Acta Biomed 2021; Vol. 92, N. 4: e2021072 DOI: 10.23750/abm.v92i4.10318

Information obligation in surgery

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Abstract. The following article aims to clarify the guidelines needed for the gaining of informed consent in surgery treatments. Legal dispositions in the provisions of law n. 219/2017, written according to the regulatory mechanism uphold by the Italian Supreme Court and medical code of practice have been properly analyzed in order answer the questions unanswered by the law. Who is supposed to inform the patient? About which risks? Does the patient's characteristics affect information obligation? Is necessary to add more information than those required by the law? How do emergency and urgency affect information obligation? Can the patient give consent in advance to an additional operation during the undergoing surgery, if needed? The answers provided by the law and by the Italian Supreme Court picture a state of obligation, where the single physician risks to encounter several responsibilities. It's important to face this problem inside sanitary facilities, creating a suitable informed consent form and planning surgeries to allow the usage of personal data according to the patient's needs.

Key words: Doctor-patent relationship, Duty to inform, Surgical treatments

Introduction

Patient centered care and evidence-based practice are getting more popular in modern medicine (1).

The personalist principle has characterized Italian judicial system (specifically art. 2, 13, 32), since the writing of republican Constitution, entered into force in 1948. It has been really enhanced though with the 1978 healthcare reform (2).

European (3) and International (4,5) law state the patient's right of giving either refusing consent to any surgery. The following law underlines the patient's freedom of choice in hisor her interactions with the physician, while it decrees the approaches that wouldn't take his or her will into consideration.

The establishment of informed consent states the patient's free of choice in refusing or continuing therapy, even when his own choice would end in worsening the disease and in consequent death.

Just the law can force the patient to undergo surgery, whilst useful for the patient's and the community's health (art.32 Cost). The case of psychiatric patients, while dangerous for themselves and the community can serve as an example (6). It's therefore clear that the individual cannot undergo a medical treatment exclusively for community's sake (7).

In giving consent the patient accepts the medical procedure the physician prescribes. As stated in medical deontology code of 2014 (8), it's important to build a "therapeutic alliance" between patient and physician and to respect the patient's freedom of choice, in order to gain informed consent (9).

Saved some references to sectoral legislation, such as law n.40/2004 on artificial insemination (10), the Italian legislators regulated informed consent only in 2017 with law n.2019 (11,12).

Regulation on giving information to patients

Regarding the rules to respect in order to fulfill information obligation, law 219/2017 states that the

patient has the right to refuse to receive all or part of information. Moreover, the patient can design a person, or a family member entitled to receive them and express consent on his behalf. The legal representative of the adult must express what the patient's will would have been. The minor's parents must choose in the best interests of the minor, but must take into account his will (13).

Said law has reaffirmed that the subject has the right to know his own health condition and to be fully and clearly informed about the diagnosis, prognosis, benefits and risks of the diagnosis verifications and the prescribed medical treatment. Moreover, the patient needs to be informed about the possible alternatives and consequences coming from treatment and or diagnosis verification refusal. Therefore, the given information has to sum up the suggested treatment's risks-benefits ratio, available alternatives, and the choice of diagnosis or treatment refusal. Being the aforesaid rule vague, some questions remain still unanswered.

Which doctor is obliged to inform the patient?

The Italian Supreme Court's settled-case law stated that the patient needs to be informed by the same physician providing professional service (14,15). Therefore, the patient's consent cannot be considered effective even if informed by authorized physicians, other than those treating the subject. The fact that the patient's treatment has been prescribed by a different physician it's not relevant, since the professional giving treatment need to decide, according to *lex artis,* whether to accept the request or not. During surgery it's required a full team of professionals with several and specific competences, aiming to reach a concrete therapeutic goal (16,17). The surgical team's activity it's coordinated by its leader. The leader has the legal obligation to inform the patient about his and the team's professional activity (18-20, 14). When the colleague's activity presents a specific risks-benefits ratio, such as for the anesthesiologist, a proper informed consent it's needed. In order to enforce this principle, Court's decisions point out that the helping surgeon, on the other hand, has no legal obligation to inform the patient, since he or her didn't have preliminary medical interview with the patient and acts exclusively during surgery itself (21).

