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Review Article

Dentistry Section

Information and Consent in Dentistry

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ABSTRACT

Consent is the essential expression of the patient's will, and thus, must be preceded by a procedure. The need for consent is based on ethical principles, legal regulations, codes of conduct and judicial doctrine. In order to be able to give valid consent, one must have the ability to make decisions. In any event if the patient is not able to do so, as in the case for minors or those with mental impairments, specific legal and medico-legal provisions must be made.

Keywords: Dental care, Ethics, Forms, Jurisprudence, Patient rights, Treatment refusal

INTRODUCTION

Several research studies have shown that, even today, in the field of dentistry, the majority of people establish a frankly paternalistic relationship of trust with their dentist, confiding entirely in their actions in the belief that he/she possesses sufficient biological knowledge and technical-manual skills to guarantee the care of dental health and acts in compliance with a set of rules and standards that ensure the appropriate use of their professional skills [1-2].

The informative process (which is, in any case, of independent value) must be followed by the provision of consent (or dissent) of the entitled person who, according to traditional doctrine and jurisprudence, is a key element (in addition to the need to act in a manner proportionate to the need for care) in the legality of any medical intervention, being the patient's expression of voluntary, informed and free consent. It is an essential element linking the power (or rather the duty) of the doctor to care and the personal right of the patient to manage his own psychological and physical health.

The informative process also encompasses the economical aspects of the medical intervention, which in private dentistry are frequently quite expensive for the patient and often represents to be a potential source of conflict with the dentist. In some countries, such as Italy, dentists are obliged to give the patient a written estimate, reporting all the interventions with their corresponding cost, which must be related to their difficulty, also indicating all the details regarding the insurance contract against professional liability of the dentist.

Moreover, it should be pointed out that failure to acquire valid consent for a medical intervention constitutes grounds for complaint and claims against the dentist for professional liability, independent of his technical ability [3].

This aspect is particularly important when considering the fact that not all professional liability insurance contracts offered by the insurance market to dentists protect them against claims for damages due to failure to acquire consent for diagnostic/therapeutic procedures [4].

Finally, some dentists wrongly presume that a simple signature by the patient in a standardised "informed consent form" could protect them against any claim regarding the acceptance of the proposed treatment plan, whereas others resignedly assume that they are always completely vulnerable when facing a patient accusing them of consent lack: that is why it is important to fully examine the information and consent acquisition process in dentistry.

DISCUSSION

The need to acquire the prior consent of the patient is not only based upon shared ethical principles, but also upon legal and ethically-inspired regulations, ethical codes and case-law doctrine [5].

The basic ethical principle is the necessity to respect the patient's self-determination – that is expressed precisely by their consent - whose foundations are historically identified in documents such as the Nuremberg Code (1947), the Helsinki Declaration (1964) and the Belmont Report (1979) [6-8].

Art. 5 of Italian Law 145/01 (derived directly and immediately from the "Convention on Human Rights and Biomedicine" (1997)) establishes explicitly that health procedures may be carried out only after acquiring the free and informed consent of the person concerned, respecting any withdrawal, which can be made at any time during the care process [9]; art. 35 of the Italian Code of Medical Ethics [10] warns the health professional not to undertake diagnostic and/or therapeutic procedures without the express and informed consent of the patient, with the obligation to respect the written refusal of the capable person.

Moreover, the essential requirements for expressing valid consent (according to the main judicial and legal guidelines) include being over the age of consent (18 years of age) and being fully competent, with the limitation (art. 5 of the Italian Civil Code) of impairments to physical well-being, today widely understood to mean good health according to the WHO definition "Health is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity" [11].

Moreover, it must also be underlined that the validity of patient consent also depends on a proper information process, whose level of detail is in proportion to the urgency/emergency of the therapy [12] and of the patient's ability to understand [13], also including, for treatments carried out by choice, information regarding adverse events occurring in 1% or less of treated patients [14].

