Submission by

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And

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To

the Ministry of Health and Family Welfare, Government of India

On

The Guidelines for Withdrawal of Life Support in Terminally Ill Patients

Issued on September 20, 2024
Seeking public comments towards revising them

Note to the submission

1. This submission contains suggestions and inputs towards strengthening the Guidelines. In that, it is to make the Guidelines clearer, self-explanatory/self-sufficient, comprehensive, and accessible – both literally and in spirit - to all the players/stakeholders involved in scenarios of end-of-life care (EoLC) across health care facilities. Attending to these aspects is critical to make the Guidelines care-receiver-centred.
2. Broadly speaking, the submission offers inputs and suggestions for making the Guidelines both structurally and substantively robust, and with minimizing ambiguities for its users or implementors. Observations relating to structural aspects of the draft Guidelines do have bearing on substantive aspects. For example, the draft Guidelines not being self-sufficient implies that care-receivers are less likely to fully appreciate the space they can exercise their agency and their rights facilitated and supported by the treating teams. Similarly, the dominance of technical language in the current draft Guidelines will most likely mean that care-receivers and their families would find these inaccessible and as a result will rely on treating teams giving up on their own space to participate in the decision making.
3. The submission is organised in alignment with the draft Guidelines sections/sub-sections. However, the submission has numbered sections/sub-sections in the draft Guidelines for easier navigation. To note that the current draft Guidelines do not have numbered sections and therefore we have numbered them.
4. The opening section numbered '0' in this submission provides comments, suggestions and presents rationale on the draft Guidelines as a whole and these will be applicable, when appropriate, to all sections in the Guidelines.

5. Each set of inputs are generally organised in the following manner: Comments/observation/questions to the drafting team; suggestions, and rationale for the suggestions being made.
6. The submission is also informed by the deliberations that took place during the e-public consultation co-hosted by Forum for Medical Ethics Society (FMES) and Bharati Vidyapeeth (Deemed to be University) Medical College (BVDTUMC) dated Saturday, October 13, 2024.
7. Our broad recommendations are that …
    a. the drafting committee is expanded while revising and finalising them to have better representation to make the guidelines inclusive, and comprehensive; and that it states upfront as how the Guidelines are care-receiver centred and how.;
    b. it clearly mentions that this is a living document to be periodically visited to revise and be informed by the learnings from its application on the ground.;
    c. it states clearly the standards of care health care facilities should comply with including opportunities for care receivers and their representations/significant others to learn about the end-of-life-care (EoLC) matters, that is, EoLC literacy.;
    d. makes the Guidelines self-sufficient, comprehensive, user-friendly. This implies taking into account needs of diversity of care-receivers – language, abilities, EoLC literacy. This may mean making these accessible in regional languages, and complementing these with user-friendly tools – audio-visuals, pictorial depictions, etc.;
    e. it states explicitly the responsibilities of health care facilities, administrators to ensure orientation and fuller understanding of the guidelines of their clinical and non-clinical teams who will be involved in EoLC decision making processes towards clarifying their doubts and any operational facets of the Guidelines.;
    f. health care facilities must make these guidelines accessible to care receivers, and staff appointed to help care receivers learn about it.;
    g. It acknowledges and appreciates the heterogeneity of the health care facilities, health care providers and the health care system on the one hand; and deeply rooted diversity of the care receivers. This would enable the revisions to the Guidelines toward making them take into account the worst scenarios and diverse contexts. The drafting committee need to note that the health care system is not a monolith and the commercialization of the health care system (eg: revenue generation aspiration of the corporate health care hospitals), and deep rooted trust deficit prevail and they will play out in implementation of these Guidelines. Necessary safeguards need to be built in.;
    h. The Guidelines needs to refer to the accountability mechanisms addressing the aspects, such as, who is responsible, what pathways of redressal mechanism, and how it interfaces with other relevant protocols and/or legal framework in the health care system?.; and
    i. Lastly, most such Guidelines include explicit articulation about sections of population who might have been subjected to discrimination due to their specific identities, for example, the LGBTQ+ and disability communities. These Guidelines must engage with issues that members of these communities may be confronted with confronted with EoLC situations. And these concerns should reflect in the Guidelines and the mechanism to avert any discriminatory practices stemming from their identities.

