Christopher W. Blackwell, Ph.D., APRN,
ANP-BC, AGACNP-BC, CNE, FAANP, FAAN
Associate Professor & Program Director
Adult-Gerontology Acute Care Nurse Practitioner Programs
Department of Nursing Practice
College of Nursing, University of Central Florida
Orlando, Florida

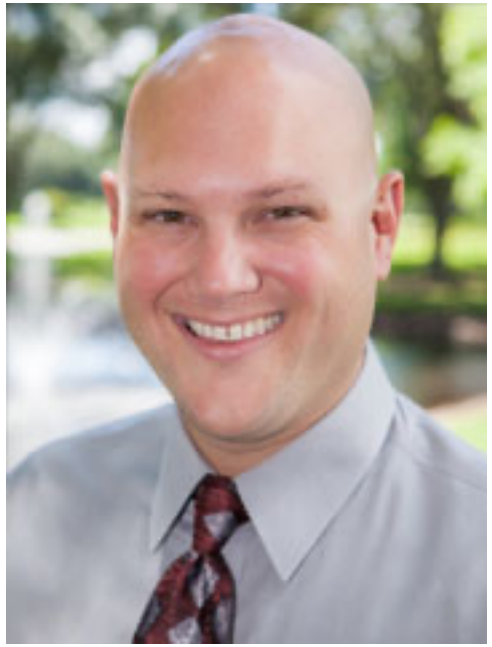
Preventing HIV in 2021: Pharmacologic & Non-Pharmacologic Strategies

2021 NATIONAL CONFERENCE
JUNE 15-AUGUST 31, 2021 Online

AANP | American Association of NURSE PRACTITIONERS®

DISCLOSURES

Dr. Blackwell has no conflicts of interest to disclose for this presentation.



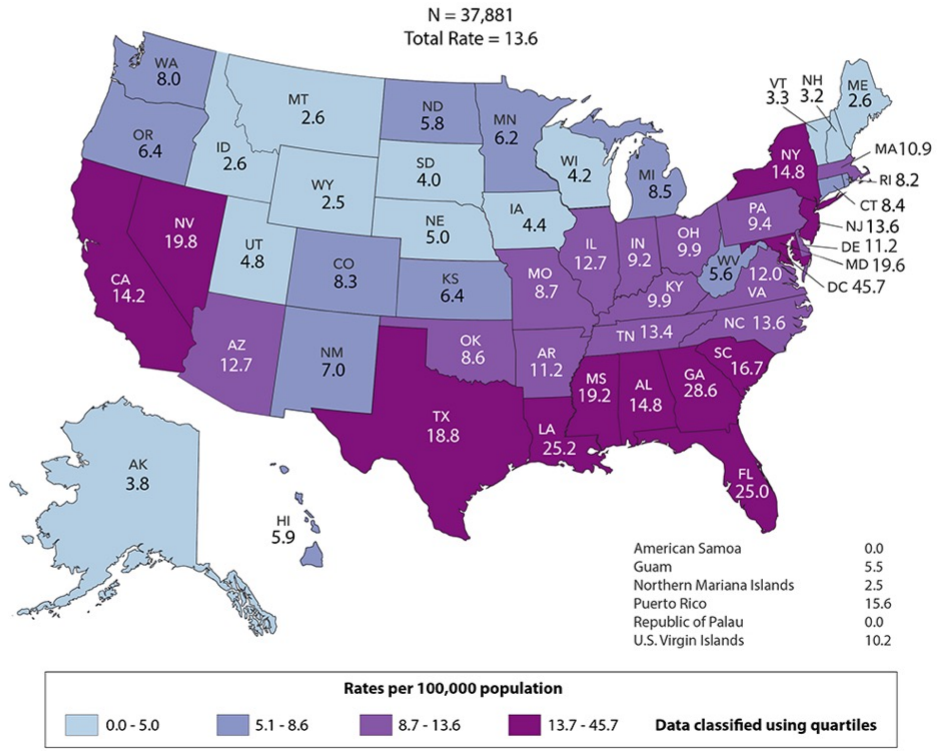
OBJECTIVES

1) At the end of this presentation, participants will describe the most recent epidemiology of HIV infection among adults and adolescents in the United States.
2) At the end of this presentation, participants will identify the two FDA-approved pharmacologic strategies used to prevent HIV infection pre-exposure.
3) At the end of this presentation, participants will outline the prevention strategy used for HIV prevention post-exposure.
4) At the end of this presentation, participants will indicate how undetectable HIV RNA levels (viral load) eliminate sexual-transmission of HIV among high-risk groups.
5) At the end of this presentation, participants will articulate the role of the nurse practitioner in leading future research and clinical practice directives in the prevention of HIV.

HIV INCIDENCE IN THE UNITED STATES

Diagnoses of HIV Infection

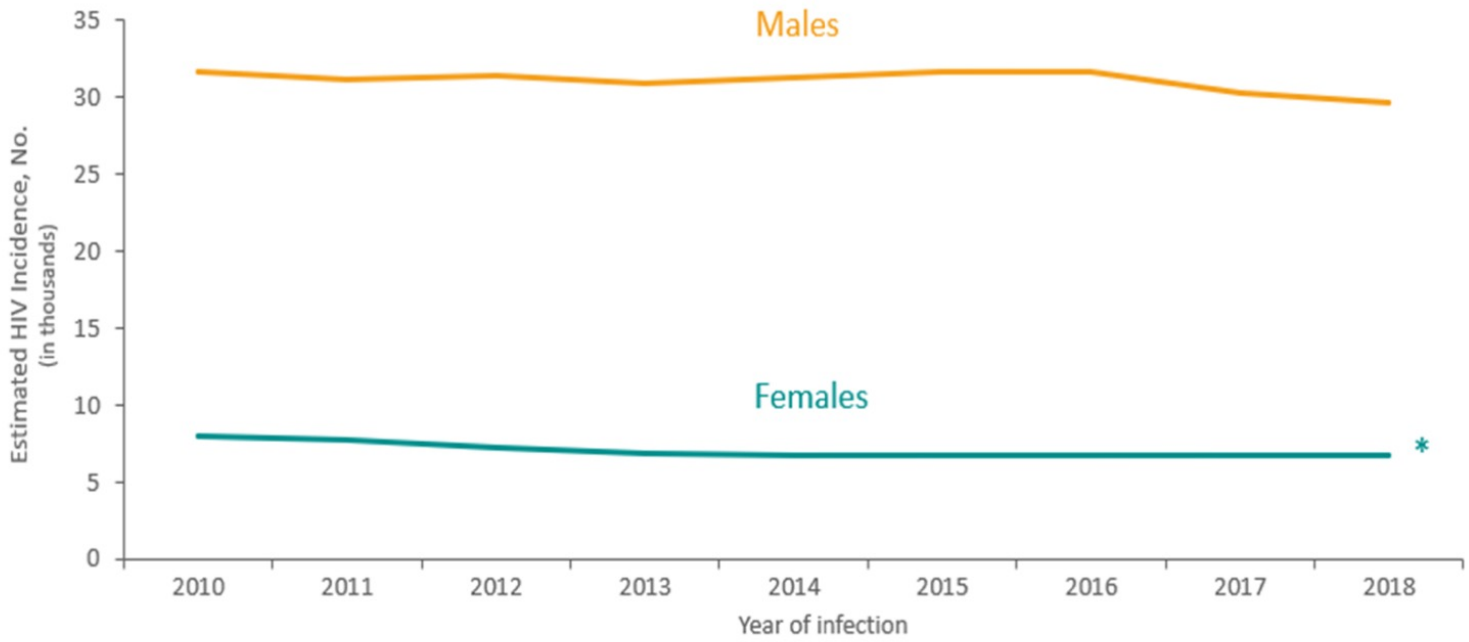
Figure 1. Rates of Diagnoses of HIV Infection among Adults and Adolescents, 2018—United States and 6 Dependent Areas



