Informed Consent and Advance Care Directives: Cornerstones and Outstanding Issues in the Newly Enacted Italian Legislation

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Abstract

This article's authors delve into, and comment on, some of the key provisions within law no. 219, passed in 2017, which came into full effect in 2018. The legislation presents several innovative aspects: (a) communication time is equated to care; (b) patients may turn down lifesaving treatments, yet doctors must put in place all suitable support processes, from a psychological standpoint as well, in order to make sure that patients make informed decisions in full awareness; (c) refusal to treatment may be expressed prior to the onset of the disease making the patient incapable, as long as the advance directive is laid out by a mentally capable adult who has been provided with all relevant medical information available as to the consequence of a refusal to undergo a given treatment; (d) artificial nutrition and hydration are tantamount to treatment; thus, they may not be carried out and kept in place in absence of valid consent; (e) patients may appoint a healthcare proxy holder, tasked with interacting with doctors and caregivers and expressing consent or refusal; (f) patient will, whether current or advance, must be complied with even under emergency or urgency conditions, provided that clinical conditions and circumstances make it possible to acquire it; (g) doctors may disregard advance directives only when specifically provided for by the law; (h) patients may not demand treatment deemed to be illegal or running counter to ethical codes or scientific evidence. The new legislation, therefore, is meant to uphold the right to exercise self-determination as well as the patient's quality of life, yet ensuring that doctors remain fully capable of making the decisions that they are best positioned to.

Summary: The Italian Parliament has for the first time regulated the issue of consent and refusal of healthcare treatments, whether currently expressed or advance. This article elaborates on recent Italian legislation that details a patient's right to consent to or refuse treatment in advance, including refusal of artificial nutrition and hydration, the duty of doctors in the event of an emergency, the shared planning treatment, the role of durable power of attorney, and advance healthcare directives.

Keywords

Advance care planning, Advance healthcare directives, Current refusal, Healthcare treatment, Informed consent, Italian law, Palliative care

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End-of-life quandaries have come to the fore in dramatic terms over the past thirty years. Technical and scientific advancements in medicine, which mainly took place in the latter half of the twentieth century, have led to the widespread use of instrumentation designed to support irretrievably damaged vital functions—mechanical ventilation, artificial feeding, cardiovascular support, dialysis—that have managed to postpone the time of one's death (Bertolini et al. 2012; Van Der Heide et al. 2003). Such ever more advanced tools have given rise to a sort of middle ground between life and death that upset and subverted the very meanings of life and death, encompassing moral, philosophical, religious, and legal issues.

Since the 1980s, the Italian legal framework has moved past the model that ascribed to doctors all of the decision-making capabilities in regard to the choice of healthcare treatments. The so-called therapeutic privilege has been called into question as well, which enabled doctors to treat patients even against the latter's will. Such a turn of events has further evolved with the enactment of law 22, on 22nd December 2017, no. 219.

Informed Consent as the Cornerstone of the Medical Profession

Thirteen draft bills have been set forth since 2004 (Casini et al. 2007), but no sooner than December 22, 2017, did the Italian Parliament enact law no. 219 ("Norms Regulating Informed Consent and Advance Treatment Directives"), which came into force on January 31, 2018 (Law 22 December 2017, no. 219). The new legislation has drawn upon legal solutions (Constitutional Court no. 438/2008),¹ founded on constitutional principles and international treaties and conventions² that have codified the voluntary nature of healthcare treatments and the participation of patients in those decisions that are closely linked to their health and the medical procedures to be performed on them (Borsellino 2015). The law is meant to govern the standards of legitimacy, the proper ways of expressing and revoking informed consent and advance healthcare directives, that is, the statements, in writing, by which the undersigned spells out his or her views on end-of-life scenarios, in case they should become irreversibly mentally incapacitated.

Specifically, in article 1, legislators make informed consent rather than the medical profession itself, the bedrock of the doctor–patient relationship.