Often in dentistry several treatment options - in terms of materials, final result quality and duration, procedural complexity, need for patient compliance, number and duration of appointments, time lapse between treatment beginning and ending - are available for the same oral health condition, quite often with different biological and economical costs. In these complex cases it is even more important for the dentist to try to understand what is the main complaint of the patient, the treatment objective that cannot be missed in order to achieve patient satisfaction, and to realise it. Furthermore, it is important to preliminary point out what is a functional request and what is an esthetic request, in order to prioritise one aspect or the other in case of conflicting treatment objectives.

Moreover, considering the fact that most often dental treatments are provided by private dentist operating in solo practices and that some procedures could request the employment of special equipments not always present in small practices, a correct information should include the treatment options that are generally available even if they are not delivered by that particular practitioner where the patient is seeking the dental advice.

Finally, it also true that treatment plan of complex cases could change during the treatment because of new unexpected findings or clinical situations; for example poor patient compliance or undetected pathologies: in these cases further information must be provided to the patient and his consent must be renewed, in order to be still valid.

Ultimately, the quality of the information process is regarded as a key element to ensuring the truly informed consent of a patient [15-16].

It must be pointed out that, although consent in written form is required by Italian law only in specific cases (explant of organs, tissues and cells from a living person; the voluntary termination of a pregnancy; medically assisted procreation; change of phenotypic sex; determination of an HIV infection; compensation for individuals harmed by compulsory vaccinations, transfusions and the administration of blood products; clinical trials), it appears appropriate for it to be given in written form in the case of particularly complex dental procedures or for “at-risk” patients. In this regard, it is useful to refer to the opinion expressed by the CNB (Italian Committee for Bioethics) [1], according to which "for interventions with a small probability of adverse events, the dentist is reasonably exempt from the obligation to acquire written consent, this being implicit in the request for that specific procedure. On the other hand, the most frequent complications must be carefully explained verbally, as well as being indicated on the form".

The latter, being in general for chosen and non-urgent procedures, could be left for the patient to examine himself or have examined by a person of trust, so that, before the signature for acceptance of the treatment and the start of the therapy, he/she may request further explanation. It would also be appropriate not to limit acceptance to merely a signature at the bottom of the form, but to have the patient himself declare in writing that he/she understands the nature, purposes, risks of treatment and his/her undertakings during the post-treatment period, such as checkups, hygiene rules, the need for possible further procedures, etc. [1].

The "duties of the patient" may take on particular importance for implantology and orthodontics, as a positive outcome is mostly linked, perhaps more than in other fields, to strict compliance with clearly defined rules.

The patient signing the "cost estimate" agreement or providing the patient with a generic pre-printed document with no indication of the treatments to be carried out, do not constitute proof of properly informing the patient.

Similarly, but for the opposite reasons, a signature at the bottom of a consent form containing very specific information and drafted using highly technical terminology cannot be considered proof of effectively informing the patient, due to the high probability that the information in the pre-printed document is impossible to understand by the patient.

Few years ago, the Court of Milan stated that: “the signing of any pre-printed form can never be reduced to a formal act, with the aim of relieving in advance the doctor from his medical responsibility. A patient should sign the consent form after a detailed information process and a careful reflection, after an appropriate lapse of time, in order to be fully aware of all aspects regarding the treatment” [17].

Where the treatment is for minors, that frequently occurs in dentistry, it may only be undertaken with the express consent of both parents or of one parent in the event of unavailability (due to distance, incapacity or impediment) of the other, or of the parent who was granted custody of the child in the event of separation or divorce. In the event of conflict between spouses on issues of particular importance, the Court gives the decision-making power to the parent that, in that specific case, is deemed most eligible to act in the best interests of the child [18].

In the event of dissent by both parents, implementation of the dental care on the child is dependent on the degree to which it can be delayed: suspending the treatment is permitted if there is no urgency and no immediate need (unless there is a change in the position of those holding the parental rights or the young patient reaches adulthood, in so far as, in that case, the decision-making power will be transferred to him/her); reference must be made to the Judicial Authority (court of law) in cases of relative urgency; that there is an obligation to intervene in the case of existing immediate need [19].

