



Informed consent in dentistry: a standard of good clinical practice

Maria Noel Marzano Rodrigues Petruzzi^a, Lívia Haygert Pithan^b, Maria Antonia Zancanaro de Figueiredo^a, João Batista Blessmann Weber^a

Abstract

Respect for patient's autonomy is a principle in healthcare highlighted in the Brazilian Professional Ethical Code of Dentistry and a desirable conduct in every day clinical practice. Informed consent comprises the professional duty of inform all the possible risks, benefits and alternatives for proposed clinical procedures, even for diagnosis or treatment, to the patient. This process is considered a clue for personal autonomy and discloses that they are value options made in the dental clinic context. In health care decision making the best course of action is that one which allies a correct clinical judgment and patient's personal interest based on cultural and socio-economics issues. However, despite informed consent process being a proper conduct, dental assistance in Brazil continues to be guided by a paternalistic approach. Moreover, the misuse of contracts of adhesion as surrogates of informed consent is not unusual in dental assistance. The present literature review discusses the informed consent process as a prerequisite for mediating the professional/patient relationship in the contemporary clinical practice that ensures patient's to make an informed decision.

Keywords: Dentistry; bioethical Issues; ethics; dental; informed consent; personal autonomy; practice management

^a Postgraduate Program in Dentistry, Pontifical Catholic University of Rio Grande do Sul (PUCRS), Porto Alegre, RS, Brazil

^b Law School, Pontifical Catholic University of Rio Grande do Sul (PUCRS), Porto Alegre, RS, Brazil

O consentimento informado na Odontologia: um padrão de boa prática clínica

Resumo

O respeito à autonomia do paciente é um princípio mencionado no Código de Ética Odontológica Brasileiro e uma conduta desejável na prática clínica. O consentimento informado compreende o dever profissional de informar ao paciente todos os possíveis riscos, benefícios e alternativas para os procedimentos diagnósticos ou terapêuticos propostos. Esse processo é considerado essencial para a autonomia pessoal e sugere que há opções de valores permeando a prática da odontologia clínica. A decisão terapêutica para determinar o melhor curso de ação é aquela que alia o julgamento clínico correto ao melhor interesse do paciente, contemplando simultaneamente as questões culturais e socioeconômicas. Apesar do processo de consentimento informado ser uma conduta adequada, a assistência odontológica no Brasil continua a ser orientada pelo modelo paternalista. Também, o uso indevido de contratos de adesão como substitutos do consentimento informado não é incomum na assistência odontológica. A presente revisão da literatura discute o consentimento informado como um pré-requisito para mediar a relação profissional/paciente na prática clínica contemporânea, assegurando ao paciente o direito de escolha informada.

Palavras-chave: Odontologia; temas bioéticos; ética odontológica; consentimento livre e esclarecido; autonomia pessoal; gerenciamento da prática profissional

Correspondence:

João Batista Blessmann Weber
jbweber@pucrs.br

Received: August 22, 2012

Accepted: February 11, 2013

Conflict of Interests: The authors state that there are no financial and personal conflicts of interest that could have inappropriately influenced their work.

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ISSN: 1980-6523

Introduction

Respect for patients' autonomy is a moral health care principle highlighted in the Brazilian Professional Code of Dentistry [1] and is considered proper ethical conduct [2] in therapeutic settings.

Although informed consent (IC) is considered a prerequisite for mediating the professional/patient relationship in contemporary clinical practice, dental assistance in Brazil is mostly guided by a paternalistic approach. However, advances in information technology continuously provide patients with easier access to medical information [3], resulting in an increasingly dentally literate population [4]. This sociocultural phenomenon proposes a new paradigm of dental attention mostly centered on the patient. At the same time, litigation against dentists for alleged malpractice has been on the rise [3], which has contributed to the use of contracts of adhesion (CA) as surrogates for IC by professionals and health care institutions to avoid administrative or civil processes [5,6].

In this context, it is necessary to discuss the influence of the following bioethical questions on daily activities in dental practice. Should patients influence their dentists' decisions? Must professionals make decisions for their patients' well-being, choosing considerations of beneficence over individual autonomy? What amount of information should be provided to allow true consent about dental treatments? What constitutes an adequate method to obtaining a patient's consent? Does IC constitute valid proof of an autonomous decision-making? This literature review aims to present dentists with a simple guide for a better understanding of the IC process.

What is informed consent?

No uniform term exists in Portuguese for the English expression, "informed consent". The terminologies, "*consentimento pós-informação*", "*consentimento consciente*", "*consentimento informado*" and "*consentimento livre e esclarecido*" are currently used [2,7].

