HIV PREVENTION IN 2026: PREP, PEP, & BEYOND

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DISCLOSURES -

- Dr. Blackwell has no conflicts of interest or other disclosures for this presentation.
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OBJECTIVES

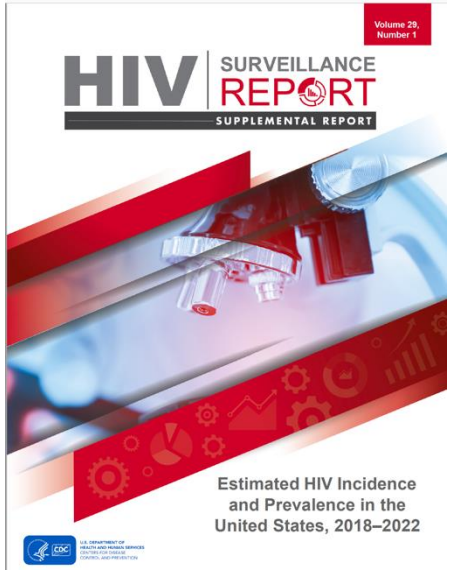
- At the end of this presentation, participants will outline current epidemiologic data and trends reported during the most recent CDC evaluation period regarding HIV infection among adults and adolescents in the United States
- At the end of this presentation, participants will describe oral, injectable, and 2-1-1 pharmacologic pre-exposure prophylaxis (PrEP) pharmacologic regimens.
- At the end of this presentation, participants will describe the regimen for the pharmacologic prevention of HIV through post-exposure prophylaxis (PEP).

HIV EPIDEMIOLOGY IN THE US: 2018-2022

INCIDENCE OF HIV INFECTION

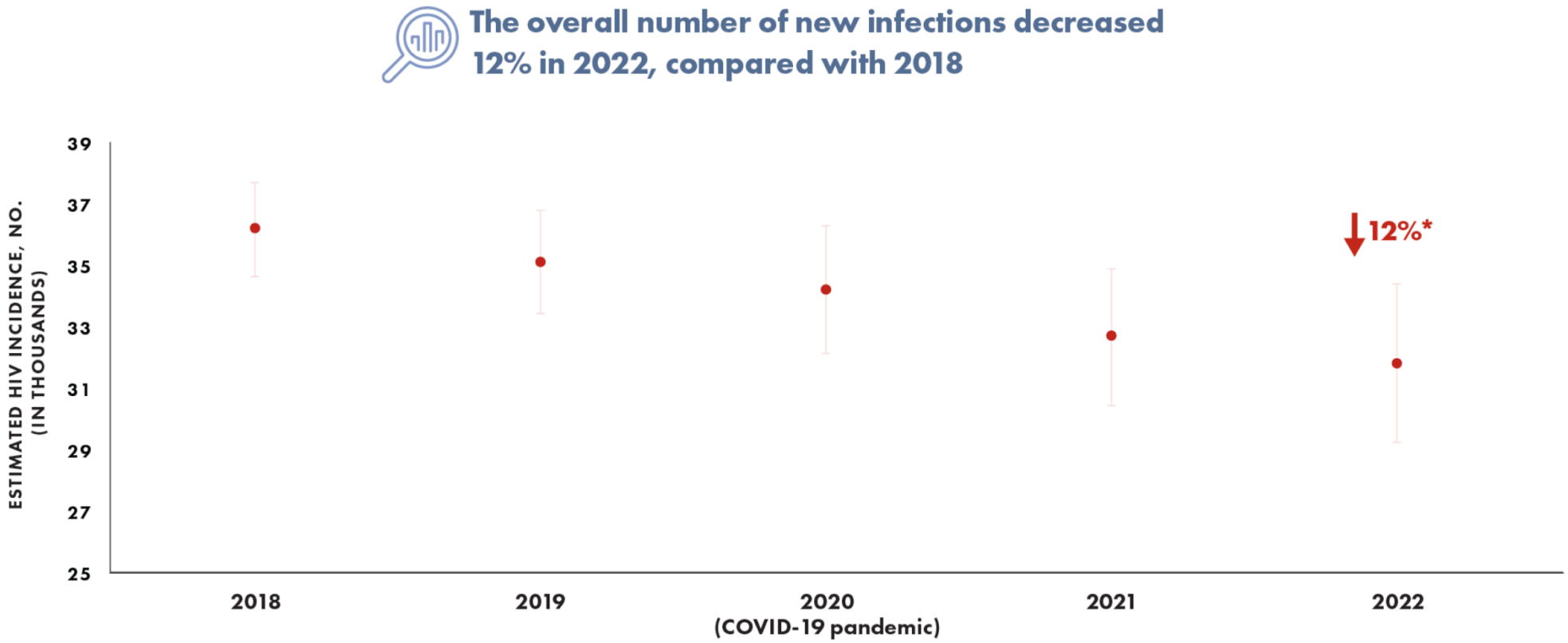
- Review of Centers for Disease Control and Prevention (CDC) Data: Updated through 2022 (2018-2022)

- These can all be obtained from:
  - Centers for Disease Control and Prevention. (2024). Estimated HIV incidence and prevalence in the United States, 2018–2022. *HIV Surveillance Supplemental Report,* 29(1).
- https://stacks.cdc.gov/view/cdc/156513/cdc_156513_DS1.pdf
- The figures on slides 4-13 all come from these CDC sources



INCIDENCE OF HIV INFECTION & AIDS 2018-2022: TAKE AWAY POINTS

Figure 1. Estimated HIV incidence among persons aged ≥13 years, 2018–2022—United States



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INCIDENCE OF HIV INFECTION & AIDS 2018-2022: TAKE AWAY POINTS

Figure 11. Estimated HIV incidence among persons aged ≥13 years, by area of residence, 2022—United States and Puerto Rico

In 2022, 57% of new infections were in eight states:

- California
- Florida
- Georgia
- Illinois
- New York
- North Carolina
- Ohio
- Texas

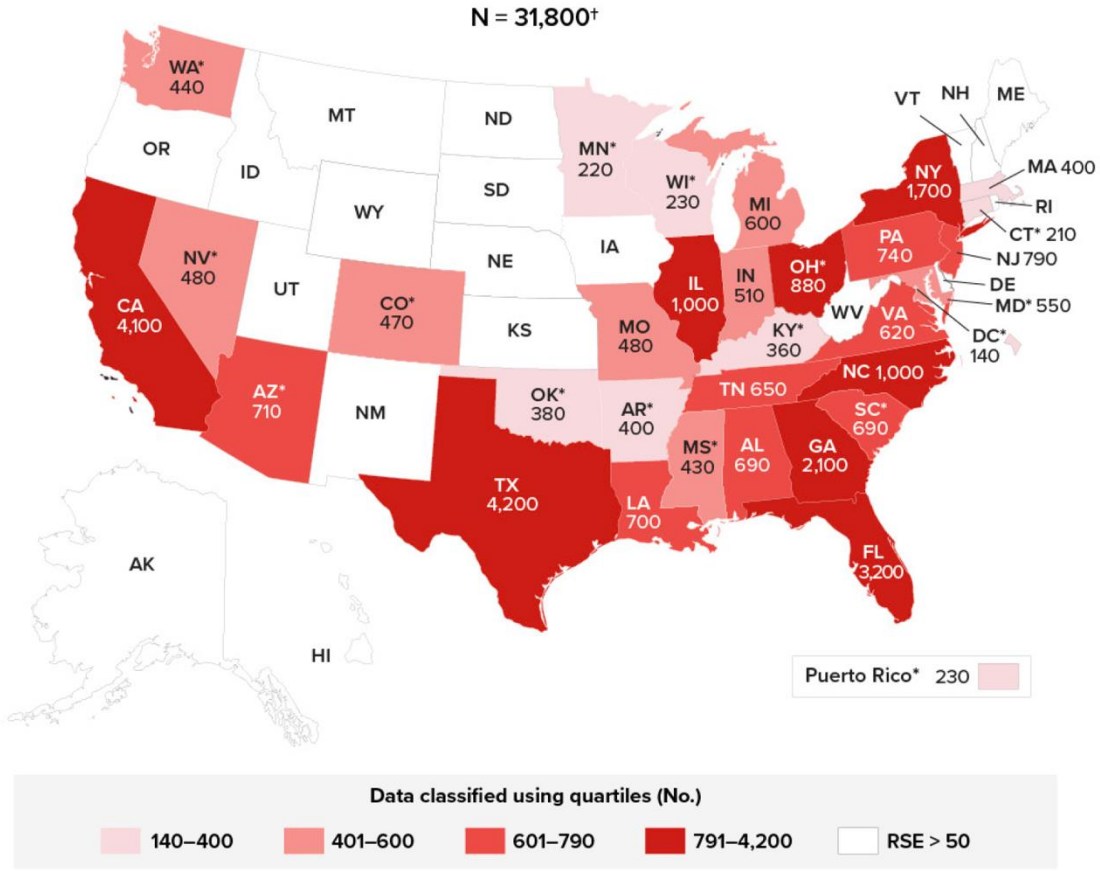


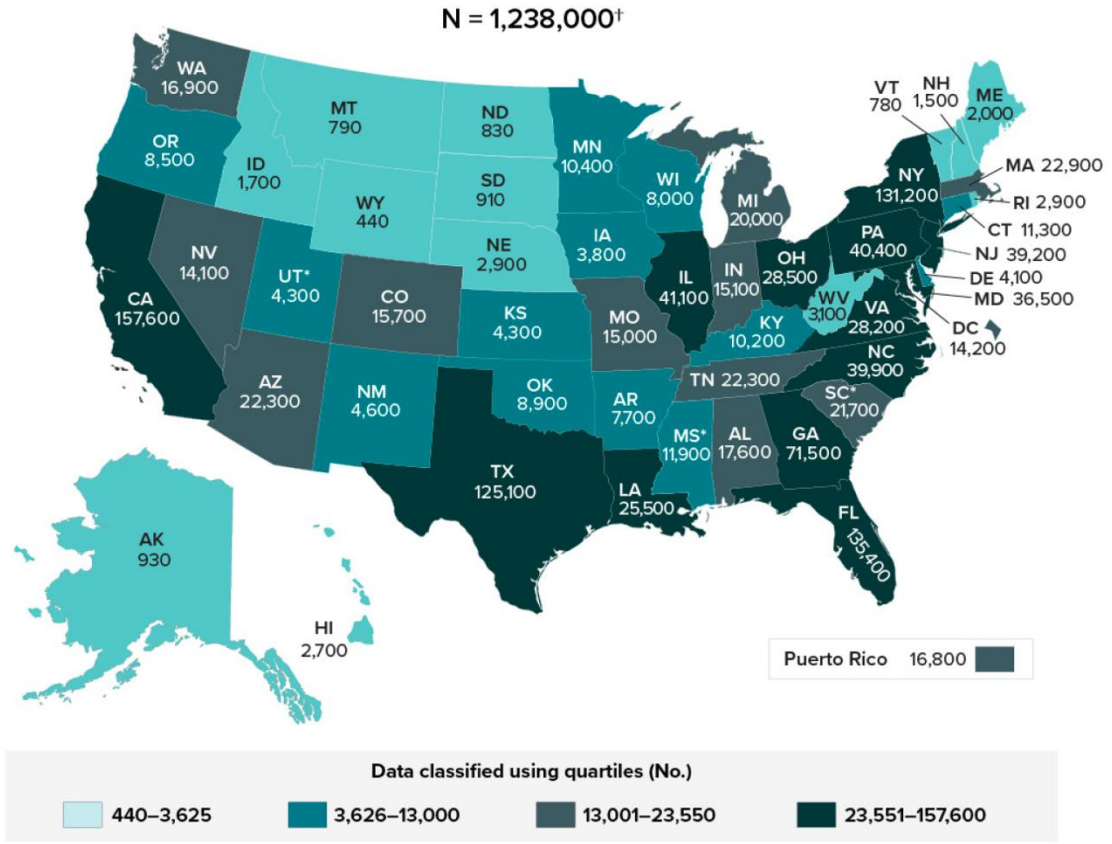
Image licensed through: CDC: https://stacks.cdc.gov/view/cdc/156513/cdc_156513_DS1.pdf