From 2014 through 2018, the annual number and rate of diagnoses of HIV infection in the United States and 6 dependent areas decreased (Table 1b). In the United States and 6 dependent areas, the overall rate in 2018 was 11.5; among adults and adolescents, the rate was 13.6 (Figure 1). From 2014 through 2018, by region, the rate of diagnoses of HIV infection in all regions decreased. In 2018, the rates were 15.6 in the South, 9.9 in the Northeast, 9.7 in the West, and 7.2 in the Midwest (Table 1b).

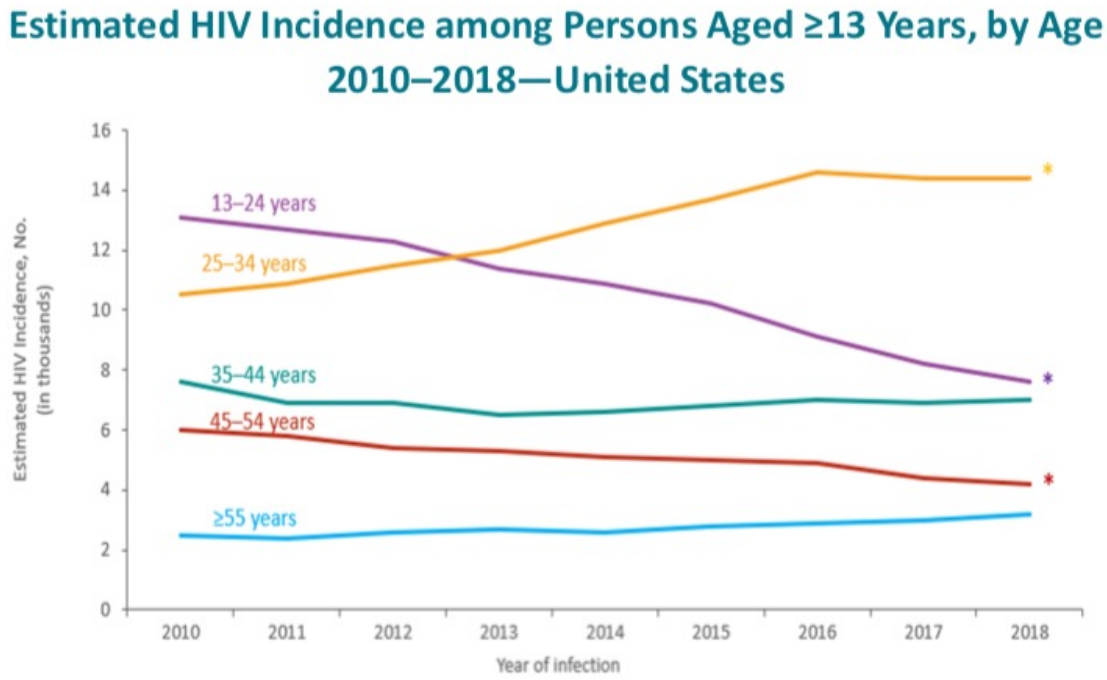
HIV INCIDENCE IN THE UNITED STATES

Estimated HIV Incidence among Persons Aged ≥13 Years, by Sex at Birth 2010–2018—United States



Note. Estimates were derived from a CD4 depletion model using HIV surveillance data.
* Difference from the 2010 estimate was deemed statistically significant (P < .05).

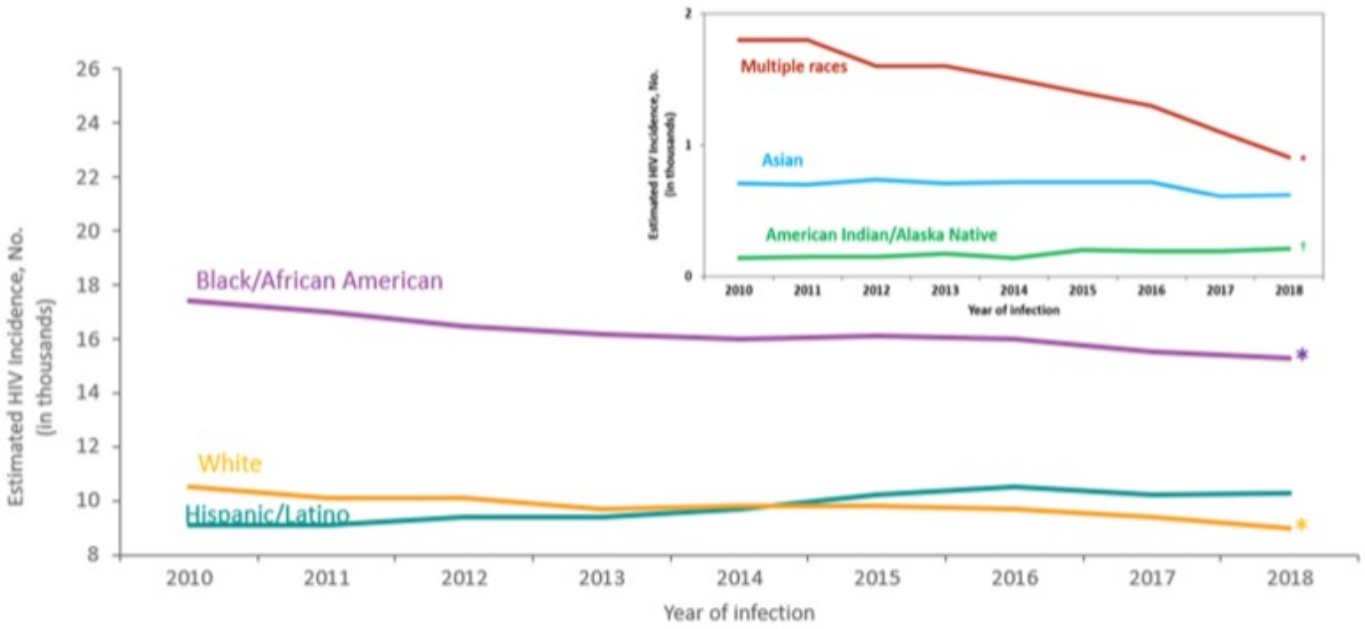
HIV INCIDENCE IN THE UNITED STATES



Note. Estimates were derived from a CD4 depletion model using HIV surveillance data.
* Difference from the 2010 estimate was deemed statistically significant (P < .05).

