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.[1,2,3] 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).[4,5,6] In 2021, only 7% of the HIV PrEP prescriptions written in the United States were for women.[5] 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.[5] 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. This lesson will address the use of HIV PrEP in women, including use of HIV PrEP in pregnant women.

Epidemiology of HIV in Women

The following discussion is based on CDC HIV Surveillance Reports for females, including women and girls.[3] In 2022, there were an estimated 5,900 new HIV infections among females (13 years of age and older) in the United States.[3] There was a steady, slight decrease in new HIV infections in women during the years 2018-2022, with the exception that the estimated number in 2020 was artificially low due to inadequate reporting during the COVID-19 pandemic.[3] The number of new HIV infections in the United States in 2022 was much higher in males than in females, with females accounting for just under one-fifth of the new infections. In 2022, females with new HIV infections in 2022 acquired HIV primarily through heterosexual sex (83%)and less often via injection drug use (17%).[2] Among different racial/ethnic groups, the estimated number of new HIV infections among females in 2022 was highest among Black females, accounting for nearly half of the new infections in females (Figure 2).[2]

[Q] HIV Acquisition Risk in Women

Evidence for HIV PrEP in Women

As compared with 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), oral tenofovir alafenamide-emtricitabine (TAF-FTC), long-acting injectable cabotegravir (CAB-LA), and lenacapavir subcutaneous injections (LEN-SQ). In addition, there are no published phase 2b or phase 3 studies that were designed to evaluate HIV PrEP in pregnant or breastfeeding 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).[7] Among all couples enrolled, 38% of the HIV seronegative partners were women.[7] 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.[7] 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.[7] Among the HIV seronegative women enrolled, when compared with placebo, the efficacy of TDF was 71% and TDF-FTC was 66%.[7] 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.[7]
- **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).[8] 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).[8] 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).[8]

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).[9] 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.[9] 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.[9]
- **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.[10] Participants were seen at monthly follow-up visits, and the study drugs were discontinued among women who became pregnant during the trial.[10] 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.[10] Adherence was low in this trial, with detectable plasma drug levels in less than 50% of the women assigned to TDF-FTC.[10]
- **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.[11] 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.[11] The study was stopped in the group receiving oral TDF and the group receiving topical tenofovir after interim analysis determined futility.[11] 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.[11]

- **PURPOSE-1**: The PURPOSE-1 trial was a phase 3, randomized, double-blind HIV PrEP study comparing oral TAF-FTC, oral TDF-FTC, and LEN-SQ among 5,338 adolescent and young women, not using HIV PrEP at enrollment, from South Africa and Uganda (Figure 6).[12] Participants were randomized 2:2:1 comparing LEN-SQ administered every 26 weeks, daily oral TAF-FTC, and daily oral TDF-FTC.[12] There were zero new HIV infections among the 2,134 participants who received LEN-SQ (HIV incidence 0 per 100 person years) compared with 39 of 2,136 participants who received TAF-FTC (HIV incidence 2.02 per 100 person years), and 16 of 1,068 of the participants who received TDF-FTC (HIV incidence 1.69 per 100 person years).[12] Participants who became pregnant could remain in the trial and continue the trial drug after a new informed-consent process reviewing the risks and benefits. Adherence with oral HIV PrEP was low.[12] A subsequent unpublished analysis of women in the TAF-FTC arm reported an 89% reduction in risk for HIV acquisition in women in the study who had biomarker evidence of taking at least a mean of 2 doses of TAF-FTC per week.[13]

HIV PrEP Studies Enrolling Women Who Inject Drugs

- **Bangkok Tenofovir Study**: The Bangkok Tenofovir Study (BTS) was a phase 2/3, CDC-sponsored, double-blind, placebo-controlled trial that randomized 2,413 HIV-seronegative persons who inject drugs (PWID) to receive either daily oral tenofovir DF (TDF) or placebo.[14] Among the enrolled participants, 20% were women. All participants also received access to addiction support services, methadone programs, bleach for cleaning needles, condoms, and primary care medical services.[14] After a median follow-up time of 4.6 years, the relative risk reduction in HIV was 49% among study participants in the TDF arm; the relative risk reduction was 70% in a subgroup analysis of individuals with detectable plasma tenofovir levels. Among 1,007 women enrolled in the trial, there were only 2 new HIV infections; the relative risk reduction was 79% in women.[14][Q] PURPOSE 1

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.[15] During pregnancy, HIV PrEP is efficacious, but pharmacokinetics and pharmacodynamics that impact medication levels can be altered during pregnancy.[16] Although pharmacokinetic data for HIV PrEP use in pregnancy are minimal, some studies have demonstrated lower drug levels during pregnancy.[17,18] Thus, daily adherence is important if taking oral HIV PrEP during pregnancy. When oral 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.[16,19] Data regarding efficacy of injectable HIV PrEP options during pregnancy are more limited.

