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Multi-stakeholder analysis of needs, perceptions, and sociocultural influences on multipurpose prevention technologies (MPT) in India

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Abstract

Background To ensure the acceptability and effectiveness of potential Multipurpose Prevention Technologies (MPTs), understanding user needs, and preferences are crucial to inform the design of MPTs. This article aims to explore the perceptions towards potential MPT use and to explore the needs of multiple stakeholders in India within their social and behavioural contexts.

Methods A qualitative multicentric study was conducted in three Indian states—Maharashtra, Karnataka, and Tamil Nadu. The study involved a total of 222 interviews: 77 in-depth interviews with women, including those from the general population, HIV-positive women, and street and brothel-based Female Sex Workers (FSWs); 84 in-depth interviews with men and 61 key informant interviews were conducted. Three focus group discussions were conducted with FSWs. Interviews explored perceptions of the potential MPTs, needs, and factors that may potentially affect their use and adherence. Interviews and FGDs were transcribed and translated verbatim. Thematic analysis approach was used to analyse the data in NVivo version 8.

Result The following themes highlight the need and preferences among women for the potential MPT product: 1) Overall perceptions about new MPT, 2) People at high risk need long acting products, 3) Condom versus new MPT: potential of MPT, 4) Women empowerment through MPTs 5) Secrecy and confidentiality 6) Non-stigmatising MPT product positioning.

Conclusion Several stakeholders in this study expressed their need for new MPTs, but concerns regarding confidentiality, privacy, stigma and, adherence were identified. Besides efficacy, characteristics such as the size, packaging, formulation, and texture of MPTs, should be taken into account when designing the MPT products, also considering the needs of women, specially, female sex workers.

Keywords Multipurpose Prevention Technology (MPT), Product design, HIV/STI prevention, Pregnancy prevention, Female sex workers, Women, Qualitative research, India

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Introduction

Globally, around 222 million women experience an unmet need for modern contraception [1] with the greatest need in regions with higher risks of maternal mortality. In the least developed countries, 60% of women who do not wish to become pregnant or want to delay their next pregnancy do not use any modern contraception method [1]. This results in approximately 88 million unintended pregnancies annually in Low- and Middle-Income Countries, accounting for 43% of total pregnancies and 89% of total unintended pregnancies [2].

Despite advances in HIV treatment and prevention, AIDS remains the leading cause of death among women of reproductive age globally [3]. In addition to the biological vulnerability of women for HIV acquisition, [4, 5], their risk of HIV and unintended pregnancy is influenced by social determinants such as limited access to education, healthcare, economic opportunities, and exposure to violence [6, 7]. Currently, condoms are the only available 'multipurpose prevention technology' (MPT) product to prevent HIV, other STIs, and pregnancy. However, male condoms present challenges for women in terms of negotiation [8], female condoms face limited acceptance due to barriers to access and acceptability, especially among male partners [9, 10].

Ongoing research is focused on developing new MPTs that aim to prevent HIV/STIs, and unintended pregnancies simultaneously. The Initiative for Multipurpose Prevention Technologies database currently lists 24 MPT products at various stages of development for HIV and other STI prevention, some of them also include contraception [11]. These methods come in different formulations/delivery such as intravaginal rings, gels, implants, injectables, vaginal films, fast-dissolving vaginal inserts or tablets, douches, microarray patches and, oral tablets [11]. Community perspectives on discontinuation rates in clinical trials and pre-exposure prophylaxis (PrEP) demonstration projects [12] and microbicides [13] in other settings have raised questions about community expectations and their willingness to adopt new prevention technologies.

The unmet contraception need in India has decreased from 12.9% in the National Family Health Survey (NFHS) 4 (2015–2016) to 9.4% in NFHS 5 (2019–2021) [14]. In India, the most commonly used contraceptive method among currently married women are female sterilization (38%), followed by male condoms (9.5%) [15, 16], while among sexually active unmarried women 27% used male condoms [15]. In economically disadvantaged Indian women of reproductive age, low contraceptive use is linked to concerns about potential side effects, gender preferences for children, familial dissent, limited

awareness about contraceptive methods, and a lack of motivation to use them [17].

In India, adult HIV prevalence (15–49 years) is 0.21% [18]. The prevalence is 0.22% among males and 0.19% among females [18], and almost half of the total new infections are reported within the age group of 25 to 49 years [18]. The prevalence of HIV among Female Sex Workers (FSWs) is high (1.85%) as compared to women in the general population [18]. FSWs face challenges in accessing contraceptive methods other than condoms, especially, permanent contraception methods [19], because, in India, a woman is required to be legally married to obtain a permanent method of contraception [20].

Therefore, to address unmet contraception needs and HIV prevention needs, understanding user preferences, needs, and motivations is crucial for designing MPTs that are both acceptable and effective [21]. A qualitative study was conducted to explore the perceptions towards potential MPTs and to investigate the needs of various stakeholders within the Indian social and behavioural context, encompassing concerns, barriers, facilitators, and the community willingness.

Methods

Study settings

A multi-centric qualitative study was conducted in three states of India: Maharashtra (MH), Karnataka (KA), and Tamil Nadu (TN). Within each state, two districts categorized as 'A' and 'B' by National AIDS Control Organization (NACO) based on HIV prevalence were selected as study sites [22, 23]. The selected districts were Pune and Satara in Maharashtra, Belgaum (now Belagavi) and Dharwad in Karnataka, and Chennai and Vellore in Tamil Nadu.

Study procedures

This study is reported using the CONSolidated criteria for REporting Qualitative research (COREQ) guidelines [24]. In-depth interviews were conducted with women including brothel and street-based FSWs, women in the general population and HIV-positive women. Men including bisexual men, HIV-positive men, male clients of FSWs, men in the general population and truckers and migrants were also interviewed. Key informant interviews (KIIs) were conducted with healthcare providers, brothel owners, NGO representatives, HIV program personnel, women leaders, youth leaders, and mother-in-law of women. Focus Group discussions (FGDs) were conducted with FSWs at each site.

Participant recruitment

Purposive and snowball sampling technique was employed to recruit participants. The different categories

of respondents were identified after literature review, and opinions of the experts, program officials and grassroots level workers working with women and HIV key populations. Respondents were identified and recruited through personal contacts, referrals, local NGOs and CBOs and institutional contacts. Truckers, bisexual men, FSWs, men and women from the general population were recruited with the support of CBOs, NGOs. Considering the greater experience of the study topics among the participants, each participant was requested to provide contacts of potential participants who had similar experiences and would be interested in sharing them. The research assistants approached these persons face-to-face and recruited them for the study if eligible.

