

## **Review Article**

### **Informed consent: context in modern clinical practice – Review**

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**Abstract:** Informed consent is a process for getting permission before conducting any research activity, surgery, invasive procedure or any kind of drug management on a person directly or indirectly or with his records under medical clause. 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 work or action. To give informed consent, the individual concerned must have adequate reasoning faculties and be in possession of all relevant facts of that research work. There are three important elements that form valid informed consent viz disclosure, capacity and voluntariness. The patient should be clearly stated regarding its implications, use, advantages and disadvantages, risk – benefits etc. It is prior duty of a physician to maintain patient autonomy and justice. The informed consent can act as protective shield by doctors. The informed consent protects the doctors from false and misleading allegations. There are few exceptions to informed consent viz. minor patients, unconscious or mentally disturbed patients etc. The objectives of writing this review are highlighting the importance of informed consent and its ethical values in clinical practice. With this background, present review explains informed consent outline elements and significance in modern clinical practice.

**Keywords:** Informed consent, clinical practice, autonomy.

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#### **Introduction:**

Informed consent is a process for getting permission before conducting any research activity, surgery, invasive procedure or any kind of drug management on a person directly or indirectly or with his records under medical clause [1]. 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 work or action. To give informed consent, the individual concerned must have adequate reasoning faculties and be in possession of all relevant facts of that research work [2]. The objectives of writing this review are highlighting the importance of informed consent and its ethical values in clinical practice. In Indian scenario, various judgments issued by Indian courts underlined the need and must know issue concern with informed consent [3].

Factors that prevents informed consent being basic intellectual or emotional immaturity, high levels of stress such as PTSD or a severe intellectual disability, severe mental illness, intoxication, severe sleep deprivation, Alzheimer's disease, or being in a coma The objectives of writing this review are

highlighting the importance of informed consent and its ethical values in clinical practice which leads to impairments to reasoning and judgment [4]. Whenever such situations are faced by principle investigator, the authorizing person can sign such consent in situations beneficiary to that patient. Example for any trial if there is requirement of children below 2-3 years, that time his parents can be acts as there as authority signatory. But situation or emergency need is quite important at that time [5]. The principles of bioethics are very important in such situations. Such situations should be handled with view of independent human being rather than only patient. Another very important issue of adequate information. The patient or an individual should provide sufficient and clear information. The serious ethical may arises in such situations when insufficient information is provided to form a reasoned decision. For practical use various forms or templates necessary for informed consent are available on WHO website [6].

#### **Why informed consent is needed?**

**Protection of doctor:** Informed consent plays an important and valid signatory document in any legal allegations obtained by patients.

1. **Patient autonomy:** Informed consent not only protects doctors but is an important document protecting patient autonomy. It is obligatory duty of every doctor to explain all possibilities to patient before preceding any procedure.
2. **Trust:** Trust is major linkage between doctor-patient relationships.
3. **Personal integrity**
4. **Prevention of abusive conduct**
5. **Non-dominance approach**

#### Consent assessment:

Informed consent can be complex to evaluate, because neither expressions of consent, nor expressions of understanding of implications, necessarily mean that full adult consent was not in fact given, nor that full comprehension of relevant issues is internally digested. Consent may be implied within the usual subtleties of human communication, rather than explicitly negotiated verbally or in writing. In some cases, consent cannot legally be possible, even if the person protests he does indeed understand and wish. There are also structured instruments for evaluating capacity to give informed consent, although no ideal instrument presently exists [7, 8].

Thus, there is always a degree to which informed consent must be assumed or inferred based upon observation, or knowledge, or legal reliance. This especially is the case in sexual or relational issues. In medical or formal circumstances, explicit agreement by means of signature—normally relied on legally—regardless of actual consent, is the norm. This is the case with certain procedures, such as a "do not resuscitate" directive that a patient signed prior to their illness [8].

Brief examples of each of the above:

1. A person may be verbally agreed to something from fear, perceived social pressure, or psychological difficulty in asserting true feelings. The person requesting the action may honestly be unaware of this and believe the consent is genuine, and rely on it. Consent is expressed, but not internally given [9].
2. A person may be claim to understand the implications of some action, as part of consent, but in fact has failed to appreciate the possible consequences fully and may later deny the validity of the consent for this reason. Understanding needed for informed consent is present but is, in fact (through ignorance), not present [9].
3. A person signs a legal release form for a medical procedure, and later feels he did not really consent. Unless he can show actual misinformation, the release is usually persuasive or conclusive in law, in that the

clinician may rely legally upon it for consent. In formal circumstances, a written consent usually legally overrides later denial of informed consent [9].

#### Valid informed consent elements:

- There are three important elements that form valid informed consent viz disclosure, capacity and voluntariness [10].
- While Disclosure requires the researcher to supply the subject with the information necessary to make an autonomous decision, the investigators must ensure that subjects have adequate comprehension of the information provided. This latter requirement implies that the consent form be written in lay language suited for the comprehension skills of subject population, as well as assessing the level of understanding during the meeting [11].
- Capacity pertains to the ability of the subject to both understand the information provided and form a reasonable judgment based on the potential consequences of his/her decision.
- Voluntariness refers to the subject's right to freely exercise his/her decision making without being subjected to external pressure such as coercion, manipulation, or undue influence.

