



Common Drug Review *Patient Group Input Submissions*

Emtricitabine / tenofovir disoproxil fumarate (Truvada) for HIV-1 infection, pre-exposure prophylaxis

Patient group input submissions were received from the following patient groups. Those with permission to post are included in this document.

AIDS Committee of Toronto — permission granted to post.

Canadian Treatment Action Council — permission granted to post.

Maggie's: Toronto Sex Workers Action Project – permission not granted to post.

CADTH received patient group input for this review on or before March 28, 2016

The views expressed in each submission are those of the submitting organization or individual; not necessarily the views of CADTH or of other organizations.

While CADTH formats the patient input submissions for posting, it does not edit the content of the submissions.

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AIDS Committee of Toronto

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest	Truvada; Emtricitabine/tenofovir disoproxil fumarate; HIV-1 infection, pre-exposure prophylaxis
Name of the patient group	AIDS Committee of Toronto
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1.1 Submitting Organization

ACT (the AIDS Committee of Toronto) was founded in 1983 by a group of volunteers to address the emerging and urgent challenges of HIV and AIDS. Since then ACT has grown into Canada's largest HIV service organization, and offers a comprehensive slate of free and confidential capacity building programs and support services. These are available to anyone living with HIV in Toronto, with an emphasis on young people and women at increased risk of HIV and gay men. ACT also works as community advocates and sexual health educators to reduce the rates of HIV transmission and prevent new infections from occurring. ACT's vision is a Toronto where there are no new HIV infections, and the people and communities living with or most affected by HIV and AIDS live long and healthy lives free from stigma and discrimination. As a community-based organization, ACT's membership is composed of service users and other people living with HIV, volunteers (including the Board of Directors), staff, community partners and allies, and donors.

1.2 Conflict of Interest Declarations

ACT's Community Health Forums, a series of educational events attended by people living with HIV, are funded in part by Gilead Sciences Canada, along with several other pharmaceutical companies. Gilead's contributions to ACT are restricted to funding the Community Health Forums and are not used for any other purpose. We have no declaration(s) of conflict of interest in respect of those playing a significant role in compiling this submission

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

This submission is based on three focus groups conducted by ACT. A total of 23 gay, bi and queer men participated. Each group brought a unique perspective to pre-exposure prophylaxis (PrEP) for HIV infection (in submission "PrEP" refers to Truvada taken as HIV PrEP). The first group (FG 1) was made up of HIV-negative men who currently take PrEP or who had taken PrEP in the past. The second group (FG 2) contained HIV-negative men who tried to access PrEP but couldn't, as well as men who had thought about PrEP as an HIV-prevention method but hadn't yet accessed it. The third group (FG 3) was HIV-

positive men who have sex with HIV-negative men. The groups each ran for 90 minutes and participants were given a \$30 honorarium. The groups were recorded with two separate devices and then transcribed. The quotes included in this submission are taken from that transcription. There were two note-takers also in the room who captured the general flow of conversation and affect of the room.

Recruitment for the groups was done through using ACT's existing social media as well as email lists from program staff. Several community partners, such as HIV testing and treatment clinics were also given recruitment posters.

Within the groups there was a diversity of race, age, employment status and sexual orientation. There were no self-identified transgender participants. The participants ranged in age from 20 to 54 years old, with an average age of 30. 82% of participants identified as gay, 4% as queer, 4% as bisexual, 4% as MSM and 4% as mostly gay. In regards to race and ethnicity, 69% identified as white, 9% as South Asian, 13% as Latino, 4% as African Canadian and 4% as Middle Eastern. Regarding employment, 65% had full-time employment, 9% part-time, 13% were students and 13% were unemployed. One person was deaf and participated through an ASL interpreter.

For the group that had used or were using PrEP, there were seven participants. The length of time on PrEP varied throughout the group:

- 7-12 months: 1 person (10 months)
- 13-18 months: 4 people (13, 14, 15, 17 months)
- 19-24 months: 2 people (20, 21 months)

There was also a number of different ways whereby people had accessed PrEP:

- clinical trial: 3 people
- out of pocket: 1 person
- out of pocket in combination with private insurance: 1 person
- employment insurance: 2 people

Two one-on-one interviews were conducted with ACT counsellors to capture their perspective on PrEP and how they saw it impacting their role as caregivers. This information was only drawn upon to complete Section 2.4.

