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Tenofovir gel for HIV prevention for women: Perspectives of Key Opinion Leaders from India



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Abstract

Objectives: Country decision-making regarding adoption of new health technologies is a lengthy process that is informed by scientific, public health, and policy analyses. Key Opinion Leaders (KOLs), who include a range of influential individuals (e.g., Ministry of Health officials, leaders of medical and pharmacy associations, civil society representatives, donors), play a critical role in country decision-making around adoption and availability of new HIV-prevention tools. Their perspectives can shape public opinion and influence policy, programming, and procurement decisions.

Methods: In-depth face-to-face interviews with a dozen purposefully selected national KOLs in India were conducted to gain their perspectives around ARV-based prevention for women, focusing on microbicides in general and tenofovir vaginal gel specifically. Theme-based content emerged and was analyzed using ATLAS.ti software.

Results: While generally supportive, KOLs expressed caveats regarding the role tenofovir gel might play in the overall HIV-prevention program. Key outstanding issues that would need to be addressed include product effectiveness, potential for resistance, product cost, feasibility of HIV testing and re-testing, and effective targeting of key populations for public health impact.

Conclusions: As new HIV-prevention technologies advance through clinical trials, there is a concomitant necessity to engage in policy analysis exercises. Formative research with stakeholders early in the process is an important yet often overlooked step. The potential role that the tenofovir gel could play in India will depend in large part on epidemiological, public health, and economic factors. Understanding target populations' perspectives on the product will also be critical for its successful introduction.

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Introduction

Although HIV continues to spread in many settings, during the last decade several countries have made important progress in addressing the epidemic [1]. India's strong

commitment and ability to address the HIV epidemic has contributed to more than 50% decline in new HIV infections from 2000 to 2009. The initial response focused on awareness generation and preventing HIV acquisition in the general population. As data and experience provided a more in depth understanding of the epidemic, a targeted approach has emphasized containing HIV transmission from high-risk groups - female sex workers (FSWs), men having sex with men (MSM), and injection drug users (IDUs) - to the general population. Importantly, India has also provided a growing program of treatment and care for people living with HIV.

In the evolution of the national response, the government has increasingly encouraged the involvement of a range of stakeholders. As a policy [2], the government involves actors such as representatives of nongovernmental organizations (NGOs) and international development agencies in HIV policy and program planning. The comprehensive national consultative process recently conducted by National AIDS Control Organization (NACO) to shape the fourth phase of the National AIDS Control Program (NACP IV) illustrates this process [3]. The stakeholders involved in this consultation comprised diverse individuals and organizations including, but not limited to, health practitioners, public health experts, representatives of NGO, and civil society groups (e.g. women's groups), and international development organizations. Each stakeholder group has the potential to influence HIV policy and programs in the country. The policy environment makes it imperative to understand the perspectives of all stakeholders prior to introduction of any new HIV-prevention technology.

A critical lesson from the experience to date is that women in India face greater social and economic vulnerability compared with men, and are at higher risk for acquiring HIV. Currently, women constitute more than one-third (39%) of the HIV-positive population in India [4], and many more are vulnerable to acquiring HIV and other sexually transmitted infections (STIs) from their male partners. As a result of the traditional Indian socio-cultural milieu that ascribes women to a lower social status than men, women have little or no decision-making power or control over their sexual lives. Men's risk-taking behavior increases women's HIV risk. An effective user-controlled HIV-prevention method could mitigate women's HIV risk. For many years, Indian researchers have actively collaborated in global efforts to find an effective vaginal microbicide, and clinical trials for several microbicide candidates have been included in sites in India [5-7]; among them tenofovir gel has also been utilized [8]. Worldwide, the results of tenofovir gel trials have been mixed. The CAPRISA 004 trial in South Africa showed a 39% reduction in women's risk of HIV infection through vaginal sex compared with a placebo, providing the first clinical evidence that a vaginal gel can be effective in HIV prevention [9]. FACTS 001, a large-scale trial underway in South Africa, is replicating the same dosing strategy for tenofovir gel that was used in the CAPRISA 004 trial. The results from the FACTS trial, expected in 2014, will provide a clearer picture of tenofovir gel effectiveness. However, even when information on the scientific status of tenofovir gel becomes available, its inclusion in a country's program is likely to be a lengthy process which will require strategic commitment and

policy-level decision-making. This necessitates understanding the social and policy environment for effective introduction of the product in the country. We conducted this study at an opportune time when researchers and programmers are awaiting the results of tenofovir gel trials. We believe the timeliness of this study will aid in the process of understanding stakeholders' views, stimulate discussion among them, and, ultimately, foster support from a range of stakeholders, which is essential given the comprehensive consultative processes followed by policy-makers in India.

Given the urgent need for HIV-prevention options for women, a number of efforts are underway to prepare for introduction of tenofovir gel should it be shown to be effective in reducing the risk of HIV acquisition. One of these is a toolkit designed to assist policy-makers and program managers in identifying the most strategic opportunities for introducing tenofovir gel. The toolkit includes three related components: a landscape analysis; a discussion guide for Key Opinion Leaders; and a program planning guide. We have used this toolkit to develop a case study to illustrate the process of preparation for potential introduction of tenofovir gel in India. The landscape analysis for India reviewed the epidemiologic context of the HIV epidemic and included a scan of key policies and programs related to HIV [10].

Key Opinion Leaders (KOLs), who include a range of influential individuals (e.g., senior Ministry of Health officials, leaders of medical and pharmacy associations), play a critical role in shaping public opinion and influencing policy. To a large extent, they help shape the overall policy and program environment and their actions can foster or impede access to new HIV-prevention tools. Recognizing the critical gate-keeping role KOLs can play in India, the Population Council conducted a descriptive study using the discussion guide with KOLs. The aim of the study was to capture attitudes, opinions, and insights on policy and program issues related to ARV-based prevention, including tenofovir gel, from a diverse range of opinion leaders. This study was conducted as part of broader agenda-setting discussions on vaginal microbicides in India.

Conceptual framework

Conceptual frameworks used in HIV-prevention research have often focused on individual behaviors [11]; some have been proposed for scaling-up of new prevention tools within HIV programs [12]. These frameworks are not suitable for a proactive assessment of the broader social and policy environment that can influence decisions about adoption of new HIV-prevention products, such as inclusion of vaginal gels in HIV programs in India. We therefore used the ecological framework that has also been used for similar analysis of development of policy for the HPV vaccine in low-income countries, including India [13].

We found the ecological framework particularly suitable because it distinctively emphasizes the role of sociocultural and environmental factors in health behavior and promotion at multiple levels [14]. Applying the ecological theory, Cohen and colleagues [15] have provided a structural model that identifies four changeable environmental factors that influence population-level health behaviors: **availability**

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