PREVALENCE OF HIV INFECTION 2018-2022: TAKE AWAY POINTS

Figure 23. Estimated HIV prevalence among persons aged ≥13 years, by area of residence, 2022—United States and Puerto Rico

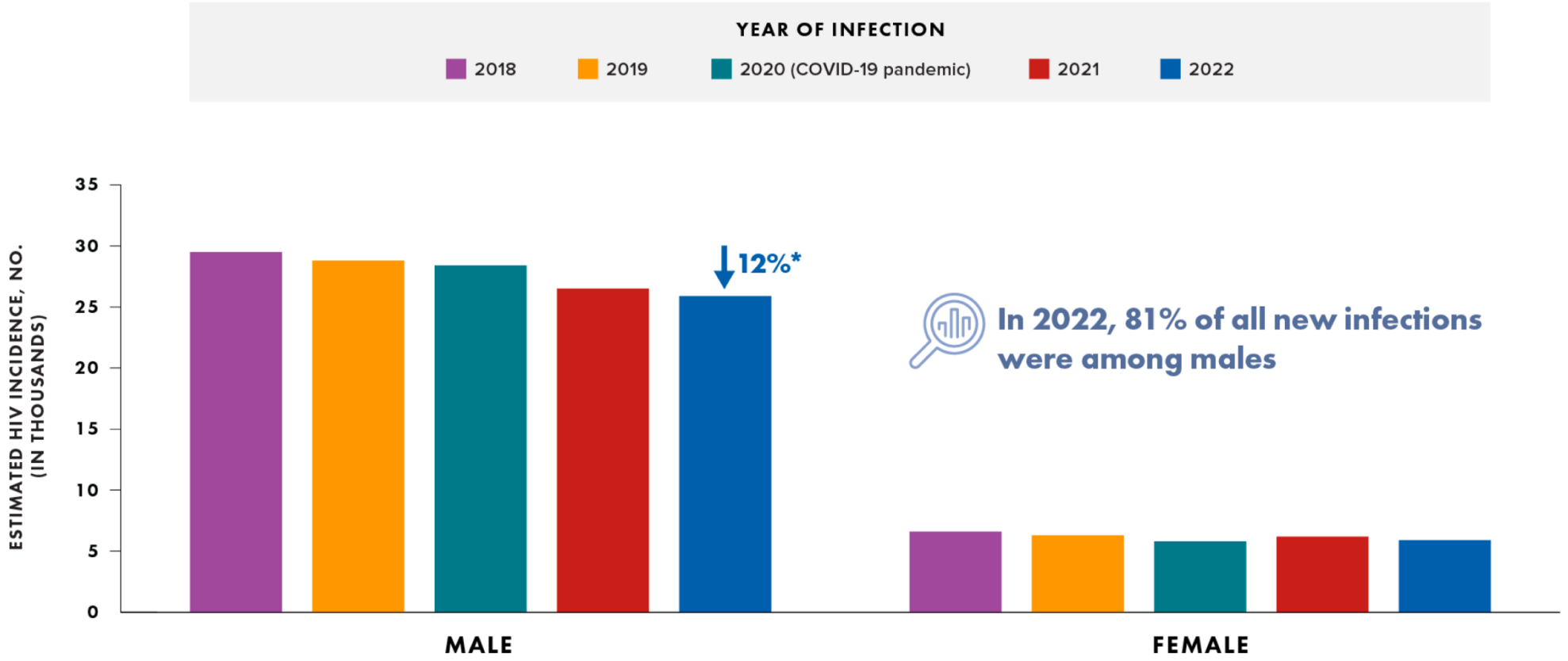
In 2022, states with lowest estimated HIV prevalence:

- Alaska
- Hawaii
- Idaho
- Maine
- Montana
- Nebraska
- New Hampshire
- North Dakota
- Rhode Island
- South Dakota
- Vermont
- West Virginia
- Wyoming



INCIDENCE OF HIV INFECTION 2018-2022: TAKE AWAY POINTS

Figure 2. Estimated HIV incidence among persons aged ≥13 years, by sex assigned at birth, 2018–2022—United States



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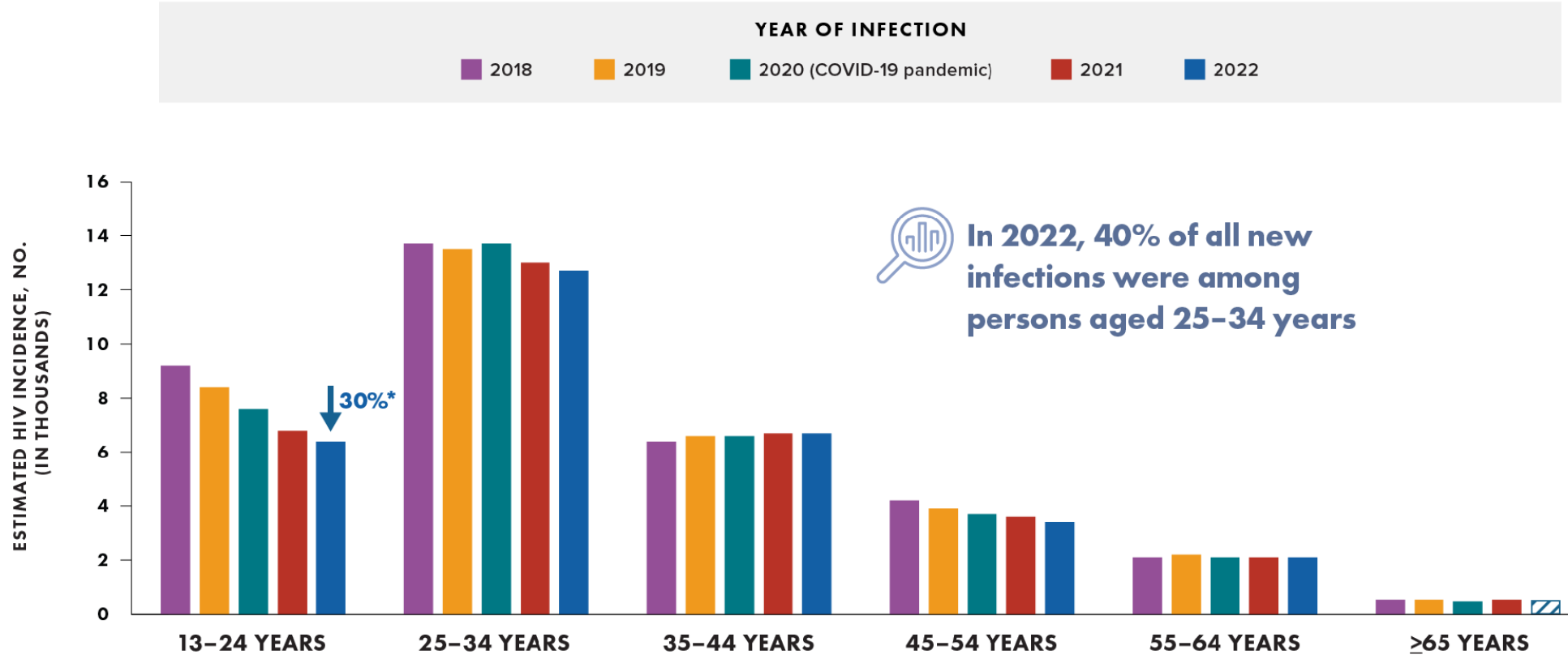
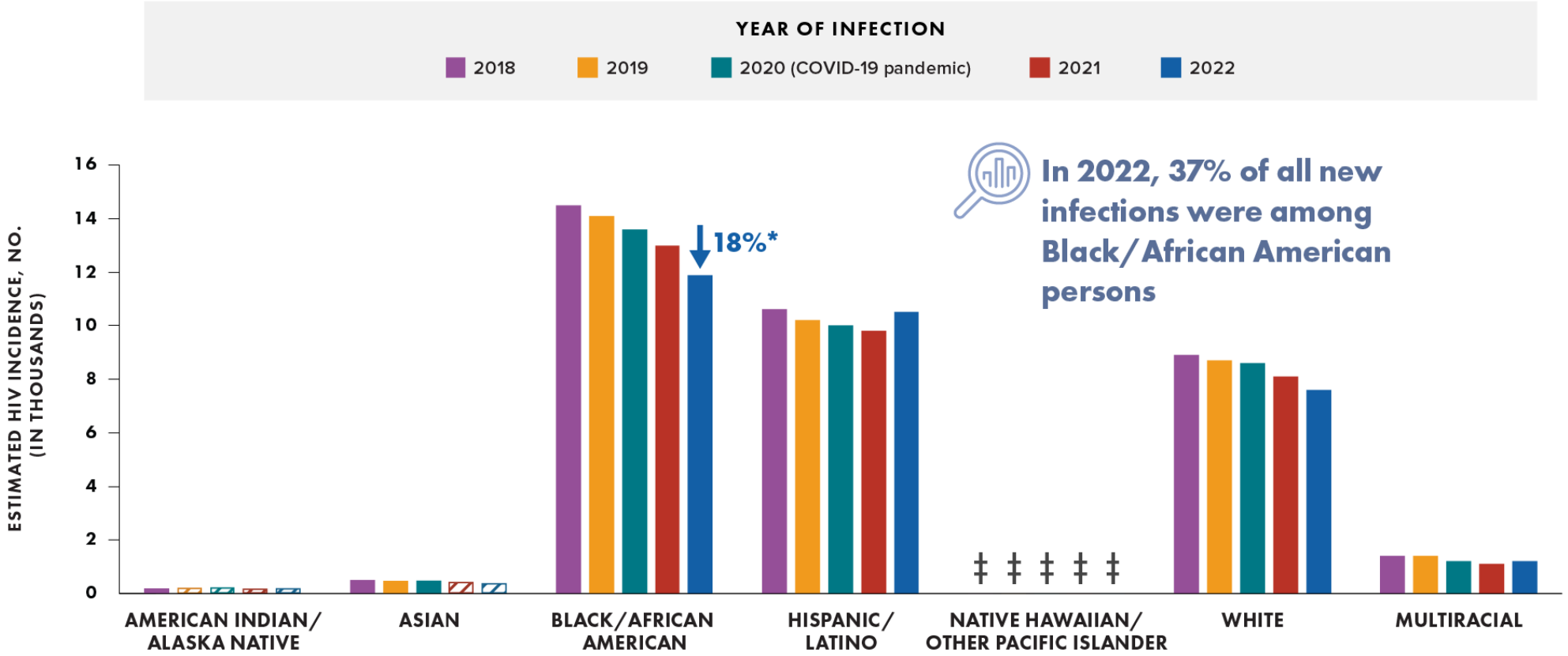
INCIDENCE OF HIV INFECTION 2018-2022: TAKE AWAY POINTS