2.2 Impact of Condition on Patients

A persistent condition described by HIV-negative men not using PrEP was the fear of becoming HIV-positive through sex. Participants described recurring experiences of anxiety in the lead up, during and following a range of sexual encounters with partners whose HIV status was both known and not known to them. Repeated experiences of anxiety had significant negative effects on participant's sexual and mental health, as well as on their personal and sexual relationships. Some described how they ended relationships with partners after they learned that their partners were living with HIV.

For some, anxiety about HIV transmission meant they were unable to have sex with HIV-positive partners or partners whose status was unknown to them. Many expressed that this anxiety was a barrier to forming meaningful, truly intimate relationships with people as the persistent need – the impossibility of not having – to use a condom for sex was a barrier to taking relationships further. It is important to consider the impact of this fear and anxiety about seroconverting on people already living with HIV.

- *“My sex life exists under a giant shadow of paranoia and fear, and while [PrEP] is not foolproof and it doesn’t cover other STIs, I still don’t fear contracting anything like I fear contracting HIV.” (FG 2)*
- *“Every time I get tested, and I get tested every three months, the week before I’m shaking and worried I’m going to test positive – I’m really really anxious about it.” (FG 2)*
- *“HIV has always been a present part of conversations for me. My mother used to literally end every conversation we had with ‘I hope you’re using condoms!’...I don’t think my straight friends labour under the same sort of anxiety that my gay friends do when it comes to HIV. I don’t think that they necessarily consider that to use condoms or not use condoms is a decision when it comes to intimacy. For them, having sex together is intimate and whether they choose to use condoms or not isn’t a judgment of society. When we choose not to use condoms, for whatever reason, whether it’s intimacy or pleasure, we’re vilified.” (FG 1)*
- *“I was having sex with a guy and then, he didn’t tell me at first, but then one day I asked him and he said he’s [HIV-positive and] undetectable. I didn’t want to but unconsciously I started pulling away, not visiting him anymore. I think if I was on PrEP I wouldn’t mind at all because I was into the guy. It’s bad and wrong that that happened but I couldn’t control it. We were at a point where we were going to have bareback sex...but the fact that he wanted to have bare sex and was undetectable but I was not up for it because of my fear of getting infected.” (FG 2)*

2.3 Patients’ Experiences With Current Therapy

The fear, anxiety, and paranoia about seroconverting is a condition that affects HIV-negative participants’ mental well-being, personal relationships and sexual health.

Condoms were the primary method of preventing HIV among HIV-negative participants not using PrEP; however, they still experienced considerable fear of becoming HIV-positive. Participants voiced concern about the efficacy of using condoms alone. They spoke of experiences where condoms broke during sex. They also expressed that the overall efficacy of condoms was inadequate to quell anxieties about becoming HIV-positive, even though many were taking care to use condoms each time they had sex.

- *“I didn’t know what to do the first time the condom broke, in 2013. I was doing my Masters [at a University.] After I was going through a terrible time at university because I was thinking about it all of the time. For me it was very difficult to work on my thesis.” (FG 2)*

People also shared experiences where condomless sex occurred, without breakage, and people felt terrible about it after, voicing a combination of fear, guilt and shame.

- *“I often don’t like using condoms. And I’m sure that there’s a lot of psychological issues around that and there’s a lot of guilt and shame that comes with around wanting that, as well. To know that in a situation I can be spontaneous and not worry about the stress or the post-coital shame – whatever comes after it – that just knowing that I can take preparation before I actually get put in that situation where you don’t think clearly or rationally, that I can prepare myself to have a backup plan in that case...To have that safety net that if something does go wrong – if there is a lack of communication – then it’s not a foregone conclusion.” (FG 2)*
- *“I had always been very adherent to condoms, constantly, but I had unreasonable physical irritation from them. I’ve never been diagnosed with an allergy to them or anything like that, but it was enough that sex was not fully pleasurable, not as much as it should have been. And it was in 2014 that I had my first kind of slip-up, where I had condomless sex, and I didn’t experience that irritation*

that came from that. And it was eye-opening. I remember being a little bit afraid because I recognized how much I enjoyed it.” (FG 1)

2.4 Impact on Caregivers

Counsellors at ACT who work in bathhouses doing outreach and on-site counselling serve primarily people who are HIV-negative. These people access counselling to address fears and anxiety of becoming HIV-positive. Counsellors walk people through various strategies to manage that condition, including counselling supports and the range of available HIV risk reduction strategies and tools beyond condoms, including PrEP, the use of HIV medications by HIV-positive people to reduce infectiousness, and shifting to less risky sexual practices.

