HIV PrEP for Adolescents and Young Adults

This is a PDF version of the following document:
Module 2: HIV PrEP In-Depth Topics
Lesson 1: HIV PrEP for Adolescents and Young Adults

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Background

Adolescence and young adulthood are stages of life that often encompass sexual debut, sexual exploration, and sexual experimentation.[1] When these periods intersect with activities such as substance use or decreased condom use, youth become increasingly prone to HIV acquisition.[1] In 2022, individuals aged 13 to 24 years of age accounted for approximately 20% of persons who newly acquired HIV in the United States.[2] For youth living in the United States, HIV preexposure prophylaxis (PrEP) is a known, effective, data-proven biomedical tool for HIV prevention.[3] In 2012, tenofovir DF-emtricitabine (TDF-FTC) was approved by the US Food and Drug Administration (FDA) for HIV PrEP in adults, but there was little initial uptake among young adults. In 2018, the FDA changed the criteria for HIV PrEP in youth to be based on weight, with approval for those weighing at least 35 kg (77 lb).[3]

HIV PrEP Coverage for Youth

In the United States, HIV PrEP has been underused as an HIV prevention tool in adolescents and young adults (Figure 1).[4] In 2022, only about 24% of youth 16–24 years of age who had an indication for PrEP actually received HIV PrEP (the percentage of people receiving HIV PrEP versus those with an HIV PrEP indication is often referred to as “PrEP coverage”).[4] Several studies have identified barriers in the HIV PrEP care cascade for adolescents, including lack of HIV PrEP awareness among adolescents or their guardians, reluctance to use HIV PrEP, and under prescribing by clinicians for adolescents who have a substantial risk of acquiring HIV.[5,6] These studies underscore the need for a multipronged approach to addressing deficits in the HIV PrEP care cascade—from awareness to prescribing to uptake to adherence, in order to successfully harness HIV PrEP to advance the goal of ending the HIV epidemic in the United States. Further, several factors among clinicians contribute to low HIV PrEP prescribing for youth, including lack of knowledge, hesitancy to prescribe, and inability to effectively conduct sexual history discussions with youth.

Epidemiology of STIs and HIV in Youth

Youth Sexual Health Behaviors

National surveillance data suggest that many adolescents in the United States may be engaging in activities that place them at risk for acquiring HIV. The Youth Risk Behavior Surveillance System (YRBSS) is a population-based data tool used by the CDC to monitor different categories of health behaviors among students in grades 9 through 12 in the United States.[7] Sexual risk behavior data from the 2023 YRBSS for high school students indicates that 32% of high school students reported ever having sexual intercourse; the percentage was similar for females (31%) and males (32%).[7] Among students who reported being sexually active, only 52% reported condom use at their last sexual encounter.[7] In this survey, only 7% of students had ever been tested for HIV, highlighting ongoing gaps in HIV prevention and screening among adolescents.[7]

STIs in Adolescents and Young Adults

Adolescents and young adults carry a disproportionate burden of sexually transmitted infections (STIs). The Centers for Disease Control and Prevention (CDC) annual surveillance data on STIs includes data for adolescents and young adults, defined as individuals 15–24 years of age.[8] In recent years, STI rates have been very high among young people 15 to 24 years of age, with this age group accounting for 48% of newly reported cases of STIs for the year 2023 (Figure 2).[8] The STI rates in adolescents and young adults are notably higher in certain racial/ethnic groups, especially Black individuals.

HIV in Adolescents and Young Adults

According to the most recent CDC HIV surveillance data, an estimated 6,400 new HIV infections in the United States in 2022 involved persons 13 to 24 years of age.[2] The number of estimated annual HIV infections in this age group has steadily declined since 2019. Overall, this age group accounted for an estimated 20% of all persons with new HIV infection during 2022.[2] For persons 13 to 24 years of age who were newly diagnosed with HIV in 2021, most (79%) were young adults (20 to 24 years of age).[2] Among all persons 13 to 24 years of age newly diagnosed with HIV, 84% were male.[2] New HIV infections in persons 13 to 24 years of age were highest among Black and Hispanic youth.(Figure 3)

Evidence for HIV PrEP in Youth

ATN 110

Adolescent Trials Network 110 (ATN 110) was an open-label study that examined adherence with oral daily HIV PrEP in young (18 to 22 years of age) men who have sex with men (Figure 4).[9] Investigators enrolled 200 young men in 12 United States cities who reported risk for HIV acquisition in the prior 6 months.[9] All participants were prescribed daily oral TDF-FTC for 48 weeks.[9] The rates of STIs were high at baseline (22% of participants) and remained high throughout the study. Four individuals had HIV seroconversion during the study (3.29 per 100 person-years).[9] Investigators assessed medication adherence by determining tenofovir diphosphate levels in dried blood spots and found adherence declined as the study progressed, with a significant drop-off occurring at week 24.[9] Study participants reported different reasons for nonadherence, including being away from home, forgetting to take medication, and being busy with other activities.[9]

ATN 113 (Project PrEPare)

The ATN 113 (Project PrEPare) study was conducted to assess the safety and adherence of TDF-FTC as HIV PrEP for adolescent men who have sex with men who were 15–17 years of age (Figure 5).[10] This was the first major adolescent-specific HIV PrEP demonstration project based in the United States, and it showed that daily oral TDF-FTC was well tolerated and safe, but adherence waned significantly during the study.[10] Although 95% of study subjects had detectable drug levels during the first 12 weeks of the study, only 17 (22%) had levels associated with taking four or more pills per week by week 48 of the study.[10] Individuals without protective serum levels of tenofovir reported the following reasons for nonadherence: being too busy, forgetfulness, being away from home, and changes to their routine. Among the 78 enrolled persons, the HIV incidence rate was high (6.4% per 100 person-years), and the three participants who had HIV seroconversion had very low levels of tenofovir-diphosphate, as measured in dry blood spots at the time of seroconversion. This study highlights the importance of addressing medication adherence and the challenges that are commonplace among youth who are taking HIV PrEP.[10].

HPTN084

The HPTN 084 study was a phase 3, double-blind, randomized clinical trial comparing the efficacy of CAB-LA as HIV PrEP to once-daily oral TDF-FTC in 3,224 adult women from sub-Saharan Africa.[11] Although all study participants were adults, approximately 50% were younger than 25 years of age.[11] For the 1,717 participants enrolled who were younger than 25 years of age, there were 20 incident HIV seroconversions in the TDF-FTC arm compared to three in the CAB-LA arm, representing an 85% risk reduction for HIV acquisition with CAB-LA.[11] This trial did not provide a specific, further age breakdown of participants younger than 25 years of age, but presumably included a substantial number of young adults 18-21 years of age.[11]

HPTN-084-01

Whereas HPTN-084 established the efficacy of CAB-LA in adult women, HPTN-084-01 was a single-arm, open-label, phase 2b study conducted in South Africa, Uganda, and Zimbabwe to evaluate the safety, tolerability, and acceptability of CAB-LA among sexually active adolescent girls younger than 18 years of age.[12] Fifty-five participants met inclusion criteria; all weighed at least 35 kg and agreed to use long-acting contraception.[12] The mean age was 16 years.[12] Participants had substantial risk for HIV acquisition, with 71% reporting a recent primary sexual partner, 22% reporting exchange sex, and 40% diagnosed with an STI at baseline.[12] Although 93% of participants reported at least one grade 2 or higher adverse event, no participant discontinued CAB-LA because of intolerance.[12] One participant discontinued treatment due to pregnancy.[12] Notably, 62% reported they would consider using CAB-LA for HIV prevention in the future.[12]