In absence of these, it is likely that the Guidelines remain a document meant for a handful of health care facilities and health care providers and impacting its optimum utilisation on the ground to uphold Indian citizens' right to die with dignity.

0. Overall critical review of the draft Guidelines

0.1 Title of the Guidelines

Observation/s: The title only refers to 'withdrawal of the life support'. However, the body of the draft Guidelines includes also the matters relating to 'initiating life support', that is, 'withholding of life support'.

Suggestion/s: The title of the Guidelines to include both these aspects clearly and explicitly.

Rationale: For clarity for all diverse users of these Guidelines and not struggle to know if they are applicable to both these important decision-making spaces when they are confronted with the situations.

0.2 Mandate of the Guidelines

Observation/s: Nowhere, the current draft mentions if these Guidelines have relationships with the judgements by the Supreme Court of India (SC) on this matter, and if the Guidelines are only to operationalize the SC judgements.

Suggestion/s: If the Guidelines are the operationalisation of the SC judgement/s, the Guidelines must …

i. state it upfront, explicitly, and clearly.;

ii. state its implications in terms of its scope, and especially limitations to the decision-making for all diverse users of the Guidelines as result of it being rooted into SC judgement/s. For example, what can be done and what can't be done.

iii. state upfront that what is the legal standing of these Guidelines, especially if these are rooted in the SC judgements. Will they enforceable or otherwise? What implications it might have for users, especially if situations of redressal arise from either care givers or care-receivers or their representative/s?

Rationale: Users must know enforceability of the Guidelines, and legal liabilities if any that stem from violation of appropriate application of these guidelines on the ground.

0.3 **Guideline drafting committee:** The current draft Guidelines do not mention the drafting committee, its mandate and brief and related matters. It is a normative practice

do so for any such Guidelines, especially those issued by the governments-ministries and other government apex bodies.

We suggest that Guidelines present in the document the following:

i. the drafting committee,
ii. the processes involved in drafting the document,
iii. involvement of the various key stakeholders/key constituencies in the drafting of the Guidelines,
iv. the appoint office (who appointed/constituted the committee) and
v. the brief/mandate of the committee.

Rationale:

i. On such an important matter, it is important for the audience to know the drafting committee, and their mandate, and processes involved. For example, drafting committee's expertise, representation of the diverse voices in the Committee to ensure comprehensive, and inclusive guidance in terms of expertise, representation of the care-receivers, health care professionals working in different settings.
ii. It will help lend legitimacy to the Guidelines
iii. It has archival value and subsequent revisions to the Guidelines and the members who will be involved in revising could reach out the members of this drafting committee for advice, clarifications etc.

0.4 The scope of the Guidelines, that is, which health care facilities could apply/use/implement them and if it covers residences/homes of care-receivers.

Sites of application of these guidelines and need for clarifications in the guidelines | Hospitals vs smaller health care facilities; public vs private health care facilities; rural vs urban health care facilities; and only health care facilities and/or homes/residences of patients in rare situations.

Observation/s

Sites of application of these Guidelines: The current draft Guidelines do not state the scope of Guidelines. It is not clear if these are applicable across health care facilities – private vs public, type of health care facilities (size and preparedness), rural vs urban based health care facilities; and if they will be applicable to patients in other settings, such as, long term care homes, and residences.

Suggestion/s:

a. Needs to clearly state as where can these Guidelines be applicable. It is not clear if this covers both private and public health care facilities, all types of health care facilities, and homes/residences if such life support is provided (although these will be rare instances).

b. Making explicit the sites of application of these guidelines relates with the preparedness of a particular health care facility to consider application of these Guidelines. It is not clear if there should be 'standards of care' laid out for health care facilities to be in position to apply these Guidelines.

Rationale:

a. To note, is that, although the title only mentions withdrawing of the life support, the content of the draft Guidelines refers to the decisions relating to initiating the life support, that is, whether to withhold life support or initiate it. Since they are also about withholding life support related matters/decision-making, and the fact that there will be instances of care receivers in long term care homes, or at their own residences, it is important to mention this explicitly and clearly.
b. Care receivers and their representatives/significant others would know about these matters while confronted with such situations.

