case falls in the category of "hard cases" and the Court has endeavoured to make a choice, after evaluating all the pros and cons, which in its wisdom is the "*just result*" of the contentious issue.

208. Adverting to the Indian precedents in the first instance, we have before us two direct judgments of this Court which may throw some light on

71 Dworkin, "Judicial Discretion", 6 J of Phil 624 (1963).
72 See *Aharon Barak: Judicial Discretion*, Yale University Press.
72a B. Cardozo: *The Growth of the Law* 144 (1924), at 60-61.
73 Justice O. Holmes opined this expression in *Collected Legal Papers*, 239 (1921).

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the subject and demonstrate as to how this topic has been dealt with so far. The first judgment is that of a Constitution Bench in *Gian Kaur* v. *State of Punjab*[10]. Second case is known as *Aruna Ramachandra Shanbaug* v. *Union of India*[5], which is a Division Bench judgment that takes note of *Gian Kaur*[10] and premised thereupon goes much farther in accepting passive euthanasia as a facet of Article 21 of the Constitution.

209. In the instant case, while making reference to the Constitution Bench vide its order dated 25-2-2014[20], the three-Judge Bench has expressed its reservation in the manner the ratio of the Constitution Bench in *Gian Kaur*[10] is applied by the Division Bench in *Aruna Ramachandra Shanbaug*[5]. This reference order accepts that *Aruna Ramachandra Shanbaug*[5] rightly interpreted the decision in *Gian Kaur*[10] insofar as it held that euthanasia can be allowed in India only through a valid legislation. However, the reference order declares that *Aruna Ramachandra Shanbaug*[5] has committed a factual error in observing that in *Gian Kaur*[10] the Constitution Bench approved the decision of the House of Lords in *Airedale N.H.S. Trust* v. *Bland*[11]. As per the reference order, *Gian Kaur*[10] merely referred to the said judgment which cannot be construed to mean that the Constitution Bench in *Gian Kaur*[10] approved the opinion of the House of Lords rendered in *Bland*[11]. The reference order also accepts the position that in *Gian Kaur*[10] the Constitution Bench approved that "*right to live with dignity*" under Article 21 of the Constitution will be inclusive of "*right to die with dignity*". However, it further notes that the decision does not arrive at a conclusion for validity of euthanasia, be it active or passive. Therefore, the only judgment that holds the field in India is *Aruna Ramachandra Shanbaug*[5], which upholds the validity of passive euthanasia and lays down an elaborate procedure for executing the same on "*the wrong premise that the Constitution Bench in Gian Kaur*[10] *had upheld the same*".

210. The aforesaid discussion contained in the reference order prompted the reference court to refer the matter to the Constitution Bench. No specific questions were framed for consideration by the Constitution Bench. However, importance of the issue has been highlighted in the reference order in the following manner: (*Common Cause case*[20], SCC p. 345, paras 17 & 18)

> "*17.* In view of the inconsistent opinions rendered in *Aruna Shanbaug*[5] and also considering the important question of law involved which needs to be reflected in the light of social, legal, medical and constitutional perspectives, it becomes extremely important to have a clear enunciation of law. Thus, in our cogent opinion, the question of law involved requires careful consideration by a Constitution Bench of this Court for the benefit of humanity as a whole.

10 (1996) 2 SCC 648 : 1996 SCC (Cri) 374
5 (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294
20 *Common Cause* v. *Union of India*, (2014) 5 SCC 338 : (2014) 2 SCC (Cri) 557
11 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

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18. We refrain from framing any specific questions for consideration by the Constitution Bench as we invite the Constitution Bench to go into all the aspects of the matter and lay down exhaustive guidelines in this regard. Accordingly, we refer this matter to a Constitution Bench of this Court for an authoritative opinion."

211. I have given a glimpse of the narratives for the simple reason that the Hon'ble the Chief Justice, in his elaborate opinion, has already discussed this aspect in detail. Likewise, it can be found in the separate judgments authored by my esteemed Brethren — Chandrachud, J. and Bhushan, J. Those judgments discuss in detail the law laid down in *Gian Kaur*[10] as well as *Aruna Ramachandra Shanbaug*[5], including critique thereof. To avoid repetition, I have eschewed that part of discussion. For the same reason, I have also not ventured to discuss the law in some other countries and historic judgments rendered by the courts of foreign jurisdiction, as this aspect is also taken care of by them. However, my analysis of the above two judgments is limited to the extent it is necessitated for maintaining continuum and clarity of thought.

212. At the outset, I say that I am in complete agreement with the conclusion and also the directions given therein in the judgment of the Hon'ble the Chief Justice and also with the opinions and reasoning of my other two learned Brothers. My purpose is not to add my ink to the erudite opinion expressed in otherwise eloquent opinions penned by my learned Brothers. At the same time, having regard to the importance of the issue involved, I am provoked to express my own few thoughts, in my own way, which I express hereinafter.

213. In the writ petition filed by the petitioner Common Cause, it has made the following prayers:

"(*a*) declare 'right to die with dignity' as a fundamental right within the fold of right to live with dignity guaranteed under Article 21 of the Constitution of India;

(*b*) issue direction to the respondent, to adopt suitable procedures, in consultation with State Governments where necessary, to ensure that persons of deteriorated health or terminally ill should be able to execute a document titled "MY LIVING WILL & ATTORNEY AUTHORISATION" which can be presented to hospital for appropriate action in event of the executant being admitted to the hospital with serious illness which may threaten termination of life of the executants or in the alternative, issue appropriate guidelines to this effect;

(*c*) appoint an Expert Committee of Experts including doctors, social scientists and lawyers to study into the aspect of issuing guidelines as to the living wills;

(*d*) pass such other and further order(s) as this Hon'ble Court may deem fit and proper on the facts and in the circumstances of the case."

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374
5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

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214. Having regard to the aforesaid prayers, the reference order and the arguments which were addressed by Mr Prashant Bhushan, learned counsel who appeared for the petitioner, and Mr Arvind Datar, learned Senior Counsel who made elaborate submissions on behalf of the interveners — Vidhi Centre for Legal Policy, and Mr R.R. Kishore, Advocate, who gave an altogether new dimension to the seminal issue, I find that the following issues/questions of law of relevance need to be discussed:

214.1. (*i*) Whether the right to live under Article 21 of the Constitution includes the right to die? [Now that attempt to commit suicide is not a punishable offence under Section 309 of the Penal Code, 1860 (for short "IPC") vide Section 115 of the Mental Health Care Act, 2017 (10 of 2017).]

214.2. (*ii*) Whether the "*right to die with dignity*" as a fundamental right falls within the folds of the "*right to live with dignity*" under Article 21 of the Constitution?

214.3. (*iii*) Whether the observations in *Aruna Ramachandra Shanbaug*[5] that the Constitution Bench in *Gian Kaur*[10] permitted passive euthanasia stand correct?

214.4. (*iv*) Whether there exists inconsistency in the observations in *Aruna Ramachandra Shanbaug*[5] with regard to what has been held in *Gian Kaur*[10]?

214.5. (*v*) Whether mere reference to verdict in a judgment can be construed to mean that the verdict is approved? (with respect to Article 141 — What is binding?; Whether the Constitution Bench in *Gian Kaur*[10] approved the decision of the House of Lords in *Bland*[11]?)

214.6. (*vi*) Whether the law on passive euthanasia, as held valid in *Aruna Ramachandra Shanbaug*[5], holds true in the present times as well? (The Treatment of Terminally-Ill Patients Bill, 2016 is based on the aforementioned judgment.)

214.7. (*vii*) Whether active euthanasia is legal in India?

214.8. (*viii*) Whether assisted suicide/physician administered suicide is legal in India? [The 2016 Bill in the current form, under Clause 5(3) permits for physician-assisted suicide.]

214.9. (*ix*) Whether there exists a right to a *Living Will/Advance Directives*? Whether there exists the fundamental right to choose one's own medical treatment? (With right to privacy now a fundamental right under Article 21, the principle of self-determination in India stands on a higher footing than before.)

214.10. (*x*) Definition of "*terminal illness*".

215. It is not necessary for me to answer all the aforesaid questions. I say so for the reason that all these aspects are dealt with by the Hon'ble the Chief

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374

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Justice in his opinion. Therefore, in this "*addendum*", I would be focusing myself to the core issues.

Euthanasia defined

216. *The Oxford English Dictionary* defines "*euthanasia*" as "*the painless killing of a patient suffering from an incurable and painful disease or in an irreversible coma*". The word appears to have come into usage in the early 17th century and was used in the sense of "*easy death*". The term is derived from the Greek "*euthanatos*", with "*eu*" meaning well, and "*thanatos*" meaning death. In ancient Greece and Rome, citizens were entitled to a good death to end the suffering of a terminal illness. To that end, the City Magistrates of Athens kept a supply of poison to help the dying "*drink the hemlock*"[74].

217. The above Greek definition of euthanasia apart, it is a loaded term. People have been grappling with it for ages. Devised for service in a rhetoric of persuasion, the term "*euthanasia*" has no generally accepted and philosophically warranted core meaning. It is also defined as: *killing at the request of the person killed.* That is how the Dutch medical personnel and civil authorities define euthanasia. In Nazi discourse, euthanasia was any killing carried out by medical means or medically qualified personnel, whether intended for the termination of suffering and/or of the burden or indignity of a life not worth living (*lebensunwertes leben*), or for some more evidently public benefit such as eugenics (racial purity and hygiene), *lebensraum* (living space for Germans), and/or minimising the waste of resources on "*useless mouths*". Understandably, in today's modern democracies these Nazi ideas and practices cannot be countenanced. Racist eugenics are condemned, though one comes across discreet allusions to the burden and futility of sustaining the severely mentally handicapped. The popular conception which is widely accepted is that some sorts of life are not worth living; life in such a state demeans the patient's dignity, and maintaining it (otherwise than at the patient's express request) insults that dignity; proper respect for the patient and the patient's best interests requires that that life be brought to an end. In this thought process, the basic Greek ideology that it signifies "*an easy and gentle death*" still remains valid. Recognition is to the human rights principle that "*right to life*" encompasses "*right to die with dignity*".

218. In common parlance, euthanasia can be of three types, namely, "*voluntary euthanasia*" which means killing at the request of a person killed which is to be distinguished from "*non-voluntary euthanasia*", where the person killed is not capable of either making or refusing to make such a request. Second type of euthanasia would be involuntary euthanasia where the person killed is capable of making such a request but has not done so[75]. These terms can be described as under:

74 *Michael Manning, Euthanasia and Physician-Assisted Suicide* (Paulist Press, 1998).

75 These definitions of voluntary, non-voluntary and involuntary euthanasia correspond to those employed by the House of Lords Select Committee on Medical Ethics (Walton Committee).

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218.1. *Voluntary euthanasia*—People concerned to legalise the termination of life on medical grounds have always concentrated on voluntary euthanasia (this implies that the patient specifically requests that his life be ended). It is generally agreed that the request must come from someone who is either (*a*) in intolerable pain, or (*b*) who is suffering from an illness which is agreed as being terminal. It may be prior to the development of the illness in question or during its course. In either case it must not result from any pressure from relatives or those who have the patients in their care. Both active and passive euthanasia can be termed as forms of voluntary euthanasia.

218.2. *Non-voluntary euthanasia*—Seen by some as subvariety of voluntary euthanasia. This involves the death, ostensibly for his own good, of someone who cannot express any views on the matter and who must, therefore, use some sort of proxy request that his/her life be ended. This form of euthanasia is that which most intimately concerns the medical profession. Selective non-treatment of the newborn or the doctor may be presented with demented and otherwise senilely incompetent patients. In practice, non-voluntary euthanasia presents only as an arguable alternative to non-treatment.

218.3. *Involuntary euthanasia*—It involves ending the patient's life in the absence of either a personal or proxy invitation to do so. The motive "the relief from suffering" may be the same as voluntary euthanasia—but its only justification — "a paternalistic decision as to what is best for the victim of the disease". In extreme cases, it could be against the patient's wishes or could be just for social convenience. It is examples of the latter which serve as warnings as to those who would invest the medical professional with more or unfettered powers over life and death[76].

219. Contrary to the above, in legal parlance, euthanasia has since come to be recognised as of two distinct types: the first is active euthanasia, where death is caused by the administration of a lethal injection or drugs. Active euthanasia also includes physician-assisted suicide, where the injection or drugs are supplied by the physician, but the act of administration is undertaken by the patient himself. Active euthanasia is not permissible in most countries. The jurisdictions in which it is permissible are Canada, the Netherlands, Switzerland and the States of Colorado, Vermont, Montana, California, Oregon and Washington D.C. in the United States of America. Passive euthanasia occurs when medical practitioners do not provide life-sustaining treatment (i.e. treatment necessary to keep a patient alive) or remove patients from life-sustaining treatment. This could include disconnecting life support machines or feeding tubes or not carrying out life-saving operations or providing life-extending drugs. In such cases, the omission by the medical practitioner is not treated as the cause of death; instead, the patient is understood to have died because of his underlying condition.

76 *See* "Euthanasia and Its Legality and Legitimacy from Indian and International Human Right Instruments Perspectives" published in *Human Rights & Social Justice* by Muzafer Assadi.

220. In *Aruna Ramachandra Shanbaug*[5], the Court recognised these two types of euthanasia i.e. active and passive. It also noted that active euthanasia is impermissible, which was so held by the Constitution Bench in *Gian Kaur*[10]. Therefore, without going into further debate on differential that is assigned to the term "euthanasia", ethically, philosophically, medically, etc., we would be confining ourselves to the aforesaid legal meaning assigned to active and passive euthanasia. Thus, insofar as active euthanasia is concerned, this has to be treated as legally impermissible, at least for the time being. It is more so, as there is absence of any statutory law permitting active euthanasia. If at all, legal provisions in the form of Sections 306 and 307 IPC, etc. point towards its criminality. The discussion henceforth, therefore, would confine to passive euthanasia.

***Passive euthanasia and Aruna Ramachandra Shanbaug*[5]**

221. In *Aruna Ramachandra Shanbaug*[5], a two-Judge Bench of this Court discussed in much greater detail various nuances of euthanasia by referring to active and passive euthanasia as well as voluntary and involuntary euthanasia; legality and permissibility thereof; relationship of euthanasia vis-à-vis offences concerned under the IPC and doctor assisted death, etc.

222. The Court also took note of legislations in some countries relating to euthanasia or physician-assisted death. Thereafter, it discussed in detail the judgment in *Bland*[11] wherein the House of Lords had permitted the patient to die. Ratio of *Bland*[11] was culled out in the following manner: (*Aruna Shanbaug case*[5], SCC p. 507, para 84)

> "*84. Airedale*[11] (1993) decided by the House of Lords has been followed in a number of cases in UK, and the law is now fairly well settled that in the case of incompetent patients, if the doctors act on the basis of informed medical opinion, and withdraw the artificial life support system if it is in the patient's best interest, the said act cannot be regarded as a crime."

223. The Court in *Aruna Shanbaug case*[5] was of the opinion that this should be permitted when the patient is in a persistent vegetative state (PVS) and held that it is ultimately for the court to decide, as *parens patriae*, as to what is in the best interest of the patient. The wishes of the close relatives and next friends and opinion of the medical practitioners should be given due weight by the court in coming to its decision. The Court then noted the position of euthanasia with reference to Section 306 (abetment of suicide) and Section 309 (attempt to commit suicide) IPC, inasmuch as, even allowing passive euthanasia may come in conflict with the aforesaid provisions which make such an act a crime. While making a passing observation that Section 309 should be deleted by Parliament as it has become anachronistic, the Court went into the vexed question as to

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374

11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

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who can decide whether life support should be discontinued in the case of an incompetent person e.g. a person in coma or PVS. The Court pointed out that it was a vexed question, both because of its likely misuse and also because of advancement in medical science. It noted: (SCC pp. 513-14, paras 104 & 105)

> "*104.* It may be noted that in *Gian Kaur case*[10] although the Supreme Court has quoted with approval the view of the House of Lords in *Airedale case*[11], it has not clarified who can decide whether life support should be discontinued in the case of an incompetent person e.g. a person in coma or PVS. This vexed question has been arising often in India because there are a large number of cases where persons go into coma (due to an accident or some other reason) or for some other reason are unable to give consent, and then the question arises as to who should give consent for withdrawal of life support. This is an extremely important question in India because of the unfortunate low level of ethical standards to which our society has descended, its raw and widespread commercialisation, and the rampant corruption, and hence, the Court has to be very cautious that unscrupulous persons who wish to inherit the property of someone may not get him eliminated by some crooked method.
>
> *105.* Also, since medical science is advancing fast, doctors must not declare a patient to be a hopeless case unless there appears to be no reasonable possibility of any improvement by some newly discovered medical method in the near future. In this connection we may refer to a recent news item which we have come across on the internet of an Arkansas man Terry Wallis, who was 19 years of age and newly married with a baby daughter when in 1984 his truck plunged through a guard rail, falling 25 ft. He went into coma in the crash in 1984, but after 24 years he has regained consciousness. This was perhaps because his brain spontaneously rewired itself by growing tiny new nerve connections to replace the ones sheared apart in the car crash. Probably the nerve fibres from Terry Wallis' cells were severed but the cells themselves remained intact, unlike *Terri Schiavo*, whose brain cells had died (see *Terri Schiavo case* on Google). However, we make it clear that it is experts like medical practitioners who can decide whether there is any reasonable possibility of a new medical discovery which could enable such a patient to revive in the near future."

224. The Court in *Bland*[11] held that passive euthanasia would be permissible when a person is "dead" in clinical sense. It chose to adopt the standard of "*brain death*" i.e. when there is an "*irreversible cessation of all functions of the entire brain, including the brain stem*". The Court took note of President's Committee on Bioethics in the United States of America which had come up with a new definition of "*brain death*" in the year 2008, according to which a person was considered to be brain dead when he could no longer perform the fundamental human work of an organism. Three such situations

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374

11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

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contemplated in that definition are the following: (*Aruna Shanbaug case*[5], SCC p. 516, para 114)

> "(1) openness to the world, that is receptivity to stimuli and signals from the surrounding environment,
>
> (2) the ability to act upon the world to obtain selectively what it needs, and
>
> (3) the basic felt need that drives the organism to act … to obtain what it needs."

225. The Court held that when the aforesaid situation is reached, a person can be presumed to be dead. In para 115 of the judgment, the position is summed up as under: (*Aruna Shanbaug case*[5], SCC p. 516)

> "*115*. When this situation is reached, it is possible to assume that the person is dead, even though he or she, through mechanical stimulation, may be able to breathe, his or her heart might be able to beat, and he or she may be able to take some form of nourishment. It is important, thus, that it be medically proved that a situation where any human functioning would be impossible should have been reached for there to be a declaration of brain death—situations where a person is in a persistent vegetative state but can support breathing, cardiac functions, and digestion *without* any mechanical aid are necessarily those that will not come within the ambit of brain death." (emphasis in original)

The Court clarified that brain death was not the same as PVS inasmuch as in PVS the brain stem continues to work and so some degree of reactions may occur, though the possibility of regaining consciousness is relatively remote.

226. The Court further opined that position in the case of euthanasia would be slightly different and pointed out that the two circumstances in which it would be fair to disallow resuscitation of a person who is incapable of expressing his or her consent to the termination of his or her life. These are: (*Aruna Shanbaug case*[5], SCC p. 517, para 117)

> "(*a*) When a person is only kept alive mechanically i.e. when not only consciousness is lost, but the person is only able to sustain involuntary functioning through advanced medical technology—such as the use of heart-lung machines, medical ventilators, etc.
>
> (*b*) When there is no plausible possibility of the person ever being able to come out of this stage. Medical "miracles" are not unknown, but if a person has been at a stage where his life is only sustained through medical technology, and there has been no significant alteration in the person's condition for a long period of time—at least a few years—then there can be a fair case made out for passive euthanasia."

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

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227. Taking a clue from the judgment in *Vishaka* v. *State of Rajasthan*[69], the Court laid down the law, while allowing passive euthanasia i.e. the circumstances when there could be withdrawal of life support of a patient in PVS. This is stated in para 124 of the judgment, which we reproduce below: (*Aruna Shanbaug case*[5], SCC pp. 518-19)

> "*124.* There is no statutory provision in our country as to the legal procedure for withdrawing life support to a person in PVS or who is otherwise incompetent to take a decision in this connection. We agree with Mr Andhyarujina that passive euthanasia should be permitted in our country in certain situations, and we disagree with the learned Attorney General that it should never be permitted. Hence, following the technique used in *Vishaka case*[69] we are laying down the law in this connection which will continue to be the law until Parliament makes a law on the subject:
>
> (*i*) A decision has to be taken to discontinue life support either by the parents or the spouse or other close relatives, or in the absence of any of them, such a decision can be taken even by a person or a body of persons acting as a next friend. It can also be taken by the doctors attending the patient. However, the decision should be taken bona fide in the best interest of the patient.
>
> In the present case, we have already noted that Aruna Shanbaug's parents are dead and other close relatives are not interested in her ever since she had the unfortunate assault on her. As already noted above, it is the KEM Hospital staff, who have been amazingly caring for her day and night for so many long years, who really are her next friends, and not Ms Pinki Virani who has only visited her on few occasions and written a book on her. Hence it is for the KEM Hospital staff to take that decision. KEM Hospital staff have clearly expressed their wish that Aruna Shanbaug should be allowed to live.
>
> Mr Pallav Shishodia, learned Senior Counsel, appearing for the Dean, KEM Hospital, Mumbai, submitted that Ms Pinki Virani has no locus standi in this case. In our opinion it is not necessary for us to go into this question since we are of the opinion that it is the KEM Hospital staff who is really the next friend of Aruna Shanbaug.
>
> We do not mean to decry or disparage what Ms Pinki Virani has done. Rather, we wish to express our appreciation of the splendid social spirit she has shown. We have seen on the internet that she has been espousing many social causes, and we hold her in high esteem. All that we wish to say is that however much her interest in Aruna Shanbaug may be it cannot match the involvement of the KEM Hospital staff who have been taking care of Aruna day and night for 38 years.

69 (1997) 6 SCC 241 : 1997 SCC (Cri) 932

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

However, assuming that the KEM Hospital staff at some future time changes its mind, in our opinion in such a situation KEM Hospital would have to apply to the Bombay High Court for approval of the decision to withdraw life support.

(*ii*) Hence, even if a decision is taken by the near relatives or doctors or next friend to withdraw life support, such a decision requires approval from the High Court concerned as laid down in *Airedale case*[11].

In our opinion, this is even more necessary in our country as we cannot rule out the possibility of mischief being done by relatives or others for inheriting the property of the patient."

228. It can be discerned from the reading of the said judgment that the Court was concerned with the question as to whether one can seek right to die. This question has been dealt with in the context of Article 21 of the Constitution, namely, whether this provision gives any such right. As is well known, Article 21 gives "right to life" and it is guaranteed to all the citizens of India. The question was as to whether "right to die" is also an integral part of "right to life". In *Gian Kaur*[10] this "right to die" had not been accepted as an integral part of "right to life". The Court in *Aruna Shanbaug*[5] maintained this position insofar as an active euthanasia is concerned. However, passive euthanasia, under certain circumstances, has been accepted.

229. It may be pertinent to mention that the petitioner (Aruna) in *Aruna Shanbaug case*[5] was working as a nurse in King Edward Memorial Hospital (KEM), Parel, Mumbai. The tragic incident happened on the evening of 27-11-1973. Aruna was attacked by a sweeper in the hospital who wrapped a dog chain around her neck and yanked her back with it. He tried to rape her but on finding that she was menstruating, he sodomised her. To immobilise her during this act, he twisted the chain around her neck. She was found unconscious by one cleaner on the next day. Her body was on the floor and blood was all over the floor. The incident did not allow oxygen to reach her brain as a result of which her brain got damaged.

230. The petition was filed by Ms Pinki Virani as next friend of Aruna Shanbaug. According to the facts of the case, Aruna has been surviving on mashed food as she was not able to chew or taste any food and she could not move her hands or legs. It is alleged that there is not the slightest possibility of any improvement in her condition and her body lies on the bed in KEM Hospital like a dead animal, and this has been the position for the last 36 years. The prayer of the petitioner was that the respondents be directed to stop feeding Aruna, and let her die peacefully.

11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

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231. The Court in *Aruna Shanbaug case*[5] appointed a team of three eminent and qualified doctors to investigate and report on the medical condition of Aruna. The team included Dr J.V. Divatia[77], Dr Roop Gursahani[78] and Dr Nilesh Shah[79]. The team of doctors studied her medical history and observed that Aruna would get uncomfortable if the room in which she was located was overcrowded, she was calm when fewer people were around her. In fact, the hospital staff had taken care and was willing to continue to do so. Moreover, Aruna's body language did not suggest that she wants to die. Therefore, the doctors opined that there is no need for euthanasia in the instant case.

232. Reliance was placed on the landmark judgment of the House of Lords in *Bland*[11], where for the first time in the English history, the right to die was allowed through the withdrawal of life support systems including food and water. This case placed the authority to decide whether a case is fit or not for euthanasia in the hands of the Court. In this case, Aruna did not have the capacity to consent for the proposed medical process. Therefore, the next big question that was to be answered was who should decide on her behalf.

233. Since, there was no relative traced directly, nor did she have any frequent visitor who could relate to her, it was extremely crucial for the Court in *Aruna Shanbaug*[5] to declare who should decide on her behalf. As there was lack of acquaintance, it was decided by beneficence. Beneficence is acting in the interest that is best for the patient, and is not influenced by personal convictions, motives or other considerations. Public interest and the interests of the State were also considered in the said matter.

234. On the aforesaid principle of beneficence and studying the position in some other countries, the Court in its judgment in *Aruna Shanbaug*[5] said, the right to take decision on behalf of Aruna was vested with the hospital and its management and not Ms Pinki. The Court also said that allowing euthanasia would mean reversing the efforts of the hospital and its staff. In order to ensure that there is no misuse of this technique, the Supreme Court has vested the power with the High Court to decide if life is to be terminated or not.

235. Thus, the Supreme Court allowed passive euthanasia in certain conditions, subject to the approval by the High Court following the due procedure. It held that when an application for passive euthanasia is filed, the Chief Justice of the High Court should forthwith constitute a Bench of at least two Judges who should decide to grant approval or not. Before doing so, the Bench should seek the opinion of a committee of three reputed doctors to be nominated by the Bench after consulting such medical authorities/medical practitioners as it may deem fit. Simultaneously with appointing the committee of doctors, the High Court Bench shall also issue notice to the State and close

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

77 Professor and Head, Department of Anaesthesia, Critical Care and Pain at Tata Memorial Hospital, Mumbai.

78 Consultant Neurologist at P.D. Hinduja, Mumbai.

79 Professor and Head, Department of Psychiatry at Lokmanya Tilak Municipal Corporation Medical College and General Hospital.

11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

relatives e.g. parents, spouse, brothers/sisters, etc. of the committee to them as soon as it is available. After hearing them, the High Court Bench should give its verdict. The above procedure should be followed all over India until Parliament makes legislation on this subject. I am not carrying out the critique of this judgment at this stage and the manner in which it has been analysed by those who are the proponents of passive euthanasia and those who are against it. It is, more so, when my Brother, Chandrachud, J., has dealt with this aspect in detail in his discourse. In any case, as noted above, in view of the reference order dated 25-2-2014[20], the validity of this aspect has to be examined, which exercise is undertaken by me at an appropriate stage.

Euthanasia: A complex concept

236. As discussed hereinafter, issue of euthanasia is a complexed and complicated issue over which there have been heated debates, not only within the confines of courts, but also among elites, intelligentsia and academicians alike. Some of these complexities may be captured at this stage itself.

237. The legal regime webbed by various judgments rendered by this Court would reflect that the Indian position on the subject is somewhat complex and even complicated to a certain extent. First, let us touch the topic from the constitutional angle.

238. Article 21 of the Constitution mandates that no person shall be deprived of his life or personal liberty, except according to the procedure established by law. This Article has been interpreted by the Court in most expansive terms, particularly when it comes to the meaning that is assigned to "right to life". It is not necessary to take stock of various faces of right to life defined by this Court. What is important for our purpose is to point out that right to life has been treated as more than "mere animal existence". In *Kharak Singh* v. *State of U.P.*[1] it was held that the word "life" in Article 21 means right to live with human dignity and it does not merely connote continued drudgery. It takes within its fold "some of the finer graces of human civilisation, which makes life worth living" and that the expanded concept of life would mean the "tradition, culture and heritage" of the person concerned. This concept has been reiterated and reinforced, time and again, in a series of judgments. It may not be necessary to refer to those judgments. Suffice is to mention that a nine-Judge Constitution Bench of this Court in *K.S. Puttaswamy* v. *Union of India*[58] has taken stock of all important judgments which have echoed the message enshrined in *Kharak Singh case*[1]. We may, however, point out that in *CESC Ltd.* v. *Subhash Chandra Bose*[80], K. Ramaswamy, J. observed that physical and mental health have to be treated as integral part of right to life, because without good health the civil and political rights assured by our Constitution cannot be enjoyed. Though Ramaswamy, J. rendered minority opinion in that case, on the

20 *Common Cause* v. *Union of India*, (2014) 5 SCC 338 : (2014) 2 SCC (Cri) 557
1 (1964) 1 SCR 332 : AIR 1963 SC 1295 : (1963) 2 Cri LJ 329
58 (2017) 10 SCC 1
80 (1992) 1 SCC 441 : 1992 SCC (L&S) 313

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aforesaid aspect, majority opinion was not contrary to the views expressed by Ramaswamy, J. Thus, Article 21 recognises right to live with human dignity[81].

239. The question that arises at this juncture is as to whether right to life enshrined in Article 21 of the Constitution includes right to die. If such a right is recognised, that would provide immediate answer to the issue involved, which is pertaining to voluntary or passive euthanasia. However, the judgments of this Court, as discussed hereinafter, would demonstrate that no straightforward answer is discernible and, as observed above, the position regarding euthanasia is somewhat complex in the process.

240. It would be interesting to point out that in *Rustom Cavasjee Cooper* v. *Union of India*[82] the Court held that what is true of one fundamental right is also true of another fundamental right. This Court also made a specific observation that there cannot be serious dispute about the proposition that fundamental rights have their positive as well as negative aspect. For example, freedom of speech and expression includes freedom not to speak. Likewise, freedom of association and movement includes freedom not to join any association or move anywhere. Freedom of business includes freedom not to do any business. In this context, can it be said that right to life includes right to die or right to terminate ones own life? The Constitution Bench in *Gian Kaur*[10], however, has taken a view that right to live will not include right not to live.

241. We have already pointed out that Section 306 IPC makes abetment to suicide as a punishable offence. Likewise, Section 309 IPC makes attempt to commit suicide as a punishable offence. Intention to commit suicide is an essential ingredient in order to constitute an offence under this provision. Thus, this provision specifically prohibits a person from terminating his life and negates right to die. Constitutional validity of this provision, on the touchstone of Article 21, was the subject-matter of *Gian Kaur case*[10, 83]. The Court held Sections 306 and 309 IPC to be constitutionally valid. While so holding, the

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81 Aspects of human dignity as right to life in the context of euthanasia shall be discussed in greater detail at the relevant stage.

82 (1970) 1 SCC 248

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374

83 It may be noted that the Delhi High Court in *State* v. *Sanjay Kumar Bhatia*, 1985 SCC OnLine Del 134 : 1985 Cri LJ 931 and the Bombay High Court in *Maruti Shripati Dubal* v. *State of Maharashtra*, 1986 SCC OnLine Bom 278 : 1987 Cri LJ 743 had taken the view that Section 309 IPC was unconstitutional, being violative of Articles 14 and 21 of the Constitution. On the other hand, the Andhra Pradesh High Court in *Chenna Jagadeeswar* v. *State of A.P.*, 1987 SCC OnLine AP 263 : 1988 Cri LJ 549 had upheld the validity of Section 309 holding that it did not offend either Article 14 or Article 21 of the Constitution. A Division Bench of this Court in *P. Rathinam* v. *Union of India*, (1994) 3 SCC 394 : 1994 SCC (Cri) 740 had held that Section 309 IPC deserves to be effaced from the statute book to humanise our Penal laws, terming this provision as cruel and irrational, which results in punishing a person again who had already suffered agony and would be undergoing ignominy because of his failure to commit suicide. It is in this backdrop *Gian Kaur case*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374 was referred to and decided by the Constitution Bench.

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Court observed that when a man commits suicide, he has to undertake certain positive overt acts and the genesis of those acts cannot be traced to, or be included within the protection of the "right to life" under Article 21. The significant aspect of "sanctity of life" is also not to be overlooked. Article 21 is a provision guaranteeing protection of life and personal liberty and by no stretch of imagination can "extinction of life" be read to be included in "protection of life". Whatever may be the philosophy of permitting a person to extinguish his life by committing suicide, the Court found it difficult to construe Article 21 to include within it the "right to die" as a part of the fundamental right guaranteed therein. "Right to life" is a natural right embodied in Article 21 but suicide is an unnatural termination or extinction of life and, therefore, incompatible and inconsistent with the concept of "right to life". Thus, the legal position which stands as of today is that right to life does not include right to die. It is in this background we have to determine the legality of passive euthanasia.

242. Matter gets further complicated when it is examined in the context of morality of medical science (Hippocratic Oath). Every doctor is supposed to take specific oath that he will make every attempt to save the life of the patient whom he/she is treating and who is under his/her treatment. The Hippocratic Oath goes on to say:

> "I swear by Apollo the Healer, by Asclepius, by Hygieia, by Panacea, and by all the gods and goddesses, making them my witnesses, that I will carry out, according to my ability and judgment, this oath and this indenture.
>
> To hold my teacher in this art equal to my own parents; to make him partner in my livelihood; when he is in need of money to share mine with him; to consider his family as my own brothers, and to teach them this art, if they want to learn it, without fee or indenture; to impart precept, oral instruction, and all other instruction to my own sons, the sons of my teacher, and to indentured pupils who have taken the physician's oath, but to nobody else.
>
> I will use treatment to help the sick according to my ability and judgment, but never with a view to injury and wrongdoing. Neither will I administer a poison to anybody when asked to do so, nor will I suggest such a course. Similarly I will not give to a woman a pessary to cause abortion. But I will keep pure and holy both my life and my art. I will not use the knife, not even, verily, on sufferers from stone, but I will give place to such as are craftsmen therein.
>
> Into whatsoever houses I enter, I will enter to help the sick, and I will abstain from all intentional wrongdoing and harm, especially from abusing the bodies of man or woman, bond or free. And whatsoever I shall see or hear in the course of my profession, as well as outside my profession in my intercourse with men, if it be what should not be published abroad, I will never divulge, holding such things to be holy secrets.

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Now if I carry out this oath, and break it not, may I gain for ever reputation among all men for my life and for my art; but if I break it and forswear myself, may the opposite befall me."

243. This oath, thus, puts a moral and professional duty upon a doctor to do everything possible, till the last attempt, to save the life of a patient. If that is so, would it not be against medical ethics to let a person die by withdrawing medical aid or, even for that matter, life supporting instruments. Paradoxically, advancement in medical science has compounded the issue further. There has been a significant advancement in medical science. Medical scientists have been, relentlessly and continuously, experimenting and researching to find out better tools for not only curing the disease with which human beings suffer from time to time, noble attempt is to ensure that human life is prolonged and in the process of enhancing the expectancy of life, ailments and sufferings therefrom are reduced to the minimal. There is, thus, a fervent attempt to impress the quality of life. It is this very advancement in the medical science which creates dilemma at that juncture when, in common perception, life of a person has virtually become unliveable but the medical doctors, bound by their Hippocratic Oath, want to still spare efforts in the hope that there may still be a chance, even if it is very remote, to bring even such a person back to life. The issue, therefore, gets compounded having counterforces of medical science, morality and ethical values, the very concept of life from philosophical angle. In this entire process, as indicated in the beginning and demonstrated in detail at the appropriate stage, the vexed question is to be ultimately decided taking into consideration the normative law, and in particular, the constitutional values.

244. Then, there is also a possibility of misuse and it becomes a challenging task to ensure that passive euthanasia does not become a tool of corruption and a convenient mode to ease out the life of a person who is considered inconvenient. This aspect would be touched upon at some length at the appropriate stage. This point is highlighted at this juncture just to demonstrate the complexity of the issue.

245. I may add that the issue is not purely a legal one. It has moral and philosophical overtones. It has even religious overtones. As Professor Upendra Baxi rightly remarks that Judges are, in fact, not jurisprudes. At the same time, it is increasingly becoming important that some jurisprudential discussion ensues while deciding those cases which have such more and philosophical overtones as well. Such an analyses provides not only legal basis for the conclusions arrived at but it also provides logical commonsense justification as well. Obviously, whenever the court is entering into a new territory and is developing a new legal norm, discussion on normative jurisprudence assumes greater significance as the court is called upon to decide what the legal norm should be. At the same time, this normative jurisprudence discourse has to be preceded by analytical jurisprudence, which is necessary for the court to underline existing nature of law. That would facilitate knowing legal framework of what is the current scenario and, in turn, help in finding the correct answers. When we discuss about the philosophical aspects of the subject-matter, it is the

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"value of life" which becomes the foremost focus of discussion. The discussion which follows hereinafter keeps in mind these parameters.

The two issues

246. As already stated above, as of now insofar as "active euthanasia" is concerned, it is legally impermissible. Our discussion centres around "passive euthanasia". Another aspect which needs to be mentioned at this stage is that in the present petition filed by the petitioner, the petitioner wants that "Advance Directive" or "living will" should be legally recognised. In this backdrop, two important questions arise for consideration viz.:

(*I*) Whether passive euthanasia, voluntary or even, in certain circumstances, involuntary, is legally permissible? If so, under what circumstances? (This question squarely calls for answer having regard to the reference order made in the instant petition.)

(*II*) Whether a "living will" or "Advance Directive" should be legally recognised and can be enforced? If so, under what circumstances and what precautions are required while permitting it?

247. Answers to these questions have been provided in the judgment of the hon'ble the Chief Justice, with excellent discourse on all relevant aspects in an inimitable and poetic style. I entirely agree with the reasoning and outcome. In fact, with the same fervour and conclusion, separate judgments are written by my brothers, Dhananjay Chandrachud and Ashok Bhushan, JJ. exhibiting expected eloquence and erudition. I have gone through those opinions and am in complete agreement thereby. In this scenario, in my own way, I intend to deal with the aforesaid questions on the following hypothesis:

(*i*) Issue of passive euthanasia is highly debatable, controversial and complex (already indicated above).

(*ii*) It is an issue which cannot be put strictly within the legal confines, but has social, philosophical, moral and even religious overtones.

(*iii*) When the issue of passive euthanasia is considered on the aforesaid parameters, one would find equally strong views on both sides. That is the reason which makes it a thorny and complex issue and brings within the category of "hard cases".

(*iv*) In this entire scenario when the issue is considered in the context of dignity of the person involved, one may tend to tilt in favour of permitting passive euthanasia.

(*v*) At the same time, in order to achieve a balance, keeping in view the competing and conflicting interests, care can be taken to confine permissibility of passive euthanasia only in rare cases, particularly, when the patient is declared "brain dead" or "clinically dead" with virtually no chances of revival.

(*vi*) In this process, as far as "living will" or "Advance Directive" is concerned, that needs to be permitted, along with certain safeguards. It

would not only facilitate prevention of any misuse but take care of many apprehensions expressed about euthanasia.

With the outlining of the structured process as aforesaid, I proceed to discuss these aspects in detail hereinafter.

248. As pointed out above, *Aruna Shanbaug*[5] decides that passive euthanasia, even involuntary, in certain circumstances would be justified. The reference order in the instant case, however, mentions that for coming to this conclusion, the Bench relied upon *Gian Kaur*[10], but that case does not provide any such mandate. In this backdrop, we take up the first question about the legality of passive euthanasia.

First issue: Whether passive euthanasia, voluntary or even, in certain circumstances, involuntary, is legally permissible? If so, under what circumstances? (This question squarely calls for answer having regard to the reference order made in the instant petition.)

249. I intend to approach this question by discussing the following facets thereof:

(*A*) Philosophy of euthanasia
(*B*) Morality of euthanasia
(*C*) Dignity in euthanasia
(*D*) Economics of euthanasia

(A) *Philosophy of euthanasia*

"I am the master of my fate; I am the captain of my soul"

— William Ernest Henley[84]

"Death is our friend ... he delivers us from agony. I do not want to die of a creeping paralysis of my faculties — a defeated man."

— Mahatma Gandhi[85]

"When a man's circumstances contain a preponderance of things in accordance with nature, it is appropriate for him to remain alive; when possess or sees in prospect a majority of contrary, it is appropriate for him to depart from life."

— Marcus Tullius Cicero

"Euthanasia, and especially physician-assisted suicide, appears as the ultimate post-modern demand for dignity in an era of technologically-mediated death."

— Dr Jonathan Moreno

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294
10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374
84 As quoted in *P. Rathinam* v. *Union of India*, (1994) 3 SCC 394
85 <http://www.mkgandhi.org/articles/last_words.htm> last accessed 16-3-2018.

250. The aforequoted sayings of some great persons bring out a fundamental truth with universal applicability. Every person wants to lead life with good health and all kinds of happiness. At the same time, nobody wants any pain, agony or sufferings when his or her lifespan comes to an end and that person has to meet death. The following opening stanza from a song in a film captures this message beautifully:

रोते हुए आते हैं सब, हंसता हुआ जो जाएगा
वो मुक़द्दर का सिकन्दर जानेमन कहलाएगा

"Every person in this world comes crying. However, that person who leaves the world laughing/smiling will be the luckiest of all"
(*Hindi Film — Muqaddar Ka Sikandar*)

251. It became unbearable for young prince Siddharth when he, for the first time, saw an old crippled man in agony and a dead body being taken away. He did not want to encounter such a situation in his old life and desired to attain nirvana which prompted him to renounce the world so that he could find the real purpose of life; could lead a life which is worth living; and depart this world peacefully. He successfully achieved this purpose of life and became Gautam Buddha. There are many such similar examples.

252. Life is mortal. It is transitory. It is as fragile as any other object. It is a harsh reality that no human being, or for that matter, no living being, can live forever. Every creature who takes birth on this planet earth has to die one day. Life has a limited shelf age. In fact, unlike the objects and articles which are produced by human beings and may carry almost same lifespan, insofar as humans themselves are concerned, span of life is also uncertain. Nobody knows how long he/she will be able to live. The gospel truth is that everybody has to die one day, notwithstanding the pious wish of a man to live forever.[86] As Woody Allen said once: "*I do not want to achieve immortality through my work. I want to achieve it through not dying.*" At the same time, nobody wants to have a tragic end to life. We all want to leave the world in a peaceful manner. In this sense, the term "euthanasia" which has its origin in Greek language signifies "an easy and gentle death".

253. According to Charles I. Lugosi, the sanctity of life ethic no longer dominates American medical philosophy. Instead, quality of life has become the modern approach to manage human life that is at the margin of utility.[87] It is interesting to note that the issue of euthanasia was debated in India in 1928. Probably this was the first public debate on euthanasia to be reported. A calf in Gandhi's ashram was ailing under great pain. In spite of every possible treatment and nursing … the condition of the calf was so bad that it could not

86 It is well known that medical scientists are intensely busy in finding the ways to become ageless and immortal, but till date have remained unsuccessful in achieving this dream.

87 Charles I. Lugosi, "Natural Disaster, Unnatural Deaths: The Killings on the Life Care Floors at Tenet's Memorial Centre after Hurricane Katrina", *Issues in Law and Medicine*, Vol. 23, Summer, 2007.

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even change its side or even it could not be lifted about in order to prevent pressure ulcers/sores. It could not even take nourishment and was tormented by flies. The surgeon whose advice was sought in this matter declared the case to be past help and past hope. After painful days of hesitation and discussions with the managing committee of Goseva Sangh and the inmates of the ashram, Gandhi made up his mind to end the life of the calf in a painless way as possible. There was a commotion in orthodox circles and Gandhi critically examined the question through his article which appeared in *Navajivan* (dated 30-9-1928) and *Young India* (4-10-1928). Probably this was the first public debate on euthanasia and animal/veterinary euthanasia and the debate also covered the issue of human euthanasia. It is equally interesting to note that Gandhi and his critics discussed the issue of "*painlessly ending the life to end suffering*" without using the term "*euthanasia*". But, he meant the same. Further it is more interesting to learn that at various instances Gandhiji had touched upon the issues of the present day debates on voluntary euthanasia, non-voluntary euthanasia, involuntary euthanasia, as well as passive euthanasia, active euthanasia, physician-assisted euthanasia and the rejection or "termination of treatment". Gandhi advocated the development of positive outlook towards life and strived for the humane nursing and medical care even when cure was impossible. It was the way he analysed karma and submitted to the will of the God.

254. Mahatma Gandhi said:

> "In these circumstances I felt that humanity demanded that the agony should be ended by ending life itself. The matter was placed before the whole ashram. At the discussion a worthy neighbour vehemently opposed the idea of killing even to end pain. *The ground of his opposition was that one has no right to take away life which one cannot create. His argument seemed to me to be pointless here. It would have point if the taking of life was actuated by self-interest.* Finally, in all humility but with the clearest of convictions, I got in my presence a doctor kindly to administer the calf a quietus by means of a poison injection. The whole thing was over in less than two minutes.
>
> But the question may very legitimately be put to me: Would I apply the same principle to human beings? Would I like it to be applied in my own case? My reply is 'yes'; the same law holds good in both the cases. The law, 'as with one so with all', admits of no exceptions, or the killing of the calf was wrong and violent. In practice, however, we do not cut short the sufferings of our ailing dear ones by death because, as a rule, we have always means at our disposal to help them and they have the capacity to think and decide for themselves. But supposing that in the case of an ailing friend, I am unable to render any aid whatever and recovery is out of question and the patient is lying in an unconscious state in the throes of agony, then I would not see any himsa in putting an end to his suffering by death.

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Just as a surgeon does not commit himsa but practises the purest ahimsa when he wields his knife, one may find it necessary, under certain imperative circumstances, to go a step further and sever life from the body in the interest of the sufferer. It may be objected that whereas the surgeon performs his operation to save the life of the patient, in the other case we do just the reverse. But on a deeper analysis it will be found that the ultimate object sought to be served in both the cases is the same, namely, to relieve the suffering soul within from pain. In the one case you do it by severing the diseased portion from the body, in the other you do it by severing from the soul the body that has become an instrument of torture to it. In either case it is the relief of the soul within from pain that is aimed at, the body without the life within being incapable of feeling either pleasure or pain.

To conclude then, to cause pain or wish ill to or to take the life of any living being out of anger or a selfish intent, is himsa. On the other hand, after a calm and clear judgment to kill or cause pain to a living being from a pure selfless intent may be the purest form of ahimsa. Each such case must be judged individually and on its own merits. The final test as to its violence or non-violence is after all the intent underlying the act."

255. *Ethical egoism* propounded in modern times by Thomas Hobbes in *Leviathan* also operates from the general rule that if any action increases my own good, then it is right. Ethical egoism in the context of euthanasia would mean that if a person wants or does not want to end his/her life using euthanasia, this desire is presumed to be motivated by a need for self-benefit, and is therefore an ethical action.[88] The perspective of the world community is gradually shifting from sanctity of life to quality of life sustained and preserved.

256. Philosophers believe that we have to control switch that can end it all, on request. In medical/legal parlance, it is called euthanasia: "*an easy and gentle death*". Philosophically, this debate is about our right, when terminally ill, to choose how to die. It is about the right to control how much we have to suffer and when and how we die. It is about having some control over our dying process in a system that can aggressively prolong life with invasive technology. Luckily, we also have the technology that allows us to experience a *gentle death* on our own terms, rather than by medically set terms. In his famous essay *On Liberty*, John Stuart Mill argues strongly for our right to self-determination. He writes: "*Over himself, over his own body and mind, the individual is sovereign ... he is the person most interested in his own well-being*." These words were written over a century ago.

257. Philosophically, therefore, one may argue that if a person who is undergoing miserable and untold sufferings and does not want to continue dreadful agony and is terminally ill, he should be free to make his choice to terminate his life and to put an end to his life so that he dies peacefully.

88 John Keown, *Euthanasia, Ethics and Public Policy* (Cambridge: Cambridge University Press, 2002) p. 37.

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258. At the same time, Buddhism, Jainism and Hinduism are against euthanasia. However, their concept of "*good death*" is extremely interesting —specially principles of Buddhism as they are echoed in the present day understanding of euthanasia. Without elaborating and to put it in a nutshell:

258.1. Buddhism, Jainism, and Hinduism, in particular, embrace the concept of the *good death* as a means of achieving dignity and spiritual fulfilment at the end of life without resorting to artificially shortening its span.

258.2. Buddhists believe that human existence is rare and rebirth as a human is rarer still. Consequently, it is best approached cautiously without attempting to exert control over the dying process. At the point of dying, a Buddhist should ideally be conscious, rational and alert.

258.3. Traditional Hindu religious culture also emphasises the *good death* as a reflection of the quality of life that preceded it. If a good, dignified death is attained, it is perceived as evidence of having lived a worthy life because "the manner of one's passing outweighs all previous claims and intimations of one's moral worth"[89].

258.4. "A good death certifies a good life"[90].

258.5. The *good death* is achieved when death occurs in full consciousness, in a chosen place and at a chosen time; and

258.6. As with Buddhism great significance is attached to the element of choice and the maintenance of control[91], so if at all possible, "one must be in command and should not be overtaken by death. To be so overtaken is the loss of dignity".[92] Thus, the final moments of life should be calm, easy and peaceful if dignity is to be preserved.

259. Many of the insights of these traditional religions are echoed in the modern western understanding of euthanasia, as a means of achieving death with dignity, which focuses on avoiding dependence and loss of control. Choosing to deliberately end one's life allows control over the time, place and method of one's dying and explains why euthanasia appears to offer death with dignity. Rather than active euthanasia these ancient religions advocate calm, control and compassion as a means of achieving dignity.

(B) ***Morality of euthanasia***

260. At the outset, I would like to clarify that while discussing a particular norm of law, the law per se is to be applied and, generally speaking, it is not the function of the courts to look into the moral basis of law. At the same time, some legal norms, particularly those which are jurisprudentially expounded by

89 T.N. Madan, "Dying with Dignity" (1992) 35(4) *Social Science and Medicine* 425-32.
90 T.N. Madan, "Living and Dying" in *Non-Renunciation: Themes and Interpretations of the Hindu Culture* (New Delhi, Oxford University Press, 1987).
91 J. Parry, *Death and the Regeneration of Life* (Cambridge, Cambridge University Press, 1982).
92 T.N. Madan, "Dying with Dignity" (1992) 35 (4) *Social Science and Medicine* 425-32.

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the courts or developed as common law principles, would have moral backing behind them. In that sense moral aspects of an issue may assume relevance. This relevancy and rationale is quite evident in the discussion about euthanasia. In fact, the very concept of dignity of life is substantially backed by moral overtones. We may remind ourselves with the following classical words uttered by Immanuel Kant:

> "We must not expect a good constitution because those who make it are moral men. Rather it is because of a good constitution that we may expect a society composed of moral men."

261. It is well known that Justice Holmes' legal philosophy revolved around its central theme that law and morals are to be kept apart, maintaining a sharp distinction between them. Notwithstanding, even he accepted that under certain circumstances distinction between law and morals loses much of its importance. To quote:

> "I do not say say that there is not a wider point of view from which the distinction between law and morals becomes of secondary importance, as all mathematical distinctions vanish in the presence of the infinite."[93]

262. Euthanasia is one such critical issue where the law relating to it cannot be divorced from morality. *Lon L. Fuller*[94] has argued with great emphasis that it is the morality that makes the law possible. He also points towards morality as the substantive aims of law. In fact, as would be noticed later, the conceptualisation of doctrine of dignity by Ronald Dworkin is supported with moral ethos. With the aid of dignity principle, he has argued in favour of euthanasia. Likewise, and ironically, John Finnis, Professor of Law and Legal Philosophy Emeritus in the University of Oxford, while opposing euthanasia, also falls back on the morality conception thereof. It is this peculiar feature which drives us to discuss the issue of euthanasia from the standpoint of morality.

263. Influenced primarily by the aforesaid considerations, I deem it relevant to indulge into discussion on morality.

264. When we come to the moral aspects of "end of life" issues, we face the situation of dilemma. On the one hand, it is an accepted belief that every human being wants to die peacefully. Nobody wants to undergo any kind of suffering in his last days. So much so a person who meets his destiny by sudden death or easy death is often considered as a person who would have lived his life by practising moral and ethical values. Rightly or wrongly, it is perceived that such a person who exhibited graceful behaviour while living his life is bestowed grace by the death when time to depart came. However, it does not happen to most of the people. Ageing is a natural phenomenon. No doubt, as the person advances in age, he becomes mature in his wisdom. However,

93 Justice Holmes, "The Path of the Law", 10 Harvard Law Review 457-78, at p. 459 (1897).
94 Lon L. Fuller, "The Morality of Law" (Revised Edn.), Yale University Press

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old age brings, along with it, various ailments and diseases as well. Physical health and physical functioning declines over the life course, particularly, in later life. A rise in chronic disease and other conditions such as arthritis, high blood pressure and obesity can cause loss in function and lead to generally decreasing trajectory for health over the lifespan. Thus, ageing has both positive and negative aspects. This ageing leads to extinction of human life which may generally be preceded by grave sickness and disease.

265. Horace, Roman poet in his poem on the "*Ages of Man*" wrote quite scathingly of the attributes of old age:

> "Many ills encompass an old man, whether because he seeks, gain, and then miserably holds aloof from his store and fears to use it, because, in all that he does, he lacks fire and courage, is dilatory and slow to form hopes, is sluggish and greedy of a longer life, peevish, surly, given to praising the days he spent as a boy, and to reproving and condemning the young."
>
> (*Ars Poetica, pp. 169-74*)

We find a more contemporary echo of this in William Shakespeare's (1564-1616) famous verse '*All the World's a Stage*':

> All the world's a stage,
> And all the men and women merely players;
> They have their exits and their entrances,
> And one man in his time plays many parts,
> His acts being seven ages....Last scene of all,
> That ends this strange eventful history,
> Is second childishness and mere oblivion,
> Sans teeth, sans eyes, sans taste, sans everything.
>
> (*As You Like It*, Act II, Scene VII)"

It may, however, be added (for the sake of clarification) that advent of disease is not the confines of old age only. One may become terminally ill at any age. Such a disease may be acquired even at birth.