IPREX Trial

The Preexposure Initiative (iPrEx) study was a phase 3, randomized, double-blind, placebo-controlled international trial that evaluated daily oral TDF-FTC as HIV PrEP in HIV-seronegative adult men who have sex with men, of whom 50.1% were 18 to 24 years of age.[13] In the subanalysis for those younger than 25 years of age, new HIV infections were diagnosed in 22 of 591 (3.7%) in the TDF-FTC group, compared with 37 of 662 (5.6%) in the placebo group; this was a 34% reduction in HIV infections.[13]

Plus-Pills

Plus-Pills was an open-label, single-arm, phase 2 study conducted in South Africa that enrolled sexually active male and female adolescents, 15 to 19 years of age, to evaluate the safety and feasibility of daily oral TDF-FTC as HIV PrEP.[14] Similar to ATN 113, Plus-Pills validated that oral TDF-FTC was safe and tolerable in an adolescent population while also demonstrating medication adherence problems among youth.[14]

Partners PrEP Trial

The PARTNERS PrEP Trial enrolled HIV-serodifferent heterosexual couples from Kenya and Uganda and compared three oral daily HIV PrEP options to be taken by the partner without HIV: TDF alone, TDF-FTC, or placebo.[15] Although this trial was not designed specifically as an adolescent HIV PrEP study, 11.2% of the enrolled couples had a seronegative partner younger than 25 years of age.[15] Overall, the study showed a reduced risk of HIV acquisition for HIV-seronegative participants (women and men) who took either TDF or TDF-FTC compared with those individuals who took placebo.[15] Similar protection was observed among participants younger than 25 years of age, with HIV acquisition rates per 100 person-years of 1.07 in the TDF group, 2.34 in the TDF-FTC group, and 4.04 in the placebo group.[15]

PURPOSE-1 Trial

The PURPOSE-1 trial provided the first evidence that twice-yearly injectable lenacapavir subcutaneous injections is highly effective for HIV prevention among adolescent girls and young women. In this phase 3, double-blind, randomized, controlled trial in South Africa and Uganda, 5,388 participants aged 16–25 years were assigned to injectable lenacapavir, daily oral TDF-FTC, or daily oral TAF-FTC as HIV PrEP.[16] Fifty-five incident HIV infections were observed; no HIV infections occurred among individuals receiving lenacapavir, corresponding to a 100% reduction in HIV incidence as compared with both background HIV incidence and daily oral TDF-FTC.[16] No meaningful difference in HIV incidence was observed between the TAF-FTC and TDF-FTC arms [incidence rate ratio, 1.20; 95% CI, 0.67 to 2.14].[16] Notably, adherence to oral HIV PrEP was low, based on dried blood spot analyses from a randomly preselected subset of participants.[16]

Clinic Visits and Obtaining a Sexual History in Adolescents

Approach to Clinical Visit for Prevention Services

Providing optimal care for adolescents and young adults requires a sensitive and flexible approach to establish a trusting, confidential and therapeutic relationship. To this end, every effort must be taken to ensure that the adolescent or young adult can talk alone with the clinician in the absence of parents or guardians. Typically, the American Association of Pediatrics recommends initiating one-on-one adolescent patient-provider visits at the age of 11. By collaborating with parents/guardians to establish these individual sessions as a part of routine health care, the clinician can continue such visits into the patient's adolescent years. During those individualized clinic periods, the provider should build rapport and trust by being forthright in explaining the scope and limits of patient-provider confidentiality, including instances when confidentiality may be breached.[17] A commonly used psychosocial framework for obtaining a clinical history is HEEADSSS: home, education and/or employment, eating, activities, drugs, sexuality, suicide and/or depression, and safety.

Obtaining a Sexual History

Eliciting a comprehensive history, including social and sexual history, should take place in a non-threatening environment, using non-judgmental, open-ended questions and without assumptions about the youth's sexual activities. In general, when obtaining a sexual history, the CDC recommends using the five "Ps" as a reminder: partners, practices, protection from STIs, past history of STIs, and prevention of pregnancy.[18] The "Taking a Sexual History" tool from the Sexual Information and Education Council of the United States (SIECUS) provides detailed guidance on how to take a sexual history in all youths.[19] When engaging in these discussions, it is extremely important for the health care professional to understand and contextualize other activities and circumstances that impact sexual activity, such as substance use, sexual or emotional abuse, peer pressure and bullying, mental illness, food insecurity, unstable housing, interactions with the juvenile justice system or transactional sexual encounters.

Assessing for HIV PrEP in Youth

The following summarizes indications for prescribing HIV PrEP to adolescents or young adults. These recommendations are based on the 2021 CDC HIV PrEP Guidelines.[3]

Sexually Active Adolescents and Young Adults

Adolescents and young adults who weigh at least 35 kg (77 lb) AND who have had anal or vaginal sex in the past 6 months may be eligible for HIV PrEP if they have any of the following (Figure 6):

- A sex partner who is HIV-seropositive (especially if the sex partner has an unknown or detectable HIV RNA level)
- One or more bacterial STIs in the prior 6 months: gonorrhea, chlamydia, and syphilis for men who have sex with men, including those who inject drugs; gonorrhea and syphilis for heterosexual women and men, including persons who inject drugs
- History of inconsistent or no condom use with sex partner(s)

Adolescents and Young Adults who Inject Drugs

Adolescents and young adults, weighing at least 35 kg (77 lb) and who inject drugs or have injected in the past 6 months, should also be assessed for their sexual risk of HIV. These individuals should be prescribed HIV PrEP if they have any of the following (Figure 7):

- An injecting partner who has HIV
- Share injection equipment
- Engage in sexual activity that increases the risk of acquiring HIV

US Preventive Services Task Force

The 2023 United States Preventive Services Task Force (USPSTF) has given an “A” rating for HIV PrEP for adolescents and adults who are at high risk of HIV acquisition and who weigh at least 35 kg (77 lb).[20]

Society for Adolescent Health and Medicine

The Society for Adolescent Health and Medicine (SAHM) issued a position paper in 2018 that provides context and guidance for pediatricians and adolescent medicine health care professionals to promote and enhance the use of HIV PrEP for youth to decrease the risk of acquiring HIV.[21] The SAHM position states that “adolescent and young adult health professionals should develop evidence-based, developmentally appropriate, and accessible HIV PrEP service delivery models as part of routine care offered to adolescents and young adults.” To achieve this goal, medical providers are encouraged to counsel patients about PrEP, describe it as a safe and effective HIV prevention strategy in combination with other prevention strategies, and refer patients to available health care professionals for initiation and monitoring of HIV PrEP.[21]

HIV PrEP Medications for Youth

FDA-Approved Medications for HIV PrEP

The FDA has approved four medications that can be used for HIV PrEP in young adults who weigh at least 35 kg (77 lb): daily oral tenofovir DF-emtricitabine (TDF-FTC), daily oral tenofovir alafenamide-emtricitabine (TAF-FTC), long-acting injectable cabotegravir (CAB-LA), and lenacapavir subcutaneous injections (LEN-SQ). Note that TAF-FTC is not FDA-approved for women, regardless of age, to prevent vaginal acquisition of HIV. Further, although no medication has been FDA-approved to prevent HIV acquisition associated with injection drug use and needle sharing, as noted below, the CDC has recommended TDF-FTC and LEN-SQ as options for HIV PrEP in people who inject drugs and share needles, based on published data in the Bangkok Tenofovir Trial and based on expert opinion.[3,22,23] The following summarizes potential medication options and CDC recommendations for HIV PrEP in adolescents and young adults.[3]

