Commentary

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Rules on informed consent and advance directives at the end-of-life: the new Italian law

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Abstract

Background. End-of-life decisions are an emergent issue for bio-ethical debates and practical concerns among health professionals.

On December 2017, Italy enacted a new law named "Rules about informed consent and advance directives", which promotes the relationship of care in a fiduciary sense through the implementation of a correct and exhaustive information. It is also prescribed to record in writing all the patients' decisions about consent or refusal. Furthermore, the law explicitly forbids unreasonable therapeutic obstinacy for terminal patient, legitimizing deep palliative sedation.

Finally, the law establishes the use of "advance directives" as a written document by which adults and capable people can express their wishes regarding health treatments and diagnostic tests in anticipation of a possible future incapacity. The law provides that doctors must comply with these directives, unless they appear clearly incongruous or not corresponding to the patient's current clinical condition. ***Clin Ter 2020; 171 (2):e94-96. doi: 10.7417/CT.2020.2195***

Key words: *bioethics, palliative care, treatment planning, advance directives*

Introduction

On the 14th of December 2017 Italy enacted a new law entitled: "Rules about informed consent and advance directives". The last vote in Senate ended with 180 deputies in favor and only 71 against. Rather than other Countries in the world (1,2,3), Italy had not adopted any specific regulation in the field of end-of-life, yet. Nonetheless, in recent years, the scientific and political debate, together with the attention of the public, have been catalyzed by some events in the news. The most emblematic case is probably that of Eluana Englaro (4), but the most recent one has been the case of Dj Fabo. He was affected by an acquired post-traumatic tetraplegia and,

after unsuccessfully attempting experimental therapies, finally decided to freely access to euthanasia abroad, in Switzerland (5).

These and other similar ones were the occasion for a fervent debate on the legitimacy of euthanasia (6), on the right of the terminally ill patients to their decision-making autonomy (7), as well as on the legal value of the "living wills" (8). The approval of the current law was the arrival point of a long legislative process that began and gradually matured on the thrust of this common feeling.

The provisions of the law

Article 1 is dedicated to the regulation of informed consent and refusal of treatment. The article states that no medical treatment can be initiated or pursued without the free and informed consent of the person concerned, except in cases expressly provided for by law (9,10). This assumption recalls the principles enunciated in the constitution and in the Charter of the Fundamental Rights of the European Union. These are, in particular, the rights to life, health, dignity and self-determination of the person (articles 1,2,3) (11).

The intent of the legislator is the promotion and enhancement of the relationship of care between patient and doctor in a fiduciary sense. The basis of this relationship is the informed consent that allows the patient's autonomy to be satisfied on the one hand, and the professional competence and responsibility of the doctor on the other.

The information to which the patient is entitled concerns not only the simple health conditions, but the updated and comprehensible details on diagnosis, prognosis, benefits and risks of the diagnostic tests and health treatments indicated for his condition, as well as the possible alternatives and the consequences of a possible refusal. A further new feature is found in the explicit and precise reference to all those who contribute to the care relationship: all the health providers and any other person that is involved in health care; the patient; anyone else close to the patient that he wants to involve in the right to be informed. The patient may even refuse to receive information about him directly and appoint a trusted person for him (12).

In order to exclude future grounds of liability, the law provides that consent is recorded in writing or documented through video recordings or by other means that reflect the

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patient's effective communication skills. Even the case of renunciation of information with indication of a person in charge must be noted in the medical record.

Beyond these even if opportune clarifications the most innovative brought of the article is contained in the explicit classification of the hydration and artificial feeding as health treatments and, as such, possible object of free rejection by the patient. It is evident that the legislator shares the opinion of those who consider these procedures as any other medical treatment, because they are administered on prescription for health reasons and through special devices (13).

In case of renunciation or refusal of treatments necessary for survival, the physician is obliged to communicate the consequences of this decision and the possible alternatives, avoiding the patient's abandonment but on the contrary resorting, where necessary, to dedicated psychological assistance services. To enforce the obligation for the doctor to abide by the will expressed by the patient, the law explicitly excludes any professional liability that could derive from it, both in criminal and civil matters. The literal interpretation of the text, therefore, should allow to overcome some objections about the effective observance of the patient's wishes that have been raised elsewhere (14).

The law contains not only provisions in favor of patient self-determination. In fact, it states that no one can demand treatments contrary to the law, professional ethics and good practices. In case of a state of need, then, the doctor and the rest of the health team ensure the necessary care, respecting the patient's will if able to express it. In analogy to the provisions of the code of medical deontology, it is claimed that the time dedicated to communication enters to all effects in the treatment time. The latest provision on informed consent constitutes the obligation for health authorities to comply with the law, including through the training of staff on communication, pain therapy, palliative care.

