Abstract

The paper’s authors aim to elaborate on law 22 dicembre 2017, n. 219, designed to regulate informed consent practices and advance health care directives", which has sparked a passionate debate centered on the substantial innovation achieved over the past decades in biomedical science and at the same time, the noteworthy accomplishments made in enforcing human and personal rights. Within the paper, article three is delved into, which covers the creation of the so-called DAT ("Disposizioni anticipate di trattamento", advance health care directives), by which patients, in light of possible future incapacity to choose, can express their convictions and decisions on how to be treated and their consent or dissent to undergo treatments and procedures, including artificial nutrition and hydration. The authors peruse the new law’s provisions through a medical perspective, and observe how they are heavily tilted towards patient choice, thus making doctors little more than mere tools of such decisions. Clin Ter 2018; 169(2):e77-81. doi: 10.7417/CT.2018.2058

Key word: living will, advance directives, informed consent, principle of self-determination, Italian legislation

Introduction

Over the past few years, the debate on advance health care directives has raged on the print press, TV networks, as well as in the Italian Parliament, on the heels of highly emotional and widely covered cases that have all but engrossed the attention of legal scholars and of the public at large. Cases such as Englaro (1), Welby (2), Monicelli (3) immediately come to mind, and the events surrounding the Walter Piludu (4) and Fabiano Antoniani (a.k.a. djFabo) (5) cases. Over the past four decades, a culture of autonomy and self-determination has asserted itself, coupled with ever greater attention to patients viewed as individuals, to their wishes and their judgment (6). Furthermore, in the past decades, the breakthrough discovery of new molecules has significantly enhanced human cognitive abilities,(7), but above all, medical technologies have made unprecedented giant strides; medically assisted procreation techniques (8), critical care, organ transplants that pose thorny issues of clinical and bioethical nature, (among which uterine transplant) (9,10), instrumental diagnosis technologies capable of affording valuable opportunities in all fields of medicine, in order to fulfill diagnostic pathways and better define therapeutic interventions (11) have positively affected people’s lives, and resulted in longer life expectancy rates. Nonetheless, along with valuable technological advancements, the rate of hospital-acquired infections has substantially increased as well (12,13). Such an evolution has had the unintended consequence of creating new issues related to patient conditions, terminal ones especially, and on the other hand, to the role of doctors and health care providers (14). The study titled Norms relative to informed consent and advanced directives is centered on the new piece of legislation, and is meant to stress that doctors are themselves an integral part of the “trust and care-based relationship” (art. 1, subsection 2). The law leaves in fact no room for the exercise of “conscientious objection” on the part of doctors that consider it against their principles to actively become part of a process that will inevitably result in a patient’s death, even through omission.

Advance health care directives: the Italian situation

The living will, in its various denominations (personal directive, advance directive, medical directive or advance decision, Durable Power of Attorney for Health Care) is a tool designed to ensure that patient volition is complied with. According to the definition set forth by the Italian National Bioethics Committee, “living will” is characterized as an array of directives through which someone, while retaining their full mental capacity, expresses their will as to the medical treatments that they agree, or disagree, to undergo in case they should become incapacitated, as a result of disease or sudden trauma, to grant or deny their informed...
consent” (15,16). It was legally introduced in the United States of America in 1991.

Recently, several European nations (such as France, through Law 2016-87 2nd February 2016; Germany, with a law amending the BGB, on 18th June 2009; England, by the Mental Capacity Act 2005) have regulated such practices by means of new legislation. In Holland, Belgium and Luxembourg, euthanasia can be legally resorted to. Outside of Europe, living wills legally regulated in several US states, Canada and Australia, where advance directives are regulated by two pieces of legislation dated 1998 and 2000.

Law n. “Norms relative to informed consent and advanced directives”(17)

From a legislative vantage point, there are references as to advance directives; it is worth mentioning, in that regard, law n. 145 from 28th March, 2001, by which Italy has ratified the 1997 Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Oviedo Convention) (18) which states, in article 9, that “the previously expressed wishes of Biology and Medicine (Oviedo Convention) (18) which Dignity of the Human Being with regard to the Application of Biology and Medicine (Oviedo Convention) (18) which states, in article 9, that “the previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account”.

Article 3 of the Charter of Fundamental Rights of the European Union, solemnly proclaimed on 7th December 2000 in Nice, spells out that “Everyone has the right to respect for his or her physical and mental integrity”, and that “In the fields of medicine and biology, the following must be respected in particular: the free and informed consent of the person concerned, according to the procedures laid down by law” (19). Article 3 of law n. 219 from 21st October 2005 (new discipline of blood transfusion services and the national production of hemoderivatives), (20) and article 6 from law 40, 19th February 2004 (regulations for medically assisted procreation procedures) (21,22), and article 33 from law 833, 23rd December 1978 (Institution of the National Health Care Service), plainly state that patients must be informed as to the therapeutic pathways to be undertaken, and treatments must be administered on a voluntary basis, i.e. no one can be compelled to undergo any treatment if not lawfully mandated. The Italian Code of Medical Ethics itself, in articles 32 and 33 contemplates and regulates the patient’s informed consent procedures - or the patient’s legal guardian - as a necessary requirement for the legal implementation of diagnostic and therapeutic activities from doctors. Therefore, an individual’s right to self-determination when making medical decisions is well-established, as well as the right to turn down any treatment (23-25).