Centers for Disease Control and Prevention Recommendations

Regardless of sex, TDF-FTC, CAB-LA, and LEN-SQ are recommended options for adolescents and young adults who weigh at least 35 kg (77 lb) to reduce the risk of acquiring HIV through sexual activity.[3,23] Adolescents and young adults who weigh at least 35 kg (77 lb) can also use TAF-FTC to reduce the risk of HIV infection from sexual acquisition, but the CDC does not recommend use of TAF-FTC for individuals at risk of acquiring HIV through receptive vaginal sex.[3] For adolescents and young adults, TDF-FTC and LEN—SQ are the medication options recommended for preventing the acquisition of HIV via injection drug use and needle sharing.[3,23] The following summarizes potential medication options and CDC recommendations for HIV PrEP in adolescents and young adults.[3,23]

- **Tenofovir DF-Emtricitabine (TDF-FTC)**: Daily oral TDF-FTC is recommended as an option for the prevention of sexual acquisition of HIV in adolescents and adults who weigh at least 35 kg (77 lb). In addition, daily oral TDF-FTC is recommended for use as HIV PrEP to prevent HIV acquisition in persons who inject drugs who weigh at least 35 kg (77 lb). The recommended dosing for oral TDF-FTC is one tablet daily. TDF-FTC should not be used in persons with a creatinine clearance of less than 60 mL/min. TDF-FTC is considered safe for use in pregnancy.
    - **On-Demand (2:1:1) HIV PrEP**: Oral TDF-FTC is the only medication that has been studied for the use of on-demand (2:1:1) HIV PrEP and this has been studied only for use in men who have sex with men who are 18 years of age and older. Based on available data, the CDC lists on-demand HIV PrEP with TDF-FTC as an alternative for HIV PrEP in young adult men who have sex with men who are 18 years of age and older. In addition, the use of on-demand HIV PrEP has not been studied in persons younger than 18 years of age, and therefore it is not recommended for this age group. Note that the on-demand dosing strategy has not been approved by the FDA for people of any age. For more detailed information, see the On-Demand Dosing Guide on this website.
- **Tenofovir alafenamide-Emtricitabine (TAF-FTC)**: Daily oral TAF-FTC is recommended as an option for prevention of sexual acquisition of HIV in adolescents and adult males who weigh at least 35 kg. Note that TAF-FTC is not FDA-approved for women, regardless of age, to prevent vaginal acquisition of HIV. Although data from the PURPOSE-1 trial showed no significant difference in HIV incidence between the TAF-FTC and TDF-FTC arms, there are unpublished data that 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.[16,24] The use of TAF-FTC is considered safe in pregnancy. For persons with an estimated creatinine clearance of less than 30 mL/min, TAF-FTC is not recommended.
- **Long-Acting Injectable Cabotegravir (CAB-LA)**: CAB-LA is recommended for HIV PrEP to prevent the sexual acquisition of HIV in adolescents and young adults, regardless of sex, if the adolescent weighs at least 35 kg (77 lb). There are no restrictions on prescribing CAB-LA based on renal function. At this time, due to lack of data, CAB-LA is not recommended for use in pregnancy. For detailed information about CAB-LA, including dosing for the optional oral lead-in, see the Cabotegravir Guide

on this website.

- **Lenacapavir Subcutaneous Injection (LEN-SQ)**: LEN-SQ is recommended for HIV PrEP to prevent the sexual acquisition of HIV in adolescents and young adults who weigh at least 35 kg (77 lb), regardless of sex. There are no restrictions on prescribing LEN-SQ based on renal function. The CDC guidance notes that LEN-SQ can be used in pregnant women or continued in women who become pregnant while receiving LEN-SQ, using provider-client shared decision-making and taking into account the woman's risk for HIV without HIV PrEP.[23] For detailed information about LEN-SQ, including dosing for the optional oral lead-in, see the Lenacapavir Guide on this website.

Tolerability and Safety Data

For adolescents younger than 18 years of age, several studies suggest TDF-FTC is safe when used as HIV PrEP in adolescents and young adults, but there are no published safety data with TAF-FTC when used as HIV PrEP in this age group.[9,10,14] Substantial long-term HIV antiretroviral treatment experience with TDF-FTC and TAF-FTC—as components of antiretroviral therapy for the treatment of persons with HIV—has shown excellent tolerance and safety profiles.[17,25,26] Data from the HPTN-084-01 study on the use of CAB-LA as HIV PrEP in adolescent women support the safety of cabotegravir in those less than 18 years of age weighing at least 35 kg.[12] Data from the PURPOSE-1 Trial also support the tolerability and safety of LEN-SQ in adolescents and young adults.[16] The following summarizes major tolerability and safety concerns for adolescents and young adults.

- **Start-Up Syndrome**: Safety data in adults have shown that about 10% of persons starting oral TDF-FTC for HIV PrEP experience a "start-up syndrome" that consists of mild to moderate gastrointestinal symptoms, fatigue, and headache.[3,27] Less often, some will develop unintentional transient weight loss that may last for up to 24 weeks.[3,27]
- **Bone Mineral Density Changes**: Safety data from the ATN 110 study showed a modest decrease in bone mineral density of adolescents receiving TDF-FTC.[9] The clinical significance of these changes is unknown, and available data suggest these changes are reversible among persons younger than 25 years of age.[9,28] With regard to effects on the skeletal system, no medication-attributable fractures were reported in the ATN 113 study, but the increase in bone mineral density that is expected during this late adolescent age period was slightly blunted.[10] More research is necessary to ascertain the long-term clinical impact of TDF on bone density in adolescents who are receiving this medication for HIV PrEP, especially for those who take TDF for longer than 1 year.[14]
- **Nephrotoxicity**: The ATN 110 and 113 studies of TDF-FTC in adolescents demonstrated negligible renal adverse effects.[9,10]
- **Injection Site Reactions**: The major adverse effects with CAB-LA and LEN-SQ have been injection site reactions, which have resulted in the discontinuation of CAB-LA or LEN-SQ in less than 2% of persons receiving these long-acting injectable medications. Injection site reactions in adolescents and young adults were reported in 5.7% from CAB-LA in HPTN-084-01 and in 68.8% from LEN-SQ in PURPOSE-1.[12,16]

Baseline Laboratory Evaluation

Baseline Evaluation

Adolescents and young adults who are interested in and willing to take HIV PrEP should undergo a baseline evaluation to obtain screening laboratory tests and to counsel the individual on taking HIV PrEP. As part of the baseline evaluation, it is essential to confirm the individual considering HIV PrEP (1) weighs at least 35 kg (77 lb) and (2) does not already have HIV. In addition, as part of the baseline evaluation for women, it is important to evaluate pregnancy status unless it is already known that the woman is pregnant. The routinely recommended baseline laboratory studies recommended by the CDC for adults are the same for youth.[3,23] These baseline 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 laboratory studies are available in the Laboratory Monitoring Guide on this website.

