Stakeholder conversations to inform delivery of multiple HIV prevention methods in Kenya

INTRODUCTION

The dapivirine vaginal ring (the "PrEP ring" or "ring") received a positive opinion from the European Medicines Agency in 2020 and was endorsed by the World Health Organization (WHO) in 2021. The International Partnership for Microbicides (IPM), which developed the ring, plans to introduce it as an additional HIV prevention option for women when oral PrEP is not or cannot be used or is not available. Another form of pre-exposure prophylaxis (PrEP), injectable cabotegravir (CAB PrEP or CAB-LA), has recently shown great promise in clinical trials as an additional, highly effective HIV prevention method that could be made available in the future. Experience has shown that multiple methods are necessary to meet the HIV prevention needs of women, especially adolescent girls and young women, and that expanded method choice has the potential to increase uptake overall. However, little is known about what is needed for health care providers (HCPs) to ensure adequate counseling on method choice, referral mechanisms, and supportive follow-up with regards to multiple biomedical HIV prevention methods. The goal of these conversations with stakeholders, implemented by LVCT Health Kenya as part of the PROMISE Collaboration, was to gain input on implementation considerations from provider and potential end-user perspectives to inform the introduction of the PrEP ring alongside oral PrEP and future inclusion of additional prevention methods for women.

METHODS

From September - November 2021, four experienced qualitative research assistants conducted in-person and virtual individual and group conversations using thematic discussion guides adapted for each stakeholder group and aligned with national priorities. Convenience sampling was used to select participants who were either female sex workers (FSWs), young women (YW), or healthcare providers (HCPs). FSWs (n=17) were identified for participation by the site in-charges in two LVCT Health drop-in centers (DiCEs), Sokoni in Nairobi County and Muhuru in Migori County. YW (n=18) were selected by site in-charges in two LVCT Health DREAMS (Determined, Resilient, Empowered, AIDS-free, Mentored and Safe) sites, Korogocho in Nairobi and Kaksingri West in Homa Bay. HCPs (n=22) were selected from LVCT Health facilities and from three public health facilities (Mukuru Health Centre, Kangemi Health Centre, and Lunga Lunga Health Centre) where LVCT Health is implementing a PrEP-family planning (FP) integration activity.

Sample composition

Q

Female sex workers

8

18 Young womer



Providers

(this was combined between PrEP provider and FP provider)









TABLE 1: SELECTION CRITERIA BY STAKEHOLDER CATEGORY

Stakeholder category	Selection criteria
FSW	Current use of a modern contraceptive and had never used oral PrEP, had used oral PrEP and stopped, or were currently using oral PrEP
YW	Currently using a modern contraceptive and had never used oral PrEP, had used oral PrEP and stopped, or were currently using oral PrEP
НСР	Offering either oral PrEP or contraceptives services within the DREAMS project, Key Population project, or within public health facilities

Verbal permission was received from participants prior to the start of the conversations, which were audiorecorded to support fluid and interactive discussion. Detailed notes were also taken during the conversations, with any personally identifiable information omitted. This activity was conducted following the COVID-19 prevention guidelines and precautions set by the Kenya government and USAID mission. The activity was determined not to be research by FHI 360's Office of International Research Ethics (IRBNet ID: 1733984-1).

We used a rapid qualitative analysis method to analyze data from the conversations via a two-step process. First, LVCT Health research assistants listened to recordings and referred to notes from each conversation to summarize data for each theme, including relevant illustrative quotes, in a structured table in Microsoft Excel. Next, PROMISE staff consolidated the summaries from the table by participant type (i.e., provider, potential end user) to identify common themes and to allow comparison across groups.

RESULTS

Whom did we consult during the conversations?

