

Informed Consent: Corner Stone in Ethical Medical and Dental Practice

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ABSTRACT

Progress in health care technologies has enabled patients to be better informed about all aspects of health care. Patients' informed consent is a legal regulation and a moral principle which represents patients' rights to take part in the clinical decisions concerning their treatment. With increasing awareness among the patients, the concept of informed consent is also evolving in developing countries like India. It is important for the medical and dental practitioners to have a written and signed informed consent from their patients before performing any invasive or irreversible procedures. Informed consent is also needed when providing medical care to children, foreign patients, and incorporating images of the patients while conducting medical and dental research. The present review addresses some of the vital issues regarding informed consent when providing medical and dental care with current review of the literature.

Keywords: Children, dentistry, informed consent, medicine, risks, smart consent

Introduction

Law in the field of health care is an established concept in developed countries but remains in its infancy in developing countries. Due to global advancements, the situation is now changing because of increased awareness of the patients' rights, and it is just a matter of time before we fall prey rightfully or wrongfully to an ever-evolving legal framework for the health care industry including dentistry.^[1] It is a general legal and ethical principle that one must get valid consent before starting treatment or physical investigation, or providing personal care, for a patient or conducting research involving human participants.^[2] In medical terms, informed consent implies to "providing sufficient information for a patient to make an informed and rational choice, the information includes the inherent risks and alternatives that a reasonable doctor would provide having regard to the particular circumstances of the patient."^[3] This principle reflects the right of patients to decide what happens to their own bodies and is an essential part of good practice. In health and social care

research, informed consent can be defined as "The process of agreeing to take part in a study based on access to all relevant and easily digestible information about what participation means, in particular, in terms of harms and benefits."^[4]

A patient's informed consent to investigations or treatment is a fundamental aspect of the proper provision of dental care as well. Without informed consent to treatment, a dentist is vulnerable to criticism on a number of counts. The concept of consent to treatment is increasingly becoming contested in courts of law in many western countries like United Kingdom.^[5] Any practitioners who cannot demonstrate that a patient has properly consented to treatment are laying themselves open to litigation. A survey was conducted to determine the quality of information given to patients before the endoscopic procedures in countries that are members of the European Society of Gastrointestinal Endoscopy. Although information about the procedure is given to the patients in 96% of the responding countries, in only 77% is there sufficient time for the patients to ask questions about the nature of the procedure. In 15% of the countries, neither the diagnostic nor the therapeutic alternatives to endoscopy are discussed nor the potential complication rates.^[6] Results of a

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recent Italian National Survey conducted to investigate informed consent practice for elective tracheostomy procedure in critically ill conscious and unconscious patients revealed that in conscious patients, informed consent was obtained by 82.4% of intensive care units; and in unconscious patients, informed consent was obtained in only 61.8% with different procedures not following the current Italian law.^[7] According to the results of a study conducted on Bulgarian dentists, even though almost 100% of the dentists thought that it is necessary to get informed consent, only 80% of them obtained it in practice.^[8] It is self-evident, therefore, that every practitioner, therapist, and hygienist needs not only a thorough understanding of the principles of consent, but also an awareness of how to apply these principles in the wide variety of circumstances that can arise in the practice of dentistry.^[9] The present paper aims to provide fundamental information regarding informed consent when providing medical and dental care and a review of current literature.

Literature Search

Literature search for the present article was done both electronically and manually. Electronic search was conducted using databases like PubMed, Medline, and so on extracting relevant articles published in peer-reviewed journals. Various web-based search engines like Google Scholar were also used for finding relevant articles. Full text of the articles which were not available electronically was manually retrieved from PGIMER Library, Chandigarh electronically. Various key words and their combinations were used for literature search like informed consent, medicine, dentistry, children, risks, dental profession, treatment, procedures, and so on. The present review also emphasized on informed consent in special cases like medical and dental tourism, using photographs of patients in journals and research and new technologies like SmartConsent.

When considering consent, following questions should be kept in mind

- What does the patient or the patient's carer need to know and understand?
- Is the patient capable of understanding?
- Does the patient have capacity to give consent?
- If not, is the carer not only capable, but also qualified to consider the best interests of the patient?
- Is consent given voluntarily?
- Does the law resolve any conflict between patient and carer?