Medication Adherence

Reduced Adherence

Adherence is essential for HIV PrEP to effectively prevent the acquisition of HIV. For adolescents and young adults, medication adherence is often challenging and typically more problematic than with adults (Figure 8).[9,10,14,29] Factors associated with suboptimal adherence in younger persons taking HIV PrEP may include susceptibility to peer influence, an underdeveloped cognitive ability for organization and long-term planning, socioeconomic or familial stressors, mental illness, or substance use issues.[17,27] In HIV PrEP studies, adherence has been estimated based on tenofovir diphosphate levels in dried blood spots. Tenofovir diphosphate levels of at least 700 fmol/punch are consistent with taking at least four pills of TDF-FTC per week, a threshold most experts believe is required to provide adequate protection for HIV acquisition when taking daily oral TDF-FTC.[30]

- **ATN 110**: In the open-label ATN 110 study, young MSM 18 to 22 years of age were offered oral daily TDF-FTC for HIV PrEP.[10] Based on tenofovir diphosphate levels in dried blood spots, the estimated adequate adherence was 56% at week 4 and declined to 34% by week 48.[9] The most common reasons reported for missing pill doses were forgetting, being away from home, and being too busy with other things.[9]
- **ATN 113**: In this open-label study, young MSM 15–17 years of age were offered oral daily TDF-FTC for HIV PrEP.[10] Similar to ATN 110, using tenofovir diphosphate levels in dried blood spots, the estimated adherence was 54% at week 4 and declined to only 22% at week 48.[10] The most common reported reasons for missing doses were being away from home, being too busy, and forgetting.
- **Plus Pills**: In this open-label study conducted in South Africa, young females and males 15–19 years of age who were at risk of acquiring HIV were offered HIV PrEP with daily oral TDF-FTC.[14] Two-thirds of the participants were female.[14] Estimated adherence, based on tenofovir diphosphate levels in dried blood spots, was 55% at week 4 and declined to 16% at week 48.[14] Major reasons identified for adherence problems were forgetting, tablet size, and decreased perception of risk.[14]
- **RADAR Cohort**: In a longitudinal cohort study involving young MSM 16 to 29 years of age living in the Chicago metropolitan area who reported use of HIV PrEP, investigators evaluated HIV PrEP discontinuation.[31] Overall, for these participants who used HIV PrEP in the prior 6 month period, 65 of 197 (33%) discontinued taking HIV PrEP, and 79% of those who discontinued HIV PrEP did not notify a health care professional prior to stopping HIV PrEP.[31] The main reasons identified for HIV PrEP discontinuation included trouble getting to medical appointments, issues related to insurance coverage or loss, and the belief they were no longer at risk of acquiring HIV.[31]

Strategies for Improving Adherence

Some adolescent oral HIV PrEP clinical trials have shown that more frequent clinic visits, particularly during HIV& PrEP initiation, resulted in improved medication adherence.[9,10] These visits should be used as an opportunity to routinely screen for potential barriers to adherence, as well as provide advice, support, and/or resources to overcome these obstacles in order to retain these individuals within the HIV PrEP continuum of care. Technology-based interventions, including use of mobile devices, are an evolving field to support HIV PrEP adherence. In addition, interventions that have improved antiretroviral adherence in youth can be leveraged for the HIV PrEP arena.[32,33,34,35,36] Use of injectable HIV PrEP medications may overcome adherence challenges associated with daily oral medications, but efforts to promote ongoing engagement and HIV PrEP persistence remain essential.[12,16]

Follow-Up and Laboratory Monitoring

Clinical Follow-Up for Persons Receiving HIV PrEP

Adolescents and young adults who start on oral HIV PrEP should have follow-up visits every 3 months.[3] At each visit, clinicians should assess medication adherence and tolerance, as well as any changes in routines and schedules that could impact HIV PrEP use. With adolescents, it is particularly important to include discussions regarding adherence at every clinic visit. For those receiving CAB-LA, the first follow-up visit should occur 1 month after the first initiation injection and then every 2 months thereafter in conjunction with the maintenance CAB-LA injections.[3] With LEN-SQ follow-up visits should occur every 6 months and coincide with each LEN-SQ injection. Regardless of the HIV PrEP regimen, follow-up visits should include a discussion of the need for ongoing HIV PrEP, a review of any symptoms that would suggest acute HIV infection, HIV testing, and evaluation for symptoms suggestive of a current STI.[3] Visits should also provide opportunities for the adolescent/young adult to ask questions and discuss concerns. Individuals with symptoms consistent with an STI should undergo prompt STI testing and receive appropriate treatment as clinically indicated, regardless of the timing of their next routine STI screening.

Laboratory Monitoring While on PrEP

The CDC recommended follow-up laboratory studies for persons taking HIV PrEP are the same for youth and adults.[3,23] These 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 initial laboratory studies are available in the Laboratory Monitoring Guide on this website.

Legal and Insurance Issues

Medical providers who care for adolescents, especially for sexual health services, must be well-informed regarding legal issues, especially pertaining to consent for clinical care and confidentiality. A CDC review of the statutes and regulations related to minors' informed consent to receive STI and HIV services concluded that as of 2020, all states and the District of Columbia had explicit laws permitting minors of a specific minimum age to provide informed consent to access STI diagnosis and treatment.[37] The age threshold is uniquely defined by each state or jurisdiction. Further, nuances exist in the interpretation and implementation of these laws with regard to HIV services, including HIV PrEP. As an example, in certain areas, HIV services could be included under general STI services, since the law may not explicitly distinguish between HIV and other STIs.[37] In other cases, certain statutes or regulations may allow for HIV prevention (hence HIV PrEP) to be considered under general preventive health care. The key point is that no state or jurisdiction in the United States bans a minor from providing their autonomous informed consent to receive HIV PrEP.[17,37] It is also important to recognize that an adolescent's ability to consent to HIV PrEP does not necessarily guarantee the confidentiality of care. Limitations to confidentiality exist and vary by state (e.g., billing documentation from commercial health insurance plans, mandatory child abuse reporting, or neglect reporting laws). Therefore, an adolescent care clinician must scrutinize the HIV PrEP prescription landscape in the context of local laws on autonomous health care decision-making by minors. Ideally, clinicians can serve as key sexual health advocates for their young patients by forging a constructive, therapeutic partnership with parents or guardians while also balancing the need for adolescent autonomy to the extent that is permissible by law.[17]

The following sites provide information related to HIV and STI consent and minors:

- Centers for Disease Control and Prevention (CDC): Minor's Consent Law
- Guttmacher Institute: Minor's Access to STI Services
- National Alliance of State and Territorial AIDS Directors (NASTAD): Minor Consent and Confidentiality Laws for PrEP and HIV Treatment

Insurance Issues Pertaining to Prescribing PrEP to Adolescents

Barring feasibility due to logistical or patient safety reasons (e.g., concerns for abuse), an adolescent health provider must make every effort to engage both adolescents and their parent(s) in mutual discussion, prior to HIV PrEP initiation. Ideally, the clinician should first obtain consent from the adolescent to engage parent(s) followed by parental consent. The latter is important because parents/guardians could be made aware of such information from other sources, such as routine health plan communication or insurance plan documentation (e.g., explanation of benefits letter). Uninsured minors may be eligible for medication access support for HIV PrEP, but this may also need parental/guardian consent. If circumstances warrant absolute confidentiality for the minor, then adolescent health providers may need to pursue creative strategies, such as appealing to medication access programs.