HIV INCIDENCE IN THE UNITED STATES

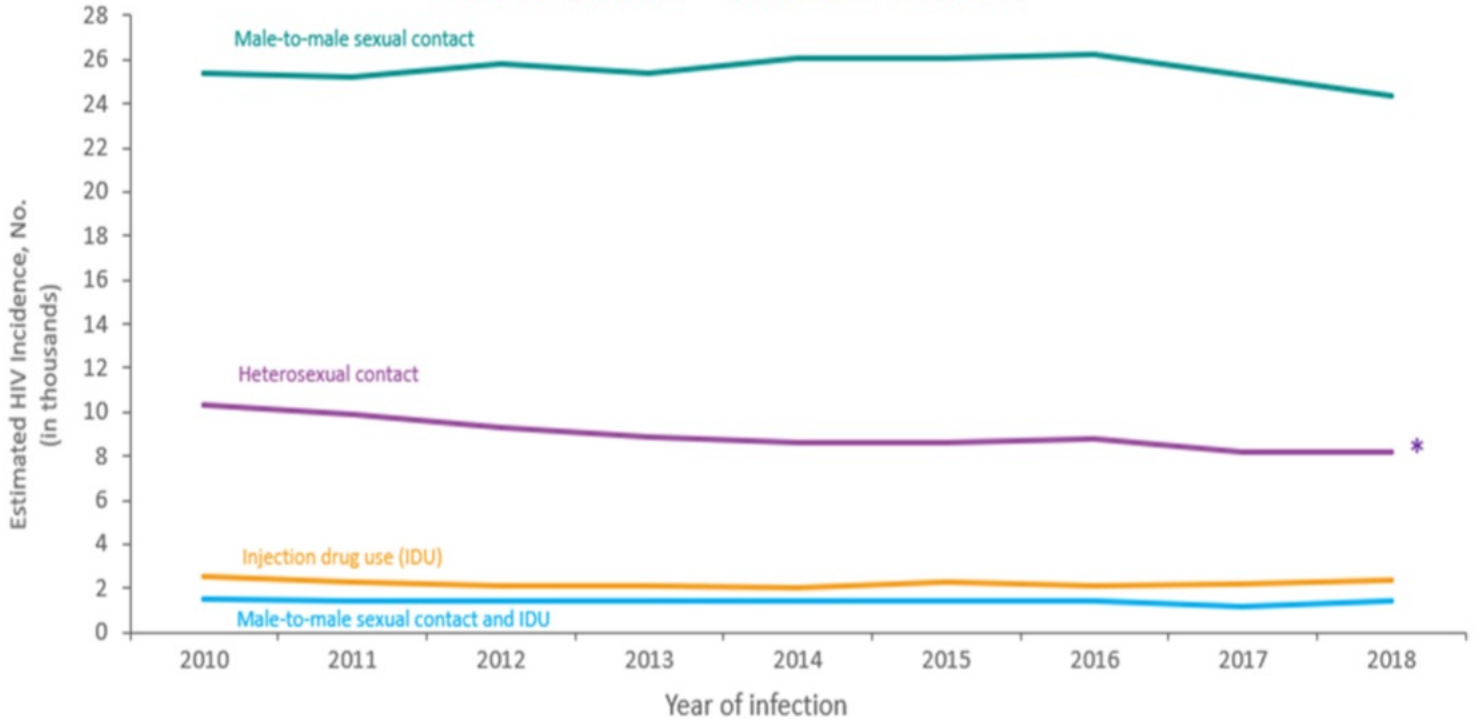
Estimated HIV Incidence among Persons Aged ≥13 Years, by Race/Ethnicity 2010–2018—United States



Note. Estimates were derived from a CD4 depletion model using HIV surveillance data. Hispanics/Latinos can be of any race.
* Difference from the 2010 estimate was deemed statistically significant (P < .05).
† Estimates should be used with caution; relative standard errors are 30%–50% .

HIV INCIDENCE IN THE UNITED STATES

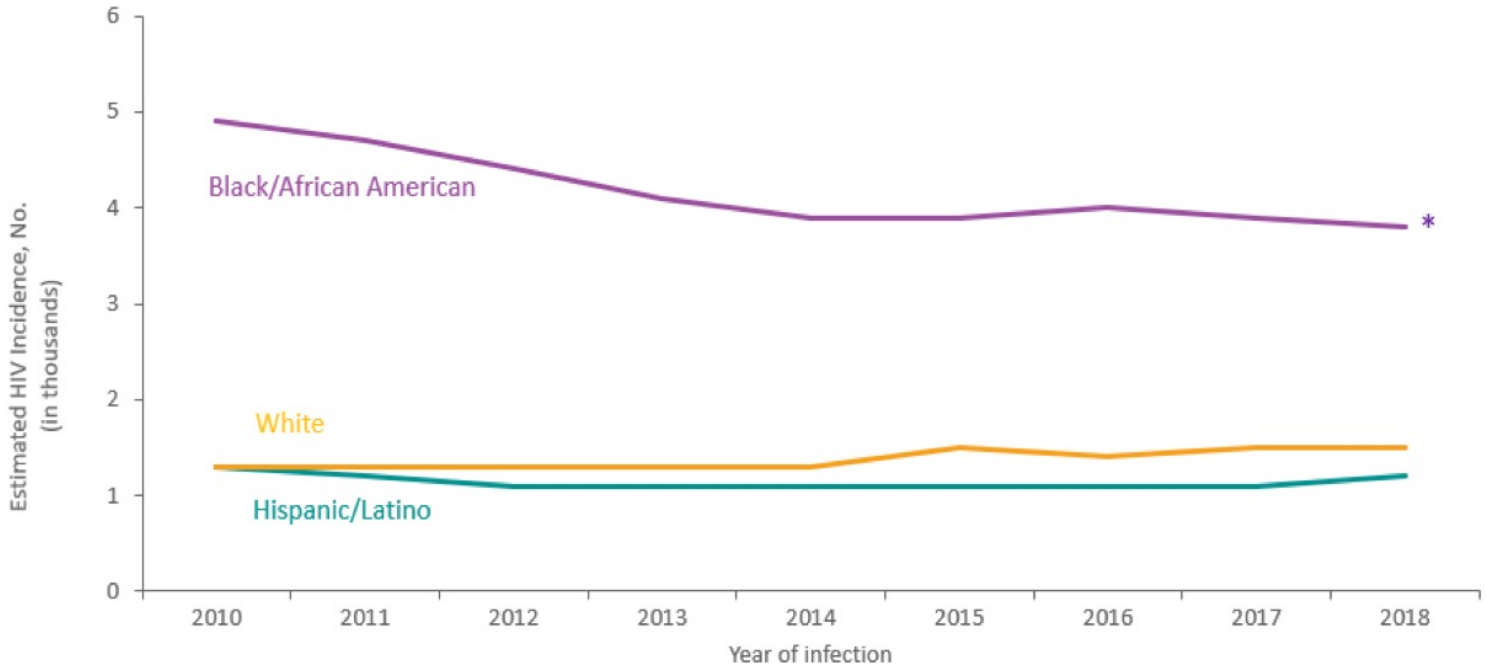
Estimated HIV Incidence among Persons Aged ≥13 Years, by Transmission Category 2010–2018—United States



Note. Estimates were derived from a CD4 depletion model using HIV surveillance data. Data have been statistically adjusted to account for missing transmission category. Heterosexual contact is with a person known to have, or to be at high risk for, HIV infection.
* Difference from the 2010 estimate was deemed statistically significant (P < .05).

