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Facilitators and Barriers Affecting PrEP Adherence among Thai Men Who Have Sex With Men (MSM) in the HPTN 067/ADAPT Study

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Abstract

The HPTN 067/ADAPT Study evaluated the feasibility, acceptability and patterns of adherence and coverage for three randomly assigned oral FTC/TDF pre-exposure prophylaxis (PrEP) dosing regimens to prevent HIV infection: daily, time-driven (twice a week with a post-sex dose), and event-driven (pre/post-sex dosing). Using qualitative methods, we explored facilitators and barriers for each regimen among a subset of men who have sex with men (MSM) participants in Bangkok, Thailand. Between August 2013 and March 2014, 32 (of 179) HPTN 067/ADAPT participants joined in six focus group discussions, and six attended key-informant interviews – two per each study regimen. Facilitators of PrEP adherence included use of strategies to have PrEP available when needed and constructing convenient dosing regimens, simplicity in regimen requirements with recognition that more complex regimens may take some time to master, ability to plan for sex (non-daily regimens), receipt of social and technology support, ability to use a PrEP regimen that best matches to one's own patterns of sex, and experiences with PrEP as a part of health and well-being. Challenges to PrEP adherence included perceptions of no or low HIV risk, difficulties following regimens when drinking (intoxicated), concerns about short or long-term side-effects of PrEP, experience of HIV stigma (fears of being misidentified as HIV positive), inability to forecast sex events for non-daily regimens, and affordability of PrEP outside of study context influencing uptake and use in the community. Preferences for regimens varied, suggesting that multiple PrEP

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DISCLAIMER

The findings and conclusions presented in this paper are those of the authors and do not necessarily represent the views of the U.S. Centers for Disease Control and Prevention.

CONFLICTS OF INTEREST

There are no conflicts of interest.

effective regimen options (daily and non-daily) should be available to fit those with different needs.

Keywords

HIV; PrEP; men who have sex with men; young; Thailand

INTRODUCTION

In Thailand, men who have sex with men (MSM) are one of the most at-risk populations for HIV acquisition (Ananworanich et al., 2013; UNAIDS, 2013; Beyrer et al., 2012; Peerapatanapokin, 2012; FHI 360, 2008). Since 2003, the Thailand Ministry of Public Health-U.S. Centers for Disease Control and Prevention Collaboration (TUC) and the Thai Bureau of Epidemiology have reported prevalence rates of HIV among Thai MSM ranging from 17–30% (van Griensven et al., 2015) and UNAIDS reported HIV prevalence among MSM in Bangkok at 28.6% in 2016 (UNAIDS, 2016). Given such high prevalence, several studies have been exploring HIV prevention methods, including biomedical interventions such as oral pre-exposure prophylaxis (PrEP) (Amico, 2012; Amico & Stirratt, 2014; Baeten et al., 2012; Baeten & Celum, 2012; Baeten & Grant, 2013; Celum, 2011; Centers for Disease Control and Prevention [CDC], 2009; Grant et al., 2010; Guest et al., 2008; Karim et al., 2013; Mayer et al., 2013; Woodsong, 2013). For prevention of HIV among MSM, and transgender women (TGW), a considerable amount of research now supports the use of tenofovir disoproxil fumarate plus emtricitabine (FTC/TDF) as an effective daily, oral PrEP drug that reduces risk of acquisition by over 90% when taken regularly (Anderson et al., 2012; Grant et al., 2014).

The HIV Prevention Trial Network 067 (HPTN 067), or Alternative Dosing to Augment PrEP Pill-Taking (ADAPT) study, a phase 2, randomized, open-label, pharmacokinetic and behavioral equivalence study of daily versus non-daily oral FTC/TDF PrEP, aimed to evaluate the feasibility of intermittent PrEP dosing, was conducted in three sites: USA, South Africa, and Thailand. Each site was powered for separate analyses, based on the premise that social context is important for PrEP uptake and use. Participants were randomly assigned to 34 weeks of self-administered daily, time-driven, and event-driven dosing, with a primary outcome to evaluate coverage of sex events with pre- and post-sex PrEP dosing. Primary outcomes have been reported elsewhere. (Grant et al., 2018; Bekker et al., 2018)

Given the limited data available on experiences with daily and non-daily PrEP among MSM and TGW in Thailand, we conducted a qualitative exploration among a subset of HPTN067/ADAPT study participants to explore the acceptability and perception of these PrEP regimens, targeting facilitators and barriers to adherence for each regimen and to collect recommendations from participants and additional insights into PrEP roll-out in this at-risk population.

