

Preventing HIV in 2022: Integrating Evidence into Practice

Christopher W. Blackwell, Ph.D., APRN,
ANP-BC, AGACNP-BC, CNE, FAANP, FAAN

Associate Professor & Program Director
AGACNP Programs, College of Nursing
Academic Health Sciences Center
University of Central Florida
Orlando, Florida

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DISCLOSURES

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

Note: Some data presented here overlap with data presented in presentations 22.2.155 and 22.3.025.



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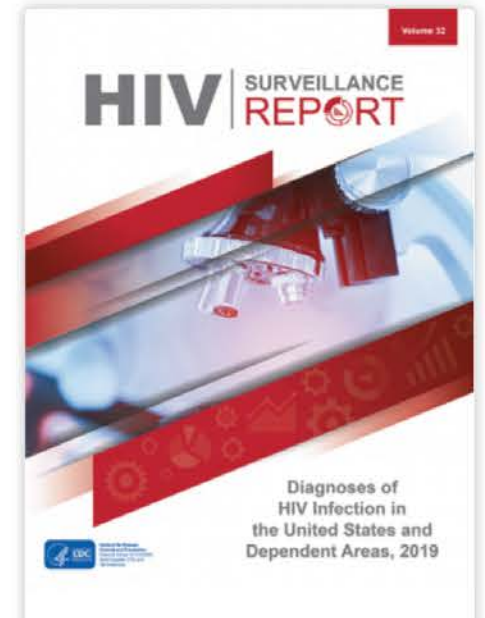
OBJECTIVES

- 1) Describe the safe prescribing of the two FDA-approved pharmacologic agents used for pre-exposure prophylaxis (PrEP);
- 2) Indicate appropriate long- and short-term treatment of patients taking PrEP;
- 3) Initiate proper CDC algorithms for preventing HIV through post-exposure prophylaxis using pharmacologic and non-pharmacologic approaches;
- 4) Interpret CD4 counts and HIV RNA levels (viral load) and identify the significance of getting patients to an undetectable viral load to eliminate risk of sexual transmission;
- 5) Define the role of the nurse practitioner in leading future research and clinical practice initiatives aimed at preventing HIV infection and reducing health disparities in vulnerable populations.



INCIDENCE OF HIV INFECTIONS & AIDS

- Review of Centers for Disease Control and Prevention (CDC) Data: Updated through 2019 (2015-2019)
- These can all be obtained from the *2019 CDC HIV Surveillance Report*:
- <https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-32/index.html>
- The figures on slides 5-11 all come from these CDC sources.



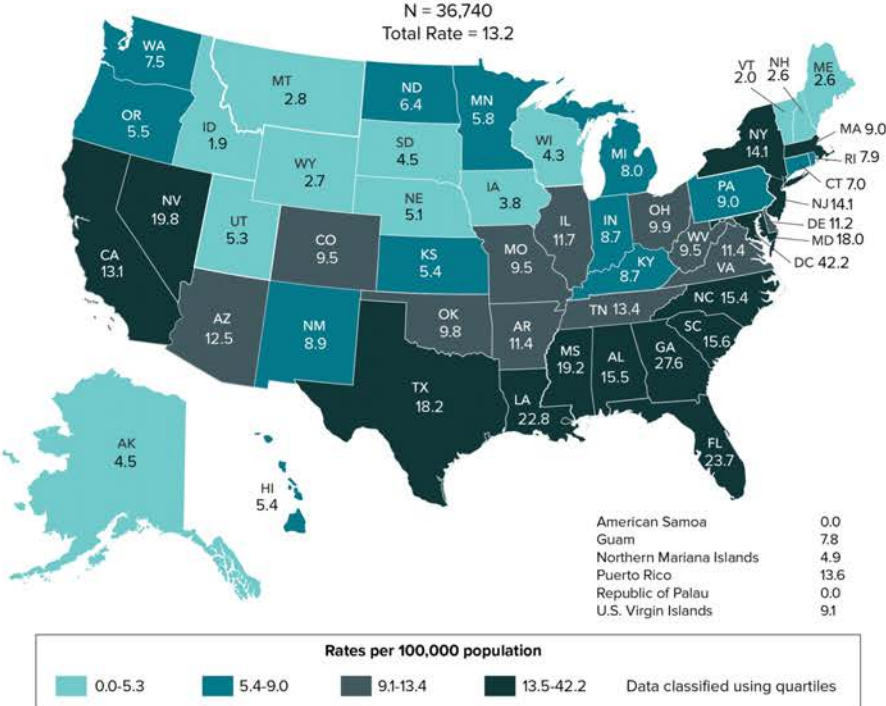
INCIDENCE OF HIV INFECTION & AIDS: 2015-2019 TAKE AWAY POINTS

DIAGNOSES

Diagnoses of HIV infection

From 2015 through 2019, the annual number and rate of diagnoses of HIV infection in the United States and 6 dependent areas decreased (Table 1b). By region, the rate of diagnoses of HIV infection in all regions decreased. In 2019, the overall rate was 11.1; among adults and adolescents, the rate was 13.2 (Figure 1). By region, the rates were 15.2 in the South, 9.4 in the Northeast, 9.2 in the West, and 7.0 in the Midwest (Table 1b).

