

Setting the Stage for ARV-based Prevention for Women: A Snapshot of the Zimbabwean Context



Zimbabwe has seen a substantial shift in the HIV landscape in the last decade, with prevalence among adults aged 15 and above decreasing from an estimated 24.3 percent of the population in 2001 to less than 15 percent in 2012 (UNAIDS 2013). The reduction in the number of people living with HIV (PLHIV) has been attributed to scaling up both treatment and prevention (Hargrove et al. 2011). In particular, increased emphasis on behavioural interventions, such as condom use and reduction of sexual partners has been credited with nearly halving the number of new infections annually between 2001 and 2012 (Gregson et al. 2010; Halperin et al. 2011). Yet, despite this progress, many people, especially women, are still at high risk and efforts to identify and implement additional HIV prevention options remain critical.

These developments have taken place against the backdrop of unprecedented socio-economic decline in Zimbabwe, which has significantly compromised the avail-

ability, use, and quality of health and social services. As a result, coverage of most basic health services has decreased, leading to stagnation or deterioration of some health indicators.

Despite the political and economic situation in Zimbabwe, clinical research is of the highest caliber, and Zimbabwe has participated in many large-scale HIV prevention trials, including safety and effectiveness studies of tenofovir gel and several other candidate microbicides. Topically applied microbicides are under development as a method women could use to reduce their risk of HIV and possibly other sexually transmitted infections. Tenofovir gel has been shown to reduce the risk of HIV acquisition by 39 percent in the CAPRISA 004 trial in South Africa, the first candidate microbicide to show effectiveness in a clinical trial (Abdool Karim et al. 2010). The confirmatory FACTS 001 trial of tenofovir gel is now underway in South Africa, with results expected in 2014.



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Background on this Brief

Given the urgent need for HIV prevention options for women, a number of projects are underway to prepare for introduction of tenofovir gel should it be shown effective. One of these is a toolkit developed by the Population Council to assist policymakers and programme 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 leader interviews; and a programme planning tool. The landscape analysis, summarised in this programme brief, includes a review of the epidemiologic context of the HIV epidemic along with a scan of key policies and programmes related to HIV and most relevant to tenofovir gel. It draws on a desk review of peer-reviewed and grey literature as well as interviews with key decision makers. The full report and annexes are available at www.popcouncil.org.

HIV in Zimbabwe

Zimbabwe, with an estimated population of 12.7 million people, is among the countries in sub-Saharan Africa most affected by the HIV epidemic. In 2012, a total of 1.2 million adults and children were living with HIV and AIDS. This includes an estimated 14.7 percent of the population 15–49 years old, with an estimated 69,000 new infections in 2012 (UNAIDS 2013). HIV in Zimbabwe is characterised by variation among and within provinces at the local and district levels. Many HIV treatment and prevention programmes have targeted these defined geographic areas, and such a focus may be appropriate for ultimate delivery of tenofovir gel.

Zimbabwe has a generalised, heterosexually driven HIV epidemic; heterosexual transmission accounts for over 90 percent of HIV infections in the country (UNAIDS 2012). Vertical transmission, where HIV is passed from a mother to child during pregnancy, childbirth, and/or breastfeeding, is the second most

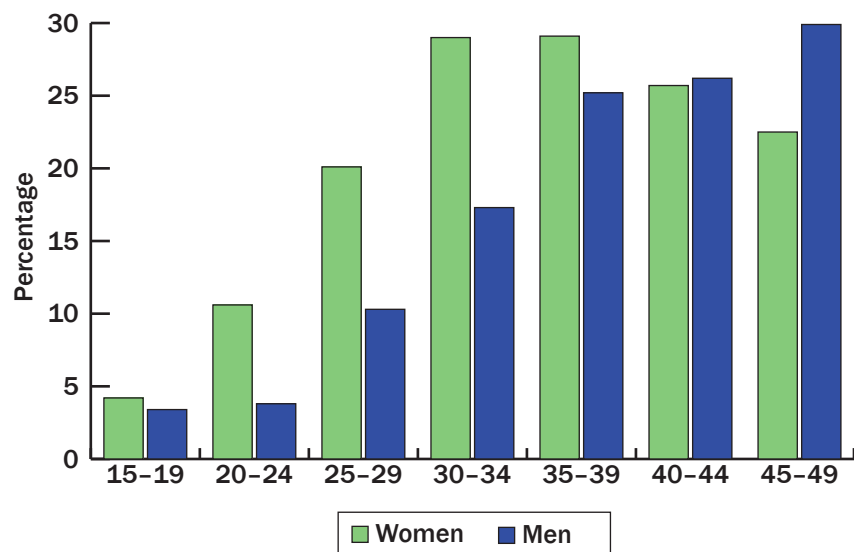
common source of HIV in the country. Both modes of transmission remain pressing public health challenges despite considerable attention to address them.

