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Title: **Informed consent process: a challenging issue of health research in India**

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**ABSTRACT:**

Informed consent, a prerequisite for enrolling participants in biomedical research, is becoming a challenge for the researchers in India. The aim of this study was to explore the perception of researchers on challenges of informed consent process.

The study was designed as qualitative type, through semi-structured interviews. Interview guide was prepared to explore researchers’ experiences in informed consent process, behavior and interactions of the patients participating in research studies. The data were analyzed using thematic framework approach.

The challenges perceived by the researchers in informed consent process were multifaceted. In regulated clinical trials, they were related to time and duration of the whole process, especially in audiovisual recording of consent process, legalized in India. Patients’ comprehension on risk and benefit in drug trial was found to be another challenging issue. In questionnaire based studies, issues like decision making, expectations, certain cultural norms were playing significant role resulting in increase in refusals for participation. It was also revealed that there was failure in conveying adequate information by the researchers to patients on the study to be carried out because of apprehension of the researchers towards changing decision or refusal to consent by the participants in the study.

The issue of informed consent in research done in India is a challenge due to various complexities of culture, level of education and demographics resulting in increased nonparticipation or refusal to give consent. The guidelines, prepared in line with western culture, need to be relooked in light of the complexities and sociocultural diversities in India.

**INTRODUCTION:**

According to ICH-GCP (1), informed consent is a prerequisite for enrolling participants in all types of biomedical research including; diagnostic, therapeutic, interventional, bioequivalence, social and behavioral studies and for all research conducted domestically or abroad. Obtaining consent involves informing the participants about his or her rights, the purpose of the study, the procedures to be undergone, the potential risks and/or benefits of participation and alternative treatments available if any. In any study, participants must participate willingly only after consenting based on the information provided (2, 3). It has been mentioned by Nijhawan et al (4) that the investigator must explain comprehensively and completely the risks involved in participating in the research study and allow them to discuss with other family and community members to get informed consent from these participants. But, getting a meaningful and ethical informed consent is becoming a challenge for the researchers due to differences in cultural values and local customs in developing countries (5, 6). The focus now, however, is on “negligence and the failure” on the part of researchers “to adequately inform patients of the nature and possible consequences of the procedure that is to be carried out” (7).

Compared to western countries, the ethical principles for primary decision making for participation may not be applicable in Indian system, being culturally and socially different. As a result, certain limitations are creeping in the research process either in restricting sample size or delay in the study which are alarming signals.

It is generally understood that, informed consent rests on the “principle of autonomy, or the right to self-determination” (7). For a research involving human participants, it is mandatory that the information given to a participant must be sufficient to satisfy a fully informed reasonable participant so that he/she can decide whether or not to take part in the research study. Presently informed consent is perceived to be an imperfect tool of protection both by the researchers and the participants leading to more of refusal to consent. Therefore there is a need to explore the actual scenario and the underlying cause.

**AIM:**

This paper attempts to explore the perception of researchers in relation to barriers on informed consent process with reasoning.

**METHODOLOGY:**

The study was comprised of semi-structured interviews of four groups of researchers who were involved in various types of research study namely (1) regulated and (2) non-regulated clinical trials, (3) funded ( but not trial related) and (4) non-funded research projects. As this was a qualitative study, 2 to 3 researchers involved in each type of researches were interviewed. So there were 9 interviews of the Researchers. An interview guide was prepared to explore and understand researchers’ experiences towards informed consent process, behaviour and interactions of the patients/participants participating in research studies contributing to challenges in the research process. Interviews lasted between 30-45 minutes. The topic guide included the following issues to elicit participant’s view and experience on (i) the process (ii) time span, (iii) barriers and influences and (iii) any suggestion on improvement.

The data were analyzed using thematic framework approach (8).

**OBSERVATION :**

**Description of own experience of ICP**

The first step was to explore and then to interpret the experience of Informed consent process of the Investigators (mostly Doctors) involved in various research projects. The issues taken into consideration as per interview guide were comprehension, time dedicated and other issues involved in limiting the consent process. Analysis of perception of the Investigators was done by thematic analysis of semi structured interview and the findings are presented according to analytical typology (9). Results of analysis of perception of Investigators are in the form of narratives and thereby interpretations shown in table 1, 2 and 3 respectively.

**Table 1: Researchers’ feedback on challenges during informed consent process**

|  |  |  |
| --- | --- | --- |
| **Areas of semi structured interview** | **Topic guide** | **Verbatim** |
| **Description of own experience of ICP**  **Challenges :**  **Time span –**  **Place**  **Patient factor -** | Information communicated to research participants  **Understanding, behavior, cooperation** | “ …..too lengthy”  “…many patients don’t understand the purpose of research and informed consent”  “…. We can’t tell every details related to research to patients, they run away”  “….. AV recording takes a long time…patients refuse for videography”  “…patients don’t give time to listen to the information related to research”  “… Patients in OPD do not take part in questionnaire based research study”  “….we (Clinicians) have no time for taking consent”  “….they feel uncomfortable in OPD setup”  “….no suitable place for talking with the patients on research study”  **(in Patients’ verbatim)**  “….I know nothing, whatever you (Clinician/Researcher) say”  “…. I am confused”  “…..I am not interested”  “…. Can I get free treatment or investigations done?”  “…. What will you (Researcher) give me”  “……why to sign in paper?”  “…..I have to ask my….”  “…..we have come for treatment…, Dr, you decide” |
| **Changing pattern** |  | “……if consent is to be taken ideally, patients don’t agree, recruitment is less,...... otherwise we have to bluff”  “…..we are doing with smaller sample size”  “….Taking consent should not be a priority or mandate by the doctors” |

**Table 2: Interpretation of Researchers' opinion on challenges during informed consent process in medical research**

**Table 3: Interpretation of researchers’ feedback on challenges from patients’ perspective during informed consent process**

**DISCUSSION:**

Health care providers are required by law or institutional policies to obtain informed consent before administering any medical procedures, including experimental methods or procedures.An informed consent in research more importantly in clinical trials, can only be said to have been given once a clear appreciation and understanding of the facts is established, implications and future consequences of an action is understood. In order to give informed consent, the individual, here the research participant, must have adequate reasoning capacity and should understand all relevant facts at the time of giving consent (10). It is generally understood that principle of autonomy addresses the issue of informed consent, i.e. research must respect and protect the rights and dignity of participants.