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.[16,19]

- **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).[20] 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.[20] 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.[20]
- **Partners PrEP Study**: In the Partners PrEP Study, a total of 431 pregnancies occurred.[15] 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.[15] Among pregnant women in the three study arms, there were no statistically significant differences in pregnancy loss, preterm birth, birth anomalies, or infant growth.[15]
- **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.[21] 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.[21]
- **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.[22]
- **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.[23]

- **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.[9] For these pregnancies, none were associated with a neural tube defect or other congenital abnormality.[9] A secondary analysis of pregnant women during the blinded phase of HPTN 084 reported similar safety outcomes between those in the CAB-LA arm and those in the TDF-FTC arm.[24] Further evaluation will be conducted on CAB-LA related to pregnancy and breastfeeding in the ongoing unblinded phase of the HPTN 084 study.[9]
- **PURPOSE 1**: In the PURPOSE-1 trial, women were randomized to receive LEN-SQ, oral TDF-FTC, or oral TAF-FTC.[12] Among the 2,134 women enrolled in the LEN-SQ arm, there were 193 pregnancies and at the time of the analyses, 54.4% of the pregnancies completed and 45.6% were ongoing.[12] Of the 105 completed pregnancies, 55 resulted in birth and 50 were interrupted; 20 were spontaneous abortions and 30 were induced abortions.[12] In one woman in the LEN-SQ arm, a congenital anomaly of polydactyly was observed in an infant born to a woman who had a strong family history of polydactyly; investigators concluded this was likely unrelated to the HIV PrEP medication.[12] Overall, the limited human data that exist on use of LEN-SQ during pregnancy suggest no increases in drug-associated risks for adverse pregnancy, birth, or infant outcomes when compared with daily oral HIV PrEP or background rates.[25]

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.[26] Tenofovir was not detected in 94% of plasma samples from infants.[26] 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.[16] Currently, CAB-LA is not recommended for women who are breastfeeding due to inadequate data.[19] The Tshireletso Clinical Trial will evaluate the safety, efficacy, and feasibility of CAB-LA in postpartum women who are breastfeeding in Botswana. There are limited human data regarding the use of LEN-SQ during breastfeeding, but available data suggest no increases in drug-associated risks for adverse infant outcomes when compared with daily oral HIV PrEP or background rates.[25] In addition, further analysis of postpartum women in the PURPOSE-1 trial is planned to evaluate breastmilk and infant pharmacokinetic data.

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.[19] 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.[19]

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.[16] 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.[16] 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.[27] 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.[28] 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.[16] Similarly, CAB-LA or LEN-SQ for HIV PrEP may be initiated or continued in women who may become pregnant while receiving injections, if after shared decision-making, it is determined that anticipated benefits outweigh risks.[19,25]

Recommended HIV PrEP Medication Options for Women

Daily oral TDF-FTC, every 2-month CAB-LA injections, and every 6-month LEN-SQ injections& are FDA-approved for women to prevent the vaginal acquisition of HIV. Although TAF-FTC is not FDA-approved as HIV PrEP to prevent the vaginal acquisition of HIV, unpublished data from the PURPOSE-1 trial suggest an 89% reduction in risk for HIV acquisition in women who had biomarker evidence of taking at least a mean of 2 doses of TAF-FTC per week.[13] In addition, 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 thus 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. For details on baseline laboratory testing and laboratory monitoring while on HIV PrEP, see the Laboratory Monitoring Guide on this website. The following summarizes the recommendations in the 2021 CDC HIV PrEP Guidelines and the 2025 CDC LEN-SQ HIV PrEP Guidelines for the use of HIV PrEP in women and pregnant women.[19,25]

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

Hormonal Contraception in Women Taking HIV PrEP

Health care professionals should offer all women at risk of acquiring HIV counseling about reproductive goals and contraception options, and they should emphasize the importance of HIV prevention measures, including treatment as prevention strategies in partners with HIV, limiting the number of sex partners, the correct and consistent use of condoms, and availability of HIV PrEP and HIV PEP, regardless of the method of contraception chosen.

Hormonal Contraception Use and Risk of HIV Acquisition

Systematic reviews of available data have concluded that no clear association exists between the use of non-injectable hormonal contraceptives, such as oral contraceptive pills, intrauterine devices, and implants, and the risk of HIV acquisition.[29,30,31,32] In contrast, several observational studies have suggested a possible increased risk of HIV acquisition with the use of the injectable progestin-only contraceptive DMPA.[33,34,35,36,37] Experts proposed several possible mechanisms for the observed increased risk of HIV acquisition associated with DMPA, including biologic changes (thinning of the vaginal epithelium or changes in vaginal flora), immune system changes (alteration in cytokines and antimicrobial peptides, increased inflammation, increased frequency of activated HIV target cells in the cervix, and changes in CCR5 expression), and behavioral factors (decreased condom use in the setting of reliable contraception).[30,35,38,39] Other studies, however, have contradicted concerns of DMPA and enhanced HIV acquisition, and several recent systematic reviews found no increased risk of HIV acquisition with the non-DMPA injectable progestin norethisterone enanthate (NET-EN).[33,40,41] The results of a randomized, open-label trial of intramuscular DMPA, copper IUDs, and levonorgestrel implants were published in 2019; this study, which enrolled approximately 7,800 women seronegative for HIV across multiple sites in 4 African countries, did not find any of these contraception methods to be associated with a higher rate of HIV acquisition.[42]