It is very important to find out what your patients want to know, as well as telling them what you think they need to know. Information which patients may want to know include: Why you think a proposed treatment is necessary, the risks and benefits of the proposed treatment, what might happen if the treatment is not carried out, and other forms of treatment, their risks and benefits, and whether or not you consider the treatment is appropriate. Always make clear to the patient: The nature of the contract and in particular whether the patient is being accepted for treatment under any government health service or privately and; the charge

for an initial consultation and the probable cost of further treatment.^[2] If you are working in a group practice, it is better to involve other members of the health care team in discussion with the patient, where appropriate. They may have valuable knowledge about the patient's background and particular concerns.

Types of Informed Consent

Informed consent is basically of three types which are as follows^[10]

1. Implied consent: Implied consent refers to when a patient passively cooperates in a process without discussion or formal consent. The principles of good communication apply in these circumstances and health professionals need to provide the patient with enough information to understand the procedure and why it is being done. Implied consent does not need to be documented in the clinical record.
2. Verbal consent: A verbal consent is where a patient states their consent to a procedure verbally but does not sign any written form. This is adequate for routine treatment such for diagnostic procedures and prophylaxis, provided that full records are documented.
3. Written consent: A written consent is necessary in case of extensive intervention involving risks where anesthesia or sedation is used, restorative procedures, any invasive or surgical procedures, administering of medications with known high risks, and so on.

Medical Procedures Requiring Informed Consent

Written informed consent is needed in case of following medical procedures^[11]

- Most surgeries, even when they are not done in the hospital.
- Other advanced or complex medical tests and procedures. Examples are an endoscopy (placing a tube down your throat to look at the inside of your stomach) or a needle biopsy of the liver.
- Radiation or chemotherapy to treat cancer.
- Most vaccines.
- Some blood tests, such as HIV testing (need for written consent varies by countries).

Informed consent is not needed in an emergency when delayed treatment would be dangerous for the patient. Some people are no longer able to make an informed decision, such as someone with advanced Alzheimer's disease. Another example is someone who is in a coma. In both cases, the patient would not be able to understand information to decide what medical care they want. In this type of situation, health care provider would try to obtain informed consent for your treatment from a surrogate, or substitute, decision-maker.^[11]

Dental procedures requiring informed consent

As the need for informed consent becomes more evident to the dental profession, a dental professional should know that

which procedures actually require written, informed consent. The answer to that question is relatively straightforward: Any procedure that is “invasive or irreversible” requires informed consent. The fact that a patient visits a dental office for an exam implies that he or she wants the doctor to conduct some type of clinical examination to determine what treatment might be needed, but most dentists take for granted the fact that more than 90% of their procedures are surgical in nature. All procedures, from a simple buccal pit restoration to the removal of a complicated, full boney, impacted third molar, require an irreversible change to bodily tissues with the risk of some type of complication or unwanted side effect. Even minor occlusal/incise adjustments can affect the surrounding dentition, cuspid rise, masticatory function, or TMJ (Temporomandibular Joint stability) stability. The mouth is an extremely dynamic environment, subject to the forces of the tongue, lips, cheeks, and teeth. Any change to that environment, even with the best of intentions by the practitioner, may lead to unwanted results, and those possibilities need to be presented to the patient and documented in writing.^[12]

Although “invasive and irreversible” procedures require informed consent, most diagnostic procedures such as general clinical examinations, periodontal probing, and radiographs do not require such formal consent. It is assumed, for the most part, that patients want the doctor to obtain all of the information necessary to make a complete and accurate assessment of the general and oral condition when scheduling for an initial examination or any concerned pain. On occasion, however, patients will specifically state that they wish to forgo diagnostic procedures such as radiographs or periodontal probing. The practitioner’s focus must immediately obtain “informed refusal” in these cases.^[12]

Risks to be discussed with the patient

A health care practitioner needs to inform patients of potential risks where there is a reasonable chance of a “serious” adverse outcome. Legal matters often use the phrase material risks when describing which risks should be reviewed prior to treatment. Material risks are defined as those risks that are most relevant to the patient (i.e. the most common and the most serious). For example, if an oral surgeon knows that a certain percentage of patients will experience an infection after a procedure, it would be appropriate to discuss that risk with the patient. Similarly, if a patient could experience permanent nerve damage as a result of anesthesia (an inferior alveolar nerve block), the risk should be discussed with the patient, even though the percentage of patients experiencing permanent paresthesia is minimal. Informed consent is necessary when there is a significant chance of problems or where potential problems are devastating.^[13]

