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Informed Consent and the Dentist

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Abstract

Doctors, as members of the health care profession are looked upon with reverence and respect. A doctor-patient, especially a dentist-patient relationship is a special one. The foundation for this relationship is trust that the dentist will perform his duty with the patient's best interests in mind. Dentists support this relationship by practicing in a professionally responsible manner and letting the ethical principles of their profession guide actions while performing duties of care to patient. It is also the responsibility of dentists to assist patients to make well informed decisions about treatment procedures. The act of asking for consent, specifically informed consent from the patient fulfills three aspects. Firstly, respect for the patients' right to make a choice regarding his body, secondly as an ethical and moral obligation and finally a legal necessity to safeguard the dentist from possibility of future legal action. Failure to do so violate patients' trust in dentists and increases dentists' liability to malpractice suits. The following review article addresses an important ethical principle of informed consent. It also focuses on various types of consent and methods to help dentists improve their skills in obtaining a legally and ethically valid patient consent.

KEYWORDS: dentist, ethics, informed consent, legal

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Informed Consent and the Dentist

INTRODUCTION

A doctor-patient, especially a dentist-patient relationship is a special one as the patient seeks help from the dentist for relief from pain and for restoration of their oral health. They permit the dentists to see, touch and manipulate structures in and around the oro-facial region and also divulge information about themselves they wouldn't normally reveal. They do this because they trust the dentist to maintain their confidentiality and also believe that that dentist will act in their best interests. The various ethical principles act as guides to enable the dentist to perform his duty to the patient. At times, the commercial element of dentistry may override the professional aspect and patients may at times feel that the dentist has not acted in their best interest. They are either dissatisfied with the treatment provided or feel unwanted treatment was performed on them or risks of a procedure were not explained to them. There is an increasing awareness among patients regarding their rights as a consumer of health care services. Currently, the medical and dental professions are facing an ever increasing rate of malpractice suits (Bal, 2009; Jena, Seabury, Lakdawalla, and Chandra, 2011; Leflar, 2009; Pepper and Slabbert, 2011; Traina, 2009). King's **s**tudy (2001) found that patients felt they were ill informed about their treatments and that all treatment options were not discussed with them. They also felt that dentists assume that they understood everything that was told to them when in reality they did not. Patients facing such situations may seek legal aid for redressal of their grievances.

A 5 year retrospective survey on dental malpractice claims in Teheran, Iran (Kiani & Sheikhazadi, 2008) found that in 57% of clinical cases, and 40% of non clinical cases, dentists were found to be guilty of malpractice. In a similar study in Turkey, (Gundogmus, Erdogan, Sehiralti, &Kurtas, 2005) 48% of the dentists were liable for malpractice suits which included

negligence, inappropriate treatment, and diagnostic failure. In a Riyad study, (Al-Ammar & Guile, 2000) it was found that mistakes during treatment were the most frequent allegation and in 87% of the cases the dentist was found to be the guilty party. Therefore, one of the most important legal safeguards and moral obligations of dentists to their patients are obtaining consent for any course of health care action.

Literature reviews (Al-Ammar& Guile, 2000; Avramova & Yaneva, 2011; Kotrashetti, Kale, Hebbal, & Hallikeremath, 2010) regarding obtaining consent in dental practice have shown that most dentists agree as to the importance of consent before performing any dental procedures. Consent was usually a general consent rather than treatment specific and written consent was only taken in the event of invasive dental procedures.

In a cross-sectional analytic study in Pakistan, (Tahir, Ghafoor, Nusarat, & Khan 2009) it was found that the first year graduates were more cognizant of the importance of obtaining consent and practiced taking informed consent from the patients in comparison to third and fourth year students. 68% of the students felt that consent was essential to protect the dentist while only 9% felt that it was an essential patient right.

