HIV PrEP for Transgender and Gender-Diverse People

This is a PDF version of the following document:

Module 2:	HIV PrEP In-Depth Topics
Lesson 2:	HIV PrEP for Transgender and Gender-Diverse People

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Background

Transgender and gender-diverse (TGD) people—persons whose gender identity or expression differs from societal expectations based on their sex at birth—experience a disproportionately high rate of HIV infection as compared to cisgender persons (individuals whose gender identity or expression corresponds with societal expectations related to their birth sex). In the United States, approximately 1.6 million people identify as transgender, including 300,000 who are 13-17 years of age (Figure 1).[1] Although transgender people make up less than 1% of the total population in the United States, people who identify as transgender account for about 2% of new HIV diagnoses.[2,3,4] A number of intersecting systemic and socioeconomic factors contribute to a lower likelihood of receiving health care and HIV preventative measures, which contributes to an overall higher risk of HIV acquisition among transgender persons.[5,6] For example, the overall utilization of HIV preexposure prophylaxis (PrEP) by transgender people in the United States remains low due to a complex interplay of structural dynamics, stigmatization, difficulty accessing concomitant gender-affirming care, and other barriers.[6,7,8] Therefore, enhancing access to HIV PrEP would benefit many TGD people and should be a public health priority. The following content will address a spectrum of issues related to HIV PrEP for TGD people.

Introduction to Transgender Terms Concepts and Terms

A general understanding of terminology is important when discussing HIV PrEP for TGD individuals and for communicating with and counseling patients. Terminology changes and evolves, varies culturally and geographically, and is a personal decision. Thus, the most critical step is to ask each individual about the terms and pronouns they use to describe themselves and to never make assumptions.

Gender-Related Terms

- *Gender identity*: a person's inner sense of gender; this does not determine their sexual orientation, nor does it determine the genders of their sex partners
- *Gender expression*: the way in which a person expresses their gender externally, such as through behavior and appearance, including name, pronouns, hairstyle, clothing
- *Cisgender*: a person whose gender identity corresponds with societal expectations related to their sex assigned at birth
- *Transgender*: a person whose gender identity is different from societal expectations related to sex assigned at birth
- *Transgender woman (or trans woman)*: a woman who was assigned male sex at birth
- *Transgender man (or trans man)*: a man who was assigned female sex at birth
- *Trans feminine person*: A person who identifies more with femininity than with masculinity and who was assigned male sex at birth

- *Trans masculine person*: A person who identifies more with masculinity than with femininity and who was assigned female sex at birth

- *Gender nonbinary: (may overlap with gender diverse or genderqueer)*: a person whose gender identity or expression is beyond girl/woman/female or boy/man/male categories
- *Gender fluid*: an individual whose gender identity or expression is dynamic over time
- *Sex at birth*: most infants are assigned a sex at birth, either female or male, based on whether they have a vagina or penis; approximately 1% of infants are born as intersex (defined below)
- *Intersex*: Describes an infant with a congenital variation in sex development and anatomy beyond traditional notions for female or male
- *Sexual orientation*: a person's sexual orientation describes their physical, emotional, and romantic attachments to other people (it is very important not to confuse gender identity and sexual orientation)

For a more expansive glossary, please see the National LGBT Health Education Center's LGBTQIA+ Glossary of Terms for Health Care Teams. In the exercise below, review and test your knowledge of common gender-related terms (Figure 2).

Gender Affirmation

The term gender affirmation describes the process by which a person receives support for their gender identity and expression. This often involves steps in multiple domains, including psychological, social, legal, medical, and surgical actions. The process and needs are different for each individual. For example, gender affirmation may include changing one's name and pronouns, changing one's clothing, changing gender markers on official government-issued documentation, and/or medical interventions, such as hormonal therapy or gender-affirming surgeries. Individuals may pursue some of these means of gender affirmation and not others, and none are required for a person to identify as TGD.

- **Medical Care**: The medical aspects of gender affirmation are highly individualized. Some TGD people may take estradiol plus an anti-androgen (such as spironolactone) to achieve specific physical

features. Similarly, some TGD people may take testosterone to achieve specific physical features. Not every TGD individual will want these medications or particular formulations; if the individual chooses to take gender-affirming medications, the formulations (oral, transdermal, or parenteral) and dosages will depend on their personal goals. The specific gender-affirming medications one takes are important to recognize when considering drug interactions with HIV PrEP medications, although none of the medications commonly used for hormonal gender affirmation preclude the use of HIV PrEP.

- **Surgical Procedures**: Gender-affirming procedures and surgeries are also highly varied and tailored to each individual. For example, some TGD people may pursue breast augmentation (also called “top surgery”) or feminizing vaginoplasty (sometimes called “bottom surgery”). In addition, some people may undergo orchiectomy, facial feminization procedures, reduction thyrochondroplasty (shaving of the tracheal cartilage), voice modification procedures, hair removal, and others. Similarly, other TGD people may pursue breast reduction and mastectomy procedures (“top surgery”), phalloplasty/scrotoplasty/metoidoplasty (“bottom surgery”), hysterectomy, oophorectomy, and others. Of note, none of these are required, and some TGD people never pursue surgical procedures. If a surgical option is elected, the TGD individual should choose the procedures that meet their personal goals.

A history of prior medical and surgical treatments informs medical care, including cancer screening and other aspects of primary care and preventative medicine. Furthermore, anatomy, sexual behavior, and sexual partner characteristics affect HIV risk estimation and influence the recommendations for choosing an HIV PrEP medication. These characteristics cannot be assumed based on gender identity, and they should be determined by taking a thorough history. For example, tenofovir alafenamide-emtricitabine (TAF-FTC) has proven efficacy for HIV PrEP when the risk factor is rectal sex, but efficacy has not been proven for receptive vaginal (or front hole) intercourse and the medication is not yet approved for individuals whose risk is receptive vaginal (or front hole) sex. For a TGD individual, clinicians should confirm the specific anatomy and activities involved with sex partners so that they know if their risk is from receptive rectal or vaginal/front hole (including neovaginal) sex, both, or neither.

Epidemiology of HIV Among Transgender and Gender-Diverse People

To optimize the use and impact of HIV PrEP for TGD persons in the United States, it is important to understand trends in HIV incidence and HIV PrEP use, as evidenced by data specific to TGD people. Most of the existing HIV epidemiology data from the Centers for Disease Control and Prevention (CDC) related to TGD is provided only for transgender women and transgender men; HIV epidemiology data for gender-diverse people, including gender nonbinary people, are limited.

