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REVIEW

The Italian law on informed consent and advance directives: its impact on intensive care units and the European legal framework

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ABSTRACT

The Italian Parliament has recently approved a law on informed consent, advance directives and advance care planning. The law also deals with health care proxy and health care decisions for minors and adults who are not able to give consent. The Italian law arrived quite late in comparison with other European countries. After several years of debate on the need to approve such a law, the focus has now shifted to the assessment of the legislative provisions and their impact on clinical practice. In this article, the authors firstly offer an overview of the findings from the empirical research regarding the use of the different legal tools in the field of intensive care medicine; secondly, they present the tools now provided by law no. 219/2017 particularly with regard to the decision-making processes in the Intensive Care Unit (ICU); thirdly, the authors offer a comparison between the new Italian law and other European legal orders, with special reference to France, Spain, Germany and England. The aim of the article is to assess the degree of innovation of the law vis-à-vis the previous framework.

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KEY WORDS: Advance directives; Advance care planning; Health care; Proxy; Intensive Care Unit.

A number of studies have conclusively shown that the majority of patients admitted to an ICU are not able to make decisions and their wishes are known in a small proportion of cases.[1-9]

"Implicit" consent to treatment is therefore still considered the standard approach by intensivists.[10, 11]

Lack of knowledge of these patients' wishes in terms of intensive care and the related decisions to be made carries the risk that clinicians carry out some treatments that the patients would have probably refused if they had been sound of mind.[12-15]

In December 2017 the Italian Parliament approved the law no. 219/2017 (Supplementary Digital Material 1, Supplementary Text File).[16] This law provides for a comprehensive discipline on informed consent to medical treatments, advance directives and advance care planning (in the Italian text respectively: "Dichiarazioni Anticipate di Trattamento" e "Pianificazione Condi-

visa delle Cure"). The law also deals with health care proxy (in the Italian text:"Fiduciario") and decisions for minors and adults who are not able to give consent.

Medically assisted suicide and euthanasia are still prohibited.

Intensivists have now to deal with the impact of this law on the relationships with patients, their families, health care proxies and legal representatives.

Law N. 219/2017: general principles

The rationale of law no. 219/2017 is to ensure legal certainty based on solid ethical grounds. Therefore, under the new law, the legal approach to end-of-life issues is centered on an effective doctor-patient relationship, based on the respect of human dignity, self-determination and health care of the sick person, in compliance with the constitutional rights, relevant case law, and principles set out by the Italian Code of Medical Ethics.

In this sense, the law is aimed at giving legislative shape to the principle of informed consent, allowing doctors and patients to define together the extent, limits and criteria for medical treatments. Therefore, the law provides some tools to effectively ensure the respect of patients' autonomy in different medical scenarios, including medical emergencies and, more generally, the patients' incapacity.

Legal tools provided by the new law to achieve patients' self-determination are:

- Advance Directives (ADs, Art. 4);
- Advance Care Planning (ACP, Art. 5);
- Health Care Proxy (HCP, Art. 1.2 and Arts. 3; 4; 5);
- Legal representative (LR, Arts. 3; 4.4; already provided by Art. 315 ff. and 404 ff. Civil Code – in the Italian text "Amministratore di Sostegno" e "Tutore").

The Law does not systematically cover the case where doctors have to make decisions concerning an incompetent patient who lacks an LR or an HCP. Except for art. 1.7 on emergency situations and art.4.4, concerning the case of ADs without an HCP available, general principles apply to this situation.

The doctor-patient relationship is aimed at guaranteeing patients the best possible state of physical and mental health. This goal is defined on one hand by clinical appropriateness criteria and, on the other, by the patient's criteria based on his/her assessment of the burden and perception of the benefit deriving from any treatment (proportionality-balance between burden and benefits).

The doctor-patient relationship is consensual and should be tailored to the patient's conditions and to his/her ability and willingness to acquire information, understand his/her own condition and plan his/her future.

