



KASTURBA HOSPITAL

MANIPAL

(Teaching hospital of KMC Manipal, a unit of MAHE)

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BLUE MAPLE

Before Life Ends, **U**nderstand and **E**valuate the Choice of Medical Treatment Offered

Methodised **A**ction **P**lan for **L**imitation of Life-Sustaining Treatment and **E**nd of Life

**(Palliative Medicine & Supportive care
Department)**

Kasturba Hospital, Manipal

		
Prepared by Head of the Department	Reviewed by Quality Management Representative	Approved by Medical Superintendent




Standard Operating Procedures on Limitation of Life-Sustaining Treatment and End of Life Care



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FOREWORD

		
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Annexure 3C, 3D, 3E

The templates were originally co-created by Dr Nandini Vallath and Dr Naveen Salins, which is suitably modified by the legal team for this document.

Annexure 5A, Annexure 5B, Annexure 5E

The original document is the creation of the International Collaborative for the Best Care of the Dying (Dr John Ellllershaw and Dr Susie Wilkinson), which is modified to the Indian setting by Dr Stanley Macaden, Dr Jeremy Johnson, and Dr Naveen Salins. It is currently being tested across India for its effectiveness and utility.

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“Whenever the illness is too strong for the available remedies, the physician surely must not expect that it can be overcome by medicine ... To attempt futile treatment is to display ignorance that is allied to madness” (Hippocratic Corpus)

Preamble

End of life care is a person-centred, a personalised perception of “Good Death” which encompasses all aspects of comprehensive care of an individual at his or her end of life. It involves a. Applicability to any person, place or illness b. Relief of physical, psychological, social, spiritual and existential symptoms c. To die at the preferred place of choice d. To receive appropriate care by a trained health care provider and e. To have access to palliative care at the end of life. Every individual has a right to a good, peaceful and dignified end of life care and death.

Clinical decision making in advanced and critical illness is often technologically and ethically complicated. As multiple stakeholders are involved in clinical decision making, it is easy to lose perspective of the illness, futility, outcomes of interventions and patient’s autonomy. The Blue Maple document mandates the due processes involved in these critical and urgent decisions. It

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describes methodical execution of the process with adequate safeguards in place to balance between the ease of use and prevention of abuse.

Background




According to the Global Atlas of Palliative care, palliative and end of life care need in the South East Asia Region (SEAR) are estimated to be around 175-275 per 100,000 population. SEAR constitutes 24% of the world's palliative and end of life care needs. The 2015 Quality of Death Index ranking palliative care across the world has ranked India 67th among the 80 countries studied? According to this report, poor quality of end of life care delivery in India is secondary to lack of government-led strategy towards national level palliative care, shortage of specialist palliative care providers, limitation of public funds, lack of availability of opioid analgesics and poor public awareness about palliative and end of life care.

The majority of the hospitals in India subject patients with terminal and critical illness to inappropriate life-sustaining interventions without any clinical benefit. The patients experience poor control of symptoms, families receive incomplete health-related communication, and often the health care providers lack training in providing end of life care. The patients are continued on disease-modifying treatments until the last weeks of life and often receive futile life-sustaining interventions. These patients are seldom referred to palliative care. Moreover, goals of care discussion, advanced care planning and anticipatory directives are never addressed.

Providing aggressive life-sustaining treatment is often futile and may cause needless suffering in terminal illness. It may be against the patient's interest and may contribute to needless pain, burden and suffering. Limiting life-sustaining treatment in terminally ill patients at the end of life allows the individual to die with dignity. The document aims to make this process as simple and safe to protect patients' right to receive a dignified end of life care and limit needless harm due to inappropriate interventions at the end of life.

Overview of the Structure and Steps

The structure of this document closely follows the joint society guidelines on "End of Life Care Policy: An integrated care plan for the dying" developed by the Indian Society of Critical Care medicine and Indian Association of Palliative Care. The purpose was to develop end-of-life care (EOLC) policy for patients who are dying with advanced life-limiting illness and provide practical procedural guidelines for limiting inappropriate therapeutic medical interventions. It is an attempt to improve the quality of care of the dying within an ethical framework and

		
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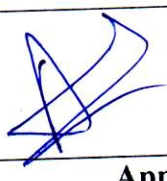
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through a professional and family/patient consensus process. It follows a 12-step approach and this document has five parts that encompasses these 12 steps.

[Myatra SN, Salins N, Iyer S, Macaden SC, Divatia JV, Muckaden M, Kulkarni P, Simha S, Mani RK. End-of-life care policy: An integrated care plan for the dying. Indian J Crit Care Med 2014; 18:615-35]

Parts	Item	Steps of 12-Step Pathway
Part A	Recognition of Medical Futility	Step 1 Physician's objective and subjective assessment of medical futility
Part B	Physician Consensus	Step 2 Consensus among health care providers
Part C	Communication, Decision Making and Documentation	Step 3 Honest, accurate and early disclosure of prognosis to the best available knowledge of the physicians Step 4 Discussion and communication of all modalities of End of Life Care Step 5 Shared decision making and achieving consensus between health care providers and patients with repeated and open discussion Step 6 Transparency and consistency in documentation Step 7 Ensuring consistency among the caregivers by a family meeting
Part D	Implementation of Withholding and Withdrawing	Step 8 Implementing the process of withholding and withdrawal of life-sustaining treatment
Part E	End of Life Care	Step 9 Palliative Care in End of Life Step 10 After death care Step 11 Bereavement support Step 12 Review of the care process

All the terminologies used in this document are as per ICMR Commission Report on Definitions of terms used in Limitation of Treatment and providing Palliative Care at the end of Life.