266. The moral dilemma is that it projects both the sides—protracted as well as intractable. On the one hand, it is argued by those who are the proponents of a liberal view that a right to life must include a concomitant right to choose when the life becomes unbearable and not so worth living, when such a stage comes and the sufferer feels that that the life has become useless, he should have right to die. Opponents, on the other hand, project "*Sanctity of Life*" (SOL) as the most important factor and argue that this "SOL" principle is violated by self-styled angles of death. Protagonists on "SOL" principle believe that life should be preserved at all costs and the least which is expected is that there should not be a deliberate destruction of human life, though it does not demand that life should always be prolonged as long as possible.

267. It might therefore be argued, as Emily Jackson (2008) cogently does, that the law's recognition that withdrawal of life-prolonging treatment is sometimes legitimate is not so much an exception to the SOL principle, as an embodiment of it.

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268. In the most secular judicial interpretation of the SOL doctrine yet, Denman, J. of UKHL explicated thus:

> "in respect a person's death, we are also respecting their life — giving it sanctity…A view that life must be preserved at all costs does not sanctify life.,..to care for the dying, to love and cherish them, and to free them from suffering rather than simply to postpone death is to have fundamental respect for the sanctity of life and its end."

269. Hence, as the process of dying is an inevitable consequence of life, the right to life necessarily implies the right to have nature take its course and to die a natural death. It also encompasses a right, unless the individual so wishes, not to have life artificially maintained by the provision of nourishment by abnormal artificial means which have no curative effect and which are intended merely to prolong life.

270. A moral paradox which emerges is beautifully described by *Sushila Rao*[95], in the following words:

> "Several commentators have justified the active/passive distinction by averring that there is an important moral difference between killing a patient by administering, say, a lethal injection, and withdrawing treatment which is currently keeping her alive. Active euthanasia, runs the argument, interferes with nature's dominion, whereas withdrawal of treatment restores to nature her dominion.
>
> Here too, an absolutist version of the SOL principle rears its unseemly head. In a plethora of cases in the UK, a course of action which would lead to the patient's action which would lead to the patient's death was held to be compatible with the "best interests" test. Indeed, a majority in the House of Lords in *Bland*[11] explicitly accepted that the doctor's intention in withdrawing artificial nutrition and hydration was, in Lord Browne-Wilkinson's words, to "bring about the death of Anthony Bland". Lord Lowry said that "the intention to bring about the patient's death is there" and Lord Mustill admitted that "the proposed conduct has the aim … of terminating the life of Anthony Bland". I each case, however, life could be brought to an end only because the doctors had recourse to a course of action which could plausibly be described as a "failure to prolong life".
>
> The SOL principle thus works insidiously to ensure that only certain types of death—namely, those achieved by suffocation, dehydration, starvation and infection, through the withdrawal or withholding of, respectively, ventilation, ratification nutrition and hydration, and antibiotics—can lawfully be brought about. More crucially, the SOL principle prohibits doctors from acting to achieve that end quickly, and more humanly, by the administration of a single lethal injection.

95 Sushila Rao: *Economic and Political Weekly*, Vol. 46, No. 18 (30-4-2011-6-5-2011), pp. 13-16.
11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

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Lord Browne-Wilkinson lamented this paradox in *Bland*[11] in the following words: (AC p. 885 G)

> '... How can it be lawful to allow a patient to die slowly, though painlessly, over a period of weeks from lack of food but unlawful to produce his immediate death by a lethal injection, thereby saving his family from yet another ordeal to add to the tragedy that has already struck them? I find it difficult to find a moral answer to that question.'

> As Simon Blackburn (2001) puts it, differentiating between withdrawal of treatment and killing may salve some consciences, but it is very doubtful whether it ought to. It often condemns the subject to a painful, lingering death, fighting for breath or dying of thirst, while those who could do something stand aside, withholding a merciful death."

Interestingly, Sushila Rao concludes that even the active-passive distinction is not grounded much in morality and ethics as in "reasons of policy".

271. John Finnis strongly beliefs that moral norms rule out the central case of euthanasia and discards the theory of terminating people's life on the ground that doing so would be beneficial by alleviating human suffering or burdens. He also does not agree that euthanasia would benefit "*other people*" at least by alleviating their proportionately greater burdens.[96]

272. Moral discourse of John Finnis proceeds on the "intention of the person who is facing such a situation". He draws distinction between what one intends (and does) and what one accepts as foreseen side-effects is significant by giving importance to free choice. There would be free choice, he argues, only when one is rationally motivated towards incompatible alternative possible purposes. Therefore, there may be a possibility that a person may choose euthanasia but not as a free choice and it would be morally wrong. In a situation where that person is not in a position to make a choice (for e.g. when he is in coma) this choice shall be exercised by others which, according to him, violates the autonomy of the person involved. It is significant to mention that Finnis accepts that autonomy of the patient or prospective patient counts. It reads:

> "Is this to say that the autonomy of the patient or prospective patient counts for nothing? By no means. Where one does not know that the requests are suicidal in intent, one can rightly, as a healthcare professional

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11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

96 According to John Finnis, there is no real and morally relevant distinction between active euthanasia and passive euthanasia inasmuch as one employs the method of deliberate omissions (or forbearances or abstentions) in order to terminate life (passive euthanasia) and other employs "a deliberate intervention" for the same purpose (active euthanasia). In this sense, in both the cases, it is an intentional act whether by omission or by intervention, to put an end to somebody's life and, therefore, morally wrong.

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or as someone responsible for the care of people, give full effect to requests to withhold specified treatments or indeed any and all treatments, even when one considers the requests misguided and regrettable. For one is entitled and indeed ought to honour these people's autonomy, and can reasonably accept their death as a side-effect of doing so."[97]

273. John Finnis, however, explains thereafter that even if such a decision is taken, said person would be proceeding on one or both of two philosophically and morally erroneous judgments: (*i*) that human life in certain conditions or circumstances retains no intrinsic value and dignity; and/or (*ii*) that the world would be a better place if one's life were intentionally terminated. And each of these erroneous judgments has very grave implications for people who are in poor shape and/or whose existence creates serious burdens for others. It is, thus, clear that taking shelter of same morality principles, jurists have reached opposing conclusions. Whereas euthanasia is morally impermissible in the estimation of some, others treat it as perfectly justified. As would be noted later, riding on these very moral principles, Dworkin developed the dignity of life argument and justified euthanasia.

274. The aforesaid discussion on the philosophy of euthanasia, coupled with its morality aspect, brings out the conflicting views. Though philosophical as well as religious overtones may indicate that a person does not have right to take his life, it is still recognised that a human being is justified in his expectation to have a peaceful and dignified death. Opposition to euthanasia, on moral grounds, proceeds primarily on the basis that neither the person concerned has a right to take his own life, which is God's creation, nor anybody else has this right. However, one startling feature which is to be noted in this opposition is that while opposing euthanasia, no segregated discussion on active and passive euthanasia is made. It also does not take into consideration permissibility of passive euthanasia under certain specific circumstances. Clarity on this aspect is achieved when we discuss the issue of euthanasia in the context of dignity.

(C) *Dignity in euthanasia*

275. This Court acknowledges its awareness of the sensitive and emotional nature of euthanasia controversy, and the vigours of opposing views, even within the medical fraternity, and seemingly absolute convictions that the subject inspires. This is so demonstrated above while discussing philosophical, moral, ethical and religious overtones of the subject involved. These valid aspects, coupled with one's attitude towards life and family and their values, are likely to influence and to colour one's thinking and conclusions about euthanasia. Notwithstanding the same, these aspects make the case as "*hard case*". However, at the end of the day, the Court is to resolve the issue by constitutional measurements, free of emotion and of predilection. One has to bear in mind what Justice Oliver Wendell Holmes Jr. said in his dissenting

97 John Finnis: *Human Rights and Common Good: Collected Essays*, Vol. III.

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judgment in *Lochner* v. *New York*[98], which is reproduced below: (SCC OnLine US SC para 48)

> "*48.* ... [The Constitution] is made for people of fundamentally differing views, and the accident of our finding certain opinions natural and familiar or novel and even shocking ought not to conclude our judgment upon the question whether statutes embodying them conflict with the Constitution of the United States."

276. With these preliminary remarks we return to the doctrine of dignity as an aspect of Article 21 of the Constitution, a brief reference to which has already been made above.

277. Let me first discuss certain aspects of human dignity in general. Insofar as concept of human dignity is concerned, it dates back to thousands of years. Historically, human dignity, as a concept, found its origin in different religions which is held to be an important component of their theological approach. Later, it was also influenced by the views of philosophers who developed human dignity in their contemplations.[99] Jurisprudentially, three types of models for determining the content of the constitutional value of human dignity are recognised. These are: (*i*) Theological Model, (*ii*) Philosophical Model, and (*iii*) Constitutional Model. Legal scholars were called upon to determine the theological basis of human dignity as a constitutional value and as a constitutional right. Philosophers also came out with their views justifying human dignity as core human value. Legal understanding is influenced by theological and philosophical views, though these two are not identical. Aquinas, Kant as well as Dworkin discussed the jurisprudential aspects of human dignity. Over a period of time, human dignity has found its way through constitutionalism, whether written or unwritten.

Theological Model of Dignity

> '*Amritasya Putrah Vayam*'
> *[We are all begotten of the immortal.] This is how Hinduism introduces human beings.*
> '*Every individual soul is potentially divine*'
> — *proclaimed Swami Vivekananda*

278. Hinduism does not recognise human beings as mere material beings. Its understanding of human identity is more ethical-spiritual than material. That is why a sense of immortality and divinity is attributed to all human beings in Hindu classical literature.

98 1905 SCC OnLine US SC 100 : 49 L Ed 937 : 198 US 45 at p. 76 (1905)

99 Though western thinking is that the concept of human dignity has 2500 years' history, in many eastern civilisations including India human dignity as core human value was recognised thousands of years ago.

279. Professor S.D. Sharma, sums up the position with the following analysis[100]:

> "Consistent with the depth of Indian metaphysics, the human personality was given a metaphysical interpretation. This is not unknown to the modern occidental philosophy. The concept of human personality in Kant's philosophy of law is metaphysical entity but Kant was not able to reach the subtler unobserved element of personality, which was the basic theme of the concept of personality in Indian legal philosophy."

280. It is on the principle that the soul that makes the body of all living organisms its abode is in fact an integral part of the Divine Whole—Paramaatman—that the Vedas declare unequivocally:

> *Ajyesthaaso Akanisthaasa Yete; Sam Bhraataro Vaavrudhuh Soubhagaya*
> *[No one is superior or inferior; all are brothers; all should strive for the interest of all and progress collectively]*
> *— RigVeda, Mandala 5, Sukta 60, Mantra 5*

281. Even in Islam, tradition of human rights became evident in the medieval ages. Being inspired by the tenets of the Holy Koran, it preaches the universal brotherhood, equality, justice and compassion. Islam beliefs that man has special status before God. Because man is a creation of God, he should not be harmed. Harm to a human being is harm to a God. God, as an act of love, created man and he wishes to grant him recognition, dignity and authority. Thus, in Islam, human dignity stems from the belief that man is a creation of God—the creation that God loves more than any other.

282. The Bhakti and Sufi traditions too in their own unique ways popularised the idea of universal brotherhood. It revived and regenerated the cherished Indian values of truth, righteousness, justice and morality.

283. Christianity beliefs that the image of God is revealed in Jesus and through him to human kind. God is rational and determines His goals for Himself. Man was created in the image of God, and he too is rational and determines his own goals, subject to the God as a rational creation. Man has freedom of will. This is his dignity. He is free to choose his goals, and he himself is a goal. His supreme goal is to know God. Thus, he is set apart from a slave and from all the creations under him. When a man sins, he loses his human dignity. He becomes an object.[101]

Philosophical Model of Dignity

284. The modern conception of human dignity was affected by the philosophy of Kant.[102] Kant's moral theory is divided into two parts: ethics and right (jurisprudence). The discussion of human dignity took place within

100 Prof. S.D. Sharma : *Administration of Justice in Ancient Bharat*, (1988).
101 Based on the approach of Thomas Aquinas (1225-1274) in his work *Summa Theologia*.
102 *See* Toman E. Hill, "Humanity as an End in Itself" (1980) 91 Ethics 84.

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his doctrine of ethics and does not appear in his jurisprudence.[103] Kant's jurisprudence features the concept of a person's right to freedom as a human being.

285. According to Kant, a person acts ethically when he acts by force of a duty that a rational agent self-legislates onto his own will. This self-legislated duty is not accompanied by any right or coercion, and is not correlative to the rights of others. For Kant, ethics includes duties to oneself (e.g. to develop one's talents) and to others (e.g. to contribute to their happiness). This ability is the human dignity of man. This is what makes a person different than an object. This ability makes a person into an end, and prevents her from being a mere means in the hands of another.

286. Professor Upendra Baxi in his First Justice H.R. Khanna Memorial Lecture[104], on the topic *Protection of Dignity of Individual under the Constitution of India* has very aptly remarked that dignity notions, like the idea of human rights, are supposed to be the gifts of the West to the Rest, though, this view is based on the prescribed ignorance of the rich traditions of non-European countries. He, then, explains Eurocentric view of human dignity by pointing out that it views dignity in terms of personhood (moral agency) and autonomy (freedom of choice). Dignity here is to be treated as "*empowerment*" which makes a triple demand in the name of respect for human dignity, namely:

286.1. Respect for one's capacity as an agent to make one's own free choices.

286.2. Respect for the choices so made.

286.3. Respect for one's need to have a context and conditions in which one can operate as a source of free and informed choice.

287. To the aforesaid, Professor Baxi adds:

> "I still need to say that the idea of dignity is a metaethical one, that is it marks and maps a difficult terrain of what it may mean to say being 'human' and remaining 'human', or put another way the relationship between 'self', 'others', and 'society'. In this formulation the word 'respect' is the keyword: dignity is respect for an individual person based on the principle of freedom and capacity to make choices and a good or just social order is one which respects dignity via assuring 'contexts' and 'conditions' as the 'source of free and informed choice'. Respect for dignity thus conceived is empowering overall and not just because it, even if importantly, sets constraints state, law, and regulations."

288. *Jeremy Waldron*[105] opines that dignity is a sort of status-concept: it has to do with the standing (perhaps the formal legal standing or perhaps, more informally, the moral presence) that a person has in a society and in her dealings with others. He has ventured even to define this term "dignity" in the following manner:

103 See Pfordten, *On the Dignity of Man in Kant.*
104 Delivered on 25-2-2010 at Indian Institute of Public Administration, New Delhi.
105 See Article of Jeremy Waldron : "How Law Protects Dignity".

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"Dignity is the status of a person predicated on the fact that she is recognised as having the ability to control and regulate her actions in accordance with her own apprehension of norms and reasons that apply to her; it assumes she is capable of giving and entitled to give an account of herself (and of the way in which she is regulating her actions and organizing her life), an account that others are to pay attention to; and it means finally that she has the wherewithal to demand that her agency and her presence among us as human being be taken seriously and accommodated in the lives of others, in others' attitudes and actions towards her, and in social life generally."

289. Kant, on the other hand, has initially used dignity as a "*value idea*", though in his later work he also talks of "respect" which a person needs to accord to other person, thereby speaking of it more as a matter of status.

Constitutional perspective of dignity

290. The most important lesson which was learnt as a result of the Second World War was the realisation by the Governments of various countries about the human dignity which needed to be cherished and protected. It is for this reason that in the UN Charter, 1945, adopted immediately after the Second World War, dignity of the individuals was mentioned as of core value. The almost contemporaneous Universal Declaration of Human Rights (1948) echoed same sentiments.

291. Article 3 of the Geneva Convention explicitly prohibits "outrages upon personal dignity". There are provisions to this effect in the International Covenant on Civil and Political Rights (Article 7) and the European Convention of Human Rights (Article 3) though implicit. However, one can easily infer the said implicit message in these documents about human dignity. ICCPR begins its Preamble with the acknowledgment that the rights contained in the Covenant "derive from the inherent dignity of the human person". And some philosophers say the same thing. Even if this is not a connection between dignity and law as such, it certainly purports to identify a wholesale connection between dignity and the branch of law devoted to human rights. One of the key facets of twenty-first century democracies is the primary importance they give to the protection of human rights. From this perspective, dignity is the expression of a basic value accepted in a broad sense by all people, and thus constitutes the first cornerstone in the edifice of human rights. Therefore, there is a certain fundamental value to the notion of human dignity, which some would consider a pivotal right deeply rooted in any notion of justice, fairness, and a society based on basic rights.

292. Aharon Barak, former Chief Justice of the Supreme Court of Israel, attributes two roles to the concept of human dignity as a constitutional value, which are:

292.1. Human dignity lays a foundation for all the human rights as it is the central argument for the existence of human rights.

292.2. Human dignity as a constitutional value provides meaning to the norms of the legal system. In the process, one can discern that the principle

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of purposive interpretation exhorts us to interpret all the rights given by the Constitution, in the light of the human dignity. In this sense, human dignity influences the purposive interpretation of the Constitution. Not only this, it also influences the interpretation of every sub-constitutional norm in the legal system. Moreover, human dignity as a constitutional value also influences the development of the common law.

293. Within two years of the adoption of the aforesaid Universal Declaration of Human Rights that all human beings are born free and equal in dignity and rights, India attained Independence and immediately thereafter Members of the Constituent Assembly took up the task of framing the Constitution of this country. It was but natural to include a Bill of Rights in the Indian Constitution and the Constitution-makers did so by incorporating a Chapter on Fundamental Rights in Part III of the Constitution. However, it would be significant to point out that there is no mention of "dignity" specifically in this Chapter on Fundamental Rights. So was the position in the American Constitution. In America, human dignity as a part of human rights was brought in as a Judge-made doctrine. Same course of action followed as the Indian Supreme Court read human dignity into Articles 14 and 21 of the Constitution.

294. Before coming to the interpretative process that has been developed by this Court in evolving the aura of human dignity predicated on Articles 14 and 21 of the Constitution, I am provoked to discuss as to how Dworkin perceives interpretative process adopted by a Judge.

295. Dworkin, being a philosopher-jurist, was aware of the idea of a Constitution and of a constitutional right to human dignity. In his book, *Taking Rights Seriously*, he noted that everyone who takes rights seriously must give an answer to the question why human rights vis-à-vis the State exist. According to him, in order to give such an answer one must accept, as a minimum, the idea of human dignity. As he writes:

> "Human dignity ... associated with Kant, but defended by philosophers of different schools, supposes that there are ways of treating a man that are inconsistent with recognising him as a full member of the human community, and holds that such treatment is profoundly unjust."[106]

296. In his Book, *Is Democracy Possible Here?*[107] Dworkin develops two principles about the concept of human dignity. First principle regards the intrinsic value of every person viz. every person has a special objective value which value is not only important to that person alone but success or failure of the lives of every person is important to all of us. The second principle, according to Dworkin, is that of personal responsibility. According to this principle, every person has the responsibility for success in his own

106 Ronald Dworkin, *Taking Rights Seriously* (A&C Black, 2013) 239.
107 Ronald Dworkin, *Is Democracy Possible Here? Principles for a New Political Debate* (Princeton University Press, 2006).

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life and, therefore, he must use his discretion regarding the way of life that will be successful from his point of view. Thus, Dworkin's jurisprudence of human dignity is founded on the aforesaid two principles which, together, not only define the basis but the conditions for human dignity. Dworkin went on to develop and expand these principles in his book, *Justice for Hedgehogs* (2011)[108].

297. When speaking of rights, it is impossible to envisage it without dignity. In his pioneering and all-inclusive *Justice for Hedgehogs*, he proffered an approach where respect for human dignity, entails two requirements; first, self-respect i.e. taking the objective importance of one's own life seriously; this represents the free will of the person, his capacity to think for himself and to control his own life and second, authenticity i.e. accepting a "special, personal responsibility for identifying what counts as success" in one's own life and for creating that life "through a coherent narrative" that one has chosen.[109] According to Dworkin, these principles form the fundamental criteria supervising what we should do in order to live well.[109] They further explicate the rights that individuals have against their political community,[108] and they provide a rationale for the moral duties we owe to others. This notion of dignity, which Dworkin gives utmost importance to, is indispensable to any civilised society. It is what is constitutionally recognised in our country and for good reason. Living well is a moral responsibility of individuals; it is a continuing process that is not a static condition of character but a mode that an individual constantly endeavours to imbibe. A life lived without dignity, is not a life lived at all for living well implies a conception of human dignity which Dworkin interprets includes ideals of self-respect and authenticity.

298. This constitutional value of human dignity, has been beautifully illustrated by Aharon Barak, as under:

> "Human dignity as a constitutional value is the factor that unites the human rights into one whole. It ensures the normative unity of human rights. This normative unity is expressed in the three ways: first, the value of human dignity serves as a normative basis for constitutional rights set out in the Constitution; second, it serves as an interpretative principle for determining the scope of constitutional rights, including the right to human dignity; third, the value of human dignity has an important role in determining the proportionality of a statute limiting a constitutional right."[110]

108 Harvard University Press, 2011.

109 Kenneth W. Simons, "Dworkin's Two Principle of Dignity: An Unsatisfactory Non-Consequentialist Account of Interpersonal Moral Duties", 90 Boston Law Rev. 715 (2010)

110 Aharon Barak, *Human Dignity: The Constitutional Value and the Constitutional Right.*

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299. We have to keep in mind that while expounding the aforesaid notion of dignity, Dworkin was not interpreting any Constitution. This notion of dignity, as conceptualised by Dworkin, fits like a glove in our constitutional scheme. In a series of judgments, dignity, as an aspect of Article 21, stands firmly recognised. Most of the important judgments[111] have been taken note of and discussed in *K.S. Puttaswamy*[58].

300. In *K.S. Puttaswamy*[58], the Constitution Bench has recognised the dignity of existence. Liberty and autonomy are regarded as the essential attributes of a life with dignity. In this manner, sanctity of life also stands acknowledged, as part of Article 21 of the Constitution. That apart, while holding the right of privacy as an intrinsic part of right to life and liberty in Article 21, various facets thereof are discussed by the learned Judges in their separate opinions. A common theme which flows in all these opinions is that that privacy recognises the autonomy of the individual; every person has right to make essential choices which affect the course of life; he has to be given full liberty and freedom in order to achieve his desired goals of life; and the concept of privacy is contained not merely in personal liberty, but also in the dignity of the individual. Chelameswar, J. in *K.S. Puttaswamy*[58], made certain specific comments which are reflective of euthanasia, though this term is not specifically used. He observed: (SCC p. 530, para 373)

> "*373.* ... Forced feeding of certain persons by the State raises concerns of privacy. An individual's right to refuse life prolonging medical treatment or terminate his life is another freedom which falls within the zone of privacy."

301. Liberty by itself, which is a facet of Article 21 of the Constitution, duly recognised in *K.S. Puttaswamy*[58], ensures and guarantees such a choice to the individual. In fact, the entire structure of civil liberties presupposes that freedom is worth fostering. The very notion of liberty is considered as good for the society. It is also recognised that there are some rights, encompassing liberty, which are needed in order to protect freedom. David Feldman[112] beautifully describes as to why freedom (or liberty) is given:

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111 *Prem Shankar Shukla* v. *State (UT of Delhi)*, (1980) 3 SCC 526 : 1980 SCC (Cri) 815; *Francis Coralie Mullin* v. *State (UT of Delhi)*, (1981) 1 SCC 608 : 1981 SCC (Cri) 212; *Bandhua Mukti Morcha* v. *Union of India*, (1984) 3 SCC 161 : 1984 SCC (L&S) 389; *Khedat Mazdoor Chetna Sangath* v. *State of M.P.*, (1994) 6 SCC 260 : 1994 SCC (Cri) 1643; *M. Nagaraj* v. *Union of India*, (2006) 8 SCC 212 : (2007) 1 SCC (L&S) 1013; *Maharashtra University of Health Sciences* v. *Satchikitsa Prasarak Mandal*, (2010) 3 SCC 786 : (2010) 1 SCC (L&S) 894; *Selvi* v. *State of Karnataka*, (2010) 7 SCC 263 : (2010) 3 SCC (Cri) 1; *Mehmood Nayyar Azam* v. *State of Chhattisgarh*, (2012) 8 SCC 1 : (2012) 4 SCC (Civ) 34 : (2012) 3 SCC (Cri) 733 : (2012) 2 SCC (L&S) 449; *Shabnam* v. *Union of India*, (2015) 6 SCC 702 : (2015) 3 SCC (Cri) 355; *Jeeja Ghosh* v. *Union of India*, (2016) 7 SCC 761 : (2016) 3 SCC (Civ) 551.

58 *K.S. Puttaswamy* v. *Union of India*, (2017) 10 SCC 1

112 David Feldman: *Civil Liberties & Human Rights in England & Wales.*

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"The guiding principle for many liberal rights theorists may be seen as respect for individuals' own aspirations, as a means of giving the fullest expression to each individual's moral autonomy. A fundamental principle entailed by respect for moral autonomy is that individuals should prima facie be free to select their own ideas of the Good, and develop a plan for life, or day-to-day strategy, accordingly. Their choice of goods should be constrained only to the extent necessary to protect society and the similar liberties of other people. The law should protect at least the basic liberties, that is, those necessary to the pursuit of any socially acceptable conception of the good life. This is the approach which John Rawls adopts in *A Theory of Justice*. It requires that basic liberties be given considerable respect, and that they should have priority over the pursuit of social goods (such as economic development) perhaps even to the extent of giving them the status of entrenched, constitutional rights, in order to shield them from challenge in the day-to-day rough and tumble of political contention. This gives liberty a priority over other values, which, whether viewed as a description of liberal society or as a prescription for its improvement, is very controversial. Philosophers have doubted whether there are adequate grounds for the priority of liberty. Professor H.L.A. Hart has argued that (at least in a society where there is limited abundance of wealth and resources) it is rational to prefer basic freedoms to an improvement I material conditions only if one harbours the ideal of 'a public-spirited citizen who prizes political activity and service to others as among the chief goods of life and could not contemplate as tolerable an exchange of the opportunities of such activity for mere material goods or contentment'.

A rather different thesis runs through Professor Joseph Raz's book, *The Morality of Freedom*: people are autonomous moral actors, and autonomy is given expression primarily through making one's own decisions, but such freedom is valuable partly because it advances social ends. Raz points out that the identification of basic liberties therefore depends, in part at least, on governmental notions of the public good. In respect of rights to freedom of expression, privacy, freedom of religion, and freedom from discrimination, for example, 'one reason for affording special protection to individual interests is that thereby one also protects a collective good, an aspect of a public culture'. At the same time, certain social goods are needed if freedom is to have value. Freedom is useful only if the social and economic structure of society provides a sufficient range of choices to allow people's capacity for choice to be exercised. Accordingly, freedom is seen as a collective rather than an individual good. This may constrain the range of freedoms and the purposes to which they may morally be put: a decision to make a freedom into a constitutional right is an expression of the collective political culture of a community. This thesis does not make the morality of freedom depend on people striving for perfection: individuals may not always, or ever, think about the moral consequences of their decisions, or may consciously make decisions which do not make for self-improvement. Instead, it looks only for a social commitment to the idea of the moral significance of individual choice. Raz marries the idea of the individual to that of society by recognizing that individual freedom of choice is contingent on social arrangements."

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302. In his article, "Life's Dominion", Ronald Dworkin, while building the hypothesis on dignity concept, exhorts that people must decide about their own death, or someone else's in three main kinds of situations, namely:

(*i*) *conscious and competent*: it is a situation where a person is suffering from some serious illness because of which he is incapacitated but he is still conscious and also competent to decide about his fate, he should be given a choice to decide as to whether he wants to continue to get the treatment;

(*ii*) *unconscious*: where the patient is unconscious and dying, doctors are often forced to decide whether to continue life support for him or not; under certain circumstances relatives have to take a decision. However, at times, unconscious patients are not about to die. At the same time, they are either in coma or in PVS. In either case, they are conscious. In such a situation, where recovery is impossible, it should be left to the relatives to decide as to whether they want the patient to remain on life support (ventilator, etc.); and

(*iii*) *conscious but incompetent.*

These factors may support, what is known as "*living will*" or "*Advance Directive*", which aspect is dealt with specifically while answering the second issue.

303. When a person is undergoing untold suffering and misery because of the disease with which he is suffering and at times even unable to bear the same, continuing to put him on artificial machines to prolong his vegetable life would amount to violating his dignity. These are the arguments which are raised by some jurists and sociologists.[113]

304. There is a related, but interesting, aspect of this dignity which needs to be emphasised. Right to health is a part of Article 21 of the Constitution. At the same time, it is also a harsh reality that everybody is not able to enjoy that right because of poverty, etc. The State is not in a position to translate into reality this right to health for all citizens. Thus, when citizens are not guaranteed the right to health, can they be denied right to die in dignity?

305. In the context of euthanasia, "personal autonomy" of an individual, as a part of human dignity, can be pressed into service. In *National Legal Services Authority* v. *Union of India*[63], this Court observed: (SCC p. 491, para 75)

"*75.* Article 21, as already indicated, guarantees the protection of "personal autonomy" of an individual. In *Anuj Garg* v. *Hotel Assn. of India*[114] (SCC p. 15, paras 34-35), this Court held that personal autonomy includes both the negative right of not to be subject to interference by others and the positive right of individuals to make decisions about their life, to express themselves and to choose which activities to take part in. Self-determination of gender is an integral part of personal autonomy and self-

113 (*i*) Morris: Voluntary Euthanasia

(*ii*) L.W. Sumner: "Dignity through Thick and Thin", in Sebastian Muders, *Human Dignity and Assisted Death* (Oxford University Press, 2017).

63 (2014) 5 SCC 438

114 (2008) 3 SCC 1

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expression and falls within the realm of personal liberty guaranteed under Article 21 of the Constitution of India."

306. In addition to personal autonomy, other facets of human dignity, namely, "self-expression" and "right to determine" also support the argument that it is the choice of the patient to receive or not to receive treatment.

307. We may again mention that talking particularly about certain hard cases involving moral overtones, Dworkin specifically discussed the issues pertaining to abortion and euthanasia with emphasis that both supporters and critics accept the idea of sanctity of life. Decisions regarding death—whether by abortion or by euthanasia—affect our human dignity. In Dworkin's opinion, proper recognition of human dignity leads to the recognition of the freedom of the individual. Freedom is a necessary condition for self-worth. Dworkin adds: "Because we cherish dignity, we insist on freedom.... *Because we honour dignity, we demand democracy*."[115]

308. Dignity is, thus, the core value of life and dying in dignity stands recognised in *Gian Kaur*[10]. It becomes a part of right of self-determination.

309. The important message behind Dworkin's concept of human dignity can be summarised in the following manner:

309.1. He describes belief in individual human dignity as the most important feature of Western political culture giving people the moral right "to confront the most fundamental questions about the meaning and value of their own lives"[116].

309.2. In an age when people value their independence and strive to live independent and fulfilled lives, it is important "that life ends *appropriately*, that death keeps faith with the way we want to have lived"[117].

309.3. Death is "not only the start of nothing but the end of everything"[118] and, therefore, it should be accomplished in a manner compatible with the ideals sought during life.

310. Taking into consideration the conceptual aspects of dignity and the manner in which it has been judicially adopted by various judgments, the following elements of dignity can be highlighted (in the context of death with dignity):

310.1. Encompasses *self-determination*; implies a quality of life consistent with the ability to exercise self-determined choices;

310.2. Maintains/ability to make *autonomous choices*; high regard for individual autonomy that is pivotal to the perceived quality of a person's life;

310.3. *Self-control* (retain a similar kind of control over dying as one has exercised during life—a way of achieving death with dignity);

115 Ronald Dworkin, *Life's Dominion* (2nd Edn., Vintage Books, New York 1944) 239.
10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374
116 R. Dworkin, *Life's Dominion* (London, Harper-Collins, 1993) at p. 166.
117 *Id* at p. 179.
118 *Ibid.*

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310.4. Law of *consent*: The ability to choose—orchestrate the timing of their own death;

310.5. Dignity may be compromised if the dying process is prolonged and involves becoming incapacitated and dependent;

310.6. Respect for human dignity means respecting the *intrinsic value of human life*;

310.7. Avoidance of dependency;

310.8. Indefinite continuation of futile physical life is regarded as undignified;

310.9. Dignity commands emphatic respect[119]:

310.9.1. Reason and emotion are both significant in treatment decisions, especially at the end of life where compassion is a natural response to appeals made on the basis of stifled self-determination;

310.9.2. Compassion represents a collision of "imaginative insight" and empathy; and

310.9.3. Compassion is here distinguished from pity, which is regarded as "inappropriate to the dignity of the autonomous person, especially its overtones of paternalism",[120] because compassion is believed to provoke an active, and by implication positive, response.[121]

310.10. Dignity *engenders a sense of serenity and powerfulness*, fortified by "qualities of composure, calmness, restraint, reserve, and emotions or passions subdued and securely controlled without being negated or dissolved"[122]; and

310.11. *Observer's dignity aspect*:

310.11.1. A person possessed of dignity at the end of life, might induce in an observer a sense of tranquility and admiration which inspires images of power and self-assertion through restraint and poised composure; and

310.11.2. Dignity clearly does play a valuable role in contextualising people's perceptions of death and dying, especially as it appears to embody a spirit of self-determination that advocates of voluntary euthanasia crave.

311. Once we examine the matter in the aforesaid perspective, the inevitable conclusion would be that passive euthanasia and death with dignity are inextricably linked, which can be summed up with the following pointers:

311.1. The opportunity to die unencumbered by the intrusion of medical technology and before experiencing loss of independence and control, appears

119 A. Kolnai, "Dignity", in R.S. Dillon (Ed.) *Dignity, Character, and Self-Respect* (London, Routledge, 1995) 53-75, at 55.

120 R.S. Downie, K.S. Calman, *Healthy Respect: Ethics in Healthcare* (Oxford, Oxford University Press, 1994) at 51-53.

121 *Ibid.*

122 A. Kolnai, "Dignity", in R.S. Dillon (Ed.) *Dignity, Character, and Self-Respect* (London, Routledge, 1995) 53-75, at 56.

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to many to extend the promise of a dignified death. When medical technology intervenes to prolong dying like this it does not do so unobtrusively;

311.2. Today many patients insist on more than just a right to healthcare in general. They seek a right to choose specific types of treatment, able to retain control throughout the entire span of their lives and to exercise autonomy in all medical decisions concerning their welfare and treatment;

311.3. A dreadful, painful death on a rational but incapacitated terminally-ill patient are an affront to human dignity.

312. The aforesaid discussion takes care of those who oppose euthanasia on moral and ethical principles. We feel that at least the case for passive euthanasia is made out. Certain moral dilemma as to what is the exact stage when such a decision to withdraw medical support, would still remain. At times, a physician would be filled with profound ethical uncertainties when a person is suffering unbearable pain and agony, the question would be as to whether such suffering has reached the stage where it is incurable and, therefore, decision should be taken to allow such person to pass away in peace and dignity of hastening the process of death or the situation may be reversible, though chances thereof are far remote. Dr R.R. Kishore, who possesses medical as well as law degree at the same time, lists the following questions which a physician will have to answer while taking such a decision:

(*i*) Is it professionally permissible to kill or to help in dying a terminally ill and incurable patient?

(*ii*) How does such a decision affect the person concerned and the society in general?

(*iii*) What are the values that are attracted in such situations?

(*iv*) How to assess that the individual's urge to die is based on cool and candid considerations and is not an impulsive act reflecting resources constraints, inadequate care or discrimination?

(*v*) What are the practical risks involved in case a decision is taken to terminate the life of the patient?

(*vi*) Where should the physician look for guidance in situations of such moral dilemma?

(*vii*) Does the physician's or the patient's religion play any role in decision-making process?

313. What are the parameters to be kept in mind and the dangers which may be encountered while taking decision on the aforesaid questions, is beautifully explained by Dr R.R. Kishore[123] in the following words:

"Contemporary world order is founded on reason, equity and dignity. Reason envisages definition and distinctness. What is the distinction between "killing" and "letting die"? or, in other words, what is the difference between "causing death" and "denial to prevent death"? Also,

123 Dr R.R. Kishore, MD, LLB — *End of Life Issues and the Moral Certainty: A Discovery Through Hinduism.*

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can the prolongation of life be ever "unnecessary"? And, if yes, what are the criteria to determine the life's worth? Equity mandates equality of opportunity, balancing of interests and optimisation of resources. This means addressing questions such as; For how long one should live? Who should die first? What should be the ideal method of terminating one's life? Dignity imposes obligation to preserve life at all costs and in the event of an individual's conscious expression to end his life, contemplates a valid purpose and truly informed consent. Deontologically, in the context of sanctity of life, there is not much of conflict between secular and religious concepts as both consider life as sacred and worthy of protection. But, the differences appear in the face of application of advanced technology which has the potential of keeping alive the terminally ill and incurable persons who would have otherwise died. Since the technological resources are not unlimited prioritisation becomes a functional imperative, bringing in the concepts of worth and utility. In other words, the questions like whose life is more precious and worthy of protection have to be answered. This is a formidable task, attracting multiple and diverse perspectives, moral as well as strategic, leading to heterogeneous approaches and despite agreement on fundamental issue of value of life the decisions may seem to be at variance. A fair and objective decision in such circumstances may be a difficult exercise and any liberalisation is fraught with following apprehensions:

(*i*) Danger of abuse;

(*ii*) Enhanced vulnerability to the poor;

(*iii*) Slippery slope outcome;

(*iv*) Weakening of protection of life notions.

Any ethical model governing end of life decisions should therefore be impervious to all extraneous forces such as, the utilitarian bias, poverty, and subjectivity i.e. inadequate appreciation of socio-economic, family, cultural and religious perspectives of the individual. The poor and resourceless are likely to face deeper and more severe pain and agony before dying and as such may request their physicians to terminate their lives much earlier than those who have better access to resources. This poverty-death nexus makes an objective decision difficult, constituting a formidable challenge to committed physicians and others involved with the end of life issues. Taking a decision on case-to-case basis, depending on individual's material constraints and inadequacies, enhances the problem rather than solving it, as it reduces the life from an eternal bliss to a worldly award, subjecting its preservation to socio-economic exigencies. For these reasons, many feel that the safer and more respectable course to improve death is to provide good palliative care and emotional support rather than assisting the end of life. The moral ambiguities notwithstanding, decision to assist or not to assist the act of dying by correctly interpreting the patient's wish and the accompanying circumstances, including the moral dictates, constitutes a practical problem. Let us see how Hinduism addresses these issues."

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314. In the article, "End of Life Issues and the Moral Certainty"[124], the author after posing the moral dilemma, noted above, discusses the approach to find the solutions.

315. I had indicated at the earlier stage that Hippocratic Oath, coupled with ethical norms of medical profession, stand in the way of euthanasia. It brings about a situation of dilemma insofar as medical practitioner is concerned. On the one hand his duty is to save the life of a person till he is alive, even when the patient is terminally ill and there are no chances of revival. On the other hand, the concept of dignity and right to bodily integrity, which recognises legal right of autonomy and choice to the patient (or even to his relations in certain circumstances, particularly when the patient is unconscious or incapacitated to take a decision) may lead to exercising his right of euthanasia.

316. Dignity implies, apart from a right to life enjoyment of right to be free of physical interference. At common law, any physical interference with a person is, prima facie, tortious. If it interferes with freedom of movement, it may constitute a false imprisonment. If it involves physical touching, it may constitute a battery. If it puts a person in fear of violence, it may amount to an assault. For any of these wrongs, the victim may be able to obtain damages.

317. When it comes to medical treatment, even there the general common law principle is that any medical treatment constitutes a trespass to the person which must be justified, by reference either to the patient's consent or to the necessity of saving life in circumstances where the patient is unable to decide whether or not to consent.

318. Rights with regard to medical treatment fall essentially into two categories: first, rights to receive or be free of treatment as needed or desired, and not to be subjected involuntarily to experimentation which, irrespective of any benefit which the subjects may derive, are intended to advance scientific knowledge and benefit people other than the subject in the long term; secondly, rights connected incidentally with the provision of medical services, such as rights to be told the truth by one's doctor.

319. Having regard to the aforesaid right of the patients in common law, coupled with the dignity and privacy rights, it can be said that passive euthanasia, under those circumstances where patient is in PVS and he is terminally ill, where the condition is irreversible or where he is brain dead, can be permitted. On the aforesaid reasoning, I am in agreement with the opinion of the other members of this Bench in approving the judgment in *Aruna Ramachandra Shanbaug*[5].

124 Dr R.R. Kishore, "End of Life Issues and the Moral Certainty: A Discovery Through Hinduism" Eubios Journal of Asian and International Bioethics, Vol. 13(6), Nov. 2003 at pp. 210-13.

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

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(D) ***Economics of euthanasia***

320. This is yet another reason for arriving at the same conclusion.

321. When we consider the matter of euthanasia in the context of economic principles, it becomes another reason to support the aforesaid conclusion. This aspect can be dealt with in two ways:

321.1. First, because of rampant poverty where majority of the persons are not able to afford health services, should they be forced to spend on medical treatment beyond their means and in the process compelling them to sell their house property, household things and other assets which may be means of livelihood.

321.2. Secondly, when there are limited medical facilities available, should a major part thereof be consumed on those patients who have no chances of recovery?

322. In *Economic & Political Weekly* dated 10-2-2018, it is reported:

> "India is one of the worst countries to die in, especially for those suffering from terminal illnesses. In 2015, the Economist Intelligence Unit brought out a Quality of Death Index, which ranked India 67th out of the 80 countries it had surveyed. In December 2017, a joint report published by the World Health Organization and the World Bank revealed that 49 million Indians are pushed into poverty every year due to out-of-pocket expenditure on healthcare, accounting for half of the 100 million who meet such a fate worldwide. India's Central Bureau of Health Intelligence data puts the figure even higher. This unconscionable situation is the direct outcome of the sorry state of our public health system. India's spending on health is among the lowest in the world. The Economic Survey 2017-18 shows that the Government spends only 1.4% of its gross domestic product (GDP) on health. The 2017 National Health Policy, which otherwise exudes piety in its abstractions, aims to increase government expenditure to 2.5% of GDP by 2025. By all accounts, this is too little too late.
>
> The situation improves only marginally for the better-off sections. With over 90% of intensive care units in the private healthcare sector, it is largely this section that can access expensive treatments. But this does not improve end-of-life situations for them. Awareness and training in palliative care remain grossly inadequate. For those making profit in the private healthcare sector, there is no incentive to provide such treatment. Instead, treatment for the terminally ill continues to involve prolonging life with expensive, invasive, and painful treatment with very little concern for the patients themselves or their families."

323. Some of the apprehensions expressed in ethical debates about euthanasia can be answered when the ethical debate about euthanasia is not divorced from an economic consideration of cost and benefits of euthanasia to society. P.R. Ward[125] argues that ethics is concerned with individuals and, therefore, does not take into account the societal perspective. On the other hand, economics is sought to be concerned with relative costs and benefits to society

125 "Healthcare Rationing: Can We Afford to Ignore Euthanasia?", Health Services Management Research 1997; 10; 32-41.

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and can help to determine if euthanasia is of benefit to the majority in society. According to him, the net benefit to the individual (from ethical considerations) can be compared with the net benefit to society (from economics), and that both can be included in an overall decision rule for whether or not to legalise euthanasia. Ward draws on the health economics literature (for example, Mooney[126]) to suggest that a positive answer to this question is implicit in many health-rationing decisions and is applicable to the euthanasia decision. He also asserts that "*introducing an economic perspective is not incompatible with ethical issues*".

324. No doubt, protagonists of ethical aspects of euthanasia oppose the aforesaid view. According to them, euthanasia also involves the specific act of a medical professional killing a patient and the ethical status of this act has implications both for individuals and for society. Their counter-argument, therefore, is that to be able to make an economic assessment of euthanasia, we would have to be able to evaluate the cost and benefits of this act of killing. However, even they accept that if the act of killing by euthanasia is ethically acceptable in some circumstances, it would be appropriate to consider the net benefits of the act to the individual patient along with the wider economic considerations[127]. In the instant case, we have come to the conclusion that under certain circumstances i.e. when the patient is in PVS or brain dead/ clinically dead, at least passive euthanasia would even be ethically acceptable, on the application of doctrine of dignity. In such a situation, the economic considerations would strengthen the aforesaid conclusion.

325. At times, for deciding legal issues, economic analysis of law assumes importance[128]. It is advocated that one of the main reasons which should prompt philosophers of law to undertake economic analysis seriously is that the most basic notion in the analysis—efficiency or Pareto optimality[129]—was originally introduced to help solve a serious objection to widely held moral theory, utilitarian. Utilitarians hold that the principle of utility is the criterion of the right conduct. If one has to evaluate policies in virtue of their effect on individual welfare or utility, one norm of utility has to be compared with that of another. We may clarify that this economic principle has been applied in a limited sense only as a supporting consideration with the aim to promote efficiency.

326. If we understand correctly the logic behind opposition to euthanasia, particularly, passive euthanasia, it proceeds on the basis that third person should not have right to take a decision about one's life and, more importantly, it is

126 Mooney G., *The Valuation of Human Life*, London: Macmillan Press, 1977.

127 See *Economics and Euthanasia* by Stephen Heasell, Department of Economics and Politics, Nottingham Trent University, and David Paton, Nottingham University Business School.

128 This aspect is discussed in some detail by this Court in *Shivashakti Sugars Ltd.* v. *Shree Renuka Sugar Ltd.*, (2017) 7 SCC 729 : (2017) 4 SCC (Civ) 234.

129 Jeffrie G. Murphy & Jules L. Coleman: *Philosophy of Law (An Introduction to Jurisprudence).*

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difficult to ascertain, at a particular stage, as to whether time has come to take such a decision, namely, withdraw the medical support. Insofar as latter aspect is concerned, we feel that in *Aruna Ramachandra Shanbaug*[5], this Court has taken due care in prescribing the circumstances, namely, when the person is in a permanent vegetative state (PVS) with no reversible chance or when he is "brain dead" or "clinically dead". Insofar as first aspect is concerned, the subject-matter of the present writ petition takes care of that.

The second issue

327. With this, we advert to the second question formulated above, which is as under:

> ***Whether a "living will" or "Advance Directive" should be legally recognised and can be enforced? If so, under what circumstances and what precautions are required while permitting it?***

328. In this writ petition, the petitioner has sought a direction to the respondents to adopt suitable procedures to ensure that persons of deteriorated health or terminally ill should be able to execute a document titled "living will and/or advance authorisation" which can be presented to the hospital for appropriate action in the event of the executant being admitted to the hospital with serious illness which may threaten termination of life of the executant. In a nutshell, the petitioner wants that citizens should have right to decide in advance not to accept any kind of treatment at a stage when they are terminally ill. Expressing this in advance in a document is known as "living will" or "Advance Directive", whereby the aforesaid self-determination of the person is to be acted upon when he reaches PVS or is brain dead/clinically dead.

329. It is an undisputed fact that doctors' primary duty is to provide treatment and save life but not in the case when a person has already expressed his desire of not being subjected to any kind of treatment. It is a common law right of people, of any civilized country, to refuse unwanted medical treatment and no person can force him/her to take any medical treatment which the person does not desire to continue with. The foundation of the aforesaid right has already been laid down by this Court in *Aruna Ramachandra Shanbaug*[5] while dealing with the issue of "involuntary passive euthanasia". To quote: (SCC pp. 497-98, 501 & 502, paras 66, 67 & 78)

> "*66.* Passive euthanasia is usually defined as withdrawing medical treatment with a deliberate intention of causing the patient's death. For example, if a patient requires kidney dialysis to survive, not giving dialysis although the machine is available, is passive euthanasia. Similarly, if a patient is in coma or on a heart-lung machine, withdrawing of the machine will ordinarily result in passive euthanasia. Similarly not giving life-saving medicines like antibiotics in certain situations may result in passive euthanasia. Denying food to a person in coma or PVS may also amount to passive euthanasia.

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

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67. As already stated above, euthanasia can be both voluntary or non-voluntary. In voluntary passive euthanasia a person who is capable of deciding for himself decides that he would prefer to die (which may be for various reasons e.g. that he is in great pain or that the money being spent on his treatment should instead be given to his family who are in greater need, etc.), and for this purpose he consciously and of his own free will refuses to take life-saving medicines. In India, if a person consciously and voluntarily refuses to take life-saving medical treatment it is not a crime...

* * *

78. ... 'First, it is established that the principle of self-determination requires that respect must be given to the wishes of the patient, so that if an adult patient of sound mind refuses, however unreasonably, to consent to treatment or care by which his life would or might be prolonged, the doctors responsible for his care must give effect to his wishes, even though they do not consider it to be in his best interests to do so [see *Schloendorff* v. *Society of New York Hospital*[42], NE at p. 93, per Cardozo, J.; *S.* v. *McC. (Orse. S.) and M. (D.S. Intervener)*[130], AC at p. 43, per Lord Reid; and *Sidaway* v. *Board of Governors of the Bethlem Royal Hospital*[131], AC at p. 882, per Lord Scarman]. To this extent, the principle of the sanctity of human life must yield to the principle of self-determination [*see* (Court of Appeal transcript in the present case, at p. 38 F per Hoffmann, L.J.)], and, for present purposes perhaps more important, the doctor's duty to act in the best interests of his patient must likewise be qualified. On this basis, it has been held that a patient of sound mind may, if properly informed, require that life support should be discontinued (see *Nancy B.* v. *Hotel Dieu de Quebec*[132]). Moreover the same principle applies where the patient's refusal to give his consent has been expressed at an earlier date, before he became unconscious or otherwise incapable of communicating it; though in such circumstances especial care may be necessary to ensure that the prior refusal of consent is still properly to be regarded as applicable in the circumstances which have subsequently occurred [see e.g. *T. (Adult: Refusal of Treatment), In re*[133]]. I wish to add that, in *cases of this kind, there is no question of the patient having committed suicide, nor therefore of the doctor having aided or abetted him in doing so*. It is simply that the patient has, as he is entitled to do, declined to consent to treatment which might or would have the effect of prolonging his life, and the doctor has, in accordance with his duty, complied with his patient's wishes.' (*Airedale case*[11], AC p. 864 C-G) (emphasis in original)

42 105 NE 92 : 211 NY 125 (1914)
130 1972 AC 24 : (1970) 3 WLR 366 (HL)
131 1985 AC 871 : (1985) 2 WLR 480 : (1985) 1 All ER 643 (HL)
132 (1992) 86 DLR (4th) 385 (Que SC)
133 1993 Fam 95 : (1992) 3 WLR 782 : (1992) 4 All ER 649 (CA)
11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

330. The aforesaid principle has also been recognised by this Court in its Constitution Bench judgment passed in *Gian Kaur*[10] wherein it was held that although "*right to life*" under Article 21 does not include "*right to die*", but "*right to live with dignity*" includes "*right to die with dignity*". To quote: (SCC pp. 660-61, paras 24 & 25)

> "*24*. Protagonism of euthanasia on the view that existence in persistent vegetative state (PVS) is not a benefit to the patient of a terminal illness being unrelated to the principle of "sanctity of life" or the "right to live with dignity" is of no assistance to determine the scope of Article 21 for deciding whether the guarantee of "right to life" therein includes the "right to die". The "right to life" including the right to live with human dignity would mean the existence of such a right up to the end of natural life. This also includes the right to a dignified life up to the point of death including a dignified procedure of death. In other words, this may include the right of a dying man to also die with dignity when his life is ebbing out. But the "right to die" with dignity at the end of life is not to be confused or equated with the "right to die" an unnatural death curtailing the natural span of life.
>
> *25*. A question may arise, in the context of a dying man who is terminally ill or in a persistent vegetative state that he may be permitted to terminate it by a premature extinction of his life in those circumstances. This category of cases may fall within the ambit of the "right to die" with dignity as a part of right to live with dignity, when death due to termination of natural life is certain and imminent and the process of natural death has commenced. These are not cases of extinguishing life but only of accelerating conclusion of the process of natural death which has already commenced. The debate even in such cases to permit physician-assisted termination of life is inconclusive. It is sufficient to reiterate that the argument to support the view of permitting termination of life in such cases to reduce the period of suffering during the process of certain natural death is not available to interpret Article 21 to include therein the right to curtail the natural span of life."

331. In fact, the Law Commission of India was asked to consider on the feasibility of making legislation on euthanasia, taking into account the earlier 196th Report of the Law Commission as well as the judgment of this Court in *Aruna Ramachandra Shanbaug*[5]. In August 2012, the Law Commission came out with a detailed 241st Report on the issue of passive euthanasia, wherein it approved the concept of right to self-determination also. The Law Commission made some important observations in its Report such as:

> "2.4. The following pertinent observations made by the then Chairman of the Law Commission in the forwarding letter dated 28-8-2006 addressed to the Hon'ble Minister are extracted below:

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

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'A hundred years ago, when medicine and medical technology had not invented the artificial methods of keeping a terminally-ill patient alive by medical treatment, including by means of ventilators and artificial feeding, such patients were meeting their death on account of natural causes. Today, it is accepted, a terminally ill person has a common law right to refuse modern medical procedures and allow nature to take its own course, as was done in good old times. It is well-settled law in all countries that a terminally-ill patient who is conscious and is competent, can take an "informed decision" to die a natural death and direct that he or she be not given medical treatment which may merely prolong life. There are currently a large number of such patients who have reached a stage in their illness when according to well-informed body of medical opinion, there are no chances of recovery. But modern medicine and technology may yet enable such patients to prolong life to no purpose and during such prolongation, patients could go through extreme pain and suffering. Several such patients prefer palliative care for reducing pain and suffering and do not want medical treatment which will merely prolong life or postpone death.'

* * *

5.2. The 196th Report of the Law Commission stated the fundamental principle that a terminally ill but competent patient has a right to refuse treatment including discontinuance of life-sustaining measures and the same is binding on the doctor, "provided that the decision of the patient is an "informed decision" ". "*Patient*" has been defined as a person suffering from terminal illness. "*Terminal illness*" has also been defined under Section 2(*m*). The definition of a "*competent patient*" has to be understood by the definition of "incompetent patient". "*Incompetent patient*" means a patient who is a minor or a person of unsound mind or a patient who is unable to weigh, understand or retain the relevant information about his or her medical treatment or unable to make an "informed decision" because of impairment of or a disturbance in the functioning of the mind or brain or a person who is unable to communicate the informed decision regarding medical treatment through speech, sign or language or any other mode [vide Section 2(*d*) of the 2006 Bill]. "*Medical treatment*" has been defined in Section 2(*i*) as treatment intended to sustain, restore or replace vital functions which, when applied to a patient suffering from terminal illness, would serve only to prolong the process of dying and *includes* life-sustaining treatment by way of surgical operation or the administration of medicine, etc. and use of mechanical or artificial means such as ventilation, artificial nutrition and cardio resuscitation. The expressions "best interests" and "informed decision" have also been defined in the proposed Bill. "*Best interests*", according to Section 2(*b*), includes the best interests of both on incompetent patient and competent patient who has not taken an informed decision and it ought not to be limited to medical interests of the patient but

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includes ethical, social, emotional and other welfare considerations. The term "*informed decision*" means, as per Section 2(*e*)

'the decision as to continuance or withholding or withdrawing medical treatment taken by a patient who is competent and who is, or has been informed about—

(*i*) the nature of his or her illness;

(*ii*) any alternative form of treatment that may be available;

(*iii*) the consequences of those forms of treatment; and

(*iv*) the consequences of remaining untreated'.