0.5 **Numbering sections, sub-section, and clauses:**

Observation/s: The current draft does not number the sections, sub-sections, clauses under each section in a uniform manner.

Suggestions:

i. Every section, sub-section, clauses/items to carry number that can be referred to. For example, each section numbered (roman numbers) and items under each section are numbered as I.1, I.2…; II.1, II.2… etc.

Rationale: It will easier to navigate through the Guidelines. Needs to ensure that every items/clause can be referred to by only mentioning a number as it is practiced for any such document. From the point of view of using these Guidelines in practice, multiple stakeholders will be referring to sections and clauses during the conversation, and beyond it, especially if there may be redressals sought, it is important to number the sections and clauses. Any communication gaps on this front may potentially run the risk of the treating team confusing steps/action to be taken, and human error could lead to harming care receiver, maybe unintentionally.

0.6 **Glossary**

Observations: The current draft Guidelines do not have comprehensive glossary of concepts-terms other than enlisting a few.

Suggestion: The Guidelines include …

i. a comprehensive glossary of all the acronyms that feature in the main document, and
ii. if needed, glossary be appropriately sourced (cite the literature)

Rationale: It holds salience given that the diverse players/stakeholders – professionals, such as, health care providers, lawyers, counsellors; patients and their families, and public at large; and possibly also pastures/faith leaders if families choose to engage with

them on their own – are very much part of these conversation regarding withdrawal or withholding of life support.

It is important that the Guidelines are easily accessible in terms of the language, technical and medical terms, and legal terms that form the core of these conversations. Without these, the Guidelines will remain a document for health care professionals.

Making the Guidelines accessible to care receivers and their 'significant others' – family members, guardian, legally authorised representative – is an important element and part of the state's obligation to make the health care system 'patient-centred'.

0.7 **Inclusion of a preamble:**

Observation/s: Current draft does not have any preamble. The current 'Background' is rather cryptic. It makes quite challenging for its users to understand/appreciate the context, purpose, limitations, due diligence by the health care system and providers, and desired outcome of implementation of these Guidelines.

In a way, it assumes that every other health care provider, and other players would know the context of these Guidelines and the other aforesaid aspects. This either might lead to keeping away from these, adversely impacting care receivers confronted with end-of-life situations or might be implemented inadequately or with appropriate due diligence ensuring quality end-of-life care delivery.

Suggestion/s: The drafting committee…

i. adds a substantively robust preamble to the Guidelines. This will help to set the tone, and space to articulate key advantages, and limitations of the Guidelines. Amongst others, preamble must mention that it is a 'living document' and will be revisited periodically to respond to the experiences, learnings from its implementation; advances in health care sciences relevant to end-of-life care. Such an articulation will serve as a commitment of the government and respective Ministries to keep the Guidelines up-to-date in alignment with the aforesaid matters, and advances.
ii. refers to some of the guidelines issued by Ministries, especially the Ministry of Health and Family Welfare (MoH&FW), Government of India (GoI) in other areas. The committee Drawing upon these past Guidelines will benefit these Guidelines. It will help improvise these Guidelines regarding all aspects – substantive coverage, focus, clarity, and presentation formats-styles for comprehensiveness and for being self-contained.

    For example, the 'GUIDELINES & PROTOCOLS - Medico-legal care for survivors/victims of sexual violence' issued by the MoH&FW, GoI dated March 19, 2014. (please note that the title of the said Guidelines are hyperlinked for ready reference)

    It will also be worthwhile to review some of the guidance document on the topic of end-of-life care (EoLC) in other countries.

Some of the guidelines on other topics may also be useful to refer to and draw upon. For example, The WHO guidelines on ethical issues in public health surveillance.

Rationale: As mentioned earlier, and later in this submission, if these Guidelines are meant for diverse constituencies/players/stakeholders involved in EoLC conversations, it is inevitable that they are comprehensive, self-explanatory, and legible.

On a related note, if the drafting committee expects that users – all those including health care system (health care professionals, health administrators) and care receivers – it is unreasonable to expect them to have a good handle on medico-legal-ethics parlance that dominates the current draft Guidelines and for them to keep referring to a range of orders and judgements that are included in the current draft Guidelines as Annexure 1. To note, that a number of health care professionals sought clarifications during the e-public consultation is an indication that the Guidelines need to be clearer, and comprehensive.

