Obtaining Informed Consent in Bangladesh

To the Editor: Informed consent is essential for research involving human subjects. However, little is known about whether researchers manage to communicate to potential study participants the required information as outlined in the Helsinki Declaration.[1] The potential participants in a developing country may be illiterate and may have limited experience with medical care and research. The researchers' communication skills are particularly important in such situations.[2] Only a few empirical studies have addressed this issue.[3]

We studied informed consent among pregnant women participating in a community-based study of iron supple-

TABLE 1. RATES OF POSITIVE RESPONSES TO QUESTIONS RELATED TO THE COMPREHENSIBILITY AND ADEQUACY OF INFORMATION GIVEN TO 105 POTENTIAL STUDY PARTICIPANTS IN BANGLADESH.

QUESTION	% RESPONDING YES
Were you informed about the objectives of the research?	94
Did you know that you were free to abstain from participating?	65
Did you know that after giving consent you were free to withdraw from participation at any point in time?	48
Did you get the impression that participation was only part of routine health care?	53
Did you get the impression that participation might mean such great advantages that it was difficult to say no?	87

mentation. The study was conducted in rural Bangladesh in 1998 and involved 105 women. Informed consent was obtained after the study had been explained in detail to the women during their first visit to an antenatal care center. Field assistants unaffiliated with the study of iron supplementation collected the data regarding informed consent, using a structured questionnaire. About two thirds of the study women were illiterate, and three fourths were from households with insufficient land for subsistence farming.

The information we elicited on the adequacy of informed consent varied. Although most women were informed about the objectives of the study, many of them did not understand that they were free to decline to participate (Table 1). Even fewer women understood that they might choose to leave the study. About half believed that participation was part of ordinary, routine health care. Eighty-seven percent indicated that they participated because they believed that doing so might carry such great advantages, primarily in terms of medical treatment for themselves or improved health for their babies, that it was difficult to say no.

These results are discouraging. The problem is not limited to developing countries, however; there have been similar experiences in Sweden, for example. Of 42 Swedish women participating in a gynecologic clinical trial, 17 did not know that they were free to withdraw from participation, and 4 women got the impression that a surgical diagnostic procedure, performed only for the purposes of research, was part of routine care.[4] But in settings with limited health care facilities, the reality may be that participation in medical research offers an opportunity to have access to services that are not otherwise readily available. The vulnerability of potential research subjects demands that researchers take seriously their responsibility to ensure the rights of the participants.

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