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# "A qualitative study exploring the perceptions of MSM/TGW on using PrEP and Rectal Microbicides in India

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ABSTRACT

Very little information is available about the acceptability of new biological prevention tools such as Pre Exposure Prophylaxis ( PrEP) and Rectal Microbicides (RM) among men sex with men(MSM) in whom HIV risk is high. We explored knowledge and willingness about these tools among MSM community in India in a qualitative study using in-depth interviews with 39 consenting MSM in Pune. ''Expert peer'' and social networking helped in the recruitment. All participants lacked knowledge about PrEP. PrEP was acceptable as it provided added protection in cases of condom nonuse and failure, multiple partners and for stress-free sex life. While daily pill intake was fine but intake before sex was preferred as sex was infrequent. Efficacy more than 90% desired. Concerns about side- effects especially those affecting physical appearance and functioning of internal organs were not acceptable. Willingness to use the RM was universal as they were habituated to using lubricants and favored gel formulation and libido enhancing RM. Creating awareness about PrEP is essential for successful positioning in HIV prevention repertoire. Tools should be effective, easily available, low cost and without major side-effects.

**Key words**: Acceptability, MSM, PrEP, Rectal microbicides, HIV/AIDS

## INTRODUCTION

Globally in 2019, key populations viz. gay men and men who have sex with men (MSM), people who inject drugs (PWID), sex workers, transgender (TG) and prisoners along with their partners accounted for 62% of all new HIV infections. The number of HIV infections among female sex workers (FSW), PWID and transgender women have reduced marginally, while HIV infections among gay men and other MSM increased by an estimated 25% between 2010 and 2019 (UNAIDS, 2020). The risk of acquiring HIV is now 26 times higher among gay men and other MSM compared to the general population as against 19 times reported by others as compared to the general population of reproductive age (UNAIDS, 2019; Baral, Cleghorn and Beyrer,2007). Efforts need to be made for HIV prevention in this population. Treatment as prevention is successfully demonstrated in prevention of mother

to child infection, and in case of post-exposure prophylaxis (PEP). Results of HPTNO52 study have demonstrated that anti-retroviral (ARVs) could be effective in the prevention of sexually transmitted HIV infection (Cohen et al., 2011). Clinical trials of vaginally applied and daily oral tenofovir-based pre-exposure prophylaxis (PrEP) have proven to be efficacious in preventing HIV-1 infection in different at-risk populations showing no safety concerns or increase in sexual risk-taking behaviors (Karim A, et al., 2010). Food and Drug Administration was first to approve the use of Truvada as PrEP for prevention of HIV transmission in adults at high-risk of HIV infection (US FDA., 2012). However, this policy is not yet accepted by many countries with high HIV burden. Higher dose of drug MIV-150 would be required for it to be effective at preventing the rectal transmission as was noted from the trial results of rectal microbicides at HIV R4P Virtual Conference, 2021. The addition of PrEP and RM to the basket of HIV prevention strategies may be critical in bringing down the rates of HIV transmission. Few studies based on the use of microbicides and PrEP have emphasized the importance of consistently using these methods, as acceptability will impact adherence (Gengiah, Moosa, Naidoo & Mansoor, 2014).

Two studies are reported on PrEP and MSM from India. The study using RDS methodology was conducted across 22 sites in India. It reported PrEP awareness was among 8% MSM, while willingness to use PrEP was 67.6% (Belludi et al., 2021).Second study explored the acceptability of PrEP among MSM and identified facilitators for PrEP use like potential for covert use, sex without condoms, and anxiety-less sex; while stigma, fear of disclosures to one's family and being labeled as HIV-positive or promiscuous by peers were identified as barriers to future PrEP uptake (Chakrapani et al., 2015). India with an estimated population of half a million MSM will benefit substantially from the success of PrEP and RM (when available). Nevertheless, for effective implementation of PrEP, there is a need to include PrEP in current HIV prevention efforts. While PrEP has become available, RM is still under clinical trials. For an effective uptake of these prevention options it is important to understand the level of awareness about these options among the potential users and the factors that determine their acceptability (Kohli et al.,2014). We report here the findings of a qualitative research study conducted among MSM with a view to assess their level of awareness, understand the factors that influence their willingness to use and their place in the collection of risk-reduction strategies.

