PHARMACOLOGIC AND NON-PHARMACOLOGIC PREVENTION OF HIV IN 2025

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DISCLOSURES -

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

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OBJECTIVES

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

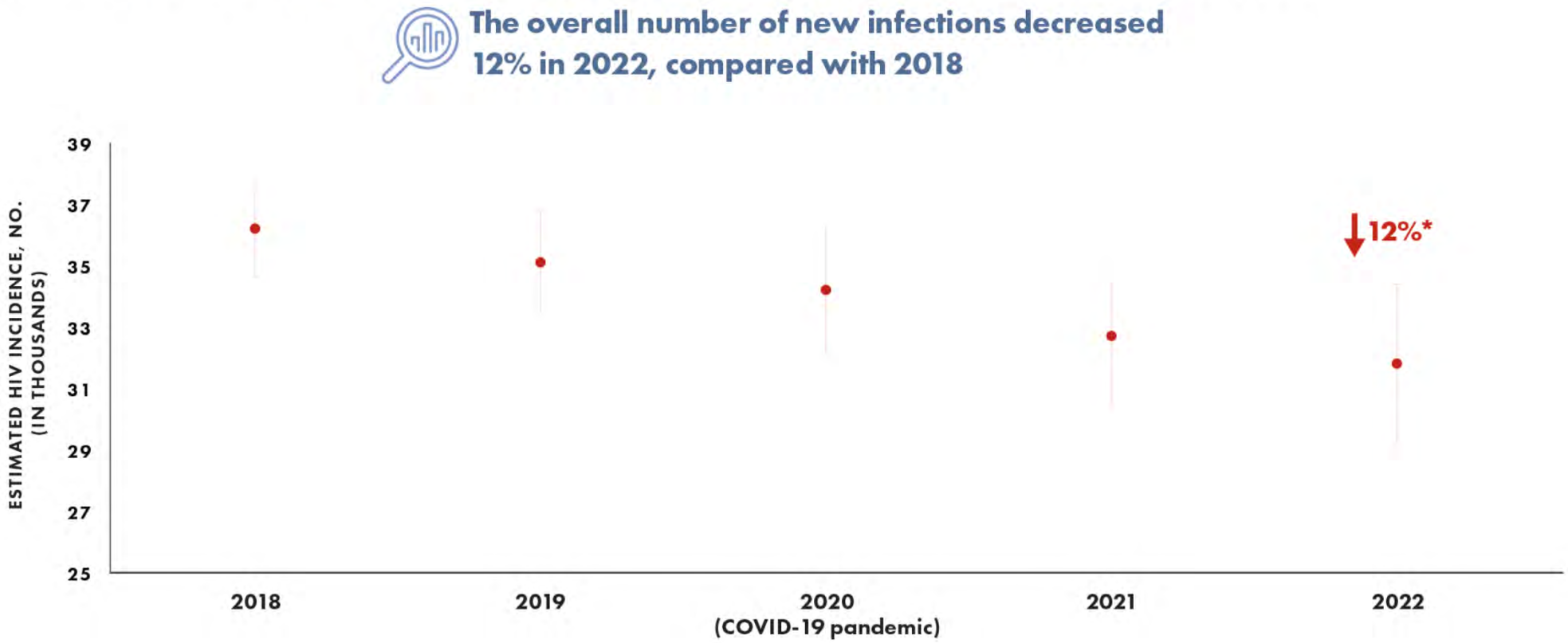
INCIDENCE OF HIV INFECTION & AIDS

- 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://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-34/index.html
- The figures on slides 4-11 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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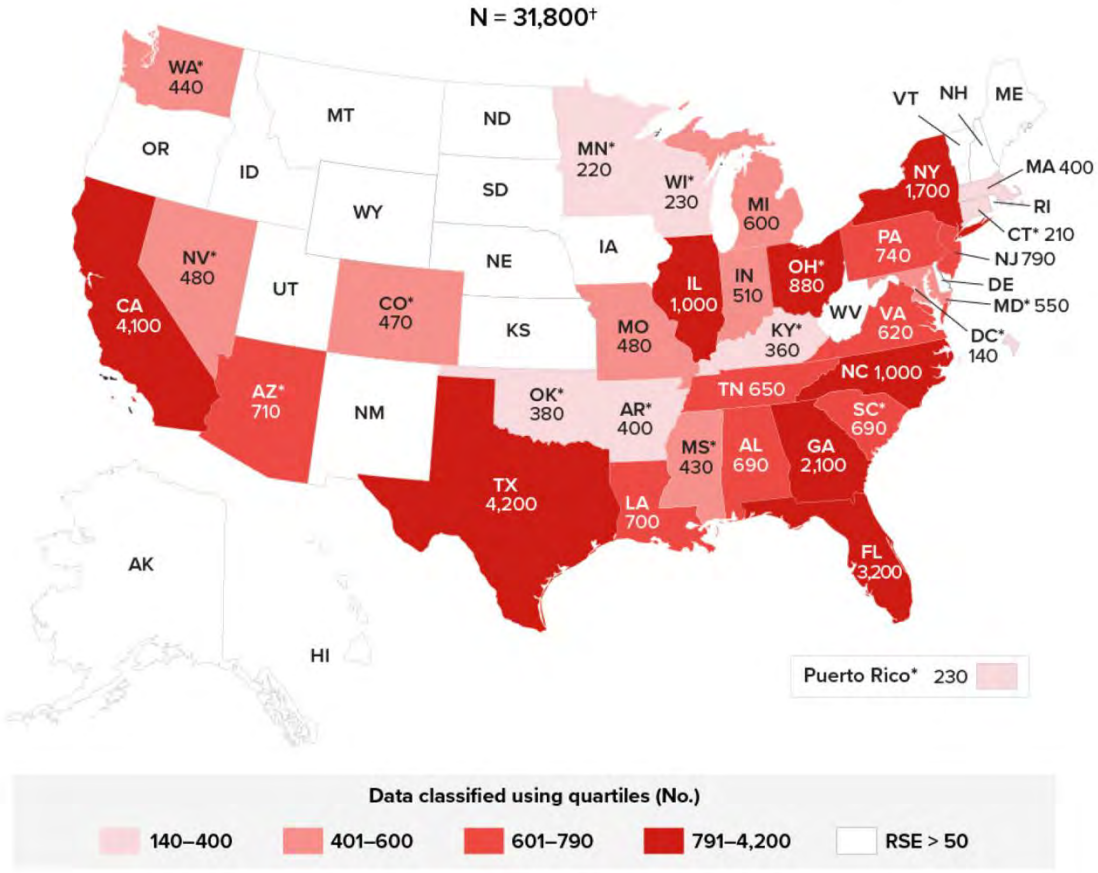
INCIDENCE OF HIV INFECTION & AIDS 2018-2022: TAKE AWAY POINTS