Which risks must a physician disclose to a patient?

According to the Italian Supreme Court, the physician needs to inform the patient thoroughly about all the scientific aspects concerning the therapy or the surgery, adding details from the respective procedures to the slightly probable consequences (22-24). The doctor has the obligation to inform the patient accordingly about all the consequences coming from pharmacological therapy, especially about the most dangerous ones, such as sleepiness for drivers (25). The given information should be as more detailed as possible, in order to give the patient the possibility to choose consciously (26,27). Information doesn't involve just a list of eventual medical complication, as it explains their meaning, their consequences and the incidence of adverse effects related to the patient's physical conditions (28).

We consider the rule excessively strict and vague, since it doesn't allow the physician to take in consideration the peculiarity of each patient (29).

Is it necessary to give more information than the law guarantees, to defend the patient's self-determination?

It's fundamental to inform the patient not only about the risks or the success rate of the proposed treatment, but also about further aspects, allowing the subject to fully understand the surgery's risks-benefits ratio. As a matter of fact, choosing consciously implies a full awareness of all the possible consequences, being them cosmetic, positive, negative, coming from surgery itself or surgery refusal. Therefore, the information should cover all the surgery's consequences affecting the patient routine, the eventual pain felt during the procedure, the pharmacological treatment following surgery (30,31). It's necessary to inform the patient completely about the recovery time, when possible, to allow him or her to plan surgery accordingly (8,20). Moreover, the physician has to fully inform the patient about the post-surgery recovery, stressing the fact that not following the prescribed indications would affect the healing process and, therefore, the very purpose of surgery (art. 33, par. 1, Cod. Med. Deont.). In addition, the Italian Supreme Court has several times remarked that the physician has the duty to inform the patient about the medical equipment at disposal where the surgery will be performed, adding details about

their efficiency. The surgeon must inform the patient whether the clinic it's lacking proper equipment, or the equipment in use it's obsolete, and consequently suggest another medical facility (30,32).

Do patient's characteristics influence information obligation?

According to the Italian Supreme Court, for the purpose of consent, patient's intellectual traits and cultural characteristics do not affect the information the physician needs to provide. They affect the doctor's information delivery, that the physician molds on the patient's education and specific knowledge level (33). As a consequence, information contents don't change, while the physician has to put information in a comprehensible form for the patient (34,35). The physician, therefore, has the obligation to inform the patient in a comprehensible and timely form, even when the subject works as doctor. Similarly, as the patient presents a low capacity of understanding, the physician must commit to make information understandable. Even in case of patient's incompetency, given that it's necessary to acquire consent or refusal from the subject's guardian, the law states that the patient must express his/her opinion, when possible (art. 3, comma 3) (36). As a matter of fact, the patient must be informed in case of prejudice for his or her decision-making ability (37-40).

Consent in emergency and urgency

Art. 1, par. 7 of law n.219 from 22 December 2017 states that during emergencies the physician and the members of the medical team provide the necessary treatment, respecting the patient's will, when his or her clinical conditions allows it. Therefore, this regulation clarifies the connection between the right to health and the right to self-determination. The right to health, that is the obligation to cure, prevails when informing the patient (if responsive) or waiting to acquire his or her advanced healthcare directive (if non-responsive) leads to a delay in medical treatment, and, as a result, to a worsening of the patient's conditions: otherwise the patient's will must be respected. Consequently, the law confirms that waiting the emergency to occur without informing the patient, in order to act without the patient's consent is by all means a wrongful behavior harming the right to self-determination (41,42). As previously stated, the possibility of presuming consent, as occurs during childbirth when unexpected events happen (43,44), does not exempt the physician from informing the patient, since it's important to defend the patient's dignity. When the responsive patient refuses the prescribed treatment, the physician has to make sure the patient's aware of the choice. As a result, the physician has to offer an efficient support to the patient, providing, if necessary, a psychological support service (art. 1, par. 5). Treatment refusal, when conscious, must be respected (art. 1, par.6). Unless completely incongruous or non-corresponding the actual patient's clinical condition, as, for example, the existence upon subscription of unforeseeable treatments efficient in improving the patient's health condition, the subject's advanced healthcare directives must be respected (art. 4, par.5) (45). Since advanced healthcare directives do not guarantee actual choice awareness, those have been harshly criticized for their binding nature (46,47).