TABLE 2: PARTICIPANTS AND DATA COLLECTION

Type of Participant	Data Collection	Total Number of People
Young women	Individual interviews	18
Female sex worker	Individual interviews	17
PrEP provider	Individual interviews	9
	1 Group discussion	8
FP provider	Individual interviews	5



Potential end users

Thirty-five potential end users of the ring participated in the conversations (see Table 3). Individual interviews were carried out with 18 YW ages 18–29, four of whom were pregnant and/or breastfeeding at the time. Individual interviews were also conducted with 17 FSWs ages 21–42.

TABLE 3: PARTICIPANT CHARACTERISTICS: POTENTIAL END USERS

Group	Age Range	Marital Status	Education	Use/d Oral PrEP
YW (n=18) *4 YW participants were pregnant and/or breastfeeding; 1 participant identified as an FSW	18-29	Married (n=7) In a relationship (n=4) Single (n=7)	Primary (n=5) Secondary (n=11) College (n=2)	Used and stopped (n=8) Currently using (n=5) Never used (n=7)
FSWs (n=17)	21-42	Married (n=2) In a relationship (n=1) Cohabitating (n=1) Single (n=13)	Primary (n=7) Secondary (n=7) University/College (n=3)	Used and stopped (n=9) Currently using (n=5) Never used oral PrEP (n=3)

A total of 17 PrEP providers participated in individual and group discussions in Kenya. Nine individual interviews were conducted in Nairobi County, and eight providers from Nairobi (n=4) and Western (n=4) counties participated in a group discussion. Five FP providers from Nairobi County participated in individual interviews.

TABLE 4: PARTICIPANT CHARACTERISTICS: PROVIDERS

Provider type	Type of facility	Designation	Experience	Age Range	Use/d Oral PrEP
PrEP provider (n=17)	Public health (6) NGO-based (n=11)	Clinical officer (n=12) HIV testing services (HTS) counselor (n=4) Registered nurse (n=1)	>5 years (n=4) ≤5 years (n=13)	20-39 years (n=14) 40-59 years (n=3)	Has ever used oral PrEP (n=0) Never used oral PrEP (n=17)
FP provider (n=5)	Public health (n=5)	Registered nurse (n=5)	>5 years (n=2) ≤5 years (n=3)	20-39 years (n=4) 40-59 years (n=1)	Has ever used oral PrEP (n=0) Never used oral PrEP (n=5)

¹⁶ Providers had been trained in FP, oral PrEP, and HIV services. 13 of those providers were primarily PrEP providers; 3 were primarily FP providers.

What have stakeholders already heard about new PrEP products?

Only one YW, who happened to also identify as an FSW, had heard about the PrEP ring or CAB PrEP. This participant had heard about both methods from a field officer of the Bar Hostess Empowerment & Support Programme, a nongovernmental organization (NGO) that provides health services to women who are members of key populations in Kenya. YW mentioned using and being familiar with oral PrEP,

TABLE 5: KNOWLEDGE OF NEW PREP PRODUCTS

Number who had heard of new PrEP products			
	PrEP Ring	CAB PrEP	
YW (n=18)	1	1	
Female sex workers (n=17)	6	2	
PrEP providers (n=17)	8	6	
FP providers (n=5)	4	1	

condoms, practicing abstinence, and frequent HIV testing for HIV prevention. Four YW said they did not use any HIV prevention method.

Fewer than half of the FSW participants (n=6) had heard about the PrEP ring for HIV prevention. Those who knew about the ring had learned about it from LVCT Health (n=5) or a friend (n=1). Only two of the FSW participants had heard about injections for HIV prevention — one from LVCT Health and another from a peer FSW. All participants who had heard about the ring

were able to recall that it is vaginally inserted and prevents HIV, with some also stating that the ring is not 100% effective, can be used for 28–30 days, does not protect against other sexually transmitted infections (STIs) or pregnancy, and can be used in conjunction with oral PrEP.