0.8 **Resource-intensiveness reflected in the draft Guidelines in terms of t**ime that will be required to navigate through the pathways as per the Graphic, complexities involved, and power imbalances between treating team and care receivers

Observations: A broader concern is if the resource intensive nature of the processes implied would obstruct their meaningful implementation without obstructing the processes being care-receiver centred.

a. The processes seem rather long winded and may lead to unnecessary delays in arriving at a final decision. This may add to the stress to families, especially in absence of EoLC literacy, and little access to social capital.
b. May mean that the Guidelines being of little relevance in real-life situations, especially to those from certain sections of population and/or "marginalised" communities.;

0.9 Making the Guidelines fuller and self-sufficient

This submission has already highlighted matters related to scope for making the Guidelines fuller, self-sufficient, and comprehensive. Towards this, the submission elicits some of the key Guidelines issued by the Ministry of Health and Family Welfare in the past to draw upon.

One such matter is regarding the documentation of processes.

Observations: Pathways, and other matters related to processes involved in implementation of the Guidelines will require standard templates for the purpose of documentation. The current draft Guidelines don't seem to have such a set of standard forms.

Suggestions: A set of standard forms for documentation need to be designed and templates included in the Guidelines.

Rationale: As mentioned elsewhere in this submission to make the Guidelines self-sufficient and fuller; and to standardize the processes and documentation across health care facilities and care receivers allowing necessary flexibility to accommodate specificities of contexts.

I. Background

Comments/observations, and suggestions:

a. This section should set the stage and offer readers the insights into the work done in this area so far both in India and outside to locate the guidelines into context. Locating them into the broader context in India with reference to constitutional rights of persons in terminally ill condition, health policies, relevant legal frameworks/acts to ensure alignment, eliminating potential contradictions will help making them self-sufficient and self-explanatory, and comprehensive. The current draft Guidelines do not present such context. It is missing entirely.
b. It must mention rationale/motivations/purpose of the "Guidelines", and expected impact/usefulness for users, especially care receivers. The opening section such as this must explicitly state motivations behind drafting the Guidelines, objectives, and the how it is expected to facilitate making EoLC matters-situations easier to navigate through for all those involved – treating teams, patients, and their families and others.
c. Substantively speaking, these guidelines must articulate that these are founded on 'right to die with dignity' and that this itself is rooted into the broader health rights-health-justice-health equity discourse, and related policies, legislative frameworks, and relevant UN conventions to which India is a signatory and that these rights flow from these commitments made by the GoI.
d. Furthermore, it offers little guidance and clarity on its scope. For example, it is not clear if the Guidance is bindings to the entire health care sector – public and private; and at all levels of health care provision. For example, the guidance is also to help decide whether life support should be initiated or not. Such situations arise not necessarily only in tertiary care facilities. Guidelines need to take into account various such possible scenarios into account.
e. It must explain the processes involved in drafting the document, who appointed the committee, committee members, and any public engagement or consultations seeking inputs from.
f. Similarly, given the specificities of LGBTQ+ and disabilities, the range of legislative frameworks that guide their rights, including those relating to access to health care, the Guidelines ought to refer to those legal frameworks, including UN Conventions, and Indian laws as a way of providing broader context – local and global. To note is that there is sufficient empirical evidence that health care providers and the health care system are not necessarily aware of, and equipped with appropriate competencies to engage with these communities. If so, Guidelines must present some of these challenges and the ways that health care providers involved in EoLC and the health care system to address them. This is likely to be enabled by closer and deeper engagement with representatives from these communities. Suggest that their inputs are sought.
g. There are some specifics stemming from a set of legal framework and UN conventions with regards to disability community which may have bearing on the Guidelines. For example, the Parliament of India has ratified the United Nations Convention on the Rights

of Persons with Disabilities (UNCRPD). As a result, there is a legal binding to harmonize all its laws and policies and guidelines in line with the UNCRPD. The Article 12, UNCRPD is about equal recognition before law, and its compliance requires abolishing substitute decision making and replacing with supported decision making. The UN committee has recommended the Government of India that it needs to repeal all type of guardianship from all national and state legislations, including the rights of personal Disabilities Act, and the Mental Health Care Act. They also recommended introducing supported decision-making system which is respectful of the autonomy. These developments in other spaces seem to have bearing on the draft Guidelines. A diligent engagement with such matters is warranted towards making the Guidelines reflect these complexities and mechanisms to maintain the alignment with related legal frameworks.

h. The opening section requires to help readers understand the organisation of the document, that is the main thematics/topics, and rationale behind it. For example, it is not clear if there will situations of misuse, and what will be redressal mechanisms for care receivers-families-significant others.
i. Section heading 'Introduction' will be better suited to this opening section in a re-drafting/drafting afresh the section in this manner.