In fact, Zimbabwe is on track to achieve the Millennium Development Goal of halting and reversing the spread of HIV/AIDS by 2015 due both to high AIDS mortality rates and to changes in sexual behaviour. These behaviour changes, such as increased use of condoms in casual relationships and partner reduction, have resulted largely from personal experience with AIDS mortality (Gregson et al. 2010; Halperin et al. 2011). Although Zimbabwe is one of the few countries in the region to have experienced a substantial reduction in HIV prevalence, HIV/AIDS continues to be a significant contributor to the overall burden of disease.

Women, Girls, and HIV

HIV prevalence is higher among women than men across all age groups, except those 40–49 years old (see Figure 1). In particular, prevalence in some younger age groups is almost twice as high among women as among men (UNAIDS 2013). Sex with high-risk partners and multiple partners continues to be strongly associated with risk of HIV infection among women. Young women's risk is driven by a complex array of biological, social, economic and structural factors, including gender-based violence and men's alcohol use.

Figure 1 HIV prevalence by age and gender



Source: ZIMSTAT and ICF International. 2012. Demographic and Health Survey [DHS]

As in many other settings, gender-based violence is associated with HIV in Zimbabwe. The 2010–11 ZDHS (ZIMSTAT/ICF International 2012) found that sexual and physical violence occurred in intimate and other relationships across culture and class. Thirty percent of women aged 15–49 reported having experienced physical violence since the age of 15. The most common perpetrator was a current or former husband or partner. Married women who had experienced physical and/or sexual violence were significantly more likely to be HIV positive than those who had not experienced any physical or sexual violence (Nyamayemombe et al. 2010).

Men's alcohol use has also been correlated with increasing women's risk of HIV; consumption of alcohol is associated with men having higher numbers of sexual partners, and higher rates of HIV infection (Fraser et al. 2011). In Zimbabwe, research on the role of beer halls in the HIV epidemic shows that going to beer halls was associated with concurrent sexual partnerships (Lewis et al. 2005) and that men who reported having sex while drunk were more likely to report unprotected sex with casual partners and when paying for sex (Fraser et al. 2011).

Most at-risk Populations

Data on prevalence and incidence are scarce among those identified by UNAIDS as the most at-risk populations—men who have sex with men (MSM), sex workers, and injecting drug users (IDUs). Little information is available about the overall HIV prevalence in these populations, and to date no systematic size estimations have been conducted. Sex work and homosexuality are both illegal in Zimbabwe, and this, combined with definitional and measurement problems, means that both are likely to be underreported. The lack of legal status and protections for sex workers and MSM presents obstacles to effective HIV prevention, treatment, care and support in these populations. Despite these challenges, some groups focused on HIV prevention have identified “hot spots” among these groups and provided services for sex workers and MSM, as well as IDUs.

Reproductive Health Indicators

Contraceptive Prevalence

According to the 2010–2011 Zimbabwe Demographic Health Survey (ZDHS), 59 percent of all married women surveyed reported using family planning, nearly all using a modern method. Oral contraceptive pills were the most common method, used by 41 percent of women, while use of injectables, male and female condoms, implants and sterilization was less common (ZIMSTAT/ICF International 2012). Given the relatively high overall use of family planning programmes, efforts to deliver tenofovir gel could build on this system, including the logistics for product storage and distribution of contraceptive commodities.

Sexually Transmitted Infections (STIs)

HIV infection is clustered among people with a history of STIs, especially genital ulcer disease. According to the 2010–2011 ZDHS, 10 percent of women and seven percent of men had had an STI or STI symptoms in the year preceding the survey. Of those, 47 percent of women and 48 percent of men sought advice or treatment from a clinic, hospital, private doctor, or other health professionals (ZIMSTAT/ICF International 2012). STI prevention is now part of HIV prevention programmes in Zimbabwe and is linked to other programmes including antenatal care (ANC), sexual and reproductive health, HIV testing and counselling (HTC), prevention of mother-to-child transmission (PMTCT), antiretroviral treatment (ART) and condom promotion (UNAIDS 2012).