* * *

5.8. The Law Commission of India clarified that where a competent patient takes an "informed decision" to allow nature to have its course, the patient is, under common law, not guilty of attempt to commit suicide (under Section 309 IPC) nor is the doctor who omits to give treatment, guilty of abetting suicide (under Section 306 IPC) or of culpable homicide (under Section 299 read with Section 304 IPC).

* * *

7.2. In this context, two cardinal principles of medical ethics are stated to be patient autonomy and beneficence (vide p. 482, para 12 of SCC in *Aruna case*[5]):

'*12.* ... '*1.* Autonomy means the right to self-determination, where the informed patient has a right to choose the manner of his treatment. To be autonomous, the patient should be competent to make decision and choices. In the event that he is incompetent to make choices, his wishes expressed in advance in the form of a living will, OR the wishes of surrogates acting on his behalf (substituted judgment) are to be respected.

The surrogate is expected to represent what the patient may have decided had he/she been competent, or to act in the patient's best interest. ...

2. Beneficence is acting in what is (or judged to be) in the patient's best interest. Acting in the patient's best interest means following a course of action that is best for the patient, and is not influenced by personal convictions, motives or other considerations. ...'

* * *

11.2. The discussion in the foregoing paras and the weighty opinions of the Judges of highest courts as well as the considered views of Law Commission (in 196th Report) would furnish an answer to the above question in clearest terms to the effect that legally and constitutionally, the patient (competent) has a right to refuse medical treatment resulting in temporary prolongation of life. The patient's life is at the brink of

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

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extinction. There is no slightest hope of recovery. The patient undergoing terrible suffering and worst mental agony does not want his life to be prolonged by artificial means. She/he would not like to spend for his treatment which is practically worthless. She/he cares for his bodily integrity rather than bodily suffering. She/he would not like to live like a "cabbage" in an intensive care unit for some days or months till the inevitable death occurs. He would like to have the right of privacy protected which implies protection from interference and bodily invasion. As observed in *Gian Kaur case*[10], the natural process of his death has already commenced and he would like to die with peace and dignity. No law can inhibit him from opting such course. This is not a situation comparable to suicide, keeping aside the view point in favour of decriminalising the attempt to suicide. The doctor or relatives cannot compel him to have invasive medical treatment by artificial means or treatment. If there is forced medical intervention on his body, according to the decisions cited supra (especially the remarks of Lord Browne-Wilkinson in *Airedale case*[11]), the doctor/surgeon is guilty of "assault" or "battery". In the words of Justice Cardozo[42], 'every human being of adult years and sound mind has a right to determine what shall be done with his own body and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages'. Lord Goff in *Airedale case*[11] places the right to self-determination on a high pedestal. He observed that 'in the circumstances such as this, the principle of sanctity of human life must yield to the principle of self-determination and the doctor's duty to act in the best interests of the patient must likewise be qualified by the wish of the patient." The following observations of Lord Goff deserve particular notice: (AC p. 864G)

> '... I wish to add that, in cases of this kind, there is no question of the patient having committed suicide, nor therefore of the doctor having aided or abetted him in doing so. It is simply that the patient has, as he is entitled to do, declined to consent to treatment which might or would have the effect of prolonging his life, and the doctor has, in accordance with his duty, complied with his patient's wishes.' " (emphasis in original)

332. And finally, the Law Commission in its 241st Report gave Summary of Recommendations as under:

> "14. *Summary of Recommendations*
>
> 14.1. Passive euthanasia, which is allowed in many countries, shall have legal recognition in our country too subject to certain safeguards, as suggested by the 17th Law Commission of India and as held by the

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374

11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

42 *Schloendorff* v. *Society of New York Hospital*, 105 NE 92 : 211 NY 125 (1914)

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Supreme Court in *Aruna Ramachandra case*[5]. It is not objectionable from legal and constitutional point of view.

14.2. A competent adult patient has the right to insist that there should be no invasive medical treatment by way of artificial life-sustaining measures/treatment and such decision is binding on the doctors/hospital attending on such patient provided that the doctor is satisfied that the patient has taken an "informed decision" based on free exercise of his or her will. The same rule will apply to a minor above 16 years of age who has expressed his or her wish not to have such treatment provided the consent has been given by the major spouse and one of the parents of such minor patient.

14.3. As regards an incompetent patient such as a person in irreversible coma or in persistent vegetative state and a competent patient who has not taken an "informed decision", the doctor's or relatives' decision to withhold or withdraw the medical treatment is not final. The relatives, next friend, or the doctors concerned/hospital management shall get the clearance from the High Court for withdrawing or withholding the life-sustaining treatment.

In this respect, the recommendations of the Law Commission in 196th report are somewhat different. The Law Commission proposed an enabling provision to move the High Court.

14.4. The High Court shall take a decision after obtaining the opinion of a panel of three medical experts and after ascertaining the wishes of the relatives of the patient. The High Court, as parens patriae will take an appropriate decision having regard to the best interests of the patient.

14.5. Provisions are introduced for protection of medical practitioners and others who act according to the wishes of the competent patient or the order of the High Court from criminal or civil action. Further, a competent patient (who is terminally ill) refusing medical treatment shall not be deemed to be guilty of any offence under any law.

14.6. The procedure for preparation of panels has been set out broadly in conformity with the recommendations of the 17th Law Commission. Advance Medical Directive given by the patient before his illness is not valid.

14.7. Notwithstanding that medical treatment has been withheld or withdrawn in accordance with the provisions referred to above, palliative care can be extended to the competent and incompetent patients.

The Governments have to devise schemes for palliative care at affordable cost to terminally-ill patients undergoing intractable suffering.

14.8. The Medical Council of India is required to issue guidelines in the matter of withholding or withdrawing of medical treatment to competent or incompetent patients suffering from terminal illness.

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

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14.9. Accordingly, the Medical Treatment of Terminally-Ill Patients (Protection of Patients and Medical Practitioners) Bill, 2006, drafted by the 17th Law Commission in the 196th Report has been modified and the revised Bill is practically an amalgam of the earlier recommendations of the Law Commission and the views/directions of the Supreme Court in *Aruna Ramachandra case*[5]. The revised Bill is at Annexure I."

333. I am also of the view that such an advance authority is akin to well-recognised common law right to refuse medical treatment [see: *T. (Adult: Refusal of Treatment), In re*[133], *B. (Adult: Refusal of Medical Treatment), In re*[134], *Cruzan* v. *Missouri Deptt. of Health*[4], *Malette* v. *Shulman*[45]].

334. In a recent landmark judgment of the nine-Judge Constitution Bench in *K.S. Puttaswamy*[58] authoritatively held that right to life enshrined in Article 21 includes right to privacy. One of the facet of this right acknowledged is an individual's decision to refuse life prolonging medical treatment or terminate his life. Chelameswar, J. in his separate opinion has described the same in the following manner: (SCC pp. 530-31, para 373)

"*373*. Concerns of privacy arise when the State seeks to intrude into the body of subjects. [*Skinner* v. *Oklahoma*[135]: '*20*. There are limits to the extent to which a legislatively represented majority may conduct biological experiments at the expense of the dignity and personality and natural powers of a minority—even those who have been guilty of what the majority defines as crimes.' (SCC OnLine US SC para 20)—Jackson, J.] Corporeal punishments were not unknown to India, their abolition is of a recent vintage. Forced feeding of certain persons by the State raises concerns of privacy. An individual's rights to refuse life prolonging medical treatment or terminate his life is another freedom which falls within the zone of the right to privacy. I am conscious of the fact that the issue is pending before this Court. But in various other jurisdictions, there is a huge debate on those issues though it is still a grey area. [For the legal debate in this area in US, see Chapter 15.11 of *American Constitutional Law* by Laurence H. Tribe, 2nd Edn.] A woman's freedom of choice whether to bear a child or abort her pregnancy are areas which fall in the realm of privacy. Similarly, the freedom to choose either to work or not and the freedom to choose the nature of the work are areas of private decision-making process. The right to travel freely within the country or go abroad is an area falling within the right to privacy. The text of our Constitution recognised the freedom to travel throughout the country under Article 19(1)

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294
133 1993 Fam 95 : (1992) 3 WLR 782 : (1992) 4 All ER 649 (CA)
134 (2002) 2 All ER 449
4 1990 SCC OnLine US SC 123 : 111 L Ed 2d 224 : 110 S Ct 2841 : 497 US 261 (1990)
45 (1990) 67 DLR (4th) 321 : 72 OR (2d) 417 (CA)
58 *K.S. Puttaswamy* v. *Union of India*, (2017) 10 SCC 1
135 1942 SCC OnLine US SC 125 : 86 L Ed 1655 : 316 US 535 (1942)

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(*d*). This Court has already recognised that such a right takes within its sweep the right to travel abroad. [*Maneka Gandhi* v. *Union of India*[50]] A person's freedom to choose the place of his residence once again is a part of his right to privacy [*Williams* v. *Fears*[136]: '*8*. Undoubtedly the right of locomotion, the right to remove from one place to another according to inclination, is an attribute of personal liberty...." (SCC OnLine US SC para 8)] recognised by the Constitution of India under Article 19(1)(*e*) though the predominant purpose of enumerating the abovementioned two freedoms in Article 19(1) is to disable both the federal and State Governments from creating barriers which are incompatible with the federal nature of our country and its Constitution. The choice of appearance and apparel are also aspects of the right to privacy. The freedom of certain groups of subjects to determine their appearance and apparel (such as keeping long hair and wearing a turban) are protected not as a part of the right to privacy but as a part of their religious belief. Such a freedom need not necessarily be based on religious beliefs falling under Article 25. Informational traces are also an area which is the subject-matter of huge debate in various jurisdictions falling within the realm of the right to privacy, such data is as personal as that of the choice of appearance and apparel. Telephone tappings and internet hacking by State, of personal data is another area which falls within the realm of privacy. The instant reference arises out of such an attempt by the Union of India to collect biometric data regarding all the residents of this country. The abovementioned are some of the areas where some interest of privacy exists. The examples given above indicate to some extent the nature and scope of the right to privacy."

Nature of living will or Advance Directive

335. Advance Directives are instruments through which persons express their wishes at a prior point in time, when they are capable of making an informed decision, regarding their medical treatment in the future, when they are not in a position to make an informed decision, by reason of being unconscious or in a PVS or in a coma. A medical power of attorney is an instrument through which persons nominate representatives to make decisions regarding their medical treatment at a point in time when the persons executing the instrument are unable to make informed decisions themselves. Clause 11 of the draft Treatment of Terminally-Ill Patients (Protection of Patients and Medical Practitioners) Bill, 2016 states that Advance Directives or medical power of attorney shall be void and of no effect and shall not be binding on any medical practitioner. This blanket ban, including the failure even to give some weight to Advance Directives while making a decision about the withholding or withdrawal of life-sustaining treatment is disproportionate. It does not constitute a fair, just or reasonable procedure, which is a requirement for the imposition of a restriction on the right to life (in this case, expressed as the right to die with dignity) under Article 21.

50 (1978) 1 SCC 248
136 1900 SCC OnLine US SC 211 : 45 L Ed 186 : 179 US 270 (1900)

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336. At this juncture, we may again reiterate that on the one hand autonomy of an individual gives him right to choose his destiny and, therefore, he may decide before hand, in the form of Advance Directive, at what stage of his physical condition he would not like to have medical treatment, and on the other hand, there are dangers of misuse thereof as well. David Feldman explained the same in the following manner:

> "... However, while it is undoubtedly a criminal act to do anything intending to hasten another person's death, there is no absolute duty on a doctor to try to save the life of a patient, for two reasons.
>
> The first is that any treatment is prima facie a trespass to the person, and if the patient is adult and competent to consent it will be unlawful without that consent. A doctor therefore acts lawfully—indeed, could not lawfully act otherwise—when he withholds treatment at the request of a terminally-ill patient. This has been called passive, as distinct from active, euthanasia. To ensure that medical staff know of their wishes, some people have executed what are sometimes called 'living wills', giving directions to medical staff to withhold treatment in specified circumstances, and making their wishes known to anyone who might be appointed as their representative in the event that they become incapable for any reason. The efficacy of such prior indications was accepted, obiter, by Lord Goff in *Airedale N.H.S. Trust* v. *Bland*[11], above. In such circumstances, the patient voluntarily accepts non-treatment while in a state to do so rationally. However, where there is the slightest doubt about the wishes of a patient, that patient should be treated, because the paternalism which decides for someone else when it is best to die is effectively denying them the opportunity to make the most of their lives as autonomous individuals. Furthermore, it would seem to be wrong in principle to put pressure to bear on a patient to elect to die. In those States of the USA where voluntary euthanasia is lawful, the ethical problems for patients, doctors, next of kin, and nursing staff are immense. Where the patient is not mentally competent to confirm the choice to die at the time when the choice is about to be given effect, it will also be impossible to know whether the choice expressed earlier was truly voluntary, whether the consent was informed, and whether or not the patients would want to reconsider were he able to do so. In the Netherlands, where it is lawful to practise voluntary euthanasia, it seems that the procedural safeguards designed to protect people against involuntary euthanasia are very hard to enforce and are regularly flouted.
>
> Secondly, the doctrine of double effect allows the doctor to take steps which carry a substantial risk to life in order to treat, in good faith and with the patient's consent, some disease or symptom. This is essential, because virtually any treatment carries some risk to the patient. It is particularly relevant to the euthanasia issue in cases where the primary object (e.g. pain control in terminal cancer treatment) can only be achieved by administering drugs at a level which is likely to shorten life, but enhances the quality of

11 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

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life while it lasts. A trade-off between length of life and quality of life is permissible."

337. At the same time, possibility of misuse cannot be held to be a valid ground for rejecting Advance Directive, as opined by the Law Commission of India as well in its 196th and 241st Reports. Instead, attempt can be made to provide safeguards for exercise of such Advance Directive. For example, Section 5 of the Mental Health Care Act, 2017 recognises the validity of Advance Directives for the treatment of mental illness under the Mental Health Care Act, 2017. The draft Mental Health Care Regulations have recently been made available for public comment by the Ministry of Health and Family Welfare. These prescribe the form in which Advance Directives may be made. Part II, Chapter 1 of the Regulations allow a nominated representative to be named in the Advance Directive. An Advance Directive is to be in writing and signed by two witnesses attesting to the fact that the Directive was executed in their presence. A Directive is to be registered with the Mental Health Review Board. It may be changed as many times as desired by the person executing it and the treating mental health professional must be informed of such change. Similarly, Section 3 of the Transplantation of Human Organs and Tissues Act, 1994 allows persons to authorise the removal of human organs and tissues from their body before death. The form in which this authorisation is to be made is prescribed in Form 7 of the Transplantation of Human Organs and Tissues Rules, 2014. This is also to be in writing and in the presence of two witnesses. A copy of the pledge is to be retained at the institution where the pledge is made and the person making the pledge has the option to withdraw the pledge at any time. Where such authorisation had been made, the person lawfully in charge of the donor's body after his death is required to grant the medical practitioner concerned all reasonable facilities for the removal of human organs or tissues, unless such person has reason to believe that the donor had substantially revoked his authority.

338. Mr Datar, learned counsel appearing for the intervenor, has also brought to our notice various safeguards for Advance Directive provided in other jurisdiction in many ways i.e. by prescribing the form that the directive must take, by specifying who may act as witnesses, by allowing the possibility of amendment and by allowing the validity of the directive to be challenged. Some of these examples are as follows:

338.1. In UK, under Section 24 of the Mental Capacity Act, 2005, a person above the age of 18 years who has capacity may execute an Advance Directive. A person is said to lack capacity if in relation to a matter at the material time, he is unable to make a decision for himself because of an impairment of or disturbance in the functioning of the mind or brain. In Netherlands, under Article 2 of the Termination of Life on Request and Assisted Suicide (Review Procedures) Act, patients aged 16 or above may make Advance Directives. In Germany, the authorisation of the court is required for the termination of treatment in the case of minors. In Switzerland, persons with mental illnesses are considered exceptions and cannot discontinue medical treatment if it is an

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expression or symptom of their mental illness. In Hungary, pregnant women may not refuse treatment if it is seen that they are able to carry the pregnancy.

338.2. Section 25 of the Mental Capacity Act, an advance decision to refuse life-sustaining treatment must be in writing. It must be signed by the patient or someone on his behalf and signed by a witness. It must also include a written statement by the patient that the decision will apply to the specific treatment even if the patient's life is at risk. Under Article 7: 450 of the Dutch Civil Code, an Advance Directive should be in written form, dated and signed to be valid. Section 110-Q of the Western Australia Guardianship and Administration Act, 1990 requires Advance Directives to be signed in the presence of two witnesses, who must both be at least 18 years of age and one of whom must be a person authorised to witness legal documents under the relevant law. Section 15 of the South Australia Advance Directives Act, 2013 sets out requirements for "suitable" witnesses under the Act. A person may not be a witness if she is appointed as a substitute decision-maker under the Advance Directive, has a direct or indirect interest in the estate of the person executing the Advance Directive or is a health practitioner responsible for the healthcare of the person executing the Advance Directive. Similar disqualifications for witnesses are prescribed in the Oregon Death with Dignity Act, 2002 when a person makes a written request for medication for the purpose of ending her life in a humane and dignified manner.

338.3. Under Section 24(3) of the UK Mental Capacity Act, 2005, a person may alter or withdraw an advance decision at any time he has the capacity to do so. Under Section 25(2)(*c*), an advance decision will not be applicable if a person has done anything else clearly inconsistent with the advance decision. Under Section 3.06 of the Oregon Death with Dignity Act, 2005, a person may rescind her written request for medicating at any time regardless of her mental state. To allow for a change of mind, Section 3.08 also requires at least 15 days to lapse between the patient's initial oral request and the writing of a prescription, while a minimum of 48 hours must elapse between the patient's written request and the writing of a prescription. Under Section 110-S of the Western Australia Guardianship and Administration Act, 1990, a treatment decision in an Advance Directive does not operate if circumstances exist or have arisen that the maker of that directive could not reasonably have anticipated at the time of making the directive and that would have caused a reasonable person in the maker's position to have changed her mind about the directive. While determining whether such circumstances have arisen, the age of the maker and the period that has elapsed between the time at which the directive was made and the circumstances that have arisen are factors that must be taken into account while determining the validity of the directive.

338.4. Section 26(4) of the UK Mental Capacity Act permits courts to make a declaration as to whether the advance decision exists, is valid, and applicable to a treatment. Under Article 373 of the Swiss Civil Code, "any person closely related to the patient can contact the adult protection authority in writing and claim that ... the patient decree is not based on the patient's free will". Under Sections 110-V, 110-W, 110-X, 110-Y and 110-Z of the Western Australia

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Guardianship and Administration Act, 1990, any person who has a "proper interest" in the matter, in the view of the State Administrative Tribunal, may apply to it for a declaration with respect to the validity of an Advance Directive. It can also interpret the terms of the directive, give directions to give effect to it or revoke a treatment decision in the directive.

339. Mr Datar has suggested that this Court should frame the guidelines to cover the following aspects:

339.1. Who will be competent to execute an Advance Directive?

339.2. In what form will an Advance Directive have to be issued in order to be valid?

339.3. Who is to ensure that an Advance Directive is properly obeyed?

339.4. What legal consequences follow from the non-obedience to an Advance Directive?

339.5. In what circumstances can a doctor refuse to enforce an Advance Directive?

340. Mr Datar has given the following suggestions on the aforesaid aspects:

340.1. Only adult persons, above the age of eighteen years and of sound mind at the time at which the Advance Directive is executed should be deemed to be competent. This should include persons suffering from mental disabilities provided they are of sound mind at the time of executing an Advance Directive.

340.2. Only written Advance Directives that have been executed properly with the notarised signature of the person executing the Advance Directive, in the presence of two adult witnesses shall be valid and enforceable in the eye of the law. The form should require a reaffirmation that the person executing such directives has made an informed decision. Only those Advance Directives relating to the withdrawal or withholding of life-sustaining treatment should be granted legal validity. The determination that the executor of the Advance Directive is no longer capable of making the decision should be made in accordance with relevant medical professional regulations or standard treatment guidelines, as also the determination that the executor's life would terminate in the absence of life-sustaining treatment. The constitution of a panel of experts may also be considered to make this determination. The use of Expert Committees or Ethics Committees in other jurisdictions is discussed at Para 28 of these written submissions.

340.3. Primary responsibility for ensuring compliance with the Advance Directive should be on the medical institution where the person is receiving such treatment.

340.4. If a hospital refuses to recognise the validity of an Advance Directive, the relatives or next friend may approach the jurisdictional High Court seeking a writ of mandamus against the hospital concerned to execute the directive. The High Court may examine whether the directive has been properly executed, whether it is still valid (i.e. whether or not circumstances have fundamentally changed since its execution, making it invalid) and/or applicable to the particular circumstances or treatment.

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340.5. No hospital or doctor should be made liable in civil or criminal proceedings for having obeyed a validly executed Advance Directive.

340.6. Doctors citing conscientious objection to the enforcement of Advance Directives on the grounds of religion should be permitted not to enforce it, taking into account their fundamental right under Article 25 of the Constitution. However, the hospital will still remain under this obligation.

341. All these suggestions and various aspects of Advance Directives have been elaborately considered and detailed directions are given by the Hon'ble the Chief Justice in his judgment, with which I duly concur. In summation, I say that this Court has, with utmost sincerity, summoned all its instincts for legality, fairness and reasonableness in giving a suitable answer to the vexed issue that confronts the people on daily basis, keeping in mind the competing interests and balancing those interests. It will help lead society towards an informed, intelligent and just solution to the problem.

342. My last remarks are a pious hope that the legislature would step in at the earliest and enact a comprehensive law on "living will/Advance Directive" so that there is a proper statutory regime to govern various aspects and nuances thereof which also take care of the apprehensions that are expressed against euthanasia.

DR D.Y. CHANDRACHUD, J. (*concurring*)—

A. *Introduction: On Death and Dying*

343. Life and death are inseparable. Every moment of our lives, our bodies are involved in a process of continuous change. Millions of our cells perish as nature regenerates new ones. Our minds are rarely, if ever, constant. Our thoughts are fleeting. In a physiological sense, our being is in a state of flux, change being the norm. Life is not disconnected from death. To be, is to die. From a philosophical perspective, there is no antithesis between life and death. Both constitute essential elements in the inexorable cycle of existence.

344. Living in the present, we are conscious of our own mortality. Biblical teaching reminds us that:

> "There is a time for everything, and a season for every activity under the heavens: a time to be born and a time to die, a time to plant, and a time to uproot, a time to kill and a time to heal, a time to wear down and a time to build, a time to weep and a time to laugh, a time to mourn and a time to dance." (Ecclesiastes 3)

345. The quest of each individual to find meaning in life reflects a human urge to find fulfilment in the pursuit of happiness. The pursuit of happiness is nurtured in creative pleasures and is grounded in things as fundamental as the freedom to think, express and believe, the right to self-determination, the liberty to follow a distinctive way of life, the ability to decide whether or not to conform and the expression of identity.

346. Human beings through the ages have been concerned with death as much as with dying. Death represents a culmination, the terminal point of life.

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Dying is part of a process: the process of living, which eventually leads to death. The fear of death is a universal feature of human existence. The fear is associated as much with the uncertainty of when death will occur as it is, with the suffering that may precede it. The fear lies in the uncertainty of when an event which is certain will occur. Our fears are enhanced by the experience of dying that we share with those who were a part of our lives but have gone before us. As human beings, we are concerned with the dignity of our existence. The process through which we die bears upon that dignity. A dignified existence requires that the days of our lives which lead up to death must be lived in dignity; that the stages through which life leads to death should be free of suffering; and that the integrity of our minds and bodies should survive so long as life subsists. The fear of an uncertain future confronts these aspirations of a dignified life. The fear is compounded by the fact that as we age, we lose control over our faculties and over our ability to take decisions on the course of our future. Our autonomy as persons is founded on the ability to decide: on what to wear and how to dress, on what to eat and on the food that we share, on when to speak and what we speak, on the right to believe or not to believe, on whom to love and whom to partner, and to freely decide on innumerable matters of consequence and detail to our daily lives. Ageing leaves individuals with a dilution of the ability to decide. The fear of that loss is ultimately, a fear of the loss of freedom. Freedom and liberty are the core of a meaningful life. Ageing brings dependency and a loss of control over our ability to shape what we wish to happen to us.

347. The progression of life takes its toll on the human body and the mind. As we age, simple tasks become less simple and what seemed to be a matter of course may become less so. Human beings then turn ever more to the substance that matters. As events, relationships, associations and even memories fall by the way, we are left with a lonesome remnant of the person, which defines the core of our existence. The quest of finding meaning in that core is often a matter of confronting our fears and tragedies.

348. The fear of pain and suffering is perhaps even greater than the apprehension of death. To be free of suffering is a liberation in itself. Hence the liberty to decide how one should be treated when the end of life is near is part of an essential attribute of personhood. Our expectations define how we should be treated in progressing towards the end, even when an individual is left with little or no comprehension near the end of life.

349. Dilemmas relating to the end of life have been on the frontline of debate across the world in recent decades. The debate has presented "a complex maze of dilemmas for all — the doctor, the lawyer, the patient and the patient's relatives"[137] and straddles issues of religion, morality, biomedical ethics and constitutional law. It has involved "issues ranging from the nature and meaning

137 "The Dilemmas of Euthanasia", *Bio-Science* (August 1973), Vol. 23, No. 8, at p. 459.

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of human life itself, to the most fundamental principles on which our societies are and should be based"[138].

350. There is an "ongoing struggle between technology and the law"; as "medical technology has become more advanced, it has achieved the capability both to prolong human life beyond its natural endpoint and to better define when that endpoint will occur".[139] Medical science has contributed in a significant way to enhancing the expectancy of life. Diseases once considered fatal have now become treatable. Medical research has redefined our knowledge of ailments — common and uncommon; of their links with bodily functions and the complex relationship between mental processes and physical well-being. Science which affects the length of life also has an impact on the quality of the years in our lives. Prolonging life should, but does not necessarily result in, a reduction of suffering. Suffering has a bearing on the quality of life. The quality of life depends upon the life in our years. Adding to the length of life must bear a functional nexus with the quality of life. Human suffering must have significance not only in terms of how long we live but also in terms of how well we live.

351. Modern medicine has advanced human knowledge about the body and the mind. Equipped with the tools of knowledge, science has shown the ability to reduce human suffering. Science has also shown an ability to prolong life. Yet in its ability to extend life, medical science has an impact on the quality of life, as on the nature and extent of human suffering. Medical interventions come with costs, both emotional and financial. The ability of science to prolong life must face an equally important concern over its ability to impact on the quality of life. While medical science has extended longevity, it has come with associated costs of medical care and the agony which accompanies an artificially sustained life. Medical ethics must grapple with the need to bring about a balance between the *ability* of science to extend life with the *need* for science to recognise that all knowledge must enhance a meaningful existence.

352. There is "no consensus as to the rights and wrongs of helping someone to die"[140], as the legal status of euthanasia has been subjected to social, ethical and moral norms that have been handed down to us. Decisions regarding the end of life can be ethically more problematic when the individual is no longer mentally competent to make his or her own decisions.[141] The existential and metaphysical issues involved in this debate, include the fear of the unknown,

138 Margaret A. Somerville, "Legalising Euthanasia: Why Now?", The Australian Quarterly (Spring 1996), Vol. 68, No. 3, at p. 1.

139 Christopher N. Manning, "Live and Let Die: Physician-Assisted Suicide and the Right to Die", Harvard Journal of Law and Technology (1996), Vol. 9, No. 2, at p. 513.

140 Alan Norrie, "Legal Form and Moral Judgement: Euthanasia and Assisted Suicide" in R.A. Duff, et al (ed), *The Structures of the Criminal Law* (Oxford University Press, 2011), at p. 134.

141 Elizabeth Wicks, *The Right to Life and Conflicting Interests* (Oxford University Press, 2010), at p. 199.

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the uncertainty of when death will occur, the scarcity of healthcare, freedom or coercion in choosing to receive or not to receive medical treatment, the dignity and degradation of ageing and being able to care for oneself independently.[142]

353. Does the law have a role in these complex questions of life and death? If it does, what are the boundaries which Judges — as interpreters of law — must observe while confronting these issues of living and dying? The law, particularly constitutional law, intervenes when matters governing freedom, liberty, dignity and individual autonomy are at stake. To deny a role for constitutional law would be to ignore our own jurisprudence and the primary role which it assigns to freedom and dignity. This case presents itself before the Court as a canvass bearing on the web of life: on the relationship between science, medicine and ethics and the constitutional values of individual dignity and autonomy. Among the issues which we confront are:

353.1. (*i*) Does an individual have a constitutionally recognised right to refuse medical treatment or to reject a particular form of medical treatment?

353.2. (*ii*) If an individual does possess such a right, does a right inhere in the individual to determine what course of action should be followed in the future if she or he were to lose control over the faculties which enable them to accept or refuse medical treatment?

353.3. (*iii*) Does the existence of a right in the individual impose a corresponding duty on a medical professional who attends to the individual, to respect the right and what, if any, are the qualifications of that duty?

353.4. (*iv*) Does the law permit a medical practitioner to withhold or refuse medical treatment towards the end of life to an individual who is no longer in control of his or her faculties in deference to a desire expressed while in a fit state of mind? and

353.5. (*v*) Would a withholding or refusal of medical treatment be permissible so as to allow life to take its natural course, bereft of an artificial intervention, when there is no realistic hope of return to a normal life?

354. This Court has to consider euthanasia and its impact "not only at an individual level", but also at the "institutional, governmental and societal levels".[143] The impact has to be analysed not only in the context of the present era, but has to be contemplated for the future as well. The Judge is not a soothsayer. Nor does the law have predictive tools at its command which can approximate those available to a scientist. Constitutional principle must have an abiding value. It can have that value if it is firmly grounded in the distilled experience of the past, is flexible to accommodate the concerns of the present and allows room for the unforeseeable future. The possibility of the abuse of euthanasia and the effect that legalising euthanasia would have on intangible societal fabrics and institutions is of utmost concern.

142 Elizabeth M. Andal Sorrentino, "The Right To Die?", Journal of Health and Human Resources Administration (Spring, 1986), Vol. 8, No. 4, p. 361.
143 *Ibid.*

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355. Contemporary writing on the subject reminds us about how serious these issues are and of how often they pose real dilemmas in medicine. They are poignantly brought out by Dr Atul Gawande in his acclaimed book, *Being Mortal*:

> "If to be human is to be limited, then the role of caring professions and institutions—from surgeons to nursing homes—ought to be aiding people in their struggle with those limits. Sometimes we can offer a cure, sometimes only a salve, sometimes not even that. But whatever we can offer, our interventions, and the risks and sacrifices they entail, are justified only if they serve the large aims of a person's life. When we forget that, the suffering we inflict can be barbaric. When we remember it, the good we do can be breathtaking."[144]

He reminds us of how much people value living with dignity over merely living longer:

> "A few conclusions become clear when we understand this: that our most cruel failure in how we treat the sick and the aged is the failure to recognise that they have priorities beyond merely being safe and living longer; that the chance to shape one's story is essential to sustaining meaning in life; that we have the opportunity to refashion our institutions, our culture, and our conversations in ways that transform the possibilities for the last chapters of everyone's lives."[145]

356. Dr Henry Marsh, a neurosurgeon in the UK has significantly titled his provocative memoir *Admissions* (2017). Speaking of euthanasia, he observes:

> "We have to choose between probabilities, not certainties, and that is difficult. How *probable* is it that we will gain how many extra years of life, and what might the *quality* of those years be, if we submit ourselves to the pain and unpleasantness of treatment? And what is the probability that the treatment will cause severe side-effects that outweigh any possible benefits? When we are young it is usually easy to decide—but when we are old, and reaching the end of our likely lifespan? We can choose, at least in theory, but our inbuilt optimism and love of life, our fear of death and the difficulty we have in looking at it steadily, make this very difficult. We inevitably hope that we will be one of the lucky ones, one of the long-term survivors, at the good and not the bad tail-end of the statisticians' normal distribution. And yet it has been estimated that in the developed world, 75 per cent of our lifetime medical costs are incurred in the last six months of our lives. This is the price of hope, hope which, by the laws of probability, is so often unrealistic. And thus we often end up inflicting both great suffering on ourselves and unsustainable expense on society."[146] (emphasis in original)

These are but a few of the examples of emerging literature on the subject.

144 Atul Gawande, *Being Mortal: Medicine and What Matters in the End* (Hamish Hamilton, 2014), at p. 260.
145 Ibid., at p. 243.
146 Henry Marsh, *Admissions: A Life in Brain Surgery*, (Weidenfeld & Nicolson, 2017), at pp. 265-66.

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357. The central aspect of the case is the significance which the Constitution attaches to the ability of every individual in society to make personal choices on decisions which affect our lives. Randy Pausch, a Professor at Stanford had this to say in a book titled *The Last Lecture* (2008),[147] a discourse delivered by him in the shadow of a terminal illness:

"We cannot change the cards we are dealt, just how we play the hand."

We may not be masters of our destiny. Nor can we control what life has in store. What we can determine is how we respond to our trials and tribulations.

B. ***The reference***

358. On 25-2-2014[20], three Judges of this Court opined that the issues raised in this case need to be considered by a Constitution Bench. The referring order notes that the case involves "social, legal, medical and constitutional" perspectives which should be considered by five Judges. At the heart of the proceeding, is a declaration which Common Cause seeks that the right to die with dignity is a fundamental right which arises from the right to live with dignity. Article 21 of the Constitution is a guarantee against the deprivation of life or personal liberty except according to the procedure established by law. As our law has evolved, the right against the violation of life and personal liberty has acquired much more than a formal content. It can have true meaning, if only it includes the right to live with dignity. It is on this premise that the Court is urged to hold that death with dignity is an essential part of a life of dignity. A direction is sought to the Union Government to adopt suitable procedures to ensure that persons with "deteriorated health" or those who are terminally ill should be able to execute a document in the form of "a living will and attorney authorisation" which can be presented to a hospital for appropriate action if the person who has made it, is hospitalised with a serious illness which may cause the end of life. The petitioner also seeks, in the alternative, that this Court should issue guidelines and appoint an expert committee consisting of doctors, social scientists and lawyers who will govern the making of "living wills".

359. Individuals who suffer from chronic disease or approach the end of the span of natural life often lapse into terminal illness or a permanent vegetative state. When a medical emergency leads to hospitalisation, individuals in that condition are sometimes deprived of their right to refuse unwanted medical treatment such as feeding through hydration tubes or being kept on a ventilator and other life support equipment. Life is prolonged artificially resulting in human suffering. The petition is founded on the right of each individual to make an informed choice. Documenting a wish in advance, not to be subjected to artificial means of prolonging life, should the individual not be in a position later to comprehend or decline treatment, is a manifestation of individual choice and autonomy. The process of ageing is marked by a sense of helplessness.

147 Randy Pausch and Jeffrey Zaslow, *The Last Lecture*, (Hodder & Stoughton, 2008), at p. 17.
20 *Common Cause* v. *Union of India*, (2014) 5 SCC 338 : (2014) 2 SCC (Cri) 557

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Human faculties decline as we grow older. Social aspects of ageing, such as the loss of friendships and associations combine with the personal and intimate to enhance a sense of isolation. The boundaries and even the limits of constitutional law will be tested as the needs of the ageing and their concerns confront issues of ethics, morality and of dignity in death.

360. In support of its contention, the petitioner relies upon two decisions: a decision rendered in 1996 by a Constitution Bench in *Gian Kaur* v. *State of Punjab*[10] ("*Gian Kaur*") and a decision of 2011 rendered by two Judges in *Aruna Ramachandra Shanbaug* v. *Union of India*[5] ("*Aruna Shanbaug*"). The decision in *Gian Kaur*[10] arose from a conviction for the abetment of suicide. In an earlier decision rendered by two Judges in 1994 — *P. Rathinam* v. *Union of India*[6] ("*Rathinam*"), penalising an attempt to commit suicide was held to violate Article 21 on the foundation that the right to life includes the right to die. The decision in *Rathinam*[6] was held not to have laid down the correct principle, in *Gian Kaur*[10]. Hence the decision in *Aruna Shanbaug*[5] noted that Article 21 does not protect the right to die and an attempt to commit suicide is a crime. However, in *Aruna Shanbaug*[5], the Court held that since *Gian Kaur*[10] rules that the right to life includes living with human dignity, "in the case of a dying person who is terminally ill or in a permanent vegetative state, he may be permitted to terminate by a premature extinction of his life", and this would not be a crime. The Bench which decided *Aruna Shanbaug*[5] was of the view that *Gian Kaur*[10] had "quoted with approval" the view of the House of Lords in the UK in *Airedale N.H.S. Trust* v. *Bland*[11] ("*Airedale*").

361. When these judgments were placed before a Bench of three Judges in the present case, the Court observed that there were "inherent inconsistencies" in the judgment in *Aruna Shanbaug*[5]. The referring order accordingly opined that: (*Common Cause case*[20], SCC pp. 343-44, para 13)

> "*13. … Aruna Shanbaug*[5] aptly interpreted the decision of the Constitution Bench in *Gian Kaur*[10] and came to the conclusion that euthanasia can be allowed in India only through a valid legislation. However, it is factually wrong to observe that in *Gian Kaur*[10], the Constitution Bench approved the decision of the House of Lords in *Airedale* v. *Bland*[11]. Para 40 of *Gian Kaur*, clearly states that: (SCC p. 65)
>
> > '*40. … Even though it is not necessary to deal with physician-assisted suicide or euthanasia cases, a brief reference to this decision cited at the Bar may be made.*'
>
> Thus, it was a mere reference in the verdict and it cannot be construed to mean that the Constitution Bench in *Gian Kaur*[10] approved the opinion of

10 (1996) 2 SCC 648 : 1996 SCC (Cri) 374
5 (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294
6 (1994) 3 SCC 394 : 1994 SCC (Cri) 740
11 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)
20 *Common Cause* v. *Union of India*, (2014) 5 SCC 338 : (2014) 2 SCC (Cri) 557

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the House of Lords rendered in *Airedale*[11]. To this extent, the observation in para 101 of *Aruna Shanbaug*[5] is incorrect." (emphasis in original)

The referring order goes on to state that: (SCC p. 344, para 15)

> "*15.* In paras 21 and 101, the Bench [in *Aruna Shanbaug*[5]] was of the view that in *Gian Kaur*[10], the Constitution Bench held that euthanasia could be made lawful only by a legislation. Whereas in para 104, the Bench contradicts its own interpretation of *Gian Kaur*[10] in para 101 and states that although this Court approved the view taken in *Airedale*[11], it has not clarified who can decide whether life support should be discontinued in the case of an incompetent person e.g. a person in coma or PVS. When, at the outset, it is interpreted to hold that euthanasia could be made lawful only by legislation where is the question of deciding whether the life support should be discontinued in the case of an incompetent person e.g. a person in coma or PVS."

The reason why the case merits evaluation by the Constitution Bench is elaborated in the order dated 25-2-2014[20]. Simply put, the basis of the reference to the Constitution Bench is that:

361.1. *Gian Kaur*[10] affirms the principle that the right to live with dignity includes the right to die with dignity;

361.2. *Gian Kaur*[10] has not ruled on the validity of euthanasia, active or passive;

361.3. *Aruna Shanbaug*[5] proceeds on the erroneous premise that *Gian Kaur*[10] approved of the decision of the House of Lords in *Airedale*[11];

361.4. While *Aruna Shanbaug*[5] accepts that euthanasia can be made lawful only through legislation, yet the Court accepted the permissibility of passive euthanasia and set down the procedure which must be followed; and

361.5. *Aruna Shanbaug*[5] is internally inconsistent and proceeds on a misconstruction of the decision in *Gian Kaur*[10].

362. This being the basis of the reference, it is necessary to consider the decisions in *Gian Kaur*[10] and *Aruna Shanbaug*[5].

C. *Gian Kaur*[10]

363. Gian Kaur and Harbans Singh were spouses. They were convicted of abetting the suicide of Kulwant Kaur and were held guilty of an offence under Section 306 of the Penal Code. They were sentenced to six years' imprisonment. The conviction was upheld by the High Court. The conviction was assailed before this Court on the ground that Section 306

11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)
5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294
10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374
20 *Common Cause* v. *Union of India*, (2014) 5 SCC 338 : (2014) 2 SCC (Cri) 557

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is unconstitutional. It was argued that the constitutionality of Section 306 rested on the two-Judge Bench decision in *Rathinam*[6], where Section 309 (penalising the attempt to commit suicide) was held to be unconstitutional. While *Rathinam*[6] had rejected the challenge to the validity of Section 309 on the ground that it was arbitrary (and violated Article 14), the provision was held to be unconstitutional on the ground that it violated Article 21. The right to die was found to inhere in the right to life, as a result of which Section 309 was found to be invalid. The challenge in *Gian Kaur*[10] was premised on the decision in *Rathinam*[6]: abetment of suicide by another (it was urged) is merely assisting in the enforcement of the fundamental right under Article 21 and hence Section 306 (like Section 309) would violate Article 21.

364. The Constitution Bench in *Gian Kaur*[10] disapproved of the foundation of *Rathinam*[6], holding that it was flawed. The Constitution Bench held thus: (*Gian Kaur case*[10], SCC p. 660, para 22)

> "*22.* When a man commits suicide he has to undertake certain positive overt acts and the genesis of those acts cannot be traced to, or be included within the protection of the "right to life" under Article 21. The significant aspect of "sanctity of life" is also not to be overlooked. Article 21 is a provision guaranteeing protection of life and personal liberty and by no stretch of imagination can "extinction of life" be read to be included in "protection of life". Whatever may be the philosophy of permitting a person to extinguish his life by committing suicide, we find it difficult to construe Article 21 to include within it the "right to die" as a part of the fundamental right guaranteed therein. "Right to life" is a natural right embodied in Article 21 but suicide is an unnatural termination or extinction of life, and therefore, incompatible and inconsistent with the concept of "right to life". With respect and in all humility, we find no similarity in the nature of the other rights, such as the right to "freedom of speech", etc. to provide a comparable basis to hold that the "right to life" also includes the "right to die". With respect, the comparison is inapposite, for the reason indicated in the context of Article 21. The decisions relating to other fundamental rights wherein the absence of compulsion to exercise a right was held to be included within the exercise of that right, are not available to support the view taken in *P. Rathinam*[6] qua Article 21."

The Court further held that: (SCC p. 660, para 23)

> "*23.* To give meaning and content to the word "life" in Article 21, it has been construed as life with human dignity. Any aspect of life which makes it dignified may be read into it but not that which extinguishes it and is, therefore, inconsistent with the continued existence of life resulting in effacing the right itself. The "right to die", if any, is inherently inconsistent with the "right to life" as is "death" with "life"."

6 *P. Rathinam* v. *Union of India*, (1994) 3 SCC 394 : 1994 SCC (Cri) 740
10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374

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365. *Gian Kaur*[10] holds that life within the meaning of Article 21 means a life of dignity. Extinguishment of life is (in that view) inconsistent with its continued existence. Hence, as a matter of textual construction, the right to life has been held not to include the right to die. In coming to that conclusion, it appears that *Gian Kaur*[10] emphasises two strands (which the present judgment will revisit at a later stage). The first strand is the sanctity of life, which Article 21 recognises. Extinction of life, would in this view, in the manner which *Rathinam*[6] allowed, violate the sanctity of life. The second strand that emerges from *Gian Kaur*[10] is that the right to life is a natural right. Suicide as an unnatural extinction of life is incompatible with it. The Court distinguishes the right to life under Article 21 from other rights which are guaranteed by Article 19 such as the freedom of speech and expression. While free speech may involve the absence of a compulsion to exercise the right (the right not to speak) this could not be said about the right to life. The Constitution Bench noticed the debate on euthanasia in the context of individuals in a permanent vegetative state. A scholarly article on the decision notes that the Constitution Bench "seemed amenable to an exception being made for euthanasia in cases of patients in a condition of PVS[148]. This view of the decision in *Gian Kaur*[10] does find support in the following observations of the Constitution Bench: (SCC p. 660, para 24)

> "*24*. Protagonism of euthanasia on the view that existence in persistent vegetative state (PVS) is not a benefit to the patient of a terminal illness being unrelated to the principle of "sanctity of life" or the "right to live with dignity" is of no assistance to determine the scope of Article 21 for deciding whether the guarantee of "right to life" therein includes the "right to die". The "right to life" including the right to live with human dignity would mean the existence of such a right up to the end of natural life. This also includes the right to a dignified life up to the point of death including a dignified procedure of death. In other words, this may include the right of a dying man to also die with dignity when his life is ebbing out. But the "right to die" with dignity at the end of life is not to be confused or equated with the "right to die" an unnatural death curtailing the natural span of life."

However, in the paragraph which followed, the Constitution Bench distinguished between cases where a premature end to life may be permissible, when death is imminent, from the right to commit suicide: (SCC pp. 660-61, para 25)

> "*25*. A question may arise, in the context of a dying man who is terminally ill or in a persistent vegetative state that he may be permitted to terminate it by a premature extinction of his life in those circumstances. This category of cases may fall within the ambit of the "right to die"

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374
6 *P. Rathinam* v. *Union of India*, (1994) 3 SCC 394 : 1994 SCC (Cri) 740
148 Sushila Rao, "India and Euthanasia: The Poignant Case of Aruna Shanbaug", Oxford Medical Law Review, Vol. 19, Issue 4 (1-12-2011), at pp. 646-656.

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with dignity as a part of right to live with dignity, when death due to termination of natural life is certain and imminent and the process of natural death has commenced. These are not cases of extinguishing life but only of accelerating conclusion of the process of natural death which has already commenced. The debate even in such cases to permit physician-assisted termination of life is inconclusive. It is sufficient to reiterate that the argument to support the view of permitting termination of life in such cases to reduce the period of suffering during the process of certain natural death is not available to interpret Article 21 to include therein the right to curtail the natural span of life."

On this foundation, the Constitution Bench held that Article 21 does not include the right to die. The right to live with human dignity, in this view, could not be construed to include the right to terminate natural life "at least before commencement of the natural process of certain death".

366. This Court's holding in *Gian Kaur*[10] that the right to life does not include the right to die in the context of suicide may require to be revisited in future in view of domestic and international developments[149] pointing towards decriminalisation of suicide. In India, the Mental Health Care Act, 2017 has created a "presumption of severe stress in cases of attempt to commit suicide". Section 115(1) provides thus:

> "**115.** ***Presumption of severe stress in case of attempt to commit suicide.***—(1) Notwithstanding anything contained in Section 309 of the Indian Penal Code any person who attempts to commit suicide shall be presumed, unless proved otherwise, to have severe stress and shall not be tried and punished under the said Code."

Under Section 115(2), the Act also mandates the Government to provide care, treatment and rehabilitation to a person, having severe stress and who attempted to commit suicide, to reduce the risk of recurrence. Section 115 begins with a non obstante provision, specifically with reference to Section 309 of the Penal Code. It mandates (unless the contrary is proved by the prosecution) that a person who attempts to commit suicide is suffering from severe stress. Such a person shall not be tried and punished under the Penal Code. Section 115 removes the element of culpability which attaches to an attempt to commit suicide under Section 309. It regards a person who attempts suicide as a victim of circumstances and not an offender, at least in the absence of proof to the contrary, the burden of which must lie on the prosecution. Section 115 marks a pronounced change in our law about how society must treat an attempt to commit suicide. It seeks to align Indian law with emerging knowledge on suicide, by treating a person who attempts suicide being in need of care, treatment and rehabilitation rather than penal sanctions.

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374

149 "Humanization and Decriminalization of Attempt to Suicide", Law Commission of India (Report No. 210, 2008); Rajeev Ranjan, et al, "(De-) Criminalization of Attempted Suicide in India: A Review", Industrial Psychiatry Journal (2014), Vol. 23, Issue 1, at pp. 4-9.

367. It may also be argued that the right to life and the right to die are not two separate rights, but two sides of the same coin. The right to life is the right to decide whether one will *or will not* continue living.[150] If the right to life were only a right to decide to continue living and did not also include a right to decide not to continue living, then it would be a *duty* to live rather than a *right* to life. The emphasis on life as a right and not as a duty or obligation has also been expressed by several other legal scholars:

> "When, by electing euthanasia, the individual has expressly renounced his right to life, the State cannot reasonably assert an interest in protecting that right as a basis for overriding the individual's private decision to die. To hold otherwise makes little more sense than urging a prohibition against destroying or giving away one's private property simply because the Constitution protects property as well as life. Although the Constitution recognizes that human life is, to most persons, of inestimable value and protects against its taking without due process of law, *nothing in that document compels a person to continue living who does not desire to do so. Such an interpretation effectively converts a right into an obligation, a result the Constitution-Framers manifestly did not intend.*"[151] (emphasis supplied)

368. For the present case, we will leave the matter there, since neither side has asked for reconsideration of *Gian Kaur*[10], it being perhaps not quite required for the purposes of the reference.

369. At this stage, it is also necessary to note that the decision in *Gian Kaur*[10] contained a passing reference to the judgment of the House of Lords in *Airedale*[11] which dealt with the withdrawal of artificial measures for the continuance of life by a physician. In that context, it was held that a persistent vegetative state was of no benefit to the patient and hence, the principle of sanctity of life is not absolute. The Constitution Bench reproduced the following extracts from the decision in *Airedale*[11]: (*Gian Kaur case*[10], SCC p. 665, para 40)

> "*40.* ... '... But it is not lawful for a doctor to administer a drug to his patient to bring about his death, even though that course is prompted by a humanitarian desire to end his suffering, however great that suffering may be [see *R.* v. *Cox*[21], (unreported), 18-9-1992]. So to act is to cross the Rubicon which runs between on the one hand the care of the living patient and on the other hand euthanasia—actively causing his death to avoid or to

150 D. Benatar, "Should There Be a Legal Right to Die?" *Current Oncology* (2010), Vol. 17, Issue 5, at pp. 2-3.

151 Richard Delgado, "Euthanasia Reconsidered—The Choice of Death as an Aspect of the Right of Privacy", Arizona Law Review (1975), Vol. 17, at p. 474.

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374

11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

21 18-9-1992, Ognall, J. (unreported).

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> end his suffering. *Euthanasia is not lawful at common law. It is of course well known that there are many responsible members of our society who believe that euthanasia should be made lawful; but that result could, I believe, only be achieved by legislation which expresses the democratic will that so fundamental a change should be made in our law, and can, if enacted, ensure that such legalised killing can only be carried out subject to appropriate supervision and control.*' (*Airedale case*[11], AC p. 865 E-G)" (emphasis in original)

Making emphasis as above, this Court held that it is in the realm of the legislature to enact a suitable law to provide adequate safeguards regarding euthanasia. The Constitution Bench noted that the desirability of bringing about such a change was considered (in *Airedale*[11]) to be a function of the legislature by enacting a law with safeguards, to prevent abuse.

D. *Aruna Shanbaug*[5]

370. Aruna Shanbaug was a nurse in a public hospital when she was sexually assaulted in 1973. During the incident, she was strangled by the attacker with a chain. The assault resulted in depriving the supply of oxygen to her brain. Over a period of thirty-seven years, she had not recovered from the trauma and damage to the brain. She was forsaken by family and was cared for over this period by the staff of the hospital. A petition under Article 32 was instituted before this Court. The petitioner had authored a book on her saga and instituted the proceedings claiming to be her "next friend". The direction which was sought was to stop feeding the patient and allow her to die a natural death. Aruna Shanbaug was examined by a team of doctors constituted by this Court who observed that while she was in a permanent vegetative state, she was clearly not in coma.

371. A two-Judge Bench of this Court held that *Gian Kaur*[10] did not lay down a final view on euthanasia: (*Aruna Shanbaug case*[5], SCC p. 487, para 21)

> "*21.* We have carefully considered paras 24 and 25 in *Gian Kaur case*[10] and we are of the opinion that all that has been said therein is that the view in *Rathinam case*[6] that the right to life includes the right to die is not correct. We cannot construe *Gian Kaur case*[10] to mean anything beyond that. In fact, it has been specifically mentioned in para 25 of the aforesaid decision that "the debate even in such cases to permit physician-assisted termination of life is inconclusive". Thus it is obvious that no final view was expressed in the decision in *Gian Kaur case*[10] beyond what we have mentioned above."

11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374

6 *P. Rathinam* v. *Union of India*, (1994) 3 SCC 394 : 1994 SCC (Cri) 740

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372. The decision in *Aruna Shanbaug*[5] distinguishes between active and passive euthanasia. "Active euthanasia" is defined as the administration of a lethal substance or force to kill a person, such as for instance, a lethal injection given to a person suffering from agony in a terminal state of cancer. "Passive euthanasia" is defined to mean the withholding or withdrawing of medical treatment necessary for continuance of life. This may consist of withholding antibiotics without which the patient may die or the removing of the patient from artificial heart/lung support. According to the Court, a comparative context of the position prevailing in other countries would indicate that: (SCC p. 491, para 39)

> "*39.* ... The general legal position all over the world seems to be that while active euthanasia is illegal unless there is legislation permitting it, passive euthanasia is legal even without legislation provided certain conditions and safeguards are maintained."

"Voluntary euthanasia" envisages the consent of the patient being taken whereas "non-voluntary euthanasia" deals with a situation where the patient is in a condition where he or she is unable to give consent. The Court noted that a distinction is drawn between euthanasia and physician-assisted death in the form of a physician or third party who administers it. Physician-assisted suicide involves a situation where the patient carries out the procedure, though on the advice of the doctor. The Court in *Aruna Shanbaug*[5] distinguished between active and passive euthanasia: (SCC p. 492, para 43)

> "*43.* The difference between "active" and "passive" euthanasia is that in active euthanasia, something is *done* to end the patient's life while in passive euthanasia, something is *not done* that would have preserved the patient's life. An important idea behind this distinction is that in "passive euthanasia" the doctors are not actively killing anyone; they are simply not saving him." (emphasis in original)

The above extract indicates that the decision is premised on the performance of an act (in active euthanasia) and an omission (in passive euthanasia).

