



Community Engagement

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Community engagement in research is a process through which community partners are involved in aspects of research initiatives in their communities, including the decisions and resources that affect the research. Community engagement in the FEM-PrEP clinical trial refers to the partnership between the researchers and the community stakeholders, particularly the population directly affected by the trial. The community program for the FEM-PrEP clinical trial aims to foster this partnership, to improve the community's understanding of and trust in clinical research, to build the community's capacity to participate in clinical research studies, and to promote ongoing communication about rumors, misconceptions, and other concerns about the FEM-PrEP trial.

The community activities for the FEM-PrEP trial began in 2007 during a six-month preparedness phase at the site in Bondo, Kenya. Other sites followed suit, and similar activities were conducted in Pretoria and Bloemfontein, South Africa; Arusha/Moshi, Tanzania; and Harare, Zimbabwe. Staff members at the sites stayed in touch with community stakeholders throughout the FEM-PrEP trial, mainly through community education, community advisory boards, and focus group discussions with community stakeholders. See *Fact Sheet on the Socio-Behavioral Aspects of FEM-PrEP* for details on the focus group discussions.

What is the role of community educators?

Community educators were part of the FEM-PrEP team at each site. They conducted outreach and education sessions to create widespread awareness of HIV/AIDS as well as of the FEM-PrEP trial and to identify and address community concerns. These efforts focused on individuals, groups, and organizations in the areas of the community where recruitment took place and at the district and provincial levels. The community educators documented questions and rumors that the community members raised, allowing for ongoing evaluation of community concerns, prompt responses to those concerns, and the correction of misinformation. They also participated in community-wide HIV awareness events such as World AIDS day and attended programs organized by local public health stakeholders.

What is the role of the community advisory board?

Each of the five study sites established its own community advisory board (CAB) or similar advisory group made up of diverse stakeholders that represented the community members and trial participants. Members of these advisory groups were volunteers, trained on the basics of clinical trials, research ethics, and the specifics of the FEM-PrEP trial. Refresher trainings were organized during the trial. The CABs met regularly and provided input on key components of the trial such as acceptability of the study,

recruitment, development of community education plans, informed consent, how to address rumors, and the referral process for women who became HIV positive during the trial.

What are some specific examples of successful community-engagement activities?

- In Bondo, Kenya, ongoing meetings with men from the community markedly reduced concerns regarding their partners' participation in the trial. Chiefs' *barazas* (routine gatherings convened by local chiefs) also reinforced the legitimacy of the research among key individuals and groups.
- In Pretoria, South Africa, community educators networked extensively with local and national health and voluntary counseling and testing (VCT) campaigns to educate the community about HIV prevention, clinical research, and the FEM-PrEP trial. These collaborations also supported recruitment, as potentially eligible women could be referred directly to FEM-PrEP staff.
- In Bloemfontein, South Africa, outreach workers distributed male and female condoms, as well as literature on HIV prevention and tuberculosis, to sex workers in "hotspots," and to residents of informal settlements. Also, health fairs were held in communities where no health services or facilities existed. These additional educational activities helped to build trust and rapport in historically underserved communities.
- In Arusha/Moshi, Tanzania, community advisory group members were instrumental in identifying appropriate HIV care and treatment services for participants who became HIV positive during the trial.
- In Harare, Zimbabwe, the CAB reviewed FEM-PrEP's informed consent forms and recommended site-specific issues to be integrated into the forms for the Zimbabwe site.

What is next for the FEM-PrEP community program?

Community educators and other study staff will hold community meetings and contact key stakeholders individually to explain the decision to initiate an orderly closure of FEM-PrEP over the next few months and to answer any questions or concerns they may have.

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

Please contact Beth Robinson, Associate Director, Project Communications. E-mail: brobinson@fhi.org