Basic Principles and Rationale for HIV PrEP

This is a PDF version of the following document:
Module 1: HIV PrEP Fundamentals
Lesson 1: Basic Principles and Rationale for HIV PrEP

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Background

What is HIV Preexposure Prophylaxis (PrEP)?

HIV preexposure prophylaxis (PrEP) is when a person without HIV takes antiretroviral medications to prevent the acquisition of HIV. The goal of HIV PrEP is to prevent new HIV infections.

Need for HIV PrEP

In the United States, there is an immediate need to increase the availability, implementation, and use of HIV PrEP. The following summarizes the rationale for why a major scale-up in HIV PrEP is needed in the United States.

- **HIV Incidence Remains High**: The number of new HIV infections continues to occur at a substantial rate in the United States—estimated at about 32,000 new HIV infections per year.[1]
- **HIV PrEP is Effective**: When taken as prescribed, HIV PrEP is more than 90% effective for preventing sexual acquisition of HIV and at least 70% effective in preventing HIV acquisition among people who inject drugs.[2,3,4,5,6,7,8]
- **HIV PrEP is Underutilized**: Overall, only about one in three persons who would benefit from HIV PrEP are receiving HIV PrEP.[9]
- **HIV PrEP is Usually Covered**: Most insurance plans and state Medicaid programs cover HIV PrEP, including laboratory and medication costs. For people who do not have medical insurance and are not receiving Medicaid, coverage may be available through other avenues.[10]

HIV PrEP Fundamentals Training Module

This *HIV National PrEP Curriculum HIV PrEP Fundamentals* training module is designed for health care professionals who are interested in any aspect of providing HIV PrEP. In the United States, a larger number of trained clinicians are needed to meet the growing demand for HIV PrEP. Multiple studies have shown that increasing medical provider awareness and knowledge about HIV PrEP is associated with an increased likelihood of prescribing HIV PrEP. More clinicians are needed with an interest and skill to provide HIV PrEP. Health care professionals who complete the HIV PrEP Fundamentals module training and receive a passing score on the 20-question, open-book, open-website final assessment will receive a *National HIV PrEP Curriculum: HIV PrEP Training Certificate*. The major goal of this *HIV PrEP Fundamentals* module is to provide health professionals with the basic knowledge, skills, and core competencies to achieve the following:

1. Identify persons who are candidates for and may benefit from HIV PrEP

2. Perform a baseline evaluation prior to starting HIV PrEP
3. Choose an appropriate HIV PrEP regimen for the HIV PrEP candidate
4. Effectively monitor someone who is receiving HIV PrEP

Coverage and Goals for HIV PrEP in the United States

In 2019, the United States Department of Health and Human Services (HHS) launched the Ending the HIV Epidemic initiative with a stated goal to reduce new HIV infections in the United States by 90% by the year 2030, with the achievement of this goal accomplished through the scale-up of HIV prevention and treatment strategies.[11] The Centers for Disease Control and Prevention (CDC) published data on HIV PrEP coverage in the United States for the years 2017-2022, with HIV PrEP coverage defined as the number of persons 16 years of age and older having been prescribed HIV PrEP during the specified year divided by the estimated number of persons 16 years of age and older who had one or more indications for HIV PrEP during the specified year.[9] Data from 2022 indicated HIV PrEP coverage of 36% in the United States, a significant increase from 2017, but this represents only modest progress toward the Ending the HIV Epidemic goal of 50% of eligible persons receiving HIV PrEP in the year 2025.[9] (Figure 1)[Q] HIV PrEP Prescribing in United States

