

The state of knowledge of young Italian medicolegal doctors on the law of provisions for informed consent and advance treatment directives: a multi-centric survey two years after the enactment of Law 219 of 2017

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Abstract Background. On 22 December 2017, Law No. 219 was approved in Italy entitled “Provisions on informed consent and advance treatment directives”. This article reports the results from a survey of the knowledge of medico-legal experts in Italy on these provisions, in addition to the ability of university health-care facilities in Italy to implement the principles of this new law. **Methods.** A survey questionnaire was sent to members of a scientific society. The society had 357 members and represented more than 75% of doctors in training and 32 university healthcare facilities in Italy. 27 of those facilities and 45% of the society’s members participated in this enquiry. **Results.** The majority (68%) of those interviewed felt they had acquired an adequate knowledge of the law but only 60% of them were able to indicate how to file legally valid advance directives (60% vs. 40%); only 37% knew how to draft a shared care plan. 89% of the pool felt that legal recognition of patient self-determination enhanced the care relationship. 74% of the facilities analyzed have organized training activities on the contents of the law but only 26% have updated their informed consent forms and procedures. 60% of the facilities perform medico-legal consultation activities and in 15% of the facilities there has been resistance to applying the law. **Conclusion.** Many of the facilities have set up training activities but lack effective implementation of those activities. With increased knowledge and organization this could be remedied. (www.actabiomedica.it)

Keywords: informed consent, self-determination, advance directives, shared care plan, conscientious objection, legal medicine

Introduction

On 22 December 2017, Law No. 219/2017, entitled “Provisions on informed consent and advance treatment directives”, was approved by the Italian Parliament. This legislative provision arrived as the result of a long period of debate in the civil sector and Italian case law, especially as regards the option of refusing healthcare treatment in the event of a pathological situation that renders the patient incapable of making conscious decisions regarding the treatments that he or she desires (1- 7).

Law No. 219/2017 provides indications that affect the care relationship established between patients and doctors. It recognizes the patient’s decision-making autonomy within the care relationship, which has been reinforced, and overcomes the biologically-imposed physical and temporal limits on the patient’s consciousness. In addition, it remains legally valid even if the patient becomes incapacitated. This recent legislation began with previous measures. The first was the constitutional provision of Art. 32, which states: “No one can be forced to accept a certain medical treatment unless provided for by law. The law may not in any way violate the limits imposed by respect for the human person”. Thereafter, Law No. 833/1978, which instituted the National Health Service in Italy, states that “Physical and mental health protection must be achieved with respect for the dignity and freedom of the human person” (Art. 1), stating the exceptional nature of obligatory medical treatments, which in any case must “be performed in conjunction with initiatives to ensure the consent and participation of the person thereby obliged” (Art. 33). Even the Convention on Human Rights and Biomedicine, adopted in Oviedo on 4 April 1997, ratified in Italy by Law No. 145 dated 28 March 2001, and therefore substantively recognized in our legal system, reiterated the importance of providing information and obtaining patient consent as fundamental elements of the care relationship.

The new law provides: 1) clear boundaries for informed consent: the terms of the information to be given to the patient, the methods accepted for expressing consent, the insuperability of the patient’s wishes as regards unwanted healthcare treatments, including artificial hydration and nutrition, express release from

liability for doctors who do not administer treatments that are necessary for the patient’s safety but refused by the patient; 2) specific indications as regards the imminence of death and the prohibition of unreasonable obstinacy in therapeutic activities with the guarantee of access to pain therapy; 3) the opportunity to consent to or refuse care and treatments prior to the occurrence of an illness or loss of autonomy by means of the following tools: a) advance treatment directives: a written document, filed with a notary or with the offices of the municipality and binding upon medical professionals, and b) shared care plan: jointly drafted by the care team and the patient in the event the latter were to become incapacitated as a consequence of an illness or medical treatment.

