HIV PrEP for Women

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Module 2: HIV PrEP In-Depth Topics
Lesson 2: HIV PrEP for Women

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Background

In the United States, women account for roughly one in four persons living with HIV and nearly one in every five of all new HIV infections.[1,2] Although HIV preexposure prophylaxis (PrEP) is a discreet, effective method for women to prevent HIV, the use of HIV PrEP for women continues to be markedly underutilized (Figure 1).[3,4,5] In 2021, only 7% of the HIV PrEP prescriptions written in the United States were for women.[4] Further, in 2021, only about 1 in 7 women who had an indication for HIV PrEP were prescribed HIV PrEP, which is far below the Ending HIV Epidemic 2025 goal of prescribing HIV PrEP to at least 50% of people who have indications for HIV PrEP.[4] The use of HIV PrEP in women who are pregnant is particularly important since HIV acquisition during pregnancy creates an enhanced risk of HIV perinatal transmission, especially if the diagnosis of HIV is delayed. In addition, some women are at higher risk for violence against them, including intimate partner violence.[6,7] This increased risk of violence and the potential need to participate in survival sex can lead to more sex partners, substance use, forced sex, and condomless sex—all of which increase HIV risk.[7] In this lesson, we address the use of HIV PrEP in women.

Epidemiology of HIV in Women

The following discussion is based on CDC HIV Surveillance Reports for females, including women and girls.[1]

- **Females with Diagnosed HIV**: At year-end 2021, among all persons living with diagnosed HIV in the United States, 22.9% (246,029 of 1,072,267) were females.[1] Approximately 77% of females living with diagnosed HIV acquired the infection through heterosexual contact and 20% by injection drug use.[1] Among all females with diagnosed HIV, 58% were Black females.[1]
- **Females with New HIV Diagnoses**: The data for new HIV diagnoses are reported for a specific year, but the number of new HIV diagnoses reported in a year is not the same as the actual number of new HIV infections in that same year, since many persons who acquire HIV obtain their diagnosis of HIV at least 1 year after initially acquiring HIV. Among the 35,769 persons newly diagnosed with HIV in 2021 in the United States, 6,554 (18%) were females.[1] In 2021, among female adults and adolescents newly diagnosed with HIV, 83% reported acquisition of HIV through heterosexual contact and 16% through injection drug use.[1] More than one-half of females newly diagnosed with HIV in 2021 were Black females (Figure 2).[1]

[Q] HIV Acquisition Risk in Women

Evidence for HIV PrEP in Women

As compared to HIV PrEP studies in men, there have been relatively few HIV PrEP studies in women. The following summarizes major phase 2b and 3 data for HIV PrEP studies involving women. These studies have involved oral tenofovir DF (TDF) alone, oral tenofovir DF-emtricitabine (TDF-FTC), and long-acting injectable cabotegravir (CAB-LA). There are no major published HIV PrEP studies in women that have used tenofovir alafenamide-emtricitabine (TAF-FTC). In addition, there are no phase 2b or phase 3 studies that have examined HIV PrEP in pregnant women. Note that most HIV PrEP studies involving women have predominantly enrolled women in Africa; there are relatively limited data for HIV PrEP in women in the United States. The following does not include studies on the dapivirine vaginal ring, since the developers of this ring withdrew the New Drug Application from the United States Food and Drug Administration (FDA) in 2021.

HIV PrEP Studies Enrolling Heterosexual Women and Men

- **Partners PrEP**: The Partners PrEP trial was a phase 3, randomized, double-blind, placebo-controlled study that enrolled 4,758 HIV-serodifferent heterosexual couples in Uganda and Kenya to receive either daily oral TDF alone, oral daily TDF-FTC, or placebo to prevent HIV acquisition (Figure 3).[8] Among all couples enrolled, 38% of the HIV seronegative partners were women.[8] The partners with HIV were not being prescribed antiretroviral therapy (because they were not eligible per local treatment guidelines that existed at the time the study was conducted.[8] Pregnant women were excluded from the trial; if pregnancy occurred during the study, participants were still followed, but the study medication was held until they were no longer pregnant or lactating.[8] Among the HIV seronegative women enrolled, when compared with placebo, the efficacy of TDF was 71% and TDF-FTC was 66%.[8] The relative efficacy of HIV PrEP in women was lower than in men—the HIV acquisition in women was 0.88 per 100 person-years compared with 0.25 per 100 person-years in men.[8]
- **TDF2**: The Botswana TDF2 Trial, a phase 3, randomized, double-blind, placebo-controlled study of the safety and efficacy of daily oral TDF-FTC as HIV PrEP, enrolled 1,219 heterosexual men and women in Botswana who had tested negative for HIV; of those enrolled, 46% were women (Figure 4).[9] In the as-treated cohort, 3 women in the TDF-FTC arm and 13 in the placebo arm had new HIV infection, with a TDF-FTC protective efficacy of 75.4 (p=0.02).[9] In the intention-to-treat analysis, 7 women in the TDF-FTC arm and 14 in the placebo arm had new HIV infection, with protective efficacy cited as 49.4 (p = 0.11).[9]

