

Acceptability of HIV Pre-Exposure Prophylaxis (PrEP) and Implementation Challenges Among Men Who Have Sex with Men in India: A Qualitative Investigation

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Abstract

This qualitative study explored the acceptability of HIV pre-exposure prophylaxis (PrEP) among MSM in India, and identified facilitators and barriers to future PrEP uptake. In 2014, we conducted 10 focus groups ($n=61$) among a purposive sample of diverse MSM recruited through community-based organizations in Chennai and Mumbai, and 10 key informant interviews with community leaders and health care providers. Participants' mean age was 26.1 years (SD 4.8); 62% completed secondary education, and 42% engaged in sex work. No focus group participants had heard of PrEP, but once explained, most reported they would likely use it. PrEP was alternately perceived as a 'back-up plan', a condom substitute, or a burden with concurrent condom use. Facilitators were potential for covert use, sex without condoms, and anxiety-less sex. Potential barriers emerged around stigma associated with PrEP use, fear of disclosures to one's family, wife, or male steady partner, and being labeled as HIV-positive or promiscuous by peers. Preferences emerged for intermittent rather than daily PrEP use, injectable PrEP, and free or subsidized access through community organizations or government hospitals. Key informants expressed additional concerns about risk compensation, non-adherence, and impact on ART availability for treatment. Demonstration projects are needed in India to support PrEP implementation tailored for at-risk MSM. Educational interventions for MSM should address concerns about PrEP effectiveness, side effects, and mitigate risk compensation. Community engagement may facilitate broad acceptability and challenge stigma around PrEP use. Importantly, provision of free or subsidized PrEP is necessary to making implementation feasible among low socioeconomic status MSM in India.

Introduction

PRE-EXPOSURE PROPHYLAXIS (PrEP) is emerging as an important tool for controlling the HIV epidemic and a recommended element of combination HIV prevention strategies, including consistent condom use, risk reduction counseling, and HIV testing.¹ Oral PrEP (a combination of two antiretrovirals, emtricitabine and tenofovir) has been shown to reduce HIV infection risk by 92%² to 100%.³ PrEP may be especially useful for populations most at risk for HIV, including men who have sex with men (MSM) and sex workers. PrEP is recommended for use among at-risk MSM in developed countries, including by US government agen-

cies⁴ and professional bodies in the UK.⁵ In 2014, the World Health Organization issued recommendations and guidelines for PrEP use among MSM in developing countries.⁶

In India, although antiretroviral treatment (ART) is available for free in public hospitals, antiretrovirals are not licensed for prevention, and PrEP is not yet provided through public hospitals. Nevertheless, private practitioners and nongovernmental clinics in India are prescribing PrEP for patients, especially for seronegative partners of HIV-positive heterosexual spouses.⁷ Anecdotal evidence suggests that PrEP is already used by some educated, higher socioeconomic status MSM in India, who pay out-of-pocket for PrEP with prescriptions from private practitioners.⁷

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As awareness of PrEP increases among MSM in India, demand also may increase, and PrEP could serve as a significant addition to combination prevention. This is especially important in that amidst an estimated 57% reduction in new HIV infections nationally in the previous decade,⁸ national average HIV prevalence among MSM (4.4%) remains 12 times higher than among the general population (0.35%). Furthermore, this national ‘average’ among MSM masks substantially higher HIV prevalence of 10–15% documented among MSM in several HIV sentinel serosurveillance sites of the National AIDS Control Organisation, with a trend of increasing prevalence in Chandigarh, Delhi, Goa, and Maharashtra, including Mumbai.^{9,10} MSM in India continue to be at disproportionately high risk for HIV infection.

In order to assess readiness for PrEP and to support future implementation strategies to promote PrEP uptake and adherence, we conducted a qualitative study among MSM in two major Indian cities to understand their perspectives on facilitators and barriers to PrEP use.

Methods

From September to December 2014, we conducted 10 focus groups among a purposive sample of five subgroups of MSM: kothi (‘feminine’ and primarily receptive sexual role), double-decker (insertive and receptive sexual roles), panthi (‘masculine’ and primarily insertive sexual role), gay-identified, and bisexual.¹¹ Participants were recruited through community-based organizations (CBOs) working with MSM in Chennai (Social Welfare Association for Men and Sahodaran) and Mumbai (The Humsafar Trust). We did not screen participants by HIV status; however, we conducted targeted recruitment at meetings and events designed for HIV-negative/unknown status MSM, rather than at clinics or support groups for people living with HIV.

