

ANALYSIS OF THE MEDICAL TREATMENT OF TERMINALLY-ILL PATIENTS (PROTECTION OF PATIENTS AND MEDICAL PRACTITIONERS) BILL, 2016

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EXECUTIVE SUMMARY

This report critically analyses the provisions of the draft Medical Treatment of Terminally-Ill Patients (Protection of Patients and Medical Practitioners) Bill, 2016. There are three kinds of shortcomings that the Bill exhibits: i) drafting deficiencies, through the use of imprecise language and contradictory provisions; ii) failure to consider the interaction of the Bill with the Mental Healthcare Bill, 2016; and iii) refusal to grant validity to advance medical directives or medical powers-of-attorney. Together, these shortcomings constitute a violation of the fundamental principle of patient autonomy and the right to die with dignity guaranteed under Article 21 of the Indian Constitution.

End-of-life decision-making is a complex issue, therefore, we first set out six principles that ought to guide decision-making regarding the withholding or withdrawal of medical treatment. Apart from autonomy and the right to die with dignity mentioned above, these principles also require that every effort be made to enable patients to exercise autonomy and take informed decisions, that decisions be guided by the best interests of the patient when options for the exercise of patient autonomy have been exhausted, that communication and consultation between medical practitioners, family and friends constitute the bedrock of decisions made in the patient's best interests, and finally, that judicial intervention in end-of-life decision-making be minimised.

Our analysis of the provisions of the Bill reveals that these principles are violated in a number of ways. The most fundamental violation is Clause 11 of the Bill, which refuses to recognise the legal validity of advance directives. Other violations of the guiding principles flow from this provision. For example, Clause 9 of the Bill appears to require the permission of the High Court in *every* instance of withholding or withdrawing medical treatment from incompetent patients. Other problems with the Bill include the denial of autonomy to *competent* patients who have not made an informed decision and requiring medical practitioners to record their opinion on the necessity of withholding or withdrawing treatment even in the case of competent patients. The Bill also contradicts itself by stating that decisions by competent patients to withhold or withdraw treatment are binding on medical practitioners while also making exemption from legal liability for such withholding or withdrawal dependent on an assessment that such decision was in the best interests of the patient.

Given its many problematic provisions, it is our recommendation that the Bill in its current form be scrapped, and a fresh Bill be drafted after carefully surveying comparable legislation in other jurisdictions. If this option is not pursued, we have pointed out all the provisions of the Bill that require amendment. One of the key changes that we have suggested is to Clause 9 of the Bill. Instead of approaching the High Court to withhold or withdraw treatment from incompetent patients, we recommend instead that Ethics Committees be constituted at designated tertiary hospitals, comprising a mix of medical practitioners, lawyers, social workers and laymen. In the event of disagreement among medical practitioners, family and friends of an incompetent patient regarding the withholding or withdrawal of life-saving treatment, we recommend that the dispute be

referred first to such Ethics Committees, which will serve all the hospitals, nursing homes and other clinical establishments within a specified radius. Appeals from the decisions of such Committees ought to be permitted to the High Court only on very narrow grounds—material error of fact or *mala fide*.

We also believe that the medical and legal communities have an important role to play in strengthening the legal and regulatory framework governing end-of-life decision-making. **The medical community, whether through the Medical Council of India, or through other associations, ought to frame model Standard Treatment Guidelines for the administration of palliative care as well as the withholding or withdrawal of treatment.** Although the community has been waiting to take its cues from Parliament and the courts, we believe it important that it now take the lead in framing at least draft guidelines as if it were not constrained by existing judicial decisions and the absence of a legal framework. In the face of organised medical opinion on end-of-life care, Parliament might be persuaded to create a legal regime more beneficial to the exercise of patient autonomy.

Similarly, the legal fraternity ought to recommend ways in which a regime that recognises advance medical directives could be operationalised smoothly without the fear of litigation that previous reports of the Law Commission apprehend. Important steps have already been made in this direction through the recognition of advance directives for the treatment of mental illness under the Mental Healthcare Bill, 2016. Apprehensions about accurately verifying the validity of advance medical directives or their potential as tools of litigation can be addressed by designing a regime with appropriate safeguards as other countries have done—they ought not to constitute barriers to the exercise of Constitutional and international human rights altogether.

This report is the first in a series of reports that will look at different aspects of end-of-life medical care and decision-making. The other reports in the series will propose suitable legal frameworks for the administration of palliative care and the operationalisation of advance medical directives by surveying best practices in other jurisdictions, while taking into account the distinctive features of the Indian healthcare system.

