

Challenges in Obtaining Informed Consent in Qualitative Research and Suggestions to Improve It- A Descriptive Qualitative Study

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ABSTRACT

Introduction: The dynamic and flexible nature of qualitative studies is expected to impose new challenges upon the researchers in obtaining informed consent. The study objectives were to explore the challenges perceived by the researchers in obtaining informed consent in qualitative research and their suggestions to improve it.

Material and Methods: It was a descriptive qualitative study in which In-depth interviews were conducted among ten qualitative researchers purposively selected from one medical college in Puducherry. Transcripts prepared from the audio recordings were thematically analyzed manually.

Results: The challenges identified were inadequate knowledge of the researcher in designing qualitative consent form, reluctance to sign consent document by participant, ensuring confidentiality and risk benefit communication. The main suggestions provided by the participants were to use of multimedia tools to improve their understanding and creating a rapport to enhance their trust to participate in the study.

Conclusions: Since most of the challenges were related to the reluctance of participants to provide consent due to various reasons and lack of adequate knowledge of the researcher, creating a good rapport with the participants and providing simple information through multimedia approaches and ethical training of qualitative researchers will aid us to overcome majority of these challenges.

Key words: Informed consent, challenges, solutions, qualitative research

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INTRODUCTION

In the current scenario, due to the constant changes in needs of the community and changing trends in knowledge production, the researchers need to adopt a more comprehensive approach for their researches. Hence there is growing interest among the researchers to conduct qualitative studies. Qualitative and quantitative studies have considerable difference in respect to their research questions, methodology, analysis and their interpretations and hence the challenges faced by researchers in conducting these studies are also unique. One such challenge is obtaining informed consent for qualitative studies.¹ Realizing the need and importance of informed consent in qualitative research, recent ICMR Ethical Guidelines on Biomedical Research 2017 has included few points on this aspect.

Informed consent is an ethical and legal requirement for research involving human participants. It is a continuous process involving three main components- Providing relevant information to potential participants, ensuring competence of the individual, ensuring that the information is easily comprehended by the participants and assuring voluntariness of participation. Informed voluntary consent protects the individual's freedom of choice and respect the individual autonomy.²

Though few previous studies have explored the challenges in obtaining informed consent in quantitative research, the dynamic and flexible nature of qualitative studies is expected to impose new challenges upon the researchers in obtaining informed consent.³⁻⁷

Hence the present study is planned with the objectives to explore the challenges perceived by the researchers in obtaining informed consent in qualitative research and their suggestions to improve the informed consent process.

METHODOLOGY

The study was conducted among qualitative researchers in one medical college in Puducherry. This was a descriptive qualitative study in which in-depth interviews (IDI) were conducted.

Sample size and Sampling: Purposive sampling was used to select ten qualitative researchers from a medical college in Puducherry. Those who have undergone training in qualitative research and have published at least one qualitative article in a scientific journal or involved in qualitative data collection.

Data collection procedure: The study was conducted after obtaining clearance from the Research committee and Institutional Ethics Committee of SMVMCH (IEC Approval no:325/2019). After obtaining informed written consent, In-depth interviews were conducted among the qualitative researchers from a tertiary care teaching hospital in Puducherry,

to explore the challenges perceived by them in obtaining informed consent in qualitative research and their suggestions to overcome it. Interviews were conducted by a female faculty trained in qualitative methods at the prefixed date, time, and venue using a semi structured interview guide which consists of broad, open-ended questions. After obtaining informed written informed consent, the interviews were audio-recorded and important points were noted down in the diary.

Data analysis: The transcripts were prepared on the same day as that of data collection and were prepared in verbatim in English. Thematic analysis of the transcripts was done manually by two trained qualitative researchers. Descriptive codes were derived from the transcripts. Similar codes were merged together to form the categories. Later, similar categories were combined to form major themes.

RESULTS

The mean age of the participants was 39.6 + 6.0 (SD) years. Out of total ten participants, six (60%) were females and four (40%) were males. Seven (70%) of them were faculties from pre and para clinical departments and three (30%) belonged to clinical departments.