Data to Support HIV PrEP

HIV PrEP Efficacy

Four medications have been approved by the U.S. Food and Drug Administration (FDA) as HIV PrEP for the prevention of sexual acquisition of HIV: tenofovir DF-emtricitabine (TDF/FTC), tenofovir alafenamide-emtricitabine (TAF-FTC), long-acting injectable cabotegravir (CAB-LA), and lenacapavir subcutaneous injections (LEN-SQ). Based on multiple HIV PrEP studies, available data suggest that oral and injectable HIV PrEP has an efficacy of at least 90% for preventing new sexual acquisition of HIV when taken as prescribed.[10] The efficacy of HIV PrEP for people who inject drugs has not been as thoroughly studied, but available data suggest oral HIV PrEP with TDF-FTC has an efficacy of at least 70% in preventing the acquisition of HIV in people who inject drugs.[10] Multiple studies have shown that HIV PrEP medication adherence is a critical factor in the efficacy of oral HIV PrEP in preventing HIV acquisition.[10] In a study of HIV PrEP coverage during 2012-2022 in the United States, investigators showed that as HIV PrEP usage increased, yearly HIV infection rates decreased, with a finding that areas that had higher HIV PrEP coverage had progressively larger declines in new HIV diagnoses than areas with low HIV PrEP coverage.[12]

Major HIV PrEP Studies

The following summaries provide an overview of key studies that have evaluated the efficacy of HIV PrEP with the four medications that are approved by the U.S. Food and Drug Administration for HIV PrEP. These studies are presented in alphabetical order based on the name that is most often used when the study is discussed. Note that each study has a brief name, followed by the medication that was studied, the patient population in the trial, and the formal name of the trial.

- **ATN 110**: In 2013, the Adolescent Trials Network 110 (ATN 110) study enrolled 200 adolescent males (aged 18 to 22 years) who have sex with other males to receive open-label TDF-emtricitabine (TDF-FTC) for HIV PrEP.[13] Using tenofovir diphosphate levels in dried blood spots as a marker for HIV PrEP medication adherence, the investigators concluded there was a major decline in adherence at week 24.[13] The rates of sexually transmitted infections were high at baseline (22% of participants) and remained high throughout the study.[13]
- **ATN 113**: The Adolescent Trials Network 113 (ATN 113) study was conducted in multiple cities in the United States, and it enrolled 78 adolescent males (15 to 17 years of age) who have sex with other males.[14] All participants received open-label daily oral tenofovir DF-emtricitabine (TDF-FTC) for HIV PrEP.[14] The TDF-FTC for HIV PrEP was found to be safe and well tolerated, but medication adherence, based on tenofovir diphosphate levels in dried blood spots, decreased markedly over time during the study.[14] The HIV seroconversion rate was 6.4 per 100 person-years, and the incidence of sexually transmitted infections was 18 per 100 person-years.[14]
- **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 to receive either daily oral TDF or placebo.[4] All participants also received access to addiction support services, methadone programs, bleach for cleaning needles, condoms, and primary care medical services.[4] After a median follow-up of 4.6 years, the relative risk reduction in HIV was 49% among study participants in the TDF arm and 70% in a subgroup of individuals who had detectable plasma tenofovir levels.[4]
- **DISCOVER**: This phase 3, randomized, double-blind trial compared the safety and efficacy of daily oral TAF-FTC with daily oral TDF-FTC for HIV PrEP with an enrolled population that was 99% adult men who have sex with men.[15] Primary efficacy analysis at week 48 (for all participants) and week 96 (for half the participants) indicated the incidence of documented new HIV infections in the daily TAF-FTC arm (0.16 per 100 person-years) was similar to the daily TDF-FTC arm (0.34 per 100 person-years).[15] Participants receiving TAF-FTC, when compared with those receiving TDF-FTC, had favorable bone mineral density measurements and biomarkers of renal safety but experienced greater weight gain (about 1.2 kg difference).[15]

