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When and why women might suspend PrEP use according to perceived seasons of risk: implications for PrEP-specific risk-reduction counselling

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Abstract

Oral pre-exposure prophylaxis (PrEP) using the antiretroviral drug emtricitabine/tenofovir disoproxil fumarate (Truvada) has been shown to dramatically reduce the risk of HIV acquisition for women at higher risk of infection if taken daily. Understanding when and why women would intentionally stop using an efficacious oral PrEP drug within the context of their "normal" daily lives is essential for delivering effective PrEP risk-reduction counselling. We conducted 60 qualitative interviews with women at higher risk of HIV in Bondo, Kenya, and Pretoria, South Africa, as part of a larger study. Participants charted their sexual contacts over the previous six months, indicated whether they would have taken PrEP if available, and discussed whether and why they would have suspended PrEP use. Nearly all participants said they would have used PrEP in the previous six months; half indicated they would have suspended PrEP use at some point. Participants' reasons for an extended break from PrEP were related to partnership dynamics (e.g., perceived low risk of a stable partner) and phases of life (e.g., trying to conceive). Life events (e.g., holidays and travel) could prompt shorter breaks in PrEP use. These circumstances may or may not correspond to actual contexts of lower risk, highlighting the importance of tailored PrEP risk-reduction counselling.

Keywords

HIV prevention; pre-exposure prophylaxis; PrEP counselling; Kenya; South Africa; women

Introduction

Now that oral emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) has been shown to be efficacious as pre-exposure prophylaxis (PrEP) (Baeten et al. 2012; Grant et al. 2010; Thigpen et al. 2012), critical questions focus on who should take PrEP, when they should

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take it, and for how long. Addressing the first question, recent US Centers for Disease Control and Prevention (CDC) and WHO guidance on who might most benefit from PrEP broadens the recommendations to include "all population groups at substantial risk of HIV infection", including heterosexual women in non-mutually-monogamous relationships who do not regularly use condoms (WHO 2015, p.1; CDC 2014). Additionally, there is some evidence on dose response for men who have sex with men (MSM) (Seifert et al. 2014) that begins to address the question of when PrEP should be started and stopped with reference to potential exposure, though there is little similar evidence available on pharmacokinetics and dose response for women (US Public Health Service 2014).

Discussions around how long a person might take PrEP typically assume periods of PrEP use that correspond with periods of increased HIV risk. Mugo spoke of *seasons of vulnerability* at the International AIDS Conference in 2012 (Mugo 2012) to reference times when a woman might have increased sexual risk for HIV infection, such as when trying to conceive or at the beginning of a relationship. Others have spoken similarly of *seasons of risk* (Grant 2013; Elsesser et al. 2015) or *seasons of PrEP* to describe the time-delimited use of PrEP that corresponds to these changes in risk status (Baeten et al. 2013). This concept is also at the heart of what has been forwarded as prevention-effective PrEP adherence, or "the use of PrEP only during periods of risk exposure such that it leads to effective protection against HIV acquisition" (Haberer et al. 2015, p.1278). Despite recognition of these seasons, little has been published on how potential users of PrEP might define or recognise the endings of these periods, which would signal an intentional suspension of PrEP use – and an important time for tailored risk reduction counselling.

Particularly in sub-Saharan Africa, where the HIV epidemic is generalised rather than concentrated (Beyrer and Karim 2013) and women are often at higher risk than men, understanding when and why women might suspend PrEP use based on their changing seasons of risk is essential for delivering effective counselling on PrEP discontinuation. These types of PrEP implementation considerations are increasingly pressing since emtricitabine/tenofovir disoproxil fumarate (Truvada) has recently been approved as PrEP in both Kenya and South Africa (AVAC 2015). To begin addressing this concern, we explored when and why women at higher risk of HIV in those two countries would consider stopping PrEP.