Maternal Health Care

The 2010–11 ZDHS shows that 90 percent of women who gave birth in the previous five years received antenatal care from a trained health professional for their last birth. The majority of women in Zimbabwe deliver in a health facility with a trained attendant; 65 percent of births were delivered in a health facility.

A cohort study showed that HIV incidence was very high during the first nine months after childbirth (5.7/100 women-years-at-risk). Women who knew that their partners had other sexual partners were about four times more likely to acquire HIV (Munjoma

et al. 2010). These data suggest that the post-partum period may be a particularly important time to reach women with new HIV prevention technologies or strategies, and that post-partum or infant care programmes might be considered as potential venues for pilot programmes. The relatively high proportion of births delivered in a health facility may provide an opportunity to encourage women to come for follow-up services, including making HIV prevention methods available.

Policy Environment

Zimbabwe's policies, strategies and programmes have both anticipated and responded to established priorities and emerging approaches to HIV prevention. Zimbabwe's national response to the HIV epidemic has been guided by the National Policy on HIV and AIDS, which was adopted in December 1999 through an act of Parliament. The current Zimbabwe National HIV and AIDS Strategic Plan (ZNASP) 2011–2015 is driven by the National AIDS Council (NAC), and its implementation is spearheaded by the Ministry of Health (MoH). It is supported by the National AIDS Trust Fund (NATF), a three percent levy on personal and corporate income. Its priorities are:

- Prevention of new HIV infections in adults and children, aiming to reduce the rate of annual infections by 50 percent by 2015;
- Reduction of mortality among people living with HIV, aiming to reduce annual AIDS deaths by 38 percent by 2015.

Complementing and building on these overall policies are various sector-level policies, strategies and workplans, many of which emphasise the importance of prevention in Zimbabwe's response to HIV. Specific guidelines covering the range of standard and emerging biomedical interventions are based on local evidence as well as international standards. Zimbabwe is also increasingly looking at policies to address broader structural factors that drive HIV risk. For example, the US Centers for Disease Control and Prevention is assisting Zimbabwe to develop an alcohol policy, indicating recognition of the role that alcohol use plays in driving risky behavior and HIV incidence. This

policy environment reflects the country's commitment to fulfilling a number of international and regional obligations related to HIV, and a degree of openness to new prevention approaches even in the face of considerable economic constraints.

Despite significant political and economic uncertainty, Zimbabwe has relatively well-developed policy and regulatory environments, along with technical experts who have played pivotal roles in a number of trials of microbicides and other female-initiated prevention technologies. Zimbabwe's commitment to and success with introducing and making available the female condom is noteworthy (see below). This policy and scientific expertise can be brought to bear on a thorough analysis of how tenofovir gel can address the specific prevention needs of the country.

Regulatory Processes

Several entities will need to be involved in the regulatory process in Zimbabwe, should tenofovir gel be proven efficacious. The Medicines Control Authority of Zimbabwe (MCAZ) is the key regulatory body responsible for product licensure, while the MoH oversees overall HIV prevention programmes. The National Medicines and Therapeutics Policy Advisory Committee (NMTPAC) has the mandate to advise the MoH on the introduction of new drugs into Zimbabwe. Ad hoc expert committees are convened to review data and make a recommendation to NMTPAC as to whether or not a new drug should be introduced. Then the NMTPAC makes a recommendation to the MoH, which ultimately determines whether a drug will be made available in Zimbabwe. Licensure by MCAZ is an essential step before the MoH draws up guidelines for use and distribution. Given MCAZ's central role in reviewing clinical trial data it may be useful to involve this group as soon as possible to speed the approval process in Zimbabwe.

Programmes and Strategy

The public health system in Zimbabwe has a number of programmes that could potentially serve as the setting for introducing tenofovir gel. Some key elements of these programmes are summarised below.

Condoms

Male condoms

Zimbabwe has developed a strong infrastructure for condom distribution from the national to community levels, including social marketing initiatives. In 2008, 95.5 million male condoms were distributed, although the current 2011–2015 strategic plan's annual target of 150 million has not yet been met. Reported condom use is relatively high during high-risk sex (47 percent of females; 71 percent of males), but condom use with regular partners remains low (4 percent of females, 8 percent of males) (Fraser et al. 2011).