Figure 1. Rates of diagnoses of HIV infection among adults and adolescents, 2019—United States and 6 dependent areas

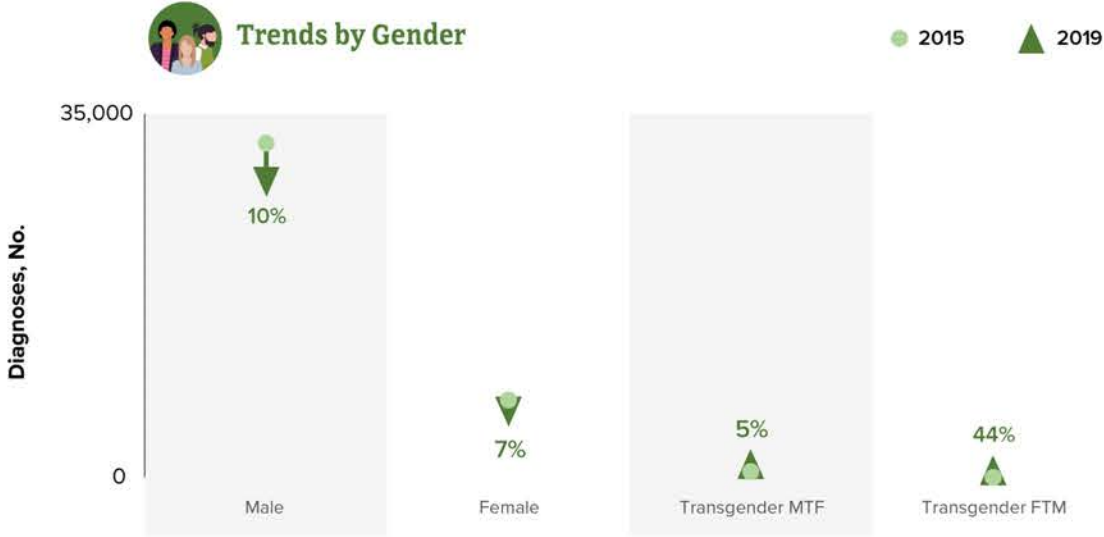


INCIDENCE OF HIV INFECTION & AIDS: 2015-2019 TAKE AWAY POINTS

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- **Gender:** From 2015 through 2019 in the United States and 6 dependent areas, the number of diagnoses of HIV infection for transgender male-to-female (MTF) and transgender female-to-male (FTM) adults and adolescents increased (Figure 2). The number of diagnoses among male and female adults and adolescents decreased. In 2019, diagnoses of HIV infection among all males (79%) and females (19%) accounted for approximately 98% of HIV diagnoses (Table 1b). Transgender MTF accounted for slightly more than 1% of annual diagnoses and transgender FTM accounted for less than 1%. Please use caution when interpreting data for additional gender identity (AGI) adults and adolescents: the numbers are small.

Figure 2. Diagnoses of HIV infection among adults and adolescents, by gender, 2015–2019—United States and 6 dependent areas



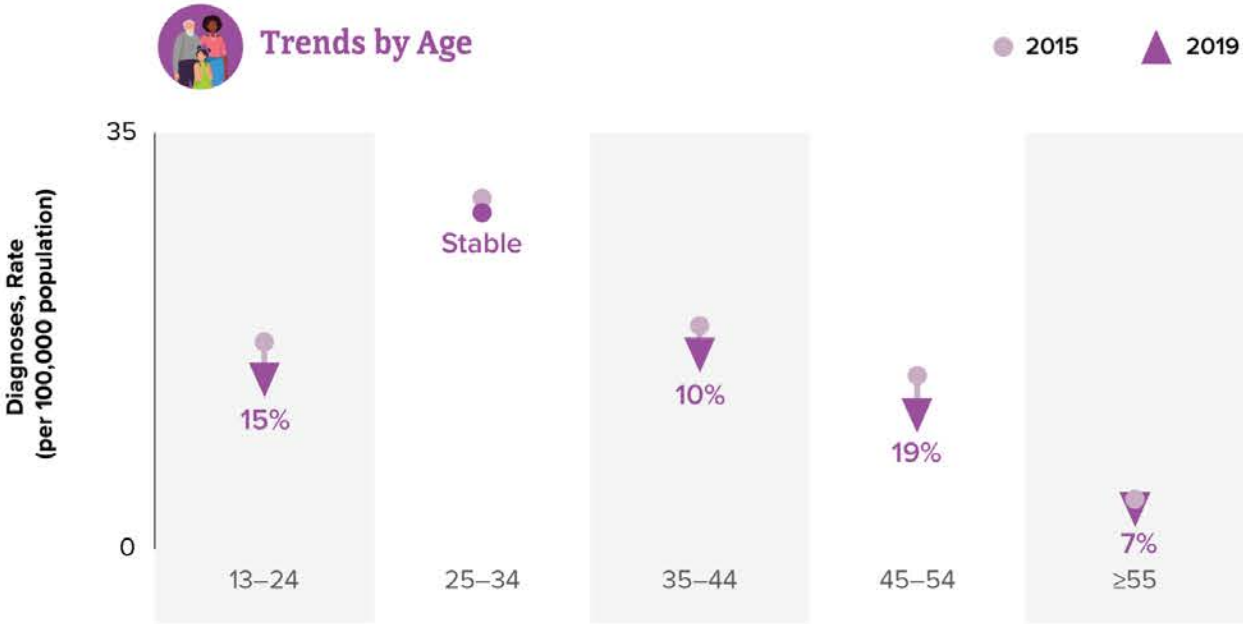
Note. See section D2.2 in Technical Notes for more information on gender.