Such provisions are to be integrated into the previous scenario, characterized by the basic respect for the principles contained in the new law (8-14). However, the provision has given due and unequivocal recognition to the supremacy of the patient’s wishes as opposed to paternalistic medical presumptions and it has done this by means of specific methods and tools such as advance treatment directives and shared care plans. It is therefore to be expected that such innovations may present some initial implementation difficulties due to the need to acquire an understanding of the new regulatory boundaries.

The role of medico-legal experts in such circumstances is thus useful and necessary, due to the “clinical” dimension of the discipline, i.e. in conjunction with the clinical staff, in order to provide support in utilizing the provisions of the law in processes connected to the therapeutic alliance, rendering all those concerned more aware of their potential contribution to the doctor-patient relationship.

Given legal medicine has such a significant role, it is beneficial not only for ensuring patient rights and the serenity of professionals, but also for preventing potential disputes before they arise (15).

This raises a new and important issue of whether medico-legal experts are adequately prepared to handle this task and whether the facilities in which they work have, to date, made adequate provisions in order to promote application of the law.

In this article, we aim to survey the extent to which young medico-legal experts in Italy have

acquired knowledge of these legislative provisions and the ability of university healthcare facilities in Italy to implement the principles of this new law.

The questionnaire. A preliminary draft of a questionnaire was created in Italian containing closed questions on aspects such as general knowledge of Law 219 and the opinions of doctors on its contents. To determine if the questions were clear, the preliminary draft was proof-read by a group of legal and clinical experts.

After a slight modification of the first draft, the final version of the questionnaire contained 5 closed questions on each doctor's personal opinion and knowledge of the law (Table 1) and 5 closed questions addressed to the territorial representative of the association on the activities and changes that have been introduced in the workplace since the introduction of the new law (Table 2). The questionnaires were completely anonymous and distributed beginning 01.12.2019 to the members of the association by an

e-mail and a cover letter explaining the objectives of the research. Members were asked to reply within 30 days. The data was collected through IT applications such as Google Form Survey.

Participants. In order for the information coverage to include all of Italy, the authors developed the project in conjunction with the Board of Young Italian Medico-legal Experts. This national scientific society includes young medico-legal experts within five years of achieving specialist status in legal medicine and doctors in specialist training who are enrolled in schools for specialization in legal medicine in Italy. The association represents over 90% of forensic doctors in Italy under the age of 40. All members of this national scientific society were involved in the study.

In 2019, the society had 357 members and represented over 75% of doctors in training and 32 university healthcare facilities in Italy. The invitation to participate in the survey was accepted by 27

Table 1. Questions related to personal knowledge about medicolegal issues of the Italian law No. 219/2017

Questions related to personal knowledge about medicolegal issues of the Italian law No. 219/2017	YES	NO
1. Do you deeply know Italian law No. 219/2017?	(109) 68%	(52) 32%
2. Do you know the different possibilities of recording of advance declarations of treatment?	(97) 60%	(64) 40%
3. Do you know how the must be done?	(60) 37%	(101) 63%
4. Do you think that the Italian law No. 219/2017 change the way of thinking and approaching to the end of the life?	(68) 42%	(93) 58%
5. Do you think that the recognition of the patient self-determination, described in the Italian law No. 219/2017, could be help the care relationship?	(143) 89%	(18) 11%

Table 2. Questions related to the changes in hospital management after Italian law No. 219/2017

Questions related to the changes in hospital management after Italian law No. 219/2017	YES	NO
1. Did your medical-legal School organize training events to promote Italian law No. 219/2017?	20 (74%)	7 (26%)
2. Did your medical-legal School change or create new procedures or operating protocols for the applications of the Italian law No. 219/2017?	7(26%)	20 (74%)
3. Did your Hospital change the informed consent form, after the Italian law n No. 219/2017?	7(26%)	(74%)
4. Did you perform medico legal consulting about the Italian law No. 219/20 17 in your Hospital?	16 (60%)	11 (40%)
5. Did you find or do you find some difficulties in applying the Italian law No. 219/2017 by healthcare professional in your hospital?	4(15%)	23 (85%)

representatives of the association at the local hospital level and 45% (161) of the society's members. Only complete questionnaires were considered.