HIV PrEP Studies Enrolling Women Only

- **HPTN 084**: The 084 study was a phase 3, randomized, double-blind trial to compare CAB-LA with daily oral TDF–FTC for the prevention of HIV infection in women at risk of acquiring HIV (Figure 5).[10] The study enrolled 3,224 women from seven countries in sub-Saharan South Africa. The cabotegravir regimen consisted of a 5-week lead-in with oral cabotegravir (30 mg daily), followed by 2 doses of CAB-LA (600 mg) 4 weeks apart, followed by CAB-LA every 8 weeks.[10] There were 36 new HIV infections (incidence 1.85 per 100 person-years) in the TDF-FTC group and 4 infections (incidence 0.20 per 100 person-years) in the CAB-LA arm. In this study, CAB-LA was superior to TDF-FTC for the prevention of HIV in women.[10]
- **FEM-PrEP**: The FEM-PrEP trial was a phase 3, randomized, double-blind, placebo-controlled study of the HIV prevention efficacy and clinical safety of daily oral TDF-FTC among heterosexual women in South Africa, Kenya, and Tanzania.[11] Participants were seen at monthly follow-up visits, and the study drugs were discontinued among women who became pregnant during the trial.[11] The trial was stopped in 2011 when an interim analysis determined that the trial would be unlikely to detect a statistically significant difference in efficacy between the two study groups.[11] Adherence was low in this trial, with detectable plasma drug levels in less than 50% of the women assigned to TDF-FTC.[11]
- **VOICE**: The Vaginal and Oral Interventions to Control the Epidemic (VOICE) trial was a phase 2b, randomized, double-blind HIV PrEP study comparing oral TDF, oral TDF-FTC, and topical vaginal

tenofovir antiretroviral regimens against corresponding oral and topical placebos among 5,029 heterosexual women without HIV from East Africa and South Africa.[12] Adherence estimates based on face-to-face interviews and audio computer-assisted self-interviews were high in all 3 groups (84% to 91%), but when random plasma drug levels were obtained, the percentage of samples with detectable drug was less than 40% in all study drug groups, and the drug levels declined throughout the study.[12] The study was stopped in the group receiving oral TDF and the group receiving topical tenofovir after interim analysis determined futility.[12] The group receiving oral TDF-FTC continued through study completion, but no reduction in HIV acquisition was observed in the TDF-FTC arm when compared with placebo.[12]

Evidence for HIV PrEP in Pregnant Women and During Breastfeeding

Efficacy of HIV PrEP in Pregnancy

Data regarding the efficacy of HIV PrEP during pregnancy comes mostly from HIV PrEP demonstration studies, non-placebo study extensions, and open-label extensions conducted in women.[13] During pregnancy, HIV PrEP is efficacious, but pharmacokinetics and pharmacodynamics that impact medication levels can be altered during pregnancy.[14] Although pharmacokinetic data for HIV PrEP use in pregnancy are minimal, some studies have demonstrated lower drug levels during pregnancy.[15,16] Thus, daily adherence is of critical importance if taking HIV PrEP during pregnancy. When HIV PrEP is started during pregnancy, the recommendation is to use other prevention methods (i.e., condoms) until HIV PrEP has been taken for at least 20 days; after this time frame, no back-up protection is needed as the woman should be considered protected from HIV acquisition.[14,17]

Safety of HIV PrEP During Pregnancy

Most data regarding the safety of antiretroviral medications in pregnancy come from studies that have involved women with HIV who were taking antiretroviral therapy for treatment. Limited data regarding the safety of HIV PrEP during pregnancy are available from (1) HIV PrEP use during early pregnancy before the study drug was discontinued once pregnancy was detected, (2) use of HIV PrEP during periconception, pregnancy, and breastfeeding from demonstration projects, (3) TDF use during late pregnancy for HBV treatment in women who are HIV negative, and (4) use of TDF-FTC and TAF-FTC as part of an antiretroviral regimen used by pregnant women with HIV.[14,17]

- **CAP016**: This randomized, open-label, single-site, non-inferiority trial randomized 540 women (without HIV) who were between 14 weeks and 28 weeks' gestation, to receive either immediate initiation of HIV PrEP with TDF-FTC or to defer HIV PrEP (to begin once breastfeeding ended).[18] The immediate HIV PrEP was non-inferior to deferred HIV PrEP for safety outcomes of preterm birth, small for gestational age, and the composite adverse pregnancy outcome.[18] An HIV PrEP policy change in South Africa, which extended HIV PrEP eligibility to pregnant women, led to early suspension of recruitment in the trial, reaching only 64% of the intended sample, precluding ability to conclude non-inferiority for less frequent adverse pregnancy outcomes, such as very preterm birth, low birthweight, very low birthweight, and stillbirth.[18]
- **Partners PrEP Study**: In the Partners PrEP Study, a total of 431 pregnancies occurred.[13] Women who became pregnant were instructed to discontinue the study medication (placebo or TDF alone or TDF-FTC) upon pregnancy detection, but they continued to have follow-up visits.[13] Among pregnant women in the three study arms, there were no statistically significant differences in pregnancy loss, preterm birth, birth anomalies, or infant growth.[13]
- **PRISMA Pregnancy PrEP Projects**: The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA), a systematic review of HIV PrEP projects in pregnant women, consisted of 5 sub-analyses of completed clinical trials and a total of 1,042 HIV PrEP-exposed pregnancies; no differences in pregnancy outcomes or perinatal outcomes were observed in four of the five studies.[19] One of the five studies found that HIV PrEP-exposed infants had a lower z-score for length at 1 month of age, though no difference was observed at 1 year of age.[19]
- **PrIYA Program**: Investigators conducting the PrEP Implementation in Young Women and Adolescents (PrIYA) program evaluated 206 Kenyan women with prenatal HIV PrEP use and 1,324 without HIV PrEP use and found no difference in pregnancy outcomes (preterm birth or low birthweight). In addition, when comparing the two groups, they found similar infant growth at 6 weeks postpartum.[20]
- **TDF Systematic Data Review**: In a systematic review of 26 studies in women with HIV and 7 studies in women without HIV using TDF and FTC during pregnancy or breastfeeding, the authors did not identify safety concerns that would lead either to limiting the use of HIV PrEP in pregnancy or in breastfeeding or require discontinuation of HIV PrEP in women who became pregnant while taking HIV PrEP.[21]

