Indian Country PrEP ECHO

HIV Pre-Exposure Prophylaxis

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Conflict of Interest Disclosure Statement

- Speaker has nothing to disclose.

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Learning Objectives

1. Differentiate HIV PEP from HIV PrEP and identify the indications for each.

2. Identify appropriate candidates for HIV PEP and PrEP.

3. Recognize the potential adverse drug events from HIV PEP and PrEP.

Reducing Acquisition of HIV

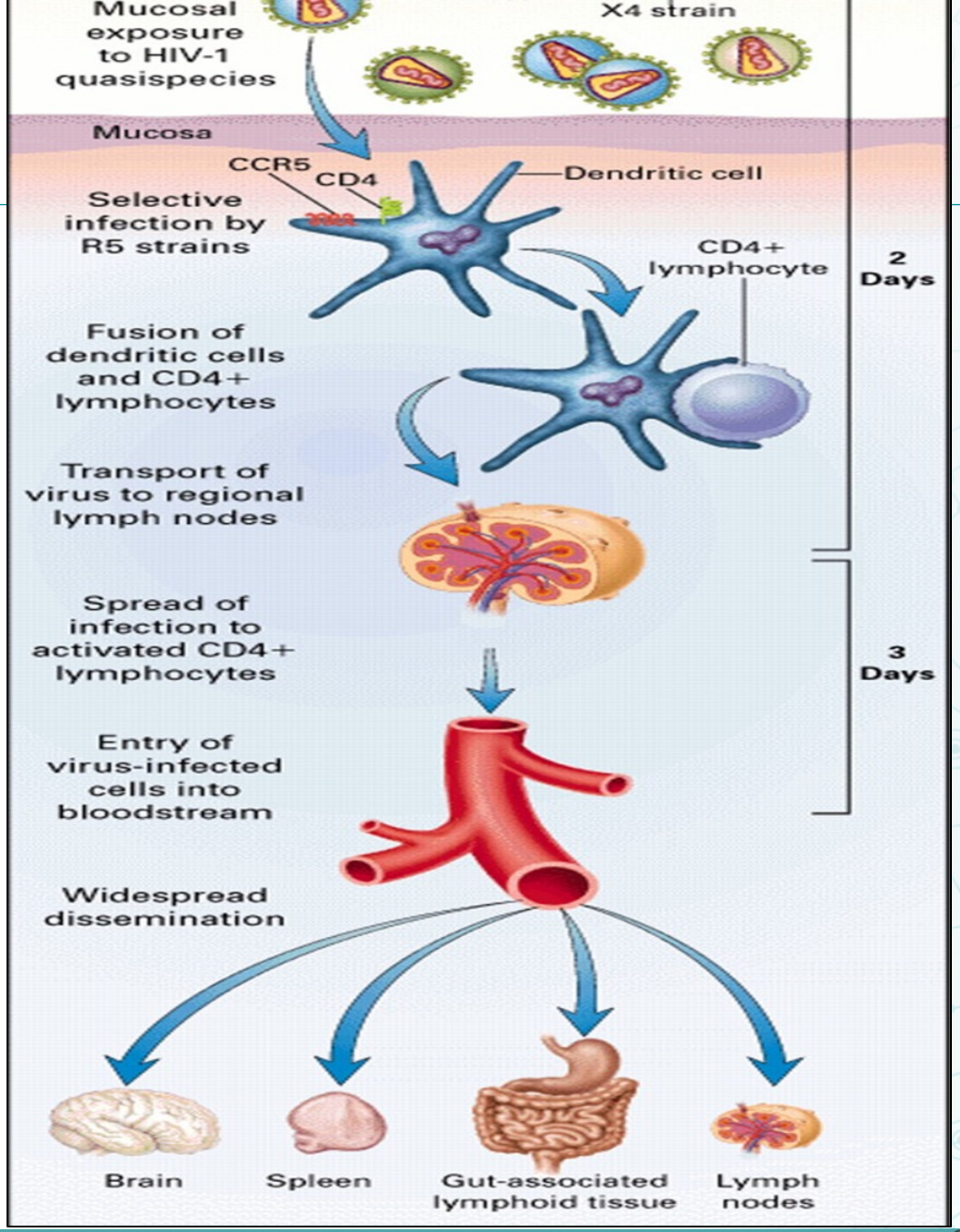
- Increased testing & linkage to care
- Delayed or fewer partners
- Less risky activities
- Condom use
- Empowerment & negotiation skills
- Reducing alcohol/drug use
- Reduce psychosocial barriers
- Circumcision
- Sexually transmitted infection treatment
- HIV Post-exposure prophylaxis (PEP)
- HIV Pre-exposure prophylaxis (PrEP)

