OPEN LETTER

Community Inclusion in PrEP Demonstration Projects: Lessons for Scaling Up [version 1; peer review: awaiting peer review]

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Abstract
Pre-exposure prophylaxis (PrEP) has emerged as a new HIV prevention strategy. A series of demonstration projects were conducted to explore the use of PrEP outside of clinical trial settings. Learning from the failures in community consultation and involvement in early oral tenofovir trials, these PrEP projects attempted to better engage communities and create spaces for community involvement in the planning and roll out of these projects. We briefly describe the community engagement strategies employed by seven
Bill & Melinda Gates Foundation-funded PrEP demonstration projects and the lessons these projects offer for community engagement in PrEP implementation.

Keywords
pre-exposure prophylaxis, demonstration projects, HIV, prevention, sex work, serodiscordant couples

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Background

Pre-exposure prophylaxis (PrEP) is a new HIV prevention intervention for people who consider themselves at risk of acquiring HIV. Current protocols and guidelines outline PrEP use as the intake of a daily pill (the combination of the antiretroviral therapies tenofovir and emtricitabine). In September 2015, the World Health Organization (WHO) recommended that people at “substantial risk” of HIV infection have access to PrEP as part of comprehensive HIV prevention strategies.

A number of randomized control trials have demonstrated clinical efficacy of PrEP. However, early oral tenofovir trials among marginalized communities, including in Cambodia, Cameroon, Nigeria, and Malawi among female sex workers (FSWs) and in Thailand among people who inject drugs, drew international attention with concerns over ethical violations in research practices. Organized community action led to a halt of the trials in Cambodia and Cameroon, and a failure to start trials in Malawi. Although significant concerns were raised about the Thai trial, it ultimately proceeded, while the trial in Nigeria was discontinued by the research team based on non-protocol adherence.

The community actions articulated that each of these trials was unethically conducted on the basis of not collaborating sufficiently with communities, providing selective information about potential adverse effects, and being unwilling to provide comprehensive health insurance and care for participants. In order to find ways to move towards a more collaborative approach to biomedical HIV prevention research, a series of consultations following these study closures led to the creation of the Good Participatory Practice: Guidelines for biomedical HIV prevention trials. These guidelines, prepared by UNAIDS and AIDS Vaccine Advocacy Coalition (AVAC), highlight community engagement in biomedical HIV prevention clinical trials as an ethical imperative. This was further stressed in an additional guidance note prepared by UNAIDS and the World Health Organization on Ethical considerations in biomedical HIV prevention trials.

These guidelines and the lessons learned from the initial controversies paved the way for more inclusive research practices. PrEP clinical trials and demonstration projects designed and implemented after these controversies were more proactive in their community engagement practices, engaging communities and creating spaces for community participation from planning through implementation of these projects. With confirmation of PrEP efficacy, the WHO called for implementation studies to inform product effectiveness and implementation. The Bill and Melinda Gates Foundation (BMGF) funded several demonstration projects with the aim of providing data on the implementation of PrEP in a diverse range of settings and populations. The aim of this paper is to articulate the community engagement practices implemented in seven BMGF-funded demonstration projects (listed in Table 1). We describe the use of various community engagement strategies and engagement with a wide range of stakeholders in a diverse range of settings and populations.

Assessment of the research projects

Throughout the course of the demonstration projects, BMGF conducted meetings involving implementers from the different project sites. The purpose of these meetings was to share project updates and facilitate cross-learning. The possibility of joint publications were discussed in these meetings and crystallized during a multi-site meeting in Benin in 2016. During this meeting, a joint manuscript was planned to capture the community engagement strategies employed in the various demonstration project sites.

Members of each of the seven research projects completed an open-ended questionnaire exploring the objectives of their project, demand generation strategies, and role of the community in planning, recruitment, follow up, and retention. The first and second authors then conducted follow up phone interviews with a number of the sites to clarify their responses and gather more details about their work. A draft case study of each site was prepared, shared with the partners, and finalized with their inputs.