- **ACT Counsellor 1:** *“Whether or not they are using condoms every time they have sex, some guys really really struggle with anxiety around HIV. And you know I’d say that anxiety is manifested through sex but what it really prevents is intimacy...There will also be guys who are tormented by instances where they have condomless sex, whether that’s deliberate or through breakage. Even when guys use condoms every time they have sex, and one time a condom breaks, they think fuck, I am doing everything I can and this still isn’t enough, I still am terrified.”*
- **ACT Counsellor 2:** *“Most of my time is spent in bathhouses talking to [HIV-negative] guys who are worried about HIV. But I know there’s other stuff bothering them about their sex lives, things like body image and depression and self-worth. But mostly we end up talking about condoms and paranoia.”*

Men living with HIV also play a ‘caregiver’ role to the HIV-negative men in their lives, in the context of friendships, sexual relationships and intimate partnerships. In practice, they often bear the responsibility of educating partners about HIV, explaining what their partner’s risk is and how to manage that risk. Given their experience taking HIV antiretroviral medications, HIV-positive men have become primary sources of information about PrEP access, efficacy, adherence and potential side-effects, and strategies to communicate with healthcare providers about sex, HIV-risk, fear, anxiety and pleasure. Men living with HIV also expressed their own set of anxieties around being the partner who was ‘responsible’ for managing both the real risk of transmission (their viral load) and the barriers used for sex (condoms, dental dams). In a way they are forced to be both caregiver and patient in this situation.

These caregivers expressed that anxiety about the effectiveness of condoms (expressed as a fear of becoming HIV-positive) was a burden to them, something that often got in the way of forging meaningful relationships with HIV-negative partners. In other cases, men living with HIV were rejected when they disclosed their status to HIV-negative partners prior to having sex, as their partners did not feel adequately protected by condoms, even if the other person had an undetectable viral load.

- *“I find that as a positive person, [HIV]negative guys are turning to me and saying what do you know about PrEP? They often aren’t comfortable talking to their doctor about it, so they think why don’t I talk to someone who is positive who has been on meds and hear about their experience.” (FG 3)*
- *“A lot of my regular sex partners that are HIV-negative are now, more and more, asking questions about PrEP. I think it’s opened a topic of discussion that is making things a lot more comfortable, sexually, with my negative partners. Before I was often anxious being undetectable playing with my negative partners but now I’m getting to be more comfortable, being undetectable and they have PrEP, and once they’re on this I won’t have this burden and liability to pass [HIV] on to that next person.” (FG 3)*

- *“I’ve had it with a couple of guys where they’re okay having sex with you knowing you’re undetectable but then after they freak right out and run away or leave me to deal with their shit.” (FG 3)*

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

The information that will be used for completing Section 3 was obtained through the same set of focus groups that informed Section 2.

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had With the New Drug?

Among participants who had not been able to access PrEP and were HIV-negative, there was a majority view that PrEP would alleviate the pervasive anxiety stemming from the fear of becoming HIV-positive.

- *“It would be nice to be able to still that voice in the back of my head, which is ongoing even when I’m having sex, and just go ahead and do it. [PrEP] would provide a peace of mind in ways that would help me with my relationships with other people.” (FG 2)*
- *“There’s an unparalleled fear around seroconversion for me that might not completely disappear if I was on PrEP but I would feel infinitely more comfortable and have a lot less fear.” (FG 2)*
- *“Taking PrEP would make it easier for me to have conversations about safe sex with people who claim they are HIV-negative. I’m deaf and it’s hard to have conversations about this so I really appreciate how PrEP could help with that if I can’t talk to people.” (FG 2)*
- *“I’m looking to have a relationship and I’ve met a lot of great poz guys, but I could never go further with them. But if I was on PrEP I could go further.” (FG 2)*
- *“I would still wear condoms but I would be more confident.” (FG 2)*

These participants also expressed a willingness to accept general side effects as a trade off for less anxiety, better sexual and mental health.

- *“I’m okay to take the side-effects. If it damages my heart I might think more, but my kidney, that’s ok. I think if I get HIV there are more side-effects from that and those last my entire life. But if taking PrEP were to reduce my life from 90 to 80, I’d go for it. Or even 80 to 70 I’d go for it.” (FG 2)*
- *“I would use PrEP despite the side effects. I’d still use condoms but PrEP would be my second layer.” (FG 2)*

Among participants who had used PrEP, the experience was reported as being positive, empowering and liberating.

