

## Review

# Ethics review: End of life legislation - the French model

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## Abstract

French law 2005-370 of April 22, 2005 (Leonetti's law) brings new rights to patients and clarifies medical practices regarding end of life care. This new law prohibits unreasonable obstinacy in investigations or therapeutics and authorizes the withholding or withdrawal of treatments when they appear "useless, disproportionate or having no other effect than solely the artificial preservation of life". Relief from pain is a fundamental right of patients. With regard to pain control, the law also allows doctors to dispense to patients "in an advanced or final phase of a serious and incurable affliction" anti-pain treatments as needed, even if these treatments, as a side effect, hasten their death. The drafting of advance directives regarding end of life constitutes a new right of patients. The decision to withdraw or withhold a treatment from a patient unable to express their will has to take into account the wishes they might have expressed through advance directives, and/or the wishes of a trusted person or, lastly, of the family. Before making any decision, physicians should respect a collegial medical procedure. Euthanasia defined as the act of terminating one's life on a patient's explicit request remains illegal.

## Introduction

Currently, medical care at the end of life is often driven by technology [1] and there is a widespread perception that intensive care at the end of life may represent excessive and inappropriate use of technology [2]. In American intensive care units (ICUs), it has been observed that most deaths are preceded by a decision to limit or withdraw life-sustaining care [3]. A European study conducted in 1999 to 2000 has shown that life support was limited in 73% of hospitalized patients and 10% of ICU admissions, but shortening of the death process remained rare [4].

Rationing of ICU admission according to survival benefits and to avoid unreasonable pointless obstinacy is critical to decrease undue ICU admissions. Allowing clear mandates

from patients about when to forgo life-sustaining therapy will also probably greatly decrease the proportion of patients admitted to ICU shortly before death [5]. The constantly increasing elderly population in developed countries will require more effective advanced care planning and augmented specific palliative capacity to care for dying patients [5]. Nowadays, the necessity to set limits on life support has become commonplace [2]. Avoidance of inappropriate care in the ICU is a major concern but remains a difficult goal to achieve, particularly in the absence of any consensual approach to end of life care. Fears related to judicial rulings also have a significant impact on medical practice [2].

In France, the LATAREA 1 survey conducted in 1997 has shown that 50% of deaths in French ICUs were related to a LATA (limitation ou arrêt des thérapeutiques actives) decision [6]; of the concerned patients, 75% were unable to express their will [6]. But before 2005 in France, the law did not allow such decisions and practices. This established fact justifies legal measures to frame the withholding and withdrawing of treatment in cases where poor quality of life is expected or in futile situations.

The case of Vincent Humbert, a young man suffering post-traumatic locked-in syndrome [7], and public opinion concerning end of life medical choices prompted a government initiative: the French Parliamentary Mission for Information on End-of-life Supportive Care was created in 2003. It was made up of politicians, jurists, ethicists, clergymen, ministers, physicians and caregivers involved in intensive care and palliative care, and representatives of civil society. After a 9-month inquiry, 60 statements by individuals, and a 600-page report, the Parliamentary Commission proposed a law on

ICU = intensive care unit.

**Table 1**

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**Selected articles of Law 2005-370 of April 22, 2005 relating to Patients' rights and to the End of life**

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**Article 1**

"The acts of prevention, investigation or treatment must not be continued with unreasonable obstinacy. When they seem useless, disproportionate or to have no other effect than solely the artificial preservation of life, they can be withheld or withdrawn. In that case, the doctor safeguards the dignity of the dying and ensures the quality of their life."

**Article 5**

"When a person is not in a condition to express their will, treatment limitation or cessation that could endanger their life cannot be realised without first respecting the collegial procedure defined by the code of medical ethics and without consulting the trusted person or the family or, failing this, one of their close relations and, if appropriate, the advance directives of the person. The motivated decision to limit or discontinue treatment is registered in the medical record."

