

GUIDELINES FOR WITHDRAWAL OF LIFE SUPPORT IN TERMINALLY ILL PATIENTS

BACKGROUND

Many patients in the ICU are terminally ill, and not expected to benefit from life sustaining treatments (LST) that include (but are not limited to) mechanical ventilation, vasopressors, dialysis, surgical procedures, transfusions, parenteral nutrition or Extracorporeal Membrane Oxygenation (ECMO). In such circumstances, LST are non-beneficial and increase avoidable burdens and suffering to patients and therefore, are considered excessive and inappropriate. Additionally, they increase emotional stress and economic hardship to the family and moral distress to professional caregivers.¹ Withdrawal of LST in such patients is regarded as a standard of ICU care worldwide and upheld by several jurisdictions.^{2,3} Such decisions have medical, ethical and legal considerations. It may be considered that the above mentioned also applies at the time of initiating Life support treatments to individuals with.

DEFINITIONS^{4,5}

Terminal illness: An irreversible or incurable condition from which death is inevitable in the foreseeable future. Severe devastating traumatic brain injury which shows no recovery after 72 hours or more is also included.

Withdrawal (WD): A considered decision in a patient's best interests, to stop or discontinue ongoing life support in a terminally ill disease that is no longer likely to benefit the patient or is likely to harm in terms of causing suffering and loss of dignity. The following conditions must apply:

- a) Any individual declared brainstem death as per THOA Act.
- b) Medical prognostication and considered opinion that patient's disease condition is advanced and not likely to benefit from aggressive therapeutic interventions
- c) Patient/surrogate documented informed refusal, following prognostic awareness, to continue life support
- d) Compliance with procedure prescribed by the honourable Supreme Court^{5,6}

Withholding (WH): A considered decision in a patient's best interests, to not start a life supporting measure in a terminally ill patient, that is unlikely to benefit the patient and is likely to harm in terms of suffering and loss of dignity. The same above three conditions must apply.

Do-Not-Attempt-Resuscitation (DNAR): A considered decision not to perform cardio pulmonary resuscitation (CPR) in the event of anticipated cardiac arrest if there is no realistic possibility of survival or meaningful recovery.

Advance Medical Directives (AMD): A written declaration made by a person with decision-making capacity documenting how they would like to be medically treated or not treated should they lose capacity.

Best Interests: A principle that behoves physicians to ensure that potential benefits of treatments outweigh potential harms or to avoid treatments that serve no therapeutic purpose.

WD, WH and DNAR are collectively termed Foregoing of Life Support (FLST)

Autonomy: It is the right of an individual to make a free and informed decision.

Beneficence: A principle that makes it obligatory on the part of physicians to act in the best interests of patients.

Non-maleficence: A principle that directs physicians to first of all, not harm.

Distributive Justice: In the context of medical care, requires that all people be treated without prejudice and that healthcare resources be used equitably.

Surrogate: Surrogate is a person or persons other than the healthcare providers who is/are accepted as the representatives of the patient's best interests, who will make decisions on behalf of the patient when the patient loses decision-making capacity.

If the patient has made a valid AMD, the surrogate will be the person or persons named in the directive.

If there is no valid AMD, the surrogate will be the next of kin(family) or the next friend or guardian (if any) of the patient. To identify next of kin, one may refer to the definition of 'near relative' in Section 2(i) of the Transplantation of Human Organs and Tissues Act, 1994.⁷ Under this provision, 'near relative' includes: available spouse, son, daughter, father, mother, brother, sister, grandfather, grandmother, grandson or granddaughter.

Active Euthanasia is the intentional act of killing a terminally ill patient on voluntary request, by the direct intervention of a doctor for the purpose of the good of the patient. It is illegal in India.

PRINCIPLES OF FLST AND COMPASSIONATE CARE^{5,8}

1. Respect for patient Autonomy
2. Adherence to physician duties of Beneficence, Non-maleficence and Distributive Justice
3. Open, honest, timely and compassionate communication and care
4. Compliance with legal requirements
5. Transparency and documentation
6. Transitioning to palliative care

LEGAL PRINCIPLES OUTLINED BY THE HONORABLE SUPREME COURT^{5,6}

1. An adult patient capable of taking healthcare decisions may refuse LST even if it results in death
2. LST may be withheld or withdrawn lawfully under certain conditions from persons who no longer retain decision-making capacity, based on the fundamental right to Autonomy, Privacy and Dignity
3. AMD that meets specified requirements is a legally valid document
4. For a patient without capacity, FLST proposals should be made by consensus among a group of at least 3 physicians who form the Primary Medical Board (PMB)
5. The PMB must explain the illness, the medical treatment available, alternative forms of treatment, and the consequences of remaining treated and untreated to fully inform the surrogate
6. A Secondary Medical Board (SMB) of 3 physicians with one appointee by the Chief Medical Officer (CMO) of the district must validate the decision by the PMB

7. Active Euthanasia is not lawful

CONSTITUTION OF MEDICAL BOARDS AND HOSPITAL OVERSIGHT

Primary Medical Board (PMB)

The Primary Medical Board is constituted by the hospital/institution for each case, consisting of the primary physician and at least 2 subject experts with ≥ 5 years' experience.