If the patient is not able to take part in decisions on treatments, and in the absence of ADs, ACP and HCP, the doctor will guide treatment choices according to the criteria of appropriateness/proportionality trying to reconstruct the patient's will.

The patient's self-determination is also realized by the right to refuse medical treatments. This right might also be ensured by forgoing a medical treatment in place. Thus, withholding (WH) or withdrawing (WD) a medical treatment are equally part of the right to refuse.

Even if ADs are presumably rarely available in most ICU patients because of the sudden and unpredictable organ failure's onset in a healthy person at that time, ADs may be much more likely in this scenario than in acute-on-chronic organ failure thanks to the ACP, a specific tool provided by the law (Art. 5) for patients suffering from a chronic and disabling disease with a severe prognosis. By agreeing with this perspective, Figure 1 shows how the legal tools provided by law 219/2017 apply to the most recurrent scenarios in ICU.

The new law in the ICU setting

Advance directives

In a patient-centered approach to caring for sick persons, decision-making is based on communication and interaction between the doctor, the patient and/or his/her family as depicted in Figure 2, where the shared decision-making process (SDMP) is specifically referred to the ICU patients.[17]

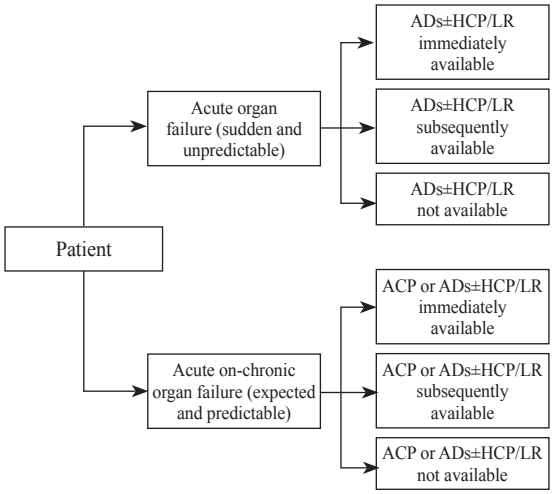

Figure 1.—The most frequent scenarios in ICU related to ADs, ACP, HCP/LR.
The most frequent scenarios in ICU are acute organ failure or acute-on-chronic organ failure. In both scenarios, the impact of the law relies on the existence and availability of ADs, ACP and HCP/LR. In both cases an HCP could have been indicated by the patient. Also, if the patient was already incapable, an LR could have been previously appointed by a judge.
ICU: Intensive Care Unit; ADs: advance directives; ACP: advance care planning; HCP: health care proxy; LR: legal representative.

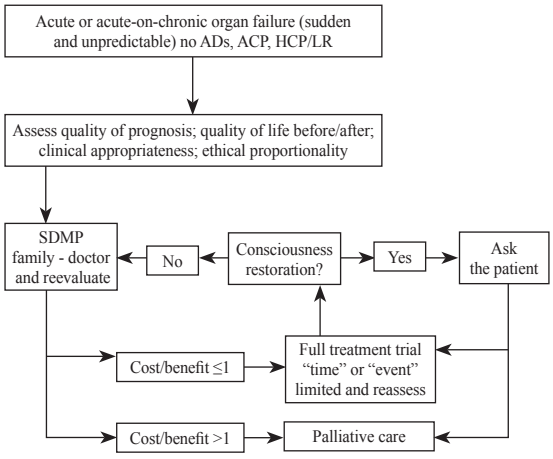

Figure 2.—Shared decision making process when ADs, ACP, HCP/LR are not available.
If the ADs, ACP or HCP/LR are not available, an SDMP 17 will be started with the patient and/or family members in order to define the quality of the prognosis and the estimated quality of his/her future life (balance between clinical appropriateness and ethical proportionality — burdens and benefits ratio), opting for a further treatment trial or for forgoing life-sustaining treatments (withholding/withdrawing treatments) and starting a palliative care program.
ICU: Intensive Care Unit; ADs: advance directives; ACP: advance care planning; HCP: health care proxy; LR: legal representative; SDMP: shared decision-making process.