Figure 3. Estimated HIV incidence among persons aged ≥13 years, by age at infection, 2018–2022—United States



INCIDENCE OF HIV INFECTION 2018-2022: TAKE AWAY POINTS

Figure 4. Estimated HIV incidence among persons aged ≥13 years, by race/ethnicity, 2018–2022—United States



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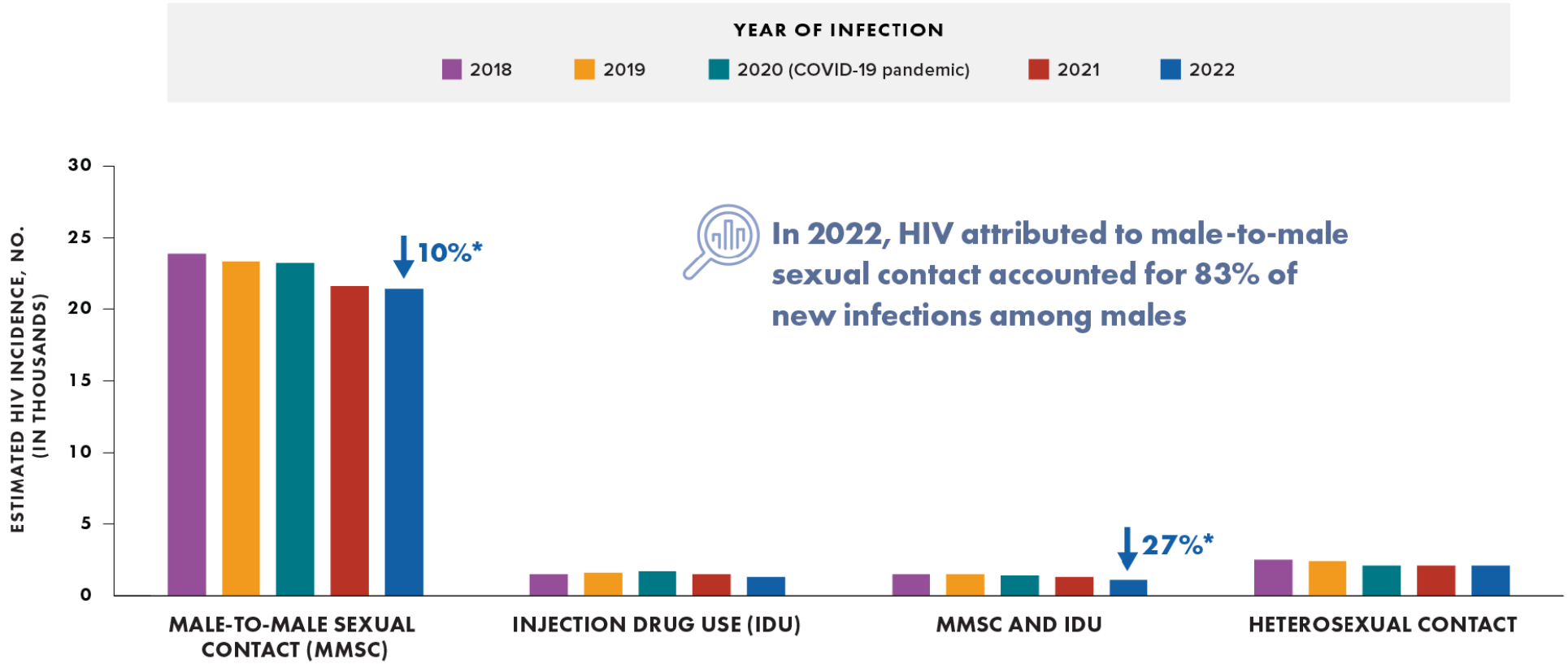
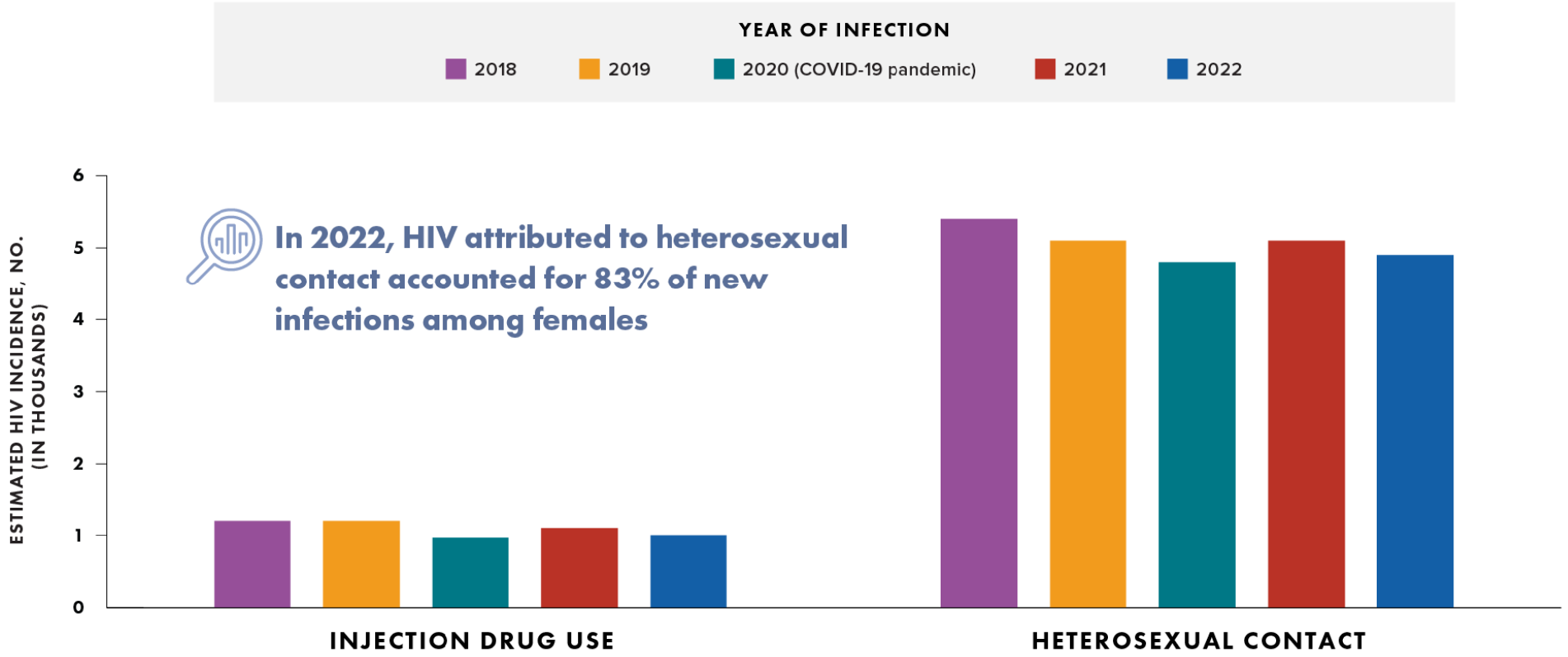
INCIDENCE OF HIV INFECTION 2018-2022: TAKE AWAY POINTS

Figure 8. Estimated HIV incidence among males aged ≥13 years, based on sex assigned at birth, by transmission category, 2018–2022—United States



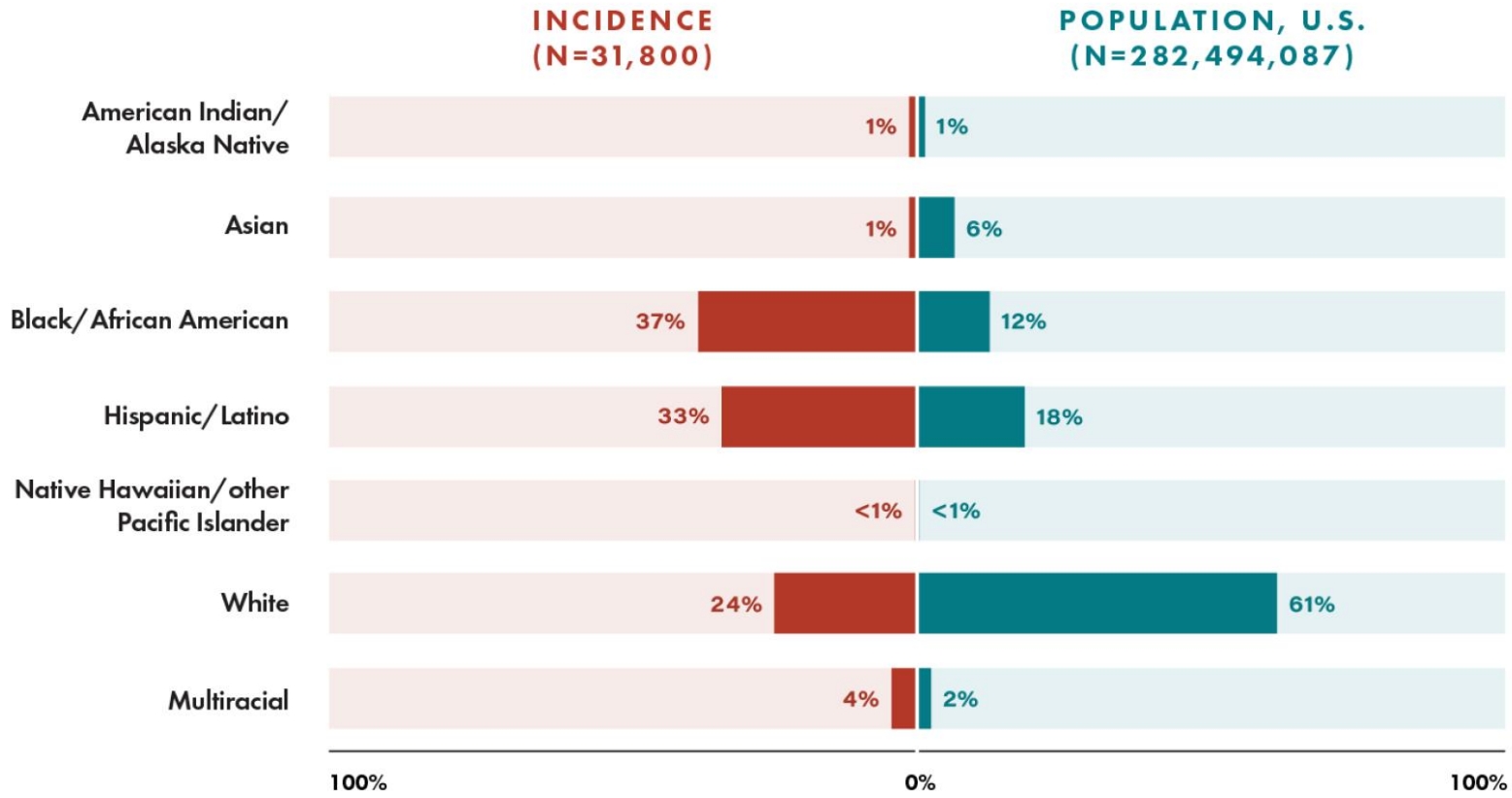
INCIDENCE OF HIV INFECTION 2018-2022: TAKE AWAY POINTS