INCIDENCE OF HIV INFECTION & AIDS: 2015-2019 TAKE AWAY POINTS

Figure 3. Rates of diagnoses of HIV infection among adults and adolescents by age at diagnosis, 2015–2019—United States and 6 dependent areas

In

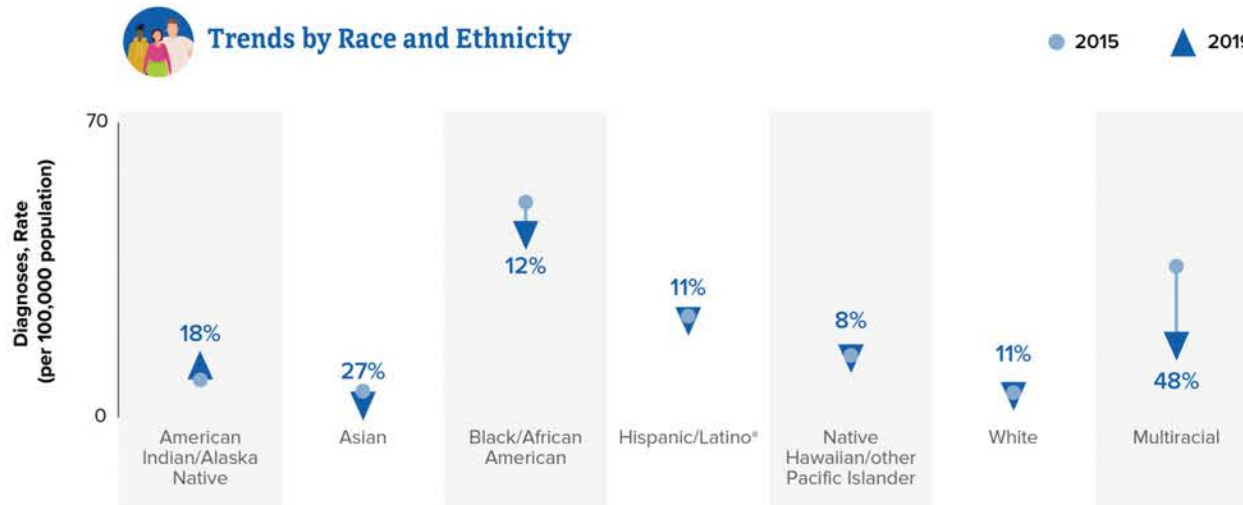


INCIDENCE OF HIV INFECTION & AIDS: 2015-2019 TAKE AWAY POINTS

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- **Race/ethnicity:** From 2015 through 2019 in the United States, the rate for diagnoses of HIV infection among American Indian/Alaska Native adults and adolescents increased (Figure 4). The rates of diagnoses of HIV infection for Asian, Black/African American, Hispanic/Latino, Native Hawaiian/other Pacific Islander, White, and multiracial adults and adolescents decreased. In 2019, the highest rate of diagnosis of HIV infection was 45.0 for Black/African American adults and adolescents, followed by 21.5 for Hispanic/Latino, 18.8 for multiracial, 13.5 for Native Hawaiian/other Pacific Islander, 10.5 for American Indian/Alaska Native, 5.3 for White, and 4.5 for Asian adults and adolescents.

Figure 4. Rates of diagnoses of HIV infection among adults and adolescents, by race/ethnicity, 2015–2019—United States



Note. See section D3 in Technical Notes for more information on race/ethnicity.