About half of the PrEP providers (n=8) had heard about the PrEP ring, but only six had heard of CAB PrEP. The information providers had heard about the ring varied but reflected knowledge about the ring being PrEP, vaginally inserted every 28 days, and for women. Four of the five FP providers had heard about the ring. Those who were familiar with the ring had heard it was a new, vaginally inserted HIV prevention option. Some of these providers noted that the ring should be worn for 28 days, although others were not sure of the duration. Two providers had heard different prices for the PrEP ring, ranging from 250 shillings and up. Only one FP provider — the one who had not heard of the ring — had heard of injectable PrEP. That provider had heard that CAB PrEP is an HIV prevention method with a duration of two months that is not yet available in Kenya.

What do stakeholders think about new PrEP products?



The PrEP Ring

Advantages

Most participants across all stakeholder groups mentioned as advantages of the ring that it can be used discreetly and would not involve taking a daily pill (citing forgetting to take pills daily and not liking to swallow pills or carry pills around). YW participants added being able to hide the ring from their partners as an advantage. YW appreciated the 28-day use period of the ring for its possible alignment with the menstrual cycle. Some FSW participants described potential scenarios they face as sex workers that are out of their control (rape, clients insisting on unprotected sex), adding that the ring could help prevent HIV in those scenarios without the extra burden of going to a facility for post-exposure prophylaxis (PEP).



PrEP providers also highlighted that the ring is self-inserted and can offer an alternative for women who are having trouble with oral PrEP adherence. One NGO-based PrEP provider mentioned that the ring could be administered during outreach, and a public health-based PrEP clinical officer thought it could be specifically beneficial for serodifferent couples, who are the majority of PrEP clients in many public health facilities. Two providers described how the ring might help reduce the stigma surrounding oral PrEP. "If someone gets the ring and inserts for 28 days, no one will know if you have it, so the stigma will not be as much as if someone sees you taking the pills," one of them said (female NGO PrEP provider, individual dialogue participant). Many providers from the group discussion said the ring would have been useful during COVID-19 because a user would not need to visit a facility as often because the product is self-inserted, with the potential for multi-month dispensing. FP providers also said the ring is a good option because it will help reduce the likelihood of HIV acquisition for those with high likelihood of exposure and because ring side effects could be less severe than those of oral PrEP and/or CAB PrEP.

- [6] It [the PrEP ring] will help to move away the services from being provider initiated to self-care." Female NGO PrEP provider, individual dialogue participant
- 6 You go on with your normal life with the ring inside the body. As an FSW, I know that I am protected and always ready even when a client wants unprotected sex."
 FSW, individual dialogue participant

Disadvantages

Two YW mentioned no concerns or perceived disadvantages of the PrEP ring. Among the other YW participants, disadvantages of the PrEP ring included misconceptions and concerns that it may be difficult to insert and/or remove or that it may fall out, fear or discomfort with vaginally inserted products, that a sexual partner may find out about ring use, the potential cost, and that the ring must be used with a condom.



I don't like things inserted in my vagina... I am scared about inserting the ring by myself."
YW, individual dialogue participant

Some YW had questions about the PrEP Ring:

- Can the ring be absorbed inside the body?
- Does the ring have side effects?
- Can the ring slip out when you squat?
- Can you use the ring during menses?

"[The ring] only protects one from getting infected with HIV at the vagina only, but oral PrEP protect your whole body... The fact that it is to be inserted in the vagina makes me uncomfortable with it." FSW, individual dialogue participant

The disadvantage of the ring most frequently noted by PrEP providers (n=7) was its 50% efficacy against HIV. Other disadvantages mentioned by PrEP providers were concerns about hygiene or infections (n=4) and potential issues with insertion, especially for YW and FSW. Among FP providers, the most common concerns were the possibility that a partner might feel the ring during sex and myths and/or misconceptions, including that the ring will get lost in the cervix and that it will cause discomfort during menses and urination. The 50% efficacy of the ring was also a disadvantage commonly mentioned by FP providers. Public health providers — mostly those providing FP — compared the ring to the intrauterine contraceptive device (IUCD) and share the misconception that the ring would be contraindicated for women with multiple sexual partners because of increased risk of recurrent urinary tract infections (UTI) in women, leading to frequent visits to health facilities. Another concern expressed by FP providers was the misconception that ring use would create a long-term problem with vaginal discharge. Some providers argued that this perceived problem would discourage FSWs from using it given that it may affect sex work.



