

Program and Policy Considerations for Tenofovir Gel in India: An Overview



India's strong commitment and capacity to address the HIV epidemic contributed to a more than 50 percent decline in new HIV infections from 2000 to 2009 (UNAIDS 2012). The initial response focused on awareness generation and preventing HIV acquisition in the general population. As data and experience led to a deeper understanding of the epidemic, a targeted approach has emphasised containing HIV transmission from high-risk groups to the general population. Importantly, India has also provided a growing programme of treatment and care for people living with HIV.

Globally and in India, women face significant social and economic vulnerability to HIV. Currently, women constitute more than one-third (39 percent) of the HIV-positive population in India (NIMS/NACO 2012), and many more are vulnerable to acquiring HIV and other sexually transmitted infections (STIs). Overall women have lower social status than men, and many women have little or no capacity to control or make decisions about their sexual lives. Men's risk-taking behaviour increases women's HIV risk.

An effective female-controlled HIV-prevention method could mitigate women's risk. Renewed interest and new designs for female condoms are slowly improving access; efforts in India are focused primarily on female sex workers. Vaginal microbicides are another potential tool that women could use to protect themselves from HIV acquisition, and research to identify an effective microbicide continues.

Indian researchers have actively collaborated in global efforts to find an effective vaginal microbicide, and clinical trials for several candidate products have included sites in India (Joshi et al. 2005; Joglekar et al. 2007; Van Damme et al. 2008; Mehendale et al. 2012). Tenofovir gel is the only candidate microbicide that has been shown to be effective in a clinical trial, although results from tenofovir gel trials have been mixed. The CAPRISA 004 trial in South Africa showed a 39 percent reduction in women's risk of HIV infection compared with a placebo, providing the first clinical evidence that a vaginal gel can be effective in HIV prevention (Abdool Karim 2010). Women



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in the CAPRISA trial were counseled to use the gel before and after sex. The VOICE trial tested daily tenofovir in both oral pill and vaginal gel forms, as well as daily oral Truvada; none of these three products showed an effect in reducing the risk of HIV acquisition, likely due to low adherence. (Marrazzo, et al. 2013). FACTS 001, a large-scale trial under way 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 will provide a clearer picture of tenofovir gel effectiveness.

Background on this Brief

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 effective. One of these is a Guide to assist policymakers and programme managers in identifying the most strategic opportunities for introducing tenofovir gel. The Guide 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, reviews the epidemiologic context of the HIV epidemic, highlights key policies and programmes related to HIV, and provides other information relevant to potential introduction of tenofovir vaginal gel in India. It draws on a desk review of peer-reviewed and grey literature as well as interviews with key decision-makers (Prabhughate, et al. 2014). The full report and annexes are available at www.popcouncil.org.

The policy and programme review summarised here underscores a generally favorable environment for introducing tenofovir gel in India, although the costs and benefits of such an effort would need further consideration.

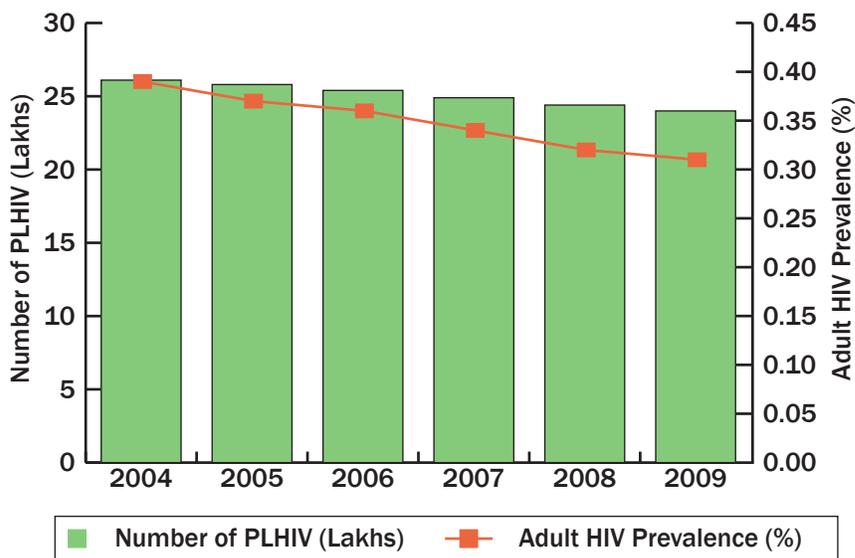
India has long been an early adopter of innovations in health as well as in other sectors. It has a robust and growing pharmaceutical industry known for low-cost drug production and, increasingly, for research and development of new drugs. At the same time the overall direction of HIV programming to-