Study inclusion criteria were being age 18 years old or above, self-identified as MSM, and able to provide informed consent. Research staff employed at the CBOs recruited potential focus group participants by word of mouth. Key informant interviews were conducted with health care providers and MSM community leaders in Chennai and Mumbai. The study protocol was approved by the institutional review boards of the University of Toronto and the Humsafar Trust.

Data collection

We developed a semi-structured focus group interview guide to explore and assess awareness and acceptability of PrEP among MSM. Domains explored were: participants’ prior knowledge of PrEP, willingness to use PrEP, perceived barriers and facilitators to future PrEP uptake, preferences for PrEP, access, and anticipated impact on condom use.

Focus groups (70–90 min) and key informant interviews (30–45 min) were conducted in participants’ native language (Tamil in Chennai; Marathi or Hindi in Mumbai). A few key informant interviews were conducted in English. Each focus group participant received INR 300 (USD 5) as compensation for his time. Written informed consent was received from all focus group participants and key informants.

After assessing focus group participants’ prior knowledge of PrEP, the group facilitator provided a standard explanation of PrEP using a pictorial card in participants’ native lan-

guage. Participants were encouraged to ask questions, and misunderstandings were clarified. Information provided in PrEP factsheets developed by AIDS Vaccine Advocacy Coalition¹² and the US Centers for Disease Control and Prevention¹³ were used by focus group moderators to respond consistently to participant queries. Based on results from iPrEx,^{2,3} participants were informed that, if taken daily, PrEP provided greater than 90% protection against HIV infection.

Data analysis

Focus groups and key informant interviews were digitally recorded, transcribed and translated into English. Research staff randomly selected 20% of transcripts to check for accuracy in comparison with their respective audio-files.

Focus group and interview data were explored using narrative thematic analysis with techniques adapted from grounded theory.^{14,15} We developed a codebook based on *a priori* codes derived from the focus group and key informant interview guides, and existing literature on PrEP acceptability. Inductive/emergent codes and categories identified from the text were then added to the codebook and used in further coding and categorizing of the data. Differences in coding were discussed among two data analysts and senior investigators and resolved by consensus. The analytic focus was on identifying factors that may impede or facilitate PrEP acceptability. Member checking¹⁶ was conducted by discussing findings and interpretations in meetings with field research teams in research sites, with attention to differences in perspectives on PrEP between key informants and MSM focus group participants.

Results

Participant characteristics

Focus group participants’ ($n=61$) mean age was 26 years (SD 4.8). A majority (54.1%) completed high school, with an additional 32.8% college graduates. Most were employed (77.0%; 42.6% as sex workers) and unmarried (78.7%), with 62.3% living with parents or a wife, and 31.1% living alone. Participants were roughly equally divided among kothi (21.3%), panthi (19.7%), double-decker (18.0%), gay (19.7%), and bisexual (21.3%) sexual self-identifications (Table 1). Among the 10 key informants, six were MSM community leaders, three physicians, and one a peer counsellor.

PrEP acceptability

The majority (55.7%) of MSM reported they would use PrEP if it became available. Over two-thirds (67.2%) reported consistent condom use in the previous month. Table 2 summarizes facilitators and barriers to PrEP acceptability among MSM in India across eight themes, which are described below along with illustrative quotations.

Awareness about PrEP

None of the focus group participants had heard of the term ‘PrEP’ nor were they aware that ART could be used to prevent HIV infection. Four participants ($n=4/61$) who initially reported that they had heard of PrEP were later found to have mistaken post-exposure prophylaxis for PrEP. When asked whether they knew of any medication to prevent HIV infection,

TABLE 1. SOCIO-DEMOGRAPHIC CHARACTERISTICS OF FOCUS GROUP PARTICIPANTS (N=61)

