Commentary

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LAW n.219/17: Reflecting on shared care plan

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Abstract

Introduction. The study in question starts from a general analysis of Law n. 219/2017 and then to deepen the patient's right to self-determination, which is exercised through the expression of an informed consent to medical therapy. The analysis refers in particular to the patient's decision-making autonomy, the professional autonomy of the doctor and his consequent responsibility.

Materials and methods. This study examines the art. 5 of the Law n. 219/2017, where the Legislator has defined the theme of shared planning of care. The authors compare the Advance Treatment Provisions (Article 4 - Law No. 219/2017) and the Shared Care Planning, to then examine the emerging relationship of care between doctor and patient.

Results. The relationship of care must be related to the patient's willingness to decide on his future and to the technical and scientific information that the doctor is required to give.

Conclusion. In conclusion, the Authors highlight the innovative content of the shared care plan, emphasizing the importance for a patient suffering from a chronic and progressive disease to be actively involved in formulating their own therapeutic plan. ***Clin Ter 2020; 171 (5):e401-406. doi: 10.7417/CT.2020.2248***

Key words: *Medical planning, Self-determination, Medical sharing*

Introduction

With Law No. 219/2017, also known with the misnomer "living will Law' ('Legge sul biotestamento' or 'Legge sul testamento biologico' in Italian), Italian lawmakers have introduced specific definitions, provisions and principles into the Italian legal system in order to standardise and align both health protocols and case law concerning patient self-determination when under therapeutic care (1 - 2).

A particular attention has been given to the doctor-patient rapport and the resulting care relationship as prerequisites to informed consent which, in turn, brings into focus both patient and doctor autonomy in clinical decision making as well as the physician's ensuing liability (3).

The structure of Law No. 219/17 highlights the need for a continuous patient's involvement in all decisions related to the treatments they undergo. Shared planning, in terms of both what patients want and what their illness may require, is also foreseen. To this end, obtaining the patient's informed consent is essential for assuring the legality of any medical or surgical treatment as well as any other diagnostic or therapeutic activity. Human dignity, individual self-determination and the inviolable right to personal freedom must all be upheld (4 -5). In particular, Law No. 219/2017 assures all individuals the right to obtain information about their health conditions. It further stipulates that anyone may decide to refuse or discontinue existing treatments, diagnostic tests and any type of life-sustaining measure (including artificial feeding and hydration, among others) (6).

Under the concept of informed consent, individuals, in order to be actively involved in decision making process concerning them, must express their conscious, personal, specific, prior and current, revocable, free and unconditioned consent. The Italian Supreme Court of Cassation with Decision No. 11749/2018 highlighted that "According to the definition provided by the Court of Cassation (Decision No. 438 dated 23rd December 2008) and shared by this Court (Court of Cassation No. 2847 dated 09/02/2010), informed consent, intended as an expression of conscious acceptance of the health treatment proposed by physicians, constitutes a real right of individuals. It is based on the principles laid down in Art. 2 of the Constitution assuring the protection and promotion of fundamental rights, and in Art. 13 and Art. 32 of the Constitution, paragraph 2, which state, respectively, that "personal freedom is inviolable" and that "no one shall be forced to undergo any specific health treatment, except by legal provision".

Therefore, the doctor must inform the patient about the nature of the proposed procedure in an understandable way to them, the range of feasible and likely outcomes that can be achieved and the implications that can be verified. The doctor has also the duty to inform the patient about any available alternatives, as well as the consequences of rejecting any treatment or diagnostic measure, or of waiving any them. Hence, a patient's consent must be informed, authentic and

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current, since it is essential for assuring the legality of any medical or surgical treatment (7).

Informed consent is a key element in the shared care plan, as provided for by Art. 5 of Law No. 219/2017. It aims to clearly set out the patient's wishes with regard to any ever-worsening consequences of a chronic and disabling disease they may be suffering from. The doctor is required to comply with these wishes, should the patient be incapacitated or unable to express their consent.

Shared care plan and advance directives (ADs) under Law No. 219/2017

Before addressing the specific steps involved in a shared care plan under Art. 5 of Law No. 219/2017, it is useful to compare it with advance directives ('disposizioni anticipate di trattamento' or 'DAT' in Italian), as specified under Art. 4 of the same law.