Summary Points

- An estimated 20% of new HIV infections in the United States in 2022 were among individuals 13 to 24 years of age.
- HIV PrEP is an important and underutilized tool for HIV prevention among adolescents and young adults at high risk for HIV acquisition.
- HIV PrEP is indicated for adolescents and young adults with sexual risk factors or injection drug use risk factors that increase susceptibility to HIV acquisition.
- Four different HIV PrEP regimens are approved for adolescents and young adults weighing at least 35 kg (77 lb). They are TDF-FTC, TAF-FTC, CAB-LA. and LEN-SQ.
- TAF-FTC is not FDA-approved for HIV PrEP in women (of any age) to prevent HIV acquisition via receptive vaginal sex.
- Risk assessment and baseline laboratory evaluation are required prior to prescribing HIV PrEP, including documentation of a negative baseline HIV test.
- On-demand (2-1-1) dosing of TDF-FTC as HIV PrEP is only recommended as an option for MSM adolescents and young adults older than 18 years of age.
- Adherence challenges exist with youth taking oral HIV PrEP and these should be discussed on a regular basis at clinic visits with efforts made to address any adherence issues.
- The need for parental consent to prescribe HIV PrEP to adolescents varies from state to state. In general, there is no state or jurisdiction in the United States that bans a minor from providing their autonomous informed consent to receive HIV PrEP.
- Ideally, clinicans must make an effort to obtain parental or guardian consent prior to prescribing HIV PrEP to a minor, but the inability to do this should not preclude an adolescent’s access to HIV PrEP.

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Figures

Figure 1 HIV PrEP Coverage for Youth

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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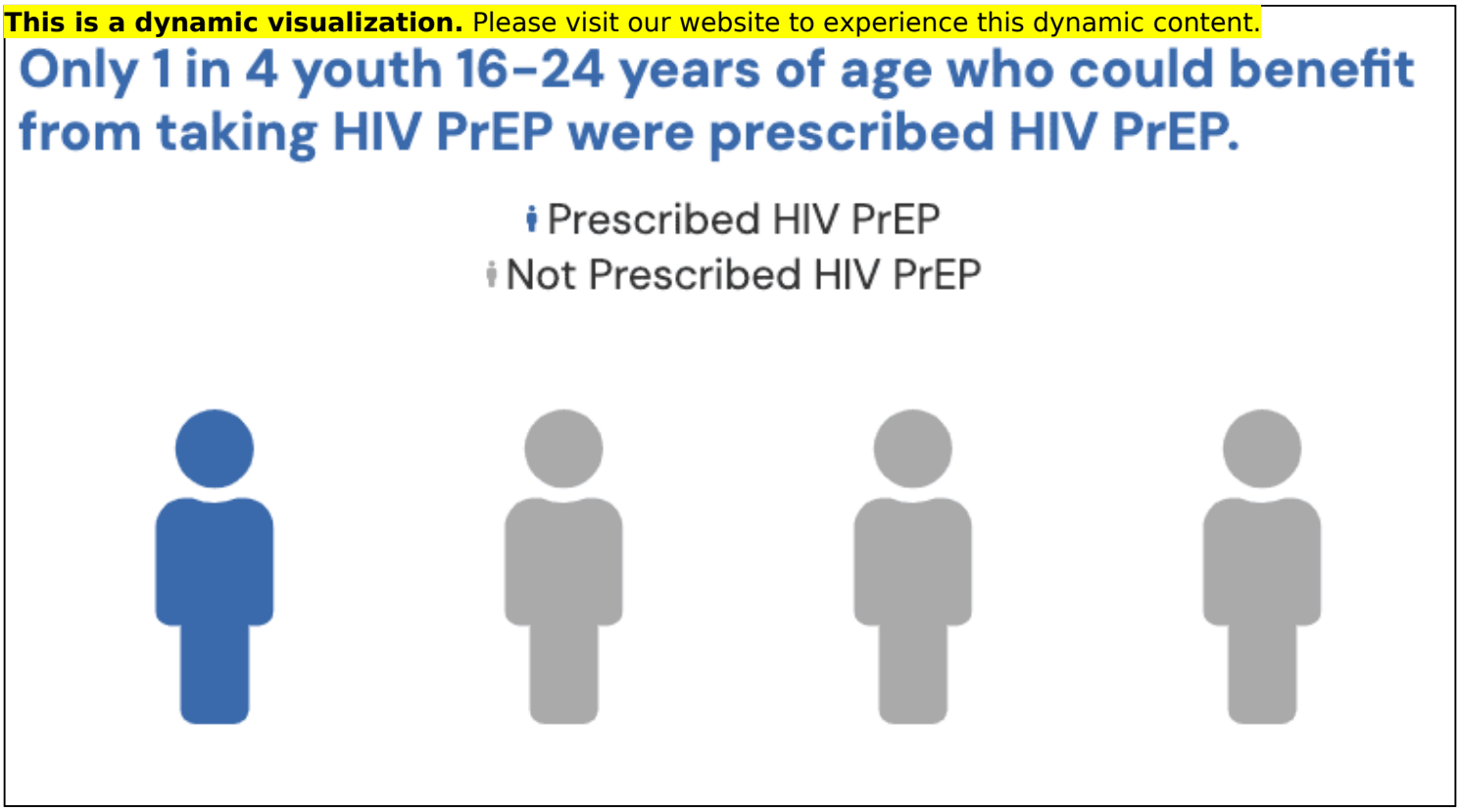


Figure 2 New Diagnoses of STIs Among Adolescents and Young Adults in the United States, 2023

Source: Centers for Disease Control and Prevention. Sexually Transmitted Disease Surveillance 2021. Atlanta: U.S. Department of Health and Human Services; April, 2023.

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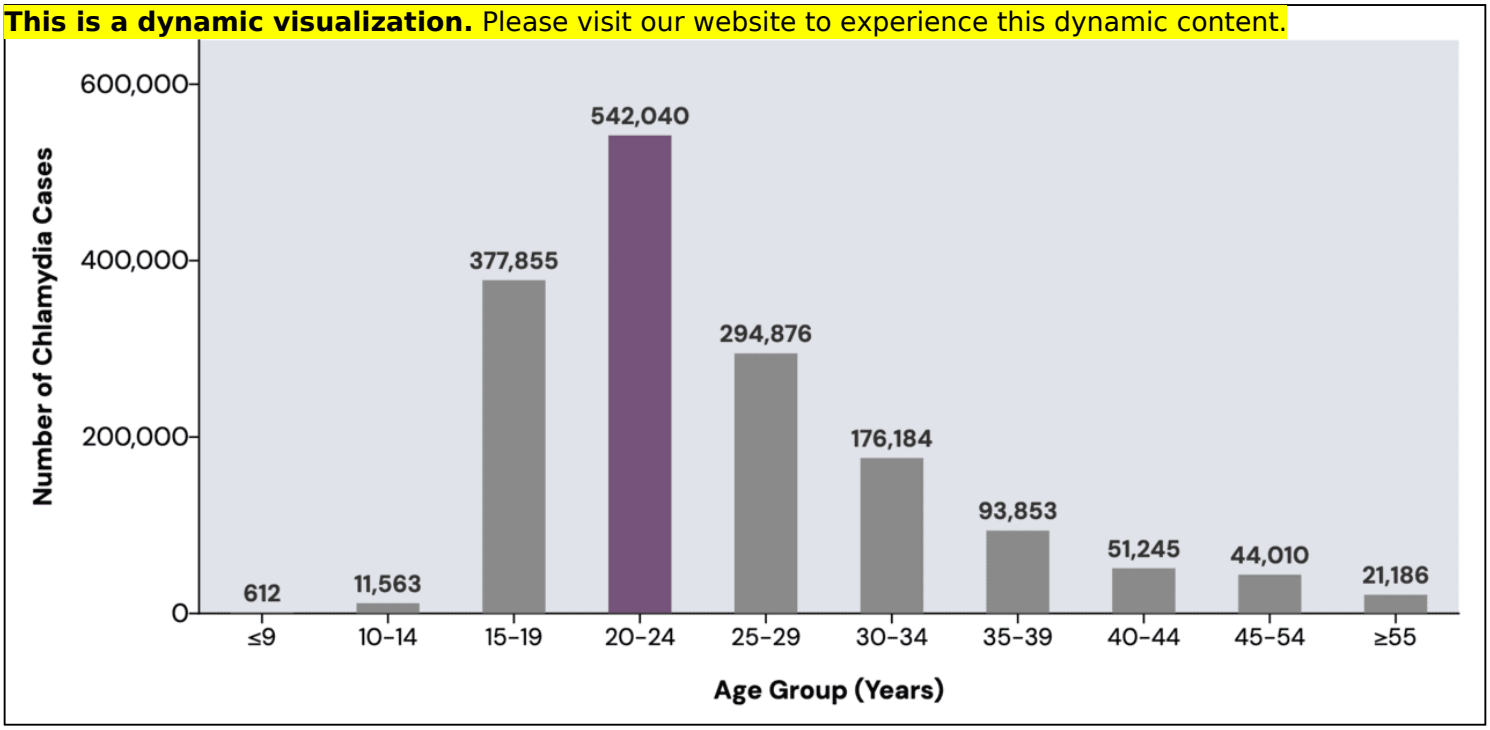


