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A SCOPING REVIEW ON ENACTMENT OF CONSENT IN HEALTH CARE

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Abstract

Introduction: In medical practice, consent is a legal requirement, not a procedural formality. Only signature on a form by patient is not consent. Without giving adequate information, if consent is signed by patient, consent may be invalid despite of signature. **Aim:** The aim of this study is to highlight the essential principles of consent so that health care professionals are not only able to safeguard themselves against litigations but can act rightfully. **Materials & Methods:** A search was obtained using three databases like Pub-med, Scopus and Google Scholar published from 2010-2023. The key-words for the survey were Consent, Informed, Healthcare, and Medical. After the relevant articles were found, the critical appraisal was made to select those that were suitable for the systematic review. Inclusion criteria of the study were surveys, clinical studies, no sample size restrictions and only English papers. Exclusion criteria were conference abstracts, case reports, and unpublished data**. Results:** On the basis of keywords, 21 relevant articles were found and of those 16 articles were selected for the systematic review. **Conclusion:** This study evaluated that any form of communication related to medical or dental should be documented.

Keywords: Consent, Informed, Healthcare, and Medical.

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INTRODUCTION

For new drugs and medical treatments to reach the market and be used, they must be first tested for their safety and efficacy on a number of human volunteers in clinical trials. To perform the trials, the participating doctors and researchers must thoroughly explain to the volunteers the purpose and risk of the trial and receive agreement from the volunteers. This agreement between the researcher and volunteers is commonly known as "consent" and is used extensively in medical practices. Because it is now standard, it is easy to forget that consent is only a recent invention that comes from an ugly history of human experimentation that has been done in the past years.[1]

The term "consent" is considered to have first appeared in 1957 in a malpractice suit in the U.S. (Salgo decision). However, it was World War II and the human experimentation done by Nazi Germany doctors that pushed forward the idea of informed consent. Along with judging war criminals, the Nuremberg trials declared 10 ethical principles (the Nuremberg Code), with consent listed first. The Nuremberg Code is the foundation of research and medical ethics and impacts all international ethical guidelines including the Declaration of Helsinki.[2]

Medical discoveries and medical practices are often the result of overcoming great challenges. Consent is continuously being developed to support these advances while protecting the patient. Consent is one example of the importance of bioethics. While research must benefit society, it must do so in an ethical way. Consent in simple terms is when everyone involved agrees to do something and is okay with it. It's like saying yes to doing something.[3]

Consent codes and laws protect both – care givers and care receivers. They help establish trust in care giver while respecting autonomy as a care seeker. In recent practice, medical professionals are more oriented towards diagnosis and treatment because of lack of time and more competition. Most of the medical professionals fail to remember to take consent. Therefore, the prime aim of this study is to understand the enactment of consent in healthcare.

WHAT IS A CONSENT FORM IN HEALTH CARE?

Consent form is a communication between a patient and a health care provider that often leads to agreement or permission for care, treatment, or services. Every patient has the right to get information and ask questions before procedures and treatments. If adult patients are mentally able to make their own decisions, medical care cannot begin unless they give consent.[4]

MATERIALS & METHODS

A literature search has been selected by 2 review authors independently in 3 different databases like Pub-Med, Scopus, Google Scholars for articles published from 2010-2023. At first, 2 different authors independently analyzed the selected articles according to titles and abstracts, which were related to the study. To avoid missing of any related articles during the initial research, authors have analyzed the references of the selected study. Removal of duplicate and cross-referenced study was done. Records were screened according to inclusion and exclusion criteria. Full-text studies were assessed for

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eligibility and qualitative synthesis was carried out. The keywords for the survey were Consent, Informed, Healthcare, and Medical. After the relevant articles were found, the critical appraisal was made to select those that were suitable for the systematic review. The inclusion criteria of the study were surveys, clinical studies, no sample size restrictions, and only English language papers. Any conference abstracts, case reports and unpublished data were excluded from the study.