II. Definitions

Comments/observations, and suggestions:

a. Suggest to revisit both the terms, 'Withdrawal (WD)' and 'Withholding (WH)' and consider 'Withdrawal of life sustaining support (WD of LST/S)' and 'Withholding of life sustaining support (WH of LST/S)
b. The THOA is referred to in the definition of 'Withdrawal (WD)'. Suggest (i) it is included in the Glossary; (ii) full reference is cited appropriately, link provided etc.
c. Under 'Best interest', the line "WD, WH and DNAR are collectively termed Foregoing of Life Support (FLST)' should be converted into a separate term and enlisted accordingly.
d. The categories of terminally patients to whom these guidelines apply should be clearly defined, such as, patents in
    i. patients in ICU
    ii. patients in the EMD
    iii. Hospitalised patients
    iv. Patients at home
e. Broadly speaking the guidelines rely on the two judgements of the Supreme Court of India which are footed as 5 and 6; and the two papers which are footnoted as 4 and 5. As a result the draft Guidelines are not self sufficient and will require readers and users, especially patients, and people at large to make extra efforts to access these resources. Suggest that (i) if necessary, some highlights are included in the main body, especially the two judgements that are sourced; and (ii) that these documents are included as annexures to the revised Guidelines.
f. More importantly, making the aforesaid resources available as Annexures can serve limited purpose. It is important to include well sourced Definition in the interest of Guidelines' self-sufficiency is warranted given the fact it relates to EoLC matters.
g. Need to ensure close-to-perfect alignment of definition of terms that are reflected/or strictly articulated in the two judgements the two published papers. If it is already done by the drafting

committee/team of these Guidelines, an explicit statement saying so will give confidence to users of these guidelines.

h. Inclusion of or reference to the term 'euthanasia' requires revisiting. In most other contexts/countries it is referred as 'assisted dying' and the legal frameworks are developed to enable assisted dying. It is not just the phrases but it reflects the deeper philosophy and perspective about enabling and upholding ailing persons' wishes and rights to dignified dying.
i. Order of terms under 'Definition': In current draft their order appears ad-hoc. Suggest that they are presented in alphabetical order for ease of access to users of the Guidelines.
j. It is not clear as to how and which way the Ethics Code of the Medical Council of India (past) or the National Medical Commission (NMC) will relate to these Guidelines, and which document will take precedence.
k. Suggest that this list of terms which is central to the Guidelines is made exhaustive enough for users without having to look to other sources to seek clarification, and avert any potential confusion.

III. PRINCIPLES OF FLST AND COMPASSIONATE CARE [5,8]

Comments/observations and suggestions:

a. This forms the foundation for the Guidelines. Yet, it is inadequately developed section. It is not sufficient to enlist these principles which read empty and verbose without much meaning to readers, especially in the context of India where ethics are little respected and inadequate understood in health care settings, and that medical schools lack any systematic training in ethics as such.
b. As mentioned earlier, if the Guidelines are to be user-friendly, these principles will need to feature in a form that are accessible to all the diverse users.
c. As mentioned elsewhere, it will be helpful to explain these principles using certain innovative ways of presentation.

