ELICIT
End of Life Care India Task Force

FICCI

Improving End-of-Life Care & Decision-Making

Information guide to facilitate execution of End-of-Life Decisions
- For Doctors and Hospital Administrators

Foreword

"Indians die badly"- This was brought home by the Quality of Death reports of The Economist in 2010 and 2015. This does not seem to depend on money alone as can be attested by many of us who have had an elderly relative pass away in a hospital ICU. Healthcare in India has improved with the best technology being available at Indian hospitals at lower costs from developed countries. But the revolution in End-of-Life Care has passed us by.

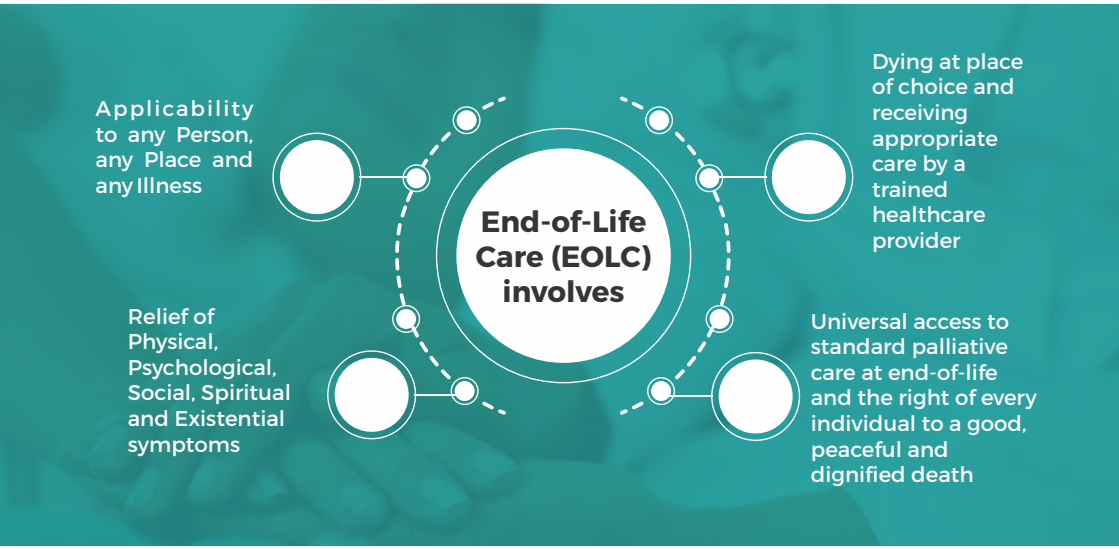
Low public health spending on primary care and the lack of insurance cover have seen the cost of dying rise significantly in the past two decades. But the unknown known or a bigger missing element is the lack of capacity in our system for providing palliative and compassionate end-of-life care. It is also because as a society we have not addressed adequately the complex issue of when to 'let go' when the time comes, avoiding burdensome non-beneficial treatments. Put together, these lead to catastrophic health expenses. Healthcare providers are often blamed, correctly or incorrectly, when medical futility results in death and debts; this further feeds into the wider narrative and public anger about the inequities in our healthcare system.

The recent Supreme Court judgments on privacy and autonomy have brought us to the cusp of evolution in how a constitutional democracy handles personal choice. Death and dying are both intensely personal and social experiences. Last year's Supreme Court judgment validating Living Wills lets Indian citizens take charge of their last days. As an advocate for policy reforms, Federation of Indian Chamber of Commerce and Industry (FICCI) sees it as part of its mandate to assist in systemic and regulatory reforms in this area by bringing the matter to attention of the policy makers, healthcare industry and the public at large. In 2015, the Indian Association of Palliative Care, the Indian Society of Critical Care Medicine and the Indian Academy of Neurology came together to form the End of Life Care in India Taskforce (ELICIT), which has provided technical assistance for drafting the Information Guides to facilitate execution of End-of-Life Decisions.

Disclaimer: This document has been developed and compiled by experts from the health sector for assistance of Doctors and Hospital Administrators with simple practical steps for end-of-life decision making within the framework of Indian Law and Constitution. Information provided in this document is not intended to supplant or supersede any applicable Law/s. In the event of any conflict between the information provided in this document and those prescribed under any applicable Law/s, the latter shall prevail.