METHODS

The HPTN 067 study site in Bangkok, Thailand, enrolled MSM and TGW who were recruited from a community clinic and clinical research site. There were 431 participants enrolled into the main HPTN 067 study at three sites, with 179 enrolled in Bangkok (Grant et al., 2018; Bekker et al., 2018). Study visits were divided into phases, starting from screening, directly observed dosing, self-administered dosing, and post-PrEP use that continued for a total of 34 weeks. Participants were randomized to one of three possible PrEP regimens. In the *daily regimen* arm participants were asked to take PrEP once a day regardless of sexual activity. In the *time-driven regimen* arm participants were asked to take a PrEP dose two days per week, three to four days apart, regardless of sexual activity, and one additional dose after sex (preferably within two hours after sexual intercourse). Finally, in the *event-driven regimen* arm, participants were asked to take a PrEP dose prior to sex (preferably 24-48 hours prior to sexual intercourse) and a PrEP dose after sex (preferably within two hours of sexual intercourse). In all three regimens, participants were advised not to take more than one tablet in a 2-hour period, two doses per day, or seven doses per week. The HPTN 067 study methodology and primary results have been previously described (Grant et al., 2018).

Between August 2013 and March 2014, we purposively selected participants completing participation in the self-administered dosing part of the study (34 weeks of study visits), and asked them to provide insight into their experience with the study medication and assigned regimen. Based on accumulated staff-participant interactions, study staff approached all participants who shared their experience during study visits about being adherent and non-adherent, and also those expressing potential difficulties with PrEP. Interested participants were scheduled for either a regimen-specific focus group or individual interview.

Two focus groups were held per study arm. Each focus group discussion (FGD) included approximately six to eight study participants. Two key informant interviews (KIIs) were conducted per study arm for a total of six participant key informants. Each participant participated in the FGDs or KIIs within three months after completing their final study visit. Each FGD and KII session lasted less than two hours.

All participants provided key demographic characteristics. Semi-structured guides were used for both the overall focus group and key informant interviews to collect the qualitative data. Questions for focus groups and individual interviews were based on experiences with PrEP, feasibility, acceptability, ease of uptake and common barriers and facilitators to following assigned regimen, support for PrEP adherence and condom use support, and disclosure of study participation, as well as whether or not and how participants may have migrated from their assigned regimen to an alternative one (e.g., assigned daily but followed an event-driven regimen during self-administration phase) and what an ideal regimen would be for them.

In each FGD or KII, an experienced moderator/interviewer who was not known previously to participants implemented the guide. All discussions and interviews were audio-recorded,

while a note taker also collected data on focus group dynamics and discourse. Audio-recordings were then transcribed removing any identifying information.

The qualitative study was conducted in a closed and private meeting room at the Silom Community Clinic @TropMed, Bangkok, Thailand to assure adequate privacy and confidentiality. All participants provided written informed consent prior to their participation in the study. This study protocol was reviewed and approved by the HPTN Scientific Review Committee, Division of AIDS Prevention Sciences Review Committee, Ethical Review Committee for Research in Human Subjects of the Thailand Ministry of Public Health, and by the Institutional Review Board of the U.S. Centers for Disease Control and Prevention.

Data Analysis

The de-identified transcribed data was double coded in the original language (Thai) using Atlas.ti (version 7.1.8). The qualitative methodologies of FGDs and KIIs were based on framework analysis within the main questions and probes from the semi-structured interview guide, including grounded theory and content analysis to further identify themes within and across each of those frames.

RESULTS

Among the 179 participants who enrolled and completed the HPTN 067 study in Bangkok, 38 participants took part in a FGD ($n = 32$) or a KII ($n = 6$). For FGDs, there were eight participants assigned to the daily regimen, nine participants in the time-driven regimen, and fifteen participants in the event-driven regimen. Participants included in the qualitative sub-study had a median age of 30 years (range: 21–50 years), with the largest proportion of participants between 31–35 years old (29%). Most participants reported full-time employment (71%) and having completed college (86%), and all of them had never been married (100%). There were no differences in demographics between the FGD/KII subset and the larger study. No TGW participated in the FGDs or KIIs.

Emerging themes from the FGDs and KIIs included six specific facilitators of adherence and six barriers.

Facilitators to PrEP Adherence

Six major themes emerged as factors facilitating PrEP adherence, four were specific to experiences in the study and two reflected recommendations for optimizing PrEP in future programs.

- 1. Keeping PrEP available for dosing:** Participants reported attempting to fit an assigned regimen into their lifestyle particularly from a perspective of keeping PrEP available for dosing. Carrying doses helped for some, while others worked out dose-times that were most convenient to their lifestyle.