The inclusion criteria for indirect stakeholders (key informants, women in the general population, men in the general population) were: aged 18 years and above and could provide written informed consent. The inclusion criteria for direct stakeholders were: self-reported at-risk category (FSW, bisexual men); bridge population (male clients of FSWs, migrant, truckers) or self-reported HIV-positive status and aged 18 years and above. The FGD participants in the study were FSWs who self-reported being above 18 years of age. The exclusion criteria were the inability to provide written informed consent and understand and respond in either Hindi, Marathi, Tamil, or Kannada languages.

Data collection

The IDIs, KIIs and FGDs were conducted using separate topic guides. The topic guides were developed following literature review and consultations with NGO/CBO representatives. The topic guide was first developed in English language and translated into Marathi, Kannada, Tamil, Hindi languages. As data collection progressed, the topic guides were modified, and additional probes were incorporated into the guide to enquire about emerging issues. IDIs using tailored topic guides for each respondent category were used to collect qualitative data, exploring aspects related to family planning, condom usage, STIs/HIV/AIDS knowledge, and perceptions on microbicides, vaginal rings, PrEP, and women's needs for HIV, STI, and pregnancy prevention. KIIs focused on exploring perceptions on women's needs, knowledge of prevention methods, and opinions and challenges related to new prevention technologies. FGDs with FSWs covered HIV/AIDS knowledge, prevention technologies, condom use, and opinions on methods for HIV/STI and pregnancy prevention.

Before data collection, three pilot interviews were conducted at each site. Pilot interviews were conducted to observe interview skills and comprehension of questions

by the respondents. Data were collected from February 2013 to February 2014. The interviews and FGDs were conducted in either Marathi, Kannada, Tamil, Hindi, or English languages by trained Masters level female social workers and MPH scholars. Potential participants were briefed by researchers that they were affiliated with national research institutes, and their training in public health, or social work; they were informed of the study objectives which focused on exploring preferences for new prevention technologies for HIV, STI, and pregnancy prevention among women. Brief information about microbicides, HIV vaccines, vaginal rings and PrEP was provided to familiarize the respondents with these products that were in the trial stage. Sociodemographic information about the study was collected from IDI participants. Because of the sensitivity and confidentiality sociodemographic information was not collected from FSW participants participating in FGDs.

Interviews were conducted at a confidential and convenient place agreed on by the participant. Each interview lasted 40–90 min, and each FGD lasted for around 45 to 60 min. Each FGD included 6 to 8 participants. Interviews were audio-recorded with participant's consent, and notes were taken. Debriefing was done each day with the research team following data collection to discuss the tenor and flow of the data and to gain immediate insights into the content of the data. Debriefing informed the need for additional information and respondent categories.

Data analysis

The audio data were transcribed verbatim using Goldwave Inc. software and then translated verbatim into English language. Goldwave Inc. software was used for audio playback of audio files of interviews; the audio files were manually transcribed by the study teams. The transcribed data was verbatim translated into English language manually, and typed into a Microsoft Office Word document. Prior to analysis, the data was de-identified. Immediate quality checks through multiple reviews was performed by principal investigators at each site to identify gaps, missing links, or the requirement for additional inquiry. The coordinating site took the lead in reviewing the interviews and overseeing the translation process. Site Principal Investigators were actively involved in reading the interviews and reviewing the data. Feedback was provided to respective sites following content analysis, ensuring accuracy across translations. All site teams were involved in developing first level of codes in a workshop mode.

Repeat interviews 3–5 at each site were conducted followed by the same data processing method. These repeat interviews were conducted after doing

the content analysis and identifying the need for additional information. Repeat interviews were conducted to explore missing information only. They were not counted as additional interviews. These repeat interviews were conducted by the same interviewers who initially collected the data.

The translated data were imported into NVivo 8 for data analysis. Thematic data analysis approach was performed [25]. An initial codebook was developed inductively by all site teams together after reading few transcripts and the team reached the consensus on the final list of codes and its descriptors. Further, data were coded by SSa, TS, and MA. As fieldwork progressed, data were continuously analyzed using constant comparison and an iterative thematic coding approach. New and emerging inductive codes were added to the existing code list as the data collection and coding progressed. Transcripts were read iteratively and theoretical connections between codes, and concepts were explored, and codes were carefully examined for similarities. A constant comparison method was employed to merge codes into similar categories. Recurring patterns were identified, leading to the emergence of themes. Data saturation was assessed through iterative analysis until no new information or themes emerged. Data collection and theoretical coding concluded with theoretical saturation. The data was presented by different stakeholder groups and aimed to compare how these themes varied by respondent categories. This allowed for identifying which themes occurred across stakeholder groups and if any themes were specific to any respondent groups [26, 27]. Data from IDIs, KIIs and FGDs were triangulated.

Ethics

The study was approved by the institutional ethics committees at each site – ICMR-National AIDS Research Institute (Pune, Maharashtra), the ICMR-National Institute of Epidemiology (Chennai, Tamil Nadu) and the Jawaharlal Nehru Medical College (Belagavi, Karnataka). Written informed consent was obtained from all the study participants for participation in the study and audio recording of their responses before conducting the IDIs, KIIs, and FGDs.

Patient and public involvement statement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

Results

A total of 222 interviews were conducted, 87 interviews were conducted in Tamil Nadu, 66 in Karnataka, and 69 in Maharashtra. None of the potential participants refused to participate, and no participant dropped out of the study. Table 1. describes the site wise respondents in various categories. Three Focus Group discussions (FGDs) were conducted with FSWs, one at each site, with 6–8 participants in each group.

Table 2 describes demographic information for the women IDI participants in the study. The FGD participants were brothel-based FSWs who self-reported being above 18 years of age.

The qualitative data was analyzed thematically to capture perceptions and needs surrounding potential MPT among multiple stakeholders in three states in India. The emerging themes were as follows:

Overall perceptions about new MPTs

Participants voiced their need for new MPTs. They indicated a potential need for long-acting formulations in the form of gels and injectable options as long as they did not compromise sexual pleasure. Gel and injection methods were perceived to be easier-to-use alternatives. Concerns were raised about intravaginal rings causing discomfort during sex and the challenge of daily using oral methods for MPT were also cited by many.