Figure 3 Estimated HIV Incidence Among Adolescents and Young Adults in the United States

Centers for Disease Control and Prevention. Estimated HIV Incidence and Prevalence in the United States, 2018–2022. HIV Surveillance Supplemental Report. 2024;29(No.13). Published May 2024.

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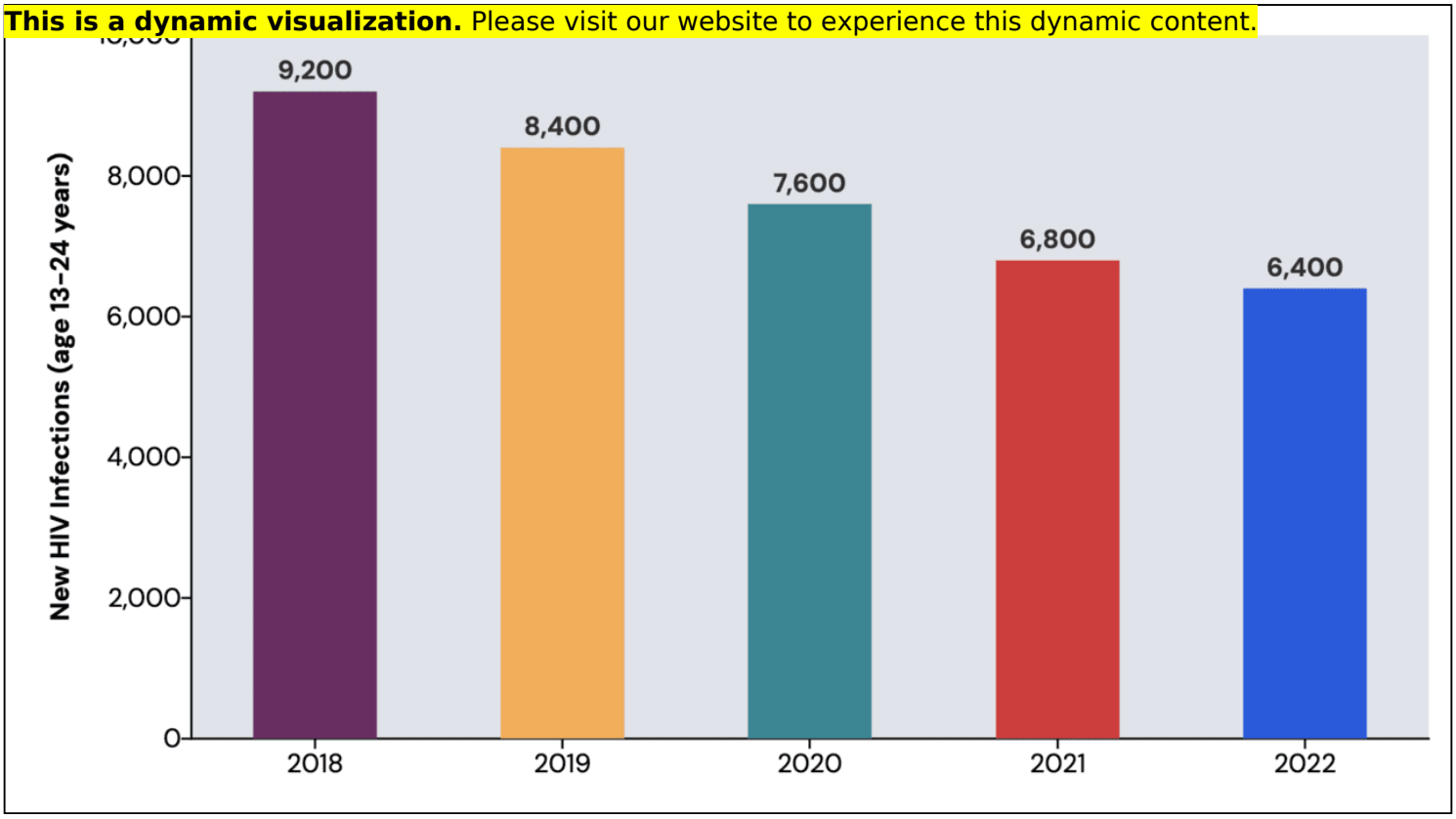


Figure 4 ATN 110 - HIV PrEP Demonstration Project and Safety Study for Young Men Who Have Sex with Men

Source: Hosek SG, Rudy B, Landovitz R, et al. J Acquir Immune Defic Syndr. 2017;74:21-9.