Hormonal Contraception in Women at Risk for HIV

The Centers for Disease Control and Prevention U.S. Medical Eligibility Criteria for Contraceptive Use (CDC U.S. MEC) uses a rating system to categorize the relative risks and benefits of each method of contraception depending on a woman's medical comorbidities or medication use (Table 1).[43] In general, the CDC U.S. MEC guidance pertaining to the use of hormonal contraception in women states that all hormonal contraception options should be available to women with enhanced risk of acquiring HIV.[43]

Although most contraceptives are not associated with an increased risk of HIV acquisition, there are concerns regarding the following two options:

- **Progestin-Only Injectable Contraception (including DMPA)**: Despite conflicting data about an increased risk of HIV acquisition in women using progestin-only injectable contraception (including DMPA), the advantages of these methods outweigh theoretical or proven risks, and progestin-only injectable contraception may be initiated or continued without restriction in women at high risk for HIV without restriction (category 1). Women considering progestin-only injectable contraception should be counseled about the concerns of increased risk of HIV acquisition in women while using this method, the unclear causal relationship, and strategies to minimize the risk of HIV infection.
- **Spermicides**: Use of spermicides containing nonoxynol-9 should not be used in women with or at risk of acquiring HIV due to concerns about this spermicide causing genital lesions, which could lead to increased risk of transmission and acquisition of HIV. Whether used alone, with condoms, or with a diaphragm, spermicides are rated category 4 (unacceptable health risk) in women at risk of acquiring HIV.

Interaction of HIV PrEP Medications with Hormonal Contraceptives

There are no significant drug interactions expected between oral HIV PrEP medications with hormonal contraceptives.[44] Thus, concurrent use of oral HIV PrEP medications with hormonal contraceptives is permissible and does not require any dose adjustments.[44] A secondary analysis of HPTN 077 evaluated the effects of oral contraceptive use on cabotegravir concentrations in persons receiving CAB-LA.[45] 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.[45] Thus, cabotegravir can be used with oral contraceptives and without any required dose adjustment.[46] Although lenacapavir has many drug interactions, no dose adjustments are necessary when used in conjunction with hormonal contraceptives.

Baseline Laboratory Evaluation for Women Starting HIV PrEP

For women starting HIV PrEP, the recommendations in the 2021 CDC HIV PrEP Guidelines and 2025 CDC LEN-SQ HIV PrEP Guidelines for baseline laboratory evaluation are the same as the general recommendations outlined for other persons starting HIV PrEP, with the exception that all women of childbearing age should have pregnancy testing before starting HIV PrEP.[19,25] 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.[19] 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.[19] 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 in men who have sex with men, 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.[47] 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.[47] 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.[47]
- **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.[48] Conversely, in the rectum, tenofovir diphosphate levels were lower in women who received TAF-FTC than women who received TDF-FTC, though still above the protective levels.[48]
- **Long-Acting Injectable Cabotegravir (CAB-LA)**: 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).[19]
- **Lenacapavir Subcutaneous Injection (LEN-SQ)**: Limited pharmacokinetic data suggest time to protection with LEN is achieved 2 hours after the 600 mg oral lenacapavir dose is administered on day 2, provided both days of oral loading (600 mg per day) are taken.[25]

Follow-Up and Laboratory Monitoring for Women Receiving HIV PrEP

For women taking HIV PrEP, the recommendations in the 2021 CDC HIV PrEP Guidelines and 2025 CDC LEN-SQ HIV PrEP Guidelines for routine follow-up laboratory monitoring are the same as outlined for the general recommendations for all 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.[19] 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, CAB-LA, and LEN-SQ have been shown to be effective as HIV PrEP in women, the uptake of HIV PrEP 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 and approved HIV PrEP options for women include TDF-FTC, CAB-LA, and LEN-SQ. The use of TAF-FTC is not currently approved 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 and LEN-SQ are the recommended HIV PrEP options for women who are seeking conception, are pregnant, or are breastfeeding. The use of LEN-SQ in this setting should be done with shared decision-making involving the medical provider and the woman taking HIV PrEP. There are insufficient HIV PrEP data regarding the use of CAB-LA in this setting.
- Women receiving hormonal contraceptives can receive concomitant HIV PrEP with TDF-FTC, CAB-LA, or LEN-SQ.

