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Full Length Research Paper

Informed Consent: A Pre-requisite in Health Research

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Abstract

Today we are living in 21st century. Dentistry has taken a long journey dated back since BC era. In the past Doctor/ dentist were considered god by patients. But now time has changed so the world. With the advent of consumer protection act the weighing scale is more towards the patient. The doctor/ dentist now need to be more cautious and careful in his work. A mere negligence either knowingly or unknowingly on the part of the operator can lead to doom of his/ her profession/ carrier. As for the patient with consumer protection act, dentist should also be protected from false cases. Informed consent form provides such a protection. As a dentist we should be fully aware of it. But one should remember that it do protect dentist but not his/her negligence.

Key words: *Informed consent, Implied consent, Verbal consent, Written consent, Elements of consent*

Introduction

Informed consent is an important and vital step in any medical and allied health sciences profession. It is a process in which patient participates in a discussion regarding any disease/ ailment of his/ her body is suffering from before any treatment procedure is undertaken. Paul G Gebhard is credited with having introduced the legal term- informed consent in 1957 in a medical practice case in USA.

So how it all began…….

We all learn from the mistakes done in the past and informed consent is an example of such mistakes. It all started during World War II when human subjects were experimented without consent. When voices arose against such experiments various guidelines were set. Nuremburg code, declaration of Geneva and declaration of Helsinki were introduced to stop such inhuman unethical malpractices. Introduction of informed consent also followed the tails of such codes and declarations set for the medical and related profession (Escobedo et al 2011).

Consent is defined as the granting of permission by the patient for another person to perform an act (Taber's Medical Dictionary) or to agree to do or allow something (Merriam Webster Dictionary).

Informed Consent has been defined as to encapsulate a doctor's moral duty to provide sufficient information for a patient to an informed & 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 (Boyd et al 1997).

Patient's informed consent is a legal regulation and a moral principle. It represents patients' rights to take part in clinical decisions concerning their owntreatment. In a professionally responsible manner, dentists must assist consider informed consent in their treatment protocol.

Classification (Mirza, 2012; Sharma et al 2011)

1. Implied consent
2. Expressed consent
   i) Verbal consent
   ii)Written consent

Implied consent

When patient arrives in a dental office, the patient himself comes and opens his/her mouth for examination and showing his/her willingness to be examined. It needs not to be documented in clinical record. Principles of good communication apply in these circumstances and are assumed by patient's attitude.

Verbal consent

Oral consent would normally be adequate for routine treatments, such as restorations and prophylaxis, provided that full records are maintained.

Written consent

It is necessary in case of extreme intervention extensive intervention and essential where a general anesthetic or conscious sedation is given (BDA 2009).

Process of Obtaining Informed Consent (WHO)

1. Obtaining genuine informed consent from research participants is best thought of as a process of sharing information and addressing questions and concerns, rather than simply obtaining a signature on a prescribed form.
2. It starts with the researcher developing an awareness of national or regional guidelines, and may involve discussions with, and the involvement of, the community and/or discussions with the family members of potential participants. Participants must then give their individual consent to participate on an informed consent form (ICF) developed specifically for the research project.
3. There are very few research situations which do not require the participant's signature on an informed consent form. Permission from an ethics review committee is always necessary for waiving off this requirement.
4. Researchers should follow an appropriate and culturally-sensitive process of information sharing leading up to, and including, obtaining the participant's signature on the informed consent form.
5. This process may continue even after the signature is obtained as it is often appropriate for researchers to check back with participants throughout the research to ensure continued consent or because a new consent is required for an additional or changed intervention.
6. This document provides information which may be helpful to researchers as they consider the informed consent process for their research.

Elements

There are three essential elements to valid consent (Faden, 1986).

- Competence: the patient has sufficient ability to understand the nature of the treatment and the consequences of receiving or declining that treatment.
- Voluntariness: the patient has fully agreed to have the treatment and there has been no coercion or undue influence to accept or decline the treatment.
- Information and knowledge: sufficient comprehensible information is disclosed to the patient regarding the nature and consequences of the proposed and alternative treatments.

All these three elements are interdependent but must be present for consent to be ethically and legally valid.

Components of Informed Consent (ICMR 2006)

1. Nature and purpose of study stating it as research
2. Duration of participation with number of participants
3. Procedures to be followed
4. Investigations, if any, to be performed
5. Foreseeable risks and discomforts adequately described and whether project involves more than minimal risk
6. Benefits to participant, community or medical profession as may be applicable
7. Policy on compensation
8. Availability of medical treatment for such injuries or risk management
9. Alternative treatments if available
10. Steps taken for ensuring confidentiality
11. No loss of benefits on withdrawal
12. Benefit sharing in the event of commercialization
13. Contact details of PI or local PI/Co-PI in multi-centric studies for asking more Information related to the research or in case of injury
14. Contact details of Chairman of the IEC for appeal against violation of rights
15. Voluntary participation
16. If test for genetics and HIV is to be done, counseling for consent for testingmust be given as per national guidelines
17. Storage period of biological sample and related data with choice offered to participant regarding future use of sample, refusal for storage and receipt of itsresults

A copy of the participant/patient information sheet should be given to the participantfor her/ his record. The informed consent should be brief in content highlightingthat it is given of free will or voluntarily after understanding the implications ofrisks and benefits and s/he could withdraw without loss of routine care benefits.Assurance is given that confidentiality would be maintained and all theinvestigations/ interventions would be carried out only after consent is obtained.