	Overall sample (N=61)	Chennai (n=31)	Mumbai (n=30)
<i>Age (years)</i>			
Mean	26.1	26.9	25.2
SD	4.8	4.3	5.3
<i>Monthly income (INR)</i>			
Mean	12245	10685	14350
SD	6066	5394	6416
	n (%)	n (%)	n (%)
<i>Highest level of completed education</i>			
<High school	8 (13.1)	6 (19.4)	2 (6.7)
High school/higher secondary	33 (54.1)	11 (35.5)	22 (73.3)
College degree	20 (32.8)	14 (45.2)	6 (20.0)
<i>Employment</i>			
Unemployed	14 (23.0)	4 (12.9)	10 (33.3)
Employed	47 (77.0)	27 (87.1)	20 (66.7)
<i>Primary identity</i>			
Kothi	13 (21.3)	7 (22.6)	6 (20.0)
Panthi	12 (19.7)	6 (19.4)	6 (20.0)
Double-decker	11 (18.0)	11 (35.5)	
Gay	12 (19.7)		12 (40.0)
Bisexual	13 (21.3)	7 (22.6)	6 (20.0)
<i>Marital status</i>			
Single	48 (78.7)	25 (80.6)	23 (76.7)
Married	13 (21.3)	6 (19.4)	7 (23.3)
<i>Current living situation</i>			
Living alone	19 (31.1)	9 (29.0)	10 (33.3)
Living with parents or wife	38 (62.3)	18 (58.1)	20 (66.7)
Living with peers or transgender community	4 (6.6)	4 (12.9)	
<i>Sex work involvement</i>			
No	35 (57.4)	12 (38.7)	23 (76.7)
Yes	26 (42.6)	19 (61.3)	7 (23.3)
<i>Consistent condom use in the past month</i>			
Yes	41 (67.2)	24 (77.4)	17 (56.7)
No	20 (32.8)	7 (22.6)	13 (43.3)
<i>PrEP acceptability</i>			
Yes	34 (55.7)	17 (54.8)	17 (56.6)
No	27 (44.3)	14 (45.2)	13 (43.4)

some participants expressed hope that such a medication would be available and expected 100% protection against HIV:

Prevention pills will be an advanced product...Condom is not 100% safe, but prevention pills once available will offer 100% protection. (FGD-5 Double-decker, Chennai)

Among the 10 key informants, two community leaders and two healthcare providers were aware of PrEP and that it is not yet available in India. Community leaders reported very limited awareness of PrEP among MSM at the grassroots level:

I think as far as I know, my kids [MSM] are very unaware of these things [PrEP]. My [agency's] target audience is MSM in the age group of 18 to 30 years...only those who have travelled abroad probably may have this knowledge. (KII-6, MSM Community Leader, Mumbai)

Detection of PrEP Use by Others

Covert use of PrEP was seen as an advantage by both MSM participants and key informants:

Mostly, panthis don't like to use condoms...Consider if the person who I have sex asks me not to use condoms...this [PrEP] will offer protection and I can take it without their knowledge...I can have sex with them without condoms and they are also satisfied. (FGD-1 Double-decker, Chennai)

Many participants believed that their sex partners—other than cohabiting male or female steady partners—would not find out about their using PrEP. The potential for covert use of PrEP was seen as especially beneficial in situations where a casual or paying partner may not want to use condoms. In contrast, MSM who lived with their parents or wife, or who lived with a steady male partner, anticipated problems in keeping their PrEP use a secret. A kothi living with his parents explained:

It will be a big issue in the family. They will think that I am hiding something from them and that's why I am taking medicine. I can't tell them that I am doing such and such thing and so I am taking tablets...If I don't tell them they may even ask the medical shop persons by showing the tablets. (FGD-7 Kothi, Mumbai)

Participants were concerned about feeling shamed if their PrEP pills were discovered and further that it might create misunderstanding and marital/relationship discord or that they might be mistaken as HIV infected. As a married participant said:

If I take tablets my wife will definitely ask. She is educated...she would question me, 'why are you taking this? Do you have HIV?'...there will be big problem within the family...it may go up to divorce. (FGD-3 Bisexual, Chennai)

Current condom use

Current condom use and participants' views on concurrent use of PrEP and condoms influenced PrEP acceptability. If condom use was inconsistent (e.g., by sex workers with clients who do not want to use condoms) or if situations in which condoms were unlikely to be used were anticipated (e.g., forced sex by ruffians or police), PrEP was seen as acceptable as 'back-up protection' or a substitute for condoms. As a double-decker in sex work said:

Some clients won't bring condoms. They only need pleasure. In that situation I need to be very careful...by taking PrEP I will be protected. (FGD-1 Double-decker, Chennai)

If current use of condoms was consistent, PrEP was seen as an additional burden despite its high efficacy. Some participants expressed that condoms alone were sufficient: "Why to use both—prevention pills and condoms? Good quality condoms offer better protection...preventive pills are not necessary." (FGD-2 Panthi, Chennai)

Some participants, however, accepted the combined use of condoms and PrEP, perceiving PrEP as 'additional protection' in case a condom breaks or slips. As a kothi in sex work said, "We are already using condoms...But taking pills [PrEP] is useful because condoms sometimes rupture." (FGD-7 Kothi, Mumbai).