I. INTRODUCTION AND GENERAL PRINCIPLES

In 2005, the organisation Common Cause filed a writ petition¹ in the public interest at the Supreme Court of India (“SC”) praying for the recognition of the validity of advance directives for medical treatment that patients would like to receive if they were to go into a persistent vegetative state, long unconsciousness or coma. A five-judge bench refused to pass an order, directing instead that the Government of India make its stand clear on the issue and that the matter be debated in Parliament. In response, the Ministry of Health and Family Welfare (“MoHFW”) published the draft Medical Treatment of Terminally-Ill Patients (Protection of Patients and Medical Practitioners) Bill (“the Bill”) in May, 2016. The Bill is essentially a replica of draft legislation that was first annexed to the 196th Report of the Law Commission of India in 2006² and later revised in 2012.³ In this report, we critically analyse the provisions of this Bill and make suggestions on moving the debate on the withdrawal or withholding of medical treatment forward in a meaningful way.

The withdrawal or withholding of medical treatment from a terminally ill person is a complex ethical issue and one which many countries have wrestled with in their attempts to introduce a legal framework for end-of-life decision-making. In creating a similar framework for India, it is useful to refer to such other legislation, while also taking into account the peculiarities of the Indian healthcare system.

First however, there are certain general principles that ought to govern such decisions, irrespective of the jurisdiction in question. We propose the following:

- I. Every person has a fundamental right to life, which includes the **right to die with dignity**.⁴ The State must take every measure within its power to ensure that this right is protected, respected and fulfilled. This includes negative measures to prevent the violation of this right by third parties, as well as positive measures to enable the effective exercise of this right.⁵

¹ *Common Cause (A Registered Society) v Union of India*, Writ Petition (Civil) No.215 of 2005.

² Law Commission of India, 196th Report on Medical Treatment to Terminally Ill Patients (Protection of Patients and Medical Practitioners) (2006).

³ Law Commission of India, ‘Passive Euthanasia-A Relook’ Report No. 241 (2012).

⁴ This has been upheld by the Indian Supreme Court (“SC”) in *Gian Kaur v State of Punjab* (1996) 2 SCC 648. It has also been recognised as an integral component of the human right to health under the International Covenant on Economic, Social and Cultural Rights (to which India is a party) by the Committee on Economic, Social and Cultural Rights (“CESCR”). See CESCR, ‘General Comment No. 14: The Right to the Highest Attainable Standard of Health’ para 25 (‘General Comment No. 14’).

⁵ General Comment No. 14, para 33. See also CESCR, ‘General Comment No. 3: The nature of States parties obligations’.

- II. **Patient autonomy** is paramount. A necessary component of the right to dignity includes the right to make decisions about one's body, including the right to refuse medical treatment.⁶
- III. Every effort ought to be made to ensure that **patients are able to exercise this autonomy**.⁷ This requires making accurate and comprehensive information available and accessible to patients, as well as allowing flexibility in the manner in which patients communicate their decisions.⁸
- IV. When avenues enabling the exercise of patient autonomy have been exhausted, a person making an **end-of-life treatment decision for a patient must be guided by the patient's best interests**.⁹ Such a decision ought not to be restricted only to the patient's medical interests, but must also take into

⁶ In *Aruna Ramchandra Shanbaug v Union of India* (2011) 4 SCC 454 ('*Aruna Shanbaug*'), the SC pointed to judicial decisions in other countries that had also affirmed this principle. It stated:

First, it is established that the principle of self-determination requires that respect must be given to the wishes of the patient, so that if an adult patient of sound mind refuses, however unreasonably, to consent to treatment or care by which his life would or might be prolonged, the doctors responsible for his care must give effect to his wishes, even though they do not consider it to be in his best interests to do so [para 69].

See also *B. Krishna Bhat s/o late B. Narayan Bhat v State of Karnataka, represented by its Secretary to Government, Health and Family Welfare Department and Others*, MANU/KA/0653/2008, where the Karnataka High Court recognised the right to refuse treatment as one in a list of patients' rights to be respected by the State Government.

⁷ The Mental Healthcare Bill, 2016, recently passed by the Rajya Sabha, is a good example of this principle. Clause 4 of the Bill states that all persons, including those with mental illness, are to be deemed to have the capacity to make decisions regarding their mental health care or treatment. Under sub-clause (2) of this provision, the information required in order to be able to make such decisions should also be communicated in simple language, including sign language or visual language. The aim is to enable the person in question to understand the information.

⁸ In *Aruna Shanbaug*, the SC recognised that the autonomy or the right to self-determination extends to both competent and incompetent patients. It says:

To be autonomous, the patient should be competent to make decisions and choices. In the event that he is incompetent to make choices, his wishes expressed in advance in the form of a living will, OR the wishes of surrogates acting on his behalf (substituted judgment) are to be respected (emphasis supplied) [para 9].