Laws on informed consent and ADs have been widely developed in order to ensure the respect of patients' autonomy even in the case of incapacity, and to overcome clinicians' paternalistic tendencies.

Two main ADs models are frequently used: "treatment oriented" (in an ADs standard form containing a list of treatments the patient ticks they he/she wishes to refuse) or "outcome oriented" (in ADs form the patient decides upon the treatments have to be discontinued or not started, in the event of a specific outcome or a poor prognosis). In turn, the decisions regarding end-of-life care may be influenced by the ways in which ADs options are presented (*e.g.* comfort of care-oriented ADs *vs.* standard ADs).[18]

In 2015, the WELPICUS study[19]defined ADs as "an instrument conveying information concerning an individual's preferences and goals regarding medical procedures and treatments, especially those used for end-of-life care. ADs intend to extend the patient's autonomy to situations in which he/she is unable to express his/her preferences regarding treatment decisions. They reflect a patient's individual moral, cultural, and religious attitudes."

The WELPICUS study has also pointed out that physicians should always:

- ask patients if they have ADs;
- discuss with patients the contents of ADs, respecting and including them in the decision-making process;
- ascertain the patient's wishes concerning life sustaining treatments (LST), directly or through the HCP/LR (in case of incapacity).

Ultimately, Ads should not be respected if:

- the doctor is asked to perform an illegal act;
- there is evidence that the patient has changed his/her mind;
- ADs are inconsistent with the illness from which the patient is suffering.

In clinical practice, however, many studies have shown that very few patients drew up an ADs document before the ICU admission;[20] when available, ADs do not guarantee consistency between received care and patients' wishes,[21-24]having little influence over the decision to limit treatments,[25-27] being static in relation to the dynamic nature of the illness,[28] deal-

ing often only with specific situations and no other types.[29] In Italy 66% of doctors consider the decision to forgo LST legitimate as long as it is in accordance with the patient's wishes,[30] but data on Italy from the multicenter study Euro Senti-MELC have shown that of the 2783 patients who were admitted to the study and died of chronic degenerative illnesses, a wish in regard to the place of death or types of treatment had been expressed respectively in only 25% and 10% of cases and only 5% of patients had appointed a reference person.[31]

Advance directives: the Italian law

Art. 4 of the Italian law provides that any adult and competent person can express his/her ADs, in view of a possible future incapacity, after having acquired adequate medical information.

ADs can be a general draft (*i.e.* written by a healthy person) or refer to a specific diagnosed illness. They can also indicate the treatments a person wishes to undergo or not undergo and can include the indication of an HCP, who will act on behalf of the patient and will represent him/her in relations with the doctor and the health care facilities.

Consequently, when the ADs of an incompetent patient are immediately available, they are binding for the doctor even in an emergency situation (Art. 1.7); in this sense, the law does not provide for any conscientious objection. Thus, doctors are not held liable under Civil or Criminal Law for having withheld or withdrawn treatments fulfilling the patient's ADs (Art. 1.6).

On the other hand, doctors have no professional obligation towards requests of patients related to treatments deemed unlawful, or conflicting with the code of medical ethics and clinical and healthcare best practices (Art. 1.6).

ADs must be written and signed as prescribed by Art. 4 of the law.

Exceptions are provided when the patient's physical condition does not permit him/her to write and sign a document (other technologies are permitted).

The law also provides for specific procedures for registering ADs.

Generally speaking, ADs are often written in view of a hypothetical future incapacity and, therefore, with no reference to the current illness, its severity and prognosis, and specific treatments needed. Thus, ADs can be partly or entirely disregarded (with the HCP's agreement, if an HCP has been indicated) only if they are clearly inconsistent or not corresponding to the patient's current clinical situation (Art. 4.5). Such contrast may become a problem in ICU. Provided that the patient's will must be always respected in case of consistency between ADs and clinical condition, in case of doubt the incompetent patient's wishes concerning medical treatments have to be assessed and reconstructed in cooperation with the HCP (if indicated), the patient's legal representative when available, or those closest to him/her when possible.