In a questionnaire study conducted by Avramova & Yaneva (2011) among Bulgarian dentists, it was found that though most dentists took consent while treating children, they were less prudent in taking consent while treating their professional colleagues, relatives, friends and longtime patients. In a study among general dental practitioners in India, **(**Kotrashetti et al, 2010) it was found that 70% practitioners felt that taking consent was a necessary safeguard for the doctor alone while only 27% felt that it was also necessary to protect both the doctor and the patient. Additionally, 18% of the dentists stated that they would refuse to give a copy of the consent form. This reaction could stem from the basic lack of knowledge regarding the dentist's

legal obligation to provide a patient with the copy of consent form, or from fear/guilt due to incomplete, incorrect, misleading or destroyed information in the consent form that would put the dentist in an unfavorable position. 46% of the dentists would give the consent form only after asking the reason for the request, while only 36% said they would provide consent form willing if it was requested by the patient. The study further highlighted the lack of patient record maintenance on part of the dentist either for purposes of documenting present and future treatment plans or as a means of protecting the dentist in the event of future litigation on part of the patient.

The studies indicate that theoretically most dentists are aware of their ethical, legal and moral obligations to take consent from their patients, but in practice many fail to do so. In fact, consent is taken only as a means of a safeguarding against a possible litigation rather than an ethical necessity. Why is the theory of ethics taught in undergraduate curriculums not translated into practical ethics? According to Bertolami (2004), a change in student behaviors is unrealistic when they are taught about ethics through literature rather than taught ethics through application and clinical practice. It is the opinion of the author that the undergraduate curriculum on ethics focuses on rote learning of theoretical ethics rather than its application in real clinical situations, hence, making the subject of ethics unappealing to the students.

According to Sharp, Kuthy & Heller, (2005) dental students perceive a variety of ethical concerns along with disagreements as to what constitutes ethical or unethical during their clinical training.

These concerns need to be addressed at the earliest stage of student training by increasing student interest in study of ethics as a subject with clinical applicability, and making the study of ethics attractive by holding skilled interactive discussions. This could include providing ethical

scenarios which would enable students to express opinions, clarify, and modify their thoughts on ethical issues and concerns. (Jensen 2005). As learning moves from passive to active, the student's ability to understand, retain and apply knowledge to future ethical conundrums improves.

This article focuses on the misunderstood principle of ethics in practice i.e. consent and its relevance and importance to the dental profession while suggesting ways to improve the dentists' ability to obtain an ethically and legally sound patient consent.

THE CONCEPT OF CONSENT TO TREATMENT

Consent to treatment consists of three essential characteristics namely competence, voluntariness and knowledge. Competence means that the patient has sufficient ability to understand the nature of the treatment and the consequences of undergoing or refusing the treatment. 'Voluntariness' means that the patient has freely agreed to submit to the treatment without any coercion or force. 'Knowledge' means that sufficient comprehensible information is disclosed to the patient regarding the nature and consequences of the proposed and alternative treatments (Corless-Smith, 2002). All these factors are influenced by the level of health literacy of the patient. The concept of health literacy and its influence on patients' ability to provide an informed consent will be further addressed in detail later in the review.

THE ETHICAL BASIS FOR CONSENT TO TREATMENT

Consent of treatment is based on two ethical principles namely: The Principle of Autonomy and the Principle of Beneficence. (Corless-Smith, 2002)

Autonomy: The predominant model in the past still adhered to by many health care professionals is the concept of paternalism. This concept implies that the doctor is knowledgeable and skilled, therefore the best person to make judgments without involving the

patient when deciding a therapeutic regimen. A shift in attitude has taken place after World War II with the Nuremberg Trials, resulting in the Nuremberg Code and The Declaration of Helsinki which stated that the voluntary consent of the human research subject is absolutely essential and that consent should be based on sufficient knowledge and understanding. From these regulations derived the concept of patient autonomy in health care. Autonomy may therefore be crudely defined as a person's ability to decide and act on the basis of rational thought and deliberation (Bridgman 2002).

When a patient is given control over decision making with respect to his bodily integrity, it indicates respect for the patient's autonomy. This is reflected by obtaining a voluntary and informed consent from the patient or a guardian before a clinical intervention.

Beneficence: In simple terms, Beneficence is a moral obligation to act in the interest or benefit of others. All health care providers have a duty to care for the patient and all health care actions performed should be done with the best interests of the patients in mind.

A conflict between patient autonomy and beneficence can result when both patient and clinician differ in what they both consider as 'in the best interest'. In such situations, a decision should be made based on the attitude of the patient and the dentists' technical judgment. In practice dentists may come across patients who seek out knowledgeable, skilled, and trustworthy doctors, but thereafter prefer to let that doctor lead in the decision making. On the other hand, the dentist will also come across patients who have strong views and want to be involved in every step of the decision making process. In this case it is imperative to provide patients with all the information that will help them make a decision regarding a course of action (Corless-Smith, 2002; Dame Turner-Warwick, 1994).