		
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[Salins N, Gursahani R, Mathur R, Iyer S, Macaden S, Simha N, Mani RK, Rajagopal M R. 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 J Crit Care Med 2018; 22:249-62]

Method of Developing the Standard Operating Procedures

The hospital end of life care task force consisted of critical care physicians, general physicians, neurologists, neurosurgeons, paediatricians, palliative care specialists, forensic experts, lawyers and hospital administrators. The task force collectively completed the document. The document was initially internally peer reviewed by the task force members and by the designated experts nominated by the hospital. The document had two tiers of external peer review, the first tier comprised of clinicians from various disciplines of medicine practising across India and second tier comprising of legal experts involved in end of the life care process and the hospital administrators across India. After the peer review, the document was finalised by the hospital quality team and was made available for dissemination.

Algorithm

Patient with Critical/Terminal Illness

Recognition of Medical Futility

Recognising Medical Futility in Critical illness/ICU – Annex 1A
 Recognising Medical Futility in Neurological illness – Annex 1B
 Recognising Medical Futility in Medical illness– Annex 1D
 Recognising Medical Futility in Paediatric Population – Annex 1E
 Recognising Medical Futility in Cancer Setting – Annex 1F

Ascertaining Medical Futility

Physician Consensus on Medical Futility

Procedure for obtaining Physician Consensus – Annex 2A
 Documentation of Medical Futility in Medical Records – Annex 2B
 Endorsement of the Medical Futility– Annex 2C

Ascertaining Physician Consensus on Medical Futility

Standardised Forms for Limiting Life-Sustaining Treatment

Family/Self consent for withholding/Withdrawing life-sustaining treatment Annex 3D-3F
 Capacity to make medical decisions and surrogate decisions Annex 3G

Communicating Prognosis

Checklist for communication of Prognosis – Annex 3A
 Template for conducting a family meeting – Annex 3B
 Guidance on documentation in Medical Records–Annex 3C

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**Communication of prognosis and limitation of treatment
Achieving consensus between health care providers and families
Documentation of the process**

Procedure for Implementation of Withholding and Withdrawal
 Procedures for implementing withholding and withdrawal of life-sustaining treatment – Annexures 4A
 Documentation of withholding/withdrawal in medical records – Annexure 4B
 Ratification of the decision of withholding/withdrawing life-sustaining treatment- Annexure 4C

Implementation of Limitation of Life Sustaining Treatment

End of Life Care
 Protocol for initial assessment of end of life care - Annex 5A
 Protocol for ongoing assessment of end of life care – Annex 5B
 Death declaration protocol – Annex 5C
 Brain stem declaration protocol – Annex 5D
 After death care protocol – Annex 5E

Providing Palliative Care at End of Life

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ANNEXURES

Part A: Recognition of Medical Futility

General Criteria in adult patients that predisposes to medical futility

- Advanced age
- Limited functional capacity
- Poor performance status
- Multiple co-morbid illnesses
- One or more end-stage organ impairment (pulmonary, cardiac, renal, hepatic etc.)

In patients admitted to an Intensive Care Unit having (Annexure 1A)

- Progressively worsening multi-organ dysfunction not responding to a reasonable duration of aggressive medical interventions
- Coma due to causes with non-reversible effects like major infarcts, intracranial bleed or traumatic brain injury
- Metastatic malignancies where there are no treatment options or where the treatment options cannot meet the goals of care
- Post-cardiac arrest status with poor neurological outcomes
- Chronic neurological conditions where there is a progressive deterioration in the cognition and functional ability leading to a poor quality of life like progressive dementia, chronic vegetative state, quadriplegia
- Any condition where the physician predicts a low probability of meaningful survival
- Extreme drug-resistant infections

With (one or more aspects provided below)

- Progressively dropping blood pressure despite all correctable measures
- Progressively worsening neurological status
- Progressively increasing need for ventilator support
- Worsening multi-organ dysfunction
- Progressively worsening metabolic parameters

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In patients with Neurological Conditions (Annexure 1B)

- Advanced cases of Alzheimer's disease with total dependence (Dementia Rating Scale 50 or above)
- Stroke survivors with GCS <4 after three days of absent corneal reflex
- Multiple Sclerosis EDSS scale 9.5 (Confined to bed and totally dependent. Unable to communicate effectively or eat/swallow)
- ALS rating scale (<6)
- Parkinson's Disease UPDRS Scale <150
- CNS Infections like meningitis and encephalitis with progressive worsening, multiorgan dysfunction that does not respond to a period of aggressive therapy
- Post-cardiac arrest status with poor neurological outcomes
- Any condition where the physician predicts a low probability of meaningful survival
- Supra refractory status epilepticus after three days of aggressive management.

In patients with Neuro-Surgical Conditions (Annexure 1B)

- Severe traumatic brain injury (GCS < 6) with dilated fixed pupils > 48 hours
- High cervical spinal cord injury with quadriplegia and absence of any spontaneous respiratory effort > 7 days
- Patients with ICH score > 5 for more than 48 hours
- Patients with Malignant ischemic infarct (pre and post-operative) with GCS < 6 and fixed dilated pupils
- Recurrent high-grade brain tumours with GCS < 6 and poor KPS < 70
- Metastatic brain disease with GCS < 6 and poor KPS < 70
- Patients with diffuse hypoxic injury secondary to any aetiology
- Congenital paediatric developmental abnormalities incompatible with prolonged survival

In patients admitted to the medical wards (Annexure 1D)

- Terminally ill patient with progressive multi organ failure needing life support systems and medicines (sepsis and MODS) not showing signs of response to therapy

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- Advanced progressive organ failure needing life support system and medicine (renal, liver, cardiac, neurological or respiratory failure) and not showing signs of response to therapy and organ transplantation or replacement therapy is not feasible
- Advanced malignancy on palliation with additional complications like severe infection, bleeding or organ failure