Treatment As Prevention

Cohen, et al. NEJM 2011; 365: 493-505. Skarbinski J, et al. JAMA Intern Med 2015;175:588-96. Bavinton BR, et al. Lancet HIV. 2018. IAS 2018 Conference http://programme.aids2018.org/Abstract/Abstract/13470

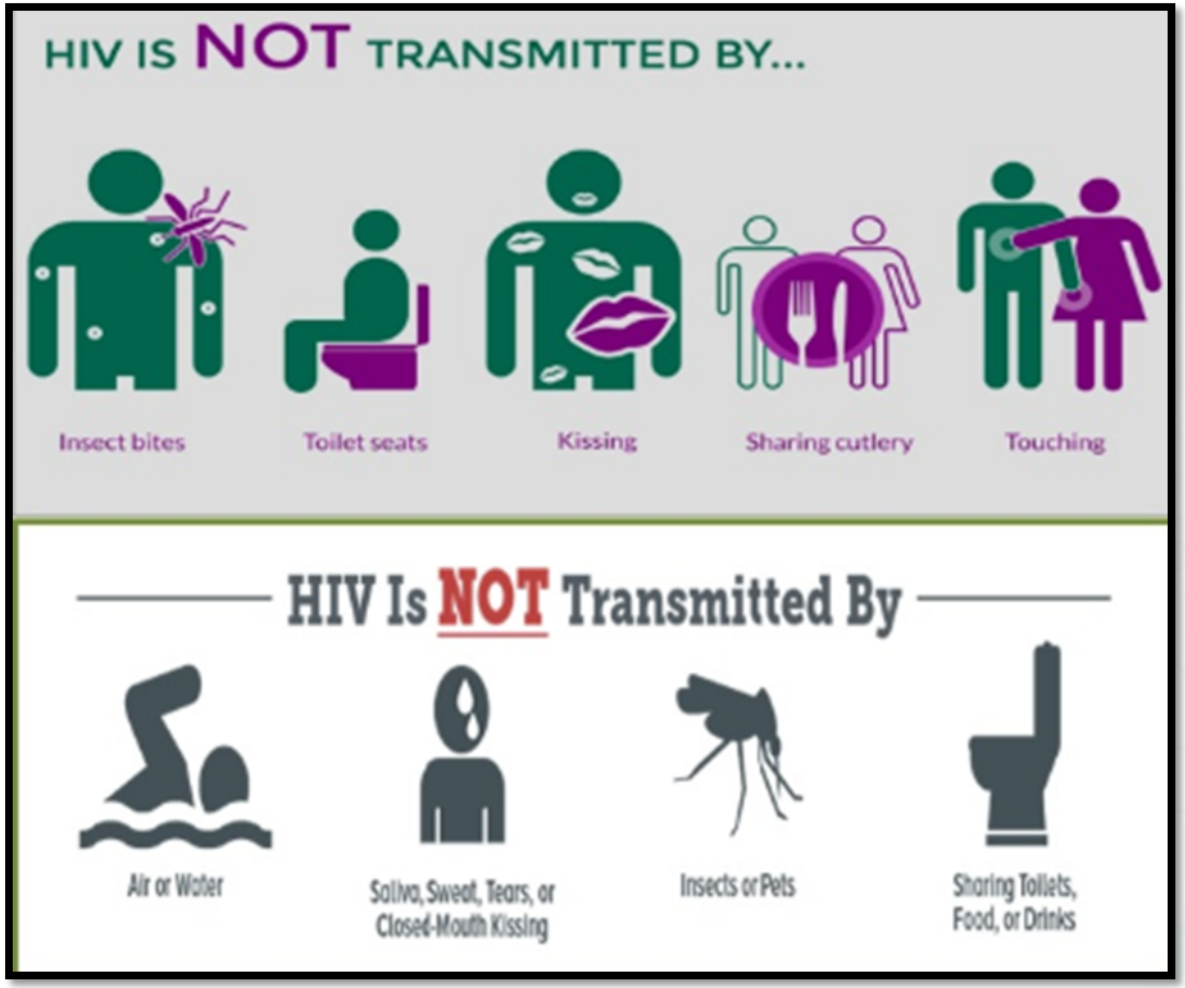
HIV Infection

- PEP must be given <72 hours after exposure
- PrEP requires therapeutic levels of drug at site of infection