TABLE 2. FACILITATORS AND BARRIERS TO PrEP ACCEPTABILITY AMONG MSM IN INDIA

Themes	Facilitators	Barriers
<i>Detection of PrEP use by others</i>	Belief that sex partners would not find out about PrEP use; potential for covert use seen as beneficial	Difficulty in hiding PrEP from family members (parents and/or wife) or cohabiting male steady partner; if discovered, might engender misunderstanding, shame and marital/relationship discord
<i>Current condom use</i>	If current use of condoms is inconsistent, or situations in which condoms are unlikely to be used are anticipated (e.g., forced sex), PrEP may serve as ‘back-up protection’ or a substitute for condoms Perception that combined use (condoms and PrEP) is ‘additional protection’ (if condom breaks or slips)	If current use of condoms is consistent, then PrEP use may be perceived as an additional burden despite its high efficacy
<i>Intimacy and love</i>	Desire to have sex with HIV-positive steady partners without apprehension; PrEP provides peace of mind as even if condoms break/slip, PrEP will afford protection Ability to have sex without condoms with HIV-negative/ unknown steady partners is a motivation to use PrEP	Fear of steady partner finding out about PrEP use; steady partner might judge the user as promiscuous or feel that the user doubts his fidelity
<i>Attitude towards PrEP users</i>	Viewing PrEP use as a responsible and rational behavior facilitates uptake	Beliefs that PrEP users are high-risk individuals – promiscuous, sex workers, or have multiple sex partners – may hinder uptake due to anticipated stigma
<i>PrEP cost and access</i>	Subsidized or free distribution of PrEP through CBOs may facilitate uptake among lower socioeconomic status MSM Some preferred PrEP to be provided through government health care settings; if dispensed through CBOs, other MSM might find out about their use and label them as promiscuous	Potential high pricing of PrEP sold through pharmacies may pose barriers to even middle-income MSM Belief that pharmacies may distribute fake PrEP undermines trust in quality and potency Anticipated fear and shame that pharmacists might consider PrEP buyers to be HIV-positive, promiscuous or MSM
<i>PrEP characteristics and side effects</i>	High efficacy of PrEP makes it worth taking the trouble to initiate and adhere to a PrEP regimen Less frequent dosing (e.g., alternative day or weekly once dosing) or intermittent use preferred Preference for PrEP as long-acting injectable (monthly or every two months)	Mistrust of reported high efficacy absent PrEP effectiveness data from India High efficacy of PrEP perceived to be associated with high probability of severe side effects Belief that daily dose regimen will be taxing decreases reported self-efficacy in adherence
<i>Dilemmas due to lack of ART access</i>	-	Ethical dilemma as to whether HIV-negative people should have free access to ART when people living with HIV face ongoing problems in ART access in India
<i>Risk compensation</i>	Having sex without condoms with steady partners (HIV-positive, HIV-negative or unknown status) is a motivation for PrEP uptake	Dilemma among community leaders that condom use norms may decrease among MSM in general if PrEP use is promoted

ART, antiretroviral treatment; CBO, community-based organization; MSM, men who have sex with men; PrEP, pre-exposure prophylaxis.

Intimacy and love

Participants reported that PrEP would be particularly useful for MSM in HIV serodiscordant relationships. They reasoned that HIV-negative MSM in such relationships would want to have sex with their HIV-positive steady partners without apprehension, as PrEP could protect against HIV infection even if a condom breaks or slips:

Even persons who are HIV positive have the right to love. But if we are not HIV positive then we will be scared...I mean I shouldn't get HIV. So I will take pills then. (FGD-6 Panthi, Mumbai)

Participants further reported differing attitudes toward using PrEP depending on the HIV status of their steady partners. Revealing one's PrEP use to an HIV-positive steady

partner was not considered to be an issue; such disclosure was expected to decrease fear or guilt among HIV-positive partners that they might infect their HIV-negative partner. In this case, PrEP use signals concern and supports intimacy. However, HIV-negative participants were concerned about adverse consequences if a male steady partner of unknown or HIV-negative status found out about their PrEP use, as they might be judged as promiscuous or their fidelity questioned: “If your regular partner sees you taking this, he will think that ‘my partner goes somewhere else’...and because of this MSM would not want to take this pill.” (FGD-4 Kothi, Chennai). Thus, in the latter case, PrEP use may engender mistrust and detract from intimacy.