CAB PrEP

Advantages

Advantages of CAB PrEP mentioned by YW participants included not having to take a pill daily, that it is the longest-acting method, and that injections are "less uncomfortable than the ring." The most common advantage mentioned by all FSW participants was that it prevents HIV. Most advantages expressed by FSW were the same as those mentioned for the ring, including that it would be discreet (n=5) and easier to use than pills because you do not have to remember to take something daily (n=5). FSW participants thought the injection might be more convenient to use than the ring.



According to most FP providers, the advantages of CAB PrEP are that the injectable is discreet, provides immediate protection once an injection is received, and provides long-acting HIV protection. Most PrEP providers listed the two-month duration of the injectable as the main reason it is a good option, specifying that the long-acting feature would facilitate adherence, cut down on clinic visits, likely improve retention of users, and allow users to avoid a daily pill burden. Two PrEP providers pointed out that providers' and users' familiarity with FP injectables could translate to better uptake and adherence with injectable PrEP. "The idea is welcomed," one of the PrEP providers said. "In fact, they have always been demanding for a PrEP method that one can inject like in the family planning injection method" (male public health PrEP provider, individual dialogue). An FP provider said that there would be preference for an injectable, based on what she has seen in FP with the daily pill burden of oral contraceptives versus contraceptive injections.

Disadvantages



YW participants noted that CAB PrEP does not prevent pregnancy or other STIs. Multiple respondents also mentioned as a disadvantage that CAB PrEP has to be administered in a hospital or facility. YW participants were worried about swelling or pain from the injections, as well as possible side effects, including interactions with hormones. Other concerns mentioned included fearing injections, fear of being injected with expired product, and whether the injection can cause infections.

Some YW had questions about CAB PrEP:

- Can injections be done in the arm?
- Can men use injectable PrEP?
- Can it be used with Depo?

Almost half of FSW participants (n=7) mentioned no possible disadvantages to CAB PrEP for HIV protection. Among those who mentioned disadvantages, the most common concern was side effects (n=6). PrEP providers (n=5) expressed similar concerns about side effects, as well as the inability to reverse an injectable

once administered and that it cannot be administered outside a health facility. One PrEP provider expressed concern about having to give different information to clients at initiation versus clients getting refills. Currently providers at safe spaces and DREAMS sites counsel all clients at once, and nonclinical staff can provide oral PrEP refills. This process would need to change to allow for counseling on multiple methods and the clinical administration of CAB-PrEP. The majority of FP providers shared that the injectable is not a good option because of the potential side effects.

- The fact that if it has adverse side effects and you have already been injected; therefore, you have to wait for the two months to end, because there is no way that you can remove that injection from your body. Like for family planning, when you get injected it stays in the body for six months, so to remove it from the body is very hard."

 FSW, individual dialogue participant
- The injection will be a real challenge because it cannot be done door-to-door"
 FSW, individual dialogue participant

How will new PrEP products affect use and choice?

Potential end users felt that new PrEP products would allow them to make decisions based on their needs and wants.

YW participants stated that new prevention products would allow them to choose the methods they want, and not just what a health care worker tells them to use.

- Ge You get to make the decision to use it, not just going to the facility and the HCW tells you, 'Today we have two new PrEP methods, the ring and the injection. Which do you want?' They should tell you the facts about the method." YW, individual dialogue participant
- [6] I am constantly in and out of hospital, and so if I can use new technology that will keep me away from hospital a bit, I will really appreciate." yw, individual dialogue participant
- 66 I want to thank the organization that has come up with this injection and the ring. It is a good chance of preventing the youths from getting HIV/AIDS. The way we are around here, mostly the youths are very much infected by HIV, and so by getting these methods, it will help us a lot."