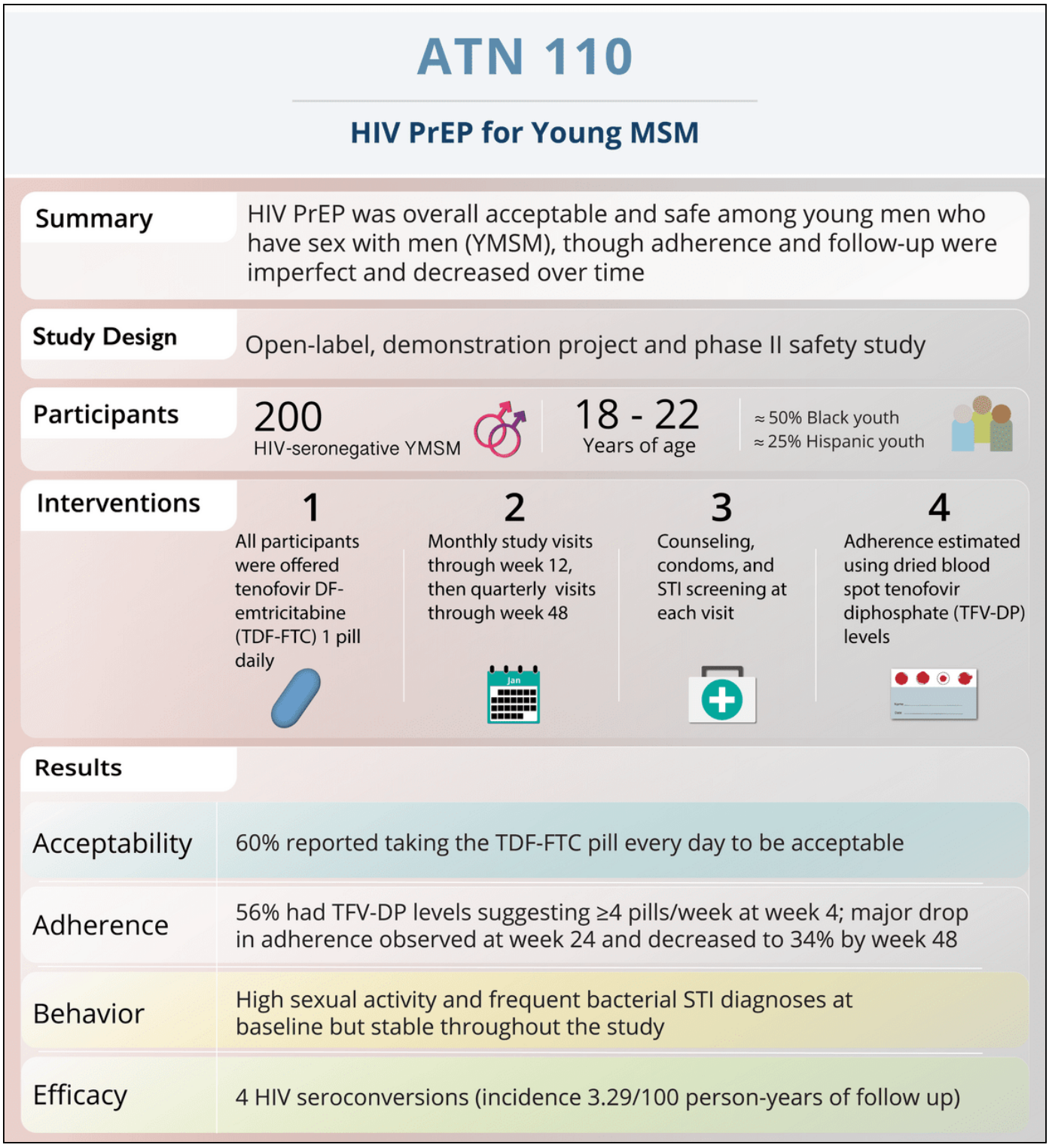


Figure 5 ATN 113 - Safety and Feasibility of HIV PrEP for Adolescent Men Who Have Sex with Men

Source: Hosek SG, Landovitz RJ, Kapogiannis B, et al. JAMA Pediatr. 2017;171:1063-71.

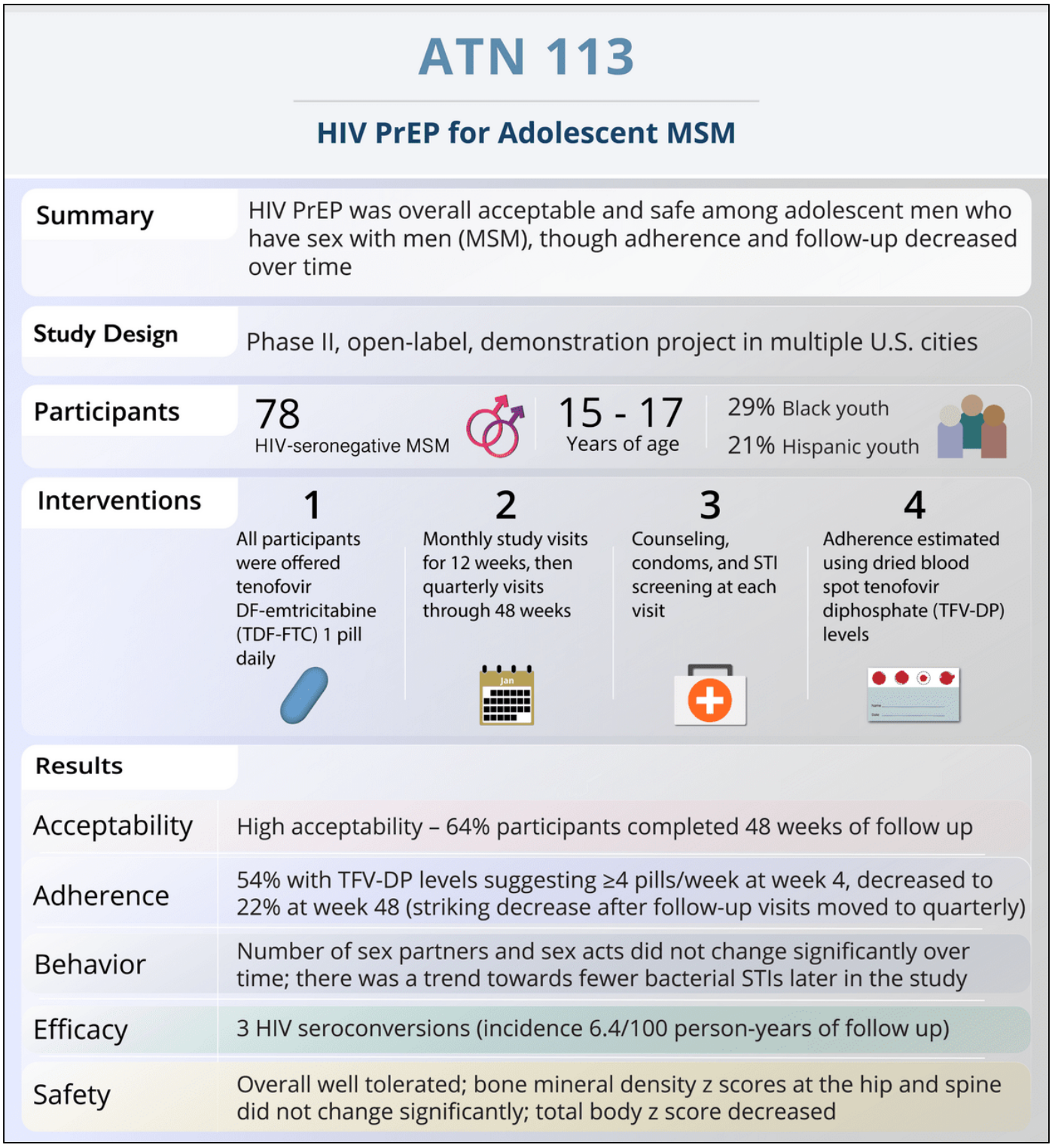


Figure 6 Assessing Indications for PrEP in Sexually Active Adolescents and Young Adults

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.