IC constitutes a dialog between the patient and the health care giver in which both parties exchange information and questions, culminating in the patient's agreement for a clinical procedure [3]. IC represents a voluntary decision made by an autonomous and capable person [7] that is considered a sign of respect resulting from dignity or personal inviolability and autonomy or free will [2,8].

The objective of IC is to secure the best interest for the person who requires medical/dental interventions [9]. This process has a major role in forming a therapeutic alliance with the patient. Health care decision-making based on IC is not focused only on beneficence and improving the patient's health but is also centered on his values and self-will [10,11].

The historical process of informed consent

Throughout the history of medical/dental ethics, extensive debates have been proposed to clarify what should come first, beneficence or respect for autonomy [12]. The central idea of the classical writings in the history of medicine, from Hippocrates (*The Hippocratic Corpus*, fifth century BC) to Thomas Percival (*Medical Ethics*, nineteenth century AD), does not clearly support the patient's right to consent [13]. In fact, keeping patients unaware about their diagnoses, treatments or prognoses, was not only a statement of professional superiority in health issues but also a practice to protect the supposedly fragile person from forbidding diagnoses [14].

Legal standards are not of major assistance in formulating a concept of IC for clinical settings because they focus on unlawful rather than unethical treatment [13]. However, the contemporary meaning of IC in medical and dental practices was derived from the known legal judgments of the cases of *Salgo v. Leland Stanford, Jr* (1957); *Canterbury v. Spence*; *Cobbs v. Grants* and *Wilkinson v. Vesey* (1972) [2,13,15].

At this historic point, consent evolved from simple, where the patient reaches the decision of being treated, to informed, where the individual opted for treatment on the basis of the amount of information afforded to him [10]. From those processes was stated the common law that an autonomous decision based on a sufficient amount of information was a patient's right [10,13]. In other words, autonomous decision-making would only be accomplished if preceded by an adequate information process [13].

Respect for autonomy: information, comprehension and voluntariness

Autonomy is a polysemous word, one of whose meanings refers to legal autonomy, which is more related to actions rather than to persons, and is known as the principle of respect for autonomy [16].

The IC process arises and is the completion of the principle of respect for autonomy that implies information, comprehension and voluntariness or intentionality, followed by the consent itself [16].

Infinite debate exists among health care professionals about how much information should be given to patients for IC. Regarding this issue, the actually applied criteria include the professional standard or the patient-oriented standard [17]. The professional standard recommends that the dentist should reveal what a reasonable professional would discuss under a similar situation. The patient-oriented standard preconizes that the dentist should disclose what a reasonable patient would find relevant under a similar circumstance. In Brazil, there are no specific legal orientations about this issue, so these established criteria usually serve as guides for dentists.

The parameters for defining a reasonable dentist or patient are rather subjective. Thus, the health care giver must consider whether the given information would render the patient capable of authorizing or declining the proposed intervention [18]. Health care decision-making might be based on a patient's comprehension of his diagnosis, treatment options – inherent benefits and risks – and the expected prognosis, with and without treatment [19].

Disclosure is the duty of the professional (dentist) who is attending the patient [10]. IC needs to be considered as a continuous process and implemented before any dental procedure, except in emergencies when dental interventions should be performed without prior consent [3].

The IC process includes not only the transmission of information but also the dentist's effort to educate and discuss findings with the patient and encourage him to make oral health care decisions [20]. This requires that the patient comprehends and processes information and, according to his values and free will, participate actively and intentionally in developing his dental care plans [18].

In dental research, voluntariness is represented by the liberty of the subject to revoke his consent without suffering any personal prejudices or external pressure to justify his decision [21]. In clinical fields, a voluntary decision also depends on the absence of coercion. However, in real-life circumstances, the patient is usually influenced in some way by internal or external forces. Consequently, in this context, the dentist should be capable of detecting substantial manipulation and guarantee that decision-making occurs in as non-controlled a way as possible [18].

Benevolence and autonomy do not always collide

Cultural diversity issues might influence the value that the individual attributes to self-determination. Brazil is a multicultural country with persons from different social, educational, religious and economic strata. It is recommended that dentists should explore the cultural characteristics of their patients before entering into a discussion on health care decision-making [22].

It is important to underscore the fact that autonomy need not be at the expense of benevolence: the dentist's opinion would remain an important part of the treatment plan. Respect for autonomy will be preserved if the patient's wishes are taken into account, regarding what information is relevant to their consent and how much they would like to participate in making their treatment decisions [11,23].