- **HPTN 084**: In HPTN 084, women were randomized to receive CAB-LA or placebo for HIV PrEP. Among the 1,614 women enrolled in the CAB-LA arm, there were 29 pregnancies, and women were instructed to switch to TDF-FTC upon pregnancy detection.[10] For these pregnancies, none were associated with a neural tube defect or other congenital abnormality.[10] Further evaluation will be conducted on CAB-LA related to pregnancy and breastfeeding in the ongoing unblinded phase of the HPTN 084 study.[10]

Data for HIV PrEP While Breastfeeding

Major studies have not yet adequately evaluated the safety of HIV PrEP for infants exposed during lactation. Even among women with HIV, data on the use of antiretroviral medications during breastfeeding are limited. Available data suggest that very little TDF-FTC is contained in breast milk. For example, in a short-term study of women breastfeeding who took TDF-FTC for 10 days, estimated infant doses from breast milk and resultant infant plasma concentrations for tenofovir were 12,500-fold lower, and for emtricitabine were greater than 200-fold lower than proposed therapeutic doses for infants.[22] Tenofovir was not detected in 94% of plasma samples from infants.[22] Thus, for postpartum women at risk of acquiring HIV, the benefits of HIV PrEP while breastfeeding outweigh any risk to the newborn, and the recommendation is to use TDF-FTC as HIV PrEP for women exposed to HIV while breastfeeding.[14] Currently, CAB-LA is not recommended for women who are breastfeeding.[17]

HIV PrEP Indications for Women

Health care professionals should provide all sexually active adult and adolescent women, including women who are pregnant, with information regarding HIV PrEP.[17] A brief sexual history is recommended to assess the risk of acquiring HIV and potential indications for HIV PrEP. In addition, HIV PrEP should be discussed with all adult and adolescent women who inject drugs. The specific indications for HIV PrEP, as recommended in the 2021 CDC HIV PrEP Guidelines, are outlined as follows.[17]

Sexually Active Adults

Anal or vaginal sex in past 6 months AND any of the following:

- Sex partner with HIV (especially if the partner has a detectable or unknown viral load)
- Bacterial sexually transmitted infection in the past 6 months (gonorrhea and syphilis for heterosexual women and men, including men or women who inject drugs)
- History of inconsistent or no condom use with sex partner(s)

Persons Who Inject Drugs

Persons who inject drugs should also be assessed for their sexual risk of HIV, particularly if they experience any of the following:

- Have an injecting partner with HIV
- Share injection equipment
- Have sexual risk for acquiring HIV

Anyone Who Asks for HIV PrEP

Some women may not feel comfortable reporting sexual or injection behaviors in a health care setting. In addition, some women may not have a current risk for acquiring HIV, but they may anticipate a risk of acquiring HIV in the future. As such, any woman who requests HIV PrEP should be offered HIV PrEP, even if no specific indications are elicited.

Women Trying to Conceive, or Pregnant, or Breastfeeding

The risk of HIV acquisition is increased during periconception, pregnancy, and the early postpartum period through 6 months.[14] At the time of conception, condomless sex contributes to enhanced risk for HIV acquisition. Once pregnancy is achieved, the risk of HIV acquisition remains high and is thought to be multifactorial, including possible condomless sex during pregnancy, increased innate and suppressed adaptive immunity, increased genital tract inflammation, alterations of the vaginal epithelium, and trauma to the genital tract during delivery.[14] In one study, even after adjustment for age, use of HIV PrEP, and male partner HIV RNA level, the probability of HIV acquisition was 2.76 times higher throughout pregnancy and the postpartum period.[23] It is particularly important to avoid new HIV infection in pregnancy, and particularly late in pregnancy, as acute HIV is associated with high HIV RNA levels, which increases the risk of perinatal transmission.[24] Health care providers should offer and promote oral TDF-FTC as HIV PrEP for all women who are at risk for HIV, even if they are trying to conceive, are pregnant, or breastfeeding.[14]

Recommended HIV PrEP Medication Options for Women

Currently, daily oral TDF-FTC and every 2-month CAB-LA injections are the only medications that are FDA-approved for women to prevent the vaginal acquisition of HIV. Although TAF-FTC is FDA-approved for HIV PrEP, this medication has not been adequately studied in women to prevent vaginally acquired HIV, and it is not FDA-approved for this indication. Similarly, on-demand (event-driven or 2-1-1) for HIV PrEP using TDF-FTC has been studied only in men who have sex with men and not in women and therefore is not recommended in women. All women considering starting HIV PrEP require baseline laboratory studies, documentation of a negative HIV status within 7 days of starting HIV PrEP, and ongoing monitoring while taking HIV PrEP. The following summarizes the recommendations in the 2021 CDC HIV PrEP Guidelines for the use of HIV PrEP in women and pregnant women.[14,17]