Members of the PMB may be from the multidisciplinary treating team.

Secondary Medical Board (SMB)

The Secondary Medical Board (SMB) constituted by the hospital/institution, consists of one Registered Medical Practitioner (RMP) nominated by the CMO and at least 2 subject experts ≥ 5 years' experience. The SMB is directed by the Supreme Court to opine within 48 hours of the referral.

- A member of the PMB cannot form part of the SMB.
- The doctor nominated by the district CMO may be from the same hospital.
- There is no bar on all doctors, in both Boards, being from the same hospital.
- A standing panel of CMO-approved physicians may be set up in every healthcare facility.

Hospital Oversight

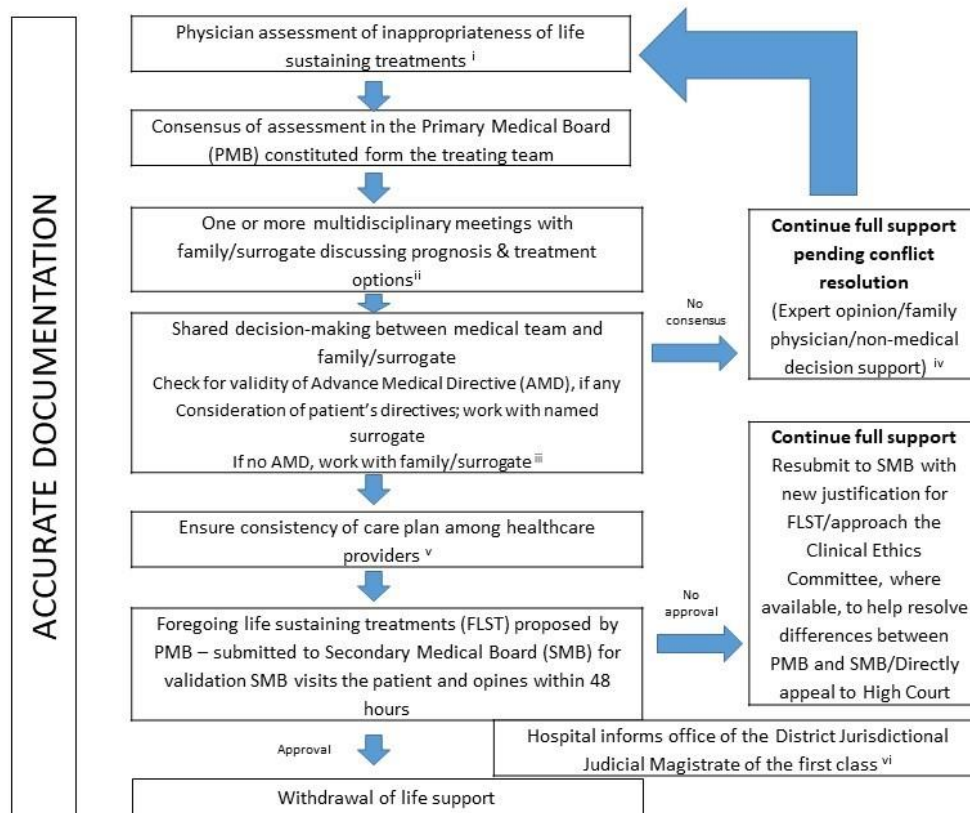
The hospital may constitute a Clinical Ethics Committee of multi-professional members for audit, oversight and conflict resolution.⁵ Proposed members include: Director/ Chief Administrator or equivalent, or his nominee, of the healthcare establishment; a senior medical practitioner of the healthcare establishment, with expertise in end of life care (EOLC); one senior medical practitioner with relevant expertise in EOLC, to be nominated from outside the healthcare establishment; a legal expert, to be nominated by the healthcare establishment; a social worker nominated by the healthcare establishment.⁹

PATHWAY FOR WITHDRAWAL AND WITHHOLDING OF LIFE SUPPORT IN TERMINALLY ILL PATIENTS

The pathway includes decision-making combining professional consensus and the honourable Supreme Court directives^{5,6}

(Adapted from Figure 1: End of Life Care Pathway in: Indian Society of Critical Care Medicine (ISCCM) and Indian Association of Palliative Care (IAPC) Expert Consensus and Position Statements for End of Life and Palliative Care in the ICU. Indian J of Crit Care Med [In Press])