Article 5, paragraph 1, provides that: *"As part of the patient-doctor relationship referred to in Article 1, paragraph 2, and regarding the ongoing consequences of a chronic disabling disease or one characterised by an ever-worsening and poor prognosis, a shared care plan can be developed by the patient and the doctor. The doctor and healthcare team are then required to follow this plan in the event the patient may later lack the capacity to provide consent"*. First of all, it is to be noted that the undertaking of a shared care plan should be limited to an illness situation in which therapeutic treatment arises, defining the *"doctor-patient relationship"*. Article 4, in contrast, states that *"advance directives* (again, 'disposizioni anticipate di trattamento', or 'DAT' for short, in Italian) *can be used by any competent adult able to make and express decisions, in anticipating a possible future inability to self-determination and after obtaining sufficient information on the consequences of their choices. ADs, then express the patient's wishes in terms of care and provide or deny their consent for diagnostic procedures, therapeutic choices and individual health treatments ..."*. The context in which ADs can be applied is limited to the pre-treatment phase for an illness, since *"each person"* (and not only the patient) can express their wishes regardless of any existing care ralationship with a doctor.

The text of the two Articles reflects the different terminology used in their drafting. At the beginning of Article 5, the lawmaker uses the term "patient" in a very precise way in order to indicate subjects who are undergoing a therapeutic *process* or suffering from a disease. On the other hand, the term "person" refers to a larger group of individuals that likely encompasses 'patients'. Any 'person', therefore, can arrange their own ADs, but only 'patients' can undertake a care plan. Another significant difference is that *"... doctors, together with a trustee for the patient, may entirely or partly ignore the advance directives (ADs) if they seem patently incongruous or inappropriate with the patient's current clinical conditions or if they unforeseen therapies become available which can tangibly improve patient quality of life..."* (See Art. 4, paragraph 5, Law 219/2017). In contrast, the doctor and the health team are required to follow the shared care plan indications *"if the patient is incapacitated or unable to express autonomous consent" (See* Art. 5, paragraph 1, Law 219/2017).

A final noteworthy difference between the two articles addresses the formalities they involve. Paragraph 6 of Art. 4 imposes highly restrictive and precise formal obligations with regard to ADs which must be drafted alternatively in the form of a public document, a notarised private agreement, or a private agreement conveyed by the settlor in person to the local civil registration office or health facilities in the municipality where they resides. In contrast, according to Article 5 no specific formalities are required with regard to the shared care plan, apart from the need for the patient's written consent (in the event the patient's physical condition does not enable to provide written consent, video or other communication devices for people with disabilities are allowed). This consent is subsequently included in the patient's medical record and digital health file.

Art. 5 of Law No. 219/2017: the care relationship

According to the Italian Bioethics Council (Consulta di Bioetica), the care relationship consists of: *"a particular relationship established between a doctor (or, more broadly speaking, a healthcare professional) and a patient suffering from an illness, involving specific moral and legal rights and duties. It is an asymmetrical relationship in which the patient is more vulnerable, being dependent on the doctor's competence and power."*[1]

Lawmakers place shared care plan within the overall care relationship between doctor and patient. Furthermore, this relationship can be updated and modified as wanted or required by the patient. To be noticed that planning is not mandatory but *"can be carried out"*, in compliance with the principle of patient self-determination. Within the doctor-patient relationship, they take on different roles which are normatively defined: *"the patient or, with his consent, other family members, a legal or cohabiting partner or trusted person"* are all considered self-determining agents in relation to the therapeutic plan provided by the doctor and medical team. The doctor has the duty to tell the patient about his or her health condition and must inform them in a comprehensive, up-to-date and understandable way about their diagnosis, prognosis, the risks and benefits of any diagnostic tests or any indicated health treatments. The doctor must also inform the patient about possible alternatives as well as the consequences of rejecting any treatment or diagnostic measure (Art.1, paragraph 3, Law 219/2017). It is worth reiterating that, despite the constitutionally guaranteed principle of self-determination, the patient still *"may entirely or in part refuse information or designate a family member or trusted person to receive this information and give consent on their behalf and according to theirs wishes "* (Art. 1, paragraph 3, Law 219/2017).

