



Ministry of Medical Services
Ministry of Public Health and Sanitation

ARV-Based HIV Prevention: State of the Science and Considerations for Implementation



**Consultation Report
Naivasha, Kenya
25-26 September 2012**

In September 2012, Kenya's National AIDS and STI Control Programme (NAS COP) and the Kenya Medical Research Institute (KEMRI), in collaboration with FHI 360, convened 43 stakeholders, including Kenyan policy makers, program managers and civil society advocates, to consider the potential introduction of microbicides and pre-exposure prophylaxis (PrEP) for HIV prevention.



The CAPRISA 004 clinical trial of a microbicide candidate found that use of tenofovir gel before and after sex reduced women's risk of acquiring HIV by 39 percent; the protective effect was 54 percent among women with high adherence to the gel. A confirmatory study, FACTS 001, is under way.

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Four trials of PrEP among heterosexuals had mixed results: two were stopped when it became clear that they would not be able to determine whether PrEP could reduce the risk of HIV. Two other trials showed that daily use of the antiretroviral (ARV) drug Truvada was 63 percent effective among HIV-negative men and women and 72 percent effective among HIV-negative men and women who had HIV-positive partners.



Given these promising results from some of the trials, countries are grappling with questions about how and when to incorporate ARV-based prevention methods in their HIV programs. Funded by the U.S. Agency for International Development (USAID) and the Bill & Melinda Gates Foundation, the consultation enabled participants to:

- Review current evidence on PrEP, microbicide gels and rings, and ARV injectables for HIV prevention, particularly for women
- Discuss the experience with microbicide and PrEP development and preparations for introduction of these methods in Kenya
- Identify potential clients, service delivery channels and approaches for PrEP and microbicide introduction.

FHI 360 research on the introduction of ARV-based prevention in Kenya

Assessing Physical Delivery of PrEP in Support of Deliverability. Funded by the Bill & Melinda Gates Foundation, this study identified potential delivery channels, barriers to access and requirements for the delivery of ARV-based prevention technologies.

Social Marketing Planning for Oral PrEP Rollout in Targeted Populations. Funded by USAID as part of a clinical trial of PrEP in Bondo, Kenya, this study is designed to facilitate local planning for PrEP rollout.

Microbicides Communication Strategy. Funded by USAID, FHI 360 will work with NAS COP and other local partners develop and evaluate a comprehensive communication strategy for potential microbicide users and health care providers.

Gender Analysis for Microbicide Introduction. This USAID-funded initiative will identify how gender norms, roles and relations are likely to affect women's ability to access tenofovir microbicide gel and use it as directed.

Take Home Messages

■ Now is the time to consider how to implement ARV-based HIV prevention methods in Kenya.

Meeting participants agreed that it is time to begin laying a foundation for the introduction of new and potential ARV-based prevention methods in Kenya. In the meeting evaluations, 95 percent of respondents agreed or strongly agreed on the need to deliver new HIV prevention methods in Kenya. Six out of 10 thought Kenya should currently be rolling out PrEP, and nine out of 10 said the government and its partners should be planning for the introduction of microbicides.

■ Leadership and support from the Kenyan government should be a priority.

The example of Kenya's voluntary medical male circumcision program shows how successful introduction of HIV prevention methods depends on government leadership and community support. Meeting participants emphasized that civil society should work closely with the government to develop appropriate procedures and regulations. They agreed the government should drive the agenda for the introduction of ARV-based HIV prevention, including the development of national guidelines.

■ Program planners must consider social norms and potential stigma when identifying focus populations and service delivery channels.

Participants said that community members — particularly women — are excited about the potential of PrEP and microbicides. They discussed possible focus populations: women in stable relationships, discordant couples (one partner is HIV-positive and the other is HIV-negative), female sex workers and adolescents.

Many participants thought groups considered at high risk of HIV should be the first priority for PrEP implementation, while microbicides could be offered to all women and perhaps to adolescents. They

Consultation participants included policy makers from NASCOP, the National AIDS Control Council and the World Health Organization; funders from USAID and the Bill & Melinda Gates Foundation; representatives from nongovernmental and faith-based organizations, including the Kenya Episcopal Conference, the Federation of Women Lawyers, the Christian Health Association of Kenya, the Network of People Living with HIV/AIDS in Kenya and AVAC; and researchers from Moi University, the University of Nairobi, Kenyatta National Hospital, KEMRI, LVCT, the London School of Hygiene and Tropical Medicine, Imperial College of London, the Population Council and FHI 360.



Photo by Tracy Irwin/UIC

noted that more than half of new HIV infections occur in young women and called for a rollout strategy that addresses this group's heightened vulnerability to the virus. Further discussion will be needed to finalize priority populations for ARV-based prevention in Kenya.

Participants agreed on the importance of conducting a gender analysis to identify the gender norms and sexual power imbalances likely to affect women's ability to use new HIV prevention products. They noted that communicating with partners about HIV prevention is particularly challenging for women in long-term relationships.

Results from the Physical Delivery of PrEP Study revealed that the greatest challenges to effective delivery of PrEP and microbicides are concerns about access and cost, the stigma associated with HIV/AIDS, and knowledge and attitudes of clinic staff. Stigma and the ability of potential users to adhere to a PrEP regimen were also identified as barriers to the use of these methods.

While recognizing that female sex workers are an important target population for both PrEP and microbicides, meeting participants expressed concern about the effects of focusing on groups that are already stigmatized by society. They thought offering ARV-based HIV prevention methods with family planning or other health services might make the methods more acceptable. Careful consideration is needed to avoid stigma.

■ Sustainable funding and cost-effective programs must be high priorities.

Meeting participants agreed that a concerted, focused effort is needed to identify sustainable funding, and then develop effective combinations of prevention and treatment options that maximize the impact of limited resources. They emphasized that a range of options should be available to women and men. The use of various methods and approaches at different times in a person's life — for example, use of PrEP until an HIV-positive partner begins treatment — should be considered in cost analyses.