## METHODS

### Ethical Approval

The study protocol and the informed consents were approved by the Ethics Committee of the ICMR-National AIDS Research Institute, Pune vide letter no; NRI/ICMR-Rectal Microbicides/12-12/63 dated 02 April, 2012 approval date 23rd May, 2012. Written informed consents were obtained from the participants before starting the interview. The recordings and the soft copies of the transcripts were stored in pass word protected devices and the hard copies in locked cabinets.

**Data Collection**

We conducted In-depth interviews (IDI) with 39 consenting MSM between March-January 2014. An "expert peer" and a closed social network was used for recruiting MSM into the study. The "Expert peer" (who self – identified himself as MSM), identified the prospective participants mainly from the cruising sites which included urinals, railway platforms, red light area etc. and collected their basic information and sought their consent for the interview. These self-identified MSM identified themselves as Kothis (receptive), Panthis (insertive), versatile (both insertive and receptive), transgender, gay (homosexual) and bisexual MSM. Purposive sampling was used to select MSM from this list for better representation of different categories of (Self-identified) MSM in the study. Some like-minded MSM with similar sexual orientation chose to remain hidden and were a part of a secretive social network. After gaining access to their, few MSM from this network were also enrolled into the study using the snow ball sampling method.

Recruitment was done at the referral clinic while some MSM were recruited at their residence. IDIs were conducted by two trained field-interviewers. Two interviews were conducted for each participant with a gap of two weeks. First interview focused on the inquiry about their risk behavior, health-seeking behavior, risk reduction behavior and their knowledge about HIV/AIDS. The information about the acceptability of RM and PrEP was collected at the second interview. Written informed consent was obtained prior to the interview, which was conducted in the local language and was audio recorded. The information was later transcribed and translated into English.

**Data Analysis**

Data collection and analysis occurred concurrently, i.e., we reviewed the first interview before the second interview was conducted to ensure that all the aspects of the first interview are covered and any gaps in the data collection are addressed in the second interview. Each interview lasted for about 1 hour to 1 and a half hour. The data was transcribed and translated into English. The analysis included steps such as familiarization, coding the data based on the code book, writing the memos and identifying significant statements under different codes and reporting the finding under different themes /codes.

Two researchers were involved in coding of the data for which a code book was developed initially and new codes were added subsequently as the analysis progressed. Any discord during coding was resolved through discussion. The thematic analysis approach is used for data analysis which was done using N6 Nudist software for qualitative analysis.

*Tools*

A meeting was held with the researchers working with MSM, clinicians, community based organizations (CBO) working with MSM, transgender (TG) and MSM representatives before finalizing the contents of the interview guide. Interview guide was piloted in 3 MSM. The guide included questions on sexual behavior, knowledge of HIV/AIDS, risk-reduction behavior, and questions on PrEP and RM. PrEP and RM were little known products at the time of data collection, hence a brief description on both these products was included in the guide, and the participants were asked the questions on PrEP and RM following this description.

Inclusion criteria was MSM above 18 years who practiced anal sex in the previous three months and were able and willing to give written informed consent were recruited.

## RESULTS

Thirty-nine MSM self-identified themselves as transgender (5), Kothis (7), Panthis (3), versatile (9), bisexuals (7), and gays (8) were interviewed. The age range of the participants was 18 to 55 years, most of them (49%) were in the age group of 26 to 33 years and 28% were younger than them. As regards their educational qualification 43 % had studied up to $12^{th}$ grade, 9 were professional and 2 were Ph.D. students. Nineteen (49%) had a regular job and 8 (20%) were having small business while 5 were in the sex work.

### *Knowledge and willingness for PrEP use*

All the participants were unaware about PrEP. Two participants mentioned PEP for HIV protection, of these one was a US citizen and the other one was actively associated with an AIDS research organization.

### Factors influencing Acceptability

*Extra Protection*

PrEP was acceptable as a preventive method by many HIV positive MSM, they agreed that it could give them great relief by providing extra protection in episodes of condom failure and nonuse, sex with multiple partners. They opined that it is essential for a stress-free and pleasurable sex life.