“My adherence was good because I tried my best to take it. I carried all pills and tried to change my lifestyle to fit with the assigned regimen.”
(FGD 1/Daily arm)

2. **Ease of the assigned regimen:** Most participants described the daily regimen to be the easiest regimen to follow during the study. The non-daily regimens were more complicated to understand. Participants reported their adherence was higher after a month of self-administration and understood more about their assigned regimen as time progressed.

“I learned how to plan for sex. I made myself understand pre- and post-sex doses. If I had to take daily pill, it would be too much. It’s all about understanding your assigned regimen.” (FGD 6/Event-driven arm)

3. **Ability to plan sex and having infrequent sex events (non-daily regimens):** Participants who were assigned to the non-daily regimens needed to have the ability to forecast their sex. When they were unable to plan sex events and locations, participants who did not carry PrEP often missed the post-sex doses. Participants with the ability to plan for sex or who had infrequent sex events described less confusion with taking PrEP. Some participants who were supposed to follow the non-daily regimens, but had very frequent sex events, turned out to unintentionally take PrEP daily.

“I’ve never thought I’d be able to plan for sex. Since I was assigned to this regimen [time-driven], planning for sex was not that difficult.” (FGD 3/Time-driven arm)

4. **Social and tech support (tools):** Support from clinic staff, social networks, and new technology was emphasized by participants as helping to remind them when to take pills.

- Clinic support – offering client-centered care

“I felt good. Staff explained and what they said benefited us. It was more like a reminder. What would we get if we take PrEP, and whether it affected us or not. When we took it, it benefited us more.” (KII 3/Daily arm)

- Social support – study participation disclosure led to better adherence

“My boyfriend asked me to join the study and took PrEP. He reminded me to take PrEP every day.” (FGD 3/Time-driven arm)

- New technology support—automated cellphone reminders

“I used the phone for reminders. It would just pop the reminding message that I had to take PrEP in the morning.” (FGD 5/Time-driven arm)

5. **Flexibility to choose a preferred PrEP regimen highly recommended:** Although participants were assigned to a regimen per study protocol, participants reported various patterns of sex events and sexual role versatility. At the time of the study, participants reported that they knew that only daily dosing had been proven to be an effective HIV prevention tool. Discourse suggested that if there

were other effective alternative PrEP regimens to choose from, adherence among MSM could potentially be higher.

“I would not like daily regimen because taking lots of drug was not good for the body. I preferred the time-driven regimen because I didn’t have sex much, maybe once a week.” (FGD 3/Time-driven arm)

6. **Optimizing investment in health promotion highly recommended:**

Participants perceived themselves in a high-risk group but also expected a healthy life ahead. If PrEP was offered, most participants would take it consistently as part of a more comprehensive prevention plan, including condom use to double their HIV prevention.

“While having sex, I kind of think that the chance of being infected is less. Usually, I use condom to protect myself. But taking PrEP makes me feel more secure.” (FGD 4/Daily arm)

Although, some participants felt PrEP was particularly beneficial for them as non-users of condoms.

“I usually don’t use condom. Every time I have sex, it’s purely from emotion. I pretended to put it on, but once my partner is not aware, I will take it off. Every time, I make love, I am aware of the risks. That’s why I think PrEP is right for me.” (KII 1/Event-driven arm)

Participants appeared well-informed about PrEP efficacy and its minimal side effects. Some participants searched for scientific evidence from research studies to prove that it was true. They reportedly adhered to their assigned regimen because they believed in PrEP efficacy.

“I think using condom made me confident. But once I got PrEP, I was even more confident. We don’t have to be nervous. I want to take PrEP often and want it in my body every day.” (FGD 5/Time-driven arm)

Barriers to PrEP Adherence

Six issues related to barriers to PrEP adherences emerged, five specific to barriers experienced during self-administration and one related to concerns with PrEP access in roll-out programs.

1. **Low/no perceived HIV risk:** Some participants stated that they felt that they were not at risk of getting HIV. Not having sex and having only one steady partner eroded some participants’ motivation to take PrEP.

“I could protect myself from HIV. I had sex but I didn’t have multiple sexual partners. I don’t think I’m at risk. I don’t usually have sex much anyway.” (FGD 1/Daily arm)

2. **Intoxication:** Participants reported not be able to adhere while they were intoxicated.

“I didn’t take it (my pill). I didn’t forget and I knew I was supposed to take it, but I was drunk. I thought I could close my eyes for a second but

I slept through morning. I didn't take it after that (sexual intercourse). I thought it was ok.” (FGD 6/Event-driven arm)

3. **Concerns about long-term side effects and side effects of PrEP:** Concerns about long-term safety and more immediate negative physical experiences attributed to PrEP were raised among the participants in the daily arm with infrequent sex events. They did not see their sex pattern matching with daily dosing. Some participants reported having minimal side effects of PrEP and even those appeared to resolve after about 2 weeks.