Nevertheless, it must be emphasized that the patient's choices are not exclusively clinical judgments, but value options made in a clinical context, that include psychosocial, economic and family issues. In these areas, the patient is the one who can decide the best course of action for himself [14]. In this framework, autonomy should not be considered only as an individual characteristic [19] but also as acceptance by the professional of the patient's values

and beliefs, regardless of agreement or disagreement with them [10].

According to the new paradigms of respect for autonomy, the dentist and the patient should share responsibility for decision-making in dental care [10].

Informed consent, consent forms and contracts of adhesion: are they different?

As proposed, IC is conditional on previous knowledge of comprehensible information that will allow the patient to understand his dental condition [24]. Hence, erroneously and not uncommonly, the IC process is confounded with the consent form [25]. This document is known in Portuguese as "*termo de consentimento informado*" or "*termo de consentimento livre e esclarecido*", as preconized by the Brazilian National Health Council [26].

The consent form is not a substitute for the verbal communication process and does not constitute IC by itself. The form uniquely records the information given and the authorization for proposed procedures [21]. The patient's signature on this document will not necessarily signify an autonomous decision. In the absence of the information process, the signed document will exclusively represent the patient's acceptance of an unknown or uncomprehended procedure due to his health care needs [5]. Additionally, in many cases the access to dental care is conditioned to the patient's acceptance of institutional and policy rules of consent, constituting a CA [13].

According to Fernandes and Pithan [21], the CA is characterized by the absence of preliminary negotiations and the submission to unspecific and pre-arranged terms. In this particular case, autonomous consent is substituted by the patient's acceptance of imposed institutional rules. The adoption of CA represents a disparity between the agents and makes the patient more vulnerable.

The validity of informed consent in civil and administrative process

The concept of IC varies from country to country, depending on legal and social issues [21]. Despite being legally required only for research in Brazil, with the exceptions of surgical sterilization [27] and assisted reproduction procedures [28] the use of IC forms has increased in private practice and in medical/dental assistance institutions in recent times [15]. However, with some exceptions, many professionals and institutions implement the IC process as part of their dental routine with the main objective of avoiding complaints, rather than giving adequate information to the patient [20]. Risk management in dental practice started in the 1970s due to an increase in litigation against dentists for alleged malpractice [29].

Dentists are subject to the rules of the Brazilian Civil Code and Consumer Protection Code, as well as to administrative norms described in the deontological code.

In the Brazilian legal system the notion of a patient's free will to make health care decisions is consecrated [30]. The national Civil Code states that nobody can be forced to undergo life-threatening treatment or medical interventions [31]. Additionally, the Consumer Protection Code underscores that the provider (dentist) should be legally responsible for providing inadequate or insufficient information to the consumer (patient) [32].

The resolutions of the Federal Medicine Council also present a basis for the implementation of IC in clinical practice. It is recommended that the patient be informed of the diagnosis, prognosis and treatment of his case and that the physician take the responsibility to provide information and ensure the patient's comprehension in all cases [33]. Inclusively, it is necessary to obtain a previous patient's IC for transferring to another professional any identified exam for complementary examination. In this context, telemedicine should be used only under strict safety standards capable of ensuring the confidentiality and integrity of information [34].

The concept of IC also exists in the Brazilian Professional Code of Dentistry, which states that exaggeration of diagnosis, prognosis or treatment and failure to adequately explain the purposes, risks, costs and alternatives of treatment for the patient constitutes a breach of ethics [35].

It is imperative to emphasize that a preformatted document, drafted with a generic text and inaccessible language where in many circumstances there are exposed institutional rules of consent, does not constitute IC. Based

on the patient's health care needs, he might sign it, but this act does not represent sufficient awareness of the information contained in the document [2,5,9,15,17].

In many litigious circumstances, a properly drafted and signed consent form preceded by an adequate disclosure of the patient's dental condition would constitute documental proof of the accomplishment of the professional duty to inform the patient [5]. However, IC process is a moral obligation for dentists and its implementation will ensure the patient's best interests [22]. It must be stated that the objective of carrying out the information process is not to provide clear proof of good clinical practice. In this case, the availability of properly filled dental records would be more effective in a civil process than the patient's signature on a CA [5,29].

How to adequately obtain patient's consent?