- **HPTN 083**: The HIV Prevention Trials Network (HPTN) 083 study was a randomized, double-blind, double-dummy, noninferiority trial comparing long-acting injectable cabotegravir (CAB-LA) with daily oral TDF-FTC for HIV seronegative adults at risk of acquiring HIV (87% of persons enrolled were men who have sex with men).[8] Women at risk of acquiring HIV through receptive vaginal sex were not included in the trial.[8] The cabotegravir regimen consisted of a 5-week lead-in phase 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.[8] In total, 4,566 participants were randomized. There were 39 new HIV infections (incidence 1.22 per 100 person-years) in the TDF-FTC group and 13 infections (incidence 0.41 per 100 person-years) in the CAB-LA arm.[8] CAB-LA was superior to TDF-FTC for the prevention of HIV in men who have sex with men; the superior efficacy of CAB-LA was driven largely by imperfect adherence to the oral TDF-FTC.[8]
- **HPTN 084**: The HIV Prevention Trials Network (HPTN) 084 study was a phase IIb/3, randomized, double-blind trial comparing CAB-LA versus daily oral TDF-FTC for the prevention of HIV infection in women at risk for acquiring HIV.[6] A total of 3,224 participants enrolled and were randomized.[6] The cabotegravir regimen consisted of a 5-week lead-in phase 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.[6] There were 34 new HIV infections (incidence 1.79 per 100 person-years) in the TDF-FTC group versus 4 infections (incidence 0.21 per 100 person-years) in the CAB-LA arm. The CAB-LA arm was superior to the TDF-FTC arm for the prevention of HIV acquisition in women.[6]
- **IPERGAY**: The ANRS Intervention Préventive de l'Exposition aux Risques avec et pour les Gays (IPERGAY) study was a phase 3, randomized, double-blind, placebo-controlled trial in France and Canada evaluating the efficacy of on-demand oral TDF-FTC, taken before and after sexual activity for the prevention of HIV among 400 sexually active men who have sex with men.[16] Participants were evaluated at weeks 4 and 8, and then every 8 weeks thereafter.[16] In addition, at each visit, all participants received a comprehensive package of risk-reduction interventions. Adherence was measured by pill count, structured interviews, and, in some participants, by plasma emtricitabine levels.[16] After a median follow-up of 9.3 months, the relative risk reduction in HIV infections was 86% in the on-demand TDF-FTC arm compared to the placebo arm.[16]
- **iPrEx**: The Preexposure Initiative (Iniciativa Profilaxis Pre-Exposición [iPrEx]) study was a phase 3, randomized, double-blind, placebo-controlled trial conducted in Peru, Ecuador, Brazil, Thailand, South Africa, and the United States that enrolled 2,499 HIV-seronegative adults, including 2,470 men who have sex with men (99% of the persons enrolled).[17] Participants were randomly assigned to receive a daily oral dose of TDF-FTC or placebo. Investigators evaluated study participants every 4 weeks with an interview, HIV testing, counseling about risk reduction and adherence to HIV PrEP medication doses, pill count, and dispensing of pills and condoms. This study documented 44% fewer new HIV infections among those prescribed daily TDF-FTC for HIV PrEP when compared to those who received placebo.[17]
- **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. The investigators randomized the HIV-seronegative partners to receive either daily oral TDF versus TDF-FTC versus placebo for the prevention of HIV acquisition.[18] The HIV-seropositive partners had a median CD4 count of 495 cells/mm^3 and were not receiving antiretroviral therapy (because they were not eligible per local treatment guidelines that existed at the time the study was conducted).[18] The trial was stopped after an interim analysis showed statistically significant lower HIV transmission rates in both the TDF and TDF-FTC groups compared with the placebo group; investigators reported a 75% reduction in HIV acquisition among the partners who were HIV-seronegative and taking daily oral TDF-FTC, and a 67% reduction among those taking only daily oral TDF.[18] Adherence was high, as measured by pills dispensed, pill count, and random plasma drug level testing.
- **PROUD**: The Preexposure Option for Reducing HIV in the UK (PROUD) study was a phase 4, randomized, open-label study at 13 clinics in England that evaluated the efficacy of daily oral TDF-FTC for the prevention of HIV among sexually active men without HIV who reported condomless anal sex with men in the previous 90 days.[19] The 544 study participants were randomized to receive daily TDF-FTC either immediately upon enrollment or after a deferral period of 1 year. The investigators assessed sexual risk behaviors and adherence via daily diaries and monthly questionnaires; plasma

tenofovir samples were collected from some participants as an objective measure of adherence. The relative risk reduction in HIV infection i the immediate arm (participants who took TDF-FTC daily) was 86%.[19]