Methods

Data collection

We conducted qualitative semi-structured interviews with 30 women each in Bondo, Kenya, and in Pretoria, South Africa, between February and May 2013. Participants were purposively selected from a larger study exploring PrEP and risk compensation among women at higher risk of HIV, defined as those who were 18 to 35 years of age, were HIV-negative, and had had at least one vaginal sex act in the past two weeks or more than one sexual partner in the past six months; women also must not have received any prior counselling on PrEP, to minimise potential for bias based on prior information. The parent study enrolled 799 women (400 in Bondo; 399 in Pretoria) to take part in a vignette-based survey about their HIV prevention behaviours in a variety of partnership contexts with and

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without PrEP (Corneli, Field, et al. 2015). Given the parent-study's ultimate objective of developing counselling guidance for women who may be likely to reduce their current HIV risk-reduction behaviours if taking PrEP (Corneli et al. 2016), the women sampled for the qualitative research were systematically selected from among survey participants whose responses suggested they were more likely to discontinue other protective behaviours if taking PrEP (e.g., participants who said they were “very likely” to use a condom in a certain risk situation if not taking PrEP but “not likely” to use a condom in that situation if taking PrEP). Women whose responses indicated the potential for risk compensation were identified in each of the four risk scenarios (deciding on taking a new sexual partner and on condom use with casual, regular, and transactional sex partners). Roughly equal numbers of women from each risk scenario were invited to participate in the interviews, starting with those with the highest potential for risk compensation.

The primary purpose of the follow-up interviews was to explore women's motivations for reducing the use of other HIV risk-reduction practices if they were to take PrEP (Corneli, Namey, et al. 2015). We also wanted to understand the context of these women's sexual lives and decision-making as it related to starting and stopping PrEP, so that their experiences and motivations might inform counselling around PrEP discontinuation. Interviews were conducted by local social science research teams and lasted roughly one hour. Each interview began with the provision of basic information about PrEP that women had previously heard during the survey (see Appendix 1), including discussion of the evidence on the efficacy of PrEP. During the interview, each woman created a timeline of the major events in her life over the past six months, and then added information on her sexual contacts (e.g., type, duration, condom use) to the corresponding dates on the timeline. We asked each woman to imagine that a year's supply of PrEP had become available to her six months ago, free of charge, and then asked her three questions while she considered her timeline: (i) would she have started taking PrEP during that period if available? (If no, the next two questions were skipped); (ii) at any point in the past six months, would she have taken a break from, or stopped, taking PrEP (beyond a missed pill here or there); (iii) at any point in the future, might she take a break from or stop taking PrEP?

Women were asked to provide explanations of why they would have taken PrEP and how/why they might decide to suspend its use. The data presented here focus on the responses to and ensuing discussion around the latter two questions.

Analysis

We conducted an applied thematic analysis (Guest, MacQueen, and Namey 2012) on English translations of the transcribed interviews, using a formalised codebook (MacQueen et al. 1998) that defined both structural (question-based) and emergent (theme-based) codes. Two coders performed inter-coder agreement checks on 20% of the transcripts, using qualitative assessment of agreement to reconcile all differences (Guest, MacQueen, and Namey 2012). Coding and code definitions were revised as necessary after each inter-coder agreement check. From questions 2 and 3 above, we identified reasons for stopping PrEP use and grouped them into sub-categories based on thematic similarities. We created summaries of each sub-category to describe themes, the frequency of occurrence, and

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exemplary narrative segments. We have labelled all quotes with pseudonyms to distinguish among research participants.

Ethics

The research was reviewed and approved by the Ethics Review Committee at the Kenya Medical Research Institute (Bondo), the Pharma-Ethics Review Board (Pretoria), and the Protection of Human Subjects Committee at FHI 360 (USA). Participants provided either verbal (Bondo) or written (Pretoria) informed consent, according to local guidelines.

