OPEN LETTER

Community Inclusion in PrEP Demonstration Projects: Lessons for Scaling Up [version 1; peer review: 2 approved with reservations, 1 not approved]

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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. The project teams grouped CHWs by region and held training sessions on PrEP and HIV serodiscordance. 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.
and discussion. At site level, community advisory committees were formed consisting of nominees from different MSM and FSW organizations. They held monthly meetings to develop and review demand generation strategies for PrEP, discuss adherence issues, develop materials on HIV prevention tailored to meet target group needs and strategies for addressing emerging community and user concerns. They acted as PrEP advocates to the communities they represented and also provided community feedback to the site in-charges where they were attached.

Peer educators were trained on PrEP and used brochures and flyers to disseminate information to their communities. They played an important role in addressing concerns and tailoring messages. Peer educators met participants where they were available and came up with targeted approaches based on the different communities. Early adopters, known as “guides” or “PrEP ambassadors” also shared their experiences taking PrEP. Peer educators played a key role in retaining participants in the study and were responsible for checking in with participants who missed appointments to understand the reasons why and address them jointly with the health care workers at participating facilities. Regular meetings were held between peers and organizational staff to discuss this work. Support group meetings were held monthly and provided opportunities for participants to share challenges with PrEP and discuss potential solutions.

At one point 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.

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 peer 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, so a lot of initial work focused on demystifying PrEP, educating the community, and getting buy-in. Cards with the project details were used for recruitment. Recruitment was done during day and night, in streets, brothels, hotels, and clinics—where peers would often accompany participants to their screening. During outreach, peer educators conducted education sessions and handed information materials to women including condom bags and discussed various issues that impacted them, such as police harassment, client abuse, violence, and STIs. Research staff attended these sessions to provide information about PrEP and respond to any questions raised. A mobile clinic service was established to access and create demand for sex workers who were based farther away from the clinics. These processes facilitated recruitment.

The peer educators played a key role in supporting participants who missed follow up appointments, by addressing concerns such as side effects and challenges with partners. Peers were best able to draw on their own experiences when addressing concerns. During the study, several challenges emerged including xenophobic riots and police raids where many participants worked and lived. Engagement with sex worker advocacy groups supported the sex workers affected by these issues.

An important outcome of the project was that the national program began initiating PrEP for sex workers in 11 clinics across South Africa even before the end of the study. This was largely possible due to the constant feedback and reporting to the National Department of Health from the research team regarding their learning and experiences on a rolling basis. Results and lessons learned from the TAPS project were used to develop the first set of national guidelines to include PrEP, which were initially focused on the rollout to sex workers.
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: serodiscord-
ant 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 pri-
mary 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\textsuperscript{30-32}. Spe-
cial attention needs to be provided to handle crises among
couples that may arise because of serodiscordancy. Serodis-
cordant 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\textsuperscript{33}. 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 com-

munity, 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 under-
stand 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 commu-
nity 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\textsuperscript{34-37}, these stud-
ies 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 organiza-
tions. 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 communi-
ties 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 biomedical-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 pre-
vention option and the importance of community engagement
in implementing PrEP\textsuperscript{38}. 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 demon-
stration 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 genera-
tion, 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 com-
munity – from its leadership to its larger networks who go on
to become the users of this important prevention tool.

Data availability

No data are associated with this article.