ward comprehensive prevention and integrated services suggests that tenofovir gel could potentially be incorporated into the health system and provided to different user groups.

The HIV Epidemic in India

The 2011 national sentinel surveillance estimated that 1.9 million people in India aged 15 and older were living with HIV (NIMS/NACO 2012). An estimated 39 percent are women. This represents a decline in the total number of people living with HIV (PLHIV) and prevalence of HIV in the country (see Figure 1) (NACO 2012). This decline has varied across states. Although HIV prevalence declined in six high-prevalence states¹ from 2007–2011, it increased in 11 other states (NIMS/NACO 2012).² Along with declining prevalence overall, there was also a downward trend in incidence and AIDS-related deaths from 2000–2009 (see Figure 2). In 2011, there was a further marginal decline in new infections (1.16 million) and AIDS-related deaths (1.5 million) (NIMS/NACO 2012). The reduction in deaths has been attributed to free antiretroviral treatment (ART) made available since 2004 (NACO 2012).

Figure 1 Trend of HIV prevalence in India (2004–2009)

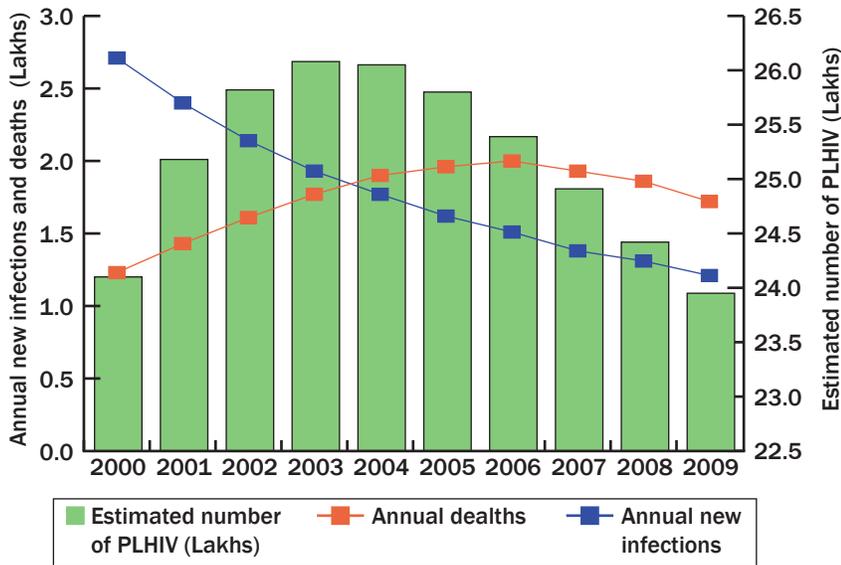


Source: Technical report on HIV estimations 2010

¹States where HIV prevalence declined between 2007 and 2011: Andhra Pradesh, Karnataka, Maharashtra, Manipur, Nagaland, and Tamil Nadu.

²States where HIV prevalence increased between 2007 and 2011: Arunachal Pradesh, Assam, Chandigarh, Chattisgarh, Delhi, Jammu and Kashmir, Jharkhand, Kerala, Odisha, Punjab, Tripura, and Uttarakhand.