Results

Study population

The mean age of the women in our sample was 23 years (range 18-32 years). Participants from the two sites were similar with the exceptions of education and marital status. Women from Bondo were less likely than women from Pretoria to have completed at least some secondary education (37% versus 97%) and more likely to be married and living with their partners (63% versus 3%). Nearly all women indicated having a primary sexual partner, with whom many never or rarely used condoms (69% in Bondo; 50% in Pretoria). Of the women who reported having a second partner in the past month (43% in Bondo; 33% in Pretoria), more than half reported always using a condom with this partner (Table 1).

Projected PrEP use and suspension

Of the 60 women in our sample, 57 (95%) reported they would have taken PrEP if offered during the six months prior to the interview, nearly all citing reduction in risk of acquiring HIV as their reason. One woman from Bondo was unsure whether she would have started PrEP, and another said she would have declined PrEP based on her dislike of drugs in general. The only woman from Pretoria in our sample who said she would not have taken PrEP cited concerns of risk compensation, feeling she would engage in riskier sexual behaviour if on PrEP. These three women were not asked about suspension of PrEP and were excluded from subsequent analyses for this paper. Of the remaining sample, 11 (19%) reported they would have taken a break from PrEP during the past six months, and 23 (40%) foresaw a reason to suspend PrEP use in the future. One woman summed up a general understanding of seasons of PrEP, saying:

> ... you cannot take pills for the rest of your life unless they are ARVs [antiretrovirals] for HIV-positive people where you have no choice ...But for PrEP it comes a situation where you will have to take a break and relax, even for some months is when you can resume again. (Agnes, a 24-year-old unmarried woman, Bondo)

Reasons for suspending PrEP

Combined, a total of twenty-seven women (47%) said they would have stopped PrEP in the past and/or foresaw stopping it in the future. Reasons for stopping were similar for the two time periods and hence are discussed together here. Sixteen women (eight per site) provided reasons why they might take what we have termed an *extended* break from PrEP – an

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intentional suspension or discontinuation of PrEP use based on a change in circumstances and/or perceived HIV risk – signalling the end of a season of PrEP. These reasons were grouped into two categories: partnership dynamics and phases of life. Additionally, 15 women (nine from Bondo; six from Pretoria) mentioned life events that might necessitate a *shorter* break from PrEP – a (sometimes intentional) lapse in adherence – driven by factors unrelated to a perceived end to a season of risk. Except where noted, the findings below reflect themes discussed at both sites.

Partnership dynamics—Twelve women cited partnership dynamics as a reason for taking an extended break from PrEP. On one end of the continuum, women described situations in which they were single either by definition (had no partner) or by geography (had a partner who was traveling or living in another location for long periods of time). In these situations, women felt they would not be having sex and therefore would stop taking PrEP until their partnership situation changed. For some, the reduction in risk was implied: “I would drink it [take the pill] if I have a partner. If I don't have a partner I wouldn't drink it” (Gontse, a 25-year-old, unmarried woman living with her partner, Pretoria). For others, the link between risk perception and suspension of PrEP was explicit: “The period when ... maybe my partner is not around during that time. I may take a rest [from PrEP] because he is not around. I know nobody will infect me with the virus” (Atieno, a 20-year-old married woman, Bondo).

On the opposite end of the spectrum were situations in which a woman's partner was regularly physically and emotionally present (most often cohabiting or married). Women cited the intensity of relationships, whether defined by marriage, stability, faithfulness, or trust, as another reason to stop using PrEP. These women said they would suspend PrEP once they established this type of stable, secure relationship:

> Maybe if I get married and I trust my husband. Maybe like you have used PrEP for like three years and you see your relationship with your partner is just ok and you are faithful to each other, you would decide to just stop taking it with confidence. (Agnes, a 24-year-old unmarried woman, Bondo)

> When a person has married you it means he trusts you and he stops doing many things...like running around [dating different women], there is trust. (Nandi, a 23-year-old unmarried woman, Pretoria)

In these examples, trust and faithfulness were expectations of marriage that reduced women's perceptions of risk and, subsequently, their perceived need for PrEP.