Figure 9. Estimated HIV incidence among females aged ≥13 years, based on sex assigned at birth, by transmission category, 2018–2022—United States



INCIDENCE OF HIV INFECTION 2018-2022: TAKE AWAY POINTS

Figure 5. Estimated HIV incidence and population among persons aged ≥13 years, by race/ethnicity, 2018–2022—United States



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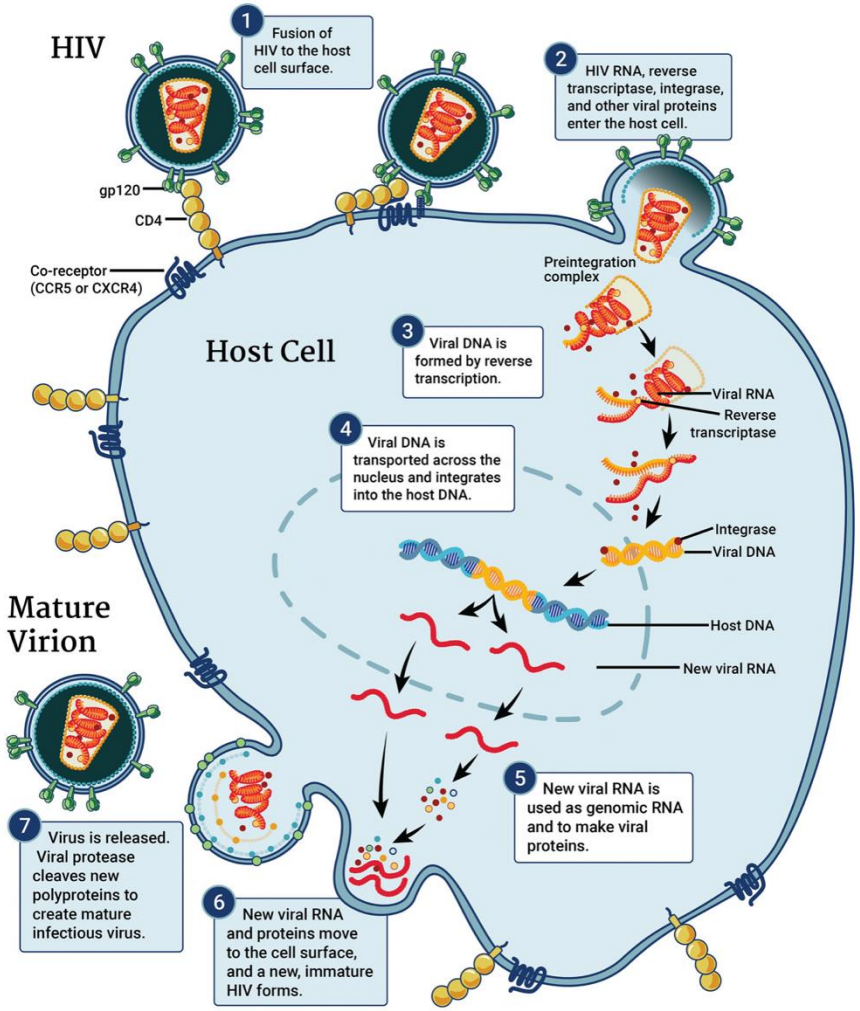
HIV REPLICATION CYCLE



PATHOPHYSIOLOGY OF HIV INFECTION

- HIV is a retrovirus, transcribing RNA-containing genetic material into DNA of the host cell nucleus by using an enzyme called reverse transcriptase
- Glycocoproteins allow HIV to attach to CD4 Cell and incorporate its RNA into the cell membrane, which then transcribes the RNA to DNA using reverse transcriptase
- This is then integrated into the CD4 nucleus using integrase. Integrated viral genes then transcribe back into genomic RNA and messenger RNA, which are translated to viral proteins
- These proteins then are cleaved with protease into new HIV particles, which release to infect other cells
- HIV progresses to AIDS
- Seroconversion (HIV- → HIV+) typically occurs in 2-12 weeks post-exposure. 95% (1 month; 99.9% by week 12)

Suggested Reference (parts 1-3): Wilkins, T. (2020). HIV 1: epidemiology, pathophysiology and transmission...Part 1 of three-part series. *Nursing Times*, *116*(7), 40–42.

PATHOPHYSIOLOGY OF HIV INFECTION

- After seroconversion, HIV antibody titers decrease as infected cells are sequestered in the lymph nodes
- This is the latent period, lasting up to 10 years
- During this period, CD4 cell lines drop as a result of infection and lysis of healthy T-Helper cells

PATHOPHYSIOLOGY OF HIV INFECTION

- As CD4 cells continue to decline, the patient becomes susceptible to opportunistic infections, malignancies, and neurological diseases
  - AIDS develops
- A very few HIV+ individuals are termed "Non-Progressors"

PATHOGENIC PROCESS OF HIV

- Exposure to HIV
- HIV Infection
- Seroconversion
- Latency Period
- Initial Symptoms of Immunodeficiency and Declining Immune Function
- Immune System Failure and AIDS
- Severe Immune Deficiency

PATHOGENIC PROCESS OF HIV

- Important Points:
- Transmission of HIV is possible at any stage of the disease process
- Risk to health workers is overall small
- With blood product screening emerging in 1985, transfusion-related HIV transmission decreased dramatically
- Since the introduction of maternal antiretroviral therapy, HIV transmission from mom to child has decreased
- *Practically Preventable*

PREVENTION OF HIV TRANSMISSION

- Sexual Transmission:
  - Alteration in Sexual Behaviors
  - Women more susceptible via vaginal mucosa compared to male penis
  - Anal intercourse (regardless of orientation) also risky secondary to rectal trauma, tearing, and fistula formation
  - Oral sex is actually very low risk
    - Hypotonicity
    - Contains thrombospondin and secretory leukocyte protease inhibitor (SLPI)
  - Viral Load is NOT a determinant of degree of safeness (theoretically)—CDC (2017) issued newer statement about this

Image Generated from M365 Copilot. (2026). *Healthy Choices* [AI-generated image].

PREVENTION OF HIV TRANSMISSION

- Pharmacologic: PrEP and PEP
- Parenteral Transmission:
  - Proper cleaning of drug paraphernalia:

    Fill with water (tap to loosen blood debris) and flush →

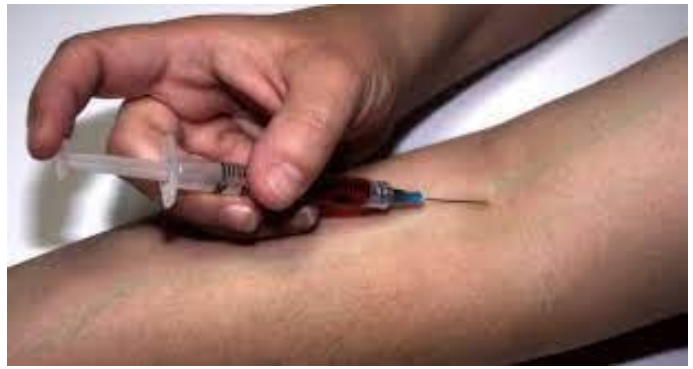
    Fill with bleach and then shake for 30 seconds, flush →

    Repeat x 3 →

    Fill with water, shake and tap x 30 seconds, flush →

    Repeat x 3

    Participation in needle exchange programs



PREVENTION OF HIV TRANSMISSION

- Perinatal Transmission:
  - HIV transmission thought to occur transplacentally in utero, intrapartally during exposure to blood and vaginal secretions during childbirth, or postpartally through breast milk

Image Generated from M365 Copilot. (2026). *Male nurse providing care to a pregnant woman* [AI-generated image].