Attitudes towards PrEP users

Participants perceived that PrEP would be particularly useful to MSM who engage in high risk behaviors. Accordingly, they reported that sex workers and MSM who have multiple sex partners would be more likely to use PrEP: “Those who are in regular sex trade, those who want sex daily can definitely take this,” (KII-1 peer counselor, Chennai). Some participants further reasoned that being on PrEP then means one admits to engaging in high risk behaviors; as a result, there is a risk of being looked down upon by others. As a panthi reported, “If my friends come to know I am taking [PrEP] they will think “With how many people he has sex?” They will start looking at me differently,” (FGD-6 Panthi, Mumbai)

In order to destigmatize PrEP use, participants suggested that it be promoted as an HIV prevention pill for everyone—not just for high-risk MSM. For example, a double-decker said:

PrEP should not be branded as useful for MSM alone. They are for anyone who is sexually active...There is no need to declare my sexual behavior...just say that this tablet is to prevent HIV so that anyone can use. (FGD-5 Double decker, Chennai)

Conversely, MSM participants who were open about their sex work, and particularly those whose livelihood primarily depended on sex work, did not express concern about stigma related to using PrEP. In fact, a few reported that being on PrEP would help them to get more clients and that clients might be willing to pay more to sex workers whom they considered to be ‘safe’ and responsible:

If tablets are released they will sell very well—they are for safety, right? MSM in Dhandha [sex work] will ask for more money from their clients...will ask for 2000 rupees instead of 1000 rupees. I am safe now, they will say like that. (FGD-1 Double-decker, Chennai)

PrEP cost and access

Participants preferred having subsidized or free PrEP distributed through CBOs as they argued that most at-risk MSM, including MSM in sex work, are of lower socioeconomic status:

Government has to distribute it [PrEP] through CBOs...Condom programming is a good example of it. If it comes through government it will be for free and if it is distributed through CBOs it will not be wasted. (FGD-1 Double-decker, Chennai)

Key informants thought the government could provide free or subsidized PrEP through CBOs based on their experiences

with existing government-CBO partnerships (providing treatment for sexually transmitted infections through CBO clinics; social marketing of condoms through CBOs). In contrast, some participants preferred PrEP to be provided through government health care settings as they were concerned that if PrEP were provided through CBOs, then other MSM might be more likely to find out about their using it and label them as promiscuous.

While many participants wanted PrEP to be available in private pharmacies as well, they noted that potential high pricing of PrEP sold through pharmacies may pose barriers in access to even middle-income MSM. Some participants expressed further concern that pharmacies might distribute fake PrEP to increase profits; thus the quality and potency of PrEP sold in pharmacies was potentially suspect. Participants also expressed concern about fear and shame in that pharmacists or others might consider PrEP buyers to be HIV positive, promiscuous, or MSM, and that this would prevent MSM from buying PrEP:

We may encounter problem in getting the [PrEP] pills from medical shops...any of our neighbors can visit the medical shop; they might ask us why are you taking this medicine...He can inform any of my family members about that. Even the chemist may wonder why I am taking this. (FGD-7 Kothi, Mumbai)

PrEP characteristics and side effects

Once participants were made aware that PrEP, if used consistently, was highly effective in protecting against HIV infection, many expressed that it would be worth taking the trouble to initiate and adhere to a daily PrEP regimen. A few participants, including a key informant, however, remained suspicious of the reported high effectiveness of PrEP as effectiveness data are not yet available from studies conducted in India. The high effectiveness was also perceived to be associated with a high probability of severe side effects. Participants believed that PrEP may affect one’s appearance (e.g., sunken cheeks) or major organs, one’s virility, or may result in sickness and thus loss of wages, including income from sex work:

I feel that after all it is a drug, so it will have side effects. If it prevents more than 90% [of HIV infections] then it will have some side effects...many people will think about that—what are its side effects and how major they are, and whether my virility will be affected. If it has little side effects, then we may take. (FGD-8 Gay man, Mumbai)

While some participants believed that they could adhere to a daily regimen, others were worried that daily use would be taxing and may detract from PrEP acceptability among many MSM. Accordingly, some participants reported preferences for less frequent dosing (e.g., every other day or once weekly) or event-driven dosing around times of anticipated increased sexual activity (e.g., increased number of sex work clients during a local festival). Some participants questioned why PrEP could not be taken intermittently for short periods of time—for example, only for those periods in which they engage in sex work, which they reported tend to occur when they travel outside their home city.