Recommendations for Women

- **Tenofovir DF-Emtricitabine (TDF-FTC)**: For women, TDF-FTC is indicated for HIV PrEP to reduce the risk of sexually acquired HIV in adults and adolescents who weigh at least 35 kg (77 lb). The dosing for TDF-FTC is one tablet taken orally once daily, with or without food; typically each prescription of daily TDF-FTC for HIV PrEP medication is given to provide a 90-day supply (until the next HIV test). The use of TDF-FTC is not recommended for persons (women or men) who have an estimated creatinine clearance of less than 60 mL/min.
- **Tenofovir alafenamide-Emtricitabine (TAF-FTC)**: There are insufficient data to recommend the use of TAF-FTC for preventing vaginal acquisition of HIV in women.
- **Long-Acting Injectable Cabotegravir (CAB-LA)**: For women, CAB-LA is indicated for HIV PrEP to reduce the risk of sexually acquired HIV for individuals who weigh at least 35 kg (77 lb). CAB-LA must be administered by a health care professional. All doses of CAB-LA consist of 600 mg cabotegravir (3 mL) given as a gluteal intramuscular injection. CAB-LA can be given after an optional 28-day oral cabotegravir (30 mg once daily) lead-in, or it can be started in a direct-to-inject method. The first two doses of CAB-LA are given 4 weeks apart (initiation injections), and all subsequent doses are given 8 weeks apart. No dosage adjustments are required for persons with renal insufficiency. For more details about CAB-LA, see the Cabotegravir Guide on this website.
- **On-Demand (2-1-1) HIV PrEP**: The use of on-demand HIV PrEP has not been studied in women. Accordingly, on-demand HIV PrEP is not recommended for women at any time.

Recommendations in the Periconception Period, During Pregnancy, or with Breastfeeding

The risk for HIV acquisition should be reassessed during periconception, pregnancy, and in the postpartum period, and women should be counseled regarding the benefits and risks of HIV PrEP use in pregnancy and/or during breastfeeding. Women should also receive counseling regarding the enhanced risk of HIV acquisition for women during pregnancy and breastfeeding.

- **Tenofovir DF-emtricitabine (TDF-FTC)**: Daily, oral TDF-FTC is the preferred option for use as HIV PrEP in women who may become pregnant, are pregnant, or are breastfeeding.[14] Women who become pregnant while taking TDF-FTC should continue daily TDF-FTC for HIV PrEP during pregnancy and during breastfeeding, if they remain at risk of acquiring HIV.[14] Women who are taking TDF-FTC to prevent HIV infection during pregnancy or while breastfeeding should receive counseling about the importance of adherence with daily TDF-FTC dosing. On-demand HIV PrEP (2-1-1 dosing) using TDF-FTC should not be used by women, including women who are pregnant or breastfeeding.
- **Tenofovir alafenamide-emtricitabine (TAF-FTC)**: Due to lack of data, the use of TAF-FTC is not recommended for use in women to prevent vaginal acquisition of HIV, including in the periconception period, at any time during pregnancy, or during breastfeeding.[14,17]
- **Long-Acting Injectable Cabotegravir (CAB-LA)**: There are insufficient data regarding the safety and efficacy of CAB-LA for HIV PrEP in the periconception period, during pregnancy, or with

breastfeeding.[14] Therefore, CAB-LA is not recommended for use in any of those settings.[14,17] Since CAB-LA has such an extremely long half-life, any injection shortly before pregnancy or during pregnancy would likely generate substantial cabotegravir exposure throughout much of the pregnancy.[14] If an woman becomes pregnant while receiving CAB-LA for HIV PrEP, current guidelines recommend discussing the limited available safety data (and the long half-life of cabotegravir) with the pregnant woman and engaging in shared decision-making regarding whether to continue or stop CAB-LA; expert consultation may be beneficial in this situation.[14] If CAB-LA is stopped and HIV exposure continues, daily TDF-FTC should be started, since this medication is the preferred HIV PrEP medication for use during pregnancy, and it has an established safety record when used in this setting.[14]

Recommendations for Preventing HIV in Women Who Inject Drugs

For women who inject nonprescription drugs and weigh at least 35 kg (77 lb), the recommended HIV PrEP option is daily TDF-FTC.[17] If the woman is pregnant or becomes pregnant, the TDF-FTC can be continued, since this is also the recommended HIV PrEP regimen for use during pregnancy.

- **Tenofovir DF-emtricitabine (TDF-FTC)**: The recommended dosing of TDF-FTC is one tablet taken orally once daily, with or without food. This medication should not be prescribed if the estimated creatinine clearance is less than 60 mL/min.
- **Tenofovir alafenamide-emtricitabine (TAF-FTC)**: This medication is not FDA-approved or recommended to prevent HIV in women through injection drug use, nor is it approved or recommended for use in women to prevent acquisition of HIV through receptive vaginal sex.
- **Long-Acting Injectable Cabotegravir (CAB-LA)**: The use of CAB-LA is not recommended to prevent HIV through injection drug use since this medication has not been studied for this purpose.