This latter aspect is very similar in all of the other foreign scenarios taken into consideration: in the absence of ADs, the patient's autonomy shall be respected anyway and previously ex-

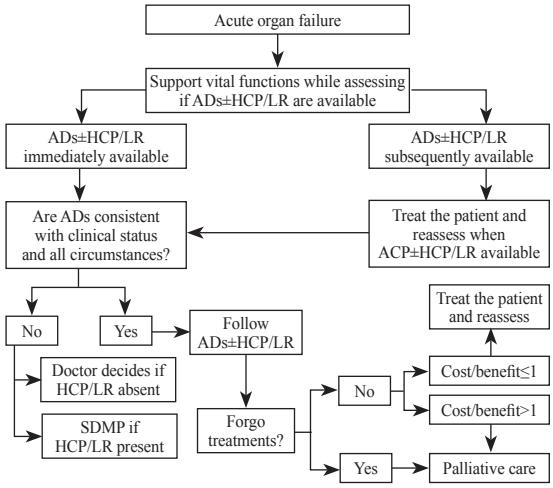

Figure 3.—The figure depicts, in light of Law 219/2017, the two situations related to the implementation of ADs (ADs immediately or subsequently available) in case of acute organ failure.
If ADs are validly expressed and immediately available, with or without HCP, the intensivist, after supporting vital functions, will evaluate together with HCP the ADs' consistency with the clinical status (Art. 4.5). In case of inconsistency (grey arm), the intensivist may not follow ADs if an HCP is not available; if an HCP is available, the intensivist may discuss with him/her the next approach in an SDMP. In case of the ADs' consistency with the patient's clinical status, the intensivist may implement ADs even if an HCP has not been appointed. If needed, a judge will appoint an LR.
ICU: Intensive Care Unit; ADs: advance directives; ACP: advance care planning; HCP: health care proxy; LR: legal representative; SDMP: shared decision-making process.

pressed personal attitudes towards medical treatments should be given due consideration.

Figure 3 depicts the decision-making process taking into account the content of the new law.

It is important to note that, in the case of ADs in line with the clinical situation, but available after the start of LST, they might lead to withdraw them.

In this regard, even though 28 out of 29 current practice guidelines[32, 33] consider WH and WD LST ethically and legally equivalent, intensivists' attitudes towards WH or WD can vary depending on cultural, religious or geographical elements and, of course, on different legal frameworks.[2, 34-36]

The decision to withdraw treatments seems to some intensivists — especially those belonging to the three monotheistic religions — comparable to a shortening of the process of dying,[37] a "grey area" where the line between killing and letting die is blurred because of doctors' active involvement.[38]

In regard to the issue of refusing treatment, law 219/2017 has defined two fundamental aspects.

Art. 1.5 recognized not only patients' right to consent, but also to refuse medical treatments, even when they are "needed for their survival" and considers revocation of consent equal to refusal. Similarly, Art. 1.6 provides that the physician has the duty to respect patients' will, including both WH and WD medical treatments.

In the case of "patients with severe short-term prognosis or in the event of impending death," the usefulness and proportionality criteria would suggest choosing WH or WD when medical treatments bring no benefits for the patient.

In the case of patients with neither ADs nor ACP, the decision-making process is centered on patients' best interest through an SDMP, as shown in Figure 2.

Advance care planning

In the West an aging population means higher rates of chronic-degenerative illnesses.[39]

With the aim of identifying the best approach to end-of-life treatment for these patients, in some countries[40-44]an ACP model has been developed in which ADs can be integrated.