New HIV Diagnosis Data Among Transgender People

Among all persons with new HIV diagnoses in the United States in 2021, approximately 2% (867 of 35,769) identified as transgender (Figure 3).[4] In 2021, there were also 44 individuals reported in the category of additional gender identity (e.g., bigender, genderqueer, and two-spirit).[4] Among the 867 transgender people newly diagnosed with HIV, 811 (94%) were transgender women.[4] Most of the transgender women and transgender men with a new HIV diagnosis were between 20-34 years of age.[4] Among all transgender women diagnosed with HIV, approximately half were Black transgender women.[4]

HIV Prevalence Data Among Transgender People

For CDC data in 2021, among the 1,072,267 people living diagnosed with HIV in the United States, 13,111 were transgender women, 574 were transgender men, and 361 were people with an additional gender identity (Figure 4).[4] Estimates for HIV prevalence rates among transgender women are variable but have consistently been greater than 10%, which is markedly higher than the less than 1.0% HIV prevalence rate in the general United States adult population.[9] In 2019 and 2020, the CDC collected surveillance data among 1,608 transgender women who were living in 7 United States cities: Atlanta, Georgia; Los Angeles, California; New Orleans, Louisiana; New York City, New York; Philadelphia, Pennsylvania; San Francisco, California, and Seattle, Washington.[7] Overall, among transgender women living in these 7 major urban areas, about 2 in every 5 (42%) tested positive for HIV.[7] In addition, the HIV prevalence in transgender women differed by race/ethnicity, with persons of color being disproportionately impacted: the HIV prevalence rate was 65% among American Indian/Alaska Native participants, 62% among Black participants, 35% among Hispanic participants, 20% among Asian participants, and 17% among White participants.[7] The HIV-specific data for transgender men are sparse, but the HIV prevalence has been estimated to be about 3% for transgender men in the United States.[9]

HIV PrEP Data in Transgender and Gender-Diverse People

There are no phase 3 HIV PrEP trials that have been designed to enroll only transgender or gender-diverse people. Nevertheless, several large phase 3 HIV PrEP trials have included transgender women as eligible participants.[10,11,12,13] Efficacy data for HIV PrEP in transgender men are lacking, though there are no biologic reasons to think that HIV PrEP would be ineffective for transgender men at risk for HIV. The following summarizes the limited data that are available for HIV PrEP and transgender persons in these large trials.

- **iPrEx Subgroup Analysis**: Among the 2,499 individuals who enrolled in the iPrEx trial (all of whom were assigned male sex at birth), 339 were included in a subsequent subgroup analysis of transgender women, including 29 who identified as women, 296 as transgender, and 14 as men who took feminizing hormones.[14] Compared with cisgender men who have sex with men (MSM), transgender women were more likely to report condomless receptive rectal sex and more than five sex partners in the preceding 3 months.[14] All participants were randomized to receive daily oral tenofovir DF-emtricitabine (TDF-FTC) or placebo, and adherence was estimated by measuring tenofovir diphosphate levels in dried blood spots.[14] There was no difference in incidence of HIV acquisition among transgender women assigned to HIV PrEP or placebo, but the risk of HIV acquisition highly correlated with adherence, which was low overall among the transgender participants.[14] For the 11 transgender women in the HIV PrEP arm who acquired HIV, none had detectable tenofovir diphosphate levels at the time of the visit when seroconversion was documented.[14] In contrast, none of the transgender women in the HIV PrEP arm acquired HIV if they took at least four doses of TDF-FTC per week (estimated based on tenofovir diphosphate levels). Overall, among transgender women, the HIV incidence was zero if drug was detected, compared to 4.9 per 100 person-years if drug was not detected.[14]
- **DISCOVER**: For the DISCOVER trial, investigators randomized cisgender MSM and transgender women with a history of sex with men to receive either daily oral tenofovir alafenamide-emtricitabine (TAF-FTC) or daily oral TDF-FTC for the prevention of HIV.[11] Among the 5,387 persons who enrolled in the study, 74 (1.4%) identified as transgender women. Forty-five of the transgender women were randomly assigned to TAF-FTC and 29 to TDF-FTC.[11] A total of 24 transgender women continued the HIV PrEP medication through the study period; this was not a large enough number for a separate analysis, but it was noted that no HIV infections occurred among the transgender women assigned to either HIV PrEP regimen.[11]
- **HPTN 083**: In the randomized, active-controlled HPTN 083 trial, investigators enrolled cisgender MSM and transgender women who had a substantial risk for HIV acquisition.[12] The investigators aimed for at least 10% of participants to be transgender women, and final enrollment included 567 (12.4%) transgender women.[12] Participants were randomized to receive either (1) an every 2-month, intramuscular, long-acting injectable cabotegravir (CAB-LA) plus a daily placebo tablet (after a 5-week oral cabotegravir lead-in) or (2) daily oral TDF-FTC plus an every 2-month placebo injection (after a 5-week lead-in with oral placebo).[12] After a median follow-up of 1.4 years, there were 13 HIV infections in persons in the CAB-LA arm, compared to 39 in the TDF-FTC arm, for a hazard ratio comparing HIV incidence of 0.34 (0.18,0.62, p=0.0005).[12] Thus, in this large trial that included greater than 10% transgender women, CAB-LA demonstrated superior efficacy for HIV prevention as compared to daily oral TDF-FTC.[12] In this study, a separate pre-specified subgroup analysis for transgender women showed comparable results as seen for cisgender MSM: hazard ratio 0.34 for transgender women and 0.35 for MSM, comparing HIV incidence with CAB-LA to incidence with oral TDF-FTC. Thus, for both cisgender MSM and transgender women, CAB-LA appeared more effective than TDF-FTC at reducing HIV acquisition.[12] The superior efficacy of CAB-LA was driven at least in part by improved adherence and coverage of sex acts as compared to daily, oral TDF-FTC (due to missed doses of the oral HIV PrEP option by participants in that study arm).

Drug Interactions between HIV PrEP Medications and Gender-Affirming Hormones

Impact of HIV PrEP Medication on Efficacy of Gender-Affirming Hormones

When considering HIV PrEP for TGD people, an important question that frequently arises is whether the HIV PrEP medications and gender-affirming hormone medications have significant drug interactions. Many TGD individuals fear that medications used for HIV PrEP may decrease the benefit of hormone therapy, and this often creates a barrier to initiating HIV PrEP or maintaining adequate adherence with HIV PrEP. For this reason, it is useful to inform and reassure TGD people interested in or taking hormone therapy that HIV PrEP medications do not significantly impact the levels or efficacy of gender-affirming hormones. Specifically, none of the medications approved for HIV PrEP (TDF-FTC, TAF-FTC, or CAB-LA) impact the efficacy of gender-affirming hormones, such as estradiol or testosterone.[15,16,17]

Impact of Gender-Affirming Hormone Medications on HIV PrEP Efficacy

Testosterone (for gender affirmation) does not appear to have any significant interaction with HIV PrEP medications.[16,18,19] In contrast, questions about the impact of estradiol (for gender affirmation) on oral HIV PrEP medication levels and efficacy have been raised and have generated debate. Investigations have yielded mixed results, but a series of small clinical and laboratory investigations have generated some evidence that suggests estrogen therapy may lower tenofovir levels.[20,21,22,23] Experts have suggested several possible mechanisms for alterations in tenofovir levels that may occur in the setting of estradiol use:[16,23]

- Increased degradation of intracellular tenofovir
- Accelerated intracellular breakdown of tenofovir metabolites
- Changes in renal function
- Alterations in renal transport enzymes

In addition, it has been theorized that differences in body mass index (BMI), drug absorption, transit time in the gastrointestinal tract, gastric pH, p-glycoprotein function, or other factors may play a role of estradiol altering tenofovir levels.[16] None of these mechanisms have been proven, and the explanation may be multifactorial. Most of the studies of interactions between gender-affirming hormones and HIV PrEP utilized TDF-FTC as the oral HIV PrEP medication. Data for TAF-FTC interactions with estradiol are more limited. Although the potential interaction between estradiol for gender affirmation and oral HIV PrEP has caused controversy and requires further investigation, taking estradiol is not a contraindication to oral HIV PrEP, and HIV PrEP should never be withheld from a person at risk for acquiring HIV if they are taking hormonal therapy. Note, for individuals taking HIV PrEP with concomitant estradiol, most experts recommend strict adherence to HIV PrEP medications along with any measures that can support and augment adherence.