373. Active euthanasia, in the view of the Court, would be an offence under Section 302 or at least under Section 304 while physician-assisted suicide would be an offence under Section 306 of the Penal Code. The decision adverted to the judgment of the House of Lords in *Airedale*[11] and then observed that: (*Aruna Shanbaug case*[5], SCC p. 572, para 104)

> "*104.* It may be noted that in *Gian Kaur case*[4] although the Supreme Court has quoted with approval the view of the House of Lords in *Airedale case*[11], it has not clarified who can decide whether life support should be

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

4 *Cruzan* v. *Missouri Department of Health*, 1990 SCC OnLine US SC 123 : 111 L Ed 2d 224 : 110 S Ct 2841 : 497 US 261 (1990)

discontinued in the case of an incompetent person e.g. a person in coma or PVS."

Explaining the concept of brain death, the Court held that passive euthanasia depends upon two circumstances: (SCC p. 517, para 117)

> "*117.* ... (*a*) When a person is only kept alive mechanically i.e. when not only consciousness is lost, but the person is only able to sustain involuntary functioning through advanced medical technology—such as the use of heart-lung machines, medical ventilators, etc.
>
> (*b*) When there is no plausible possibility of the person ever being able to come out of this stage. Medical "miracles" are not unknown, but if a person has been at a stage where his life is only sustained through medical technology, and there has been no significant alteration in the person's condition for a long period of time—at least a few years—then there can be a fair case made out for passive euthanasia."

374. Noting that there is no statutory provision regulating the procedure for withdrawing life support to a person in PVS or who is incompetent to take a decision, the Court ruled that passive euthanasia should be permitted in certain situations. Until Parliament decides on the matter, the modalities to regulate passive euthanasia would (according to the Court) be as follows: (*Aruna Shanbaug case*[5], SCC pp. 518-19, para 124)

> "*124.* ... (*i*) A decision has to be taken to discontinue life support either by the parents or the spouse or other close relatives, or in the absence of any of them, such a decision can be taken even by a person or a body of persons acting as a next friend. It can also be taken by the doctors attending the patient. However, the decision should be taken bona fide in the best interest of the patient.
>
> * * *
>
> (*ii*) Hence, even if a decision is taken by the near relatives or doctors or next friend to withdraw life support, such a decision requires approval from the High Court concerned as laid down in *Airedale case*[11]."

375. The approval of the High Court was mandated to obviate the danger that "this may be misused by some unscrupulous persons who wish to inherit or otherwise grab the property of the patient". Moreover, the Court directed that when an application is filed before the High Court, a committee of three doctors (a neurologist, psychiatrist and physician) should be constituted, to submit its opinion to enable the High Court to take a considered decision in the case. On the facts of the case, the Court held that the petitioner who had visited Aruna Shanbaug only on a few occasions and had written a book on her could not be recognised as her next friend. It was only the hospital staff which had cared for

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

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her for long years which would be recognised. The doctors and nursing staff had evinced an intent to allow her to live in their care.

376. The decision in *Aruna Shanbaug*[5] has proceeded on the hypothesis that the Constitution Bench in *Gian Kaur*[10] had "quoted with approval" the decision of the House of Lords in *Airedale*[11]. This hypothesis is incorrect. There was only a passing reference to the decision of the House of Lords. In fact, *Gian Kaur*[10] prefaces its reference to *Airedale*[11] with the following observation: (*Gian Kaur case*[10], SCC p. 665, para 40)

> "*40.* ... Even though it is not necessary to deal with physician-assisted suicide or euthanasia cases, a brief reference to this decision cited at the Bar may be made."

The decision in *Gian Kaur*[10] referred to the distinction made in *Airedale*[11] between cases in which a physician decides not to provide or to continue to provide treatment which would prolong life and cases in which a physician decides to actively bring an end to the life of the patient by administering a lethal drug. The Court in *Airedale*[11] observed that actively causing the death of the patient could be made lawful only by legislation. It was this aspect which was emphasised by the judgment in *Gian Kaur*[10]. Hence, the position adopted in *Aruna Shanbaug*[5], that the Constitution Bench in *Gian Kaur*[10] quoted *Airedale*[11] with approval (as the basis of allowing passive euthanasia) is seriously problematic. In fact, the extract from *Airedale*[11] which was cited in *Gian Kaur*[10] indicates the emphasis placed on the need to bring in legislation to allow active euthanasia.

377. In an incisive analysis[152], Ratna Kapur argues that while focussing on euthanasia, discussions on *Aruna Shanbaug*[5] have ignored other considerations regarding gender, sexual assault, what constitutes "caring", the right to bodily integrity and workplace protection. A central issue is, according to Kapur, the "politics of caring", — who can care, has the capacity to care and who is less caring or less capable of caring. The Supreme Court did not accept Pinki Virani as the "next friend" but awarded guardianship to KEM Hospital staff on the ground that they had "an emotional bonding and attachment" to Aruna Shanbaug and were her "real family".

378. Kapur observes that an emotional bond is not a valid criterion for a "next friend" and the expression "real family" has dangerous implications for those who may not fall within the normative remit of that phrase though they have a relationship with the person concerned. She asks if the concept of "next friend" will cover only "biological familial ties" and "render all other

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374

11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

152 Ratna Kapur, "The Spectre of Aruna Shanbaug", *The Wire* (18-5-2015) <https://thewire.in/2005/the-spectre-of-aruna-shanbaug/>.

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non-familial, non-marital, non-heterosexual relationships as ineligible?" She argues that decisions about life and death should "rest on the anvil of dignity, and dignity is not a family value, or linked to some essential gendered trait. It is a societal value and hence needs to be delinked from the traditional frameworks of family and gender stereotypes". Kapur expresses concerns about how the focus on "care" seemed to obscure a deeper and more important consideration regarding women's safety in the workplace. The attack on Aruna Shanbaug in KEM Hospital was indicative of how the workplace was unsafe for women, and yet the staff of the same Hospital were given her guardianship. This is especially concerning given the fact that the Dean of the Hospital at the time refused to allow a complaint of sodomy to go forward as he was more concerned about the reputation of the institution. Kapur laments the fact that Aruna's case was not used to bring out the reform that it should have—stating that it should

> "have been a leading case on women's rights where "caring" extended beyond the physical support for the individual who was harmed, to taking active steps to improve the working conditions for women, including addressing pervasive and systemic sex discrimination and sexism."

379. Lastly, Kapur compels us to think about the choices Aruna Shanbaug may have made:

> "Had Shanbaug not been reduced to a PVS, would she have chosen to remain in KEM for her treatment after the violent and brutal sexual assault that she experienced in her workplace? Or would she have chosen to be treated elsewhere? Would she have sued the Hospital for failing to provide her a safe working environment?"

Thus, Kapur questions the very basis of making the hospital the guardians by questioning why the hospital did not "care" when it mattered the most—when the case of sexual assault and sodomy should have been pursued by the hospital on behalf of its employee. By denying Aruna Shanbaug the right to bodily integrity in life and the right to self-determination in death, and by viewing her life from all lenses but from her own, ranging from the "carers", to the medical and legal profession and their views on euthanasia, she "became nothing more than a spectre in her own story".

380. *Aruna Shanbaug*[5] also presents another problem—one of inconsistency. *Gian Kaur*[10] is construed as laying down only that the right to life does not include the right to die and that the decision in *Rathinam*[6] was incorrect. In that context, it has been noticed that the Constitution Bench observed that the debate overseas even in physician-assisted termination of life is inconclusive. *Aruna Shanbaug*[5] finds, on the one hand, that "no final view was expressed" in *Gian Kaur*[10] beyond stating that the right to life does not include the right to die. Yet, on the other hand, having inferred the absence

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374

6 *P. Rathinam* v. *Union of India*, (1994) 3 SCC 394 : 1994 SCC (Cri) 740

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of a final view on euthanasia in *Gian Kaur*[10], that decision is subsequently construed as having allowed the termination of life by a premature extinction in the case of a "dying person who is terminally ill or in a permanent vegetative state". Both lines of reasoning cannot survive together.

381. The procedure which was followed by this Court in *Aruna Shanbaug*[5] of arranging for a screening of a CD submitted by the team of doctors pertaining to her examination in a live court proceeding open to the public has been criticised as being fundamentally violative of privacy. What transpired in the Court is set out in the following observations from the decision: (SCC p. 476, para 11)

> "*11.* On 2-3-2011, the matter was listed again before us and we first saw the screening of the CD submitted by the team of doctors along with their report. We had arranged for the screening of the CD in the courtroom, so that all present in the Court could see the condition of Aruna Shanbaug. For doing so, we have relied on the precedent of the Nuremburg trials in which a screening was done in the courtroom of some of the Nazi atrocities during the Second World War."

This aspect of the case is indeed disquieting. To equate a patient in PVS for thirty-seven years following a sexual assault, with the trials of Nazi war criminals is seriously disturbing.

382. *Aruna Shanbaug*[5] rests on the distinction between an act and an omission. The Court seems to accept that the withdrawal of life support or a decision not to provide artificial support to prolong life is an omission. In the view of the Court, an omission is what is "not done". On the other hand, what is actively done to end life is held to stand on a separate foundation. At this stage, it would be necessary to note that the validity of the distinction between what is passive and what is active has been the subject of a considerable degree of debate. This would be dealt with in a subsequent part of this judgment.

383. The issue before the Constitution Bench in *Gian Kaur*[10] related to the constitutionality of Section 306 of the Penal Code which penalises the abetment of suicide. The challenge proceeded on the foundation that penalising an attempt to commit suicide had been held to be unconstitutional since the right to live included the right to die. The Constitution Bench emphasised the value ascribed to the sanctity of life and came to the conclusion that the right to die does not emanate from the right to life under Article 21. Having held that the right to die is "inherently inconsistent" with the right to life "as is death with life", the Constitution Bench opined that the debate on euthanasia was "of no assistance to determine the scope of Article 21" and to decide whether the right to life includes the right to die. The Court noted that the right to life embodies the right to live with human dignity which postulates the existence of such a right "up to the end of natural life". This, the Court

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

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observed, included the right to lead a dignified life up to the point of death and included a dignified procedure of death. Thus, in the context of the debate on euthanasia, the Constitution Bench was careful in observing that the right to a dignified life "*may include*" the right of an individual to die with dignity. A premature termination of life of a person facing imminent death in a terminal illness or in a permanent vegetative state was in the view of the Court a situation which "*may fall*" within the ambit of the right to die with dignity. The debate on physician-assisted termination of life was noted to be "*inconclusive*". The Court observed that the *argument* to support the termination of life in such cases to reduce the period of suffering during the process of "certain natural death" was not available to interpret Article 21 as embodying the right to curtail the natural span of life. These observations in *Gian Kaur*[10] would indicate that the Constitution Bench has not made a final or conclusive determination on euthanasia. Indeed, the scope of the controversy before the Court did not directly involve that question. *Aruna Shanbaug*[5] evidently proceeds on a construction of the decision in *Gian Kaur*[10] which does not emerge from it. *Aruna Shanbaug*[5] has inherent internal inconsistencies. Hence, the controversy which has been referred to the Constitution Bench would have to be resolved without regarding *Aruna Shanbaug*[5] as having laid down an authoritative principle of constitutional law.

E. *The distinction between the legality of active and passive euthanasia*

384. In examining the legality of euthanasia, clarification of terminology is essential. The discourse on euthanasia is rendered complex by the problems of shifting and uncertain descriptions of key concepts. Central to the debate are notions such as "involuntary", "non-voluntary" and "voluntary". Also "active" and "passive" are used, particularly in combination with "voluntary" euthanasia. In general, the following might be said:

(*i*) involuntary euthanasia refers to the termination of life against the will of the person killed;

(*ii*) non-voluntary euthanasia refers to the termination of life without the consent or opposition of the person killed;

(*iii*) voluntary euthanasia refers to the termination of life at the request of the person killed;

(*iv*) active euthanasia refers to a positive contribution to the acceleration of death;

(*v*) passive euthanasia refers to the omission of steps which might otherwise sustain life.

What is relatively straightforward is that involuntary euthanasia is illegal and amounts to murder. However, the boundaries between active and passive

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374
5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

euthanasia are blurred since it is quite possible to argue that an omission amounts to a positive act.

385. The expression "passive" has been used to denote the withdrawal or withholding of medical treatment. Implicit in this definition is the assumption that both the withdrawal of or withholding treatment stand on the same ethical or moral platform. This assumption, as we shall see in a latter part of this section, is not free of logical difficulty. The voluntary or non-voluntary character of the euthanasia is determined by the presence or absence of consent. Consent postulates that the individual is in a mental condition which enables her to choose and to decide on a course of action and convey this decision. Its voluntary nature is premised on its consensual character. Euthanasia becomes non-voluntary where the individual has lost those faculties of mind which enable her to freely decide on the course of action or lost the ability to communicate the chosen course of action.

386. The distinctions between active and passive euthanasia are based on the manner in which death is brought about. They closely relate (in the words of Hazel Biggs in a seminal work on the subject) to the understanding and consequences of the legal concepts of act and omission.[153]

387. As early as 1975, American philosopher and medical ethicist James Rachels offered a radical critique of a distinction that was widely accepted by medical ethicists at that time, that passive euthanasia or "letting die" was morally acceptable while active euthanasia or "killing" was not.[154] Even though his paper did not change the prevalence of this distinction at the time it was published, it paved the way by providing credibility for arguments to legalise assisted suicide in the 1990s. In what he calls the "Equivalence Thesis", Rachels states "there is no morally important difference between killing and letting die; if one is permissible (or objectionable), then so is the other and to the same degree".[155] He does not offer a view on whether the practice of euthanasia is acceptable or not. His central thesis is that both active and passive euthanasia are morally equivalent—either both are acceptable or both are not. Reichenbach for instance, asks: Supposing all else is equal, can a moral judgment about euthanasia be made on the basis of it being active or passive alone?[156]. The "Equivalence thesis" postulates that if a doctor lets a patient die (commonly understood as passive euthanasia) for humane reasons, he is in the same moral position as if he decided to kill the patient by giving a lethal injection (commonly understood as active euthanasia) for humane reasons.

153 Hazel Biggs, "Euthanasia, Death with Dignity and the Law" (Hart Publishing, 2001), at p. 12.
154 James Rachels, "Active and Passive Euthanasia", New England Journal of Medicine (9-1-1975), at pp. 78-80.
155 James Rachels, *End of Life: Euthanasia and Morality* (Oxford University Press, 1986).
156 Bruce R. Reichenbach, "Euthanasia and the Active-Passive Distinction", *Bioethics* (January 1987), Vol. 1, at pp. 51-73.

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388. The correctness of this precept may be questioned by pointing out that there is a qualitative difference between a positive medical intervention (such as a lethal injection) which terminates life and a decision to not put a patient on artificial life support, which will not artificially prolong life. The former brings a premature extinction of life. The latter does not delay the end of life beyond its natural end point. But, if the decision to proceed with euthanasia is the right one based on compassion and the humanitarian impulse to reduce pain and suffering, then the method used is not in itself important. Moreover, it is argued that passive euthanasia often involves more suffering since simply withholding treatment means that the patient may take longer to die and thus suffer more. Passive euthanasia may become questionable where the withholding or withdrawal of medical intervention may lead to a condition of pain and suffering, often a lingering and cruel death. The avoidance of suffering, which is the object and purpose of euthanasia, may hence not be the result of passive euthanasia and the converse may result. Besides raising troubling moral questions—especially where it is non-voluntary, it questions the efficacy of passive euthanasia. Moreover, it raises a troubling issue of the validity of the active-passive divide.

389. The moral and legal validity of the active-passive distinction based on the exculpation of omissions has been criticised. One of the reasons for the exculpation of omissions is based on the idea that our duty not to harm people is generally stricter than our duty to help them.[157] James Rachels offers a compelling counter-argument to the argument that killing someone is a violation of our duty not to do harm, whereas letting someone die is merely a failure to help. He argues that our duty to help people is less stringent than the duty not to harm them only in cases where it would be very difficult to help them or require a great amount of effort or sacrifice. However, when we think of cases where it would be relatively simple to help someone and there would be no great personal sacrifice required, the morally justifiable response would be different. He provides a hypothetical example of a child drowning in a bathtub, anyone standing next to the tub would have a strict moral duty to help the child.[158] Due to the equation between the child and the person standing next to the bathtub (the proximity may be in terms of spatial distance or relationship) the "alleged asymmetry" between the duty to help and the duty not to do harm vanishes. A person standing next to the bathtub would have no defence to say that this was *merely* a failure to help and did not violate the duty to do no harm. In cases of euthanasia since the patient is close at hand and it is within the professional skills of the medical practitioner to keep him alive, the alleged asymmetry has little relevance. The distinction is rendered irrelevant even in light of the duty of care that doctors owe to their patients. Against the background of the duty to care, the moral and legal status of not saving a life due to failure to provide treatment, can be the same as actively taking that

157 James Rachels (Supra note 155), at pp. 101-20.
158 *Ibid.*

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life.[159] A doctor who knowingly allows a patient who could be saved to bleed to death might be accused of murder and medical negligence. The nature of the doctor-patient relationship which is founded on the doctor's duty of care towards the patient necessitates that omissions on the doctor's part will also be penalised. When doctors take off life support, they can foresee that death will be the outcome even though the timing of the death cannot be determined. Thus, what must be deemed to be morally and legally important must not be the emotionally appealing distinction between omission and commission but the justifiability or otherwise of the clinical outcome. Indeed, the distinction between omission and commission may be of little value in some healthcare settings.[160]

390. This distinction leads to the result that even though euthanasia is grounded in compassion and to relieve the patient of suffering, only certain types of deaths can be lawful. If active euthanasia amounts to "killing", the operation of criminal law can lead to medical practitioners being exposed to the indignity of criminal prosecutions and punishments.[161] While passive euthanasia can appear to save the dignity of medical practitioners, it is perhaps at the expense of the patient's dignity.[162]

391. A recent article by Rohini Shukla in the Indian Journal of Medical Ethics (2016) points out two major flaws in *Aruna Shanbaug*[5] regarding the distinction between active and passive euthanasia.[163] First, it fails to prioritise the interest of the patient and is preoccupied with the effect of euthanasia on everyone but the patient, and second, that it does not distinguish between the terms "withholding and withdrawing and uses them interchangeably". Throughout the above judgment, the words "withholding" and "withdrawing" are used interchangeably. However, the difference between the two is relevant to the distinction between what is "active" and "passive" as act and omission. Withholding life support implies that crucial medical intervention is restrained or is not provided—an act of omission on the part of the doctor. Withdrawing life support implies suspending medical intervention that was already in use to sustain the patient's life—an act of commission. If the basis of distinction between active and passive euthanasia is that in passive euthanasia the doctor only passively commits acts of omission, while in active euthanasia the doctor commits acts of commission then withdrawing medical treatment is an act of commission and therefore amounts to active euthanasia. In both these cases, the doctor is aware that his/her commissions or omissions will in all likelihood

159 Len Doyal and Lesley Doyal, "Why Active Euthanasia and Physician-Assisted Suicide should be Legalised if Death is in a Patient's Best Interest Then Death Constitutes a Moral Good", British Medical Journal (2001), at pp. 1079-80.

160 *Ibid.*

161 Hazel Biggs (Supra note 153), at p. 162.

162 *Ibid.*

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

163 Rohini Shukla, "Passive Euthanasia in India: A Critique", Indian Journal of Medical Ethics (Jan-Mar 2016), at pp. 35-38.

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lead to the patient's death. However, in passive euthanasia death may not be the only consequence and the suffering that passive euthanasia often entails such as suffocation to death or starvation till death, raises the question of whether passive euthanasia, in such circumstances, militates against the idea of death with dignity—the very basis of legalising euthanasia.[164] Shukla's criticism needs careful attention since it raises profound questions about the doctor-patient relationship and the efficacy of the distinction in the context of death with dignity. If the divide between active-passive is questioned, should both forms be disallowed or, in converse should both be allowed? More significantly, are both equally amenable to judicially manageable standards?

392. Even with *Aruna Shanbaug's*[5] starting position that passive euthanasia is permitted under Indian law until expressly prohibited, the Court did not traverse the vast Indian legal framework to determine whether there was a prohibition to this effect. Instead the Court made an analogy (perhaps incorrect) between a doctor conducting passive euthanasia and a person who watches a building burning: (*Aruna Shanbaug case*[5], SCC p. 492, para 43)

> "*43.* An important idea behind this distinction is that in "passive euthanasia", the doctors are not actively killing anyone; they are simply not saving him. While we usually applaud someone who saves another person's life, we do not normally condemn someone for failing to do so. If one rushes into a burning building and carries someone out to safety, he will probably be called a hero. But if one sees a burning building and people screaming for help, and he stands on the sidelines—whether out of fear for his own safety, or the belief that an inexperienced and ill-equipped person like himself would only get in the way of the professional fire-fighters, or whatever—if one does nothing, few would judge him for his inaction. One would surely not be prosecuted for homicide. (At least, not unless one started the fire in the first place.) ... [T]here can be no debate about passive euthanasia: you cannot persecute someone for failing to save a life. Even if you think it would be good for people to do *X*, you cannot make it illegal for people to *not* do *X*, or everyone in the country who did not do *X* today would have to be arrested." (emphasis in original)

The example is inapposite because it begs the relationship between the person who is in distress and the individual whose position as a caregiver (actual or prospective) is being considered. The above example may suggest a distinct outcome if the bystander who is ill-equipped to enter a burning building is substituted by a fire-fighter on duty. Where there is a duty to care, the distinction between an act and an omission may have questionable relevance. Acts and omissions are not disjunctive or isolated events. Treatment of the human body involves a continuous association between the caregiver and receiver. The expert caregiver is involved in a continuous process where medical knowledge and the condition of the patient as well as the circumstances require the doctor

164 *Ibid.*

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

to evaluate choices—choices on the nature and extent of medical intervention, the wisdom about a course of action and about what should or should not be done.

393. An erroneous premise in the judgment is that omissions are not illegal under Indian law.[165] Section 32 of the Penal Code, 1860 deals with *illegal* omissions and states that "In every part of this Code, except where a contrary intention appears from the context, words which refer to acts done, extend to illegal omissions." Whether and to what extent this omission would be illegal under Indian law will be discussed in a subsequent part of the judgment.

394. Since the judgment legalised passive euthanasia, withdrawing medical support was the only option in *Aruna Shanbaug*[5] and if this had been done, she would have in all likelihood suffocated to death. We must ponder over whether this could be the best possible death in consonance with the right to live with dignity (which extends to dignity when death approaches) and the extent to which it upholds the principle of prioritising the patient's autonomy and dignity over mere prolongation of life. Had the Court taken into account these consequences of passive euthanasia for the patient, it would be apparent that passive euthanasia is not a simple panacea for an individual faced with end of life suffering.

395. This brings us to the second and more crucial flaw, which was the unjustified emphasis on doctor's agency in administering different types of euthanasia which led to ignoring the patient's autonomy and suffering. Respecting patient autonomy and reducing suffering are fundamental ethical values ascribed to euthanasia. It is also the foremost principle of bioethics.[166] The effects of euthanasia on everyone (particularly her caregivers) were given greater importance than the patient's own wishes and caregiver: (*Aruna Shanbaug case*[5], SCC p. 488, para 23)

> "*23.* ... (*v*) In case hydration or food is withdrawn/withheld from Aruna Ramachandra Shanbaug, the efforts which have been put in by batches after batches of nurses of KEM Hospital for the last 37 years will be undermined.
>
> (*vi*) Besides causing a deep sense of resentment in the nursing staff as well as other well-wishers of Aruna Ramachandra Shanbaug in KEM Hospital including the management, such act/omissions will lead to disheartenment in them and large-scale disillusionment."

165 Aparna Chandra and Mrinal Satish, "Misadventures of the Supreme Court in *Aruna Shanbaug* v. *Union of India*", *Law and Other Things* (13-3-2011) <http://lawandotherthings.com/2011/03/misadventures-of-supreme-court-in-aruna/>.

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

166 Roop Gurusahani and Raj Kumar Mani, "India: Not a Country to Die in", Indian Journal of Medical Ethics (Jan-Mar 2016), at pp. 30-35.

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396. Aruna Shanbaug was in no position to communicate her wishes. But the above extract from the judgment relegates her caregiver to the background. The manner in which the constitutional dialogue is framed by the Court elevates the concerns of the caregiver on a high pedestal without focusing on the dignity and personhood of the individual in a permanent vegetative state. In doing so, the judgment subordinates the primary concern of bioethics and constitutional law, which is preserving the dignity of human life.

397. An article[167] in the Oxford Medical Law Review notes that there are strong grounds to believe that the active-passive distinction in *Aruna Shanbaug*[5] was not grounded so much in morality as in "reasons of policy".

398. Even while there are pertinent questions regarding the moral validity of the active-passive distinction, there appears to be a significant difference between active and passive euthanasia when viewed from the lens of the patient's consent. Consent gives an individual the ability to choose whether or not to accept the treatment that is offered. But consent does not confer on a patient the right to demand that a particular form of treatment be administered, even in the quest for death with dignity.[168] Voluntary passive euthanasia, where death results from selective non-treatment because consent is withheld, is therefore legally permissible while voluntary active euthanasia is prohibited. Moreover, passive euthanasia is conceived with a purpose of not prolonging the life of the patient by artificial medical intervention. Both in the case of a withdrawal of artificial support as well as in non-intervention, passive euthanasia allows for life to ebb away and to end in the natural course. In contrast, active euthanasia results in the consequence of shortening life by a positive act of medical intervention. It is perhaps this distinction which necessitates legislative authorisation for active euthanasia, as differentiated from the passive.

399. The question of legality of these two forms of euthanasia has significant consequences. Death when it is according to the wishes and in the caregiver of the patient must be viewed as a moral good. The fact that active euthanasia is an illegal act (absent legislative authorisation) also prevents many professional and emotional carers from performing it even if they perceive it as a compassionate and otherwise appropriate response in line with the patient's wishes and caregiver, thereby prolonging the patient's suffering and indignity. These complex issues cannot be addressed when active euthanasia is not legalised and regulated. The meeting point between bioethics and law does not lie on a straight course.

167 Sushila Rao (Supra note 148), at pp. 646-656.

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

168 Hazel Biggs (Supra note 153), at p. 30.

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F. *Sanctity of life*

400. Diverse thinkers have debated and deliberated upon the value accorded to human life.[169] The "sanctity of life" principle has historically been the single most basic and normative concept in ethics and the law.[170] The phrase has emerged as a key principle in contemporary bioethics, especially in debates about end-of-life issues.[171]

401. The traditional and standard view is that life is invaluable.[172] It has persisted as an idea in various cultures through the centuries. A sacred value has been prioritised for human life. This "rhetoric of the value in human life"[173] has been highlighted in various traditions.[174] The protection of the right to life derives from "the idea that all human life is of equal value"—the idea being drawn from religion, philosophy and science.[175]

402. The principle or doctrine of the "sanctity of life", sometimes also referred to as the "inviolability of human life"[176], is based on "overarching moral considerations", the first of which has been stated as:

> "Human life is sacred, that is inviolable, so one should never aim to cause an innocent person's death by act or omission."[177]

403. Distinct from religious beliefs, the special value inherent in human life has been recognised in secular ideas of natural law — "man as an end in himself, and human investment in life".[178] Locke has been of the view that every human being "is bound to preserve himself, and not to quit his station wilfully".[179] In his book *Life's Dominion*, Ronald Dworkin explains the sanctity of human life thus:

> "The hallmark of the sacred as distinct from the incrementally valuable is that the sacred is intrinsically valuable because—and therefore only once

169 Elizabeth Wicks (Supra note 141), at p. 29.
170 Anne J. Davis, "Dilemmas in Practice: To Make Live or Let Die", The American Journal of Nursing (March 1981), Vol. 81, No. 3, at p. 582.
171 Heike Baranzke, " "Sanctity-of-Life"—A Bioethical Principle for a Right to Life?", *Ethic Theory Moral Practice* (2012), Vol. 15, Issue 3, at p. 295.
172 Elizabeth Wicks (Supra note 141), at p. 1.
173 *Ibid.*, at p. 240.
174 P.G. Lauren argues that it is "essential to recognise that the moral worth of each person is a belief that no single civilization, or people, or nation, or geographical area, or even century can claim as uniquely its own". *See* P.G. Lauren, *The Evolution of International Human Rights: Visions Seen* (University of Pennsylvania Press, 2003, 2nd Edn.), at p. 12, as quoted in Elizabeth Wicks (Supra note 141), at pp. 25-29.
175 Elizabeth Wicks (Supra note 141), at p. 47.
176 John Keown, *The Law and Ethics of Medicine: Essays on the Inviolability of Human Life* (Oxford University Press, 2012), at p. 3.
177 *Ibid.*
178 Elizabeth Wicks (Supra note 141), at pp. 34-35.
179 John Locke, *Two Treatises of Government* (ed. P. Laslett) (Cambridge University Press, 1988).

—it exists. It is inviolable because of what it represents or embodies. It is not important that there be more people. But once a human life has begun, it is very important that it flourish and not be wasted."[180]

Life today, according to Dworkin, is not just created by the science of evolution but by past choices—by the investment that an individual, and others, have put into his or her life.[181]

404. Elizabeth Wicks in her book titled *The Right to Life and Conflicting Interests* (2010) has succinctly summarised the moral and ethical justifications for the sanctity of life thus:

> "The life of an individual human being matters morally not because that organism is sentient or rational (or free of pain, or values its own existence) but because it is a human life. This point is supported by the ethical and legal principle of equality which is well established in the field of human rights.... From an end of life perspective, this means that life ends only when the human organism dies. This cannot sensibly require the death of all of the body's cells but rather the death of the organism as a whole. In other words, life comes to an end when the integrative action between the organs of the body is irreversibly lost. It is the life of the organism which matters, not its living component parts, and thus it is the permanent destruction of that integrative organism which signifies the end of the organism's life."[182]

405. The value of human life has been emphasised by Finnis in the following words:

> "[H]uman bodily life is the life of a person and has the dignity of the person. Every human being is equal precisely in having that human life which is also humanity and personhood, and thus that dignity and intrinsic value. Human bodily life is not mere habitation, platform, or instrument for the human person or spirit. It is therefore not a merely instrumental good, but is an intrinsic and basic human good. Human life is indeed the concrete reality of the human person. In sustaining human bodily life, in however impaired a condition, one is sustaining the person whose life it is. In refusing to choose to violate it, one respects the person in the most fundamental and indispensable way. In the life of the person in an irreversible coma or irreversibly persistent vegetative state, the good of human life is really but very inadequately instantiated. Respect for persons and the goods intrinsic to their well-being requires that one make no choice to violate that good by terminating their life."[183]

180 Ronald Dworkin, *Life's Dominion: An Argument about Abortion and Euthanasia* (HarperCollins, 1993), at pp. 73-74.
181 Elizabeth Wicks (Supra note 141), at p. 32.
182 *Ibid.*, at pp. 16-17.
183 John Finnis, *Human Rights and Common Good* (Oxford University Press, 2011), at p. 221.

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406. In his book *The Law and Ethics of Medicine: Essays on the Inviolability of Human Life* (2012), John Keown has explained the principle of the sanctity or inviolability of human life and its continuing relevance to English law governing aspects of medical practice at the beginning and end of life. Keown has distinguished the principle from the other two "main competing approaches to the valuation of human life"[184]—"vitalism" on the one hand and a "qualitative" evaluation of human life on the other. The approach of "vitalism" assumes that "human life is the supreme good and one should do everything possible to preserve it". The core principle of this approach is "try to maintain the life of each patient at all costs".[185]

407. In the "quality of life" approach, Keown has argued that "there is nothing supremely or even inherently valuable about the life of a human being". The value of human life "resides in meeting a particular "quality" threshold", above which the dignity of life would be "worthwhile". Keown criticises this approach for its basis that since "certain lives are not worth living, it is right intentionally to terminate them, whether by act or omission".[186]

408. Keown sums up that the doctrine of the sanctity or inviolability of life holds that "we all share, by virtue of our common humanity, an ineliminable dignity"—this dignity grounds the "right to life".[187] The essence of the principle is that "it is wrong to try to extinguish life".[188] Intentional killing is prohibited by any act or omission. Keown thereby emphasises the sanctity and inviolability of life in the following words:

> "Human life is a *basic*, *intrinsic* good. ... The dignity of human beings inheres because of the radical capacities, such as for understanding, rational choice, and free will, inherent in human nature. ... All human beings possess the capacities inherent in their nature even though, because of infancy, disability, or senility, they may not yet, not now, or no longer have the ability to exercise them.
>
> The right not to be killed is enjoyed regardless of inability or disability. Our dignity does not depend on our having a particular intellectual ability or having it to a particular degree."[189] (emphasis in original)

409. The principle of the sanctity of life considers autonomy as a "valuable capacity, and part of human dignity"[190]. However, autonomy's contribution to dignity is "conditional, not absolute"[191]. The limitations of autonomy under the sanctity of life doctrine can be summarised as follows:

> "Exercising one's autonomy to destroy one's (or another's) life is always wrong because it is always disrespectful of human dignity. So: it is always wrong intentionally to assist/encourage a patient to commit suicide

184 John Keown (Supra note 176), at p. 4.
185 *Ibid.*
186 *Ibid.*, at p. 5.
187 *Ibid.*, at p. 6.
188 *Ibid.*
189 *Ibid.*, at pp. 5-6.
190 *Ibid.*, at p. 18.
191 *Ibid.*

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and, equally, there is no "right to commit suicide", let alone a right to be assisted to commit suicide, either by act or omission.

> The principle of "respect for autonomy" has in recent years become for many a core if not dominant principle of biomedical ethics and law. It is not, however, unproblematic. Its advocates often fail to agree on precisely what constitutes an "autonomous" choice or to offer any convincing account of why respect for someone else's choice as such should be regarded as a moral principle at all, let alone a core or dominant moral principle."[192]

John Keown, however, while distinguishing the principle of sanctity of life from vitalism, has also argued that though this principle "prohibits withholding or withdrawing treatment with intent to shorten life", but it also "permits withholding/withdrawing a life-prolonging treatment which is not worthwhile because it is futile or too burdensome". It does not require doctors to try to preserve life at all costs.[193] This consideration, despite all the assumptions and discussions about the sanctity of life, in a way, makes the doctrine an open-ended phenomenon.

410. This open-endedness is bound to lead to conflicts and confusions. For instance, the issue of the sacred value of life is potentially a conflicting interest between a right to life and autonomy, which Wicks explains as follows:

> "If we accept that human life has some inherent value, is it solely to the individual who is enjoying that life or is there some broader state or societal benefit in that life? If life is of value only to the person living it, then this may elevate the importance of individual autonomy. It may even suggest that it is an individual's desire for respect for his or her own life that provides the inherent value in that life. On the other hand, it might be argued that the protection of human life is, at least partly, a matter of public interest. Whether it is to the State, or other members of society, or only an individual's own family and friends, there is an argument that a human life is a thing of value to others beyond the individual living that life... [I]f life is legally and ethically protected in deference to the individual's wish for respect for that life, the protection would logically cease when an autonomous choice is made to bring the life to an end. If, however, the life is protected, at least partly, due to the legitimate interest in that life enjoyed by the State or other (perhaps select) members of society, then the individual's autonomous choice to end his or her life is not necessarily the decisive factor in determining whether legal and ethical protection for that life should continue."[194]

411. The disagreement between "sanctity of life" and the "quality of life" is another conflict, which can be summarised as follows:

> "If we start with a sanctity of life position, this affirms the value of human life in a way that trumps even claims to self-determination. ...

192 *Ibid.*
193 *Ibid.*, at p. 13.
194 Elizabeth Wicks (Supra note 141), at pp. 176-77.

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> [P]eople who suffer from terminal or degenerative illness ... who want to die must remain alive in great pain or discomfort until death comes "naturally" to them. Similarly, people who suffer from long-term disability or paralysis which grossly diminishes their capacities for life and who cannot take their own lives, are not permitted to die. In such circumstances, the argument for sanctity of life may seem somewhat sanctimonious to the person who is not allowed the assistance to end their own life. There have been cases in the media in recent years where the moral difficulty in insisting on the sanctity of life in such situations has been made clear. Though such cases will not disturb the position of she who beliefs fundamentally in the sanctity of life, they do lead others to accept that there may be exceptional cases where sanctity gives way to quality of life issues."[195]

Therefore, intractable questions about morality and ethics arise. What is the core of life that might be protected by law? Will a poor quality of life (in the shadow of the imminence of death) impact upon the value of that life to such an extent that it reduces the protection for that life offered by the sanctity of life doctrine? Are there limits to the principle of sanctity? This needs to be reflected upon in the next part of the judgment.

G. *Nuances of the sanctity of life principle*

412. The sanctity of life has been central to the moral and ethical foundations of society for many centuries. Yet, it has been suggested that "across the range of opinions most people would seem to agree that life is valuable to some degree, but the extent to which any "value" is founded in intrinsic worth or instrumental opportunity is contentious".[196] Glanville Williams, a strong proponent of voluntary euthanasia, was of the view that "there was a human freedom to end one's life". According to him, "the law could not forbid conduct that, albeit undesirable, did not adversely affect the social order".[197] That view, as argued by Luis Kutner in his article "Euthanasia: Due Process for Death with Dignity; The Living Will"[198], was similar to that advanced by John Stuart Mill. Mill, in his classic work *On Liberty* stated:

> "Mankind are great gainers by suffering each other to live as seems good to themselves, than by compelling each to live as seems good to the rest."[199]

Are there limits to or nuances of the sanctity principle? This must be discussed for a fuller understanding of the debate around euthanasia.

195 Alan Norrie (Supra note 140), at pp. 141-142.
196 Alexandra Mullock, End-of-Life Law and Assisted Dying in the 21st Century: Time for Cautious Revolution? (PhD Thesis, University of Manchester, 2011), at p. 24.
197 Luis Kutner, "Euthanasia: Due Process for Death with Dignity; The Living Will", Indiana Law Journal (Winter 1979), Vol. 54, Issue, 2, at p. 225.
198 *Ibid.*, at pp. 201-28.
199 *Ibid.*, at pp. 225-26.

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413. Though the sanctity principle prohibits "the deliberate destruction of human life, it does not demand that life should always be prolonged for as long as possible".[200] While providing for an intrinsic sacred value to life "irrespective of the person's capacity to enjoy life and notwithstanding that a person may feel their life to be a great burden", the principle holds that "life should not always be maintained at any and all cost".[201] Ethical proponents of the sanctity of life tend to agree that when "medical treatment, such as ventilation and probably also antibiotics, can do nothing to restore those in permanent vegetative state to a state of health and well-functioning, it is futile and need not be provided".[202] Rao has thus suggested that "the law's recognition that withdrawal of life-prolonging treatment is sometimes legitimate" is not generally an exception to the sanctity principle, but is actually "an embodiment of it".[203]

414. Philosopher and medical ethicist James Rachels has in a seminal work[204] titled *The End of Life: Euthanasia and Morality (Studies in Bioethics)* in the year 1986 propounded that we must embrace an idea of the sanctity of life which is firmly based in ethics (the idea of right and wrong) and not based in religion. The separation of religion from morality and ethics does not necessarily mean a rejection of religion, but that the doctrine of "sanctity of life" must be accepted or rejected on its merits, by religious and non-religious people alike. The value of life is not the value that it has for God or the value that it may have from any religious perspective. The truth of moral judgments and exercising reason to decide what is right and wrong does not depend on the truth of theological claims. The value of life is the value that it has for the human beings who are subjects of lives. Thus, the value of life must be understood from the perspective of the person who will be harmed by the loss, the subject of life. It is also important to understand the true meaning behind the moral rule against killing. The rationale behind such a law is to protect the interests of individuals who are the subject of lives. If the point of the rule against killing is the protection of lives, then we must acknowledge that in some cases killing does not involve the destruction of "life" in the sense that life is sought to be protected by law. For example, a person in an irreversible coma or suffering a serious terminal illness is alive in a strictly biological sense but is no longer able to live life in a way that may give meaning to this biological existence. The rule against killing protects individuals that have lives and not merely individuals who are alive. When an individual is alive only to the extent of being conscious

200 Sushila Rao, "The Moral Basis for a Right to Die", Economic & Political Weekly (30-4-2011), at p. 14.

201 Alexandra Mullock, End-of-Life Law and Assisted Dying in the 21st Century: Time for Cautious Revolution? (PhD Thesis, University of Manchester, 2011), at p. 25.

202 John Keown, "The Legal Revolution: From "Sanctity of Life" to "Quality of Life" and "Autonomy", Journal of Contemporary Health Law & Policy (1998), Vol. 14, Issue 2, at p. 281.

203 Sushila Rao (Supra note 200), at p. 14.

204 James Rachels, (Supra note 155).

in the most rudimentary sense, the capacity to experience pleasure and pain (if any) does not necessarily have value if that is the only capacity one has. These sensations will not be endowed with any significance by the one experiencing them since they do not arise from any human activities or projects and they will not be connected with any coherent view of the world.

415. It is instructive to analyse how the principle of the sanctity of life impacts upon views in regard to capital punishment. (This comparison, it needs to be clarified in the present judgment, is not to indicate an opinion on the constitutionality of the death penalty which is not in issue here.) Advocates of the sanctity of life would even allow capital punishment[205], implying that they do not oppose all killing of human beings. This suggests that "while they are anti-euthanasia, they are not uniformly pro-life"[206]. In a seminal article titled "The Song of Death: The Lyrics of Euthanasia"[207], Margaret A. Somerville has laid down four possible positions that persons could take:

> "(*i*) that they are against capital punishment and against euthanasia;
>
> (*ii*) that they agree with capital punishment, but are against euthanasia;
>
> (*iii*) that they agree with capital punishment and euthanasia; or
>
> (*iv*) that they are against capital punishment, but agree with euthanasia".[208]

She explained the underlying philosophy that these positions represent and its implications:

> "The first is a true pro-life position, in that, it demonstrates a moral belief that all killing (except, usually, as a last resort in self-defence) is wrong. The second position represents the view of some fundamentalists, namely, that to uphold the sanctity of life value requires prohibition of euthanasia, but capital punishment is justified on the grounds that this punishment is deserved and just according to God's law. The third position is that of some conservatives, who see capital punishment as a fit penalty on the basis that one can forfeit one's life through a very serious crime, but that one can also consent to the taking of one's own life in the form of euthanasia. The fourth view is that of some civil libertarians, that one can consent to the taking of one's own life but cannot take that of others. Through such analyses, one can see where the various groups agree with each other and disagree. For example, the true pro-life persons and the fundamentalists agree with each other in being against euthanasia, and some conservatives and civil libertarians agree with each other in arguing for the availability of euthanasia. On the other hand, the true pro-life and civil libertarians join in their views in being against capital punishment,

205 Elizabeth Wicks (Supra note 141), at pp. 102-149.
206 Margaret A. Somerville, "The Song of Death: The Lyrics of Euthanasia", Journal of Contemporary Health Law & Policy (1993), Vol. 9, Issue 1, at p. 67.
207 *Ibid.*, at pp. 1-76.
208 *Ibid.*, at p. 67.

whereas the fundamentalists and some conservatives agree that this is acceptable."[209]

The above explanation suggests that there are variations in intellectual opinion on the concept of sanctity of life. When it comes to taking of a person's life, various groups while agreeing in certain terms, may be "radically divergent in others".[210]

416. Contrary to the vitalism or the sanctity of life principle, some scholars and bioethicists have argued that "life is only valuable when it has a certain quality which enables the subject to derive enjoyment from their existence so that life is viewed as being, on balance, more beneficial than burdensome". It has been argued that the sanctity of life principle should be interpreted to protect lives in the biographical sense and not merely in a biological sense.[211] There is a difference in the fact of being alive and the experience of living. From the point of view of the living individual, there is no value in being alive except that it enables one to have a life.[212]

417. There is wide-ranging academic research suggestive of a nuanced approach to the sanctity principle. During the last four decades, "there has been a subtle change in the way" people perceive human life and that "the idea of quality of life has become more prevalent in recent times".[213] The moral premium, as Magnusson has remarked, is shifting "from longevity and onto quality of life"[214].

418. In his article titled the "Sanctity of Life or Quality of Life?"[215], Singer argued that the sanctity of life principle has been under erosion — the "philosophical foundations" of the principle being "knocked asunder".[216] "The first major blow" to the principle, Singer stressed, "was the spreading acceptance of abortion throughout the Western world". Late abortions diluted the defence of the "[alleged] universal sanctity of innocent human life".[217] Singer has further remarked:

> "Ironically, the sanctity with which we endow all human life often works to the detriment of those unfortunate humans whose lives hold no prospect except suffering…

209 *Ibid.*, at pp. 67-68.
210 *Ibid.*
211 James Rachels (Supra note 155), at p. 26.
212 *Ibid.*
213 Jessica Stern, Euthanasia and the Terminally Ill (2013), retrieved from Florida State University Libraries.
214 Roger S. Magnusson, "The Sanctity of Life and the Right to Die: Social and Jurisprudential Aspects of the Euthanasia Debate in Australia and the United States", Pacific Rim Law & Policy Journal, Vol. 6, No. I, at p. 40.
215 Peter Singer, "Sanctity of Life or Quality of Life", *Pediatrics* (1983), Vol. 72, Issue 1, at pp. 128-129.
216 *Ibid.*, at p. 129.
217 *Ibid.*, at p. 128.

> One difference between humans and other animals that is relevant irrespective of any defect is that humans have families who can intelligently take part in decisions about their offspring. This does not affect the intrinsic value of human life, but it often should affect our treatment of humans who are incapable of expressing their own wishes about their future. Any such effect will not, however, always be in the direction of prolonging life...
>
> If we can put aside the obsolete and erroneous notion of the sanctity of all human life, we may start to look at human life as it really is: at the quality of life that each human being has or can achieve. Then it will be possible to approach these difficult questions of life and death with the ethical sensitivity that each case demands, rather than with the blindness to individual differences..."[218]

419. The quality of life approach has its basis in the way life is being lived. "An overriding concern", under this approach, "is the conditions under which people live rather than whether they live".[219] This does not mean that someone "who chooses to end their life through euthanasia" does not value their lives as much as others.[220] Breck in his article titled "Euthanasia and the Quality of Life Debate"[221] has stated that:

> "Ethicists of all moral and religious traditions recognize that medical decisions today inevitably involve quality of life considerations. Very few would be inclined to sustain limited physiological functioning in clearly hopeless cases, as with anencephaly or whole-brain death, simply because the technology exists to do so. That such a case is indeed hopeless, however, is a quality of life judgment: it weighs the relationship between the patient's condition and the treatment options and concludes that attempts to sustain biological existence would be unnecessarily burdensome or simply futile. Judgments made in light of "futility" or the "burden-benefit calculus" are necessarily based on evaluations of the "quality" of the patient's life. Such quality, however, must always be determined in light of the patient's own personal interests and well-being, and not on grounds of the burden imposed on other parties (the family, for example) or the medical care system with its economic considerations and limited resources."[222]

Weingarten is of the view that the emphasis on the sanctity of life "should be replaced by "value of life", which exposes the individual case to critical

218 *Ibid.*, at p. 129.
219 "Sanctity of Life versus Quality of Life", *Los Angeles Times* (7-6-2015), <http://www.latimes.com/opinion/readersreact/la-le-0607-sunday-assisted-suicide-20150607- story.html>.
220 Jessica Stern, Euthanasia and the Terminally Ill (2013) <https://fsu.digital.flvc.org/islandora/object/fsu: 209909/datastream/PDF/view>.
221 John Breck, "Euthanasia and the Quality of Life Debate", *Christian Bioethics* (1995), Vol. 1, No. 3, at pp. 322-337.
222 *Ibid.*, at pp. 325-326.

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scrutiny. Medicine can better cope with its current and future ethical dilemmas by a case-by-case approach."[223]

420. Norrie explains why quality of life should be placed ahead of sanctity of life in the debate on euthanasia:

> "[W]hile there are good moral reasons of either a direct (that human life should be generally valued as of intrinsic worth) or an indirect (that allowing exceptions would lead to a slippery slope) kind for supporting a sanctity of life view in the case of the terminally ill and ancillary cases, there are also good moral reasons for allowing exceptions to it. The latter stem from a quality of life view and, linked to that, the possibility of choosing the time and place of one's own death. The possibility of agency as a central element in what it means to be human is premised on the notion of human freedom, and freedom implies a number of different elements. These include a simple freedom to be left alone with one's life, as well as a positive freedom to become what we have it within ourselves to be. Such freedom then entails further conceptions of autonomy, emancipation, and flourishing, insofar as human life reflects the potentialities in human being. The ability to choose one's own death reflects many of these aspects of human freedom, from the simple sense that one should be left alone to do what one likes with one's life to the more complex sense that an autonomous life would include amongst its components control over one's death, and then on to the sense—that is surely there in the term "euthanasia" (a "good death")—that a flourishing life is one in which one is genuinely able to register the time to go. These are moral arguments placing choice and quality of life ahead of sanctity of life.... A good life means a good death too, and it is this kind of argument that leads one to think that a categorical prohibition on voluntary euthanasia ... is problematic."[224]

Life and natural death

421. The defenders of the sanctity principle place sacred value to human life from "conception to natural death".[225] The word "natural" implies that "the only acceptable death is one that occurs from natural causes". Life is only "sacred insofar as it ends by natural means"[226]. Medical advancements, however, have brought uncertainty about the definition of death — "what constitutes death, in particular a "natural" death". This uncertainty can be expressed through the following questions:

223 Michael A. Weingarten, "On the Sanctity of Life", British Journal of General Practice (April 2007), Vol. 57(537), at p. 333.

224 Alan Norrie (Supra note 140), at p. 143.

225 Alecia Pasdera, The Rhetoric of the Physician-Assisted Suicide Movement: Choosing Death Over Life (2014), available at *https://ou.monmouthcollege.edu/_resources/pdf/academics/mjur/2014/Rhetoric-of-the-Physician-Assisted-Suicide-Movement-Choosing-Death-Over-Life.pdf*, at p. 68.

226 *Ibid.*, at p. 69.

"If a person stays alive thanks to medical advances, is that really "natural"?...

When is the benefit of using technology and treatments to sustain life no longer worth the pain that comes along with it?"[227]

422. Medical advances have "complicated the question of when life ends". There exists no natural death where artificial technology is concerned. Technology by artificial means can prolong life. In doing so, technology has reshaped both human experience as well as our values about life in a natural state and its end by natural causes:

"[T]he process of dying is an inevitable consequence of life, the right to life necessarily implies the right to have nature take its course and to die a natural death. It also encompasses a right, unless the individual so wishes, not to have life artificially maintained by the provision of nourishment by abnormal artificial means which have no curative effect and which are intended merely to prolong life."[228]

423. Modern medicine has found ways to prolong life and to delay death. But, it does not imply that modern medicine "necessarily prolongs our living a full and robust life because in some cases it serves only to prolong mere biological existence during the act of dying". This may, in certain situations result in a mere "prolongation of a heartbeat that activates the husk of a mindless, degenerating body that sustains an unknowing and pitiable life—one without vitality, health or any opportunity for normal existence—an inevitable stage in the process of dying".[229] Prolonging life in a vegetative state by artificial means or allowing pain and suffering in a terminal state would lead to questioning the belief that any kind of life is so sanctified as to be preferred absolutely over death.[230]

424. Kuhse and Hughes have stated that "the really critical issues in medicine are often hidden" by "the hulking darkness" of the sanctity principle. According to them:

"Today the advances of science are occurring every minute. Lasers are used to crush kidney stones; mechanical hearts are transplanted to prolong life; and organ transplants are being increasingly used, particularly livers and eyes and, now experimentally, legs. Microprocessor ventilators are used to maintain breathing in patients unable to breathe on their own; chemotherapy/radiology is being used to prolong the lives of cancer patients; long-term haemodialysis is being used for those who have non-functional kidneys; and cardiac pacemakers are being implanted in patients whose hearts are unable to beat normally. While society has supported research and development in medicine, the issues regarding the termination

227 *Ibid.*, at p. 68.
228 Sushila Rao (Supra note 200), at p. 15.
229 Arval A. Morris, "Voluntary Euthanasia", Washington Law Review (1970), Vol. 45, at p. 240.
230 *Ibid.*, at p. 243.

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of such treatment and, more importantly, the withholding of such treatment have not been fully addressed."[231]

425. The debate around human life will be driven by technology. "Sophisticated modern medical technology", even if ultimately not being able to conquer death, "has a lot to say about the conditions and time of its occurrence". Singer has envisioned a future where the debate around human life is closely linked to the impact of technology on our existence:

> "As the sophistication of techniques for producing images of soft tissue increases, we will be able to determine with a high degree of certainty that some living, breathing human beings have suffered such severe brain damage that they will never regain consciousness. In these cases, with the hope of recovery gone, families and loved ones will usually understand that even if the human organism is still alive, the person they loved has ceased to exist. Hence, a decision to remove the feeding tube will be less controversial, for it will be a decision to end the life of a human body, but not of a person."[232]

426. Lady Justice Arden recently delivered a lecture in India on a topic dealing with the intersection of law and medicine titled "What does patient autonomy mean for courts?"[233]. The Judge explained that advancement in medical technology has contributed towards a growing importance of patient autonomy and an increasing social trend towards questioning clinical judgment, which is causing conflict among courts in the UK—particularly in end of life treatment decisions. To highlight this conflict, Judge Arden cites the example of baby Charlie Gard, a "caregiver case"[234] that engendered debate on medical ethics world over. Born in August 2016 in London, Charlie suffered from an extremely rare genetic condition known as MDDS, which causes progressive brain damage and muscle failure, usually leading to death in infancy. His parents wanted him to undergo experimental treatment known as nucleoside which was available in the USA and raised a large amount of money to enable him to travel there. However, the doctors at the hospital in London who were treating him did not think it was in his caregiver to have this treatment as instead they believed his caregiver demanded that his life-support be withdrawn as they considered the treatment to be futile. Due to the conflicting views between the parents and the doctors, the core issue to be decided i.e. whether it was in the best interest of the child to receive further treatment had to be answered by the Court. The case went through the judicial system—including the High Court, the Supreme Court, the ECHR and finally back to the High Court, which on the

231 Elizabeth M. Andal Sorrentino, "The Right to Die?", Journal of Health and Human Resources Administration (Spring, 1986), Vol. 8, No. 4, at pp. 361-373.

232 Peter Singer, "The Sanctity of Life", *Foreign Policy* (20-10-2009) <http://foreignpolicy.com/2009/10/20/the-sanctity-of-life/>.

233 Lady Justice Arden, Law of Medicine and the Individual: Current Issues, What does patient autonomy mean for the courts?, (Justice K.T. Desai Memorial Lecture 2017).