This is highlighted by this quote:

"*There might be some occasions when people do not have condoms, so sometimes people are like let's do it. So, people are willing to take the risk just for few moments of pleasure"* (Young receptive, HIV negative MSM).

*Drug Intake & Efficacy*

Nearly half of the respondents were fine with daily intake but others wanted it just before sex as sex was infrequent. Even MSM in sex work did not perceive the need to take PrEP daily and preferred a pill just before

sex. Reluctance for daily pill was also because they did not want their families to know about their sexual orientation and preference. As many as 9 MSM were willing to continue intake until risk behavior lasts. However, concerns about side- effects and adherence were always expressed.

Participants insisted that PrEP's efficacy should be high; nearly 100 percent. Regarding the cost 8 MSM felt PrEP should be provided free of cost, 15 respondents felt that the cost should be below Rs. 600 per month. Availability of PrEP was preferred at pharmacy with/without prescription; or NGOs/public hospital at nominal cost/free.

*Cost*

Most of the MSM expressed their concerns about side-effects of PrEP. Some were anxious about the allergic reactions and body pain that might affect their vigor, which in turn might impact their daily routine. Ailments like fever, effect on kidney, dysentery, skin problem, pain in stomach were totally unacceptable. Minor side-effects were acceptable provided they did not persist for long time. They were also concerned about PrEP adversely affecting their sexual pleasure. Long term and consistent use of the PrEP was perceived as problematic since the desire for sex decreases with age. Few responded that they would discontinue its use if it impacted their sexual performance or pleasure

***Knowledge and willingness to use Rectal Microbicide***

Lubricants like gel, oil, body lotion, Vaseline and even spit were used by MSM to have easy sex. All MSM were willing to use RM as it would provide dual benefits, HIV protection, and lubrication. If RM enhances libido it would sell very well.

Acceptance of RM as a preventive tool was high among MSM as expressed by one of the MSM, "*from the normal gel you can only get lubrication…but from this new gel [RM] we can keep ourselves safe from infection."* (A lamination operator in a printing press).

*Side Effect*

Side-effects like skin problem, burning, itching, swelling, pimples, bad smell, fungus infection, numbness were not acceptable. RM as lubricant should not hamper the sexual pleasure and enjoyment. "*Side-effects should be very limited. I have heard of long-term side-effects of pain killers on kidney functions such effects are totally unacceptable."* [An educated MSM involved in the field of education and training].

*Product characteristics*

Nineteen participants indicated that the lubricant should be in the form of a gel, water-based, colorless and odorless, while some preferred a good odor for the gel. The gel formulation was preferred because of their prior exposure to the "Mukta" gel: that was distributed as a lubricant by a CBO working for MSM.

*Logistics*

The MSM expressed that it should be available preferably in medical stores followed by distribution through CBO or both. Packaging preferences for RM were wide-ranging, some were based on cost, while others on convenience to carry and apply.

## DISCUSSION

*The Context of PrEP and RM Acceptability*

Given the high risk of HIV infection among MSM, PrEP and RM acceptability research must understand the social, cultural and interpersonal context that influences beliefs, attitudes, and adherence (Jayakumaran et al., 2016; Escudero et al., 2015). This study attempted to provide an enriched perspective on how perceptions of HIV risk, product characteristics influence the acceptability of PrEP and RM.