Studies with Gender-Affirming Hormones and HIV PrEP Medications

Studies with Gender-Affirming Hormones and Oral HIV PrEP Medications

- **Baltimore Pharmacokinetic Study**: In a small, open-label study conducted in Baltimore, Maryland, that included 8 transgender women (who were taking gender-affirming hormone therapy) and 8 cisgender men, all of whom were given oral TDF-FTC to take daily for 7 days, tenofovir and emtricitabine drug trough concentrations were 32% lower for the transgender women when compared to the cisgender men.[23] In addition, transgender women had area under the curve (AUC) concentrations that were lower (by 27% for tenofovir and 24% for emtricitabine) than for the cisgender men in the study.[23] Plasma estradiol concentrations were not affected by the HIV PrEP medications. The interpretation of these data was complicated by several variables, including transgender women participants who were taking a variety of different estradiol formulations alone or

in combination with or without spironolactone, and there were differences in baseline characteristics between the two groups of participants (such as lower serum creatinine and higher estimated creatinine clearance for the transgender participants).[23] The authors postulated that increased renal clearance of tenofovir and emtricitabine in the setting of estradiol usage might explain the findings, but this mechanism and the clinical significance were not confirmed.[23]

- **Thailand iFACT (Part 1)**: For the prospective, observational iFACT study, 20 HIV-seronegative transgender women in Thailand who had never had an orchiectomy and had not received injectable estrogen within 6 months were enrolled.[22] All participants completed three phases: (1) estradiol (oral estradiol valerate 2 mg with 25 mg cyproterone acetate [an anti-androgen] daily) without TDF-FTC, (2) estradiol with TDF-FTC, and (3) TDF-FTC alone.[22] Analyses of drug levels demonstrated no difference in the estradiol AUC in the presence of TDF-FTC, but lower blood plasma tenofovir levels occurred during periods of estradiol usage.[22] Specifically, the tenofovir AUC was 12% lower and trough concentrations 18% lower when participants took estradiol, as compared to the period without it.[22] Although the tenofovir levels were lower in the presence of estradiol, the tenofovir AUC geometric mean remained in the expected range.[22] Therefore, it was not clear if the change in plasma tenofovir levels was clinically significant. In this study, emtricitabine levels were not measured.[22]
- **iBREATHE**: In the iBREATHE study, investigators enrolled 24 transgender men and 24 transgender women who were taking a stable dose of gender-affirming hormones.[18] The transgender men were taking testosterone, and the transgender women were taking estradiol with or without spironolactone.[18] Participants received 4 weeks of directly-observed, daily, oral TDF-FTC and weekly blood draws for levels of sex hormones as well as dried blood spots for tenofovir diphosphate levels.[18] Drug levels of participants were compared to historical controls from samples taken from 17 cisgender women and 15 cisgender men.[18] Notably, tenofovir diphosphate concentrations after 4 weeks were similar between transgender women and transgender men and between transgender women and cisgender men.[18] Levels were lower among transgender men compared to cisgender women for unclear reasons, but all persons in all groups maintained tenofovir diphosphate levels above thresholds that have been correlated with effective HIV prevention.[18] Serum concentrations of testosterone and estradiol were not impacted by TDF-FTC use.[18]
- **Nebraska Medical Center PK Study**: The University of Nebraska conducted a small pharmacokinetic (PK) study that analyzed the impact of estradiol on tenofovir and emtricitabine levels.[20] In this study, 15 transgender women who were taking estradiol received TDF-FTC for 14 days, with close drug-level monitoring.[20]& Tenofovir and emtricitabine levels were measured in plasma and intracellularly (in peripheral blood mononuclear cells) in the transgender women who participated and then compared with historical levels in cisgender women.[20] The transgender women had lower plasma and intracellular levels of tenofovir and emtricitabine when compared with historical controls, but the intracellular levels were higher than previously reported.[20]
- **University of North Carolina PrEP Pharmacology in Blood and Rectal Tissue**: A separate, small, observational study enrolled four cisgender women, four cisgender men, and four transgender women.[21] Some participants were HIV seropositive and some seronegative, though all were taking TDF-FTC. In addition to assessing drug levels in blood, investigators examined tenofovir and emtricitabine levels in rectal tissue and compared levels of tenofovir and emtricitabine active metabolites, as well as competing deoxynucleotides in tissue samples.[21] The overall concentrations of the drugs and metabolites in blood and rectal tissue were similar between the cisgender and transgender participants.[21] The median tenofovir diphosphate to adenosine triphosphate (ATP) ratio (a marker of HIV PrEP potency) in rectal tissue was seven times lower among the transgender participants, as compared to the cisgender participants, and inversely correlated with estradiol concentrations.[21] Levels in peripheral blood mononuclear cells, however, were similar, and the clinical significance of these findings remains unknown.[21] Unlike in other studies, plasma tenofovir concentrations were not lower for the transgender participants in this observational trial.[21]
- **DISCOVER Trial**: In the randomized, multicenter DISCOVER trial, there were 27 transgender women enrolled to receive HIV PrEP who were also taking high-dose gender-affirming hormones (17 in the TAF-FTC arm and 10 in the TDF-FTC arm).[11] After 4 weeks of participants taking the HIV PrEP medications, investigators measured trough tenofovir diphosphate and emtricitabine triphosphate

concentrations in peripheral blood mononuclear cells.[11] Drug levels for both regimens were similar in the transgender women and cisgender MSM who were receiving these regimens.[11] In addition, the measured drug concentrations were above the estimated 90% effective concentration (EC90) level.[11] This study found that estradiol, when used with daily oral HIV PrEP, did not significantly impact tenofovir or emtricitabine levels.[11]

Studies in Persons Taking Gender-Affirming Hormones and CAB-LA

- **HPTN 077 Hormone Secondary Analysis**: In a secondary analysis of HPTN 077, investigators evaluated the impact of oral hormone contraceptive use on the pharmacokinetics of cabotegravir.[24] In this phase 2a trial, levels of cabotegravir in 18 cisgender women receiving CAB-LA and oral hormonal contraceptives were compared with 8 subjects taking CAB-LA and no oral hormonal contraceptives.[24] Persons receiving oral hormonal contraceptives had lower peak cabotegravir levels, but no other differences in pharmacokinetic parameters were observed. Although this study did not directly evaluate the impact of hormone therapy on cabotegravir in transgender women, these findings in cisgender women suggest the combination of CAB-LA and oral hormonal contraceptives can be used together without a significant impact on cabotegravir levels or efficacy.[24]

Recommendations

Most experts agree that HIV PrEP medications do not reduce the efficacy of gender-affirming hormone therapy. The impact of gender-affirming hormone therapy on HIV PrEP medications is more complex. Studies have demonstrated a modest reduction (in the range of 12 to 27%) in tenofovir and emtricitabine levels for transgender women taking hormone therapy that includes estradiol, but available data suggest that daily dosing of TDF-FTC and TAF-FTC remain effective HIV PrEP options for transgender women who take hormone medications.[15,16] Further, although plasma tenofovir and emtricitabine concentrations are lower in transgender women taking gender-affirming hormone therapy (as compared to levels in cisgender MSM), the intracellular levels appear to remain adequate for HIV prevention. The following summarizes key recommendations.