[1] See https://www.consultadibioetica.org/rapporto-medico-paziente/

In general, the care relationship that exists between doctor and patient can already be considered a shared care plan. The doctor offers his technical and scientific expertise to ensure the patient fully understands their condition and to plan an overall treatment plan. The patient, in turn, expresses their consent by choosing whether to follow the therapeutic plan proposed by the doctor or not.

A closer analysis, however, reveals that the shared care plan emerges only in case of *"ever-worsening consequences of a chronic, disabling, and inevitably progressing pathology or one with a poor prognosis"* (Art. 5, paragraph 2, Law 219/17).

Shared care plan then is allowed only under certain conditions that include the existence of a chronic and disabling disease, that is a disease which is understood to have prolonged effects over time, leading to the loss of the ability to perform daily activities. Another condition is a *"poor prognosis"* which means a clinical assessment by the doctor who believes that the patient's disease will generally have negative outcomes compared to what *"the patient can realistically expect in terms of quality of life"* (Art. 5, paragraph 2, Law 219/17).

The wishes of the patient and the technical and scientific information given by the doctor

Law No. 219/2017 repeatedly states that the patient has the right to self-determine the outcome of their illness condition and that the doctor must always respect this choice (8). Therefore, the patient must be fully aware of all the consequences arising from their decisions and the doctor with the entire medical team involved in the therapeutic *process* must supervise the patient in order to ensure this requirement. The medical team must make the patient aware of the potential evolution of their ongoing illness, possible clinical interventions, palliative care and what to realistically expect in terms of outcomes and related quality of life impacts.

In such a context, it is essential for the patient and, before them, their doctors, to have a clear understanding of the difference between health treatments aiming to therapeutic purposes impacting on their lifespan, and the so-called palliative care affecting primarily the quality of life rather than its length.

The word 'palliative' comes from the Latin *pallium* (cloak), which gives the idea of covering, wrapping, protecting (as with a cloak).

The World Health Organization has established that: "Palliative care is an approach that improves the quality of life of patients (adults and children) and their families who are facing problems associated with life-threatening illness. It prevents and relieves suffering through the early identification, correct assessment and treatment of pain and other problems, whether physical, psychosocial or spiritual"[2].

[2] https://www.who.int/news-room/fact-sheets/detail/palliative-care

Firstly, when reading this definition, its wide scope is immediately clear: support must be provided both to patients and their families. In this light, Law No. 219/2017 seems to pursue the same goal. Indeed, with the patient's consent, also family members or cohabitants, or even civil union partners may be involved in the care relationship.

Secondly, clearly enough, palliative care must include not only treatments aiming to handle physical disorders, but also any kind of support helping to relieve psychological and spiritual issues. It is therefore clear that when referring to palliative care, a multi-professional approach must be intended as designed to improve the overall quality of life of terminally ill patients and their families. It shall be adjusted according to the complexity of any specific clinical case taking advantage from the synergistic collaboration of all the various healthcare professionals involved.

Palliative care is a recognized component of the right to healthcare, guaranteed in Italy by Art. 32 of the Constitution.

From a regulatory point of view, Law No. 38/2010 on "Provisions to ensure access to palliative care and pain management" is the end point of an evolutionary, conceptual, and cultural process that began in Italy around the '80s of the last century.

The above-mentioned Law represented a turning point since, for the first time, it ensured patients' access to palliative care and pain management as one of the "Essential Levels of Care" (Livelli Essenziali di Assistenza, or LEA for short, in Italian), whose purpose was to guarantee the respect for the dignity and autonomy of individuals, their right to health, as well as a fair access to care and an appropriate, high quality care.

In particular, in Article 1, Lawmakers' aimed to protect "citizens' right to access palliative care and pain management", so as to enshrine patients' right not to suffer and, consequently, to require the protection of this principle by the healthcare professionals involved in the care relationship.

Art. 2 provides a comprehensive definition of what palliative care means, namely: "all the therapeutic, diagnostic and care interventions addressed both to patients and their families aiming to an ongoing and complete care of patients whose underlying disease, being characterized by an inexorable progress and poor prognosis, is no longer responsive to any specific treatments".