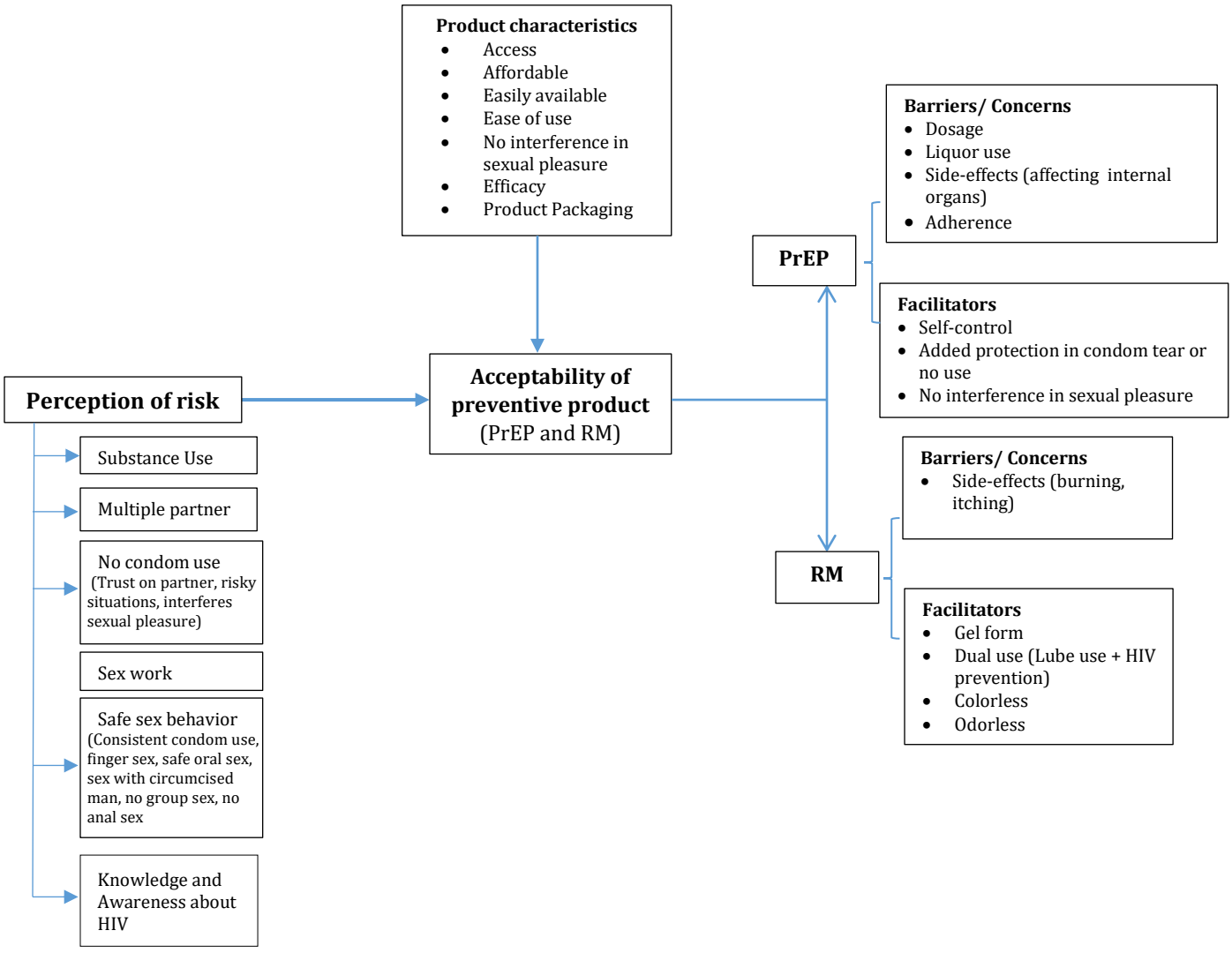


Figure 1. Emergent Conceptual Model of PrEP and Rectal Microbicide Acceptability

Based on the study findings, figure1 hypothesizes the relationships between perception of risk and the product characteristics and the way it influences the acceptability of these prevention options. The acceptability of each of these products is further determined by few personal and product characteristics. The acceptability of the RM is largely on account of the need for lubrication, protection and previous experience. Consequently, there is considerable clarity among the participants about desired product attributes of RM. We suggest that contextual factors influencing initial acceptance and consistent use of these products will vary i.e. participants were not likely to consider using PrEP and RM unless they perceived themselves at risk of HIV. This perception of risk is an interplay of many social and personal factors like their knowledge and awareness about HIV and AIDS, extent of condom use, occupation, substance use and the adoption of other risk-reduction behaviors. Even the MSM who were using condoms more or less consistently were willing to use PrEP for enhanced protection, Acceptability of RM was less influenced by its effectiveness as participants were willing to consider even a less effective RM too due to its dual action and ability of its clandestine use, Whereas for PrEP to be acceptable it had to be more efficacious, devoid of serious side-effects, long-lasting, less expensive, and preferably event driven.