- Most experts would feel comfortable prescribing daily oral TDF-FTC or daily oral TAF-FTC as HIV PrEP for transgender women who are taking gender-affirming hormone therapy, but would emphasize the importance of strict adherence with daily dosing of HIV PrEP in this setting.
- Most experts would not recommend on-demand (2-1-1 dosing) with TDF-FTC for HIV PrEP in transgender women taking gender-affirming hormones, due to concern that potential lowering of tenofovir levels with hormones may not be adequate with this type of dosing. On demand (2-1-1) dosing with TAF-FTC is not recommended regardless of hormone therapy.
- Available limited data suggest CAB-LA can be used for HIV PrEP in transgender people who are taking gender-affirming hormone therapy.
- Data on the impact of testosterone on HIV PrEP medications in transgender men are limited; studies to address this issue are ongoing, but at present most experts believe any HIV PrEP medication and testosterone can be safely used together.

Obtaining a Sexual History with Transgender and Gender-Diverse People

In the CDC's A Guide to Taking a Sexual History, there are five recommended core components of taking a sexual history; these elements are referred to as the five Ps (5Ps):[25]

- Partners
- Practices
- Protections for sexually transmitted infections
- Past history of sexually transmitted infections
- Prevention of pregnancy

When providing care for TGD people, HIV PrEP should be considered for all with risk of acquiring HIV. To estimate HIV risk, one should elicit a careful sexual history and screen for illicit drug use.[15,25] When obtaining a sexual history, it is important to distinguish a person's gender identity from their sexual orientation. In addition, there are several key considerations for clinicians taking a sexual history with TGD people, including asking open-ended questions, asking questions that can capture the diversity of sexual partnerships and practices, and maintaining sensitivity to language throughout the interview. When taking a sexual history with TGD people, experts have recommended expanding the 5Ps to the 8Ps:

- Preferences
- Partners
- Practices
- Protections for sexually transmitted infections
- Past history of sexually transmitted infections
- Prevention of pregnancy
- Pleasure
- Partner violence

Indications for HIV PrEP with Transgender and Gender-Diverse People

In general, the indications for HIV PrEP center on the type of sexual activity and gender of sex partners, not a person's gender. For TGD people, HIV PrEP should be offered to any individual engaging in condomless anal sex, condomless vaginal (front hole) sex with partners who have significant risk for HIV, survival or exchange sex, injection drug use, and persons with a history of bacterial sexually transmitted infection (Figure 5).[15] Additional factors that increase HIV risk and contribute to a need for HIV PrEP include the use of cocaine, methamphetamine, club drugs, or chemsex. Several tools have also been developed to help estimate HIV risk and can help to educate patients about indications and benefits for HIV PrEP. In addition, the 2021 CDC HIV PrEP Guidelines recommend providing HIV PrEP for any person who requests it, regardless of reported HIV acquisition risk.[15] The rationale for this recommendation is that some people may not want to disclose information regarding past or current activities that would place them at risk and some people may anticipate upcoming risk for HIV acquisition, even if minimal or no risk has existed in the past.

HIV PrEP Medication Options for Transgender and Gender-Diverse People

The following summarizes HIV PrEP medication options and recommendations from the United States FDA and the CDC PrEP guidelines for transgender persons.[15]

- **Tenofovir DF-Emtricitabine (TDF-FTC)**: In 2012, the FDA approved TDF-FTC for HIV PrEP for adults. The indication is for individuals at substantial risk for HIV infection who have creatinine clearance above 60 mL/min and have been documented to be seronegative for HIV infection. For adolescents, the minimum requirement is a weight of at least 35 kg (77 lb). Based on available data, daily oral TDF-FTC is expected to have high efficacy for TGD people, regardless of the route of sexual risk. Generic, single-tablet formulations of oral TDF-FTC and TDF-FTC are now available, and these less expensive products are assumed to have similar efficacy as the brand-name version.
- **Tenofovir Alafenamide-Emtricitabine (TAF-FTC)**: In 2019, the FDA approved TAF-FTC for HIV PrEP for individuals with substantial risk of HIV infection who have creatinine clearance above 30 mL/min. The approval indications include cisgender MSM and other individuals whose risk factor for HIV is condomless rectal sex, but it excludes cisgender women and other individuals whose risk factor is vaginal sex. Therefore, when considering TAF-FTC for HIV PrEP for TGD people, it is important for clinicians to consider the individual's anatomy and sexual activities. For example, TAF-FTC would not be recommended as HIV PrEP for TGD people whose risk factor for HIV acquisition is vaginal/front hole sex (this would apply to TGD individuals who were assigned female sex at birth who have not had genital surgery and who need HIV prevention for vaginal/front hole sex). There are no published data on the efficacy of HIV PrEP for TGD individuals who have a neovagina following vaginoplasty.
- **Long-Acting Injectable Cabotegravir (CAB-LA)**: Bimonthly intramuscular CAB-LA for HIV PrEP was found to have superior efficacy to oral TDF-FTC for HIV PrEP in a trial that included cisgender MSM and transgender women who have sex with men and in a separate trial that enrolled cisgender women. The CAB-LA option is an important option for individuals with a creatinine clearance below 30 mL/min. Although there has not been a trial of CAB-LA as HIV PrEP for transgender men, it is expected to be highly effective for transgender men as well.
- **On-Demand (2-1-1) Oral HIV PrEP (also referred to as 2-1-1, Event-Driven, and non-daily)**: There have not been any major studies of on-demand dosing of TDF-FTC for TGD people and no major studies have been conducted with on-demand dosing of TAF-FTC with any population. In addition, the possible lowering of tenofovir and emtricitabine drug concentrations in TGD persons receiving estradiol has raised concerns about potential efficacy with on-demand dosing. For these reasons, on-demand oral HIV PrEP is not recommended for transgender persons.

Baseline and Follow-Up Laboratory Evaluation

For TGD individuals, the recommendations in the 2021 CDC HIV PrEP Guidelines for routine baseline laboratory evaluation, follow-up clinical monitoring, and follow-up laboratory monitoring for HIV PrEP are generally the same as for cisgender individuals. The baseline and follow-up laboratory studies are summarized and discussed in detail in the H*IV PrEP Fundamentals* module lessons on Baseline Evaluation and Starting HIV PrEP and **Follow-Up Care and Monitoring on HIV PrEP**. In addition, summary tables for initial and follow-up laboratory studies are available in the Laboratory Monitoring Guide on this website. In TGD people, there are a few unique considerations as summarized below.