Essentially, the dentist which assumed the dental care planning must have sufficient knowledge of future clinical procedures to obtain valid consent [37]. The drafting of the consent form must follow the completion of the verbal information process. Additionally, the document must contain, in detail, clear form and accessible language without any technical terminology, all the information previously given to the patient [5,36]. As recommended, the proposed treatment, the risks and benefits and the prognosis of the suggested clinical procedure, the necessity of follow-up and the costs [29].

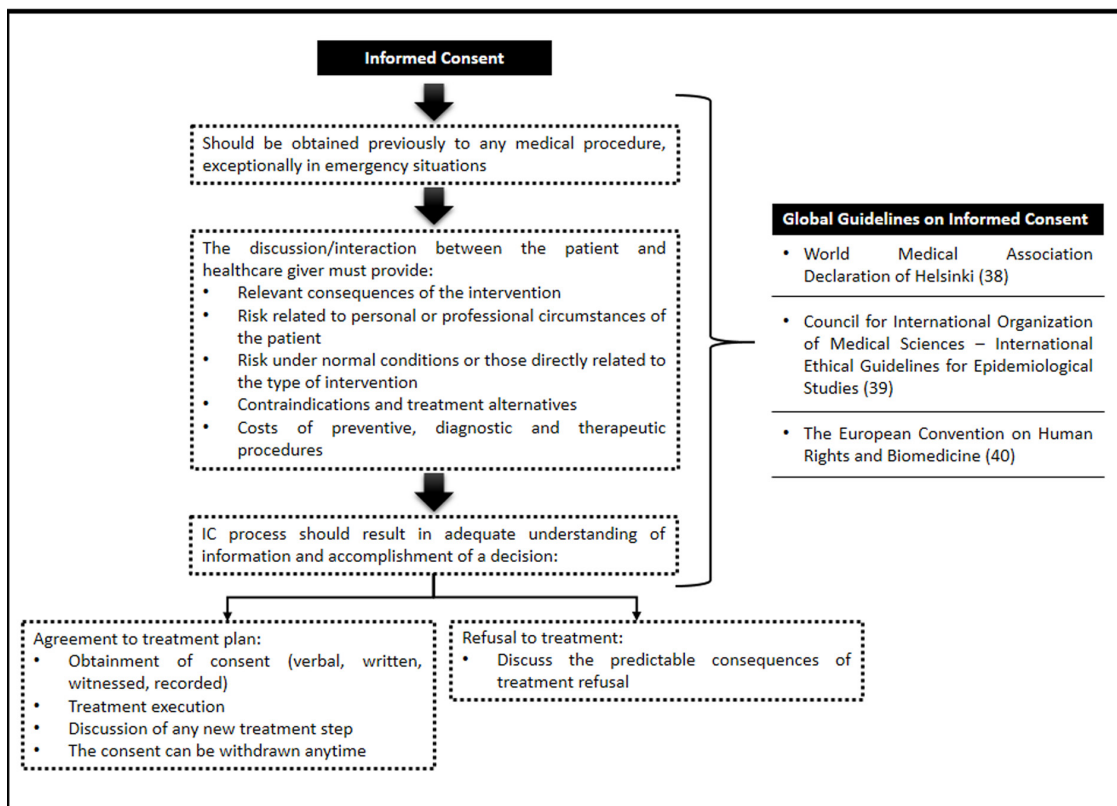


Fig. 1. Conceptual framework for the process of obtaining informed consent, according to global guidelines.



As proposed by Kirby et al. [37] the dentist must be aware if the patient is understanding, retaining and weighting all the relevant information for and autonomous decision making and if he is capable of unequivocally communicate his judgment. In advance of obtaining consent a copy of the form should be provided to the patient. This conduct will offer to him the opportunity to reflect, ask further questions and if necessary search for a second dental opinion.

Patient's consent must be given in advance, at the time when procedures are booked and re-confirmed immediately before treatment's execution [37]. Figure 1 presents a conceptual framework for the process of obtaining IC according to regulations of major international parties [38-40], which would be a helpful tool to adequately obtain IC in dental settings.

Final considerations

The objective of implementing the IC process is not to avoid complaints of malpractice or to produce advanced evidence of good clinical practice. The main purpose is to give to the patient all the information that he needs to make an autonomous decision of the course of action that better represents his interests. It is imperative to remember in daily dental practice that there are value options made in the dental clinical context.

The IC becomes a process of mutual decision-making and will reduce the risk of alleged malpractice lawsuits. The concern of suffering an administrative or civil process should never replace professional judgment, which should serve to ensure the value of the actions. Communication between dentists and patients is the beginning of a relationship based on trust.

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