RESEARCH ETHICS

Cultural barriers, 'competence' and informed consent in population-based surveys

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In India social science research in health benefited from the evolution of ethical guidelines through a national initiative during 1997–1999. These guidelines provide a concrete framework within which a study design can be developed, ethical issues can be thought through, and researchers can visualise real-life situations and the problems they will face—all before starting work. However, despite this process, questions that were not anticipated come up in the course of fieldwork.

This essay draws upon a study on the incidence of abortion to identify some challenges that researchers face in large, population-based sample surveys. It is hoped that the points raised here will further the discussion.

A community-based study of abortion

The Centre for Enquiry into Health and Allied Themes (CEHAT), based in Maharashtra, has been engaged in a statewide, community-based household survey on abortion incidence, care and cost. The research developed from our earlier work on various aspects of abortion with three important stakeholders—women, abortion service providers and state administrators. The fieldwork took place between September 2001 and March 2002, and between 21 and 27 field researchers were involved at different stages. This team underwent extensive training to impart a common perspective and the necessary skills. Complex statistical methods were used to identify the sample of 5,284 households and 5,575 eligible women from these households, from villages and urban blocks all over the state. Two different protocols were used to collect household-level information and individual information from eligible women, that is, ever married between 15 and 55 years of age. Their pregnancy histories were recorded.

The project underwent review by CEHAT's Institutional Ethics Committee (IEC) at two stages. First, the study design and methodology were presented for review. Then, after the field work was completed, the team discussed its experiences and raised certain questions for the IEC's response.

We faced a number of difficult decisions throughout the data collection process. This essay discusses seeking informed consent in three different situations.

Seeking informed consent

Individual informed consent was sought. Potential participants were given an oral explanation as well as a letter of introduction in the local language. Both the oral explanation and note contained information on: CEHAT, the context and objective of the study, the significance of participation in the study and the way that data would be utilised. Participants were informed of their right to *refuse to participate in the study* and stop the interview whenever they wanted, and their right to seek clarifications both before and after the interview. They were also given the names and contact details of the staff at CEHAT responsible for the project.

We repeatedly encouraged potential participants to clarify their doubts with us. Although we made efforts to seek written informed consent, we did not insist on this. Participants were given the option of verbal consent. If they were willing to participate but reluctant to sign, the researcher recorded their consent as verbal consent. When interviews were conducted in more than one sitting, we sought the participants' consent afresh at each sitting. Researchers underwent a six–seven-week training. We believe that the time spent in explanation, the Pune senior staff's telephonic responses to some participants' queries, incidents of post-interview written informed consent as well as verbal consent demonstrates that the spirit of seeking true informed consent was maintained.

It was comparatively more difficult to get written informed consent in urban areas than in rural areas. Potential participants in urban areas asked more questions, and expressed scepticism more often before signing. It was felt that the refusal rate was greater in the urban areas though these figures are still under analysis.

Language and cultural barriers

There were about 12 study units or communities, which were predominantly tribal, from different parts of the state. Language as well cultural barriers were faced in all these tribal communities surveyed. We translated the in-

formed consent sheet and the interview into a language which the local community would understand. However, the material could not be simplified beyond a point and this remained a constraint. This was perhaps because members of the tribal communities were minimally exposed to the outside world. We used concepts such as rights, ethical responsibilities, women's secondary position in families and society, poor healthcare services, India as a country, Maharashtra as a state, and so on. In the information sheet we also explained how individuals had been selected, as part of our ethical responsibility. We felt that many of these concepts were alien to them. Second, the barriers between the world views of the researchers and local communities persisted throughout.

Tribal communities

We are uncomfortable about the interviews done in the tribal communities. Here, we spent almost double the time that we normally spent to seek informed consent. We tried to ensure that the people we approached were given sufficient time to understand the material presented to them, at their own pace. Field researchers were asked to use their discretion while assessing research participants' needs in these situations. If they felt unable to handle situations on their own, they sought assistance from their team members to facilitate the process.

Research participants gave no indication that they were unwilling to participate. They did not distrust us though we were outsiders. They willingly signed the informed consent letters. However, we did not get a good sense of their understanding and did not feel that we could assess whether their participation was a result of the power relationship that exists between urban-based researchers and tribal community members.

This was a challenge to us. How does one break the language and cultural barriers with tribal communities? How does one to facilitate the researcher's assessment of a participant's grasp of what must be known in order to make an informed decision?

Inclusion of people labelled mentally ill

A few of the people who we had planned to approach to participate in the study were described as mentally ill by someone in the community or family. In such cases, we would have to ask ourselves if it would be appropriate to include that person in the study. Would s/he be in a position to give informed consent in the true sense?