The latter has in fact an authentic ethical and altruistic value, which is not limited to the mere freedom to exercise self-determination. Doctors often find themselves having to act on unconscious patients who have never signed any advance directives. Informed consent is grounded in the principles laid out in article 2 of the Italian Constitution, which upholds fundamental rights, and in articles 13 and 32 of the same chart, which assert that personal freedom is inviolable and no healthcare treatment may be started or carried forward if free and informed consent from patients has not been granted by the patient who should undergo it, except for those cases specified by the law (subsection 1), such as vaccinations (Montanari Vergallo et al. 2018) and in cases of mental patients in need of urgent therapeutic treatments.

Lawmakers thus reassert the definition of consent as hallmark in the healthcare and trust-based relationship between patients and their doctors. Its main function is, on the one hand, to enforce the patients' right to self-determination but even more so to safeguard their healthcare-related choices.¹ Patients are therefore no longer at the receiving end of medical care; rather, they become active participants. The fundamental significance of the former half of the law is not to mandate that informed consent be granted in itself but rather rests with the fostering of a truly effective therapeutic alliance, in which healthcare providers should not merely listen to the patient's stated wishes, but rather "they should fathom his or her personality and the environmental surroundings" (Italian National Bioethics Committee 1992).

The law does not mandate that doctors keep records as to the recovery rates or the technical details of each treatment. It is indisputable that patients, particularly those suffering from chronic, degenerative diseases, need not only information, data, and figures but even more urgently to be able to rely on someone and share with them fears and concerns. Hence, patients are entitled to thorough and proper information, gauged according to the *healthcare relationship*, which calls for a reasonable amount of time set aside for dialogue. In that regard, the newly passed legislation grapples with an issue that is well-known in professional ethics but never turned into law until now: the time frame devoted to the doctor–patient conversation equates care time (article 1, subsection 10). Information should therefore be provided taking all the time necessary (which is tantamount to healthcare time) and laying the groundwork for a doctor–patient relationship in which both parties are integral parts of the process. "Any healthcare professional and provider who is

part of the hospital crew” (thus including nurses, other doctors, physiotherapists, technicians, etc.) can partake in that relationship, as well as patients’ relatives or anyone else who is close to them. All of them may be made acquainted with all relevant information (with prior consent from the patient). Subsection 2 within article 1 makes reference to healthcare professionals in order to highlight that the communication and guiding process encompasses the whole crew and should affect every single moment of the relationship with the diseased individual. It is then acknowledged that twentieth-century medical care, all treatment-related activities are carried out in a multiprofessional, and most likely multidisciplinary, fashion.

Such a dialogue should not be limited to individual medical measures but rather should be extended to the whole therapeutic pathway, including diagnosis, prognosis, benefits and risks of diagnostic testing procedures, and recommended healthcare treatments, as well as possible alternatives and consequences of refusing or giving up on all of the abovementioned procedures (under article 1, subsection 3). Doctors ought to “take it upon themselves” to guide patients through the therapeutic pathway, getting through to them all information necessary to make a sound, sensible decision.

Still article 1, subsection 3, spells out the possibility that patients may decline part or all of the information, if they wish. In such instances, they may reference a relative or other trustworthy individual who would be informed in their place. Such a provision has been included in order to uphold the patient’s self-determination (who may choose if, when, and to what extent he or she will be informed) and indirectly reasserts that the first party to be addressed should be the patient, if mentally capable. All of that confirms that the practice, in situations of serious illness, for example, of totally excluding the patient and first informing relatives is wrong.

Informed consent should be documented in writing or via video recording or, in cases of disabled patients, by means of all appropriate devices enabling them to communicate. Informed consent, however expressed, ought to be included in the patient records and in the electronic folder (under article 1, subsection 5).

Patients Are Entitled to Turn Down Treatment

Doctors have a duty to abide by the patient’s decisions, if the patient is mentally capable of making them. Therapeutic pathways should take into

account that patients may refuse, whether wholly or partially, to go forward with a diagnostic procedure or a given treatment. This is so even then the treatment is one that doctors deem advisable (even one based on the best scientific evidence available), even when such a refusal would entail the withdrawing of said procedure, possibly including artificial nutrition and hydration (under subsection 5). The phrasing used by the Italian Bioethics Committee appears to be much more clearly defined, according to which by the term “refusal,” a request to withhold treatment is implied, whereas “renouncing” is tantamount to a demand to withdraw or discontinue a treatment that was already in progress (Italian National Bioethics Committee 2008).