Figure 2 Trend of prevalence and incidence of HIV, and deaths due to AIDS in India (2000–2009)



Source: Technical report on HIV estimations 2010

The main route of HIV transmission is unprotected sex (87.4 percent heterosexual and 1.3 percent homosexual), except in northeastern states where injection drug use is the predominant route of transmission (NACO 2011a). The epidemic is concentrated, as prevalence remains high among specific high-risk groups (now often referred to as most-at-risk populations), which include injection drug users, men who have sex with men, and female sex workers, and bridge populations of male migrants and truckers (see Figure 3) (NACO 2012). In 2009, prevalence among high-risk groups was much higher than the national prevalence—9.2 percent in injection drug users, 7.3 percent in men who have sex with men, and 4.9 percent in female sex workers (UNAIDS 2010).

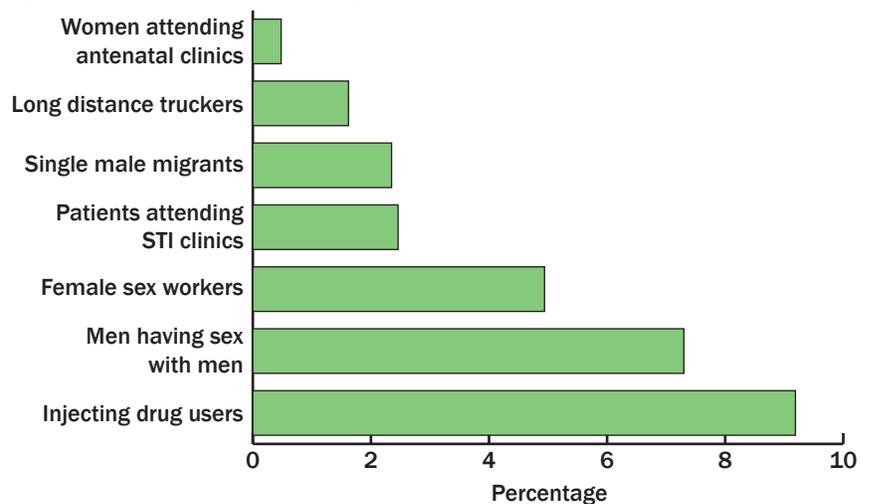
In response, the National AIDS Control Programme-III (NACP-III, 2007–2012) emphasised targeted interventions for prevention focused on high-risk groups and bridge populations. These were peer-led interventions implemented through nongovernmental organizations (NGOs) and community-based organizations (CBOs) supported and monitored by government agencies.

Women’s Vulnerabilities and Risks

A variety of social and economic vulnerabilities place women at risk of HIV. Female sex workers’ particular vulnerabilities are recognised in the NACP, with concomitant programme responses. While the NACP now identifies women as a vulnerable population, many other risk factors specific to women are not addressed in the programme. These include: young age at marriage; male migration; men who have sex with men and women; and intimate partner violence.

Age at marriage. Many women in India marry at a young age: 74 percent of married women are married before age 20 (IIPS and Macro International 2007). In some states,³ more than 50 percent of women get married before age 18, the minimum legal age. The young age of marriage corresponds with early sexual intercourse, and with other social and health risks. Marriage and first sexual experience at an early age expose women to a prolonged period of vulnerability to acquiring HIV and other STIs from their husbands. Women married as adolescents are also at increased risk of marital violence (see below) (Raj et al. 2010).

Figure 3 HIV prevalence among HRGs in India (2008–2009)



Source: HIV sentinel surveillance, 2008–2009

³These states include: the northern states of Bihar, Chattisgarh, Jharkhand, Madhya Pradesh, Rajasthan, Uttar Pradesh, and West Bengal, and the southern state of Andhra Pradesh.

Male migration. Recent research regarding migration underscores that partner migration increases women's risk of acquiring HIV. A case-control study in seven districts with high rates of out-migration among men found that HIV prevalence was higher among women with migrant husbands. Attributable risk for women associated with male migration ranged from 32.7 percent to 56.9 percent (Saggurti et al. 2012).