With (one or more aspects provided below)

- Progressively dropping blood pressure despite all correctable measures
- Progressively worsening neurological status
- Progressively increasing need for ventilator support
- Worsening multi-organ dysfunction
- Progressively worsening metabolic parameters

In patients with cancer (Annexure 1E)

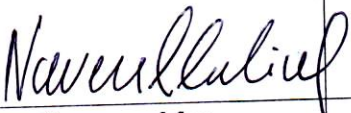

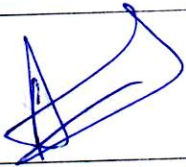
- Metastatic cancer or advanced cancer with no scope of further disease modifying treatment
- Expected survival weeks to days
- Poor performance status and needing significant assistance with activities of daily living
- Multiple unplanned admissions and ER visits in the last 12 months

With (one or more aspects provided below)

- Progressively dropping blood pressure despite all correctable measures
- Progressively worsening neurological status
- Progressively increasing need for ventilator support
- Worsening multi-organ dysfunction
- Progressively worsening metabolic parameters

In children admitted to the ward or paediatric intensive care (Annexure 1F)

- 1) Medically futile conditions in Paediatrics / Neonatal period
 - a) The child in a permanent vegetative state: Permanent vegetative state can occur as a result of a variety of insults, such as hypoxia or trauma. The child is totally dependent on others for all aspects of care and does not react to, or interact with, the outside world. (absence of cortical peaks in the somatosensory evoked potential (SSEP) / post cardiac arrest with no poor neurological outcome

		
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<p>b) The “no chance” situation: The “no chance” category covers the child for whom life-sustaining treatment will merely delay death, without significantly relieving the suffering caused by the disease e.g. spinal muscular atrophy and myopathies / end stage solid organ tumours / Leukaemia’s with worst prognosis with relapses</p> <p>c) The “no purpose” situation: “No purpose” refers to when a child's life may be saved by medical treatment, but the degree of mental or physical impairment may be so great that the quality of life for the child is intolerable e.g. Meningomyelocele / cauda equina syndrome/ caudal regression syndrome / anencephaly / massive hydrocephalus / severe neuronal migration defects/ hypo-plastic left heart syndrome / pulmonary atresia and complex congenital heart diseases / interrupted aortic arch / prune belly syndrome</p> <p>d) The “unbearable situation”: In the face of progressive disease, additional treatment may only cause further suffering, despite the possibility that it might have some potential benefit on the underlying condition without curing it. e.g. Muscular dystrophy / myopathies / severe inborn errors of metabolism / focal segmental glomerulosclerosis with progressive renal failure / end-stage pulmonary (Chronic interstitial lung diseases), renal (ESRD), cardiac (cardiomyopathies), hepatic diseases (biliary cirrhosis), progressively worsening multiorgan dysfunction when a transplant is unavailable or refused</p> <p>2) Medically futile conditions at birth</p> <p>a) a baby with congenital anomaly or anomalies that are incompatible or may be compatible with life, but the expected quality of life may be poor or a big drain on resources of family/ society.</p> <p>b) Very low birth weight and gestational age are such that survival (as per the data of intact survival of the NICU), especially intact survival, may be almost impossible and feasibility of transfer to a tertiary care neonatal unit is not possible.</p> <p>c) Severe birth asphyxia with Grade IV IVH,</p> <p>With (one or more aspects provided below)</p> <ul style="list-style-type: none"> • Progressively dropping blood pressure despite all correctable measures • Progressively worsening neurological status • Progressively increasing need for ventilator support • Worsening multi-organ dysfunction • Progressively worsening metabolic parameters
--

Although there may be a consensus about medical futility, end of life care should not be triggered in the following situations.

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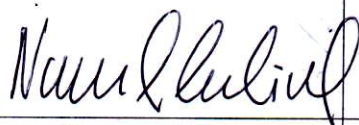

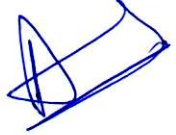
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- a) When the outcome is doubtful (may or may not improve the situation)
- b) When there is a conflicting opinion among the family members
- c) When the responsible next of kin is not available for discussion
- d) When the patient does not consent (if the patient is capable of exercising his/her judgement and making his/her wishes known about limiting life-sustaining treatment, but not capable of signing a consent document, then an audio-visual recording of his/her consent may be used as a substitute to informed consent)
- e) When the treating doctors do not agree to DNR decisions, it should never be accepted based on the suggestions of parents or relatives

The inability of the patient to pay for advanced care should never be a factor in determining whether or not his/her condition is medically futile

		
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Part B: Physician consensus on Medical Futility

Procedure for obtaining Physician Consensus (*Annexure 2A*)

1. Agreed upon by the primary treating physician(s) involved in the care and the futility is documented in the medical care records and signed
2. The futility is endorsed by two consultants preferably of the same or related speciality not directly involved in the care of the patient.
3. In the case of children, futility is assessed by two paediatricians not involved in the care of the patient and the adult physicians cannot endorse futility in children.
4. In cancer setting the futility of care has to be endorsed by two oncologists not involved in the care of the patient or preferably by the hospital tumour board
5. If there is no consensus on futility, the situation can be reviewed again after a time- limited trial.
6. Once there is consensus on medical futility, there should be detailed documentation justifying the futility decision.
7. Once there is consensus on futility (primary physician + 2 consultants not directly involved in the care), the decision to withhold/withdraw life-sustaining treatment has to be ratified by the hospital End of Life Care (EOLC) Review Committee. In the absence of an EOLC Review Committee, the decision can be ratified by the Hospital Clinical Ethics Committee.
8. After consensus on medical futility, a mandatory referral has to be made to palliative care services for assessment of palliative care needs if such service is available.
9. Communication of the medical futility to the families/caregivers has to be made by the primary treating physician during a family meeting.