The decisions of patients must be respected even when “life-sustaining treatments” are involved. In such cases, doctors must elaborate upon the “consequences that the decision to withdraw or withhold the treatment would entail, as well as possible alternatives, and carry out any measure meant to back the patient, even with the aid of psychological support services” (under article 1, subsection 5). Doctors, for instance, are required to inform patients diagnosed with amyotrophic lateral sclerosis (ALS) about all available treatments including the possibility to resort to artificial ventilation and feeding. Patients should also be reassured that pursuing a form of social life is indeed possible, by means of digital and eye-controlled communication devices. Furthermore, doctors ought to convey such alternatives to their patients in a considerate and respectful fashion, helping them figure out which of the alternatives set forth might enable them to best fulfill their life plans (Azzalini 2008).

Lawmakers, at any rate, were keen to avert the risk that a right to turn down any therapy may potentially translate into “therapeutic relinquishment.” Clarifying that patients are entitled to turn down any treatment, even lifesaving ones, and doctors have a duty to refrain from intervening, without being held liable for it, might well sound pleonastic or redundant. In our view, however, the clarification is indeed needed, since there seem to be plenty of doubts, uncertainties, and resistance toward what is called “therapeutic abandonment” (Borsellino 2015), mostly because such stances often become closely identified with euthanasia.

Artificial Nutrition and Hydration

Lawmakers make it clear that “artificial feeding and hydration are to be considered healthcare treatments by virtue of their being administration of nutrients,

on medical prescription, by means of specifically geared medical devices" (article 1, co. 5). The exact nature of such procedures has always been contentious.

By artificial feeding and hydration, chemical compounds are administered to patients, that is, a mixture of substances necessary to sustain life. Such practices require maneuvers that are quite invasive in nature (e.g., the insertion of a nasogastric feeding tube) and for which "specific scientific skills are necessary, which are first applied by doctors, although non-doctors may pick up from there, eventually" (Italian Supreme Court no. 21748/2007; Battimelli 2011). Medical personnel, moreover, would have to deal with possible complications arising from the insertion of such devices.

Their classification as healthcare treatments is widely reflected in scientific literature,³ though not universally so. The Italian National Bioethics Committee contends that artificial feeding and hydration should not be deemed as "futile treatment." In fact, the Committee argues that providing food and fluids to patients, even to those in "borderline" clinical conditions, amounts to a moral duty; it is a "distinctive sign of civility," dictated by humanity and solidarity. The Committee therefore does not deny that those practices are "artificial." It argues that the end justifies the means, and the ultimate goal is to provide basic, life-sustaining support to patients. It further observes that, on the contrary, discontinuing artificial nutrition and hydration is a *moral imperative* when their continuation would not result in any real benefit to the patient or may give rise to clinical complications (hemorrhages, infections), or in terminal cases, in which the system is no longer in any condition to assimilate the nutrients artificially provided (Italian National Bioethics Committee 2005).

Consent under Urgent or Emergency Conditions

How to regulate informed consent under urgent or emergency circumstances, that is, when acting swiftly to preserve health or even save a life is non-negotiable, constitutes a noteworthy subject. Under similar conditions, "doctors and other healthcare personnel must guarantee all necessary measures and initiatives are put in place, taking account at all time the patient's will, whenever he or she is capable of making and expressing decisions" (article 1, subsection 7). The rule of law, therefore, demands that patients be taken care of and treated whenever they are incapable of manifesting their wishes. It is not clear, however, whether such wishes that must be

considered only include current ones or even those possibly to be found in advance health directives.

Advance Statements Instead of Advance Directives: Binding Power

Article 4 arguably constitutes the most innovative and contentious part of the new legislation. By virtue of this article, every individual, in the age of majority and mentally capable, if stricken with a serious or terminal illness, is entitled to dictate to their doctors or other healthcare staff members some directives. These may be aimed at ensuring the continuation of treatment or its discontinuation. The bottom-line approach is that anyone, whether healthy or suffering from a disease, has a right to indicate "now for then" what medical procedures he or she is willing or unwilling to undergo. Practically speaking, "now" means the time at which an individual is still capable of making choices and decisions that will be fulfilled at that future time, that is, in case the individual in question should become incapable of deciding and in need of treatment (Montanari Vergallo 2018).