- **PURPOSE 1**: In the phase 3, double-blind, randomized PURPOSE 1 trial, LEN-SQ administered every 6 months was compared with oral TDF-FTC and oral TAF-FTC for HIV prevention in women 16–25 years of age in South Africa and Uganda.[5] Among participants, LEN-SQ was 100% effective in preventing HIV acquisition (0 new HIV infections); the incidence of HIV among participants who took LEN-SQ was significantly lower than background HIV incidence and lower than seen with participants in either of the other study arms (oral TDF-FTC and oral TAF-FTC).[5]
- **PURPOSE 2**: In the phase 3, multinational, double-blind, randomized PURPOSE 2 trial, LEN-SQ, administered every 6 months, was compared with daily oral TDF-FTC in populations that predominantly consisted of men who have sex with men.[7] Among the 2,179 participants in the LEN-SQ study group, there were 2 new HIV infections, which corresponded with a 96% reduction in HIV incidence compared with the expected background HIV incidence.[7] In addition, the HIV incidence was 89% lower in the LEN-SQ group (2 of 2,179 participants) than in the oral TDF-FTC group (9 of 1,086 participants).[7]
- **TDF2**: The Botswana TDF/FTC Oral HIV Prophylaxis Trial (TDF2), a phase 3, randomized, double-blind, placebo-controlled study of the safety and efficacy of daily oral TDF-FTC, enrolled 1,219 heterosexual men and women in Botswana who had tested negative for HIV.[20] In this study, daily oral use of TDF-FTC resulted in a 62% reduction in HIV acquisition when compared with placebo.[20] Adherence by pill count was 84% in both medication groups.

Visual Abstracts of Major HIV PrEP Studies

The HIV PrEP visual abstracts shown below provide brief visual summaries (Figure 2) for each of the major HIV PrEP studies listed above. Note that the visual abstract series can be downloaded as a PDF document.

Addressing Barriers Related to HIV PrEP Use

HIV PrEP Access and Use

Despite the well-established HIV PrEP efficacy, it is underutilized and under-prescribed in the United States. The low rate of uptake of HIV PrEP is the result of a complex interplay of social, economic, environmental, behavioral, and educational factors, including nonmedical factors that influence health outcomes. Differences exist when examining HIV PrEP usage by geographic location, income, insurance status, education level, substance use, and other factors.[21,22,23,24,25] A 2020 systematic review and meta-analysis highlighted disproportionately low rates of HIV PrEP prescriptions in the South and in youth.[26] Access to and use of HIV PrEP is impacted by regional differences in insurance qualifications for HIV PrEP, discrepancies in access by state, and whether the state has expanded Medicaid coverage.[27,28,29] Availability of HIV PrEP clinics is uneven and was found to be disproportionately lower in counties with more residents living in poverty, lacking health insurance, and among persons identifying as African American or Latino/Hispanic.[30] In the United States, women have relatively lower rates of HIV PrEP use when compared with HIV PrEP use among men who have sex with men.[31,32,33,34,35] The CDC HIV PrEP usage data show major differences in HIV PrEP usage in the United States based on sex, age, and race/ethnicity (Figure 3).[9]