RESULTS

Of 37 articles, 21 abstracts were recruited. These 37 articles were found through the databases. Finally, 16 studies were selected for the review. 05 articles were rejected as they included case reports, pilot studies and incomplete data. All the published articles were written in English. From a total of 21 papers from different databases, 16 papers fulfilled the inclusion criteria. Authors did not find any papers by hand searching. Very few studies were carried out for the implication of consent in healthcare. Also, limited articles were available on the utilization of consent in healthcare.

SIGNING INFORMED CONSENT MEANS

-They have received all the information about treatment options from their health care provider.
-They understand the information and they have had a chance to ask questions.
-They utilize this information to decide if they want to receive the recommended treatment option(s) that have been explained to them. Sometimes, they may choose to receive only part of the recommended care.
-If they agree to receive all or some of the treatment options, they give their consent (agree) by signing a consent form. The completed and signed form is a legal document that lets their doctor go ahead with the treatment plan.[5]

WHO CAN GIVE CONSENT

-Consent can be given by any person who is conscious mentally well and is of and above 12 years of age as provided under section 88 and 90of the Indian Penal Code[IPC]1860.
-Under section 11, only those who are of and above 18 years of age are competent to enter into a contract
-As Doctor - Patient relationship is same as entering into a contract, it is advisable that consent should be obtained, specially written consent, from parents/ guardian of a patient who is below 18 years so that validity of the contract is not challengeable.[6]

WHEN CONSENT IS NOT VALID

When Consent is given by the patient under any kind of fear, fraud or misrepresentation of facts, or by a person who is ignorant of the implications of the consent, or who is under 12 years of age is invalid [section 90,IPC].

SITUATIONS WHERE CONSENT MAY NOT BE OBTAINED[5]

-Medical emergencies- The well being of the patient is paramount and medical rather than legal
-In case of a person where the court may order for psychiatric examination.

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-Under section 53, a person can be examined at the request of the police, by use of force.
-Patient is incapacitated
- Inadequate time to obtain consent
- Voluntary waived consent

DISCUSSION

It is very important to maintain good communication and provide adequate information to enable patient to make a rational decision. Always take consent in patient's vernacular language. It is always better to make patient write his consent in the presence of witness. Patient information sheets depicting procedure related information including pre-operative and post-operative precautions in patient's understandable local language with pictorial presentation may facilitate the content process. Health care professionals should be aware of following principles before taking consent.

PRINCIPLES OF CONSENT IN HEALTH CARE

1.An informed consent must be obtained by the practitioner before commencing a procedure.
2.Consent should be taken from the competent patient himself.
3.Consent should be free and voluntary.[7,8]
4.Patient must have the choice to withdraw his consent anytime.
5.No consent should be taken by the practitioner for an illegal procedure or any malpractice .
6.Consent should be elaborated or documented in the most appropriate way possible.
7.Consent can be taken in the presence of a witness if the patient is illiterate.
8.Consent must be signed by patient and the doctor both.
9.In surgical cases an informed consent for anaesthesia must be taken by the anaesthesiologist along with surgeon.
10.Consent must be taken before commencing a surgery, must not be during the course of surgery.
11.For every repeat procedure/treatment a fresh consent must be taken from the patient.
12. Blanket consent is invalid.

"Blanket consent- is a broad based general consent which recites that physician and his designees may do what they think is essential."

13. Procedure specific consent is valid, unlike BLANKET consent.[9,10]
14.Before any blood transfusion a specific informed consent from the patient must be obtained.
15.Consent should be written and explained to patient in the most elaborative way possible including risk, benefits, prognosis, available alternatives, risk of refusing treatment and treatment cost.[1]

[1,12]

Following Data can be included in Consent Form:

- Date and time
- Patient related: Name, age and signature of the patient/proxy decision maker
- Doctor related: Name, registration number and signature of the doctor
- Witness: Name and signature of witness
- Disease-related: Diagnosis along with co-morbidities if any

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CONTENTS OF THE CONSENT

The patients should be informed about of all the following before the documentation of the consent :-

A) Description of the proposed treatment .