It is essential that the clinician use one of the most powerful tools in his armory – a patient friendly manner of communication, for the effective delivery of health care. Poor communication between patients and clinicians is a major factor leading to malpractice lawsuits (Weiss, (Ed.) 2007).

CONSENT IN THE CONTEXT OF INDIAN LAW

According to the Indian Civil law - Indian Contract Act of 1872, a doctor patient relationship is considered to be a contractual and legal agreement for professional services. Section 13 of the act defines consent as when "two or more persons agree on the same thing in the same sense." Section 14 of the same act defines 'free consent' as one that is "given without the existence of coercion, undue influence, fraud, misrepresentation or mistake". Therefore according to this act, a contract is valid only if it is entered into with the free consent of the parties concerned in this case, the dentist and patient **(**Indian Contract act 1872, Sections 11-18; Dhillon & Singhal, 2009). The Indian Criminal Law also deals with consent under the Indian Penal Code of 1860 under Sections 87-92. (IPC 1860)

Who can give consent?

The age of consent is bound by legal definitions and within the context of the Indian law there are two schools of thought. Section.90 of the Indian Penal Code of 1860 states that "Consent by intoxicated person, person of unsound mind or a person below twelve years of age is invalid." This therefore implies that a person above 12 years of age can consent to medical/surgical/dental treatment if it is intended for their benefit and undertaken in good faith. On the other hand, according to Sec. 11 of the Indian Contract Act of 1872 - a competent person of sound mind who has attained the age of majority of 18 years (according to the Indian Majority Act of 1875) can legally enter into a contract. Since the dentist-patient relationship is essentially

a contract, it implies that only persons 18 years of age and above can enter into a doctor-patient contract and can give consent for treatment. (Bastia, Kuruvilla & Saralaya, 2005; IPC 1860; Kohli, 2007).

In the absence of clear cut legislation, the majority of doctors/dentists in India consider the consent of a person above twelve and less than eighteen years of age valid for medical/dental examination only, but for dental interventions prefer to take the consent of the parents/guardians. This is a definite safeguard against civil liability.

When is consent invalid? (IPC 1860, Sec 90)

It is essential to keep in mind various situations where consent could be invalidated.

1. Consent given under fear, fraud or misrepresentation of facts,
2. Persons under the influence of alcohol,
3. or by a person who is ignorant of the connotations of the consent,
4. or a person who is under 12 years of age

Situations where consent may not be obtained: (Bansal and Singh, 2007).

Though consent is an essential aspect in a doctor-patient relationship it need not be obtained in the following situations:

1. In the event of Medical Emergencies.
2. In case of a person suffering from a notifiable diseases
3. Immigrants.
4. Members of Armed Forces.
5. Handlers of food and dairymen.
6. New admission to Prisons.
7. In case of a court order or request of the police

For how long is consent valid? (ACT Health Procedure Consent to treatment, 2008)

Though there is no legally defined time period for consent to be valid, it can be considered valid until the patient withdraws it or there is a change in the patient's circumstances, which may include:

1. Improvement/deterioration in the patient's condition
2. Availability of new treatment options since consent was given.
3. Due to disease progression the treatment choice has changed from cure to palliation.

UNDERSTANDING CONSENT IN THE CONTEXT OF HEALTH LITERACY

It is essential to determine the health literacy level of the patient to assess the level of understanding, competence, and ability to obtain and process basic health information and services needed to make appropriate health decisions and follow instructions for treatment. The factors that contribute to an individual's health literacy are (1) a person's general level of literacy, (2) an individual's amount of experience in the health care system, (3) complexity of information provided, (4) cultural factors that may influence decision making, and (5) the manner in which the health related material is communicated. (Weiss, (Ed.) 2007)

Effects of limited health literacy

A patient's limited ability to read and understand health related information often translates into less knowledge, poor health outcomes of healthy behaviors, less awareness of preventive health measures, less knowledge of medical conditions, and less self-care instructions than their more literate counterparts. All these factors can affect the validity of the informed consent given by the patients.