Documentation of the Medical Futility in the Medical Records (*Annexure 2B*)

The futility documentation should comprise of the following

1. Procedures confirming diagnosis/prognosis that satisfy the requirements of medical futility

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2. Statements stating that the patient has a terminal or critical illness with no reasonable chance of recovery and the burden or/and harm of the medical interventions outweigh the benefit.
3. Summary of treatment provided till date and outcomes
4. Life-sustaining treatments currently provided
5. Life-sustaining treatments proposed to be withheld/withdrawn
6. Alternatives to life-sustaining treatment proposed

Endorsement of the Medical Futility by consultants not involved in the care of the patient (Annexure 2C)

We hereby certify thatbearing Hospital
No..... admitted at,
has.....

We feel that initiating or continuing life-sustaining treatment in this patient is medically futile because.....

We recommend withholding/withdrawing of all life-sustaining measures in this patient such as.....

We recommend palliative care referral for symptom control and end of life care for this patient.

Place:
Date:
Name Signature of the treating consultants:
(along with seal of the Department)

- 1.
- 2.

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Part C: Communication of Medical Futility

Communication Checklist while discussing Prognosis and Medical Futility (Annexure 3A)

The communication and discussion of limitation of life-sustaining treatment should comprise of



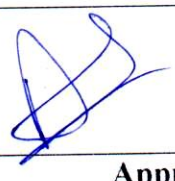
1. Refractory nature of the illness
2. Burden versus benefit of continuation of aggressive medical management
3. The transition of care i.e. from a disease centred approach to a quality of life centred approach
4. End of life care as an alternative to futile aggressive medical interventions
5. Discussion on aspects related to prognosis, life expectancy, future course of illness, and what to expect in the future
6. Addressing fears about future symptoms and course of illness and providing reassurance
7. Discussing symptom control and quality of life improvement strategies
8. Introducing palliative care services and explaining their scope in the management of the patient
9. Exploring any myths, misunderstandings about the limitation of treatment and clarifying.
10. Exploring conflict and taking steps toward conflict resolution
11. Discussing the process of dying, optimisation of medications, nutrition and hydration at end of life and exploring any religious/cultural preferences
12. The option of transferring to another clinical establishment may be presented if the patient or her family is unable to agree with the treating team about medical futility.

Template for documentation of Family Meeting during the Medical Futility discussion (Annexure 3B)

We the family members of the patient....., bearing hospital number..... hereby acknowledge that we have attended the family meeting on the below-mentioned date and time convened by the department of

In this family meeting, the treating physicians have explained and apprised to us the above-mentioned patient's current clinical condition, nature of the diagnosis, prognosis and outcomes of the treatment.

In the family meeting, we have asked questions and clarified our queries regarding the patient's clinical condition, nature of the diagnosis, prognosis and outcomes of the treatment.

		
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We understand from this family meeting that that patient has advanced critical/terminal illness where the benefit of initiating or continuing life-sustaining medical interventions has a higher potential to cause harm and suffering without any reasonable clinical benefit.

We acknowledge that the patient is able/unable to participate in his/her clinical decision making. We the family of the patient are collectively and consensually making treatment decisions for/with the patient. We present here represent the patient's wishes and state that there is no conflict in the family regarding treatment decision making for the patient.

Signatures of the family members attending the meeting

Sl.no	Name	Age	Relationship	Signature

Signature of the doctors conducting the meeting

Sl.no	Name	Designation	Signature

Date and Time:

Place:

Family Directive for Withholding Life Sustaining Treatment (Annexure 3C)

I/We understand that our _____ Ms /Mr/Master _____, bearing hospital number _____ is admitted at _____, and has a critical/terminal illness where the disease modifying treatment options are no more relevant and he/she has complications related to the progressive nature of the disease which is potentially life threatening.

I/We understand that as the disease is advanced and the general health is poor, he/she, has/could develop serious life-threatening complications that could threaten the quality of life. We understand that these complications are seldom reversible and the burden of treating these complications using life sustaining measures has a higher potential to cause harm and suffering without any reasonable clinical benefit. Considering these circumstances, our goal of care for our patient would be symptom relief, comfort measures and quality of life.

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I/We understand the futility of critical care interventions for supporting life such as endotracheal intubation, cardiopulmonary resuscitation and aggressive intensive care measures. I/We have considered the decision to withhold new interventions or not to escalate existing interventions for life support as mentioned above with the understanding that the treatment has a higher potential to cause pain and suffering than resolution of organ failure and overall health and the disease process has progressed beyond the possibility of reasonable recovery.

I/We understand that signing this document would not deprive our patient of any necessary medical and nursing care, pain and symptom relief measures, and specific supportive care measures as appropriate with the highest priority to maintain dignity and quality of life.

I/We request for not initiating life sustaining measures for our patient

I/We hereby request you to allow natural death in the event of cardio-pulmonary arrest i.e. (no external chest compressions, no intubation, no chemical or electrical cardio version)

I/We understand that life sustaining treatment is not in the best interest of my patient, and may be inappropriate due to his/her condition and may prolong his suffering without any clinical benefit. After extensive discussion with the treating doctors, I/We have decided and request the treating doctors to withhold the life sustaining treatments on behalf of the patient

“At our request, we were permitted to consult another physician outside the hospital and we have decided not to consult another physician outside this hospital OR Having considered his recommendation, we have decided to permit the treating team to withhold life sustaining treatment”.

“We have also been given the option of shifting the patient to another clinical establishment if we desire to do so.”