In the context of Law No. 38/2010, a "sick person" is identified as someone "suffering from a chronic and ever-worsening disease for which there are no available therapies or, if any, they have been proved inappropriate or ineffective not only in stabilizing the disease or in extending significantly the patient's life expectancy, but also in delaying moderate-to-severe chronic disease progression and relieving painful condition.

Law no. 219/2017makes clear the analogy with the concept of "sick person" who can access to an advance care plan.

According to a WHO estimate, palliative care is used in patients experiencing a wide range of mostly chronic conditions, the most frequent being: cardiovascular disorders (38.5%), cancer (34%), chronic respiratory diseases (10.3%), AIDS (5.7%), and diabetes (4.6%). Other conditions that may require palliative care include kidney failure, chro-

nic liver disease, multiple sclerosis, Parkinson's disease, rheumatoid arthritis and some infectious diseases such as drug-resistant tuberculosis.

Chronic pain is one of the symptoms that most frequently afflict patients, who are candidates for palliative care. For example, about 80% of patients with AIDS or cancer and 67% of patients with cardiovascular disorders or chronic obstructive pulmonary disease experience moderate to severe pain during the course of the disease.

Looking at these data, therefore, chronic pain management is clearly one of the most frequent and important goals of a palliative care team's daily work. It is also clear that, given the high frequency of pain symptoms in patients suffering from chronic disease, pain relief is often part of the shared care plan.

During their last days and hours of life, terminally ill patients may experience a variety of symptoms, including delirium, agitation, anxiety, terminal restlessness, dyspnoea, pain, vomiting, both psychological and physical distress. In some cases, these symptoms can worsen progressively and become unmanageable with supportive and palliative care, no matter how specific and targeted it is (9): under these circumstances, deep palliative sedation might be needed.

Sometimes, palliative sedation has been defined in different and contradicting ways. In any case, the key concept lies in the intentional decrease of a patient's level of consciousness in order to relieve their distress and suffering. Patients in their last days of life suffering from refractory symptoms is a necessary precondition for the use of palliative sedation.

In such cases, palliative sedation may differ in duration – intermittent or continuous until death – and depth – mild or deep. In any case, the aim should not be to accelerate a patient's death, but to provide relief from distressing symptoms. For this purpose, titrated doses of Midazolam are usually administered until the above goal is achieved (10).

This issue has also been tackled by Law No. 219/2017, in particular in Article 2 which states that: "In cases of patients with poor short-term prognosis or imminent death, doctors must abstain from administering unnecessary or disproportionate treatment with foolish obstinacy. In the presence of treatment-refractory pain and with patients' consent, physicians may resort to continuous deep palliative sedation in association with pain-relief therapy. The use or rejection of continuous deep palliative sedation shall be justified and recorded in both patients' medical chart and Electronic Health Record (EHR)".

The Court of Cassation with Decision No. 26889/2018 ruled that "deep sedation ... is part of palliative medicine whereby drugs are intentionally administered, in the required dose, in order to reduce or nearly to achieve zero patients' level of consciousness. The aim is to relieve them from unbearable physical or mental suffering, when they are in conditions of imminent death with a prognosis of a few hours or little longer for an incurable advanced illness, but subject to their informed consent".

Deep palliative sedation is an extremely sensitive issue, requiring primarily bioethical and purely practical considerations.

Therefore, it is essential that, when planning care with a patient who, in a more or less near future, is likely to need it, the entire decision-making process must be clear, well defined, and documented. Above all, the patient must be fully aware of it.

At this stage, it is important to identify the correct doctor and team because together they will carry out the care plan once the patient has been adequately informed and the therapy is agreed upon based on latter's wishes.

With regard to the doctor's role, it is crucial to identify a physician immediately since he or she is the professional who will guide the patient's therapeutic *process*.