In a study, Taiwo and Kass (2009) assessed the post-consent understanding among dental subjects who were participating in oral health research in Nigeria, and discovered that nearly all

the study participants were unaware that they were part of a research study. They also had poor understanding of some key elements of informed consent, which included confidentiality, voluntariness, risks associated with the study and perceived benefits of the research. The researchers identified poverty and illiteracy as two main issues of the study's participants. Additionally, a lack of training among the dental researchers in regards to the ethics of conducting research all served as compromising factors of informed consent.

UNDERSTANDING INFORMED CONSENT **(**Murkey, Khandekar, Tirpude & Ninave, 2006)

In order to understand the evolution and importance of informed consent it is essential to have background knowledge of the other types of consent which are routinely used in dental practice. They include:

Implicit (tacit) consent: This is the most common type of consent one encounters in a dental clinic or hospital. Here consent is implied when the patient indicates a willingness to undergo a certain procedure or treatment by his or her behavior. For example, consent for an oral examination is implied by the action of opening one's mouth.

Explicit consent: This type of consent is given orally or in writing. It is required for minor examinations or invasive procedures. It is preferable that a disinterested third party act as witness to the consent.

Proxy consent (Substitute consent): This type of consent is utilized in the event the patient is unable to give consent because he/she is a minor or mentally unsound/unconscious. In such situations a parent or close relative can provide proxy consent.

Loco parentis (Krishnan & Kasthuri, 2007)**:** In an emergency situation in case of children, when parents / guardians are not available, consent can be obtained from the person bringing the child for dental examination or treatment (For example:. school teacher, warden, etc).

Open/broad/blanket consent (Lunshof, Chadwick, Vorhaus & Church, 2008; Manthous, DeGirolamo, Haddad & Amoateng-Adjepong 2003) is usually consent signed at the time of hospital admission, to cover any subsequent procedures. This type of consent implies that there are no restrictions to the scope and duration of the consent, and does not inform patients adequately about risks. It is said to be an inappropriate form of consent because it is equivalent to requesting *carte blanche* permission for medical procedures

Verbal consent: Verbal consent is where a patient states their consent to a procedure verbally but does not complete a written consent form.

Valid Consent: Consent is valid if the following four elements have been satisfied:

1. Patient is competent to give consent
2. Full information of risks, benefits, alternatives and costs has been provided
3. Consent is freely given, and
4. Consent is specific to the procedure.

(ACT Health Procedure Consent to treatment, 2008)

Informed consent: The concept of explicit consent has been expanded to include a feature called informed consent originating in America during the 1950's and 1960's during the civil rights movement (Bridgman, 2002).

Informed consent means that once the clinician has obtained the basic information from the patient and evaluated the facts acquired during the clinical examination and diagnostic procedures, the diagnoses should be derived. This is followed by the construction of a step-by-step treatment plan. The treatment plan includes specific information regarding the nature of the procedures/materials to be used, number of appointments/time frame needed to accomplish this care, behaviour guidance techniques, risks and benefits, alternatives, expectations if no

intervention is provided, as well as fee for proposed procedures. All these issues should be explained to the patient, preferably in the local language, in comprehensible, non-medical terms. Subsequent to the provision of information and assessing the extent of understanding and competence, the patient is required to sign a consent form which must be accurately and unambiguously worded. It should be understood that obtaining a valid informed consent is both a legal and ethical obligation of the dentist.

Tahir, Mason, & Hind, (2002) conducted an observational study to determine whether parents of children attending out-patient general anesthesia at a Dental Hospital fully understood the proposed treatment. The results were assessed on the basis of their knowledge of actual treatment procedures, type of anesthesia, as well as number and type of teeth being extracted. Results indicated that 40% of the written informed consent was not valid because the parents were unable to answer all the questions correctly although specifics in regards to the procedure had been explained in detail to them earlier. The study also showed that the parents' knowledge improved on the actual day of the procedure, thereby increasing the validity of the consent. However, 19% still did not fully understand the procedure thereby invalidating their informed consent.

