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Title	High acceptability, adherence and tolerability of HIV pre-exposure prophylaxis among Toronto gay and bisexual men: a pilot study
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Reviewer 1	Pierre-Paul Tellier
Institution	Students Health Services, McGill University, Montréal, Que.
General comments (author response in bold)	1. …it would be important to state what the throat samples were tested for (line 123). At that point in time Health Canada had not accepted NAAT for use in throat or anal sampling, unless the researchers had obtained a permission from Health Canada to use the test for this purpose. So, one is left to assume that the throat swabs were cultures for gonorrhea. This is should be stated. **The cited sentence already stated that at all visits except month 1, participants underwent "screening for gonorrhea and chlamydia infections, using urine nucleic acid amplification testing as well as pharyngeal and rectal swabs for culture".** 2. Line 141, is missing a word which assume to be "assessed". **We have corrected this by using the word "quantified".** 3. The report of results starts with stating the numbers of inquiries about the studies that were received. They state that there was substantial interest, giving a comparable would be useful to better understand this statement. **In response to this comment and comment #14 from the Editors, we have removed the word "substantial".** 4. They state that one participant was hospitalized for severe diarrhea. It would have been useful to explain what the reason for this was, i.e. recurrence of a previously diagnosed inflammatory bowel disease, and infection with a bacteria or parasite possibly related to sexual activity. However, we are simply told that there was no relationship to the study medication. **We have now specified that the severe diarrhea was due to a "self-limited infectious colitis for which no specific etiology was identified".**
Reviewer 2	Mark Hull
Institution	Division of Infectious Diseases, University of British Columbia, Vancouver, BC
General comments (author response in bold)	1. It would be interesting and I think important for future roll-out projects to provide further information regarding the 36% of individuals who screened out of this study. Individuals either were not being considered at elevated risk for HIV based on self-reported condomless sex or HIRI-MSM score. **See response to Editor's comment #12 for a general discussion of these issues.** a. Were these individuals more likely to have been self-referred or referred from the community organizations screening for the study? This would help us determine the utility of using these methods for future PrEP scale-up interventions. **There was no statistically significant difference in referral source (self-referred versus community organization) between those who were screened-out versus enrolled in the study. We agree with the Reviewer that comparing the risk profile of self-referred individuals versus those referred from community organizations is useful for evaluating the utility of these methods for PrEP scale-up, and this topic is the subject of a previously reported publication by our team (citation 16).** b. Were the demographic characteristics similar to included individuals? **As stated in response to Editor's comment #12c, we found no statistically significant differences in age, ethnicity, sexual orientation, income and education level for these two groups.** c. Similarly did any of those individuals excluded from the study have other risks that would make them eligible for PrEP under current guidelines (specifically did any of them have STIs?). **Unfortunately, data regarding the STI history of excluded individuals are not available.** 2. When evaluating the median HIRI-MSM score of participants, it was in fact well over 10 – it was in the highest quartile with median score 29. This is in the context of individuals being selected via a relatively non-targeted recruitment strategy. Since this quartile has been found to be particularly cost-effective in prior studies, it might be worthwhile for the authors to highlight this in the results or interpretation section. **The high HIRI-MSM score was likely the result of our study eligibility criteria, as alluded to in response to Editor's comment #12a, as opposed to being a result of chance. As such, while we agree with the Reviewer that PrEP is particularly cost-effective in such populations, we have opted not to discuss this issue further in the manuscript.** 3. Please include some description of substance use in the baseline demographics of the study population, notably at least for crystal methamphetamine. **In response to this comment, we have added data on the frequency of recent (past 3 months) recreational drug use (specifically for amphetamines and poppers, which are most strongly correlated with incident HIV) to the description of baseline characteristics of the study population in Table 1.** 4. The data on STI's is interesting, but the authors make no effort to provide any further context of the association with PrEP use. There is no report on changes in sexual behaviour in terms of numbers of condomless sex acts over the study period (at minimum for condomless receptive anal sex) or changes in numbers of partners over the study period. There should be some attempt to provide further information regarding PrEP-related behavioural changes which may have contributed to the findings of incident STI's. **We agree with the Reviewer that it is important to understand the sexual behaviours driving STI incidence among PrEP users. However, because this was not one of the pre-planned secondary objectives of the study and because of space restrictions, this topic will be the subject of a separate manuscript that is currently under preparation. We have now mentioned in the Methods section that "Data on sexual behaviours were collected during the study but were not a protocol-defined secondary objective, and will be the subject of a separate publication".** 5. The STI data should be broken down if possible into rectal vs. other sites for chlamydia, gonorrhea and LGV, and if possible also by symptomatic (ie presenting for testing) vs. asymptomatic (ie diagnosed by screening) to provide further support for routine multi-site STI testing during PrEP monitoring. **In response to this comment, and in order to remain within the manuscript word limits, we have added a small**

	Table summarizing STI data according to anatomic site, and included data on incidence per 100 person-years of follow-up. Unfortunately data on the presence or absence of symptoms are not available.