On the other hand, finding the medical team requires a higher effort because a complex disease involves the technical and scientific contributions of not just one, but several doctors and in some cases of other health professionals (nurses, technicians, etc...), coming from different hospitals and providing their expertise at different times during the patient's illness. In our view, in such cases the shared care plan can be assumed as an open-ended activity *"updatable as the disease progresses"* that will necessarily involve all the doctors who constructively participate and collaborate in administering therapy. Each of them is then responsible for the specific actions they are entrusted with the care plan. The team, therefore, includes all health professionals who are involved in treating the patient's disease and who have been informed about any existing plan by the doctors already providing treatment. The doctors who make up the team will also have to inform the patient of the activities they will be undertaking. In this way, the team can also contribute to updating the shared care plan.

In this regard, according to the legal theory, if the doctor or team (either freelance consultants or staff) deviate from the shared care plan, they are contractually liable to the patient since the legal nature of the plan is a contractual outcome. In other words, the plan is the result of a voluntary agreement entered into by the parties (patient and doctor/team) preparing the therapeutic plan.

According to this approach, the fact that the care plan may - rather than must - be defined by patients with their doctors confirms the voluntary nature of such an act, which is also meant to specify all relevant contents and regulate its legal effects (11).

In our opinion, despite the contractual nature of the shared care plan, the liability of the doctor or team carrying out their medical services within a "structured" health care company should be judged according to tort liability (11). This is because the agreement engaged in and shared between the patient and doctor or team is framed by a previous relationship between the patient and health service structure that is solely liable for fulfilling the contractual obligation, pursuant to Art. 7 of Law 24/2017 (12-13).

As a matter of fact, contractual liability can be invoked upon whenever the damage is the consequence of a breach of duty arising from a legal relationship – which can also refer to the agreed planning of a series of actions – between the aggrieved party and the defaulting party. In the case of shared care planning, the patient (the aggrieved party), before agreeing on their therapeutic planning with the individual physician and their team, has established a legal relationship with the health service structure through his/her hospitalisation. Liability for failure to comply with the guidelines contained in the shared care plan refers to this

relationship. It will be in contract for the structure and in tort for the hospital physician[3].

Finally, it is important to mention the key figure of trustee covered by Article 5, paragraphs 2, 3 and 4. In the event the doctor is not present, or the patient is incapacitated, the trustee will be liable for managing the situations outlined in the shared care plan. In this situation, it will be the trustee who will also have to disclose the care plan to any health professionals who may not be aware of it. The trustee will further have to liaise with health professionals in case of an unclear plan with respect to any situation the patient might suffer.

Conclusions

The inclusion of both the concepts of advanced directives and shared care plan into the Italian law system is undoubtedly a key and an essential step to pursue protection of every citizen's right to self-determination, which is already guaranteed under the Italian Constitution.

In particular, shared care plan is a tool through which patients suffering from chronic and progressive diseases can actively participate in formulating their own care plan. Thus, they have the opportunity to be fully informed about their condition, its course, and future perspectives. In this way, they are also able to express consciously their preferences and, together with doctors, concurrently plan the therapeutic plan they will be undergoing. Quite important is also the possibility to involve actively the so-called patients' 'social network', namely their family.

The issues covered by Law No. 219/2017 represent a major legislative innovation, since they have opened up a new frontier with significant repercussions on the care relationship between doctor and patient, and given them new and different roles from the past.

In this new scenario, patient/the sick become more and more focused and involved in their own healthcare decisions. Through a shared care plan, they can be actively involved in their own therapeutic destiny. Clearly enough, however, for this to happen, healthcare professionals need to literally take their patients by the hand and guide them to make decisions that are not only shared, but also perfectly conscious. In this context, therefore, it is essential for doctors to be fully familiar with the clinical circumstances in which they are working, as well as with the regulatory framework, and with both its actual impact – difference between advance directives and shared care planning and importance of informed consent – and any likely repercussions (liability-related issues) on their daily work.

A closer analysis reveals that for a full and thorough implementation of the law, every healthcare professional, not only those who normally deal with terminally ill people, should be familiar with these issues.

Consider, for example, the General Practitioners (GPs) role. GPs are key figures in the process of advance and shared care planning being able to detect chronic diseases early on. Therefore, before life-threatening conditions occur, they can make both patients and their families aware of their condition and refer them to the right consultant.