I/We have discussed all the details with the doctors in the language we understand and I/we are making an informed decision.

I/ We say that I/We are making this declaration out of free will and there is no coercion, undue influence and fraud.

Relationship	Name	Signature	Date /Time
Doctor / Depart			

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Family Directive for Withdrawing Life Sustaining Treatment (Annexure 3D)

I/We understand that our _____ Ms /Mr/Master _____, bearing hospital number _____ is admitted at _____, has a critical/terminal illness where disease modifying treatment options are no more relevant and has complications related to the progressive nature of the disease which is potentially life threatening.

I/We understand that as the disease is advanced and the general health is poor, he/she, has serious life-threatening complications threatening the quality of life. We understand that these complications are seldom reversible and the burden of treating these complications using life sustaining measures has a higher potential to cause harm and suffering without any reasonable clinical benefit. Considering these circumstances, our goal of care for our patient would be symptom relief, comfort measures and quality of life.

I/We understand that as the disease is advanced, he/she had developed serious complications [difficulty with breathing, asphyxia, cardio-respiratory arrest.], which was addressed urgently through cardio-pulmonary resuscitation and advanced life support measures including intubation and ventilation.

I/We understand the futility of continuing above critical care interventions, as there are no realistic hopes of our patient returning to pre-arrest state and we acknowledge that continuing these life sustaining interventions amounts to prolongation of the process of dying.

I/We care deeply for the dignity and comfort of our beloved/..... I/We have considered the decision to withdraw the existing artificial life support measures with the understanding that the treatment has a higher potential to cause pain and suffering than resolution of the multiple organ system failure as the disease process has progressed and is evaluated to have reached a point of no return.

I/We understand that signing this document would not deprive our patient of any necessary medical and nursing care, pain and symptom relief measures, and specific supportive care measures as appropriate with the highest priority to maintain dignity and quality of life.

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I /We request for not continuation of life sustaining measures for our patient

I/We hereby request you to allow natural death in the event of a cardio-pulmonary arrest i.e. (no external chest compressions, no intubation, no chemical or electrical cardio version)

I /We understand that continuation of the life sustaining treatment is not in the best interest of my patient, and may be inappropriate due to his/her condition and may prolong his suffering without any clinical benefit. After extensive discussion with the treating doctors, I/We have decided and requested the treating doctors to withdraw the life sustaining treatments on behalf of the patient

“At our request, we were permitted to consult another physician outside the hospital and We have decided not to consult another physician outside this hospital OR Having considered his recommendation, we have decided to permit the treating team to withhold life sustaining treatment”.

“We have also been given the option of shifting the patient to another clinical establishment if we desire to do so.”

I/We have discussed all the details with the doctors in the language we understand and I/we are making an informed decision.

I/ We say that I/We are making this declaration out of free will and there is no coercion, undue influence and fraud.

Relationship	Name	Signature	Date /Time
Doctor / Depart			

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Self-Consent for Withholding/Withdrawing Life Sustaining Treatment (Annexure 3E)

I _____ bearing hospital number _____ admitted at the Kasturba Hospital, Manipal, have a critical/terminal illness where disease modifying treatment options are no more applicable and has complications related to the progressive nature of the disease which is potentially life threatening.

I understand that as the disease is advanced and the general health is poor, I could develop/have developed serious life-threatening complications that could threaten my quality of life. I understand that these complications are seldom reversible and the burden of treating these complications using life sustaining measures has a higher potential to cause harm and suffering without any reasonable clinical benefit. Considering these circumstances, my goal of care would be symptom relief, comfort measures and quality of life.

I understand the futility of critical care interventions for life support such as endotracheal intubation, cardiopulmonary resuscitation and aggressive intensive care measures. I have considered the decision to withhold new interventions or not to escalate existing interventions for life support as mentioned above with the understanding that the treatment has a higher potential to cause pain and suffering than resolution of organ failure and overall health and the disease process has progressed beyond the possibility of reasonable recovery.

I understand that signing this document would not deprive me of any necessary medical and nursing care, pain and symptom relief measures, and specific supportive care measures as appropriate with the highest priority to maintain dignity and quality of life.

I request for not initiation/continuation of life sustaining measures

I hereby request you to allow natural death in the event of cardio-pulmonary arrest i.e. (no external chest compressions, no intubation, no chemical or electrical cardio version)

I understand that life sustaining treatment is not in my best interest, and may be inappropriate due to my condition and may prolong my suffering without any clinical benefit. After extensive discussion with the treating doctors. I have decided and requested the treating doctors to withhold/withdraw the life sustaining treatments.

“At my request, I was permitted to consult another physician outside the hospital and I have decided not to consult another physician outside this hospital OR Having considered his recommendation, I have decided to permit the treating team to withhold life sustaining treatment”.

“I have also been given the option of shifting to another clinical establishment if I desire to do so.”

I have discussed all the details with the doctors in the language I understand and I am making an informed decision.

I say that I am making this declaration out of free will and there is no coercion, undue influence and fraud.

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Name of the patient		Signature	Date /Time
Doctor / Depart			

Capacity to make medical decisions and surrogate decision making (Annexure 3G)

During the process of consenting, it is important to determine whether the patient has the capacity to make medical decisions or whether a surrogate should take decisions on his/her behalf.

The capacity of the person to make healthcare related decisions should be assessed by the healthcare provider.