The bone of contention in the ongoing debate is article 32 of the Italian Constitution, which characterizes health as a fundamental right of the individual and as a collective interest (subsection 1), stated that no one may be obliged to undergo any health treatment except under the provisions of the law (subsection 2) and that the law may not under any circumstances violate the limits imposed by respect for the human person (subs.3). The Constitutional Court itself has ruled that “informed consent is grounded in principles expressed in articles 2, 13 and 32 of the Italian Constitution, which assert, respectively, that «personal freedom is inalienable», and that «no one may be obliged to undergo any health treatment except under the provisions of the law».

Over the past years, the Italian legislative branch has debated a variety of bills seeking to regulate advance health care directives, which have been substantially amended, revised and merged, but never translated into law. Lastly, the Italian parliament has enacted law carrying “norms relative to informed consent and advanced directives”. The new piece of legislation is subdivided into two parts: a more general one, centered on health care treatments and one about the lay-out of advance health care directives (26). It is made up of 5 articles, which are worth mentioning in detail.

Article 1 promotes and enhances the patient-doctor relationship based on care, trust and informed consent. All doctors making up the medical team contribute to such a relationship (5) and, as the patient sees fit, family members including partners in civil unions, i.e. trustworthy people from the patient’s perspective (subs.2). In subsection 3, the article reiterates the object of informed consent, and specifies that any individual “has a right to be informed of his or her health conditions in a thorough and understandable fashion as to the diagnosis, prognosis, risks an benefits associated with diagnostic procedures and indicated treatments”, and “the possible alternatives and the consequences of turning down any given treatment or diagnostic testing” (subsection 3). By all means, patients are entitled to turn down completely or partially (27) the information provided to them, entrusting family members or any other person of their choice with receiving it and possibly expressing consent on their behalf.

Subsection 4 mandates that consent be expressed in writing. If the patient’s physical conditions make that impossible, videotaping may be resorted to. Such an option should be documented in the patient’s medical record and the electronic health care file.

In addition to that, the bill mandates that in emergency situations, doctor ought to ensure a necessary degree of care, provided that it does not conflict with the patient’s will, whenever possible. Refusing or forgoing any indicated treatment may not result in the discontinuation of a therapeutic pathway. (co.8) (28).

Subsection 9 is administrative in nature, and views any communication between doctors and patients as provision of care. Subsection 10 establishes that health care facilities, whether public or private, must guarantee the thorough implementation and application of all legal provisions, according to their organizational standards, making sure that the proper information is provided to patients and that personnel is adequately trained.

Article 2 extends the option to grant informed consent to parents, or legal guardians of minors or incapacitated adults. All of the above mentioned have a right to “the acknowledgement of their cognitive skills and decision-making capabilities, and are entitled to be informed about the choices made in relation to their health in a way befitting their capabilities and to express their own will”. (subs.1)

The cornerstone of the new legislation is article 3, which covers the contentious and widely debated issue of advance health care directive, and asserts that: “Every mentally capable adult, foreseeing possible future conditions of in ability
to exercise their right to self-determination, may express his or her convictions and preferences on the health care treatments to be administered, or the refusal of therapeutic choices or single treatments, including artificial nutrition and hydration, through advance directives. Moreover, they may appoint trustworthy individuals (“trustees”) to make such decisions on their behalf and to act as their representatives in their interactions with doctors or health facilities. Only mentally capable adults may be appointed trustees.

Advance directives must be in writing, dated and undersigned in presence of a public official, a doctor and two witnesses, or through electronic communication devices. Subsection 6 further adds that advance directives may be renewed, amended or voided at any time and in writing. Lastly, the trustee’s declaration of acceptance is provided by signing on to the directives, or by a following statement in writing, later added to the directives. Revocation must be expressed in writing (subs. 2).

Doctors must comply with their patients directives. However, they may disregard such directives in cases they were blatantly unsuitable, or if new therapies were available, which were not when the directives were signed, that could possibly enable real improvement in life conditions” (subs.5). All of that would not result in medical liability, even though patient will had been disregarded.

Regions that use electronic patient records or medical files may regulate the gathering of advance directing through the application of their own procedures, including appointments of trustees, for storage in regional databases. Patients may still choose whether to produce a copy or indicate where to find it.

Article 4, named “shared treatment planning” centers on the unfolding clinical relationship and extends the notion of informed consent to include disease development as a whole. (29) It entails the obligation for doctors to inform their patients and their relatives as to “the likely development of the disease and what to expect in terms of quality of life, clinical opportunities for intervention, palliative care” (subs. 2), as well as honoring their patients’ will even in cases where the latter may be incapable of granting their consent or in any other condition of incapacity” (subs.1) (30).