⁹ *Aruna Shanbaug*. The SC noted that:

The surrogate is expected to represent what the patient might have decided had he/she been competent, or to act in the patient's best interest. [para 9.1]

Absent any indication from a patient who is incompetent, the test which is adopted by Courts is what is in the best interest of the patient whose life is artificially prolonged by such life support [para 27].

account the values and belief systems of the patient, in so far as they can be reasonably ascertained.¹⁰

- V. **Communication and consultation** between medical practitioners and the guardian, family or friends of the patient (as applicable) ought to be a key component in determining the patient's best interests.¹¹
- VI. **Judicial intervention in end-of-life decision-making ought to be kept to a minimum**, warranted only when there is serious disagreement about what constitutes the patient's best interests.

Unlike Principles I-V that have either been recognised by the SC or are accepted norms of medical practice, Principle VI is at odds with the SC's assertion of *parens patriae* jurisdiction in *Aruna Shanbaug*. In this case, the SC laid down the law that would govern the withdrawal of life support from patients in a permanent vegetative state in the absence of a Parliamentary enactment. In paragraph 126 of its judgment, it stated that any decision to withdraw such life support, whether taken by near relatives, doctors or next friends, would require approval from the concerned High Court. The seal of judicial authority for such decisions is confirmed in paragraph 132, when it stated that 'it is the Court alone, as *parens patriae*, which ultimately must take this decision, though, no doubt, the views of the near relatives, next friend and doctors must be given due weight.'

This requirement of the High Court's approval for every instance of withdrawal of life support from incompetent patients in a permanent vegetative state is not a viable proposition given the time-sensitive nature of end-of-life decision-making and lengthy delays in the Indian judicial system, not to mention the difficulty that patients and doctors in rural areas would face in accessing High Courts. Additionally, there is nothing to suggest that

¹⁰ This conception of best interests is derived from s 4 of the United Kingdom Mental Capacity Act, 2005. The draft Bill, under discussion in this report, also defines best interests broadly to include not only medical, but also 'ethical, social, moral, emotional and other welfare considerations.'

¹¹ This question was also discussed in *Aruna Shanbaug*, albeit with some confusion. In one part of the judgment [para 126], the SC stated that a decision to discontinue life support has to be taken either by the parents, spouse or other close relatives, and in their absence, by a person or body of persons acting as a next friend. However, in the next line, the SC also went on to say that doctors attending the patient may also take this decision. Conflicts about end-of-life decision-making are likely to arise precisely because of disagreement between the patient's family and the attending doctors. Although it was important for the SC to clarify that the decision ought to be taken *bona fide* in the best interests of the patient irrespective of the decision-maker, its refusal to specify an order of priority among different decision-making groups leaves open a crucial existing source of conflict regarding end-of-life decision-making. However, some paragraphs later, the SC stated that such a decision, regardless of who takes it, would require the approval of the Court. Ultimately, the SC further strengthened the role of the Court by stating that such a decision would have to be taken by the Court *alone*, acting in its *parens patriae* jurisdiction. Due weight would be given to the next friends, near relatives and doctors [para 132].

courts are best equipped to make end-of-life decisions on a routine basis, as the judgment in *Aruna Shanbaug* appears to require.

Therefore, we believe that it is desirable to have a guiding principle that minimises judicial intervention while encouraging communication and consultation between doctors and the family and friends of the patient. In any case, even in *Aruna Shanbaug*, *parens patriae* jurisdiction was conferred on High Courts only because there was no legislation in force governing the issue. While enacting a law on the withholding or withdrawal of medical treatment, it is not necessary to replicate resort to the High Court in the manner required as an interim measure in *Aruna Shanbaug*.

In the next part, the provisions of the Bill are analysed against the six principles set out above. Where relevant, suitable amendments to the Bill are also suggested.

II. SHORTCOMINGS OF THE BILL

The Bill falls short of the general principles set out in Part I in the following ways:

A. The Right to Die with Dignity

The first principle that ought to govern a decision with respect to the withholding or withdrawal of life-saving treatment for a patient suffering from a terminal illness is the right to die with dignity. However, several provisions of the Bill conflict with this right and require suitable amendment.

1. The failure to recognise and give effect to Advance Medical Directives.

Sub-clauses (a) and (h) of Clause 2 of the Bill define ‘advance medical directive’ and ‘medical power-of-attorney’ respectively. However, Clause 11 of the Bill states that such instruments ‘shall be void and of no effect and shall not be binding on any medical practitioner.’

