Article

The protection of health in the care and trust relationship between doctor and patient: Competence, professional autonomy and responsibility of the doctor and decision-making autonomy of the patient

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Significance for public health

Doctrine, jurisprudence and the most recent legislation in Italy have consolidated the centrality of the individual in the decision-making process for health protection. Even with incapacity, considering "subjective" components is essential to guaranteeing protection of the person while enhancing and promoting autonomy. Law No. 219/2017 does not introduce new principles to those already in the legal system, but makes an important contribution to the helpful and certain implementation of health care by protecting the best interest of the patient and placing the person, their dignity and their self-determination at the centre of the care and trust relationship. The law recognises the patient's freedom to choose therapy, including refusing or renouncing health care and, by defining the boundaries of medical action, increases certainty on the consequences of such action.

Abstract

The Authors review Law No. 219/2017, with its important contribution to defining the roles and responsibilities of subjects in care relationship – a dynamic relationship (over time, for the condition of the interested party, to people who may be involved) – and regulating advance directives and shared planning of care. The Law promotes and enhances the relationship of care and trust between doctor and patient, which includes the competence, professional autonomy and responsibility of the doctor and the decisional autonomy and right to self-determination – to make an informed and voluntary choice about treatment proposed by the doctor - of the patient. For concrete implementation of the Law, an adequate information system and all the measures to guarantee certainty about the consequences of behaviour and protection of the rights of all the subjects involved are now essential. In addition, for advance directives, it is essential to reflect on the adequacy of medical information required by the Law itself for its drafting, considering that the citizen can contact qualified professionals and also independently find this information autonomously, selecting the sources of information.

The Law

In Italy, the Law of 22 December 2017, No. 219 on informed consent and advance directives[i] detailed aspects are already affirmed by doctrine and jurisprudence. It also defined aspects with important implications for the doctor-patient relationship and in particular roles and responsibilities for the care relationship subjects, focusing on the person of the patient and in particular on decision-making related to health treatments, also in view of their unexpected inability to understand and to express their will.

The Law promotes and enhances the care and trust relationship between doctor and patient, within which communication time is *cure time* and which includes the competence,[ii] professional autonomy and responsibility of the one and decision-making autonomy of the other. The law dutifully includes the professional figures that make up the health *team* and who contribute to the care relationship based on their respective competences and also enriches the doctor-patient relationship through the potential involvement of subjects such as family members, parties to a civil union, the cohabitant or someone trusted by the patient.

The law thus contributes to identifying the limits and extent of the care mandate by defining the boundaries of the care relationship within which the doctor is responsible for identifying and proposing health treatments, with a fundamental informative role towards the patient.

Patient autonomy is applied primarily for the right to information *i.e.* the right to complete, up-to-date and comprehensible information regarding the diagnosis, prognosis, benefits and risks of diagnostic tests and indicated health treatments, the possible alternatives and the consequences of any refusal or renunciation of these. On the other hand, the patient is entitled to a "right not to know" *i.e.* to refuse to receive the information in whole or in part, or to indicate family members or a trusted person in charge of receiving it and expressing consent in their place.[iii]

In the Law the rule of consent to health treatment – which finds its legal basis in the Constitutional Charter – is then made explicit in general terms (Article 1): no treatment can be initiated or continued without the free and informed consent of the person concerned, with the exception of cases expressly provided for by law. More specifically, the Law provides that each subject capable of acting has the right to refuse, in whole or in part, any assessment or treatment, or any individual acts of the same and to revoke consent at any time, even when revocation leads to interruption of the treatment. Consent is an unavoidable requirement for the lawfulness of the treatment. In this sense, just as it is necessary to acquire consent before beginning the treatment, consent must remain for the duration of the treatment and is always revo-

[i] Law 22 December 2017, No. 219 on informed consent and advance directives, published in the Official Journal No. 12 of 16 January 2018.

[ii] In this sense, the Italian Medical Code of ethics (2014) (available from: https://portale.fnomceo.it/wp-content/uploads/2018/03/CODICE-DEONTOLOGIA-MEDICA-2014.pdf, accessed 22June 2018) establishes under section 20 that the relationship between doctor and patient is based on the freedom of choice as well as the identification and sharing of the respective autonomies and responsibilities and that the doctor pursues a covenant of care based on mutual trust and mutual respect for values and rights and on comprehensible and complete information, considering communication time as cure time.

