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Original Research Article

Critical Analysis of Errors in Informed Consent Form – A Retrospective Study

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Abstract: Informed consent is a process for getting permission before conducting a healthcare intervention on a person, for conducting some form of research on a person, or for disclosing a person's information. The detailed analysis of the informed consent form yields following results. Out of a total of 50 form analysed, only 15(30%) were found to be completely filled and correct. A Total of 10(20%) certificates contained major errors and 25(50%) contained minor errors. 30(60%) forms contained both major and minor errors.

Keywords: Informed Consent, Major Error, Minor Error.

INTRODUCTION

Informed consent is a process for getting permission before conducting a healthcare intervention on a person, for conducting some form of research on a person, or for disclosing a person's information. A health care provider may ask a patient to consent to receive therapy before providing it, a clinical researcher may ask a research participant before enrolling that person into a clinical trial, and a researcher may ask a research participant before starting some form of controlled experiment. Informed consent is collected according to guidelines from the fields of medical ethics and research ethics.

Free consent is a cognate term enshrined in the International Covenant on Civil and Political Rights. The Covenant was adopted in 1966 by the United Nations, and supposed to be in force by 23 March 1976. Article seven prohibits experiments conducted without the "free consent to medical or scientific experimentation" of the subject [1]. As of September 2019, the Covenant has 173 parties and six more signatories without ratification [2].

An informed consent can be said to have been given based upon a clear appreciation and understanding of the facts, implications, and consequences of an action. To give informed consent, the individual concerned must have adequate reasoning faculties and be in possession of all relevant facts. Impairments to reasoning and judgment that may prevent informed consent include basic intellectual or emotional immaturity, high levels of stress such as posttraumatic stress disorder (PTSD) or a severe intellectual disability, severe mental disorder, intoxication, severe sleep deprivation, Alzheimer's disease, or being in a coma.

Obtaining informed consent is not always required. If an individual is considered unable to give informed consent, another person is generally authorized to give consent on his behalf, e.g., parents or legal guardians of a child (though in this circumstance the child may be required to provide informed assent) and conservators for the mentally disordered, or consent can be assumed through the doctrine of implied consent, e.g., when an unconscious person will die without immediate medical treatment.

In cases where an individual is provided insufficient information to form a reasoned decision, serious ethical issues arise. Such cases in a clinical trial in medical research are anticipated and prevented by an ethics committee or Institutional Review Board.

OBJECTIVE

The aim of the project is to be aware of the extent of errors occurring while filling up informed consent form.

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MATERIALS AND METHODS

A Retrospective, cross sectional study was undertaken at tertiary care hospital in Karnataka, using 50 informed consent forms between January 2021 and june 2021. A copy of these certificates was obtained from the Medical Records department after clearance was obtained from Institutional Ethical Committee and Medical Superintendent of the hospital grants permission. The form were analysed to see if they were filled according to the guidelines or not. Errors are divided into major and minor errors.

Major errors

1. Diagnosis not written
2. Complications not written
3. Alternate treatment not written
4. Patients and witness signature not done

Minor errors

1. Patient ID not written
2. Patient name not written
3. Treating doctor name not written

RESULTS

The detailed analysis of the informed consent form yields following results. Out of a total of 50 form analysed, only 15(30%) were found to be completely filled and correct. A Total of 10(20%) certificates contained major errors and 25(50%) contained minor errors. 30(60%) forms contained both major and minor errors.

DISCUSSION

According to a study by St. John *et al*., in faze one, 99 hand-written consent forms were assessed and the domain failure rates were: patient details 10%; procedure details 30%; and patient sign-off 27%. Laparoscopic cholecystectomy was the most common procedure (7/99) but there was significant variability in the documentation of complications: 12 in total, a median of 6 and a range of 2–9. In phase two, 44% (27/61) of hand-written forms were missing essential complications. There were no domain failures amongst 29 electronically-produced consent forms and no variability in the documentation of potential complications [3].