Statistical analysis. The questionnaires contained closed questions only with two possible answers (yes / no). No other data concerning the characteristics of the participants was collected as they are part of a previously selected group and representative of the population of forensic doctors in Italy. All data was processed in strict anonymity, without collecting data on the participant of origin through Excel. The results have been expressed as a percentage, using the total number of respondents as the total (161) for the first questionnaire and the total number of respondent facilities as the total (27) for the second questionnaire.

Results

In the section dedicated to questions regarding the professionals' personal knowledge (Table 1), the majority (68% vs. 26%) of those interviewed felt they had acquired an adequate knowledge of the principles of Law 219.

However, that percentage decreased when asked if they would be able to indicate the methods for filing legally valid advance directives (60% vs. 40%) and decreased even further when asked if they knew the methods for drafting a shared care plan; the majority of the pool admitted they did not (37% vs. 63%). These young medico-legal experts seem to have a positive opinion on the structure and potential of the new law. The majority of the pool (89% vs. 11%) felt that legal recognition of patient self-determination enhanced the care relationship.

The results from the section of the questionnaire dedicated to the activities performed by the respective university healthcare facilities (Table 2) showed that the majority of those facilities (74% vs. 26%) had organized training and updating activities in connection with the contents of Law 219. However, the percentages inverted when asked if procedures regarding the practical implementation of the law had been created or updated (26% vs. 74%). The same percentage was found regarding whether consent forms had been updated since December 2017 (26%

vs. 74%). The results showed that medico-legal consultation activities pertaining to the aspects covered by Law 219 were being performed in only 60% of the facilities interviewed. Resistance to applying the law was detected on the part of healthcare professionals in a limited number of facilities (15% vs. 85%).

Discussion

Prior to Law 219/2017, there was no procedure for filing legally valid advance directives on matters of care and medical activities, and in cases where patients refused treatment that doctors deemed life-saving, some doubts remained, though opposed by those who already abided by the previously mentioned regulations as regards the appropriacy of activities that could be performed. For these reasons, Law 219/2017 was met with noteworthy media attention, the focus being the advance directives. This explains, at least in part, the fact that in answer to the questions pertaining to the professionals' personal knowledge more than two thirds of the pool (68%) stated they possessed adequate knowledge of the contents of the law and a similar, although slightly smaller, percentage (60%) stated they knew the methods for filing the advance directives. The results on the question regarding shared care plans were very different: only 37% of those interviewed stated that they knew the methods.

Shared care plans. Shared care plans are an extraordinary tool that allies patients and care teams. The objective is to create a patient-oriented service in which people with complex medical and social needs can receive treatment in accordance with their values, needs and preferences (16-19). These plans take into account the potential development of an illness, the clinical intervention options, and the patient's wishes and life expectations in terms of quantity and quality. This tool, which for practical purposes translates into a document, is drafted as a result of meetings held to ensure the patient is in possession of adequate information. It is signed by the patient and medical practitioners "at the patient's bedside" and becomes binding to all persons concerned, even in the event the patient were to become incapacitated in the future. It may be implemented by medical staff autonomously, although,

at least for the more complex situations and in the initial implementation stages, it is a clinical medico-legal activity where the medico-legal expert provides support to the clinician and patient during those meetings and when drafting the document.

The fact that a significant part of the interviewed pool (63%) stated that they were not aware of the methods for drafting the shared care plan and that a non-insignificant part of the pool (32%) stated they were not aware of the contents of the law demonstrates the need for training in medico-legal activities. Although the topic of legal medicine has been expanded in recent years to include topics concerning predominantly laboratory interests, it is important to avoid losing training capability on the conventional topics of clinical legal medicine. The teaching of legal principles and principles pertaining to consultation activities should constitute fundamental activities in schools for specialization, including for the purposes of following through on ministerial directions on training profiles that justify awarding specialization scholarships for the “needs of the National Health Service”.