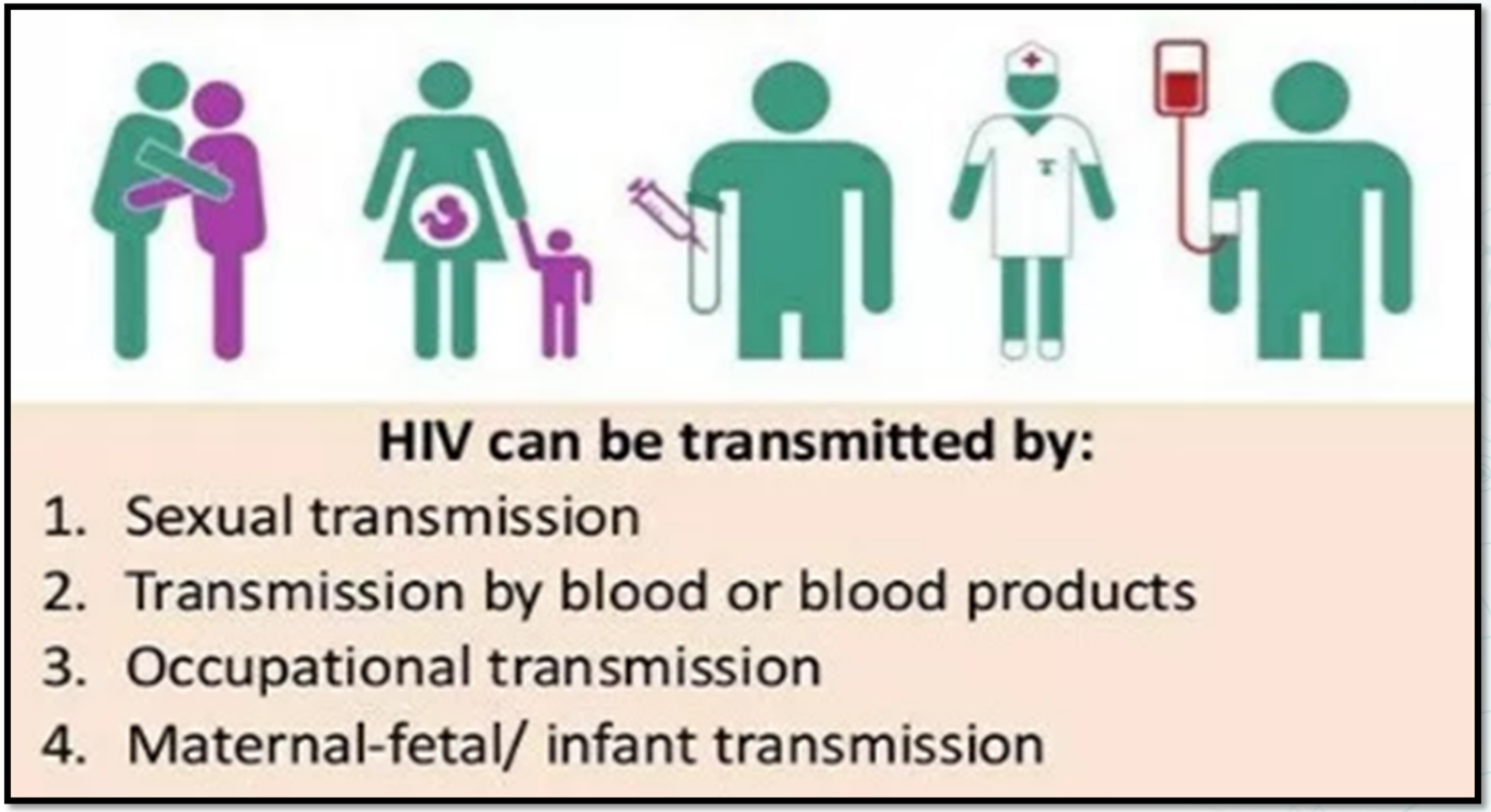
Spira AI, Marx PA, Patterson BK, et al. J Exp Med 1996;183:215–25.