[Q] HIV PrEP Prescribing in Different Populations

Barriers to Receiving HIV PrEP

A literature review identified multiple complex hurdles to HIV PrEP coverage in the United States.[36] Obstacles can exist at each step of the HIV PrEP care continuum, such as individual perception of HIV risk and awareness of HIV PrEP, access to a knowledgeable HIV PrEP provider, comfort discussing HIV PrEP with a health care professional, willingness to take HIV PrEP, concerns about medication side effects, and costs of HIV PrEP.[37] The HIV PrEP-related financial concerns include costs for medications, clinic visits, and the cost of laboratory monitoring.[38] Qualitative studies that engaged women found low perceived HIV risk and fear of partner reactions to be significant barriers. Medical provider factors that may contribute to HIV PrEP barriers include lack of medical awareness, skills, knowledge, training, and willingness to prescribe HIV PrEP.[39,40,41] A survey in New York found that access to a health care provider who was knowledgeable about HIV PrEP was a critical factor associated with their interest in taking HIV PrEP.[42]

Addressing Barriers to HIV PrEP Access

Overall, the barriers to HIV PrEP must be acknowledged, better understood, and addressed through interventions at the clinic, community, and systems level. User-centered approaches to promote improved access and usage will contribute to disseminating HIV PrEP to those in need and to reducing the number of new infections in the country. The interventions needed to address the multiple barriers to HIV PrEP access are complicated, but the following measures can be utilized by medical practitioners and healthcare institutions to help address and overcome these barriers.

- Use clear and welcoming messaging, since this is crucial for engaging individuals at risk for HIV acquisition and promoting HIV PrEP access, whether in a clinic setting or in larger public health campaigns.
- Normalize HIV screening and conversations about HIV PrEP.
- Integrate HIV PrEP into routine primary care services, including at clinics that provide sexual health care, addiction treatment, and family planning services.[43,44] Ideally, such integrated services are combined with peer navigation and collaboration with community-based organizations.[45]
- Incorporate expansion of HIV PrEP delivery models, such as HIV PrEP via telemedicine, pharmacist-prescribed HIV PrEP, or home delivery; these expanded HIV PrEP delivery options can ease the burden of seeking a clinic and finding a knowledgeable provider and thus facilitate HIV PrEP.[46]
- Address medical provider education and financial support for HIV PrEP, as well as any technology-

mediated models that facilitate HIV PrEP access, reduce barriers, and enhance medication adherence.[36]

- Utilize a community-informed approach to HIV PrEP messaging, meaning gathering community input on research, quality improvement interventions, and policy to help optimize protocols and messaging.
- Create community partnerships to help connect individuals who may benefit from HIV PrEP with leaders from the community who can help with HIV PrEP education and support. Similarly, engage HIV PrEP navigators and other community advocates to help build relationships. Social support is another key facilitator of HIV PrEP acceptance and usage.

Status Neutral Approach to HIV Prevention and Care

In 2022, the CDC posted the document Status Neutral HIV Care and Service Delivery.[47] The status neutral approach incorporates HIV prevention and care into routine health care with the goal of delivering high-quality, culturally affirming health care and services to people with and without HIV, thereby advancing health equity and reducing barriers to health care access.[47] The rationale for this approach is that many of the clinical and social services needed for HIV treatment and HIV prevention are the same, and there are advantages of combining these services in a single location for people with and without HIV. When using this approach with HIV testing, persons who test negative should receive prevention services, including HIV PrEP, if indicated, and persons who test positive should promptly receive HIV treatment (Figure 4).[47]

Summary Points

- New HIV infections continue to occur at a substantial rate in the United States, estimated at 32,000 new infections per year.
- HIV PrEP is the use of medications to prevent HIV acquisition and reduce HIV infection rates, and multiple HIV PrEP studies in the United States and globally have demonstrated the efficacy and safety of HIV PrEP for preventing HIV acquisition.
- Among people who take HIV PrEP medications as prescribed, the medications are more than 90% effective for preventing sexual acquisition of HIV and at least 70% effective in preventing HIV acquisition among people who inject drugs.
- In 2019, the U.S. Department of Health and Human Services (HHS) launched the Ending the HIV Epidemic (EHE) initiative with a goal to reduce new HIV infections by 90% (from baseline) by 2030 and HIV PrEP was designated to have a significant role in reaching this goal.
- Multiple, complex, intersectional, structural, social, and behavioral barriers at patient and provider levels contribute to poorer uptake in the use of HIV PrEP in the United States.
- Patient barriers include individual perception of HIV risk and awareness of HIV PrEP, access to and comfort discussing HIV PrEP with a knowledgeable health care provider, willingness to take HIV PrEP, and costs related to HIV PrEP.
- There exist significant differences in HIV PrEP uptake by age, race/ethnicity, sex, and geographic location.
- Medical provider factors that may contribute to HIV PrEP barriers include lack of medical awareness, skills, knowledge, training, and willingness to prescribe HIV PrEP.
- Strategies to address HIV PrEP barriers include normalization and integration of HIV screening and HIV PrEP in primary care services; expansion of HIV PrEP delivery models and provider education; community involvement in HIV PrEP messaging; and addressing financial support for HIV PrEP users.