The capacity for healthcare is determined using the four-component model of decision capacity.

a. *Understanding*: The understanding refers to the ability of the individual to comprehend the information being disclosed in regard to his/her condition as well as the nature and potential risks and benefits of the proposed treatment and alternatives (including no treatment).

b. *Appreciation*: The appreciation refers to the ability to apply the relevant information to one's self and own situation.

c. *Reasoning*: The reasoning refers to evidence that the person's decisions reflect the presence of a reasoning process, i.e. ability to engage in consequential and comparative reasoning and to manipulate information rationally.

d. *Expression of a Choice*: At its most basic level, it simply refers to the ability to communicate a decision. However, no adverse inference ought to be drawn from an inability to communicate verbally.

If the patient does not have the capacity to make medical decisions or unable to participate in the medical decision making, the process of decision-making rests on patient surrogates, which is usually patient's family or friends who makes the medical decision in consultation with the treating team in best interests of the patient.

If there are no documented surrogate decision makers, the next of kin hierarchy according to the 1994 Transplantation of Human Organs Act i.e. hierarchically, spouse, son, daughter, father, mother, brother, sister, grandfather, grandmother, grandson or granddaughter will be the surrogate decision makers.

The surrogate(s) acting in the best interest of the patient is expected to

- a. Consider all relevant circumstances and options without discrimination
- b. Consider any beliefs or values likely to influence the individual if they had capacity
- c. Consult with family members as to whether the individual previously had expressed any opinions or wishes about their future care.
- d. Consult with the clinical team caring for the individual

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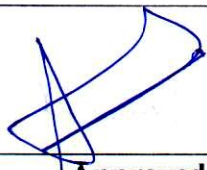
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e. If there is an advance directive that the patient has made, the surrogate should use that as one of the factors in guiding his/her decision as well.

The surrogate(s) should neither make any judgement using clinician's view of quality of life and nor motivated by a desire to hasten or prolong the person's death

		
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Part D: Implementation of Withholding and Withdrawing Life Sustaining Measures

Procedure of implementing withholding and withdrawing life sustaining treatment (Annexure 4A)

1. The first step is to establish the medical futility decision made by the primary treating physician, which is endorsed by two consultants of the same or related speciality not directly involved in the care of the patient,
2. The second step is the ratification of the decision to withhold/withdraw treatment by the End of Life Care (EOLC) Review Committee. In the absence of an EOLC Review Committee, the decision can be ratified by the Hospital Clinical Ethics Committee.
3. The third step is communication of the medical futility decisions and limitation of life sustaining treatment to the family/patient, during the family meeting and obtain consent to withhold/withdraw from the family/patient
4. The family/patient should be informed prior to the initiation of the withholding/withdrawal process.
5. If palliative care services are available, Withholding/Withdrawal of life sustaining treatment should be done under palliative care supervision to ensure maximum symptom relief and comfort during and after the process.

Documentation in the medical records during the process of withholding/withdrawing of the life sustaining treatment (Annexure 4B)

The documentation of the process of withholding/withdrawing should comprise of

1. Reasons underpinning the withholding/withdrawal decision
2. Nature of life sustaining treatment withheld/withdrawn
3. The exact process involved in withholding/withdrawal of treatment
4. Alternative palliative care measures provided during the process of withholding/withdrawal
5. Information provided to families/patient prior, during and after the process of withholding/withdrawal

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Ratification of the decision of withholding/withdrawing life sustaining treatment by the End of Life Care Review Team or Hospital Clinical Ethics Committee (Annexure 4C)

We hereby certify thatbearing Hospital No..... admitted at the Kasturba Hospital, Manipal, has.....

We concur with the decision of the primary treating physician(s) and the two consultants not involved in the care of the patient endorsing futility of life sustaining treatment.

We concur with the family/patient decision on withholding/withdrawing life sustaining treatment.

We agree that the decision to withhold/withdraw life sustaining is done in the best interest of the patient with no coercion, malaise, undue influence or fraud.

We recommend withholding/withdrawing of the life sustaining treatment and recommend palliative care involvement to facilitate end of life care.

Place:

Date:

Name Signature of the EOLC Review Team Consultants:
(along with seal of the Department)

1.

2.

3.

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Part E: End of Life Care

Protocol for initial assessment of End of Life Care Needs (Annexure 5A)

Person's Full Name: M F	Hospital Number:
Setting of care plan: HOSPITAL. Ward:	DOB:
Diagnosis:	

SECTION 1: INITIAL ASSESSMENT: Care Plan for the Dying Person	
This care plan will be reviewed in its entirety by a clinician daily.	
1. Recognition of dying and shared decision making by- - Healthcare professionals - Dying Person - Relative / Carer	
<ul style="list-style-type: none"> Have all <u>potentially reversible</u> causes of the patient's deterioration been excluded? E.g.: Dehydration, hypoglycaemia; opioid toxicity; hypercalcaemia; renal failure, infection, etc 	Y N
<ul style="list-style-type: none"> Is there a decision for organ transplantation? 	Y N
Comments:	

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• Does the team believe the patient is in the last few hours / days of life? Y N

Indicate all that are relevant (This is only to support and not replace your clinical judgement):

- Profound weakness / bedbound / requiring all care
- Drowsy or reduced cognition / semi-conscious / unconscious
- Diminished intake of food / only able to take sips of fluids
- No longer able to take oral medication
- No interest in food / drink / surroundings
- Multi-organ failure

Documenting the decision
(Agreed by clinician and at least one trained nurse who knows the person)

Doctor's Name: _____ Signature: _____

Nurse's name: _____ Signature: _____

Date: _____ Time: _____ am / pm

Is there an advanced care plan or clearly expressed wish by the person to refuse treatment?
Y N

If other specialists involved a professional consensus of having reached a point of futility and that the person is now dying, is obtained & documented *
Y N

Family conference(s) to convey early, accurately, and sensitively the above decision
Y N

Family understand person is dying
Y N

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Family consensus and agreement for comfort care only is documented**

Y N

Family is explained the various options for further care and de-escalation of inappropriate treatment.