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



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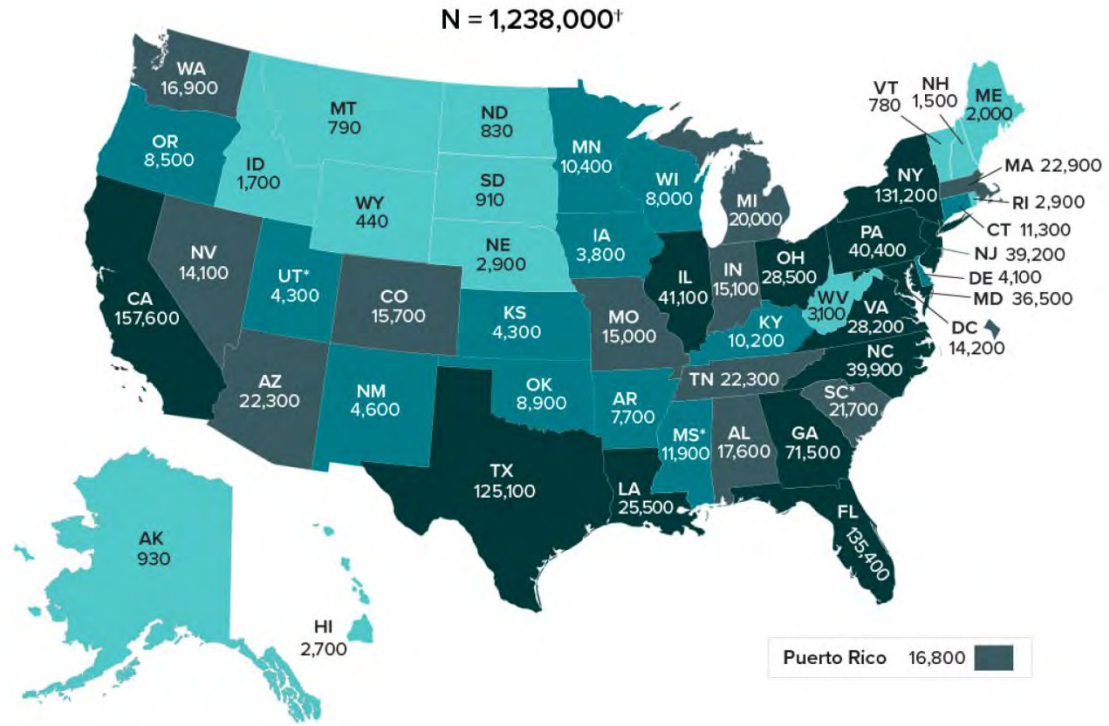
INCIDENCE OF HIV INFECTION & AIDS 2018-2022: TAKE AWAY POINTS

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



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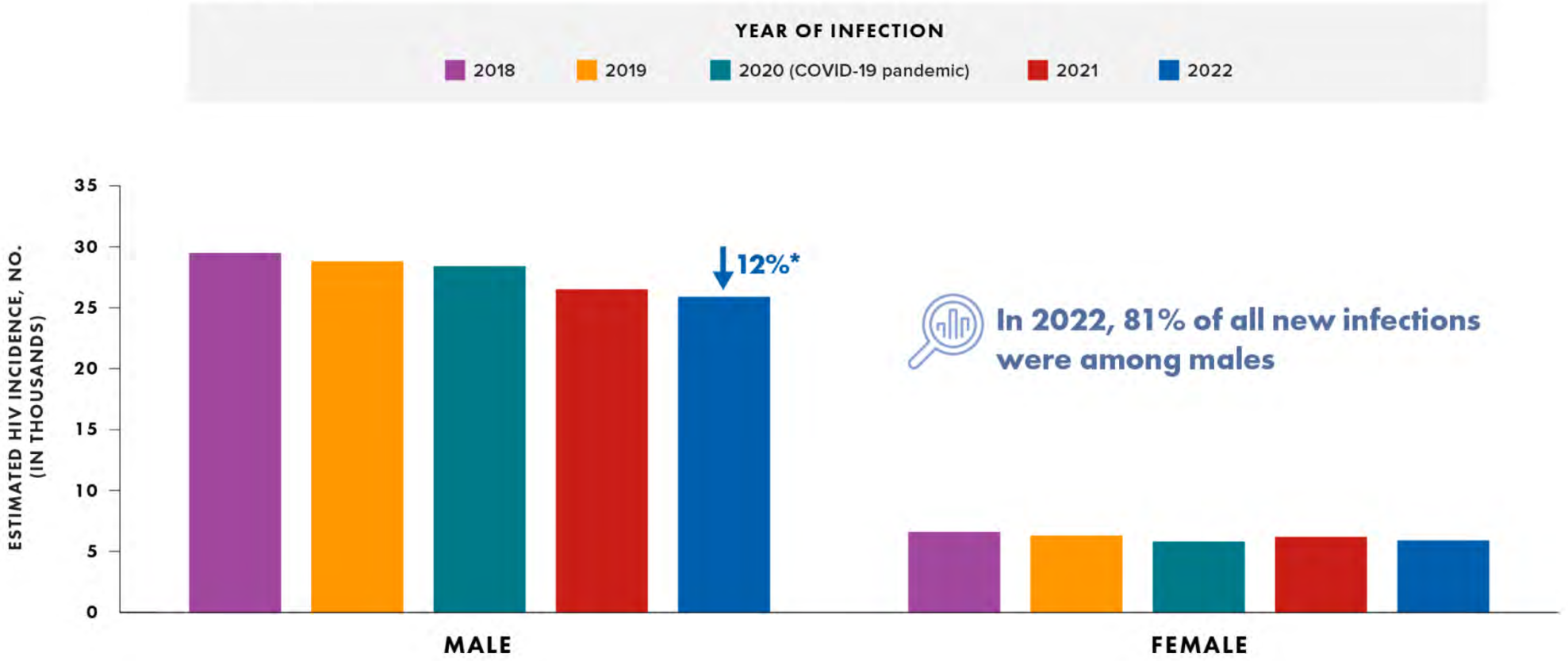
INCIDENCE OF HIV INFECTION & AIDS 2018-2022: TAKE AWAY POINTS