 YW, individual dialogue participant

Providers reflected on the variety of clients they see, how each client has their own individual needs, and who could benefit from having a choice of new prevention products. One public health PrEP clinical officer noted that given the diversity of his usual clientele (FSWs, gay men and women, and serodifferent couples), he expects clients to choose a method based on their own needs.

Providers described discussing FP options with clients by talking about available options, client knowledge, client history (both medical history and method history), advantages and disadvantages of methods (especially side effect management), and cultural or religious beliefs that may affect method selection (e.g., if someone's religious beliefs influence their condom use). FP providers said they decide which options to recommend based on income, client health, and method history, guidelines for methods and WHO criteria, and side effects.

What is needed to support informed choice and continued use of PrEP products?

The majority of YW respondents (n=11) mentioned that they needed more information — about the products and available methods, HIV prevention, product demonstrations, and side effects broadly — to help them make the best decisions about prevention. Most YW participants preferred to get this information from hospitals, DREAMS sites, and safe spaces. Doctors, LVCT Health, and videos were also mentioned as preferred sources of information on prevention methods. Some YW participants said that HCPs should listen to end users. Two YW respondents added that HCPs should offer advice on whether to disclose PrEP use to partners and should share with clients their personal experiences using PrEP products. One YW participant mentioned that HCPs should be open-minded and honest to help end users decide whether to use a method:

They should not force you. You are the one to make the decision. It's voluntary."

YW, individual dialogue participant

Similarly, all FSW participants who responded (n=14) said they would like more information about available options and their side effects. Overall, participants were particularly interested in understanding which method would work best for them and would lead to the fewest side effects.

Some PrEP providers stated that service providers need training in new prevention methods and best practices for quality counseling on new methods. Other PrEP providers focused on the need for information (and information sharing) on the methods, adherence, and how to use the method. PrEP providers also thought information and counseling would need to change based on what was available and to accommodate different education levels. An NGO-based HIV testing services (HTS) counselor noted that one-on-one counseling would be good for both the ring and CAB PrEP:

Logistical needs to support informed choice were also mentioned. PrEP providers stated that it would be necessary to increase the number of health personnel to allow for counseling and adequate time spent with each client. They said that the increased time spent counseling could be burdensome and could lead to longer queues and client wait times.

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Other PrEP providers noted that marketing needs and testing requirements for initiation could be a challenge. One NGO-based HTS counselor was clear in her response that community-based distribution of new products would be beneficial:

While there is no challenge with the commodity, clients don't come back to the clinic regularly. We have people who go away for three to six months, so now if we integrate, where someone will have to come to the clinic every day or bring their partner every month, then it becomes a challenge. So, if these services can be differentiated and taken to the community or be moved away from a health center to the community, I think it would be much easier, because we could even offer mobile clinics to the communities, because much of the need is there than in the facility." Female NGO PrEP provider, individual dialogue participant

Training for peer workers, as well as providers, was mentioned. There is a need to strengthen the connections between communities and facilities to improve the referral system.

66 Sometimes people are referred from the community to come to the facility, but they don't have transport or don't have means, so they end up not coming, so the cascade is not complete. The clients should be able to call the facility and a mobile clinician can go and offer those services in the community as opposed to asking a client to come and maybe logistically they are not able to." Female NGO Prep provider, individual dialogue participant

One provider said to consider the different circumstances of clients and "differentiate this type of care and take the services to where the people are, because it is hard for someone to come from like Nairobi to come here to get PrEP every month. There is a cost implication, but if these services are around them or accessible to them it will be easier for them to uptake the services" (female NGO PrEP provider, individual dialogue participant).