In 2015, the Vidhi Centre for Legal Policy (“Vidhi”) made an intervention application¹² in the matter of *Common Cause v Union of India*, and asked the SC to declare that the ‘right to die with dignity’ is a fundamental right arising from the right to life guaranteed under Article 21 of the Indian Constitution. Consequently, Vidhi asked the SC to permit persons to execute advance directives which could be presented to hospitals and medical care providers to withhold or withdraw medical treatment when the executor of the directive is not in a position to express her decision. In its application, Vidhi argued that the right to refuse life-saving treatment is available to all persons as a form of voluntary passive euthanasia.

Advance medical directives are merely an extension of this right—they are tools through which the will of the patient can be given effect to when they are *not* in a condition to consent to withdrawing or continuing treatment. They are therefore crucial to ensure patient autonomy and bodily integrity.

In declaring advance directives null and void, the relevant provisions of the Bill (if passed as legislation) would fall foul of the right to die with dignity that has been recognised as a part of the right to life in *Aruna Shanbaug* and *Gian Kaur*.

2. The definition of ‘terminal illness’ under the Bill

Sub-clause (m) of Clause 2 of the Bill defines ‘terminal illness’ as:

¹² The complete submissions can be accessed at <http://vidhilegalpolicy.in/reports-1/2015/6/26/legality-of-living-wills-intervention-application>

- (i) Such illness, injury or degeneration of physical or mental condition which is causing extreme pain and suffering to the patients and which, according to reasonable medical opinion, will inevitably cause the untimely death of the patient concerned, or
- (ii) Which has caused a persistent and irreversible vegetative condition under which no meaningful existence of life is possible for the patient.

This understanding of terminal illness in terms of ‘meaningful existence’ is inconsistent with the right to die with dignity. ‘Meaningful existence’ is a vague and imprecise term, and lends itself to subjectivity in as much as a third party would have to decide whether a person’s existence is meaningful. It is also problematic because of its implications for how it measures the worth of the lives of people with severe disabilities or those highly dependent on other people, the community or the State for their subsistence. No other jurisdiction makes use of similar terminology in defining the scope of their euthanasia legislation and the term does not find mention in medical literature either.

There are two other problems with the definition of terminal illness under the Bill. **First, sub-clause (i) of the definition appears to suggest that a *mental* condition is capable of causing death.** Assuming that ‘mental’ has been used in the sense in which it is ordinarily understood and not as a substitute for ‘neurological’, the definition is factually incorrect in as much as it is medically impossible for a mental condition to *cause* death. The only sense in which a mental condition can *cause* death is if it drives a patient to suicide. **This has the alarming implication of potentially treating patients with mental illnesses as suffering from a terminal illness under the Bill. Not only would this be an entirely inaccurate medical characterisation, but it would also violate the rights of patients with mental illness to autonomy and dignity, which the Mental Healthcare Bill, 2016 (“MH Bill”) strives to guarantee by allowing mentally-ill persons to make advance directives for the treatment of their illnesses.**

Second, the use of the word ‘untimely’ in the definition to describe the death of a terminally ill patient is not appropriate. **The death of a patient suffering from a terminal illness but considerably advanced in years may not, according to the general understanding of the term, be deemed untimely *per se*.** This might have the effect of excluding patients advanced in years from the definition of ‘terminally ill’, thereby denying them the right to refuse medical treatment as legalised by the Bill. Applying the criterion of untimely death is unnecessary and may have the unintended consequence of excluding precisely the class of patients that the Bill is intended to help.

3. The need to extend immunity from prosecution to palliative care practitioners

Under Clause 6 of the Bill, even though medical treatment has been withheld or withdrawn by the medical practitioner, he or she is not debarred from administering palliative care. However, it is widely understood that the administration of such care might have the unintended effect of hastening the death of the patient; therefore **it is desirable that the express immunity provided to medical practitioners under Clause 8 of the Bill for withholding or withdrawing medical treatment also be extended to the administration of palliative care.** Palliative care is the minimum care that ought to be given to patients, even if their treatment has been withheld or withdrawn, and an essential aspect of the right to die with dignity.¹³ Therefore, the scope of protection afforded in Clause 8 of the Bill ought to be expanded to allow medical practitioners to administer palliative care without fear of prosecution.

Clause 8 deems the actions of medical practitioners withholding or withdrawing medical treatment lawful only when they comply with the requirements of Clauses 3 and 5 of the Bill. The question is whether these requirements also ought to apply to the administration of palliative care in order to exempt medical practitioners from liability. Clause 3 requires the medical practitioner to: i) obtain the free and informed consent of the patient to the withholding or withdrawal of medical treatment; and ii) communicate this decision to the patient's family or friends and allow three days to pass after such communication before giving effect to the decision. Clause 5 requires the practitioner to maintain a record with the personal details of the patient, the nature of her illness, the treatment being given and the names of her family, any requests or decisions communicated by her and the practitioner's opinion whether the withholding or withdrawal of medical treatment would be in the patient's best interests. The necessity of such withholding or withdrawal ought to be communicated by the practitioner to the patient, if conscious, as well as her family.