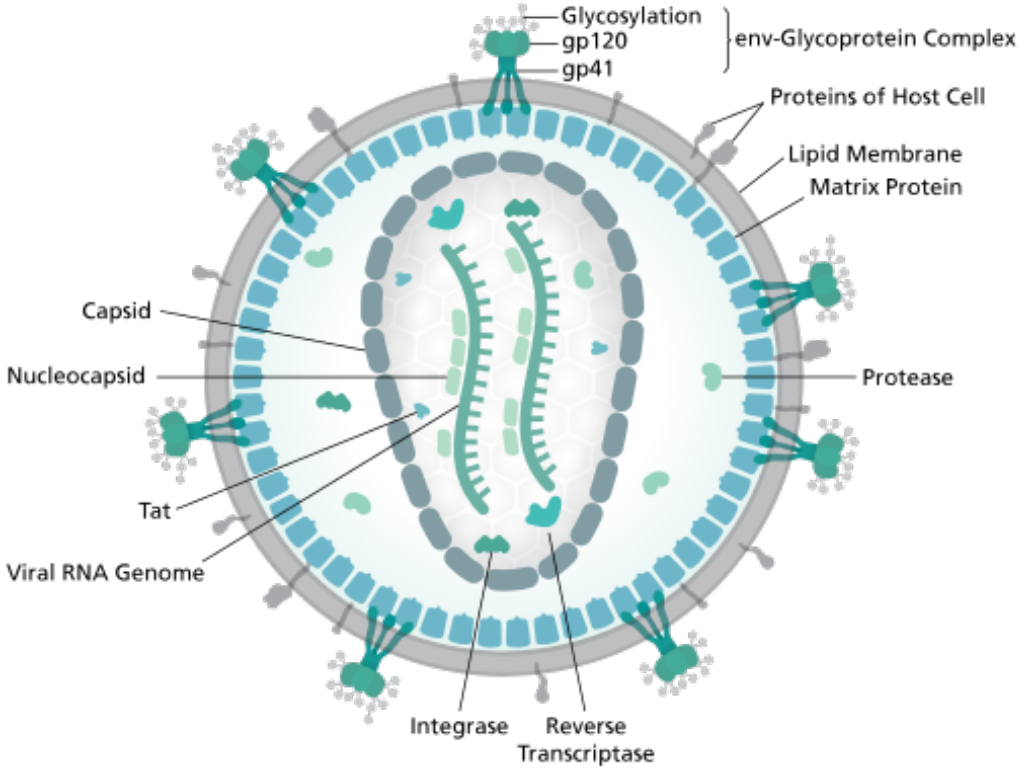
HIV INCIDENCE IN THE UNITED STATES

Estimated HIV Incidence among Females Aged ≥13 Years by Race/Ethnicity, 2010–2018—United States



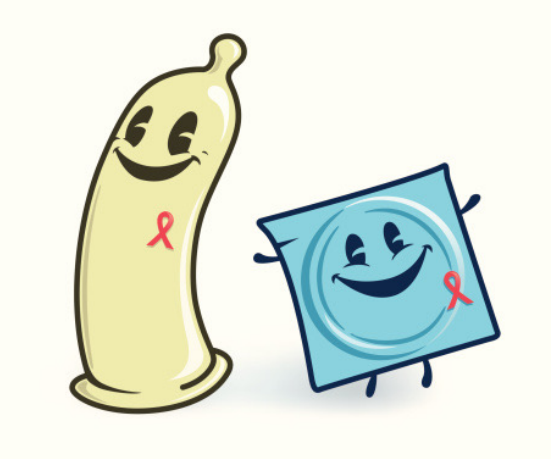
Note. Estimates were derived from a CD4 depletion model using HIV surveillance data. Hispanics/Latinos can be of any race.
* Difference from the 2010 estimate was deemed statistically significant (P < .05).

HIV



https://commons.wikimedia.org/wiki/File:HI-virion-structure_en.svg

PATHOGENIC PROCESS OF HIV/AIDS



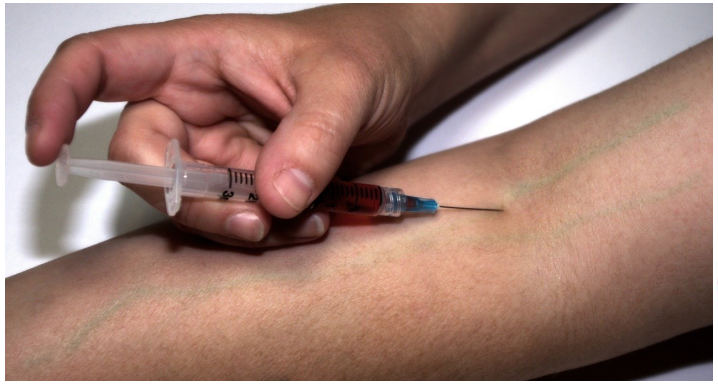
- Exposure to HIV
- HIV Infection
- Seroconversion
- Latency Period
- Initial Symptoms of Immunodeficiency and Declining Immune Function
- Immune System Failure and AIDS
- Severe Immune Deficiency

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 a determinant of degree of safeness—CDC (2017) issued new statement about this.

PREVENTION OF HIV TRANSMISSION

- Parenteral Transmission:
  - Proper cleaning of drug paraphernalia:
    (filled and flushed with water x 3→ filled with bleach and then shaken for 30 sec. x 3 → flushed with water x 3)
    - See the YouTube video prepared by Idaho Clean Needle Project
  - Participation in needle exchange programs.