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



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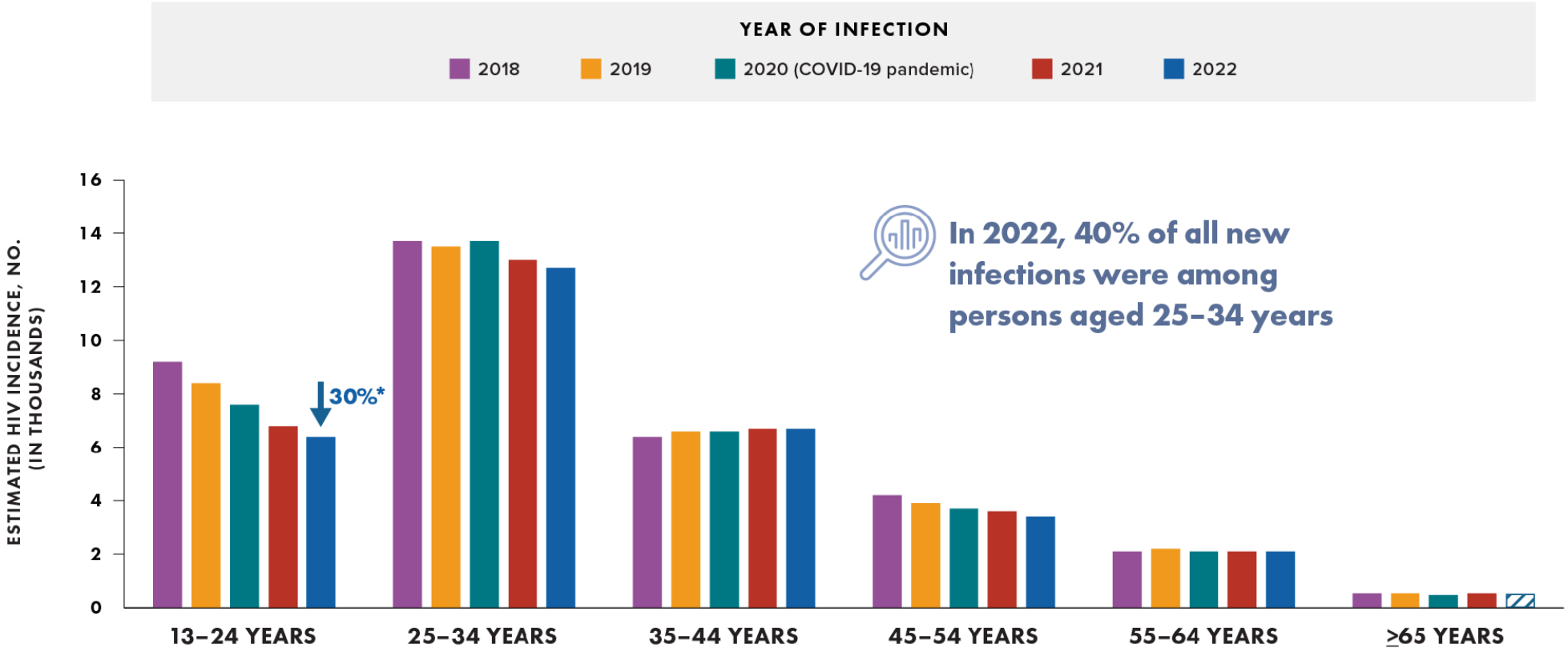
INCIDENCE OF HIV INFECTION & AIDS 2018-2022: TAKE AWAY POINTS

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



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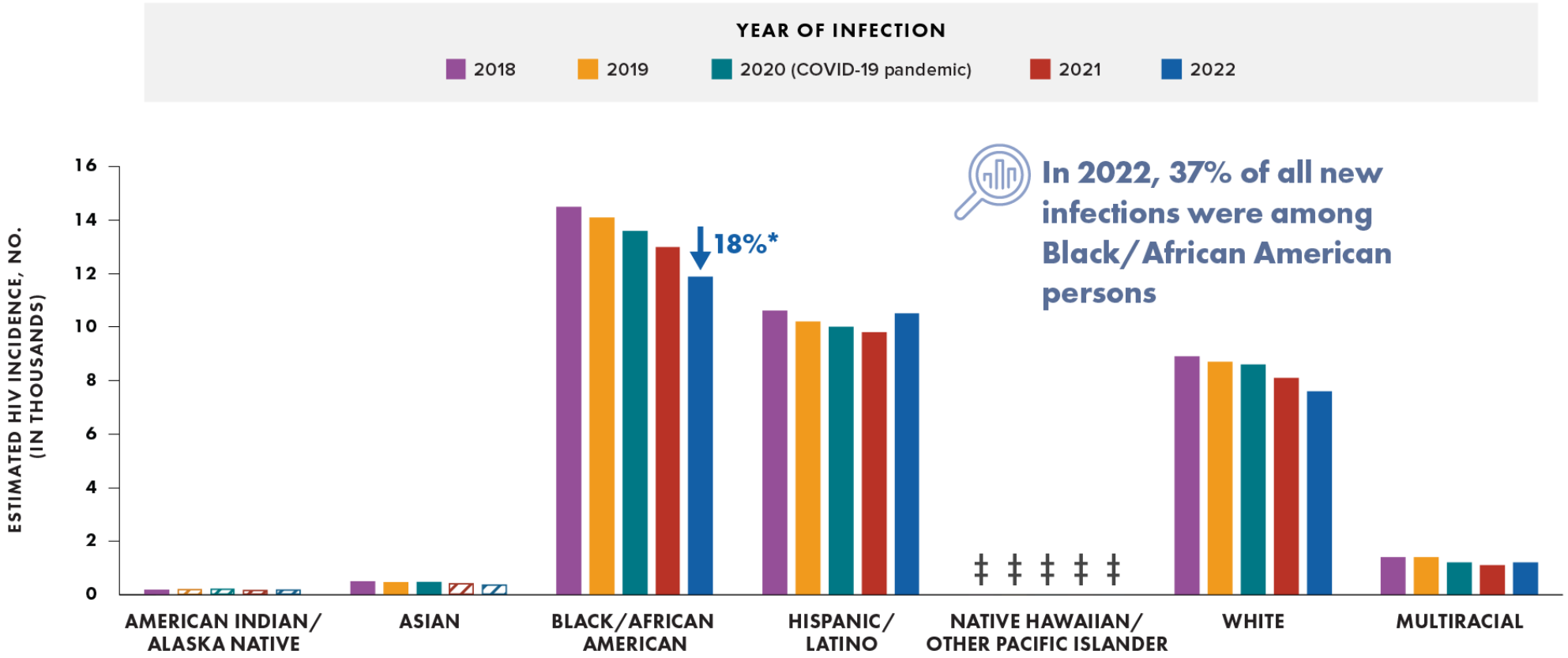
INCIDENCE OF HIV INFECTION & AIDS 2018-2022: TAKE AWAY POINTS