[iii] The medical Code of ethics establishes under section 33, that the doctor respects the necessary confidentiality of the information and the will of the patient not to be informed or to delegate the information to another person, reporting it in the health records.

cable by the patient. In the event that the patient renounces or refuses medical treatment necessary for their survival, the doctor proposes to the patient and – if they consent – to their family, the consequences of this decision and the possible alternatives, and gives full support to the patient, including psychological assistance services.[iv,v]

Composition of the autonomy that subjects in the care relationship are entitled to clearly emerges from the provisions according to which the doctor must respect the will expressed by the patient to refuse or renounce health treatment; this consequently is exempt from civil or criminal liability. However, the patient cannot demand health treatments that are contrary to the law, professional ethics or good clinical-care practices. In the face of these requests, the doctor has no professional obligations.

This legal clarification seems fundamental to guarantee certainty and awareness of the consequences of medical action and respect for patient self-determination.

According to some authors this law clearly and explicitly defines the doctor's obligations and excludes the possibility of continuing to refer to an alleged guarantee position of the doctor to overcome and nullify the patient's wishes.[1]

Others show that it has long been desirable that the legislator unequivocally sanctions the lawfulness and legitimacy of the doctor's active behaviour – necessary to implement the patient's right to renounce continued health treatment – especially to guarantee a definitive consolidation of the constitutional roots of the principle of informed consent/ refusal in the doctor-patient relationship, considering also that in the absence of such a clear regulatory disposition, the patient's fear of being irrevocably bound to the continuation of the treatment causes serious distortions in the relationship of care, accentuated in the current context where defensive medicine attitudes – which lead the doctor to not respect the patient's will to avoid the risk of judicial litigation – are widespread.[2]

The tendency to put "the person" at the centre of physician – patient relationship clearly emerges from the provisions aimed at guaranteeing an enhanced capacity of minors and incapable people to understand and make decisions (Article 3). Although parents or the legal representative are entitled to a decision-making power, under age or incapable people are entitled to receive information on choices relating to their health in accordance with their ability and to be put in conditions to express their own will.

With a view to protecting the right to life, health, dignity and self-determination of the individual, the Law establishes the doctor's duty to use appropriate means for the patient's condition to alleviate their suffering, even in the event of revocation or refusal of treatment, guaranteeing appropriate pain therapy and palliative care[vi] (Article 2) - expressly providing for the use of deep and continuous palliative sedation, with the consent of the person concerned – as well as the doctor's duty to refrain from any unreasonable obstinacy in the administration of treatment and from the use of unnecessary and disproportionate treatments, for a patient with a poor short-term prognosis or imminent death, in conformity with what has already been established in the codes of ethics.[vii] The debate on decision-making about withholding or withdrawing of life support is very critical in the field of intensive care and oncology.[3]

The law therefore governs advance directives ("Disposizioni Anticipate di Trattamento" – DAT). Numerous bills presented in past legislatures, attention from jurisprudence on the opportunity for legal regulation of the matter,[viii] identification in the institute of court-appointed guardianship ("amministrazione di sostegno") of a possible vehicle for introducing DAT in our legal system,[4] the establishment in many municipalities of registers for their management and conservation as well as legislative activity in some Italian Regions[ix,x] have for some time denoted the urgency of regulating this important tool for the autonomy of the patient and

[iv] For the right to refuse treatment, the Legislator specifies that for the purposes of this Law artificial nutrition and artificial hydration are considered health treatments as they administer nutrients using medical devices, by prescription.
In the medical Code of ethics, section 53 states that the doctor informs the capable person of the consequences that a prolonged refusal to eat involves for their health – documenting the willingness of the patient – and continues assistance, not taking constrictive initiatives or collaborating in coercive procedures of feeding or artificial nutrition.
In this regard, some Authors (Adamo U. Alcune osservazioni critiche a proposito delle prospettive de jure condendo nella legislazione italiana in tema di 'direttive' anticipate di trattamento. Consulta Online. 2016;3:427. Available from: http://www.giurcost.org/studi/adamo2.pdf, accessed 22 June 2018) ask themselves if ignoring the question of whether hydration and nutrition are medical treatment (to be refused) or basic care (by nature not renounceable), they constitute a restriction of personal freedom if imposed against an expressed will, and affirm in this regard that any intervention not required or in any case not desired by the person constitutes a violation of personal freedom.