PATHWAY FOR WITHDRAWAL OF LIFE SUPPORT IN TERMINALLY ILL PATIENTS



FOOTNOTES

i Prognostication is best achieved through objective and subjective assessments

ii Initial meeting held at outset before adverse prognosis becomes apparent to build a relationship of trust. One may use the words “comfort care” in place of palliative care

iii Goals of care in patient’s best interests are set through combining medical recommendations (Beneficence and nonmaleficence) with patient’s choices (Autonomy) expressed either directly or if incapacitated, through valid AMD or in case of patient’s delegation/incapacity without AMD, through family/ surrogate. Communication should be candid, realistic, respectful and sensitive. The benefits and burdens of each treatment or care option should be explored.

iv Family elder/counsellor/independent medical panel/ethics board/religious guide/social worker

v Caregiver team should be debriefed after each family meeting

vi Only notification. Approval is not required

vii WD: Withdrawal; WH: Withholding. Includes Do-not-Attempt-Resuscitation (DNAR), Do-Not-Intubate (DNI), Non-escalation/de-escalation decisions

viii Prioritising patient comfort over avoidance of side effects of pharmacological therapies, stopping superfluous tests, monitoring and therapies, liberalising visitation policy, displaying cultural sensitivity, allowing non-intrusive religious rituals, expressing non-abandonment, having therapeutic

conversations, facilitating transfer to location of choice, providing professional caregivers administrative support for complex decision-making

APPENDICES

Appendix 1

Draft Orders for State Ministries of Health to notify District Chief Medical Officers regarding the appointment of Registered Medical Practitioners (RMPs) for secondary medical boards.

Government of Odisha, Health and Family Welfare Department, Office Order No-HFW-LEGAL-LEGAL-0003-2023 22376/H. dated 07.09.2023.

https://docs.google.com/document/u/0/d/1E2CYrk_txZZifMnSZXzUJNU5WTF4nj_ztRH2gUfEbNw/mobilebasic?pli=1

Appendix 2

Format for intimating District Jurisdictional Judicial Magistrate of the first class

Model Intimation Form to be sent to the District Jurisdictional Judicial Magistrate of the First Class

[Following are the details that must be mentioned in the Form]

Name of the patient:

Procedures confirming diagnosis/prognosis that are able to confirm that further medical treatment is not likely to be beneficial:

Statements stating that the patient has a terminal illness with no reasonable chance of recovery and the burden and/or harm of the medical interventions outweigh the benefit

Medical treatment proposed to be withheld or withdrawn:

Date:

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(Signature of the treating physician)

Attached copies of:

1. Dated and signed decision of Primary Medical Board
2. Dated and signed decision of Secondary Medical Board
3. Dated and signed consent of the person named in the advance medical directive of the patient, if any
4. Dated and signed consent of the next of kin/next friend/guardian, if no valid advance medical directive exists.

REFERENCES

1. Piers RD, Azoulay E, Ricou B, Ganz FD, Decruyenaere J, Max A et al. Perceptions of appropriateness of care among European and Israeli intensive care unit nurses and physicians. *Jama*. 2011;306(24):2694-703. doi: 10.1001/jama.2011.1888
2. Sprung CL, Ricou B, Hartog CS, Maia P, Mentzelopoulos SD, Weiss M et al. Changes in end-of-life practices in European intensive care units from 1999 to 2016. *Jama*. 2019; 322(17):1692-1704. doi: 10.1001/jama.2019.14608
3. *Common Cause v Union of India* (2018) 5 SCC 1
4. Salins N, Gursahani R, Mathur R, Iyer S, Macaden S, Simha N et al. Definition of terms used in limitation of treatment and providing palliative care at the end of life: The Indian council of medical research commission report. *Indian journal of critical care medicine: peer-reviewed, official publication of Indian Society of Critical Care Medicine*. 2018; 22(4):249-262. doi: 10.4103/ijccm.IJCCM_165_18.
5. Indian Society of Critical Care Medicine (ISCCM) and Indian Association of Palliative Care (IAPC) Expert Consensus and Position Statements for End of Life and Palliative Care in the ICU. *Indian J of Crit Care Med* [In Press]
6. Order dated 24 January 2023, in Miscellaneous Application No. 1699 of 2019, Writ Petition (Civil) No. 215 of 2005 (Modified Order).
7. Ministry of Health and Family Welfare, Govt of India. The Transplantation of Human Organs and Tissues Rules, 2014. New Delhi: MoHFW:2014 Mar 27 [cited 2018 Aug 1]. Available from: <http://www.mohanfoundation.org/THO-Rules-2014.pdf>
8. Mathur R. ICMR Consensus Guidelines on 'Do Not Attempt Resuscitation'. *Indian Journal of Medical Research*. 2020; 151(4):303-310. doi: 10.4103/ijmr.IJMR_395_20
9. Vidhi Centre for Legal Policy and End of Life Care in India Task Force, *End of Life Care in India: A Model Legal Framework* (2019) https://vidhilegalpolicy.in/wp-content/uploads/2019/11/191031_End-of-Life-Care-in-India-A-Model-Legal-Framework.pdf