Methods to improve informed consent:

Most health professionals including dentists pride themselves on the fact that they take time to explain health care actions/interventions, home care instructions, drug use, follow up procedures etc., despite their busy schedules. Whereas, in fact, their communications are not always comprehensible even to well educated individuals. Use of medical/dental jargon further complicates the communication process. The health professional is then completely astounded and feels victimized when he is faced with litigations regarding failure to explain adverse effects

or is accused of performing unwanted procedures or negligence. These situations could be avoided by improving communication with the patient thereby obtaining a valid informed consent.

The first step in the communication process is to assess the health literacy of the patient by observing for a few simple signs.

1. A low level of health literacy in indicated when the following signs are noticed.
    - Patient's registration forms are incomplete or inaccurately entered.
    - Patient regularly misses appointments and does not follow through with the recommended laboratory tests and shows non compliance with medication regimen.
    - Patient is unable to name the drug, the timing or the reason why a medication has been prescribed to them.
    - Patient shows reluctance or avoidance of read written health information provided to them.
2. After gauging the level of understanding of the patient start off with a verbal discussion. Draw or show pictures to improve patients recall. Medical or Dental jargon should be avoided and plain and simple – preferably local language should be employed. A reliable interpreter, maybe someone from the dental team to assist in case the clinician is unable to communicate efficiently in the language of the patient.
3. Encourage the patients to ask questions and clarify doubts. Use the Ask-Me-3 which serves as an activation tool that encourages patients to ask and physicians to answer, three basic questions during every medical/dental encounter. Patients should be made aware of the program through posters and brochures displayed in the office.

4. Provide information to patients in an easy to read written format so that the patient can assimilate the information at his own pace.
5. In case of complex treatment procedures audiovisual aids or models can be used to explain the procedure.
6. Use the "teach-back" technique. Confirm that patients understand by asking them to repeat back your instructions.
7. Allow the patient sufficient time so that he is able to digest the information provided and arrive at an informed decision.
8. Consent should also be repeated before carrying out the actual treatment procedure, especially if some time has elapsed between the signing of the consent form and the actual time of treatment. (Weiss, B. D. (Ed.). 2007)

Informed refusal: Competent patients have the right to refuse treatment, even when the refusal will result in pain or disability. In case a patient refuses essential treatment even after all the consequences of such a refusal are explained to him, it should be made clear to him that he is doing so at his own risk. An informed refusal form should be signed by the patient preferably in the presence of a disinterested third party.

Consequences of failing to obtain informed consent

Failure to obtain consent before performing an invasive procedure could result in either trespass (assault and battery) to a person or negligence. Simply defined, assault involves the threat of using force while battery involves the actual usage of force, either intentionally or negligently, against another person, without lawful justification or excuse.

Assault is covered under Section 351-358 of the Indian Penal Code (The Indian Penal Code (Act No. 45 of 1860)).

Failure on part of the dentist to provide adequate information about the procedure and its associated risks can amount to negligence. The dentist can be held accountable for this breach of duty of care under the Consumer Protection Act (CPA), 1986. This act provides for a three-tier quasi judiciary system (district, state and national level) to settle consumer disputes. Since the health care professional is considered a provider of service and the patient the consumer of such service, the health profession came under the purview of the CPA in 1995 to deal with deficiency of service (Rao, 2009).

Singh et al (2010) study among dental and medical health professionals found that the medical professionals had greater awareness of CPA when compared to dental professionals. Similarly, postgraduates and private practitioners of both professions had significantly more awareness than the graduates and academics respectively. The lack of awareness of CPA among dentists and graduates in particular implies that they are ill-equipped to deal with litigations that may arise in their dental practice.

CONCLUSION

As members of the health care fraternity, dentists have a duty of care for their patients. It is essential that dentists perform their duties keeping in mind the ethical principles of the profession and the law of the land. It is observed that consent when taken was usually of the nature of a general consent rather than treatment specific. Written informed consent was mainly used only for invasive surgical procedures and was taken with the purpose of protecting the dentist from legal problems. There is a need to stress that the presence of a signed consent form maybe a safeguard to the dentist against possible litigation, but it is still of secondary importance in the event it can be proven that the patients have not been adequately informed about the treatment procedure or its risks. In this event, the clinician may be held liable and charged with

negligence. Hence, informed consent should not be treated only as a legal tool but rather as a moral process which informs and empowers the patients' to make decisions regarding their oral health.

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