Communication

Dealing with pre-exposure prophylaxis-associated condom migration: changing the paradigm for men who have sex with men

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Abstract.   The behavioural aspects of pre-exposure prophylaxis (PrEP) are challenging, particularly the issue of condom migration. Three vital questions are: (1) at the population-level, will condom migration lead to increases in non-viral sexually transmissible infections?; (2) how can clinic-based counselling best promote the dual use of condoms and PrEP?; and (3) in future PrEP trials, what are the 'best practices' that should be used to avoid type 1 and type 2 errors that arise without accounting for condom use behaviours? This communication piece addresses each question and suggests the risk of a 'PrEP only' focus to widening health disparities.

Introduction

Globally, the stage is set for pre-exposure prophylaxis (PrEP) to become a mainstay of HIV prevention.[1–3] The behavioural aspects of PrEP, however, may prove challenging.[4] Uptake and adherence issues have emerged as a result of PrEP.[5–12] A third behavioural issue has received much less attention: the occurrence of condom migration. This phenomenon occurs when perceived protection from one prevention method precludes, or reduces, the use of a second method.[13–16] In the field of sexual health, this concept was initially described relative to the inverse association between hormonal contraceptive use and condoms[17–21] (thus prompting the practice of promoting dual use).[22]

Rather than reviewing current evidence pertaining to condom migration, this communication piece suggests that the question of whether individual-level condom use decreases, stays the same, or increases during periods of PrEP use, is not a useful one because it provides little practical information relative to prevention. Instead, there are three questions that are highly pertinent to public health: (1) at the population-level, will condom migration lead to substantial increases in non-viral sexually transmissible infections (STIs)?; (2) at the individual-level, how can PrEP-associated counselling sessions best promote the dual use of condoms and PrEP?; and (3) in future clinical trials of PrEP, what are the 'best practices' that

should be used to avoid type 1 and type 2 errors that may arise in the absence of precisely accounting for condom use behaviours?

Rather than conflating heterosexual populations with populations of MSM, this communication piece will primarily focus on PrEP-associated condom migration issues that pertain to the national emergencies among MSM. The crisis among MSM is severe and the corresponding health disparity for MSM is becoming larger, especially for minority MSM.[23,24]

Population-level condom migration

Auerbach and Hoppe suggested that the issue of condom migration is not important because PrEP efficacy is strong enough to offer protection without condom use and robust to the synergistic effect of STIs on the acquisition and transmission of HIV.[25] This point is quite valid, but it is made in the paradigm of ending AIDS.[26] Moving away from an 'ending AIDS only' paradigm to a larger paradigm of sexual health, it is noteworthy in the United States that 2014 surveillance data showed substantial increases in STI cases occurring, for the first time in more than one decade.[27] Whether population-level increases in STIs are occurring as a result of PrEP use, is a very different question than one addressed in other studies, such as that reported by Volk *et al.* who noted a substantial (28.4%) 12-month incidence of non-viral STIs among 657 PrEP initiators.[28] Whether non-HIV viral STIs (e.g. HPV, herpes)

may similarly increase is questionable given the relatively low efficacy of condoms against these infections; nonetheless, small increases are possible. If PrEP-associated condom migration is a contributing factor to population-level increases in STIs, it would occur through a network-based spread of infections. Thus, simply assessing STI incidence in only those using PrEP would be inadequate.

Given the intent of PrEP for persons other than those having a primary seropositive sex partner, it is quite plausible that many people taking PrEP occupy fairly central positions in their sexual networks. Thus, even small amounts of PrEP-associated condom migration, or a perceived freedom to increase the number of sex partners, may substantially amplify STI transmission rates. The only way to rule out the possibility of PrEP being a cause of greater STI incidence rates is to find an absence of correlation between PrEP consumption (perhaps assessed through aggregate data from pharmacies) and STI rates. The absence of at least a moderate correlation would negate the possibility of a cause-and-effect relationship. Conversely, the presence of at least a moderate correlation would only suggest potential causation, thereby warranting more definitive, and costly, study designs.