"It's good if it comes in gel, or ointment so that it is easy to apply. They feel fear and no interest in using this product [/ring type/] because it may get stuck into the vagina during sex." [##IDI 06-10-75## brothel-based FSW, TN]

Gel formulation was perceived to be easier to use than tablet or injection methods because gel can be washed away easily.

"It [/product in gel form/] is safe and easy to use unlike tablets or injection...tablet may have side effects. It can be easily washed off after intercourse." [##IDI 05-20-07## HIV positive woman, TN]

FSW participants perceived that gels would be easier to use since they would require application with their own hands, unlike injectable methods that would have to be administered by someone else. FSW participants perceived vaginal gels to be pleasure inducing due to their ability to prevent dryness and additionally it provided dual protection.

"Why gel was good... because most of the time... am... someone has dryness in vaginal track, isn't it? Dryness will not be there, get prevention from HIV, STIs." [##IDI 01-10-56## street-based FSW, MH]

Table 1 Number of interviews/ FGDs conducted at each site

Participants	Karnataka	Maharashtra	Tamil Nadu	Total
In-depth interviews with women (n = 77)				
Brothel based FSWs	8	6	6	20
Street based FSWs	7	6	6	19
Women in the general population	5	6	8	19
HIV positive women	6	5	8	19
Total	26	23	28	77
In-depth interviews with men (n = 84)				
Bisexual men	3	5	6	14
HIV positive men	8	8	10	26
Male clients of FSWs	4	5	6	15
Men in the general population	1	2	3	6
Truckers, migrants	8	7	8	23
Total	24	27	33	84
Key informant interviews (n = 61)				
Brothel owners	1	3	3	7
Mother-in-laws	2	1	3	6
Women leaders, youth leaders	4	4	6	14
Healthcare providers	7	8	9	24
NGO representatives	2	2	3	7
Program personnel	-	1	2	3
Total	16	19	26	61
Grand total interviews at each site	66	69	87	222
FGDs conducted at each site (n = 3)				
FSWs (Brothel-based)	1	1	1	3

There were concerns about regular use of condom among FSWs.

“They will get tired from using these things daily because women doing profession [/sex work/] will do laziness [/to not use condom?/]” [##IDI 01-10-13## street-based FSW, MH]

The gel may raise suspicion in the minds of clients as cited by the same respondent. She also indicated a need for a product applicable prior to the event to prevent any suspicion from client.

“...customer will know. Customer will misunderstand-she is using this after I came, maybe she is having the illness [/HIV/]. Why did she apply something after I came?” [##IDI 01-10-13##street-based FSW, MH]

The preferred effective duration was expected to be half an hour or more by all participant categories.

“Its [/gel’s/] effectiveness should at least be for half an hour. It should be applied every time before inter-

course...they [/FSW/] will anyway go to the bathroom after every intercourse. So, there will be no problem.” [##KII 06-60-42## NGO representative, TN]

“...It can be used every time before sex. Should be effective for about half an hour.” [##IDI 05-20-04## HIV positive woman, TN]

“It will be good if it [/microbicide/] works at least one hour” [##FSW-6## FGD participant, TN]

“For customers [/sex work/] we spend one hour.” [##FSW-8## FGD participant, TN]

Men also shared their desire to have condomless sex and suggested formulations like gel or liquid for both men and women:

“The bottle, in that the liquid is there, suppose, when the relation [/sex/] is going to happen; apply it instantly with the help of fingers, or spray it on the vagina or the gender [/penis/] before the relations... easy.” [##IDI 01-30-15## HIV-positive male, MH]

Table 2 Demographic profile of in-depth interview women participants (n = 77)

Characteristics	Brothel-based FSW (n = 20) (%)	Street-based FSW (n = 19) (%)	HIV Positive women (n = 19)	Women General population (n = 19)
Age				
19–25	3 (15.0)	3 (15.8)	2 (10.5)	4 (21.1)
26–35	7 (35.0)	7 (36.8)	8 (42.1)	13 (68.4)
36–45	9 (45.0)	6 (31.6)	8 (42.1)	2 (10.5)
Above 45	1 (5.0)	3 (15.8)	1 (5.3)	0
Education				
Illiterate	8 (40.0)	5 (26.3)	0	1 (5.3)
Primary	4 (20.0)	5 (26.3)	3 (15.8)	2 (10.5)
Upper Primary	3 (15.0)	4 (21.1)	7 (36.8)	2 (10.5)
Secondary	4 (20.0)	5 (26.3)	6 (31.6)	4 (21.1)
Higher Secondary	1 (5.0)	0	3 (15.8)	3 (15.8)
Undergraduate	0	0	0	4 (21.1)
Post Graduate	0	0	0	2 (10.5)
Missing data	0	0	0	1 (5.3)
Occupation				
Labourer	0	1 (5.3)	0	1 (5.3)
Only sex work	15 (75.0)	12 (63.2)	0	0
Private service	1 (5.0)	0	6 (31.6)	6 (31.6)
Working with CBO, NGO	4 (20.0)	6 (31.6)	0	0
Homemaker	0	0	4 (21.1)	6 (31.6)
Agriculture	0	0	1 (5.3)	0
Government service	0	0	1 (5.3)	1 (5.3)
Small business	0	0	4 (21.1)	5 (26.3)
Missing data	0	0	3 (15.8)	1 (5.3)
Marital status				
Live-in relationship	2 (10.0)	1 (5.3)	0	0
Married	8 (40.0)	9 (47.3)	11 (57.8)	13 (68.4)
Separated/Divorced	4 (20.0)	2 (10.5)	3 (15.0)	4 (20.0)
Unmarried	2 (10.0)	3 (15.8)	0	0
Widowed	4 (20.0)	3 (15.8)	5 (15.0)	1 (5.0)
Missing	0	1 (5.3)	0	1 (5.0)
Family type				
Joint	3 (15.0)	3 (15.8)	5 (26.3)	6 (31.6)
Living alone	7 (35.0)	8 (42.1)	0	2 (10.5)
Nuclear	10 (50.0)	8 (42.1)	13 (68.4)	11 (57.9)
Extended	0	0	1 (5.3)	0

Men also expressed a desire for MPT in the form of gel. As clients of sex workers, they recognized two benefits of the gel: preventing pregnancy with their wives and preventing the acquisition of HIV while engaging in intercourse with sex workers.