- *“You wear a condom, you safeguard yourself from a specific amount of diseases but the biggest one you fear the most is HIV. That’s the reality. We all fear it. Despite the many breakthroughs in medicine today in regards to HIV, we still fear HIV. And as an individual who still maintains some fear of becoming HIV-infected, PrEP gives me more confidence that I’m protecting myself from getting infected.” (FG 1)*
- *“PrEP has made me so much less anxious. It decreases my feelings of guilt, anxiety, depression and my self-worth – oh my god.” (FG 1)*

Participants who had used PrEP expressed complete acceptance of side effects, as the benefits of PrEP far outweighed the drawbacks.

- *“I’d rather be on PrEP when I’m young because the alternative is me getting HIV and having to take those drugs anyway, and that’s for my entire life. I could be on them for 30 or 40 years because I got HIV or I could be on them for 10 years, prevent it, and then go back off of them.” (FG 1)*
- *“I think because I’m high risk I probably would contract HIV at one point if I continued having sex the way I do. So I look at the possibility of being on PrEP versus being on antiretrovirals and HIV-positive – if it means having nausea, lower bone density or other kidney function effects – I’d be willing to take those side-effects for the use of PrEP as opposed to probably have those same side effects of having to use antiretrovirals anyway.” (FG 1)*
- *“My bone density has gone down from using PrEP. So I had to make the decision of is that enough to make me not want to use PrEP again. And I’ve decided that no it wasn’t enough. Now I know that my bone density does decrease so now I can work to prevent that bone density decrease, and that’s stuff like diet and working out. So if I use it I’m contributing to a better overall lifestyle and I am fine with that.” (FG 1)*
- *“I get to choose if the side effects are worth it for me before I need to deal with the side effects no matter what.” (FG 1)*

Participants also valued PrEP because it represents a method of preventing HIV that could be initiated before situations occurred in which people lost their inhibitions, weren’t in a position to insist on using condoms, or otherwise did not feel in complete control of (and thus comfortable with) their sex.

- *“When you’re a meth-head like I am, from time to time...being able to have that extra protection, PrEP gives you the guarantee ok, even though I have lost all of my fucking inhibitions, at least when that time comes I have another possible barrier.” (FG 2)*

Section 4 — Additional Information

“I would like to articulate to the whole MSM community, and the people who don’t identify as MSM, that [PrEP] is good for everyone as a preventative tool – regardless of how sexually active you are and regardless of how much you want to bareback – it is a tool of efficacy that is excellent for the vast majority of us.” (FG 1)

“In my mind, taking PrEP protects my health, and invariably through the connections I have with my partners, it protects theirs. I think that’s a really important part of PrEP to me – it breaks the chain of infection. It encourages people to have these conversations. It encourages people to get tested for not just HIV but other STIs and on a regular basis. We are now having real conversations around PrEP and what it means for people, especially gay men.” (FG 1)

Canadian Treatment Action Council

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest	Truvada (emtricitabine / tenofovir disoproxil fumarate) for Pre-Exposure Prophylaxis of HIV-1 Infection
Name of the patient group	Canadian Treatment Action Council
Name of the primary contact for this submission:	[REDACTED]
Position or title with patient group	[REDACTED]
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1.1 & 1.2 Submitting Organization & Conflict of Interest

The Canadian Treatment Action Council (CTAC) is Canada's national non-governmental organization addressing access to treatment, care and support for people living with HIV and hepatitis C. CTAC meaningfully engages community members, service providers, policymakers and other stakeholders to identify, develop, and implement policy and program solutions. In fiscal 2015/16, CTAC received unrestricted organizational and educational grants from Gilead Sciences, AbbVie, and Viiv Healthcare.

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

CTAC held two public national consultation webinars (14 and 15 March 2016) for Truvada for HIV pre-exposure prophylaxis (PrEP) attended by a total of 21 people. In each webinar we reviewed the regulatory pathway, from clinical trials through public formulary listings. We presented clinical trials data and clinical indications as per the Product Monograph, and responded to questions. The webinars were advertised through CTAC's website, social media, and CTAC member/partner communications. Webinar attendees were invited to complete an on-line, anonymous survey. A recording of the webinar, and a link to the on-line survey, were posted on CTAC's website and promoted on social media. **Twenty surveys were completed and analyzed for this submission. Quotes contained in this submission are reproduced exactly from those surveys.** (Note that not all questions were mandatory, and some answers were not mutually exclusive so values may not add up to 20 or 100%.) Respondents' age range was 25 to 58 years, median 33 years. Fifteen of 18 respondents reported male gender, with two female and one transgender man. Seventeen of 18 reported gay, bisexual or queer sexual orientation. Respondents reported obtaining prescription medications out of their own money (28%), through private insurance (56%), public drug programs (39%), or clinical trial participation (6%), and one person reported importing. **Nine of 20 respondents (45%) reported current or past use of Truvada for HIV PrEP.** Seven (78%) of those people reported current PrEP use for median of 12 months (range 3 to 36 months); 2 reported past use for 12 months.