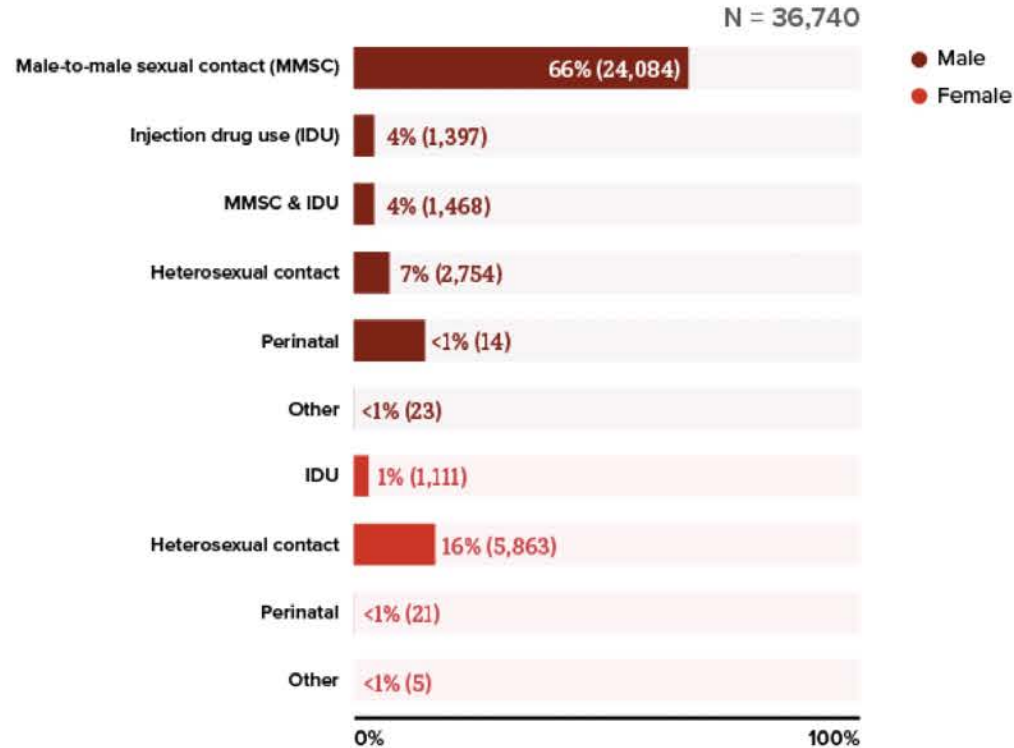
^a Hispanic/Latino persons can be of any race.



INCIDENCE OF HIV INFECTION & AIDS: 2015-2019 TAKE AWAY POINTS

In

Figure 6. Diagnoses of HIV infection among adults and adolescents, by transmission category, 2019—United States and 6 dependent areas