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References

1. CDC, Pre-Exposure Prophylaxis (PrEP) for HIV Prevention. 2014. Reference Source
2. World Health Organization: Guidance on oral pre-exposure prophylaxis (PrEP) for serodiscordant couples, men and transgender women who have sex with men at high risk of HIV: recommendations for use in the context of demonstration projects. 2012. Reference Source
3. World Health Organization: Pre-exposure prophylaxis, 2015. Reference Source
4. Baeten JM, Donnel D, Ndase P, et al.: Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. N Engl J Med 2012; 367(5): 399–410. Published Abstract | Publisher Full Text | Free Full Text
5. Choo PY, Martin M, Sunharasamai P, et al.: Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial. Lancet 2013; 381(9883): 2083–90. Published Abstract | Publisher Full Text
6. Grant RM, Lama JR, Anderson PL, et al.: Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. N Engl J Med 2010; 363(27): 2587–99. Published Abstract | Publisher Full Text | Free Full Text
7. Haberer JE, Bangsberg DR, Baeten JM, et al.: The impact of adherence to pre-exposure prophylaxis on the risk of HIV infection among people who inject drugs. AIDS 2015; 29(7): 819–24. Published Abstract | Publisher Full Text
8. McCormack S, Dunn DT, Desai M, et al.: Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomised trial. Lancet 2016; 387(10013): 53–60. Published Abstract | Publisher Full Text | Free Full Text
9. Ndaase R, Celem C, Campbell J, et al.: Successful discontinuation of the placebo arm and provision of an effective HIV prevention product after a positive interim efficacy result: the partners PrEP study experience. J Acquir Immune Defic Syndr. 2014; 66(2): 206–12. Published Abstract
10. Peterson K, Folayan MO, Idoko J, et al.: Antiretroviral prophylaxis for heterosexually transmitted HIV infection in Botswana. N Engl J Med. 2012; 367(5): 423–34. Published Abstract | Publisher Full Text
11. Ulqinaj M, Peterson K: Oral tenofovir controversy II: Voices from the field. A series of reports of the oral Tenofovir trials with perspectives of community voices from Cambodia, Cameroon, Nigeria, Thailand and Malawi. New HIV Vaccine and Microbicides Advocacy Society (NHVMAS), Lagos, Nigeria. 2009. Reference Source
12. Haire BG: Because we can: clashes of perspective over researcher obligation in the failed PrEP trials. Dev World Bioeth. 2011; 11(2): 63–74. Published Abstract | Publisher Full Text
13. Peterson K, Folayan MO, Chegudere E, et al.: Saying ‘No’ to PrEP research in Malawi: what constitutes ‘failure’ in offshored HIV prevention research? Antipode 2015; 47(2): 278–94. Published Abstract | Publisher Full Text
14. Kaplan K: The Thailand Story. In Oral Tenofovir Controversy II: edited by Morenike Ulqinaj and Kris Peterson. Lagos: NHVMAS. 2009. Reference Source
15. Peterson K, Folayan MO: Ethics and HIV prevention research: An analysis of the early tenofovir PrEP trial in Nigeria. Bioethics. 2019; 33(1): 35–42. Published Abstract | Publisher Full Text
16. UNAIDS: Good participatory practices: guidelines for biomedical HIV prevention trials. Geneva: UNAIDS. 2011. Reference Source
17. UNAIDS, WHO: Ethical considerations in biomedical HIV prevention trials [additional guidance point added in 2012]. 2012. Reference Source
18. Helfron R, Ngure K, Otsubo J, et al.: Pre-exposure prophylaxis for HIV-negative persons with partners living with HIV: uptake, use, and effectiveness in an open-label demonstration project in East Africa [version 1; peer review: 2 approved]. Gates Open Res. 2017; 1: 3. Published Abstract | Publisher Full Text | Free Full Text
19. Baeten JM, Helfron R, Kidogochi L, et al.: Integrated delivery of antiretroviral treatment and pre-exposure prophylaxis to HIV-1-serodiscordant couples: a prospective implementation study in Kenya and Uganda. PLoS Med. 2016; 13(8): e1002099. Published Abstract | Publisher Full Text | Free Full Text