PREVENTION OF HIV TRANSMISSION

- Perinatal Transmission (Ctd):
  - Review of prior HIV-related illnesses and past CD4 T lymphocyte (CD4) cell counts and plasma HIV RNA levels;
  - Current CD4 cell count;
  - Current plasma HIV RNA copy number;
  - Assessment of the need for prophylaxis against opportunistic infections such as Pneumocystis jirovecii pneumonia and Mycobacterium avium complex

(see Adult and Adolescent Opportunistic Infections Guidelines)

PREVENTION OF HIV TRANSMISSION

- Perinatal Transmission (Ctd):
  - Screening for hepatitis C virus and tuberculosis in addition to standard screening for hepatitis B virus (HBV) infection;
  - Assessment of the need for immunizations per guidelines from the American College of Obstetricians and Gynecologists, with particular attention to hepatitis A, HBV, influenza, pneumococcus, and Tdap immunizations;
  - Complete blood cell count and renal and liver function testing;
  - HLA-B*5701 testing if abacavir (Ziagen®) use is anticipated;
  - History of prior and current antiretroviral (ARV) drug use, including prior ARV use for prevention of perinatal transmission or treatment of HIV and history of adherence problems

PREVENTION OF HIV TRANSMISSION

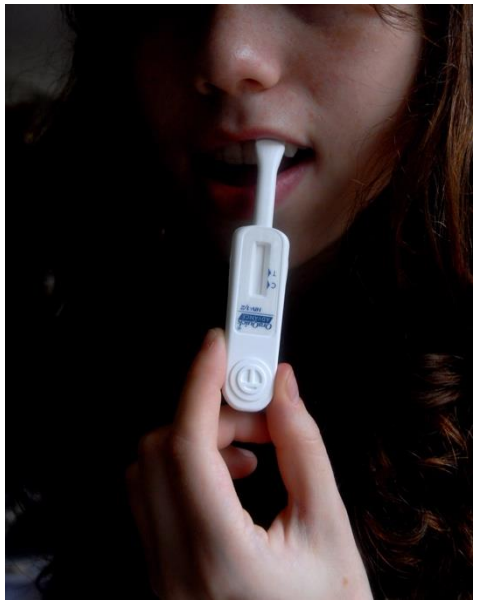
- Perinatal Transmission (Ctd):
  - Infected with HIV and on ART?:
    - Keep taking ART!
  - Infected with HIV and not on ART or with unknown or high HIV RNA load?:
    - Begin zidovudine (Retrovir®) IV near time of delivery
    - C-section in @ 38 weeks gestation
  - Neonate will also be treated with ART
  - Most recent guidelines (updated 2025): https://clinicalinfo.hiv.gov/en/guidelines/perinatal/whats-new

SCREENING FOR HIV

- Traditional: ELISA → Western Blot (99.5% accurate)
  - Substitution of Western Blot with antigen tests that differentiate HIV1 from HIV2
- Pre-Test and Post-Test Counseling can be valuable but is NOT CDC recommended as a requirement any longer
  - Check your state regulations for guidance
- General consent for Tx implies consent for HIV
  - Healthcare institutions and acute care facilities differ on consent requirements

SCREENING FOR HIV

- Antibody tests are specifically designed for the routine testing of HIV in adults, are inexpensive, and are very accurate
- Antibody tests give false negatives results during the *window period* of between three weeks and six months from the time of HIV infection until the immune system produces detectable amounts of antibodies
- Much screening done as POS



SCREENING FOR HIV

- Most people have detectable antibodies after three months
- A six-month window is extremely rare with modern antibody testing
- During this window period an infected person can transmit HIV to others, without their HIV infection being detectable using an antibody test
- ART during the window period can delay the formation of antibodies and extend the window period beyond 12 months

Image Generated from M365 Copilot. (2026). *HIV screening* [AI-generated image].

SCREENING FOR HIV

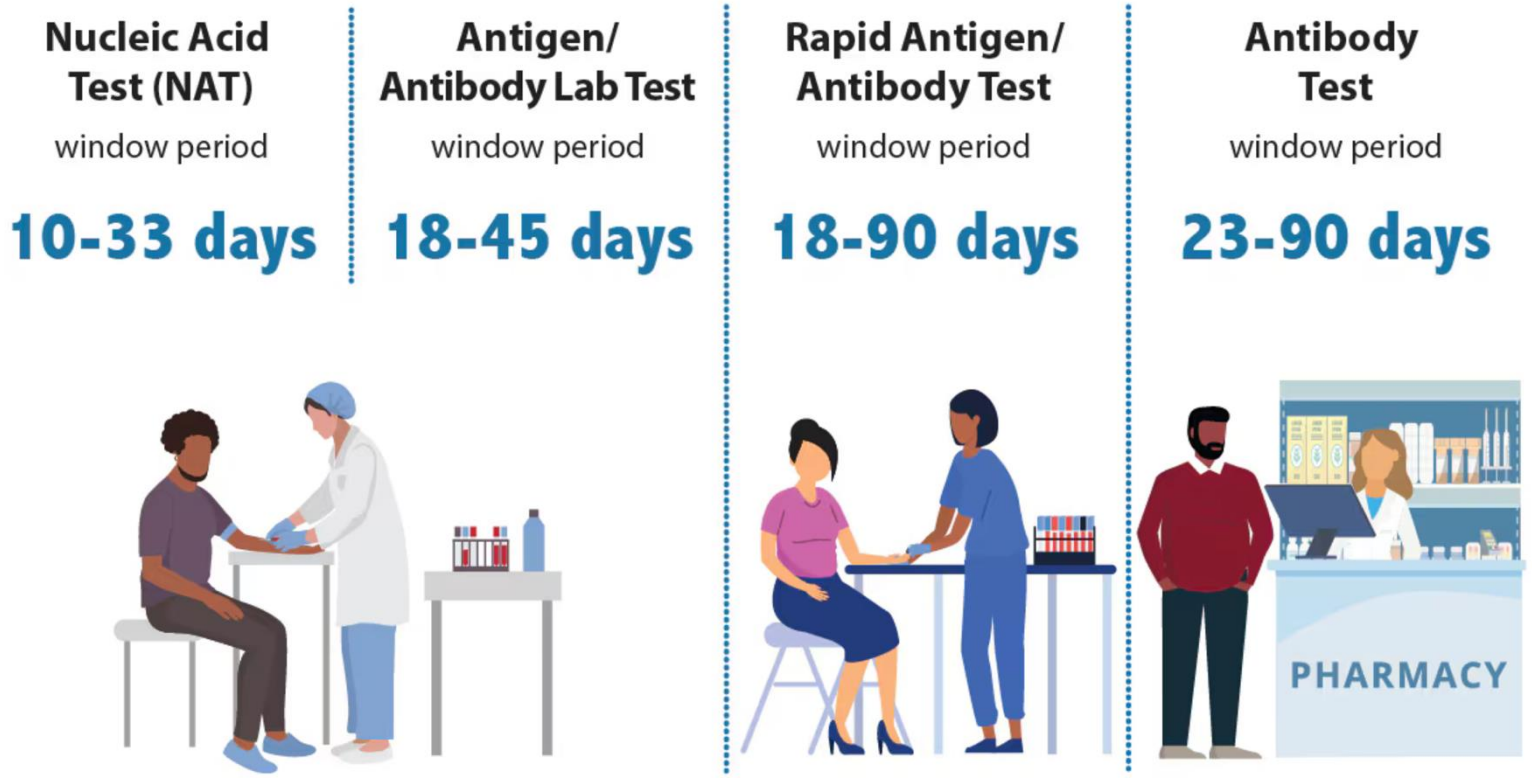
- OraSure® saliva—collected on oral wand device placed between gum and cheek for 2-5 min--mixed in a vial with solution, wand snapped off, vial closed and sent to lab
  - It is an antibody test which first employs ELISA, then Western Blot
- OraQuick® Advance is an HIV test which uses saliva, plasma, fingerstick, or whole blood specimen
    - Sample is obtained and mixed in a buffer → Device inserted into buffer → Results in 20-40 min
    - CLIA-waived for saliva, fingerstick, and venipuncture whole blood
  - There is also a urine test; it employs both the ELISA and the Western Blot method
  - Home Access Express HIV-1 Test is an FDA-approved home test: the patient collects a drop of blood and mails the sample to a laboratory; the results are obtained over the phone

Image Generated from M365 Copilot. (2026). *HIV screening* [AI-generated image].

SCREENING FOR HIV

- **Antigen Tests:**
  - The **p24 antigen test** detects the presence of the p24 protein of HIV (also known as CA), a major core protein of the virus
  - This test is now used routinely to screen blood donations, thus reducing the window to about 16 days
- **Nucleic Acid-Based Tests:**
  - Nucleic acid-based tests amplify and detect a 142 base target sequence located in a highly conserved region of the HIV *gag* gene
  - Since 2001, donated blood in the US has been screened with nucleic acid-based tests, shortening the window to about 12 days
  - Since these tests are relatively expensive, the blood is screened by first pooling some 10-20 samples, testing these together, and if the pool tests positive, each sample is retested individually

SCREENING FOR HIV



The window period depends on the type of HIV test.

Image licensed through CDC: https://www.cdc.gov/hiv/testing/index.html#:~:text=A%20rapid%20antigen%2Fantibody%20test%20done%20with%20blood%20from%20a,to%2033%20days%20after%20exposure.

HIV/AIDS SURVEILLANCE AND DX

- CD4 Testing:
  - Declining CD4 T-cell counts are a marker of the progression of HIV infection.
  - In PLWH, AIDS is officially diagnosed when the count drops below 200 cells or when certain opportunistic infections occur; CDC guidelines recommend beginning ART AT TIME OF Dx (2015)
  - Low CD4 T-cell counts are associated with a variety of conditions, including many viral infections, bacterial infections, parasitic infections, sepsis, tuberculosis, coccidioidomycosis, burns, trauma, intravenous injections of foreign proteins, malnutrition, over-exercising, pregnancy, normal daily variation, psychological stress, and social isolation

Image Generated from M365 Copilot. (2026). *Patient getting blood drawn* [AI-generated image].

HIV/ AIDS SURVEILANCE AND DX

- CD4 Testing:
  - The lower the number of T cells, the lower the immune system's function will be
  - Normal T4 counts are between 500 and 1500 CD4+ T cells per microliter and the counts may fluctuate in healthy people, depending on recent infection status, nutrition, exercise and other factors -- even the time of day
  - Women tend to have somewhat lower counts than men

Image Generated from M365 Copilot. (2026). *Patient getting blood drawn* [AI-generated image].

HIV/AIDS SURVEILLANCE AND DX

- Viral Load Testing:
  - Evidence shows that keeping the viral load levels as low as possible for as long as possible decreases the complications of HIV disease and prolongs life
  - Most recent public health guidelines state that treatment should be considered for asymptomatic HIV-infected people AT TIME OF Dx
  - There are several methods for testing viral load; results are not interchangeable, so it is important that the same method be used each time
  - Keep viral loads undetectable = decrease/ eliminate transmission

Image Generated from M365 Copilot. (2026). *Patient getting blood drawn* [AI-generated image].