2.2 Impact of Condition on Patients

In Canada, HIV infection is significant from individual clinical and population health perspectives. Adults at substantial risk of HIV infection have sought Truvada "off-label" and through clinical trials to reduce

their risk of acquiring HIV infection. The human immunodeficiency virus (HIV) is a retrovirus that left untreated progressively destroys a person's immune system, resulting in excessive morbidity and premature death. Among heterosexuals, it has been estimated that the consistent use of condoms results in 85% reduction in HIV incidence arising from heterosexual intercourse, a reduction similar to, although lower than, that for contraception. (Weller 2009; CD003255) Recently it has been estimated in a study of men who have sex with men (MSM), condom effectiveness was 70% among those who use condoms consistently—yet only 16% of MSM reported consistent condom use. (Smith 2015; PMID: 25469526) Recent Canadian data summarized by the Public Health Agency of Canada shows that despite the fact that condom-less anal intercourse is the most common risk factor for HIV acquisition, a significant subset of MSM engage in condom-less anal sex. Factors associated with condom-less anal intercourse included unavailability and difficulty using condoms, trust and relationship issues, momentary lapses, depression and stress, and assumptions about partners and situations. (PHAC 2013; ISBN: 978-1-100-21880-9)

Over the past decade in Canada, HIV incidence peaked in 2008 and has only gradually declined since that time, despite available methods of preventing HIV transmission. In 2014, 2044 new HIV cases were reported to PHAC. Where exposure pathway was reported, approximately 49% of cases were attributable to sex among MSM, 29% to heterosexual sex, and 13% to injecting drug use. (PHAC 2015; ISSN 1701-4158) Estimates of HIV incidence and prevalence eclipse these case reports. PHAC estimates that 75,500 (range 63,400 to 87,600) people were living with HIV and that 16,020 (range 13,000 to 19,000) people with HIV were undiagnosed at the end of 2014, representing 21% of all cases. (PHAC 2015; ISBN: 978-0-660-03780-6) A recent analysis of the ongoing HIV epidemic among BC gay men highlights the need for multi-pronged strategies to prevent HIV: “The challenge with current approaches to sexual health and related HIV prevention strategies is that they are simplistic and reductionist, assuming that decisions about sex are made based solely on knowledge about HIV transmission and weighing of potential risks; thus, they fail to recognize the intrinsically human feelings and desires that propel human sexuality.” (BCMOH 2014; [HIV, Stigma and Society](#)) The complex interplay of behaviours and socially structured life experiences also challenge existing HIV prevention efforts among other populations disproportionately affected by HIV in Canada (i.e., Aboriginal people, people who inject drugs, and people from countries where HIV is endemic).

2.3 Patients' Experiences With Current Therapy

Current HIV risk reduction: Among all respondents, condoms were the most commonly reported method or tool for HIV risk reduction, followed by having sex with partners of the same HIV-status (i.e., sero-sorting), then choosing lower risk activities such as being the insertive partner for anal intercourse. Sixty-four percent of people reported that these methods or tools addressed their HIV-prevention needs, while 36% reported they did not. A number of respondents cited an increase in pressure to have, or preference for, condom-less sex among gay men.

- *Condoms. Sero-sorting. Choosing lower risk activities. [30 yr, gay man, Alberta]*
- *high risk group [unknown, unknown, Manitoba]*
- *Condoms. Not always effective, not always desired. [26 yr, gay male, Nova Scotia]*
- *Most folks I engage in sex with prefer not to use condoms [30 yr, gay male, Ontario]*
- *I fall in the group with high risk indicators, inconsistent condom use, occasional STI occurrence, unknown or HIV+ (undetected) status partners. [50 yr, gay male, Manitoba]*
- *Abstinence - not desirable (nor practical). "Insertive" partner (Top) - ok, but limited my sexual experience. Condoms - For me not desirable, as I find it very hard to maintain an erection while using condoms [50 yr, gay male, Manitoba]*

- *I'm a single guy who's used to condomless sex with a regular partner, so it's challenging to use/insist on condoms all the time, putting me at increased risk for infection. [31 yr, gay male, Ontario]*

Fear and anxiety associated with sex: Five of 7 PrEP-experienced people reported fear, anxiety, guilt and/or shame associated with sex, and any illnesses perceived to be acute HIV infection, prior to going on PrEP.

