CASE STUDY

Research in a tribal community

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The case presents the problems grappled with during a study done as part of post-graduate thesis work during 2000–2001 among certain tribal communities in north-central India, and the way they were resolved at the time.

This sero-epidemiological study was done to estimate the point prevalence of kala-azar infection in a certain tribe in north-central India. The study was undertaken because of the high morbidity and mortality due to kala-azar, a vector-borne disease, among this fast dwindling community. The tribe has minimum contact with the outside world. Fewer than two per cent are literate.

The study required three drops of blood from the study participants, using the finger prick method, for the direct agglutination test and the intradermal leishmanin skin test. In addition, baseline information and patient histories were to be gathered through individual interviews. Participants were chosen by systematic random sampling from a population of 9,020. Four *padas* (tribal hamlets) were chosen and 182 blood samples were collected for the study.

Seeking informed consent

Based on our understanding of the community organisation, we first approached community leaders in each *pada* to explain who we were and the purpose of our study, and to ask for their cooperation in carrying out the study. Then, in consultation with the community leaders, we scheduled meetings for the next day. The community leaders sent a local person to prospective participants, along with our translator, to inform them of the venue and time of the scheduled meeting. Prospective participants were not informed of the agenda of the meeting.

During the community meetings—which included other members of the community as they were held in open public spaces—the community leader introduced the research team, namely, the technician who served as the translator, and myself. We then explained the purpose of the study, and also spoke on topics such as kala-azar, its manifestations, diagnosis, treatment and vector control. We did not use any visual media. The technician, who was not familiar with the subject matter, translated my explanations on the spot.

Informed consent was sought after the meeting got over and before potential participants were asked to give blood. Following this, individuals were asked to undergo the finger-prick test, followed by a short (four to five minutes) interview. We collected information on demographic variables and a brief medical history. Both tests and interviews were conducted at the place of the meeting. We found this logistically convenient.

Informed consent forms, prepared in the vernacular, contained information on the purpose of the study and the possible risks. Since the community was illiterate and spoke a language unfamiliar to us, we deliberated for some time on the appropriate method of seeking informed consent. The idea of asking for written consent—with signatures or thumb impressions—was dropped; these are associated with giving away land rights or signing promissory notes. The following alternatives were considered:

Codes: These could be colours, with green representing acceptance and red refusal to participate in the study, or markings, with a 'tick mark' for agreement and a cross for refusal. However, the significance of such codes was alien to this community. **Audio recorded consent** seemed appropriate, but we could not afford this. We also considered **community consent** of the village head. Another option was to explain the purpose of the study to the community representative, who would then discuss it with the community and convey the community's decision to us. We considered this the most appropriate alternative since this is the way the community functions traditionally. Community leaders' decisions are binding on the community as a whole, contrary to modern value systems premised on individual autonomy.

Community consent had an additional appeal; it would mean a phenomenal saving of time and energy to be invested in translating the consent form, and explaining it to every prospective research participant. However, our ethics advisors did not approve of substituting individual consent by community consent on the grounds that it potentially compromised the autonomous character of informed consent.

Some ethical questions

Should we thrust, on tribal communities, a value system premised on 'individualism' which potentially could disregard their 'communitarian' value system? Is it not advisable to design methodologies that accommodate the socio-cultural practices of the communities being researched? Are we not overriding the authority of the village head by approaching individual community members for their consent, when they indicate that the village head's decision is more important than their own? Should researchers tamper with the value system of the tribal community to meet their own requirements?

Finally, is providing appropriate treatment to everyone in the community inflicted with the illness under study an ethical obligation or an inducement?

We expected to come across people in the community with kala-azar who required health care attention. We were guided on this by the Indian Council of Medical Research guidelines which state: '.... it is generally considered unethical to withhold (an) intervention or services' (1). This guideline indicates that cases identified during the study should be referred to an appropriate health care institution, especially if the treatment involved is expensive. Our ethics consultants recommended abiding by this guideline strictly, as the community was cut off from health care facilities. So we referred cases of malaria and kala-azar, detected during the screening, for medical examination and care, and also bore the expenses. We did the same for those who were not research participants. By doing so, we won the confidence of the community in general and study participants in particular. As a result, prospective research participants also expressed their consent to participate by giving their thumb impression on the informed consent form, and some younger, literate participants signed the consent forms.

In fact, providing treatment changed the community's attitude to the study, and its willingness to give written informed consent. This left us asking: How do we balance the conflict between the ethical responsibility to attend to the community's health care needs and the need to avoid inducement to ensure individuals' autonomous voluntary participation?

Acknowledgements

I acknowledge Mohammed Anish for assisting in field work and translation.

Reference

1. Indian Council of Medical Research. *Ethical guidelines for biomedical research on human subjects*. New Delhi: ICMR, **2000:**45.