Patient consent must be documented in medical records or medical files.

Should the doctor disregard his or her patients’ will, that would be grounds for malfeasance charges, as laid out in article 1, subsection 7, which plainly states that “doctors must abide by their patients’ will, and by virtue of such compliance, they are exempted from civil or criminal liability”.

Lastly, art. 5 of the new law, named “transitional norms”, deals with the issue of those statements that have been entrusted to a notary or to city authorities, to which “the same opportunities for intervention, palliative care” (subs. 2), as well as honoring their patients’ will even in cases when the latter may be incapable of granting their consent or in any other condition of incapacity” (subs.1) (30).

Patient consent must be documented in medical records or medical files.

The first critical aspect shows up in the title: «advance health care directives», in which the term «declarations» used in previous bills far less binding for doctors, has been replaced by «directives».

In fact, the term “declarations” points to a document drafted by patients that doctors must take into account, without being compelled to apply it to the letter. The term directive, on the other hand, binds doctors to abide by their patients’ decisions.

Medical practice has been founded for centuries upon the principle of beneficence and identified with the preservation of patients’ lives and their psycho-physical integrity, in addition to the care and abatement of their sufferings. Instead, the bill in question would make informed consent the centerpiece of the doctor-patient relationship, thus the doctor’s main concern. Often times though, the amount of time devoted to “informed consent” is incompatible with medical decisions often made within a few minutes’ time. For instance, the case of a vigilant patient in an emergency room who urgently needs surgery. Two possible scenarios may come into being: the doctors, according to the law’s provisions, stops to thoroughly expound upon the patient’s clinical situation and on the procedure to be made, in order to get his or her informed consent. Meanwhile, as time goes by, the doctors has not initiated all the procedures that are routinely performed in such cases. Such behavior may compromise the patient’s health, or even cause his or her death. Another scenario would see the doctor quickly providing cursory information and go forward with the necessary surgery in order to save the patient’s life. However, such behavior may cause the doctor to be held legally liable, since he or she failed to get the informed consent as mandated by the new draft bill’s provisions. Although article 1, subsection 8, clearly states that “in emergency situations, doctors must provide necessary, life-saving treatment, in conformity with their patients’ will, whenever possible”, said article fails to mention what procedures should be put in place in order to assess urgency. Hence, if patients and/or trustees and/or family members are dissatisfied with the care provided, they may file a suit that might result, in either case, in the doctor’s conviction. An additional situation may take shape: an unconscious patient who left directives years before to suspend treatment in case of a disease with a potentially deadly outcome. In the meantime, new therapies and medicines may have been developed, which could possibly combat the disease with high chances of success. Two scenarios might arise: if the doctor fully complies with the patient’s will, thus letting him or her die, he or she might be sued according to tort law, or be held criminally liable by the trustees and/or family members who will cite his or her failure to apply the latest, more effective therapies. On the other hand, should the doctor disregard the patient’s advance directives and treat him or her according to the new techniques, he or she could be held responsible all the same: recovery may not happen, and the patient might turn out disabled and his or her directives were not complied with (31) Any reference to a trustee do not necessarily shield doctors from liability. Trustees may in fact be unavailable at the time the emergency takes place. Insurance coverage could be equally ineffective. Insurance companies, in fact, do not pay based on a compensation request, but start a probe, and if it turns out that the doctor failed to honor the patient’s directives, coverage is very likely to be denied (32-33).

One more critical point is the possible failure to resort to conscientious objection (34), which make doctors bound to their patients’ will, with no ability to mediate through
their medical expertise for any treatment. It is the authors’ view that there is no real pressing need for new legislation on patient consent to care, treatments and therapies to be administered to terminal patients: instances of conflict between the abandonment of therapy and futile medical care can be solved through the application of the principles enshrined in the Code of Medical Ethics and the Oviedo Convention, which clearly states that a patient’s wishes with regard to medical treatments and therapies “shall be taken into account”. Several provisions within the new draft bill that the authors have eviscerated herein run counter to the very same principles that inspire the Code of Medical Ethics, which states in article 4 that “doctors in the exercise of their profession are inspired by the principles and rules of medical ethics without being subjected to special interests, impositions or external influences of any nature”.

For the first time, lawmakers encode in the Italian legislation the principle of “availability” of human life, which has been asserted over the past decades via judicial interventions. On the contrary, the principle of “unavailability” of human life is enshrined in the Italian Constitution, in the civil code (article 5 forbids any act meant to dispose of one’s body) and in the criminal code, which punishes the homicide of any consenting individual and the instigation and aid to commit suicide.

Conclusions

Provisions within the law appear to be heavily tilted in order to favor patients, making doctors, who ought to act according to science as well as their conscience, into little more than executors of their patients’ will. Thus, the doctor-patient relationship morphs into a contract-based, commercial relationship, characterized by a total lack of reciprocity. In our estimation, the new legislation should have introduced clear directives aimed at preventing judicial intervention from being necessary; on the contrary, in its current form, the bill would favor it, owing to its confused and inconsistent set of norms.

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