Y N

Family' choice of the place for further care is recorded and plans made to facilitate this

Y N




Guidance and Care Plan for the Dying (GCP-D) is explained and initiated

Y N

Doctor and nurse who know the person, documenting the shared decision

Accountable Doctor's Name & Signature:

Trained nurse's Name & Signature

		
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At the recognition of dying is the person:

In Pain	Y N	Able to swallow	Y N	Confused	Y N
Agitated	Y N	Continent (bladder)	Y N	(Record whichever is applicable)	
Nauseated	Y N	Catheterised	Y N	Conscious	Y N
Vomiting	Y N	Continent (Bowels)	Y N	Semi-conscious	Y N
Dyspnoeic	Y N	Constipated	Y N	Unconscious	Y N

Experiencing respiratory tract secretions

N

Y

Experiencing any other symptoms (e.g. oedema, itch, etc.)

Is person on ventilator?

Y N

2. Communication: Recognition of dying / Information exchange

The person is able to take full and active part in communication?

N NA

Y

The person is aware that they are dying

NA

Y

N

The relative / carer is able to take full and active part in communication?

Y

N

They are aware that their relative / friend is dying?

N

Y

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They are aware of what support the Hospital can offer Hospital information & facilities leaflet is given N	Y
Next of Kin and up-to-date Contact information is available N	Y
3. Spirituality	
The person is given the opportunity to discuss what is important to them N NA E.g.: their wishes, feelings, faith, beliefs, values, concerns	Y
The relative / carer is given the opportunity to discuss what is important to them. N Eg: their wishes, feelings, faith, beliefs, values, concerns	Y

Person's name

Sticker

Hospital / Hospice No:

4. Clinical decision making - medication	
The person has medication prescribed on an "as required" / prn basis for all of the following symptoms which may develop in the last few days of life:	
Pain	<input type="checkbox"/>
Nausea / vomiting	<input type="checkbox"/>
Terminal agitation or potential bleed	<input type="checkbox"/>
Dyspnoea	<input type="checkbox"/>
Respiratory tract secretions	<input type="checkbox"/>

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Anticipatory prescribing in this manner will ensure there is no delay in responding to a symptom if it occurs and there is no doctor immediately available.

Medicines for symptom control will only be given when needed, at the right time, just enough and no more than is needed to manage the symptom.

Current Medication assessed and non- essentials discontinued.

Equipment is available for the person to support a continuous subcutaneous infusion (CSCI)/intravenous infusion of medication where required (e.g. syringe driver/pump) or regular intermittent and prn subcutaneous (SC) injections:

Already in place SC/IV Not required Using regular & prn boluses

If a CSCI is to be used, explain the rationale to the person, carer or relative.

Not all persons who are dying will require a CSCI.

A 4 hourly check list should be in place to monitor and support the use of a CSCI.

5. Clinical decision making –

Review all interventions in the best interest of the person at this moment in time

Have the following been assessed and discontinued if inappropriate / causing harm?

	N/A	Continued	Discontinued	Commenced
Routine blood tests				
IV fluids / antibiotics				
Blood glucose monitoring				
Recording vital signs				
Oxygen therapy				

Person's Name:

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Hospital / Hospice No:			Sticker
Cardio-Pulmonary resuscitation			
	YES	NO	Not Appropriate
Have the issues been considered?			
Is a Comfort Care Only / Allow Natural Death (AND) order in place?			
Has it been discussed with the person?			
Has it been discussed with the Relative / carer?			
If in place, the implantable Cardioverter Defibrillator (ICD) is deactivated			
Has this been discussed with Person / Relative?			
			Details
The person's skin integrity has been assessed			
If bed sore present: site(s), size, grades 1- 2 - 3 - 4			

6. The person's need for <u>nutrition</u> is assessed and reviewed				
Does the person need Clinically Assisted (artificial) Nutrition (CAN)?				
Continued	Discontinued	Not required		
If already in place, which route?	NG/RT	PEG/PJ	NJ	TPN

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As appropriate, discussed with person / relative / carer

7. The person's need for fluids is assessed and reviewed

Does the person need Clinically Assisted (artificial) Hydration (CAH)?

Continued	Discontinued	Not required
If already in place, which route? IV SC NG/RT PEG/ PJ		

As appropriate, discussed with person / relative / Carer?

Person's name: _____ Sticker
 Hospital / Hospice No: _____

8. Communication regarding the current Care Plan

	YES	NO	Not appropriate
A full explanation of the care plan has been given to the person			
Is the person aware that good nursing and medical care will continue?			
A full explanation of the care plan has been given to the relative / carer?			
A leaflet is given to the carers explaining what changes may occur before death			
The referring medical team is aware that the person is dying			

Additional information
 Have the person / family / carers been given the opportunity to express their concerns?

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Do we know the preferred place of death?	Y	N
In Hospital / Hospice?	At home?	Elsewhere?
Are there any arrangements / decisions in place following death? E.g.: burial / cremation / special requests – embalming / organ donation, etc		
Any other comments / observations of note?		
SECTION 1: INITIAL ASSESSMENT – PROGRESS NOTES		
Record significant events / conversations / medical review / 2 nd opinion	Signature	

Protocol for ongoing assessment of End of Life Care Needs (Annexure 5B)

SECTION 2: ONGOING ASSESSMENT OF THE CARE PLAN	Date:
Day:	
Undertake a Team review of this plan if at any time there is an improvement in: <ul style="list-style-type: none"> ➤ Conscious level, ➤ Functional ability, oral intake, mobility, or ability to perform self-care or ➤ Concerns expressed regarding the management plan from either person, carer or team This plan must be reviewed daily by one of the end of life care trained doctors	

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Sign (at the bottom) during each assessment– a signature indicates the patient was assessed as given below:

Yes (achieved) = Y

No (not achieved) = N

If the outcome was not achieved, then an explanation / comment will be recorded on the progress notes (overleaf).

