

Healthcare professionals and patient information: a fresh look from the recent Italian law on consent

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Abstract

This article discusses the importance of providing patients with adequate information and creating the care relationship, particularly focusing on the role of healthcare professionals in this activity. It examines the main legislative references on this topic at a European level and the new law, No. 219/2017, in Italy on informed consent that serves as a starting point for recalling important legal and ethical principles regarding the information to be provided to patients in the therapeutic relationship. *Clin Ter 2021; 172 (2):104-108. doi: 10.7417/CT.2021.2293*

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Introduction

After having provided all necessary information, obtaining patient consent for a particular medical activity is a fundamental requirement in the work of healthcare professionals in the healthcare systems of developed countries (1, 2).

One possible legal definition of the concept of consent to medical-surgical activities is that it is a 'permit' by means of which the power to act is conferred upon the recipient (3-5). This definition has particular characteristics of a legal nature, but from a clinical and ethical point of view, it is not completely satisfactory in view of the complexity of the relationship created between the healthcare professional and the patient. It is therefore necessary to go beyond this definition in order to grasp the authentic meaning of the term consent. The term expresses a conformity of intents, the premise for the final act where the patient adheres to the healthcare professional's recommendation or agrees with said professional to perform a particular activity on his or her person with a specific objective. Consent is therefore to be understood as both adherence to any recommendations of medical activity and, more extensively, as participation and agreement.

Therefore, consent must necessarily involve: 1) recognition of the relationship between a healthcare professional and a patient, and 2) respect of patient self-determination, and can only be obtained after (a) the patient has received adequate information regarding his or her condition and the possibilities and limitations associated with the recommended medical activities and (b) the patient has developed adequate awareness of the contents of the aforementioned information.

Consent to a medical activity is therefore valid not only if it is informed but above all when conscious, that is, expressed by a capable and aware person. Although there are many applicable methods of expressing and obtaining consent, which is usually reductively categorized as informed, the underlying principle is respect for the autonomy of the patient, who has the right to define his or her objectives and make decisions in order to achieve them (6-8).

In this article, we intend to focus on the main legal sources on an international level regarding the discipline of informed consent and to analyze the specific indications derived from Italian Law No. 219 dated 22 December 2017 with a view to defining the importance of healthcare professionals other than doctors in the process of providing patients with information and obtaining consent in relation to the various healthcare activities

International Principles

Art. 3 of the Charter of Fundamental Rights of the European Union, proclaimed for the first time on 7 December 2000 in Nice and then on 12 December 2007 in Strasbourg, states: "Right to the integrity of the person. 1. Everyone has the right to respect for his or her physical and mental integrity. In the fields of medicine and biology, the following must be respected in particular: a) the free and informed consent of the person concerned, according to the procedures laid down by law; b) the prohibition of eugenic practices, in particular those aiming at the selection of persons; c) the prohibition of making the human body and its

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parts as such a source of financial gain; d) the prohibition of the reproductive cloning of human beings. (...)”. Article 11 on the freedom of expression and information states: “1. Everyone has the right to freedom of expression. This right shall include freedom to hold opinions and to receive and impart information and ideas without interference by public authority and regardless of frontiers. 2. The freedom and pluralism of the media shall be respected”.

Consent obtained after providing information and expressed without conditioning is therefore an essential requirement for performing activities that affect the person’s physical and mental integrity.

Article 5 of “The Convention on Human Rights and Biomedicine” (or the Oviedo Convention), adopted on 4 April 1997 at the behest of the European Council, ratified in Italy by Law No. 145 dated 28 March 2001, states: 1. An Intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. 2. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. 3. The person concerned may freely withdraw consent at any time (...). Article 10 states: Private life and right to information. “(...) 2. Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed”.

Article 5 lays down the obligation to inform, apparently portraying said obligation in a limited light, because 1) the information is presented as second to the objective of obtaining consent, and 2) its contents relate only to an intervention in the healthcare field.

This provision must therefore be considered an addition to that provided for in article 10, the contents of which, specifically regarding information as such, are wider in scope, referring to the global view of the concept of health and not to one specific intervention. Therefore, the information contained in Article 10 pertains to the person’s health in its entirety and that of Article 5 to medical intervention dependent on consent. In addition to the obvious information with the specific aim of obtaining consent, “basic” information must also be provided free from any contingent objective, which enriches the person’s cultural awareness and constitutes the method for enabling him or her to consciously define his or her life plan.