- **Reference Range for Serum Creatinine**: When checking serum creatinine for renal function, confusion can arise when comparing the result to the normal range because the normal range automatically populated in the electronic health record may be the person's sex assigned at birth and not gender identity. It is generally accepted that if a person has been taking gender-affirming hormone therapy for at least 6 months, their gender identity (not sex assigned at birth) should be used to judge the normal range.
- **Screening for Bacterial STIs**: For TGD individuals who take HIV PrEP and whose risk factor for HIV acquisition is via sexual activity, screening for bacterial STIs should occur at least every 3 to 4 months; the testing should take into account the person's sexual activities and include screening of all sites of exposure, regardless of gender identity. For example, if sexual history includes oral and rectal sex, then nucleic acid amplification testing (NAAT) of the oropharynx and rectum for gonorrhea and chlamydia should be included, in addition to serum syphilis testing and urine gonorrhea and chlamydia tests.
- **Impact of Past Surgical Procedures**: For TGD individuals, it is important to know and understand past surgical procedures, which may affect bacterial STI screening. For example, bacterial STIs, herpes simplex virus (HSV), and human papillomavirus (HPV) infection may occur following vaginoplasty, though the specific STIs that may occur depend in part on the type of tissue used for creation of the neovagina.[26,27] If a TGD individual is at risk for STIs of the neovagina, screening, such as with vaginal swab NAAT and/or urine NAAT (it has not been determined which is more effective in this scenario) for gonorrhea and chlamydia is indicated, especially if mucosal or mesothelial graft tissue was used.[28]

Time to Achieve Protection After Initiating PrEP

Time to Achieve Protection

The exact duration between initiating oral HIV PrEP and achieving protection against HIV is unknown; this determination is complicated by the lack of consensus on the tissue-specific drug concentration required to provide protection against HIV infection and the significant variation in the pharmacokinetics of tenofovir and emtricitabine in different tissues.[15] For these reasons, the CDC does not provide specific recommendations on how long a person must be taking daily HIV PrEP to achieve protection against HIV. Although there is no clear guidance on the number of days TGD should take oral TDF-FTC for HIV PrEP before it is effective, our recommendation is to counsel persons that it may take up to 3 weeks before this drug offers maximum protection against HIV. It is also unclear if the time to protection may differ for TGD persons who are taking estradiol or other gender-affirming hormones. Therefore, clinicians should also counsel TGD persons initiating HIV PrEP about these unknowns, encourage other measures to decrease their chance of HIV acquisition, and be familiar with and share information from current recommendations, as per the CDC guidelines:

- **TDF-FTC**: Data from pharmacokinetic studies that were performed in individuals without HIV suggest that maximum intracellular concentrations of tenofovir diphosphate are achieved in peripheral blood mononuclear cells after approximately 7 days, in rectal tissue at approximately 7 days, and in cervicovaginal tissues at approximately 20 days.[15] These data are based on time to maximum concentrations, as opposed to protective concentrations, but these time durations give a general sense by which to help guide patients. The estimates can likely be extrapolated to TGD persons who engage in receptive rectal or vaginal sex; it is unclear how drug levels may compare in the tissue of a neovagina or penile tissue following phalloplasty or metoidioplasty.
- **TAF-FTC**: There are insufficient pharmacokinetic data on the time to achieve maximal tissue concentrations after initiating TAF-FTC for the prevention of HIV acquisition in TGD persons.
- **CAB-LA**: There are no data that provide any estimates for the time to achieve maximal tissue concentrations after initiating CAB-LA for HIV PrEP.

Addressing Barriers to HIV PrEP for Transgender and Gender-Diverse People

Transgender and gender-diverse people often have unique barriers to accessing or adhering to HIV PrEP, including identifying and accessing a medical provider with whom they are comfortable discussing their gender, as well as prevention options based on their risk of acquiring HIV. They may also experience an intersection or layering of stigmatization secondary to overlapping personal factors, such as gender, race/ethnicity, socioeconomic status, mental health issues, substance use, and others. For TGD people, the patient-provider relationship is crucial to developing trust and overcoming barriers to HIV PrEP initiation. Clinical care models in which HIV PrEP services are provided in welcoming, gender-affirming environments—and in the same context as gender-affirming medical interventions—increase the likelihood of success with HIV PrEP prescribing and persistence among TGD people. It is within the purview of primary care medical providers to offer both gender-affirming care and HIV PrEP services. In clinical situations in which this is not feasible, it is important for TGD people to have easy access to both HIV preventative care and gender-affirming care. Co-location of these services—along with behavioral health services, substance use disorder treatment, social work, and other services—promotes success with engagement in preventative care for TGD people at risk for HIV.[29]

Common Barriers

Numerous barriers may impede access to HIV PrEP initiation and adherence for TGD people. These barriers include a lack of awareness of HIV PrEP, difficulty accessing a gender-affirming clinical practice or provider, lack of health insurance, competing priorities for basic needs (housing, food, and employment), and concerns about drug interactions with gender-affirming hormone therapy.[30,31,32] In addition, TGD people often avoid health care in general due to stigma, discrimination, mistrust, and traumatic experiences with prior medical care.[30,32] Adolescents may face even greater barriers due to legal implications and a desire not to disclose to parents.[30] In one focus group of trans women, concerns cited about HIV PrEP included side effects, difficulty taking pills, stigma, exclusion of trans women in advertising, and lack of research specific to trans women.[33] According to results of another focus group with trans women, overall knowledge of HIV PrEP was low, though interest was high once participants learned about the option. Barriers cited by participants included past negative experiences with health care, lack of gender-inclusive marketing in HIV PrEP materials, medical mistrust, and prioritization of hormone use.

HIV PrEP Awareness and Importance of Medical Provider Education

Some studies have shown low awareness of HIV PrEP among TGD people.[5] Lack of awareness among health care practitioners, or discomfort raising the issue of HIV risk, may also prevent important discussions about HIV prevention options, including HIV PrEP. In a focus group discussion with trans men, participants shared that many of their medical providers had avoided conversations about sexual behavior and risk.[34] Many TGD people also do not feel trust or comfort with their medical provider and are reluctant to initiate these conversations. Thus, clinicians should initiate these discussions and make efforts to raise awareness about HIV PrEP. Counseling TGD people about HIV risk, prevention methods, and HIV PrEP should include a discussion related to any potential concerns related to drug interactions with gender-affirming hormones and oral HIV PrEP medications and the need for strict adherence if taking these medications concomitantly. Numerous studies have identified concern about drug interactions as a barrier for TGD people to initiate and adhere to HIV PrEP.[2,35,36,37] For many TGD people, gender-affirming hormone therapy is a priority, and reassurance that HIV PrEP will not interfere with hormone levels or efficacy can go a long way towards encouraging HIV PrEP adherence. Patient and provider education are important steps toward supporting HIV PrEP dissemination and access for individuals who need it.

Creating a Welcoming Environment and offering Gender-Affirming Care

In the focus group of transgender women, the most important factor that supported HIV PrEP uptake and adherence was the ability to access a gender-affirming medical provider.[38] This theme has emerged in other research as well: patient-provider communication and quality of relationship with a provider is a critical step towards alleviating barriers to HIV PrEP uptake for TGD people.[32,39] Therefore, one of the most important strategies for reducing barriers and promoting access and adherence to HIV PrEP for TGD people is to provide HIV PrEP in the context of gender-affirming care in a clinic environment that is welcome to people of all genders.[30,40,41] Creating a welcoming and gender-inclusive environment requires a number of steps, including correctly and consistently using names and pronouns and documenting these in the medical chart. Forms, policies, clinic processes, and sexual histories should be free of assumptions about sexual orientation, gender identity, and anatomy. Gender-inclusive imagery in the clinical setting can help convey a welcoming atmosphere. Transgender and gender-diverse people, including adolescents, should also be included in prevention campaigns and marketing materials. Patients should have access to single-stall and/or all-gender restrooms. Hiring TGD staff in the clinic also makes it feel more welcoming to people of all genders. Peer education and peer navigation services can also make a dramatic difference in supporting HIV PrEP access.[40].

