# HIV PrEP Considerations for Gender Diverse Patients

TRANS CARE BC
Provincial Health Services Authority

**HIV PrEP is safe and effective.**

While less studied in transgender people compared to cisgender men who have sex with men, **HIV PrEP with Tenofovir and Emtricitabine (Truvada) appears to be a good option for gender diverse people at high risk for acquiring HIV.**

The literature does not yet present good data on HIV PrEP efficacy and gender diverse people because information about gender, hormone and surgical status have not been collected uniformly across studies. To date, HIV PrEP clinical trials have largely excluded transgender persons, and trans women are often aggregated with cisgender men who have sex with men. We also lack information about the risk of HIV transmission and the effectiveness of HIV PrEP in individuals who have had gender-affirming lower surgeries. However, the lack of research is not a reason for gender diverse people not to consider the use of HIV PrEP if they are at risk of acquiring HIV.

In addition to the intersecting factors that can contribute to someone being more vulnerable to HIV acquisition, other factors that may be pertinent to transgender patients and HIV risk include:

- After starting hormone therapy, individuals can experience changes in sexual interest and desire, and may join new sexual networks that have higher rates of HIV;
- Individuals may not have the information, skill sets or autonomy needed to negotiate safer sex practices;
- Individuals may fear negotiating for safer sex due to the fear of rejection or risk of violence; and
- Individuals may have sex while using substances or alcohol to help loosen inhibitions and decrease anxiety.

Although evidence specific to this population is limited, there are many reasons, including (but not limited to) harm reduction, to have conversations about PrEP in the context of hormone therapy and other gender-affirming interventions. The following pages provide considerations for clinicians when discussing HIV PrEP with patients on gender-affirming hormone therapy or who have had gender-affirming interventions.

This document is not intended to be used as a teaching guide for HIV PrEP or replace existing guidelines. Up-to-date provincial guidelines and resources about HIV PrEP can be accessed through the BC Centre for Excellence in HIV/AIDS.

# HIV PrEP in the context of Gender-Affirming Testosterone Treatment

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## Barriers to use:

- Lack of access to trans-inclusive and culturally competent services;
- Lack of representation in HIV PrEP health promotional campaigns;
- Lack of trust with service providers;
- Social stigma;
- Concerns about PrEP interactions with gender-affirming hormones.

## Effectiveness & interactions with hormone therapy:

- **HIV PrEP is safe and effective.** While less studied in transgender people compared to cisgender men who have sex with men, HIV PrEP appears to be a good option for gender diverse people at high risk for acquiring HIV.
- **There are no suspected interactions between PrEP drugs and testosterone;** however there is no data on interactions between these medications.

## Effects on hormone levels:

- **Medications in PrEP do not change serum testosterone levels**
- Hormone therapy is primarily metabolized by the liver and the drugs in PrEP do not specifically act on any of the metabolic pathways, which make interactions between the drugs less likely.

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## Clinical implications:

- Work to build therapeutic relationships and safer clinical interactions;
- Initiate conversations about sexual health and HIV PrEP with gender diverse clients;
- Explore concerns and beliefs that may affect adherence;
- Explore barriers to taking medication regularly;
- Assess appropriately for risk factors (do not assume all trans men have cisgender female partners)
- Discuss considerations specific to the impact of gender-affirming hormone therapy or surgery:
    - Different body parts respond differently to HIV PrEP. High adherence (daily dosing) is needed for high effectiveness in the genitals compared to the rectum, since Tenofovir takes longer to reach maximum levels in genital (vaginal) tissue compared with rectal tissue. For example:
        - Time from PrEP initiation to effective prevention:
            - Anal sex: 7 days
            - Genital (vaginal) sex: up to 21 days
        - Adherence for effective prevention based on type of sex:
            - Anal sex: Studies have shown that taking HIV PrEP at least four days a week still provided adequate drug levels with effective prevention compared to those that took it two days or less a week. Regardless, the present recommendation is to take PrEP daily.
            - Genital (vaginal) sex: Almost perfect adherence (daily use with very few missed doses) is required, suggesting On-demand PrEP is likely not effective for frontal sex, and use of PrEP in an on-demand fashion has not been evaluated in gender diverse or heterosexual populations.
    - Genital atrophy (which may result from testosterone use) can put someone at higher risk of tissue trauma during receptive sex, resulting in increased risk for STI acquisition, including HIV. Discuss using lube & treatment options for genital atrophy.
    - Patients who have had metoidioplasty or phalloplasty should be advised that there is no data on the effectiveness or PrEP drug concentrations in the urethral tissue.
- Patients who are not part of a social subculture with regular discussion about routine STI screening and HIV PrEP may benefit from additional appointments for education and de-stigmatization.