As far as the administration of palliative care is concerned, only the first of the requirements in Clause 3 i.e. obtaining free, informed consent ought to be complied with. Compliance with the second requirement i.e. allowing three days to elapse before administering the palliative care, would defeat the very purpose of such care. As for the requirement in Clause 5, medical practitioners ought to be required to maintain records

¹³ Several international human rights bodies, such as the United Nations Committee on Economic and Social and Cultural Rights, the UN Special Rapporteur on Torture, the 2015 Inter-American Convention on the Human Rights of Older Persons and the World Health Assembly have recognised the right to palliative care as a human right. Although access to palliative care does not form the focus of this report, its status as a human right emphasises the importance of ensuring that there is no legal barrier to its administration by doctors.

regarding the administration of palliative care only to the extent that such records are routinely maintained for other kinds of medical treatment. In accordance with Principle V, it is also desirable that information about the administration of palliative care be shared as far as possible with the family and friends of the patients, although the ultimate decision about such treatment ought to be taken by the patient, if competent.

Apart from this bar on legal liability, there are other enabling conditions to **ensure that end-of-life care is administered in a manner consistent with the right to die with dignity**. Clause 12 of the Bill empowers the Medical Council of India to issue guidelines for the guidance of medical practitioners regarding the withholding or withdrawal of medical treatment. An additional obligation to frame Standard Treatment Guidelines for the administration of palliative care should also be imposed on the Council. Medical and para-medical students should also receive appropriate training on palliative care, and curricula and syllabi should accordingly be revised.

KEY RECOMMENDATIONS FROM THIS SECTION

1. The right to refuse life-saving treatment is constitutionally guaranteed, and advance medical directives are an extension of this right. The Bill must thus create a legal framework for the operation of such directives.
2. The definition of 'terminal illness' should be revised, and the phrase '... meaningful existence of life' ought to be removed.
3. Since it is medically impossible for a mental illness to cause a patient's death, it is recommended that the phrase '... or mental condition' be removed from clause 2(m)(i) of the Bill.
4. Requiring that a patient be about to suffer from an 'untimely death' would prevent several groups, such as patients considerably advanced in years, from availing benefits under the Bill. It is thus recommended that this condition be removed from the clause.
5. It is recommended that immunity from prosecution be extended to medical practitioners who administer palliative care.
6. Medical practitioners should only be required to obtain free and informed consent from patients before they administer palliative care.
7. To ensure that palliative care is administered in a manner consistent with the right to die with dignity, the Medical Council of India should frame guidelines for the withholding or withdrawing of medical treatment and Standard Treatment Guidelines for the administration of palliative care. Further, medical and para-medical students should be trained to administer palliative care.

B. The Right to Patient Autonomy

The previous section, as well as Vidhi's intervention application, already demonstrate that the failure to give effect to an advance medical directive or a medical power-of-attorney violates the right to die with dignity. Clause 11 of the Bill is also a violation of the right to autonomy set out in Principle II of the first part.

1. Discrimination against incompetent patients with terminal illnesses

We have argued elsewhere¹⁴ that **the failure to give effect to advance medical directives might violate the right to equality guaranteed under Article 14 of the Indian Constitution by creating an irrational distinction between two categories of patients**—those that are competent to consent to refuse life-saving treatment at the time at which such decision is required to be made, and those that are not competent at the time, even though they have already made the decision to refuse such treatment through an advance directive.

For the first category of patients, any decision to refuse life-saving treatment is binding on their medical practitioners under sub-clause (2) of Clause 3 of the Bill. However, as far as the second category of patients is concerned, Clause 11 of the Bill gives no effect to their decision. Instead, under Clause 9 of the Bill, the withholding or withdrawal of medical treatment from this category of patients requires 'any near relative, next friend, legal guardian of patient, the medical practitioner or para-medical staff generally attending on the patient or the management of the hospital where the patient has been receiving treatment or any other person obtaining the leave of court' to apply to the High Court for permission. **Therefore, it is the High Court that is empowered to take decisions about the refusal of life-saving treatment, rather than the patient herself, denying her the right to autonomy that is extended to the first category of patients.**