The directive aims to avert the risk that doctors may carry out procedures and therapies that would run counter to the patient's desires, beliefs, and personal views as to what degree of life quality he or she finds to be acceptable (Puccetti et al. 2009). From that standpoint, the new legislation goes a long way in enforcing the principle of autonomy. Having regulated advance directives along with informed consent within the same piece of legislation confirms that the lawmakers view both aspects as expressions of people's volition.

Nevertheless, it seems quite obvious that the fundamental differences between the two elements make any equivalence untenable. Consent and refusal constitute well thought-out decisions made in proximity of the treatment's implementation. Advance directives do not share such characteristics and therefore cannot be deemed to be instrumental to the enforcement of the one's freedom to self-determination. Conversely, they may lead to therapeutic choices that would not have been made by the patient, had he or she been mentally capable at the time of their implementation.

Italian legislators, drawing upon the French end-of-life legislation (law no. 87/2016, Clays-Leonetti; Aubry 2016), have used the wording "advance statements" rather than "advance directives," which the Italian National Bioethics Committee had introduced back in 2003 (Italian National Bioethics

Committee 2003). Such a choice of words effectively clarified what the legislators meant: the wording “advance directives” would keep the doctors’ decision-making prerogatives intact, enabling them to determine what value to ascribe to a patient’s expressed will before “incapacity.” On the other hand, the phrasing “advance statements” stresses the binding nature of the patient’s preferences, as previously expressed with regard to healthcare decisions. Doctors will therefore be bound to abide by such statements and will be able to disregard them only (1) when it is ascertained by the doctors along with the patient’s healthcare proxy holders or power of attorney holder that there is no coincidence between the patient’s documented living will and his or her current clinical conditions; (2) when the statement appears to be “manifestly inconsistent”; (3) when new therapies have become available, which were not at the time the advance health care statement (AHCS) had been signed, which could reasonably lead to an improvement in the patient’s quality of life (under article 4, subsection 5); (4) if the directive indicates a preference for treatments that are against the law or run afoul of ethical norms or good healthcare practices (article 1, subsection 6).

In case a conflict should arise between the doctor and the power of attorney holder, with the latter opposing the therapeutic choices viewed by the doctor as “appropriate and necessary” (article 3, subsection 5), an intervention by a civil judge will be set. The judge’s ruling will be aimed at upholding the fundamental rights of the individual (to life, health, dignity).

Requirements to Be Met in Order to Complete Advance Health Statements

Three legal requisite conditions must be satisfied: age of majority, mental fitness to make decisions, and formal requirements. Foreigners and stateless individuals legally residing in Italy may resort to advance statements as well. Underage individuals (i.e., under the age of eighteen) are barred. AHCS may be drafted by people of legal age who have been legally debarred or placed under durable power of attorney, as long as they have the cognitive power to lay out and manifest a planned treatment preference.

Under article 4, subsection 6, it is mandated that healthcare statements be outlined by public deed, before a public official, or privately written and signed, personally handed in to the municipality where the undersigned resides, and recorded,

whenever arranged by law, or to healthcare institutions that have instituted computer-based management of medical records. In order to enable doctors nationwide to access patients’ advance statements, under article 1, subsection 418, within law no. 205, 27th from December 2017, a database has been instituted for the purpose of storing all healthcare statements as laid out by patients.

In a recent opinion, the Italian Council of State has cleared up that (a) the national database—on account of all the information therein being accessible throughout the nation—upon the individual’s demand must keep a copy of the AHCSs, including the indication of a legal guardian, unless the person who makes the statement wants to specify only where they are stored; (b) the national registry should keep the AHCSs from those who are not enrolled in the national healthcare service; (c) the AHCSs are not bound in terms of what their contents should be: the individual who makes one must be able to limit it to a single disease or extend it to any future possibilities, deciding whether to sign a healthcare proxy. The minister of health care will be tasked with providing a standardized form in order to aid the citizens and residents who wish to make an AHCS; (d) access to AHCSs is granted to doctors and legal guardian, as long as they are in charge (Italian Council of State 2018).