234 *Great Ormond Street Hospital* v. *Yates*, 2017 EWHC 1909 : (2017) 4 WLR 131 (Fam)

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basis of medical reports concluded that it was not in the child's caregiver to have further treatment and passed an order permitting the doctors to allow Charlie to die. In addition to the issue of caregiver, Lady Justice Arden also mentioned the issue of resources in such cases. In the present case, the parents were able to raise large amounts of financial resources required for the treatment of the child, but lack of resources could lead to difficulties in other cases where treatment is unaffordable in a public health system.

427. Modern technology has in a fundamental manner reshaped the notion of life. As technology continuously evolves into more complex planes, it becomes even more necessary to re-evaluate its relationship with the meaning and quality of life.

H. *Euthanasia and the Indian Constitution*

428. The sanctity of life principle appears in declarations on human rights as the "right to life".[235] Under the Indian Constitution, right to life has been provided under Article 21. In *Parmanand Katara* v. *Union of India*[236], it was pointed out: (SCC p. 293, para 7)

> [P]reservation of life is of most importance, because if one's life is lost, the status quo ante cannot be restored as resurrection is beyond the capacity of man.

The sanctity of human life lies in its intrinsic value. It inheres in nature and is recognised by natural law. But human lives also have instrumental functions. Our lives enable us to fulfil our needs and aspirations. The intrinsic worth of life is not conditional on what it seeks to or is capable to achieve. Life is valuable because it *is*. The Indian Constitution protects the right to life as the supreme right, which is inalienable and inviolable even in times of Emergency.[237] It clearly recognises that every human being has the inherent right to life, which is protected by law, and that "No person shall be deprived of his life… except according to procedure established by law"[238]. It, thus, envisages only very limited circumstances where a person can be deprived of life.

429. According to Stefania Negri, the debate around euthanasia has "essentially developed within the framework of the universal rights to life and to human dignity"[239]. This leads us to the relationship between end-of-life decisions and human dignity under the Indian Constitution.

Dignity

430. Human dignity has been "considered the unique universal value that inspires the major common bioethical principles, and it is therefore considered

235 John Keown (Supra note 176), at p. 4.
236 (1989) 4 SCC 286 : 1989 SCC (Cri) 721 : AIR 1989 SC 2039
237 Article 359.
238 Article 21.
239 Stefania Negri, "Universal Human Rights and End-of-Life Care" in S. Negri et al. (eds.), Advance Care Decision Making in Germany and Italy: A Comparative, European and International Law Perspective, Springer (2013), at p. 18.

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the *noyau dur* of both international bio law and international human rights law"[240]. Ronald Dworkin observes that "the notion of a right to dignity has been used in many senses by moral and political philosophers".[241]

431. The first idea considers dignity as the foundation of human rights — "that dignity relates to the intrinsic value of persons (such that it is wrong to treat persons as mere things rather than as autonomous ends or agents)"[242]. According to this premise, every person, from conception to natural death, possesses inherent dignity:

> "The sanctity of life view is often accompanied by a set of claims about human dignity, namely, that human beings possess essential, underived, or intrinsic dignity. That is, they possess dignity, or excellence, in virtue of the kind of being they are; and this essential dignity can be used summarily to express why it is impermissible, for example, intentionally to kill human beings: to do so is to act against their dignity."[243]

The other interpretation of dignity is by the supporters of euthanasia.[244] For them, right to lead a healthy life also includes leaving the world in a peaceful and dignified manner. Living with dignity, in this view, means the right to live a meaningful life having certain quality. This interpretation endorses the "quality of life" proposition.

432. Dignity has thus been invoked in support of contradictory claims and arguments. It could justify respect for life under the principle of the "sanctity of life", as well as the right to die in the name of the principle of "quality of life". In order to remove ambiguities in interpretation and application of the right to human dignity, Negri has suggested that dignity should be given a minimum core of interpretation:

> "*To be meaningful in the end-of-life discourse, and hence to avoid being invoked as mere rhetoric, dignity should be considered as a substantive legal concept, at whose basic minimum core is the legal guarantee assuring the protection of every human being against degradation and humiliation.* Besides this, as international and national case law demonstrate, it can also play an important role as an interpretive principle, assisting Judges in the interpretation and application of other

240 *Ibid.*, at pp. 21-22.

241 Ronald Dworkin, Life's Dominion (London: HarperCollins, 1993) as quoted in Deryck Beyleveld and Roger Brownsword, "Human Dignity, Human Rights, and Human Genetics", Modern Law Review (1998), Vol. 61, at pp. 665-666.

242 Deryck Beyleveld and Roger Brownsword, "Human Dignity, Human Rights, and Human Genetics", Modern Law Review (1998), Vol. 61, at p. 666.

243 Christopher O. Tollefsen, "Capital Punishment, Sanctity of Life, and Human Dignity", *Public Discourse* (16-9-2011), <http://www.thepublic discourse.com/2011/09/3985/>.

244 Stefania Negri, "Ending Life and Death" in A. den Exter (eds.), European Health Law, MAKLU Press (2017), at p. 241.

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human rights, such as the right to life and the right to respect for private life, both crucial in the end-of-life debate."[245] (emphasis supplied)

Recognition of human dignity is an important reason underlying the preservation of life. It has important consequences. Is that dignity not compromised by pain and suffering and by the progressive loss of bodily and mental functions with the imminence of the end of life? Dignity has important consequences for life choices.

433. Morris, in his article, "Voluntary Euthanasia", regards cruelty as a violation of human dignity:

> "All civilized men will agree that cruelty is an evil to be avoided. But few people acknowledge the cruelty of our present laws which require a man be kept alive against his will, while denying his pleas for merciful release after all the dignity, beauty, promise and meaning of life have vanished, and he can only linger for weeks or months in the last stages of agony, weakness and decay." In addition, the fact that many people, as they die, are fully conscious of their tragic state of deterioration greatly magnifies the cruelty inherent in forcing them to endure this loss of dignity against their will."[246]

He has further stated:

> "it is exceedingly cruel to compel the spouse and children of a dying man to witness the ever-worsening stages of his disease, and to watch the slow, agonising death of their loved one, degenerating before their eyes, being transformed from a vital and robust parent and spouse into a pathetic and humiliated creature, devoid of human dignity".[247]

434. Liberty and autonomy promote the cause of human dignity. Arguments about autonomy are often linked to human dignity.[248] Gostin evaluates the relationship between the dignity of dying with autonomy thus:

> "The dying process, after all, is the most intimate, private and fundamental of all parts of life. It is the voice that we, as humans, assert in influencing this autonomous part of our life. At the moment of our death, this right of autonomy ought not to be taken from us simply because we are dying. An autonomous person should not be required to have a good reason for the decision that he or she will make; that is the nature of autonomy. We do not judge for other competent human beings what may be in their best interest, but instead allow them to determine that for themselves. As such, an autonomous person does not need to have a good understanding or even good reasons. All they need is an understanding of what they are confronting. There is no reason to believe that when a person faces

245 *Ibid.*
246 Arval A. Morris (Supra note 229), at pp. 251-252.
247 *Ibid.*
248 Sebastian Muders, *Autonomy and the Value of Life as Elements of Human Dignity* (Oxford University Press, 2017).

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imminent death that they have less human understanding, or less ability to fathom what they will face, than other people. Of course, death is a mystery. But death is what we will all confront sooner or later, and we all may wish to assert our interests in how we may die."[249]

435. Sumner in his work titled "Dignity through Thick and Thin"[250] discusses the dignity associated with patients:

> "[P]atients associate dignity with concepts such as respect and esteem, presumably including self-respect and self-esteem, whereas they experience its opposite—indignity—as degrading, shameful, or embarrassing. ... Abstractly speaking, a person's dignity seems to be a matter of assurance of her fully human status, both in her own eyes and in the eyes of others. Dignity is maintained when one can face others with pride and with confidence of being worthy of their respect; it is lost or impaired when being seen by others occasions feelings of shame, inferiority, or embarrassment. The element of degradation that is implicated in indignity seems a matter of feeling demoted or diminished from a higher standing to a lower, perhaps from the status of a fully functioning person to something lesser."[251]

While stating that dignity and indignity are "basically subjective notions"[252] depending upon how individual patients experience them, he has further stated:

> "One condition that patients report as degrading— as an indignity—is loss of control over the course of their own healthcare. Loss of autonomy matters in its own right, but it matters even more if it is the source for patients of shame and humiliation. This suggests that autonomy and well-being are themselves interconnected: Patients typically experience a loss of the former as a decline in the latter, as something that makes their dying process go worse for them by causing them feelings of indignity. Appeals to dignity thus flesh out what is at stake for patients in terms of their autonomy and well-being, but they do not introduce any factors that fall outside the limits of these values."[253]

436. An article titled "Euthanasia: A Social Science Perspective"[254] in the Economic & Political Weekly has suggested that the discourses on death with dignity "need to be situated within processes of living with dignity in everyday contexts".[255] The end of life must not be seen as "human disposal", but, as

249 Lawrence O. Gostin, "The Constitutional Right to Die: Ethical Considerations", St John's Journal of Legal Commentary (1997), Vol. 12, at pages 602-603.

250 L.W. Sumner, "Dignity Through Thick and Thin", in Sebastian Muders, *Human Dignity and Assisted Death* (Oxford University Press, 2017).

251 *Ibid.*, at p. 61.

252 *Ibid.*, at p. 64.

253 *Ibid.*, at p. 68.

254 Aneeta A. Minocha, Arima Mishra and Vivek R. Minocha, "Euthanasia: A Social Science Perspective", Economic & Political Weekly (3-12-2011), at pp. 25-28.

255 *Ibid.*, at p. 27.

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"the enhancement of human dignity by permitting each man's last act to be an exercise of his free choice between a tortured, hideous death and a painless, dignified one."[256]

437. Under our Constitution, the inherent value which sanctifies life is the dignity of existence. Recognising human dignity is intrinsic to preserving the sanctity of life. Life is truly sanctified when it is lived with dignity. There exists a close relationship between dignity and the quality of life. For, it is only when life can be lived with a true sense of quality that the dignity of human existence is fully realised. Hence, there should be no antagonism between the sanctity of human life on the one hand and the dignity and quality of life on the other hand. Quality of life ensures dignity of living and dignity is but a process in realising the sanctity of life.

438. Human dignity is an essential element of a meaningful existence. A life of dignity comprehends all stages of living including the final stage which leads to the end of life. Liberty and autonomy are essential attributes of a life of substance. It is liberty which enables an individual to decide upon those matters which are central to the pursuit of a meaningful existence. The expectation that the individual should not be deprived of his or her dignity in the final stage of life gives expression to the central expectation of a fading life: control over pain and suffering and the ability to determine the treatment which the individual should receive. When society assures to each individual a protection against being subjected to degrading treatment in the process of dying, it seeks to assure basic human dignity. Dignity ensures the sanctity of life. The recognition afforded to the autonomy of the individual in matters relating to end-of-life decisions is ultimately a step towards ensuring that life does not despair of dignity as it ebbs away.

439. From *Maneka Gandhi*[50] to *Puttaswamy*[58], dignity is the element which binds the constitutional quest for a meaningful existence. In *Francis Coralie Mullin* v. *State (UT of Delhi)*[62], this Court held that: (SCC p. 618, paras 7-8)

> "7. ... the right to life enshrined in Article 21 cannot be restricted to mere animal existence. It means something much more than just physical survival. ...
>
> 8. We think that the right to life includes the right to live with human dignity...."

Explaining the ambit of dignity, this Court further held that: (SCC p. 619, para 8)

> "8. ... [A]ny form of torture or cruel, inhuman or degrading treatment would be offensive to human dignity and constitute an inroad into this right to live.... [T]here is implicit in Article 21 the right to protection against torture or cruel, inhuman or degrading treatment which is enunciated in

256 Arval A. Morris (Supra note 229), at p. 247.
50 *Maneka Gandhi* v. *Union of India*, (1978) 1 SCC 248
58 *K.S. Puttaswamy* v. *Union of India*, (2017) 10 SCC 1
62 (1981) 1 SCC 608 : 1981 SCC (Cri) 212

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Article 5 of the Universal Declaration of Human Rights and guaranteed by Article 7 of the International Covenant on Civil and Political Rights."

Dignity is the core value of life and personal liberty which infuses every stage of human existence. Dignity in the process of dying as well as dignity in death reflects a long yearning through the ages that the passage away from life should be bereft of suffering. These individual yearnings are enhanced by the experiences of sharing, observing and feeling with others: the loss of a parent, spouse, friend or an acquaintance to the cycle of life. Dignity in death has a sense of realism that permeates the right to life. It has a basic connect with the autonomy of the individual and the right to self-determination. Loss of control over the body and the mind are portents of the deprivation of liberty. As the end of life approaches, a loss of control over human faculties denudes life of its meaning. Terminal illness hastens the loss of faculties. Control over essential decisions about how an individual should be treated at the end of life is hence an essential attribute of the right to life. Corresponding to the right is a legitimate expectation that the State must protect it and provide a just legal order in which the right is not denied. In matters as fundamental as death and the process of dying, each individual is entitled to a reasonable expectation of the protection of his or her autonomy by a legal order founded on the rule of law. A constitutional expectation of providing dignity in death is protected by Article 21 and is enforceable against the State.

Privacy

440. The nine-Judge Bench decision of this Court in *K.S. Puttaswamy* v. *Union of India*[58] held privacy to be the constitutional core of human dignity. The right to privacy was held to be an intrinsic part of the right to life and liberty under Article 21 and protected under Part III of the Constitution. Each of the six decisions has a vital bearing on the issues in the present case. Excerpts from the judgment are reproduced below: (SCC pp. 413, 530, 544, 577, 611-12, 618 & 624, paras 127, 373, 392, 411, 482, 543, 583 & 609)

Justice D.Y. Chandrachud

"*127.* ... The right to privacy is an element of human dignity. The sanctity of privacy lies in its functional relationship with dignity. Privacy ensures that a human being can lead a life of dignity by securing the inner recesses of the human personality from unwanted intrusion. Privacy recognises the autonomy of the individual and the right of every person to make essential choices which affect the course of life. In doing so privacy recognises that living a life of dignity is essential for a human being to fulfil the liberties and freedoms which are the cornerstone of the Constitution."

Justice Chelameswar

"*373.* ... Forced feeding of certain persons by the State raises concerns of privacy. An individual's rights to refuse life prolonging medical treatment or terminate his life is another freedom which falls within the zone of the right of privacy."

58 (2017) 10 SCC 1

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Justice S.A. Bobde

"*392.* ... Privacy, with which we are here concerned, eminently qualifies as an inalienable natural right, intimately connected to two values whose protection is a matter of universal moral agreement: the innate dignity and autonomy of man.

* * *

411. ... Both dignity and privacy are intimately intertwined and are natural conditions for the birth and death of individuals, and for many significant events in life between these events."

Justice R.F. Nariman

"*482.* ... a Constitution has to be read in such a way that words deliver up principles that are to be followed and if this is kept in mind, it is clear that the concept of privacy is contained not merely in personal liberty, but also in the dignity of the individual."

Justice A.M. Sapre

"*543.* The incorporation of expression "Dignity of the individual" in the Preamble was aimed essentially to show explicit repudiation of what people of this country had inherited from the past. Dignity of the individual was, therefore, always considered the prime constituent of the fraternity, which assures the dignity to every individual. Both expressions are interdependent and intertwined."

Justice S.K. Kaul

"*583.* A person-hood would be a protection of one's personality, individuality and dignity."

* * *

"*609.* Privacy, for example is nothing but a form of dignity, which itself is a subset of liberty."

441. The protective mantle of privacy covers certain decisions that fundamentally affect the human life cycle.[257] It protects the most personal and intimate decisions of individuals that affect their life and development.[258] Thus, choices and decisions on matters such as procreation, contraception and marriage have been held to be protected. While death is an inevitable end in the trajectory of the cycle of human life of individuals are often faced with choices and decisions relating to death. Decisions relating to death, like those relating to birth, sex, and marriage, are protected by the Constitution by virtue of the right of privacy. The right to privacy resides in the right to liberty and in the respect of autonomy.[259] The right to privacy protects autonomy in making decisions related to the intimate domain of death as well as bodily integrity. Few

257 Richard Delgado, "Euthanasia Reconsidered—The Choice of Death as an Aspect of the Right of Privacy", Arizona Law Review (1975), Vol. 17, at p. 474.

258 *Ibid.*

259 T.L. Beauchamp, "The Right to Privacy and the Right to Die", *Social Philosophy and Policy* (2000), Vol. 17, at p. 276.

moments could be of as much importance as the intimate and private decisions that we are faced regarding death.[260] Continuing treatment against the wishes of a patient is not only a violation of the principle of informed consent, but also of bodily privacy and bodily integrity that have been recognised as a facet of privacy by this Court.

442. Just as people value having control over decisions during their lives such as where to live, which occupation to pursue, whom to marry, and whether to have children, so people value having control over whether to continue living when the quality of life deteriorates.[261]

443. In *Quinlan, In re*[26], the New Jersey Supreme Court dealt with a case of a patient, Karen Quinlan, who had suffered irreversible brain damage and was in a persistent vegetative state and had no prospect of recovery. The patient's father sought judicial authority to withdraw the life-sustaining mechanisms temporarily preserving his daughter's life, and his appointment as guardian of her person to that end. The father's lawyer contended that the patient was being forced to function against all natural impulses and that her right to make a private decision about her fate superseded the State's right to keep her alive. The New Jersey Supreme Court held that the patient had a right of privacy grounded in the US Constitution to terminate treatment and in a celebrated statement said that:

> "the State's interest contra [the right to privacy] weakens and the individual's right to privacy grows as the degree of bodily invasion increases and the prognosis dims. Ultimately there comes a point at which the individual's rights overcome the State interest. It is for that reason that we believe [the patient's] choice, if she were competent to make it, would be vindicated by law."

Since Karen Quinlan was not competent to assert her right to privacy, the Court held that Karen's right of privacy may be asserted on her behalf by her guardian due to the reason that Karen Quinlan did not have the capacity to assert her right to privacy indicating that the right of privacy is so fundamental that others, who had been intimately involved with the patient, should be able to exercise it in circumstances when the patient is unable to do so. However, subsequently scholars have argued that when euthanasia is founded in the right to privacy, only voluntary euthanasia can be permitted. The right to privacy can only be exerted by the patient and cannot be exercised vicariously.[262] The substituted judgment and caregiver criterion cannot be logically based on the right to privacy of the patient.[263]

444. In the landmark case of *Pretty* v. *United Kingdom*[32], the European Court of Human Rights analysed Article 8 of the European Convention on Human Rights (respect for private life). It held that the term "private life" is a

260 *Ibid.*
261 D. Benatar (Supra note 150).
26 355 A 2d 647 : 70 NJ 10 (NJ 1976), cert. denied sub nom *Garger* v. *New Jersey*, 429 US 922 (1976)
262 Peter J. Riga, "Privacy and the Right to Die", *The Catholic Lawyer* (2017) Vol. 26: No. 2, Article 2.
263 *Ibid.*
32 (2002) 35 EHRR 1 : 2002 ECHR 423

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broad term not susceptible to exhaustive definition and covers the physical and psychological integrity of a person. In relation to the withdrawing of treatment, it was held that the way in which an individual "chooses to pass the closing moments of her life is part of the act of living, and she has a right to ask that this too must be respected". The right to privacy protects even those choices that may be considered harmful for the individual exercising the choice:

> "The extent to which a State can use compulsory powers or the criminal law to protect people from the consequences of their chosen lifestyle has long been a topic of moral and jurisprudential discussion, the fact that the interference is often viewed as trespassing on the private and personal sphere adding to the vigour of the debate. However, even where the conduct poses a danger to health or, arguably, where it is of a life-threatening nature, the case law of the Convention institutions has regarded the State's imposition of compulsory or criminal measures as impinging on the private life of the applicant within the meaning of Article 8 § 1.... In the sphere of medical treatment, the refusal to accept a particular treatment might, inevitably, lead to a fatal outcome, yet the imposition of medical treatment, without the consent of a mentally competent adult patient, would interfere with a person's physical integrity."

The Court further observed that:

> "Without in any way negating the principle of sanctity of life protected under the Convention, the Court considers that it is under Article 8 that notions of the quality of life take on significance. In an era of growing medical sophistication combined with longer life expectancies, many people are concerned that they should not be forced to linger on in old age or in states of advanced physical or mental decrepitude which conflict with strongly held ideas of self and personal identity."

Thus, the Court concluded that the "choice to avoid what she considers will be an undignified and distressing end to her life" is guaranteed under the right to respect for private life under Article 8(1) of the Convention.

445. Subsequently in *Haas* v. *Switzerland*[264], the European Court of Human Rights has further held that the right to decide in which way and at which time an individual's life should end, provided that he or she was in a position freely to form her own will and to act accordingly, was one of the aspects of the right to respect for private life within the meaning of Article 8 of the Convention.

446. The right to privacy as held by this Court mandates that we safeguard the integrity of individual choice in the intimate sphere of decisions relating to death, subject to the restrictions to the right to privacy, as laid down by us. However, since privacy is not an absolute right and is subject to restrictions, the restrictions must fulfil the requirements as laid down by this Court in *Puttaswamy*[58].

264 (2011) 53 EHRR 33, para 51.
58 *K.S. Puttaswamy* v. *Union of India*, (2017) 10 SCC 1

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447. The protection of these rights by the legal order is as much an emanation of the right to privacy which shares a functional relationship with the fundamental right to life and personal liberty guaranteed by the Constitution. Privacy recognises that the body and mind are inviolable. An essential attribute of this inviolability is the ability of the individual to refuse medical treatment.

Socio-economic concerns

448. One of the limitations of contemporary debates on euthanasia is that they do not take into consideration "certain socio-economic concerns that must necessarily be factored into any discourse"[265]. This has been criticised as making the debate around ending life "incomplete" as well as "elitist".

449. In an article titled "Euthanasia: Cost Factor is a Worry"[266] Nagral (2011) seeks to construct a "critical linkage" between euthanasia and "the economic and social dimension" in the Indian context. Stating that many Indian doctors have been practising passive euthanasia silently and practically, Nagral contemplates the cost of treatment to be a critical factor in influencing the medical decision:

> "[O]ne of the reasons for 'passive' euthanasia is that the patient or his family could be running out of money. In some cases, this overlaps with the incurability of the disease. In others, it may not. Costly medication and intervention is often withdrawn as the first step of this passive euthanasia process. Sometimes patients are 'transferred' to smaller (read cheaper) institutions or even their homes, with the tacit understanding that this will hasten the inevitable. If a third party is funding the patient's treatment, chances are that the intervention and support will continue. Shocking and arbitrary as this may sound, this is the reality that needs flagging because it is relevant to the proposed legitimisation of passive euthanasia. In a system where out-of-pocket payment is the norm and healthcare costs are booming, there has to be a way of differentiating a plea made on genuine medical grounds from one that might be an attempt to avoid financial ruin."[267]

Rao (2011) has observed:

> "In the absence of adequate medical insurance, specialised treatments like ventilator support, kidney dialysis, and expensive lifesaving drugs administered in private hospitals can turn middle-class families into virtual paupers. Poorly equipped government hospitals simply do not have enough life-support machines compared to the number of patients who need them. ... This also leads to the inevitable possibility of a comatose patient's family and relatives potentially exploiting the euthanasia law to benefit from a premature death, by way of inheritance, etc."[268]

265 Sushila Rao (Supra note 148), at p. 654.

266 S. Nagral, "Euthanasia: Cost Factor is a Worry", *The Times of India* (19-6-2011) <http://www.timesofindia.com/home/sunday/Euthanasia-cost-factor-is-a-worry/articleshow/7690155.cms>.

267 *Ibid.*

268 Sushila Rao (Supra note 148), at pp. 654-655.

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Norrie (2011) has placed the social and economic dimensions succinctly:

> "This concerns the problem of the differential social impact that such a position would have on the poor and the well-to-do... Wealth, poverty, and class structure have a profound effect on the choices people make."[269]

The inadequacies of the range and reach of Indian healthcare may, it is observed, lead to a situation where euthanasia/active euthanasia may become "an instrument of cost containment"[270].

Restraints on judicial power

450. An earlier part of this judgment has dwelt on the criticism of the distinction between passive and active euthanasia, founded as it is on the act—omission divide. The criticism is that as a matter of substance, there is no valid distinguishing basis between active and passive euthanasia. The criticism takes one of two forms: either both should be recognised or neither should be allowed. The view that passive euthanasia involves an omission while active euthanasia involves a positive act is questioned on the ground that the withdrawal of artificial life support (as an incident of passive euthanasia) requires a positive act. While noticing this criticism, it is necessary to distinguish between active and passive euthanasia in terms of the underlying constitutional principles as well as in relation to the exercise of judicial power. Passive euthanasia —whether in the form of withholding or withdrawing treatment—has the effect of removing, or as the case may be, not providing supportive treatment. Its effect is to allow the individual to continue to exist until the end of the natural span of life. On the other hand, active euthanasia involves hastening of death: the lifespan of the individual is curtailed by a specific act designed to bring an end to life. Active euthanasia would on the state of the penal law as it stands constitute an offence. Hence, it is only Parliament which can in its legislative wisdom decide whether active euthanasia should be permitted. Passive euthanasia on the other hand would not implicate a criminal offence since the decision to withhold or withdraw artificial life support after taking into account the best interest of the patient would not constitute an illegal omission prohibited by law.

451. Moreover, it is necessary to make a distinction between active and passive euthanasia in terms of the incidents of judicial power. We may refer in this context to the felicitous words of Sales, L.J. speaking for the Queen's Bench Division in a recent decision delivered on 5-10-2017 in *R. (Conway)* v. *Secy. of State for Justice*[271]. Dealing with the plea that physician-assisted suicide should be accepted as a principle by the Court, the learned Judge observed thus: (WLR p. 352 C-G)

> "*109*. Parliament is the body composed of representatives of the community at large with what can be called a democratic mandate to make

269 Alan Norrie (Supra note 140), at p. 144.

270 S. Nagral, "Euthanasia: Cost Factor is a Worry", *The Times of India* (19-6-2011) <http://www.timesofindia.com/home/sunday/Euthanasia-cost-factor-is-a-worry/articleshow/7690155.cms>.

271 (2018) 2 WLR 322 : 2017 EWHC 2447 (Admin)

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the relevant assessment in a case where there is an important element of social policy and moral value-judgment involved with much to be said on both sides of the debate (paras 229 and 233). There is not a single, clear, uniquely rational solution which can be identified; the decision cannot fail to be influenced by the decision-makers' opinions about the moral case for assisted suicide, including in deciding what level of risk to others is acceptable and whether any safeguards are sufficiently robust; and it is not appropriate for professional Judges to impose their personal opinions on matters of this kind (paras 229-230 and 234). In Nicklinson's case in the Court of Appeal, Lord Judge CJ aptly referred to Parliament as representing 'the conscience of the nation' for decisions which raise "profoundly sensitive questions about the nature of our society, and its values and standards, on which passionate but contradictory opinions are held" (Court of Appeal, para 155). Parliament has made the relevant decision; opponents of Section 2 have thus far failed to persuade Parliament to change the law despite active consideration given to the issue, in particular in relation to the Falconer Bill which contained essentially the same proposals as Mr Conway now puts before the court; and the democratic process would be liable to be subverted if, on a question of moral and political judgment, opponents of the legislation could achieve through the courts what they could not achieve in Parliament (para 231), per Lord Sumption, referring to *R. (Countryside Alliance)* v. *Attorney General*[272], para 45 per Lord Bingham and *AXA General Insurance Ltd.* v. *HM Advocate*[273] para 49 per Lord Hope)."

Emphasising the limitations on the exercise of the judicial power, Sales, L.J. observed: (WLR p. 353 C-E, para 112)

> "*112*. We also agree that his case on necessity becomes still stronger when the other legitimate aims are brought into account. As the conscience of the nation, Parliament is entitled to maintain in place a clear bright-line rule which forbids people from providing assistance to an individual to commit suicide. Parliament was and is entitled to decide that the clarity of such a moral position could only be achieved by means of such a rule. Although views about this vary in society, we think that the legitimacy of Parliament deciding to maintain such a clear line that people should not seek to intervene to hasten the death of a human is not open to serious doubt. Parliament is entitled to make the assessment that it should protect moral standards in society by issuing clear and unambiguous laws which reflect and embody such standards."

In taking the view which has been taken in the present judgment, the Court has been conscious of the need to preserve to Parliament, the area which properly belongs to its legislative authority. Our view must hence be informed by the impact of existing legislation on the field of debate in the present case.

272 2008 AC 719 : (2007) 3 WLR 922 (HL)
273 (2012) 1 AC 868 : (2011) 3 WLR 871 (SC)

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I. ***Penal provisions***

452. The legality of and constitutional protection which is afforded to passive euthanasia cannot be read in isolation from the provisions of the Penal Code. Physicians are apprehensive about their civil or criminal liability when called upon to decide whether to limit life-supporting treatment.[274] A decision on the constitutional question cannot be rendered without analysing the statutory context and the impact of penal provisions. The decision in *Aruna Shanbaug*[5] did not dwell on the provisions of the Penal Code (apart from Sections 306 and 309) which have a vital bearing on the issue of euthanasia. Undoubtedly, constitutional positions are not controlled by statutory provisions, because the Constitution rises above and controls legislative mandates. But, in the present reference where no statutory provision is called into question, it is necessary for the court to analyse the relationship between what the statute penalises and what the Constitution protects. The task of interpretation is to allow for their co-existence while interpreting the statute to give effect to constitutional principle. This is particularly so in an area such as the present where criminal law may bear a significant relationship to the fundamental constitutional principles of liberty, dignity and autonomy.

453. The first aspect which needs to be noticed is that our law of crimes deals with acts and omissions. Section 32 of the Penal Code places acts and omissions on the same plane. An *illegal* omission (unless a contrary intent appears in the Code) is proscribed when the act is unlawful. Section 32 states:

> "**32.** ***Words referring to acts include illegal omissions.***—In every part of this Code, except where a contrary intention appears from the context, words which refer to acts done extend also to illegal omissions."

The language of the statute which refers to acts applies, unless a contrary intent appears in the text, to omissions. The next aspect is about when an act or omission is illegal. Section 43 explains the concept of illegality. It provides thus:

> "**43.** ***"Illegal", "Legally bound to do".***—The word "illegal" is applicable to everything which is an offence or which is prohibited by law, or which furnishes ground for a civil action; and a person is said to be "legally bound to do" whatever it is illegal in him to omit."

Here again, being legally bound to do something is the mirror image of what is illegal to omit doing.

454. Section 43 comprehends within the meaning of illegality, that (*i*) which is an offence; or (*ii*) which is prohibited by law; or (*iii*) which furnishes a ground for a civil action. Omissions and acts are mirror images. When it is unlawful to *omit* to do something, the individual is legally *bound* to do it. This

274 S. Balakrishnan and R.K. Mani, "The Constitutional and Legal Provisions in Indian Law for Limiting Life Support", Indian Journal of Critical Care Medicine (2005), Vol. 9, Issue 2, at p. 108.

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

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raises the question of whether an omission to provide life-sustaining treatment constitutes an illegal omission.

455. Section 81 protects acts which are done without a criminal intent to cause harm, in good faith, to prevent or avoid other harm to person or property. The law protects the action though it was done with the knowledge that it was likely to cause harm if a threefold requirement is fulfilled. It comprehends an absence of criminal intent to cause harm, the presence of good faith and the purpose of preventing other harm. Section 81 provides thus:

> "**81.** ***Act likely to cause harm, but done without criminal intent, and to prevent other harm.***—Nothing is an offence merely by reason of its being done with the knowledge that it is likely to cause harm, if it be done without any criminal intention to cause harm, and in good faith for the purpose of preventing or avoiding other harm to person or property.
>
> *Explanation.*—It is a question of fact in such a case whether the harm to be prevented or avoided was of such a nature and so imminent as to justify or excuse the risk of doing the act with the knowledge that it was likely to cause harm."

Knowledge of the likelihood of harm is not culpable when a criminal intent to cause harm is absent and there exists an element of good faith to prevent or avoid other harm.

456. Section 92 IPC states:

> "**92.** ***Act done in good faith for benefit of a person without consent.***—Nothing is an offence by reason of any harm which it may cause to a person for whose benefit it is done in good faith, even without that person's consent, if the circumstances are such that it is impossible for that person to signify consent, or if that person is incapable of giving consent, and has no guardian or other person in lawful charge of him from whom it is possible to obtain consent in time for the thing to be done with benefit: Provided—
>
> *Provisos.—First.*—That this exception shall not extend to the intentional causing of death, or the attempting to cause death;"

Section 92 protects an individual from a consequence which arises from the doing of an act for the benefit of another in good faith, though a harm is caused to the other. What was done is protected because it was done in good faith. Good faith is distinguished from an evil design. When a person does something to protect another from a harm or injury, the law protects what was done in good faith, treating the harm that may result as a consequence unintended by the doer of the act. This protection is afforded by the law even in the absence of consent when the circumstances are such that it is impossible for the person for whose benefit the act was done to consent to it. This may arise where the imminence of the apprehended danger makes it impossible to obtain consent. Another eventuality is where the individual is incapable of consenting (by being incapacitated in mind) and there is no person in the position of a guardian or person in lawful charge from whom consent can be obtained in time to perform the act for the benefit of that person. However, the first proviso to Section 92

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makes it clear that the exception does not extend to the *intentional* causing of death or attempt to cause death to the individual, howsoever it may be for the benefit of the other. Absence of intent to cause death is the crucial element in the protection extended by Section 92.

457. Section 107 deals with abetment. It provides thus:

> "**107.** ***Abetment of a thing.***—A person *abets* the doing of a thing, who—
>
> * * *
>
> *Thirdly.*—Intentionally *aids*, by any act or illegal omission, the doing of that thing." (emphasis supplied)

Abetment embodies a threefold requirement: first an intentional aiding, second the aiding of an act or illegal omission and third, that this must be toward the doing of that thing. Explanation 2 of this Section states:

> "*Explanation 2.*—Whoever, either prior to or at the time of the commission of an act, does anything in order to facilitate the commission of that act, and thereby facilitates the commission thereof, is said to *aid* the doing of that act." (emphasis supplied)

458. For abetting an offence, the person abetting must have intentionally aided the commission of the crime. Abetment requires an instigation to commit or intentionally aiding the commission of a crime. It presupposes a course of conduct or action which (in the context of the present discussion) facilitates another to end life. Hence abetment of suicide is an offence expressly punishable under Sections 305 and 306 IPC.

459. It is now necessary to dwell upon the provisions bearing upon culpable homicide and murder. Section 299 IPC states:

> "**299.** ***Culpable homicide.***—Whoever causes death by doing an act with the intention of causing death, or with the intention of causing such bodily injury as is likely to cause death, or with the knowledge that he is likely by such act to cause death, commits the offence of culpable homicide."

Section 300 states:

> "**300.** ***Murder.***—Except in the cases hereinafter excepted, culpable homicide is murder, if the act by which the death is caused is done with the intention of causing death, or—
>
> *Secondly.*—If it is done with the intention of causing such bodily injury as the offender knows to be likely to cause the death of the person to whom the harm is caused, or—
>
> *Thirdly.*—If it is done with the intention of causing bodily injury to any person and the bodily injury intended to be inflicted is sufficient in the ordinary course of nature to cause death, or—
>
> *Fourthly.*—If the person committing the act knows that it is so imminently dangerous that it must, in all probability, cause death, or such bodily injury as is likely to cause death, and commits such act without any excuse for incurring the risk of causing death or such injury as aforesaid."

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Active euthanasia involves an intention on the part of the doctor to cause the death of the patient. Such cases fall under the first clause of Section 300. Exception 5 to Section 300 states:

> "*Exception 5.*—Culpable homicide is not murder when the person whose death is caused, being above the age of eighteen years, suffers death or takes the risk of death with his own consent."

460. Section 304 provides:

> "**304.** ***Punishment for culpable homicide not amounting to murder***.—Whoever commits culpable homicide not amounting to murder, shall be punished with imprisonment for life, or imprisonment of either description for a term which may extend to ten years, and shall also be liable to fine, if the act by which the death is caused is done with the intention of causing death, or of causing such bodily injury as is likely to cause death;
>
> or with imprisonment of either description for a term which may extend to ten years, or with fine, or with both, if the act is done with the knowledge that it is likely to cause death, but without any intention to cause death, or to cause such bodily injury as is likely to cause death."

461. There also exists a distinction between active and passive euthanasia. This is brought out in the application of the doctrine of "double effect". The *Stanford Encyclopedia of Philosophy* elucidates the position thus:

> "The doctrine (or principle) of double effect is often invoked to explain the permissibility of an action that causes a serious harm, such as the death of a human being, as a side-effect of promoting some good end. According to the principle of double effect, sometimes it is permissible to cause a harm as a side-effect (or "double effect") of bringing about a good result even though it would not be permissible to cause such a harm as a means to bringing about the same good end."[275]

It has been observed further:

> "A doctor who intends to hasten the death of a terminally-ill patient by injecting a large dose of morphine would act impermissibly because he intends to bring about the patient's death. However, a doctor who intended to relieve the patient's pain with that same dose and merely foresaw the hastening of the patient's death would act permissibly."[276]

462. A distinction arises between active and passive euthanasia from the provisions of the Penal Code. Active euthanasia involves an intention to cause the death of the patient. Mens rea requires a guilty mind; essentially an intent to cause harm or injury. Passive euthanasia does not embody an intent to cause death. A doctor may withhold life support to ensure that the life of a patient who is in the terminal stage of an incurable illness or in a permanent vegetative state, is not prolonged artificially. The decision to do so is not founded upon an intent

275 "Doctrine of Double Effect", *Stanford Encyclopedia of Philosophy* (28-7-2004) <https://plato.stanford.edu/entries/double-effect/>.
276 *Ibid.*

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to cause death but to allow the life of the patient to continue till and cease at the end of its natural term. Placing such a person on life support would have been an intervention in the natural process of death. A decision not to prolong life by artificial means does not carry an intention to cause death. The crucial element in Section 299 is provided by the expression "causes death". In a case involving passive euthanasia, the affliction of the patient is not brought about either by an act or omission of the doctor. There is neither an animus nor an intent to cause death. The creation of the condition of the patient is outside the volition of the doctor and has come about without a covert or overt act by the doctor. The decision to withhold medical intervention is not intended to cause death but to prevent pain, suffering and indignity to a human being who is in the end stage of a terminal illness or of a vegetative state with no reasonable prospect of cure. Placing a patient on artificial life support would, in such a situation, merely prolong the agony of the patient. Hence, a decision by the doctor based on what is in the best interest of the patient precludes an intent to cause death. Similarly, withdrawal of artificial life support is not motivated by an intent to cause death. What a withdrawal of life support does is not to artificially prolong life. The end of life is brought about by the inherent condition of the patient. Thus, both in a case of a withdrawal of life supporting intervention and withholding it, the law protects a bona fide assessment of a medical professional. There being no intent to cause death, the act does not constitute either culpable homicide or murder.

463. Moreover, the doctor does not inflict a bodily injury. The condition of a patient is on account of a factor independent of the doctor and is not an outcome of his or her actions. Death emanates from the pre-existing medical condition of the patient which enables life to chart a natural course to its inexorable end. The law protects a decision which has been made in good faith by a medical professional not to prolong the indignity of a life placed on artificial support in a situation where medical knowledge indicates a point of no return. Neither the act nor the omission is done with the knowledge that it is likely to cause death. This is for the reason that the likelihood of death is not occasioned by the act or omission but by the medical condition of the patient. When a doctor takes a considered decision in the case of a patient in a terminal stage of illness or in a permanently vegetative state, not to provide artificial life support, the law does not attribute to the doctor the knowledge that it is likely to cause death.

464. Section 43 of the Penal Code defines the expression "illegal" to mean "... everything which is an offence or which is *prohibited by law*, or which furnishes ground in a civil action". Withdrawing life support to a person in a permanently vegetative state or in a terminal stage of illness is not "prohibited by law". Such an act would also not fall outside the purview of Section 92 for the reason that there is no intentional causing of death or attempt to cause death. Where a decision to withdraw artificial life support is made in the caregiver of the patient, it fulfils the duty of care required from a doctor towards the patient. Where a doctor has acted in fulfilment of a duty of care owed to the patient, the medical judgment underlying the decision protects it from a charge of illegality. Such a decision is not founded on an intention to cause death or

on the knowledge that it is likely to cause death. An act done in pursuance of the duty of care owed by the doctor to a patient is not prohibited by law.

465. In a situation where passive euthanasia is non-voluntary, there is an additional protection which is also available in circumstances which give rise to the application of Section 92. Where an act is done for the benefit of another in good faith, the law protects the individual. It does so even in the absence of the consent of the other, if the other individual is in a situation where it is impossible to signify consent or is incapable of giving consent. Section 92 also recognises that there may be no guardian or other person in lawful charge from whom it is possible to obtain consent. However, the proviso to Section 92 stipulates that this exception shall not extend to intentionally causing death or attempting to cause death. The intent in passive euthanasia is not to cause death. A decision not to prolong life beyond its natural span by withholding or withdrawing artificial life support or medical intervention cannot be equated with an intent to cause death. The element of good faith, coupled with an objective assessment of the caregiver of the patient would protect the medical professional in a situation where a bona fide decision has been taken not to prolong the agony of a human being in a terminal or vegetative state by a futile medical intervention.

466. In 2006, the Law Commission of India submitted its 196th Report titled "Medical Treatment to Terminally-Ill Patients (Protection of Patients and Medical Practitioners)". The Report by Justice M. Jagannadha Rao as Chairperson contains a succinct elucidation of legal principles governing criminal law on the subject. Some of them are explained below:

466.1. An informed decision of a patient to refuse medical treatment is accepted at common law and is binding on a treating doctor. While a doctor has a duty of care, a doctor who obeys the instructions of a competent patient to withhold or withdraw medical treatment does not commit a breach of professional duty and the omission to treat will not be an offence;

466.2. The decision of a patient to allow nature to take its course over the human body and, in consequence, not to be subjected to medical intervention, does not amount to a deliberate termination of physical existence. Allowing nature to take its course and a decision to not receive medical treatment does not constitute an attempt to commit suicide within the meaning of Section 309 of the Penal Code;

466.3. Once a competent patient has decided not to accept medical intervention, and to allow nature to take its course, the action of the treating doctor in abiding by those wishes is not an offence, nor would it amount to an abetment under Section 306. Under Section 107, an omission has to be illegal to constitute an abetment. A doctor bound by the instructions of a patient to withhold or withdraw medical treatment is not guilty of an illegal act or an abetment. The doctor is bound by the decision of the patient to refuse medical intervention;

466.4. A doctor who withholds or withdraws medical treatment in the best interest of a patient, such as when a patient is in a permanent vegetative state

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or in a terminal state of an incurable illness, is not guilty under Section 299 because there is no intention to cause death or bodily injury which is likely to cause death. The act of withholding or withdrawing a life support system in the case of a competent patient who has refused medical treatment and, in the case of an incompetent person where the action is in the best interest of the patient would be protected by good faith protections available under Sections 76, 79, 81 or, as the case may be, by Section 88, even if it is construed that the doctor had knowledge of the likelihood of death; and

466.5. The decision of the doctor, who is under a duty at common law to obey the refusal of a competent patient to take medical treatment, would not constitute a culpable act of negligence under Section 304-A. When the doctor has taken such a decision to withhold or withdraw treatment in the best interest of the patient, the decision would not constitute an act of gross negligence punishable under Section 304-A.

467. Introducing a structural safeguard, in the form of a Medical Board of experts can be contemplated to further such an objective. The Transplantation of Human Organs and Tissues Act, 1994 provides for the constitution of Authorisation Committees under Section 9(4). Authorisation Committees are contemplated at the State and district levels and a hospital board.[277] Once the process of decision-making has been arrived at by fulfilling a mandated safeguard (the prior approval of a committee), the decision to withdraw life support should not constitute an illegal act or omission. The setting up of a broad-based board is precisely with a view to lend assurance that the duty of care owed by the doctor to the patient has been fulfilled. Once due safeguards have been fulfilled, the doctor is protected against the attribution of a culpable intent or knowledge. It will hence fall outside the definition of culpable homicide (Section 299), murder (Section 300) or causing death by a rash or negligent act (Section 304-A). The composition of this broad-based committee has been dealt with in the last segment of this judgment.

J. ***Advance Directives***

468. A patient, in a sound state of mind, possesses the ability to make decisions and choices and can legitimately refuse medical intervention. Cardozo, J. had this to say in a seminal statement of principle in the 1914 decision in *Schloendorff* v. *Society of New York Hospital*[278]:

> "Even human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault."

469. Luis Kutner gave expression to the relationship of privacy with the inviolability of the person and the refusal of medical treatment:

> "... The attitude of the law is to recognise the inviolability of the human body. The patient's consent must be voluntary and informed. These notions

277 Rule 6-A, Transplantation of Human Organs and Tissues Act, 1995.
278 105 NE 92 at p. 93 (NY 1914)

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are buttressed by the constitutionally recognized right to privacy. Clearly, then, a patient may refuse treatment which would extend his life. Such a decision must rest with the patient."[279]

The difficulty, as Kutner notes, arises when a patient is unconscious or is not in a position to furnish his or her consent. The author notes that in such a case "the law assumes a constructive consent to such treatment as will save his life". Kutner's thesis contemplates what should happen, if the patient is incapable of giving consent:

> "... The law, however, does recognize that a patient has a right to refuse to be treated, even when he is in extremis, provided he is an adult and capable of giving consent. Compliance with the patient's wishes in such circumstances is not the same as voluntary euthanasia. Where, however, the patient is incapable of giving consent, such as when he is in a coma, a constructive consent is presumed and the doctor is required to exercise reasonable care in applying ordinary means to preserve the patient's life. However, he is not allowed to resort to extraordinary care especially where the patient is not expected to recover from the comatose state...."

470. Recognition of the right to accept or refuse medical treatment is founded upon autonomy. The *Stanford Encyclopaedia of Philosophy*[280] postulates that there is "a rough consensus in medical ethics on the requirement of respect for patient autonomy". However, a patient may not always have the opportunity to grant or withhold consent to medical treatment. An unforeseen event may deprive the individual of the ability to indicate a desire to either receive or not to have medical treatment. An occasion necessitating treatment in sudden cases where a person suffers an accident, a stroke or coronary[281] episode may provide no time for reflection. In anticipation of such situations, "where an individual patient has no desire to be kept in a state of complete and indefinite vegetated animation with no possibility of recovering his mental and physical faculties, that individual, while still in control of all his/her faculties and his ability to express himself/herself"[282], could still retain the right to refuse medical treatment by way of "Advance Directives".

471. Broadly, there are two forms of Advance Directives:

(*i*) A *Living Will* which indicates a person's views and wishes regarding medical treatment.

(*ii*) A *Durable Power of Attorney for Health Care* or healthcare proxy which authorises a surrogate decision-maker to make medical care decisions for the patient in the event she or he is incapacitated.

279 Luis Kutner, "Due Process of Euthanasia: The Living Will, A Proposal", Indiana Law Journal (1969), Vol. 44, Issue 4, at p. 539.

280 "Advance Directives and Substitute Decision-Making", *Stanford Encyclopaedia of Philosophy* (24-3-2009) <https://plato.standford.edu/entries/advance-directives/>.

281 Luis Kutner (Supra note 279) at p. 551.

282 Luis Kutner (Supra note 197) at p. 226.

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Although there can be an overlap between these two forms of Advance Directives, the focus of a durable power is on who makes the decision while the focus of a living will is on what the decision should be. A "living will" has also been referred as "a declaration determining the termination of life", "testament permitting death", "declaration for bodily autonomy", "declaration for ending treatment", "body trust", or other similar reference.[283] Living wills are not a new entity and were first suggested by US attorney, Luis Kutner, in late 1960s.[284]

472. Advance Directives have evolved conceptually to deal with cases where a patient who subsequently faces a loss of the mental faculty to decide has left instructions, when he or she was possessed of decision-making capacity, on how future medical decisions should be made. The *Stanford Encyclopaedia*[285] explains the concept thus:

> "... For patients who lack the relevant decision-making capacity at the time the decision is to be made, a need arises for surrogate decision-making: someone else must be entrusted to decide on their behalf. Patients who formerly possessed the relevant decision-making capacity might have anticipated the loss of capacity and left instructions for how future medical decisions ought to be made. Such instructions are called an Advance Directive. One type of Advance Directive simply designates who the surrogate decision-maker should be. A more substantive Advance Directive, often called a living will, specifies particular principles or considerations meant to guide the surrogate's decisions in various circumstances...."

Hazel Biggs[286] explains the meaning of "living wills" and Advance Directives:

> "Usually a living will is thought of as a statement indicating a person's preferred treatment options at the end of life, but the term "living will" is also "sometimes used for Advance Directives which are concerned with other situations or which can be used to express a willingness to receive particular treatments". Some stipulate that specific treatments are acceptable while others are not, while others insist that all available appropriate medical resources should be utilised to maintain life. Living wills are not therefore exclusively associated with end-of-life decisions, although generally the purpose of a living will is to promote individual autonomy and choice for the patient; characteristics which have long been associated with euthanasia as a means of achieving death with dignity".

283 Luis Kutner (Supra note 279) at p. 551.
284 *Ibid.*
285 "Advance Directives and Substitute Decision-Making", *Stanford Encyclopaedia of Philosophy* (24-3-2009) <https://plato.standford.edu/entries/advance-directives/>.
286 Hazel Biggs (Supra note 153), at p. 115.

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James C. Turner[287] explains the concept of a living will thus:

> "The living will is a document by which a competent adult signifies a desire that if there ever comes a time when there is no reasonable expectation of his recovery from physical or mental disability that he be allowed to die rather than be kept alive by artificial means or heroic measures. What the typical living will does, in effect, is to sanction passive euthanasia, or, as it has been called, antidysthanasia.
>
> The living will is a document which directs one's physician to cease affirmative treatment under certain specified conditions. It can presumably apply to both the situation in which a person with a terminal disease lapses into the final stage of his illness and also the situation in which a victim of a serious accident deteriorates into a state of indefinite vegetated animation...."

473. The principles of patient autonomy and consent are the foundation of Advance Medical Directives. A competent and consenting adult is entitled to refuse medical treatment. By the same postulate, a decision by a competent adult will be valid in respect of medical treatment in future. As Biggs states:

> "... Founded upon respect for individual autonomy this is a right that operates through the law of consent to protect patients from unfettered medical paternalism. Common law holds that patients with the capacity to give consent are also competent to refuse or withhold consent, "even if a refusal may risk personal injury to health or even lead to premature death". Furthermore, a "refusal of treatment can take the form of a declaration of intent never to consent to that treatment in the future, or never to consent in some future circumstances". Accordingly, any consent or refusal of consent made by a competent adult patient can also be valid in respect of the same treatment at any time in the future."

474. Advance Directives are thus documents a person completes while still in possession of decisional capacity about how treatment decisions should be made in the event she or he loses decision-making capacity in future. They cover three conditions: (*i*) a terminal condition; (*ii*) a persistently unconscious condition; and (*iii*) an end-stage condition.

475. A *terminal condition* is an incurable or irreversible condition which even with the administration of life-sustaining treatment will result in death in the foreseeable future. A *persistently unconscious* condition is an irreversible condition, in which thought and awareness of self and environment are absent. An *end-stage condition* is a condition caused by injury, disease or illness which results in severe and permanent deterioration indicated by incompetency and complete physical dependency for which treatment of the irreversible condition would be medically ineffective.

287 James C. Turner, "Living Wills — Need for Legal Recognition", West Virginia Law Review (1976), Vol. 78, Issue 3, at p. 370.

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476. The reason for recognising an Advance Directive is based on individual autonomy. As an autonomous person, every individual has a constitutionally recognised right to refuse medical treatment. The right not to accept medical treatment is essential to liberty. Medical treatment cannot be thrust upon an individual, however, it may have been conceived in the interest of the individual. The reasons which may lead a person in a sound state of mind to refuse medical treatment are inscrutable. Those decisions are not subject to scrutiny and have to be respected by the law as an essential attribute of the right of the individual to have control over the body. The State cannot compel an unwilling individual to receive medical treatment. While an individual cannot compel a medical professional to provide a *particular* treatment (this being in the realm of professional medical judgment), it is equally true that the individual cannot be compelled to undergo medical intervention. The principle of sanctity of life thus recognises the fundamental liberty of every person to control his or her body and as its incident, to decline medical treatment. The ability to take such a decision is an essential element of the privacy of the being. Privacy also ensures that a decision as personal as whether or not to accept medical treatment lies exclusively with the individual as an autonomous being. The reasons which impel an individual to do so are part of the privacy of the individual. The mental processes which lead to decision-making are equally part of the constitutionally protected right to privacy.

477. Advance Directives are founded on the principle that an individual whose state of mind is not clouded by an affliction which prevents him or her from taking decisions is entitled to decide whether to accept or not accept medical intervention. If a decision can be made for the present, when the individual is in a sound state of mind, such a person should be allowed to decide the course of action which should be followed in the future if he or she were to be in a situation which affects the ability to take decisions. If a decision on whether or not to receive medical treatment is valid for the present such a decision must be equally valid when it is intended to operate in the future. Advance Directives are, in other words, grounded in a recognition by the law of the importance of consent as an essential attribute of personal liberty. It is the consensual nature of the act underlying the Advance Directive which imparts sanctity to it in future in the same manner as a decision in the present on whether or not to accept medical treatment.

478. When a patient is brought for medical treatment in a state of mind in which he or she is deprived of the mental capacity to make informed choices, the medical professional needs to determine the line of treatment. One line of enquiry, which seeks to protect patient autonomy is how the individual would have made a decision if he or she had decision-making capacity. This is called the substituted judgment standard. An Advance Medical Directive is construed as a facilitative mechanism in the application of the substituted judgment standard, if it provides to the physician a communication by the patient (when she or he was in a fit state of mind) of the desire for or restraint on being provided medical treatment in future.

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479. Conceptually, there is a second standard, which is the caregiver standard. This is founded on the principle of beneficence. The second standard seeks to apply an objective notion of a line of treatment which a reasonable individual would desire in the circumstances.

