

PB69 Assess Factors affecting the Understanding of the Informed Consent Forms in the Pilot phase - A Zambian Case

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ABSTRACT TEXT

Background:

Informed consent form is one of the key documents that has been used in MDP study to indicate the wiliness of the clients to participate in the study. It is also an ethical and legal document that could be used to show that the participants consented to participate in the study. Some of the study components where emphasis was focused were that the gel doses not prevent the transmission of HIV and that the condom does prevent the transmission of HIV. However, there has been very limited understanding of the purpose and the content among the participants.

Objective:

The objective of this paper is to assess factors that affected the understanding of the informed consent forms in the Pilot phase of MPD 301 in Mazabuka Zambia.

Method:

During the pilot phase, in Mazabuaka — Zambia, 97 women were screened out of which 40 were enrolled. Participant information sheet and the informed (part I) consent were administered to all the women who were screened. Informed consent form — part II was administered to the 40 women who were eligible to participate in the pilot phase. During the period of the pilot study, (which lasted for one month), in-depth interviews were conducted with the 40 enrolled women. One component of the in-depth interviews was to assess participant's comprehension of content of the informed consent form.

Results:

The in-depth interviews revealed that about 28% (11) of the enrolled women did not understand the key message of the pilot study. They either mentioned that the condom does not prevent HIV or that the gel prevents the transmission of HIV. It was observed that level of education, language with which the participant information sheet and the informed consent form were the major factors that contributed to the understanding of the purpose of the study and content of the informed consent. A higher proportion of the clients that women did not understand the key message of the pilot study did not go as far as secondary school level, while about 45% (5) the participants were interviewed by a counsellor whose main language was not similar to the language the participants speak at home.

Conclusion:

The major factors that seem to affect the understanding of the purpose of the study and content of the informed consent form, among other things, were the education of the participants and the language in which the participants information sheet and the consent form were administered.

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