What Should Be Borne in Mind While Drawing Up an AHCS?

Before setting out to complete an AHCS, it is highly advisable to gather “relevant medical information as to the possible consequences of one’s choices” (according to article 4, subsection 1). The advance decision must therefore be made based on the most updated information of medical-scientific nature (di Luca et al. 2018).

The wording makes no explicit reference as to end-of-life procedures such as artificial feeding and ventilation, but since those have been characterized as healthcare treatments (in article 1, subsection 5), it is indisputable that they too may be included in AHCSs.

The law does not specify whether it would be general practitioners who should provide patients with medical information or it would be necessary to consult with a specialist, with regard to the diseases and treatments on which to express one’s advance statement. It is just as unclear whether the undersigned may autonomously seek out the information. It is worth bearing in mind that AHCSs necessarily operate in absence of a specific disease and a clearly defined therapeutic plan. Consequently,

it comes down to making a decision from a very wide spectrum of pathological and therapeutic hypothesis, in which the individual could easily get lost. In our view, only specialists can effectively provide medical information befitting patients who are keen to formulate an AHCS. Such a provision is stricter than the one found in article 38 of the Italian Code of Medical Ethics (Ricci et al. 2016), which merely mentions “medical information.” It is reasonable to assume that lawmakers had meant to stress the need for people to make well thought-out decisions, in order to ward off the risk of patients falling victims of their own previous reckless choices.

Nonetheless, in order to guarantee patient self-determination, it would have been preferable to require a consultation with a specialist in the medical field to which the refused treatment would belong, as well as documented proof that a relationship with the doctor has been established.

Although the new legislation does not openly mandate it, we believe that the information received by the patient should be clearly mentioned in the AHCS, as it is the case for any informed consent and as it is prescribed in article 38 of the Code of Medical Ethics. The abovementioned opinion from the Italian Council of State makes it clear that the acquisition of such information cannot be documented by the undersigned along with the AHCS. There must be, in fact, absolute certainty as to the “soundness” and thoroughness of the information acquired by the AHCS undersigned and particularly dealing with the consequences of the choices that have been made (Italian Council of State 2018).

Another moot aspect, which even the Council of State failed to clarify, pertains to the who, when, and how of determining whether the information provided to the AHCS signee was indeed thorough enough. In absence of clear provisions from lawmakers, it appears safe to assume that such an assessment would fall to all doctors treating the patient because all of them are vested with the duty to avoid their patient’s death, as stated in article 40, subsection 2, of the Italian Criminal Code. The assessment of accuracy and suitability of the information should be made in light of all currently available scientific evidence not merely of that which was available when the AHCS was compiled, since new research findings could make a previous decision null and void.

Patient Self-Determination and Choices by Doctors

Advance directives undoubtedly make the doctor–patient relationship more complex. A serious issue

comes to the fore: the *current* nature of consent, which inevitably is not there in *advance* directives/statements, by their very definition. There is in fact a considerable gap between the scenario that was foreseen at the moment when the choice was made and stated in the advance directive and the actual situation in the present. The lack of current value in the advance directives with respect to pathological conditions under which doctors have to operate may lower the effectiveness of the doctor’s action. Since the patient is unconscious or incapacitated, there can be no dialogue between him or her and the doctor about the choices that were made and that may prove ill-suited to the current situation. The therapeutic alliance, on which the doctor–patient relationship should be based and which entails constant and updated communication, is bound to collapse. It should be noted that the statements might well be hazy and hard to interpret for doctors, especially if the patient were unable to clearly define the clinical circumstances about which the directives were meant to be made. An example of such a development is a Modena Courthouse ruling from January 18, 2018. A patient, suffering from muscular dystrophy, which causes a progressive weakening of musculature, had expressed a wish to “keep on living without being tracheotomized.” When the need for a tracheotomy arose, the doctors realized that the patient’s statement constituted a contradiction in terms and wholly abiding by the patient’s directive was impossible. Hence, they chose to prioritize the first part of the statement: the patient wanted to keep on living. The doctors referenced the state of necessity, which warrants lifesaving actions irrespective of the will of patients or their proxy holders (Modena Courthouse January 18, 2018).

