Consent for Participation in the Bloemfontein Vitamin A Trial: How Informed and Voluntary?

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According to international regulatory authorities[1] and local institutional guidelines,[2] informed consent is a prerequisite for participation in every clinical trial. Consent implies that participation is voluntary. Furthermore, the participant must know the implications of participation.[3] Even if a participant has signed an informed consent form, the participant does not necessarily understand what the participation will entail, and consent thus may not be informed.[4] On the other hand, a study conducted in a South African hospital found that patient consent for HIV testing was informed but not truly voluntary.[5]

The aim of this study was to investigate whether the consent for HIV testing and subsequent participation in a randomized, double-blind, placebo-controlled trial investigating the effect of vitamin A on mother-to-child transmission of HIV[6] was informed and voluntary. Participants' knowledge about HIV and AIDS and the trial was used to measure how informed their consent was, and participants' perceptions about their willingness to participate, about their ability to withdraw, and about whether they would no longer receive good medical care if they withdrew were used to measure how voluntary their consent was. The trial was conducted from September 1997 to December 2000 in Bloemfontein, Free State, South Africa. In 1997, in the annual survey of the South African Department of Health of women attending public health antenatal clinics, 20% of the Free State women were found to be HIV positive, with the national figure being 17%.[7] Despite these figures, no

routine intervention has been aimed at preventing vertical transmission in South Africa.

METHODS

Participants in the Bloemfontein vitamin A trial were 303 women from metropolitan Bloemfontein who were HIV positive. The majority (56%) lived in informal settlements, and all attended public health facilities. For the trial, women were asked to volunteer for HIV testing during their first antenatal visit. Pretest counseling was done in groups, and posttest counseling was done individually. Seropositive women were asked to participate in the trial. All trial participants gave separate informed consent for the trial. All patients were recruited by 1 study physician and received verbal or written information (Sesotho, English, or Afrikaans information sheets).

The sample for this descriptive study consisted of all women attending postnatal follow-up trial visits from mid-July 1999 to mid-October 1999. A retired nursing matron who was fluent in Sesotho, Afrikaans, and English used a structured questionnaire in Afrikaans or Sesotho to conduct private interviews. Selected information was taken from the patient's trial case record form.

RESULTS

Of the 96 patients approached for inclusion in this study, 4.2% refused to participate. Ninety-six percent of the interviews were conducted in Sesotho. The median age of the 92 respondents was 27 years. Their median education level was standard 8 (10 years schooling), with 87.9% having attended high school (standard 6 or higher). The median time since inclusion into the trial was 14 months.

The vast majority indicated that they were counseled and gave consent for HIV testing (Table 1). Knowledge of HIV transmission and prevention was generally good; more than 80% gave correct answers regarding modes of transmission.

Only 3.3% stated that they felt forced to take part in the trial. However, only 24.2% believed that they could withdraw at any time, and 92.3% stated that they thought that they would no longer get good medical care if they withdrew from the trial (Table 1). Knowledge about the trial was poor (Table 2).

DISCUSSION

The time that had elapsed between the patient's HIV test and inclusion into the trial and the interview was on average more than a year, which could influence recall. Furthermore, nonattendance was a problem in the trial,[6] and respondents in this study were likely to be the most positive and informed participants, having remained in the trial for so long. Any estimates regarding the extent of the consent being informed and voluntary therefore may be overestimates.

The good knowledge about HIV and AIDS transmission and prevention may reflect the good knowledge that exists in the community rather than good counseling. However, many respondents still had questions about HIV (40%), and many had incorrect knowledge or were uncertain about the fatality and cure of HIV.

The respondents, despite most having 8 years of schooling or more, had poor knowledge about the most basic details of the trial. Their participation thus cannot be seen as informed. Repeating and discussing these details at each trial visit may address this problem. In approximately a third of the recruiting interviews, Sesotho translators were used, although the vast majority of patients taking part in the consent study chose to be interviewed in Sesotho. The recruiting doctor who also saw the patients at subsequent trial visits was struck by how few questions the participants asked, despite ample opportunity given for questions. Researchers should consider

TABLE 1—Vitamin A Trial Participants' Perceptions Regarding HIV Testing and Trial Participation

	Yes	No	Unsure
HIV testing			
Was counseling given to you before the HIV test? (n = 92)	94.6%	5.4%	0%
If yes,			
Did you understand the counseling? (n = 86)	95.3%	3.5%	1.2%
Do you feel you now know enough about HIV? (n = 86)	41.9%	55.8%	2.3%
Do you have more questions about HIV? (n = 91)	39.6%	60.4%	0%
Did you consent to be tested for HIV? (n = 91)	98.9%	1.1%	0%
Trial participation (n = 91)			
Did you want to participate in the trial?	98.9%	1.1%	0%
Did you feel forced to take part in the trial?	3.3%	96.7%	0%
Can you withdraw from the trial at any time?	24.2%	73.6%	2.2%
Were you allowed to ask questions when you decided to take part in the trial?	91.2%	8.8%	0%
Do you feel that you will no longer get good medical care when you stop taking part in the trial?	92.3%	7.7%	0%

TABLE 2—Vitamin A Trial Participants' Knowledge Regarding the Trial (n = 92)

Medication used in trial	
Vitamin A (correct answer)	40.2%
Vitamins	5.4%
Description given of appearance	13.0%
Unsure	35.9%
Other incorrect answers	5.5%
Reason that medication is administered	
Mother-to-child transmission (correct answer)	28.3%
Cure HIV	26.1%
Unsure	17.4%
Doctor did not explain, or I did not ask	6.5%
Other incorrect answers	21.7%
How long postnatal visits must continue	
18 mo (correct answer)	30.4%
Unsure	33.7%
Have not been told	9.8%
Until doctor says I must stop	9.8%
Other incorrect answers	16.3%

eliciting any problems more actively. Sanne et al.[8] have suggested that a social worker should be introduced to participants at the start of a trial to witness the consent procedure and to act as a patient advocate during the trial.

Although the respondents believed that their participation in the trial was voluntary, they were clearly aware of the lack of alternative sources of care. During the time of this trial, the lack of routine treatment for pregnant women who are HIV positive in South Africa received widespread media attention. ■

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Contributors

All authors took an active part in the planning of the study. G. Joubert supervised the data collection, analyzed the data, and wrote the initial draft of the brief. The other authors helped to interpret the data and gave critical comments on drafts of the brief.

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Human Participant Protection

The protocol was approved by the Faculty of Health ethics committee of the University of the Free State.

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