



REVIEW ARTICLES

Implementation Status and Efficacy of PrEP as Part of India's HIV Prevention Strategy: A Review

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Abstract: India faces a significant burden of HIV/AIDS, with a substantial number of new infections reported annually. To combat this epidemic, the implementation of new and effective preventive strategies is critical. PrEP (Pre-exposure prophylaxis), a biomedical intervention involving the use of antiretroviral medication to prevent HIV transmission in high-risk individuals, has emerged as a promising tool in the global fight against the spread of the virus. This review explores the implementation and impact of PrEP in India's efforts to combat HIV/AIDS, focusing on key populations such as men who have sex with men, transgender individuals, female sex workers, and people who inject drugs. A comprehensive review of acceptability among key populations, highlighting concerns, motivations, and barriers is presented. The paper underscores the importance of targeted awareness campaigns, anti-stigma initiatives, and persistent advocacy for comprehensive sexual health education to maximise PrEP's potential in India's fight against HIV/AIDS.

Keywords: HIV, FSW (Female Sex Workers), India, MSM (Men who have sex with Men), PrEP, Transgender

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Background

Human Immunodeficiency Virus (HIV) and its subsequent advanced stage of infection, Acquired Immunodeficiency Syndrome (AIDS), have had a profound impact on global health since their first reported cases in the early 1980s.

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Initially identified among sexually active gay men in Los Angeles, the disease rapidly spread, leading to a surge in opportunistic infections and immune-related disorders within the affected communities. The Centers for Disease Control (CDC) in the United States introduced the term AIDS in 1982, defining it as a condition resulting from a dysfunctional immune response, particularly prevalent in the homosexual community.

After the first initial disease outbreak in India in the 1980s, the epidemic primarily affected high-risk groups, including FSW, MSM, and IDU (intravenous drug users) (Paranjape & Challacombe, 2016). However, the heterosexual pathway was responsible for the majority of transmissions (Paranjape & Challacombe, 2016). Initially, infections primarily affected truck drivers and female sex workers, but they quickly spread to housewives and the wider public. Men having sex with men (MSM) both involved and not involved in sex work, injecting drug users (IDU), and migrant workers and their spouses currently have the highest prevalence.

As of 2021, the national adult HIV prevalence has come down to 0.21% in India with a significant decline since the peak in 2000 (0.55%). According to the National AIDS Control Organisation, around 2.4 million people today are HIV-positive, and regional variations have been highlighted in terms of prevalence with the highest being the northeastern states of Mizoram, Nagaland, and Manipur. Despite a steady decline in HIV prevalence, India still grapples with the world's third-largest HIV epidemic. The majority of early efforts to stop the spread have focused on educating, informing, and communicating with important groups of people. Enhancing the accessibility of condoms and promoting their use, along with treating sexually transmitted infections, have been crucial elements of preventative initiatives.

At present, no cure exists for HIV infection, but advancements in ART (Antiretroviral therapy) have transformed the disease from a fatal condition into a chronic one. ART helps in reducing the viral load in infected individuals, allowing them to lead healthier and longer lives. India's primary HIV prevention measures have included increasing access to antiretroviral medication (ART), preventing mother-to-child transmission, and enhancing capacity building in addition to the introduction of free ART, scaling up PMTCT (preventing mother-to-child transmission) programmes and decentralisation of program implementation. However, difficulties in adherence to ART have resulted in the emergence of drug-resistant strains that ultimately present challenges in managing the disease globally, particularly in developing nations like India committed *"towards the attainment of United Nations' Sustainable Development*

Goals 3.3 of ending the HIV/AIDS epidemic as a public health threat by 2030 through a comprehensive package of prevention, detection and treatment services" (Belludi et al., 2021) (Sahay, Bangar & Chandhiok, 2023).

In response to the growing epidemic, researchers have developed Pre-exposure prophylaxis (PrEP), a preventive measure for individuals at high risk of contracting HIV. PrEP involves taking antiretroviral medications regularly to reduce the risk of infection through sexual contact or drug use. It has proven highly effective when used consistently, providing an essential tool in the fight against HIV transmission. PrEP is not a drug to prevent other STDs; it is only for HIV prevention. The United States Food and Drug Administration first granted approval for the HIV prevention drug PrEP in 2012 (Tetteh et al., 2017). After studies carried out in Europe demonstrated that PrEP helped reduce HIV risk among MSM (Men Having sex with Men) and transgender women, the World Health Organisation also encouraged its usage in 2015. Daily pill consumption affects how well PrEP works because research has indicated that the more days a week an HIV-negative person who is at high risk of catching the disease takes PrEP medication, the greater the risk reduction. When taken as directed, PrEP lowers the chance of contracting HIV by 99%, and for those who inject drugs, the medication is at least 74% effective when used as directed.