[v] In this sense, according to the Italian Supreme Court (Supreme Court, I Civil Section, ruling 16 October 2007, No. 21748, available from: http://www.biodiritto.org/index.php/item/187-englaro-cassazione, accessed 9 May 2018), faced with the refusal of treatment by the person concerned, there is room – in the framework of the "therapeutic alliance" that unites the patient and the doctor in the combined search of what is good respecting the cultural paths of each – for a strategy of persuasion, because the task of the legal system is also to offer support of maximum concrete solidarity in situations of weakness and suffering; and there is, first of all, the duty to verify that the refusal is informed, authentic and current. But when the refusal has such connotations, there is no possibility of disregarding it in the name of a duty of care as a principle of public order.

[vi] Section 3 of the Medical Code of Ethics establishes that duties of the doctor are the protection of life, of psycho-physical health, the treatment of pain and the relief of suffering, respecting the freedom and dignity of the person, without any discrimination, whatever the institutional or social conditions in which they operate. More specifically, section 39 states that the doctor does not abandon the patient with a poor prognosis or a definitely compromised state of consciousness, but continues to assist them and if in a terminal condition, works to sedate pain and relieve suffering, protecting the patient's will, dignity and quality of life. When a patient's state of consciousness is definitely compromised, the doctor continues with pain treatment and palliative care, implementing treatments to support vital functions as long as they are considered proportionate, taking into account the advance decisions on treatment.

[vii] Section 16 of the medical Code of ethics more specifically states that the doctor, taking into account the wishes expressed by the patient or their legal representative and the principles of effectiveness and appropriateness of care, does not undertake or insist on clinically inappropriate and ethically disproportionate diagnostic procedures and therapeutic interventions, which cannot be fully expected to provide an actual health benefit and/or improvement in the quality of life. Effective pain control is seen, in all clinical conditions, as an appropriate and proportionate treatment. The doctor who abstains from unreasonable treatments does not under any circumstances behave as if aiming to cause death. Thus, the ethical code for nurses (2009) (available from: http://www.fnopi.it/norme-e-codici/deontologia/il-codice-deontologico.htm, accessed 22 June 2018), having stated in section 3 that the responsibility of the nurse consists of assisting, caring for and taking care of the person in respect of life, health, freedom and dignity of the individual, states that the nurse is bound to prevent and combat pain and alleviate suffering (section 34); the nurse provides assistance whatever the clinical condition and to the end of life of the patient, recognising the importance of palliative care and environmental, physical, psychological, relational and spiritual comfort (Section 35); the nurse protects the patient's will to place limits on treatments that are not proportionate to their clinical condition and consistent with their concept of quality of life (section 36).

[viii] The Milan Court of Appeals, 17 October 2003 (Available from: https://www.unipv-lawtech.eu/files/englarocamilano2003.pdf, accessed 22 June 2018) in this regard warned that the lack of rules damages rights and interests that correspond to constitutionally guaranteed values (Articles 2, 3, 13, 32 Cost.) and is also an obstacle to the solution of practical problems. The Court hoped that the ordinary legislator will identify and prepare the appropriate instruments for effective protection of the person and respect for their right to self-determination, underlining as legislative intervention could avoid instrumentalization and suffering and contribute to the accountability of the community.

[ix] The Supreme Court, in its Ruling No. 23707 of 20 December 2012 (Available from: http://www.neldiritto.it/appgiurisprudenza.asp?id=8936#.VG2q5a90wdU) considered the possibility of supplementing the act for the designation in advance of the court-appointed guardian (Law 9 January 2004, No. 6, published in the Official Journal No 14 of 19 January 2004, available from: http://www.camera.it/parlam/leggi/04006l.htm, accessed 22 June 2018) with the intentions of the subject and therefore the suitability of that document to convey the advance decisions on treatment; it being understood that, since the state of incapacity is a constitutive element of the court-appointed guardianship, judicial intervention could only be contextual to manifest the need to protect the subject.