PROPHYLACTIC PREVENTION OF HIV INFECTION: POST-EXPOSURE

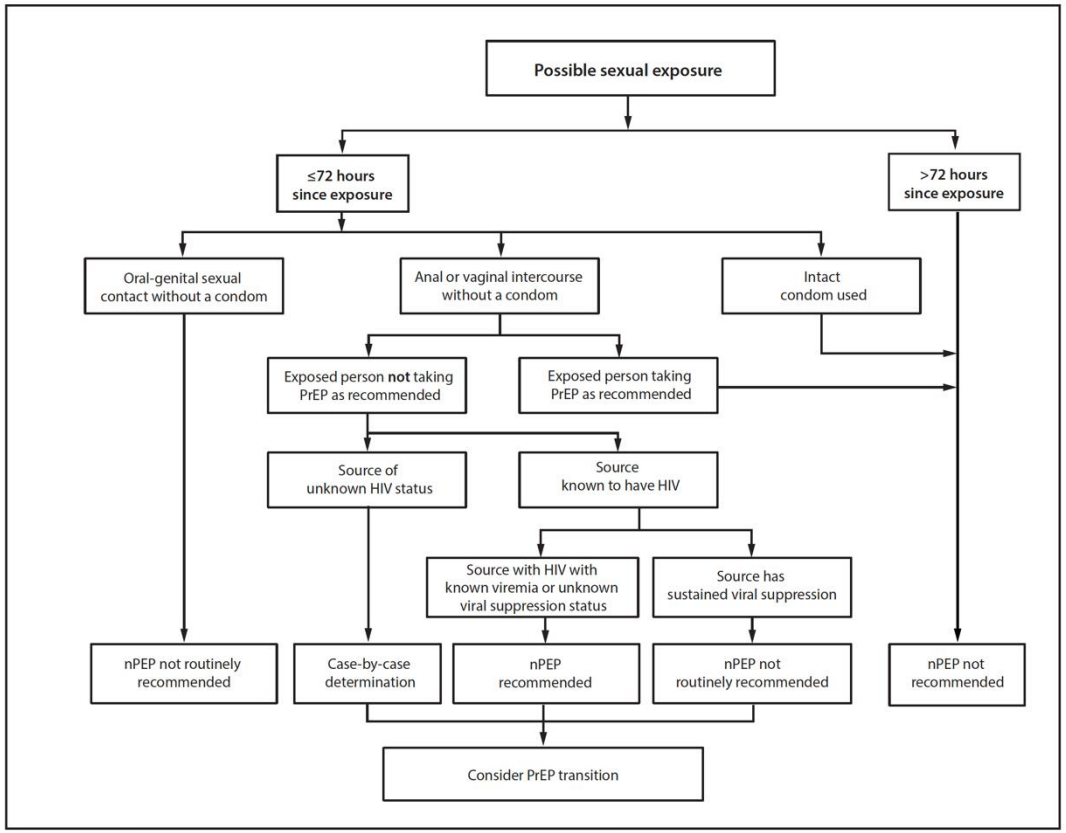
- Although large-scale studies about PEP are lacking, PEP is clinically effective (80%) and recommended (National Institutes of Health, 2025a) when:
  - The source is known to be HIV+
  - The source is of unknown serostatus (test source in occupational exposure)
  - The source has an increased likelihood of being HIV+:
    - MSM, MSM/W, commercial sex workers, history of incarceration, residence in a county with a seroprevalence rate ≥ 1%
  - The behavior has an increased (≥ 1%) likelihood of transmitting HIV (National Institutes of Health, 2025b):
    - Receptive Anal Intercourse = 1.4% chance of infection
    - Insertive Anal Intercourse = .11% chance of infection
    - Receptive Vaginal Intercourse = .08% chance of infection
    - Insertive Vaginal Intercourse = .04% chance of infection
    - Oral Intercourse: Few documented cases
    - Needle Sharing: .0063% per needle-sharing event
- Ideally, begin PEP within 36 hours but no more than 72 hours after exposure

References: National Institutes of Health. (2025a). *Post-exposure prophylaxis (PEP)*. https://hivinfo.nih.gov/understanding-hiv/fact-sheets/post-exposure-prophylaxis-pep

National Institutes of Health (2025b). *Understanding how HIV is transmitted*. https://hivinfo.nih.gov/understanding-hiv/fact-sheets/understanding-hiv-transmission

PROPHYLACTIC PREVENTION OF HIV INFECTION: POST-EXPOSURE

FIGURE 2. HIV nonoccupational postexposure prophylaxis in the setting of possible sexual exposure — CDC recommendations, United States, 2025 *,†



Abbreviations: nPEP = nonoccupational postexposure prophylaxis; PrEP = pre-exposure prophylaxis.

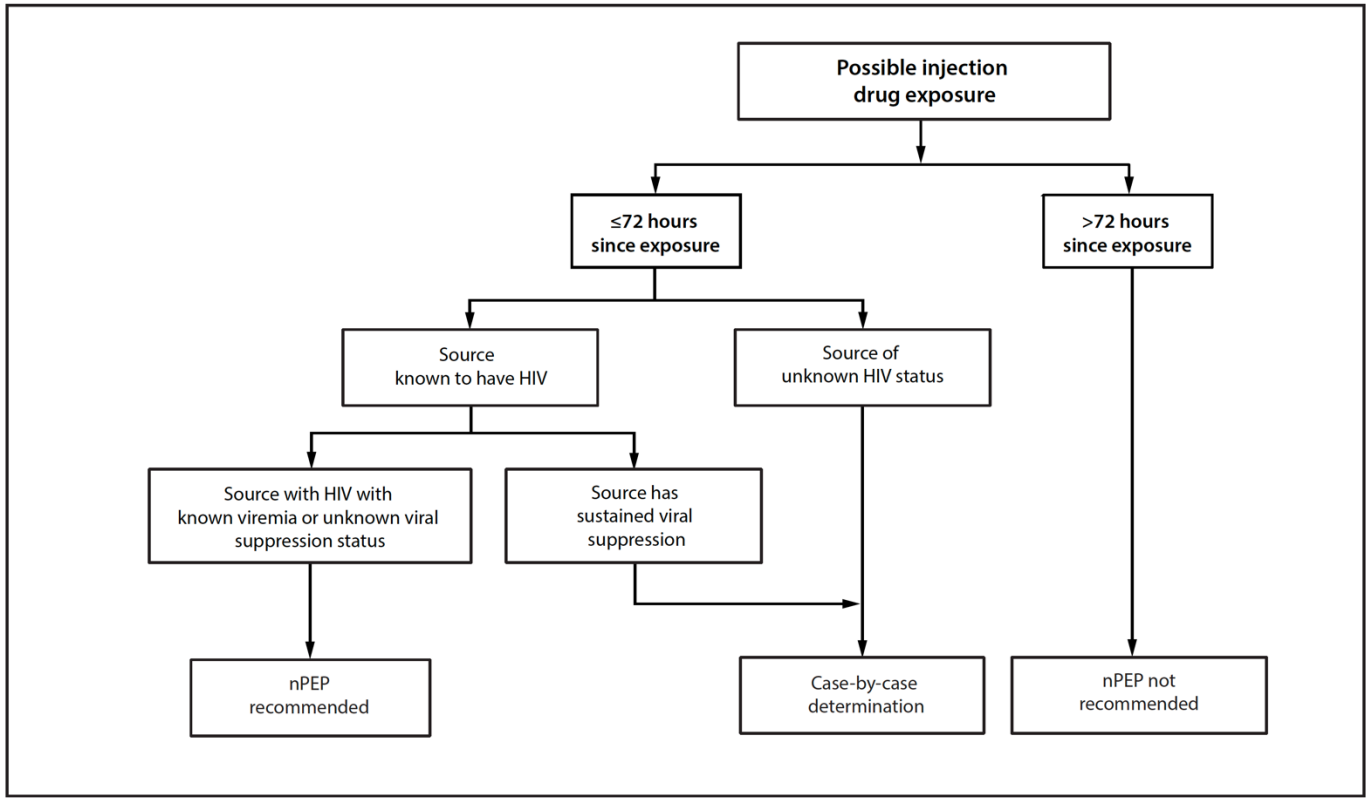
* Evidence is insufficient to recommend nPEP initiation later than 72 hours postexposure. However, certain experts have argued that risk versus benefit considerations could favor a longer initiation window.

† See Appendix A for more information on case-by-case determinations. Health care professionals unfamiliar with nPEP should use local infectious diseases or other expert consultation resources or consult the National Clinical Consultation Center PEPline at 888-448-4911 or https://nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis, or the Perinatal HIV Line at 888-448-8765 or https://nccc.ucsf.edu/clinician-consultation/perinatal-hiv-aids.

Source: https://stacks.cdc.gov/view/cdc/177225

PROPHYLACTIC PREVENTION OF HIV INFECTION: POST-EXPOSURE

FIGURE 3. HIV nonoccupational postexposure prophylaxis in the setting of possible injection drug use — CDC recommendations, United States, 2025*



Abbreviation: nPEP = nonoccupational postexposure prophylaxis.

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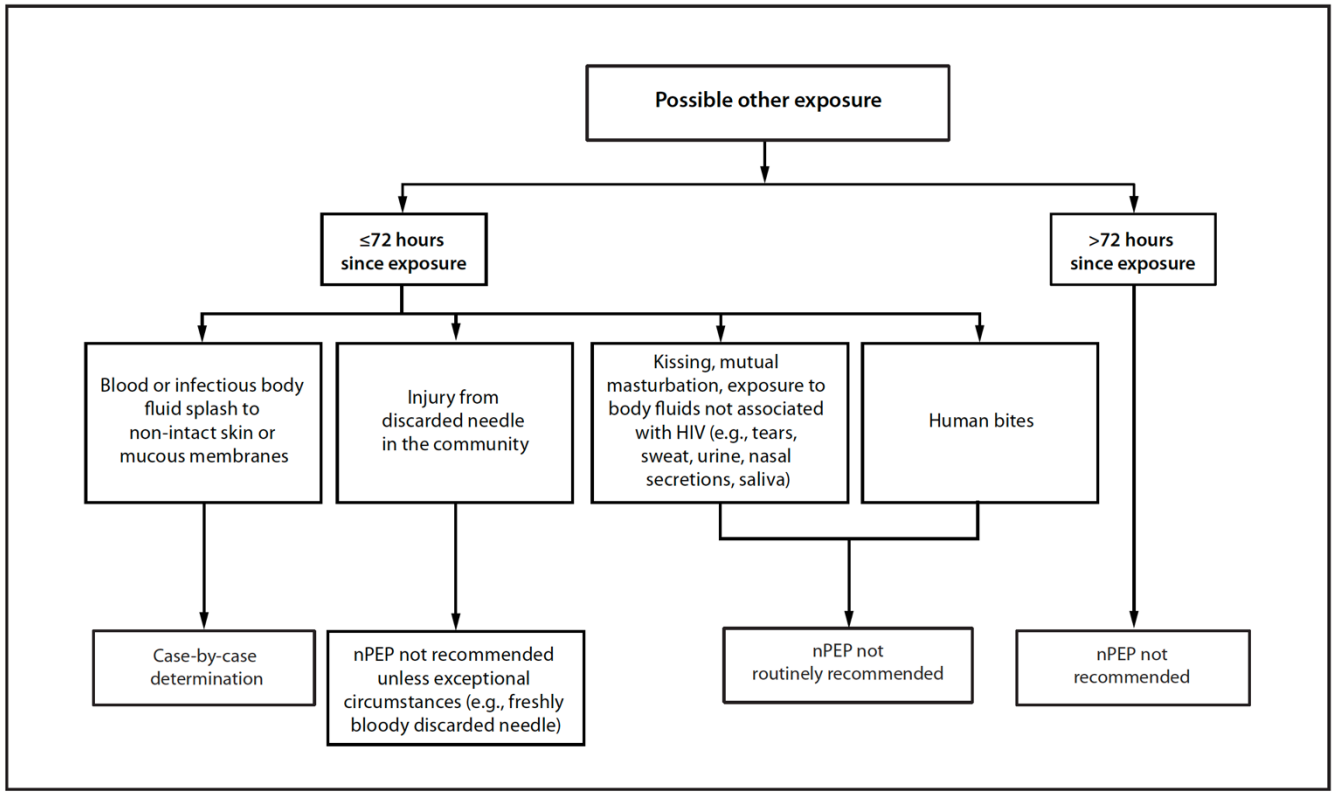
Source: https://stacks.cdc.gov/view/cdc/177225