“Gel type is good.... It’s good to prevent from three reasons [/HIV, STI, pregnancy/], but it is difficult to use with my wife, she has to be okay with this product. At the same time it is very useful to pre-

vent from child birth [/pregnancy/] ...In home I use [/condom/] as contraceptive to prevent from child birth, and when I go outside [/FSW/] it prevents me from the diseases. [##IDI 05-30-34## male client of FSW, TN]

Preferences regarding product characteristics such as fragrance, lubrication, and ease of use emerged. Expectation was that pleasure should not be compromised while using these products.

“Some people like fragrance, and smell, but some may dislike it due to excess lubrication. If it is less lubricating, there is no problem in using the product.” [##IDI 06-30-48## male client of FSW, TN]

“If it helps in their emotional excitement, it's fine, otherwise, they will come and say it smells, slippery etc...People won't like anything messy to be put inside the vagina.” [##KII 06-50-58## Healthcare provider, private, TN]

“Means, there is different smell for condom. It is good if it smells, should be like flower's smell or like perfume smell.” [##KII 04-30-48## bisexual man, KA]

While men in the general population wanted lubrication, FSWs also desired lubrication, but women in the general population had reservations pertaining to lubrication.

“If it is greasy and sticky, it may reduce the cleanliness of genitals.” [##IDI 05-20-06## spouse of HIV positive man, TN]

Women in the general population had some reservations, such as uncertainty about its practical use, and its impact on fertility.

“It will be good if it comes in the form of gel and cream type but I don't know whether it can be applied for daily use...also we don't know when we would have sex...it may have some side effects like infertility” [##IDI 05-20-50## spouse of HIV positive man, TN]

It was also believed that if the gel does not reach inside a woman's body, there was a perceived risk of HIV, causing fear and prompting reconsideration of relying on condom alone.

“If that tube is being used...If it doesn't reach inside through the opening of the vagina then that woman has a risk for her life [/HIV/], so more than that it is ok to use mostly condoms.” [##KII 01-60-03## Key influencer, MH]

Affordability was considered crucial by all stakeholder categories for medical products like vaccines, and gels, with a suggested price range of 50 INR (0.60 USD) or free of cost for sustained use. It was emphasized that affordability is essential to ensure the regular use of these products.

“Suppose 50 rupees, injection. Suppose this vaccine should be taken through the injection if it is in 50 rupees, it is reasonable, if it is in 10 rupees, then it will be affordable to every person...but if the cost is increased...suppose it is 100 rupees or 500, then I

don't have ...will see if[/ I can/] take it later.” [##IDI 01-30-15## HIV-positive male, MH]

“Gel...it can be in between 20 to 30 rupees. Women [/FSW/] will not be having money.” [##IDI 04-07-27## street-based FSW, KA]

IDI participants (FSWs and HIV-positive individuals) and FGD participants (FSW) shared their preference for the formulation of the MPT product. Most of the KII and IDI participants, raised concerns about discomfort, side effects and practicality of daily use of MPTs.

People at high risk need long-acting products

Risk based preference for injectable MPT emerged. A low-risk woman's perception was that persons at high-risk need long-acting injectable products because they won't have time to use any other method.

“Drivers...they visit sex workers, people who migrate most of the time, domestic [/local/] people are at low risk, they are satisfied with their children and do not have much risk. They [/sex workers/] have the people [/clients/] every day and it's not possible for them to eat tablets, or apply the ointment. They don't have that time. If they apply ointment, they, the people don't like it. Injection method is easier for them.” [##IDI 01-20-23## spouse of HIV positive male, MH]

“Once it [/the MPT gel/] is used its effect should be there for 2 to 3 times because we [/bisexual/] are going to going [/for sex/] with 2 to 3 persons.” [##04-30-48## bisexual man, KA]

Similarly, a healthcare provider advocated the need for long acting option due to her professional burden:

“FSWs must make their clients use condoms—very difficult. Best option is something that doesn't have to be used every day.” [##KII 06-50-58## Healthcare provider, private, TN]

The application of MPT in a gel form was considered time-consuming and thus not preferred by FSWs.

“When we use gel we will have to clean after having sex. Again, we have to take the gel in hand and apply it to the genitals. It will take time.” [##IDI 05-10-19## street-based FSW, TN]

A street-based FSW eloquently describes the need and the process of decision making for long acting MPT:

“I will like vaccine, because, I cannot use it [/gel/] daily with everyone...Men will go at least once in a month outside [/to a sex worker to have sex/] during wife's delivery. That is why I said one out of two definitely will do [/sexual contacts outside/][laughs].

I drink alcohol, it means I cannot eat that tablet [/Pre-Exposure Prophylaxis/]. Suppose I have white discharge then also I will not eat that tablet [/initially/]; I will eat on second day as I have severe white discharge. I will become angry and drink one quarter [/of alcohol/]. Woman has such [/habit/] and only 5 out 100 women do not drink. ...drink everyday...after drinking, don't even know whether that tablet works or not. People will come [/to take MPT injection/] by thinking like this - my husband goes [/outside for sex/], I love this-this person; and I sit [/have sex/] with him like this- without condom." [##IDI 01-10-13## FSW, Street based, MH]

"....if 4 customers came in one day then who will apply [/gel/] 4 times?.." [##FSW-6## FGD participant, MH]

FSW participants during IDI and FGD preferred long-acting MPTs for their convenience over gels due to the challenges associated with frequent or daily use. Healthcare providers (KIIs), also favoured injectable methods, citing the practical challenges for daily use of non-injectable methods for FSWs.

Condom versus new MPT: potential of MPT

Condoms were seen as a way to prevent 'diseases' and unwanted pregnancies making them an important choice among all IDI participants. The 'low risk' men and women in the 'general population' associated condoms with specific populations such as sex workers, drivers, migrants, and individuals who engage in extramarital or 'illegal [/illegitimate/]' sexual activities. However, the condom as MPT was still preferred due to familiarity and availability, and because it is discreet and "known only to husband and wife, not to others."

Women in the general population thought that marital dissatisfaction from condom use could lead husbands to seek happiness elsewhere.