End-of-Life Care and Decision-Making

Ensuring a Death with Dignity



- End-of-Life Care (EOLC) is a person centred, personalized perception of "Good Death" which encompasses all aspects of comprehensive care of an individual at his/her end-of-life[1]
- EOLC is an integral part of medical care and is an important quality requirement for accreditation of hospitals by the NABH in its 4th Edition of published list[2]
- It is recognized worldwide that in the last phase of illness, goals of treatment change from focusing on cure to giving care, avoiding any disproportionate treatments. Thus, a terminally ill patient is spared the iatrogenic burdens and suffering associated with technological interventions aimed at sustaining life
- Disproportionate treatment is especially rife in ICUs where it is estimated to constitute at least one-fourth of all interventions[3]
- Standard treatment and evidence-based guidelines recommend weighing benefit vs harm associated with the medical treatment. Appropriate withdrawal and withholding is a part of everyday decision making for critically ill patients[4]

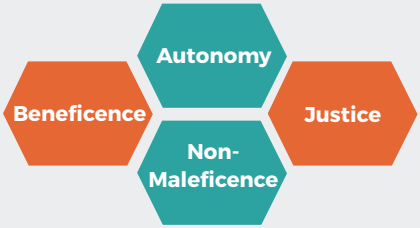
Legal Provisions in India

Patient's Rights

- The right to refuse treatment is Common Law and is further strengthened by the Law Commission recommendations and two of the recent Supreme Court judgments:
- In Justice Puttaswamy vs The Union of India, the right to privacy was declared an independent fundamental right which further protects patient Autonomy[5]
- In Common Cause vs The Union of India, the Supreme Court clarified the legal validity of Living Will or Advance Medical Directive (AMD) and appropriate withdrawal or withholding of life support also called Foregoing of Life Support (FLS)[6]
- The Indian patient/citizen has the right to execute an AMD that will be operational when he/she loses decision-making capacity. Appropriate withdrawal or withholding of life support will not attract criminal liability
- By International consensus[4], patients do not have the right to demand treatments that are not considered appropriate by their healthcare provider, as these are essentially medical decisions

Physician Obligations

- According to bioethical norms in today's practice[7], the physician must integrate the four cardinal principles of:



- Respect for autonomy is central to all medical practice today. Interventions despite the refusal of the patient or his/her surrogates could be deemed as battery by the law
- Like consent, refusal should also be duly documented
- Physicians should be guided by standard treatment guidelines on EOLC while weighing the benefit and harm of providing life-sustaining treatment

Legal Provisions in India

On Issues Related to FLS

- In the Aruna Shanbaug case[8], 'passive euthanasia' or FLS was legally permitted within certain safeguards, for the first time in India
- For a competent patient, refusal of treatment must be honored. However, if a patient is incompetent, the Supreme Court laid down a procedure involving the High Court. Since the real-world requirements are for decisions within hours or a few days, this provision has remained unutilized since the judgment in 2011
- In the Common Cause vs The Union of India[6], AMD and FLS decisions were held valid

However, the procedure for implementation remains problematic. It is required that a duly executed AMD be countersigned by the Judicial Magistrate of the First Class (JMFC) and physical and digital copies of it be preserved by the relevant District Court. Further requirements in implementing FLS need:

- A preliminary opinion by a hospital Medical Board
- Confirmation of this opinion by an external Medical Board to be constituted by the jurisdictional Collector
- Implementation of the AMD and FLS decision after the JMFC actually visits the patient

Recommendations of National & International Professional Societies

- ISCCM-IAPC (Indian Society of Critical Care Medicine and Indian Association of Palliative Care) guidelines published in 2014 recommend a deliberate procedure to arrive at a treatment limitation decision[9]
- As elsewhere in the world[4], the physician and caregiver team first identify the terminal nature of the illness
- Respecting patient autonomy, the patient/family/surrogates* are informed openly and sensitively about the prognosis through one or more counselling sessions. This could be an iterative process until the situation is reasonably clear
- The patient/surrogates are also apprised of the treatment options and transitioning wholly to palliative care
- When consensus decision is for the palliative care option, the modalities of treatment limitation (allow natural death, withdrawal or withholding) are discussed and the final decision is documented
- When the patient no longer has the capacity to make a decision, FLS decisions are taken by at least three physicians with one or more of family members/ surrogates through the process of "shared decision-making"#
- Established guidelines inform the actual implementation, ensuring comfort and freedom from distressful symptoms for the patient
- Referral to a Hospital EOLC Committee is required only for dispute redressal and oversight

*Surrogate: Person(s) 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

Shared Decision Making is defined as 'A dynamic process with responsibility for decisions about the medical care of a patient being shared between the health care team and the patient or the patient's surrogates'

Action Plan: End-of-Life Care and Decision-Making

- For Doctors and Administrators

Respect a competent patient's decision

When the patient who is competent refuses treatment this should be honored. Respecting the patient's decision is required by the law. This decision should be respected even if the patient's family members express a different opinion regarding FLS.