Addressing Trauma and Mental Health Issues

It is also important to remember that many TGD persons have experienced significant discrimination and trauma in their lives, including verbal, physical, and sexual abuse. Transgender and gender-diverse people experience more frequent stigma, harassment, and violence victimization than the general population, including when attempting to access health services.[42] In the context of this gender minority stress, TGD people may be more likely to experience depression, anxiety, posttraumatic stress, and substance use.[42] They may come to expect rejection and avoid engaging in health care due to medical mistrust. Gender-affirming mental health services should, therefore, ideally be offered within welcoming and inclusive environments, in an integrated manner with HIV prevention and care, along with access to mental health and substance-use treatment. Approaching care with a trauma-informed lens, developing trust, screening for experiences of trauma, screening for substance use and mental health symptoms, acknowledging and discussing past trauma when the person feels comfortable doing so, and referring to mental health services or addiction treatment as needed is critical for establishing and maintaining rapport, a therapeutic alliance, and engagement in HIV prevention services.[29]

Additional Steps Towards Improving HIV PrEP Initiation and Adherence

If attending appointments in a clinic is challenging for TGD people, there may be benefits to same-day HIV PrEP (starting HIV PrEP at the first clinic visit to decrease the need for follow-up face-to-face visits) or to offer visits via telehealth. Coordinating regular laboratory testing with telehealth visits can be difficult, but at-home testing options may be available. In the clinic, some TGD people may feel discomfort around physical examinations or medical provider collection of specimens, such as for STI NAAT testing, so options for self-collection of specimens can be helpful. Walk-in visits may also help individuals who have difficulty adhering to scheduled appointment times. State and other medication assistance programs can be critical to help address cost barriers and lack of healthcare insurance.

Overview and Resources

Overview Lecture

There are a number of factors that go into offering and providing HIV PrEP for transgender and gender-diverse people. In the following lecture, Dr. Kevin Ard, from Harvard Medical School provides an overview on **HIV PrEP for Transgender and Gender Diverse People** (*12 minutes*). In this overview lecture, Dr. Ard explores HIV epidemiology and HIV PrEP uptake among transgender and gender-diverse people, three key HIV PrEP studies that included transgender people, review of four key considerations when selecting a medication for HIV PrEP medications for transgender people, concerns about how HIV PrEP medications may interact with gender-affirming hormone therapy, and how to embed HIV PrEP within gender-affirming care to may increase access and HIV PrEP uptake.

This video is part of our mini lecture section.

Additional HIV PrEP Resources for Transgender and Gender-Diverse People

The following list includes several excellent HIV PrEP resources for transgender and gender diverse people:

- Centers for Disease Control and Prevention: HIV Prevention and Care for Transgender People
- National LGBTQIA+ Health Education Center: Glossary of LGBTQIA+ Glossary of Terms for Health Care Teams
- National LGBTQIA+ Health Education Center: Ready, Set, Go!: A Guide for Selecting Data on Sexual Orientation and Gender Identity
- Please PreP Me: PrEP for Trans Women
- United Nations Development Programme: Implementing Comprehensive HIV and STI Programmes with Transgender People

Summary Points

- Transgender individuals are disproportionately affected by HIV in the United States, with relatively higher rates of new diagnoses as compared to cisgender persons, especially among young transgender women.
- Assessment of HIV risk and indications for HIV PrEP should take into account a person's sexual history, including sexual behavior and partners, and it is important to remember that a person's gender identity does not indicate their sexual orientation or determine their sexual risk.
- Transgender women have been included in several HIV PrEP clinical trials, and oral TDF-FTC and CAB-LA are recommended HIV PrEP options for transgender women and men; oral TAF-FTC is a recommended option for transgender or gender-diverse individuals whose risk factor for HIV acquisition is rectal sex (not vaginal sex).
- TGD people can be reassured that none of the HIV PrEP options affect levels or efficacy of gender-affirming hormones.
- Some data suggest that gender-affirming hormones (such as estradiol with or without an anti-androgen) may lower the levels of tenofovir, though most studies find that intracellular levels remain within an expected therapeutic range; therefore, daily oral TDF-FTC or TAF-FTC can be prescribed to an individual taking feminizing hormones, though adherence with daily dosing should be emphasized.
- Most experts would not recommend using on-demand (2-1-1) dosing of TDF-FTC with concomitant use of gender-affirming hormones due to the possible lowered tenofovir levels, which could be problematic with this type of dosing. On-demand dosing with TAF-FTC is not recommended, regardless of concomitant hormone use.
- There is no evidence that feminizing hormone therapy affects cabotegravir levels.
- There is no evidence that masculinizing hormone therapy lowers the levels or efficacy of any HIV PrEP medications.
- The baseline laboratory evaluation and laboratory monitoring for transgender and gender-diverse individuals receiving HIV PrEP are generally the same as for cisgender persons, though if a person has taken gender-affirming hormone therapy for more than 6 months, experts recommend using their gender identity (not sex assigned at birth) to determine the normal range for the serum creatinine.
- TGD people may experience numerous barriers to health care and to HIV PrEP access, including stigmatization and trauma. Offering gender-affirming care at the same location as HIV preventative care can help to alleviate barriers and increase HIV PrEP utilization, as can co-locating mental health and addiction treatment or facilitated referral for these services.

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Figures

Figure 1 Transgender People in the United States

Source: Herman JL, Flores AR, O'Neill KK. How many adults and youth identify as transgender in the United States. Williams Institute: UCLA School of Law. June 2022.