20. Haberer JE, Kidogochi L, Heffron R, et al.: Alignment of adherence and risk for HIV acquisition in a demonstration project of pre-exposure prophylaxis among HIV serodiscordant couples in Kenya and Uganda: a prospective analysis of prevention-effective adherence. J Int AIDS Soc. 2017; 20(2): 21842. Published Abstract | Publisher Full Text | Free Full Text
21. Mitchell KM, Lépine A, Terris-Prestholt F, et al.: Modelling the impact and cost-effectiveness of combination prevention among HIV serodiscordant couples in Nigeria. AIDS. 2015; 29(15): 349. Published Abstract | Publisher Full Text | Free Full Text
22. Chevrier C, Khan S, Reza-Paul S, et al.: Prioritizing Risk in Preparation for a Demonstration Project: A Mixed Methods Feasibility Study of Oral Pre-Exposure Prophylaxis (PrEP) among Female Sex Workers in South India. PLoS One. 2016; 11(4): e0151716. Published Abstract | Publisher Full Text | Free Full Text
23. Eakle R, Gomez GB, Naicker N, et al.: How I wish this thing was initiated 100 years ago! willingness to take daily oral pre-exposure prophylaxis among men who have sex with men in Kenya. PLoS One. 2016; 11(4): e0152444. Published Abstract | Publisher Full Text | Free Full Text
24. Eakle R, Mutamba N, Mogoa J, et al.: Designing PrEP and early HIV treatment interventions for implementation among female sex workers in South Africa: developing and learning from a formative research process. BMJ Open. 2016; 6(6): e011292. Published Abstract | Publisher Full Text | Free Full Text
25. Ngure K, Heffron R, Curran K, et al.: Successful discontinuation of the placebo arm and provision of an effective HIV prevention product after a positive interim efficacy result: the partners PrEP study experience. J Acquir Immune Defic Syndr. 2014; 66(2): 206–12. Published Abstract
26. Msuya SE, Mbizvo EM, Hussain A, et al.: Low male partner participation in antenatal HIV counselling and testing in northern Tanzania: implications for preventive programs. AIDS Care. 2008; 20(6): 700–9. Published Abstract | Publisher Full Text
27. Beawambale FM, Sali SN, Byaruhanga S, et al.: Voluntary HIV counselling and testing among men in rural western Uganda: implications for HIV prevention. BMC Public Health. 2009; 9(1): 263. Published Abstract | Publisher Full Text | Free Full Text
28. Desgries-du-Louë A, Ome-Gilemmann J: Couple-centred testing and counselling for HIV serodiscordant heterosexual couples in sub-Saharan Africa. Reprod Health Matters. 2008; 16(32): 151–61. Published Abstract | Publisher Full Text
29. Ngure K, Heffron R, Curnan K, et al.: ‘I Knew I Would Be Safer’...: experiences of men who have sex with men in Kenya. PLoS One. 2015; 10(5): e0126889. Published Abstract | Publisher Full Text | Free Full Text
30. Lazarus L, Reza-Paul S, Pasha A, et al.: Exploring the role of community-based peer support in improving access to care and antiretroviral treatment for sex workers in Mysore, India. HIV Social Services. 2012; 11: 152–168. Published Full Text
31. Chevrier C, Khan S, Reza-Paul S, et al.: ‘No one was there to care for us’: Ashodaya Samithi’s community-led care and support for people living with HIV in Mysore, India. Glob Public Health. 2016; 11(4): 423–36. Published Abstract | Publisher Full Text
32. Enriquez M, Cheng AL, Bandera J, et al.: ‘A Peer-Led HIV Medication Adherence Intervention Targeting Adults Linked to Medical care but without a Suppressed Viral Load. J Int Assoc Provid AIDS Care. 2015; 14(5): 441–8. Published Abstract | Publisher Full Text | Free Full Text
33. WHO Implementation tool for pre-exposure prophylaxis (PrEP) of HIV infection. Module 2: Community educators and advocates. Geneva: World Health Organization; 2017. Reference Source
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Summary:

• The open letter is a valuable description of the community engagement practices implemented in seven BMGF-funded PrEP demonstration projects in various sites in Kenya, Uganda, Nigeria, Benin, Senegal, South Africa, and India. The projects focused primarily on serodiscordant couples and female sex workers and were variously implemented by in-country and expat research centres, as well as community-based and advocacy organizations. Direct governmental participation in the projects is unclear and it would be helpful to have that clarified.

• The projects varied with regard to the community engagement strategies used. Using data from an open-ended questionnaire completed by members of each project and follow-up phone interviews with some projects, case studies were developed describing the role of community at various stages of the projects. With input from the projects, the case studies were then assessed for commonalities and lessons learned.

• The rationale for the open letter is clearly articulated in the Background section. The authors cite the controversial history of early PrEP trials that led to more proactive community engagement. They note the importance of sustaining community participation in the context of PrEP demonstration projects, especially given the diversity of settings and at-risk populations. The letter seeks to add to the documentation of practice and lessons learned across the diverse settings, providing a range of views and experiences on the topic.

Major points to address:

• To more adequately represent the diversity of opinion on community engagement (CE) in the projects, it would be helpful if the authors included a statement describing how each project conceptualized the role of CE in their project and how success was defined by each project. This
information is woven into the case studies (for the most part) but the reader would benefit from articulation of role/desired outcomes in the opening paragraph for each case study.

- The richness of the case studies is quite variable, and it is difficult to determine if this is due to the complexity or comprehensiveness of the CE work across projects/sites or due to limitations in the data collected for each case study. Clarification on this is needed.

- The descriptions of post-project outcomes related to sustainability of PrEP access, dissemination, PrEP advocacy, and on-going work related to community engagement in these processes is very helpful. Explicit commentary on barriers and challenges would also be helpful, especially if any of the projects have reflected on what they would do differently based on their experience. Some of this alluded to but not explicitly addressed, making it difficult for the reader to parse across the case studies.

- P. 3, under Findings: The opening paragraph lists populations targeted but omits MSM and young women, who are described as participants in some case studies.

- P. 4, Table 1: The Implementer column is ambiguous as to whether the organizations listed were responsible for the PrEP demonstration project, the community engagement work, or both. Clearer understanding of the relative independence of the CE work for each project would help the reader and potentially add insight to the lessons learned.

- P. 4, Partners Project: From the description it appears that the CHWs had built considerable trust with the community prior to their engagement with the project. The project was then able to leverage this existing trust — an important nuance. A key question then becomes, how did implementers build trust with the CHWs? CHWs risked undermining the community trust they previously established, if they did not negotiate trust-building with the implementers. This is important context to understand for lessons learned.

- P. 6, second full paragraph: The last sentence states that CWs in Benin “simultaneously addressed concerns in the community” while working one-on-one with project participants. What strategies did the CWs use to address community concerns? What types of concerns emerged? How were they addressed?

- Pp. 6-7, IPCP project: It is unclear whether or how the project CAB and site level community advisory committees interacted or had overlapping membership; this should be clarified. Also, to what extent were these two types of advisory groups engaged in addressing the LVCT crisis when the young men stormed the offices? Was representation at the site level expanded to include young men? Or was expanded stakeholder engagement distinct from the established advisory mechanisms?

- P. 7, TAPS project: It is unclear whether the mobile clinic service for sex workers was established specifically to facilitate project recruitment, or to address unmet needs for sex workers generally. I.e., was the mobile clinic exploiting unmet needs for recruitment purposes or was the project leveraged to address those needs with an eye toward sustainability beyond the project?

- P. 8, Ashodaya Samithi project: The authors state that sex work community leaders were the first participants who then “went on to recruit and mobilize participants through their peer networks.” To what extent was this recruitment/mobilization role fostered by the project staff? Were the leaders
an integral part of the sex work collective implementing the project? If not, were they paid for taking on the recruitment/mobilization role? How was their role related to the community mobilizers, who are also described as having major roles in recruitment and follow-up?

Discussion section: It would be helpful to include an explicit discussion of gender power dynamics and how these were handled in the various projects. Some sites broadened outreach to stakeholders with power/authority over young women (YW) and FSWs in particular, to gain the support of such stakeholders for participation of YW/FSW in the PrEP programmes. Gender integration is often conceptualized as a continuum from exploitation to accommodation to transformation of inequalities/inequities. To what extent were projects consciously addressing this continuum in their choice of strategies? What lessons emerged with regard to gender integration in the various PrEP programmes?

Is the rationale for the Open Letter provided in sufficient detail?
Yes

Does the article adequately reference differing views and opinions?
Partly

Are all factual statements correct, and are statements and arguments made adequately supported by citations?
Yes

Is the Open Letter written in accessible language?
Yes

Where applicable, are recommendations and next steps explained clearly for others to follow? 
Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Social, behavioral and ethical dimensions of biomedical HIV prevention research; community engagement in research; Good Participatory Practice in research; community-based participatory research; qualitative research; mixed-methods research

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 04 Dec 2019
Lisa Lazarus, University of Manitoba, Winnipeg, Canada

The open letter is a valuable description of the community engagement practices implemented in seven BMGF-funded PrEP demonstration projects in various sites in Kenya, Uganda, Nigeria, Benin, Senegal, South Africa, and India. The projects focused primarily on serodiscordant couples and female sex workers and were variously implemented by
in-country and expat research centres, as well as community-based and advocacy organizations. Direct governmental participation in the projects is unclear and it would be helpful to have that clarified.

