

The informed consent for wound care treatment: legislative - juridical analysis and proposal of a model for single treatment

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ABSTRACT

In 2017 informed consent was further defined by law in Italy; in 2018 the processing of personal data was regulated and in 2019 a series of judgments by the Italian Highest Court of Justice have finally clarified the responsibilities inherent the misinformation and the lack of information of the patient. The judgements analysis of the body of law has revealed a grey area: the obligation to provide information to the patient by non-medical staff in disciplines, such as wound care, where these health professionals have wide autonomy within the execution of medical prescriptions. The aim of the present work is to analyze the context and provide a model of informed consent for every professional involved in complex wounds treatment.

INTRODUCTION

A recent judgment by the Supreme Court¹ reaffirmed the importance of correctly present informed consent to health treatment, reiterating that this act must be: i) suitable to the patient's knowledge level; ii) specific to the treatment (not a generic form);

It can also be given verbally, when supported by documents showing the complete information in the interviews/visits prior to the medical-surgical act; it is also valid if signed in the surgical room and even if there are handwritten additions.

The burden of proof regarding patient information is

the obligation on the healthcare provider and the sanitary structure.

According to another sentence by the Supreme Court in 2019,² an incorrect administration of consent may cause a double damage: *"to health, when it is reasonable to believe that the patient, who bears the relative burden of proof, if properly informed, would have avoided undergoing the intervention and suffering its disabling consequences,"* and another *"damage due to the impairment of the right to self-determination in itself, which exists when, due to the information deficit, the patient has suffered a damage, economic or non-economic (and, in the latter case, of appreciable gravity), different from the violation of the right to health."*

In the same year, a third sentence of the Supreme Court³ established that the physician can be called upon to compensate the damage to the health of the patient if the latter demonstrates, even presumptively, the refusal to surgery, if the expected complications were known and then occurred, despite the fact that treatment has been carried out as to perfection.

The obligatory nature of consent for each medical act is now mandatory and jurisprudence is slowly moving to expand this certified information to other medical practices. However, the indication to administer a written consent or to leave a trace in the health documents of the occurred information varies for each category of health professionals who collaborate with the physician.

The law of 22 December 2017 n. 219 has transformed the concept of consent, as it states that *"a patient may refuse to receive information, either completely or partially, or designate a family member or a trusted person in charge of receiving them and to give the consent on his behalf."* This decision must be reported in the medical report.

Another obstacle to health information, especially to family members/relatives, is given by the conversion into law of the European legislation on the treatment and pro-

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cessing of personal data⁴ and by the subsequent statements by the Privacy Authority with the resolution of December 2018⁵ and the act of 7 March 2019,⁶ which impose strict limits and a series of obligations, in order to constrain the traditional relationship healthcare professional-patient and healthcare professional-patient's family members.

The law, however, is referred exclusively to physicians and seems to virtually exclude other healthcare professionals (nurses, physiotherapists etc.), relegated to the role of intermediaries between medical communication and the understanding of the patient.

MATERIALS AND METHODS

Informed consent is described in Article 32 of the Constitution of the Italian Republic⁷ and was subsequently defined by various regulations and sentences.

An analysis of the recent judgments of the Supreme Court, of the laws and the codes of conduct of professional healthcare and medical associations has been done, in order to understand what obligations exist into the laws and into the legal traditions, aimed at ensuring a better protection of the professionals which collaborate with the physician and, indirectly, of physician himself.

The examination of the deontological codes of every professional associations of healthcare has revealed the situation highlighted below.

Nurses

Article 4 of the Ethical Code⁸ provides that *“while acting professionally, the Nurse establishes a care relationship, adopting listening and dialogue [...] involving, with the consent of the person concerned, its figures of reference, as well as other professional and institutional figures. Relationship time is treatment time.”* Article 13 explicitly states that the nurse *“shall ensure that the person assisted has the same information shared with the team, relevant for his/her life needs and for the conscious choice of the proposed treatment paths;”* the article 15 clarifies that *“the person concerned or the person indicated by the patient as a reference, receives accurate, complete, and immediate information on the state of his/her health, shared with the team of care, in compliance with his needs and in a culturally appropriate manner.”*

The role of the nurse as mediator and certifier of correct health information is evident using dialogue for this purpose and involving (if authorized) other professionals. All these procedures should be annotated in the nursing timetable as care practices and time dedicated to the patient.

Physiotherapists

The Article 23 of the code of ethics⁹ obliges the professional to obtain consent on his/her fee. Moreover the

Article 24 indicates what information the specialist has to provide, while Article 26 imposes that *“no one may be subjected to any diagnosis and/or therapeutic treatment without the acquisition of the explicit and informed consent of the assisted person or whoever is authorized to express them in his stead. The Physiotherapist have to ensure that the consent is documented in written form only in cases indicated by the law and/or when an unequivocal manifestation of the decision-making will of the assisted person is necessary.”* Article 30 states the need of compliance with the legislation on the processing of sensitive data and related information.