The patients must be aware of the treatment procedure they are about to undergo.

B) Materials or foreseeable risks.

The materials to be used during the treatment should be told about to the patients beforehand to avoid any foreseeable risks.

C) Benefits and prognosis of the proposed treatment.

Patients have their right to know about the perks/plus points of the treatment aided with the prognosis of the same .

D) Alternatives to proposed treatment.

Any other possible substitute / option of the proposed treatment must be explained to the patient beforehand.

E) Risks, benefits and prognosis of the alternative treatment.

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The alternative treatment should be elaborated likewise the proposed treatment.[13]

TYPES OF CONSENT [14,15]

1) INFORMED CONSENT

" To be informed, consent must be given by persons who are competent to consent, have consented voluntarily, are fully informed about the research."

- Unless they are emancipated minors, individuals under 18 may never give consent.
- If the person is not legally competent to give consent, a parent or legal guardian has to give it.

2) IMPLIED CONSENT

In some medical situations, consent between the patient and the attending physician or other medical professional is implied. Implied consent depends on the facts and circumstances of the situation. While express consent is usually given on paper, and sometimes verbally, implied consent is generally provided through actions.

For instance, when you show up to doctor's office for any seasonal flu shot and roll up your sleeve, you are essentially implying that you consent to receive a flu vaccination. The same applies if you go to a lab to have your blood drawn or if you showed up for a routine physical exam. By showing up for the exam, you are essentially consenting to the exam.

Implied consent can also play a role in medical emergencies. For instance, if a person has been in an accident and is unconscious or otherwise unable to communicate, then medical personnel will assume that the victim would want them to render aid if they were conscious or could communicate. If a doctor needs to perform life-saving surgery on the unconscious victim of a car accident, for instance, consent is implied.

3) EXPLICIT CONSENT/EXPRESSED CONSENT

Participant give consent by answering a specific questions about their willingness to participate. This may be done in written (consent form) or oral form.

- **Written**

Participant give their consent by filling out consent form.
Written consent guarantees active and explicit consent, thus offering highest guarantees to the participant.
It is most appropriate and is useful for studies that contains some level of risk.

- **Oral**

Oral consent should be considered when obtaining explicit, active consent is essential but the risk or discomfort involved in this process is too big to make written consent a valid option.
Verbal consent may be obtained for relatively minor examinations or procedures, in the presence of a witness.

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Oral consent is valid option for participants that are uncomfortable reading and writing and may be too embarrassed by written consent process to participate in research.

4) PROXY CONSENT

Proxy consent occurs when an individual is provided with legal right to make decisions on behalf of another who is unable to do so for himself/herself.

5) **BLANKET CONSENT**

Incomplete, vague consent without any proper information, risks and nature of treatment.
It is a broad based general consent to do whatever is necessary.
In research, Blanket consent refers to a process by which individuals donate their samples without any restrictions. Therefore it allows multiple usage of the samples in the future, leads to the development of new diagnostics and therapy. It is advantageous for the researchers, as the cost and time-consuming procedures are avoided.

CONSENT AND CONFIDENTIALITY[16]

- *In common law*, confidentiality should be essentially maintained which means that when a person shares any information in confidence, it should never be disclosed until and unless there is some form of legal authority or justification.
- *In practice,* this means that the information cannot be disclosed without that person's consent.

Principle of confidentiality

Confidentiality refers to the duty to protect privileged information and to share entrusted information responsibility.

Example of Confidentiality

Persons phone number and address, medical records etc.

Ways to maintain Confidentiality

- Control access
- use confidential waste bins
- Lockable document storage cabinets
- secure delivery of confidential documents
- Employee training

CONCLUSION

It is not only ethical to impart correct and important information to a patient prior to conducting any medical or dental procedure, but is also paramount legally. Any form of communication related to

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medical or dental should be documented.

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