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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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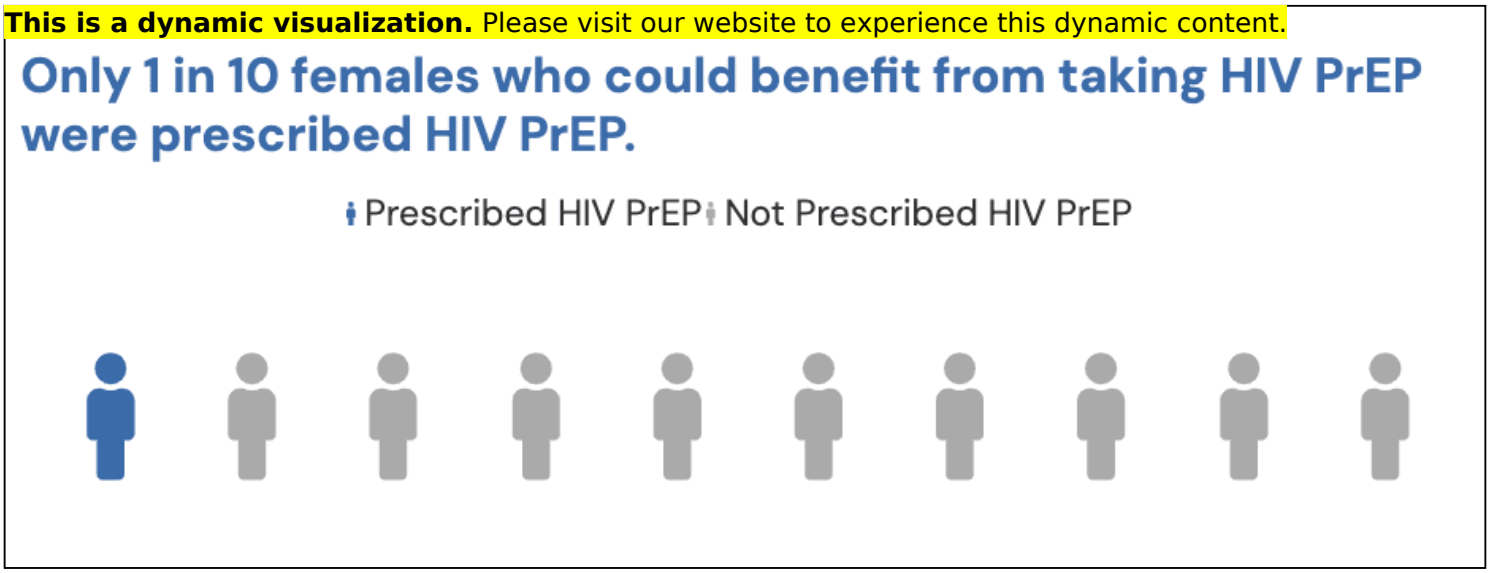

Figure 2 New HIV Infections Among Females in the United States

Source: Centers for Disease Control and Prevention. Estimated HIV Incidence and Prevalence in the United States, 2018–2022. HIV Surveillance Supplemental Report. 2024;29(No. 1):1-131. Published May 2024.

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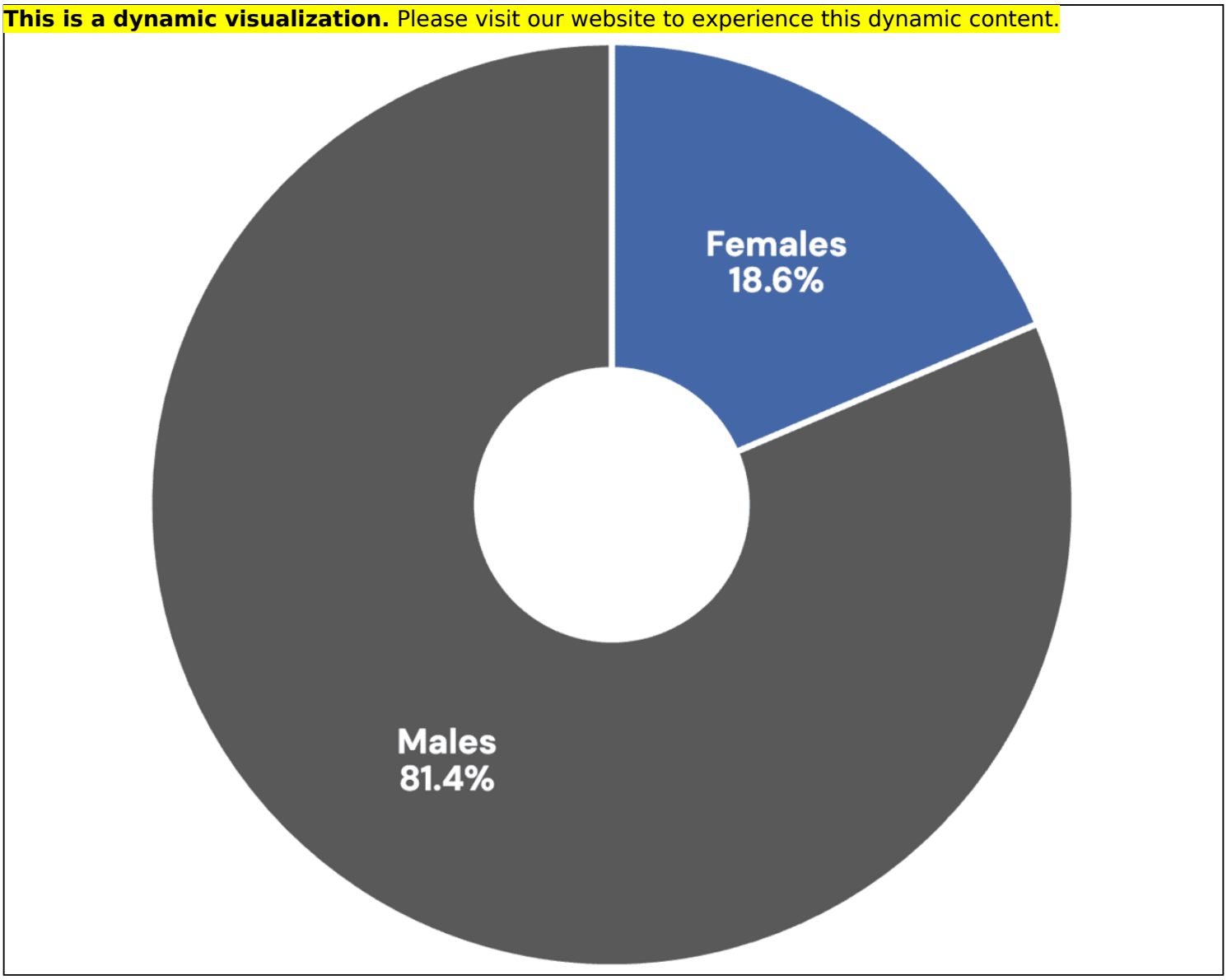