- *Before PrEP I was living in fear of "when" I would become HIV+, and if I did become HIV+ would I unknowingly infect someone else and how would I deal with the stigma associated with being HIV+ [50 yr, gay male, Manitoba]*
- *I found myself engaging in condomless sex with casual partners, especially when drinking. This led to stress and anxiety about HIV. It also caused upset in my relationship with my partner, as it disrupted our sex life when we needed to use condoms with each other as a result of me engaging in high risk sex with other people. I experienced guilt and shame around my sexual choices, because I did not want to put my partner at risk. [29 yr, trans queer man, Ontario]*
- *I have had some experiences of inconsistent (delayed) condom use that have worried me. [32, gay/queer male, Ontario]*
- *I was having condom-less sex regularly. I had a lot of anxiety from the moment I did it until I'd get tested. [37 yr, gay male, Ontario]*
- *I have multiple partners and I'm active in the kink community, so I often have group sex or consensually place myself in situations in which I'm vulnerable to my partner. I use protection almost always, but I'm very fearful that a slip up, condom breakage, or situation outside my control will result in seroconversion. I get anxious about acute HIV infection each time I get sick. [25 yr, gay male, Ontario]*

These feelings and states of mind were shared by some respondents who have not taken PrEP.

- *I've experienced significant anxiety over my HIV infection risk, which makes it not only difficult to enjoy sex as fully as I'd like to, but makes life in general more stressful. [31 yr, gay male, Ontario]*

Considering Truvada for HIV PrEP: Six out of 10 respondents who have not been on PrEP reported considering PrEP.

- *Anonymous sex with persons who may lie about their status and/or adherence to medications for treatment [26 yr, gay male, Nova Scotia]*
- *I like the medical science behind it; instead of covering up (i.e., condom) it actually provides medicine to warn off the virus [26 yr, gay male, Nova Scotia]*
- *Meeting people for casual sex who are on PrEP and do not want to have anal sex without a condom. [53 yr, gay male, Ontario]*
- *It adds to the repertoire of things I can do to stay HIV negative. I have been HIV negative and lived in the midst of the HIV epidemic as an out gay man for 30 years. It has not always been easy to do. PrEP could add an additional measure of protection. [53 yr, gay male, Ontario]*
- *Within the context of being in an open relationship and having sex with others... With an increase in condomless sex throughout the communities we have sex in, as well as in ongoing relationships with other dates, there can be pressure to have sex without condoms, which is unfortunate -- a) that pressure exists, b) that this is seen as a barrier to intimacy – but based on my current life circumstances and how that squares off with sexual decision-making, the incentives aren't there for me to begin PrEP at this time. [23, gay/queer male, Ontario]*

Decision to take Truvada for HIV PrEP: Five of 9 PrEP-experienced respondents reported inconsistent or no condom use for sexual intercourse, with two reporting that they “hate” condoms, and two reporting

erectile problems associated with condoms. Some reported other life circumstances that caused them to decide on PrEP.

- *I'm very sexually active and hate condoms. So I was looking for a solution to have a safe sex without using condom and heard about the trial. [38 yr, gay male, Ontario]*
- *My partner and I opened our relationship, so I was starting to have casual sex with partners outside of my relationship [29 yr, trans queer man, Ontario]*
- *Despite successfully using condoms very consistently for over 20 years, I found it increasingly difficult to continue to do so. After a bout with depression, and possibly because I was approaching mid-life, I had more and more problems with erections. I am usually the insertive partner. So condoms were no longer a viable option to reduce my risk. I still wanted to do everything I could to avoid HIV while still enjoying a healthy sex life. Condoms worked perfectly well for me for over 20 years. But not with my new life circumstances. [46 yr, gay male, Quebec]*
- *I am in relationships where I do bareback, and I am in an open relationship.[42 yr, gay male, Ontario]*

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

The information in this section was gathered in the same means as described in section 2.1.

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had With the New Drug?

Life changes associated with Truvada for HIV PrEP: Overall, 78% (7/9) of PrEP-experienced respondents reported “extremely positive” or “positive” effects of PrEP on their health and well-being; the remaining 2 people reported “no effect.” Among those people who reported changes, people consistently cited lower anxiety, greater enjoyment of sex, and increased sense of safety, control and closeness in their sexual and/or intimate relationships. A minority of participants also reported other health promoting behaviours like accessing health services, and engaging in HIV risk reduction discussions with sex partners.