Female condoms

Female condom promotion and distribution is spearheaded by the MoH, the Zimbabwe National Family Planning Council (ZNFPC) and Population Services International (PSI). Female condoms are sold through pharmacies and hair salons, as well as barber shops, sex worker networks, and support groups for PLHIV. Female condom distribution has been relatively successful in Zimbabwe. For example, between 2004–2007 Care brand female condom distribution increased by 150 percent and public sector distribution tripled (CHANGE 2009). Although delivery of tenofovir gel will be different, involving the formal health system to manage testing, monitoring and other issues, experience with the female condom can help inform how programmes in Zimbabwe and elsewhere can successfully reach women with a new female-initiated prevention technology.

PMTCT

Provision of PMTCT services in Zimbabwe has continued to improve. In 2009, 56 percent of pregnant women who tested positive for HIV benefitted from antiretroviral (ARV) prophylaxis, although HIV testing reached only 46 percent of pregnant women (UNICEF 2010). At the end of 2009, 55 percent of ANC facilities were registered to offer comprehensive PMTCT services and the rest were providing a minimum package of PMTCT services. More efficacious treatment regimens for mothers were piloted and the PMTCT treatment guidelines were amended in 2010 (Ciaranello et al. 2011).

HIV Testing

Overall testing availability and use is relatively high in Zimbabwe. HIV testing and counselling (HTC) has evolved to a nationwide programme of provider-initiated testing and counselling (PICT). HTC services are provided through mobile outreach, workplace programmes, and family planning clinics. These services are also available at Level 1 health facilities, a large proportion of which offer PICT and voluntary counselling and testing (VCT). The 2011 ZDHS reported generally uniform coverage rates (79–82 percent) of HIV testing among women across all age groups.

With the advent of the WHO guidelines suggesting initiating treatment at a CD4 count of 350, the NAC has encouraged people to be re-tested so that they may be put on ARV treatment (NAC 2013). While data on re-testing is minimal, programme experience and estimates suggest an increase in re-testing among people who have previously tested HIV negative. This has been attributed to increased access to ART medication. Further analysis of these clients and programmes may provide insights for structuring the testing and re-testing that will be needed for ARV-based prevention implementation. While it is possible that adding tenofovir gel may create a burden for the already taxed HIV testing system, it would also give providers something to offer to women who test negative, and potentially attract women to HIV testing services.

Financing

Both domestic and international sources of support have funded Zimbabwe's HIV and AIDS response. The Government of Zimbabwe's main source of domestic funding is generated through the NATF. The Ministry of Finance channels these funds directly to the NAC. According to the UNAIDS 2012 country report, NATF contributed approximately US\$5 million in 2009, US\$20.5 million in 2010, and US\$26.5 million in 2011 towards HIV programmes. Approximately 50 percent of these funds were used for ARV procurement, and the remainder supported other HIV programmes, administration and coordination (UNAIDS 2012).

International contributions for HIV and AIDS also increased sharply from approximately US\$54 million in 2009 to US\$114 million in 2010, attributable in part to monies from Global Fund Round 8 Phase 1 funds (UNAIDS 2012). During this time, the proportion of total HIV/AIDS spending for prevention decreased from 39 percent in 2006 to 22 percent in 2009, reflecting the shift of resources and programme emphasis to treatment roll-out. Of the 2009 expenditure for prevention, over 40 percent was spent on PMTCT activities; about 17 percent on communication for social and behaviour change; and about 15 percent on VCT.

Given that the challenging economic climate in Zimbabwe will likely remain a significant barrier to government financing for tenofovir gel introduction, external agencies will be needed to help support the cost of both programming and subsidizing product, at least initially.

Looking Ahead

Zimbabwe can build on its policy and scientific capacity to determine whether tenofovir gel offers added benefits relative to costs within the evolving context of prevention interventions, including relatively new approaches such as treatment as prevention, medical male circumcision and oral pre-exposure prophylaxis. If Zimbabwe determines that tenofovir gel would be a useful addition to its HIV prevention programme, pilot demonstration projects will be critical to determine the most strategic entry points for tenofovir gel introduction. These may include services for family planning, and HIV testing and re-testing, as well as programmes for post-partum women and sero-discordant couples. Such projects would assess the overall feasibility of introduction as well as identify ways to address specific operational issues. Zimbabwe's momentum in reducing HIV, experience with new technologies and clinical trials, as well as its capacity for operations research, makes it a conducive setting to design and conduct such demonstration projects, and initial planning and protocol development can begin now.

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