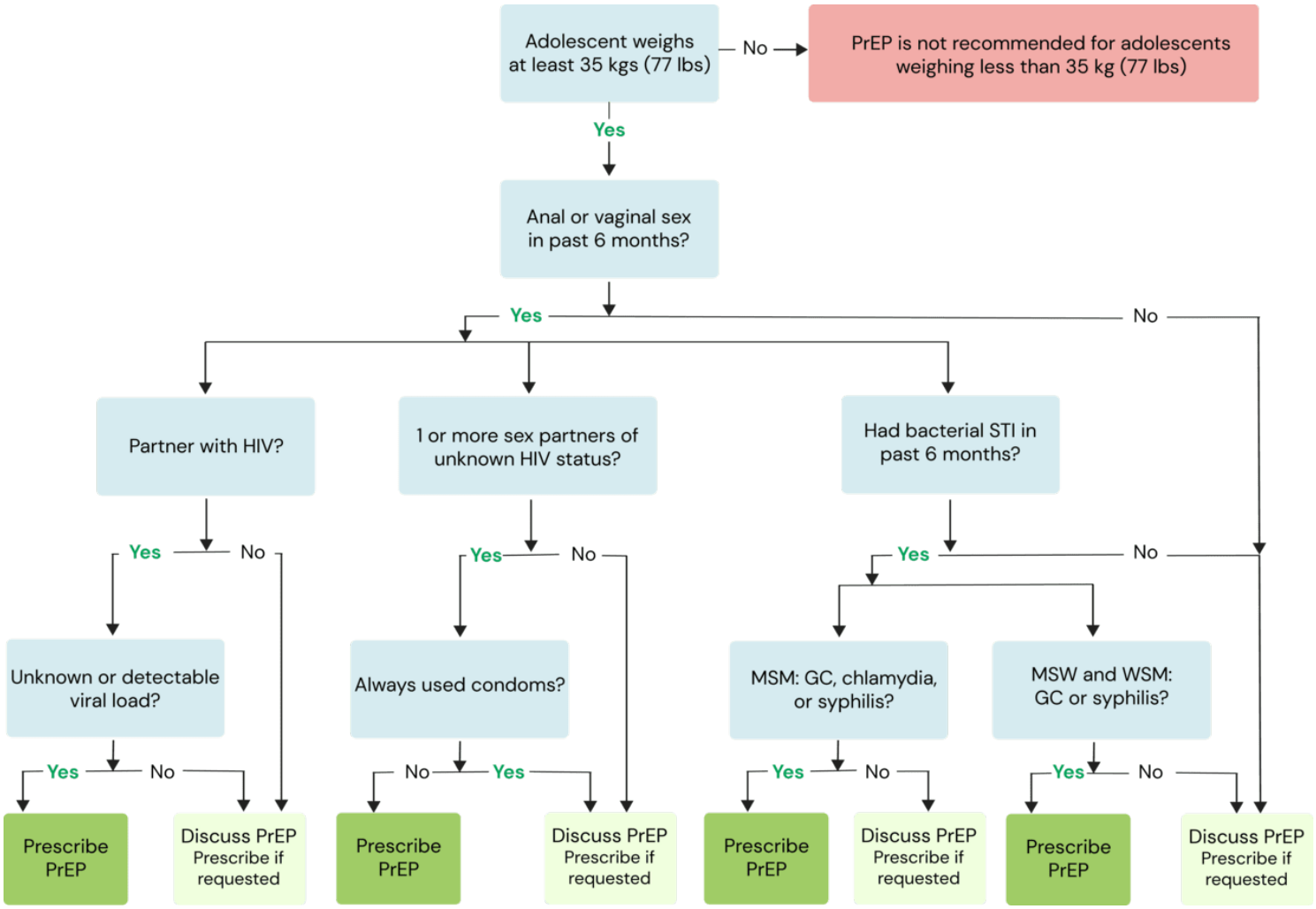


Figure 7 Assessing Indications for PrEP in Young Adults Who Inject Drugs

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.

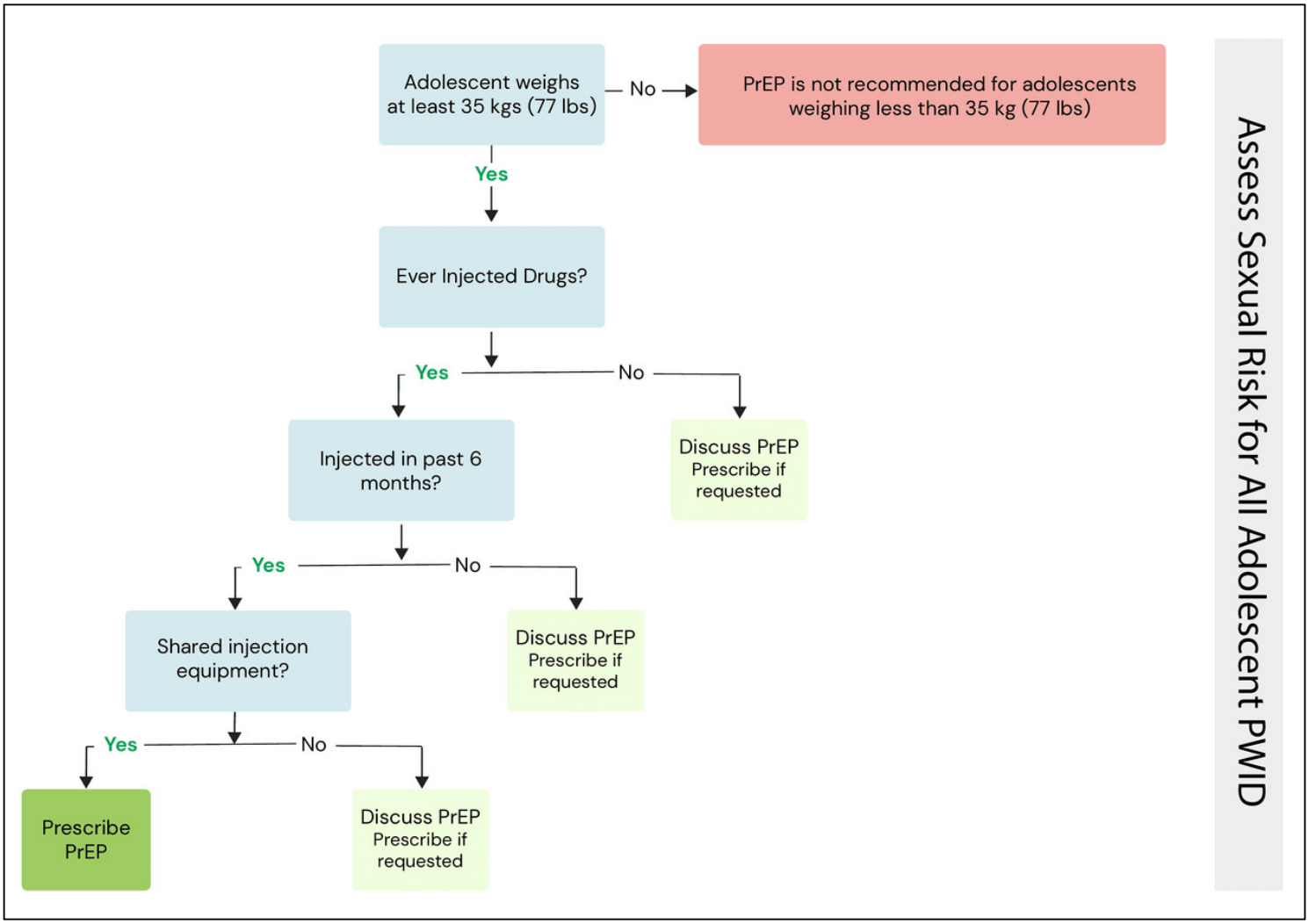


Figure 8 Adolescent PrEP Adherence

Source: (1) ATN-110: Hosek SG, Rudy B, Landovitz R, et al. J Acquir Immune Defic Syndr. 2017;74:21-9.(2) ATN-113: Hosek SG, Landovitz RJ, Kapogiannis B, et al. JAMA Pediatr. 2017;171:1063-71. (3) Gill K, Johnson L, Dietrich J, et al. 2020;4:875-83.

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