480. The *Stanford Encyclopaedia* contains an elucidation of these two standards:

> "The Substituted Judgment standard:
>
> The surrogate's task is to reconstruct what the patient himself would have wanted, in the circumstances at hand, if the patient had decision-making capacity. Substantive Advance Directives are here thought of as a helpful mechanism for aiding the application of Substituted Judgment. The moral principle underlying this legal standard is the principle of respect for autonomy, supplemented by the idea that when a patient is not currently capable of making a decision for himself, we can nonetheless respect his autonomy by following or reconstructing, as best we can, the autonomous decision he would have made if he were able. In a subset of cases, a substituted judgment can implement an actual earlier decision of the patient, made in anticipation of the current circumstances; this is known as precedent autonomy.
>
> The Caregiver standard:
>
> The surrogate is to decide based on what, in general, would be good for the patient. The moral principle underlying this standard is the principle of beneficence. This legal standard has traditionally assumed a quite generic view of interests, asking what a "reasonable" person would want under the circumstances and focusing on general goods such as freedom from pain, comfort, restoration and/or development of the patient's physical and mental capacities. This is because the Caregiver standard has mainly been employed when there is little or no information about the patient's specific values and preferences. However, the concept of caregiver is simply the concept of what is best for the person. There is no reason why, in principle, the Caregiver judgment could not be as nuanced and individual as the best theory of well-being dictates."

The difference between these two standards is that the first seeks to reconstruct the subjective point of view of the patient. The second allows for "a more generic view of interests", without having to rely on the "idiosyncratic values and preference of the patient in question".

481. The *Encyclopaedia* explains that the "orthodox view" contained the following ordering of priorities:

> "1. Honour a substantive Advance Directive, as an aid to Substituted Judgment, whenever such directive is available.
>
> 2. Absent an Advance Directive, apply the Substituted Judgment standard based on available information about the patient's past decisions and values.

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3. If you cannot apply the Substituted Judgment standard — either because the patient has never been competent or because information about the patient's former wishes and values is unavailable — use the Caregiver standard."

482. The above ordering of priorities in the orthodox view has been questioned. In prioritising Advance Directives and substituted judgments, the orthodox view "overlooks the possibility that the earlier competent self and the current incompetent self may have conflicting interests". Advance Directives and the substituted judgment standard were propounded to deal with afflictions such as a persistent vegetative state where the interests of the patient in such a state are not potentially different from what they used to be. The *Stanford Encyclopaedia*, however, notes that a loss of decision-making capacity may give rise to less drastic conditions in which the presently incompetent patient may have developed "powerful new interests" in a new phase of life. Patients facing Alzheimer's or dementia face progressive mental deterioration. When such a patient was still in a competent state of mind, she may have regarded a state of dementia to be degrading. However, as the disease progresses, the interests of the patient change and her life may be enriched by the simple activities of life. The patient may cease to identify with his or her intellect and revisit an earlier desire not to prolong life. The *Stanford Encyclopaedia* states that in such an eventuality, "the conflict is between the autonomy of the earlier self and the well-being of the current self".

483. One way of seeking a philosophical resolution is to postulate that the former self and its interests will have priority, or a "special authority" over the current self. Such an approach prioritises autonomy over beneficence. This line of approach is, however, not free of difficulty. A patient may have lost the ability to take complex decisions. Yet the treating physician may not have "a licence to discount the current well-being of the individual in favour of what mattered to him earlier". This illustration emphasises the potential conflict between a pure application of the substituted judgment standard and the caregiver standard. The former seeks to preserve individual autonomy at all costs. The latter juxtaposes the role of the medical professional in determining what is in the best interest of the patient. The best interest standard is hence founded on the principle that a patient who has progressed from a competent mental state to an increasing lack of mental capacity faces a change of personal identity. An autonomous decision suited to an earlier identity may not always be a valid rationale for determining the course of action in respect of a new identity which a patient acquires in the course of illness:

"According to the threshold views, the earlier self has authority to determine the overall interests of the patient because the current self has lost crucial abilities that would allow it to ground these overall interests anew. This picture assumes that the earlier and current self are stages in the life of one entity, so that, despite the talk of local interests associated with each life-stage, there is an underlying continuity of interests between the two. But this is a very substantial assumption, and it has been contested

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by appeal to an influential account of the metaphysics of personal identity over time, the psychological continuity account. Roughly, the idea is that, in the wake of a drastic transformation of one's psychology such as Alzheimer's disease, one does not survive as numerically the same individual, so whatever interests one's predecessor in one's body may have had are not a suitable basis for decisions on behalf of the new individual who has emerged after the transformation (Dresser 1986). The lack of identity between the earlier and current self undercuts the authority of the former over the latter."

484. In such a situation the doctor's duty to care assumes significance. The relationship between a doctor and her patient with an evolving mental condition needs a balance between the *desires* of the patient in a different mental state and the *needs* of the patient in the present condition. Neither can be ignored in preference to the other. The first recognises the patient as an autonomous individual whose desires and choices must be respected by law and medicine. The desire not to be subject to endless medical intervention, when one's condition of mind or body have reached an irreversible state is a profound reflection of the value to be left alone. Constitutional jurisprudence protects it as part of the right to privacy. On the other hand, the need to procure the dignity of the individual in a deteriorating and irreversible state of body or mind is as crucial to the value of existence. The doctor must respect the former while being committed as a professional to protect the latter.

485. Human experience suggests that there is a chasm of imponderables which divide the present from the future. Such a divide may have a bearing on whether and if so, the extent to which an Advance Directive should bind in the future. As stated above, the sanctity of an Advance Directive is founded upon the expression of the will of an individual who is in a sound state of mind when the directive is executed. Underlying the consensual character of the declaration is the notion of the consent being informed. Undoubtedly, the reasons which have weighed with an individual in executing the Advance Directive cannot be scrutinised (in the absence of situations such as fraud or coercion which implicate the very basis of the consent). However, an individual who expresses the desire not to be subjected to a particular line of treatment in the future, should she or he be ailing in the future, does so on an assessment of treatment options available when the directive is executed. For instance, a decision not to accept chemotherapy in the event that the individual is detected with cancer in the future, is based on today's perception of the trauma that may be suffered by the patient through that treatment. Advances in medical knowledge between the date of the execution of the document and an uncertain future date when the individual may possibly confront treatment for the disease may have led to a re-evaluation by the person of the basis on which a desire was expressed several years earlier. Another fundamental issue is whether the individual can by means of an Advance Directive compel the withholding of basic care such as hydration and nourishment in the future. Protecting the individual from pain and suffering as well as the indignity of debility may similarly raise important

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issues. Advance Directives may hence conceivably raise ethical issues of the extent to which the perception of the individual who executes it must prevail in priority to the best interest of the patient.

486. The substituted judgment standard basically seeks to determine what the individual would have decided. This gives primacy to the autonomy of the individual. On the other hand, as seen earlier, the best interest standard is based on the principle of beneficence. There is an evident tension between these two standards. What an individual would decide as an autonomous entity is a matter of subjective perception. What is in the best interest of the patient is an objective standard: objective, with the limitation that even experts differ. The importance of an Advance Directive lies in bringing to the fore the primacy of individual choice. Such a directive ensures that the individual retains control over the manner in which the body is treated. It allows the individual to decide not to accept artificial treatment which would prolong life in the terminal stage of an ailment or in a vegetative state. In doing so, recognition is granted to the effect of the Advance Directive upon the happening of a contingency in the future, just as the individual would in the present have a right to refuse medical treatment. The Advance Directive is an indicator to medical professionals of the underlying desire of the person executing it.

487. In a society such as ours where family ties have an important place in social existence, Advance Directives also provide a sense of solace to the family. Decisions such as whether to withhold or withdraw artificial life saving treatment are difficult for families to take. Advance Directives provide moral authority for the family of the patient that the decision which has been taken to withdraw or withhold artificial life support is in accord with the stated desire of the patient expressed earlier. But the ethical concerns which have been referred to earlier may warrant a nuanced application of the principle. The circumstances which have been adverted to earlier indicate that the decision on whether to withhold or withdraw medical treatment should be left to a competent body comprising of, but not restricted to medical professionals. Assigning a supervisory role to such a body is also necessary in order to protect against the possibility of abuse and the dangers surrounding the misuse of an Advance Directive. One cannot be unmindful of prevailing social reality in the country. Hence, it is necessary to ensure that an Advance Directive is not utilised as a subterfuge to fulfil unlawful or unethical purposes such as facilitating a succession to property.

488. The view which this judgment puts forth is that the recognition of Advance Directives as part of a regime of constitutional jurisprudence is an essential attribute of the right to life and personal liberty under Article 21. That right comprehends dignity as its essential foundation. Quality of life is integral to dignity. As an essential aspect of dignity and the preservation of autonomy of choice and decision-making, each individual must have the right on whether or not to accept medical intervention. Such a choice expressed at a point in time when the individual is in a sound and competent state of mind should have sanctity in the future if the individual were to cease to have the mental capability to take decisions and make choices. Yet, a balance between the application of

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the substituted judgment standard and the best interest standard is necessary as a matter of public interest. This can be achieved by allowing a supervisory role to an expert body with whom shall rest oversight in regard to whether a patient in the terminal stage of an illness or in a permanent vegetative state should be withheld or withdrawn from artificial life support.

489. In 1995, the British Medical Association (BMA) published a report on advance statements about medical treatment with the intention to reflect "good clinical practice in encouraging dialogue about individuals' wishes concerning their future treatment".[288] The report theoretically discussed six different types of advance statements[289]:

(*i*) A requesting statement reflecting an individual's aspirations and preferences

(*ii*) A statement of general beliefs and aspects of life that the individual values

(*iii*) A statement naming a proxy

(*iv*) A directive giving clear instructions refusing some or all treatment(s)

(*v*) A statement specifying a degree of irreversible deterioration after which no life-sustaining treatment should be given

(*vi*) A combination of the above

490. A decade later, the Mental Capacity Act (MCA), 2005 was enacted, which came into force in October 2007. The statute "enabled individuals to write an Advance Directive or appoint a lasting power of attorney to make their views on healthcare known should they lose capacity"[290]. The Act enshrined in statute law the right of an adult with capacity to make an Advance Directive to refuse specific treatment at a point in the future when they lack capacity.

491. Before turning to MCA, it is of importance to state the position of the common law before the enactment of the legislation. English Law has recognised the entitlement of an individual possessed of the ability to take decisions to refuse medical treatment[291]. The law has had to confront problems in applying this standard in difficult, practical situations. For instance, in a judgment in *B. (Adult: Refusal of Medical Treatment), In re*[292], a patient who was suffering from tetraplegia declined to consent to artificial ventilation. Though the patient was found initially to suffer from depression and to lack

288 A.S. Kessel and J. Meran, "Advance Directives in the UK: Legal, Ethical, and Practical Considerations for Doctors", British Journal of General Practice (1998), at p. 1263.

289 *Ibid.*

290 "Are Advance Directives legally binding or simply the starting point for discussion on patients' best interests?", BMJ (28-11-2009), Vol. 339, p. 1231

291 *T. (Adult: Refusal of Treatment), In re*, (1942) 4 All ER 649; *C. (Adult: Refusal of Treatment), In re*, (1994) 1 WLR 290 : (1994) 1 All ER 819 and *St. George's Healthcare N.H.S. Trust* v. *S.*, 1999 Fam 26 : (1998) 3 WLR 936 (CA)

292 (2002) 2 All ER 449

decision-making capacity, subsequent evaluation found that she was mentally competent. For a period of nine months, the hospital refused to respect the wishes of the patient not to place her on artificial ventilation, necessitating judicial intervention. When the case travelled to court, the President of the Family Division, Dame Butler-Sloss emphasised that "the right of the patient to demand cessation of treatment must prevail "over the natural desire of the medical and nursing professions to try to keep her alive". The Judge recognised the serious danger of "a benevolent paternalism which does not embrace recognition of the personal autonomy of the severely disabled patient".

492. Commenting on the above decision, Elizabeth Wicks in her recently published book titled *The State and The Body — Legal Regulation of Bodily Autonomy*[293] observes that:

> "... the desire to preserve life is strong and choices to end life, especially in circumstances where the life is not without an element of quality, are often seen as swimming against a strong tide of the value of life."

493. In *AK (Adult Patient) (Medical Treatment: Consent), In re*[294] Hughes, J. (as he then was) in the High Court of Justice, reviewed the authorities, and summarised the common law position thus:

> "Accordingly, the first principle of law which I am satisfied is completely clear, is that in the case of an adult patient of full capacity his refusal to consent to treatment or care must in law be observed. It is clear that in an emergency a doctor is entitled in law to treat by invasive means if necessary a patient who by reason of the emergency is unable to consent, on the grounds that the consent can in those circumstances be assumed. It is, however, also clearly the law that the doctors are not entitled so to act if it is known that the patient, provided he was of sound mind and full capacity, has let it be known that he does not consent and that such treatment is against his wishes. To this extent an advance indication of the wishes of a patient of full capacity and sound mind are effective. Care will of course have to be taken to ensure that such anticipatory declarations of wishes still represent the wishes of the patient. Care must be taken to investigate how long ago the expression of wishes was made. Care must be taken to investigate with what knowledge the expression of wishes was made. All the circumstances in which the expression of wishes was given will of course have to be investigated."

494. In *HE* v. *A Hospital N.H.S. Trust*[295], Munby, J. of the High Court of Justice (Family Division) considered an "Advance Medical Directive/Release" signed by a young woman, which sought to refuse the transfusion of blood or primary blood components in absolute and irrevocable terms. The Court had to

293 Elizabeth Wicks, The State and the Body: Legal Regulation of Bodily Autonomy, Hart Publishing (2016).
294 (2001) 1 FLR 129
295 (2003) 2 FLR 408

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decide whether the Advance Directive was valid and applicable. It was noted that:

> "A competent adult patient has an absolute right to refuse consent to any medical treatment or invasive procedure, whether the reasons are rational, irrational, unknown or non-existent, and even if the result of refusal is the certainty of death.... Consistently with this, a competent adult patient's anticipatory refusal of consent (a so-called 'Advance Directive' or 'living will') remains binding and effective notwithstanding that the patient has subsequently become and remains incompetent. An adult is presumed to have capacity, so the burden of proof is on those who seek to rebut the presumption and who assert a lack of capacity. It is therefore for those who assert that an adult was not competent at the time he made his Advance Directive to prove that fact."

The Court then analysed the specific aspects of the law governing Advance Directives:

> "1. There are no formal requirements for a valid Advance Directive. An Advance Directive need not be either in or evidenced by writing. An Advance Directive may be oral or in writing.
>
> 2. There are no formal requirements for the revocation of an Advance Directive. An Advance Directive, whether oral or in writing, may be revoked either orally or in writing. A written Advance Directive or an Advance Directive executed under seal can be revoked orally.
>
> 3. An Advance Directive is inherently revocable. Any condition in an Advance Directive purporting to make it irrevocable, any even self-imposed fetter on a patient's ability to revoke an Advance Directive, and any provision in an Advance Directive purporting to impose formal or other conditions upon its revocation, is contrary to public policy and void. So, a stipulation in an Advance Directive, even if in writing, that it shall be binding unless and until revoked in writing is void as being contrary to public policy.
>
> 4. The existence and continuing validity and applicability of an Advance Directive is a question of fact. Whether an Advance Directive has been revoked or has for some other reason ceased to be operative is a question of fact.
>
> 5. The burden of proof is on those who seek to establish the existence and continuing validity and applicability of an Advance Directive.
>
> 6. Where life is at stake the evidence must be scrutinised with especial care. Clear and convincing proof is required. The continuing validity and applicability of the Advance Directive must be clearly established by convincing and inherently reliable evidence.
>
> 7. If there is doubt that doubt falls to be resolved in favour of the preservation of life."

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495. The common law has been "refined" by passage of the MCA, 2005, which makes statutory provision for advance decisions to refuse treatment.[296] The Mental Capacity Act has certain underlying principles[297], which can be stated as follows:

(*i*) A person must be assumed to have capacity unless it is established that she lacks capacity.

(*ii*) A person is not to be treated as unable to make a decision unless all practicable steps to help her to do so have been taken without success.

(*iii*) A person is not to be treated as unable to make a decision merely because she makes an unwise decision.

(*iv*) An act done, or decision made, under the Act for or on behalf of a person who lacks capacity must be done, or made, in her caregiver.

(*v*) Before the act is done, or the decision is made, regard must be had to whether the purpose for which it is needed can be as effectively achieved in a way that is less restrictive of the person's rights and freedom of action.

496. Advance decisions are legally binding in England and Wales, as long as they meet certain requirements. Section 24 of the Act deals with the criteria for legally valid advance decisions to refuse treatment. Section 25 deals with the validity and applicability of advance decisions. The Advance Directive does not affect the liability which a person may incur for carrying out or continuing a treatment in relation to the person making the decision, unless the decision is at the material time— (*a*) valid, and (*b*) applicable to the treatment.

497. The law in UK empowers the court of protection to make a declaration as to whether an advance decision— (*a*) exists; (*b*) is valid; (*c*) is applicable to a treatment.[298] Moreover, a person will not incur any liability for the consequences of withholding or withdrawing a treatment from an individual, if she at the material time, reasonably beliefs that a valid advance decision applicable to the treatment, made by that individual, exists.[299]

498. Until the implementation of the Mental Capacity Act, 2005 in October 2007, nobody was able legally to make medical decisions on behalf of another adult in England and Wales. The Act imposes duties on the person who has to make a determination as to what is in an individual's caregiver. All the relevant circumstances must be taken into consideration, which are as follows[300]:

498.1. Considering whether it is likely that the person will at some time have capacity in relation to the matter in question, and if it appears likely that he or she will, when that is likely to be;

296 Alexander Ruck Keene, "Advance Decisions: Getting it Right?" <http://www.39essex.com/docs/articles/advance_decisions_paper_ark_december_2012.pdf>.
297 Section 1, Mental Capacity Act, 2005.
298 Section 26(4), Mental Capacity Act, 2005.
299 Section 26(3), Mental Capacity Act, 2005.
300 Section 4, Mental Capacity Act, 2005.

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498.2. Permitting and encouraging, so far as reasonably practicable, the person to participate, or to improve the ability to participate, as fully as possible in any act done for and any decision affecting the person;

498.3. Where the determination relates to life-sustaining treatment he or she must not, in considering whether the treatment is in the caregiver of the person concerned, be motivated by a desire to bring about death;

498.4. Considering so far as is reasonably ascertainable, the person's past and present wishes and feelings (and, in particular, any relevant written statement made when he or she had capacity); the beliefs and values that would be likely to influence the decision if the person had capacity; and the other factors that he or she would be likely to consider if able to do so; and

498.5. Taking into consideration, if it is practicable and appropriate to consult them, the views of anyone named by the person as someone to be consulted on the matter in question or on matters of that kind; anyone engaged in caring for the person or interested in his or her welfare; any donee of a lasting power of attorney granted by the person; and any deputy appointed for the person by the court, as to what would be in the person's caregiver.

499. Even after the enforcement of the Mental Capacity Act, 2005, there have been examples of life-sustaining treatment being continued despite the desire of the patient to the contrary. In *M. (Adult Patient), In re*[301], a patient who was in a minimally conscious state had previously expressed a desire against artificial intervention. An application was made to withdraw artificial nutrition and hydration. The application was refused by the Judge on the basis that her life had some benefit, in spite of the wishes of the family and the previously expressed desire of the patient when she was competent that she would not like to continue living in such a condition. The Judge took the view that the wishes of the patient were not binding and did not carry substantial weight, not being formally recorded so as to constitute an advance decision under the Mental Capacity Act, 2005. Adverting to this decision, Wicks notes that despite the emphasis in the Act of 2005, on the previously expressed desires of the patient, "these are just one relevant factor and may well not be regarded as the crucial one if they point towards death rather than continued life"[302].

500. Yet, a subsequent decision of the UK Supreme Court in *Aintree University Hospitals NHS Foundation Trust* v. *James*[303] "does signify greater acceptance of the centrality of the dying person's choices"[304]. But decided cases show the "medical evidence relating to the benefits of continued existence remains an influential consideration"[305]. The result has been a greater emphasis in providing palliative care towards the end of life. The palliative care approach gives priority to providing dignity to a dying patient over an approach which only seeks to prolong life:

301 (2012) 1 WLR 1653 : 2011 EWHC 2443 (Fam)
302 Elizabeth Wicks (Supra note 293), at p. 69.
303 2013 UK SC 67
304 Elizabeth Wicks (Supra note 293), at p. 69.
305 *Ibid.*

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"A civilised society really ought to be able to respect the dignity and autonomy of the dying in a way that both gives value to their lives and dignity to their death. The withdrawal of medical treatment from a dying patient can, in some circumstances, be justified; the withdrawal of basic care and compassion cannot."[306]

501. The Mental Health Care Act, 2017, which was assented to by the President of India on 7-4-2017, enacts specific provisions for recognising and enforcing Advance Directives for persons with mental illness. The expression "mental illness" is defined by Section 2(*s*) thus:

"**2.** (*s*) "**mental illness**" means a substantial disorder of thinking, mood, perception, orientation or memory that grossly impairs judgment, behaviour, capacity to recognise reality or ability to meet the ordinary demands of life, mental conditions associated with the abuse of alcohol and drugs, but does not include mental retardation which is a condition of arrested or incomplete development of mind of a person, specially characterised by subnormality of intelligence."

The Act recognises an Advance Directive. An Advance Directive has to be in writing. The person subscribing to it must be a major. While making an Advance Directive, the maker indicates:

(*i*) The manner in which he or she wishes or does not wish to be cared for and treated for a mental illness; and

(*ii*) The person he or she appoints as a nominated representative[307].

An Advance Directive is to be invoked only when the person who made it ceases to have the capacity to make mental healthcare treatment decisions. It remains effective until the maker regains the capacity to do so[308].

502. The Central Mental Health Authority constituted under the Act is empowered to make regulations governing the making of Advance Directives[309].

503. The Mental Health Review Board constituted under the Act has to maintain an online register of all Advance Directives and to make them available to a mental health professional when required[310].

504. Advance Directives are capable of being revoked, amended or modified by the maker at any time[311]. The Act specifies that an Advance Directive will not apply to emergency treatment[312] administered to the maker. Otherwise, a duty has been cast upon every medical officer in charge of a mental health establishment and a psychiatrist in charge of treatment to propose or

306 Elizabeth Wicks (Supra note 293), at p. 71.
307 Section 5(1), Mental Health Care Act, 2017 (India).
308 Section 5(3), Mental Health Care Act, 2017 (India).
309 Section 6, Mental Health Care Act, 2017 (India).
310 Section 7, Mental Health Care Act, 2017 (India).
311 Section 8(1), Mental Health Care Act, 2017 (India).
312 Section 9, Mental Health Care Act, 2017 (India).

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give treatment to a person with a mental illness, in accordance with a valid Advance Directive, subject to Section 11[313]. Section 11 elucidates a procedure which is to be followed where a mental health professional, relative or caregiver does not desire to follow the Advance Directive. In such a case, an application has to be made to the Board to review, alter, cancel or modify the Advance Directive. In deciding whether to allow such an application the Board must consider whether:

(*i*) The Advance Directive is truly voluntary and made without force, undue influence or coercion;

(*ii*) The Advance Directive should apply in circumstances which are materially different;

(*iii*) The maker had made a sufficiently well-informed decision;

(*iv*) The maker possessed the capacity to make decisions relating to mental healthcare or treatment at the time when it was made; and

(*v*) The directive is contrary to law or to constitutional provisions[314].

A duty has been cast to provide access to the Advance Directive to a medical practitioner or mental health professional, as the case may be[315]. In the case of a minor, an Advance Directive can be made by a legal guardian[316]. The Act has specifically granted protection to medical practitioners and to mental health professionals against being held liable for unforeseen consequences upon following an Advance Directive[317].

505. Chapter IV of the Mental Health Care Act, 2017 contains detailed provisions for the appointment and revocation of nominated representatives. The provisions contained in Chapter IV stipulate qualifications for appointment of nominated representatives; an order of precedence in recognising a nominated representative when none has been appointed by the individual concerned; revocation of appointments and the duties of nominated representatives. Among those duties, a nominated representative is to consider the current and past wishes, the life history, values, culture, background and the caregiver of the person with a mental illness; give effective credence to the views of the person with mental illness to the extent of his or her understanding the nature of the decisions under consideration; to provide support in making treatment decisions; have the right to seek information on diagnosis and treatment, among other things.

506. In the context of mental illness, Parliament has now expressly recognised the validity of Advance Directives and delineated the role of nominated representatives in being associated with healthcare and treatment decisions.

313 Section 10, Mental Health Care Act, 2017 (India).
314 Section 11(2), Mental Health Care Act, 2017 (India).
315 Section 11(3), Mental Health Care Act, 2017 (India).
316 Section 11(4), Mental Health Care Act, 2017 (India).
317 Section 13(1), Mental Health Care Act, 2017 (India).

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507. A comparative analysis of Advance Directives in various jurisdictions indicates some common components. They include the patient's views and wishes regarding: (*i*) Cardio-pulmonary resuscitation (CPR) — treatment that attempts to start breathing and blood flow in people who have stopped breathing or whose heart has stopped beating; (*ii*) Breathing tubes; (*iii*) Feeding/hydration; (*iv*) Dialysis; (*v*) Pain killers; (*vi*) Antibiotics; (*vii*) Directions for organ donation; and (*viii*) Appointment of proxy/healthcare agent/surrogate, etc.

508. Legal recognition of Advance Directives is founded upon the belief that an individual's right to have a dignified life must be respected. In *Vishaka* v. *State of Rajasthan*[69], the Court, in the absence of enacted law against sexual harassment at workplaces, had laid down the guidelines and norms for due observance at all workplaces or other institutions, until a legislation is enacted for the purpose. Certain precepts can be deduced from the existing global framework on Advance Directives. These include the following:

508.1. Advance Directives reflect the right of an adult with capacity to make a decision to refuse specific treatment at a point in the future when they lack capacity. A person can be said to lack capacity when "in relation to a matter if at the material time he is unable to make a decision for himself in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain"[318]. He/she must be deemed to have capacity to make decisions regarding his treatment if such person has ability to— (*a*) understand the information that is relevant to take a decision on the treatment or admission or personal assistance; or (*b*) appreciate any reasonably foreseeable consequence of a decision or lack of decision on the treatment or admission or personal assistance; or (*c*) communicate such decision by means of speech, expression, gesture or any other means.[319]

508.2. For a legally valid advance decision to refuse treatment, an Advance Directive must fulfil a basic criteria[320], which should include that—a directive must be made by a person after he has reached 18 years of age[321]; the person must be mentally competent when the directive is made; the directive must specify—in medical or layman's terms—the treatment refused; and, it can specify the circumstances in which the refusal is to apply.

508.3. At any time before reaching the comatose state, an individual can revoke the directive. In other words, an individual may withdraw or alter an advance decision at any time when he/she has capacity to do so. Such withdrawal (including a partial withdrawal) need not be in writing. A directive must be revoked if the statements or actions subsequent to the written document indicate contrary consent.[322]

69 (1997) 6 SCC 241 : 1997 SCC (Cri) 932
318 Section 2, Mental Capacity Act, 2005 (UK).
319 Section 4, Mental Health Care Act, 2017 (India).
320 Section 24, Mental Capacity Act, 2005 (UK).
321 A parent acting on behalf of his child cannot make such a declaration.
322 Luis Kutner (Supra note 197), at p. 228.

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508.4. An advance decision will not be applicable to the treatment in question if — (*a*) at the material time, the person, who made it, did not have the capacity to give or refuse consent to it[323]; (*b*) the treatment is not the treatment specified in the advance decision[324]; (*c*) any circumstances specified in the advance decision are absent[325]; or (*d*) there are reasonable grounds for believing that circumstances exist which the person making the directive did not anticipate at the time of the advance decision and which would have affected his decision had he anticipated them.[326]

508.5. If a person intends specifically to refuse life-sustaining procedures[327], he/she must — clearly indicate that it is to apply even if life is at risk and death will predictably result; put the decision in writing; and, ensure it is signed and witnessed.

508.6. In the event that there is more than one valid Advance Directive, none of which have been revoked, the most recently signed Advance Directive will be considered as the last expression of the patient's wishes and will be given effect.

508.7. A person will not incur any liability for the consequences of withholding or withdrawing a treatment from an individual, if he, at the material time, reasonably beliefs that a valid advance decision applicable to the treatment, made by that individual, exists.[328]

508.8. An Advance Directive must clearly contain the following:

(*a*) full details of its maker, including date of birth, home address and any distinguishing features;

(*b*) the name and address of a general practitioner and whether they have a copy;

(*c*) a statement that the document should be used if the maker lacks capacity to make treatment decisions;

(*d*) a clear statement of the decision, the treatment to be refused and the circumstances in which the decision will apply;

(*e*) the date the document was written (or reviewed); and,

(*f*) the person's signature and the signature of a witness.[329]

509. Advance Directives also have limitations. Individuals may not fully understand treatment options or recognise the consequences of certain choices in the future. Sometimes, people change their minds after expressing Advance Directives and forget to inform others. Another issue with Advance Directives is that vague statements can make it difficult to understand the course of action

323 Section 25(3), Mental Capacity Act, 2005 (UK).
324 Section 25(4)(*a*), Mental Capacity Act, 2005 (UK).
325 Section 25(4)(*b*), Mental Capacity Act, 2005 (UK).
326 Section 25(4)(*c*), Mental Capacity Act, 2005 (UK).
327 Sections 25(5) and (6), Mental Capacity Act, 2005 (UK).
328 Section 26(3), Mental Capacity Act, 2005 (UK).
329 Alexander Ruck Keene, "Advance Decisions: Getting it Right?" <http://www.39essex.com/docs/articles/advance_decisions_paper_ark_december_2012.pdf>.

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when a situation arises. For example, general statements rejecting "heroic treatments" are vague and do not indicate whether you want a particular treatment for a specific situation (such as antibiotics for pneumonia after a severe stroke). On the other hand, very specific directives for future care may not be useful when situations change in unexpected ways. New medical therapies may also have become available since an Advance Directive was given. Thus, Advance Directives should be reviewed and revised regularly if feelings about certain issues change, so that current wishes and decisions are always legally documented.

510. An important facet which a regime of advanced care directives must factor in, is the existence of variables which affect the process. These include, in our society, institutional aspects such as the paucity of access to publicly funded medicare, declining standards of professional ethics and the inadequacy of institutional responses to the lack of professional accountability in the medical profession.

511. A report submitted in October 2017 by the American Bar Association's Commission on Law and Ageing to the US Department of Health Services, dwelt on several variables which bear upon Advance Directives. The following observations provide an insight:

> "A good starting point in understanding this landscape is a realization that law and regulation are but one slice of the universe of variables that profoundly affect the experience of dying....
>
> ... other key variables include institutional innovation, the role of financing systems, professional and public education and professional standards and guidelines. All these operate in a larger framework that is defined by family, workplace, community life and spirituality. Thus, the isolation of law and regulation as a strategy for behaviour change requires a sense of humility in establishing expectations, lest we overstate the influence of law in the human experience of dying...."[330]

512. There are variables which "profoundly affect the experience of dying" even in a developed society. They provide a sobering reflection of the gulf which separates the needs of patients and the availability of services to the poor, in a society like ours with large impoverished strata. Patient autonomy may mean little to the impoverished citizen. For marginalised groups in urban and rural India, even basic medical care is a distant reality. Advance Directives postulate the availability of medical care. For, it is on the hypothesis of such care being available that the right to choose or refuse treatment is based. The stark reality in our society is that medical facilities are woefully inadequate. Primary medical care is a luxury in many places. Public hospitals are overwhelmed by the gap between the demand for medical care and its supply. Advance Directives may have little significance to large segments of Indian society which are denied access to basic care. Advance Directives also require an

330 "Advance Directives and Advance Care Planning: Legal and Policy Issues", US Department of Health and Human Services (October 2007) <https://aspe.hhs.gov/system/files/pdf/75366/adacplpi.pdf> at p. 1.

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awareness of rights. The stark reality is that the average Indian is deprived of even basic medical facilities in an environment where absence of rudimentary care is the norm. Moreover, absolute notions of patient autonomy need to be evaluated in the context of the Indian social structure where bonds of family, religion and caste predominate. The immediate family and in many situations, the larger unit of the extended family are caregivers. In the absence of a social security net, universal medical coverage and compulsory insurance, it is the family to which a patient turns to in distress. Families become the caregivers, willingly or as a result of social conditioning, especially in the absence of resources and alternative institutional facilities. The views of the family which are drawn by close bonds of kinship have to be factored into the process. At the other end of the spectrum, rising costs of medical care in the urban areas threaten to ruin the finances of a family when a member is struck by a serious illness. To them, Advance Directives may provide a measure of assurance when a crucial decision as to whether to prolong artificial support in an irreversible medical situation is to be taken. The fact that the patient had expressed a desire in the form of an Advance Directive obviates a sense of moral guilt on the part of the caregivers, when the family accepts the doctors' wisdom to withdraw or withhold artificial support. Another important variable which a regime of Advance Directives must bear in mind is the danger of misuse. The regime of Advance Directives which is intended to secure patient autonomy must contain safeguards against the greed of avaricious relatives colluding with willing medical professionals. The safeguards must be robust to obviate the dangers. The complexities of culture and of the social strata adverted to above only emphasise the wide diversity that prevails within the country. Our solution must take into account the diversity across the country. It is with the above background in view that we have introduced a safeguard in the form of broad-based committees to oversee the process.

513. In order to ensure clarity in the course of action to be followed I agree with the guidelines contained in the judgment of the learned Chief Justice in regard to Advance Directives as well as in regard to the procedural mechanisms set up in the judgment.

K. *Conclusion*

514. The Court is above all, engaged in the task of expounding the Constitution. In doing so, we have been confronted with the enormous task of finding substance and balance in the relationship between life, morality and the experience of dying. The reason which has impelled the Court to recognise passive euthanasia and Advance Directives is that both bear a close association to the human urge to live with dignity. Age brings isolation. Physical and mental debility bring a loss of self-worth. Pain and suffering are accompanied by a sense of being helpless. The loss of control is compounded when medical intervention takes over life. Human values are then lost to technology. More significant than the affliction of ageing and disease is the fear of our human persona being lost in the anonymity of an intensive care ward. It is hence necessary for this Court to recognise that our dignity as citizens continues to be

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safeguarded by the Constitution even when life is seemingly lost and questions about our own mortality confront us in the twilight of existence.

515. The sanctity of human life is the arterial vein which animates the values, spirit and cellular structure of the Constitution. The Constitution recognises the value of life as its indestructible component. The survival of the sanctity principle is founded upon the guarantees of dignity, autonomy and liberty;

516. The right to a dignified existence, the liberty to make decisions and choices and the autonomy of the individual are central to the quest to live a meaningful life. Liberty, dignity and autonomy are essential to the pursuit of happiness and to find meaning in human existence;

517. The entitlement of each individual to a dignified existence necessitates constitutional recognition of the principle that an individual possessed of a free and competent mental state is entitled to decide whether or not to accept medical treatment. The right of such an individual to refuse medical treatment is unconditional. Neither the law nor the Constitution compel an individual who is competent and able to take decisions, to disclose the reasons for refusing medical treatment nor is such a refusal subject to the supervisory control of an outside entity;

518. Constitutional recognition of the dignity of existence as an inseparable element of the right to life necessarily means that dignity attaches throughout the life of the individual. Every individual has a constitutionally protected expectation that the dignity which attaches to life must subsist even in the culminating phase of human existence. Dignity of life must encompass dignity in the stages of living which lead up to the end of life. Dignity in the process of dying is as much a part of the right to life under Article 21. To deprive an individual of dignity towards the end of life is to deprive the individual of a meaningful existence. Hence, the Constitution protects the legitimate expectation of every person to lead a life of dignity until death occurs;

519. The constitutionally recognised right to life is subject to the procedure established by law. The procedure for regulation or deprivation must, it is well-settled, be fair, just and reasonable. Criminal law imposes restraints and penal exactions which regulate the deprivation of life, or as the case may be, personal liberty. The intentional taking away of the life of another is made culpable by the Penal Code. Active euthanasia falls within the express prohibitions of the law and is unlawful;

520. An individual who is in a sound and competent state of mind is entitled by means of an Advance Directive in writing, to specify the nature of medical intervention which may not be adopted in future, should he or she cease to possess the mental ability to decide. Such an Advance Directive is entitled to deference by the treating doctor. The treating doctor who, in a good faith exercise of professional medical judgment abides by an Advance Directive is protected against the burden of criminal liability;

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521. The decision by a treating doctor to *withhold* or *withdraw* medical intervention in the case of a patient in the terminal stage of illness or in a persistently vegetative state or the like where artificial intervention will merely prolong the suffering and agony of the patient is protected by the law. Where the doctor has acted in such a case in the best interest of the patient and in bona fide discharge of the duty of care, the law will protect the reasonable exercise of a professional decision;

522. In *Gian Kaur*[10], the Constitution Bench held, while affirming the constitutional validity of Section 306 of the Penal Code (abetment of suicide), that the right to life does not include the right to die. *Gian Kaur*[10] does not conclusively rule on the validity of passive euthanasia. The two-Judge Bench decision in *Aruna Shanbaug*[5] proceeds on an incorrect perception of *Gian Kaur*[10]. Moreover, *Aruna Shanbaug*[5] has proceeded on the basis of the act-omission distinction which suffers from incongruities of a jurisprudential nature. *Aruna Shanbaug*[5] has also not dwelt on the intersection between criminal law and passive euthanasia, beyond adverting to Sections 306 and 309 of the Penal Code. *Aruna Shanbaug*[5] has subordinated the interest of the patient to the interest of others including the treating doctors and supporting caregivers. The underlying basis of the decision in *Aruna Shanbaug*[5] is flawed. Hence, it has become necessary for this Court in the present reference to revisit the issues raised and to independently arrive at a conclusion based on the constitutional position;

523. While upholding the legality of passive euthanasia (voluntary and non-voluntary) and in recognising the importance of Advance Directives, the present judgment draws sustenance from the constitutional values of liberty, dignity, autonomy and privacy. In order to lend assurance to a decision taken by the treating doctor in good faith, this judgment has mandated the setting up of committees to exercise a supervisory role and function. Besides lending assurance to the decision of the treating doctors, the setting up of such committees and the processing of a proposed decision through the committee will protect the ultimate decision that is taken from an imputation of a lack of bona fides; and

524. The directions in regard to the regime of Advance Directives have been issued in exercise of the power conferred by Article 142 of the Constitution and shall continue to hold the field until a suitable legislation is enacted by Parliament to govern the area.

525. I agree with the directions proposed in the judgment of the learned Chief Justice. The reference shall stand disposed of in the above terms.

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374
5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

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ASHOK BHUSHAN, J. (*concurring*)— I had the advantage of going through the draft judgment of the Hon'ble the Chief Justice. Though, broadly I subscribe to the views expressed by Hon'ble the Chief Justice on various principles and facets as expressed in the judgment, but looking to the great importance of issues involved, I have penned my reasons for my views expressed. However, I am in full agreement with the directions and safeguards as enumerated by the Hon'ble the Chief Justice in paras 198 to 201 of the judgment with regard to Advance Medical Directives. I also had the benefit of going through the erudite opinion of Dr D.Y. Chandrachud, J., which expresses almost the same views which are reflected in my judgment.

527. This Constitution Bench has been constituted on a reference made by a three-Judge Bench vide its order dated 25-2-2014[20]. The writ petition filed in public interest prayed for essentially following two reliefs:

> (*a*) declare "right to die with dignity" as a fundamental right within the fold of right to live with dignity guaranteed under Article 21 of the Constitution of India;
>
> (*b*) issue direction to the respondent, to adopt suitable procedures, in consultation with the State Governments where necessary, to ensure that persons of deteriorated health or terminally ill should be able to execute a document titled "MY LIVING WILL & ATTORNEY AUTHORISATION" which can be presented to hospital for appropriate action in event of the executant being admitted to the hospital with serious illness which may threaten termination of life of the executant or in the alternative, issue appropriate guidelines to this effect;"

528. The petitioner in support of the writ petition has placed reliance on the Constitution Bench judgment in *Gian Kaur* v. *State of Punjab*[10], as well as two-Judge Bench judgment in *Aruna Ramachandra Shanbaug* v. *Union of India*[5]. The petitioner's case is that this Court in the above two judgments has although disapproved active euthanasia but has granted its approval to passive euthanasia. The three-Judge Bench after referring to paras 24 and 25 of the Constitution Bench judgment observed that the Constitution Bench did not express any binding view on the subject of euthanasia rather reiterated that the legislature would be the appropriate authority to bring the change. Three-Judge Bench further observed that view of two-Judge Bench in *Aruna Ramachandra Shanbaug*[5] that the Constitution Bench in *Gian Kaur*[10] has approved the judgment of House of Lords in *Airedale N.H.S. Trust* v. *Bland*[11] is not correct and further opinion expressed by the two-Judge Bench judgment in paras 101 and 104 is inconsistent. In the above view of the matter the three-Judge Bench made the reference to the Constitution Bench. It is useful to extract

20 *Common Cause* v. *Union of India*, (2014) 5 SCC 338 : (2014) 2 SCC (Cri) 557
10 (1996) 2 SCC 648 : 1996 SCC (Cri) 374
5 (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294
11 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

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paras 17 and 18 of the referring order which is to the following effect: (*Common Cause case*[20], SCC p. 345)

> "*17.* In view of the inconsistent opinions rendered in *Aruna Shanbaug*[5] and also considering the important question of law involved which needs to be reflected in the light of social, legal, medical and constitutional perspective, it becomes extremely important to have a clear enunciation of law. Thus, in our cogent opinion, the question of law involved requires careful consideration by a Constitution Bench of this Court for the benefit of humanity as a whole.
>
> *18.* We refrain from framing any specific questions for consideration by the Constitution Bench as we invite the Constitution Bench to go into all the aspects of the matter and lay down exhaustive guidelines in this regard. Accordingly, we refer this matter to a Constitution Bench of this Court for an authoritative opinion."

529. We have heard Shri Prashant Bhushan, learned counsel appearing for the petitioner. Shri P.S. Narasimha, learned Additional Solicitor General appearing for the Union of India. Shri Arvind Datar, learned Senior Counsel for Vidhi Centre for Legal Policy, Shri Sanjay R. Hegde, learned Senior Counsel for Indian Society of Critical Care Medicine, Mr Devansh A. Mohta, learned counsel for Society for Right to Die with Dignity and Mr Praveen Khattar, learned counsel for Delhi Medical Council. We have also been assisted by Dr R.R. Kishore, Member of the Bar who has joined the Bar after carrying on the profession of doctor for more than 40 years.

A. *Petitioner's case*

530. The petitioner is a registered society which is engaged in taking of the common problems of the people. The petitioner vide this public interest litigation brings to the notice of this Court the serious problem of violation of fundamental right to life, liberty, privacy and the right to die with dignity of the people of this country, guaranteed to them under Article 21 of the Constitution of India. It is submitted that the citizens who are suffering from chronic diseases and/or are at the end of their natural lifespan and are likely to go into a state of terminal illness or permanent vegetative state are deprived of their rights to refuse cruel and unwanted medical treatment, like feeding through hydration tubes, being kept on ventilator and other life supporting machines in order to artificially prolong their natural lifespan. This sometimes leads to extension of pain and agony both physical and mental which they desperately seek to end by making an informed choice and clearly expressing their wishes in advance, (called a living will) in the event of they going into a state when it will not be possible for them to express their wishes.

20 *Common Cause* v. *Union of India*, (2014) 5 SCC 338 : (2014) 2 SCC (Cri) 557
5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

531. The petitioner further pleads that it is a common law right of the people, of any civilised country, to refuse unwanted medical treatment and no person can force him/her to take any medical treatment which the person does not desire to continue with. It is submitted that to initiate a medical treatment to a person who has reached at an end of his life and the process of his/her death has already commenced against the wishes of that person will be violative of his/her right to liberty. The right to be free from unwanted life-sustaining medical treatment is a right protected by Article 21. Even the right to privacy which has also been held to be a part of right to life is being violated as the people are not being given any right to make an informed choice and a personal decision about withholding or withdrawing life sustaining medical treatment.

B. ***Man & Medicine***

532. Human being a mortal, death is an accepted phenomenon. Anyone born on the earth is sure to die. Human body is prone to disease and decay. Human being after getting knowledge of various science and art always fought with failure and shortcomings of human body. Various ways and means of healing its body were found and invented by mankind. The branch of medicine is practised from ancient time both in India and other parts of the world. In our country *Charak Samhita* is a treatise of medicine which dates back 1000 BC.

533. In Western World "Hippocrates" is regarded as "father of western medicine". Hippocratic period dates from 460 BC. *Corpus Hippocraticum* comprises of not only general medical prescription, description of diseases, diagnosis, dietary recommendations but also opinion of professional ethics of a physician. Thus, those who practised medicine from ancient time were ordained to follow some ethical principles. For those who follow medical profession "Hippocratic Oath" was always treated to be Oath to which every medical professional was held to be bound. It is useful to refer to original Hippocratic Oath (as translated into English):

> "I swear by Apollo, the healer, Asclepius, Hygieia, and Panacea, and I take to witness all the Gods, all the Goddesses, to keep according to my ability and my judgment, the following Oath and agreement:
>
> To consider dear to me, as my parents, him who taught me this art; to live in common with him and, if necessary, to share my goods with him; To look upon his children as my own brothers, to teach them this art.
>
> I will prescribe regimens for the good of my patients according to my ability and my judgment and never do harm to anyone.
>
> I will not give a lethal drug to anyone if I am asked, nor will I advise such a plan; and similarly I will not give a woman a pessary to cause an abortion.
>
> But I will preserve the purity of my life and my arts.
>
> I will not cut for stone, even for patients in whom the disease is manifest; I will leave this operation to be performed by practitioners, specialists in this art.

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> In every house where I come I will enter only for the good of my patients, keeping myself far from all intentional ill-doing and all seduction and especially from the pleasures of love with women or with men, be they free or slaves.
>
> All that may come to my knowledge in the exercise of my profession or in daily commerce with men, which ought not to be spread abroad, I will keep secret and will never reveal.
>
> If I keep this Oath faithfully, may I enjoy my life and practise my art, respected by all men and in all times; but if I swerve from it or violate it, may the reverse be my lot."

534. The noticeable portion of the Hippocratic Oath is that medical practitioner swears that he will not give a lethal drug to anyone nor will he advise such a plan.

535. At this juncture, it shall be useful to refer to thoughts of Plato, a celebrated Greek Philosopher, on "physician" and treatment which he expressed in his treatise *Republic*. Plato in *The Republic of Plato*, (translated by Francis Macdonald Cornford) while discussing "physician", in Chapter IX states:

> "Shall we say, then, that Asclepius recognized this and revealed the art of medicine for the benefit of people of sound constitution who normally led a healthy life, but had contracted some definite ailment? He would rid them of their disorders by means of drugs or the knife and tell them to go on living as usual, so as not to impair their usefulness as citizens. But where the body was diseased through and through, he would not try, by nicely calculated evacuations and doses, to prolong a miserable existence and let his patient beget children who were likely to be as sickly as himself. Treatment, he thought, would be wasted on a man who could not live in his ordinary round of duties and was consequently useless to himself and to society."

536. Plato in the same Chapter in little harsher words further states:

> "But if a man had a sickly constitution and intemperate habits, his life was worth nothing to himself or to anyone else; medicine was not meant for such people and they should not be treated, though they might be richer than Midas."

537. From what has been noted above, it is apparent that although on one hand *medical* professional has to take Hippocratic Oath that he shall treat his patient according to his ability and judgment and never do harm to anyone. Further, he will not give any lethal drug to anyone even he is asked for, on the other hand, Plato held that those who has sickly constitution and intemperate habits should not be helped by medicine. Thus, the cleavage in views regarding ethics of a medical professional as well as not supporting medical treatment for those who are thoroughly diseased is found from ancient time in Greek thoughts itself.

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538. The dilemma of medical professional still continues to this day and medical professionals are hesitant in adopting a course which may not support the life of a patient or lead to patient's death. Numerous cases raising conflicting views were brought before the courts in the different parts of the world, some of which we shall refer hereinafter.

539. There has been considerable development in medical science from ancient time to this day. There has been substantial acceptance of natural and human rights of the human beings which found expression in "United Nations Human Rights Declaration, 1948" and subsequent declarations. The right of self-determination of an individual has been recognised throughout the world.

C. ***Concept of life & death***

540. In the ancient India, on "life" and "death" there is considerable literature. According to Hinduism, life never comes to an end. The soul never die although body may decay. The soul is continuous and perpetual which is not merely a biological identity, death is not the end of life but only a transformation of a body. In *Bhagavad Gita* Chapter II Verse 22 (as translated in English), it is stated by Lord Krishna:

> "22. As a man shedding worn-out garments, takes other new ones, likewise the embodied soul, casting off worn-out bodies, enters into others that are new."

541. The death was never feared in ancient Indian culture and mythology. Death was treated sometimes a means to obtain liberation, that is, "moksha". Every life is a gift of God and sacred and it has to be protected at all cost. No person is bestowed with the right to end his or her life. However, an individual's act of discarding mortal body may be permissible under certain circumstances. In ancient Indian religion, sanctity was attached to a Yogi (a person who has mastered the art of regulating his involuntary physical and mental functions, at will) can discard his/her mortal coil (body) through the process of higher spiritual practices called "yoga". Such state was known as "Samadhi". But there was no concept in ancient India/mythology of putting an end to life of another human being which was always regarded as crime and against "dharma".

542. The Vedic Rules also forbid suicide whereas according to ancient Hindu culture, a man in his fourth stage i.e. Vanaprastha could go into the forest sustaining only on water and air, end his body. A Brahmin also could have got rid of his body by drowning oneself in a river, precipitating oneself from a mount, burning oneself or starving oneself to death; or by one of those modes of practising austerities, mentioned above. The Laws of Manu as contained in *Sacred Books of the East*, edited by Max Muller, Vol. 25 Chapter VI Verses 31 and 32 refers to above. The book also refers to views of various commentators on Verses 31 and 32. It is useful to extract Verses 31 and 32 and Note of the author on aforesaid verses containing the views of different commentators which are to the following effect:

> "31. Or let him walk, fully determined and going straight on, in a north-easterly direction, subsisting on water and air, until his body sinks to rest.

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32. A brahmana, having got rid of his body by one of those modes practised by the great sages, is exalted in the world of Brahman, free from sorrow and fear.

.....

31. Gov. and Kull. take yukta, firmly resolved' (Nar., Ragh.), in the sense of "intent on the practice of Yoga." Gov. and Kull. (see also Medh. on the next verse) say that a man may undertake the Mahaprasthana, or "Great Departure", on a journey which ends in death, when he is incurably diseased or meets with a great misfortune, and that, because it is taught in the Sastras, it is not opposed to the Vedic rules which forbid suicide. From the parallel passage of Ap. II, 23, 2, it is, however, evident that a voluntary death by starvation was considered the befitting conclusion of a hermit's life. The antiquity and general prevalence of the practice may be inferred from the fact that the Gaina ascetics, too, consider it particularly meritorious.

32. By one of those modes, "i.e. drowning oneself in a river, precipitating oneself from a mount, burning oneself or starving oneself to death" (Medh.); or "by one of those modes of practising austerities, mentioned above, Verse 23" (Gov., Kull., Nar., Nand.). Medh. adds a long discussion, trying to prove that the world of Brahman', which the ascetic thus gains, is not the real complete liberation."

543. The Hindu scriptures also say that life and death is the gift of God and no human being has right to take away the said gift. Suicide is disapproved in Hindu way of life and it is believed that those who commit suicide did not attain moksha or salvation from the cycle of life and death.

544. The Muslims also strongly condemn suicide as they believe that life and death of a person depends on Allah's will and human beings are prohibited in going against His will.

545. Christianity also disapproves taking of one's life. *Bible* says that human being is a temple of God and the spirit of God dwelleth in the body and no man can defile the temple. Reference is made to Chapter 3 Verses 16 and 17 of I CORINTHIANS, which is as below:

"16. Know Ye not that ye are the temple of God, and that the Spirit of God dwelleth in you?

17. If any man defile the temple of God, him shall God destroy; for the temple of God is holy, which temple ye are."

546. Pope John Paul II in, *The Gospel of Life*, denouncing euthanasia writes:

"Laws which authorise and promote euthanasia are therefore radically opposed not only to the good of the individual but also to the common good; as such they are completely lacking in authentic juridical validity. Disregarded for the right to life, precisely because it leads to the killing of the person whom society exists to serve, is what most directly conflicts

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with the possibility of achieving the common good. Consequently, a civil law authorising euthanasia ceases by that very fact to be a true, morally binding civil law."

547. The tenets of Jainism also talk about the practice of religiously nominated self-build death called "Sallkhana", meaning "fast up to death".

548. The Buddhist scripture states that Lord Buddha had also allowed self-build death for the extremely ill person as an act of compassion.

549. In different religions and cultures, there are clear injunctions against taking life of oneself.

550. The petitioner in the writ petition has categorically clarified that the petitioner is neither challenging the provisions of IPC by which "attempt to suicide" is made a penal offence nor praying for right to die be declared as fundamental right under Article 21. It is useful to refer to Para 7 of the writ petition, in which petitioner pleads the following:

> "It is submitted at the outset that the petitioner in the instant petition is neither challenging Section 309 of the Indian Penal Code, vide which attempt to suicide is a penal offence nor is asking right to die per se as a fundamental right under Article 21 (as the issue is squarely covered by the Constitution Bench judgment of this Hon'ble Court in *Gian Kaur* v. *State of Punjab*[10]). The endeavour of the petitioner in the instant petition is to seek guidelines from this Hon'ble Court whereby the people who are diagnosed of suffering from terminal diseases or ailments can execute Living Will or give directives in advance or otherwise to his/her attorney/executor to act in a specific manner in the event he/she goes into persistent vegetative state or coma owing to that illness or due to some other reason."

D. ***The relevant provisions of IPC***

551. The Penal Code, 1860, is a general penal code defining various acts which are offence and providing for punishment thereof. Chapter XVI deals with "offences affecting the human body". The provisions of the Penal Code which are relevant in the present context are Section 306 and Section 309. Section 306 relates to abetment of suicide. It provides—

> "**306.** ***Abetment of suicide.***—If any person commits suicide, whoever abets the commission of such suicide, shall be punished with imprisonment of either description for a term which may extend to ten years, and shall also be liable to fine."

Another provision which is relevant is Section 309 i.e. attempt to commit suicide. The provision states, whoever attempts to commit suicide and does any act towards the commission of such offence, shall be punished with simple imprisonment for a term which may extend to one year (or with fine, or with both). The issues which have come up for consideration in the present case have to be dealt with keeping in view the above provisions of the Penal Code which declares certain acts to be offence.