Interaction of HIV PrEP Medications with Hormonal Contraception

There are no significant drug interactions expected between TDF-FTC with hormonal contraceptives.[25] Thus, concurrent use of TDF-FTC with hormonal contraceptives is permissible and does not require any dose adjustments.[25] A secondary analysis of HPTN 077 evaluated the effects of oral contraceptive use on cabotegravir concentrations in persons receiving CAB-LA.[26] Although oral contraceptive use was associated with a lower cabotegravir maximum serum concentration (Cmax) when compared to women not taking any oral contraception, there were no significant differences in other cabotegravir pharmacokinetic parameters.[26] Thus, cabotegravir can be used with oral contraceptives and without any required dose adjustment.[27]

Baseline Laboratory Evaluation for Women Starting HIV PrEP

For women, the recommendations in the 2021 CDC HIV PrEP Guidelines for baseline evaluation and baseline laboratory studies are the same as outlined for other persons starting on and receiving HIV PrEP, with the exception that all women of childbearing age should have pregnancy testing before starting HIV PrEP.[17] A positive pregnancy test does not preclude a woman from receiving HIV PrEP, but counseling should occur regarding current understanding of the safety and efficacy of HIV PrEP during pregnancy. The routinely recommended baseline evaluation and laboratory studies are summarized and discussed in detail in the *HIV PrEP Fundamentals* module lesson on Baseline Evaluation and Starting HIV PrEP. In addition, summary tables for initial and follow-up laboratory studies are available in the Laboratory Monitoring Guide on this website.

Time for Women to Achieve Protection After Initiating HIV PrEP

There is no optimal guidance on how long it takes to achieve protection after initiating HIV PrEP, including for women having receptive vaginal sex.[17] Pharmacokinetic studies with tenofovir DF-emtricitabine suggest maximal intracellular concentrations of tenofovir diphosphate are reached in cervicovaginal tissues at approximately 20 days, which is significantly longer than the estimated 7 days required for maximum rectal tissue levels.[17] There are no clear recommendations for counseling women on the exact time until HIV PrEP medications are reliably protective. The effect of taking an initial double dose of TDF-emtricitabine, such as used in the IPERGAY on-demand HIV PrEP study, on the time to reach protective cervicovaginal concentrations remains unknown. In general, tenofovir levels are much higher in rectal tissue than in cervicovaginal tissue, and it does take longer to reach protective levels in the cervicovaginal tissues. The following summarizes limited data on this topic.

- **TDF-FTC:** In a study of 15 individuals (8 males and 7 females) given a single dose of TDF-FTC and followed for the next 14 days, tenofovir and emtricitabine concentrations were measured in their blood plasma, and the active phosphorylated forms (tenofovir diphosphate and emtricitabine triphosphate) were measured in genital secretions.[28] In rectal tissues, tenofovir and tenofovir diphosphate concentrations were detectable for 14 days and were 100-fold higher than concentrations in vaginal and cervical tissues.[28] In contrast, after a single oral dose of emtricitabine, tissue concentrations of emtricitabine triphosphate measured 14 days later were 10- to 15-fold higher in cervical and vaginal tissues than in rectal tissues.[28]
- **TAF-FTC**: Less is known about the efficacy or levels of daily TAF-FTC in women. In a study that assessed the pharmacokinetics of tenofovir diphosphate concentrations in 99 women without HIV who were given either TDF-FTC or TAF-FTC, the tenofovir diphosphate concentrations in vaginal tissues were approximately 6-fold higher in women who received TAF-FTC than in those who received TDF-FTC.[29] Conversely, in the rectum, tenofovir diphosphate levels were lower in women who received TAF-FTC than in those who received TDF-FTC, though still above the protective levels.[29]
- **Cabotegravir**: There are no data yet available about the time to protection with lead-in oral cabotegravir or with directly initiating HIV PrEP with CAB-LA (without an oral lead-in).[17]

Follow-Up and Laboratory Monitoring for Women Receiving HIV PrEP

For women, the recommendations in the 2021 CDC HIV PrEP Guidelines for routine follow-up clinical evaluations and follow-up laboratory studies are the same as outlined for other persons receiving HIV PrEP, with the exception that all women of childbearing age should have pregnancy testing conducted regularly as part of the laboratory monitoring while they are receiving HIV PrEP.[17] A positive pregnancy test does not preclude a woman from continuing on HIV PrEP, but counseling should occur regarding current understanding of the safety and efficacy of HIV PrEP during pregnancy. The clinical follow-up and recommended monitoring laboratory studies are summarized and discussed in detail in the *HIV PrEP Fundamentals* Module lesson on Follow-Up Care and Monitoring on HIV PrEP. In addition, summary tables for follow-up laboratory studies are available in the Laboratory Monitoring Guide on this website.

Summary Points

- Women account for approximately 18% of new HIV diagnoses in the United States, and thus prevention of HIV in women is a significant priority.
- Although daily oral TDF-FTC and CAB-LA have been shown to be effective as HIV PrEP in women, HIV PrEP uptake in women remains low. The CDC recommends informing all sexually active adults, including adult women, about HIV PrEP.
- The major indication for HIV PrEP in sexually active women is a history of vaginal or anal sex in the past 6 months in conjunction with either a bacterial STI, a history of inconsistent or no condom use with sex partners, or a sex partner with HIV.
- Other potential indications for HIV PrEP in women include injection drug use.
- In addition, any woman who asks for HIV PrEP should be considered for HIV PrEP. The rationale for this recommendation is that some women may not disclose HIV acquisition risks and some may anticipate risks of acquiring HIV in the future.
- Women who may become pregnant should receive counseling regarding the increased risk of HIV acquisition during periconception, pregnancy, and the early postpartum period.
- Recommended HIV PrEP options for women include TDF-FTC or CAB-LA. The use of TAF-FTC is not recommended for preventing HIV acquisition through receptive vaginal sex.
- The use of on-demand HIV PrEP, including on-demand with TDF-FTC, has not been studied for preventing HIV acquisition through vaginal sex and is not recommended for this indication.
- Daily oral TDF-FTC is the only recommended HIV PrEP option for women who are seeking conception, are pregnant, or are breastfeeding. There are insufficient HIV PrEP data regarding the use of TAF-FTC, CAB-LA, or on-demand (2-1-1) TDF-FTC in these settings.
- Women receiving hormonal contraceptives can receive concomitant HIV PrEP with either TDF-FTC or CAB-LA.