Men who have sex with men and women. Research among men who have sex with men and women confirms women's increased risk of acquiring HIV. Studies with men who have sex with men and women have shown that women are at risk of HIV acquisition due to unprotected sex or inconsistent condom use. (Phillips et al. 2010; Dandona et al. 2004).

Intimate partner violence. Married women and female sex workers experiencing physical or sexual intimate partner violence are at risk of acquiring and/or transmitting HIV infection. Violence or fear of violence may limit women's ability to exercise choice in sexual activity and/or condom use. In the 2006 National Family Health Survey (NFHS), more than one-third of married women reported physical intimate partner violence from their husbands (IIPS and Macro International 2007). Those women experiencing both physical and sexual IPV were four times more likely to have HIV than women not experiencing intimate partner violence (Silverman et al. 2008). Female sex workers are also vulnerable to intimate partner violence, with a number of implications for their sexual and reproductive health. Female sex workers experiencing intimate partner violence are at greater risk of HIV acquisition due to inconsistent condom use and a range of other reproductive health problems, including pregnancy, pregnancy loss, and forced termination of pregnancy (Swain et al. 2011; Deering et al. 2011).

Key Health Issues and Implications for Tenofovir Gel

Contraception and dual protection. The overall contraceptive prevalence rate in India is 56 percent (IIPS and Macro International 2007) and the vast majority of those using contraception use modern methods: condoms, injectables, intrauterine devices, male and female sterilization, pills. Importantly, female sterilization accounts

for two-thirds of total contraceptive use and 77 percent of modern method use (IIPS and Macro International 2007). The widespread use of female sterilization as a family planning method can compromise women's ability to negotiate condom use. Husbands of sterilised women are not likely to perceive the need for using any contraceptive method, and in India there is little knowledge and awareness about the use of condoms as a "dual protection" method for family planning and HIV prevention. This underscores the need for a woman-controlled HIV-prevention method like tenofovir gel.

Maternal health. The maternal mortality rate (MMR) has been declining across all the regions of India in the past decade, but this decline has been uneven. Although MMR has declined in the Empowered Action Group states,⁴ it remains high (308 as of 2009). In contrast, the southern states⁵ lower MMR of 127 as of 2009 provides hope of achieving the Millennium Development Goal target of 109 (Office of Registrar General, India 2011).

STIs and reproductive tract infections (RTIs). A 2009 National AIDS Control Organization (NACO)-led review and analysis found variation in the rates of STIs/RTIs (NACO 2009) and a considerable burden of STIs among women. HSV2 seropositivity (IgG) was somewhat higher in women compared to men in the general population (NACO 2009).

Women's vulnerability and increased HIV risk is evidenced in the epidemiology of HIV as well as indicators of family planning and maternal health. A woman-controlled HIV- prevention product such as tenofovir gel that women can access and use would be of value in mitigating this risk.

Policy Environment

Soon after identification of the first HIV case in India in 1986, the national government responded with policies and well-structured initiatives focused on generating data and designing programmes to address the emerging patterns

⁴The Empowered Action Group states are: Assam, Bihar, Chattisgarh, Jharkhand, Madhya Pradesh, Odisha, Rajasthan, Uttar Pradesh, and Uttarakhand.

⁵The southern states referred to above are: Andhra Pradesh, Karnataka, Kerala, Tamil Nadu.

of the HIV epidemic in the country (NACPP 2002).⁶ Each initiative had specific objectives and strategies (NACO 2002; NACO and Ministry of Health and Family Welfare 2006). As the national programme evolved over the last two decades, NACO has developed several policy and operational guidelines, which are updated periodically and available at http://nacoonline.org/About_NACO/Policy_Guidelines/Policies_Guidelines1.