Findings: The role of community in PrEP demonstration projects

We present mini-case studies of each project that detail the overall role of community in various stages of the projects, challenges, and achievements related to community involvement. While we recognize that community is a loaded term that can mean different things in different contexts, for the purpose of the case studies presented, community includes the populations targeted by the demonstration projects (serodiscordant couples and sex workers) and the key stakeholders working with these populations.

Demonstration projects involving serodiscordant couples

The Partners Demonstration Project: Kenya and Uganda

The Partners Demonstration Project explored delivery approaches among HIV-1 serodiscordant couples in Kenya and Uganda, with two sites in each country. PrEP was offered to the HIV-uninfected partner until the partner living with HIV had initiated and used ART for at least 6 months. The project ran from November 2012 to June 2016 and enrolled 1013 HIV serodiscordant couples across sites.

The project’s community strategy involved engagement with a wide range of stakeholders, community education on PrEP, and dispelling myths about HIV serodiscordance. Community entry was initiated through seeking approval from national and local government authorities in the Ministry of Health and Public Works, which was followed by meetings with lead members of community organizations (non-governmental, community-based, and faith-based), HIV serodiscordant couples support groups, and national and local health care authorities. The site projects instituted community advisory groups (CAGs), comprised of representatives of the above groups and members representing HIV serodiscordant couples. The CAGs acted as a link between the community and the project. They provided input on the study implementation, reviewed and advised the
proposed recruitment approaches, and addressed community concerns. The research team worked with stakeholders to dispel myths, rumors, social taboos, concerns, and misconceptions related to HIV serodiscordance.

Community health workers (CHWs) were the backbone to community entry. They conducted outreach and built trust about the project among the community. During project implementation the CHWs discussed challenges faced by HIV serodiscordant couples and proposed strategies for recruitment. The HIV serodiscordant couple groups and other civil society organizations were agents who interacted with the local communities creating a receptive environment. Various leaders (opinion, religious, and others) supported couples HIV testing. Radio and TV stations were used to reach a wider audience with the benefits of couple testing and PrEP as a prevention option. There were regular engagements with various stakeholders on the safety and efficacy of PrEP.

Recruitment strategies utilized a multi-prong approach that included capacity building of the HCWs, community education through posters and flyers that emphasized benefits of couples HIV counseling and testing (CHCT); community mobilization by peer recruiters and CHWs through the use of skits, music, puppets, and dances. Special attention was taken to develop messages for men who were generally more reluctant to go for testing. Recruitment strategies included referrals from existing voluntary counseling and testing centers, public promotion of CHCT by well-known individuals, community organizations (such as churches), and mobilization around events (for example, around Valentine’s Day and market days). Discordant couples support groups used to meet regularly to promote further participation, retention, discuss challenges, and means of addressing them, including rumors.

The Kenya Ministry of Health has since rolled out PrEP for persons at risk of HIV, including HIV-serodiscordant couples, as part of its combination strategy.

The Nigeria PrEP Demonstration Project
The Nigeria PrEP Demonstration Project aimed at providing PrEP to HIV-negative partners in HIV-1 serodiscordant relationships until the HIV-positive partner was virologically
suppressed. It used community-designed models that recruited 345 HIV-1 serodiscordant coupled across three main sites and six satellite sites in Nigeria. The study took place between 2012–2018 and was designed through stakeholder consultation that engaged HIV service providers, consumers, policymakers, as well as other key stakeholders in the design and implementation of the project. The project first had a roadmap developed through stakeholder engagement. The roadmap was divided into three phases. The first phase involved a modeling study to determine if PrEP would be of benefit to the national HIV prevention program. The second phase included formative research to help determine the study design and the study target population. The third phase rolled out the design and implementation of the main demonstration project.