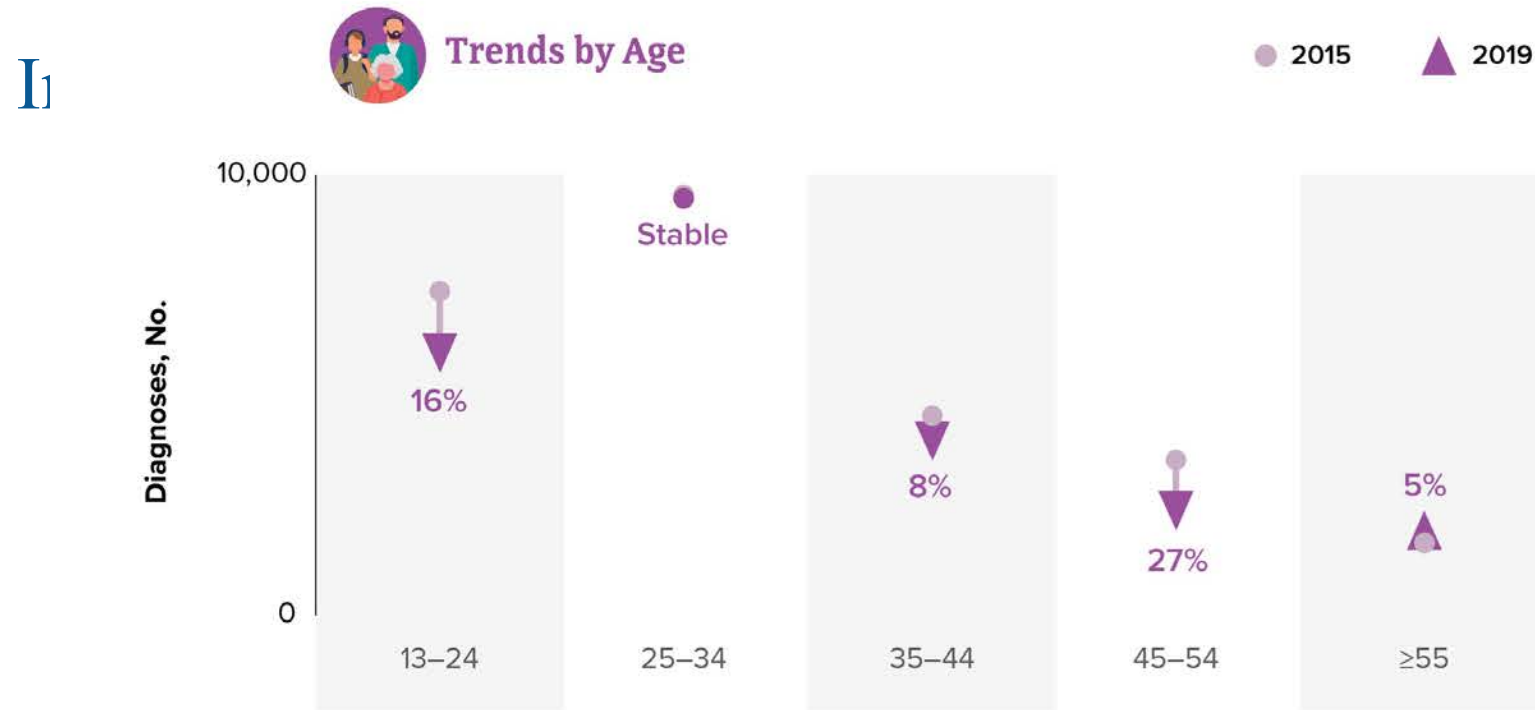


Note. Data have been statistically adjusted to account for missing transmission category. See section D4 in Technical Notes for more information on transmission categories.



INCIDENCE OF HIV INFECTION & AIDS: 2015-2019 TAKE AWAY POINTS

Figure 11. Diagnoses of HIV infection among men who have sex with men, by age group, 2015–2019—United States and 6 dependent areas

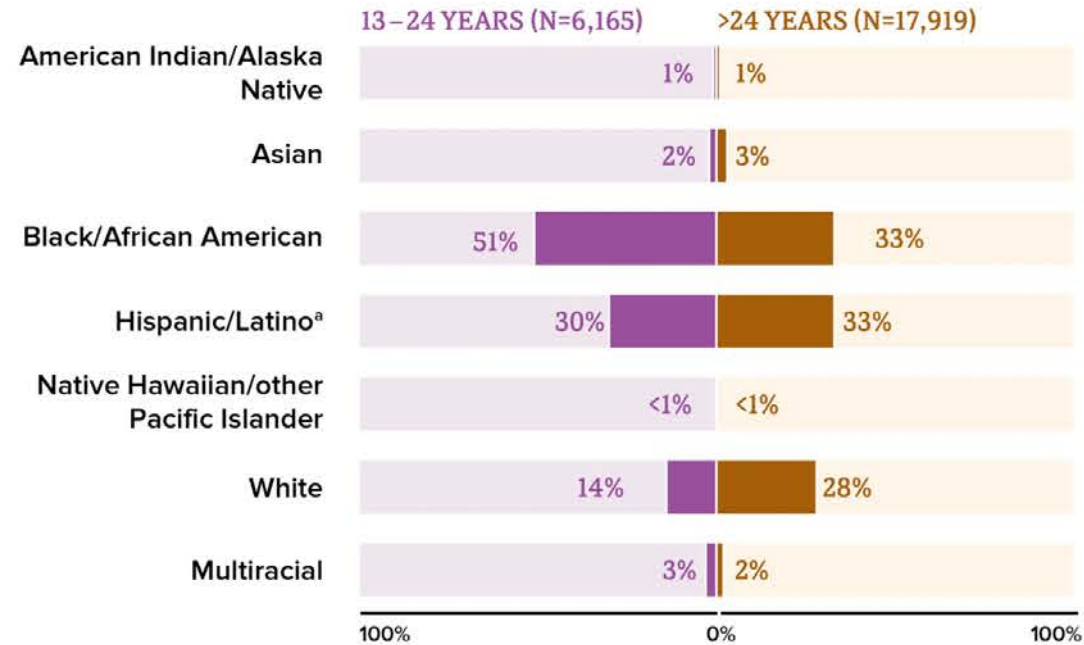


Note. Data have been statistically adjusted to account for missing transmission category. See section D4 in Technical Notes for more information on transmission categories.



INCIDENCE OF HIV INFECTION & AIDS: 2015-2019 TAKE AWAY POINTS

Figure 13. Percentages of diagnoses of HIV infection among men who have sex with men, by age group and race/ethnicity, 2019—United States and 6 dependent areas



Note. Data have been statistically adjusted to account for missing transmission category. See sections D3 and D4 in Technical Notes for more information on race/ethnicity and transmission categories.

^a Hispanic/Latino persons can be of any race.