# HIV PrEP in the context of Gender-Affirming Estrogen & Testosterone Blocker Treatment

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## Barriers to use:

- Lack of access to trans-inclusive and culturally competent services;
- Lack of representation in HIV PrEP health promotional campaigns;
- Lack of trust with service providers;
- Social stigma;
- Concerns about PrEP interactions with gender-affirming hormones.

## Effectiveness & interactions with hormone therapy:

- **HIV PrEP is safe and effective.** While less studied in transgender people compared to cisgender men who have sex with men, HIV PrEP appears to be a good option for gender diverse people at high risk for acquiring HIV.
- The iPrEx RCT study is the only HIV PrEP study to date that has explicitly reported findings on trans women as a subgroup. Their evidence suggests that PrEP is effective at preventing HIV in trans women when taken consistently on a daily basis, though some trans women may have concerns that may impact adherence:
    - Acceptable drug levels were seen in none of the trans women who seroconverted and in only 18% of those who did not seroconvert, compared to the acceptable levels seen in 52% of the men who did not seroconvert. This suggests that barriers to adherence are a significant issue for trans women using HIV PrEP.
- **There are no suspected interactions between PrEP drugs and estrogen and testosterone blockers;** however there is almost no data on interactions between these medications.

## Effects on hormone levels:

- **Medications in PrEP do not change serum estrogen levels**
    - Hormone therapy is primarily metabolized by the liver and the drugs in PrEP do not specifically act on any of these metabolic pathways, which make interactions between the drugs less likely. On the other hand, the trans women in the iPrex study had lower serum levels of Tenofovir and Emtricitiabine when compared to cisgender men who have sex with men, particularly when they used estrogen. The clinical significance of this is not yet known and Tenofovir and Emtricitiabine levels are still within therapeutic range.

# HIV PrEP in the context of Gender-Affirming Estrogen & Testosterone Blocker Treatment

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## Clinical implications:

- Work to build therapeutic relationships and safer clinical interactions;
- Initiate conversations about sexual health and HIV PrEP with gender diverse clients;
- Explore concerns and beliefs that may affect adherence;
- Explore barriers to taking medication regularly;
- Assess appropriately for risk factors (do not assume all trans women need to be on HIV PrEP)
- Discuss considerations specific to the impact of gender-affirming hormone therapy or surgery:
    - Different body parts respond differently to HIV PrEP.
        - Patients who have had vaginoplasty should be advised that there is no data on the effectiveness or HIV PrEP drug concentrations in vaginal tissue.
        - Risk levels will likely differ based on surgical technique. For example, vaginal lining may be squamous epithelium (with penile inversion) or mucosal lining (peritoneal vs intestinal, etc).
        - Vaginal hypergranulation tissue and other tears can result in increased risk for STI acquisition, including HIV. Discuss maintaining a regular dilation schedule, using lube & treatment options for hypergranulation.
    - Adherence for effective prevention:
        - Trans women on hormones may need greater adherence (daily use with very few missed doses) to oral PrEP as serum levels of Tenofovir may be reduced in presence of estrogen.
        - There is no data for On-Demand PrEP in gender diverse populations, and most current guidelines explicitly recommend not using it at all.
- Patients who are not part of a social subculture with regular discussion about routine STI screening and HIV PrEP may benefit from additional appointments for education and de-stigmatization.
- Discuss ways to maintain bone health, as there may be an increased cumulative risk for osteoporosis with both Truvada and estrogen-based hormone therapy.

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