Figure 3 Partners HIV PrEP: HIV PrEP for Heterosexual Men and Women

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

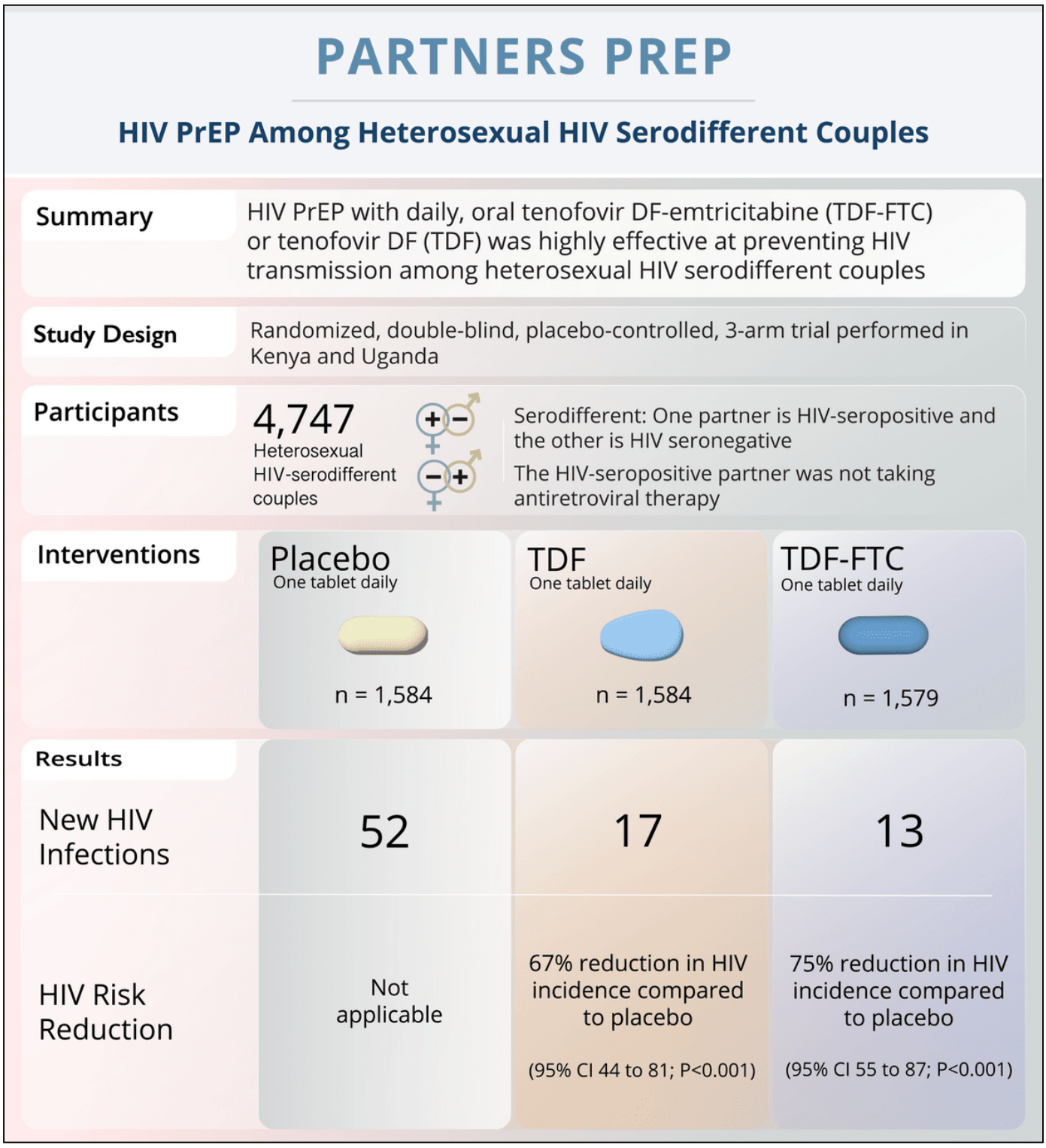

Figure 4 TDF2: HIV PrEP for Heterosexual Men and Women in Botswana