HIV REPLICATION CYCLE

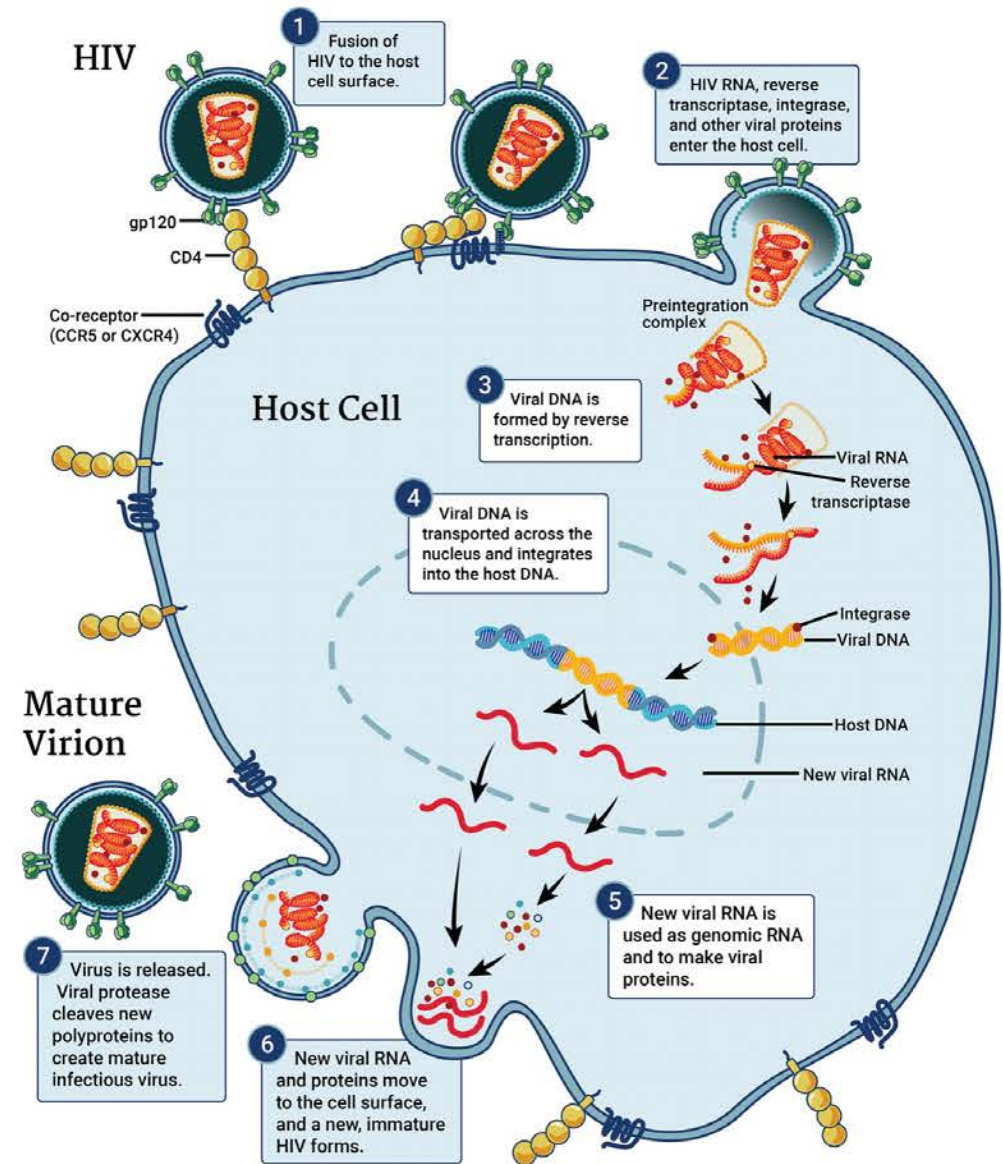


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PATHOPHYSIOLOGY OF HIV INFECTION

- HIV is a retrovirus, transcribing RNA-containing genetic material into DNA of the host cell nucleus by using an enzyme called reverse transcriptase.
- Glycoproteins 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/AIDS

- 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 new 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.

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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:
<https://clinicalinfo.hiv.gov/en/guidelines/perinatal/antiretroviral-management-newborns-perinatal-hiv-exposure-or-hiv-infection>



SCREENING FOR HIV

- ELISA → Western Blot (99.5% accurate)
 - Newer guidelines (CDC, 2014) are calling for substitution of Western Blot with antigen tests that differentiate HIV1 from HIV2.
- Confidentiality is **INCREDIBLY** important (i.e. no phone messages, personal names, etc.).
- 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.



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 (OraSure® or OraQuick® testing methods)



SCREENING FOR HIV

- The vast majority of 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

- The specificity of Rapid Antibody Tests in low-risk populations has not been evaluated
- Designed for high-risk individuals
 - OraQuick is an antibody test that provides results in 20 minutes. The blood, plasma or oral fluid is mixed in a vial with developing solution, and the results are read from a sticklike testing device
 - Orasure is an HIV test which uses mucosal transudate from the tissues of cheeks and gums. It is an antibody test which first employs ELISA, then Western Blot
 - 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



HIV/ AIDS SURVEILLANCE AND DX

- CD4 Testing:
 - Declining CD4 T-cell counts are considered to be a marker of the progression of HIV infection.
 - In HIV+ people, 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 SURVEILLANCE AND DX

- CD4 Testing:
 - Generally speaking, 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 $\geq 1\%$
 - The behavior has an increased ($\geq 1\%$) 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