The Italian Code of Medical Ethics takes a similar tone (Italian Code of Medical Ethics: "art. 37 - Consent or dissent of the legal representative: in the case of patients under the age of consent or incompetent patients, the doctor receives their consent or dissent from the legal representative informed of the diagnostic procedures and/or therapeutic interventions. The doctor shall notify the competent authority the refusal of the necessary medical treatment expressed by an informed and aware minor or the person who exercises parental responsibility and, in relation to the clinical condition of the patient. By prohibiting the minor, it subjects the diagnostic-therapeutic procedure to the consent of the legal representative, providing that the physician/dentist must refer to the judicial authority in the event of opposition to a necessary and non-deferrable intervention, or proceed without delay according to need for essential care in event of threat to the life or serious risk to the health of patients who are minors or incompetent [20].

The widely shared but non-overlapping position expressed by the CNB (Italian Committee for Bioethics) is that, it is impossible to seek independent consent under 7 years of age, but it is perhaps conceivable between the ages of 7 and 12 (but always not entirely independent and to be considered together with that of the parents), proposing a minimum age of 14 years for informed consent (Italian Committee for Bioethics. Information and consent to the medical act, 20 June 1992) [21].

Furthermore, although the minor’s consent has no legal value, it is appropriate for them to be involved in the information and decision-making process, considering that from 7-12 years of age they can be part of a therapeutic alliance, being able to take responsibility for related health choices at that age.

In case the patient is an adult with permanent or temporary mental impairments, which renders him/her incapable of acting in his own interests, there is no doubt that, in the case of complex treatments, the dentist must seek permission from the legal guardian or, in his absence, the prior authorisation of the court. Furthermore there are those who believe it to be legitimate, at least from an ethical point of view, to intervene in the absence of prior approval for treatment that does not involve any major issues or foreseable negative consequences, or that is necessary to alleviate the patient’s suffering in any case, cannot be delayed.

In American society, two reference principles are described, whose ethical value is widely recognised, which are adopted as the basis for therapeutic decisions to be taken on behalf of patients who are unable to express their consent due to partial or total compromise of their natural capacity [22]. In Italy these general principles can help the dentist to take the correct clinical decision case by case, even if it is not possible to state in advance which of the two principles must be chosen in a particular case.

The first principle is known as "Substituted Judgement". According to this principle, the clinician must choose the therapy that the patient would have chosen if conscious [22].

The adoption of this principle requires knowledge of the patient's opinion on the type of care or, in any case, of the values, principles and interests that have guided the same patient in past treatment choices.

Where there is no knowledge of such information, or even where there is contradictory information or persons who have never been capable of choice (young children or people with serious mental illness from birth), reference must be made to the second principle, which consists of doing everything in the best interest of the patient.

There is a general agreement regarding this decision-making approach, even if there is any official legal protocol to be followed: the choice of the therapeutic option to be adopted is subjected to the decision-making autonomy of the dentist and his conscience.

Finally, considering that the law to be followed is standard at an international level but the applicability varies based on the existing situation in each country, it must be considered that the authors are currently located in Italy.

CONCLUSION

A hierarchy of subjects with the right to information and to give informed consent to medical procedures can be established placing mentally competent adults in top position, followed by minors or significantly disturbed patients whose inclination to accept dental procedures is acceptable only by way of indication, in direct relation to the level of maturity and inverse relation to the severity of the harm and the consequent endangerment of life. In third position is the legal guardian (parent, guardian) in the case of minors/disabled/incompetent persons, provided that his decision is not manifestly detrimental to the patient.

The dentist can be called upon to make decisions in the case of emergency conditions due to immediate danger to life or potential serious harm to an incompetent patient's health. In the same way, consulted court-appointed guardian can be called upon in cases which do not fall under the categories above, who is ultimately able to request a court order in controversial cases.

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