PROPHYLACTIC PREVENTION OF HIV INFECTION: POST-EXPOSURE

FIGURE 4. HIV nonoccupational postexposure prophylaxis in the setting of infective fluid splash or exposure, needle injury, or human bites — CDC recommendations, United States, 2025*



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Source: https://stacks.cdc.gov/view/cdc/177225

PROPHYLACTIC PREVENTION OF HIV INFECTION: POST-EXPOSURE

Dolutegravir (DTG) + tenofovir alafenamide (TAF) *or* tenofovir disoproxil fumarate (TDF) + emtricitabine (FTC)
or
Bictegravir (BIC)/FTC/TAF *or* lamivudine (3TC) new recommendations (2025), with lower evidence

BOX 2. CDC recommendations for HIV nonoccupational postexposure prophylaxis, United States, 2025

HIV nPEP Indications

- nPEP is recommended when an exposure has occurred within the past 72 hours that presents a substantial risk for HIV transmission and the source has HIV without sustained viral suppression or their viral suppression information is not known (**good practice statement, existing recommendation**).
- A case-by-case determination is required when an exposure has occurred within the past 72 hours that presents a substantial risk for HIV transmission, but it is not known whether the source has HIV (**good practice statement, existing recommendation**).
- nPEP is not recommended if the exposure presents no substantial risk for HIV transmission (**good practice statement, existing recommendation**).
  - nPEP should be stopped if at any point during the course the source is found to not have HIV (**good practice statement, existing recommendation**).

Time to Initiation of HIV nPEP

- Initiate nPEP as soon as possible, but no later than 72 hours after exposure (**NEW*: good practice statement, existing recommendation**).

HIV nPEP Regimens

- Complete a clinical assessment before prescribing nPEP, including assessing for medical comorbidities, current medications, and allergies (**good practice statement, standard of care**).
- The recommended nPEP course is 28 days (**good practice statement, existing recommendation**).
- The preferred regimens for adults and adolescents without relevant contraindications are
  - bictegravir (BIC)/emtricitabine (FTC)/tenofovir alafenamide (TAF) (**NEW*: recommendation, very low certainty of evidence**) OR
  - dolutegravir (DTG) plus (tenofovir alafenamide [TAF]) OR tenofovir disoproxil fumarate [TDF]) plus (emtricitabine [FTC] OR lamivudine [3TC]) (**NEW*: recommendation, very low certainty of evidence**).
- Selection of a regimen should be individualized based on comorbid conditions (e.g., renal or hepatic dysfunction), pregnancy, drug interaction potential with concurrent medications, previous exposure to ARV regimens (including long-acting injectable ARV exposure), the source's history, and regimen factors that might influence continuation of treatment (e.g., pill burden, dosing frequency, side effects, cost, and access) (**good practice statement, standard of care**).

Laboratory Testing and nPEP Follow-Up

- Persons being assessed due to a known or possible exposure to HIV should be tested for HIV (**good practice statement, existing recommendation**).
- At the initial nPEP medical visit, a rapid (also referred to as point-of-care), laboratory-based antigen/antibody combination (Ag/Ab) HIV test, or both, is recommended (**good practice statement, existing recommendation**).
- For persons with long-acting injectable PrEP ARV exposure during the past 12 months, a diagnostic HIV nucleic acid test (NAT) is recommended at the initial medical evaluation, in addition to an Ag/Ab HIV test (**NEW*: good practice statement, indirect data; existing recommendation**).
- Perform interim HIV testing with both a laboratory-based HIV Ag/Ab test plus a diagnostic HIV NAT test 4–6 weeks after exposure (**good practice statement, standard of care**).
  - HIV testing 4–6 weeks post-nPEP initiation may be deferred for persons who started nPEP within 24 hours of a known or possible HIV exposure and who did not miss any nPEP doses.
- Perform final HIV tests using laboratory-based HIV Ag/Ab combination immunoassay and diagnostic HIV NAT 12 weeks after exposure (**NEW*: good practice statement, standard of care**).
- Routine laboratory testing recommended for persons starting nPEP includes serum creatinine, alanine aminotransferase (ALT), and aspartate aminotransferase (AST), as well as HIV, hepatitis B virus (HBV), and pregnancy testing (**good practice statement, existing recommendation**).
- Testing and treatment of hepatitis C virus (HCV) infection, other sexually transmitted infections including gonorrhea, chlamydia, and syphilis, and other medical treatment should be tailored to the clinical situation (**good practice statement, existing recommendation**).

Transitioning to PrEP After PEP

- An immediate transition from nPEP to PrEP, including HIV testing at the completion of the nPEP regimen with a prompt transition to a recommended PrEP regimen, might be beneficial for persons with anticipated repeat or ongoing potential HIV exposures (**good practice statement, existing recommendation**).

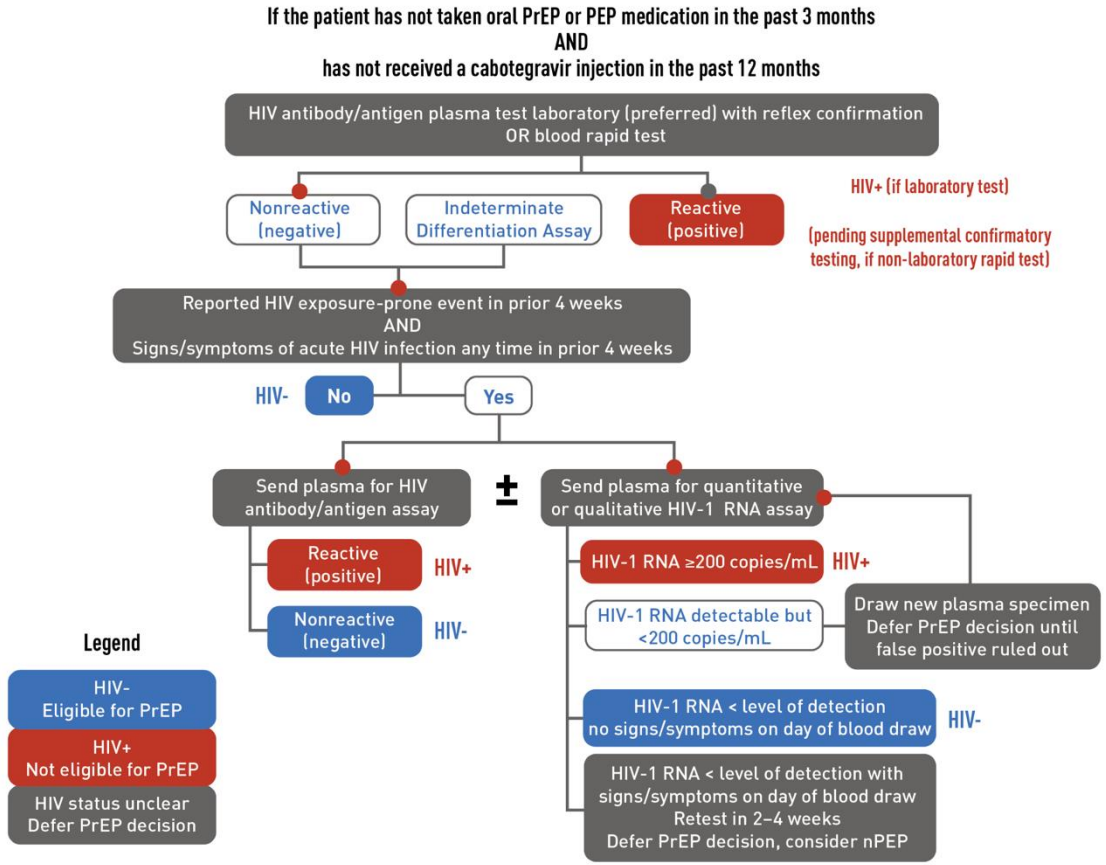
*NEW indicates a new recommendation or an update to an existing recommendation.

Source: https://stacks.cdc.gov/view/cdc/177225

PRE-EXPOSURE PROPHYLAXIS

- PrEP therapy is indicated for patients considered high risk for sexually acquired HIV
- Examples of such individuals might include a non-HIV-infected partner of an HIV infected individual

PRE-EXPOSURE PROPHYLAXIS



Source: https://www.cdc.gov/hivnexus/media/pdfs/2024/04/cdc-lsht-prevention-brochure-clinicians-quick-guide-what-is-oral-hiv-prep.pdf

ORAL PRE-EXPOSURE PROPHYLAXIS

- The PrEP dosage is one tablet (emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg [FTC/TDF {Truvada®}] *or* emtricitabine 200 mg and tenofovir alafenamide 25 mg [FTC/TAF {Descovy®}])
- Emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg
  - *Approved for adult and adolescent cisgender/ transgender males and females*
- Emtricitabine 200 mg and tenofovir alafenamide 25 mg
  - *Approved for adult and adolescent cisgender males and transgender females only*
- Taken PO with or without food and should be prescribed with a frequency of once daily
- In addition to the medication, which should be prescribed in no more than a 90-day supply, the patient should be educated about risk reduction strategies, particularly consistent use of condoms during every sexual encounter

ORAL PRE-EXPOSURE PROPHYLAXIS

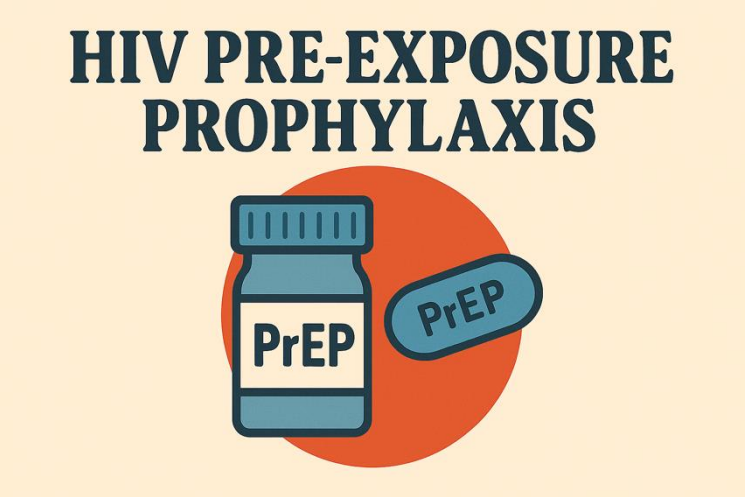
- Ongoing Assessments during Oral Tx:

At least every 3 months	• Repeat HIV antigen/antibody and HIV-1 RNA tests and assess for signs or symptoms of acute HIV infection to confirm that patients do not have HIV. • Provide a prescription or refill authorization of daily oral PrEP medication for no more than 90 days (until the next HIV test). • Assess and provide support for medication adherence and risk-reduction behaviors. • Test sexually active patients with signs or symptoms of sexually transmitted infections (STIs). Screen asymptomatic MSM with certain risk factors for recurrent bacterial STIs (oral, rectal, urine, blood). Examples of MSM who should be screened include those with syphilis, gonorrhea, or chlamydia at prior visits or multiple sex partners. • Provide access to sterile needles/syringes and substance use disorder treatment services for people who inject drugs. • Respond to new questions and provide any new information about PrEP use.
At least every 6 months	• Monitor estimated creatinine clearance (eCrCl) for patients age ≥50 years or who had an eCrCl <90 mL/min when they started oral PrEP. • If there are other threats to kidney safety (e.g., hypertension, diabetes), kidney function may need to be monitored more often or checked using additional tests (e.g., urinalysis for proteinuria). • A rise in serum creatinine is not a reason to withhold PrEP if eCrCl remains ≥60 mL/min for F/TDF or ≥30 mL/min for emtricitabine/tenofovir alafenamide (F/TAF). • If eCrCl is declining steadily (but still ≥60 mL/min for F/TDF or ≥30 mL/min for F/TAF), consult with a nephrologist, if needed, or evaluate other possible threats to kidney health. • Screen sexually active people for STIs (vaginal, oral, rectal, urine, as indicated; blood): syphilis and gonorrhea for all PrEP users; chlamydia for MSM and transgender women, even if asymptomatic. • Assess interest in continuing or stopping PrEP.
At least every 12 months	• Monitor eCrCl for all patients continuing oral PrEP medication. • Monitor triglyceride and cholesterol levels and weight for patients prescribed F/TAF for PrEP. • Screen heterosexually active people for chlamydia (vaginal, urine), even if asymptomatic.

Reference: https://www.cdc.gov/hivnexus/hcp/prep/index.html

ORAL PRE-EXPOSURE PROPHYLAXIS

- "2-1-1" Dosing



- Oral PrEP with emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) can be prescribed off-label using "2-1-1" dosing for adult MSM.

- When using 2-1-1 dosing, the patient takes FTC /TDF doses based on when they plan to have sex: **two pills 2-24 hours before sex, one pill 24 hours after the first two-pill dose, and one pill 48 hours after the first two-pill dose.**
- Off-label 2-1-1 dosing is not approved by the FDA and not recommended by the Centers for Disease Control and Prevention (CDC).
  - However, it can be prescribed to MSM who meet the following criteria:
    - Request non-daily dosing
    - Have sex infrequently (e.g., less often than once a week)
    - Can anticipate sex (or delay sex) to permit the doses at least 2 hours prior to sex

2-1-1 dosing should not be prescribed for MSM who might have problems adhering to a complex dosing regimen (e.g., adolescents, patients with an active substance use disorder).

Image Generated from M365 Copilot. (2026). *HIV pre-exposure prophylaxis (PrEP)* [AI-generated image].

ORAL PRE-EXPOSURE PROPHYLAXIS

- Prevention effectiveness occurs after 7-20 days
- The financing of antiretrovirals for PrEP is emerging as an important healthcare policy issue
- Daily cost of brand Oral PrEP up to $16,193 per year (Schmid & Herwig, 2022)
- Additional monitoring and screening costs per person have been estimated to be $1,300 per year.
- USPTF A Recommendation (6/19), most private insurance companies must cover PrEP

Reference: Centers for Disease Control and Prevention. (2024). *Preventing HIV with PrEP*. https://www.cdc.gov/hiv/prevention/prep.html

INJECTABLE PRE-EXPOSURE PROPHYLAXIS (CAB)

- Data strongly suggest use of every 2-month injectable cabotegravir (Cab; [Apretude®]) (600 mg/ 3mL), in concert with safer sex practices, reduces risk of HIV-1 acquisition by approximately 99%, with only a very small number of infections (related to resistant HIV strains) occurring in those who are adherent
- This administration approach might be beneficial to those at risk for HIV infection for which adherence may be challenging
    - Young men who have sex with men (MSM), people with substance abuse disorders, those living in poverty or who have depression, conceal their use of PrEP, or are otherwise challenged with adherence
- Before starting injectable PrEP, patients should be screened for HIV, bacterial STIs, and hepatitis B; baseline renal and hepatic function should also be assessed
    - MSM and people who injecting drugs (PWIDs) should also be screened for hepatitis C
    - A negative HIV screening should be obtained within 1 week of starting injectable cabotegravir

INJECTABLE PRE-EXPOSURE PROPHYLAXIS (CAB)

- Using an injectable lead-in strategy, an initial dose of cabotegravir 600 mg (in 3 mL) is administered IM in the dorsal gluteal muscle; a second dose is given 4-weeks after this first dose; then every 8 weeks thereafter.
    - An oral lead-in approach no longer recommended.
- Ongoing lipid and renal evaluations are unnecessary.
- Common adverse events associated with injectable cabotegravir include injection site reactions, diarrhea, headache, pyrexia, and fatigue.
- Clinicians should provide continuing guidance on safer sexual decision making and answer any questions that arise while using PrEP throughout the ongoing regimen.

INJECTABLE PRE-EXPOSURE PROPHYLAXIS (CAB)

- Ongoing Assessments during Injectable Tx with Cabotegravir:

At visit 1 month after initial injection (month 1)	• Test for HIV with antigen/antibody and HIV-1 RNA assays and assess for signs or symptoms of acute infection. • Administer CAB injection. • Respond to new questions. • Provide medication adherence and behavioral risk-reduction support.
At least every 2 months (beginning in month 3)	• Test for HIV with antigen/antibody and HIV-1 RNA assays and assess for signs or symptoms of acute infection. • Administer CAB injection. • Provide access to sterile needles/syringes and substance use disorder treatment services for people who inject drugs. • Respond to new questions and provide any new information about CAB for PrEP. • Discuss the benefits of persistent CAB for PrEP use and adherence to schedule injection visits.
At least every 4 months (beginning in month 3)	• Conduct bacterial STI screening for MSM and transgender women who have sex with men (oral, rectal, urine, blood).
At least every 6 months (beginning in month 7)	• Screen all heterosexually active people for bacterial STIs (vaginal, rectal, urine, as indicated; blood).
At least every 12 months (beginning in month 13)	• Assess desire to continue PrEP injections and screen heterosexually active people for chlamydia (vaginal, urine), even if asymptomatic.

Reference: https://www.cdc.gov/hivnexus/hcp/prep/index.html

INJECTABLE PRE-EXPOSURE PROPHYLAXIS (LENACAPAVIR)

- Newer Drug Approved by FDA in June 2025
  - Lenacapavir (Yeztugo®)
    - Antiretroviral medication capsid inhibitor injected every six months as pre-exposure prophylaxis (PrEP) for HIV
    - Data suggest lenacapavir is highly efficacious, distinctly being the first PrEP regimen to ever show zero infections during Phase III clinical trials
    - Lenacapavir is being lauded as a major advancement in the eradication of HIV as a major public health threat

INJECTABLE PRE-EXPOSURE PROPHYLAXIS (LENACAPAVIR)

- Lenacapavir:
  - First ABD SQ injection along with two oral tablets, followed by two more oral tablets on day 2, and then ABD SQ injections every 6 months
    - 2 weeks before or 2 weeks after scheduled dose = OK
  - Common Adverse Events:
    - Injection Site Reactions:
      - *Most* Frequent Reaction (60%+): Pain, edema, nodules, erythema, pruritus, hematoma, warmth (may last several weeks)
    - Headache: 2%-8% of cases
    - Nausea: 2%-11% of cases
    - Less reported adverse events: Dizziness, vomiting, diarrhea
    - Interactions:
      - CYP3A: E.g. Rifampin, phenytoin, St. John's wort
  - **BLACK BOX WARNING: HIV RESISTANCE IN UNDIAGNOSED PLWH**

INJECTABLE PRE-EXPOSURE PROPHYLAXIS (LENACAPAVIR)

- Ongoing Assessment with Lenacapavir:
  - Negative HIV screening before initiating Tx
  - **Repeat HIV q6 months**
  - Routine STI screenings q 3-6 months, with more frequency recommended for sexually active patients:
    - Bacterial STI (oral, rectal, urine, blood) screening in MSM & transgender women q 3 months
    - Bacterial STI (vaginal, oral, rectal, urine, blood) screening in heterosexuals q 6 months
    - Chlamydial screening q 12 months (vaginal, urine)
  - Safe during pregnancy

M365 Copilot. (2026). *Patient getting blood drawn* [AI-generated image].

PRE-EXPOSURE PROPHYLAXIS

- Evaluating patient appropriateness for PrEP, performing pretreatment evaluations prior to initiation of treatment, and close monitoring of therapy are all responsibilities NPs will assume as this treatment becomes more widespread in the U.S. healthcare system.
- Cost of the therapy is also a major blockade to its implementation, and this will continue to be a prevalent issue in the foreseeable future
  - Cost can be mitigated: How do I Pay for PrEP?

PRE-EXPOSURE PROPHYLAXIS AANP RESOURCES

- Two Practice Briefs are available:
  - Log into AANP Site
  - Click on Practice
  - Click on Clinical Resources
  - Scroll down to Point of Care Tools and Clinical Practice Briefs
    - Click Access Point of Care Tools
  - Click on Clinical Practice Briefs
  - Scroll down to Infectious Disease
    - Click on "View the Brief" under:
      - Pre-Exposure Prophylaxis for HIV Prevention– Injectable
      - Pre-Exposure Prophylaxis for HIV Prevention– Oral
  - Additional Brief from American College of Obstetricians & Gynecologists:
    - ACOG PrEP Practice Brief

MOVING FORWARD

- Community and Public Health Outreach
- Prevention Education in the Clinical Setting
- Future Research and the Responsibility of the Nurse Practitioner

REFERENCES

Please see the supplemental handout, which includes a bibliography and additional resources for more information.

Scan the QR Code to access the online bibliography!

Andrew Todd, MLIS, BSN, RN
Reference Librarian, College of Nursing
University of Central Florida Libraries

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IMAGE REFERENCES

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HIV PREVENTION IN 2026: PREP, PEP, & BEYOND

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