Informed consent in case of children

If a person is below 18 years of age, he or she is considered child and is not eligible to give consent. Generally, a guardian of a child or minor (usually a parent) has the authority to consent

to their treatment and procedures, provided that it is in the best interest of the child. Consent of either parent will generally be sufficient, but if the parents are separated it is a good idea to enquire if that parent has authority to consent to treatment, particularly if the treatment is risky. When a parent consents to treatment, the parent must be provided with the information that is relevant to that treatment. Generally, in the case of mentally disabled children, parents/guardians have the capacity to consent for treatment on the child’s behalf.^[14]

Children are particularly helpless, vulnerable, and liable to exploitation. They rely on their parents for love and protection and to ask parents to agree to their child’s participation in an experiment places a heavy burden on them. For the investigator, there is a dual responsibility—to children and to their parents—and he must assume a greater responsibility to ensure that the means and ends of the research are necessary, worthy, and possible at minimal risk.^[14]

A study was conducted to find out which children can be involved in consenting to their dental care. The results from this study suggest that children want to be involved in the decision-making process and they want this to be in the form of a discussion between the dentist, their parents, and themselves.^[15] Children want adults to recognize and help promote their evolving autonomy by listening to them and acknowledging their contribution in consenting to dental care. This increases their understanding and satisfaction with their dental care.

Informed consent in medical and dental photography

There are many reasons for using patient images in medical practice and research. They are incorporated into the medical and dental record as an adjunct to clinical care, displayed to colleagues, students and other audiences in educational settings, and published in scientific journals or other media as part of dental research. In each case, it is not only prudent, but also necessary for the patients’ protection and interest that appropriate consent be obtained. While scientific journals invariably require written consent for photographs that may identify the patient, the format of the photograph consent form is usually neither specified, nor is it always clear which images require consent. With the proliferation of published images on the internet, it has become particularly important to obtain permission for all uses that will be made of medical and dental images, including worldwide distribution through various electronic media.^[16]

Dental tourism and informed consent

Dental treatment provided to patients who travel across international borders for the purpose of receiving dental care comes under dental tourism. It is a growing phenomenon that raises many ethical issues, particularly regarding the dentist-patient relationship. Various issues related to this phenomenon include patient autonomy over practitioner choice, patient safety, continuity of care, informed consent and doctor-patient communication, among other factors. In

particular, patients partaking in medical tourism should be informed of its potential problems and the importance of proper planning and posttreatment care to guarantee high-quality treatment outcomes.^[17]

Personalized consent form

A health professional can create his or her own consent form adapted to the needs of the dentist, clients, and practice. It is important that the content of the form complies with the law and the requirements for a written agreement. Moreover, the form must not only be legible, but also intelligible for the patient, which means that it is written using clear and precise terms. The form, which exists primarily for legal purposes, is truly effective when the patient thoroughly understands its content. In this case, it is recommended that medical and dental health professionals consult a provincial or federal medical association for guidance.^[18]

Smartconsent

Communicating personalized information to patients about the risks, benefits, and other critical information about a disease and its treatment is often difficult for providers. A research was conducted at the University of Texas Health Science Center at Houston to develop a novel informed consent prototype that can accurately translate and communicate information to patients in a standardized and effective manner based on their diagnosis and prescribed treatment. This technology is called as SmartConsent. In future work, it is aimed to integrate SmartConsent into the institutional electronic patient record and determine its effectiveness in a randomized controlled study.^[19]

Conclusion

The present paper is written to make dentists aware of their obligation to adequately inform their patients before providing medical and dental care and to give health practitioners tools that can help them avoid disputes for failing to do so. Although the idea of informed consent is not new to health care profession, but its uptake and widespread use in the dental community has been slow to evolve. Even in dentistry, like other health care fields sometimes unforeseen mishaps occur despite our best efforts. Therefore, it is mandatory for all health care practitioners to obtain informed consent from their patients prior to every invasive and irreversible procedure. A written and signed informed consent is the only evidence that can save a practitioner frequent visits to the courtroom and large sum of money in legal fees in case of a mishap. Health care practitioners should keep them updated regarding changing laws by consulting their concerned organizations.

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