2. Paternalism by medical practitioners

Under sub-clause (3) of Clause 3 of the Bill, the medical practitioner is required to communicate to the next of kin of the patient the 'need or otherwise' of withholding or withdrawing treatment from a competent patient who has made an informed decision to refuse medical treatment. However, **once such a decision has been made by a competent patient, all that should be required to be communicated to the next of kin is the *fact* that a decision has been made, not an *opinion* on whether such an action (of withdrawing treatment) is needed.** Instead, the practitioner's opinion regarding the

¹⁴ Alok Prasanna Kumar and Dhvani Mehta, 'The rights of the terminally ill' *The Hindu* (9 June 2016) <<http://www.thehindu.com/opinion/columns/The-rights-of-the-terminally-ill/article14391902.ece>> accessed 4 January 2017.

necessity of the treatment is ‘information relevant to an informed decision about his or her medical treatment’ under sub-clause (d) of Clause 2 of the Bill. This opinion ought to be communicated to the patient *before* she makes a decision, in accordance with Principle III.

3. Incorrect understanding of competence

Under Clause 9 of the Bill, specified persons can apply to a High Court to seek permission to withhold or withdraw treatment from an ‘incompetent patient’ or ‘a competent patient who has not taken an informed decision’. This second category of patients, however, is irrational. **A patient can either be competent or incompetent; there is no question of a competent patient who has not taken an informed decision.** As per sub-clause (e) of Clause 2 of the Bill, a decision is informed when a competent patient has been informed about a list of factors—the nature of her illness, alternative treatments available, consequences of the available treatments and the consequences of remaining untreated. A competent patient can only be considered not to have taken an informed decision when she has not been given any of this information. **If it is felt that a competent patient has not taken an informed decision, one simply needs to ensure that the patient is given such information, in accordance with Principle III. The answer is not to take away the decision-making power of the patient and require an application to the High Court instead, as Clause 9 of the Bill currently provides.**

In its current form, Clause 9 violates Principle II, which guarantees autonomy to patients regarding decisions about their medical treatment. It must therefore be amended to remove the reference to ‘a competent patient who has not taken an informed decision.’ Clause 9 requires other changes as well, which are discussed in later sections.

This phrase is also used in sub-clause (b) of Clause 2 of the Bill, while defining ‘best interests’. The provision states that ‘best interests include the best interests of a patient: (i) who is an incompetent patient, or (ii) *who is a competent patient but who has not taken an informed decision.*’ **Again, there ought to be no question of acting in the best interests of a *competent patient*.** So long as a patient is competent, the opportunity to ensure that she exercises autonomy by making an informed decision always remains, by providing her with the necessary information set out in sub-clause (e) of Clause 2. Allowing medical practitioners or the High Court, as the case may be, to act in the best interests of *competent* patients allows the substitution of a third-party judgment for that of the patient, thereby eroding patient autonomy and violating Principle II. Like Clause 9, the definition of ‘best interests’ must also be amended to remove the reference to ‘a competent patient who has not taken an informed decision.’

4. The requirement for an assessment of 'best interests' by medical practitioners under the Bill

The phrase 'best interests' has been used thrice in the Bill. Since the definition is inclusive, it refers to the best interests not only of incompetent patients and competent patients who have not taken an informed decision, but all other patients as well. Best interests are not limited to the medical interests of the patient, but also 'include ethical, social, moral, emotional and other welfare considerations.'

The term is used for the first time in Clause 5 which requires the medical practitioner attending the concerned patient to maintain a record of the patient, which *inter alia* includes his opinion on whether the withholding or withdrawing of treatment is in the *best interests* of the patient. The second time, it is used in Clause 8 which states that where a medical practitioner withdraws or withholds medical treatment in respect of a competent patient on the basis of the desire expressed by the patient which, on the assessment of a medical practitioner is in her or his *best interest*, his action shall be deemed to be lawful. The term is then used in sub-clause (5) of Clause 9, which allows a third party to apply to the High Court for the withholding or withdrawal of treatment from a patient, and the court may pass orders permitting the same on the basis of *inter alia* the *best interests* of the patient.