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

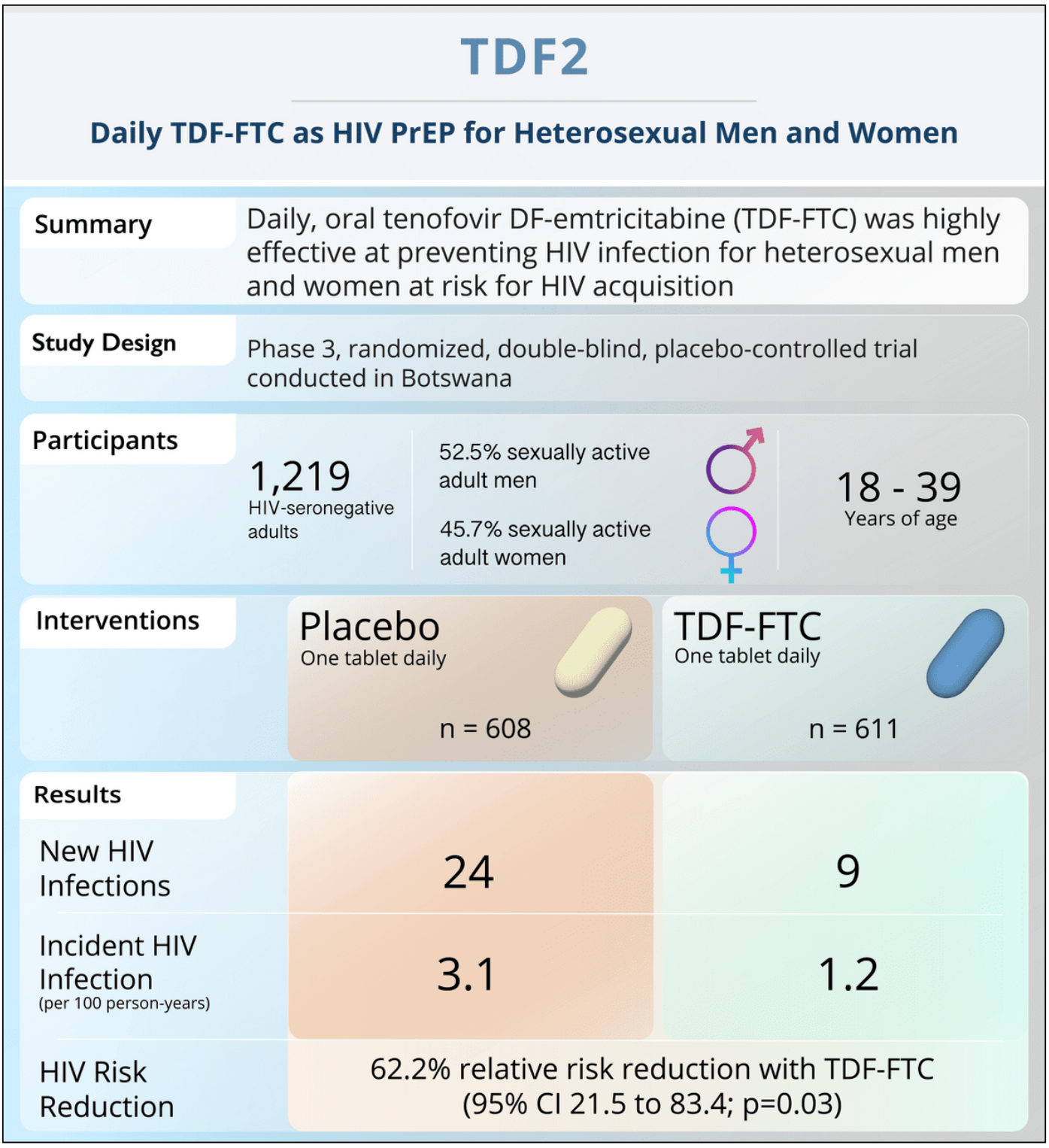

Figure 5 HPTN 084: Long-Acting Injectable Cabotegravir for the Prevention of HIV-1 in Women