The first question to be asked in this situation was: who determines that the person is mentally ill? For example, some people were introduced by their family members as 'mad'. But when we interacted with them, we found the person to be coherent with no evidence of abnormal speech or behaviour. We included such individuals in the study. Initially we grappled with the question of a mechanism to be used by all field researchers when there were indications of inadequate coherence, or of mental illness. We were also troubled by the question of whether the person had been mentally ill in the past, as we were to gather women's pregnancy histories during their entire life span. Eventually, we decided to go by our own assessment of that person, rather than that of family members.

Who should determine whether a person is mentally ill and how? How are a person's cognitive abilities and competence affected by mental illness? These questions are of critical concern to researchers. Researchers should only be concerned about a person's cognitive abilities, and that is how we dealt with the situation.

Should researchers be concerned about participants' cognitive abilities only in the case of the mentally ill? How should this issue be addressed? What about the barriers put up by language, culture and world view? These differences can affect a person's competence to give informed consent in a given situation.

Should we exclude from our study samples in population surveys those described by the community as mentally ill? What implications will such exclusion have for generalisation of data for the population it represents? On the other hand, if we include those described as mentally ill, is there a protocol for assessing their competence? Should everyone approached for the study take a test of competence for participation? Should we decide on the basis of 'natural elimination', excluding the participant during the process if s/he is unable to respond to the entire protocol in a coherent manner?

Translations

Since the survey was statewide, we anticipated having to interview non-Marathi speaking people. Therefore, in addition to Marathi protocols, we prepared Hindi and English ones assuming that the non-Marathi population would be able to manage with one of these. However, in four of the study units we came across people who were not proficient in either of these languages. We decided to involve translators in these situations. In these four units, between 4% and 100% needed a translator. The total number of people who required translators was 1% of the total sample covered in this statewide survey.

In three cases, we sought the help of translators from outside the study units because of our concern that a translator would gain access to personal information. If the translator was from within the community, she could potentially abuse this privileged information. We did try to get

a translator with some research background, but this proved to be too difficult. The translators were women with between four and 10 years of schooling.

We oriented the translators on the research study, its context and relevance. We explained all the questions in the protocol. The translators accompanied field researchers during process of seeking informed consent and interviewing. The field researcher conducted the interview with the help of the translator, recorded the responses and filled in the protocols.

The languages used by these communities—Gond, Telugu and Kannada—were very different from Marathi, the language used by the field researchers. This meant that the field researchers had no way of knowing if truly informed consent was obtained, or if there were problems while completing the interviews. Since the translators were not part of the initial collective training process, they may not have properly understood the context of the research, the need for ethical research practices, significance of seeking informed consent, rationale behind each question, etc.

Though we tried to make our decisions in the field with a constant focus on both science and ethics, looking back on the experience we came up with many doubts. When we became aware of the language barriers for some groups within our research population, should we have proceeded with data collection with the help of translators? Having conducted these interviews, should we exclude the data from these interviews because we cannot be confident of the quality of consent, and the data? If this is not ethically sound, do we use the data or not? Is it ethical not to use the data at this stage? Is it scientific to use the data?

Common concerns and issues

There may be possible alternative methods of overcoming the problems that we faced in these three different situations. For example, as regards the issue of translations, we could follow the same method of developing protocols in these languages as we did for Marathi. There are two interconnected pragmatic issues involved in this. First, researchers sometimes learn that the protocol must be translated into a particular language only after entering the study area. This will have implications for the fieldwork and project time-frame and would create a range of logistical problems. The other related issue is about the cost-efficiency of developing such protocols by expending resources for a very small percentage of the sample (about 1%). The same is true in the case of tribal communities.

Would exclusion of these communities/individuals from the sample have been an alternative to address the issue? To us, it wasn't. This would have had implications for both the science and ethics of the research undertaken. Such exclusion would obstruct generalisation of the findings at least to some extent, undermining the very purpose of undertaking such population-based sample surveys. It is also not ethically correct to keep some communities or individuals out of the purview of study because of constraints at the researchers' end.

Conclusion

The overarching issues in all three situations are the quality of understanding that would not only affect informed consent but may also have implications for the understanding of the protocols/interview schedules and the responses; the cost-efficacy involved in working out the most ethically and scientifically sound strategies to address the ethical issues, as cost-inefficient mechanisms themselves would be unethical.

The issue has been also that of the 'unanticipated' nature of the problems faced. At CEHAT, researchers have checklists to facilitate thrashing out ethical issues in proposed research and while preparing the study for ethical review. These checklists are still evolving. Experiences in this study indicate the need to improve upon the checklists by adding these issues in the checklists, thereby enabling researchers to address them adequately in advance.

In this light, it seems that more such documentation of the problems faced and the strategies used to resolve them would help the research community address these issues in a better way. The are no easy answers to these problems. Researchers need to strive for better strategies to deal with them enabling maintenance of both the scientific and ethical rigour of research.

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