A Possible Settlement?

The Convention for the Protection of Human Rights and Dignity of the Human Being in respect of the Application of Biology and Medicine, also known as the Oviedo Convention, it has ascribed a nonbinding, orientative value to advance healthcare directives (Patti 2008; Sesta 2010). The Convention, in fact, states under article 9: “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*. Similarly, article 38 of the Italian Code of Medical Ethics mandates that “doctors take into account advance healthcare statements.”

Such wordings reflect the awareness that it is risky to view previous statements, which were made at a time and under conditions that were completely different from the ones when the disease manifests itself, as

binding. It is arguably impossible to equate current consent with advance consent. In fact, a doubt would linger as to whether the will expressed by the patient in the advance health care statement would match the one that the patient would voice if they had retained their capacity to do so, at the time when the medical procedure becomes necessary. The citizen/patient, in fact, makes his or her directives while healthy and cannot foresee the state in which he or she will be in when ill.

An additional concern with advance directives is that the specificity requirement is missing from the picture. A thoroughly informed decision, in fact, either in favor or against a given treatment, must necessarily rest upon detailed information about the risk–benefit ratio in that specific treatment. Hence, generic refusal of lifesaving treatments can hardly be deemed valid. As far as lifesaving treatments are concerned, in fact, countless techniques are available; therefore, the risk–benefit ratio needs to be assessed on the basis of the patient’s individual conditions. Such a situation makes it unthinkable to view the patient’s decision as a thoroughly informed one. In other words, the very contents of the advance directive, as detailed, in abstract terms, as they may be, will turn out, in most cases, to be generic, inaccurate, not necessary relevant with respect to the peculiarities of the situation to be dealt with (Di Pietro 2017).

For all those reasons, the most sensible and cautious solution appears to be assuming that healthcare directives should be viewed as relevant indications for doctors who must take them into account in order to guide their choices. Hence, they should not be binding for doctors.

Following that same rationale, if doctors have a reasonable doubt over the current value of the advance directive, they should disregard them.

In order to clear up any doubt or uncertainty as to the patient’s actual will, the law’s article 4, subsection 1, allows for the appointment of a healthcare proxy holder (characterized as “fiduciary”) who is charged with choosing whether to agree to or reject a given treatment. Proxy holders, for that reason, are tasked with figuring out what the patient would have decided were he or she still capable. It is through the proxy holder, therefore, that the lawmakers enforce the principle of autonomy.

Treatment Planning and Differences with Advance Directives/Statements

The newly passed legislation includes a different tool, denominated “shared treatment planning,”

which would be applicable in cases when “patients find themselves in a condition where they cannot express their consent or in a condition of incapacity” (article 5, subsection 1).

By means of treatment planning, patients suffering from diseases already “in progress” (subsection 2) are entitled to decide how to grapple with their illnesses and outline a therapeutic pathway. Treatment planning represents a way of communicating and sharing decisions, which lasts throughout the course of the disease. In order to introduce an element of shared therapeutic planning, it is essential for patients to receive all relevant information with respect to their health conditions. At this juncture, the “personalization” of the treatment comes into being. For that reason, subsection 2 mandates that patients, or, “with their consensus” their power of attorney holder, be “properly informed” about the diagnosis, prognosis, benefits and risks of the diagnostic tests and healthcare treatments prescribed, in addition to the possible alternatives and consequences of refusing to undergo treatment, or diagnostic tests or discontinuing them. Only the patients may then express their consent to what the doctors propose (subsection 3). Such a kind of “advance” decision has profound differences in terms of ultimate goal with respect to living wills. In cases of shared treatment planning, in fact, patients have a clean-cut diagnosis. Moreover, because chronic illnesses are involved, the patient has already lived with the disease and is fully aware of all of its ramifications. Thus, although it is an advance decision in regard to the critical event, the patient’s decision is certainly informed and current. Furthermore, shared planning entails expressing a perspective on a clearly defined healthcare intervention, pertaining to a clinical scenario that is just as clear. That considerably reduces the margin for differences of interpretation from third parties (healthcare operators, legal guardians) who could come to play a role in the decision.