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

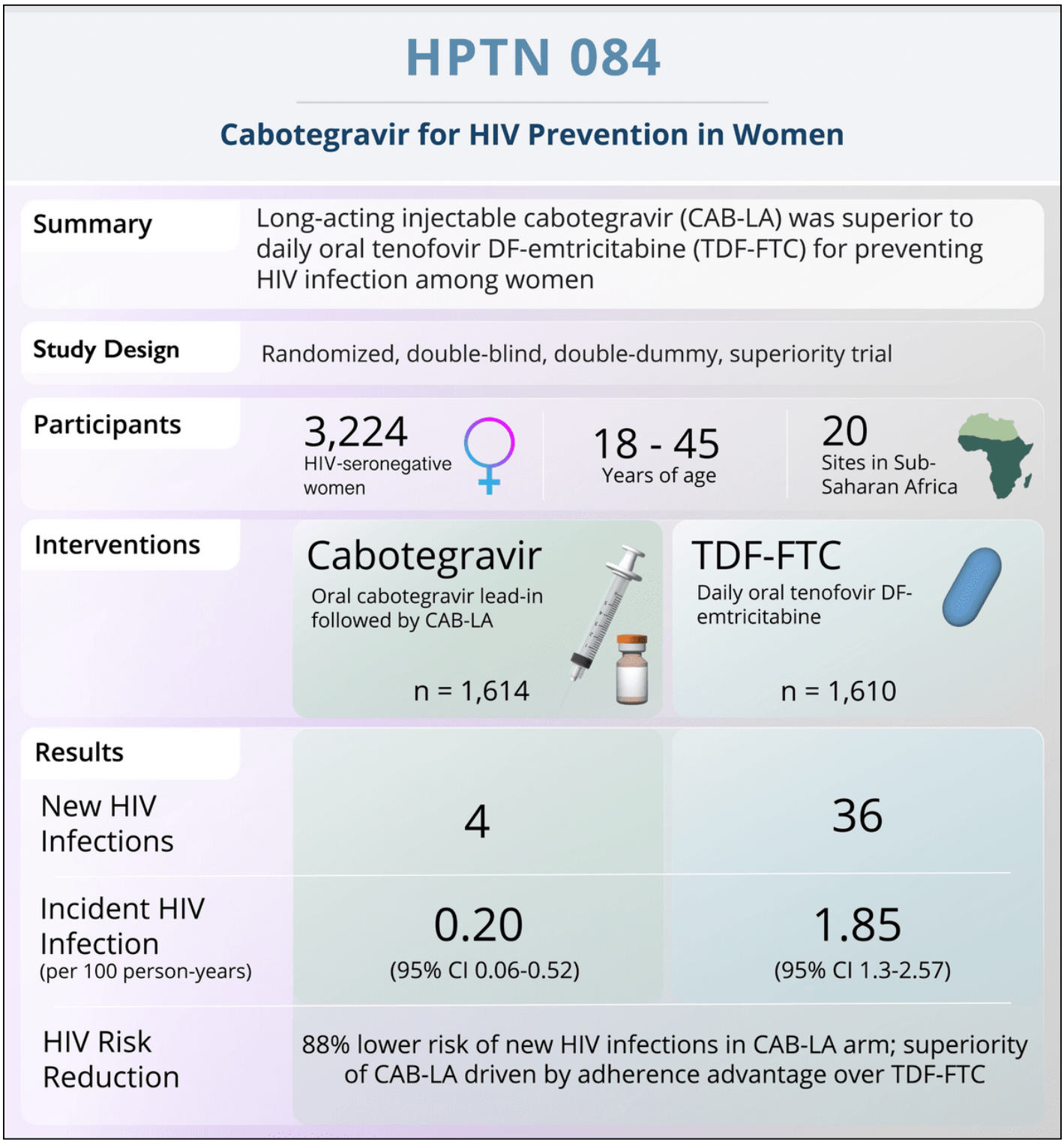

Figure 6 PURPOSE 1: Lenacapavir Subcutaneous Injection for the Prevention of HIV-1 in Women

Source: Bekker LG, Das M, Karim QA, et al. N Engl J Med. 2024;391:1179-92.