**Article 6**

"When a person in an advanced or terminal phase of a severe and incurable affliction, whatever the cause, decides to limit or to stop any treatment, the doctor must respect their will after having informed them about the consequences of their choice. The decision of the patient is registered in their medical record. The doctor safeguards the dignity of the dying and ensures the quality of their end of life."

**Article 7**

"Every person of age can prepare advance directives in case they are one day in a condition that prevents them from expressing their will. These advance directives indicate the wishes of the person concerning their end of life and the conditions surrounding the limitation or stopping of treatment. They can be revoked by the person at any time.

Provided that they were established less than three years before the state of unconsciousness of the person, the doctor takes them into account for any decision about investigation, intervention or treatment regarding them."

**Article 8**

"When a person in an advanced or terminal phase of a grave and incurable affliction, whatever the cause, and in a condition that prevents them from expressing their will, has appointed a trusted person, the opinion of this trusted person, except in cases of emergency or when it is impossible to contact them, prevails over any other non-medical opinion, with the exception of any advance directives, in the decisions concerning investigation, intervention or treatment made by the doctor."

**Article 9**

"When a person in an advanced or terminal phase of a grave and incurable affliction, whatever the cause, and in a condition that prevents them from expressing their will, the doctor can decide to limit or to stop a futile or disproportionate treatment that has no other effect than solely the artificial continuation of the life of this person, having respected the collegial procedure defined by the code of medical ethics and consulted the trusted person, the family or, failing this, one of his close relations and, if appropriate, the advance directives of the person. The doctor's motivated decision is registered in the medical record. The doctor safeguards the dignity of the dying patient and ensures the quality of their end of life."

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"Patients' rights and the end of life" [8]. In April 2005, the French parliament unanimously passed law 2005-370 regarding end of life (the so-called Leonetti's law) [9]. The main items and key points of this law are discussed below (Tables 1 and 2). (Please note that the translations of Leonetti's law presented here do not constitute an official translation and have not been validated by the French authorities.)

## Preservation of human dignity

*"The doctor safeguards the dignity of the dying and ensures the quality of their end of life."* [9]

Despite the absence of a definition of human dignity, it is a general consensus in the medical world that the preservation of a patient's dignity and choices is a goal of paramount importance. Physicians and caregivers are, however, often unaware of a patient's last will and wishes regarding their end of life [10,11] and in these circumstances care may not be consistent with the patient's feelings and wishes [12].

Patients who are likely to die are at particular risk of having their dignity endangered and their will and preferences regarding end of life disregarded. In the absence of a

patient's will being clearly recorded, the risk of unsuitable or blurred decisions that lengthen the duration of the dying process is deemed to increase [13]. The preservation of patients' dignity is a constant concern of Leonetti's law and the commitment to this is repeated several times throughout it.

## Avoidance of unreasonable obstinacy

Article 1: *"The acts of prevention, investigation or treatment must not be continued with unreasonable obstinacy. When they seem useless, disproportionate or to have no other effect than solely the artificial preservation of life, they can be withheld or withdrawn."* [9]

Unreasonable obstinacy is the French equivalent of the Anglo-Saxon concept of futility. It is defined as a combination of pointlessness and disproportion in treatment given to a patient with regard to expected benefits. Its avoidance is a legal obligation required by Leonetti's law and a moral duty (the French medical deontology code, version 2006, Article 37 has integrated the law's first article) [14]. Doctors have then to weigh the burden and acceptability of a treatment against expected benefits before deciding to initiate or withhold it.

**Table 2****Decree 2006-120 of February 6th, 2006 concerning the statutory collegial procedure 2005-370 of April 22nd, 2005 relative to the rights of patients and at the end of life**

Article 1: the article R. 4127-37 of the Code of public health is replaced by the following amendments:

Article R. 4127-37, I: In all circumstances, the doctor must endeavour to alleviate the patient's suffering by means adapted to his/her state of health and assist him/her morally. He/she must refrain from any unreasonable obstinacy in his/her investigations or therapies and may stop undertaking or pursuing treatments which appear pointless, disproportionate or which have no other aim or effect than the artificial maintenance of life.