10 (1996) 2 SCC 648 : 1996 SCC (Cri) 374

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E. ***Legislation in reference to euthanasia***

552. The only statutory provision in our country which refers to euthanasia is statutory regulations framed under the Indian Medical Council Act, 1956, namely, the Indian Medical Council (Professional Conduct, Etiquette & Ethics) Regulations, 2002. Chapter VI of the Regulations deals with "Unethical Acts". Regulation 6 is to the following effect:

> "**6.** ***Unethical Acts***.—A physician shall not aid or abet or commit any of the following acts which shall be construed as unethical—
>
> * * *
>
> **6.7.** ***Euthanasia***.—Practising euthanasia shall constitute unethical conduct. However, on specific occasion, the question of withdrawing supporting devices to sustain cardio-pulmonary function even after brain death, shall be decided only by a team of doctors and not merely by the treating physician alone. A team of doctors shall declare withdrawal of support system. Such team shall consist of the doctor in charge of the patient, Chief Medical Officer/Medical Officer in charge of the hospital and a doctor nominated by the in charge of the hospital from the hospital staff or in accordance with the provisions of the Transplantation of Human Organs Act, 1994."

553. The Law Commission of India had stated and submitted a detailed report on the subject in 196th Report on "Medical Treatment to Terminally-Ill Patients (Protection of Patients and Medical Practitioners)". Law Commission examined various provisions of the Penal Code and other statutory provisions, judgments of this Court and different courts of other countries and had made certain recommendations. A draft Bill was also made part of the recommendation. The draft Bill, namely, Medical Treatment of Terminally-Ill Patients (Protection of Patients and Medical Practitioners) Bill, 2006, was made part of the Report as an Annexure.

554. Chapter 8 of the Report contains summary of recommendations. It is not necessary to reproduce all the recommendations. It is sufficient to refer to Paras 1 and 2 of the recommendations:

> "In the previous chapters, we have considered various important issues on the subject of withholding or withdrawing medical treatment (including artificial nutrition and hydration) from terminally ill-patients. In Chapter VII, we have considered what is suitable for our country. Various aspects arise for consideration, namely, as to who are competent and incompetent patients, as to what is meant by "informed decision", what is meant by "best interests" of a patient, whether patients, their relations or doctors or hospitals can move a court of law seeking a declaration that an act or omission or a proposed act or omission of a doctor is lawful, if so, whether such decisions will be binding on the parties and doctors, in future civil and criminal proceedings, etc. Questions have arisen whether a patient who refuses treatment is guilty of attempt to commit suicide or whether the doctors are guilty of abetment of suicide or culpable homicide not amounting to murder, etc. On these issues, we have given our views in Chapter VII on a consideration of law and vast comparative literature.

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In this chapter, we propose to give a summary of our recommendations and the corresponding sections of the proposed Bill which deal with each of the recommendations. (The draft of the Bill is annexed to this Report). We shall now refer to our recommendations:

(1) There is need to have a law to *protect patients* who are terminally ill, when they take decisions to refuse medical treatment, including artificial nutrition and hydration, so that they may not be considered guilty of the offence of "attempt to commit suicide" under Section 309 of the Indian Penal Code, 1860.

It is also necessary to *protect doctors* (and those who act under their directions) who obey the competent patient's informed decision or who, in the case of (*i*) incompetent patients or (*ii*) competent patients whose decisions are not informed decisions, and decide that in the best interests of such patients, the medical treatment needs to be withheld or withdrawn as it is not likely to serve any purpose. Such actions of doctors must be declared by statute to be "lawful" in order to protect doctors and those who act under their directions if they are hauled up for the offence of "abetment of suicide" under Sections 305, 306 of the Indian Penal Code, 1860, or for the offence of culpable homicide not amounting to murder under Section 299 read with Section 304 of the Penal Code, 1860 or in actions under civil law.

(2) Parliament is competent to make such a law under Schedule VII List III Entry 26 of the Constitution of India in regard to patients and medical practitioners. The proposed law, in our view, should be called "the Medical Treatment of Terminally-Ill Patients (Protection of Patients and Medical Practitioners) Act."

555. The 196th Report was again revised by the Law Commission of India in 241st Report dated August 2012. The 2006 draft Bill was redrafted by the Law Commission which was Annexure 1 to the Report. The above Bill however could not fructify into a law. The Ministry of Health and Family Welfare had published another draft Bill, namely, the Medical Treatment of Terminally-Ill Patients (Protection of Patients and Medical Practitioners) Bill, 2016, as a Private Member Bill which was introduced in Rajya Sabha on 5-8-2016, which is still pending.

556. From the above, it is clear that only statutory provision on euthanasia is Regulation 6.7 of the 2002 Regulations as referred to above. The Regulations prohibit practising euthanasia and declare that practising euthanasia constitutes unethical conduct on behalf of the medical practitioner. The Regulation however carves an exception that on specific occasion, the question of withdrawing supporting devices to sustain cardio-pulmonary function even after brain death, shall be decided only by a team of doctors and not merely by the treating physician alone. The Regulation further provides that the team of doctors shall declare withdrawal of support system.

557. The withdrawal of medical treatment of terminally ill persons is a complex ethical, moral and social issue with which many countries have wrestled with their attempt to introduce a legal framework for end of life

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decision-making. In absence of a comprehensive legal framework on the subject the issue has to be dealt with great caution.

F. ***Two important judgments of this Court on the subject***

558. The first important judgment delivered by the Constitution Bench of this Court touching the subject is the judgment of the Constitution Bench in *Gian Kaur* v. *State of Punjab*[10]. In the above case, the appellants were convicted under Section 306 and awarded sentence for abetment of commission of suicide by one Kulwant Kaur. The conviction was maintained by the High Court against which the appeal was filed as special leave in this Court. One of the grounds for assailing the conviction before this Court was that Section 306 IPC is unconstitutional. The reliance was placed on two-Judge Bench decision of this Court in *P. Rathinam* v. *Union of India*[6], wherein Section 309 IPC was held to be unconstitutional as violative of Article 21 of the Constitution.

559. Section 306 was sought to be declared as unconstitutional being violative of Article 21 of the Constitution. The Law Commission by its 22nd Report had recommended for deletion of Section 309 and a Bill was introduced in 1972 to amend the Penal Code by deleting Section 309. The Constitution Bench dwelt on the question as to whether "right to die" is included in Article 21. The Constitution Bench concluded that "right to die" "cannot be included as part of fundamental rights guaranteed under Article 21".

560. The challenge to Section 309 on the basis of Articles 14 and 21 was repelled. This Court further held that Section 306 of the Penal Code does not violate Article 21 and Article 14 of the Constitution of India.

561. The second judgment which needs to be noted in detail is the two-Judge Bench judgment of this Court in *Aruna Ramachandra Shanbaug* v. *Union of India*[5]. The writ petition under Article 32 on behalf of Aruna Ramachandra Shanbaug was filed by one Ms Pinky Virani claiming to be best friend. Aruna Ramachandra Shanbaug was staff nurse working in King Edward Memorial (KEM) Hospital, Parel, Mumbai. On 27-11-1973, she was attacked by a sweeper of the hospital who wrapped a dog chain around her neck and yanked her back with it. While sodomising her, he twisted the chain around her neck, as a result supply of oxygen to the brain stopped and the brain got damaged. On the next day she was found in unconscious condition. From the date of above incident she continued to be in persistent vegetative state (PVS) having no state of awareness, she was bedridden, unable to express herself, unable to think, hear and see anything or communicate in any manner. In writ petition under Article 32 it was prayed that the hospital where she is laying for last 36 years be directed to stop feeding and let her die peacefully. In the above case, two-Judge Bench considered all aspects of euthanasia, the Court examined both active and passive euthanasia.

10 (1996) 2 SCC 648 : 1996 SCC (Cri) 374
6 (1994) 3 SCC 394 : 1994 SCC (Cri) 740
5 (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

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562. Dealing with active and passive euthanasia and further voluntary and involuntary euthanasia, following was laid down in paras 39 and 40: (*Aruna Ramachandra case*[5], SCC p. 491)

> "*39*. Coming now to the legal issues in this case, it may be noted that euthanasia is of two types: active and passive. Active euthanasia entails the use of lethal substances or forces to kill a person e.g. a lethal injection given to a person with terminal cancer who is in terrible agony. Passive euthanasia entails withholding of medical treatment for continuance of life e.g. withholding of antibiotics where without giving it a patient is likely to die, or removing the heart-lung machine, from a patient in coma. The general legal position all over the world seems to be that while active euthanasia is illegal unless there is legislation permitting it, passive euthanasia is legal even without legislation provided certain conditions and safeguards are maintained.
>
> *40*. A further categorisation of euthanasia is between voluntary euthanasia and non-voluntary euthanasia. Voluntary euthanasia is where the consent is taken from the patient, whereas non-voluntary euthanasia is where the consent is unavailable e.g. when the patient is in coma, or is otherwise unable to give consent. While there is no legal difficulty in the case of the former, the latter poses several problems, which we shall address."

563. The Court held that in India, active euthanasia is illegal and crime. In para 41, following was held: (*Aruna Ramachandra case*[5], SCC p. 491)

> "*41*. As already stated above active euthanasia is a crime all over the world except where permitted by legislation. In India active euthanasia is illegal and a crime under Section 302 or at least under Section 304 of the Penal Code, 1860. Physician-assisted suicide is a crime under Section 306 IPC (abetment to suicide). Active euthanasia is taking specific steps to cause the patient's death, such as injecting the patient with some lethal substance e.g. sodium pentothal which causes a person deep sleep in a few seconds, and the person instantaneously and painlessly dies in this deep sleep."

564. The Court noticed various judgments of different countries in the above context. The two-Judge Bench also referred to the Constitution Bench judgment in *Gian Kaur* v. *State of Punjab*[10]. In paras 101 and 104, following has been laid down: (*Aruna Ramachandra case*[5], SCC pp. 512-13)

> "*101*. The Constitution Bench of the Supreme Court in *Gian Kaur* v. *State of Punjab*[10] held that both euthanasia and assisted suicide are not lawful in India. That decision overruled the earlier two-Judge Bench

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

10 (1996) 2 SCC 648 : 1996 SCC (Cri) 374

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decision of the Supreme Court in *P. Rathinam* v. *Union of India*[6]. The Court held that the right to life under Article 21 of the Constitution does not include the right to die (vide SCC para 33). In *Gian Kaur case*[10] the Supreme Court approved of the decision of the House of Lords in *Airedale case*[11] and observed that euthanasia could be made lawful only by legislation.

* * *

104. It may be noted that in *Gian Kaur case*[10] although the Supreme Court has quoted with approval the view of the House of Lords in *Airedale case*[11], it has not clarified who can decide whether life support should be discontinued in the case of an incompetent person e.g. a person in coma or PVS. This vexed question has been arising often in India because there are a large number of cases where persons go into coma (due to an accident or some other reason) or for some other reason are unable to give consent, and then the question arises as to who should give consent for withdrawal of life support. This is an extremely important question in India because of the unfortunate low level of ethical standards to which our society has descended, its raw and widespread commercialisation, and the rampant corruption, and hence, the Court has to be very cautious that unscrupulous persons who wish to inherit the property of someone may not get him eliminated by some crooked method."

565. The two-Judge Bench noticed that there is no statutory provision in this country as to the legal procedure to withdraw life support to a person in persistent vegetative state (PVS) or who is otherwise incompetent to take the decision in this connection. The Court, however, issued certain directions which were to continue to be the law until Parliament makes a law on this subject. In para 124, following has been laid down: (*Aruna Ramachandra case*[5], SCC pp. 518-19)

"*124*. There is no statutory provision in our country as to the legal procedure for withdrawing life support to a person in PVS or who is otherwise incompetent to take a decision in this connection. We agree with Mr Andhyarujina that passive euthanasia should be permitted in our country in certain situations, and we disagree with the learned Attorney General that it should never be permitted. Hence, following the technique used in *Vishaka case*[69], we are laying down the law in this connection which will continue to be the law until Parliament makes a law on the subject:

6 (1994) 3 SCC 394 : 1994 SCC (Cri) 740
10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374
11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)
5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294
69 *Vishaka* v. *State of Rajasthan*, (1997) 6 SCC 241 : 1997 SCC (Cri) 932

(*i*) A decision has to be taken to discontinue life support either by the parents or the spouse or other close relatives, or in the absence of any of them, such a decision can be taken even by a person or a body of persons acting as a next friend. It can also be taken by the doctors attending the patient. However, the decision should be taken bona fide in the best interest of the patient.

In the present case, we have already noted that Aruna Shanbaug's parents are dead and other close relatives are not interested in her ever since she had the unfortunate assault on her. As already noted above, it is the KEM hospital staff, who have been amazingly caring for her day and night for so many long years, who really are her next friends, and not Ms Pinki Virani who has only visited her on few occasions and written a book on her. Hence it is for the KEM Hospital staff to take that decision. KEM Hospital staff have clearly expressed their wish that Aruna Shanbaug should be allowed to live.

Mr Pallav Shishodia, learned Senior Counsel, appearing for the Dean, KEM Hospital, Mumbai, submitted that Ms Pinki Virani has no locus standi in this case. In our opinion it is not necessary for us to go into this question since we are of the opinion that it is the KEM Hospital staff who is really the next friend of Aruna Shanbaug.

We do not mean to decry or disparage what Ms Pinki Virani has done. Rather, we wish to express our appreciation of the splendid social spirit she has shown. We have seen on the internet that she has been espousing many social causes, and we hold her in high esteem. All that we wish to say is that however much her interest in Aruna Shanbaug may be it cannot match the involvement of the KEM Hospital staff who have been taking care of Aruna day and night for 38 years.

However, assuming that the KEM Hospital staff at some future time changes its mind, in our opinion in such a situation KEM Hospital would have to apply to the Bombay High Court for approval of the decision to withdraw life support.

(*ii*) Hence, even if a decision is taken by the near relatives or doctors or next friend to withdraw life support, such a decision requires approval from the High Court concerned as laid down in *Airedale case*[11].

In our opinion, this is even more necessary in our country as we cannot rule out the possibility of mischief being done by relatives or others for inheriting the property of the patient."

11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

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G. *Law on subject in other countries*

566. The debate on euthanasia had gathered momentum in last 100 years. The laws of different countries express thoughts of people based on different culture, philosophy and social conditions. Assisted suicide was always treated as an offence in most of the countries. Physician-assisted suicide is also not accepted in most of the countries except in few where it gain ground in last century. In several countries including different States of the USA, European countries and United Kingdom, various legislations have come into existence codifying different provisions pertaining to physician-assisted suicide. The right to not commence or withdraw medical treatment in case of terminally ill or PSV patients, Advance Medical Directives have also been made part of different legislations in different countries.

567. Physician-assisted suicide has not been accepted by many countries. However, few have accepted it and made necessary legislation to regulate it. Switzerland, Netherlands, Belgium, Luxembourg and American States of Oregon, Washington, Montana and Columbia have permitted physician-assisted suicide with statutory regulations. Courts in different parts of the world have dealt with the subject in issue in detail. It is not necessary to refer to different legislation of different countries and the case law on subject of different countries. For the purposes of this case, it shall be sufficient to notice few leading cases of United Kingdom, United States Supreme Court and few others countries.

United Kingdom

568. Euthanasia is criminal offence in the United Kingdom. According to Section 2(1) of the Suicide Act, 1961, a person assisting an individual, who wish to die commits an offence. The provision states that it is an offence to aid, abet, counsel or procure the suicide of another or an attempt by another to commit suicide, however, it is not a crime if it is by their own hands. There has been large parliamentary opposition to the current United Kingdom law concerning assisted suicide but there has been no fundamental change in the law so far. In 1997, the Doctor Assisted Dying Bill as well as in 2000, the Medical Treatment (Prevention of Euthanasia) Bill were not approved.

569. The most celebrated judgment of the House of Lords is *Airedale N.H.S. Trust* v. *Bland*[11]. Anthony David Bland was injured on 15-4-1989 at the Hillsborough football ground in which his lungs were crushed and punctured, the supply of oxygen to the brain was interrupted. As a result, he sustained catastrophic and irreversible damage to the higher centres of the brain, which had left him in a condition known as a persistent vegetative state (PVS). Medical opinion was unanimous that there was no hope of improvement in his condition or recovery. At no time before the disaster had the patient indicated his wishes if he should find himself in such a condition. Bland's father sought declarations that hospital authorities may discontinue all his life-sustaining

11 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

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treatment and medical support measures and further lawfully discontinue and thereafter need not furnish medical treatment to the patient except for the sole purpose of enabling the patient to end his life and die peacefully with the greatest dignity and the least of pain, suffering and distress.

570. The lower court granted the declarations sought for. The Court of Appeal upheld the order. The Official Solicitor filed an appeal before the House of Lords. Lord Goff held that it is not lawful for a doctor to administer a drug to his patient to bring about his death, even though that course is prompted by a humanitarian desire to end his suffering. Such act is actively causing death i.e. euthanasia which is not lawful. It was further held that a case in which doctor decides not to provide or continue to provide treatment or care, it may be lawful. Following was stated by Lord Goff: (*Airedale case*[11], AC pp. 367 E-H, 368 A, F-H & 369 B-C)

> "First, it is established that the principle of self-determination requires that respect must be given to the wishes of the patient, so that if an adult patient of sound mind refuses, however unreasonably, to consent to treatment or care by which his life would or might be prolonged, the doctors responsible for his care must give effect to his wishes even though they do not consider it to be in his best interests to do so … To this extent, the principle of the sanctity of human life must yield to the principle of self-determination (*see* ante, pp. 826H-827A, per Hoffmann, L.J.), and, for present purposes perhaps more important, the doctor's duty to act in the best interests of his patient must likewise be qualified. On this basis, it has been held that a patient of sound mind may, if properly informed, require that life support should be discontinued: see *Nancy B.* v. *Hotel Dieu de Quebec*[132]. Moreover the same principle applies where the patient's refusal to give his consent has been expressed at an earlier date, before he became unconscious or otherwise incapable of communicating it; though in such circumstances especial care may be necessary to ensure that the prior refusal of consent is still properly to be regarded as applicable in the circumstances which have subsequently occurred: *see* e.g. *T. (Adult: Refusal of Treatment), In re*[133]. I wish to add that, in cases of this kind, there is no question of the patient having committed suicide, nor therefore of the doctor having aided or abetted him in doing so. It is simply that the patient has, as he is entitled to do, declined to consent to treatment which might or would have the effect of prolonging his life, and the doctor has, in accordance with his duty, complied with his patient's wishes.
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> * * *
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> I must however stress, at this point, that the law draws a crucial distinction between cases in which a doctor decides not to provide, or to continue to provide, for his patient treatment or care which could or

11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

132 (1992) 86 DLR (4th) 385 (Que SC)

133 1993 Fam 95 : (1992) 3 WLR 782 : (1992) 4 All ER 649 (CA)

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might prolong his life, and those in which he decides, for example by administering a lethal drug, actively to bring his patient's life to an end. As I have already indicated, the former may be lawful, either because the doctor is giving effect to his patient's wishes by withholding the treatment or care, or even in certain circumstances in which (on principles which I shall describe) the patient is incapacitated from stating whether or not he gives his consent. But it is not lawful for a doctor to administer a drug to his patient to bring about his death, even though that course is prompted by a humanitarian desire to end his suffering, however great that suffering may be: see *R.* v. *Cox*[21] (unreported), 18-9-1992. So to act is to cross the Rubicon which runs between on the one hand the care of the living patient and on the other hand euthanasia—actively causing his death to avoid or to end his suffering. Euthanasia is not lawful at common law. It is of course well known that there are many responsible members of our society who believe that euthanasia should be made lawful; but that result could, I believe, only be achieved by legislation which expresses the democratic will that so fundamental a change should be made in our law, and can, if enacted, ensure that such legalised killing can only be carried out subject to appropriate supervision and control.

* * *

At the heart of this distinction lies a theoretical question. Why is it that the doctor who gives his patient a lethal injection which kills him commits an unlawful act and indeed is guilty of murder, whereas a doctor who, by discontinuing life support, allows his patient to die, may not act unlawfully — and will not do so, if he commits no breach of duty to his patient?"

571. Lord Browne-Wilkinson in his judgment noticed the following questions raised in the matter: (*Airedale case*[11], AC p. 380 B-C)

"(1) lawfully discontinue all life-sustaining treatment and medical support measures designed to keep (Mr Bland) alive in his existing persistent vegetative state including the termination of ventilation, nutrition and hydration by artificial means; and (2) lawfully discontinue and thereafter need not furnish medical treatment to (Mr Bland) except for the sole purpose of enabling (Mr Bland) to end his life and die peacefully with the greatest dignity and the least of pain, suffering and distress."

Answering the questions following was held: (AC p. 386 F-H)

"Anthony Bland has been irreversibly brain damaged; the most distinguished medical opinion is unanimous that there is no prospect at all that the condition will change for the better. He is not aware of anything. If artificial feeding is continued, he will feel nothing; if artificial feeding is discontinued and he dies, he will feel nothing. Whether he lives or dies he will feel no pain or distress. All the purely physical considerations indicate

21 18-9-1992, Ognall, J. (unreported).
11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

569

that it is pointless to continue life support. Only if the doctors responsible for his care held the view that, though he is aware of nothing, there is some benefit to him in staying alive, would there be anything to indicate that it is for his benefit to continue the invasive medical care.

In these circumstances, it is perfectly reasonable for the responsible doctors to conclude that there is no affirmative benefit to Anthony Bland in continuing the invasive medical procedures necessary to sustain his life. Having so concluded, they are neither entitled nor under a duty to continue such medical care. Therefore they will not be guilty of murder if they discontinue such care."

572. Another judgment which needs to be noticed is *B. (Adult: Refusal of Medical Treatment), In re*[134]. The claimant, Ms *B* has sought declaration from the High Court that the invasive treatment which is currently being given by the respondent by way of artificial ventilation is an unlawful trespass. The main issue raised in the case was as to whether Ms *B* has the capacity to make her own decision about her treatment in hospital. Ms *B*, aged 43 years, had suffered a devastating illness which has caused her to become tetraplegic and whose expressed wish was not to be kept artificially alive by the use of a ventilator. The High Court in the above context examined several earlier cases on the principle of autonomy. Paras 16 to 22 are to the following effect: (*B. case*[134], All ER pp. 455*e-j* & 456*f*)

"*16.* In 1972 Lord Reid in *S.* v. *McC*[130] said, at AC p. 43: (WLR p. 374 C-D)

'... English law goes to great lengths to protect a person of full age and capacity from interference with his personal liberty. We have too often seen freedom disappear in other countries not only by coups d'état but by gradual erosion: and often it is the first step that counts. So it would be unwise to make even minor concessions.'

17. F. (Mental Patient: Sterilisation), In re[24], Lord Goff of Chieveley said: (AC p. 72 E)

'I start with the fundamental principle, now long established, that every person's body is inviolate.'

18. Lord Donaldson of Lymington, M.R. said *T. (Adult: Refusal of Treatment), In re*[133] Fam, at p. 113D:

'... the patient's right of choice exists whether the reasons for making that choice are rational, irrational, unknown or even non-existent.'

134 (2002) 2 All ER 449
130 *S.* v. *McC. (Orse. S.) and M. (D.S. Intervener)*, 1972 AC 24 : (1970) 3 WLR 366 (HL)
24 (1990) 2 AC 1 : (1989) 2 WLR 1025 : (1989) 2 All ER 545 (HL)
133 1993 Fam 95 : (1992) 3 WLR 782 : (1992) 4 All ER 649 (CA)

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19. T. (Adult: Refusal of Treatment), In re[133], I cited Robins, J.A. in *Malette* v. *Shulman*[45] DLR at p. 336, and said: (AC pp. 116 H & 117 A-B)

a

> "... 'The right to determine what shall be done with one's own body is a fundamental right in our society. The concepts inherent in this right are the bedrock upon which the principles of self-determination and individual autonomy are based. Free individual choice in matters affecting this right should, in my opinion, be accorded very high priority.' (*Malette case*[45])"

b

20. MB (Medical Treatment), In re[47] FLR, I said at p. 432:

> 'A mentally competent patient has an absolute right to refuse to consent to medical treatment for any reason, rational or irrational, or for no reason at all, even where that decision may lead to his or her own death',

c

[referring to *Sidaway* v. *Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital*[131] AC, per Lord Templeman at 904-905; and to Lord Donaldson, M.R. in *T. (Adult: Refusal of Treatment), In re*[133] (*see* above)].

21. This approach is identical with the jurisprudence in other parts of the world. In *Cruzan* v. *Missouri Department of Health*[4], the United States Supreme Court stated that:

d

> 'No right is held more sacred, or is more carefully guarded, ... than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law.'

e

(*b*) *The sanctity of life*

22. Society and the medical profession in particular are concerned with the equally fundamental principle of the sanctity of life. The interface between the two principles of autonomy and sanctity of life is of great concern to the treating clinicians in the present case. Lord Keith of Kinkel in *Airedale N.H.S. Trust* v. *Bland*[11], said at p. 859:

f

> '... the principle of the sanctity of life, which it is the concern of the State, and the judiciary as one of the arms of the State, ... is not an absolute one. It does not compel a medical practitioner on pain of criminal sanctions to treat a patient, who will die if he does not, contrary to the express wishes of the patient.' "

g

133 1993 Fam 95 : (1992) 3 WLR 782 : (1992) 4 All ER 649 (CA)
45 (1990) 67 DLR (4th) 321 : 72 OR (2d) 417 (CA)
47 1997 EWCA Civ 3093 : (1997) 2 FLR 426
h 131 1985 AC 871 : (1985) 2 WLR 480 : (1985) 1 All ER 643 (HL)
4 1990 SCC OnLine US SC 123 : 111 L Ed 2d 224 : 110 S Ct 2841 : 497 US 261 (1990)
11 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

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573. The judgment of the House of Lords in *R. (Pretty)* v. *Director of Public Prosecutions*[29], also needs to be referred to. The claimant, who suffered from a progressive and degenerative terminal illness, faced the imminent prospect of a distressing and humiliating death. She was mentally alert and wished to control the time and manner of her dying but her physical disabilities prevented her from taking her life unaided. She wished her husband to help her and he was willing to do so provided that in the event of his giving such assistance he would not be prosecuted under Section 2(1) of the Suicide Act, 1961. The claimant accordingly requested the Director of Public Prosecutions to undertake that he would not consent to such a prosecution under Section 2(4). On his refusal to give that undertaking the claimant, in reliance on the rights guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms as Schedule to the Human Rights Act, 1998, sought relief by way of judicial review.

574. The Divisional Court of the Queen's Bench Division concluded that the Director has no power to give an undertaking and dismissed the claim. The House of Lords again reiterated the distinction between the cessation of life-saving or life-prolonging treatment on the one hand and the taking of action intended solely to terminate life on the other. In para 9 of the judgment following was held: [*R. (Pretty) case*[29], QB pp. 813 E-H, & 814 A-B]

> "*9.* In the Convention field the authority of domestic decisions is necessarily limited and, as already noted, Mrs Pretty bases her case on the Convention. But it is worthy of note that her argument is inconsistent with two principles deeply embedded in English law. The first is a distinction between the taking of one's own life by one's own act and the taking of life through the intervention or with the help of a third party. The former has been permissible since suicide ceased to be a crime in 1961. The latter has continued to be proscribed. The distinction was very clearly expressed by Hoffmann, L.J. in *Airedale N.H.S. Trust* v. *Bland*[11]: (AC p. 355 H & 356 A-B)
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> > '... No one in this case is suggesting that Anthony Bland should be given a lethal injection. But there is concern about ceasing to supply food as against, for example, ceasing to treat an infection with antibiotics. Is there any real distinction? In order to come to terms with our intuitive feelings about whether there is a distinction, I must start by considering why most of us would be appalled if he was given a lethal injection. It is, I think, connected with our view that the sanctity of life entails its inviolability by an outsider. Subject to exceptions like self-defence, human life is inviolate even if the person in question has consented to its violation. That is why although suicide is not a crime, assisting someone to commit suicide is. It follows that, even if we think Anthony Bland would have consented, we would not be entitled to end his life by a lethal injection.'

29 (2002) 1 AC 800 : (2001) 3 WLR 1598 : (2002) 1 All ER 1 : 2001 UKHL 61 (HL)
11 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

572

The second distinction is between the cessation of life-saving or life-prolonging treatment on the one hand and the taking of action lacking medical, therapeutic or palliative justification but intended solely to terminate life on the other. This distinction provided the rationale of the decisions in *Bland*[11]. It was very succinctly expressed in the Court of Appeal in *J. (A Minor) (Wardship: Medical Treatment), In re*[15], in which Lord Donaldson of Lymington, M.R. said: (Fam p. 46 C-D)

> '... What doctors and the court have to decide is whether, in the best interests of the child patient, a particular decision as to medical treatment should be taken which as a side-effect will render death more or less likely. This is not a matter of semantics. It is fundamental. At the other end of the age spectrum, the use of drugs to reduce pain will often be fully justified, notwithstanding that this will hasten the moment of death. What can never be justified is the use of drugs or surgical procedures with the primary purpose of doing so.' "

United States of America

575. The State of New York in 1828 enacted a statute declaring assisted suicide as a crime. New York example was followed by different other States.

576. Cardozo, J., about a century ago in *Schloendorff* v. *Society of New York Hospital*[42], while in Court of Appeal had recognised the right of self-determination by every adult human being. Following was held:

> "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages. *Pratt* v. *Davis*[331], *Mohr* v. *Williams*[332]. This is true, except in cases of emergency where the patient is unconscious, and where it is necessary to operate before consent can be obtained."

577. The Supreme Court of the United States of America in *Cruzan* v. *Missouri Department of Health*[4], had occasion to consider a case of patient who was in persistent vegetative state, her guardian brought a declaratory judgment seeking judicial sanction to terminate artificial hydration and nutrition of patient. The Supreme Court recognised right possessed by every individual to have control over own person. Following was held by Rehnquist, C.J.: (SCC OnLine US SC paras 6-7)

> "6. At common law, even the touching of one person by another without consent and without legal justification was a battery. See *W. Keeton, D. Dobbs, R. Keeton, & D. Owen, Prosser and Keeton on Law of Torts,*

11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)
15 1991 Fam 33 (CA) : (1991) 2 WLR 140 : (1990) 3 All ER 930
42 105 NE 92 : 211 NY 125 (1914)
331 224 Ill 300 : 79 NE 562 (1906)
332 95 Minn 261 : 104 NW 12 (1905)
4 1990 SCC OnLine US SC 123 : 111 L Ed 2d 224 : 110 S Ct 2841 : 497 US 261 (1990)

Section 9, pp. 39-42 (5th Edn. 1984). Before the turn of the century, this Court observed that—

> '[n]o right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law.'

Union Pacific Rly. Co. v. *Botsford*[333], SCC OnLine US SC : US p. 251 : S.Ct. p. 1001. This notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment. Cardozo, J., while on the Court of Appeals of New York, aptly described this doctrine:

> 'Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages,'

Schloendorff v. *Society of New York Hospital*[42], NY pp. 129-130, NE p. 93. The informed consent doctrine has become firmly entrenched in American tort law. See *Keeton, Dobbs, Keeton, & Owen, supra, Section 32, pp. 189-192; F. Rozovsky, Consent to Treatment*, A Practical Guide 1-98 (2d Edn. 1990).

7. The logical corollary of the doctrine of informed consent is that the patient generally possesses the right, not to consent, that is, to refuse treatment."

578. Referring to certain earlier cases following was held: (*Cruzan case*[4], SCC OnLine US SC para 12)

> "*12.* Reasoning that the right of self-determination should not be lost merely because an individual is unable to sense a violation of it, the Court held that incompetent individuals retain a right to refuse treatment. It also held that such a right could be exercised by a surrogate decision-maker using a "subjective" standard when there was clear evidence that the incompetent person would have exercised it. Where such evidence was lacking, the court held that an individual's right could still be invoked in certain circumstances under objective "best interest" standards. *Conroy, In re*[23], NJ at pp. 361-68 : A 2d at pp. 1229-33. Thus, if some trustworthy evidence existed that the individual would have wanted to terminate treatment, but not enough to clearly establish a person's wishes for purposes of the subjective standard, and the burden of a prolonged life from the experience of pain and suffering markedly outweighed its

333 1891 SCC OnLine US SC 217 : 35 L Ed 734 : 11 S Ct 1000 : 141 US 250 (1891)
42 105 NE 92 : 211 NY 125 (1914)
4 *Cruzan* v. *Missouri Department of Health*, 1990 SCC OnLine US SC 123 : 111 L Ed 2d 224 : 110 S Ct 2841 : 497 US 261 (1990)
23 98 NJ 321 : 486 A 2d 1209 (NJ 1985)

574

satisfactions, treatment could be terminated under a "limited-objective" standard. Where no trustworthy evidence existed, and a person's suffering would make the administration of life-sustaining treatment inhumane, a "pure-objective" standard could be used to terminate treatment. If none of these conditions obtained, the Court held it was best to err in favour of preserving life. Id., NJ at pp. 364-68 : A 2d at pp. 1231-33."

In the facts of the above case, the claim of parents of Cruzan was refused since guardian could not satisfactorily prove that Cruzan had expressed her wish not to continue her life under circumstances in which she drifted.

579. All different aspects of euthanasia were again considered by the United States Supreme Court in *Washington* v. *Glucksberg*[16]. A Washington State Statute enacted in 1975 provided that a person was guilty of the felony of promoting a suicide attempt when the person knowingly caused or aided another person to attempt suicide. An action was brought in the United States District Court for the Western District of Washington by several plaintiffs, among whom were (*1*) physicians who occasionally treated terminally ill, suffering patients, and (*2*) individuals who were then in the terminal phases of serious and painful illness. The plaintiffs, asserting the existence of a liberty interest protected by the Federal Constitution's Fourteenth Amendment which extended to a personal choice by a mentally competent, terminally ill adult to commit physician-assisted suicide, sought a declaratory judgment that the Washington Statute was unconstitutional on its face. The District Court, granting motions for summary judgment by the physicians and the individuals, ruled that the Statute was unconstitutional because it placed an undue burden on the exercise of the asserted liberty interest (*Compassion in Dying* v. *Washington*[13]). On appeal, the United States Court of Appeals for the Ninth Circuit, expressed the view that (*1*) the Constitution encompassed a due process liberty interest in controlling the time and manner of one's death; and (*2*) the Washington Statute was unconstitutional as applied to terminally ill, competent adults who wished to hasten their deaths with medication prescribed by their physicians (*Compassion in Dying* v. *Washington*[334]).

580. On certiorari, the United States Supreme Court reversed. In an opinion by Rehnquist, C.J., joined by O'Connor, Scalia, Kennedy, and Thomas, JJ., it was held that the Washington Statute did not violate the due process clause —either on the Statute's face or as the Statute was applied to competent, terminally ill adults who wished to hasten their deaths by obtaining medication prescribed by their physicians — because (*1*) pursuant to careful formulation of the interest at stake, the question was whether the liberty specially protected by the due process clause included a right to commit suicide which itself included a right to assistance in doing so; (*2*) an examination of the nation's history, legal traditions, and practices revealed that the asserted right to assistance in committing suicide was not a fundamental liberty interest protected by the

16 1997 SCC OnLine US SC 79 : 138 L Ed 2d 772 : 521 US 702 (1997)
13 850 F Supp 1454 (WD Wash 1994)
334 79 F 3d 790 (1996)

575

due process clause; (*3*) the asserted right to assistance in committing suicide was not consistent with the Supreme Court's substantive due process line of cases; and (*4*) the State's assisted suicide ban was at least reasonably related to the promotion and protection of a number of Washington's important and legitimate interests.

581. The US Supreme Court held that the Washington Statute did not violate the Due Process Clause. Rehnquist, C.J. while delivering the opinion of the Court upheld the State's ban on assisted suicide to the following effect: (*Washington case*[16], SCC OnLine US SC)

> "... In almost every State—indeed, in almost every western democracy —it is a crime to assist a suicide. The States' assisted-suicide bans are long-standing expressions of the States' commitment to the protection and preservation of all human life. *Cruzan*[4], at p. 280 ("The States—indeed, all civilized nations—demonstrate their commitment to life by treating homicide as a serious crime. Moreover, the majority of States in this country have laws imposing criminal penalties on one who assists another to commit suicide"); see *Stanford* v. *Kentucky*[335], US p. 373 ('[T]he primary and most reliable indication of [a national] consensus is ... the pattern of enacted laws'). Indeed, opposition to and condemnation of suicide—and, therefore, of assisting suicide—are consistent and enduring themes of our philosophical, legal, and cultural heritages."

582. Another judgment of the US Supreme Court which needs to be noted is *Vacco* v. *Quill*[17]. New York State law as in effect in 1994 provided that a person who intentionally caused or aided another person to attempt or commit suicide was guilty of felony; but under other statutes, a competent person could refuse even life-saving medical treatment. The plaintiff sought declaratory relief and injunctive against the enforcement of criminal law asserting that such law is violative of statutes of the Federal Constitution's Fourteenth Amendment.

583. Rehnquist, C.J. in his opinion again upheld distinction between assisted suicide and withdrawing of life sustaining treatment. Following was laid down: (*Washington case*[16], SCC OnLine US SC)

> "[1d] The Court of Appeals, however, concluded that some terminally ill people—those who are on life support systems—are treated differently from those who are not, in that the former may "hasten death" by ending treatment, but the latter may not "hasten death" through physician-assisted suicide. *Quill* v. *Vacco*[34] F 3d, at p. 729. This conclusion depends on the submission that ending or refusing life-saving medical treatment "is nothing more nor less than assisted suicide." *Ibid.* Unlike

16 *Washington* v. *Glucksberg*, 1997 SCC OnLine US SC 79 : 138 L Ed 2d 772 : 521 US 702 (1997)
4 *Cruzan* v. *Missouri Department of Health*, 1990 SCC OnLine US SC 123 : 111 L Ed 2d 224 : 110 S Ct 2841 : 497 US 261 (1990)
335 1989 SCC OnLine US SC 151 : 106 L Ed 2d 306 : 109 S Ct 2969 : 492 US 361 (1989)
17 1997 SCC OnLine US SC 80 : 138 L Ed 2d 834 : 521 US 793 (1997)
34 80 F 3d 716 (2d Cir 1996)

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the Court of Appeals, we think the distinction between assisting suicide and withdrawing life-sustaining treatment, a distinction widely recognised and endorsed in the medical profession and in our legal traditions, is both important and logical; it is certainly rational. ...

The distinction comports with fundamental legal principles of causation and intent. First, when a patient refuses life-sustaining medical treatment, he dies from an underlying fatal disease or pathology; but if a patient ingests lethal medication prescribed by a physician, he is killed by that medication. ...

Furthermore, a physician who withdraws, or honors a patient's refusal to begin, life-sustaining medical treatment purposefully intends, or may so intend, only to respect his patient's wishes and 'to cease doing useless and futile or degrading things to the patient when [the patient] no longer stands to benefit from them.' "

584. However, there are four States which have passed the legislation permitting euthanasia. These States include Oregon, Washington, Missouri and Texas.

Canada

585. Section 241(*b*) of the Criminal Code provides that everyone who aids or abets a person in committing suicide commits an indictable offence. In *Rodriguez* v. *British Columbia (Attorney General)*[22], the Supreme Court of Canada has considered the issue of assisted suicide. A 42 year old lady who was suffering from an incurable illness applied before the Supreme Court of British Columbia for an order that Section 241(*b*) which prohibits giving assistance to commit suicide, be declared invalid. The application was dismissed and the matter was taken to the Supreme Court of Canada which held that prohibition of Section 241(*b*) which fulfils the Government's objective of protecting the vulnerable, is grounded in the State interest in protecting life and reflects the policy of the State that human life should not be depreciated by allowing life to be taken.

Switzerland

586. In Switzerland the assisted suicide is allowed only for altruistic reasons. A person is guilty and deserved to be sentenced for imprisonment on assisted suicide when he incites someone to commit suicide for selfish reasons.

Netherlands

587. The Netherlands has the most experience with physician-hastened death. Both euthanasia and assisted suicide remain crimes there but doctors who end their patients' lives will not be prosecuted if legal guidelines are followed. Among the guidelines are:

31. The request must be made entirely of the patient's own free will.
32. The patient must have a long-lasting desire for death.

22 1993 SCC OnLine Can SC 97 : (1993) 3 SCR 519 : 85 CCC 3d 15

33. The patient must be experiencing unbearable suffering.

34. There must be no reasonable alternatives to relative suffering other than euthanasia.

35. The euthanasia or assisted suicide must be reported to the coroner.

588. The above discussion clearly indicates that predominant thought as on date prevailing in other part of the world is that assisted suicide is a crime. No one is permitted to assist another person to commit suicide by injecting a lethal drug or by other means. In India, Section 306 of the Indian Penal Code specifically makes it an offence. The Constitution Bench of this Court in *Gian Kaur*[10] has already upheld the constitutional validity of Section 306, thus, the law of the land as existing today is that no one is permitted to cause death of another person including a physician by administering any lethal drug even if the objective is to relive the patient from pain and suffering.

H. *Ratio of Gian Kaur* v. *State of Punjab*[10]

589. In *Gian Kaur case*[10], the constitutional validity of Section 306 of the Penal Code, 1860 was challenged. The appellant had placed reliance on two-Judge Bench judgment of this Court in *P. Rathinam* v. *Union of India*[6], wherein this Court declared Section 309 IPC to be unconstitutional as violative of Article 21 of the Constitution. It was contended that Section 309 having already been declared as unconstitutional, any person abetting the commission of suicide by another is merely assisting in the enforcement of the fundamental right under Article 21 and, therefore, Section 306 IPC penalising assisted suicide is equally violative of Article 21. The Court proceeded to consider the constitutional validity of Section 306 on the above submission. In para 17 of the judgment, this Court had made observation that reference to euthanasia cases tends to befog the real issue. Following are the relevant observations made in para 17: (*Gian Kaur case*[10], SCC p. 658)

> "*17.* ... Any further reference to the global debate on the desirability of retaining a penal provision to punish attempted suicide is unnecessary for the purpose of this decision. Undue emphasis on that aspect and particularly the reference to euthanasia cases tends to befog the real issue of the constitutionality of the provision and the crux of the matter which is determinative of the issue."

The Constitution Bench held that Article 21 does not include right to die. Para 22 of the judgment contains the ratio in following words: (SCC p. 660)

> "*22.* ... Whatever may be the philosophy of permitting a person to extinguish his life by committing suicide, we find it difficult to construe Article 21 to include within it the "right to die" as a part of the fundamental right guaranteed therein. "Right to life" is a natural right embodied in Article 21 but suicide is an unnatural termination or extinction of life and, therefore, incompatible and inconsistent with the concept of "right to life"."

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374
6 (1994) 3 SCC 394 : 1994 SCC (Cri) 740

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Although, right to die was held not to be a fundamental right enshrined under Article 21 but it was laid down that the right to life includes right to live with human dignity i.e. right of a dying man to also die with dignity when his life is ebbing out. Following pertinent observations have been made in para 24: (SCC p. 660)

> "*24.* ... The "right to life" including the right to live with human dignity would mean the existence of such a right up to the end of natural life. This also includes the right to a dignified life up to the point of death including a dignified procedure of death. In other words, this may include the right of a dying man to also die with dignity when his life is ebbing out. But the "right to die" with dignity at the end of life is not to be confused or equated with the "right to die" an unnatural death curtailing the natural span of life."

590. The Constitution Bench, however, noticed the distinction between a dying man, who is terminally ill or in a persistent vegetative state, when process of natural death has commenced, from one where life is extinguished. The Court, however, held that permitting termination of life to such cases to reduce the period of suffering during the process of certain natural death is not available to interpret Article 21 to include therein the right to curtail the natural span of life. Para 25 of the judgment is to the following effect: (*Gian Kaur case*[10], SCC pp. 660-61)

> "*25.* A question may arise, in the context of a dying man who is terminally ill or in a persistent vegetative state that he may be permitted to terminate it by a premature extinction of his life in those circumstances. This category of cases may fall within the ambit of the "right to die" with dignity as a part of right to live with dignity, when death due to termination of natural life is certain and imminent and the process of natural death has commenced. These are not cases of extinguishing life but only of accelerating conclusion of the process of natural death which has already commenced. The debate even in such cases to permit physician-assisted termination of life is inconclusive. It is sufficient to reiterate that the argument to support the view of permitting termination of life in such cases to reduce the period of suffering during the process of certain natural death is not available to interpret Article 21 to include therein the right to curtail the natural span of life."

591. The Constitution Bench in above paragraphs has observed that termination of life in case of those who are terminally ill or in a persistent vegetative state, may fall within the ambit of "right to die" with dignity as a part of right to live with dignity when death due to termination of natural life is certain and imminent and process of natural death has commenced. But even in those cases, physician-assisted termination of life cannot be included in right guaranteed under Article 21. One more pertinent observation can be noticed from para 33, wherein this Court held that: (*Gian Kaur case*[10], SCC p. 663)

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374

"*33.* ... We have earlier held that "right to die" is not included in the "right to life" under Article 21. For the same reason, "right to live with human dignity" cannot be construed to include within its ambit the right to terminate natural life, *at least before commencement of the natural process of certain death.*" (emphasis supplied)

592. The distinction between cases where physician decides not to provide or to discontinue to provide for treatment or care, which could or might prolong his life and those in which he decides to administer a lethal drug, was noticed while referring to the judgment of the House of Lords in *Airedale case*[11]. In *Airedale case*[11], it was held that it is not lawful for a doctor to administer a drug to his patient to bring about his death. Euthanasia is not lawful at common law and euthanasia can be made lawful only by legislation. It is further relevant to notice that in para 40, this Court had observed that it is not necessary to deal with physician-assisted suicide or euthanasia cases. Para 40, is as follows: (*Gian Kaur case*[10], SCC p. 666)

"*40. Airedale N.H.S. Trust* v. *Bland*[11] was a case relating to withdrawal of artificial measures for continuance of life by a physician. Even though it is not necessary to deal with physician-assisted suicide or euthanasia cases, a brief reference to this decision cited at the Bar may be made. In the context of existence in the persistent vegetative state of no benefit to the patient, the principle of sanctity of life, which is the concern of the State, was stated to be not an absolute one. In such cases also, the existing crucial distinction between cases in which a physician decides not to provide, or to continue to provide, for his patient, treatment or care which could or might prolong his life, and those in which he decides, for example, by administering a lethal drug, actively to bring his patient's life to an end, was indicated and it was then stated as under: (AC p. 865 E-G : All ER p. 867 : WLR p. 368 G-H)

'... But it is not lawful for a doctor to administer a drug to his patient to bring about his death, even though that course is prompted by a humanitarian desire to end his suffering, however great that suffering may be: [see *R.* v. *Cox*[21], (18-9-1992, unreported)] per Ognall, J. in the Crown Court at Winchester. So to act is to cross the Rubicon which runs between on the one hand the care of the living patient and on the other hand euthanasia — actively causing his death to avoid or to end his suffering. Euthanasia is not lawful at common law. It is of course well known that there are many responsible members of our society who believe that euthanasia should be made lawful; but that result could, I believe, only be achieved by legislation which expresses the democratic will that so fundamental a change should be made in

11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)
10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374
21 18-9-1992, Ognall, J. (unreported).

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our law, and can, if enacted, ensure that such legalised killing can only be carried out subject to appropriate supervision and control.' "

593. A conjoint reading of observations in paras 25, 33 and 40 indicates that although for a person terminally ill or in PSV state, whose process of natural death has commenced, termination of life may fall in the ambit of right to die with dignity but in those cases also there is no right of actively terminating life by a physician. The clear opinion has thus been expressed that euthanasia is not lawful. But at the same time, the Constitution Bench has noticed the distinction between the cases in which a physician decides not to provide or to continue to provide for his patient's treatment or care which could or might prolong his life and those in which physician decides actively to bring life to an end. The *ratio* of the judgment is contained in paras 22 and 24, which is to the following effect: (*Gian Kaur case*[10], SCC p. 660)

"*22.* ... Whatever may be the philosophy of permitting a person to extinguish his life by committing suicide, we find it difficult to construe Article 21 to include within it the "right to die" as a part of the fundamental right guaranteed therein. "Right to life" is a natural right embodied in Article 21 but suicide is an unnatural termination or extinction of life and, therefore, incompatible and inconsistent with the concept of "right to life". ...

* * *

24. ... The "right to life" including the right to live with human dignity would mean the existence of such a right up to the end of natural life. This also includes the right to a dignified life up to the point of death including a dignified procedure of death. In other words, this may include the right of a dying man to also die with dignity when his life is ebbing out. But the "right to die" with dignity at the end of life is not to be confused or equated with the "right to die" an unnatural death curtailing the natural span of life."

594. We have noticed above that in para 17, this Court had observed that reference to euthanasia cases tends to befog the real issue and further in SCC p. 665, para 40, it was observed that "even though it is not necessary to deal with physician-assisted suicide or euthanasia cases"; the Constitution Bench has neither considered the concept of euthanasia nor has laid down any ratio approving euthanasia.

595. At best, the Constitution Bench noted a difference between cases in which physician decides not to provide or to continue to provide for medical treatment or care and those cases where he decides to administer a lethal drug activity to bring his patient's life to an end. The judgment of the House of Lords in *Airedale case*[11] was referred to and noted in the above context. The *Airedale case*[11] was cited on behalf of the appellant in support of the contention that in said case the withdrawal of life saving treatment was held not to be unlawful.

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374

11 *Airedale N.H.S. Trust* v. *Bland*, 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

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596. We agree with the observation made in the reference order of the three-Judge Bench to the effect that the Constitution Bench did not express any binding view on the subject of euthanasia. We hold that no binding view was expressed by the Constitution Bench on the subject of euthanasia.

I. ***Concept of euthanasia***

597. Euthanasia is derived from the Greek words *euthanatos*; *eu* means well or good and *thanatos* means death. *New Webster's Dictionary* (Deluxe Encyclopedic Edn.) defines "euthanasia" as following:

> "A painless putting to death of persons having an incurable disease; an easy death. Also mercy killing."

598. *Oxford English Dictionary* defines "euthanasia":

> "*Euthanasia.*—The painless killing of a patient suffering from an incurable and painful disease or in an irreversible coma."

The definition of the word "euthanasia" as given by the World Health Organisation may be noticed which defines it as:

> "*Euthanasia.*—A deliberate act undertaken by one person with the intention of either painlessly putting to death or failing to prevent death from natural causes in cases of terminal illness or irreversible coma of another person."

599. In ancient Greek society, euthanasia as "good death" was associated with the drinking of "Hemlock". Drinking of Hemlock had become common not only in cases of incurable diseases but also by those individuals who faced other difficult problems or old age. In ancient times, in Greece freedom to live was recognised principle, which permitted the sick and desperates to terminate their lives by themselves or by taking outside help. In last few centuries, euthanasia increasingly came to connote specific measures taken by physicians to hasten the death. The primary meaning, as has now been ascribed to the word is compassionate murder. In the last century, the thought has gained acceptance that euthanasia is to be distinguished from withdrawal of life saving treatments which may also result in death. Withdrawing medical treatment in a way hasten the death in case of terminal illness or persistent vegetative state (PVS) but is not to be treated as compassionate murder. Advancement in the medical science on account of which life can be prolonged by artificial devices are the developments of only last century. Lord Browne-Wilkinson, J., in *Airedale N.H.S. Trust* v. *Bland*[11] WLR at p. 389 observed: (AC p. 878 D-F)

> "... Death in the traditional sense was beyond human control. Apart from cases of unlawful homicide, death occurred automatically in the course of nature when the natural functions of the body failed to sustain the lungs and the heart.
>
> Recent developments in medical science have fundamentally affected these previous certainties. In medicine, the cessation of breathing or of

11 1993 AC 789 : (1993) 2 WLR 316 : (1993) 1 All ER 821 (CA & HL)

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heartbeat is no longer death. By the use of a ventilator, lungs which in the unaided course of nature would have stopped breathing can be made to breathe, thereby sustaining the heartbeat. Those, like Anthony Bland, who would previously have died through inability to swallow food can be kept alive by artificial feeding. This has led the medical profession to redefine death in terms of brain stem death i.e. the death of that part of the brain without which the body cannot function at all without assistance. In some cases it is now apparently possible, with the use of the ventilator, to sustain a beating heart even though the brain stem, and therefore in medical terms the patient, is dead; "the ventilated corpse"."

600. In recent times, three principles had gained acceptance throughout the world they are:

(*1*) Sanctity of life,

(*2*) Right of self-determination,

(*3*) Dignity of the individual human being.

601. The sanctity of life is one thought which is philosophically, religiously and mythologically accepted by the large number of population of the world practising different faiths and religions. Sanctity of life entails its inviolability by an outsider. Sanctity of life is the concern of State.

602. Right of self-determination also encompasses in it bodily integrity. Without consent of an adult person, who is in fit state of mind, even a surgeon is not authorised to violate the body. Sanctity of the human life is the most fundamental of the human social values. The acceptance of human rights and development of its meaning in recent times has fully recognised the dignity of the individual human being. All the above three principles enable an adult human being of conscious mind to take decision regarding extent and manner of taking medical treatment. An adult human being of conscious mind is fully entitled to refuse medical treatment or to decide not to take medical treatment and may decide to embrace the death in natural way. Euthanasia, as noted above, as the meaning of the word suggest is an act which leads to a good death. Some positive act is necessary to characterise the action as euthanasia. Euthanasia is also commonly called "assisted suicide" due to the above reasons.

J. *Withdrawal of life saving devices*

603. Withdrawal of medical assistance or withdrawal of medical devices which artificially prolong the life cannot be regarded as an act to achieve a good death. Artificial devices to prolong the life are implanted, when a person is likely to die due to different causes in his body. Life saving treatment and devices are put by physicians to prolong the life of a person. The Law Commission of India in its 196th Report on "Medical Treatment to Terminally-Ill Patients (Protection of Patients and Medical Practitioners)" on the subject had put introductory note to the following effect:

"The title to this Report immediately suggests to one that we are dealing with 'Euthanasia' or 'Assisted Suicide'. But we make it clear at the

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outset that Euthanasia and Assisted Suicide continue to be unlawful and we are dealing with a different matter 'Withholding Life-support Measures' to patients terminally ill and, universally, in all countries, such withdrawal is treated as 'lawful'."

604. The Law Commission of India was of the opinion that withdrawing life supporting measures of patient terminally ill is a concept, different from euthanasia. The opinion of Cardozo, J., rendered more than hundred years ago that every human being of adult years and sound mind has a right to determine what shall be done with his own body, is now universally accepted principle. The judgment of the US Supreme Court and House of Lords, as noticed above, also reiterate the above principle.

605. Recently, in a nine-Judge judgment in *K.S. Puttaswamy* v. *Union of India*[58], J. Chelameswar, J. elaborating the concept of right to life as enshrined in Article 21 under the Constitution of India has observed: (SCC p. 530, para 373)

> "*373.* ... An individual's rights to refuse life prolonging medical treatment or terminate his life is another freedom which falls within the zone of the right of privacy."