[x] Thus, for example, the Autonomous Region of Friuli-Venezia Giulia with Law No. 4/2015, amended by subsequent Regional Law No. 16/2015, set up a regional register to collect advance directives and any dispositions regarding the post mortem donation of organs and tissues and regulated formal requirements, as well as ways of collecting and keeping such declarations. This law was therefore declared constitutionally illegitimate with a ruling by the Constitutional Court No. 262/2016 (Constitutional Court, Ruling No. 262, 18 October 2016, Official Journal of the Italian Republic 1st Special Series - Constitutional Court, No. 51, 20 December 2016): the attribution of public significance to these manifestations of will implies the need for a complex regulation and interferes with the matter of 'civil law', attributed exclusively to the legislative competence of the State. On the other hand, the judges emphasised that, given its impact on essential aspects of the identity and integrity of the person, a regulation on the disposition of will regarding health treatments in the terminal phase of life requires uniform treatment across the country, for imperative reasons of equality.

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for an ideal continuation of the dialogue between the subjects when the patient is no longer able to take part consciously.[xi]

DAT are regulated by Article 4 as voluntary documents, containing a person's wishes regarding health treatment, as well as consent or refusal for diagnostic tests or therapeutic choices and for individual health treatments, drafted by an adult person capable of understanding and anticipating possible future incapacity to self-determination and after acquiring adequate medical information on the consequences of their choices.

The law therefore provides prior information for drafting DAT without specifying their modalities or any professional figure (family doctor, specialist) in charge of this function, or the possibility for the subject to independently find the information.

Being able to refer the DAT to a future situation, even if completely hypothetical, the threshold of adequacy of the information required by the law cannot be fixed, applied in practice, so to a large extent it becomes substantially similar to that required to provide actual informed consent or for the anticipated planning of treatment – institutes destined to operate in the presence of existing and punctually diagnosed pathologies. If therefore, a qualified professional would be a guarantee of adequacy compared to autonomous retrieval of medical information by the signatory, the person concerned must also be able to use this institute without great difficulty.[5]

Drafting the DAT can be by public deed, with authenticated private writing, or with private writing delivered personally by the signatory at the municipal civil status office or at the health facilities, where the Regions adopt electronic management of health records (a set of digital data and documents related to the patient) and regulations collecting copies of the DAT and including them in a database, while leaving the signatory the freedom to choose whether to give a copy or indicate where it can be found.

With Circular No. 1/2018 the Ministry of the Interior specified that the registry office can only receive a DAT delivered personally by a signatory resident in the municipality, bearing their signature, with the officer limited to verifying the delivery conditions, to receiving it and to providing the formal signatory with a receipt at the time of delivery. The office must limit itself to recording an ordered chronological list of the declarations, and ensure their proper conservation in accordance with the principles of confidentiality of personal data.

With the Budget Law of 2018, a database was set up at the Ministry of Health to register DAT. A Working Group established by the Ministry will define the information contents, registration and usability of the DAT and the security measures to protect personal data. These implementation steps will be indispensable in guaranteeing timely and accurate transmission of the DAT to the health structures and then for their application.

It is also possible, when the physical conditions of the patient mean these deeds cannot be produced, to use video-recording or devices that allow the disabled person to communicate. Some authors underline how this general formulation is particularly farsighted, as it allows the discipline under examination to adapt well to the tumultuous development of augmented and assisted communication technologies.[4]

The DAT can be modified and revoked at any time, with the indicated forms. Where emergency and urgency prevent withdrawal of the DAT with such forms, the revocation can be carried out with a verbal declaration collected or videotaped by a doctor, with the assistance of two witnesses.

The signatory can also indicate a person of trust, of age and able to understand – so-called "fiduciario", who takes their place and represents them in relations with the doctor and the health structures. The proxy accepts the appointment by signing the DAT or through a subsequent document, attached to the DAT and plays a fundamental role especially in relation to a generic DAT which needs to be concretised and "actualised".