Such information can be noted in the specialist's report.

Psychologist

In the code of ethics, the obligation to obtain an informed consent to research activities is established in Article 9. Article 24 states that *“in the initial phase of the professional relationship, the psychologist provides the individual, the group, the institution or the community, whether they are direct users or customers, with adequate and understandable information about his or her services, the purposes and methods, as well as about the degree and legal limits of confidentiality. Therefore those who were entitled can express informed consent. If the professional service is prolonged in time, where possible, the expected duration must be indicated”.*

Furthermore, in application of current legislation,¹⁰ Article 23 also provides¹¹ the obligation of an economic estimate before treatment.

Dietician

Chapter III of the code of ethics¹² reads as follows in Article 1: *“the dietician shall provide sufficient information to enable his or her assisted person to make competent decisions and shall ensure that he or she understands and share the care choices addressed to him or her.”*

Podiatrists

In consideration of the specific service of this rehabilitation technician, informed consent is not required in their code of ethics, but the patient information is considered mandatory; about treatment of personal data, there is a generic mention in only one of the codes of the two professional associations.¹³

Since 19 September 2018, date of the application of the European *General Data Protection Regulation* and the subsequent additions listed above, there are lots of restrictions in the processing and, above all, in the communication of health data. The Regulation provides, in addition to specific consent, the identification and disclosure of responsible persons.

These acts have recognized the validity of the rules

contained in the various professional ethical code and exempt from the informed consent all the activities aimed at the treatment of the patient (*i.e.* to fill out the medical sheet with the patient data, as well as the medical history, carry out an electrocardiogram etc.) as well as scientific research, but strongly regulates the use of smartphones apps or computer programs, permitting only those dedicated to the so-called “telemedicine” and only if exclusively accessible to health care professionals. The *General Data Protection Regulation* also includes specific sanctions in case of violation of the listed limitations.

In any case the use of such apps and the processing of data through the electronic file requires the specific consent of the person concerned.¹⁴

RESULTS

In conclusion, based on latest judgments, it is clear that any medical or surgical treatment, especially if invasive, requires the following criteria of consent: i) personal and complete, listing every complications or the possibility of failure; ii) understandable, based on the patient’s knowledge; iii) specific for the treatment; iv) indicating the possibility of alternatives and their refusal; v) highlighting the possibility of refusal of the proposed treatment at any time; vi) updated to the latest knowledge in the field.

Anyway, the current legislation about informed consent care leaves a void, a *vulnus*, particularly evident in wound care: does the consent signed to the doctor also protect the nurse who performs the dressing or the physiotherapist who practices the treatment?

For example, a predictable and known adverse event in applying negative pressure by a nurse (on medical prescription) is protected by a consent signed exclusively to the doctor who prescribes the treatment (also considering the level of implicit complexity) or should it be integrated by one of those who materially applies the treatment?

Furthermore, do podiatrists have any obligation to inform the diabetic patient of the inherent risks of their treatment when prescribing a footplate?

And, vice versa, is the physician protected against the podiatrist’s error or the nurse’s complication/malpractice?

The mentioned professional orders are not uniform on the modalities and information obligations. Nurses play a pivot role in patient’s understanding, but have no clear indications on how to certify what they do. Dieticians or podiatrists only have general obligations. Finally, psychologists and physiotherapists must also make a quote. However, no health profession except for medicine seems to be bound to leave a written and signed form to the patient.

The field of wound care, unlike any other specialization, provides a wide space for decision-making and pro-

fessional autonomy for each non-medical health figure, especially for home care patients. Very often, nurses or physiotherapists are the ones who notice complications or partially adapts the agreed treatment to a modified situation, while waiting for the medical examination.

Regarding the processing of data, the legislation is clear on when to request authorization and on the obligation to use medical applications, but there are no limitations on sharing data with other apps, subject to the explicit authorization of the patient, if carried out for medical purposes.

CONCLUSIONS

A model of informed consent was proposed to readers for the previously discussed treatment, including authorization to the storage and processing of personal data in accordance with the current legislation with delegation to their use with non-medical apps. In addition to the list of complications and risks to health and life, the following elements were explicitly included: i) acceptance of lack of guarantees of result or the possibility of worsening/failure; ii) acceptance of the entire and multidisciplinary therapeutic program/plan, in order to avoid to give consent for every act or change of medication; iii) the duty of patient to inform the professional of any other medical opinion collected, typical activity preceding a legal action.

This work is offered as a basic consensus scheme, easily modifiable for each type of therapy and each health professional.

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