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Figures

Figure 1 HIV PrEP Coverage in the United States

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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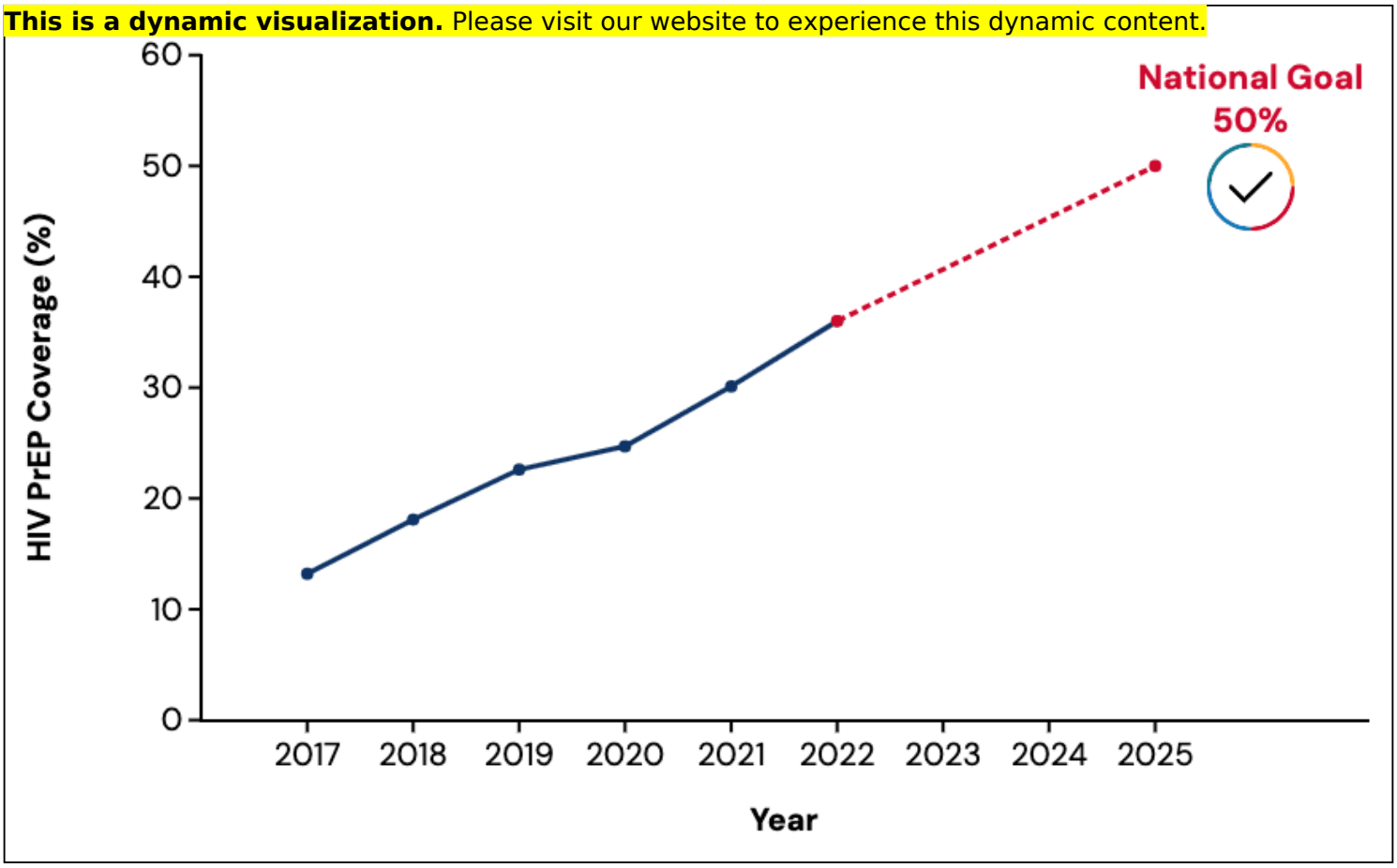