POST-EXPOSURE PROPHYLAXIS (PEP)

- 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

POST-EXPOSURE PROPHYLAXIS (PEP)

- Baseline Tests:
  - HIV Screening
  - Hepatitis B screening
  - Hepatitis C screening
  - Renal and liver function
  - STI screening if exposure from sex
- Ongoing Screening:
  - HIV in 4-6 weeks
  - Renal and liver function in 4-6 weeks
  - STI screening if exposure from sex in 12 weeks
  - HIV in 12 weeks
  - HIV in 6 months
- Help with Costs:
  - $3,200 estimated cost for 28-day regimen
  - Sexual assault victims can get for free (https://www.cdc.gov/hiv/basics/pep)
  - PEP usually covered by private insurance and worker's compensation (occupational exposure)

POST-EXPOSURE PROPHYLAXIS (PEP)

- The preferred regimen for otherwise healthy adults and adolescents
  - tenofovir disoproxil fumarate (tenofovir DF or TDF) (300 mg) with emtricitabine (200 mg) once daily ***plus***

    raltegravir (RAL) 400 mg twice daily or dolutegravir (DTG) 50 mg daily. [VI-A2ci] [VII-C]

- Alternative regimen for otherwise healthy adults and adolescents is
  - tenofovir DF (300 mg) with emtricitabine (FTC) (200 mg) once daily ***plus***

    darunavir (DRV) (800 mg) and ritonavir[a] (RTV) (100 mg) once daily. [VII-C]

- Regimens are also provided for children, persons with decreased renal function, and pregnant women (see Table 6). [VII-C]

- Health care providers considering using antiretroviral regimens for nPEP other than those listed in these guidelines as preferred or alternative are encouraged to consult with other health care providers who have expertise in antiretroviral medication use for similar patients (e.g., children, pregnant women, or those with such comorbid conditions as impaired renal function). [VII-C] [VII-E2]

PRE-EXPOSURE PROPHYLAXIS (PREP)

- Prevention of infection with type 1 HIV (HIV-1) was revolutionized when the United States Food and Drug Administration (FDA) approved once daily use of oral antiretroviral medication as pre-exposure prophylaxis (PrEP).
- Once daily emtricitabine/tenofovir fumarate (FTC/TDF) 200mg/300mg (Truvada®) or once daily emtricitabine/tenofovir alafenamide (FTC/TAF) 200mg/25mg (Descovy®), 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 adherent to it.
- FTC/TDF was approved for use as PrEP in 2012.
- Research supporting FTC/TDF as efficacious is historically rooted in the 2010 Preexposure Prophylaxis Initiative (iPrEx) study.

PRE-EXPOSURE PROPHYLAXIS (PREP)

- With detectable serum levels, participants in the iPrEx study had a 90% reduction in HIV transmission.
- As data on use of FTC/TDF for PrEP evolved, its efficacy was further supported.
  - The regimen was found to be so high in immediate participants in the 2014 Pre-Exposure Prophylaxis to Prevent the Acquisition of HIV-1 Infection (PROUD) study, participants in the deferred arm of the study were promptly offered PrEP when early data supported its efficacy.

PRE-EXPOSURE PROPHYLAXIS (PREP)

- Those enrolled in the PROUD study also showed no serious adverse events.
  - Common adverse events associated with use of FTC/TDF for PrEP included nausea, headache, and arthralgia.
  - In 2018, use of FTC/TDF for PrEP was expanded to include an indication for use in at-risk adolescents (see Blackwell, 2018).

PRE-EXPOSURE PROPHYLAXIS (PREP)

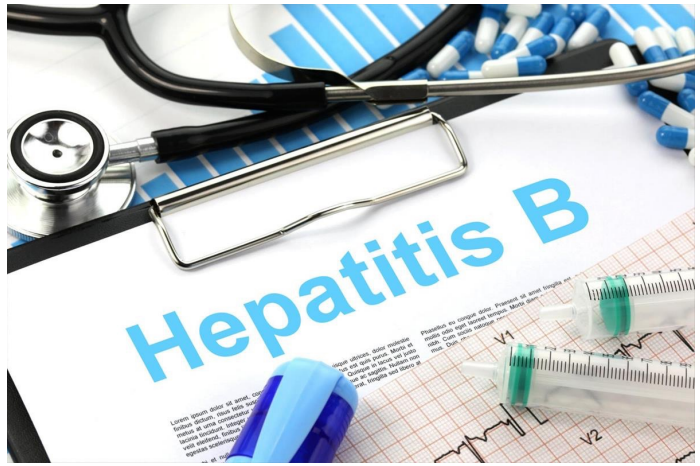
- In October 2019, emtricitabine/tenofovir alafenamide (FTC/TAF) 200mg/25mg (Descovy®) was approved as a newer agent for once daily use for PrEP in both high-risk adults and adolescents.
- Two of the major benefits often associated with FTC/TAF compared to FTC/TDF are lower incidence of renal toxicity and bone demineralization.

FTC/TAF FOR PREP: REGIMEN, SAFETY PROFILE, AND EFFICACY

- FTC/TAF for PrEP in at-risk adolescents and adults involves prescribing a once daily dose of emtricitabine/tenofovir alafenamide (Descovy®) 200mg/25mg.
  - MUST be screened for HIV and have a documented negative screening result.
- Because tenofovir prodrugs have been associated with renal impairment in both animal and human clinical trials, the patient's serum creatinine and creatinine clearance (CrCl) should be evaluated in addition to evaluating the urine for the presence of glucosuria and proteinuria.
  - The regimen can be started only after ensuring the patient's CrCl is >30 mL/minute

FTC/TAF FOR PREP: REGIMEN, SAFETY PROFILE, AND EFFICACY

- Continue to assess phosphorus levels in patients with chronic kidney disease.
- Screening for hepatitis B virus (HBV) infection is also necessary prior to prescribing FTC/TAF for PrEP.
  - This is because exacerbations of HBV are possible with discontinuation of FTC/TAF due its ability to suppress HBV.



FTC/TAF FOR PREP: REGIMEN, SAFETY PROFILE, AND EFFICACY

- Check HIV serostatus every 3 months.
  - **If the patient develops symptoms suggestive of acute HIV infection (eg. fever, fatigue, lymphadenopathy, myalgia, or rash), the regimen should be converted to a comprehensive HIV management program until a negative serostatus can be confirmed through screening.**
  - HIV screening should also accompany any diagnosis of a sexually transmitted infection (STI) while the patient remains on the regimen

FTC/TAF FOR PREP: REGIMEN, SAFETY PROFILE, AND EFFICACY

- Continuous assessment of renal function should be performed while the patient remains on the regimen; this could be assessed in conjunction with HIV serostatus every 3 months or when clinically indicated.
- Medications that may reduce renal function (eg, non-steroidal anti-inflammatory drugs [NSAIDs]) or compete with active tubular secretion (eg, probenecid, fluoroquinolones) should not be administered simultaneously with FTC/TAF.
- This is because of consequent risk for increasing concentrations of FTC, and thus, opportunities for associated adverse events.