Opt for shared decision making, if overriding an AMD is in the patient's best interest

If the patient is incompetent but has a valid AMD, this must be honored as far as possible. If there are valid grounds to override the same in the best interests of the patient, a consensus through shared-decision making should be arrived at, between caregivers and surrogates which should be duly documented.

Base the decision on wishes of the patient as well as the prognosis, when no AMD is available

If there is no AMD available, decisions between care givers and surrogates must be based on the 'values and wishes' of the patient as known to the family as well as the prognosis and best interests of the patient as judged by the treating doctors.

Only under exceptional circumstances, such as when a person is in a persistent vegetative state, can the Court-recommended procedure be implemented. For example, in a case of terminal cancer with imminent death, decision not to put the patient on a ventilator needs to be taken within hours or few days. In the common scenario, the FLS decisions must be based on refusal of consent for either initiation or continuation of life sustaining treatment in such cases. All decisions must also be duly documented to ensure transparency.

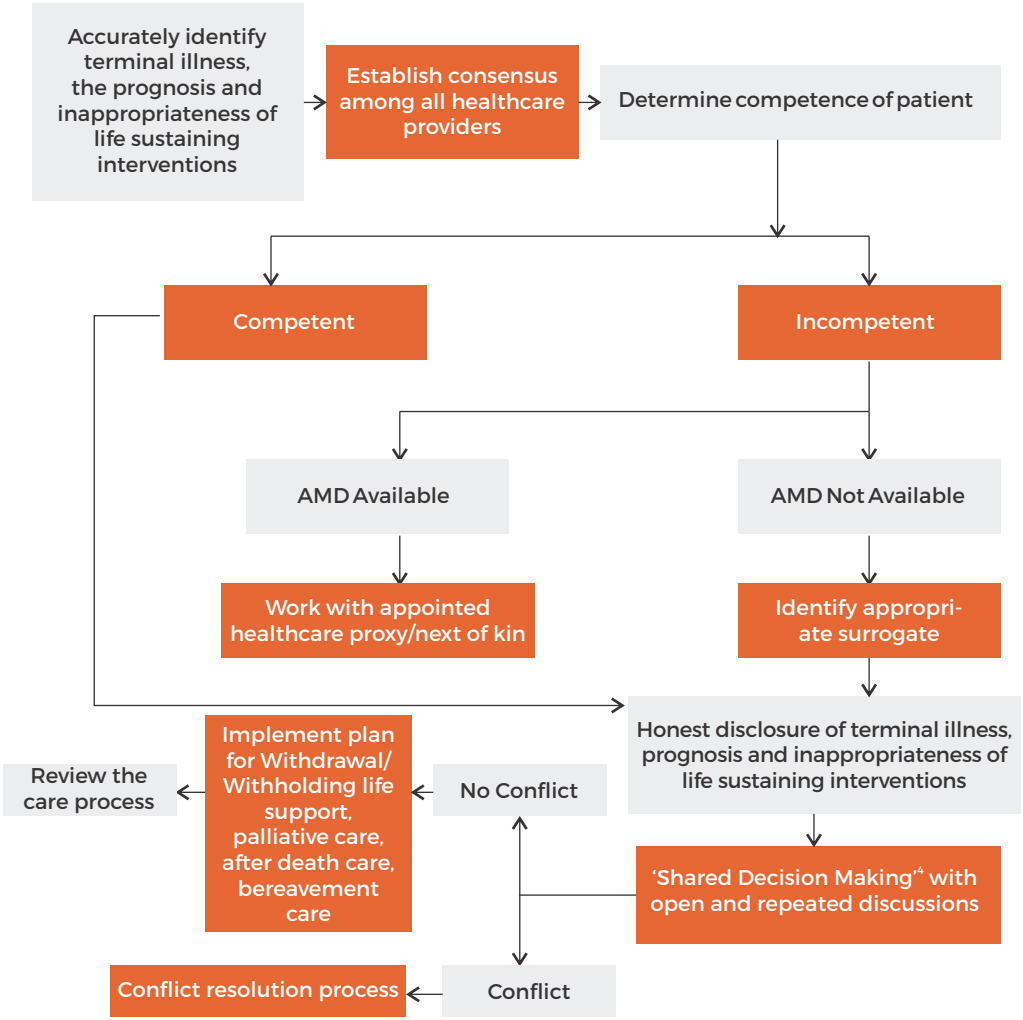
Certify and document Brain Death in accordance to the Transplantation of Human Organs and Tissues Act, 1994

Brain death should be certified and documented in the manner laid down in the Transplantation of Human Organs and Tissues Act, 1994* irrespective of whether there is consent for organ donation or not. This is in conformity with internationally accepted definitions of death. This position in Law was further reiterated in the Aruna Shanbaug Judgement#. When brain death has been so certified, the patient can be disconnected from life support unilaterally after informing and counselling the family.