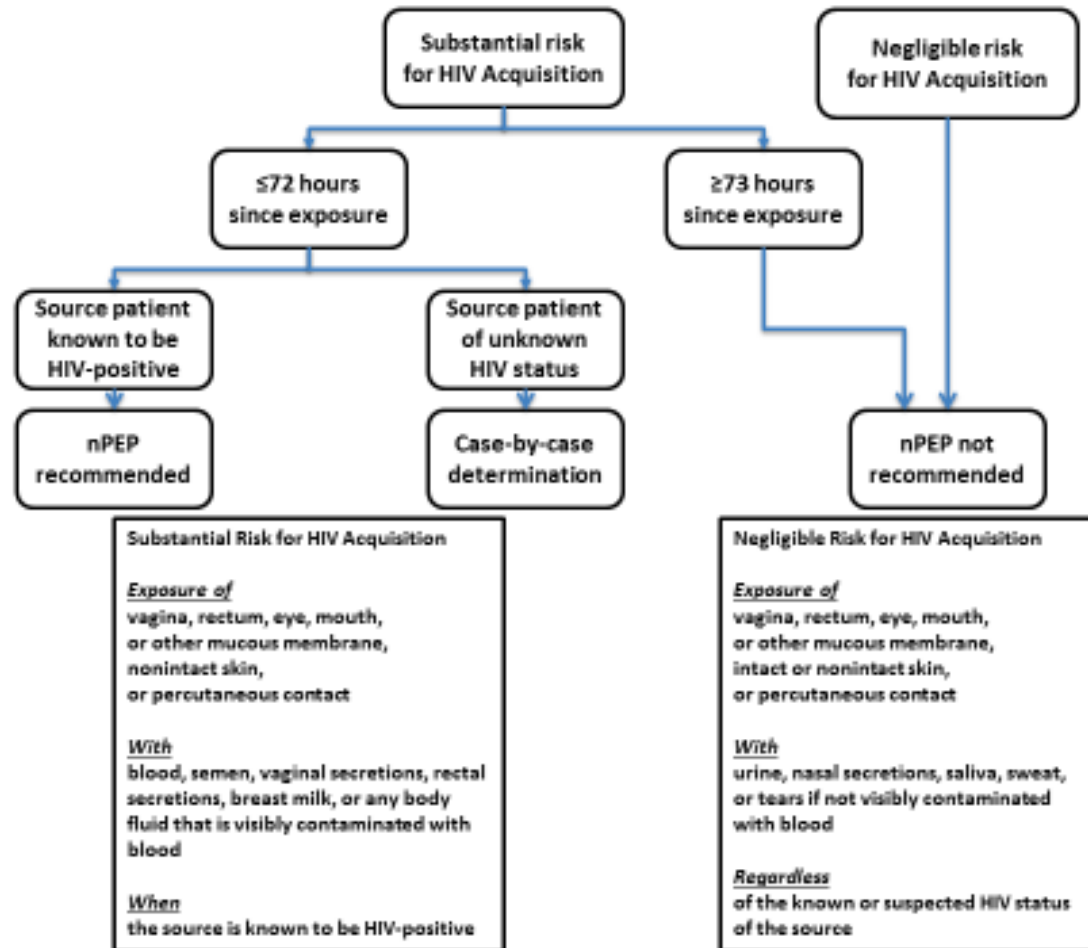
Table 1. Estimated per-act risk for acquiring human immunodeficiency virus (HIV) from an infected source, by exposure act^a

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 aminotransferase	✓	✓	✓	—	—
		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; eCrCl = [(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>