Since 2002, the National AIDS Control and Prevention Policy (NACPP) has provided overall direction and guidance for HIV and AIDS programming (NACPP 2002). The NACPP underscores the government's commitment to HIV prevention and emphasises the responsibility of both public and private entities. It recommends decentralization of the HIV and AIDS control programme and supports integration into other national programmes. The NACPP seeks to decrease vulnerability to HIV among key groups including women and children. It underscores the need to provide health care to HIV-positive people and reduce stigma and discrimination. Strategies include promoting HIV knowledge and safe behavioural practices among students, youth, and other sexually active populations, and voluntary blood donation to ensure safe blood supply.

The public, nongovernmental, and private sectors are involved in providing care, support, and treatment as well as preventive services. The public sector has been the main provider of preventive services, while the government is receptive to the involvement of the private and nongovernmental sectors. The government provides a conducive environment for national and international NGOs to pilot programmatic innovations. It generally requires approval from NACO consistent with public sector regulation of new initiatives. The public sector is generally open to collaboration to determine how best to integrate proven products and interventions into the public programme.

Programme and Strategy

The National AIDS Control Programme (NACP-III), operational from 2007-12, drew on lessons from earlier programmes and on consultations with nongovernmental and community-based stakeholders. In contrast to earlier programmes, it emphasised behaviour change

⁶Programmes initiated included the Medium Term Plan (1990–92), the first plan (NACP-I, 1992–99), second plan (NACP-II, 1999–2006), and the NACP-III (2007–12).

rather than awareness generation, a more decentralised response, and increased involvement of NGOs and networks of people living with HIV. NACP-III aimed to halt and reverse the epidemic by integrating prevention with services providing care, support, and treatment.

Prevention. NACP-III's primary focus was on prevention given that that vast majority of people in India are HIV negative. Accordingly, more than two-thirds of the total resources were earmarked for prevention activities. The programme adopted a three-pronged approach to reducing the overall epidemic which prioritised saturating high-risk groups and bridge populations with prevention messages (Ministry of Health and Family Welfare 2006). The programme also aimed to address clients of sex workers through providing condoms, social marketing campaigns, and projects with men in occupational settings. Finally, it prioritised outreach to high-risk groups in rural areas, and to other highly vulnerable groups: children, youth aged 15–19, and women.

Prevention programmes were linked with care, support, and treatment to ensure continuity of care. Specific prevention services offered include targeted interventions for high-risk groups and bridge populations, such as needle-syringe exchange and opioid substitution therapy for injection drug users; prevention interventions for migrant populations at source, transit, and destination settings; and Link Worker Schemes⁷ for vulnerable populations in rural areas. Broader programmes for both high-risk groups and the general population include: prevention and control of STIs/RTIs; blood safety; HIV counseling and testing; prevention of parent-to-child transmission; condom promotion; and information, education, and communication, and behaviour change communication.

Care, support, and treatment. Care, support, and treatment programs offer a comprehensive set of services despite commanding less than 20 percent of overall programme resources. These include: laboratory services for CD4 testing and other research, early infant diagnosis, nutritional and psychological support through Community Care Centres, drop-in centres for people living with HIV, and coordinated HIV-TB services and treatment. The programme offers free first-line and second-line ART through

⁷The Link Worker Scheme is an approach to identify and train a village-level workforce on issues of HIV/AIDS, gender, sexuality, and STIs, who reach out to high risk groups and vulnerable populations in rural areas.

a range of service settings (see Figure 4) including pediatric ART and treatment of opportunistic infections. Tenofovir oral tablets are included in the regimen of first-line ART and provided through the service delivery system.