Article 2 of the law regulates the treatment of pain and the prohibition of unreasonable therapeutic obstinacy for the protection of the dignity of the person until the final stage of life (15-17). In this regard, the law establishes that the doctor, using appropriate means, must alleviate suffering even in case of refusal of the indicated treatment, ensuring appropriate pain therapy. In the event of a poor prognosis or a terminal patient, the doctor must avoid using unnecessary or disproportionate treatments. The legal text openly legitimizes the use of continued deep palliative sedation (18) in the presence of valid consent, when clinically indicated (19). This constitutes a fundamental prerequisite for assigning the right value to the provisions of the following article 4 on advance directives (20).

Article 3 is entirely dedicated to the underage and less capable. It is established that both have the right to see enhanced their ability to understand and decide, thus receiving information which is appropriate to their possibilities so as to express their will. Informed consent to the child's medical treatment is expressed or refused by the parental or tutorial responsibility taking into consideration the will of the minor in relation to age and degree of maturity and having as its purpose the psychophysical health and life of the child in full respect of his dignity. In the event of dissent between the tutor and the doctor the decision is left to the tutelary judge (21).

Article 4 concerns advance directives and it is the central core of the law. In this way, Italy aligns finally with the other progressive countries, which have already implemented the safeguard of modern human rights in the field of "biolaw". It establishes that in anticipation of a possible future incapacity to self-determination and after acquiring adequate medical information on the consequences of their choices, adults and capable persons can express their wishes regarding health treatments as well as the consent or the refusal with respect to diagnostic tests or therapeutic choices and to single health treatments (22). Moreover, it is necessary to appoint a fiduciary, any adult and capable person, who represents them with the doctor and health facilities. The fiduciary accepts the appointment by signing living wills and receiving a personal copy; he may renounce the appointment by written act and his appointment may be revoked at any time even without justification.

Then, the doctor must respect living wills. They may be disregarded, in whole or in part, by the doctor himself, in agreement with the fiduciary, "if they appear clearly incongruous or not corresponding to the patient's current clinical condition or subsist therapies not foreseeable at the time of subscription, able to offer concrete possibilities of improvement of living conditions ."

In case of a conflict between the doctor and the fiduciary, the judge decides. The living wills must be drafted in precise and registered manner; if necessary they can be also videotaped.

This law is complemented by the importance of care planning as established from the article 5. In case of chronic and invalidating pathology or in case of pathology with poor prognosis, in fact, patient and physician can plan the treatments to which all the caregivers must be observed in case of future loss of capacity. In particular, the following must be clarified: the possible prognosis, the future quality of life, the clinical possibilities to intervene and possible palliative care. Also in this case the patient can indicate a fiduciary. Both this indication and the consent of the patient must be expressed in writing or, if it is not possible, through video recording or alternative devices. Such different manifestations of will once again must be included in the medical record and in the electronic file. The care planning can be subject to continuous updating.

The last 3 articles of the law introduce normative elements of harmonization with the remaining legal system. Article 6 provides for a transitional provision that also the advance directives deposited before the entry into force of the law are subject to the same legislation. In Article 7, however, the financial invariance clause is expressed, so that the new law does not lead to an increase in public spending. Finally, article 8 contains the obligation for the Ministry of Health to provide an annual report on the application of the law, on the basis of data collected through the intermediation of local administrations (regions).

Since the commencement of the law, there have been different ruling from the Italian Corte Costituzionale. The most recent ruling by this institution reiterated the constitutional legitimacy of law 218/2017 (23). Specifically, it was stated that the institute of the support administration provides for the possibility of the administrator to exercise exclusive representation in the health sector and consequen-

tly also the power to refuse the health treatments necessary for maintenance in life.

Conclusions

The law "Rules on informed consent and advance directives" is a good law and introduces interesting novelties in the field of healthcare assistance in Italy.

As often happens when commenting on a law on a topic so socially controversial, it could be said that it lacked the courage to define more fully the "end of life" since it did not want to intervene, in a Catholic State, on thorny issues such as assisted suicide and euthanasia.

But a step forward on the valorization of the patient's self-determination even at the end of life has been accomplished, now to the Italian doctors the task of applying with science and conscience what the law provides.

In conclusion, looking at the objectives of this study, new ruling on this law confirm its valency as a new decision-making tool for bioethical issues that could be relevant from the medico-legal point of view (24-27).

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