Clearly, causes other than PrEP-associated condom migration may be relevant. For instance, it is likely that people most at-risk of HIV acquisition (thus prioritised for PrEP) are also very likely to be involved in sexual networks where STI prevalence is high, and through the frequent STI screenings, greater case findings occur that are then mistaken as upward trends.[29] Also, it is possible that health departments have diverted resources to PrEP implementation that were previously allocated to STI-prevention and -control activities, such as contact tracing.

Dual use of PrEP and condoms

Emerging evidence suggests that adherence to PrEP may be low. Failed PrEP trials were attributed to poor adherence[30,31] and successful PrEP trials have restricted the analyses to adherent persons. This low level of adherence in efficacy trials bodes poorly for adherence in practice, given the absence of tightly controlled conditions found in clinical trials.[32] Poor adherence is one reason why researchers have tested PrEP use as 'sexual activity dependent' (a strategy with promising results)[33] and why other researchers have advocated that PrEP only be provided in the context of behavioural intervention programs.[34] Adherence challenges are compounded by the fact that, unlike antiretrovirals to treat HIV people taking PrEP are disease-free.[35]

Prior to PrEP, the prevention method of choice was the consistent and correct use of latex condoms. All too often, the 'correct' portion of the phrase 'consistent and correct condom use' is ignored by researchers.[13,36,37] A case in point applies to a recent study of condom effectiveness against non-viral STIs among heterosexuals.[38] This multi-site study found a non-significant overall association between the consistent use of condoms and the acquisition of non-viral STIs, in both males and females. However, much like PrEP trials only analysing adherent study participants, the association became significant (and strong; adjusted odds ratio of 0.41) after refining the classification to consistent and correct use. Similar bias

towards the null hypothesis applies to condom effectiveness studies for HIV conducted among heterosexuals. Thus, condoms may be far more efficacious than the current estimates suggest. Consequently, evidence-based interventions applied to promote the correct, as well as the consistent use of, condoms may be as efficacious as PrEP.[39–41] It is noteworthy that the most recently published study on condom effectiveness against HIV acquisition among MSM provided a 70% effectiveness rate for persons using condoms consistently.[42] The study, however, did not correct for lack of correct use among those using condoms consistently, thereby creating bias towards the null.[38,43,44] Assuming 70% as a conservative estimate of effectiveness, correct condom use is nonetheless as effective (or better) as estimates of PrEP efficacy obtained in the original study of MSM (point estimate = 44%, 95% CI = 15–63%).[3]

That both PrEP and condom use can be equally effective against HIV acquisition is an important counselling point for clinicians. The PrEPare study, for instance, found that 40% of MSM reported that avoiding condomless sex was their HIV prevention strategy and that 47.5% reported having condomless sex but using PrEP.[45] Clearly, not all MSM desire to be on PrEP and thus presenting men with multiple prevention options is an ethical and beneficial practice. Because MSM may use PrEP on a situation-specific basis (e.g. weekends only) and the expense of PrEP makes its use impractical during times when MSM do not have anal sex, the option of condom use (either fully or as a supplement to PrEP) must be delivered as a practical alternative or companion practice to PrEP, and clinics should consider using evidence-based counselling programs that promote the correct and consistent use of condoms in a sex-positive context.[40] This same ethic of dual use should also be applied to future PrEP delivery strategies that may be sexual-activity dependent.[33]

Best measurement practices for condom use among PrEP users

Failed trials of PrEP, such as that reported by Van Damme *et al.*,[30] may have been confounded by condom migration. If, for example, women (and/or their HIV-positive male sex partners) believing they were taking PrEP largely abandoned condom use and did not fully adhere to PrEP, this would explain the greater incidence of new infection in the intervention group. In future trials of PrEP, it will be critical to conduct rigorous assessments of condom use. Ideally, assessments should be made at the event-level, meaning that they occur soon after (e.g. 24 h) sexual events.[44,46–48] The primary confounding issue with aggregate measures of condom use is that it will not be possible to know whether PrEP use and condom use occurred simultaneously or separately. For example, a person taking PrEP only on weekends – perhaps when having sex with side partners – and also reporting condomless anal receptive sex twice each week may be fully protected or at-risk of HIV acquisition. If Tenofovir disoproxil fumarate levels are sufficiently high for the weekend sexual events and the two events of condomless sex occurred at this time, then protection is conferred, as planned. However, if the condomless events occurred during the week (e.g. Wednesday/Thursday) when Tenofovir levels were low, then risk of HIV acquisition (from perhaps a serodiscordant main partner) may be high. Because this type