FTC/TAF FOR PREP: REGIMEN, SAFETY PROFILE, AND EFFICACY

- The most common adverse events, which occurred in approximately 2% of participants in PrEP clinical trials, include diarrhea, nausea, headache, fatigue, and abdominal pain.
  - Upon initial initiation of the regimen, “start up” symptoms of diarrhea, nausea, and vomiting may occur initially; but they usually abate within three months of therapy.
- Cases of lactic acidosis with severe hepatomegaly with steatosis have been reported with use of emtricitabine, a component of FTC/TAF

FTC/TAF FOR PREP: REGIMEN, SAFETY PROFILE, AND EFFICACY

- FTC/TAF should be immediately stopped if the patient has laboratory findings confirming lactic acidosis or clinical findings such as hepatomegaly and/or steatosis.
- Pharmacologic agents that inhibit P-glycoprotein (P-gp) may increase concentrations of TAF (and risk for adverse events) while those that induce P-gp may decrease concentrations of TAF (and regimen efficacy).

FTC/TAF FOR PREP: REGIMEN, SAFETY PROFILE AND EFFICACY

Common P-gp inhibitors[14] and inducers[15]

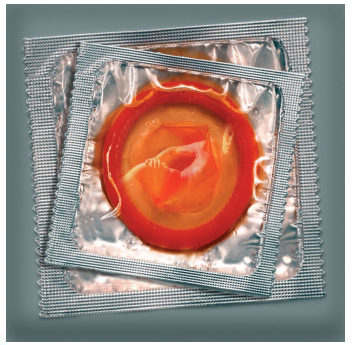
P-gp Inhibitors[a]	Drug Class or Major Indication	P-gp Inducers	Drug Class or Major Indication
Clotrimazole (eg. Lotrimin®)	Topical broad-spectrum antifungal	Amprenavir (Agenerase®)	HIV PI
Dexamethasone (eg. DexPak®)	Glucocorticoid	Carbamazepine (Tegretol®)	Anticonvulsant
Digoxin (Lanoxin®)	Cardiac glycoside	Dexamethasone (eg. DexPak®)	Glucocorticoid
Indinavir (Crixivan®)	HIV PI	Indinavir (Crixivan®)	HIV PI
Mefepristone (Korlym®)	Cortisol receptor blocker	Mefepristone (Korlym®)	Cortisol receptor blocker
Nifedipine (Procardia®)	Dihydropyridine CCB	Nelfinavir (Viracept®)	HIV PI
Reserpine (eg. Diutensen-R®)	Anti-hypertensive	Nifedipine (Procardia®)	Dihydropyridine calcium channel blocker
Ritonavir (Norvir®)	HIV PI	Reserpine Eg. Diutensen-R®)	Anti-hypertensive
Saquinavir (Invirase®)	HIV PI	Rifampicin (Rifadin®)	Anti-mycobacterial
Verapamil (eg. Calan®)	Non-dihydropyridine CCB	Saquinavir (Invirase®)	Serotonin uptake inhibitor
		Trazadone (Desyrel®)	Serotonin uptake inhibitor

Abbreviations: CCB, calcium channel blocker; HIV, human immunodeficiency virus; P-gp, P-glycoprotein; PI, protease inhibitor.
[a] Note that some of the medications listed are classified as both P-gp inhibitors and inducers.

Blackwell, C.W., & López-Castillo. (2021). HIV pre-exposure prophylaxis: Use of emtricitabine/tenofovir alafenamide. *The Journal for Nurse Practitioners*. doi: 10.1016/j.nurpra.2021.01.002.

FTC/TAF FOR PREP: REGIMEN, SAFETY PROFILE, AND EFFICACY

- While efficacy of FTC/TAF as PrEP for HIV-1 has been found to be approximately 99%, proper adherence to the once daily regimen is vital to achieve this.
- Because PrEP does not protect against other STIs, it is imperative to counsel patients on STI reduction strategies, including consistent and proper use of condoms, open discussion of HIV serostatus and HIV-1 viremic status with sex partners, and self-employment of other harm reduction approaches.

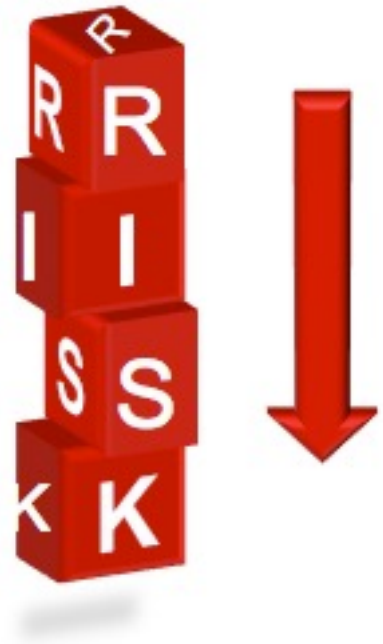


INDICATIONS AND CONTRAINDICATIONS OF FTC/TAF AS PREP

- FTC/TAF is specifically indicated as PrEP in adults and adolescents (over the age of 13) considered to be at-risk of sexually acquired HIV-1 infection.
  - These risk factors include those which are behavioral, biological, or epidemiologic:
    - Behavioral risks include condomless sex (also referred to as “barebacking”), self-identification as being at higher risk for HIV infection, or having sexual partners of unknown HIV-1 viremic status.
    - Biological risk includes diagnosis of past or current sexually transmitted infections while epidemiologic risks involve sexual activity in a high-prevalence area or network.

INDICATIONS AND CONTRAINDICATIONS OF FTC/TAF AS PREP

- FTC/TAF is not indicated for females at risk for HIV-1 acquisition through vaginal sex.
- FTC/TAF is contraindicated in persons who are HIV-infected or have an unknown HIV serostatus.



INDICATIONS AND CONTRAINDICATIONS OF FTC/TAF AS PREP

FTC/TAF Prescribing (200mg/25mg orally daily) and Monitoring Principles

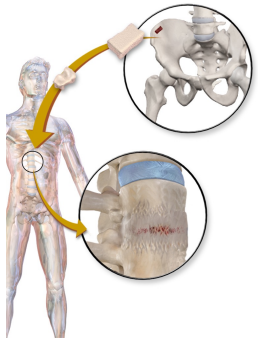
Initial Laboratory Assessments	Ongoing Evaluation	Precautions	Adverse Effects	Rx Interactions
Negative HIV Antibody Screen Serum Creatinine CrCl (> 30mL/Min) Urine: Glucosuria Proteinuria HBV Those with CKD: Phosphorus	Negative HIV Antibody Screen[a] Serum Creatinine[a] CrCl (> 30 mL/Min)[a] Negative HIV Antibody Screen w/ any new STD Diagnosis	Presentation of symptoms suggestive of acute HIV infection: 1) Change to comprehensive HIV regimen program until; 2) Negative HIV serostatus is confirmed. Avoid medications that may reduce renal function or compete with active tubular secretion (eg, NSAIDs)	Diarrhea Nausea Headache Fatigue Abdominal Pain Lactic Acidosis Steatosis	P-gp Inhibitors[b] P-gp Inducers[b]

Abbreviations: CrCl, creatinine clearance; HBV, hepatitis B virus; HIV, human immunodeficiency virus; P-gp, P-glycoprotein; STI, sexually transmitted infection.
[a] Monitor every three months.
[b] See prior table, slide 27

Blackwell, C.W., & López-Castillo. (2021). HIV pre-exposure prophylaxis: Use of emtricitabine/tenofovir alafenamide. *The Journal for Nurse Practitioners*. doi: 10.1016/j.nurpra.2021.01.002.