“The reason why I didn't want the daily dose because I was worried about bone density effect.” (FGD 2/Event-driven arm)

4. **HIV stigma:** Participants reported fears of being seen as HIV infected, especially participants in the daily arm. This is centered on HIV stigma itself, as PrEP stigma was not an issue.

“My boyfriend and friends thought I was HIV infected (laughed). I explained but they didn't understand why I needed to take pills daily if I wasn't infected.” (KII 4/Daily arm)

5. **Inability to forecast sex (non-daily arms):** Participants who were assigned to non-daily regimens expressed difficulty planning for sex caused them to miss the pre-sex dose in the event-driven regimen and the post-sex dose in both the time-driven and event-driven regimens.

“If the sexual desire starts from our side, we can control it. But if it starts from the partner's side, it is out of our control.” (KII 1/Event-driven arm)

Some participants reported that planning for pill-taking made sex no longer enjoyable. The pleasure of unexpected sex was gone when they had to plan for sex.

“It seems like a task. I had to control sex to be as planned. But in the reality, I think we need to let it be in a natural way.” (KII 1/Event-driven arm)

6. **Affordability:** Participants expressed their concerns about a daily PrEP regimen which was the only regimen proven to be effective at the time of the study and still generally unavailable outside of research studies in Thailand. Participants discussed the issue of cost for a drug taken daily when patterns of sex did not require daily coverage with the drug.

“If only daily PrEP will be recommended, how MSM with risk behaviors would be able to afford it? The patterns of sex among MSM are varied. It's not like one or two patterns... They are a lot more than that.” (FGD 4/Daily arm)

DISCUSSION

The current study collected qualitative data to identify the facilitators and barriers to PrEP adherence among MSM in Thailand receiving daily or non-daily PrEP in the HPTN 067/ADAPT study. Flexibility to choose a preferred regimen (daily or non-daily) that best mapped onto patterns of sex events, a high perceived need for HIV protection, investment in overall health, and access to and use of adherence support through social connections and technology use were discussed in reference to high PrEP adherence. Concerns about forecasting sex for pre-sex dosing in non-daily regimens were noted, as were concerns about long-term impacts, affordability, and HIV stigma across regimens.

Discourse suggested that non-daily regimens may have particular relevance to those with infrequent sex, while daily regimens may fit well for those with frequent sex events. However, complexity in instructions for following non-daily regimens may require additional attention such that tools and supports specific to assisting in forecasting and modification of dosing requirements to prevent taking more than 7 PrEP doses a week could be developed and provided.

Of note, affordability of PrEP was also noted as a factor in considering future use and whether or not a participant would want to use non-daily or daily PrEP. Consequently, participants suggested that PrEP should be added as one of the HIV prevention tools in Thai National Social Security Funding.

Overall, the participants took the study drug as prescribed, no one switched or altered their regimens. Adherence to regimen fidelity was 98% in this Thai cohort. Several patterns of sex, sexual role versatility, and age and lifestyle of individuals can lead to PrEP taking behavior change over time. Further qualitative studies could investigate in-depth PrEP adherence behavior among MSM in different sexual roles, young MSM, male sex workers, as well as further studies focusing on advanced PrEP reminder tools (including apps).

LIMITATIONS

The topics discussed in this study were sensitive and personal. Some of the participants may have felt uneasy answering questions openly in front of other participants. However, participants did appear open to discussing sensitive behaviors, including intentional non-adherence.

The purposive sampling of participants for FGDs and KIIs was conducted among those self-reporting or being observed to have poor adherence. Participants who participated in this study may not be representative of other MSM in Bangkok.

There was no TGW participated in the FGDs or KIIs. Less numbers of TGW participated in the HPTN067/ADAPT study and TGW participants may have self-reported to have higher adherence than MSM participants. Further study could be conducted specifically regarding gender identity and PrEP adherence.

The moderator/ interviewer may not cover all factors that affected the facilitators or barriers to taking PrEP. However, FGDs and KIIs guide were extensive and allowed a free range of topics among participants.

CONCLUSIONS

Participants supported adapting PrEP regimens to best reflect preferences and sexual practices. Concern about PrEP efficacy, and to some extent safety, were barriers to adherence. Participants recommended offering both daily and non-daily PrEP regimens in practice, to allow for tailoring of regimens to patterns of sex events.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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