Totally 17 codes were derived from the ten In-depth interviews which were merged to form 6 categories. These 6 categories were categorized into two themes (Challenges in obtaining informed consent in qualitative research and Suggestions to improve the informed consent process in qualitative research) presented in Table 1.

DISCUSSION

This study was mainly conducted to explore the challenges faced by the researcher during the process of obtaining informed consent for qualitative research and the suggestions given by them to improve the process. The challenges which are related to researcher were inadequate knowledge of the researcher about the informed consent process and designing a qualitative informed consent form and the challenges which were related to the participants were reluctance to sign an informed consent document, providing consent for audio visual recording and obtaining consent from illiterate participants.

The nature of qualitative research itself poses challenges in areas like risk benefit communication, obtaining consent for group techniques, ensuring confidentiality, time consuming nature of the interviews and obtaining re consent. The main suggestions provided by the participants to improve the process was to use advanced technologies, multimedia tools, pictures and illustrations to improve their understanding and creating a rapport to enhance their trust to participate in the study.

Table 1: Challenges in obtaining informed consent in qualitative research & suggestions to improve it

Theme 1: Challenges in obtaining informed consent in qualitative research	Theme 2: Suggestions to improve the informed consent process in qualitative research
<p>Cat 1: Related to researcher</p> <p>Inadequate knowledge of researchers about informed consent process- Many researchers who are involved in the qualitative research don't even have the idea that informed consent and IEC approvals should be obtained for the qualitative research methods also.</p> <p>Difficulty in designing informed consent form for qualitative research- Since many of the questions in qualitative research are unpredictable, it is difficult for the researcher to decide the components that should be added in the informed consent form. Some researchers even had a confusion whether they can use the same consent form which they use for quantitative research for qualitative research also or whether it should be modified.</p>	<p>Cat 4: To improve the knowledge of the researcher on qualitative informed consent</p> <p>*Training programs to sensitize the researchers on qualitative informed consent process</p> <p>*Seeking help of people trained in qualitative research in designing the consent form</p>
<p>Cat 2: Related to participant</p> <p>Reluctance of participants to sign the informed consent document- When dealing with sensitive issues, though some participants accept to participate in the study and provide necessary information, they are very reluctant to sign the informed consent document due to the fear that their identity might be revealed. Apart from this the participants are not confident in signing any document that might have some legal implications.</p> <p>Difficulty in obtaining consent for audio recording- The participants were reluctant to share private information with the process being audio recorded and most of the participants are not comfortable with their conversations being audio recorded. Hence most of the times the participants refuse to give consent for audio recording even in the middle of the interview</p> <p>Difficulty in obtaining informed consent from illiterate participants- Though we explain the contents of the informed consent form in front of a witness, still some participants are unwilling to put their thumb impression in a paper which they cannot read and verify it personally.</p>	<p>Cat 5: Enhancing the understanding of the participant & improve participation</p> <p>*Obtaining verbal consent instead of written consent/obtaining of waiver of consent when dealing with sensitive issues will improve the participation of research participants in qualitative research</p> <p>*Creating a rapport with participants will enhance their trust in the researcher as well as his research, which might increase their chance of providing consent for participation/audio recordings</p> <p>*Use of multimedia tools and technologies to improve the understanding of the participants</p> <p>*Apart from handing over informed consent form, the researcher can explain about the content of the form in simple language to the research participants</p> <p>*Use of pictures/illustrations to make them understand the research process easily. This method will be effective even for illiterate participants.</p>
<p>Cat 3: Related to the process/nature of the research</p> <p>Communication of risk and benefit to potential participants-Due to flexible nature of the qualitative research, it will be difficult to guess the psychological/emotional impact that the research might have on the participants and explain it prior to them while obtaining informed consent.</p> <p>Obtaining informed consent in group approach techniques in qualitative research (FGD, Group interviews)-Many researchers have a confusion while obtaining consent in group techniques about whether to obtain group consent or individual consent, whether the consent can be obtained in a single sheet/ separate sheet for each participant.</p> <p>Ensuring confidentiality/anonymity as promised in informed consent form- Since qualitative studies are usually involved in in-depth exploration of life experiences of people, the researcher ends up in a dilemma to what extent the results can be revealed, so that anonymity of the participants is protected.</p> <p>Long duration for interview process-Participants refuse to participate due to long duration of time taken for interviews.</p> <p>Difficulty in obtaining re-consent- Due to nature of the qualitative research, new findings may arise during analysis, which the research team could not predict priorly and explain to patient while getting informed consent. Sometimes it is difficult for the researcher to contact the participants, for re-consent to use the new information.</p>	<p>Cat 6: To overcome the challenges related to the nature of qualitative research</p> <p>*Get the help of experienced qualitative researchers/Ethics committee members while designing the qualitative consent form</p> <p>*Use pseudonyms to maintain anonymity and avoid descriptions that will expose the identity of the participant</p> <p>*Can conduct a discussion meeting with the colleagues about the potential risks and benefits in the study and include it the consent form</p>