#### Waiver of the requirements:

Waiver of the consent requirement may be applied in certain situations where no foreseeable harm is expected to result from the study or when permitted by law, federal regulations, or if an ethical review committee has approved the non-disclosure of certain information [12].

Following are the three important circumstances:

1. Directly benefit subjects.
2. Advance the development of a medical product necessary to the military.
3. Be carried out under all laws and regulations (i.e., Emergency Research Consent Waiver) including those pertinent to the FDA

While informed consent is a basic right and should be carried out effectively, if a patient is incapacitated due to injury or illness, it is still important that patients benefit from emergency experimentation. The Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS) joined together to create federal guidelines [13].

#### Informed consent: Review

"Informed consent" is nothing but technical term first used in a medical malpractice United States court case in 1957 [14]. In tracing its history, some scholars have suggested tracing the history of checking for any of these practices:

1. a patient agrees to a health intervention based on an understanding of it
2. the patient has multiple choices and is not compelled to choose a particular one
3. The consent includes giving permission [15].

These practices are part of what constitutes informed consent, and their history is the history of informed consent. They combine to form the modern concept of informed consent—which rose in response to particular incidents in modern research. Whereas various cultures in various places practiced informed consent, the modern concept of informed consent was developed by people who drew influence from Western tradition [16].

Historians cite a series of medical guidelines to trace the history of informed consent in medical practice [17]. The Hippocratic Oath, a 500 BC Greek text, was the first set of Western writings giving guidelines for the conduct of medical professionals [18]. It advises that physicians conceal most information from patients to give the patients the best care. The rationale is a beneficence model for care—the doctor knows better than the patient, and therefore should direct the patient's care, because the patient is not likely to have better ideas than the doctor.

Historians cite a series of Human subject research experiments to trace the history of informed consent in research.

Medicine in the United States, Australia, and Canada take a more patient-centric approach to "informed consent." [19].

#### **Obtaining informed consent:**

To capture and manage informed consents, hospital management systems typically use paper-based consent forms which are scanned and stored in a document handling system after obtaining the necessary signatures. Hospital data base system and research organizations are adopting an electronic way of capturing informed consents to enable indexing, for better comprehension, search and retrieval of consent data, thus enhancing the ability to honor to patient intent and identify willing research participants. More recently, Health Sciences South Carolina, a statewide research collaborative focused on transforming healthcare quality, health information systems and patient outcomes developed an open-source system called Research Permissions Management System (RPMS). RPM has been released as an open-source application [20].

#### **Patient competency:**

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 [21].

#### **Deception**

Research involving in process of deception is controversial given the requirement for informed consent. Deception mainly arises in social psychology, when researching a particular psychological process requires that investigators deceive subjects. For example, in the Milgram experiment, researchers wanted to determine the willingness of participants to obey authority figures despite their personal conscientious objections [22].

They had sole authority figures demand that participants deliver what they thought was an electric shock to another researcher. For the study to succeed, it was necessary to deceive the participants so they believed that the subject was a peer and that their electric shocks caused the peer actual pain [23].

Nonetheless, research involving deception prevents the subject/patient from exercising his/her basic right of autonomous informed decision-making and conflicts with the ethical principle of Respect for persons [24].

The Ethical Principles of Psychologists and Code of Conduct set by the American Psychological Association says that psychologists may not conduct research that includes a deceptive compartment unless they can justify the act by the value and importance of the study's results, and show they couldn't obtain the results by some other way [25]. Moreover, the research should bear no potential harm to the subject as an outcome of deception, be it physical pain or emotional distress. Finally, the code requires a debriefing session, in which the experimenter tells the subject about the deception, and gives subjects the option of withdrawing their data.

#### **Abortion**

In some of the U.S. States, informed consent laws require that a woman seeking an elective abortion receive factual information from the abortion provider about her legal rights, alternatives to abortion (such as adoption), available public and private assistance, and "medical facts" (some of which are disputed—see fetal), before the abortion is performed [26]. Other countries with such laws (e.g. Germany)

require that the information giver be properly certified to make sure that no abortion is carried out for the financial gain of the abortion provider and to ensure that the decision to have an abortion is not swayed by any form of incentive [27].

#### Informed consent and ethics:

It is our moral responsibility always obtains proper informed consent before every act observed with our patient. It is included from simple examination especially of female patients, any medical investigations, any operative either major or minor etc. [28]. The patient should be clearly stated regarding its implications, use, advantages and disadvantages, risk – benefits etc. It is prior duty of physician to maintain patient autonomy and justice towards patients. Risk benefit ratio should be always calculated by doctor on the basis of ethical principles [29, 30, 31]. Patient voluntariness is one of the most important issues which obeys or signifies patient autonomy. Modern healthcare system and technology applications integration can be useful [32, 33, 34].

#### Conclusion:

The informed consent can act as protective shield by doctors. The informed consent protects the doctors from false and misleading allegations. There are few exceptions to informed consent viz. minor patients, unconscious or mentally disturbed patients etc.

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