Two other reasons for suspending PrEP were related to this type of close relationship. The first of these focused on HIV testing or knowing the serostatus of one's partner(s). As Lillian, a 26-year-old unmarried woman from Pretoria said, “Yes, there will be a time where I will stop [taking PrEP], provided my partner agrees to go and have an HIV test every month.” The other reason, mentioned by two women in Pretoria, framed suspension of PrEP as a way to avoid conflict within a relationship: “[I would stop] if maybe my partner had told me to stop drinking it [taking PrEP]” (Nomsa, a 20-year-old unmarried woman). The same woman also raised a concern that “some people say that I am lying, I'm drinking the pills for

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something else," reflecting a theme raised by two other women in Bondo that social pressures from outside a primary relationship may also motivate suspension of PrEP.

Phases of life—Conception, pregnancy, and older age were phases of life that women foresaw as precipitating an extended break from PrEP. Two women at each site mentioned that a suspension of PrEP was presumed if they were trying to conceive or when they became pregnant. With regard to conception, one woman stated that, "...maybe if I get a new partner and he wants to have a baby with me and marry me, then I have to stop taking PrEP and contraceptives and have his baby" (Pamela, a 20-year-old unmarried woman from Pretoria).

In terms of pregnancy, women expressed concern about the drug affecting the fetus: "When you are pregnant, you are usually advised not to take medication anyhow that might cause miscarriages" (Dorine, a 20-year-old married woman, Bondo). In the context of both conception and pregnancy, women's decisions to take a break from PrEP were primarily driven by fear of the effects the medication may have on a foetus rather than due to a reduction in perceived HIV risk; however, women also mentioned a belief that their HIV risk would be reduced during pregnancy because of declining frequency of sex.

Similarly, two women from Bondo (and only from this site) cited the reduced frequency or cessation of sex that comes with ageing as a foreseeable reason to stop taking PrEP: "When you stop having sex, after you become older, you can stop or break from taking it...Once you stop having sexual desires [Laughs]...When you become an aged woman" (Juliana, a 25-year-old married woman, Bondo). In this situation, women viewed the suspension of PrEP as a permanent discontinuation, rather than an extended break, but an end to a season of PrEP nonetheless.

Life events—Though we anticipated that women would discuss extended breaks from PrEP, they also mentioned separate, specific shorter-term life events that would disrupt their routine and, therefore, potentially their PrEP use. For example, four women mentioned that when they were ill or during stressful periods of life they would stop taking PrEP, as they would have more pressing concerns (health or otherwise). Said one woman of her past six months, "I was stressed; I was always up and down...I would have stopped drinking them [taking PrEP pills], maybe not being able to remember" (Nandi, a 23-year-old unmarried woman, Pretoria).

Six women mentioned a combination of travelling and holiday festivals as life events that would cause them to stop taking PrEP for a period, either because they would forget to take their pills with them or because they worried that it would be difficult to carry and take PrEP pills discreetly when away from home. Reflecting on travel recorded on her timeline, one woman said: "I would have taken a break a bit then I resume....Because I was travelling... but if those journeys were not there I would have just taken it," (Mercy, a 23-year-old unmarried woman from Bondo). Similarly in Pretoria, the only site to report holidays as a reason for discontinuation, one woman said, "[I would stop in September.] That's when the festive seasons start. We will be busy going up and down to parties and won't have time to drink [take] pills" (Pauline, a 26-year-old unmarried woman). In these instances of

prolonged lapses in adherence, the context of the women's lives motivated the change in PrEP use, rather than their perceived risk.

Discussion

In this study, we were particularly interested in women's conceptions of “seasons of PrEP” and their projected reasons for discontinuing PrEP, as these can mark periods when counselling on risk and risk-reduction strategies may be helpful. Women in our sample recognised many circumstances in their lives, separate from daily adherence issues, in which they might suspend PrEP. With the exception of aging (in Bondo) and festivals (in Pretoria), the reasons women gave for potentially suspending PrEP were similar across sites.