- *I am also more comfortable talking about safer sex practices with potential partners. I get tested for general health concerns relating to the medication, as well as for sexually transmitted infections more routinely than before taking Truvada for HIV PrEP. [29 yr, trans queer man, Ontario]*
- *Since I've been on PrEP, I have been in more regular contact with my physician, which has helped to address any other non-PrEP-related health issues much more quickly than otherwise would have been the case. I now get tested for HIV and all STIs twice as often as I used to--every 3 months. [46 yr, gay male, Quebec]*
- *My sex life got much better And I was really happy during year I was taking prep. Because I was feeling Safe [38 yr, gay male, Ontario]*
- *Anxiety over risk levels definitely affected my ability to bottom. The desire was there, but I often couldn't relax enough to make sex possible. I would also get anxious whenever I get sick - looking for a rash, thrush, checking my lymph nodes over and over. On PrEP I finally feel in control and as a result I can enjoy a full and rich sex life. It's also brought me closer to my partner. [25 yr, gay male, Ontario]*

Among respondents who had never taken Truvada for HIV PrEP, 80% (4/5) perceived that it would have an “extremely positive” or “positive” effect on their overall sense of health and well-being.

- *Would rather be on PrEP to provide maximum protection and peace of mind. Relying on condoms can be a barrier - to pleasure and intimacy. [31 yr, gay male, Ontario]*
- *Limitations and fears around testing make it challenging for people to actually know their status, and it would be helpful to have access to PrEP so that I feel adequately protected from HIV infection. This*

will increase my personal agency around sex and relationships, and will help release many years of anxiety and fear about becoming positive. [31 yr, gay male, Ontario]

- *People who are bottoming and having difficulty with condom adherence, people who are having sex in communities with a high community viral load, people who are experiencing mental health and/or chaotic substance use issues, people who are having commercial sex – this [PrEP] is an important intervention and should be provided free, at point-of-service-access, and in increased multidisciplinary care settings that heretofore don't sufficiently exist anywhere in Canada for these individuals.[32, gay/queer male, Ontario]*
- *Other than protection from HIV infection, I would say increased quality of life resulting from decrease in stress and anxiety of getting infected. [31 yr, gay male, Ontario]*
- *The feeling of protection that I get from PrEP has allowed me to enjoy sex more and more frequently, explore condomless sex safely with my primary partner, and eliminated my anxiety over illness as I no longer feel at significant risk of seroconversion. PrEP has changed my life. [25 yr, gay male, Ontario]*

Truvada for HIV PrEP compared with other HIV risk reduction: All 8 PrEP-experienced respondents cited advantages of PrEP over, or in association with, other HIV risk reduction strategies such as condoms, or only being the insertive partner during anal intercourse. Many reported feeling safer or more relaxed, that Truvada was much easier to adhere to than condom use, and that they no longer feared condom breaking during sex.

- *Truvada is amazing, It let me live my life just how I love to live, I couldn't get that much safe feelings even from using condoms because condoms may break but not Truvada [38 yr, gay male, Ontario]*
- *Condoms worked perfectly well for me for over 20 years. But not with my new life circumstances PrEP proved to be a great solution that fit my needs at this particular time. If PrEP had not been available to me for the past 3 years, I may very well have become infected. [46 yr, gay male, Quebec]*
- *It [PrEP] is at least as effective at reducing my HIV risk as condoms. I am as consistent with my PrEP use as I was with my condom use. So in both cases, my HIV risk is reduced in equal measure. However, it is much easier to be consistent about my PrEP use. I just take it with my vitamin every morning. I don't need to negotiate condom use in the heat of the moment. PrEP is much better in this way. Even if I missed a dose at some point, I'd still have very high levels of protection. But I don't use a condom, I have zero risk reduction for that time. [46 yr, gay male, Quebec]*

Impact of Truvada for HIV PrEP on sexual and intimate relationships: All PrEP-experienced respondents reported a better sex, life, greater ease with sexuality or sexual expression, or improved relationships with sexual or intimate partners.

