DISCUSSION

"Informing" and "consenting": ethical concerns regarding illiterate and vulnerable participants in clinical trials

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We appreciate the article by Eric Suba (1), highlighting some inadequacies in trials comparing various methods of screening for cervical cancer. Our response pertains to his reference to the Office for Human Research Protections (OHRP) raising concerns about issues relating to informed consent. We wish to present our perspective on the process of "informing" and "consenting" vulnerable patients in low- and middle-income countries (LMICs).

We have seen in the course of our own work (RD and VP) in South India that many of the women receiving care attend the clinics with their children in their arms or poised on their hips. This, together with the fact that many have low literacy levels, means that in most cases, when consent is obtained, the woman merely listens while a social worker reads out the document and explains how the particular clinical test (for example, the Pap smear to screen for cervical cancer) will benefit her. The social worker then records that consent has been obtained for the test. In another resource-limited setting, the Lambarene region of Gabon, staff members of the Medical Research Unit of the Albert Schweitzer Hospital report that decisions to participate in research trials often appear to be based on expectations of a beneficial clinical caregiving relationship, rather than an appreciation of the risks and benefits described in the consent documents (2). A recent study has confirmed that the level of understanding of research subjects in sub-Saharan Africa has frequently been "poor", even when western methods and documents have apparently been applied carefully to obtain informed consent (3).

We find it extremely difficult to understand how the workers involved in the studies conducted by Shastri et al, or Sankaranarayanan et al, explained the risks and benefits of the different arms, as well as the process of randomisation to the women in these settings. We are also uncertain about what the women actually understood. We especially wonder how the women consented to participating in a no-treatment arm. Did the informed consent document explicitly state that "you will not have any tests done, just as you have never had any done till now and would not have any conducted in the future"? Women all over the world, including those who agree to participate in clinical trials and those who are illiterate or otherwise, are a generally intelligent, concerned and thinking lot when it comes to decisions on healthcare and family welfare. However, the pressures of the daily toil of rearing their families can lead them to become indifferent and disinterested in long-drawn explanations and discussions regarding risks and benefits. Under these circumstances, they tend to take a benefit-based view of the matter, harbouring the expectation that their well-being is paramount in a "care-taker–care-receiver" relationship.

We sincerely believe that the sacrosanct relationship between care-taker and caregiver is based on humanism and a deep respect, or even reverence – as Albert Schweitzer suggested – for each fellow human being. The existence of a signed document does not demonstrate that this respect was actually present. Serious problems have occurred in western countries too (the Tuskegee and Willowbrook studies are examples), and there have been shortcomings even after improved safeguards were put in place to address them (4). Given the trials highlighted by Dr Suba and the recent HPV vaccination trials, which were terminated abruptly in India (5,6), there is clearly an urgent need for LMICs to find ways to ensure that all persons invited to participate in a research trial are treated with full respect. Efforts must be made to ensure that their expectations of what participation means are accurate, and that their participation is truly informed and voluntary. We need further studies of the informed consent process in LMICs where trials are conducted and on the perspective of prospective research participants so as to be able to understand how to ensure this. The existence of signed documents is, by itself, inadequate to prove the existence of objective informed consent by the participants in a study or trial.

Statement of authorship

All the authors have contributed equally to this paper.

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