Some MSM reported a preference for long-acting injectable PrEP administered monthly or every two months. An additional

advantage of injections was expressed in that it would solve ‘storage problems’ [i.e., where to safely store (and conceal) PrEP tablets at home or how to carry them during travel]. A participant equated injections with long-term pre-paid cell phone cards and daily-regimen PrEP with short-term cards:

Injection is similar to having a top-up [pre-paid] card for a large amount; I can talk up to three months. Pills are like 10 Rupees top-up card; it needs to be often purchased—It will last only a day or two. (FGD-1 Double-decker, Chennai)

Dilemmas due to lack of ART access

Community leader key informants articulated concerns about efforts to make PrEP available for wider use in India. One community leader, for example, questioned how MSM will be provided with subsidized or free PrEP through the national HIV program (a possible scenario) when many people living with HIV still do not have access to free ART. A physician key informant warned about possible emergence of ART resistance due to non-adherence among PrEP users. A community leader, although he supported free PrEP availability, wondered whether the government would be able to provide it and wanted MSM not to wait for the government, but to buy it on their own—although this begs concerns about ability to pay:

Government is already providing lubricated condoms for free... We can't insist Government to provide this [PrEP] for free or spend money on this. But if they are giving it for free, I welcome it. Or else community should come forward and buy it... They have to invest money for their health. (KII-4, MSM Community Leader, Chennai)

Risk compensation

Both MSM participants and key informants anticipated decreases in condom use among PrEP users. For example, a panthi reported:

If these pills are available in market, then I will stop using condoms... after taking these pills the happiness and fun that we will have while having sex with others will be different ... this is like a shield... whatever comes from outside it has to keep outside only. (FGD-6 Panthi, Mumbai)

Similarly, a double-decker said, “MSM will think ‘I have already taken the tablet so I don’t have to use condoms’—so many will avoid using condoms,” (FGD-1 Double-decker, Chennai). Some participants also reported that PrEP users would increase their number of sexual partners or anal sex encounters.

A few participants expressed broader concerns that the availability of PrEP might result in relaxation of established and long fought for community norms that support consistent condom use. They feared the weakening of safer sex norms might lead to decreases in condom use even among MSM who do not use PrEP.

Discussion

In this qualitative study with diverse MSM in two major Indian cities, none had previously heard of PrEP. That only key informant physicians and community leaders were aware of PrEP may reflect that it has neither been tested nor licensed in India. Importantly, once PrEP was explained, however, the majority of MSM reported they would likely use it. This

suggests that PrEP may be an acceptable HIV prevention strategy among some at-risk MSM in India. Nevertheless, a variety of facilitators and barriers to PrEP acceptability emerged, some of which may be particularly relevant to PrEP implementation in the Indian context. Our study adds to the limited evidence base on factors influencing willingness to use PrEP among MSM in developing countries.^{17–20}

Among the facilitating factors, the potential for covert use of PrEP, thus not requiring partner approval or negotiation, was highly valued among a variety of MSM; this included those engaged in sex work, MSM who have multiple sex partners, and married MSM. The particular importance ascribed to covert use may be understood in the context of the reported reluctance to use condoms on the part of clients of male sex workers and broader challenges among MSM in India in talking about (or using) condoms or HIV status with steady male or female partners.^{11,21}

For MSM who were open about engaging in sex work or having multiple partners, procuring PrEP through CBOs did not emerge as a concern. In fact, MSM in sex work reported that they would proudly announce their using PrEP, thereby indicating to others that they are responsible and safe, and even increasing their business. MSM in sex work identified additional advantages of PrEP use, given frequently reported instances of forced sex by ruffians or police—even more so after the recent re-criminalization of same-sex sexual behavior in India.²² Among both those engaged in sex work and not, the desire to protect one’s steady partners also supported PrEP acceptability.

Given widespread sexual and HIV stigma in India,^{23,24} it is not surprising that MSM expressed concern about PrEP use being discovered by their family members, wife, or male steady partner, fearing negative consequences such as marital and relationship discord, and being ostracized to the point of posing threats of divorce or being ejected from their family home. MSM expressed further concerns about being labeled as HIV positive or promiscuous by their peers, as well as by pharmacists who might dispense PrEP. MSM in the present study were also concerned about PrEP users facing stigma from other MSM, similar to that reported in other contexts.^{25,26} Qualitative investigations among MSM enrolled in a phase I PrEP trial in Kenya,¹⁸ and among MSM participants in the iPrex study in Thailand,²⁶ identified stigma as an important barrier to PrEP acceptability and usage. Broad-based strategies to reduce stigma associated with PrEP are crucial to its acceptability²⁷—both within MSM communities and among the general public.