It involves two aspects of the same concept, which correspond to different stages of the relationship with the patient and to his or her various needs within the care relationship. The relationship between the healthcare professional and the patient includes the basic information, separate from the objective of obtaining consent, which is aimed at keeping the patient progressively conscious of his or her condition, and specific information aimed at clarifying the necessary details that will enable the patient to understand aspects concerning the activities for which specific consent is required. In practice, the professional needs to know how to harmonize these two aspects, without degrading his or her dignity by resorting to informing the patient only when there is a formal need to document his or her wishes.

The Oviedo Convention does not specify who is responsible for informing the person. However, the provision at Article 5 is related to “interventions in the healthcare field”.

Therefore, it relates not only to the medical field but, more extensively, to the healthcare field.

Consequently, it is clear that every healthcare professional needs to inform the patient, in the context of the specific relationship that he or she has with the patient, as regards information pertinent to his or her specific role and obtain consent relating both to the prescription of a certain activity (in line with a specific objective and/or project) and to its execution.

Italian Law on Informed Consent and Advance Treatment Directives

Law No. 219 of 22 December 2017 – “Provisions for informed consent and advance treatment directives” – is an extraordinary contribution to the issue of information and consent (9-10). Article 1 states:

“1. This law, in observance of the principles referred to in Articles 2, 12 and 32 of the Constitution and Articles 1, 2 and 3 of the Charter of Fundamental Rights of the European Union, protects the person’s right to life, health, dignity and self-determination and stipulates that no medical treatment shall be initiated or continued unless the person concerned has given free and informed consent, except in cases expressly provided for by law.

2. This promotes and enhances the relationship of care and trust between a patient and doctor, which is based on informed consent, where the patient’s decision-making autonomy meets the doctor’s expertise, professional autonomy and liability. The healthcare professionals who make up the medical team contribute to this care relationship, based on their respective skills. 3. Everyone has the right to know his or her health condition and to be informed in a complete and up-to-date manner that he or she understands regarding any diagnosis, prognosis, risks and benefits of any diagnostic tests and recommended medical treatment, as well as regarding the possible alternatives and consequences of refusing or withdrawing from medical treatment and diagnostic tests”.

In the subsequent articles, the law stipulates the tools a patient can use to determine in advance his or her treatment choices by drafting a living will or a shared care plan. In this paper, we want to concentrate on aspects of the information and consent that the law proposes.

The law confirms the patient’s right to be informed with regard to several aspects: health condition, diagnosis, prognosis, risks and benefits of diagnostic tests and recommended medical treatments, possible alternatives and consequences of refusing the recommended treatment.

The law explicitly states that information must be given to the patient in a complete, up-to-date manner that he or she understands. Therefore, the procedure to be followed in the doctor-patient relationship should include a communicative method appropriate for the patient’s condition and capability and be focused on his or her needs and characteristics without losing its complete and up-to-date nature. That excludes any partial and misleading methods of informing, aimed solely at obtaining consent for the activity suggested without the patient’s genuine and reasoned acceptance thereof.

The fundamental characteristics of information proposed by the law recognize the need for communication skills on the part of the healthcare professional towards the patient, so much so that Art. 1 states: “8. The communication time between the doctor and patient constitutes care time. 9. Every public and private healthcare facility shall guarantee the full and accurate implementation of the principles referred to in this law by their own organizational means, ensuring that patients receive the necessary information and that personnel receive adequate training. 10. The initial and continued training of doctors and others in the healthcare profession includes training in matters of relating to and communicating with the patient, pain therapy and palliative care.”

Each healthcare professional is required to carry out the active process of communication with the person: the former provides information and the latter asks for explanations and clarification of that which has been recommended. This relationship of communication is developed throughout the entire care process (11-14).

To support the effort of individual professionals, hospital institutions are required to initiate management provisions aimed at enabling the continual training of personnel in relation to communicating information to patients regarding the right to protect their autonomy.

The legislative provision indicates that the care relationship concerns not only the doctor but is extended to the healthcare team of various healthcare professionals. Consequently, healthcare professionals are involved in all activities that contribute to the creation of the care relationship and that are based on “informed consent”, i.e. on providing information and obtaining consent (15).