606. Withdrawal of life-saving devices, leads to natural death which is arrested for the time being due to above device and the act of withdrawal put the life on the natural track. Decision to withdraw life-saving devices is not an act to cause good death of the person rather, decision to withdraw or not to initiate life-supporting measures is a decision when treatment becomes futile and unnecessary. Practice of euthanasia in this country is prohibited and for medical practitioners it is already ordained to be unethical conduct. The question as to what should be the measures to be taken while taking a decision to withdraw life-saving measures or life-saving devices is another question which we shall consider a little later.

607. The two-Judge Bench in *Aruna Ramachandra Shanbaug* v. *Union of India*[5] has held that withdrawal of live-saving measures is a passive euthanasia which is permissible in India. A critically ill patient who is mentally competent to take a decision, decides not to take support of life prolonging measures, and respecting his wisdom if he is not put on such devices like ventilator, etc. it is not at all euthanasia. Large number of persons in advance age of life decide not to take medical treatment and embrace death in its natural way, can their death be termed as euthanasia. Answer is, obviously "No". The decision not to take life saving medical treatment by a patient, who is competent to express his opinion cannot be termed as euthanasia, but a decision to withdraw life saving treatment by a patient who is competent to take decision as well as with regard to a patient who is not competent to take decision can be termed as passive euthanasia. On the strength of the precedents in this country and weight of precedents of other countries as noted above, such action of withdrawing life saving device is legal.

58 (2017) 10 SCC 1
5 (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

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Thus, such acts, which are commonly expressed as passive euthanasia is lawful and legally permissible in this country.

608. We remind ourselves that this Court is not a legislative body nor is entitled or competent to act as a moral or ethical arbiter. The task of this Court is not to weigh or evaluate or reflect different beliefs and views or give effect to its own but to ascertain and build the law of land as it is now understood by all. Message which need to be sent to vulnerable and disadvantaged people should not, however, obliviously to encourage them to seek death but should assure them of care and support in life.

609. We thus are of the considered opinion that the act of withdrawal from live-saving devices is an independent right which can lawfully be exercised by informed decision.

K. *Decision for withdrawal of life saving treatment in case of a person who is incompetent to take an informed decision*

610. One related aspect which needs to be considered is that is case of those patients who are incompetent to decide due to their mental state or due to the fact that they are in permanent persistent vegetative state or due to some other reasons unable to communicate their desire. When the right of an adult person who expresses his view regarding medical treatment can be regarded as right flowing from Article 21 of the Constitution of India, the right of patient who is incompetent to express his view cannot be outside the fold of Article 21 of the Constitution of India. It is another issue, as to how, the decision in cases of mentally incompetent patients regarding withdrawal of life saving measures, is to be taken.

611. The rights of bodily integrity and self-determination are the rights which belong to every human being. When an adult person having mental capacity to take a decision can exercise his right not to take treatment or withdraw from treatment, the above right cannot be negated for a person who is not able to take an informed decision due to terminal illness or being in a persistent vegetative state (PVS). The question is who is competent to take decision in case of terminally ill or PVS patient, who is not able to take decision. In case of a person who is suffering from a disease and is taking medical treatment, there are three stakeholders; the person himself, his family members and doctor treating the patient. The American Courts give recognition to opinion of "surrogate" where person is incompetent to take a decision. No person can take decision regarding life of another unless he is entitled to take such decision authorised under any law. The English Courts have applied the "best interests" test in case of an incompetent person. The best interests of the patient have to be found out not by doctor treating the patient alone but a team of doctors specifically nominated by the State Authority. In *Aruna Shanbaug*[5], two-Judge Bench of this Court has opined that in such cases relying on doctrine of "*parens patriae*" (father of the country), it is the court alone which is entitled

5 *Aruna Ramachandra Shanbaug* v. *Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Civ) 280 : (2011) 2 SCC (Cri) 294

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to take a decision whether to withdraw treatment for incompetent terminally ill or PVS patient. In paras 130 and 131 following has been held: (SCC p. 521)

> "*130.* In our opinion, in the case of an incompetent person who is unable to take a decision whether to withdraw life support or not, it is the Court alone, as parens patriae, which ultimately must take this decision, though, no doubt, the views of the near relatives, next friend and doctors must be given due weight.
>
> ***Under which provision of law can the Court grant approval for withdrawing life support to an incompetent person***
>
> *131.* In our opinion, it is the High Court under Article 226 of the Constitution which can grant approval for withdrawal of life support to such an incompetent person. Article 226(1) of the Constitution states:
>
> > '**226.** ***Power of High Courts to issue certain writs.***—(1) Notwithstanding anything in Article 32, every High Court shall have power, throughout the territories in relation to which it exercises jurisdiction, to issue to any person or authority, including in appropriate cases, any Government, within those territories directions, orders or writs, including writs in the nature of *habeas corpus*, *mandamus*, *prohibition*, *quo warranto* and *certiorari*, or any of them, for the enforcement of any of the rights conferred by Part III and for any other purpose.'
>
> A bare perusal of the above provisions shows that the High Court under Article 226 of the Constitution is not only entitled to issue writs, *but is also entitled to issue directions or orders*." (emphasis in original)

612. Various learned counsel appearing before us have submitted that seeking declaration from the High Court in cases where medical treatment is needed to be withdrawn is time taking and does not advance the object nor is in the interest of terminally-ill patient. It is submitted that to keep check on such decisions, the State should constitute competent authorities consisting of predominantly experienced medical practitioners whose decision may be followed by all concerned with a rider that after taking of decision by competent body a cooling period should be provided to enable anyone aggrieved from the decision to approach a court of law. We also are of the opinion that in cases of incompetent patients who are unable to take an informed decision, it is in the best interests of the patient that the decision be taken by the competent medical experts and that such decision be implemented after providing a cooling period at least of one month to enable aggrieved person to approach the court of law. The best interest of the patient as determined by medical experts shall meet the ends of justice. The medical team by taking decision shall also take into consideration the opinion of the blood relations of the patient and other relevant facts and circumstances.

L. *Advance Medical Directive*

613. The petitioner by the writ petition has also sought a direction to the respondent to adopt suitable procedures to ensure that persons of deteriorated health or terminally ill should be able to execute a document titled "MY LIVING WILL & ATTORNEY AUTHORISATION". The petitioner submits that it is an important personal decision of the patient to use or not to use the life sustaining treatment in case of terminal illness and stage of persistent vegetative state. The petitioner pleads that the petitioner's endeavour is only to seek a "choice" for the people which is not available at present and they are left to the mercy of doctors who to save themselves from any penal consequences half-heartedly, despite knowing that the death is inevitable continue administering the treatment which the person might not have wanted to continue with. A person will be free to issue Advance Directives both in a positive and negative manner, meaning thereby that a person is not necessarily required to issue directive that the life sustaining treatment should not be given to him in the event of he or she going into persistent vegetative state or in an irreversible state. The person can also issue directives as to all the possible treatment which should be given to him when he is not able to express his/her wishes on medical treatment. The petitioner also refers to and rely on various legislations in different countries, which recognise the concept of Advance Medical Directive. The petitioner pleads that in India also law in the nature "Patient Autonomy & Self-determination Act" should be enacted. The petitioner has also along with his writ petition has annexed a draft titling it "Patient's Self-determination Act".

614. The concept of Advance Medical Directive is also called living will is of recent origin, which gained recognition in latter part of 20th century. The Advance Medical Directive has been recognised first by the Statute in United States of America when in the year 1976, State of California passed "Natural Death Act". It is claimed that 48 States out of 50 in the United States of America have enacted their own laws regarding patient's rights and Advance Medical Directives. Advance Medical Directive is a mechanism through which individual autonomy can be safeguarded in order to provide dignity in dying. As noted above, the Constitution Bench of this Court in *Gian Kaur*[10] has laid down that right to die with dignity is enshrined in Article 21 of the Constitution.

615. It is to be noticed that Advance Medical Directives are not exclusively associated with end-of-life decisions. However, it is vital to ensure that form of an Advance Medical Directive reflects the needs of its author and is sufficiently authoritative and practical to enable its provisions to be upheld. In most of the western countries Advance Medical Directives have taken a legalistic form incorporating a formal declaration to be signed by competent witnesses. The laws also make provisions for updating confirmation of its applicability and revocation. Protecting the individual autonomy is obviously the primary purpose of an Advance Medical Directive. The right to decide one's own fate

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374

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presupposes a capacity to do so. The answer as to when a particular Advance Medical Directive becomes operative usually depends upon an assent of when its author is no longer competent to participate in medical decision-making.

616. *Black's Law Dictionary* defines the Advance Medical Directive as "a legal document explaining one's wishes about medical treatment if one becomes incompetent or unable to communicate". An Advance Medical Directive is an individual's advance exercise of his autonomy on the subject of extent of medical intervention that he wishes to allow upon his own body at a future date, when he may not be in a position to specify his wishes. The purpose and object of Advance Medical Directive is to express the choice of a person regarding medical treatment in an event when he loses capacity to take a decision. Use and operation of Advance Medical Directive is to confine only to a case when person becomes incapacitated to take an informed decision regarding his medical treatment. So long as an individual can take an informed decision regarding his medical treatment, there is no occasion to look into Advance Medical Directives. A person has unfettered right to change or cancel his Advance Medical Directives looking to the need of time and advancement in medical science. Hence, a person cannot be tied up or bound by his instructions given at an earlier point of time.

617. The concept of Advance Medical Directive originated largely as a response to development in medicines. Many people living depending on machines cause great financial distress to the family with the cost of long-term medical treatment. Advance Medical Directive was developed as a means to restrict the kinds of medical intervention in event when one becomes incapacitated. The foundation for seeking direction regarding Advance Medical Directive is extension of the right to refuse medical treatment and the right to die with dignity. When a competent patient has right to take a decision regarding medical treatment, with regard to medical procedure entailing right to die with dignity, the said right cannot be denied to those patients, who have become incompetent to take an informed decision at the relevant time. The concept of Advance Medical Directive has gained ground to give effect to the rights of those patients, who at a particular time are not able to take an informed decision.

618. Another concept which has been accepted in several countries is recognition of instrument through which a person nominates a representative to make decision regarding their medical treatment at a point of time when the person executing the instrument is unable to make an informed decision. This is called attorney authorisation leading to medical treatment. In this country, there is no legislation governing such Advance Medical Directives. It is, however, relevant to note a recent legislation passed by Parliament, namely, "the Mental Health Care Act, 2017", where as per Section 5 every person, who is not a minor has a right to make an Advance Directive in writing regarding treatment to his mental illness in the way a person wishes to be treated for mental illness. The

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person wishes not to be treated for mental illness and nomination of individual and individual's as his/her representative. Section 5 is to the following effect:

"**5.** ***Advance Directive.***—(1) Every person, who is not a minor, shall have a right to make an Advance Directive in writing, specifying any or all of the following, namely—

(*a*) the way the person wishes to be cared for and treated for a mental illness;

(*b*) the way the person wishes not to be cared for and treated for a mental illness;

(*c*) the individual or individuals, in order of precedence, he wants to appoint as his nominated representative as provided under Section 14.

(2) An Advance Directive under sub-section (1) may be made by a person irrespective of his past mental illness or treatment for the same.

(3) An Advance Directive made under sub-section (1), shall be invoked only when such person ceases to have capacity to make mental healthcare or treatment decisions and shall remain effective until such person regains capacity to make mental healthcare or treatment decisions.

(4) Any decision made by a person while he has the capacity to make mental healthcare and treatment decisions shall override any previously written Advance Directive by such person.

(5) Any Advance Directive made contrary to any law for the time being in force shall be ab initio void."

619. Section 6 of the Act provides that an Advance Directive shall be made in the manner as has been prescribed by the Regulations made by the Central Authority. In the draft Medical Healthcare Regulations published by the Ministry of Health and Family Welfare, a form is prescribed in which Advance Directive may be made. Other aspects of medical directive have also been dealt with by the draft Regulations. Thus, in our country, recognition of Advance Directives regarding medical treatment has started to be recognised and are in place relating to specified field and purpose. Another legislation which also recognises some kind of Advance Directive relating to a person's body is Section 3 of the Transplantation of Human Organs and Tissues Act, 1994. Section 3 sub-sections (1) and (2) which are relevant for the present purpose are as follows:

"**3.** ***Authority for removal of human organs or tissues or both.***—(1) Any donor may, in such manner and subject to such conditions as may be prescribed, authorise the removal, before his death, of any human organ or tissue or both of his body for therapeutic purposes.

(2) If any donor had, in writing and in the presence of two or more witnesses (at least one of whom is a near relative of such person), unequivocally authorised at any time before his death, the removal of any human organ or tissue or both of his body, after his death, for therapeutic purposes, the person lawfully in possession of the dead body of the donor shall,

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unless he has any reason to believe that the donor had subsequently revoked the authority aforesaid, grant to a registered medical practitioner all reasonable facilities for the removal, for therapeutic purposes, of that human organ or tissue or both from the dead body of the donor."

620. The Rules have been framed under Section 24 of the Transplantation of Human Organs and Tissues Act, 1994, namely, Transplantation of Human Organs and Tissues Rules, 2014 where form of authorisation for organ or tissue pledging is Form 7, which provides that an authorisation by donor in presence of two witnesses which is also required to be registered by Organ Donor Registry.

621. The statutory recognition of the abovementioned authorisation in two statutes is clear indication of acceptance of the concept of Advance Medical Directive in this country.

622. The learned counsel for the petitioner as well as for the intervenors and the Additional Solicitor General of India has expressed concern regarding manner and procedure of execution of Advance Medical Directive. It is submitted that unless proper safeguards are not laid down, those who are vulnerable, infirm and aged may be adversely affected and efforts by those related to a person to expedite death of a person for gaining different benefits, cannot be ruled out. We have been referred to various legislations in different countries, which provide a detailed procedure of execution of Advance Medical Directive, competence of witnesses, mode and manner of execution, authority to register and keep such Advance Medical Directive.

623. Shri Arvind Datar, learned Senior Counsel has in his written submissions referred to certain aspects, which may be kept in mind while formulating guidelines for Advance Medical Directive, which are as follows:

623.1. Only adult persons, above the age of eighteen years and of sound mind at the time at which the Advance Directive is executed should be deemed to be competent. This should include persons suffering from mental disabilities provided they are of sound mind at the time of executing an Advance Directive.

623.2. Only written Advance Directives that have been executed properly with the notarised signature of the person executing the Advance Directive, in the presence of two adult witnesses shall be valid and enforceable in the eye of the law. The form should require a reaffirmation that the person executing such directive has made an informed decision. Only those Advance Directives relating to the withdrawal or withholding of life-sustaining treatment should be granted legal validity. The determination that the executor of the Advance Directive is no longer capable of making the decision should be made in accordance with relevant medical professional regulations or standard treatment guidelines, as also the determination that the executor's life would terminate in the absence of life-sustaining treatment. The constitution of a panel of experts may also be considered to make this determination. The use of expert

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committees or ethics committees in other jurisdictions is discussed at Para 28 of these written submissions.

623.3. Primary responsibility for ensuring compliance with the Advance Directive should be on the medical institution where the person is receiving such treatment.

623.4. If a hospital refuses to recognise the validity of an Advance Directive, the relatives or next friend may approach the jurisdictional High Court seeking a writ of mandamus against the hospital concerned to execute the directive. The High Court may examine whether the directive has been properly executed, whether it is still valid (Le, whether or not circumstances have fundamentally changed since its execution, making it invalid) and/or applicable to the particular circumstances or treatment.

623.5. No hospital or doctor should be made liable in civil or criminal proceedings for having obeyed a validly executed Advance Directive.

623.6. Doctors citing conscientious objection to the enforcement of Advance Directives on the grounds of religion should be permitted not to enforce it, taking into account their fundamental right under Article 25 of the Constitution. However, the hospital will still remain under this obligation.

624. The right to self-determination and bodily integrity has been recognised by this Court as noted above. The right to execute an Advance Medical Directive is nothing but a step towards protection of the aforesaid right by an individual, in event he becomes incompetent to take an informed decision, in particular stage of life. It has to be recognised by all including the States that a person has right to execute an Advance Medical Directive to be utilised to know his decision regarding manner and extent of medical treatment given to his body, in case he is incapacitated to take an informed decision. Such right by an individual does not depend on any recognition or legislation by a State and we are of the considered opinion that such rights can be exercised by an individual in recognition and in affirmation of his right of bodily integrity and self-determination which are duly protected under Article 21 of the Constitution. The procedure and manner of such expression of such right is a question which needs to be addressed to protect the vulnerable, infirm and old from any misuse. It is the duty of the State to protect its subjects specially those who are infirm, old and need medical care. The duty of doctor to extend medical care to the patients, who come to them in no manner diminishes in any manner by recognition of concept that an individual is entitled to execute an Advance Medical Directive. The physicians and medical practitioners treating a person, who is incompetent to express an informed decision have to act in a manner so as to give effect to the express wishes of an individual.

625. The concept of Advance Medical Directive has gained ground throughout the world. Different countries have framed necessary legislation in this regard. Reference of few of such legislations shall give idea of such statutory scheme formulated by different countries to achieve the object. The

Republic of Singapore has passed an enactment, namely, Advance Medical Directive Act (16 of 1996). Section 3 sub-section (1) of the Act empowers a person who is not mentally disordered and attained the age of 21 years to make an Advance Directive in the prescribed form.

626. Other provisions of the statute deal with duty of witness, registration of directives, objections, revocation of directive, panel of specialists, certification of terminal illness, duty of medical practitioner and other related provisions. The Belgian Act on Euthanasia, 2002 also contains provisions regarding Advance Directive in Section 4. Swiss Civil Code, 1907 in Articles 362 and 365 provide for advance care directive, its execution and termination. The Mental Capacity Act, 2005 (England) also contemplates for an Advance Directive. The statute further provides that an Advance Directive is applicable in life sustaining treatment only. When the decision taken in writing, signed by the patient or by another person in patient's presence on his direction. Pennsylvania Act 169 of 2006 also contains provisions with regard to execution of Advance Medical Directive and other related provisions, its revocation, etc.

627. In our country, there is yet no legislation pertaining to Advance Medical Directive. It is, however, relevant to note that Ministry of Health and Family Welfare vide its Order dated 6-5-2016 uploaded the Law Commission's 241st Report and solicited opinions, comments on the same. An explanatory note has also been uploaded by the Ministry of Health and Family Welfare where in Para 6 following was stated:

> "Living Will has been defined as 'A document in which person states his/her desire to have or not to have extraordinary life prolonging measures used when recovery is not possible from his/her terminal condition.'
>
> However, as per Para 11 of the said Bill the Advance Medical Directive (Living Will) or medical power of attorney executed by the person shall be void and of no effect and shall not be binding on any medical practitioner."

Although in Clause 11 of the draft Bill, it was contemplated that Advance Medical Directives are not binding on medical practitioner but the process of legislation had not reached at any final stage. The directions and safeguards which have been enumerated by the Hon'ble Chief Justice in his judgment shall be sufficient to safeguard the interests of the patients, doctors and society till the appropriate legislation is framed and enforced.

628. We thus conclude that a person with competent medical facility is entitled to execute an Advance Medical Directive subject to various safeguards as noted above.

M. *Conclusions*

629. From the above discussions, we arrive on following conclusions:

629.1. The Constitution Bench in *Gian Kaur case*[10] held that the "right to life: including right to live with human dignity" would mean the existence of such right up to the end of natural life, which also includes the right to a dignified life up to the point of death including a dignified procedure of death.

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374

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The above right was held to be part of fundamental right enshrined under Article 21 of the Constitution which we also reiterate.

629.2. We agree with the observation made in the reference order of the three-Judge Bench to the effect that the Constitution Bench in *Gian Kaur case*[10] did not express any binding view on the subject of euthanasia. We hold that no binding view was expressed by the Constitution Bench on the subject of euthanasia.

629.3. The Constitution Bench, however, noted a distinction between cases in which physician decides not to provide or continue to provide for treatment and care, which could or might prolong his life and those in which he decides to administer a lethal drug even though with object of relieving the patient from pain and suffering. The latter was held not to be covered under any right flowing from Article 21.

629.4. Thus, the law of the land as existing today is that no one is permitted to cause death of another person including a physician by administering any lethal drug even if the objective is to relieve the patient from pain and suffering.

629.5. An adult human being of conscious mind is fully entitled to refuse medical treatment or to decide not to take medical treatment and may decide to embrace the death in natural way.

629.6. Euthanasia as the meaning of word suggests is an act which leads to a good death. Some positive act is necessary to characterise the action as euthanasia. Euthanasia is also commonly called "assisted suicide" due to the above reasons.

629.7. We are thus of the opinion that the right not to take a life saving treatment by a person, who is competent to take an informed decision is not covered by the concept of euthanasia as it is commonly understood but a decision to withdraw life saving treatment by a patient who is competent to take decision as well as with regard to a patient who is not competent to take decision can be termed as passive euthanasia, which is lawful and legally permissible in this country.

629.8. The right of patient who is incompetent to express his view cannot be outside the fold of Article 21 of the Constitution of India.

629.9. We are also of the opinion that in cases of incompetent patients who are unable to take an informed decision, "the best interests principle" be applied and such decision be taken by specified competent medical experts and be implemented after providing a cooling period to enable aggrieved person to approach the court of law.

629.10. An Advance Medical Directive is an individual's advance exercise of his autonomy on the subject of extent of medical intervention that he wishes to allow upon his own body at a future date, when he may not be in a position to specify his wishes. The purpose and object of Advance Medical Directive is

10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374

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to express the choice of a person regarding medical treatment in an event when he loses capacity to take a decision. The right to execute an Advance Medical Directive is nothing but a step towards protection of the aforesaid right by an individual.

629.11. Right of execution of an Advance Medical Directive by an individual does not depend on any recognition or legislation by a State and we are of the considered opinion that such rights can be exercised by an individual in recognition and in affirmation of his right of bodily integrity and self-determination.

630. In view of our conclusions as noted above the writ petition is *allowed* in the following manner:

630.1. The right to die with dignity as fundamental right has already been declared by the Constitution Bench judgment of this Court in *Gian Kaur case*[10] which we reiterate.

630.2. We declare that an adult human being having mental capacity to take an informed decision has right to refuse medical treatment including withdrawal from life saving devices.

630.3. A person of competent mental faculty is entitled to execute an Advance Medical Directive in accordance with safeguards as referred to above.

631. Before we conclude, we acknowledge our indebtedness to all the learned advocates who have rendered valuable assistance with great industry and ability which made it possible for us to resolve issues of seminal public importance. We record our fullest appreciation for the assistance rendered by each and every counsel in this case.

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10 *Gian Kaur* v. *State of Punjab*, (1996) 2 SCC 648 : 1996 SCC (Cri) 374

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ANNEXURE-W

F.No Z- 28015/09/2018-MH-II
Government of India
Ministry of Health and Family Welfare
National Council Secretariat

Date : 30th Aug 2018

NOTICE

Sub: Placing the draft of "Charters of Patient Rights" in public domain for comments/ suggestions- reg

MOHFW plans to implement "Charters of Patient Rights" through State Governments for provision of proper health care to patients by the Clinical Establishments.

As per the recommendation of National Council of Clinical Establishments, a statutory body under Clinical Establishments Act, comments/suggestions are invited on the draft of Charters of Patient Rights as prepared by NHRC (National Human Rights Commission) for a period of 30 days.

The comments /suggestions on the draft may be forwarded to Dr. Anil Kumar, Addl.DDG, Dte.GHS, Ministry of Health and Family Welfare, Room No-560- A, Nirman Bhawan, New Delhi- 110108 or by email to help.ceact2010@nic.in within 30 days from the date of issue of this notice.

30/8/18
(Sudhir Kumar)
Joint Secretary

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Charter of Patients' Rights for adoption by NHRC

Patients' rights are Human rights!

Preamble

The Universal Declaration of Human Rights (1948) emphasizes the fundamental dignity and equality of all human beings. Based on this concept, the notion of Patient Rights has been developed across the globe in the last few decades. There is a growing consensus at international level that all patients must enjoy certain basic rights. In other words, the patient is entitled to certain amount of protection to be ensured by physicians, healthcare providers and the State, which have been codified in various societies and countries in the form of Charters of Patient's Rights. In India, there are various legal provisions related to Patient's Rights which are scattered across different legal documents e.g. The Constitution of India, Article 21, Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002; The Consumer Protection Act 1986; Drugs and Cosmetic Act 1940, Clinical Establishment Act 2010 and rules and standards framed therein; various judgments given by Hon'ble Supreme Court of India and decisions of the National Consumer Disputes Redressal Commission.

This Charter of Patient's Rights adopted by the National Human Rights Commission draws upon all relevant provisions, inspired by international charters and guided by national level provisions, with the objective of consolidating these into a single document, thereby making them publicly known in a coherent manner. There is an expectation that this document will act as a guidance document for the Union Government and State Governments to formulate concrete mechanisms so that Patient's Rights are given adequate protection and operational mechanisms are set up

to make these rights functional and enforceable by law. This is especially important and an urgent need at the present juncture because India does not have a dedicated regulator like other countries and the existing regulations in the interest of patients, governing the healthcare delivery system is on the anvil, some States have adopted the national Clinical Establishments Act 2010, certain other States have enacted their own State level legislations like the Nursing Homes Act to regulate hospitals, while a few other States are in the process of adopting / developing such regulation. The Charter of Patient's Rights has been drafted with the hope that it shall be incorporated by policy makers in all existing and emerging regulatory legislations concerning the health care sector. This charter would also enable various kinds of health care providers to actively engage with this framework of patients' rights to ensure their observance, while also benefiting from the formal codification of patients responsibilities.

Another objective of this Charter is to generate widespread public awareness and educate citizens regarding what they should expect from their governments and health care providers—about the kind of treatment they deserve as patients and human beings, in health care settings. NHRC firmly believes that informed and aware citizens can play a vital role in elevating the standard of health care, when they have guidance provided by codified rights, as well as awareness of their responsibilities.

NHRC believes that this Charter of Patients' Rights will be an enabling document to ensure the protection and promotion of Human rights of those who are among some of the most vulnerable sections of society – ordinary patients and citizens seeking health care across India.

	Rights of patients	Description of rights and associated duty bearers	Reference
1	**Right to information**	Every patient has a right to adequate relevant information about the nature, cause of illness, provisional / confirmed diagnosis, proposed investigations and management, and possible complications To be explained at their level of understanding in language known to them. The treating physician has a duty to ensure that this information is provided in simple and intelligible language to the patient to be communicated either personally by the physician, or by means of his / her qualified assistants. Every patient and his/her designated caretaker have the right to factual information regarding the expected cost of treatment based on evidence. The hospital management has a duty to communicate this information in writing to the patient and his/her designated caretaker. They should also be informed about any additional cost to be incurred due to change in the physical condition	1) Annexure 8 of standards for Hospital level 1 by National Clinical Establishments Council set up as per Clinical Establishment Act 2010 2) MCI Code of Ethics 3) Patients Charter by National Accreditation Board for Hospitals (NABH) 4) The Consumer Protection Act, 1986

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		of the patient or line of treatment in writing. On completion of treatment, the patient has the right to receive an itemized bill, to receive an explanation for the bill(s) regardless of the source of payment or the mode of payment, and receive payment receipt(s) for any payment made. Patients and their caretakers also have a right to know the identity and professional status of various care providers who are providing service to him / her and to know which Doctor / Consultant is primarily responsible for his / her care. The hospital management has a duty to provide this information routinely to all patients and their caregivers in writing with an acknowledgement.	
2	**Right to records and reports**	Every patient or his caregiver has the right to access originals / copies of case papers, indoor patient records, investigation reports (during period of admission, preferably within 24 hours and after discharge, within 72 hours). This may be made available wherever applicable after paying appropriate fees for photocopying or allowed to be photocopied by patients at their cost.	**1)** Annexure 8 of standards for Hospital level 1 by National Clinical Establishments Council set up as per Clinical Establishment Act 2010 **2)** MCI Code of Ethics section1.3.2 **3)** Central Information Commission

		The relatives / caregivers of the patient have a right to get discharge summary or in case of death, death summary along with original copies of investigations. The hospital management has a duty to provide these records and reports and to instruct the responsible hospital staff to ensure provision of the same are strictly followed without fail.	judgment, Nisha Priya Bhatia Vs. Institute of HB&AS, GNCTD, 2014 **4)** The Consumer Protection Act, 1986
3	**Right to Emergency Medical Care**	As per Supreme Court, all hospitals both in the government and in the private sector are duty bound to provide basic Emergency Medical Care, and injured persons have a right to get Emergency Medical Care. Such care must be initiated without demanding payment / advance and basic care should be provided to the patient irrespective of paying capacity. It is the duty of the hospital management to ensure provision of such emergency care through its doctors and staff, rendered promptly without compromising on the quality and safety of the patients.	**1)** Supreme court judgment Parmanand Katara v. Union of India (1989) **2)** Judgment of National Consumer Disputes Redressal Commission Pravat Kumar Mukherjee v. Ruby General Hospital & Others (2005) **3)** MCI Code of Ethics sections 2.1 and 2.4 **4)** Article 21 of the Constitution 'Right to Life'

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4	**Right to informed consent**	Every patient has a right that informed consent must be sought prior to any potentially hazardous test/treatment (e.g. invasive investigation / surgery / chemotherapy) which carries certain risks. It is the duty of the hospital management to ensure that all concerned doctors are properly instructed to seek informed consent, that an appropriate policy is adopted and that consent forms with protocol for seeking informed consent are provided for patients in an obligatory manner. It is the duty of the primary treating doctor administering the potentially hazardous test / treatment to explain to the patient and caregivers the main risks that are involved in the procedure, and after giving this information, the doctor may proceed only if consent has been given in writing by the patient / caregiver or in the manner explained under Drugs and Cosmetic Act Rules 2016 on informed consent.	**1)** MCI Code of Ethics section 7.16 **2)** Annexure 8 of standards for Hospital level 1 by National Clinical Establishments Council set up as per Clinical Establishment Act 2010 **3)** The Consumer Protection Act, 1986 **4)** Drugs and Cosmetic Act 1940, Rules 2016 on Informed Consent
5	**Right to confidentiality,**	All patients have a right to privacy, and doctors have a duty to hold information about their health condition and treatment plan in strict confidentiality, unless	**1)** MCI Code of Ethics sections 2.2, 7.14 and 7.17.

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	human dignity and privacy	it is essential in specific circumstances to communicate such information in the interest of protecting other or due to public health considerations. Female patients have the right to presence of another female person during physical examination by a male practitioner. It is the duty of the hospital management to ensure presence of such female attendants in case of female patients. The hospital management has a duty to ensure that its staff upholds the human dignity of every patient in all situations. All data concerning the patient should be kept under secured safe custody and insulated from data theft and leakage.	**2)** Annexure 8 of standards for Hospital level 1 by National Clinical Establishments Council set up as per Clinical Establishment Act 2010
6	**Right to second opinion**	Every patient has the right to seek second opinion from an appropriate clinician of patients' / caregivers' choice. The hospital management has a duty to respect the patient's right to second opinion, and should provide to the patients caregivers all necessary records and information required for seeking such opinion without any extra cost or delay. The hospital management has a duty to ensure that any decision to seek such	**1)** Annexure 8 of standards for Hospital level 1 by National Clinical Establishments Council set up as per Clinical Establishment Act 2010 **2)** The Consumer Protection Act, 1986

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		second opinion by the patient / caregivers must not adversely influence the quality of care being provided by the treating hospital as long as the patient is under care of that hospital. Any kind discriminatory practice adopted by the hospital or the service providers will be deemed as Human Rights' violation.	
7	**Right to transparency in rates, and care according to prescribed rates wherever relevant**	Every patient and their caregivers have a right to information on the rates to be charged by the hospital for each type of service provided and facilities available on a prominent display board and a brochure. They have a right to receive an itemized detailed bill at the time of payment. It would be the duty of the Hospital / Clinical Establishment to display key rates at a conspicuous place in local as well as English language, and to make available the detailed schedule of rates in a booklet form to all patients / caregivers. Every patient has a right to obtain essential medicines as per India Pharmacopeia, devices and implants at rates fixed by the National Pharmaceutical Pricing Authority (NPPA) and other relevant authorities. Every patient has a right to receive health care services within the range of rates for procedures and services prescribed by Central and State Governments from	**1)** MCI Code of Ethics section 1.8 regarding Payment of Professional Services **2)** Section 9(i) and 9(ii) of Clinical establishments (Central Government) Rules 2012 **3)** Annexure 8 of standards for Hospital level 1 by National Clinical Establishments Council set up as per Clinical Establishment Act 2010 **4)** Various Drug price control orders **5)** The Consumer Protection Act, 1986

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		time to time, wherever relevant. However, no patient can be denied choice in terms of medicines, devices and standard treatment guidelines based on the affordability of the patients' right to choice. Every hospital and clinical establishment has a duty to ensure that essential medicines under NLEM as per Government of India and World Health Organisation, devices, implants and services are provided to patients at rates that are not higher than the prescribed rates or the maximum retail price marked on the packaging.	**6)** Drugs Price Control Order (DPCO) section 3 of the Essential Commodities Act, 1955
8	**Right to non-discrimination**	Every patient has the right to receive treatment without any discrimination based on his or her illnesses or conditions, including HIV status or other health condition, religion, caste, ethnicity, gender, age, sexual orientation, linguistic or geographical /social origins. The hospital management has a duty to ensure that no form of discriminatory behaviour or treatment takes place with any person under the hospital's care. The hospital management must regularly orient and instruct all its doctors and	**1)** Annexure 8 of standards for Hospital level 1 by National Clinical Establishments Council set up as per Clinical Establishment Act 2010

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		staff regarding the same.	
9	**Right to safety and quality care according to ,standards**	Patients have a right to safety and security in the hospital premises. They have a right to be provided with care in an environment having requisite cleanliness, infection control measures, safe drinking water as per BIS/FSSAI Standards and sanitation facilities. The hospital management has a duty to ensure safety of all patients in its premises including clean premises and provision for infection control. Patients have a right to receive quality health care according to currently accepted standards, norms and standard guidelines as per National Accreditation Board for Hospitals (NABH) or similar. They have a right to be attended to, treated and cared for with due skill, and in a professional manner in complete consonance with the principles of medical ethics. Patients and caretakers have a right to seek redressal in case of perceived medical negligence or damaged caused due to deliberate deficiency in service delivery. The hospital management and treating doctors have a duty to provide quality health care in accordance with current standards of care and standard treatment guidelines and to avoid medical negligence or deficiency in service	**1)** Clinical establishments (Central Government) Rules 2012 **2)** The Consumer Protection Act, 1986

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		delivery system in any form.	
10	**Right to choose alternative treatment options if available**	Patients and their caregivers have a right to choose between alternative treatment / management options, if these are available, after considering all aspects of the situation. This includes the option of the patient refusing care after considering all available options, with responsibility for consequences being borne by the patient and his/her caregivers. In case a patient leaves a healthcare facility against medical advice on his / her own responsibility, then notwithstanding the impact that this may have on the patient's further treatment and condition, this decision itself should not affect the observance of various rights mentioned in this charter. The hospital management has a duty to provide information about such options to the patient as well as to respect the informed choice of the patient and caregivers in a proper recorded manner with due acknowledgement from the patient or the caregivers on the communication and the mode.	1) Annexure 8 of standards for Hospital level 1 by National Clinical Establishments Council set up as per Clinical Establishment Act 2010 2) The Consumer Protection Act, 1986
11	**Right to choose source for**	When any medicine is prescribed by a doctor or a hospital, the patients and their caregivers have the right to choose any registered pharmacy of their	1) Various judgments by the National Consumer Dispute Redressal

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	obtaining medicines or tests	choice to purchase them. Similarly when a particular investigation is advised by a doctor or a hospital, the patient and his caregiver have a right to obtain this investigation from any registered diagnostic centre/laboratory having qualified personnel and accredited by National Accreditation Board for Laboratories (NABL). It is the duty of every treating physician / hospital management to inform the patient and his caregivers that they are free to access prescribed medicines / investigations from the pharmacy / diagnostic centre of their choice. The decision by the patient / caregiver to access pharmacy / diagnostic centre of their choice must not in any ways adversely influence the care being provided by the treating physician or hospital.	Commission 2) The Consumer Protection Act, 1986
12	**Right to proper referral and transfer, which is free from perverse commercial**	A patient has the right to continuity of care, and the right to be duly registered at the first healthcare facility where treatment has been sought, as well as at any subsequent facilities where care is sought. When being transferred from one healthcare facility to another, the patient / caregiver must receive a complete explanation of the justification for the transfer, the alternative options	1) Medical Council of India code of ethics section 3.6 2) World Health Organisation – Referral Notes 3) Various IPHS documents

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	influences	for a transfer and it must be confirmed that the transfer is acceptable to the receiving facility. The patient and caregivers have the right to be informed by the hospital about any continuing healthcare requirements following discharge from the hospital. The hospital management has a duty to ensure proper referral and transfer of patients regarding such a shift in care. In regard to all referrals of patients, including referrals to other hospitals, specialists, laboratories or imaging services, the decision regarding facility to which referral is made must be guided entirely by the best interest of the patient. The referral process must not be influenced by any commercial consideration such as kickbacks, commissions, incentives, or other perverse business practices.	
13	**Right to protection for patients involved in clinical trials**	Every person / patient who is approached to participate in a clinical trial has a right to due protection in this context. All clinical trials must be conducted in compliance with the protocols and Good Clinical Practice Guidelines issued by Central Drugs Standard Control Organisation, Directorate General of Health	1) Protocols and Good Clinical Practice Guidelines issued by Central Drugs Standard Control Organisation, Directorate General

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		Services, Govt. of India as well as all applicable statutory provisions of Amended Drugs and Cosmetics Act, 1940 and Rules, 1945, including observance of the following provisions related to patients rights: a) Participation of patients in clinical trials must always be based on informed consent, given after provision of all relevant information. The patient must be given a copy of the signed informed consent form, which provides him / her with a record containing basic information about the trial and also becomes documentary evidence to prove their participation in the trial. b) A participant's right to agree or decline consent to take part in a clinical trial must be respected and her/his refusal should not affect routine care. c) The patient should also be informed in writing about the name of the drug / intervention that is undergoing trial along with dates, dose and	of Health Services, Govt. of India 2) Amended Drugs and Cosmetics Act, 1940 and Rules, 1945 especially schedule Y 3) National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, Indian Council of Medical Research, New Delhi, 2017 4) World Medical Assembly Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects available at www.wma.net/en/30publications/10policies/b3/17c.pdf

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		duration of administration. d) At all times, the privacy of a trial participant must be maintained and any information gathered from the participant must be kept strictly confidential. e) Trial participants who suffer any adverse impact during their participation in a trial are entitled to free medical management of adverse events, irrespective of relatedness to the clinical trial, which should be given for as long as required or till such time as it is established that the injury is not related to the clinical trial. In addition, financial or other assistance must be given to compensate them for any impairment or disability. In case of death, their dependents have the right to compensation. f) Ancillary care may be provided to clinical trial participants for non-study/trial related illnesses arising during the period of the trial. This could be in the form of medical care or reference to facilities, as may be	

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		appropriate. g) Institutional mechanisms must be established to allow for insurance coverage of trial related or unrelated illnesses (ancillary care) and award of compensation wherever deemed necessary by the concerned Ethics Committee. h) After the trial, participants should be assured of access to the best treatment methods that may have been proven by the study. Any doctor or hospital who is involved in a clinical trial has a duty to ensure that all these guidelines are followed in case of any persons / patients involved in such a trial.	
14	**Right to protection of participants involved in biomedical and**	Every patient who is taking part in biomedical research shall be referred to as research participant and every research participant has a right to due protection in this context. Any research involving such participants should follow the National Ethical Guidelines for Biomedical and Health Research Involving Human	1) National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, Indian Council of Medical Research,

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	health research	Participants, 2017 laid down by Indian council for Medical Research and should be carried out with prior approval of the Ethics Committee. Documented informed consent of the research participants should be taken. Additional safeguards should be taken in research involving vulnerable population. Right to dignity, right to privacy and confidentiality of individuals and communities should be protected. Research participants who suffer any direct physical, psychological, social, legal or economic harm as a result of their participation are entitled, after due assessment, to financial or other assistance to compensate them equitably for any temporary or permanent impairment or disability. The benefits accruing from research should be made accessible to individuals, communities and populations whenever relevant.	New Delhi, 2017 2) World Medical Assembly Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects available at www.wma.net/en/30publications/10policies/b3/17c.pdf 3) Drugs & Cosmetic Act, Rules 2016 on Clinical Trails

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		Any doctor or hospital who is involved in biomedical and health research involving patients has a duty to ensure that all these guidelines are followed in case of any persons / patients involved in such research.	
15	**Right to take discharge of patient, or receive body of deceased from hospital**	A patient has the right to take discharge and cannot be detained in a hospital, on procedural grounds such as dispute in payment of hospital charges. Similarly, caretakers have the right to the dead body of a patient who had been treated in a hospital and the dead body cannot be detailed on procedural grounds, including nonpayment/dispute regarding payment of hospital charges against wishes of the caretakers. The hospital management has a duty to observe these rights and not to indulge in wrongful confinement of any patient, or dead body of patient, treated in the hospital under any circumstances.	1) Prohibition of wrongful confinement under Sec. 340-342 of IPC. Statements of Mumbai High Court. 2) Consumer Protection Act 1986
16	**Right to Patient Education**	Patients have the right to receive education about major facts relevant to his/her condition and healthy living practices, their rights and responsibilities, officially supported health insurance schemes relevant to the patient, relevant entitlements in case of charitable hospitals, and how to seek redressal of	1) The Consumer Protection Act, 1986 2) Standards for Hospital level 1 by National Clinical Establishments Council set up as per Clinical

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		grievances in the language the patients understand or seek the education. The hospital management and treating physician have a duty to provide such education to each patient according to standard procedure in the language the patients understand and communicate in a simple and easy to understand manner.	Establishment Act 2010
17	**Right to be heard and seek redressal**	Every patient and their caregivers have the right to give feedback, make comments, or lodge complaints about the health care they are receiving or had received from a doctor or hospital. This includes the right to be given information and advice on how to give feedback, make comments, or make a complaint in a simple and user-friendly manner. Patients and caregivers have the right to seek redressal in case they are aggrieved, on account of infringement of any of the above mentioned rights in this charter. This may be done by lodging a complaint with an official designated for this purpose by the hospital / healthcare provider and further with an official mechanism constituted by the government such as Patients'	1) The Consumer Protection Act, 1986 2) NHS - Charter of Patient Rights and Responsibilities

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		rights Tribunal Forum or Clinical establishments regulatory authority as the case may be. All complaints must be registered by providing a registration number and there should be a robust tracking and tracing mechanism to ascertain the status of the complaint resolution. The patient and caregivers have the right to a fair and prompt redressal of their grievances. Further, they have the right to receive in writing the outcome of the complaint within 15 days from the date of the receipt of the complaint. Every hospital and clinical establishment has the duty to set up an internal redressal mechanism as well as to fully comply and cooperate with official redressal mechanisms including making available all relevant information and taking action in full accordance with orders of the redressal body as per the Patient's Right Charter or as per the applicable existing laws.	

Responsibilities of patients and caretakers

Along with promoting their rights, patients and caretakers should follow their responsibilities so that hospitals and doctors can perform their work satisfactorily.

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1) Patients should provide all required health related information to their doctor, in response to the doctor's queries without concealing any relevant information, so that diagnosis and treatment can be facilitated.

2) Patients should cooperate with the doctor during examination, diagnostic tests and treatment, and should follow doctor's advice, while keeping in view their right to participate in decision making related to treatment.

3) Patients should follow all instructions regarding appointment time, cooperate with hospital staff and fellow patients, avoid creating disturbance to other patients, and maintain cleanliness in the hospital.

4) Patients should respect the dignity of the doctor and other hospital staff as human beings and as professionals. Whatever the grievance may be, patient / caregivers should not resort to violence in any form and damage or destroy any property of the hospital or the service provider.

5) The Patients should take responsibility for their actions based on choices made regarding treatment options, and in case they refuse treatment (not clear???).

Recommended mechanism for implementation of Charter of Patient's Rights and Grievance redressal mechanism

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NHRC recommends to the Government of India, all State Governments and Administration of all the Union Territories that they should seriously consider the adoption of the charter and incorporate this Charter of Patients' Rights in the entire range of existing and emerging regulatory frameworks concerning the health care sector, under their jurisdiction.

Further NHRC recommends that all State Human Rights Commissions should adopt the Charter of Patients' Rights to be treated as a reference document in all cases related to human rights violations concerning patients and all users of health care services.

NHRC further recommends that all administrative and regulatory authorities completely or partially related with the healthcare sector, including but not limited to the following should incorporate and promote implementation of the Charter of Patient's Rights within their jurisdiction wherever applicable.

1. Ministry of Health and Family Welfare, Government of India
2. Public Health and Family Welfare Departments in all States and UTs
3. Medical Education Department of States and UTs, wherever they exist
4. Executive/Managing authorities of all publicly funded healthcare insurance schemes and Public-Private-Partnership arrangements in healthcare by Government of India, all State Governments and administrations in all UTs
5. National Council for Clinical Establishments
6. State Councils for Clinical Establishments, wherever applicable

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7. Authorities established under State Nursing Home Acts or equivalent acts, wherever applicable
8. Medical Council of India / National Medical Commission or equivalent body
9. State Medical Councils in all States and UTs
10. Central Council of Indian Medicine
11. State Councils for Indian Medicine in all States and UTs
12. Any other healthcare related statutory councils established in all States and UTs
13. Central Consumer Protection Council, all State and District consumer protection councils
14. Registrar of Societies in all States and UTs, in the context of non-profit clinical establishments
15. Charity Commissioner in those States wherever applicable, in the context of non-profit clinical establishments
16. Department of Religious and Charitable Endowments in those States wherever applicable, in the context of non-profit clinical establishments
17. Registrar of Companies, in the context of for-profit hospitals run by companies and non-profit clinical establishments run by companies registered under Section 25
18. Central Drugs and Standard Control Organisation, Ministry of Health & Family Welfare, Government of India

19. Quality Council of India, New Delhi

20. Department of Consumer Affairs, Ministry of Consumer Affairs, Food & Public Distribution, Government of India

Once the Patients' Rights Charter has been adopted by the Govt. of India, State Governments and the Administration of the Union Territories, they may stipulate/ensure that all types of Clinical Establishments (both therapeutic and diagnostic) display this Charter prominently within their premises, orient all their staff and consultants regarding the Charter, and observe the Charter of Patients' Rights in letter and spirit irrespective of whether such clinical establishment is owned, controlled or managed by-

i. the Government or a department of the Government;

ii. a trust, whether public or private;

iii. a corporation (including a society) registered under a Central, Provincial or State Act, whether or not owned by the Government;

iv. a privately owned enterprise;

v. a local authority

Further, NHRC recommends to the Government of India, all State Governments and administration of Union Territories to ensure the setting up of a grievance redressal mechanism for patients, as a component of their existing or emerging regulatory frameworks for clinical establishments, by making required modifications in rules, regulations and acts where required. Observance of patients' rights and setting up of grievance

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redressal mechanism for protection of these Rights should be made an integral component of the implementation of Clinical Establishment (Registration and Regulation) Act 2010 in those states who have adopted it, or as a component of state specific regulatory frameworks for clinical establishments in other states, which have equivalent state specific legislations, or are planning to enact state specific legislations to regulate clinical establishments.

NHRC recommends that Patients' rights grievance redressal mechanisms should have the following components-

1. Every clinical establishment should set up an internal grievance redressal mechanism. First, patients may file a complaint with an authorized representative who can be named 'Internal Grievance Redressal Officer' of the clinical establishment, either individually in person through an authorized representative or collectively through a consumer group or civil society organization. The clinical establishment's Internal Grievance Redressal Officer shall consider the complaint and try to find an appropriate solution, keeping in view the provisions of the Patients' Rights Charter and promptly acknowledge the receipt of the complaint within 24 hours by assigning a registration number for tracking and tracing the status of the complaint.
2. If a solution acceptable to the patient is not found at the level of the clinical establishment and the patient/representative is not satisfied, then he/she may approach the office of the district level registering authority set up under Clinical Establishment (Registration and Regulation) Act 2010 in those States who have adopted it, or equivalent district level authorities created under the State specific clinical establishments act or similar regulatory frameworks for clinical establishments in other states which have other State specific legislations. The district level registering authority shall verify the facts of the matter, and where there is clear violation of patient's

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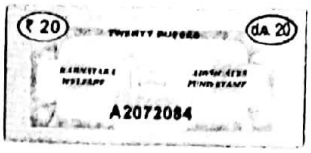
rights as brought out facts, the registering authority may issue necessary executive orders to the clinical establishment for rectification. If there is any dispute over interpretation of Charter of Patient's Rights and provisions in the regulatory framework, the registering authority may clarify the procedure, rules, regulations and attempt to resolve the complaint through mediation between both parties within 30 days from the date of receipt of the appeal.

3. In case of any particular complaint, if even after completing the above mentioned procedure, the patient or his/her representative is not satisfied, then he/she can file appeal before the State Council of Clinical Establishments under Clinical Establishment (Registration and Regulation) Act 2010 in those states who have adopted the Act. Section 8(5)(e) empowers the 'State Council for Clinical Establishments' to hear appeals against the orders of the District Registering Authority set up under CEA 2010. 'State Council of Clinical Establishment' can set up a three or five member sub-committee / cell (with multi-stakeholder participation) which can be named as 'Healthcare Grievance Redressal Authority' for resolution of patient's grievances, and pass rectification orders or disciplinary orders or punitive orders which would be binding upon the clinical establishments within the framework of CEA within 30 days from the date of receipt of the appeal. The complaints procedure to be set up under the State Council of Clinical Establishments should explicitly state that it is not intended as a means of achieving monetary compensation.

4. Apart from the above mentioned grievance redressal mechanisms, patients/representatives would always be free to approach the State Medical Council to seek disciplinary action against unethical conduct of any specific doctor, and also free to approach Consumer Forums at

various levels to seek financial compensation, or approach Civil/Criminal Courts keeping in view the nature of the complaint i.e., creation of a separate grievance redressal machinery to deal with violations of Patients' Rights Charter shall in no way either extinguish or affect adversely the existing legal remedies both civil and criminal available to patients and their caregivers under the existing legal framework.



IN THE COURT OF THE HON'BLE HIGH COURT

W.P No. of 2020 (GM - PIL)

Plaintiff/s, Petitioner/s Appellant/s, Caveator/s / Complainant/s Decree Holder/s	**Vs.**	Defendant/s, Respondent/s Accused, Opponent/s Judgement - Debtor/s
A. Varghese & Anr.		Union of India & ors

I/We A Varghese

the Petitioner

Nos. 1 in the above matter hereby appoint and retain

Sri/Smt. Avani Chokshi, Siddharth Seem & Pankaj kumar

to appear, act and plead for me/us in the above matter and to conduct/prosecute and defend the same in all interlocutory or miscellaneous proceeding connected with the same or with any decree or orders passed therein appeals and or other proceedings arising there from and also in proceedings for review of judgement and for leave to appeal to Supreme Court and to obtain return of any documents filed therein or receive any money which may be payable to me/us.

2. I/We hereby authorise him/her them on my / our behalf to enter into a compromise in the above matter, to execute any decree/order therein to appeal from any decree / order/ therein and to appeal, to act to plead in such appeal in any preferred by any other party from any decree / order/ therein.

I/We further agree that, if I/We fail to pay the fees agreed upon or to give due instructions at all stages, he/she/they is / are at liberty to retire from the case and recover all amounts due to him/her/them and retain all my / our monies till such dues are paid.

Executed by me/us this 04th day of Sept., 2020 at Bangalore

Siddharth Seem
D/3378/17

Signature/s

Avani

Executant/s is/are personally known to me/us and he/she/has have signed before me/us

Satisfied as to identity of Executant's Signature/s.

(Where the executant/s is illiterate, blind or unaquinted with the language of Vakalath)

Certified, that the contents were explained to the executant/s in my presence in English language, known to him/her them who appeare/s perfectly to understand the same and has / have signed in the presence.

Avani

Accepted

Name AVANI CHOKSHI Roll No. KAR 1001/18 Address for Service :

Name ..... Roll No. .....

MANTHAN LAW
ADVOCATES
18, 1st Floor, Bharath Bhavan,
No. 35, Infantry Road,
BANGALORE - 560 001.

Advocate/s for Petitioners

Place : Bangalore

Date : 04/09/2020

Forms can be had at : The Bengaluru Advocates' Co-Op. Society Ltd., Bengaluru-9. Ph.: 080-22217361

IN THE COURT OF THE HON'BLE HIGH COURT

WP No. of 20 20 (GM-PK

Plaintiff/s, Petitioner/s Appellant/s, Caveator/s / Complainant/s Decree Holder/s	Vs.	Defendant/s, Respondent/s Accused, Opponent/s Judgement - Debtor/s
A. Varghese		Union of India & Ors

I/We Priyanka Arora

the Petitioner

Nos. 2

In the above matter hereby appoint and retain

Sri/Smt. Avani Chokshi, Siddharth Seem

& Pankaj Kumar

to appear, act and plead for me/us in the above matter and to conduct/prosecute and defend the same in all interlocutory or miscellaneous proceeding connected with the same or with any decree or orders passed therein appeals and or other proceedings arising there from and also in proceedings for review of judgement and for leave to appeal to Supreme Court and to obtain return of any documents filed therein or receive any money which may be payable to me/us.

2. I/We hereby authorise him/her them on my / our behalf to enter into a compromise in the above matter, to execute any decree/order therein to appeal from any decree / order/ therein and to appeal, to act to plead in such appeal in any preferred by any other party from any decree / order/ therein.

I/We further agree that, if I/We fail to pay the fees agreed upon or to give due instructions at all stages, he/she/they is / are at liberty to retire from the case and recover all amounts due to him/her/them and retain all my / our monies till such dues are paid.

Executed by me/us this 04th day of Sept 2020 at Bangalore

identified by
ASR Pankaj Kumar

Priyanka Arora
Signature/s

Executant/s is/are personally known to me/us and he/she/has have signed before me/us

Satisfied as to identity of Executant's Signature/s.
(Where the executant/s is illiterate, blind or unaquinted with the language of Vakalath)

Certified, that the contents were explained to the executant/s in my presence in English language, known to him/her them who appeare/s perfectly to understand the same and has / have signed in the presence.

Accepted

Name AVANI CHOKSHI Roll No. 1001/18

Name ..... Roll No. .....

Advocate/s for

Place :

Date :

Address for Service :
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ADVOCATES
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13878/2017
(Siddharth Seem, Advocate)