Among MSM in our study, PrEP acceptability emerged as higher among those who use condoms inconsistently, with PrEP seen as a “back-up plan” or a condom substitute. Some MSM also described concurrent condom and PrEP use as an added burden. Data from the US PrEP Demonstration Project among MSM similarly indicated a positive association between risk behavior and PrEP acceptability; higher risk was a significant correlate of study enrollment.²⁸ A general preference was expressed among MSM in our study for intermittent PrEP use, which was perceived as less burdensome than a daily regimen, similar to preferences expressed among MSM and male sex workers in Kenya.¹⁸

The recent Ipergay trial supporting the high efficacy of intermittent PrEP suggests event-driven PrEP²⁹ may be a plausible option for MSM in India who do not use condoms consistently. Tailored education and implementation strategies

for MSM, particularly those of low socioeconomic status, sex workers, and married MSM—each of which face particular challenges in uptake and adherence—may help to support PrEP roll-out in India.

A notable concern arose among community leaders who lamented that over a decade of HIV prevention work promoting consistent condom use among MSM as a community norm would “go to waste.” Community leaders and health care providers also expressed challenges for PrEP roll-out in the face of suboptimal availability of ART for people living with HIV in India. Such concerns in India appear to be shared, as in a recent international AIDS conference a top Indian government health official reported that India was not ready for PrEP as the focus needs to remain on improving treatment coverage, not on providing ART for prevention.

We are aware of only one unpublished qualitative study from India³⁰ that explored PrEP acceptability among MSM ($n = 39$) in Pune. Non-use of condoms, wanting a stress-free sex life, and fear of condom failure emerged as reasons MSM might use PrEP. In addition to these factors, which similarly emerged in our study, we identified the pervasive role of stigma as a potential barrier to PrEP uptake. Stigma manifested in wide-ranging concerns about how to store and conceal PrEP from family members, one’s wife or steady male partner, and in fears about procuring PrEP from CBOs, due to stigma from other MSM, and from pharmacies.

A multi-country survey that included 128 MSM from India found that 75% reported wanting to initiate PrEP; the top two attributes that influenced potential uptake were route of administration (injections were preferred over pills) and the need for periodic HIV testing.³¹ Our qualitative findings complement these results in that diverse MSM reported preferences for intermittent dosing and injectable PrEP; however, the pervasive concerns about stigma that emerged in our study suggest the importance of contextualizing ostensibly product-specific concerns within the sociocultural milieu. That is, preferences for intermittent dosing, long-acting injectables, and concerns about from where and from whom to access PrEP, may be best understood in the sociocultural context of widespread stigma associated with HIV and MSM in India, and the enduring centrality, and often proximity, of family, including the prevalence of heterosexual marriage among MSM.

Our previous research with MSM in India similarly identified stigma as a significant barrier to HIV testing³² and extensive fears about HIV status disclosure.¹¹ Unfortunately the 2013 Indian Supreme Court decision recriminalizing same-sex behaviors in India, reversing a Delhi High Court order that had decriminalized ‘homosexual acts’ since 2009, is likely to exacerbate these challenges to PrEP implementation, and to HIV prevention for MSM more broadly.^{11,33}

Limitations and strengths

The use of qualitative methods and purposive sampling limits the generalizability of the findings. However, our focus was on exploring issues that may emerge around PrEP implementation among MSM in the Indian sociocultural context, in which PrEP usage remains largely unexplored. The results are more likely to be transferrable to other similar settings—cities with diverse MSM (in terms of identities, socioeconomic and educational status) and with long-standing HIV preventive interventions. Another limitation

is that study participants were primarily recruited through community-based organizations; the acceptability of PrEP may be different for MSM unaffiliated with CBOs serving MSM communities.

General acceptability of PrEP in the present sample was expressed despite lack of any previous awareness; nevertheless, concerns about stigma and disclosure of same-sex sexuality, and of PrEP’s automatic association with HIV may be even greater among MSM who are not affiliated with community organizations. Also, as this was a small qualitative study, we cannot characterize wholesale differences between different MSM subgroups; however we have indicated possible differences that emerged, and the diversity of the MSM sample is a strength in the breadth of issues explored, including those among married MSM and MSM engaged in sex work.

Implications

Given the established effectiveness of PrEP^{2,3} and the WHO recommendation that PrEP be provided to MSM in developing countries,⁶ it may be beneficial for India to consider providing free or subsidized PrEP to high risk MSM (and other key populations). PrEP could be provided through existing government outlets in the national HIV program, possibly in a separate wing within existing government-run ART centers. However, concerns about being perceived to be HIV-positive, a barrier to PrEP uptake that arose in our study, suggest the importance of providing alternate sites for PrEP administration, which might include MSM community-based organizations.