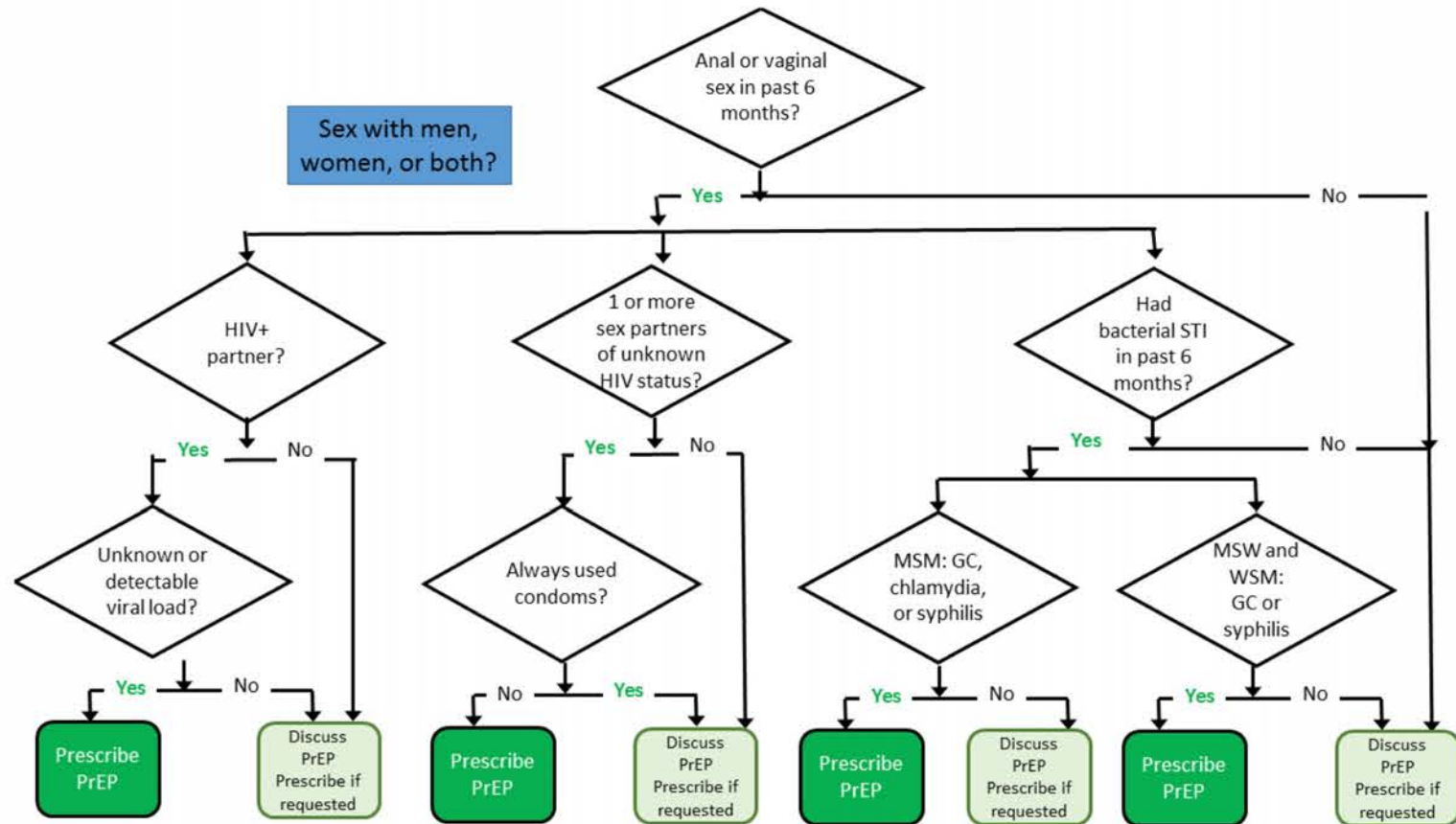


PRE-EXPOSURE PROPHYLAXIS

- 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>



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



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Pre-Exposure Prophylaxis

Treatment Monitoring Recommendations

- Document HIV-negative AB test every 2-3 months
- Ensure adherence and counsel on safer sex practices at every visit
- Screen for STIs, even if asymptomatic, q6 months
- In females, document a negative urine pregnancy test
- Assess creatinine clearance 3 months after Tx initiation and q6 months



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 PrEP up to \$1750/month, which equals \$21,000 per year
- Additional monitoring and screening costs per person have been estimated to be \$1,300 per year.
- USPTF A Recommendation (6/19), thus private insurance companies must cover PrEP



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PRE-EXPOSURE PROPHYLAXIS

- PrEP therapy with the use of FTC/TDF or FTC/TAF is a newer approach to preventing HIV in individuals at high risk for sexually acquired infection
- The once-daily regimen has been shown as significantly effective at preventing HIV in both men and women including heterosexual and bisexual persons



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



MOVING FORWARD

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

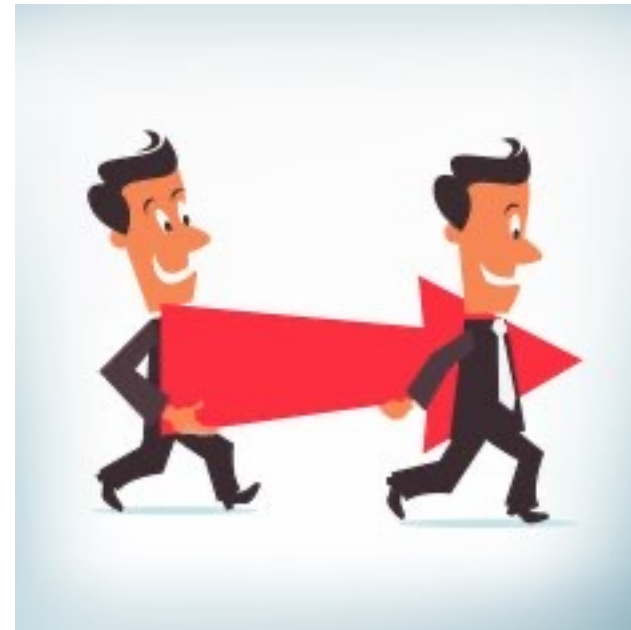


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REFERENCES

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

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References

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Phone: 407.823.2744 • Fax: 407.823.5675 • Web: nursing.usf.edu

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Preventing HIV in 2022: Integrating Evidence into Practice

Christopher W. Blackwell, Ph.D., APRN,
ANP-BC, AGACNP-BC, CNE, FAANP, FAAN

Associate Professor & Program Director
AGACNP Programs, College of Nursing
Academic Health Sciences Center
University of Central Florida
Orlando, Florida

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