- The projects varied with regard to the community engagement strategies used. Using data from an open-ended questionnaire completed by members of each project and follow-up phone interviews with some projects, case studies were developed describing the role of community at various stages of the projects. With input from the projects, the case studies were then assessed for commonalities and lessons learned.

- The rationale for the open letter is clearly articulated in the Background section. The authors cite the controversial history of early PrEP trials that led to more proactive community engagement. They note the importance of sustaining community participation in the context of PrEP demonstration projects, especially given the diversity of settings and at-risk populations. The letter seeks to add to the documentation of practice and lessons learned across the diverse settings, providing a range of views and experiences on the topic.

- We thank the reviewer for their feedback on our open letter and have provided detailed responses to the specific queries below.

Major points to address:

- To more adequately represent the diversity of opinion on community engagement (CE) in the projects, it would be helpful if the authors included a statement describing how each project conceptualized the role of CE in their project and how success was defined by each project. This information is woven into the case studies (for the most part) but the reader would benefit from articulation of role/desired outcomes in the opening paragraph for each case study.

-Thank you for raising this important point. We have included statements on how each project conceptualized community engagement at the start of each case study, following the overall objective, and also worked to describe project success towards the end of each case study.

- The richness of the case studies is quite variable, and it is difficult to determine if this is due to the complexity or comprehensiveness of the CE work across projects/sites or due to limitations in the data collected for each case study. Clarification on this is needed.

-Thank you for this query. The variability is due to the different levels of engagement, based on the existing roles of communities in each environment. We have attempted to address this in the Discussion with the following statement: "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."

- The descriptions of post-project outcomes related to sustainability of PrEP access, dissemination, PrEP advocacy, and on-going work related to community engagement in these processes is very helpful. Explicit commentary on barriers and challenges would also be helpful, especially if any of the projects have reflected on what they would do differently based on their experience. Some of this alluded to but not explicitly addressed, making it difficult for the reader to parse across the case studies.

-Thank you for raising this important point. We have added details about challenges faced and whether there are some steps that projects would have done differently to the case studies.
- P. 3, under Findings: The opening paragraph lists populations targeted but omits MSM and young women, who are described as participants in some case studies.

  Thank you for catching this. It was been corrected.

- P. 4, Table 1: The Implementer column is ambiguous as to whether the organizations listed were responsible for the PrEP demonstration project, the community engagement work, or both. Clearer understanding of the relative independence of the CE work for each project would help the reader and potentially add insight to the lessons learned.

  All implementers were involved in leading the project. Where appropriate, community organizations involved in all aspects of study implementation have also been included in the Table. Details of community partners involved in some areas of community engagement are included in the case studies.

- P. 4, Partners Project: From the description it appears that the CHWs had built considerable trust with the community prior to their engagement with the project. The project was then able to leverage this existing trust — an important nuance. A key question then becomes, how did implementers build trust with the CHWs? CHWs risked undermining the community trust they previously established, if they did not negotiate trust-building with the implementers. This is important context to understand for lessons learned.

  We have clarified that the Partners PrEP demonstration project builds on the previous PrEP trial. CHWs had been involved in the previous trial, therefore the demonstration project builds from this previous work and previously developed relationships.

- P. 6, second full paragraph: The last sentence states that CWs in Benin “simultaneously addressed concerns in the community” while working one-on-one with project participants. What strategies did the CWs use to address community concerns? What types of concerns emerged? How were they addressed?

  Thank you for this question. We have revised the Benin case study to provide more details. Specifically, we have clarified that catchment areas were divided in a way that allowed for CWs, who were from NGOS working with sex workers, to frequently meet and support FSWs in the field. CWs worked to promote adherence, addressed concerns about side effects, and located women lost to follow up during their field visits.