The main objective of the demonstration project was to determine the effectiveness of PrEP delivery models in reducing HIV transmission among HIV serodiscordant couples. The project also prioritized the formation of community engagement structures at the three sites. First, New HIV Vaccine and Microbicide Advocacy Society (NHVMAS) developed a protocol for its community engagement project in line with Good Participatory Practice: Guidelines for biomedical HIV prevention trials. Next, it held a public engagement meeting with a wide range of stakeholders – policymakers, HIV programmers, community advocates, traditional leaders, religious leaders, journalists, and researchers. The PrEP demonstration project was introduced to the community members, and decisions were collaboratively made on the community engagement structure, including the composition of the Community Advisory Board (CAB) and civil societies to conduct the public education program. Letters were sent to the identified organizations and institutions to be represented on the CAB. Monthly meetings were facilitated between the community stakeholders and the research team by NHVMAS. The boards had a standing operating procedure manual guiding their monthly meetings. Study staff participated in the monthly meetings in order to give updates on the project and to hear and learn from the CAB members about community concerns about the research.

Representatives from the civil society were initially trained on the use of a developed and pilot-tested flipchart for educating the public about PrEP. They were also equipped with educational pouches that contained samples of biomedical HIV prevention tools discussed in the flipchart to show during public education programs. This included samples of PrEP. Monthly meetings were also held for the public educators to report back on targets reached during their public education programs, discuss questions asked and challenges faced during their public engagement. The issues were jointly resolved with NHVMAS.

A quarterly research literacy capacity building training for CAB members and the civil society organization representatives was conducted at each of the research sites. A curriculum was developed for this educational program. Four two-day capacity building workshops were conducted at each of the study sites throughout the project. In addition, a social surveillance system was instituted by the project. Social surveillance was included in the study design to ensure semi-annual monitoring of individual, facility, and community concerns about the study. The surveillance was managed by social scientists located at each of the study sites and coordinated by the lead persons managed by the National Agency for the Control of AIDS (NACA). The results of their monitoring exercises were fed back in real time into the project implementation process.

A media engagement project was conducted at one of the three sites. The aim was to assess the impact of public engagement through the use of the media on study participant recruitment and retention. Analysis showed that although the media engagement resulted in a significant increase in public inquiry at the study intervention site, it was not significantly associated with an increase in study participant recruitment or retention. The project did lead to an increase in awareness and public education about PrEP in Nigeria. Other community members, such as FSWs and men who have sex with men (MSM), took part in consultative meetings on how to maximize the study outcome to address PrEP needs. Stakeholders successfully mobilized and advocated for the inclusion of PrEP in national guidelines in 2016. Research findings were disseminated to community members at the annual civil society organization accountability forum in 2018.

**Demonstration projects involving sex workers**

**Early antiretroviral therapy and PrEP for HIV prevention among FSWs: Benin, West Africa**

The CHU de Québec – Université Laval Research Centre has been working with FSW projects in Benin since 1992. The PrEP demonstration project was aimed at assessing the feasibility and usefulness of integrating treatment as prevention (TasP) and PrEP to the combination prevention package offered to sex workers in Benin. The project was initiated from the end of 2014 until December 2016 in Cotonou. After a community preparedness phase, 256 FSWs were recruited for PrEP. All participants were followed up for 12 months.

During the community preparedness phase, community workers (CWs) worked with FSWs and provided information on the project in small groups and in one-on-one sessions. CWs were field workers who had at least 15 years of experience in working with sex workers (but were not sex workers themselves). CWs carried out these activities in two teams. Each team was responsible for covering one of the two zones forming the catchment area. This enabled the same CWs to closely follow up with participants and address their concerns throughout the study (screening, enrolment, and follow up). Before intervening in an area, CWs first contacted the owners or managers of the sex work sites to determine the most suitable timings for their interventions. They then provided background information on HIV and about the project. Information about the study was also shared with a sex worker organization (Association Solidarité) to garner support and facilitate mobilization to participate in the study. The mobilization for screening was carried out in groups of 7–10 followed by individual meetings. Simultaneously, peer educators (especially those working with project Équité en santé, another CHU de Québec – Université Laval-led
HIV prevention project) also mobilized the FSWs who were part of their network.