ACP is a process in which the chronically ill person, by consulting with doctors, family members and other contacts, decides at what level of intensity and quality of treatment he/she wishes to undergo if he/she becomes incompetent, making it easier for providers to respects his/her wishes.[45] ACPis therefore a two-way informational process that allows health care professionals to know the expectations, preferences and values of patient in light of his life plan, and the latter to understand the seriousness of illness, the prognosis and the diagnostic and therapeutic means needed to face it, promoting informed choices.[46]

ACP models based on specific situations of illness show that a coordinated, systematic and patient-centered approach improves the quality of treatment[47, 48]andreduces the psychological stress of all those involved.[49, 50]

There is also clear evidence that complex ICU procedures, based on pre-existing ACP, can be more effective in satisfying patients' preferences compared to only ADs.[51]

Advance care planning: the Italian Law

Based on law no. 219/2017 (Art. 5), an ACP can be carried out within a doctor-patient relationship "as regards the development of a chronic and disabling disease, or one with a severe short-term prognosis." Should the patient no longer be able to make decisions, the doctor and the medical team are obligated to respect the ACP. In an ACP, as in ADs, the patient can appoint a trusted person to act on his/her behalf in relations with the doctor.

ACPs have a significant advantage over ADs: they are agreed between doctor and patient with regard to the specific context of the illness. Consequently, if the patient becomes incompetent, it is unlikely that they would end up being inappropriate or too generic for the actual clinical situation. If ACPs are included in patients' medical records and electronic dossiers, they should be easy to retrieve even in the event that the patient is admitted to an ICU in a different facility. The possible decision-making process for intensivists in the case of a patient with ACP can be visualized in Figure 4.

In other European countries, ACPs are not ex-

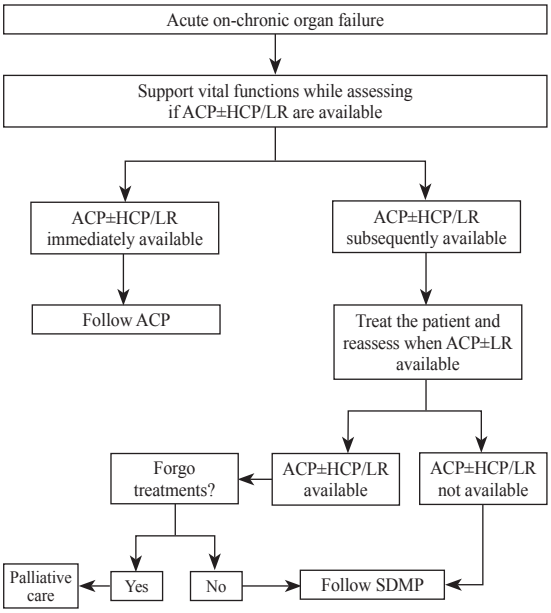

Figure 4.—The figure depicts, in light of Law 219/2017, the two situations related to the implementation of ACP (ACP immediately or subsequently available) in case of acute-on-chronic organ failure.
In case of acute-on-chronic organ failure, the patient will likely have already planned and shared his/her care process, with or without an HCP. The patient might also be provided with an LR appointed by the judge. While vital functions are supported, there is an assessment of whether the patient already has an ACP available. If the ACP is immediately available, the most appropriate approach is to follow the provisions of the law (Art. 5, subsection 1), following what the patient planned in advance with or without an HCP/LR. If an ACP were available at a later stage and required the interruption of any life-support treatments that had already begun, this will be taken into account and implemented.
ICU: Intensive Care Unit; ADs: advance directives; ACP: advance care planning; HCP: health care proxy; LR: legal representative; SDMP: shared decision-making process.

pressly included in the legislation on informed consent and ADs, even though they are widely used in clinical practice, especially in the context of elderly care.[52, 53]

Health care proxy and legal representative

To forgo treatments for an incompetent patient at the end of life is one of the most difficult decisions that can be made in ICU. In these cases, intensivists and family members often take on this responsibility through an SDMP.