When the Patient Disagrees:

- When a Patients arrive in pain he just want pain to be subsided no matter what the consequences are. It is best to alleviate the pain first with LA. In the eyes of the law, a person cannot consent to anything if his / her judgment is impaired in any way - often meant to include drugs and alcohol, yet pain should also be included in this category (Mirza 2012).
- A subset of informed consent known as informed refusal should be obtained when the patient does not wish to undergo treatment recommended by the dentist. Itprotects the dentist by documenting it. (Shridhar 2012)

Waiver of Informed Consent (Bruscino 2012)

1. Patient at times may not wish to hear about the risks and may waive the right to be informed. The responsibility of deciding the treatment plan rests ondentist who may decide based on its best judgment.
2. Therapeutic privilege is a circumstance in which dentist decides not to inform patient if patient harm would be serious by disclosure than non-disclosure.
3. In Emergency situations when the patient is unable to provide consent. Dentist could proceed with treatment, but preferably obtain consent from a professional colleague.

Applications of informed Consent (Indian Penal Code, 1860, Act no. 45 of 1860)
It is important to know about the law in our country so I have mentioned the penal codes which are important to us as a dentist.

Section 87 IPC states that nothing which is not intended to cause death, or grievous hurt, and which is not known by the doer to be likely to cause death or grievous hurt, is an offence.

Section 88 IPC states that nothing, which is not intended to cause death, is an offence.

Section 89 IPC states that nothing which is done in good faith for the benefit of a person under twelve years of age, or of unsound mind, by or by consent, either express or implied, of the guardian or other person having lawful charge of that person, is an offence.

Section 90 IPC states that consent is not such consent as is intended by any section of this Code, if the consent is given by a person under fear of injury, or under a misconception of fact.

Section 91 IPC states that Exclusion of acts which are offences independently of harm cause. Exceptions in sections 87, 88 and 89 do not extend to acts which are offences independently of any harm which they may cause, or be intended to cause, or be known to be likely to cause, to the person giving the consent, or on whose behalf the consent is given.

Section 92 IPC states that if the circumstances are such that it is impossible for that person to signify consent or if that person is incapable of giving consent, and has no guardian or other person in lawful charge of him from whom it is possible to obtain consent in time for the thing to be done with benefit:

Section 93 IPC states that no communication made in good faith is an offence by reason of any harm to the person to whom it is made, if it is made for the benefit of that person.

The informed consent documents needs to be preserved for an appropriate time for medico-legal purposes. The time frame for preserving such records depends on the regulations prescribed by the governing authority. As per DCI regulations, dentists shall maintain patient records as well as a register of certificates, money receipts and official notifications issued by them for a period of at least 3 years. A sample copy of the informed consent document is available as an appendix in drafts ethics regulations 2003 for the benefit of practicing dentists (Draft Dentists (Code of Ethics) Regulations, 2003).

Conclusion

It is important for a doctor/ dentist to discuss with the patient the existing condition and various treatment options available as it is the patient's mouth and not our property. In case of a competent patient who can voluntarily participate in the discussion and is able to make judgment of his own, consent is taken by the patient. According to law, Children below 18 years of age or insane / elderly

patient who cannot sign the consent,the duty goes to parents/ lawful charge of that patient. Thus *'informed consent is a continous educational process rather than a single step process.'*

References

BDA (2009) British Dental Association Advice Sheet - Ethics in Dentistry, B 1; Available from http:www. dentiststudybuddy.org.uk/wp.../ethics-in-dentistry-advisory-sheet.pdf

Boyd, K.M., Higg, R., Pinching, A.J. (Eds) (1997) The New Dictionary of Medical E, BMJ Books, London

Bruscino, T. (2012) Basic Ethics in Dentistry, Dental Learning & OSHA Training. Available from www.dentallearning.org/course/Ethics/Ethics.pdf

Draft Dentists (Code of Ethics) Regulations, 2003: 1-10. Available from: http://www.wbdc.org.in [Last accessed on 2014 March].

Escobedo. C, Guerrero. J, Lujan G, Ramirez A, Serrano D. Ethical Issues with Informed Consent. (Last accessed on 2011 Apr 29). Available from: http://www.cstep.cs.utep.edu/research/ezine/EzineEthicalIssueswithInformedConsent.pdf

Faden, R.R. (1986) in: A History and Theory of Informed Consent. Oxford University Press, USA

ICMR (2006) Ethical Guidelines for Biomedical Research on Human Participants. Pub: ICMR, New Delhi

Indian Penal Code. Ch.IV. General Exceptions. The Indian Penal Code, 1860. Act no. 45 of 1860.

Mirza, A.M. (2012) Importance of informed consent in dentistry. International Dental Journal of Student's Research, 1(2):13-16.

Sharma, A., Chhabra, A., Sharma, A., Bopiah, C. (2011) Patient Consent in Dentistry: Are we Legally Safe? Jour Oral Health Comm Dent 5(2): 68-72.

Shridhar, G. (2012) Informed consent in clinical dentistry and biomedical research. Journal of education and ethics in dentistry. 2(2):65-68.

WHO, Research Ethics Review Committee, The Process of Obtaining Informed Consent; Available from www.who.int/rpc/research_ethics/Process_seeking_IF_printing.pdf