- Pp. 6-7, IPCP project: It is unclear whether or how the project CAB and site level community advisory committees interacted or had overlapping membership; this should be clarified. Also, to what extent were these two types of advisory groups engaged in addressing the LVCT crisis when the young men stormed the offices? Was representation at the site level expanded to include young men? Or was expanded stakeholder engagement distinct from the established advisory mechanisms?

  We have clarified the different memberships and roles of the national-level CAB, as compared to the site and population specific community advisory committees in the IPCP case study. We have also specified that both the CAB and CAC were involved in addressing the crisis, along with engaging other important stakeholders.

- P. 7, TAPS project: It is unclear whether the mobile clinic service for sex workers was established specifically to facilitate project recruitment, or to address unmet needs for sex workers generally. I.e., was the mobile clinic exploiting unmet needs for recruitment purposes or was the project leveraged to address those needs with an eye toward sustainability beyond the project?

  Thank you for this query. We have clarified the above with the following statement: “A mobile clinic service was established to access and create demand for sex workers who were based farther away from the clinics. The mobile clinic was leveraged from the SWP clinic to recruit FSWs who
were not able to access the clinic either because of distance or due to the clinic operating hours. These processes facilitated recruitment.”

- P. 8, Ashodaya Samithi project: The authors state that sex work community leaders were the first participants who then “went on to recruit and mobilize participants through their peer networks.” To what extent was this recruitment/mobilization role fostered by the project staff? Were the leaders an integral part of the sex work collective implementing the project? If not, were they paid for taking on the recruitment/mobilization role? How was their role related to the community mobilizers, who are also described as having major roles in recruitment and follow-up?

- Thank you for this question. As Ashodaya is a sex work-led organizations, community leaders took on central roles in all aspects of the project from design to implementation. We have clarified that: “Sex work community leaders and community mobilizers, who are longstanding members of the organization and were involved in the discussions surrounding initiating and planning the demonstration project, volunteered to be the first participants enrolled in the study, which built trust in the project.”

Discussion section: It would be helpful to include an explicit discussion of gender power dynamics and how these were handled in the various projects. Some sites broadened outreach to stakeholders with power/authority over young women (YW) and FSWs in particular, to gain the support of such stakeholders for participation of YW/FSW in the PrEP programmes. Gender integration is often conceptualized as a continuum from exploitation to accommodation to transformation of inequalities/inequities. To what extent were projects consciously addressing this continuum in their choice of strategies? What lessons emerged with regard to gender integration in the various PrEP programmes?

- While we agree that an analysis of gender power dynamics would make an important contribution to this work, it is beyond the scope of this open letter. The independent project sites will explore this in their own site-specific papers.

**Competing Interests:** No competing interests were disclosed.
importance of inclusive community engagement in such studies by citing the lack of such work in the early tenofovir trials. Overall the article provides a concise summary and includes descriptions that may be of interest to researchers planning future HIV prevention or global health intervention studies. A few suggestions follow.

Major comments:

1. It would be helpful for the abstract to mention some of the key actual lessons learned, rather than only stating that lessons learned are included in the body of the article.

2. It would be helpful if each of the case studies were structured in a similar way and contained the same key elements. At present, most open with a paragraph outlining who the study implementers were, and then describe who the key actors were for the community engagement, specific activities undertaken by those community-based actors, challenges encountered, and commentary about the current status of PrEP funding in the local setting. In particular, only a minority of the case studies clearly describe challenges faced by the study teams in working with community, which may be of particular interest to those hoping to learn from these experiences. Also, statements about the availability and cost of PrEP in some of the examples could be clearer (e.g. India, Partners does not comment on Uganda). Finally, it would be appropriate to add a clear brief statement about the overarching goal or primary objective for each project; this was often but not always done.