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Figures

Figure 1 HIV PrEP Coverage for Women

Source: Centers for Disease Control and Prevention. Core indicators for monitoring the Ending the HIV Epidemic initiative (preliminary data): National HIV Surveillance System data reported through September 2022; and preexposure prophylaxis (PrEP) data reported through June 2023. HIV Surveillance Data Tables 2023;4(No. 4). Published December 2023.

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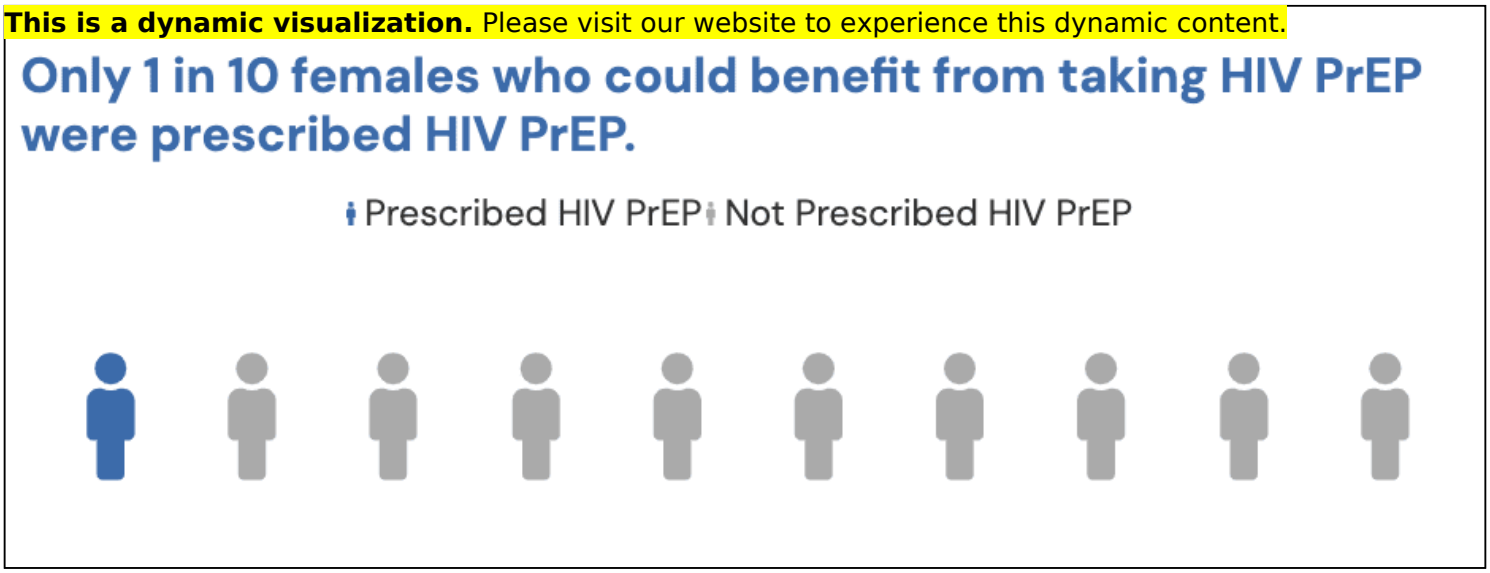