The HCP is usually chosen by the patient alongside his/her closest family members. The decision can sometimes have its drawbacks.[54]

Often family members feel anxiety and depression when the life of their loved one is at risk and this condition of stress is made worse if the information is inconsistent and contradictory due to inadequate communication between doctors and family members.[55] Furthermore, when information is provided under conditions of stress, anxiety and confusion, they paradoxically reduce the ability to understand the complexity of the situation, causing in listeners a constant tension between informational and emotional needs.[56, 57]

For this reason, family members often prefer not to take part in the decision-making process.[58]

An HCP, because it is agreed between family members, can face the same kind of issues, since often his/her function goes beyond that of merely representing the patient's wishes, and can take on responsibilities towards other family members, while carrying the decision's burden.[59]

This evidence shows that adequate communication skills of the ICU staff are, once again, a keypoint in reducing family distress and allowing the HCP to adequately fulfil his/her legal duties.[60]

Health care proxy and legal representative: the Italian Law

The Italian law takes a step forward, following the legal developments in other European countries.

Before the law, there was no specific HCP regulation for decisions on one's own health, and the only reliable way to select a substitute was to resort to a prior nomination and appoint a supporter (Court Appointed Supporter: Art. 408 civil code).

In the case of ongoing illness, the law takes into account, first of all, patients' entourage. If patients so wish, "family members or civil-union partners, or any other trusted persons" also need to be involved in the healthcare relationship (Art. 1.2 and Art. 5.2). Patients can therefore decide to delegate a part or all of the informational process or decision making to family members or to a trusted person (Art. 1.3).

Law 219/2017 also established that patients can nominate an HCP in ADs or in an ACP.

This person must be of age and sound of mind, freely chosen by the patient to act on his/her be-

half and represent him/her in relations with the doctors and healthcare facilities if the patient is not able to make decisions for him or herself (Art. 4.1 and 4.2 and Art. 5.3). The person of trust must accept the responsibility (but can also renounce *ex post*) and the patient can revoke it at any time.

The law also provides that, where ADs/ACP are in place without the appointment of an HCP or the HCP has renounced the role, an LR (Court Appointed Supporter) should be appointed only "if needed" (Art. 4.4).

Even in the absence of ADs/ACP, an LR will be nominated to take part in healthcare decisions on behalf of the ill person, should this protective measure be necessary (Art. 404 ff. civil code and Art. 3.4 law 219/2017).

Finally, in case of conflict between LR or HCP and physicians, the decisions shall be remitted to the competent Court.

The international context

The issues faced by Italian lawmakers are similar to those posed by many other legal systems (Table I).

As far as ADs are concerned, it is well known that, since the 1990s, many western legal systems have started to regulate their effectiveness and validity. The main aspects regard: 1) the methods for ensuring awareness by the patient of the consequences; 2) the methods for ensuring that the ADs are current; 3) the issue of accessibility of doctors who will be treating the patient.

In some countries there are explicit limits to their effectiveness.

First of all, it is worth pointing out that, although the wording may vary, all countries allow doctors a certain degree of interpretation that might deviate from the ADs, while still respecting patients' wishes.

Secondly, all the foreign systems examined prefer up holding more or less detailed formal requirements to ensure the certainty of ADs. They generally need to be in writing and signed (in some cases even in the presence of witnesses). ADs can be accessed by doctors in most cases by filing them in patients' medical records.

When a patient has not drafted his/her ADs, the principle that should guide doctors' actions, both in the systems examined and in Italy, is the respect for the criteria of appropriateness and proportionality of treatments. From a subjective point of view, any guidelines previously laid out by the patient (even if not formalized in ADs) should be taken into account. From a legal perspective, these principles come not only from national laws and the respective Codes of Medical Ethics, but also from applying the principles expressed in the European Convention on Human Rights (ECHR), the Oviedo Convention and the European Union Charter of Fundamental Rights and their respective judicial interpretation.

One aspect that varies significantly from country to country relates to the role and responsibilities of the person appointed to represent the patient in his/her relationship with doctors. Each legal system has identified a different type of representative (for example, *fiduciario* in Italy; *personne de confiance* in France; *representante* in Spain). The methods of appointment and the powers of each representative vary in each system. One feature in common is that the HCP acts and takes part in the doctor-patient relationship when the patient is unable to express his/her consent. Other variations regard the possible existence of additional representatives (legal representatives, next of kin, etc.) besides HCPs that are regulated differently in each system and a judge's ruling in the case of disagreement on decisions to be made or in the case of interruption of LST.