Shared treatment planning is a valuable tool, especially for patients with brain degenerative diseases, such as Parkinson’s and Alzheimer’s diseases and ALS, which call for a choice among different possible options for intervention (Montanari Vergallo 2018). In the course of such diseases, for instance, patients might experience respiratory failure, thus the need for artificial ventilation. In that case, without having to wait for the critical development, which would not allow the patient to participate in the decision-making process, it is possible to decide with the patient, prior to the event, what

kinds of interventions to carry out when the need arises.

Article 5, subsection 4, enunciates that in cases of “shared planning,” patient consent and the appointment of a healthcare proxy holder can be included in the patient records and in the digital records, which is a similar procedure to the one outlined for advance statements (see article 4, subsection 7).

It is still quite hazy—as it is for advance statements under article 4—whether patients may refuse (similarly to what is prescribed under article 1, subsection 3, with respect to “informed consent”), partly or totally, to receive information, leaving it up to family members, or those in a civil union, cohabitants, or guardians, to make any decision in regard to the case.

The law mandates that doctors and all of the healthcare professionals involved comply with the agreed planning (article 5, subsection 1). That holds valid even though the crew was not completely involved in the stages when the patient was informed (thus developing and voicing his or her preferences). Such an omission may cause problems if some other crew member does not agree with the doctor’s guidance.

The law allows for the possibility of revising the contents of the treatment planning in relation to the progressing of the disease, “upon demand from the patient or a suggestion from the doctor” (subsection 4).

Subsection 5 spells out a conclusive norm, referencing what has not been overtly regulated to the provisions of article 4. This takes on considerable relevance with respect to dubious cases because article 4, subsection 5, regulates the contrasts between legal guardians and doctors, and the possibility that medical innovations, therapies and drugs that were unavailable at the time when the treatment planning took place.

Conclusions

The Italian Parliament has set out to preserve patients’ right to self-determination as well as their quality of life. The new legislation, in fact, clearly states that (a) patients are not bound to be informed nor must they personally decide whether to accept or reject any treatment proposed by doctors; patients may entrust their previously appointed guardians or their doctors with making that decision; (b) time devoted to providing information is to be regarded as time of care; that

equation makes it so that information time and therapeutic time are equally worth, since both phases are instrumental in ensuring that the dignity of patients in need is preserved; (c) as previously pointed out, patients may not require treatments that run afoul of current legislation, or those who fail to meet the standards laid out in ethical codes and best clinical practices; patients may therefore not demand procedures conducive to euthanasia or assisted suicide.

From a critical perspective, concerns linger that decisions made long before falling ill may not coincide with what they might have been (if possible at all) after the onset of the disease (Fagerlin and Schneider 2004; Scianca 2018). Consequently, the law does not appear to be thorough and well-defined in clarifying contents and characteristics as to the kind information that needs to be provided prior to drawing up advance directives. Certainly, the first Court cases in which the law will be applied are going to help figure out whether corrective amendments could be necessary.

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Notes

1. In Constitutional Court ruling, 23rd December 23, 2008, no. 438, the Justices have cleared up that informed consent plays a role in summing up two fundamental personal rights to self-determination and health.
2. The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Oviedo Convention, 1997) and the Charter of Fundamental Rights of the European Union (Nice 2000), reaffirmed in the Lisbon Treaty (2009), constitutional articles (2, 3, 13, 32).
3. Such an assumption was espoused on an international level since the late 1980s, by many scientific societies, such as the American Medical Association and the American Academy of Neurology. In Italy, it is

shared by the Italian Society of Neurology and the Italian Society of parenteral and enteral nutrition from 2007. They clearly stated that artificial nutrition is to be considered in every respect a medical treatment for therapeutic or preventive purposes. Artificial nutrition is not an ordinary health-care measure (such as washing or spoon-feeding incapacitated patients). As every other medical treatment, artificial nutrition has indications, contraindications, and unwanted side effects and, as such, it requires valid informed consent.

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