"[/If/] you can make your husband happy [/condom-less sex/], then why will your husband go out? Since you never make him happy, he is away from home. That's why he never knows if women have HIV? Then, he brings this disease to us." [##KII 01-60-08## NGO representative, MH]

Cultural norms of having children for newly married couples deter condom use among general population women. Condom use in marriage raised suspicion:

"You use a condom means, you have eaten cow dung somewhere [/phrase meaning - having sexual relation with someone else/]...that's why you do this [/use a condom/] with me...." [##KII 01-60-07## NGO representative, MH]

Among women in general population, condoms were being used mainly to avoid pregnancy in marital settings, however condom was perceived to reduce pleasure.

"By [/using/] condom, do not feel like having sex. There is no pure satisfaction to mind during that time. If not using [/condom/], then took that tablet [/contraceptive pills/]." [##IDI 01-43-04W## woman from the general population, MH]

The decision to undergo family planning or use a condom was influenced by the male partner. An HIV infected man convinces his uninfected spouse and tries to procrastinate the decision for family planning:

"I try to convince her not to have family planning right now. We should not do operation right now... will do it later." [##IDI 01-42-22-1## HIV positive male of HIV discordant couple, MH]

An HIV positive woman shared her experience of multiple pregnancies when she was not able to use condom showing a need of long acting MPT.

"Within 2 years I delivered 3 children and 3 of them all failed [/abortion/]. Later, I became pregnant again, and I felt becoming pregnant without gap [/repeatedly/] is not good, then, I planned to take tablet.... I delivered 7 babies but only 3 survived that means 4 failed....I was fed up of giving birth and throwing babies frequently... Yes, later he [/husband/] told me to put copper-T [/intrauterine device for pregnancy prevention/]." [##IDI 04-20-51## HIV positive woman, KA]

The effectiveness of contraceptive tablets like Mala D (contraceptive pill brand) in spacing between children depends on regular use and women felt that insertion of Copper-T (intrauterine device for pregnancy prevention) was risky. Thus, condom seemed to be popular as contraceptive, but most respondents wanted freedom from 'condom use' as soon as the family was considered complete. Prevention of STI or HIV was never on their horizon.

A client of an FSW shared about not using a condom with his spouse regularly.

"Whenever we feel that woman [/spouse/] is going to be pregnant [/fertile days/], at that time only [/use condom/]. Not daily. Condoms are used when nappkins happen [/menstruation/]." [##IDI 01-30-01## male client of FSW, MH]

Permanent method of contraception was desired only once the family size was complete. Sterilization was viewed as an alternative to condom use:

“What is the main objective behind the operation, when you have children [/family size is complete/], and the family is blocked [/sterilized/] it stops...people became carefree...no use of condom then.” [##IDI 01-30-15## HIV positive male, MH]

Men’s risky practices seemed so normalized that protection of spouse gets eschewed because only concern is the pregnancy:

“If it [condom/] has to be used between husband and wife in a family, sometimes it seems to prevent the happiness [/pleasure/] of the couple. Some people think that we have done the operation [/sterilization/] and so she [/wife/] is not going to get pregnant.” [##IDI 06-30-73## male client of FSW, TN]

“we also keep the relations with both male and the female...while using condoms if they tear...do not know if the person has HIV...Nothing [/no need/] to use condom in between husband and wife.. If we never used the condom with wife and suddenly, then she would become doubtful [/suspicious/]...what exactly is the matter?” [##IDI 01-30-28##Bisexual man, MH]

Condomless sex among FSWs was due to financial constraints, clients tearing condom, violence and suspicion when condom use was discussed in regular partner setting. An FSW participant in the FGD shared:

“We cannot insist all to use condoms. If we insist husband or partner use a condom, then they will suspect us [/of distrust/] and violence may happen.” [##FSW-2## FGD participant, TN].

“if they [/clients/] are going to wear the condom, they tear it with their nail....does not come to know...” [##FSW-5## FGD participant, MH].

“Some person will call us and ask us to have sex at nearby bushes, if we go, then there will be 6 to 7 people! It is difficult to handle the situation, cannot use condom with all.” [##FSW-4## FGD participant, TN].

Another brothel based HIV positive FSW narrated her plight of contextual nature of condomless sex:

“I came to know about my HIV 15 years ago....pregnant, tested blood, told me that you have a big disease [/HIV/]...said we cannot touch you, told me to leave. Then I went to civil [/government/] hospital. There they told me to remove it[/abortion/].... I never used to go [/do sex work without condom/].... they took me to some place and there were 10-12 people who did [/sex/] with me the whole night,

that is why I got that disease.... My partner knows everything, he does not have anything [/HIV/]; he comes without protection, and I ask him to use it [/condom/], he says that this is not necessary for us, insists that we do not need it.” [##IDI 03-10-10## HIV positive brothel-based FSW, KA]

Instances of intoxication contributed to unprotected sexual encounters among FSWs.

“After drinking alcohol, the ugly person also looks beautiful [/and/] so they have sex with anyone.” [##IDI 01-30-10## HIV-positive male, MH]

“Similarly, if the alcoholic person comes, it is very much difficult to use a condom.” [##IDI 06-10-44## brothel-based FSW, TN]

FSWs encountered situations where they were unable to use condoms, such as when clients refused or during group sex encounters.

“Simultaneously four people [/clients/] come and surround us [/FSW/], we cannot do anything...similarly, if 5-6 people come at a time [/group sex/] they don’t use condom and refuse us from using female condom.” [##IDI 06-10-43## street-based FSW, TN]

The consideration of using MPT gel prompted the brothel owner to speculate that FSWs might no longer need to use condoms.

“It must come in gel type then it will be good to apply and use. If we use gel type there will be no need of using a condom.” [##KII 06-60-45## brothel owner, TN]

Women empowerment through MPTs

Limitations and challenges associated with condom use highlighted the importance of developing and promoting additional contraceptives and HIV, and STI prevention options to meet the diverse needs of the participants, especially FSWs.

“Every woman can use this without anyone’s support. She would not have to take such support for applying cream or gel. [/It/] definitely will help to decrease [/prevent/] HIV and this [/pregnancy/]. Most of women can use [/these microbicides/] in their home.” [##KII 01-60-07## NGO representative, MH]

“Customer should agree to use condoms. To not get HIV [/infection/], and to not become pregnant... we can take such medicine [/MPT/] for our safety.” [##FSW-5## FGD participant, MH]

Women participants shared that the prevention products a woman opts and decides about, she settles with her

choices, it brings ownership leading to an adherence of higher order.