Conclusions

In Italy, the long process that ended in the drafting of a shared legal text and the approval of a law on informed consent and ADs has been accompanied by major legal cases that have influenced public opinion and the political debate.

From this point of view the law has implemented and strengthened the principles already established in the case law: in particular with regard to the effectiveness of the right to refuse treatments in accordance with Art. 32 of the Constitution and in reference to respecting patients' self-determination.

The law grounds the guarantee of the respect

TABLE I.—*The table summarizes and compares similarities and differences between certain aspects of regulations on informed consent and ADs in France, Spain, Germany, England.*

Right to refuse medical treatments even if life-sustaining	France, Germany, Spain, England
Legal discipline on informed consent	France, Germany, Spain, England
Legal discipline on ADs	France, Germany, Spain, England
Legal discipline on ACP	In all these countries ACP are commonly used in clinical practice. The level and detail of legislative provision and implementation of ACP in clinical practice considerably vary from one country to another and has necessarily to be considered together with the national discipline on ADs and its many shades.
ADs forms and registration All of these countries' legislations provide for written ADs, with some exceptions concerning patients' health situation. In some cases the signature of witnesses or the person indicated as healthcare proxy is required.	France: written, dated and signed (if the patient is unable to sign, two witnesses certify that the written document reflects the patient's will). ADs filed in the patient's medical record or kept by the attending doctor or a different doctor selected by the patient or, if hospitalized, filed in the medical record or kept by the patient him/herself or someone else. Germany: written. Oral declarations can be taken into account. Spain: written. Other specific aspects are regulated at a regional level. National database created in 2007. England: written and signed, signed by a witness. An "advance decision" is a special type of advance statement that represents an actual decision to refuse treatment, albeit at an earlier date. A withdrawal ADs (including a partial withdrawal) need not be in writing. An alteration of an advance decision need not be in writing.
ADs validity and efficacy In all of these countries ADs are legally binding for physicians. The legislation provides for specific cases in which ADs lose efficacy or may be disregarded by doctors, for example when they are not compliant with the patient's clinical situation.	France: three-year validity, renewable. ADs are binding for doctors, except for in case of vital urgency, limited to the amount of time needed for a complete assessment of the situation, and in cases in which they appear manifestly inappropriate or inconsistent with the medical situation. Germany: The patient's will, as expressed in the ADs (or presumed), is binding for doctors and for the LR or HCP; close relatives and other next of kin of the patient can be heard before taking medical decisions. If existing ADs are not applicable to current life or health conditions, the Judicial Appointed supporter (Betreuer) or the Health Care Proxy (Bevollmächtigte) must determine the presumed will of the patient by discussing it with the attending doctor, based on concrete facts and also taking into account the patient's previous written or oral statements, ethical or religious beliefs and other personal values. Spain: ADs are binding for doctors. ADs that are against the law or the "lexartis" or that are inconsistent with the factual circumstances indicated by the patient may not be applied. More criteria for validity / efficacy / applicability are specified in regional laws. England: ADs are legally binding. ADs are not applicable: if the treatment is not specified in the ADs; if any circumstances specified in the advance decision are absent; there are reasonable grounds for believing that circumstances exist which the patient did not anticipate at the time of the advance decision and which would have affected his/her decision had he/she anticipated them. In case of doubt, a Court can make a declaration on the validity or applicability of ADs.
HCP/LR In the legislation of all these countries there are general provisions for Court-appointed LR and specific provisions for a HCP. However, the regulations concerning their appointment, powers and roles vary significantly from one country to another.	France: An LR can be appointed by the Court under the Civil Code in order to protect the incapacitated patient. The patient may also have signed a "mandat de protection future" under the Civil Code. The patient can, finally, designate a "personne de confiance". If the patient is incompetent, doctors shall consult the *personne de confiance* or the mandatary. In their absence, a family member or relative is consulted. The decision to forgo life-sustaining treatments for a person who is unable to express his/her will is, in any case, always taken following a collegial procedure specified by the law. Germany: A *Betreuer* can be nominated if a health care proxy is absent. When ascertaining the patient's will, the *Betreuer* or the HCP must discuss decisions with the doctors; close relatives and other next of kin of the patient should also be given the opportunity to make a statement. In some cases (*i.e.* when the decision might imply significant damage to the health of the patient or his/her death) a declaration by the competent Court is required. Spain: "In the ADs the person can designate a *representante*, a representative who can, if necessary, serve as an interlocutor with the doctor or the medical team to ensure compliance with the ADs. When the patient is not able to make decisions or when his/her incapacity has been judicially ascertained, consent is given by the designated representative or by the legal representative. If the patient lacks a legal representative, the consent is given by persons related to him/her for family or de facto reasons. England: A person (donor) can appoint a donee, by means of a lasting power of attorney. A lasting power of attorney is a power of attorney under which the donor confers on the donee authority to make decisions on several matters, including his/her personal welfare. If the patient lacks capacity, a Court may, by making an order, make a decision on the patient's behalf, or appoint a person (deputy) to make decisions on the patient's behalf. In any case, the decision must be taken in the patient's best interest.