Overall awareness about PrEP has been reported to be low in United States where PrEP is licensed for use (Lachowsky et al., 2016). In India we have seen an increase in the level of awareness with time while Chakrapani et al (2015) and the present study reports no awareness about PrEP but Belludi et al (2021) reports awareness of 8% among MSM.

Acceptability dropped after the hypothetical product became available for use. Peinado et al. reported high acceptance of either oral or rectal use of bill with preference for rectal application among participants from Peruvian, Indian and Thai men (Peinado et al., 2013; Galea et al., 2011; Schneider et al., 2012; Wheelock et al., 2013). PrEP is found to be highly acceptable, while moderate acceptability is noted by other researchers (Eisingerich et al., 2012; Grov et al., 2015; Rocha et al., 2014).

Eisingerich et al. pointed that the route of administration is the most important attribute (2012).

Like others gel formulations are preferred than Suppositories (Carballo-Diéguez et al., 2008). While preference for daily oral pill is reported by Rocha et al. followed by intermittent intake (2014). In our study too gel (RM) is preferred over pill. Pill is acceptable provided it is very effective, devoid of serious side-effects, long lasting, but preference is for event driven intake. Stigma and fear of disclosure of their sexual identity is another reason for avoiding daily intake as many MSM stay with their families. Preference for the rectal application could be because of their prior experience with gel use and possibility of its clandestine use. Rectal applications had an edge over the oral intake elsewhere too (Marra & Hankins, 2015). MSM wanted a pill that could be taken just before sex and till risk behavior lasts. In view of the recent findings event driven PrEP use is found to be effective in HIV prevention and can enhance the acceptability of PrEP among MSM (Antoni et al., 2020). Wheelock et al. reported that in their study the MSM sought a daily pill, longer-lasting injection or a pill with slow-release preparations (Eisingerich et al., 2012) indicating the issues with adherence.

Correlates of acceptability included out-of-pocket cost, efficacy and potential side-effects (Galea et al., 2011). Other reported factors include no recent HIV testing, high-risk behavior, self-perceived HIV risk, pleasure in

unprotected sex, romantic relationship, multiple partners, knowledge of PrEP, lethargy for safe-sex and paid male, less education, regular gay scene attendance, 'high-risk' anal intercourse, stigma, less knowledge, higher service provider stigma, and violence influencing willingness for PrEP (Grov et al., 2015; Lim et al., 2017). Apart from the current study, other researchers too reported that PrEP was perceived as additional protection (Yadav et al., 2014). We noted potential sexual risk disinhibition as a consequence of PrEP use, others too reported similarly (Chakrapani et al., 2015; Galea et al., 2011).

In view of WHO's recommendation that PrEP be provided to MSM in developing countries, it may be beneficial for India and other countries where MSM constitute significant key population to consider providing free/subsidized PrEP to high-risk MSM (WHO, 2020). In India Drug maker Cipla has received regulatory approval in May 2016 to sell its version of Truvada for reduction of HIV risk (Datta, 2021). Explicit guidelines for provision of PrEP to MSM and other at-risk populations would facilitate quality delivery of PrEP through private and non-governmental clinics, a recommendation made at the national consultation on PrEP (PHFI & WHO consultation, 2013). After MSM show willingness to use the PrEP and RM, there is a potential of its assimilation into the HIV prevention options for at-risk populations. A demonstration study among MSM is currently underway in NARI, Pune to gauge the best mode of PrEP delivery. Of particular relevance to PrEP roll-out is the involvement of MSM community leaders and select health care providers serving MSM communities.

## CONCLUSION

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 the client's needs and concerns when PrEP becomes available in India.

**Limitations of the study:** It was not easy to gain access to the MSM community specially the high profile participants and lot of effort was made to identify and recruit them. Some participants refused to share their contact details so the peer had to visit the cruising site several times to meet them and ask them to come for the second interview. The population involved in the study had to be dealt strategically making special efforts to mind their sensitivities.

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