The problem with the usage of the phrase in the abovementioned clauses is that under Clause 5, the medical practitioner is required to record his or her opinion on the best interests factor and then under Clause 8 it is made a basis for deeming his action to be lawful or not. **Given that the definition of best interests is not limited to medical interests, there appears to be no rationale for linking the legal liability of a medical practitioner to his ability to assess the 'ethical, social, moral, emotional and other welfare considerations' in respect of the withholding or withdrawal of medical treatment from a patient.**

However, there is a more fundamental problem with the manner in which Clause 8 is phrased. It exempts the medical practitioner from legal liability for the withholding or withdrawal of medical treatment only when: i) such withholding or withdrawal is on the basis of the desire expressed by a competent patient; AND ii) such withholding or withdrawal is the patient's best interests. This second condition defeats the objective of respecting patient autonomy. **So long as the medical practitioner has determined that the patient in question is competent, giving effect to her decision about withholding or withdrawing medical treatment ought to be the only condition necessary to exempt the practitioner from liability.**

It may well be the case that the practitioner might not consider the withholding or withdrawal of medical treatment to be in the patient's best interests; however, this ought to have no bearing on the practitioner's liability. In fact, **Clause 8, which additionally requires the practitioner to assess the best interests of the patient contradicts sub-clause (2) of Clause 3, which states that an informed decision about the withholding or withdrawal of medical treatment by a medical practitioner made by a competent patient in the exercise of her free will is *binding* on the medical practitioner.** Clause 8, therefore, creates legal uncertainty for medical practitioners, besides violating patient autonomy, and ought to be amended to remove the requirement to assess the best interests of the patient. Clause 5 should be similarly amended.

KEY RECOMMENDATIONS FROM THIS SECTION

1. Once a competent patient has made an informed decision to withhold medical treatment, the medical practitioner must only be required to communicate to the next of kin that such a decision has been made, and not their medical opinion on the withdrawal. Sub-clause (3) of Clause 3 of the Bill should be suitably amended.
2. In cases where a competent patient has not taken an informed decision, the remedy provided should not be an application to the High Court. Instead, information must be provided to them in accordance with sub-clause (e) of Clause 2 to enable them to make an informed decision and to ensure patient autonomy. Thus, sub-clause (b) of Clause 2, and Clause 9 should be suitably amended to remove references to competent patients who have not taken an informed decision.
3. Under Clauses 5 and 8, the legal liability of medical practitioners should not be linked with their assessment of the best interests of the patient. A determination that the patient was competent to make an informed decision should be enough to exempt the medical practitioner from legal liability.
4. In requiring the medical practitioner to assess the best interests of the patient, Clause 8 is inconsistent with sub-clause (2) of Clause 3, which states that the informed decision of a competent patient is binding on the medical practitioner. It is thus recommended that Clause 8 be amended to remove the requirement to determine the best interests of a competent patient.

C. Facilitating the Exercise of Patient Autonomy

This Bill overlooks provisions of the MH Bill, which might potentially undermine the rights of patients to refuse life-saving medical treatment that have been recognised in this Bill.

Clause 7 of the Bill excludes legal liability under the Indian Penal Code, 1860 (“IPC”) for competent patients who choose to refuse medical treatment under this Bill. However, it is not just the threat of criminal action that may pose a barrier to the ability of a person to make such a decision; such barriers may also be created by provisions in the MH Bill that permit physical restraints on persons with mental illness in certain situations. The MH Bill provides for ‘supported admissions’ of people with mental illnesses to mental health establishments for a period of 30 days if they threaten to or attempt to cause bodily harm to themselves or demonstrate an inability to take care of themselves to the extent that they are at risk of harming themselves.¹⁵ This forced admission may be extended beyond 30 days if two psychiatrists sign off on it. Further, the provisions for ‘Emergency Treatment’ under the MH Bill permit *any* medical treatment to be given to a person to prevent death or irreversible harm to the health of the patient or to prevent the person from inflicting serious harm to herself.¹⁶ The person may also be subjected to seclusion, solitary confinement or physical confinement if it is the “only means available” to prevent imminent and immediate harm to the person.¹⁷

The definition of ‘incompetent patient’ under sub-clause (d) of Clause 2 of the Bill includes persons of unsound mind. Such persons are not granted the right to make decisions about withholding or withdrawing medical treatment. However, since ‘unsoundness of mind’ is a narrower category than ‘person with mental illness’, it is possible that a competent patient (of sound mind) also has a mental illness. Given the broad definition of ‘mental illness’ under the MH Bill¹⁸, its provisions would be applicable to such ‘competent patients’ as understood in this Bill. Consequently, the provisions with respect to supported admissions, emergency treatment and solitary confinement under the MH Bill could be invoked to prevent such patients from making an informed decision to withdraw treatment. **Therefore, there is a possibility of the provisions under the MH Bill being misused to prevent people from making informed autonomous decisions. It is important that the Bill accounts for other legislation (such as the MH Bill) that might potentially affect or hinder the ability of patients to exercise their choice to withhold or withdraw treatment under this Bill.**

¹⁵ The Mental Healthcare Bill, 2016; Clause 89

¹⁶ The Mental Healthcare Bill, 2016; Clause 94

¹⁷ The Mental Healthcare Bill, 2016; Clause 97

¹⁸ The Mental Healthcare Bill, 2016; Clause 2(s)

KEY RECOMMENDATION FROM THIS SECTION

The Mental Healthcare Bill, 2016, will permit physical restraints to be placed on persons with mental illnesses who are attempting to cause bodily harm to themselves. These provisions might affect a patient's ability to exercise the choice to withhold or withdraw medical treatment under this Bill. It is thus recommended that appropriate provisions be introduced to ensure that persons with mental illnesses, but who are competent patients, are not hindered from giving effect to their informed decisions.