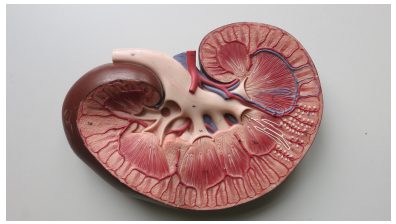
FTC/TAF AND FTC/TDF: A FOCUSED COMPARISON

- While FTC/TAF is a newer agent for PrEP, it is noninferior to FTC/TDF in preventing HIV-1 infections.
- While FTC/TAF has been associated with lower incidences of associated renal toxicity and bone demineralization as adverse events, the overall incidence of both with use of FTC/TDF is low.
- Research has shown small but statistically significant decreases in bone mineral density that stabilizes after 24-weeks of FTC/TDF treatment.



FTC/TAF AND FTC/TDF: A FOCUSED COMPARISON

- Similarly, data suggest FTC/TDF as being associated with a low incidence of a very mild and nonprogressive decrease in CrCl in some users.
  - However, this has been found to be reversible and managed with routine serum creatinine monitoring.
- FTC/TDF has been supported for use in everyone at-risk for HIV-1 infection compared to FTC/TAF, which is supported for use in gay and bisexual men and transwomen who have sex with men.



FTC/TAF AND FTC/TDF: A FOCUSED COMPARISON

- A small amount of weight loss has been associated with use of FTC/TDF compared to a small amount of weight gain with FTC/TAF.
- Variation in effects of these agents on lipids has also been reported.
- Use of FTC/TDF may drop HDL, LDL, and total cholesterol minimally; small increases in LDL and triglycerides have been seen with use of FTC/TAF

FTC/TAF AND FTC/TDF: A FOCUSED COMPARISON

Major Differences Between FTC/TDF and FTC/TAF

General Characteristics	**FTC/TDF**	**FTC/TAF**
Date Approved	2012	2019
Brand	Truvada®	Descovy®
Tablet shape	Capsular	Rectangular
Tablet color	Blue	Blue
Tablet imprint	GILEAD/701	GILEAD/225
Tablet size	19 mm	13 mm
Daily Dosing Regimen	200 mg/300 mg once per day	200 mg/25 mg once per day
Indications for HIV-1 PrEP for	Populations at risk	Men who have sex with men; Transwomen who have sex with men
Cost without insurance	$1845/month	$1845/month
Generic	Available	Not available
Assistance	Available	Available
Efficacy Information	**FTC/TDF**	**FTC/TAF**
HIV-1 prevention efficacy	>99%	>99%
Safety Information	**FTC/TDF**	**FTC/TAF**
Common adverse effects	Low (diarrhea, nausea, vomiting; usually improves within 3 months of Tx)	Low (diarrhea, nausea, vomiting; usually improves within 3 months of Tx)
Bone mineral density	Low risk; stabilizes at 24 weeks treatment	Lower risk of adverse effects
Renal toxicity	Low risk; nonprogressive; reversible with routine serum creatinine monitoring	Lower risk of adverse renal effects
Weight changes	Possible small degree of weight loss	Possible small degree of gain
Serum lipids	Possible small decrease in HDL, LDL, and total cholesterol	Possible small increase in LDL and triglycerides

Abbreviations: FTC, emtricitabine; HDL, high-density lipoprotein cholesterol; LDL, low-density lipoprotein cholesterol; TAF, tenofovir alafenamide; TDF, tenofovir fumarate.

Blackwell, C.W., & López-Castillo. (2021). HIV pre-exposure prophylaxis: Use of emtricitabine/tenofovir alafenamide. *The Journal for Nurse Practitioners*. doi: 10.1016/j.nurpra.2021.01.002.

COST AND ACCESSIBILITY OF PREP IN THE UNITED STATES

- Without insurance or cost support from drug manufacturer assistance programs, both FTC/TDF and FTC/TAF could be considered expensive.
- Estimates indicate both medications cost approximately $1,845/month.
- However, Gilead®, the manufacturer of FTC/TDF (sold under the brand name Truvada®) and FTC/TAF (sold under the brand name Descovy®), offers assistance programs to help patients offset the costs for both medications.
- FTC/TDF is also available as a generic through Teva®.
  - Currently costs about $1,455/month
  - High-cost secondary to emtricitabine component, which doesn't come off patent until 9/21
  - Teva® also offers co-pay assistance program:
    - https://www.tevahivgenerics.com/Truvada-generic/support

COST AND ACCESSIBILITY OF PREP IN THE UNITED STATES

- As of November 2020, Gilead's assistance co-pay program for the commercially insured covers up to $7,200 in co-pays per year with no monthly limit for both agents.
- Gilead® also offers several options to assist patients who are uninsured in obtaining these medications.
- Providers can find more information on the assistance programs offered by Gilead® on the company's Web site.
- Finally, providers should consult their local health departments to determine any accessibility assistance or other PrEP resources offered

SUMMARY AND CONCLUSION

- Pre-exposure prophylaxis (PrEP) is making inroads in the global prevention of HIV-1 infection.
- The once daily regimen of emtricitabine/tenofovir fumarate (FTC/TDF) 200mg/300mg or emtricitabine/tenofovir alafenamide (FTC/TAF) 200mg/25mg has shown to prevent HIV-1 infection by approximately 99% in both at-risk adults and adolescents.

SUMMARY AND CONCLUSION

- While the PrEP regimen using FTC/TDF has been established since 2012, the regimen employing FTC/TAF is newer, gaining FDA approval in 2019.
- Clinicians should be familiar with the indications and contraindications of FTC/TAF as PrEP, details regarding the appropriate and safe prescribing and initiation of the regimen, its efficacy and safety profile (including adverse events and interactions) and required ongoing monitoring.

SUMMARY AND CONCLUSION

- Providers must also be able to articulate the differences between FTC/TDF and FTC/TAF.
- While both regimens are costly without insurance, nurse practitioners, physicians, and physician assistants should have a working knowledge of the resources available to help patients better afford and access PrEP and PEP.
- These resources include those offered by the drugs' manufacturer in addition to local and state health departments.
- Coupled with the use of safer sex practices, PrEP can substantially and universally impact the HIV pandemic.

SUMMARY AND CONCLUSION

- Nurse practitioners can play an important role as patient and public health advocates in reaching the vulnerable populations disproportionately at risk for HIV-1 infection.
- Encourage both HIV seronegative and seropositive patients to be self-empowered in **their** prevention of HIV through positive lifestyle changes.
- Implement PEP and PrEP as an essential preventative tool in these individuals.