During community mobilization, coupons for screening visits were handed out to the women. Active tracking was carried out for those who missed appointments. The CWs reminded the women of the appointment on three occasions, one week, three days, and one day prior to the appointment, either by telephone or by meeting them at their residence, workplace, or place of their choice. In case of a missed screening visit, participants were contacted to see if they were still willing to participate in the study and were provided with a new appointment. Often peer educators also reminded the women of their appointments by repeatedly visiting them.

Following the screening visit, an auxiliary nurse reviewed the recruitment and the CWs were responsible for contacting the participants to confirm the appointment. The CWs were also responsible for promoting adherence and informing the participants about side effects during their field visits for community-based distribution of condoms and PrEP and for locating women lost to follow up. They simultaneously addressed concerns in the community.

Upon completion of the study, sex workers were involved in dissemination of the results. A dissemination workshop was conducted with various stakeholders including FSWs and policymakers. In the short-term following the workshop in May 2017, there was no government plan to scale up PrEP in Benin. However, it has now been possible to provide PrEP to the study participants who still requested it and the Benin Ministry of Health is now in the process of implementing PrEP access for key populations and serodiscordant couples.

**Senegal case study**

A PrEP demonstration project was conducted in Dakar, Senegal among FSWs. The project explored the feasibility of providing daily oral PrEP for 12 months to enrolled participants at four Ministry of Heath-run clinics. A total of 350 participants were screened during an accrual period of 3 months (from June 2015 to October 2015) and 267 eligible participants were enrolled.

The community has been involved in all phases of the project. The planning phase occurred over 5 weeks in 2015. The feasibility study provided information regarding sex workers’ perceptions on PrEP, its acceptability, and strategies to resolve challenges, including stigma.

Four peer educators per study site were recruited by the study team, in collaboration with local organizations working on HIV prevention and trained for the implementation phase. They were chosen based on their leadership within the sex worker community and their experience in HIV prevention efforts. Peer educators worked closely with the social workers at each of the study sites and facilitated recruitment and follow up. They also sensitized the health care staff on the needs of the community. They were tasked with identifying potential participants in the neighborhoods, provided them with information about PrEP, and referred interested participants to the nearest clinics where PrEP was provided. Social workers and midwives were responsible for informing sex workers about the study procedures. Peer educators played a key role designing communication strategies on PrEP. They were responsible for following up with participants in-person twice a week, along with phone calls, and home visits for those who missed appointments. During their interactions, they tried to find out the reasons for missed appointments, re-educated participants on PrEP, encouraged them to come in for routine clinic visits, and addressed issues related to stigma, family, and adherence. The peer educators who were taking PrEP became role models and shared their experiences with the participants. With time, participants were calling the free study phone number on their own to follow up on appointments.

Preliminary findings and scale up strategies have been shared at a national scientific meeting organized by the Ministry of Health. Further dissemination is planned to advocate for the inclusion of PrEP as an HIV prevention option for the national program.

**The Introducing PrEP into HIV Combination Prevention (IPCP) Project: Kenya**

LVCT Health is an indigenous Kenyan non-governmental organization that provides HIV and sexual reproductive health services to MSM, FSWs, and young women (YW). This project aimed to demonstrate how daily oral PrEP can be delivered as part of an HIV combination prevention package among these three populations. Between August 2015 and October 2016, the project recruited 796 FSWs, 597 MSM, and 723 YW. Participants were offered daily oral PrEP and followed over a period of 12 months.