In some contexts, such as the absence of a partner or infrequent sex, decisions to stop PrEP were related to a perceived reduction in HIV risk. In the case of longer partner absences, counsellors need to provide advice on how long a woman should take PrEP after the last potential HIV exposure and when she should start taking PrEP in advance of the anticipated resumption of sexual activity. Additional research among women is needed in both of these areas, as only preliminary data (US Public Health Service 2014) or those based on pharmacokinetic studies with MSM are available (Seifert et al. 2014). Open discussion of current information may help women decide to remain on daily PrEP despite relatively infrequent visits from a partner, switch to event-driven dosing (Seifert et al. 2014) if efficacy of this approach is established for women, or to choose another HIV prevention method.

In other situations in which women might suspend PrEP use, such as marriage or stable relationships, a perceived reduction in HIV risk might drive the decision while the potential for risk may stay the same. In these cases, although the season of risk is perceived to be ending, counsellors may play a role in helping women carefully assess whether risk is actually likely to decrease. For instance, counsellors may share information about how the risk of HIV remains relatively high for some women regardless of marital status (Santelli et al. 2013; Ramjee and Daniels 2013) and that negotiating condom use often becomes more difficult with marriage (Anglewicz and Clark 2013; Chimbiri 2007; Maharaj and Cleland 2005), leading to more in-depth discussion of both relationship dynamics and self-efficacy in the context of a woman's current partnership and risk assessments. Couples counselling and male-engagement strategies warrant consideration within the context of PrEP, as they do within the context of microbicides (Domanska and Teitelman 2012; Woodsong and Alleman 2008) and vaginal rings (van der Straten et al. 2012), to avoid undermining relationships.

For a few of the reasons cited for suspending PrEP, women's HIV risk might actually increase. For instance, the risk of HIV acquisition during a given sex act increases during pregnancy (Mugo et al. 2011), as does the risk of perinatal transmission to an infant when a mother becomes infected during pregnancy (Johnson et al. 2012). Counselling here might focus on discussion of the risks and benefits of PrEP use (US Public Health Service 2014) for the woman and her foetus that is grounded in scientific evidence (Mugo et al. 2014; Hoffman et al. 2015) and current guidance that PrEP can be used during pregnancy (WHO 2015), while acknowledging socio-cultural norms. This would also serve as a point to

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discuss other risk-reduction methods if she decides to discontinue PrEP while trying to conceive or during pregnancy.

Regarding shorter-term life events that may disrupt PrEP use (e.g., travel, holidays, and festive seasons), again risk may increase during these periods, particularly if alcohol or drug use is present or more frequent than usual. In its guidance on creating PrEP adherence plans, the CDC recommends asking, "When you travel or spend the night outside of your home, what will you do about taking the pill?" (US Public Health Service 2014a, p. 24). It may be useful to add a question about other foreseeable disruptions to a woman's normal routine, such as holidays or festivals, to initiate a discussion about how PrEP use might be continued (US Public Health Service 2014a) can be used. Refinement of discussions about adherence to focus on prevention-effective PrEP adherence as outlined by Haberer et al. (2015) may also be useful in this regard, by helping women recognise the time-delimited nature of their risk and subsequent PrEP use. Or, as the WHO guidance suggests, support groups and social media that enable PrEP users to share experiences and challenges may bolster adherence for these shorter-term lapses in PrEP use (WHO 2015).

We recognise the limitations of the hypothetical nature of this research, yet aimed to ground women's responses in the reality of their sexual relationships over the prior six months through the use of the timeline. In the absence of wide-scale availability and implementation of PrEP among women in sub-Saharan Africa at the time of the research, this approach offered the possibility of providing data on the range of times when and reasons why women might suspend PrEP use in the context of a generalised epidemic. We also acknowledge the limitations of our small sample size, and that the women in our sample – who were selected because they were more likely to reduce or stop using risk reduction measures when they initiated PrEP – might have had different views about suspending or discontinuing PrEP use compared to women who were not likely to change their current risk reduction practices. We cannot say how representative this sample was of the larger population of at-risk women. Nonetheless, our data drawn from two culturally distinct sites provide examples of where counselling around PrEP suspension might focus.