While PrEP is currently not a part of India's National HIV Prevention Strategy, to adopt PrEP, the Indian government has issued national guidelines and has launched experimental/demonstration projects. To guarantee fair access to and efficient application of this life-saving strategy, however, more work still needs to be done. India can take major steps towards HIV/AIDS control and safeguarding the health and well-being of its inhabitants by tackling the obstacles and utilising PrEP's enormous potential. This review study aims to critically analyse the impact of PrEP on national AIDS control strategies and gain a thorough grasp of its implementation status and efficacy in key populations across the nation.

Methods and Methodology

The research articles reviewed in this paper have been obtained through the search engines PubMed and Google Scholar. The keywords used for the search were various combinations of 'PrEP', 'India', 'MSM', 'Transgender', 'FSW', and 'HIV'. All studies have been conducted between 2015 and 2023 as PrEP was approved by the Drug Controller General of India in 2016. All the research articles chosen were open access distributed under the Creative

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Acceptability

The Indian government has declared the national PrEP technical guidelines. However, understanding the challenges that key populations have in accessing HIV prevention services, as well as their level of awareness, willingness to utilise PrEP, and perception of its efficacy are the crucial first steps in implementation research.

Indian Council of Medical Research task force on HIV prevention commissioned a study on the acceptability of PrEP among MSM and TGW (Transgender Women) in metropolitan cities (Ramanaik et al., 2023) which revealed that compared to the MSM group, TGW populations in both Delhi and Bengaluru had a greater grasp of PrEP having heard of it through peer networks, the internet, social media, and NGOs; though were uncertain about its cost, availability, consumption instructions, or impact on HIV prevention. A small percentage of individuals from both communities even confused PEP (post-exposure prophylaxis) with PrEP. Perceived motivations for using PrEP varied slightly, across MSM and TGW with transgender people positively assured of PrEP's efficacy in HIV prevention despite their frequent violent sexual encounters or serodiscordant relationships. Men who have sex with Men perceived PrEP to be an effective way of keeping their sexual orientations a secret within households in place of condoms. Concerns about PrEP in India's MSM and transgender communities revolve around supply chain disruptions, high costs impacting sex workers, and potential stigma due to similarities with ART. Travelling Hijras and late working hours raise adherence concerns. Participants suggest free or low-cost PrEP, accessible through familiar outlets like NGO offices and self-service condom points, to overcome these barriers and encourage PrEP use in this vulnerable population.

Additionally, a qualitative study on the acceptability of PrEP among transgender women (Chakrapani et al., 2020) reiterates the findings of Ramanaik et al. (2023). while adding that concerns about PrEP among India's TGW community also include potential misuse by younger individuals in sex work-seeking corrective-surgery funds, who might abandon condom use due to PrEP's effectiveness. Alcohol use as well as stigma around disclosure also raise concerns about adherence and secrecy. Potential drawbacks were anticipated interactions with feminising hormones, obvious side effects, and associated stigma. To address these, TGW and healthcare providers suggest

options like intermittent or event-driven PrEP while emphasising continued condom use. Tackling the stigma surrounding sex work, drug use, and HIV remains crucial for successful PrEP implementation among this vulnerable population.

A cross-sectional survey of the MSM of India (Chakrapani et al., 2021) revealed that willingness to use PrEP was strongly and independently correlated with both PrEP eligibility and perceived HIV risk. A subset of MSM who qualified for PrEP, however, expressed a lack of willingness to utilise the treatment, which was linked to a low perception of HIV risk and a poor impression of PrEP's advantages. A similar study on PWID (people who inject drugs), and MSM in a multi-city community-based cross-sectional survey (Belludi et al., 2021) reinforced the severe lack of awareness among these key populations with a higher percentage of MSM expressing WTUP (willingness to use PrEP) against PWID. One-third of PWID who declined PrEP cited low perceived HIV risk. Other reasons included: concerns about side effects (for both oral and injectable PrEP), fear of stigma about being mistaken for already having HIV/AIDS, and potential cost concerns. It is suggested that using the existing service pathways for PWID such as syringe service programs could be better suited for PrEP delivery as the use of these programs was found to be significantly correlated with increased acceptance of PrEP and a willingness to use.