The table is a summary of the legislations of these countries and offers a basic outline of certain issues, without any claim to being complete, but just to give a "glance."
ICU: Intensive Care Unit; ADs: advance directives; ACP: advance care planning; HCP: health care proxy; LR: legal representative.

of previously expressed wishes in the event of a patient's incapacity on the full respect of the principle of informed consent.

Meeting this need are the legal provisions on ADs and ACP, even though the latter was already widely in practice in clinical care,[61] while the HCP represents an innovation from a legal point of view, in line with similar innovations introduced in the other countries examined above.

Lastly, forgoing treatments lies at the crossroads between the medical obligation to offer only appropriate and proportionate treatments and the patient's right to refuse treatments (even life-sustaining ones). These principles and rights are now widely recognized in many legal systems.[62]

In conclusion, applying the principles of the new law in the clinical practice of intensive care medicine will enable healthcare professionals to better respect patients' dignity. Patients' dignity is not an illusory and abstract concept, but it requires medical doctors to fulfil, case by case, the fundamental rights of patients: the right to the best available treatments; to the best possible quality of life during and after the illness or to a peaceful and painless death; to personal integrity; to self-determination.

An examination of the results of the treatments on the patient's quality of life during and after the illness, and/or, conversely, of their limitations according to the criteria of clinical appropriateness and proportionality, will provide a way to measure with how much dignity each individual patient has been treated.

All of the above means that additional value needs to be attributed to doctors' dignity by taking on new explicit decision-making responsibilities within a new certain legal framework.

Law 219/2017 has shown doctors the way. It is up to them to follow it.

Key messages

• Law no. 219/2017 is aimed at giving legislative shape to the principle of informed consent. The new legal framework allows doctors and patients to define together the extent, limits and criteria for medical treatments in light of the respect of human dignity, self-determination and health care of the sick person, in compliance with the constitutional rights, relevant caselaw, and principles set out by the Italian Code of Medical Ethics.

• Legal tools provided by the new law to achieve patients' self-determination are: Advance Directives; Advance Care Planning; Health Care Proxy; Legal representative.

• In some circumstances, the patient's self-determination might be realized by the refusal of medical treatments. This is a right of the patient and can be ensured by both withholding or withdrawing (*i.e.* forgoing a medical treatment already in place) a medical treatment.

• Even in emergency situations, doctors are bound to respect the will expressed by patients to refuse medical treatments.

• Doctors who respect the patients' refusal are not held liable under Civil or Criminal Law; on the other side, they have no professional obligation towards requests of patients related to treatments deemed unlawful, or conflicting with the code of medical ethics and clinical and healthcare best practices.

• Conscientious objection is not provided by this law. So it could not be invoked by doctors in this field.

• The time devoted to doctor-patient communication has to be intended as a time of care.

• The ignorance of the law is not legally justifiable. Therefore, the intensivists must know how the law 219/2017 has changed the doctor-patient relationship.

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