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



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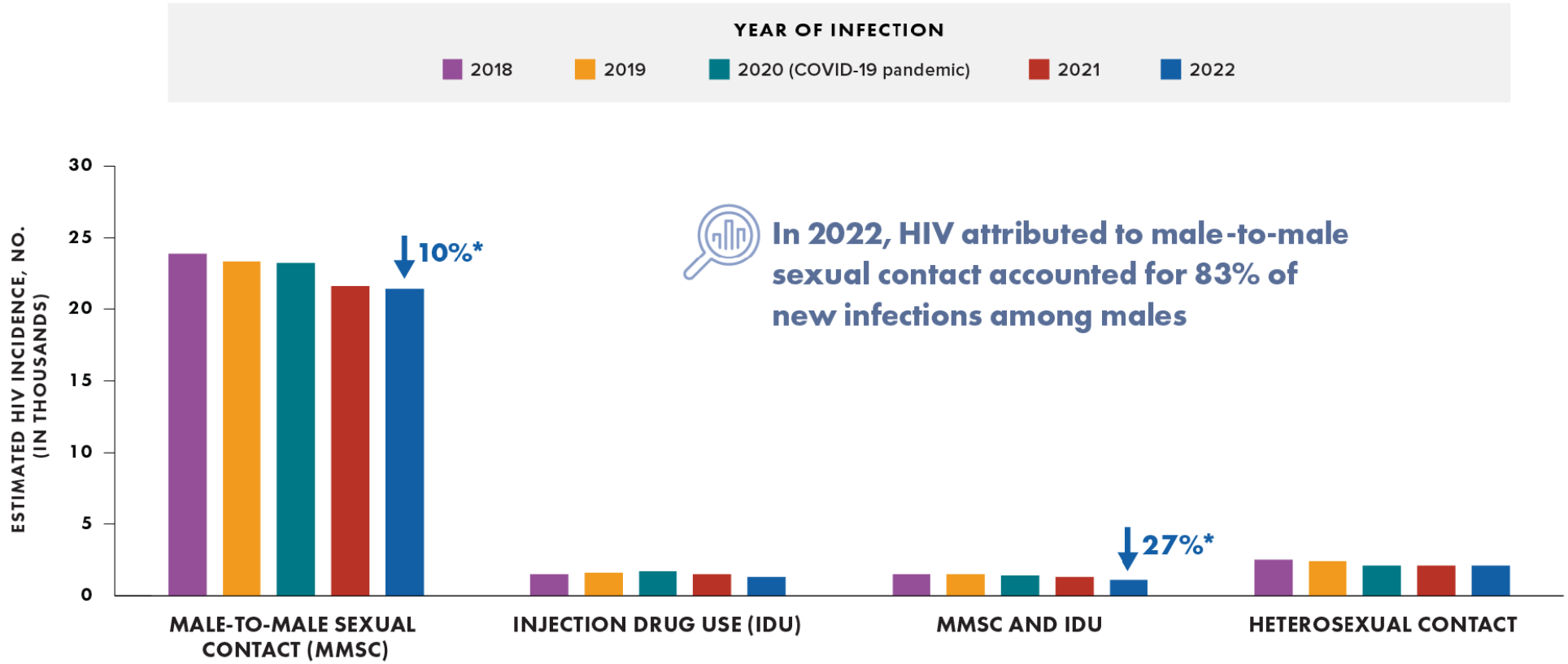
INCIDENCE OF HIV INFECTION & AIDS 2018-2022: TAKE AWAY POINTS

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



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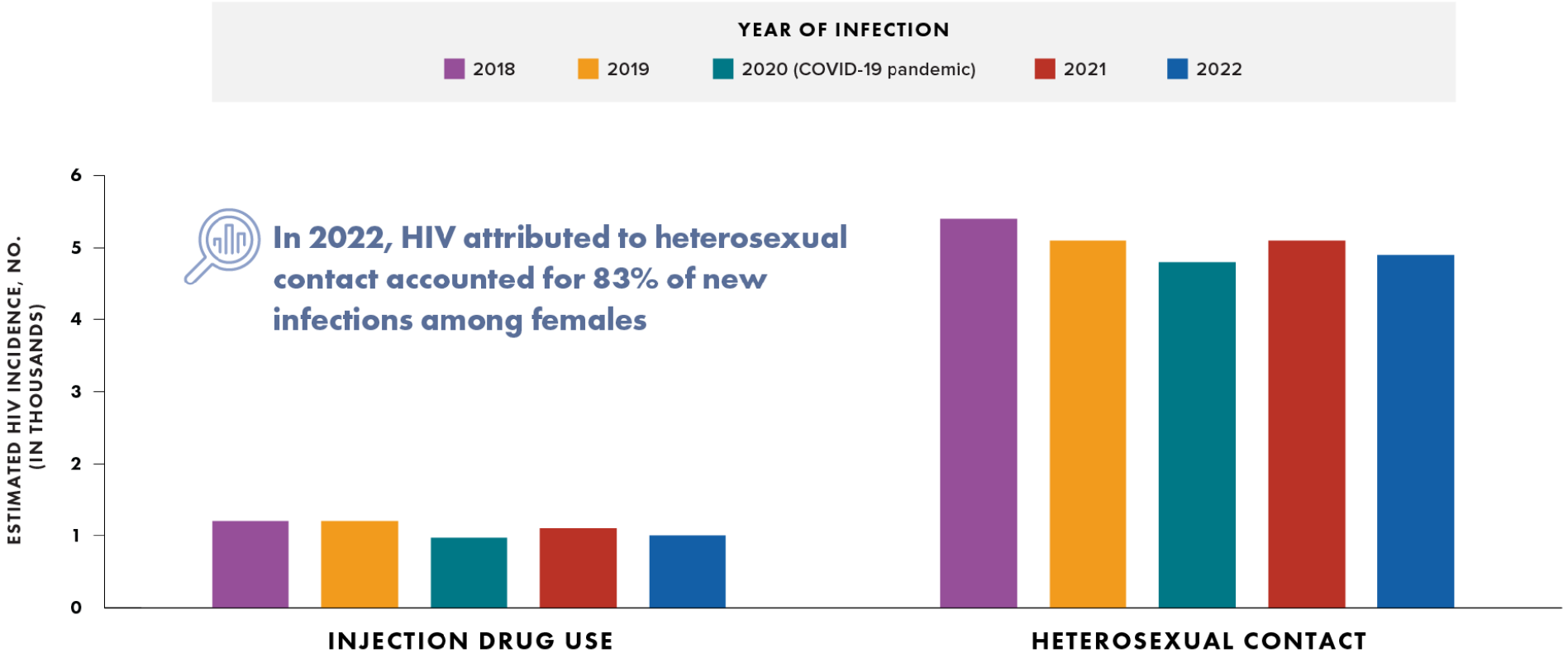
INCIDENCE OF HIV INFECTION & AIDS 2018-2022: TAKE AWAY POINTS