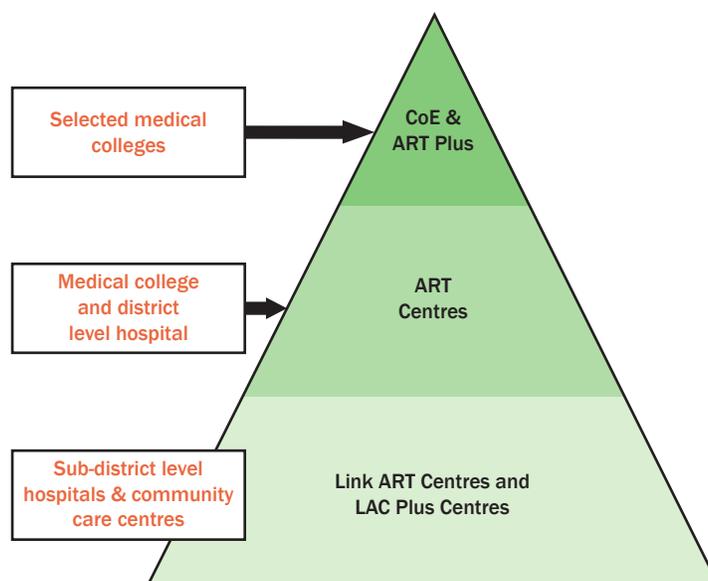
Antiretroviral (ARV) service delivery. Access to free ART, initiated in 2004 in six high-prevalence states, has expanded rapidly, and second-line therapy is now also available in a limited number of ART Plus Centres. A structured service-delivery system aims to reduce loss-to-follow-up and ensure continuity of care and access to the entire spectrum of treatment, care, and support services. NACP-IV, operational through 2017, emphasises scaling up access to ARVs and to treatment and prevention for opportunistic infections, as well as strengthening linkages among relevant service-delivery systems (NACO 2011b).

Focus on women. Many national policies have acknowledged women's vulnerability and HIV risk, and that it derives from diverse factors that limit women's access to health services and control in sexual decision making. Under NACP-III concerted efforts were made to mainstream HIV/AIDS interventions for women's empowerment, and guidelines were developed to ensure gender-sensitive HIV interventions for both men and women (NACO 2012).

The female condom programme, initiated in 2008, is now in its second phase. This programme, focused mainly on female sex workers, emphasises capacity building, training, and behaviour change communication activities to increase use of female condoms. After successful implementation in four states,⁸ the programme has been scaled up through a social marketing organization contracted by NACO.

Integration of HIV with other health services. Both the NACP and Department of Health and Family Welfare (DHFV) have addressed integration of HIV and sexual and reproductive health. In 2010 a joint committee identified areas of convergence between NACO's programmes and India's core programme on maternal health (Ministry of Health and Family Welfare N.D.). The rationale was to leverage the technical progress of the AIDS programme managed by NACO and the extensive infrastructure of

Figure 4 Structure of ART service provision



the DHFW programmes. Areas identified for convergence have included RTI/STI service provision, voluntary counseling and testing, prevention of parent-to-child transmission, and condom promotion. While operational issues have limited implementation of the plan for convergence (Ahsan 2011), several states highlight examples of successful integration.

Regulatory Environment

The Drug Controller General of India (DCGI) is the licensing authority that must approve the manufacture and/or marketing of any new drug in India (Government of India). A drug approved by the DCGI must be re-registered as a new drug for each new route of administration (Central Drugs Standard Control Organization)⁹. This means that while tenofovir is approved by the DCGI as an oral tablet and included in first-line ART treatment in the national ART guidelines, the vaginal gel will need to be registered as a new drug and for a new indication in the Indian market.

The regulations for import of new drugs¹⁰ stipulate that trials need to be carried out in India in accordance with guidelines provided by the Central Drugs Standard Control Organization (CDSCO)¹¹. The DCGI can waive the requirement for trials in India after considering data from other countries. The DCGI may grant a waiver in consideration of the larger public interest, or if the new drug has

⁸Andhra Pradesh, Maharashtra, Tamil Nadu, and West Bengal.

⁹Rule 122-Eb of the Drugs and Cosmetics Act (CDSCO N.D.)

¹⁰Rule 122-A of the Drugs and Cosmetics Act (CDSCO N.D.)

¹¹Schedule Y (Government of India 2005)

been approved and marketed for several years in other countries and the DCGI is satisfied that the published evidence regarding the drug's safety is adequate. To register a new drug, manufacturers have to submit an application to the CDSCO as per the guideline for submitting a Common Technical Document (CDSCO 2011).