IV. LEGAL PRINCIPLES OUTLINED BY THE HONORABLE SUPREME COURT 5,6

IV.1 An adult patient capable of taking healthcare decisions may refuse LST even if it results in death

Observations: Clarity and explicitness, eliminating any ambiguities and minimising scope of interpretations leading to burden on treating teams

a. What if patient or family requests continuation of LST in the face of clear futility, that is, imminent death?
b. Clarity and explicitness | Which therapies are included in life sustaining treatments? Some suggestions are:
    i. Intravenous fluids and medications including antibiotics
    ii. Artificial feeding by nasogastric tube or gastrostomy
    iii. Dialysis

iv. Artificial respiratory support including
    a. Oxygen therapy
    b. Non-invasive respiratory support
    c. Invasive respiratory support
    d. Suction
c. Chemotherapy
d. Cardio-pulmonary resuscitation

IV.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

Observation/s

a. It is not clear as how is the decision-making capacity assessed, what are the sources of guidance to assess such a capacity. For example, any specific legal framework or other sources.
b. It is also not clear if there are multiple sources of such an assessment, and if they do not align with each other, which source should take a precedence, and rationale for the same.
c. Similarly, the concept of 'best interest' which must be very central to these Guidelines is sketchily presented. It doesn't mention sources of the concept in the Indian context. For example, whether it is the medical ethics code of the National Medical Council (NMC) or some other sources is not clear.
d. The draft Guidelines do not make reference to specificities of certain communities, for example, LGBTQ+ and disability communities and that the some of the judgements in the past suggest that there could issues around surrogate decision makers.

Suggestions:

a. The Guidelines must mention explicitly the source of guidance on assessment of the decision-making capacity of patients.
b. If there are multiple sources, the draft Guidelines must mention as to which source takes precedence and present the rationale for the same.
c. Sources of terms such as 'best interest' which ought to be central to these Guidelines, need to be mentioned; if there are multiple sources, and if they conflict with each other, Guidelines must mention which source to take precedence and why. The same approach to other terms/concepts which reflect in the guidelines will be necessary.
d. Specificities of LGBTQ+ and disability communities need to be taken into account. Past judgement on aspects, such as, surrogate decision maker should inform the Guidelines to make them inclusive.

Rationale: As has been the case many other suggestions in this submission, it is to facilitate efficient application of the Guidelines with focus on patients**.**

IV.3 AMD that meets specified requirements is a legally valid document

Observations:

a. The draft Guidelines do not refer to situations if the wishes of the patient have been expressed verbally or if the written document does not meet specified requirements.

Suggestions:

a. Guidelines must explicitly provide guidance on these situations.

Rationale: : As has been the case many other suggestions in this submission, it is to facilitate efficient application of the Guidelines with focus on patients**.**

IV.4 For a patient without capacity, foregoing life sustaining treatments (FLST) proposals should be made by consensus among a group of at least 3 physicians who form the Primary Medical Board (PMB)

IV.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

IV.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

IV.7 Active Euthanasia is not lawful

Comments

a.

V. CONSTITUTION OF MEDICAL BOARDS AND HOSPITAL OVERSIGHT

V.1 *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.

Observations:

a. As mentioned earlier, it appears burdensome and resource intensive to follow the given pathway of having to constitute two boards.

b. In addition to the two boards – PMB and SMP, there is also reference to hospital ethics committee. Overall, this could be burdensome and likely delay decision making.

Suggestions:

a. If there is clear consensus between all patient/family members and treating physicians, can we expedite withdrawal thru primary board alone and use SMB only for ratification.
b. Also, if any dispute arises, it could be directed to hospital ethics committee rather than having to constitute SMB.

Rationale: To help make it pragmatically feasible to implement the Guidelines.

VI. PATHWAY FOR WITHDRAWAL OF LIFE SUPPORT IN TERMINALLY ILL PATIENTS

Observations:

a. Pathway graphic does not clearly articulate the commitment of the health care facility and the treatment to provider quality palliative care to the care receiver regardless of.
b. It is not adequately clear if this flow/pathway apply to all types/categories of patients.
c. It is not clear as what might be the criteria for discharging patients admitted to ICU, and how triage related matters be resolved.
d. Informed refusal to continue the life support, many consider, is a grey area. For example, it is not clear in the draft Guidelines as who and how to assess if advance directive is authenticated one, if there exist one; how the treating team or concerned health care professional determine the custodians of the advance directive document.
e. If there is no advance directive document, and if the patient in terminally ill condition is not in position to communicate, it is not clear in the draft Guidelines, as who will sign the informed consent to withdrawal or withholding of life-supporting interventions, and who will authenticate it at that point in time.
f. It appears from the reading of the draft Guidelines that the proposal for FLST is to be initiated by the treating team and/or the health care facility/the concerned authorities in the health care facility.
g. It is not clear if alimentation, that is, tube feeding other than infusion should also be included in FLST in case the patient is unresponsive or in coma.
h. The current draft Guideline do not mention much about what happens to the patient once FLST is declared. For example, it is not clear whether they should be removed from the ICU to be taken care of by the relatives, or can they be taken care of in their homes.
i. The draft Guidelines do not refer to the 'palliative care' term.
j. There is no Model AMD (Advanced Medical Directive) included in the draft Guidelines.
k. As mentioned earlier, mutli-dimensional specificities relating to certain communities, such as, LGBTQ+ and disability communities don't feature in the draft Guidelines.