“That will be more effective, or its acceptance will be more. This means people won’t need to hide. Those products that will depend on females’ decision-making, will be more effectively used. As a woman, in my opinion, when a female decides to use something, her adherence is higher because it’s her decision. She takes that responsibility. Females desire this protection but may not share it with husbands or partners.” [##KII 01-60-16## NGO representative, MH]

Expectations for covert use was similar in Maharashtra, and Karnataka as stated above and in Tamil Nadu as shared in ensuing lines. Healthcare provider brought the commonality of need of covert use of prevention product among all women; be it FSW or non-FSW:

“Female clients often complain that the male partners don’t cooperate in using these products. Need something that females [/non-FSW/] could use without knowledge of male partners, commercial sex workers could use without knowledge of clients etc.” [##KII 05-50-13## Govt. Obstetrician and gynaecologist, TN]

“We can hide and keep it, and we can say it is cream.... we can keep it in a bag or anywhere else. In villages, literacy levels are low, so only those have bought it, will know what it is.” [##IDI 03-10-04## brothel-based FSW, KA]

Throughout the study, the patriarchal context emerged in relation to the usage of MPTs. Patriarchy refers to the male domination both in public and private spheres. True to this, women seemed to have no power over the use of MPT which were their private space. The foremost issue was fear of men controlling pregnancies. In the context of introducing an MPT in an oral tablet form, HIV-positive woman indicates covertness to be part of the roll-out program. She felt an MPT if positioned as ‘contraceptive’, it will be of no use as men control pregnancy because they want children while for an FSW, children might be additional responsibility. Being an HIV infected woman, she shared that a woman with HIV infection would not want to conceive child as she would not want her child to be infected. The ensuing quote from Karnataka woman in a gist summarises the subordination of women-whether HIV infected or uninfected, a man would want child anyhow. In an HIV discordant setting, she, who is not infected, cautions about positioning of MPT product any other than contraceptive which men will probably prevent women to use:

“Government should say that this tablet [/potential MPT in an oral tablet form/] is only to prevent HIV, they must not say that it can prevent conceiving. Men want children in any situation. But we women think about the disease. Our child may also be [HIV/] positive, for how long can we survive? Only a few days. Then who will be the caretaker for children?...So women prefer less children, one or two. But men want many children as possible. What can women do?...Important to not disclose that it stops pregnancy, instead they must say that it only prevents HIV, and then we can have this tablet secretly. We can say-how would I know for what reason I am not conceiving?” [##IDI 03-42-23## HIV positive woman of a discordant couple, KA]

For FSW, context might not be similar to the women in the general population but even her goal is ‘covert usage product.’ An FSW shares her consideration of discreetly using the gel, indicating her distrust in men’s condom use:

“Man has to do this, has to use condom then do sex [laughs]. I have no faith on men. [Pause] Is it or not? [Am I right or not?/]...Not to tell them only? [/that a gel has been used/]...if it has bad smell then they will come to know. If the smell will be perfumed then how will they come to know?...I can keep with me.” [##IDI 01-10-56## street-based FSW, MH]

Participants ranked prevention methods based on women-initiated and women-controlled options. FSWs expressed their openness to various MPT methods, with gels, creams, and vaccines being considered the most usable, while vaginal rings and tablets were deemed less desirable. Most respondents from all the study sites preferred options in the form of a vaccine or gel that would be easily available, easy to use, affordable, and with no side effects. Microbicides or gels ranked highest for protecting without the partner’s knowledge, while vaccines were favoured for being long-acting, and reducing the need for condom use.

Creams and gels were considered easier to carry and store compared to condoms, and they could be applied without raising suspicion:

“Like... we can carry it with us; putting on cream is easier than condom.” [##IDI 01-20-18## HIV positive woman of a discordant couple, MH]

All participants highlighted the need for covert use of prevention products, emphasizing female-initiated and controlled options. FSW participants expressed a strong preference for discreet methods like gels and

creams due to distrust in men's condom use and the desire to prevent unwanted pregnancies without male partners' knowledge. KII participants, including NGO representatives and healthcare providers, highlighted the need for covert products across various populations owing to challenges posed by patriarchal norms.

Secrecy and confidentiality

Secrecy and privacy regarding purchasing and usage was crucial. Participants stressed discreet microbicides storage proposing pouches that can be carried in pockets or unidentifiable bottles.

"That cream, we can keep anywhere and it will not come to know easily. And condom etc... is understood by children. So, if they see it [cream/], it will not create any problem to store it." [##IDI 01-20-18## HIV positive woman of a discordant couple, MH]

Women in the general population also preferred MPT in discreet form of packaging.

"I like plain [not coloured/] gel...can read the package and use it...tube they can take more [more people will prefer to take tube/]. All creams that we are using for other purpose are in a tube. So if it is in a packet [versus in a tube/], [we/] will not feel like using. Fear of mother-in-law, father-in-law, if they see while using, then there will be a problem." [##IDI 04-20-50##, spouse of HIV positive male, KA]

A street-based FSW from Maharashtra shared that she needed an MPT which would protect her from the social risks such as maintaining confidentiality. She eloquently describes the characteristic which informs product developers.

"Let it be in any form but it should be secret. Should give me protection from three sides -I must entertain the customer. I don't want children and I also should not get STI or HIV. If I want to become safe from these three things but my opposite person [partner, client, children/] should not come to know." [##IDI 01-10-13## street-based FSW, MH]

Another brothel-based FSW from Karnataka also wanted invisible MPT:

"Colour... simple one... Not even white, [it should be/] like oil, there is an oil called Tel [Oil/], they should not come to know. ... Tablet- we can hide and we can swallow it at once." [##IDI 04-10-28## brothel-based FSW, KA]

For covert use, men and women suggest that products should be available in small, discreet pouches.