Several community organizations assisted in this study but two key populations organizations, Bar Hostess Empowerment and Support Programme (BHESP) and Health Options for Young Men on HIV/AIDS/STI (HOYMAS) were direct implementing partners. Two representatives of these two organizations were co-investigators on the project. These organizations were involved in various stages of the project. During the project design, the peer-led organizations were involved in: the selection of the implementation sites; providing leadership on community education on combination HIV prevention and PrEP, sharing community perspectives on PrEP with the project team, ensuring community buy-in, mobilizing community for participation, advising on strategies to address emerging community concerns regarding PrEP, and the constitution of a CAB with members of various MSM and FSW organizations. BHESP and HOYMAS were also involved in the feasibility study that assessed willingness to take PrEP among the target populations.

During implementation, the CAB supported different aspects of the project, such as project monitoring, PrEP advocacy at the community and national level, and results dissemination.
were invited to participate. Post screening, eligible FSWs from Pretoria, South Africa were included in the TAPS Demonstration Project, conducted by Wits RHI.

As PrEP became available in public and community-based facilities in Kenya, LVCT Health and other implementing partners worked with the Government to engage communities in demand generation, awareness creation, and adherence support during PrEP scale up. Community ambassadors continue to play a critical role in scaling up PrEP in Kenya.

The Treatment And Prevention for Female Sex Workers (TAPS) Demonstration Project: South Africa

The TAPS Demonstration Project was conducted by Wits RHI between March 2015 and July 2017 in Johannesburg and Pretoria, South Africa. FSWs from the surrounding sites were invited to participate. Post screening, eligible FSWs were either offered ART or PrEP along with the range of Wits RHI clinic services through their Sex Worker Project (SWP). Overall, 351 women were screened and 219 were enrolled for the PrEP arm of the study.

Meetings with various stakeholders including community organizations, FSWs, and other stakeholders started in the summer of 2013. These meetings helped in designing the formative research, which then informed TAPS. A ten-person CAB, comprised of representatives from various organizations and two-to-three FSWs, was formed in 2014. The CAB meetings were used as a platform for identifying any training needs of CAB members, advising research staff on sex worker community norms and expectations, and creating a supportive environment for the project by raising awareness and dispelling myths/rumors about PrEP. CAB members also facilitated recruitment by identifying contacts.

The TAPS study collaborated with the existing peer educators from the SWP who were instrumental in delivering education about PrEP by incorporating PrEP messages into their existing outreach activities, getting buy-in by the community, and identifying high-risk FSWs from their network. Peer educators were responsible for follow up. Little was known about PrEP at the start of the study. During implementation, young men in one of the urban sites stormed LVCT offices and demanded a stop of the project alluding that it was providing their YW a drug that would make them infertile. LVCT halted the project for a few days and used this time to engage the wider community including young men who were not a target population. The teams worked with the local village administrative chiefs, families, male opinion leaders, and partners of the participants, to increase awareness about PrEP and educate the wider community to support enrollment and retention. The project continued to keep community members aware of the progress and undertook regular community awareness activities such as utilizing the local area Chief’s community meetings, participating in talk shows at the local radio station, and utilizing a community-level HIV prevention champions to talk about PrEP and the project.

As PrEP is now available in public and community-based facilities in Kenya, LVCT Health and other implementing partners work with the Government to engage communities in demand generation, awareness creation, and adherence support during PrEP scale up. Community ambassadors continue to play a critical role in scaling up PrEP in Kenya.
India: The Closing a Critical Prevention Gap project
The Closing a Critical Prevention Gap project took place at two sites in India to evaluate PrEP delivery strategies, monitor adherence to and discontinuation of PrEP, and evaluate unintended consequences of the use of PrEP in these communities. The University of Manitoba, as the technical partner, supported two well-established community-based organizations that implemented demonstration projects in two distinctive settings.