*Transplantation of Human Organs and Tissues Act, 1994, a "deceased person" means a person in whom permanent disappearance of all evidence of life occurs, by reason of brain-stem death or in a cardio-pulmonary sense, at any time after live birth has taken place.

#Aruna Ramchandra Shanbaug v Union of India and Others P 82, para 106: ....“It follows that one is dead when brain dead...”

Flowchart for End-of-Life Decision-Making



Resolution of Conflict

Authoritative policy statements[10] recommend that requests for potentially inappropriate treatment (including both Withholding/Withdrawal of Life Support and continuation of treatment) from families that remain inflexible despite intensive communication and negotiation should be approached by a seven-step process:

Additional requirements from Hospitals

Administrators' Duties

- Provide training of healthcare professionals and members of the hospital EOLC committee
- Put in place an appropriate process for end-of-life decision-making
- Create the necessary infrastructure for providing EOLC and palliative care
- Ensure maintenance of records
- Devise a mechanism to facilitate conflict resolution

Hospital EOLC Committee

A typical Hospital EOLC Committee to facilitate/oversee FLS decisions may be constituted with the following members:

- The Director or his nominee of the ICU at a Medical Facility who is not part of the team treating the patient
- The Chief Administrator or his nominee of a Medical Facility who is not part of the team treating the patient
- An invited independent senior physician who has relevant experience, but is not a staff or otherwise employed by the Medical Facility
- A legal expert appointed by the Medical Facility
- A lay person preferably involved in social service

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Resource Material:

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List of Abbreviations

AMD	Advance Medical Directive
ELICIT	End of Life Care in India Taskforce
EOLC	End-of-Life Care
FICCI	Federation of Indian Chamber of Commerce and Industry
FLS	Foregoing of Life Support
IAPC	Indian Association of Palliative Care
ICU	Intensive Care Unit
ISCCM	Indian Society of Critical Care Medicine
JMFC	Judicial Magistrate of the First Class
NABH	National Accreditation Board for Hospitals & Healthcare Providers

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About FICCI

Established in 1927, Federation of Indian Chambers of Commerce and Industry (FICCI) is the largest and oldest apex business organisation in India. Its history is closely interwoven with India's struggle for independence, its industrialization, and its emergence as one of the most rapidly growing global economies.

A non-government, not-for-profit organisation, FICCI is the voice of India's business and industry. From influencing policy to encouraging debate, engaging with policy makers and civil society, FICCI articulates the views and concerns of industry. It serves its members from the Indian private and public corporate sectors and multinational companies, drawing its strength from diverse regional chambers of commerce and industry across states, reaching out to over 2,50,000 companies.

FICCI provides a platform for networking and consensus building within and across sectors and is the first port of call for Indian industry, policy makers and the international business community.

About ELICIT

End of Life Care in India Taskforce (ELICIT) Care in India Taskforce was formed as a joint initiative of the Indian Academy of Neurology, Indian Society of Critical Care Medicine (ISCCM) and Indian Association of Palliative Care (IAPC) at a meeting held in Mumbai on 15-16 August 2015. Members of this task force have been involved in the following initiatives and activities:

- Draft End of Life Care legislation covering Advance care planning, Foregoing Life sustaining treatment (Medical futility) and a Uniform definition of death to cover brain death. This draft was submitted to the Ministry of Health and Family Welfare in June 2016.
- Intervenor (Dr Raj Mani) in the Common Cause judgment of 9 March 2018, which made living wills possible for all Indians.
- Collaboration with the ICMR to prepare a booklet on Definition of terms and to formulate actionable recommendations for Foregoing Life support
- Collaboration with Manipal Hospital to prepare the Blue Maple document on EOLC SOPs for the group's hospitals
- Lectures, symposia and courses on End of Life and Palliative care in diverse parts of the country.
- Setting up a website www.onelittlewish.org for a public conversation