Article R. 4127-37, II: When the patient is unable to express his/her will, the doctor shall not decide to limit or stop ongoing treatments without having previously implemented a collegial procedure in the following manner:

"The decision shall be reached by the doctor treating the patient, after consultation with the care team if there is one and in concordance with the opinion of at least one other doctor, called in as a consultant. The motives for the opinion shall be made explicit. There must be no hierarchical tie between the doctor treating the patient and the consultant. The opinion of a second consultant shall be requested by these doctors if this is considered useful by one of them."

"The decision shall take into account: the desires which the patient may have expressed previously, in particular in his/her advance directives, if he/she has written any; the opinion of the trusted person he/she may have appointed; as well as that of the family or, failing that, of one of his/her close relations."

"When the decision concerns a minor or a person of full age under protective supervision, the doctor shall also ask for, depending on cases, the opinion of persons having parental authority or of the guardian, except in situations where emergency might make this consultation impossible."

"The motives for the decision shall be made explicit. The views provided, the nature and meaning of the consultations that took place in the care team, and the reasons for the decision shall be noted in the patient's record."

**Respect of patients' choices**

Article 6: *"When a person in an advanced or terminal phase of a severe and incurable affliction, whatever the cause, decides to limit or to stop any treatment, the doctor must respect their will after having informed them about the consequences of their choice. The decision of the patient is registered in their medical record. The doctor safeguards the dignity of the dying and ensures the quality of their end of life."* [9]

**Advance directives**

Article 7: *"Every person of age can prepare advance directives in case they are one day in a condition that prevents them from expressing their will. These advance directives indicate the wishes of the person concerning their end of life and the conditions surrounding the limitation or stopping of treatment. They can be revoked by the person at any time."*

*Provided that they were established less than three years before the state of unconsciousness of the person, the doctor takes them into account for any decision about investigation, intervention or treatment regarding them."* [9]

Advance directives are not legally binding and do not relieve doctors of their liabilities. This European attitude of a doctor's liability despite their patient's wishes is opposite to the American attitude where a patient's autonomy is the main criterion for decision making [15].

**The mandated trusted person**

*"Every person of age can appoint a trusted person, who can be a parent, a close relative or the family doctor, who will be*

*consulted in case the person is unable to express his/her will and to receive the information necessary to achieve this. This appointment is made in writing. It can be revoked by the person at any time. If the patient wants, the trusted person can accompany them and attend medical consultations to help them in their decision making."*

*During any hospitalization in a health establishment, it is suggested to the patient that they appoint a trusted person according to the conditions specified in the previous paragraph. This appointment is valid for the hospitalization time, unless the patient arranges it otherwise."*

*"The arrangements of the present article do not apply when a measure of guardianship (protection) is ordered. However, the judge supervising a guardianship case can, when a trusted person has been previously appointed by the patient, either confirm the appointment of the previously indicated trusted person, or revoke their appointment."* [16]

Article 8: *"When a person in an advanced or terminal phase of a grave and incurable affliction, whatever the cause, and in a condition that prevents them from expressing their will, has appointed a trusted person, the opinion of this trusted person, except in cases of emergency or when it is impossible to contact them, prevails over any other non-medical opinion, with the exception of any advance directives, in the decisions concerning investigation, intervention or treatment made by the doctor."* [9]

According to Leonetti's law, the trusted person is not a surrogate decision-maker because the burden of medical

decisions is thought to remain with the physician in charge of the patient and not with the relatives. The trusted person is rather a witness who reports a patient's point of view and wishes regarding their end of life if the patient is unable to do so. The law specifies that the opinion of the trusted person prevails over any other non-medical opinion, unless advance directives have been drawn up by the patient.

Any decision of treatment cessation must be accompanied by appropriate palliative care, especially if the assessment of suffering is rendered difficult by the neurological status of the patient.