When the patient has nominated a fiduciary in advance, or the guardian or a trustee is needed, they can't express their will, as they must be loyal to the presumed will of the patient already in legal age before turning unconscious. They therefore need to consider the patient's wishes, inclinations, values, ethics, culture and religion. Even if the patient's conditions permit to acquire consent, he or her can't demand treatments not in accordance with the law, professional deontology or clinical practice guidelines (art. 1, par. 6, and art. 4, par. 5), including international guidelines (48) and those published on National of Health's website (49,50). Remains though controversial whether this disposition allows the physician to express conscientious objection (51). As there's no legal representative and there's no time to nominate one, there's no advanced healthcare directives and the patient is incapable of understanding, it's impossible to defend the right to self-determination. Therefore, it's right to act in the patient's best interest.

The rule above-cited (art.1, par.7), refers specifically to both emergency and urgency. Since it places on the level two utterly different scenarios, the aforesaid rule it's worth some criticism. As a matter of fact, emergency is a state of immediate danger and,

therefore, requires immediate action. On the other hand, urgency refers to state that, lacking adequate assistance, can turn critical. As a result, in case of emergency there's little or no time to acquire consent, whether urgency allows information processing. Even during emergency, though, it's possible that treatment refusal would be based on a meditated ideological choice (as for Jehovah's Witness). Moreover, during urgencies it's preferable to act immediately when the patient is unconscious, there's no advanced healthcare directives and it's impossible to foresee whether the patient will be conscious before the emergency starts.

The problem of consent specificity

Another issue concerns the surgeon's choices during a routine operation, as the doctor discovers the necessity of performing an additional surgery, different from the one the patient has given consent to. The Italian Supreme Court states that the physician must postpone the second operation, explain the patient the reasons that makes the surgery necessary and ask for an informed consent. As a matter of fact, the patient's manifestation of will must be his own, explicit, real and objective (save the patient is unfit to plead or found to be unsound mind), since presumed consent isn't allowed (33). When the physician treats in a state of emergency or urgency, art.1 par. 7 of law n. 219/2017 it's applied. According to the Supreme Court, even the patient's advanced consent to an eventual and life-saving change during the arranged surgery, must be considered out of any specificity. It's therefore unfit to be a declaration of informed consent, considering the concept of "necessary amendments for patient's healthcare" quite general in the meaning of the term "amendment" and "necessary", as for the concept of "healthcare" (52) (53).

This orientation must be reformulated after the applying of law n.219 of 2017. As a matter of fact, art. 1 establishes that the patient has the opportunity to refuse in advance to be informed or to nominate a trustee, receiving information and choosing on his or her behalf.

Conclusion

Considering the given overview, it's possible to underline positive elements that yet do not exclude eventual critical aspects related to informed consent acquisition. First and foremost, the Supreme Court's tendency to give univocal guidelines it's quite positive, despite the multiplicity of opinions available in literature. It's equally clear the legislator's choice to bind the physician to the patient's will. The underlying critical issues consist in the wide range of information content the physicians are supposed to deliver to the patients, in the impossibility to delegate information obligation and in the demand of a fully explicit, specific, non-presumed consent. On one hand that implies a concrete risk to be locked in a dispute, which is highly significant, since no responsibility limitation it's provided in case of information obligation violation, even if the sanitary treatment it's particularly difficult. On the other hand, informed consent isn't an issue related to patient-surgeon relationship only, while it concerns the sanitary facility's organization as well. It makes then necessary a training activity and a refresher course for healthcare professionals, the writing of adequate informed consent forms and a surgery planning, allowing an information delivery regarding the single patient's needs.

Conflict of interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article.

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Received: 22 July 2020
Accepted: 25 August 2020
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