Demonstration Projects

To understand how to effectively implement PrEP rollout in “real world” settings and ensure key populations are targeted to optimise PrEP efficacy in HIV prevention with continued support for adherence, the World Health Organisation has requested that demonstration projects be carried out in various geographical locations to assess PrEP's efficacy outside of clinical studies (Sahay, Bangar & Chandhiok, 2023). Since 2015, two such projects have been carried out at two different locations within the country.

Kolkata's high HIV prevalence among sex workers (FSWs) led to a PrEP demonstration project run by the *Durbar Mahila Samanwaya Committee* and its peer educators (trained FSWs) (Jana et al., 2021). Launched in 2016, the project enrolled 678 FSWs and emphasised “double protection” with condoms and PrEP. Notably, adherence was high (70%) and dropout rate low (11%). While self-reported sexual behaviour remained unchanged, a significant decrease in STI treatment suggests PrEP did not increase risky behaviour and there were no seroconversions. Mild gastrointestinal side effects affected about 25% of

participants initially. Overall, the project showed promising results for PrEP's feasibility and effectiveness among FSWs in Kolkata.

Similarly, Ashodaya Samithi's PrEP project in Mysore-Mandya (Reza-Paul et al., 2020) involved thorough preparation, starting with awareness sessions and a feasibility study. The main project (March 2016 - February 2018) enrolled 647 sex workers from an initial pool of 707 eligible FSWs. The project achieved remarkable success, boasting high retention (98.92%) and reported adherence (97.97%). This success is attributed to the intensive community engagement process, empowering sex workers to make informed decisions. Notably, the project revealed high acceptability of PrEP alongside positive outcomes: no HIV infections, no STI increase, and stable condom use. These results suggest PrEP's promising potential for sex workers in similar settings.

Both PrEP demonstration projects in India were met with positive reception and continued demand for post-project access. While some participants initially benefited from surplus PrEP tablets, this supply has since run out (Reza-Paul et al., 2019). To address this gap and advocate for wider PrEP adoption, the organisations involved are actively utilising media coverage and advocacy efforts to push for PrEP inclusion in India's national HIV prevention strategy. This highlights the urgent need for broader PrEP availability to sustain the positive momentum gained from these successful pilot projects.

Community-led Implementation

While PrEP offers immense promise for HIV prevention among transgender and gender-diverse individuals (MSM and TGW) in India, its acceptability faces myriad challenges rooted in socio-cultural contexts. Exploratory research, conducted in collaboration with communities, is crucial to identify these barriers. For instance, concerns around adherence to unpredictable schedules, potential interactions with hormonal therapy, and stigma within communities were uncovered. Customised approaches based on community involvement and cultural sensitivity are the need of the hour to address these issues. In both of the demonstration projects primarily sex worker collectives have emerged as successful endeavours and a step towards the eventual establishment of PrEP as one of India's National HIV Prevention Strategy providing concrete evidence of the importance of a community-led implementation strategy.

The Ashodaya PrEP project's astounding success in retaining and engaging participants can be attributed to its long history of community-driven action around sexual health. The project deliberately enrolled senior community leaders first, who then shared their positive experiences with their networks,

leveraging the power of trusted testimonials. Communal experiences of loss to AIDS further strengthened the shared sociality, driving mutual support and willingness to participate in PrEP, regardless of individual HIV status or PrEP desire. An early endorsement from community members living with HIV helped mitigate potential exclusion concerns and encourage enrollment. Ashodaya's model demonstrates that biomedical research can thrive in community-led spaces, where communities play a vital role in shaping and leading interventions (Lazarus et al., 2020). The same has been observed for the DMSC (Durbar Mahila Samanwaya Committee) PrEP project in Kolkata where the Durbar Mahila Samanwaya Committee's over 3 decades of active social work for female sex workers especially in educating, raising awareness, and providing services related to sexually transmitted diseases have created a community space for collective experiences to be shared (Reza-Paul et al., 2019). By training and involving both former and current sex workers in health-related services as peer educators initial screening, subsequent monitoring of adherence and PrEP delivery become much simplified and accessible by the women enrolled in the study ultimately leading to the success of the project (Jana et al., 2021). Such success stories across sites demonstrate that effective HIV prevention goes beyond biomedical solutions and thrives in spaces where communities actively participate in shaping and leading interventions.