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



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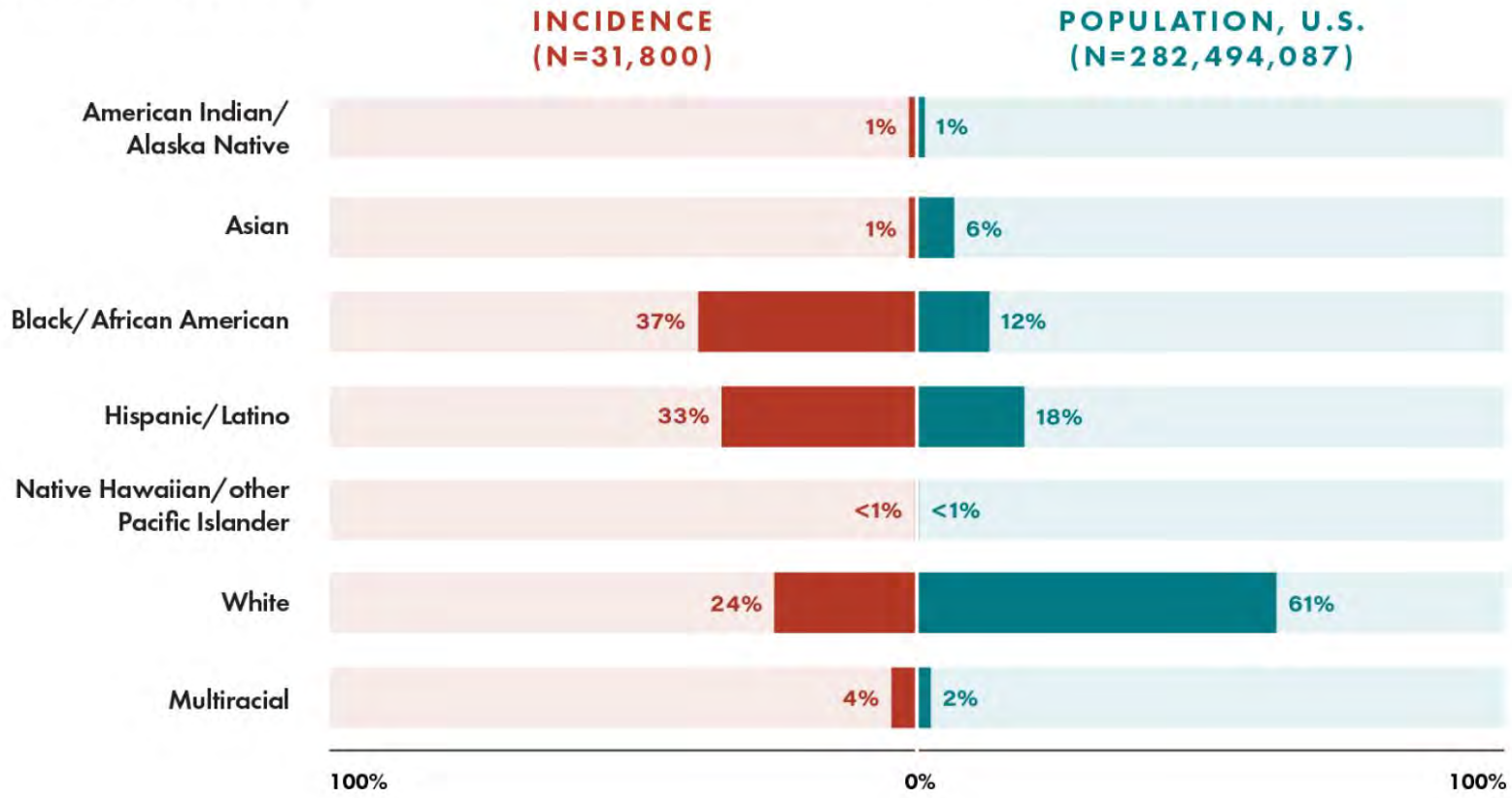
INCIDENCE OF HIV INFECTION & AIDS 2018-2022: TAKE AWAY POINTS

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



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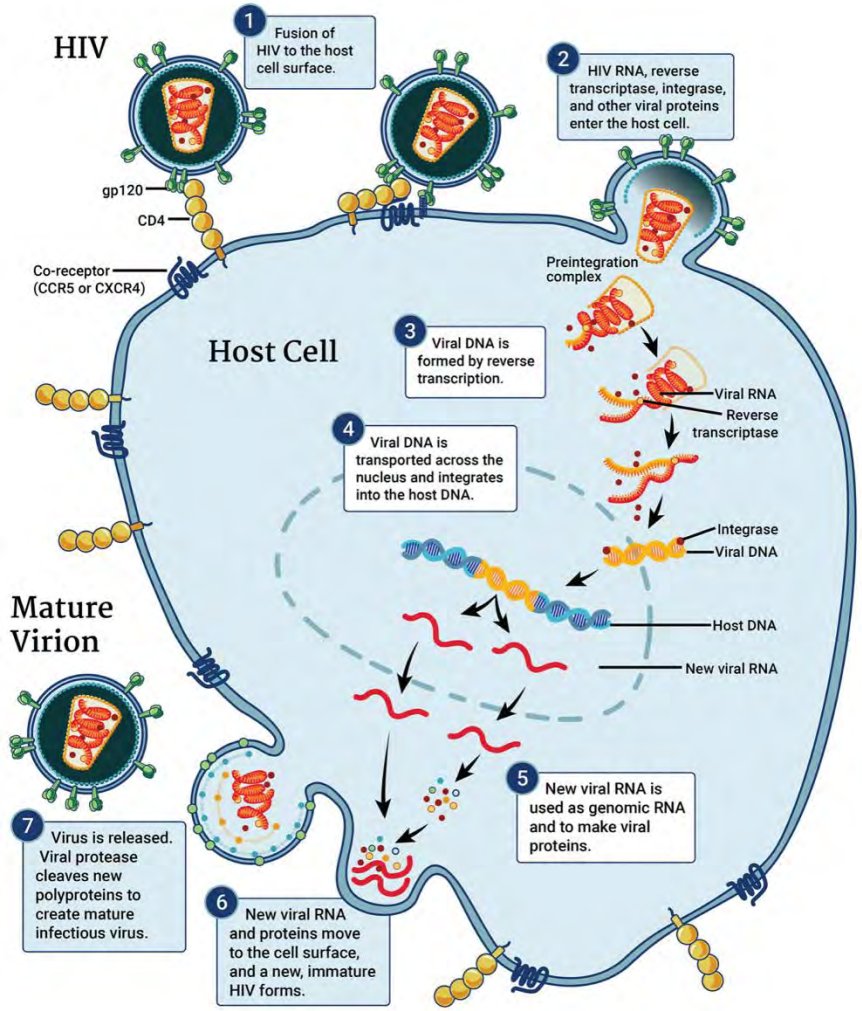
HIV REPLICATION CYCLE



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)

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
  - Viral Load is NOT a determinant of degree of safeness (theoretically)—CDC (2017) issued newer statement about this

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

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

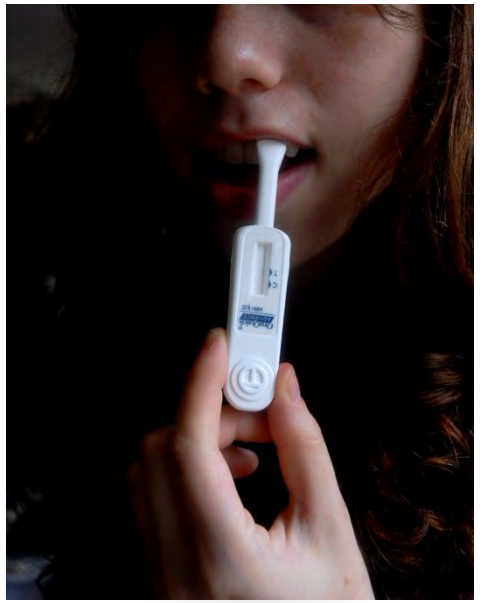
- Perinatal Transmission (Ctd):
  - Infected with HIV and on ART?:
    - Keep taking ART!
  - Infected with HIV and not on ART or with unknown or high HIV RNA load?:
    - Begin zidovudine (Retrovir®) IV near time of delivery
    - C-section in @ 38 weeks gestation
  - Neonate will also be treated with ART
  - Most recent guidelines (updated 2024): 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
  - e.g., OraSure® OraQuick® testing methods



