



Socio-Behavioral Aspects of FEM-PrEP

Socio-Behavioral Aspects of the Study

Socio-behavioral information plays an important complementary role in HIV prevention clinical trials. The behavior of the participants -- such as their regular attendance at scheduled clinic visits and their adherence to the study pill -- is fundamental to success of a clinical trial. As part of FEM-PrEP, the study team developed and monitored procedures for reaching women who were at higher risk, implemented strategies to promote adherence to the study pill, examined aspects of the clinical trial that were difficult for participants to understand, and promoted community engagement in research. Data were also gathered on adherence to the study pill and on the participants' sexual behaviors while taking the study pill.

Prior to the Initiation of FEM-PrEP

Research was conducted at three FEM-PrEP study sites prior to the start of the clinical trial to 1) inform community members about the proposed FEM-PrEP clinical trial and ensure that the trial would meet community needs, 2) identify community stakeholders and organizations, 3) explore how to best engage the community before, during, and after the trial, 4) collect data to assist with developing study procedures; and 5) identify geographic areas and places in the community where HIV incidence among women might be high.

A variety of structured interviews, in-depth interviews, and focus group discussions (FGDs) were conducted with potential participants, community members, community stakeholders, and the owners/managers, employees, and patrons of local bars/taverns and similar establishments. The data were used to assess the acceptability of the trial within the community. The data were also integrated into the trial's standard operating procedures, checklists, work plans, and other relevant materials in the following areas: recruitment, retention, informed consent, counseling to improve adherence to the study pill, risk reduction and contraceptive counseling, as well as community education and outreach.

During FEM-PrEP

During trial implementation, the study team 1) monitored and provided ongoing feedback about recruitment strategies, comprehension of the informed consent process, and counseling to improve adherence to the study pill; 2) gathered data to understand general issues of adherence and sexual behaviors in the context of a clinical trial; and 3) systematically engaged community stakeholders in the research process.

Who participated and how were the data used?

- **Trial participants:** In-depth interviews were conducted with trial participants to identify factors leading to adherence or non-adherence to the study pills, and to describe the effect of pre-exposure prophylaxis (PrEP) on risk compensation within the context of a clinical trial. Risk compensation occurs when a participant increases risky behaviors because she feels the study pill will protect her from HIV. During the interviews, participants also discussed positive and negative aspects of trial participation.
- **Women who became HIV positive:** Repeated in-depth interviews were conducted with each participant who became HIV positive during the trial. These interviews explored the participant's risk of exposure to HIV and adherence to the study pill during the trial. The interviews also explored the participant's experiences after becoming HIV positive, including coping, access to referred HIV care and treatment, and any changes in her sexual behavior.
- **Community stakeholders:** Focus group discussions were held each month with community stakeholders to complement feedback from the community advisory board and other community groups. Focus group discussions allowed for a systematic method of gathering information about community perceptions of the trial, and the data were used to identify, further understand, and explore ways to address community concerns and reactions to the trial. Focus group discussions also gave study staff the opportunity to provide community stakeholders with updates about the progress of the trial and to explore potential solutions for challenges faced, such as in recruitment and retention. Rumors that were commonly mentioned during the FGDs were communicated to the community educators, who discussed them in subsequent community engagement events. See *FEM-PrEP Fact Sheet on Community Engagement* for details on other community activities.

What type of behavioral monitoring was performed at the three study sites?

The study team monitored comprehension of informed consent, trends in recruitment, and participants' adherence to the study pills.

As part of the informed consent process at screening and enrollment, potential participants were read information about the trial, given the opportunity to ask questions, and administered a quiz to assess their understanding prior to signing the consent form. To examine the participant's comprehension of informed consent, quiz answers were regularly reviewed to identify questions that were frequently missed. Counselors discussed these data and determined strategies for providing additional explanations of these topics during the informed consent process of newer participants. The participant's comprehension of informed consent was also measured every quarter. This information was used to enhance the ongoing education about the trial.

See *FEM-PrEP Fact Sheet on Adherence* for details about how adherence was monitored. The following example explains FEM-PrEP's overall recruitment strategy at three sites and how trends in recruitment were monitored during the trial.

Example: Impact of Socio-Behavioral Research on Recruitment

FEM-PrEP researchers adapted the PLACE Method (an innovative method originally developed to improve the reach of AIDS-prevention programs) to help develop FEM-PrEP's recruitment strategy.

During trial preparation, researchers interviewed members of the general community to identify the most common establishments (such as taverns and guest houses) where people meet potential sexual partners. They then conducted interviews with managers and owners, male patrons, female patrons, and employees of these establishments to learn more about the establishments and the people who socialize there.

Using these data, as well as staff experience from conducting the preparedness research, geographical areas of higher risk were identified and prioritized for recruitment. A global positioning system (GPS) unit was used to log the coordinates of the recruitment establishments and place them on maps using a geographic information system (GIS). This also allowed for the grouping of higher-risk areas, and helped to prioritize the recruitment process at some sites.

During the implementation of FEM-PrEP, the study's staff members systematically recruited potential participants, starting with the areas that were prioritized during the preparedness research. The staff recruited from one or two priority areas at a time, focusing initially on the establishments that were identified from the interview data. They also recruited from other places in the priority areas such as voluntary counseling and testing centers, from clinics that treat sexually transmitted infections, and other establishments. Each month strategic decisions were made on where to recruit next, based on the staff's experience with the recruitment activities and a review of the screening and recruitment data.

Reference: MEASURE Evaluation. *A New Tool to Focus and Monitor AIDS Prevention Efforts: The Place Method*. MEASURE Evaluation Bulletin, Number 4, 2002. Available:

<http://www.cpc.unc.edu/measure/publications/bu-02-04/>

How can I learn more about the FEM-PrEP clinical trial?

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