Discussion and Conclusion

Social ostracisation and stigma act as barriers to comprehensive sex education and sexual healthcare services especially for the LGBTQIA+ community leading to reduced awareness of seroadaptive behaviours as well as lower use of preventive services such as condoms and HIV testing. While India has witnessed a remarkable decline in HIV prevalence since the 2000s, new infections within key populations continue thereby demanding innovative, easily accessible, and more efficient preventive services to achieve the goal of ending the HIV epidemic (Sahay, Bangar, & Chandhiok, 2023). Antiretroviral therapy though successful in India's fight against HIV is a post-exposure prophylaxis. In such a scenario, PrEP could have tremendous success in preventing HIV in high-risk HIV-negative individuals across the nation. This paper has strived to provide a comprehensive overview of the ongoing implementation research on PrEP being done in India.

Indian trans women face a double barrier in accessing PrEP for HIV prevention: low awareness due to inadequate campaigns and stigma surrounding both PrEP use and HIV status. This study reveals their concerns

about judgment from other trans people and mandatory HIV testing, while also highlighting the impact of healthcare provider discrimination on their willingness to use PrEP (Chakrapani et al., 2020, 2021). To improve PrEP uptake, targeted awareness campaigns, anti-stigma efforts within the community, and addressing healthcare bias are crucial to empower informed decision-making and protect the health of Indian trans women.

While key populations in India, like MSM and transgender women, show some interest in PrEP, implementing it effectively is a tangled task. Both groups struggle with knowledge gaps, unclear costs, and concerns about stigma or medication access. Transgender women specifically worry about misuse by younger sex workers and the impact of disclosure on alcohol use. Tailored interventions, free or low-cost PrEP accessible through familiar channels, and addressing the pervasive stigma around sex work, drugs, and HIV are crucial for success. Additionally, tackling the low perceived HIV risk among some MSM and PWID is essential. Ultimately, ensuring equitable PrEP access requires a multi-pronged approach that acknowledges and addresses the unique challenges faced by each key population.

The demonstration of PrEP projects for sex workers in Kolkata and Mysore-Mandya respectively saw high success. Both achieved strong adherence, low dropouts, and no HIV infections, proving PrEP's effectiveness. Kolkata focused on "double protection" with condoms, while Mysore-Mandya emphasised community engagement. Both strategies worked, highlighting the need for tailored interventions. However, post-project PrEP access has vanished, and wider national adoption is crucial. These projects offer hope for PrEP's potential but overcoming access, advocacy, and sustainability challenges is key to wider impact.

In conclusion, the discourse on pre-exposure prophylaxis (PrEP) in the context of HIV prevention within India illuminates the formidable challenges faced by key populations. Despite successful pilot projects demonstrating PrEP's efficacy, ensuring widespread adoption demands a comprehensive and tailored approach. Targeted awareness campaigns, anti-stigma initiatives, and addressing healthcare biases are essential to empower informed decision-making, especially among marginalised groups. It is imperative for implementation research to widen beyond participants enrolled through CBOs and NGOs to encompass individuals from dating apps, social media, and Pride collectives. While PrEP presents a promising avenue in India's fight against HIV, sustained efforts are needed to bridge knowledge gaps, ensure equitable access, and overcome challenges related to advocacy, sustainability,

and national adoption. The path forward requires a multifaceted strategy that prioritises inclusivity, community engagement, and persistent advocacy for comprehensive sexual health education and services.

Abbreviations

HIV: Human Immunodeficiency Virus

PrEP: Pre-Exposure Prophylaxis

TGW: Transgender Women

MSM: Men who have sex with Men

FSW: Female Sex Worker

PWID: People who inject drugs

WTUP: Willingness to Use PrEP

ART: Antiretroviral Therapy

Notes

An earlier version of this paper with a different title was presented as a poster at the Pre-World Anthropology Congress 2023 held at Amity University Noida, Uttar Pradesh on August 4, 2023.

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