Financing

Currently, nearly all of the overall expenditure on health in India comes from within the country, with an estimated 70–75 percent from the private sector, broadly defined. Importantly, most of this is out-of-pocket expenditure by individual consumers (WHO 2012). In contrast, the government's HIV programme is largely funded by external aid, with an estimated 69% of the most recent budget for the NACP coming from external sources (NACO 2012). At this time it is not clear whether tenofovir gel would be financed through the public or private sectors or both, nor what role external donors would play in financing procurement and delivery of tenofovir gel.

Partnerships

India's commitment to building collective responsibility for HIV and AIDS programmes is demonstrated in the mainstreaming initiatives of NACO (NACO N.D.). Chaired by the Prime Minister of India, NACO includes 31 ministries and departments in an effort to mainstream the programme at national and state levels. NACO also partners with other sectors, including corporations and civil society organizations. It has a number of ongoing partnerships with community-based organizations and NGOs, especially those that provide targeted interventions to high-risk groups. Recognizing the importance and long-term sustainability of these partnerships, NACO includes civil society representatives in programme and policy development (NACO N.D.).

The most notable public–private partnership is the targeted Condom Social Marketing Programme involving seven social marketing organizations in 13 states. The programme has led to greater condom availability for vulnerable populations. Other partnerships with the private sector include workforce interventions in which companies provide human resources and infrastructure for ART centres for their employees while NACO supports the cost of testing facilities and drugs for the community (NACO N.D.).

Looking Ahead

India is at a critical juncture in the course of its HIV epidemic. Although the country's national effort and focused programming have begun to have an impact, many challenges remain and new ones are emerging. These include the increase in prevalence in particular states and the challenge of preventing transmission from bridge populations to the general population. The growing recognition of the need to reduce HIV transmission through bridge populations creates a potential for introducing tenofovir gel, as it could be used by diverse women who are vulnerable to HIV infection.

The current prevention programme emphasises condom promotion, and including female condoms among prevention options is relatively new. If tenofovir gel becomes available, it could provide an additional option. Several service delivery points could be used to offer tenofovir gel to women if it is determined that it is appropriate and cost-effective in India. The extensive coverage achieved through targeted interventions for female sex workers offers a potential opportunity for delivering tenofovir gel in India. However, careful attention would be needed to ensure that introducing tenofovir gel would not undermine successful condom promotion efforts. The tiered service-delivery points in the ART structure may provide a setting to offer tenofovir gel to women who test negative. Tenofovir gel could also be offered to women at high risk of HIV infection, such as partners of IDUs, male migrants, and truckers at targeted service-delivery points.

The policy environment in the context NACP-IV provides an important opportunity for promoting specific interventions that can empower women to manage their HIV risk. Consultative meetings with stakeholders involved in NACP-IV planning and implementation are an important venue for targeted information about vaginal HIV-prevention products including tenofovir gel. Awareness generated through such efforts can ensure that policies and programmes are conducive to introducing tenofovir gel if and when its effectiveness is established.

Introduction of tenofovir gel will, however, have to overcome certain challenges including convincing the DCGI of its potential benefits in a larger public health context. Clear findings from the ongoing FACTS 001 trial and approval by drug licensing authorities in other countries will be needed to waive the requirement for conducting

another trial in India. Post-approval, pilot and operational studies will also be important to understand user perspectives around tenofovir gel in both general populations and female sex workers. Finally, studies demonstrating the feasibility and impact of adding tenofovir gel to the package of prevention services will be necessary to inform decision making and programming approaches.

The overall policy context reflects that India has the political commitment, legal environment, and administrative structures and guidelines to support introduction of new products and technologies to address the HIV epidemic. It also has a proven ability to promote new products through social marketing partnerships. At the same time, the only programme exclusively focusing on women is the female condom programme and there has been limited progress in integrating HIV and reproductive health services. Ultimately, careful analysis will be needed to weigh whether the challenges and costs associated with tenofovir gel introduction offer sufficient benefit in the context of India's HIV epidemic and response.

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