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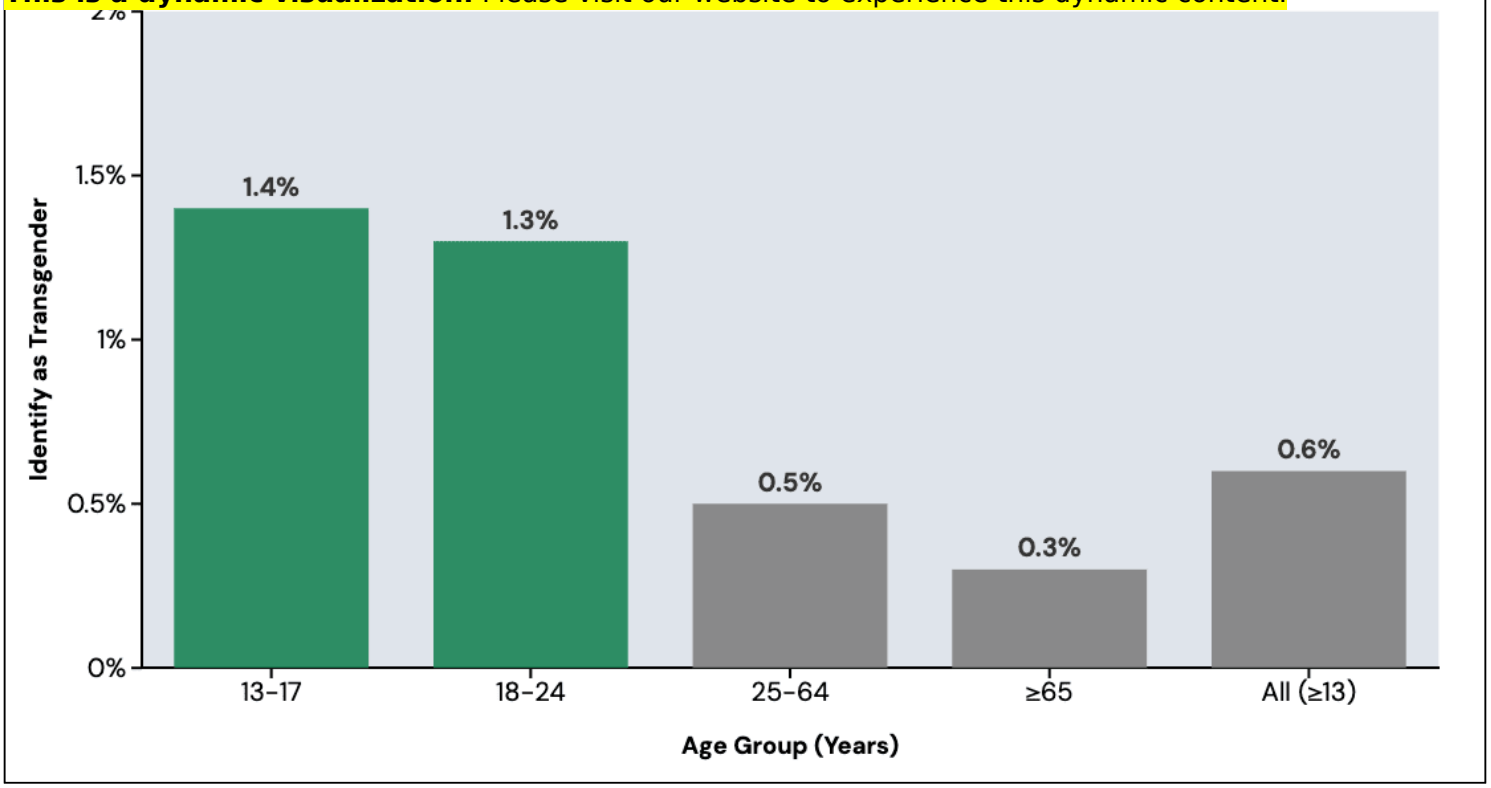

Figure 2 Gender-Related Terminology: Exercise

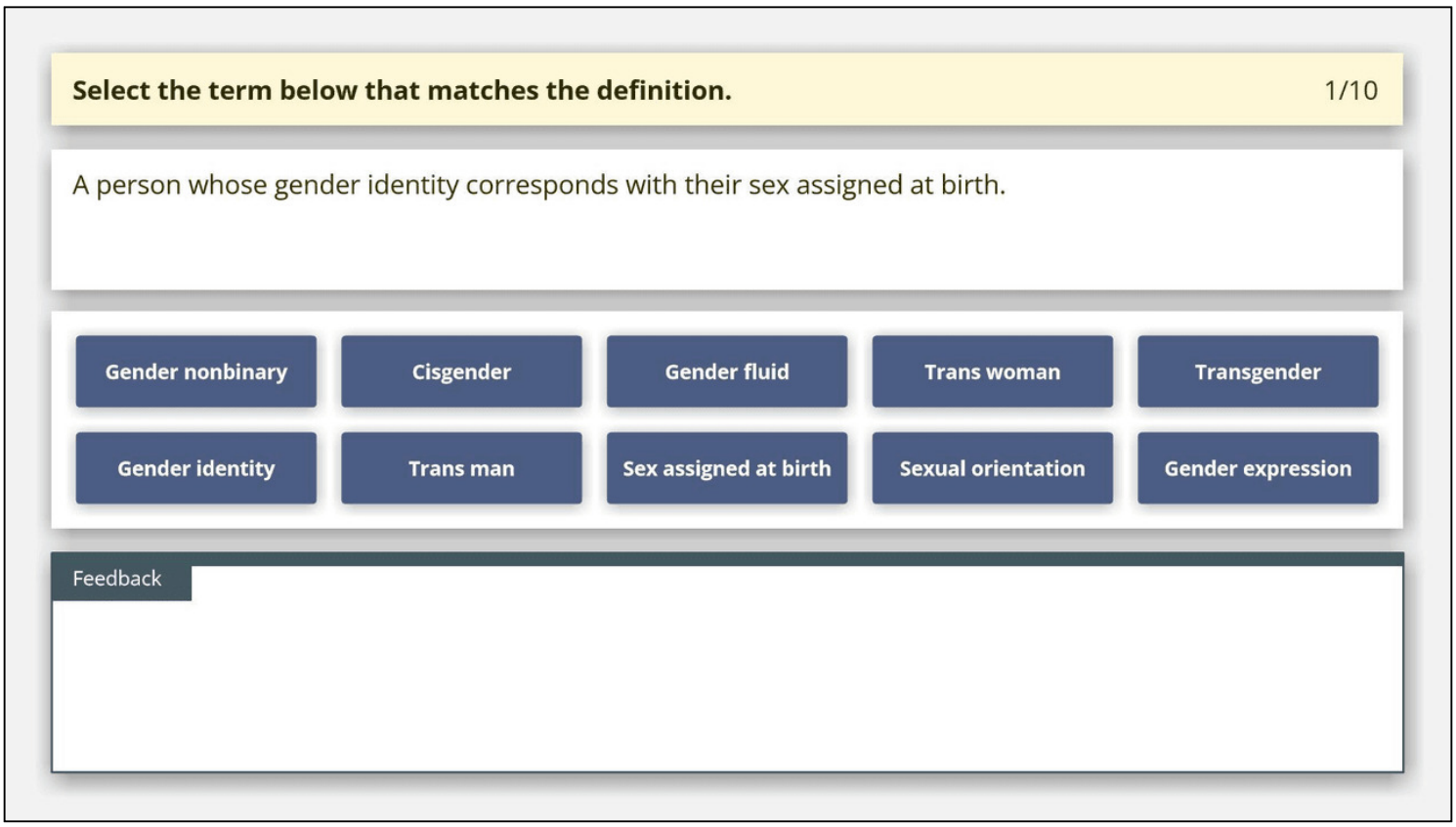

Figure 3 New HIV Diagnoses (Incidence) Among Transgender People — United States, 2021

Source: Centers for Disease Control and Prevention. Diagnoses of HIV infection in the United States and dependent areas, 2021. HIV Surveillance Report, 2021; vol. 34. Published May 2023.