Durbar Mahila Samanwaya Committee (DMSC) case study: Kolkata, India
Starting in 1992, the Sonagachi Project in Kolkata began providing HIV prevention services for FSWs. It soon grew into the Durbar Mahila Samanwaya Committee (DMSC), a community-owned sex work project of more than 60,000 FSWs. The PrEP demonstration project began by raising awareness on PrEP steered by the members of the DMSC along with the peer educators of the ongoing HIV intervention program. A feasibility study was conducted to identify possible enablers and barriers in taking PrEP. Screening for the demonstration project started in January 2016. A total of 843 FSWs were screened out of which 678 enrolled. Peer educators were trained to discuss condoms and PrEP as “double protection”. Based on the feasibility study, a potential participant list was created of women interested in PrEP and divided among the peer educators.

Although women were interested in taking PrEP, during recruitment it was found that some madams (brokers) would not let them go through the screening process as it would waste a day of work. This reinforced the importance of working with other stakeholders, including pimps and boyfriends, in addition to madams. All stakeholders were provided with information on PrEP and how it prevents HIV and therefore helps maintain health, which then helps ensure the ability to keep working and earning. To create interest, the cultural team of DMSC performed street dramas in Sonagachi, to promote the effectiveness of PrEP as a combination HIV prevention tool.

Peer educators played a vital role in walking participants through the screening and follow up. They would initially visit participants every day for the first 7 days to ensure daily intake and monitor side effects. Counselors and doctors also made home visits. Once adjusted to PrEP, peer educators started providing medicine weekly, fortnightly, and then monthly, following the first month clinical follow up. Telephone calls were also used to remind women of their follow up visits. Challenges to follow up included women leaving the area without notice. This was addressed by asking about upcoming travel plans and providing extra pills if travel was planned before the next refill date.

There is a great demand among FSWs to continue PrEP post-demonstration project. Two thirds of the participants were able to continue PrEP after their exit from the study, due to a surplus in tablets, however this supply has since ended.

Ashodaya Samithi case study: Mysore, India
Ashodaya Samithi, a female, male, and transgender sex work collective, implemented the PrEP project in Mysore-Mandya. The project began with awareness sessions and a feasibility study, between December 2014 and May 2015. The demonstration project ran from March 2016 until February 2018. In total, 647 participants were enrolled after screening 707 FSWs.

The sex work community played key roles in all phases of the design and implementation of the study. Numerous awareness sessions and small group discussions were held in the field to answer all questions about PrEP and understand community concerns. Discussions surrounded the need for PrEP, condom use, side effects, travel, and alcohol use. Community members expressed a great need for PrEP, especially in instances where they were unable to use condoms.

Sex work community leaders volunteered to be the first participants, which built trust in the project. Leaders then went on to recruit and mobilize participants through their peer networks by acting as “role models” and sharing their personal testimonials taking PrEP. Sex work leaders living with HIV further supported the usefulness of PrEP and were involved in mobilization to ensure that the study did not create social divisions in the community between those living with HIV and those who were HIV negative. Rumors about PrEP and side effects were addressed by peers at the ground level. Attempts were made to address all concerns as they arose. Sex work leaders and the technical support team conducted sensitization sessions with the police to create an enabling environment for the project and help prevent disruptions in adherence due to raids and arrests. This helped in building community trust and buy-in. Similar sensitization sessions were held with boyfriends, clients, family, and brokers as they too played key roles in ensuring retention.

The sites were divided into 10 clusters with 20 community mobilizers playing a key role in the recruitment and follow up of the participants. Following recruitment, mobilizers accompanied potential participants to screening visits. Negotiations took place with the lab for same-day test results as to not lose potential participants to follow up. Once enrolled, community mobilizers were responsible for following up with participants from their network to ensure delivery of medicine fortnightly, monitor adherence and routine quarterly clinic visits, and address any crises that may have arose. Daily check-ins provided opportunities to offer support for other health and social issues beyond PrEP to both participants taking PrEP and their wider networks.

Press and electronic media coverage is being used to disseminate findings and to help advocate for PrEP as part of the national HIV prevention package in India.