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

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 a 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

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

Nucleic Acid Test (NAT)	Antigen/ Antibody Lab Test	Rapid Antigen/ Antibody Test	Antibody Test
window period	window period	window period	window period
10-33 days	**18-45 days**	**18-90 days**	**23-90 days**

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

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

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

PROPHYLACTIC PREVENTION OF HIV INFECTION: POST-EXPOSURE

- Although large-scale studies about PEP are lacking, PEP is clinically effective (80%) and recommended (Landovitz & Currier, 2009) 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:
    - Receptive Anal Intercourse = 1%-30% chance of infection
    - Insertive Anal Intercourse = .1-10% chance of infection
    - Receptive Vaginal Intercourse = .1-10% chance of infection
    - Insertive Vaginal Intercourse = .1-1% chance of infection
    - Oral Intercourse: Few documented cases
    - Needle Sharing: .67% per needle-sharing event
- Ideally, begin PEP within 36 hours but no more than 72 hours after exposure

PROPHYLACTIC PREVENTION OF HIV INFECTION: POST-EXPOSURE

Table 1. Estimated per-act risk for acquiring human immunodeficiency virus (HIV) from an infected source, by exposure act[a]

Exposure type	Rate for HIV acquisition per 10,000 exposures
Parenteral	
Blood transfusion	9,250
Needle sharing during injection drug use	63
Percutaneous (needlestick)	23
Sexual	
Receptive anal intercourse	138
Receptive penile-vaginal intercourse	8
Insertive anal intercourse	11
Insertive penile-vaginal intercourse	4
Receptive oral intercourse	Low
Insertive oral intercourse	Low
Other[b]	
Biting	Negligible
Spitting	Negligible
Throwing body fluids (including semen or saliva)	Negligible
Sharing sex toys	Negligible

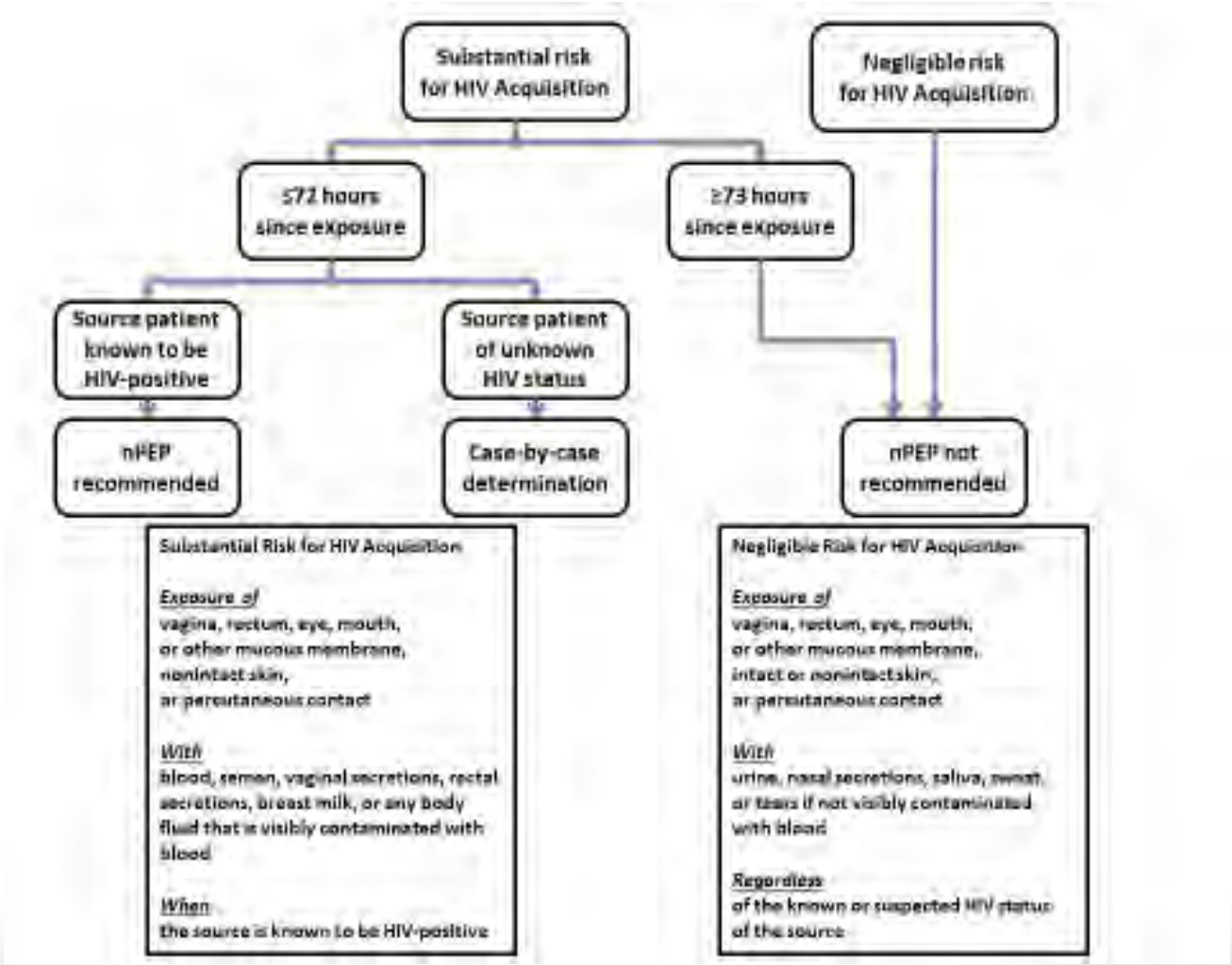
Source: http://www.cdc.gov/hiv/policies/law/risk.html

[a] Factors that may increase the risk of HIV transmission include sexually transmitted diseases, acute and late-stage HIV infection, and high viral load. Factors that may decrease the risk include condom use, male circumcision, antiretroviral treatment, and preexposure prophylaxis. None of these factors are accounted for in the estimates presented in the table.

[b] HIV transmission through these exposure routes is technically possible but unlikely and not well documented.