Table 1.   **Proposed condom assessment methodology in studies of pre-exposure prophylaxis use**

Question		
In the past 90 days, have you had anal sex with a male, as a <u>Top</u>?		
If yes, please complete the following grid-		
In the past 90 days, how many times did:	With HIV-infected	With partners not known
Sex occur (with you as the top)?	partners	to be HIV-infected
Of these times (row above) how many Involved condom use from start to finish?		
Of the times condoms were used (row above) how many times did condoms break, slip off, or slip off during withdrawal?		
Of the times condoms were used (2 rows above) how many times were condoms used that had been used previously for sex?		
In the past 90 days, have you had anal sex as a <u>Bottom</u>?		
If yes, please complete the following grid-		
In the past 90 days, how many times did	With HIV-infected	With partners not known
Sex occur (with you as the bottom)?	partners	to be HIV-infected
Of these times (row above) how many Involved condom use from start to finish?		
Of the times condoms were used (row above) how many times did condoms break, slip off, or slip off during withdrawal?		
Of the times condoms were used (2 rows above) how many times were condoms used that had been used previously for sex?		
In the past 90 days, have you had oral sex with a male?		
If yes, please complete the following grid-		
In the past 90 days, how many times did:	With HIV-infected	With partners not known
Oral sex occur with you <u>giving</u> the blow job?	partners	to be HIV-infected
Of these times (row above) how many Involved condom use from start to finish?		
Of the times condoms were used (row above) how many times did condoms break, slip off, or slip off during withdrawal?		
Of the times condoms were used (2 rows above) how many times were condoms used that had been used previously for sex? Oral sex occur with you <u>getting (receiving)</u> the blow job?		
Of these times (row above) how many Involved condom use from start to finish?		
Of the times condoms were used (row above) how many times did condoms break, slip off, or slip off during withdrawal?		
Of the times condoms were used (2 rows above) how many times were condoms used that had been used previously for sex?		

of 'weekend' PrEP use was tested in the Ipergay study and found to be effective,[33] it may become a common method of delivery. Thus, for now and in the future, simply assessing the number of days when PrEP was taken and the number of times when condomless anal sex occurred is not sufficient to avert the risk of type 1 errors (condoms were used when PrEP was used, thus inflating the efficacy of PrEP) or type 2 errors (condoms were used, rather than PrEP, with partners who were seropositive, thus conferring protection that should not be attributed to PrEP).

Ultimately, the assessment of condom use behaviours in the context of PrEP-related studies is complex and warrants much more attention to detail than it has received.[3,30,48–50] Table 1 displays a proposed assessment framework that applies to MSM.

Conclusion

Re-conceptualising PrEP as a complementary tool in the AIDS pandemic rather than a singular one is imperative. In addition to the reasons described, this is imperative because prevention efforts overly focused on PrEP may inadvertently widen the already existing racial, ethnic and economic disparities in HIV incidence. This point is clearly illustrated by a recent analysis of MSM dropping out of care for PrEP. This USA-based study estimated large cascade effects cumulating in only 12.3% of Black MSM ultimately benefitting from PrEP compared to 17.8% among White MSM.[4] Similar findings have been reported in other studies.[51,52]

Until PrEP becomes widely accepted and used correctly by substantial portions of at-risk populations, the prevention of HIV acquisition will be reliant on the consistent and correct use of male latex condoms. Evidence supports the idea that MSM may often prefer condom use as compared to PrEP,[8] and other evidence suggests that a fair portion (approximately one-third) of Black MSM may actually enjoy sex more when it is condom-protected.[53]

To avert expanding the HIV prevention disparities seen globally,[54,55] the task of the practitioners, policymakers and

behavioural scientists is to move forward with PrEP and simultaneously move forward with the less invasive and less resource-intensive methods that may be more acceptable to persons most at-risk of HIV acquisition.

Conflicts of interest

None declared.

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