Figure 2 HIV PrEP Studies: Visual Abstract Guide

National HIV PrEP Curriculum

For more information guides visit **hivprep.uw.edu**



VISUAL ABSTRACTS

HIV PrEP Studies

David H. Spach, MD[1] / Brian R. Wood, MD[1] / Kevin L. Ard, MD[2]

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ABOUT THIS INFORMATION GUIDE

This visual abstract study series is intended for health care professionals involved in care of persons who may benefit from receiving HIV preexposure prophylaxis (PrEP). These visual abstracts provide relevant information pertaining to major HIV PrEP studies. This guide has been created and produced by the University of Washington Infectious Diseases Education & Assessment Program (IDEA) as part of the federally-funded *National HIV PrEP Curriculum* project.

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Figure 3 Differences in HIV PrEP Coverage in the United States

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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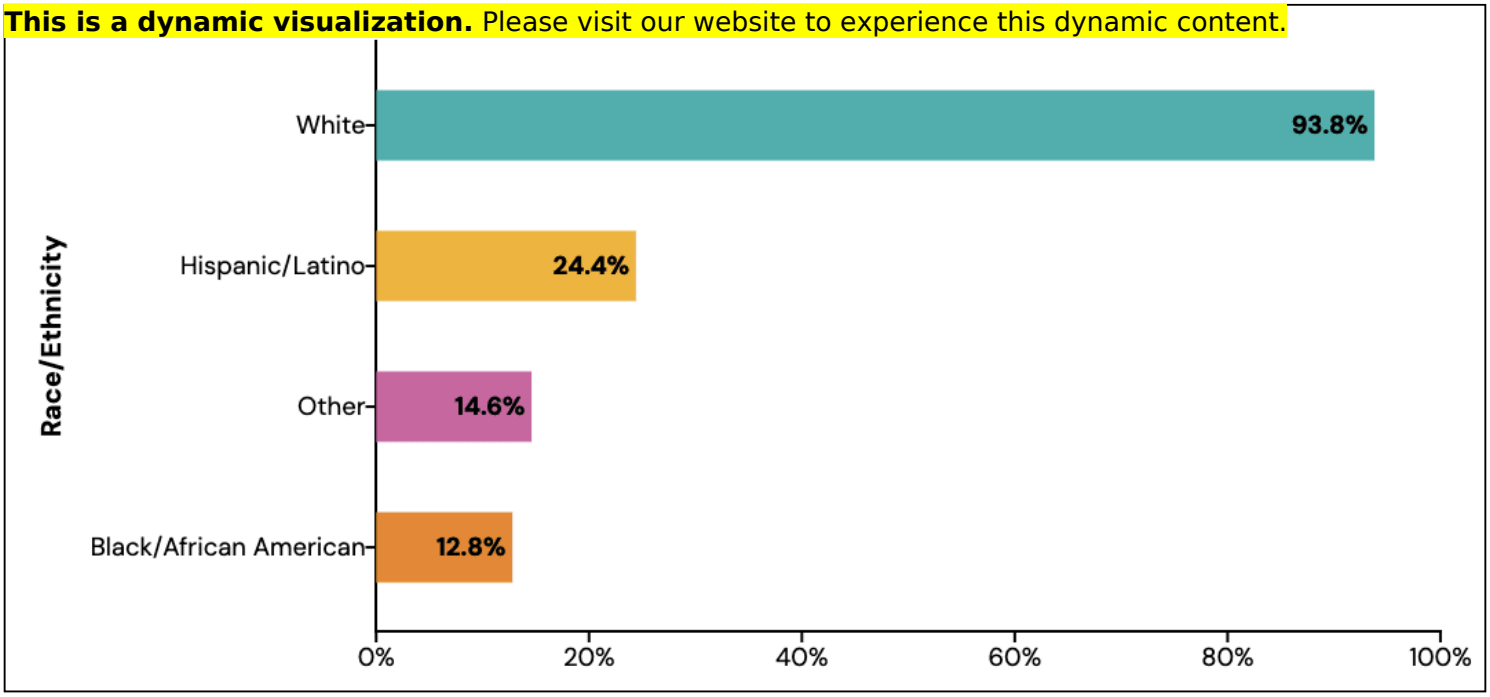
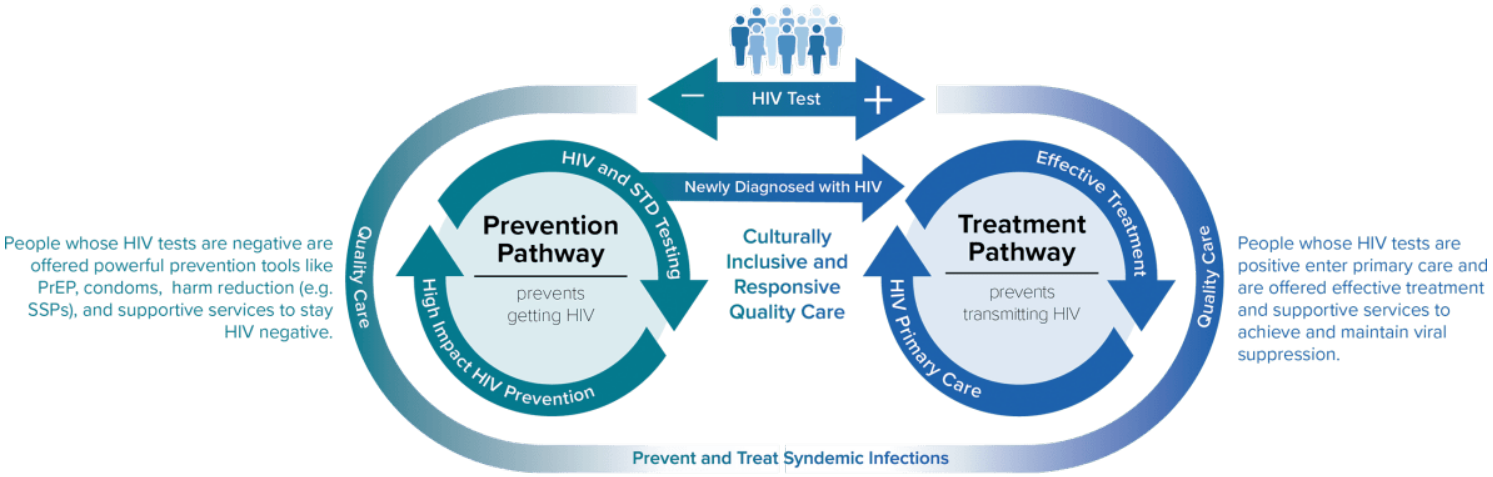


Figure 4 Status Neutral HIV Prevention and Care

Source: Centers for Disease Control and Prevention. Issue Brief: Status Neutral HIV Care and Service Delivery



Follow CDC guidelines to test people for HIV. Regardless of HIV status, quality care is the foundation of HIV prevention and effective treatment. Both pathways provide people with the tools they need to stay healthy and stop HIV.