HIV Transmission Risk



https://www.cdc.gov/hiv/risk/estimates/riskbehaviors.html.

HIV Transmission Risk



https://www.cdc.gov/hiv/risk/estimates/riskbehaviors.html.

HIV Transmission Risk

Higher risk

- Receptive anal sex
  - Per episode: 0.3 - 3%
- Needle sharing
  - Per episode: 0.67%

Lower risk

- Oral sex
  - Per episode: 0.06%
- Insertive sex
  - Per episode 0.03 – 0.14%

1. Bell DM. Am J Med 1997;102(suppl5B):9--15. 2. Ippolito G et al. Arch Int Med 1993;153:1451--8. 3. Am J Epi 1999; 150:306-11.4. Am J Epi 1999;150:306-11.5. MMWR 47;RR-17, 1998.6. NEJM 336(15):1072-8. 7. Am J Epi 1999;150:306-11.8. Rothenberg RB et al. AIDS 1998;12:2095-2105.9. MMWR 47;RR-17, 1998.10. ACTG 076.

PEP vs PrEP

- HIV PEP = post-exposure prophylaxis
- Given **after** high-risk exposure to reduce risk of HIV infection
- Start within 72 hours of exposure
- 28-day course of daily 3-drug regimen

- HIV PrEP = pre-exposure prophylaxis
- Daily regimen given **before** exposure to reduce risk of HIV infection
- Start at least 7 days prior to exposure
- Daily 2-drug regimen

https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf
https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf

Case Presentation

- A healthy 17yo man with a history of 4 prior male sexual partners for condomless anal receptive and versatile oral sex reports that his last sexual encounter was 5 weeks earlier.
- He was screened last year for HIV at Gay Pride Event and was nonreactive at that time.

Audience Response Question

Is this patient at risk of getting HIV from this exposure?

1. Yes
2. No
3. Not sure

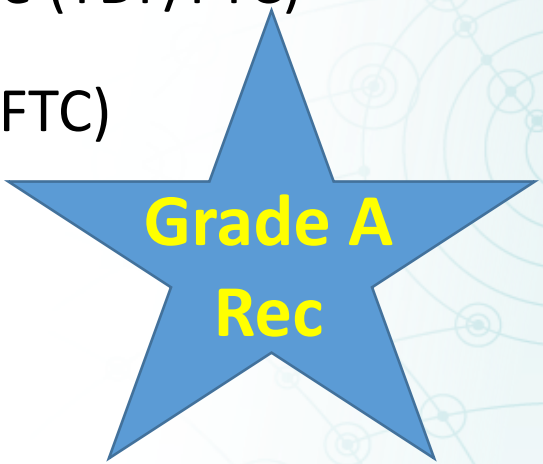
Audience Response Question

What prevention strategies would you discuss with this patient?

HIV PrEP

(Pre-Exposure Prophylaxis)

- Currently, two FDA-approved formulations:
  - Tenofovir disoproxil fumarate/emtricitabine (TDF/FTC)
  - Tenofovir alafenamide/emtricitabine (TAF/FTC)
  - 1 tablet by mouth once a day
  - Prescribe for ≤ 90-day supply
  - Approved for adolescents & adults ≥ 35kg (77 lb)



https://www.cdc.gov/hiv/guidelines/preventing.html

*USPSTF Grade A Recommendation, 6/2019

HIV PrEP is Effective

- >15 trials published to date
- Safe, well tolerated (nausea)
- iPrEx Study
  - 44% reduction in HIV
  - **92% reduction** in those with **good adherence**
- PrEP as bridge to ART: **95% reduction**
- In U.S., cost effective if used among high-risk MSM (annual incidence >2%)

MSM= men with male sex partners

Paltiel AD, et al. CID. 2009;48(6):806-815. Juusola JL, et al. Ann Intern Med. 2012;156(8):541-550. Schneider, et al. CID 2014;58:1027-34.

