

Guidelines for Withdrawal of Treatment of Irreversibly Critically Ill Patients on Assisted Respiratory Supports

I. Introduction

1. The medical profession in India, as elsewhere in the world, is committed to providing the best healthcare treatment and adopt ethical practices in the treatment of patients. Benefiting the sick and doing them no harm is the Hippocratic refrain and the oath resounds with advice to the physician to "follow the method of treatment which, according to my ability and judgments, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous". Beneficence and non-maleficence are the first articulated ethical precepts that set the physician-patient framework.
2. Increasing levels of literacy and assertion of patient autonomy have given new dimensions to informed consent for types of treatment to be addressed to a patient. Need for transparency in clinical approach is the new mantra that shall visit every day practice among the medical personnel. Managing the irreversibly critically ill patients, the nature of treatment to be administered, the time and manner for withdrawal of life support are crucial areas that require informed public debate to evolve a consensus for homogeneity of approach among the medical personnel and to avoid *ad-hocism*.
3. In a joint consultation of the medical personnel working at the Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh with the legal fraternity, mostly practicing at the High Court of Punjab and Haryana, the global best practices, studies and recommendations of medical associations and court judgments have been studied. The following proposals are being suggested to the medical fraternity in India that shall serve as an exordium for debate and formulation of guidelines for withdrawal of treatment in irreversibly critically ill patients on Assisted Respiratory Supports.

II. Why needed?

Patients with irreversible, end-stage diseases (where there are little chances of recovery) who are intubated and remain on assisted ventilation may linger on for days and sometimes for weeks or months.

- i. Factually, the process results in prolongation of "vegetative life" – a source of misery for everyone, especially for the patient and his/her family.
- ii. There is a lowering of 'dignity of death' due to futile invasive procedures and disintegration of body.
- iii. There is absolutely no chance of any improvement or survival.
- iv. It is extremely taxing on the family – physically, financially and psychologically.
- v. Family members generally know of the outcome but are in a state of conflict, unable to express and decide. A considered medical opinion will help them to resolve their conflicts, provide comfort and peace to make an informed decision.

III. Specific situations when the need for withdrawing assisted respiratory support may arise:-

1. Brain-stem death. It means the stage at which all functions of the brain-stem have permanently and irreversibly ceased and is so certified in such form and in such manner and on satisfaction of such conditions and requirements may be prescribed, by a Board of medical experts consisting of the following, namely:-
 - i. the registered medical practitioner in charge of the hospital in which brain-stem death has occurred;

- ii. an independent registered medical practitioner, being a specialist to be nominated by the registered medical practitioners specified in clause (i), from the panel of names approved by the Appropriate Authority;
- iii. a neurologist or a neurosurgeon to be nominated by the registered medical practitioners specified in clause (i), from the panel of names approved by the Appropriate Authority; and
- iv. the registered medical practitioner treating the person whose brain-stem death has occurred.

Where brain-stem death of any person, less than eighteen years of age, occurs and is certified in the manner referred to above, any of the parents of the deceased person may give authority, in such form and in such manner as may be prescribed, for the withdrawal of life support.

2. Deep coma in the presence of **all of the following**:-

- i. Chronic, previously-diagnosed and documented advanced, end stage disease.
- ii. No recognizable and treatable or reversible cause of an exacerbation.
- iii. No concurrent administration of a hypnotic/sedative/opioid overdose.
- iv. No hypothermia (body temperature more than 35 degree Celsius).
- v. All above (i to iv) are documented to be true by at least two specialist doctors.

IV. Ethical Principles related to withdrawal of life supports

1. The Indian Medical Council (Professional Conduct, and Ethics) Regulations with regard to professional conduct, etiquette and ethics term the practice of euthanasia as misconduct. The exception is withdrawal of supporting devices to sustain cardio-pulmonary function after brain death. Assisted suicide and abetment to suicide are legally proscribed and hence shall not be indulged by a medical practitioner.
2. There is an important distinction between intentional killing and allowing a person to die under circumstances mentioned as 'brain death' and 'coma' above.
3. Physicians have an obligation to make patients comfortable during dying. Withholding therapy to provide comfort is not intended to or equivalent to killing. The intentions are critically important in determining the moralities, decisions, liabilities and legalities.
4. These principles are not in any way contradictory to the existing social, religious and legal values or system in India.

V. Recommendations

1. After proper evaluation of the patient, the condition should be adequately explained and discussed with at least two of the 'next of the kin' of the patient who are known to be looking after the patient and are primarily responsible for his/her care. The 'next of the kin' should be 'legally competent' individuals from amongst the spouse and the adult children, parents and brothers/sisters as defined in the Organ Transplantation Act of India.
2. The issues of benefit and burden should be clearly and calmly explained.
3. Regarding withdrawal, adequate time (minimum 24 hours) should be given to the family to make a decision.
4. The informed and written consent should be obtained in the hospital case-records. Where there is a court appointed guardian for a patient who is mentally ill, or, where claim to custody/and or guardianship of minor children or mentally ill persons are reported to be pending in courts, the jurisdictional District Court or higher courts shall be invoked for appropriate directions.
5. Ventilator withdrawal: Generally, there are two methods which are followed:
 - i. Immediate extubation.
 - ii. Terminal weaning – Gradual
 - ☞ Prefer slow/gradual withdrawal.
 - ☞ Ensure patient comfort, relieve anxiety, use anxiolytics/sedatives and slowly reduce the ventilatory assistance.
 - ☞ Endotracheal / tracheostomy tube may be removed / left in place depending upon the need or desire of the patient and/or the family.
 - ☞ The need to keep the patient in the hospital (or to discharge) should be separately discussed with the family and decided accordingly.
6. All other routine treatments may be continued as usual.

VI. Court interventions

Permission shall be sought from the jurisdictional District Court/High Court (whichever the latter has original jurisdiction) where treatment is being given to the patient, where the patient is in a persistently vegetative state and chances of revival seem remote under one or more of the following situations

- i. There is no unanimity among the next of the kin for further management of the patient for withdrawal of life support, or
- ii. The near relative produces proof of declaration made by the patient while in a sound state of mind and health that he shall not be resuscitated or administered blood when he goes into irreversible comatose condition, or
- iii. The attending doctor or team of doctors are not indecisive or have differences of opinion of whether or not to continue the treatment, or
- iv. There exist special circumstances that require a higher judicial opinion.

VII. Publication

The text of these guidelines shall be available freely at the hospital where the patient is admitted. The availability of the document shall be displayed in the hospital and the hospital staff shall be sufficiently sensitized to explain or read the document to any patient or relative attending on the patient.