3. To make the case studies as useful as possible for readers interested in implementing similar community engagement work, it would be helpful for the case studies to be as specific as possible, perhaps including operational details such as exactly how the key actors (CAB members, community workers, peer educators etc.) were selected, how many were engaged and why, and specific activities undertaken by these individuals. In some cases, relevant details are lacking, making the information potentially less useful to readers. For instance, the Partners PrEP description contains a series of somewhat vague statements about a variety of community actors doing various general types of activities, without really specifying who was responsible for taking on which specific actions; e.g. there is mention of lead members of community organizations, CAGs, CHWs, and serodiscordant couple groups, but the rationale for and differences between these agents was not clear, and there is separate mention in different places of having “worked with stakeholders to dispel myths, rumours etc”, being “agents who interacted with the local communities”, “regular engagements with various stakeholders” etc. Similarly, in the Nigerian case study, many activities are described in the passive voice, making it again less clear which actors undertook which activities (“letters were sent…”, “monthly meetings were held…” etc); presumably many of these were activities organized by the investigators to support the community partners but this could be clearer.

4. The authors could consider including a box or Table that lists common key elements of successful community engagement in these diverse projects, with the goal of helping readers see at a glance what specific advantages there may be to such work, and how it might be approached.

Minor comments:

1. The introductory paragraph could specify the particular tenofovir prodrug as TDF (versus TAF).

2. In the background, it may be appropriate to briefly mention the ethical violations that are alluded to (and cited) in the second paragraph.
3. At the end of the background, it might be helpful to state that the purpose of the paper is not only to articulate the community engagement practices implemented in the projects but also to explicitly inform future work with appropriate community engagement/advise other investigators on how to do such work.

4. The Partners PrEP description contains a somewhat confusing statement about how community entry was initiated by seeking government approval; what exactly was meant by this?

5. Later in the same paragraph the authors say that “site projects instituted CAGs”; is this a typo that should have read “project sites”?

6. When describing lessons learned, the Discussion mentions that special attention should be paid to handling “crises” in serodiscordant couples, but this concept was not really explained in the case studies themselves (except when mentioning that some couples faced “challenges” in Partners PrEP).

Is the rationale for the Open Letter provided in sufficient detail?
Yes

Does the article adequately reference differing views and opinions?
Yes

Are all factual statements correct, and are statements and arguments made adequately supported by citations?
Yes

Is the Open Letter written in accessible language?
Yes

Where applicable, are recommendations and next steps explained clearly for others to follow?
Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Infectious diseases

We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however we have significant reservations, as outlined above.

Author Response 04 Dec 2019
Lisa Lazarus, University of Manitoba, Winnipeg, Canada

This open letter is a narrative review describing community engagement activities undertaken within seven PrEP demonstration projects funded by the Gates foundation. The authors rightly emphasize the importance of inclusive community engagement in such studies by citing the lack of such work in the early tenofovir trials. Overall the article provides a concise summary and includes descriptions that may be of interest to researchers planning future HIV prevention or global health
intervention studies. A few suggestions follow.

We thank the reviewer for their feedback on our open letter and have provided detail responses to the specific queries below.

Major comments:

1. It would be helpful for the abstract to mention some of the key actual lessons learned, rather than only stating that lessons learned are included in the body of the article.

-We have added lessons learned to the abstract.

2. It would be helpful if each of the case studies were structured in a similar way and contained the same key elements. At present, most open with a paragraph outlining who the study implementers were, and then describe who the key actors were for the community engagement, specific activities undertaken by those community-based actors, challenges encountered, and commentary about the current status of PrEP funding in the local setting. In particular, only a minority of the case studies clearly describe challenges faced by the study teams in working with community, which may be of particular interest to those hoping to learn from these experiences. Also, statements about the availability and cost of PrEP in some of the examples could be clearer (e.g. India, Partners does not comment on Uganda). Finally, it would be appropriate to add a clear brief statement about the overarching goal or primary objective for each project; this was often but not always done.

-Thank you for this important comment. We have worked to revise the case studies to ensure that they all present the overall purpose of the project, key actors involved, activities undertaken for community engagement, challenges faced, and project outcomes as they relate to the current status of PrEP in each site. In particular, we have included challenges faced and addressed in the different projects. We have also clarified current PrEP status in India and Uganda.