"I said, that jelly etc., the jelly comes from the =[NGO name]=it should be in small pouch, like this little, little pouches etc. so that the person in front of us also doesn't understand [that it/] has been applied, can take on two fingertips and apply it inside." [##IDI 01-30-11## bisexual male, MH]

"in small gutkha [smokeless tobacco product that is chewed or held in mouth/] like packet...sealed" [##IDI 03-30-03## HIV positive male, KA]

"If it can be kept in the bag and carried by ladies, then it will be good if it can be taken openly...fear that someone might see it." [##IDI 05-10-30## brothel-based FSW, TN]

"It can be like condom pack. People will think it is type of condom people will accept it easily. If new packing, they will think why to use this!" [##04-50-13## ART counsellor, KA]

Standard packages containing creams and gels should also include instructions on how to use the product within the same box, self-use without help.

"If it comes in a normal box that has creams, and gels. In that box itself, "how to use it, how should be used." [##KII 06-50-55## healthcare provider, TN]

All participants emphasized the need for secrecy and privacy in storing and using microbicides. While HIV-positive women and FSWs, focused on the need for discreet and unidentifiable packaging, healthcare providers, highlighted the importance of including clear usage instructions within standard packaging.

Non-stigmatising MPT product positioning

Preference for MPT products was in a medical form. If positioned as hygiene products advised by doctors or marketed through pharmacies, it would be used by women with lesser inhibitions. However, they also cautioned about positioning it as cosmetic which would probably be 'luxury' and hence might not be used optimally by lower socio-economic groups.

"All people will be able to use it if it comes through hospital and hygiene related. If it comes in the form of a beauty product, the lower-income group will think differently about it. So, there is a chance for them not using it." [##IDI 05-20-23## HIV positive woman, TN]

Condoms are free of cost in government hospitals in India, but people generally buy it from pharmacies. Therefore, access to MPTs through pharmacies was reported to be easier for people than clinical setups. Pharmacies were recognised as crucial in providing information on where individuals can seek further assistance if required.

“Easy access, truly, people go to the pharmacy, rather than clinical setup, easy. Important point is how to involve pharmacies completely in this program, train them. They should have resources available... that not just to give the thing [/product/], but to share information on how to use to that product... should give a page to give details on using product... people don't go to the hospital generally...condoms-everyone knows it is free in Government hospital, but take from medical stores...Sensitize, give training.” [##KII 01-60-16## NGO representative, MH]

A woman leader and NGO representative shared her concerns about the stigma associated with discovering condom packets or birth control pills at home or with the person. She emphasized the importance of linking products like microbicides with contraception and HIV prevention in the early stages of product development:

“HIV program has taken the condom on the top. Mentioning condoms may raise doubts about character among the general public. The same thing should not happen in the case of microbicide, from the very beginning...attention should be given to how both will get associated. When these trials are completed and a fool proof product enters the market, how will awareness be raised? We have used this as a prevention of STI and HIV...but there might be a stigma- she uses microbicides...a matter of HIV [/suspicion/]/...promoting as both birth control and HIV/STI prevention methods will be more successful.” [##KII 01-60-16## NGO representative, MH]

Based on personal experience, participants shared that the health care providers in the hospitals would discriminate when approached for MPT. They would prefer getting it directly from medical shop. This expectation was shared mostly by FSWs.

“Ladies can go to medical shops and buy the things. But if they go to the doctor, they get scolding, rather than getting things.” [##IDI 05-10-21##, street-based FSW, TN]

Male clients of FSWs also preferred purchasing MPT product from pharmacy stores.

“I [/will/] feel good if it is available in medical shops...feel shy to get the medicine [/MPT product/] in the hospital. So if it can be shifted to a different place, it will be better.” [##IDI 06-30-73## male client of FSW, TN]

Bisexual men proposed social marketing at the community level but still in a covert way.

“These newer techniques [/MPT products/] must keep in medical shop, and should also be kept in village level weekly or monthly camps... The title of that new thing [/MPT product/] should be non-hesitating [/covert/] word, then all will take.” [##KII 03-60-54##, youth leader, KA]

The opinions of IDI participants and KII participants on the preference for MPT products are aligned in emphasizing the need for medical positioning and accessibility through pharmacies to reduce stigma and improve uptake.

Discussion

This study brings forth the end users' perspective on MPT in India and informs product design and position considering the socio-cultural and psychosocial context. This study explored the end user's simulated experience during MPT product ideation through which critical points informing the overall usefulness of the product emerged.

The data highlights converging perspectives among IDI, KII, and FGD participants regarding the need for MPT methods in addition to condoms. IDI and KII participants emphasized the need for covert prevention methods, reflecting broader societal attitudes and the need for long-acting methods for FSWs. While IDI participants leaned towards a preference for discreet methods like gels and injectable MPT methods, KII participants suggested developing a nuanced approach to addressing cultural norms and privacy concerns during the development and introduction of these products.

To the best of our knowledge, this is the first in-depth exploration of people's need for protection against STIs, and HIV and to prevent pregnancy simultaneously. Overall in all three states, MPT was a welcome respite among all populations. Condom, the existing MPT had several pluses and minuses around it. General non-FSW women used condoms for pregnancy prevention only and their spouses, if high-risk did not use them in marital settings. FSWs wanted to have an alternative MPT as condoms posed multiple challenges pertaining to reducing pleasure, not being accessible or useless in group sex etc. FSW as against non-FSW general women, foremost wanted to prevent pregnancy. Overall, condom use went down among groups of women if family was complete or pregnancy was not required. Hence condom promotion for HIV prevention even among high-risk women was not registering optimally.

While FSWs and high-risk male populations preferred condoms as MPT and had faith in their efficacy, inconsistent use of condoms was reported. Discreet

methods were deemed necessary. Women in this study stressed sustained pleasure, product comfort, and minimal interference with sex, affordability, and privacy as key characteristics of MPTs. Long-acting MPTs in the form of injection were preferred by FSWs, while vaginal rings and oral tablets were less preferred. Past experiences with vaginal gel formulations for HIV prophylaxis demonstrated low adherence, indicating that hypothetical preferences may not align with actual usage rates [28]. It is recommended to offer multiple formulations to address single-option aversion, and different preferences and increase opportunities for use. Men and women may want choices that may reflect Mochon’s single-choice aversion phenomenon wherein people exhibit a reluctance to choose an attractive option in the absence of alternatives, as they lack a basis for comparison [29]. The diversity in desired product attributes emphasizes the need to support the ongoing development of MPTs.