Figure 2 New HIV Diagnoses Among Women in the United States

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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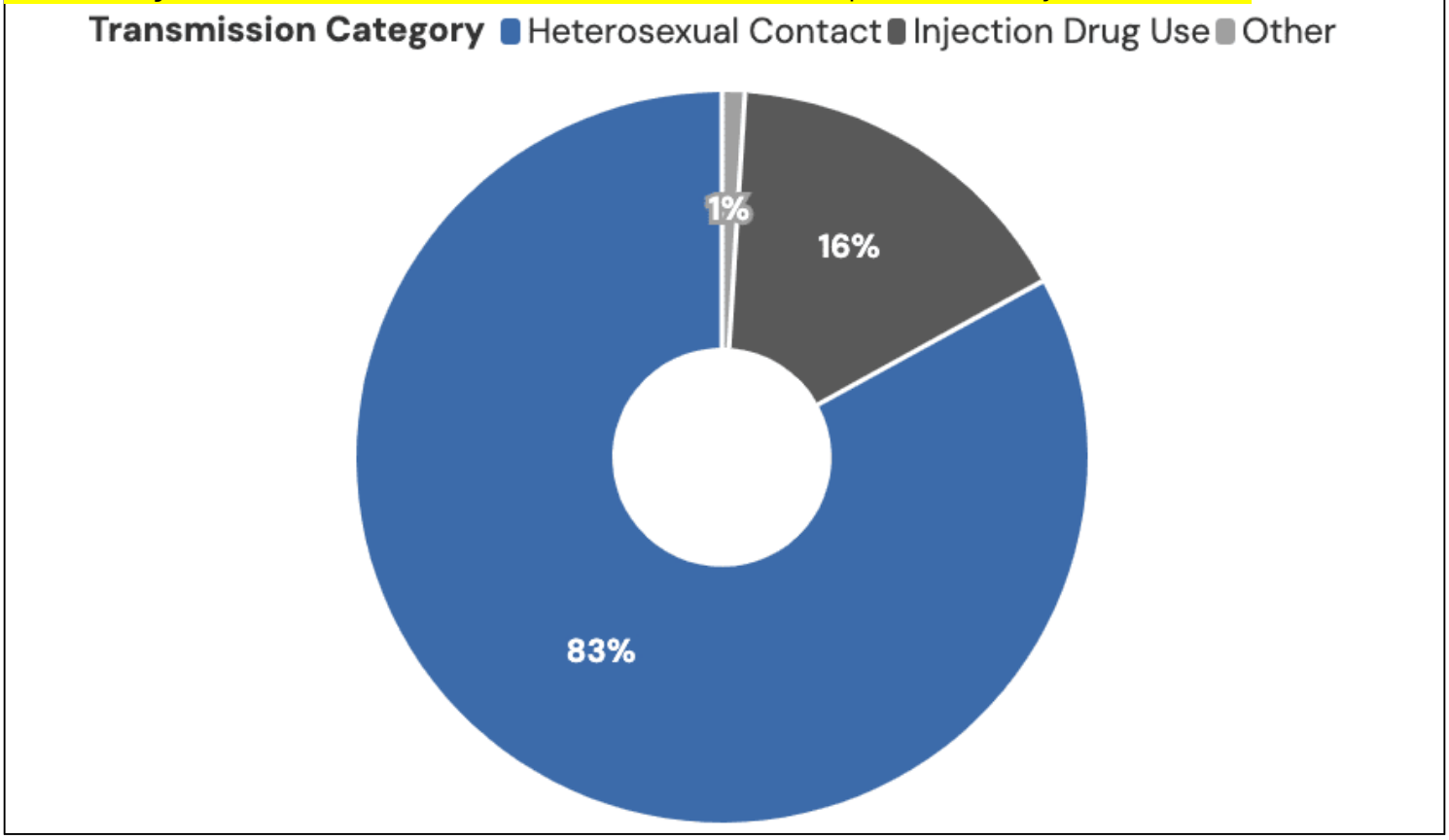

Figure 3 Partners PrEP Study: HIV PrEP for Heterosexual Men and Women

Source: Baeten JM, Donnell D, Ndase P, et al. N Engl J Med. 2012;367:399-410.