For the DAT to be effective the law establishes that, whereas the patient cannot demand health treatment contrary to the law, professional ethics or good clinical practices (Article 1),[6] the doctor must comply with the DAT, which may be disregarded, in whole or in part, by the doctor in agreement with the proxy, if they appear clearly incongruous or mismatched to the current clinical condition of the patient or where there are therapies that could not be foreseen at the time of signing which are likely to improve living conditions. In case of conflict, the tutelary judge is involved.

This rule therefore reaffirms the professional autonomy of the doctor, recognising a fundamental role in assessing the topicality and consistency of the DAT's content in correspondence with the current clinical situation in the light of technological and scientific research progress that could benefit the patient's condition.[xii]

The Law therefore provides, with respect to the evolution of a chronic and disabling pathology or a pathology with an unstoppable evolution with poor prognosis, the so-called Shared planning of care (Article 5), to which the doctor and the health team are obliged to comply if the patient cannot express their consent or is incapable.

In this context, the subjects (the patient and, with their consent, family members or part of the civil or cohabiting partnership or a trusted person) are adequately informed about the possible evolution of the disease, about the quality of life the patient can realistically expect and about possible clinical interventions and palliative care. The patient expresses their will and intentions for the future, including any indication of a trustee, in writing or, if their physical condition does not allow it, through video recording or devices that allow the person with a disability to communicate, and this is included in the medical record and in the electronic health record.

Some authors underline how this aspect is perhaps one of the most innovative profiles of Law 219,[6] considering that if even in Italy, most deaths occur as a result of an already diagnosed disease worsening, this procedure enables many patients to be informed of their specific condition and consciously manage the phases of their pathology and adherence to the proposed treatments.

Therefore, there seems to be a significant need to promote a real awareness in decision-making autonomy in a context of information about the nature and consequences of the choices expressed

[xi] At the supranational level, an important regulatory recognition of advance directives can be found in Article 9 ("Previously expressed wishes") of the "Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine" (available from: http://conventions.coe.int/Treaty/Commun/QueVoulez Vous.asp?NT=164&CM=8&DF=01/02/2012&CL=ENG, accessed 22 June 2018), approved by the European Council in Strasbourg in 1996, signed by the Italian Government in 1997 in Oviedo and subject to the Law authorising ratification, dated March 28th, 2001, No. 145. According to the Convention "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." The Italian Supreme Court, in its judgment No. 21748 of 16 October 2007 specified in this regard the status of the Italian legal system with regard to implementation of this Convention: although Parliament has authorised its ratification with the law of March 28, 2001, No. 145, the Oviedo Convention has not yet been ratified by the Italian State. But it does not follow from this that the Convention has no effect on our legal system. In fact, an agreement valid at the international level, but not yet implemented within the State, can be assigned – especially after the parliamentary ratification authorisation law – an auxiliary function on the interpretative level: it will have to yield to contrary internal rules, but it can and must be used in the interpretation of internal rules in order to give them a reading that is as consistent as possible.

xii The Explanatory Report of the Convention on Human Rights and Biomedicine (available from: http://conventions.coe.int/Treaty/en/Reports/Html/164.htm, accessed 22 June 2018), , specifies that "when the wishes were expressed a long time before the intervention and science has since progressed, there may be grounds for not heeding the patient's opinion. The practitioner should thus, as far as possible, be satisfied that the wishes of the patient apply to the present situation and are still valid, taking account in particular of technical progress in medicine".

by the patient/ signatory.

Law 219 did not introduce new principles to those already in the legal system, but makes an important contribution in the helpful and certain implementation of health protection with a view to protecting the best interest of the patient. This is not decided *a priori*, or exclusively considered in terms of "best medical interest", but by putting at the centre of the relationship of care and trust the person, their dignity, their self-determination; the law recognises the patient's freedom of choice for therapy – also to refuse/ renounce health care treatments – and, by defining the boundaries of medical action, contributes to certainty on the consequences of this.

Parallel to full acquisition of the principles specified in the legislation by the parties involved, the implementation of an adequate information system and preparation of all necessary measures to ensure certainty in the consequences of actions and protecting the rights of all involved are now fundamental for concrete implementation of the provisions of the Law.

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