Source: https://stacks.cdc.gov/view/cdc/38856

PROPHYLACTIC PREVENTION OF HIV INFECTION: POST-EXPOSURE



Source: https://stacks.cdc.gov/view/cdc/38856

PROPHYLACTIC PREVENTION OF HIV INFECTION: POST-EXPOSURE

Table 5. Preferred and alternative antiretroviral medication 28-day regimens for nPEP[a,b]

Age group	Preferred/ alternative	Medication
Adults and adolescents aged ≥ 13 years, including pregnant women, with normal renal function (creatinine clearance ≥ 60 mL/min)	**Preferred**	A 3-drug regimen consisting of tenofovir DF 300 mg ***and*** fixed dose combination emtricitabine 200 mg (Truvada[c]) once daily ***with*** raltegravir 400 mg twice daily ***or*** dolutegravir 50 mg once daily
	Alternative	A 3-drug regimen consisting of tenofovir DF 300 mg ***and*** fixed dose combination emtricitabine 200 mg (Truvada) once daily ***with*** darunavir 800 mg (as 2, 400-mg tablets) once daily ***and*** ritonavir[b] 100 mg once daily
Adults and adolescents aged ≥ 13 years with renal dysfunction (creatinine clearance ≤59 mL/min)	**Preferred**	A 3-drug regimen consisting of zidovudine ***and*** lamivudine, with both doses adjusted to degree of renal function ***with*** raltegravir 400 mg twice daily ***or*** dolutegravir 50 mg once daily
	Alternative	A 3-drug regimen consisting of zidovudine ***and*** lamivudine, with both doses adjusted to degree of renal function ***with*** darunavir 800 mg (as 2, 400-mg tablets) once daily ***and*** ritonavir[b] 100 mg once daily

Source: https://stacks.cdc.gov/view/cdc/38856

PROPHYLACTIC PREVENTION OF HIV INFECTION: POST-EXPOSURE

Table 2. Recommended schedule of laboratory evaluations of source and exposed persons for providing nPEP with preferred regimens

Test	Source	Exposed persons			
	Baseline	Baseline	4–6 weeks after exposure	3 months after exposure	6 months after exposure
		For all persons considered for or prescribed nPEP for any exposure			
HIV Ag/Ab testing[a] (or antibody testing if Ag/Ab test unavailable)	✓	✓	✓	✓	✓[b]
Hepatitis B serology, including: hepatitis B surface antigen hepatitis B surface antibody hepatitis B core antibody	✓	✓	—	—	✓[c]
Hepatitis C antibody test	✓	✓	—	—	✓[d]
		For all persons considered for or prescribed nPEP for sexual exposure			
Syphilis serology[e]	✓	✓	✓	—	✓
Gonorrhea[f]	✓	✓	✓[g]	—	—
Chlamydia[f]	✓	✓	✓[g]	—	—
Pregnancy[h]	—	✓	✓	—	—
		For persons prescribed tenofovir DF+ emtricitabine + raltegravir or tenofovir DF+ emtricitabine + dolutegravir			
Serum creatinine (for calculating estimated creatinine clearance[i])		✓	✓	—	—
Alanine transaminase, aspartate aminotranferase		✓	✓	—	—
		For all persons with HIV infection confirmed at any visit			
HIV viral load	✓	✓[j]			
HIV genotypic resistance	✓	✓[j]			

Abbreviations: Ag/Ab, antigen/antibody combination test; HIV, human immunodeficiency virus; nPEP, nonoccupational postexposure prophylaxis; tenofovir DF, tenofovir disoproxil fumarate.

[a] Any positive or indeterminate HIV antibody test should undergo confirmatory testing of HIV infection status.

[b] Only if hepatitis C infection was acquired during the original exposure; delayed HIV seroconversion has been seen in persons who simultaneously acquire HIV and hepatitis C infection.

[c] If exposed person susceptible to hepatitis B at baseline.

[d] If exposed person susceptible to hepatitis C at baseline.

[e] If determined to be infected with syphilis and treated, should undergo serologic syphilis testing 6 months after treatment

[f] Testing for chlamydia and gonorrhea should be performed using nucleic acid amplification tests. For patients diagnosed with a chlamydia or gonorrhea infection, retesting 3 months after treatment is recommended.

- For men reporting insertive vaginal, anal, or oral sex, a urine specimen should be tested for chlamydia and gonorrhea.
- For women reporting receptive vaginal sex, a vaginal (preferred) or endocervical swab or urine specimen should be tested for chlamydia and gonorrhea.
- For men and women reporting receptive anal sex, a rectal swab specimen should be tested for chlamydia and gonorrhea.
- For men and women reporting receptive oral sex, an oropharyngeal swab should be tested for gonorrhea. (http://www.cdc.gov/std/tg2015/tg-2015-print.pdf)

[g] If not provided presumptive treatment at baseline, or if symptomatic at follow-up visit.

[h] If woman of reproductive age, not using effective contraception, and with vaginal exposure to semen.

[i] eCrCl = estimated creatinine clearance calculated by the Cockcroft-Gault formula; eCrClCG = [(140 − age) x ideal body weight] ÷ (serum creatinine x 72) (x 0.85 for females).

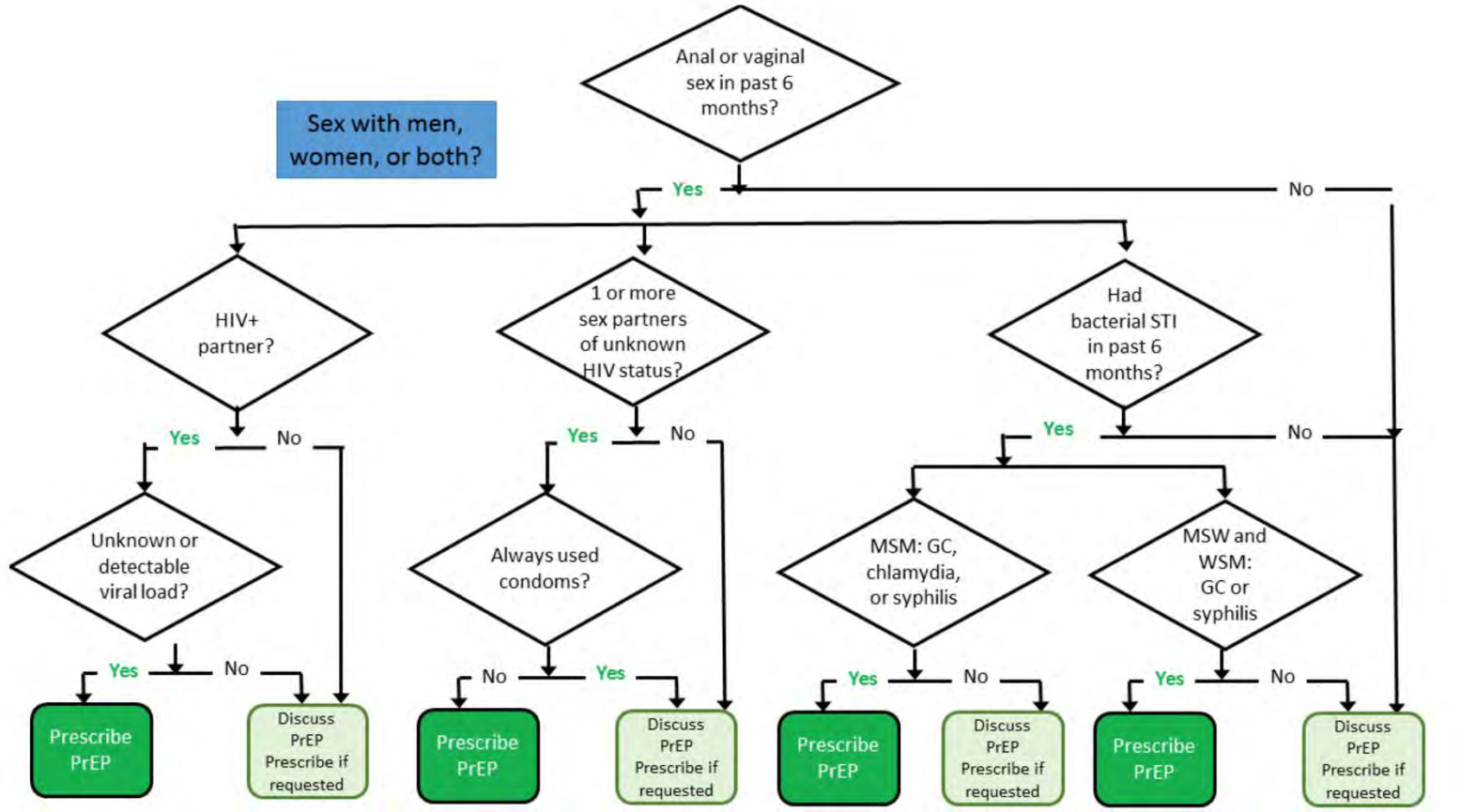
[j] At first visit where determined to have HIV infection.