FSWs and male clients of FSWs entertained thoughts of foregoing condom use when considering alternative methods of prevention of pregnancy and HIV. It will be prudent to consistently reinforce education emphasizing that MPTs may not offer complete efficacy in preventing both STI/ HIV and pregnancy (until effectively proven), thus emphasizing the continued need for one existing MPT viz. condom usage among potential users. Discreet options and ease of use were emphasized by the participants as reported in other studies [30, 31]. The physical form of a product influences the potential for discreet usage.

Table 3 describes the findings generated from this study that inform the product development to address three critical areas of end user’s interest 1) Pleasure; 2) Privacy; and 3) Stigma.

Product developers should consider enhancing formulations and physical forms from the very initiation of the product development. To ensure secrecy, and confidentiality, inconspicuous design and packaging are crucial, allowing product use without fear of judgment. Exploring strategies that empower women in decision-making processes is recommended. This may involve interventions, educational programs, or support systems facilitated by local bodies including self-help groups, gram panchayat, sex-worker collectives, CBOs, and NGOs to promote women’s autonomy and involvement in adopting MPTs.

Similar to our study, in other settings participants showed a lack of interest in products such as rings, diaphragms, and fabric that are designed to be inserted into the vagina, fearing dislodgement during sexual intercourse [32]. The potential MPT products could involve developing a long-acting formulation that provides extended protection [33–35] and can be administered monthly or quarterly, reducing the burden of daily regimens. To address concerns associated with daily regimens, alternative dosing schedules should be explored, such as non-daily administration options. This could include weekly or on-demand use, offering flexibility to users while still maintaining effectiveness. Developing reminder systems [36, 37], user-friendly packaging [38], and additional support services to facilitate timely re-administration is essential. Partnering with local CBOs and NGOs can help increase the affordability and accessibility of these methods for FSWs.

Enhancing community engagement approaches is crucial to improving knowledge dissemination about MPT among potential end users [39]. Consideration of the cultural context and literacy levels is vital when developing visually appealing materials like wall paintings, infographics, and pictures [40]. Potential MPT products

Table 3 Psycho-social framework of contextual MPT development

Psychosocial aspect to be addressed	Desired Product characteristic	Product design	Measurable Outcome
Pleasure	Texture	Colourless, not felt by touch or visible and therefore having features of transparent oil, viscosity not interfering with pleasure, should feel clean, non-messy in the body and hygienic	Pleasure Economic viability for paid sex Reduction in violence Enhanced quality of life Increased usage of the product Towards empowerment
Privacy	Packaging	Small noiseless packing which can be in a small place; easy to store and easy to destruct Instructions for users should be easy to comprehend	Fear mitigation Increase usage Increase in Self-esteem Empowered
Stigma	Positioning	MPT could be positioned as a cosmetic or hygiene product and marketed through pharmacies to prevent stigma. Women can easily buy a product at a pharmacy without hesitancy	Autonomy Empowerment Increased usage

should clearly convey key messages about positioning and benefits of MPTs while ensuring accuracy, clarity, and cultural sensitivity. Engaging local artists, community members, potential users, and volunteers with cultural knowledge may contribute to creating impactful visual representations. Distributing printed materials in local language, such as pamphlets or brochures, containing visual representations and key information about MPT products is important.

Establishing partnerships with pharmacies to actively involve them in the training and distribution process of MPT products is recommended. Community literacy among pharmacists and healthcare providers would be crucial for the success of MPT which will help build a stigma-free environment for MPT access. Training should stress confidentiality and sensitivity in customer interactions for MPTs. Sensitivity to cultural norms is vital in distribution strategies to enhance community acceptance. Thus, collaborating with community stakeholders who possess cultural knowledge and influence may be essential. This approach may enhance accessibility and foster community ownership and empowerment, leading to greater acceptance and utilization of MPTs. It is essential to address and mitigate stigma associated with HIV. One approach could be to integrate MPTs into reproductive health programs, incorporating interventions that combine reproductive health and HIV prevention.

This study provides an in-depth insight into end users' perspectives on MPTs. The data captures perspectives from multiple stakeholders which may influence the use of MPT among women. The data is not recent but there is no MPT available except condoms, therefore this data which was collected from various geographies of India applies to the MPT status today also and hence these findings are important in the current context. The end user's perception would not change since no product is in the offing, neither in India nor globally. The study also tries to capture socio-cultural context of MPT use in three states in India. The sociodemographic data of FSW FGD participants could not be collected owing to confidentiality concerns and secrecy which was a limitation.

The strength of qualitative study is in transferability which neutralises the problem of the limitation of generalizability. To ensure the rigour of the research, attempts were made to conduct this study through contextual recruitment of the participants and engaging the community for it. The process of doing content analysis while the data was being collected, informing the identification of additional data and involvement of site teams in data analysis further ensured the transferability of the findings.

Conclusion

Several stakeholders in this study reported their need for new MPTs, but concerns regarding confidentiality, privacy, stigma, and adherence were identified. Therefore, besides efficacy of the product, characteristics such as its size, packaging, formulation, texture of MPTs, should be taken into account when designing the MPT products, also considering the needs of women, specially, commercial sex workers. MPT products if designed to address end users' empathetic concerns enhancing cognitive flexibility would enhance acceptability and lead to optimal usage.

Supplementary Information

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Supplementary Material 1.
Supplementary Material 2.
Supplementary Material 3.
Supplementary Material 4.
Supplementary Material 5.

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Disclosure statement

The authors of this manuscript declare that they have no competing interests.

Authors' contributions

SSa led the conceptualization, funding acquisition, methodology, project administration, study implementation and supervision. NC, TS, MA also led the project administration at respective sites and planned and implemented the study. SSh and SSa conducted the data analysis, SSh wrote the original draft. SSa, NC, TS, MA, SB, TK were involved in providing critical review and edits to the manuscript. All authors have reviewed and approved the manuscript.

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Data availability

The dataset used and/or analysed during the current study is available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The study was approved by the institutional ethics committees at each site – ICMR-National AIDS Research Institute (Pune, Maharashtra), the ICMR-National

Institute of Epidemiology (Chennai, Tamil Nadu) and the Jawaharlal Nehru Medical College (Belagavi, Karnataka). Written informed consent was obtained from all the study participants for participation in the study and audio recording of their responses before conducting the IDIs, KIs, and FGDs.

Consent for publication

Not applicable.

Competing interests

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