D. Minimising Judicial Intervention in End-of-Life Decision-making

Clause 9 of the Bill creates uncertainty about the circumstances in which medical treatment may be withheld or withdrawn from incompetent patients.¹⁹ This in turn casts doubt on the legal liability of the different persons involved with the decision to withhold or withdraw medical treatment. **The effect of this uncertainty might either mean frequent recourse to courts by medical practitioners to secure approval for their decisions, or reluctance to withdraw treatment even when a competent patient has taken an informed decision.**

In either case, there is a real threat to the right of the patient to die with dignity.

The use of the term 'may' in sub-clause (1) of Clause 9 of the Bill does not provide clarity regarding conditions for withholding or withdrawing medical treatment. It states that 'any near relative, next friend, legal guardian of patient, the medical practitioner or para-medical staff generally attending on the patient or the management of the hospital where the patient has been receiving treatment or any other person obtaining the leave of court, *may* apply to the High Court having territorial jurisdiction for granting permission for withholding or withdrawing medical treatment of an incompetent patient or a competent patient who has not taken informed decision.'

The sense in which the term 'may' has been used in this provision is unclear. It might be the case that the Bill is mirroring the directions of the SC in *Aruna Shanbaug*, which would mean that 'may' has been used in the sense of 'shall', and *every* withdrawal of medical treatment from an incompetent patient must follow the procedure set out in Clause 9. This is undesirable for the reasons set out earlier while discussing Principle VI—access to a High Court is difficult in remote areas, judicial proceedings are lengthy and costly, and High Courts are already burdened. Additionally, in the event of consensus among the different

¹⁹ We have already made the point that the extension of Clause 9 to 'a competent patient who has not taken informed decision' is a violation of the right to autonomy. See Section B (3).

categories of persons specified in sub-clause (1) of Clause 9 regarding the withholding or withdrawal of treatment, an added layer of judicial approval appears entirely unnecessary.

Alternatively, even if 'may' is used in a discretionary sense, Clause 9 is still unclear regarding the circumstances in which the High Court ought to be approached for permission to withhold or withdraw treatment. **Ideally, judicial intervention ought to be called for only when there is disagreement among the different categories of persons specified in sub-clause (1) of Clause 9 regarding the withholding or withdrawal of treatment.**

Even in the case of disagreement, it is not desirable that the High Court be the forum of first resort, given the difficulty of access mentioned earlier. Instead, **we recommend that Ethics Committees be constituted at designated tertiary care hospitals, while making every effort to ensure that an adequate number of such hospitals are also designated in rural areas.** Like Ethics Committees constituted for clinical trials, these Committees also ought to comprise medical experts, lawyers, social workers and laypersons. These Ethics Committees should serve other hospitals within a specified radius.

When any person from among the categories specified in sub-clause (1) of clause 9 objects to the withholding or withdrawal of treatment from an incompetent patient who has not made a valid advance directive, the question ought to be referred to such Ethics Committee first. The Ethics Committee ought to make such decision in the best interests of the patient, keeping in mind that any evidence regarding what the patient herself would have desired will be relevant in determining her best interests.

If the Ethics Committee decides that the withholding or withdrawal of treatment is in the patient's best interests, its decision ought to be final. However, persons who disagree with the decision of the Ethics Committee may approach the High Court on narrow grounds: i) that the Ethics Committee has made a material error of fact; or ii) that the Ethics Committee made a *mala fide* decision.

KEY RECOMMENDATIONS FROM THIS SECTION

1. Due to the use of the word ‘may’ in clause 9 of the Bill, it isn’t clear whether it is discretionary or compulsory on the part of the categories of persons listed to seek the permission of the High Court before withholding or withdrawing treatment. It is recommended that such a provision be kept discretionary to minimise judicial intervention in the decision-making process. Such judicial intervention should be required only when there is disagreement among the categories of persons listed in the clause with respect to the treatment of an incompetent patient.
2. Further, it is recommended that Ethics Committees be constituted at designated tertiary care hospitals to act as a forum of first resort in case of disagreement as described above. Appeals may be allowed from the decision of the Ethics Committee to the High Court only on the narrow grounds of material error of fact or *mala fide*.



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