Source: https://stacks.cdc.gov/view/cdc/38856

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



Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update Clinical Practice Guideline

Source: https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.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

Treatment Monitoring Recommendations

Test	Screening/Baseline Visit	Q 3 months	Q 6 months	Q 12 months	When stopping PrEP
HIV Test	X*	X			X*
eCrCl	X		If age ≥50 or eCrCL <90 ml/min at PrEP initiation	If age <50 and eCrCl ≥90 ml/min at PrEP initiation	X
Syphilis	X	MSM /TGW	X		MSM/TGW
Gonorrhea	X	MSM /TGW	X		MSM /TGW
Chlamydia	X	MSM /TGW	X		MSM /TGW
Lipid panel (F/TAF)	X			X	
Hep B serology	X				
Hep C serology	MSM, TGW, and PWID only			MSM,TGW, and PWID only	

* Assess for acute HIV infection (see Figure 4)

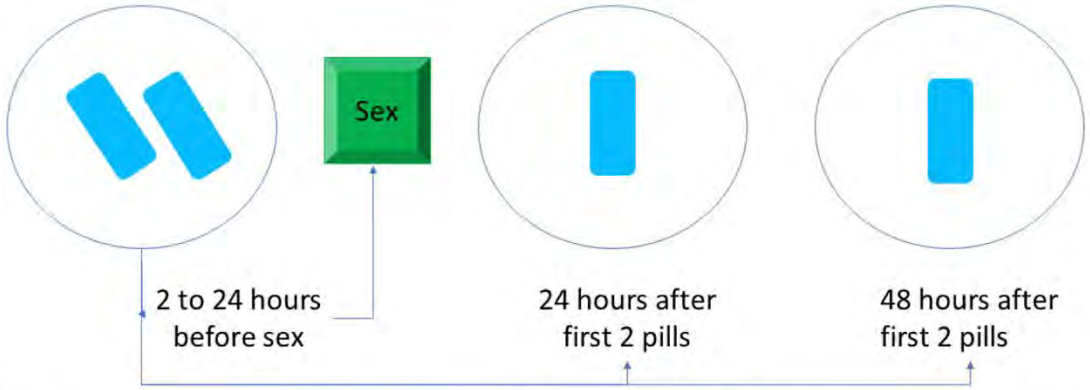
- In females, document a negative urine pregnancy test

Source: https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

ORAL PRE-EXPOSURE PROPHYLAXIS

- "2-1-1" Dosing

Figure 8 Schedule for "2-1-1" Dosing



Based on the timing of subsequent sexual events, MSM should be instructed to take additional doses as follows:

- If sex occurs on the consecutive day after completing the 2-1-1 doses, take 1 pill per day until 48 hours after the last sexual event.
- If a gap of <7 days occurs between the last pill and the next sexual event, resume 1 pill daily.
- If a gap of ≥7 days occurs between the last pill and next sexual event, start again with 2 pills.

Source: https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

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

INJECTABLE PRE-EXPOSURE PROPHYLAXIS

- Data strongly suggest use of every 2-month injectable cabotegravir (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

- 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 uses this same schedule but is preceded by at least 28 days of daily oral cabotegravir 30 mg, with the first injectable dose given on the final day of the oral lead-in.
- Injectable PrEP patients should be screened for HIV 1-month after the first injection and at follow-up visits every 2 months (both HIV Ag/Ab test AND HIV-1 RNA assay); MSM and transgender women who have sex with men should additionally be screened for bacterial STIs (oral, rectal, urine, blood) every 4 months while sexually active heterosexual men and women and men (vaginal, rectal, urine—as indicated) every 6 months
- 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

- Newer Drug in Phase III Trials
  - Lenacapavir (Sunlenca®)
    - Antiretroviral medication injected every six months as pre-exposure prophylaxis (PrEP) for HIV, currently undergoing Phase III clinical trials worldwide
    - Interim 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

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: Paying for PrEP: CDC (2022)

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

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

Scan the QR Code to access the online bibliography!

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IMAGE REFERENCES

Slide(s)	Image designation/description/position	Attribution
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4	HIV Surveillance Report	Source: https://www.cdc.gov/hiv-data/nhss/hiv-diagnoses-deaths-prevalence.html?CDC_AAref_Val=https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-34/index.html
5-13	CDC Report Figure 1 Figure 11 Figure 23 Figure 2 Figure 3 Figure 4 Figure 8 Figure 9 Figure 5	Source: https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-34/index.html
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31	Screening for HIV	Source: https://www.cdc.gov/hiv/testing/index.html#:~:text=A%20rapid%20antigen%2Fantibody%20test%20done%20with%20blood%20from%20a,to%2033%20days%20after%20exposure
36	Post-Exposure Risk	Source: https://stacks.cdc.gov/view/cdc/38856
37	Post-Exposure Algorithm	Source: https://stacks.cdc.gov/view/cdc/38856

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38	Post-Exposure Rx	Source: https://stacks.cdc.gov/view/cdc/38856
39	Post-Exposure Labs	Source: https://stacks.cdc.gov/view/cdc/38856
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