- *Since being on PrEP, my anxiety over sex has largely been eliminated and I personally have learned that the stigma toward HIV+ people can be eradicated, it has for me! [50 yr, gay male, Manitoba]*
- *Absolutely made my sex life better and I was happier [38 yr, gay male, Ontario]*
- *Positive - I am comfortable having the sex life that I want to have, without worrying about getting HIV and putting my partner at risk for getting HIV. I am less afraid of having sex with new partners, I am having more sex than before, I am having more conversations about PrEP and HIV than before. [29 yr, trans queer man, Ontario]*
- *My primary partner and I have explored condomless sex, which I previously assumed to be something that I would never safely experience in my lifetime. [25 yr, gay male, Ontario]*
- *PrEP allows me to connect and be intimate with my sexual partner in a way that was not possible with condoms. A big part of that is that the fear of HIV has gone away. You have to use a condom in the heat of the moment. But I take my pill in the morning with breakfast. So "HIV" isn't in the room with us when we're being intimate. [46 yr, gay male, Quebec]*

- *I am slightly less sexually active - I communicate more about my activity - I am enjoying myself a lot more. It helps me to relax even more, even with the recent news from Dr. Knox about someone seroconverting while taking PrEP, I can still relax a bit more. I'm able to be a bit more closer to those I play with. [42 yr, gay male, Ontario]*
- *Yes made it better Because I was able to have sex with [HIV] positive people too. [38 yr, gay male, Ontario]*
- *I no longer have anxiety with sex, I enjoy sex more. I couldn't keep an erection with condoms and so I don't need to worry about that either. I also like not having to ask guys their HIV status. Yes, my sex life is better, my sex is better, more intimate, more fun, less anxiety about going soft with condom use and my friends no longer worry about my sexual behaviors, now that I am protected from HIV with PrEP. [37 yr, gay male, Ontario]*

One survey respondent living with HIV commented on the effect of PrEP on the psychological well-being of his HIV-negative sexual partners.

- *I already have HIV, but practice safe sex with HIV- sexual partners. PrEP provides an opportunity for my HIV- partners to feel more confident that they are not at risk in case the condom breaks... [51 yrs, bisexual male, Ontario]*

Truvada side-effects: Two of 9 pre-experienced reported side effects. One reported a “bit of headache and nosia [sic] but only during the first few weeks.” The other reported “nosia [sic], vometin [sic] but not too bad, headache.” Among people who had no experience taking Truvada for HIV PrEP, an equal number would be willing, and not willing, to experience mostly minor side effects.

- *Yes [I would be willing to experience side effects.] I understand I need to get tested regularly to monitor side effects (i.e. kidney function). My understanding is that the medication is well-tolerated and that a small proportion will experience some minor, short-term side effects like nausea. [31 yr, gay male, Ontario]*

Section 4 — Additional Information

Truvada experience and cost coverage: Of people who had ever taken Truvada for HIV PrEP, 45% obtained it as a participant in a clinical trial, one third through private insurance, and one third through a public drug program—with at least one person obtaining it through multiple avenues. None of the survey respondents reported paying for Truvada out-of-pocket. One person expressed concerns regarding being unable to afford PrEP when the clinical trial in which he is enrolled comes to an end:

- *I work at a small nonprofit, so I don't have health insurance and my salary is quite low. I can't afford PrEP out of pocket, nor can I afford private insurance. Probably when my clinical trial ends I will import a generic form of PrEP from overseas by having it shipped to the USA and crossing the border to pick it up each month. [25 yr, gay male, Ontario]*

CTAC notes with concern that importation as described above is arguably contrary to the *Food and Drugs Act*, in practice highly dependent on border service agent discretion, only an option for people who are legally entitled to leave and return to Canada, and might lead to gaps in treatment and clinical follow up for the respondent (or others in similar circumstances).

One respondent expressed the health equity-related concerns related to the cost of and access to Truvada for HIV PrEP:

- *I'm also worried that disparities in the health care system (ie. people with privilege having private coverage) will mean that people who don't really need the intervention (ie. "Tops on PrEP") will get it while people who are economically and socially marginalized will have difficulty achieving access, either through coverage or a lack of point-of-care interventions. [32, gay/queer male, Ontario]*

Maggie's: Toronto Sex Workers Action Project

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest	Truvada as PrEP
Name of the patient group	Maggie's: Toronto Sex Workers Action Project
Name of the primary contact for this submission:	[REDACTED]
Position or title with patient group	[REDACTED]
Email	[REDACTED]
Telephone number(s)	vvvvv vvvvvvvv
Patient group's contact information:	
Email	[REDACTED]
Telephone	vvvvv vvvvvvvv
Address	298 A Gerrard St. E, 2 nd Floor Toronto, ON M5A 2G7
Website	http://maggiestoronto.ca/

Permission to post was not given. The patient input that was provided in this submission, along with all other patient input received for this drug, is included in the summary of patient input that is contained in the posted *CDR Clinical Review Report*.