Suggestions:

a. The pathway could start by suggesting that a palliative needs assessment be done for all patients and those that have significant palliative needs can be identified and be helped with expedited withdrawal as we would do for patients with AMD

b. Patients with advance medical directives what pathway they should follow should be clearly specified. For example, it is not adequately clear if they need to follow the same pathway as for withdrawal as depicted in the graphic/flow chart in the draft Guidelines.
c. A mention of the triage and admission discharge criteria for icu or a reference for this should be made.
d. Clearer articulation in the Guidelines regarding the aforesaid concerns about the advance directive documents and related matters is warranted.
e. The Guidelines must mention explicitly that the patients and their representatives – relatives, legally authorised representatives, significant others - can request authorities/treating teams to inform them of patients' condition that necessitates the FLST.
f. Clear articulation regarding alimentation.
g. The draft Guidelines must mention clearly once FLST decision is arrived at as what is course of action to be taken by the treating team regarding moving patients out of ICU and guidance on where to shift the patient.
h. The draft Guidelines must mention that the patient for whom FLST decision is arrived at, should be provided with quality palliative care support.
i. Palliative care related commitments to the patients after FLST must be explicitly articulated in the Guidelines.
j. Model AMD (Advanced Medical Directive) should be included in the revised Guidelines.
k. Important that the Guidelines take into account specificities of certain communities in a manner that the pathways respond to and comply with any applicable legal obligations. For example, matters related to supported decision making.
l. Guidelines must mention that the health care facilities have obligations to arrange for necessary communication support, such as, sign language to facilitate and enable communication with patients who may require such support.

Rationale: Overall rationale to revise the draft Guidelines towards including these points is to make them self-sufficient and self-explanatory.

a. Care receivers' access to quality palliative care falls under the purview of constitutional rights, and other related UN conventions that India is signatory to. As mentioned earlier, these are also the reasons, as to why Introduction section in the draft Guidelines need to refer to the set of these rights frameworks, UN conventions, Constitution of India, and relevant judgements from within Indian judiciary.
b. Will help bring clarity to the Guidelines, and there will be lesser burden on concerned office/s to respond to questions and seeking clarifications.

VI.1 Graphic | Left Hand Side | Cell 1 | Physician assessment of inappropriateness of life sustaining treatments

Questions

a. Isn't this assessment is frequently subjective (literature to support such inappropriateness is lacking for most conditions)?

b. There is financial component to these life sustaining interventions, how do you balance this with the appropriateness of LST?
c. Families react emotionally and physicians may find it difficult to establish a rapport.

VI.2 Graphic | Left Hand Side | Cell 2 | Consensus of assessment in the Primary Medical Board (PMB) constituted form the treating team

Questions

a. What if there is no consensus in the primary medical board?
b. Will the primary medical board be constituted each time for each patient or will it remain the same with only change in the primary physician?

VI.3 Graphic | Left Hand Side | Cell 3 | One or more multidisciplinary meetings with family/surrogate discussing prognosis & treatment options

Observations

a. Requires clarity regarding the course of action if there is no consensus in the family after multiple meetings between the treating team and the representatives of the patient.
b. Requires clarity regarding situations when the family does not agree to FLST (foregoing life-support as defined/conceived in the draft Guidelines) especially when family expects reimbursement from government insurance schemes and/or they are able to afford extending LSTs.
c. Requires clarity regarding patients in terminally conditions and with medico-legal matters involved.

Suggestions: To include and explain these matters adequately enough for all users.

Rationale: Clarifying these matters in the Guidelines will help their implementation efficient by averting the frequent situations of seeking clarifications.

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