Timings:						
The person does not have pain						
The person is not agitated						
The person does not have respiratory tract secretions						
The person does not have nausea						
The person is not vomiting						
The person is not breathless						
The person does not have urinary problems						
The person does not have bowel problems (bowels last opened: _____)						
The person does not have other symptoms						
If present record:						
The person's comfort & safety regarding the administration of medication is maintained						
The person receives food and fluids to support their individual needs						
The person's mouth is moist and clean						
The person's skin integrity is maintained						
The person's personal hygiene needs are met						
The person receives care in a physical environment adjusted to support their individual needs						
The person's psychological wellbeing is maintained						
The person's spiritual wellbeing is maintained						
The well-being of the relative/carer attending to the dying person is maintained						
Signature of nurse: (each assessment)						

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Death declaration protocol (Annexure 5C)

Death Declaration Standards

	Description	Minimum Acceptable Clinical Standard	Beyond the Minimum Clinical Standard Additional Testing
C-1	Cessation of circulation and breathing	<ol style="list-style-type: none"> 1. Absent palpable pulse 2. Absent breath sounds 3. Absent heart sounds 4. Absent respiratory effort or chest wall motion 5. Loss of pulsatile arterial blood pressure by non-invasive measurement 6. Coma and fixed dilated pupils 7. Electrical asystole is not required (pulseless electrical activity is acceptable). 	<ol style="list-style-type: none"> 1. Loss of pulsatile arterial blood pressure by arterial line monitoring 2. Absence of anterograde blood flow through the aortic valve on echocardiography, 3. Isoelectric ECG, 4. Absence of pulse by Doppler <p>NB: oxygen saturation pulse oximetry is an unreliable indicator of absence of pulsatile circulation.</p>
C-2	Cessation of circulation and breathing with no possibility to resume spontaneously	<ol style="list-style-type: none"> 1. The persistence of C-1 criteria over a period of time as confirmed by continuous observation and intermittent confirmation including repetition of this evaluation at the end of the period. The time period required is 2-5 min. 2. When breathing and circulation ceases following terminated CPR, the time period to reach the point of "no possibility to resume 	<ol style="list-style-type: none"> 1. Use of the same tests for a higher clinical/laboratory standard for C-1 applied after the time interval required to progress from C-1 to C-2 (2-5 min or 7 min following termination of CPR).

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		spontaneously” increases to 7 min.	
C-3	Cessation of circulation and breathing with no possibility to resume	<ol style="list-style-type: none"> 1. When CPR will not be provided, (patient fulfils criteria for not providing CPR) C-3 occurs at the moment of C-2. 2. Following termination of CPR, including a decision not to reinstitute CPR, C-3 and C-2 occur at the same time. 	1. Nothing in addition to those tests required for C-2.

Source:

[Shemie, S. D., Hornby, L., Baker, A., Teitelbaum, J., Torrance, S., Young, K., Capron, A. M., Bernat, J. L., Noel, L., The International Guidelines for Determination of Death phase 1 participants, in collaboration with the World Health Organization (2014). International guideline development for the determination of death. *Intensive care medicine*, 40(6), 788-97.]

Documenting Death Declaration in Medical Records

I, Dr. working in the department of have examined the patient, bearing hospital number On examination I have noted following findings

.....

.....

that verifies that the patient died on (date) at (time)

Signature
Name
Seal

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Brain Stem Death Declaration Protocol (Annexure 5D)

The Brain Stem Death Declaration Protocol is according to the Organ Transplant Act of India and a resource for the same can be found in the article cited below

[Ganapathy K. Brain death revisited. Neurol India 2018;66:308-15]

<http://www.neurologyindia.com/text.asp?2018/66/2/308/227287>

After Death Care protocol (Annexure 5E)

CARE AFTER DEATH	
Verification of death	
There have been none of the vital signs below forminutes	
• No signs of spontaneous respiration	<input type="checkbox"/>
• No palpable pulses, carotid, femoral or radial	<input type="checkbox"/>
• The pupils are fixed and widely dilated	<input type="checkbox"/>
• No heart sounds	<input type="checkbox"/>
Date of Death:	Recorded time of death:
Death verified by: Name:	
Staff members present at time of death:	
Relatives or Carers present:	
If not, has anyone been notified?	Y N
Name of person informed:	Relationship to deceased:
Contact number:	
Was it a good and peaceful death?	
Staff:	Y N
Family:	Y N

Prepared by Head of the Department	Reviewed by Quality Management Representative	Approved by Medical Superintendent



KASTURBA HOSPITAL

MANIPAL

(Teaching hospital of KMC Manipal, a unit of MAHE)

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As per family feedback	Y	N
Remarks:		
Are the police likely to be involved?	Y	N
Does the person have a pacemaker /ICD?	Y	N
Care of the body:		
Performed according to Institutional policy with regard to		
➤ Treated with respect and dignity	Y	N
➤ Procedures and packing (including infection risk)	Y	N
➤ Cultural rituals / Spiritual / Religious needs met?	Y	N
➤ Person's valuables and belongings	Y	N
Carers and Relatives given:		
➤ Information on next steps required	Y	N
➤ Information on ongoing bereavement support	Y	N
➤ Death Certificate / relevant paperwork	Y	N
Body handed over to:	Date:	
Time:		
Referring Dr / person informed of person's death?	Y	N
Relevant services - MRD / MIS informed of person's death	Y	N

Section 3: Care after Death: any additional information

Date / time	Signature

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