Medico-legal consultation activities. The activities performed by medico-legal services necessitate coordination at the healthcare management level. The hospital plan must also foresee the needs of the new law by gathering data as regards the consultations and planning carried out within the local hospital. The results demonstrate that 40% of the university healthcare facilities involved in the study do not provide medico-legal consultations concerning aspects pertaining to the new law. In reality, these consultations facilitate collective reasoning on individual cases, an exchange between clinicians and medico-legal experts that serves as a tool to safeguard patient health and freedom of choice. Not to be forgotten, therefore, is the fundamental contribution that clinical legal medicine can provide in all hospitals by implementing activities for the prevention and protection of the individual's health and support to medical staff including aspects pertaining to the application of the new law. Administrators who make economic and management decisions need to be aware of this aspect, giving this particular element of the discipline the right amount of time and recognition, including in terms of personnel (20).

Opinions on the legislative structure. As regards the opinions expressed by the young medico-legal experts, the results of the enquiry showed that many feel no substantial change has been made to the way clinical staff view end-of-life situations; only 42% of the pool thought that the law had brought about a change. This fact can be interpreted in two ways: on the one hand, it may be that the mature ethical conscience present prior to the implementation of this law had created a code of conduct regarding those issues, forming the basis for practices to respect patient wishes that have been in use for many years already. It is also possible that such a statement is the result of a limited knowledge of the principles of the law in the clinical setting and therefore, despite the amount of time that has passed since the law was enacted, the legislative system has not been as effective as it could have.

On the other hand, 89% of the pool seemed to agree on the fact that the law, by giving recognition to patient self-determination, can enhance the care relationship. This statement is derived from the fact that very often there is an apparent increase in litigation due to the medical liability associated with issues pertaining to consent, information and self-determination. Such litigation has contributed to the creation of a defensive climate where clear and defined boundaries within which to operate may not have existed, so much so that many doctors were pushed not to respect the patient's wishes for fear of the legal ramifications they would encounter due to the negative consequences, on both the person's life and safety, of a refusal (21). The clear legislative provision (Art. 1 (6)) regarding the fact that doctors are exempt from civil and criminal liability for the consequences of a refusal certainly provides relief. The fact that the law provides for a care relationship that involves, should the patient so desire, other people that he or she is close to such as family members or a partner is also an important source of relief and assists firstly in the information gathering and subsequently the decision-making stage. The legal provision (Art. 1 (8)) also stipulates that the time dedicated to information gathering is included in care time - adequate time to discuss values, options and preferences relating to the patient's condition and personal concept of health and the future that the patient wishes to see materialize.

Training. The data shows that 74% of the facilities have organized training activities pertaining to the contents of the law. These activities do not represent a virtuous choice, rather an obligation required by the law itself in Art. 1 (9) and (10). However, in many cases it has been noted that the training activities do not provide complete and effective implementation of the law, as procedures regarding the day-to-day application of the law have only been created and updated in 24% of the cases. These aspects are of fundamental importance in a clinical and hospital setting because they enable all to abide by simple and practical rules, thus rendering the operation of professionals and teams uniform. Achieving complete application of the law will be unlikely unless procedures are standardized.

In only 24% of cases have the facilities updated the consent forms that are used and signed by patients. This is an interesting statistic. Art. 1 (3) of the law states: “Each person has the right to know his or her health condition and be given complete and up-to-date information that the person can understand in relation to diagnoses, prognoses, benefits and risks of diagnostic tests and recommended medical treatments, in addition to the possible alternatives and the consequences of any refusal of medical treatment”. The law stipulates that information must be complete, up-to-date and include the benefits and risks; logically then, consent forms should also reflect such information, and in many cases will need to be revised.