The law acknowledges the validity of the will of conscious and capable patients to refuse life-saving treatment. A patient's decision must be constant and repeated after "a reasonable time lapse" to enable the medical team to be confident in it. In this case, treatment includes mechanical ventilation, dialysis and artificial nutrition. For this reason, emergency situations are outside the scope of the law. In every case of treatment cessation, care must be given to ascertain that the patient's suffering is appropriately treated.

## Improvement of communication and consensuality

Article 5: *"When a person is not in a condition to express his will, treatment limitation or cessation that could endanger their life cannot be realised without first respecting the collegial procedure defined by the code of medical ethics and without consulting the trusted person or the family or, failing this, one of their close relations and, if appropriate, the advance directives of the person. The motivated decision to limit or discontinue treatment is registered in the medical record."* [9]

Article 9: *"When a person in an advanced or terminal phase of a grave and incurable affliction, whatever the cause, and in a condition that prevents them from expressing their will, the doctor can decide to limit or to stop a futile or disproportionate treatment that has no other effect than solely the artificial continuation of the life of this person, having respected the collegial procedure defined by the code of medical ethics and consulted the trusted person, the family or, failing this, one of his close relations and, if appropriate, the advance directives of the person. The doctor's motivated decision is registered in the medical record. The doctor safeguards the dignity of the dying patient and ensures the quality of their end of life."* [9]

Prior studies have shown a high level of anxiety and depression among family members of critically ill patients [17], a significant burden of symptoms of post-traumatic stress disorder among family members [18], and a significant amount of conflict within the ICU team or between the team and family members around issues of withdrawing life support [19,20]. High degrees of conflict or unresolved

conflict may severely lower end of life care quality and even lead to legal issues.

A major means to gain acceptance of strategies to limit treatment is to improve communication within the clinical team and between the team, the patient if possible, and their family [21,22]. Optimal quality of inter-individual communication is critical not only during the process of decision-making to withdraw life-sustaining therapies, but also after the decision is made, to provide the best help to relatives [23]. Several topics should be covered with family members, including explanations of how the patient's comfort will be ensured, the patient's probable length of survival, the continuation of some care by the clinical team, and family or patient preferences concerning spiritual needs [23,24].

## Collegial decisions

*"The decision shall be reached by the doctor treating the patient, after consultation with the care team if there is one and in concordance with the opinion of at least one other doctor, called in as a consultant. The motives for the opinion shall be made explicit. There must be no hierarchical tie between the doctor treating the patient and the consultant. The opinion of a second consultant shall be requested by these doctors if this is considered useful by one of them."* [25]

Goals of paramount importance are to prevent the possibility of a self-fulfilling prophecy regarding a patient's prognosis, to prevent emotional judgements about the foreseeable disability of a patient, and to prevent decisions about treatment limitation being the choice of just a single physician. It is also of paramount importance to rightly differentiate physician-perceived disability from that experienced by the patient himself. The European guide to medical ethics, decreed in 1987, states in its fourth article: "The physician cannot substitute his own conception of the quality of life for that of his patient." [26]

The collegial procedure indeed involves an independent corroboration of the diagnosis and prognosis. The essential purposes are threefold: to avoid the possibility of an auto-confirmed prediction regarding the prognosis of the patient (self-fulfilling prophecy); to prevent a doctor from making solely emotional judgements about the foreseeable disability of a patient; and to give the patient and their family a guarantee that at least two independent doctors have judged the treatment as unreasonable. Decisions made outside a collective framework could result in undue limitation of treatment. The care-giving team must be consulted during the decision-making process and informed of the final decision.

If a consensus between the medical/care-giving team, the family and/or the trusted person is not reached, the treatment limitation procedure should be postponed or aborted, although this is not a legal obligation. Despite the collegial

nature of the procedure, the doctor in charge of the patient remains liable for the final decision.