3. To make the case studies as useful as possible for readers interested in implementing similar community engagement work, it would be helpful for the case studies to be as specific as possible, perhaps including operational details such as exactly how the key actors (CAB members, community workers, peer educators etc.) were selected, how many were engaged and why, and specific activities undertaken by these individuals. In some cases, relevant details are lacking, making the information potentially less useful to readers. For instance, the Partners PrEP description contains a series of somewhat vague statements about a variety of community actors doing various general types of activities, without really specifying who was responsible for taking on which specific actions; e.g. there is mention of lead members of community organizations, CAGs, CHWs, and serodiscordant couple groups, but the rationale for and differences between these agents was not clear, and there is separate mention in different places of having “worked with stakeholders to dispel myths, rumours etc”, being “agents who interacted with the local communities”, “regular engagements with various stakeholders” etc. Similarly, in the Nigerian case study, many activities are described in the passive voice, making it again less clear which actors undertook which activities (“letters were sent…”, “monthly meetings were held…” etc); presumably many of these were activities organized by the investigators to support the community partners but this could be clearer.
We have added more details to each of the case studies, including how key actors were selected for different community engagement strategies and the number of people engaged in different activities. This includes revisions to both the Partners and Nigerian case studies, in order to provide further clarity to the different activities.

4. The authors could consider including a box or Table that lists common key elements of successful community engagement in these diverse projects, with the goal of helping readers see at a glance what specific advantages there may be to such work, and how it might be approached.

-Thank you for this suggestion. We have added Box 1 in the Discussion section that highlights the common key elements of community engagement.

Minor comments:

1. The introductory paragraph could specify the particular tenofovir prodrug as TDF (versus TAF).

-This has been added.

2. In the background, it may be appropriate to briefly mention the ethical violations that are alluded to (and cited) in the second paragraph.

-Details on the ethical violations of early tenofovir trials have been added.

3. At the end of the background, it might be helpful to state that the purpose of the paper is not only to articulate the community engagement practices implemented in the projects but also to explicitly inform future work with appropriate community engagement/advise other investigators on how to do such work.

-A statement on the purpose of the paper has been added to the end of the Background section.

4. The Partners PrEP description contains a somewhat confusing statement about how community entry was initiated by seeking government approval; what exactly was meant by this?

-Thank you for pointing this out. The sentence has been edited to read: “Approval for the project was initially sought 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.” Further details on the formation of the community advisory groups has also been added to the case study.

5. Later in the same paragraph the authors say that “site projects instituted CAGs”; is this a typo that should have read “project sites”?

-Thank you for catching this. This has been corrected.

6. When describing lessons learned, the Discussion mentions that special attention should be paid to handling “crises” in serodiscordant couples, but this concept was not really explained in the case
studies themselves (except when mentioning that some couples faced “challenges” in Partners PrEP).

- We have removed this sentence as it has not been explored in the studies presented.

**Competing Interests:** No competing interests were disclosed.

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- The authors state that their intention is to describe CE strategies and lessons learned. Much of the paper reads like a progress report on recruitment and retention strategies. CE is more than that. The reader expects them to focus on strategies used, why they were selected, how useful the strategies were, and what the challenges associated with those selected strategies were. They have not even succeeded in fully articulating the various roles of the communities in the various projects. What strategies did they employ to influence acceptance and community involvement? The sections on South Africa, Kenya/Uganda and Nigeria describe some specifics on strategies.

- The discussion section also focuses very much on recruitment and retention.

- The conclusion section focuses more on PrEP roll-out than on CE. The topic could be edited to focus on community engagement strategies in PrEP demonstration projects.

- The sub-heading on "Assessment of the research projects" is misleading as the section describes documentation of CE strategies/practices.

- In the Table no sites are stated for Nigeria and some abbreviations are used for some implementers. Based on what happened to previous HIV prevention trials, CE should therefore focus on acceptance and keeping communities updated about trials and addressing concerns and misconceptions/rumours.

**Is the rationale for the Open Letter provided in sufficient detail?**
No

**Does the article adequately reference differing views and opinions?**
Yes
Are all factual statements correct, and are statements and arguments made adequately supported by citations?
Yes

Is the Open Letter written in accessible language?
Yes

Where applicable, are recommendations and next steps explained clearly for others to follow?
No

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Community engagement, research ethics, public health

I confirm that I have read this submission and believe that I have an appropriate level of expertise to state that I do not consider it to be of an acceptable scientific standard, for reasons outlined above.