Discussions and lessons learned
These case studies highlight the important role that community engagement played in the PrEP demonstration projects. As many countries are interested in initiating PrEP or scaling up PrEP access, it is important to understand the best ways to implement PrEP as part of combination HIV prevention. The case studies document various aspects of PrEP implementation, such as how to deliver PrEP and make it
available and accessible to key populations. The processes documented in these case studies highlight the programmatic approaches undertaken among two major groups: serodiscordant couples and key population that includes FSWs, MSM, and YW. Although there were context specific considerations in the design of the interventions, there are some commonalities between projects that are important lessons for PrEP roll out.

In the demonstration projects among serodiscordant couples, the community was broadly defined. It extended beyond the primary stakeholders, the HIV serodiscordant couples themselves, to include local leaders, religious leaders, and local community organizations. Key to initiating PrEP among serodiscordant couples is the promotion of couple testing. Mass media communication strategies that included the use of TV, radio, and street theatre, played an important role in promoting couples counseling and testing, and included targeted messages to men, who often show more reluctance to testing. Special attention needs to be provided to handle crises among couples that may arise because of serodiscordancy. Serodiscordant couples groups should play a critical role in providing this support, along with dispelling any myths/misconceptions about PrEP and offering adherence support. Simultaneously, capacity building for health care workers when planning PrEP access is also important. Thus, it is key to develop multi-pronged strategies of community engagement, capacity building, and mass media promotion to generate demand when implementing PrEP among serodiscordant couples.

The demonstration projects documented the critical role of community, defined here mainly as female sex workers, men who have sex with men, and YW who are at risk of getting HIV, in different aspects of the project. It is important to understand that there are varying degrees of cohesion and community involvement, keeping in mind the local context. Despite this, there are several common areas of community engagement to highlight. Each of the locations have made sure that community leaders and peer educators have played a role in developing education materials and tools in promoting awareness and demand. As seen in the projects among serodiscordant couples, projects among sex workers also reached wider community stakeholders who could influence decisions around PrEP use and adherence, such as madams, boyfriends, clients, and the police, highlighting the need for community engagement beyond just the intended users of PrEP in order to create an enabling environment for PrEP use.

Taking lessons from the proven strategies of peer-led outreach in HIV prevention and treatment programs, these studies highlight how communities play strategic roles ranging from demand generation, to PrEP distribution among their social networks, and ensuring follow up. Community leaders or peer educators were often the “early adopters,” who became “role models” in ensuring adherence. Some of these case studies highlight that the demonstration projects were steered and owned by the community through their community-based organizations. This points to the importance of providing sufficient resources to support community engagement in implementing PrEP projects.

While the case studies presented here are limited in scope, they provide important insight into the ways that communities are engaged in PrEP demonstration projects globally. As each site developed contextually-specific approaches to rolling out their demonstration projects, comparison of the case studies could not be done. Yet, context-specific designs were important for the community engagement programs to be successful. Therefore, these studies provide important insights on ways to engage communities in biomedically-focused research and programs. More detailed findings from each site will be published separately.

Conclusion
The WHO underpins the importance of PrEP as an HIV prevention option and the importance of community engagement in implementing PrEP. Several countries, such as Kenya and South Africa, have initiated PrEP scale-up post-demonstration projects. However, there is limited experience globally in providing PrEP outside the scope of clinical trials and demonstration projects. As further countries move forward with PrEP implementation, it is critical to understand how best to scale up PrEP in diverse settings. Community engagement has emerged as a critical factor for education, demand generation, dispelling rumors, and supporting adherence and follow up in the PrEP demonstration project case studies. The increasing global interest in PrEP necessitates the importance of understanding the best ways to implement PrEP in different settings as part of combination HIV prevention. PrEP as a biomedical solution has to have a huge buy-in by the community – from its leadership to its larger networks who go on to become the users of this important prevention tool.

Data availability
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