A current successful model of Indian government-funded targeted HIV preventive interventions employs licensed medical doctors to visit CBOs at regular intervals to prescribe medication for opioid substitution treatment for people who inject drugs, with nurses and outreach workers on site who follow up patients. An analogous model of PrEP administration through CBOs for MSM may help to mitigate predictable barriers to uptake. The use of government ART centers and MSM CBOs also may reduce administrative costs that might accrue with an entirely new infrastructure for PrEP administration.

PrEP is already in use in India through private practitioners and a few non-governmental organizations to prevent HIV infection in HIV serodiscordant heterosexual relationships.⁷ Explicit guidelines for provision of PrEP to MSM and other at-risk populations should facilitate quality delivery of PrEP through private and non-governmental clinics, a recommendation previously issued in the national consultation on PrEP organized by the Population Health Foundation of India and WHO in October 2013.⁷

Importantly, adherence has been identified as the “Achilles heel” of PrEP.²⁹ Data from clinical trials of PrEP conducted in North America and resource-limited settings^{2,18,29} have established a clear association between systemic drug exposure and preventive efficacy.^{2,34} There is a compelling need for intervention research to identify effective modes for supporting PrEP adherence in real world settings,³⁵ in addition to education and clinical support to prepare physicians for PrEP administration.³⁶ Effective interventions, however, are likely to vary across sociocultural contexts,³⁵ indicating the importance of qualitative research conducted *in situ*.

Findings from the present study suggest that appropriate provision of PrEP should involve exploration with MSM of practical issues that may be expected to impact on adherence: how to safely store PrEP at home in light of concerns about confidentiality, and how to navigate disclosure of PrEP use to one's male partner(s), wife and family. Our findings also suggest that culturally appropriate interventions to engage community stakeholders³⁵ and train peer educators¹⁷ may constitute key elements in supporting PrEP acceptability and adherence among MSM in India.

When PrEP becomes available in India, both health care providers and community educators need to be aware of concerns that may influence uptake and adherence. PrEP-related education should be tailored to address client's needs and concerns, such as HIV risk perception, relationship/marital status, partner's HIV status, and attitudes toward condom use. Of particular relevance to PrEP roll-out among MSM in India, gatekeepers such as MSM community leaders and select health care providers that serve MSM communities should be engaged in discussion of the benefits and potential risks of PrEP to the community. As important as is navigating practical concerns, the appropriate engagement of community stakeholders may constitute a key element in reducing the stigma associated with PrEP use and normalizing its role in health promotion for MSM (i.e., PrEP use as a responsible choice for some MSM versus stigmatizing PrEP users as promiscuous or as sex workers).

Importantly, we also identified ethical considerations among community leaders related to PrEP roll-out in a resource-limited setting, in which many persons living with HIV do not have unfettered access to ART. These concerns need to be openly discussed and addressed.³⁷ Endorsement from these leaders may be critical to the successful initiation of community-focused PrEP promotion campaigns and inculcation of positive peer norms about PrEP use.

Future survey research among MSM and other key populations in India may help to identify and quantify factors that influence PrEP acceptability and adherence. Policy-oriented research, such as examining cost-effectiveness and the potential number of HIV infections averted, may also be useful in informing policymakers and public health officials about the contribution of PrEP to decreasing the HIV epidemic. A simulation study conducted before the release of the iPrEx study results estimated a substantial positive public health impact of PrEP use in southern India.³⁸

Investigations to understand health care providers' awareness and willingness to prescribe PrEP to MSM also may be helpful in the Indian context.^{39,40} PrEP demonstration projects among MSM (and other key populations, including sex workers) to support implementation and thereby maximize PrEP's effectiveness and usefulness in India are also needed.^{6,41} To date, a PrEP demonstration project among sex workers through the acclaimed Sonagachi Project has been awaiting approval from the Health Ministry of India.⁴²

In conclusion, this qualitative investigation suggests that diverse MSM in India may find PrEP an acceptable HIV prevention option. Understanding perceived barriers to PrEP use that emerge at the social/community level (e.g., stigma towards PrEP users, fear of negative consequences of discovery of PrEP use by family members and partners) and the individual level (e.g., undue fears of side effects) may facilitate the development and implementation of strategies by the government and community agencies to promote PrEP

acceptance and adherence. As recommended by WHO,⁶ the Government of India and community-based organizations should seize this opportunity to implement evidence-informed PrEP programs within a comprehensive HIV prevention package to decrease the sustained HIV burden among MSM communities in India.

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