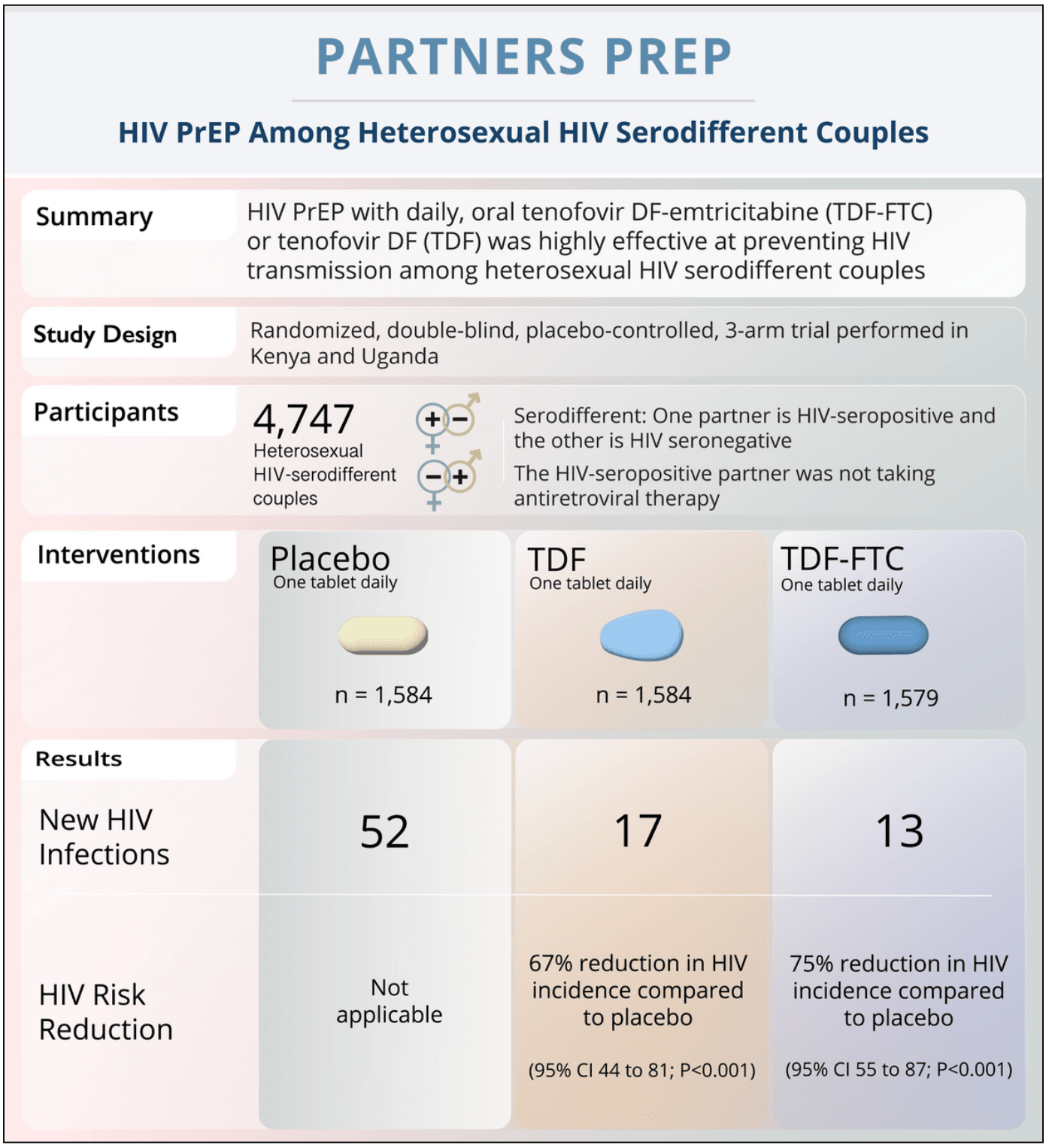

Figure 4 Study TDF2: HIV PrEP for Heterosexual Men and Women in Botswana

Source: Thigpen MC, Kebaabetswe PM, Paxton LA, et al. N Engl J Med. 2012;367:423-34.

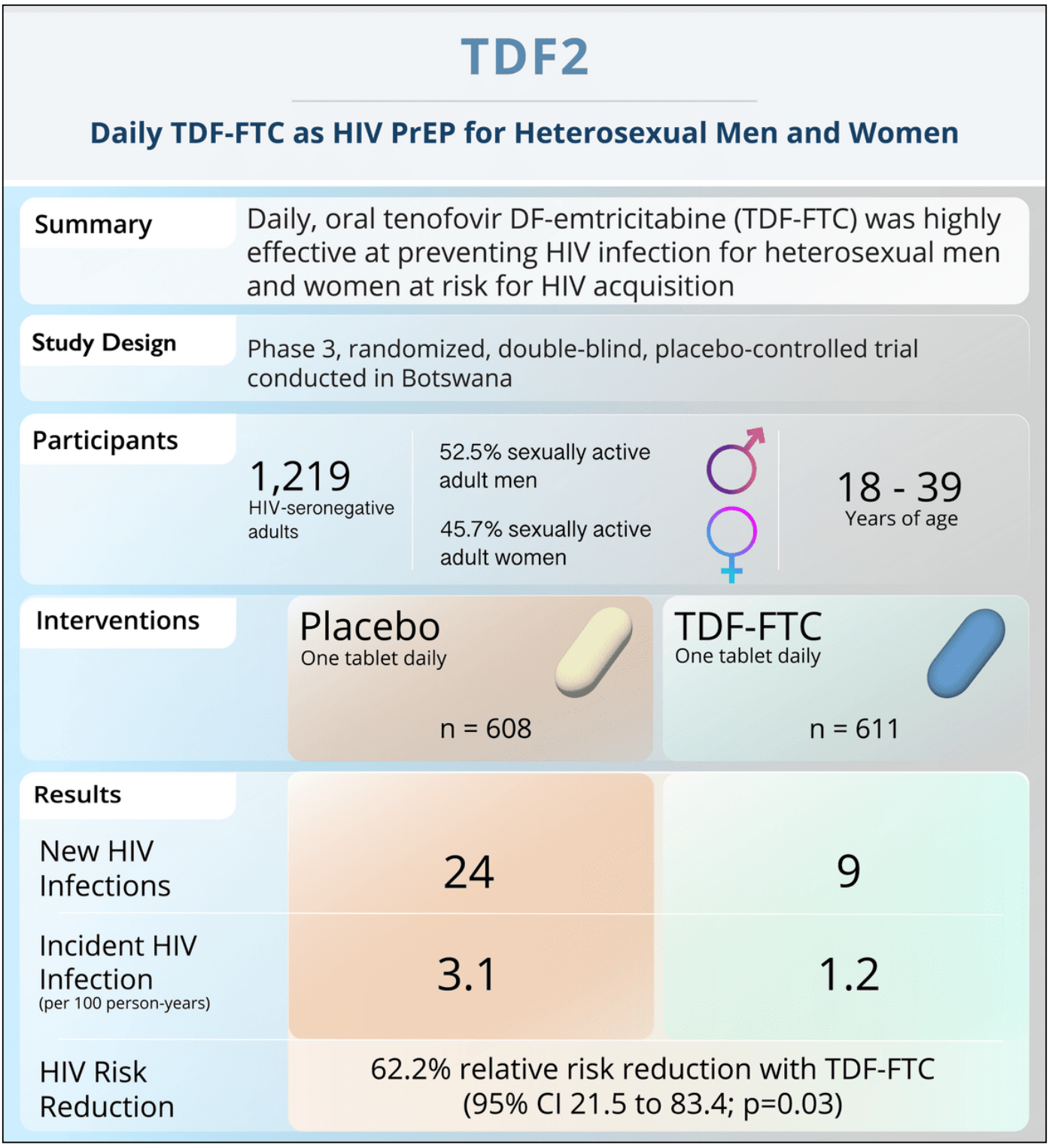

Figure 5 Study HPTN 084: Cabotegravir for the Prevention of HIV-1 in Women

Source: Delany-Moretlwe S, Hughes JP, Bock P, et al. Lancet. 2022;399:1779–89.