The challenge related to poor knowledge of the researcher about the informed consent process can be overcome by allotting time in qualitative research methods workshop for teaching ethical aspects of qualitative methods. Vice versa all ethics related workshops can also provide time for discussing about ethical issues in qualitative research apart from quantitative research. The other challenge related to the researcher was difficulty in designing informed consent form for qualitative research due to its flexible and open-ended nature. Since the probing questions are put forward on spot, deciding the direction of inquiry in advance is difficult. Hence designing a solid informed consent document with adequate information becomes practically impossible. This can be dealt by asking general consent from the participants to begin with and treating consent as an ongoing process instead of one-time approach.⁸ Another way to overcome this issue is to provide sample probing questions apart from the mandated contents of informed consent document.⁹

Challenges related to the participants such as reluctance to sign informed document, not providing consent for audio visual recording, reluctance of illiterate participant to consent, all these issues arise due to lack of proper understanding of the participants about research and consent process and lack of trust in researcher. Hence before starting with any research process, the researchers should try to develop a good rapport with the research participants to enhance their trust in the ongoing research.¹ The importance of this research and need for consent and its value should be clearly explained to the participants in simple and understandable form. Various multimedia approaches such as speaking book, small video about the research in native language, use of pictures and illustrations will enhance the understanding of the participants about the research and consent process and its importance, which in turn will increase their chance for providing consent.

Ensuring confidentiality, risk benefit communication, long duration of interview process, obtaining consent for group techniques are some of the challenges posed by the nature of qualitative research itself. Due to its unpredictable nature, the impact qualitative research will have on participants is difficult to guess priorly and communicate to them. To deal with this explain about the nature of the research to the participants before initiating the study and stop the interview at any point of time if the participants feel uncomfortable or disturbed.¹ To ensure confidentiality avoid collecting personal information or try to use pseudonyms. Before publishing the results, a discussion meeting can be conducted with the participants about the results and consent for publication can be obtained. To deal with the issue of doubts in obtaining consent for group techniques, an expert in field of qualitative research and bioethics can be consulted for deciding the consent process. Refusal to give consent due to long duration of the interview can be

overcome when participants are made to understand the importance of this research and the benefit it provides for individual/ society.

STRENGTHS AND LIMITATIONS

Though the major strength of the study is its in-depth qualitative exploration of challenges in informed consent process in qualitative research from experienced qualitative researchers by a trained qualitative investigator, the main limitation is being a qualitative study conducted among respondents from only one medical college, the results cannot be generalized.

CONCLUSION & RECOMMENDATIONS

Since most of the challenges identified in the study are related to the reluctance of participants to provide consent due to various reasons and lack of adequate knowledge of the researcher about the ethical issues in qualitative research, creating a good rapport with the participants and providing adequate and simple information through various multimedia approaches and ethical training of qualitative researchers will aid us to overcome majority of these challenges. The findings of the study will aid the future qualitative researchers in designing a qualitative consent form and also acts as a stimulant which emphasizes the need for developing separate ethical guidelines for qualitative research in future.

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