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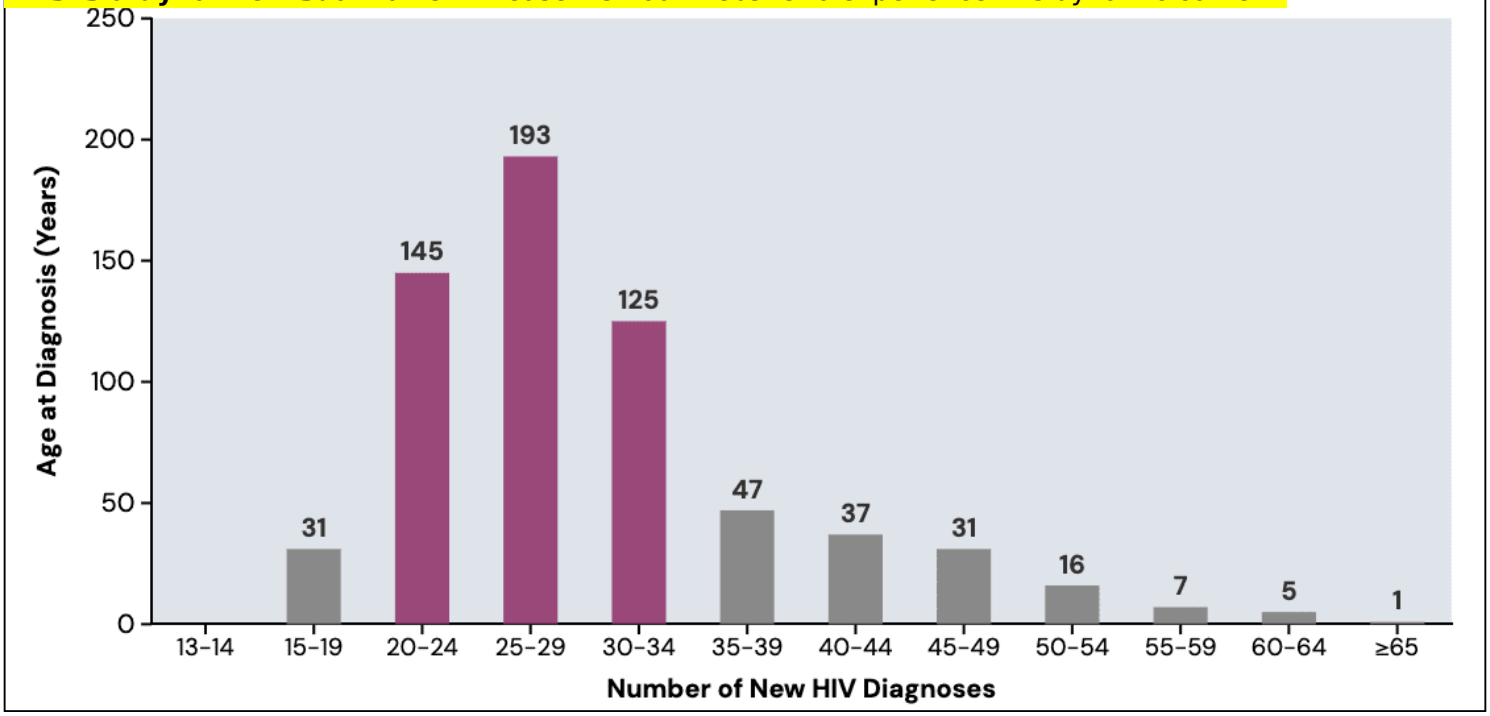

Figure 4 Transgender People Living with Diagnosed HIV (Prevalence) — United States, 2021

Source: Centers for Disease Control and Prevention. Diagnoses of HIV infection in the United States and dependent areas, 2021. HIV Surveillance Report, 2021; vol. 34. Published May 2023.

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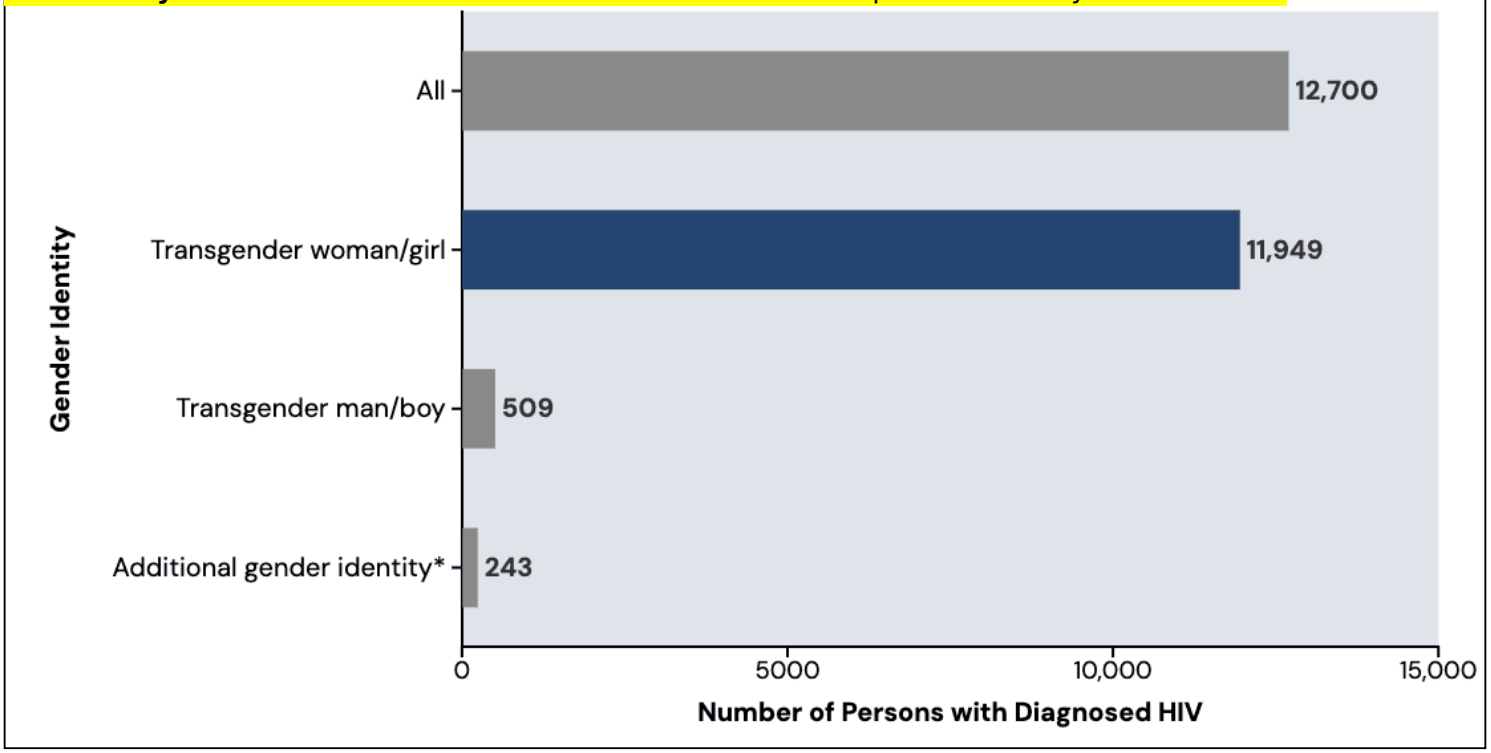

Figure 5 Assessing Indications for HIV PrEP in Sexually-Active TGD

Abbreviations: STI = sexually transmitted infection; GC = gonorrhea; MSM = men who have sex with men; MSW = men who have sex with women

Source: Source: Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. December 2021:1-108.