The abovementioned textual indications regarding the information content refer to activities and knowledge of a healthcare nature, not only medical. Nosological diagnosis is a medical prerogative and other types of diagnosis fall under the responsibility of other professionals; providing general information on the risks of a test or treatment and the potential consequences of a refusal are the doctor’s responsibility but, when such is being performed, further contingent information is provided by the healthcare professional carrying out certain actions, regarding which the patient asks to be informed.

Some of this content arises from the specific approaches used by the various healthcare professionals and their respective methods for identifying and analyzing the person’s needs and for planning the methods of intervention (16-17). The information content that each professional must ensure the patient receives needs to be defined within the team (18-20).

Integration of healthcare professions into the process of informing the patient

The aforementioned legal aspects enable us to delineate a clear ethical, practical/applicable paradigm in order to ensure the patient receives adequate information. We are no longer facing a field of information of an exclusively medical nature, rather the need to cooperate and unify intents so that each healthcare professional, in accord with his or her expertise, can provide the patient with information that will

permit him or her to give competent consent to treatments in accord with his or her wishes.

In line with that, the ethical codes of healthcare professions in Italy have over time given attention to anamnesis and the communication of health profiles. Here are just a few examples, in accord with the relative ethical codes:

- “Dieticians provide their patients with sufficient information to make sensible decisions and ensure they understand and agree with the care choices that concern them” (Chapter III, No. 1).

- “Physiotherapists respect and promote the person’s decision-making autonomy in the health field as his or her fundamental right and the most authentic expression of the solidarity that supports the care relationship. Physiotherapists undertake to uphold the principle of communication loyalty in the care relationship: they provide complete and accurate information as regards any diagnosis, prognosis, prospects and alternative treatments and on the foreseeable consequences of any decisions, adapting the style of communication to the patient’s comprehension ability. Physiotherapists undertake to provide patients with effective information needed for the treatment decision-making process, creating the most favorable conditions possible (place, time, methods) for the person to be able to guide his or her decisions with freedom and awareness” (Art. 15).

- “Nurses ensure the person concerned or the person designated by him or her receives precise, complete and timely information regarding his or her health, shared with the care team, in line with his or her needs and in a culturally appropriate method. They do not replace other professional figures in providing information that is not in their remit”.

- “Obstetricians undertake to promote the overall and reproductive health of the person by providing correct, appropriate and personalized information, taking the various lifestyles into account” (Art. 3.8). Obstetricians, except for in cases of emergency-urgency, before performing any professional activity on the person, must ensure adequate information is provided in order to obtain informed consent, based on a genuine treatment alliance with the person” (Art. 3.10).

- “Medical radiology healthcare technicians are professionals who: ... provide information on matters pertaining to their own expertise: technology, techniques, radiation protection aspects of radiological activities and, if adequately qualified, contrast media and radiopharmaceuticals; for anything outside his or her expertise, he or she shall indicate the most qualified person to attend to it (Art. 3.5) ... are aware that consent for healthcare activity is every citizen’s right. Therefore, their objective is to ensure that the person, having been duly informed, proceeds towards acceptance of the recommended activity with full awareness. They deem a mere formal signing of the relative forms as contrary to said objective” (Art. 3.10).

After the doctor has obtained the patient’s consent, for example to undergo a certain diagnostic test, the healthcare professional responsible for carrying out the related technical or manual activities is also under obligation to inform the patient as to what he or she is about to do and obtain consent. In practice, using the simplest of examples, the doctor informs the patient (who has already been made aware of his or her condition) of the opportunity to perform certain

blood chemistry tests, their objective and the modest risks associated with collecting a blood sample. Subsequently, having obtained the patient's consent, the nurse approaches the patient and informs him that she intends to take a sample as prescribed by the doctor, the procedures involved, the minimal irritation/pain that the patient will feel, the methods for stopping the bleeding after taking the sample and the possibility of a minimal transient ecchymosis. The patient listens and gives consent by presenting the crease of his elbow to the nurse.

In addition, healthcare professionals have a role in the complex activity of receiving and managing a patient's withdrawal of previously given consent. Obviously, the team must devise a plan in advance for handling the information to be conveyed at the point of actually carrying out the activity and the patient's withdrawal of consent.