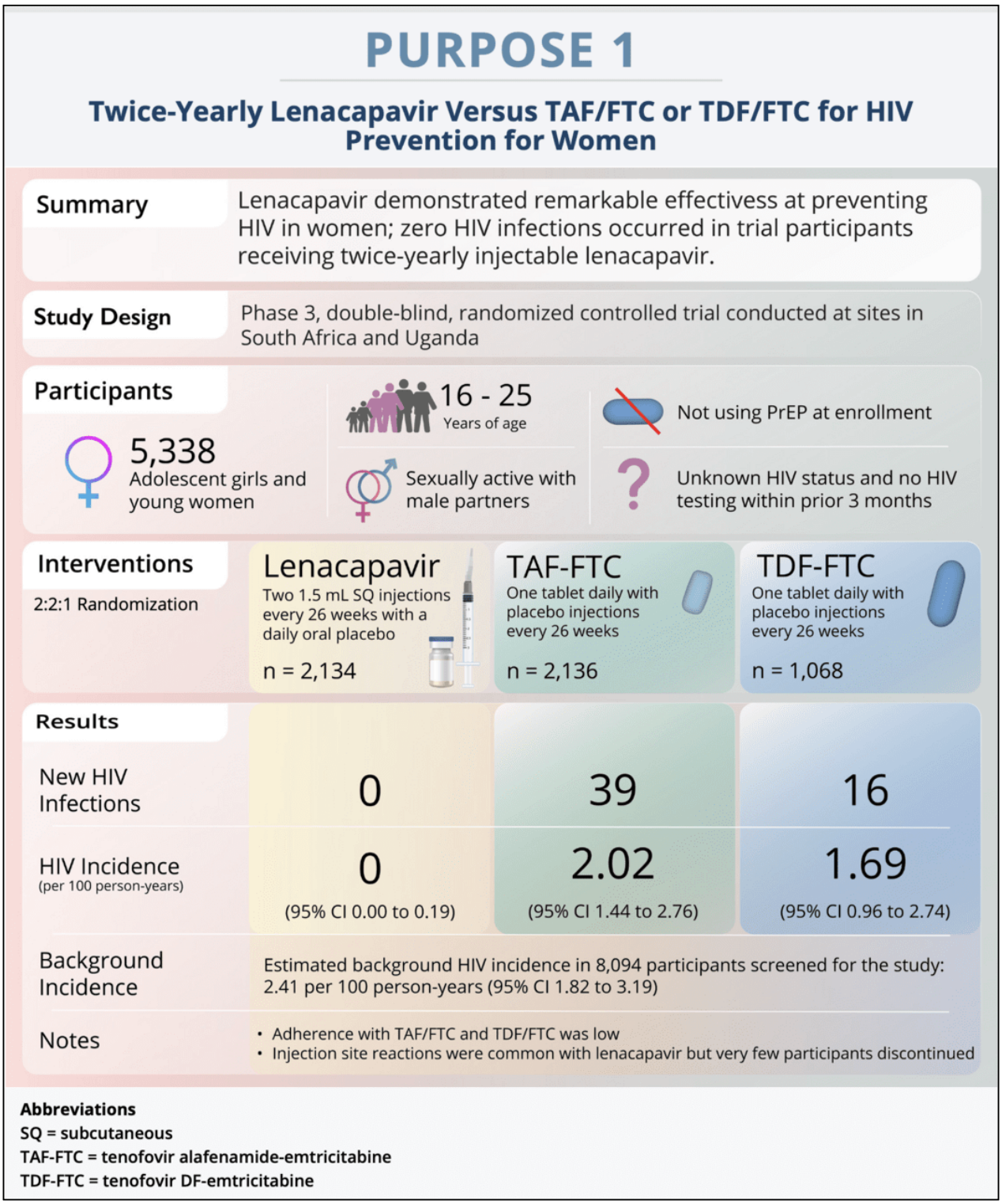

Table 1. Guidance for Contraceptive Use in Women at High Risk for HIV Infection

Copper-Containing IUD*		LNG-IUD		Implants	DMPA	POP	CHCs
Initiation	Continuation	Initiation	Continuation				
1	1	1	1	1	1	1	1

*__Clarification with IUDs__: Many women at high risk for HIV are also at risk for other sexually transmitted diseases (STDs). For these women, refer to the recommendations in the “U.S. Medical Eligibility Criteria for Contraceptive Use” for women with other factors related to STDs and the “U.S. Selected Practice Recommendations for Contraceptive Use” on STD screening before IUD insertion.

Evidence (IUDs): High-quality evidence from one randomized clinical trial, along with low-quality evidence from two observational studies, suggested no increased risk for HIV acquisition with Cu-IUD use.§ No studies were identified for LNG-IUDs.¶

Evidence (implants, DMPA, POP): High-quality evidence from one randomized clinical trial observed no statistically significant differences in HIV acquisition between DMPA-IM versus Cu-IUD, DMPA-IM versus LNG implant, and Cu-IUD versus LNG implant.¶,** Of the low-to-moderate-quality evidence from 14 observational studies, some studies suggested a possible increased risk for HIV with progestin-only injectable use, which was most likely due to unmeasured confounding.¶ Low-quality evidence from 3 observational studies did not suggest an increased HIV risk for implant users.¶ No studies of sufficient quality were identified for POPs.¶

Evidence (CHCs): Low-to-moderate-quality evidence from 11 observational studies suggested no association between COC use (it was assumed that studies that did not specify oral contraceptive type examined mostly, if not exclusively, COC use) and HIV acquisition.¶ No studies of patch, ring, or combined injectable contraception were identified.¶

Abbreviations: IUD= intrauterine device; LNG-IUD = levonorgestrel-releasing intrauterine device; DMPA = depot medroxyprogesterone acetate (injectable); POP = progestin-only pill; CHC = combined hormonal contraceptive

*Curtis KM, Tepper NK, Jatlaoui TC, Berry-Bibee E, Horton LG, Zapata LB, et al. U.S. medical eligibility criteria for contraceptive use, 2016. MMWR Recomm Rep 2016;65(No. RR-3).

†Curtis KM, Jatlaoui TC, Tepper NK, et al. U.S. selected practice recommendations for contraceptive use, 2016. MMWR Recomm Rep 2016;65(No. RR-4).

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** Evidence for Contraceptive Options and HIV Outcomes (ECHO) Trial Consortium. HIV incidence among women using intramuscular depot medroxyprogesterone acetate, a copper intrauterine device, or a levonorgestrel implant for contraception: a randomized, multicentre, open-label trial. Lancet 2019;394:303–13.

Summary of Categories for classifying contraceptives

1 = A condition for which there is no restriction for the use of the contraceptive method.

2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.

3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.

4 = A condition that represents an unacceptable health risk if the contraceptive method is used.