**Adequate information**: The focus now, however, is on how much informed is the informed consent process, and what is **adequate information**? Kegley (7) explained two standards, generally been applied to follow such process. One is the professional custom standard, according to the British legal system known as the Bolam principle. The question of sufficient information is tested against the current opinions of an informed body of medical practitioners. The second setting is followed in medical research, where informed consent is mandatory before extracting or using an individual’s biological material, be it cells, tissues or organs. This is mentioned earlier in guidelines viz., Nuremberg Code and Belmont Report. The Belmont Report tells us that “respect for persons requires that subjects to the degree they are capable, be given the opportunity to choose what shall or shall not happen to them”. Therefore, by clearly explaining the research procedure to the participant or patient and obtaining their consent, researchers can proceed both ethically and legally. In this context, though the information is imparted in vernacular language, the question always comes to researcher’s mind how and how much to convey. In developed countries, the consent forms are getting more and more lengthy to comply with the regulations to avoid possible litigations. It is being realized in our country that very long forms do not increase understanding but actually increase chances that they would not be read completely. Therefore, a good balance is required where all required information should be put in a concise and simple manner to make it understandable (11).

**Skill:** It is a common problem amongst the researchers in medical research here on the communication skill, precisely how much and how to communicate. In most of the cases these are not followed ideally for couple of reasons. Firstly they are not trained or skilled for this consent process, as a result there remains an incompleteness in conveying pertinent information. Secondly because of the fear of losing participants or drop outs, certain information is not disclosed properly.

**Comprehension:** Bhutta (12) has alluded to the difficulties faced while obtaining informed consent from patients in developing countries. Observations in this study are found to be similar in terms of **comprehension**. The patients or participants in this part of the continent are not keen to know of the extensive information on type of study and other scientific technicalities of the study design though many of them might be aware of the disease they are suffering or of certain situation based on which the research study was planned. They are more interested to know of the disease process, if not of the research process. Ganguly (13) explained some findings related to audiovisual recording of consent process of clinical trials legalized in India like “Certain elements such as uneasiness and nervousness of the patients were very obvious during the process of recording, as detected through their tone and body language. It was noted that the way of posing questions by the investigators and thereby the answers from the patients lacked a normal flow or spontaneity—both investigator and patient appeared very self-conscious on the recording”. So, in such a situation it is not clear how far the patients have understood. Moreover, patients’ comprehension on risk and benefit in drug trial was found to be another challenging issue restricting their participation. Because of fear of unknown side effects or possible risks, patients avoid consenting to drug trials. Add on to this, is the limitation in vernacular translation which often leads to different meanings, wrong interpretations occurring in all types of research studies starting from regulated trials to epidemiological studies.

Some of the participants with higher educational or socioeconomic status refuse to listen patiently and get ready to consent because of their less or no priority. Such refusals are observed more when the post graduate students are involved in consent process than the treating clinicians. It has been understood from the study that illiteracy or lower literacy or lower middle socioeconomic status is not always a barrier to informed consent. On the contrary, better cooperation and more participation in research studies are being found from this stratum. But the main challenge faced from this group is that of decision making process which is often taken by either head of the family of the most literate person in that family or from neighborhood. Here, the individual’s autonomy to give consent is guided by the agreement of household elders, friends, relatives and or even the community. This is more frequent in community oriented studies or epidemiological studies. Thus the consent may not be always given out of free will on individual basis. This actually reflects the cultural perspectives influencing informed consent in medical research. Parker and Barret (14) also mentioned that subtle cultural issues come into play when negotiating consent process. The consequence of such is evident in delaying of the whole process.

**Other factors** which are influencing the consent process include time or duration of the whole process, settings and benefits out of the research. The audiovisual recording of consent process in clinical trial is another challenging issue particularly in relation to time, duration and recording of the whole process. In reality however consents of epidemiological studies or questionnaire based studies are often obtained in crowded OPD amongst other patients or in the community where relatives are watching and listening to the discussion, which can be very distressing to the participant.

In clinical trials, participants are mainly interested to know of the benefits they will be getting out of the research study both therapeutically and financially. Refusal to consent is found maximally in questionnaire based studies because of no direct gain on the part of participants. Another interesting finding from the feedback of the Researchers was that participants from middle or lower middle class often were not willing to sign in the document with a fear of unknown exploitation of the signatures. Consent of children in terms of drop outs or refusal by parents is a significant challenge in recruitment process.

As the ethical principles of western countries require all adults to be the primary decision makers of their participation, this may not be applicable in Indian system, which is culturally and socially different from the western world (4, 15).

**CONCLUSIONS:**

The process of informed consent in India is a challenging issue for the investigators because of a lot of complexities. The regulations of Indian Council of Medical Research are based on the western guidelines. do not necessarily address the requirements of Indian population being culturally and socially different from western world(4). The guidelines, prepared in line with western culture, need to be relooked in light of the complexities and sociocultural diversities in India.

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