From a practical point of view, there are three possible situations:

- a) a healthcare intervention planned and executed by a doctor, without the intervention of other healthcare professionals: providing information and obtaining consent are the exclusive remit of said doctor.
- b) an intervention that includes a doctor's prescription and activity on the part of a healthcare professional: dual information and consent are required. First, the doctor must provide information and obtain consent regarding the reason for and objective of the intervention. Then, the healthcare professional must provide information and obtain consent regarding the methods for executing said intervention. In such cases, the practical difficulty lies in defining agreements and tailoring procedures that clarify the remits of the various professionals, specifying the contents of the information to be provided.
- c) an intervention planned and executed by a healthcare professional, in line with his or her professional profile, initiated by him or her without a doctor's prescription: obviously, providing information and obtaining consent are the exclusive prerogative of said healthcare professional.

Ultimately, the information regarding any healthcare intervention may need to be provided by various healthcare professionals in line with their particular areas of expertise; the responsibility for providing such information lies with those individual professionals.

New areas of information and consent during CoVid 19

Providing professional services in the healthcare sector usually necessitates physical contact or proximity between the service provider and the beneficiary. As a result, before the healthcare professional initiates any treatment, the patient should give consent to any intrusion into his or her privacy or to any reduction of his or physical integrity. The CoVid 19 pandemic has raised various issues including the fact that healthcare professionals, exposed as they are to the risk of contact with both symptomatic and asymptomatic patients, should inform patients that they could constitute a source of infection and that the patient has the right to choose whether to accept the risk associated with contact with that healthcare professional or to opt for a different solution. This

new reality should be reflected in the information provided to patients, specifying the risks as clearly as possible; the patient, in turn, should give specific consent to that particular professional's assistance.

Similarly, contact or proximity with the patient constitutes a risk for the healthcare professional. While just a few months ago healthcare professionals would spontaneously fulfil patient requests, now, it is reasonable for these professionals to expect to be informed regarding the fact that the patient may be a source of infection. Consequently, the patient must allow the professional to ask questions in relation to his or her lifestyle/work habits and to the various means of protection used and the precautions taken in accord with their individual circumstances. Therefore, acceptance to provide a professional service is no longer automatic; rather, the healthcare professional must accept the request in a more reasoned manner and, having gathered the necessary information, consent, although without particular formalities, to social contact with the patient. The person requiring assistance must be aware that healthcare professionals represent a human resource for the community and should therefore be honest and open when discussing his or her condition as a potentially asymptomatic infected person (e.g. when a healthcare professional unknowingly provides home care to a patient who is required to self-isolate) or if he or she has behaved in a careless manner and, as a result, could have contracted CoVid 19. Providing healthcare personnel with such information will enable them to perform their activities with awareness; it does not constitute justification to refuse to administer professional services.

On the contrary, it is the patient's right to withdraw from a treatment if informed that the healthcare professional, although protected, is in regular contact with patients infected with CoVid 19.

We must reach a new level of trust in the healthcare professional-patient relationship, providing reciprocal information as to their respective safety and integrity.

Conclusions

The care relationship that more and more often is established between the patient and a team of healthcare professionals – therefore not only between patient and doctor – means that the content of information regarding the patient's condition and care plan must be provided by each component of the team in accordance with the team's organizational plan. Such information must have standard contents, such as those listed in Italian law, but must be tailored to the patient's needs and expectations. As a result, each healthcare professional must, logically, make him or herself available to listen to the patient before providing information in order to provide information that coheres with the patient's expectations. In addition, as already stated, it is clear that information in itself is not sufficient – the patient must also understand it. The patient's threefold right to be heard, information and awareness corresponds to the threefold obligation of each individual healthcare professional to be constantly available to listen, to provide information appropriate to the patient's expectations and to ensure each time that the patient has understood said information. The team

must also ensure they acquire the skills needed to evaluate whether the threefold obligations of each individual have been met and whether they have been met effectively.

In addition, Italian law has categorized the topic of informed consent, thus including matters concerning information, as being part of the care relationship, highlighting that said relationship usually involves an entire team of professionals. Undoubtedly, each professional must be equipped to handle this relationship but must also know how to play his or her role in the team's activities, particularly in promoting analysis and discussion in order to execute projects aimed at enabling the patient's acquisition of the necessary knowledge, projects conceived collectively but implemented by individual professionals. The CoVid 19 pandemic has highlighted the fact that the care relationship has taken on a new level of complexity due to the new requirements in the healthcare professional-patient relationship, i.e. the opportunity to provide reciprocal information regarding the safety and integrity of those involved.

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