### Limiting care not related to providing comfort

The spirit of the law is to allow removal of treatments that are no longer wanted by the patient or reasonably indicated and that do not provide comfort to them. If the patient is unconscious, whether they are at the end of their life or not, the procedure of limitation or arrest of treatment has to satisfy three requirements: respect of the individual will of the patient; dialogue and medical collegiality; and traceability of all decisions in the medical record. The decision to withdraw life support as well as the rationale for this decision should be documented in the medical record, as well as the reasons for increasing sedation or analgesia if needed. Adequate analgesia and sedation should remain a priority in this setting.

### Double effect concept

Acknowledging the fact that end of life care may sometimes include a grey area between treatments administered to relieve pain and suffering and those intended to shorten the dying process, possibly entailing legal issues [27], French legislators have allowed doctors to increase the dose of sedatives and/or analgesic drugs to relieve patient suffering even if doing so might shorten a patient's life, provided that the patient or the family are informed and that shortening of the patient's life is not the goal but only a possible side effect of the therapeutics. This concept has already been stated in other countries, especially the UK.

### Development of palliative care

Article D. 311-38: *"When a general care project is planned for the application of the institution's or service's project as mentioned in Article L. 311-8, it shall define all measures ensuring the palliative care required by the state of health of patients, including specific personnel training plans."* [28]

Leonetti's law seeks to develop a palliative care culture by concurrently detailing the legal requirements of doctors and introducing an obligation to increase palliative care capacity. This obligation to acquire the capacity to provide palliative care has been extended to the medico-social establishments providing accommodation for the elderly, and to the healthcare establishments providing long-term care [9]. Public funds have been allocated to support these new obligations.

### Discussion

Attitudes towards end of life care are very diverse among the countries of the European Community [29,30]: the Netherlands, Belgium and Switzerland [31] have legalized euthanasia; the UK has endorsed a patient's or their family's autonomy, similar to in the US but without any clear legal position on a doctor's rights when facing an incompetent patient [32]; and Germany has acknowledged advance directives and allows passive and indirect assistance to die

[33,34]. The European tradition clearly keeps doctors liable for final decisions regarding end of life care.

In France, Leonetti's law is aimed at improving end of life care in several ways: by reducing the "prolongation of dying"; by legalising decisions to forego life-sustaining treatments; by promoting strategies to improve patient comfort and palliative care to alleviate patient suffering; by decreasing psychological distress for family members and reducing conflicts among ICU team members and between team and family members; and by reducing the number of concealed euthanasia procedures and subsequent feelings of guilt. Many people involved in end of life situations claim that the approach used in hospitals has not really changed since the introduction of this law, and there is, therefore, an urgent need to evaluate the impact of the law on medical practice, particularly with regard to incompetent or unconscious patients (that is, in the context of the collegial decision-making process and advance directives). At the initiative of the French parliament, this evaluation is now in progress. Besides this, a survey initiated in 2005 throughout the whole country pointed out the fact that palliative care in France is not developed enough to allow real application of Leonetti's law [35].

In France euthanasia remains illegal, although particular cases periodically make the front pages of publications in support of demands for an extension of Leonetti's law towards the legalisation of euthanasia, and public debate is ongoing.

Aspects of modern end of life care should include patient involvement and appropriateness of care. Towards this, we first need a change in medical culture that Leonetti's law enables.

### Conclusion

Leonetti's law institutes a method of care that involves: the constant seeking for consensus; the purposeful choice of options; condemnation of unreasonable therapeutic obstinacy and the right of patients to object to it. It also affirms principles, including: respect of patients' will; the need to confer with patients, and their relatives and caregivers; medical collegiality; and the expansion of palliative care [36]. In passing this law, the French Parliament pursued essentially two objectives: to acknowledge a patient's right to oppose unreasonable obstinacy; and to delineate good medical practices, both when a patient is conscious or unconscious, and whether or not they are at the end of life [36]. The main change it introduced is the possibility for physicians in France to withhold or even withdraw life support for unconscious patients.

### Competing interests

The authors declare that they have no competing interests.

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