In the context of the more inclusive WHO and CDC guidelines on who might benefit from PrEP (WHO 2015; CDC 2014), and given the recent approval of PrEP in both Kenya and South Africa (AVAC 2015), these data offer insights for future research and programmatic development related to PrEP rollout, and potentially serve as a starting point for considering similar concerns related to other HIV prevention technologies. These issues and contexts can also be examined in ongoing PrEP demonstration projects (where women are actually taking PrEP) to better ground the data in experience and provide more detail on how conditions of a woman's life could be better addressed during PrEP-specific risk-reduction counselling and development of adherence plans. Ultimately, knowing when and why women might stop taking PrEP — for a short or long time — provides a context-rich foundation for improving counselling to provide women transitioning off PrEP an opportunity to discuss risk and strategies for maintaining sexual health.

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Appendix I. Description of the brief information on PrEP provided to participants (Corneli et al. 2015)

Participants were informed that PrEP is an antiretroviral medicine that comes in the form of a tablet and must be taken daily. Using this approach, individuals take a PrEP tablet every day to reduce their chance of getting HIV; the idea is similar to HIV-positive mothers taking medicine to prevent passing HIV to their babies at birth.

Participants were told that PrEP is not 100% effective; it has been shown to reduce a woman's chance of becoming infected with HIV by 66 to 71% (based on data among women in the Partners PrEP Study that were current at the time (Donnell D 2012)).

Participants were also told that, by comparison, condoms are 97% effective when used correctly and consistently. Study staff explained that individuals should still use other proven methods to reduce their risk of HIV infection when taking PrEP, such as using condoms correctly and consistently, getting tested for HIV, getting tested and treated for sexually transmitted infections, and reducing their number of sexual partners.

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Table I

Participants' demographic characteristics and sexual partnerships and behaviours

Variable	Bondo (n=30)	Pretoria (n=30)
Demographic characteristics		
Age, years		
Mean	23	23
Range	18-32	18-31
Education, n (%)		
Completed primary school or less	19 (63)	1 (3)
Completed some or all of secondary school	9 (30)	20 (67)
Some post-secondary certificate, diploma, degree	2 (7)	9 (30)
Marital status and co-habitation, n (%)		
Not married and currently not living with partner	8 (27)	20 (67)
Not married and living with partner	1 (3)	9 (30)
Married and not living with partner	0 (0)	0 (0)
Married and living with partner	19 (63)	1 (3)
Separated	0 (0)	0 (0)
Divorced	1 (3)	0 (0)
Widowed	1 (3)	0 (0)
Occupation, n (%)[a]		
Market/street vendor	5 (17)	1 (3)
Fishing industry (Bondo only)	9 (31)	n/a
Bar, tavern, club, hotel employee; hairdresser	2 (7)	1 (3)
Agricultural work	4 (14)	0 (0)
Office work	0 (0)	1 (3)
Student	1 (3)	6 (20)
Housewife or not employed (non-student)	5 (17)	19 (63)
Other	4 (14)	2 (7)
Sexual partnerships and behaviors		
Has primary partner, n (%)	29 (97)	30 (100)
Relationship to primary partner, n (%)		
Husband	20 (69)	4 (13)
Boyfriend	9 (31)	26 (87)
Condom use with primary partner, n (%)		
Never	18 (62)	14 (47)
Rarely	2 (7)	1 (3)
Sometimes	7 (24)	6 (20)
Usually	0 (0)	0 (0)
Always	2 (7)	9 (30)
Had other partners in the past month, n (%)	13 (43)	10 (33)
Condom use with other partners, n (%)		
Never	1 (8)	1 (10)

Variable	Bondo (n=30)	Pretoria (n=30)
Rarely	2 (15)	1 (10)
Sometimes	3 (23)	2 (20)
Usually	0 (0)	1 (10)
Always	7 (54)	5 (50)

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