The doctrine of informed consent relates to professional negligence and establishes a breach of the duty of care owed to them. The doctrine of informed consent also has significant implications for medical trials of medications, devices, or procedures. Until 2015 in the United Kingdom and in countries such as Malaysia and Singapore, informed consent in medical procedures requires proof as to the standard of care to expect as a recognised standard of acceptable professional practice (the Bolam Test), that is, what risks would a medical professional usually disclose in the circumstances Loss of right in English law. Arguably, this is "sufficient consent" rather than "informed consent." The UK has since departed from the Bolam test for judging standards of informed consent, due to the landmark ruling in *Montgomery v Lanarkshire Health Board*. This moves away from the concept of a reasonable physician and instead uses the standard of a reasonable patient, and what risks an individual would attach significance to.

Medicine in the United States, Australia, and Canada also takes this patient-centric approach to "informed consent." Informed consent in these jurisdictions requires healthcare providers to disclose significant risks, as well as risks of particular importance to that patient. This approach combines an objective (a hypothetical reasonable patient) and subjective (this particular patient) approach.

The doctrine of informed consent should be contrasted with the general doctrine of medical consent, which applies to assault or battery. The consent standard here is only that the person understands, in general terms, the nature of and purpose of the intended intervention. As the higher standard of informed consent applies to negligence, not battery, the other elements of negligence must be made out. Significantly, causation must be shown: That had the individual been made aware of the risk he would not have proceeded with the operation (or perhaps with that surgeon).

Optimal establishment of an informed consent requires adaptation to cultural or other individual factors of the patient. For example, people from Mediterranean and Arab appear to rely more on the context of the delivery of the information, with the information being carried more by who is saying it and where, when, and how it is being said, rather than *what* is said, which is of relatively more importance in typical "Western" countries [4].

The informed consent doctrine is generally implemented through good healthcare practice: pre-operation discussions with patients and the use of medical consent forms in hospitals. However, reliance on a signed form should not undermine the basis of the doctrine in giving the patient an opportunity to weigh and respond to the risk. In one British case, a doctor performing routine surgery on a woman noticed that she had cancerous tissue in her womb. He took the initiative to remove the woman's womb; however, as she had not given informed consent for this operation, the doctor was judged by the General Medical Council to have acted negligently. The council stated that the woman should have been informed of her condition, and allowed to make her own decision.

To document that informed consent has been given for a procedure, healthcare organizations have traditionally used paper-based consent forms on which

the procedure and its risks and benefits are noted, and is signed by both patient and clinician. In a number of healthcare organizations consent forms are scanned and maintained in an electronic document store. The paper consent process has been demonstrated to be associated with significant errors of omission [5, 6] and therefore increasing numbers of organizations, including Imperial College Healthcare NHS Trust, are using digital consent applications where the risk of errors can be minimized, a patient's decision making and comprehension can be supported by additional lay-friendly and accessible information, consent can be completed remotely, and the process can become paperless. One form of digital consent is dynamic consent, which invites participants to provide consent in a granular way, and makes it easier for them to withdraw consent if they wish.

The ability to give informed consent is governed by a general requirement of competency. In common law jurisdictions, adults are presumed competent to consent. This presumption can be rebutted, for instance, in circumstances of mental illness or other incompetence. This may be prescribed in legislation or based on a common-law standard of inability to understand the nature of the procedure. In cases of incompetent adults, a health care proxy makes medical decisions. In the absence of a proxy, the medical practitioner is expected to act in the patient's best interests until a proxy can be found.

By contrast, 'minors' (which may be defined differently in different jurisdictions) are generally presumed incompetent to consent, but depending on their age and other factors may be required to provide informed assent. In some jurisdictions (e.g. much of the U.S.), this is a strict standard. In other jurisdictions (e.g. England, Australia, Canada), this presumption may be rebutted through proof that the minor is 'mature' (the 'Gillick standard'). In cases of incompetent minors, informed consent is usually required from the parent (rather than the 'best interests standard') although a parents patriae order may apply, allowing the court to dispense with parental consent in cases of refusal.

CONCLUSION

Completion of hand-written consent forms suffers from wide variation and is frequently suboptimal. Electronically-produced, procedure-specific consent forms can improve the quality and consistency of consent documentation.

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