ACKNOWLEDGEMENTS

- HUGE thank you to the American Association of Nurse Practitioners!

ACKNOWLEDGEMENTS

- HUGE thank you to Andrew Todd, BSN, MLIS, RN (*Associate Librarian* and College of Nursing *Subject Librarian*, University of Central Florida) for his contributions to the literature review employed in this presentation.

REFERENCES

1. Blackwell, C. HIV pre-exposure prophylaxis: Use of emtricitabine/tenofivir alafenamide. *J Nurse Pract*. 2021. https://www.sciencedirect.com/science/article/pii/S1555415521000040. Accessed March 16, 2021.
2. Clinical Resource. Post-exposure prophylaxis (PEP) checklist. https://prescriber.therapeuticresearch.com/Content/Segments/PRL/2020/Jan/Post-Exposure-Prophylaxis-PEP-Checklist-S2001001. Updated January 2020.
3. Centers for Disease Control and Prevention. HIV surveillance reports. https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html. Updated February 3, 2021.
4. Idaho Clean Needle Project. How to Clean Your Needles. Idaho Clean Needle Network. December 9, 2008. Online video. 3:44. https://www.youtube.com/watch?v=TULBAntDMB8.
5. Teva. Support and financial assistance. https://www.tevahivgenerics.com/Truvada-generic/support. Updated March 2021.
6. Blackwell C. Pre-exposure prophylaxis: An emerging clinical approach to preventing HIV in high-risk adults. *Nurse Pract*. 2014; 39(9): 50-53.
7. Side-by-side comparison: Truvada and Descovy for PrEP. https://www.sfaf.org/resource-library/side-by-side-comparison-truvada-and-descovy-for-prep/. Updated 2020. Accessed November 5, 2020.
8. Markowitz M, Grossman H, Anderson PL, Grant R, Gandhi M, Horng H, Mohri H. Newly Acquired Infection With Multidrug-Resistant HIV-1 in a Patient Adherent to Preexposure Prophylaxis. *J Acquir Immune Defic Syndr*. 2017; 76(4): e104-e106.PMC5792163.
9. McCormack S, Dunn, D, Desai, M, et al. Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): Effectiveness results from the pilot phase of a pragmatic open-label randomsed trial. *Lancet*. 2016; 387(10013): 53-60.
10. Blackwell C. Preventing HIV infection in high risk adolescents using preexposure prophylaxis. *J Assoc Nurses AIDS Care*. 2018; 29(5): 770-774.
11. DISCOVER is the largest PrEP clinical trial, with over 5300 patients. https://www.descovyhcp.com/discover-clinical-trial. Updated September 2020. Accessed November 7, 2020.

REFERENCES

12. Mills, A, Workowski, Campbell, T, et al. Renal outcomes for participants taking F/TAF vs. F/TDF for HIV PrEP in the DISCOVER trial. *Open Form Infect Dis*. 2019; 6: pS64-S64.
13. Wohl, D, Ruane, P, Hosek, S, et al. Bone safety outcomes with F/TAF vs. F/TDF for PrEP in the DISCOVER trial. *Open Form Infect Dis*. 2019; 6: pS64-S64.
14. HIV and youth. https://www.cdc.gov/hiv/group/age/youth/index.html. Updated May 2020. Accessed November 11, 2020.
15. Simple dosing with Descovy for PrEP. https://www.descovyhcp.com/dosing-and-product-offerings?utm_medium=cpc&utm_campaign=USA_GO_SEM_B_EX_Descovy-HCP-Stay+On+a+Gilead+Medication+Lead-Standard&utm_content=Descovy_Prescribing&utm_term=Descovy+prescribing+information&utm_source=google&gclid=EAIaIQobChMIu-j9zer47AIVkueGCh1fIA1pEAAYASAAEgIg3PD_BwE&gclsrc=aw.ds. Updated September 2020. Accessed November 10, 2020.
16. Blackwell, C. Men who have sex with men and recruit bareback sex partners on the Internet: Implications for STI and HIV Prevention. *Am J Men's Health*. 2008; 2(4): 306-313.
17. Watanabe, T, Hamada-Tsutsumi, S, Yokomaku, Y, Imamura, I, Suguira, W, Tanaka, Y. Postexposure prophylactic effect of hepatitis B virus—active antiretroviral therapy against HBV infection. *Antimicrob. Agents Chemother*. 2015; 59(2): 1292-1298.
18. Mizushmia, D, Takano, M, Uemura, H, et al. Prophylactic effect of PrEP against HBV infection among MSM. Poster presented at: *Annual Conference on Retroviruses and Opportunistic Infections*; March 8-11, 2020; Boston, MA.
19. Highlights of prescribing information. https://www.gilead.com/~/media/Files/pdfs/medicines/hiv/descovy/descovy_pi.pdf. Published 2015. Accessed on November 11, 2020.
20. P-glycoprotein inhibitors. https://go.drugbank.com/categories/DBCAT002667. Accessed on November 11, 2020.

REFERENCES

21. P-glycoprotein inducers. https://go.drugbank.com/categories/DBCAT002666. Accessed on November 11, 2020.
22. Mulligan, K, Glidden, D, Andersen, P, et al. Effects of emtricitabine/tenofovir on bone mineral density in HIV-negative persons in a randomized, double-blind, placebo-controlled trial. *Clin Infect Dis*. 2015; 61(4): 572-580.
23. Solomon, M, Lama, J, Glidden, J, et al. Changes in real function associated with oral emtricitabine/tenofovir disoproxil fumarate use for HIV pre-exposure prophylaxis. *AIDS*. 2014; 28(6): 851-859.
24. Glidden, J, Mulligan, K, McMahan, M, et al. Metabolic effects of preexposure prophylaxis with coformulated tenofovir disoproxil fumarate and emtricitabine. *Clin Infect Dis*. 2018; 67(3): 411-419.
25. Gilead 701. https://www.drugs.com/imprints/gilead-701-9326.html. Updated November 2020. Accessed on November 11, 2020.
26. GSI 225. https://www.drugs.com/imprints/gsi-225-24350.html. Updated November 2020. Accessed on November 11, 2020.
27. Co-pay support for the commercially insured. https://www.gileadadvancingaccess.com/hcp/financial-assistance/copay-support. Published 2020. Accessed on November 11, 2020.
28. Financial support for the uninsured—Multiple options available for enrollment. https://www.gileadadvancingaccess.com/hcp/financial-assistance/uninsured-support. Published 2020. Accessed on November 11, 2020.
29. Understanding coverage options for patients. https://www.gileadadvancingaccess.com/hcp/insurance. Published 2020. Accessed on November 11, 2020.
30. Weiss, G, Smith, D, Newman, S, Wiener, J, Kitlas, A, Hoover, K. PrEP implementation by local health departments in US cities and counties: Findings from a 2015 assessment of local health departments. *PLOS One*. 2018; 13(7): e0240745.