Resistance. Albeit in a small percentage (15%) of the facilities consulted, resistance on the part of medical professionals to applying the law has been recorded. There may be several reasons for this. Some criticism has been noted in the relevant literature as regards the structure of Law 219, especially in connection with the fact that in certain medical situations there is no time to provide the patient with adequate information and to make appropriate decisions. Requests for service often exceed the number of medical professionals in the department, and therefore they are unable to dedicate the necessary time to informing patients in the method prescribed by the law. There are also emergency situations wherein the decision cannot be shared, as required by the law (22 – 24). In addition, there is also the topic of conscientious objection, not provided for by the law, but deemed by some necessary

for a doctor who would have to desist from any activity that is not life-saving, regardless of the situation. These aspects may be the cause of the resistance noted in the investigation.

As regards providing the patient with information, it is important to remember that the exercise of rights must not be hindered due to difficulties or limitations in health care facilities. The legislator has established the patient’s right to information with certain characteristics. This right is made possible by means of legislative measures such as Law 219 and by organizational activities that guarantee that right, including drafting the necessary expense forecasts for sufficient personnel to be able to guarantee those activities. In certain emergency situations, the legislative provision of trustees can be invoked, if appointed by the patient, in order to settle doubts and make decisions. If said trustee is absent or unreachable, the doctor should uphold his or her duty of care to safeguard the patient’s health in order to make decisions for the patient if he or she experiences loss of consciousness, provided that such decisions are not in contrast with known prior refusals of specific treatments.

The issue of conscientious objection is clear, as it is for the issue of terminating a pregnancy, in that the conflict between the moral views of the doctor and those of the patient cannot be allowed to harm the rights of the latter (24). In fact, in the event a medical professional is faced with abstaining from performing potentially life-saving activities and treatments because of a patient’s previously expressed refusal, conscientious objection resulting in the patient being forced to undergo unwanted treatments is inconceivable. However, the individual professional has the right to invoke the doctor’s conscience clause contained in the code of ethics. This relationship of rights has already been thoroughly analyzed by administrative case law as a result of the *Englaro* case. The Regional Administrative Court’s judgment on this topic, reiterated by the Council of State, reads: “whoever cites grounds of conscience can and must object that only individuals have a “conscience”, whereas the “conscience” of institutions is constituted by the laws that govern them” [Regional Administrative Court of Lombardia, Div. III. 26 January 2009, No. 214, reiterated by the Council of State, Div. III, 21 June 2017,

No. 03058]. It is therefore clear that it is the administration's responsibility to make sure their personnel and activities are organized so as to ensure the respect for patient self-determination and the principles of law, so much so that it states: "Therefore, the health-care administration is under obligation, since only by means of the healthcare facilities services can the patient's right, when faced with an individual doctor's refusal, be implemented" [Council of State, Div. III, 2 September 2014, No. 4460].

These facilities, therefore, must ensure the full respect and applicability of Law 219 despite opposing professionals, monitoring the local situation and implementing necessary organizational adjustments.

Conclusion

Law 219 demonstrates a real effort to put into a law the legal, ethical and civil principles relating to the proportionality of care, combining medicine with the patient's values and inclinations.

The regulation provides legal tools that were previously non-existent such as advance treatment directives and shared care plans. These tools require knowledge and practice in implementation. Legal medicine serves as a fundamental interpreter of this legislative update (25-27). The analysis of the survey conducted on the pool of professionals showed they possessed a discreet knowledge of the law, although somewhat deficient as regards the practicalities of drafting plans. The overall opinion on the general principles seems positive, despite reports of resistance in some facilities. As regards university healthcare facilities, examples of advanced implementation of the practical principles of the law have been observed, whereas in others great difficulties. Medico-legal experts continue to serve as a necessary feature in the exercise of rights and often play a decisive role in care choices. This special role should be supported by solid, comprehensive training in legal and clinical activities in order to become the custodian of a collective and shared medico-legal culture.

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