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Community involvement for advocacy purposes and to have the product well known to the community that we are serving, so that at the end of the day we get the information, the products, and the demand to the intended people and the populations that we are serving."
Female NGO PrEP provider, individual dialogue participant

All FP providers shared the following ways in which FP providers can be involved in helping clients learn about HIV prevention services:

- $\cdot\,$ Integrate services so a client can get FP and HIV prevention services from the same person
- Offer services at multiple delivery points (HTS, comprehensive care clinics that offer antiretroviral treatment, child welfare clinics)
- · Include a health talk about PrEP when counseling on FP
- Include counseling on HIV prevention services during screening with the Rapid Screening Assessment Tool
- · Create awareness with training of clients and providers

FP providers shared challenges they experienced when counseling clients on multiple FP methods, including information overload, misconceptions about products, and clients wanting to try one method at initiation but saying they will switch to another method during the next visit. "They would tell you, 'Let me use this one, since it is the one that [I] have come for, and then next time I will switch'" (female public health FP, individual dialogue participant). Regarding FP options, providers said availability of the commodities, sensitization and continuing health education during facility visits, and comprehensive information on the methods are needed to help FP clients decide on a method.

Where should HIV prevention methods be delivered?

YW participants said they would prefer to obtain additional HIV prevention methods from a government facility (i.e., public and county hospitals) or NGO site, such as a DREAMS site or LVCT Health facility. Reasons for preferring these locations included that government and public health facilities provide free services, confidentiality, safety, friendliness, professionalism, and a comfort with LVCT Health services.

All FSW participants described positive aspects of the HIV services they currently receive from LVCT Health, including that staff are respectful to sex workers, privacy is maintained, and services are good. FSW participants preferred to access HIV services in locations that specifically cater to sex workers, are close to where they live, provide free services, and are already providing other services to FSWs (e.g., contraception, PEP, and support for those affected by gender-based violence). Finally, one participant said new HIV prevention methods should be available "everywhere," and another noted that having ring dispensers in public toilets would improve access for people who cannot get to facilities.

Interestingly, one YW participant mentioned that the private sector will try to profit from HIV prevention products and therefore should not be allowed to offer them; two participants mentioned specifically disliking "chemists," referring to those at unlicensed service points. Participants also mentioned the possibility of counterfeit products at chemists. YW participants expressed concerns about breaches of confidentiality when working with community health volunteers. All but one FSW participant said they would seek HIV prevention methods from LVCT Health, with one person stating she would go to the hospital instead.

KEY FINDINGS & RECOMMENDATIONS

Although new PrEP methods are not well known and myths and misconceptions about them already exist, end users and providers are open to and eager for HIV prevention options. Potential end users and providers emphasized the need for comprehensive information on all methods, including advantages, disadvantages, side effects, and product demonstrations, to inform and support decisions about their use. Once new methods were explained, dialogue participants thought that potential end users would prefer to use either the PrEP ring or CAB PrEP because they are long acting, discreet, and more convenient than taking pills.

Disadvantages and concerns about the PrEP ring among all participants included lower effectiveness, discomfort with a vaginally inserted product, and fear of it falling out or being noticed during sex. Participant concerns about CAB PrEP included fear of injections, potential side effects of the injection, that users may need to continue taking oral PrEP for up to a year after the injection is discontinued if they may still be exposed to HIV, and not being able to get the injection outside of a health facility. Comprehensive information and sensitization on new methods should take place in health facilities and communities to address concerns, myths, and misconceptions. Providers and peer educators should be properly trained on new prevention methods and how to counsel clients and conduct health talks in facilities and communities.

Potential end users described multiple important components of service delivery that would facilitate uptake and continued use of new PrEP products, including professional and trustworthy services. They value facilities that provide free services and are friendly and confidential. End users need to feel confident that they are getting legitimate prevention products from locations that maintain confidentiality and cater to their needs. These factors should be considered when assessing where prevention methods will be distributed.

Potential end users and providers emphasized the importance of community involvement — including having mentors and ambassadors in the community — to support informed choice and continued use of PrEP methods. Community involvement is also needed to increase awareness of and demand for the products.

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In addition to providing comprehensive information and sensitization, programs much ensure the accessibility of all methods. Community-based distribution of prevention methods should be assessed. Providers should be able to distribute prevention methods during outreach, and end users should be able to obtain methods in locations outside of a health facility.