Last but not least, the Authors believe that, to ensure an effective and complete implementation of the examined legal provisions, *ad hoc* guidelines or practical recommendations are still needed. Under their guidance, every healthcare professional – regardless they are working in outpatient settings or in hospitals – will be able to plan, for and together with each patient, a customized healthcare pathway, in a simplified and updatable manner. Also, each patient should be provided with an IT device to store and further share any health information data.

Undoubtedly, this delicate decision will need to be perfected from time to time and on a case-by-case basis. At the same time, patient self-determination must be ensured as well as dialogue and trust between doctor and patient.

References

1. AA.VV Forum: La Legge 219 del 2017, Norme in materia di consenso informato e di disposizioni anticipate di trattamento (AA.VV Forum: Law 219 of 2017, Regulations in the area of informed consent and advance directives). BiowLaw Journal 2018; Issue 1, 66-0
2. De Filippis B. Biotestamento e fine vita (Living Wills and the end of life). Cedam, Padua 2018
3. Vallini A. Pianificazione condivisa delle cure, medicina palliativa. I nuovi paradigmi del "fine vita" (Shared care plan, palliative medicine. New paradigms for the "end of life"). Riv. It. Med. Leg. (Italian Journal of Legal Medicine), 2016; 38, 3:1139-1154
4. Pucella R. Autodeterminazione e responsabilità nella relazione di cura (Self-determination and responsibility in the care relationship). Giuffrè Milan, 2010
5. Cacace S. Ma quanto è debole il consenso informato! L'ultima giurisprudenza sul rifiuto all'emotrasfusione. Apologia di un principio inutile (e qualche tentativo esegetico) (How weak informed consent is! The latest case law on the refusal of blood transfusions. An apology for a useless principle (and an exegetical attempt)), Riv. It. Med. Leg. (Italian Journal of Legal Medicine) 2017; 139: 1:17-29
6. Baldini G. Prime riflessioni a margine della legge n. 219/17 (Initial reflections in light of Law No. 219/17). Rivista di BioDiritto (Journal of BioRights), 2018; 2: 56-0.
7. Viola RV, Di Fazio N, Del Fante Z, et al. Rules on informed consent and advance directives at the end-of-life: the new Italian law. Clin Ter. 2020 Mar-Apr;171(2):e94-e96
8. Cacace S. Autodeterminazione in salute (Self-determination and health). Giappichelli ed. Turin, 2017

[3] In summary: pursuant to ex Article 1218 of the Italian Civil Code contractual liability provides that the statute of limitations for breach of duty arising from a binding obligation in force before the non-performance is ten years. Patients must provide evidence of the existence of the contract, or of the obligation, as well as of the evidence of the damage suffered, without having to prove the error. The debtor (healthcare facility or freelance consultant) must prove that they could not have achieved any better results. Pursuant to ex Article 2043 of the Italian Civil Code liability in tort provides that the statute of limitations for breach of a right *erga omnes* is five years and the legal burden of proof falls on the patient, who shall have to prove both damage and error.

9. Beller EM, Van Driel ML, McGregor L, et al. Palliative pharmacological sedation for terminally ill adults. Cochrane Database of Systematic Reviews 2015: 1
10. Payne SA, Hasselaar J. European Palliative Sedation Project. J Palliat Med. February 2020
11. Gonzati A, Benci L. Legge Gelli e mancato rispetto della pianificazione condivisa delle cure: ritorno alla responsabilità contrattuale? (Gelli Law and non-compliance with shared care plan: back to contractual liability?). Rivista Quotidianosanità.it (Quotidianosanità Journal), 2018. Available online at http://www.quotidianosanita.it
12. Rodríguez D, Aprile A. La "pianificazione condivisa delle cure". Una novità che coglie impreparati sia medici che pazienti (The "shared care plan". A new issue that has caught both doctors and patients unprepared). Rivista Quotidianosanità.it (Quotidianosanità Journal), 2018. Available on-line at http://www.quotidianosanita.it
13. Fiori A, Marchetti D. Medicina Legale della responsabilità medica (Legal Medicine and Medical Responsibility). Second edition. Giuffrè Francis Lefebvre, 2018