Indications for HIV PrEP

Indications for PrEP	
Men Who Have Sex With Men (MSM)	1. HIV positive partner* 2. Recent STI (particularly syphilis) 3. High number of sex partners 4. Inconsistent/no condom use 5. Commercial Sex Work
Heterosexual Men & Women	1-5. Same as above 6. High prevalence area
People Who Inject Drugs (PWID)	1. HIV positive injection partner 2. Shares injection equipment 3. Recent drug treatment + still injecting

*Particularly if HIV-partner does not have an undetectable HIV viral load on HAART

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf

Contraindications to HIV PrEP

Contraindications to Tenofovir/Emtricitabine for PrEP	
Active HIV Infection	Need ART: active medications from different classes
Renal Dysfunction	TDF metabolized by kidney, can cause renal toxicity • Do not start if CrCl <60 • Stop if CrCl <50 TAF not indicated if CrCl <30
Allergy to TDF or FTC	Currently no alternative

Caution with active HBV Infection as discontinuation of tenofovir/emtricitabine can lead to hepatitis flair

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf

CrCl=creatinine clearance; marker of renal function

Labs Before Prescribing HIV PrEP

- HIV Screen
  - rapid vs routine blood draw
- Hepatitis B virus serologies:
  - HBV Surface Antigen, HBV Surface Antibody, HBV Total Core Antibody
- Hepatitis C Antibody
- Creatinine
- Urinalysis
- Sexually transmitted infection (STI) screening
- Pregnancy screening

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf

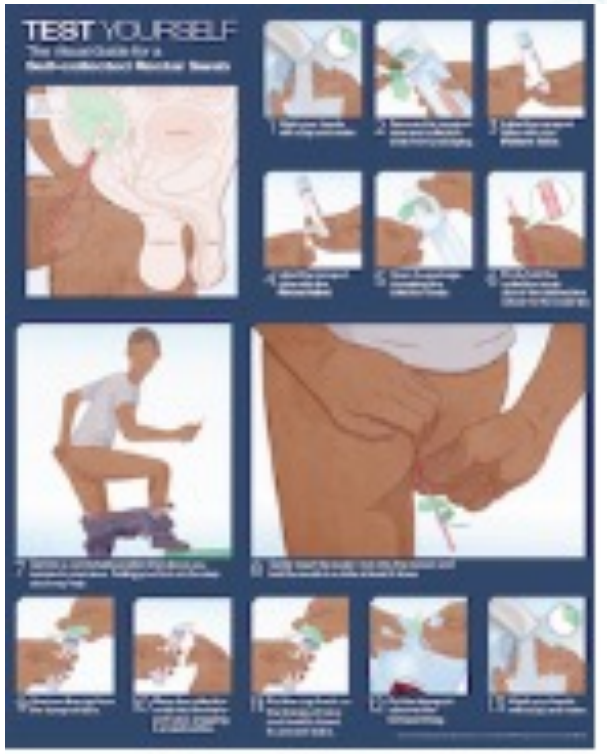
Monitoring on HIV PrEP

- Assess adherence
- Assess for side effects
  - rare nausea
- Discuss risk reduction
  - Referrals if needed
- HIV testing q3 mo
- Creatinine at 3 mo then q6 mo after
- Urinalysis (consider q1 yr)
- STI testing q3-6mo
- At least annual HCV
- Assess Pregnancy Intention
  - Pregnancy testing q3mo, if indicated

Sexually Transmitted Infection Screening

- Gonorrhea/Chlamydia Nucleic acid amplification test (GC/Chl NAAT)
  - Test all relevant sites
  - Urine, urethral, vaginal
  - Oral
  - Rectal
- Syphilis is on the rise
  - *Treponema pallidum* Antibody
  - RPR

- Self collection



https://www.cdc.gov/std/tg2015/default.htm
http://uwptc.org/

Case Presentation

- A 28yo woman with Type I DM and intermittent injection drug use with methamphetamine and a prior episode of pelvic inflammatory disease returns for a PrEP follow-up visit.
- She reports good adherence and tolerability.
- Routine labs show a creatinine 1.7 (0.6 baseline), HIV screen, STI screen, and pregnancy screen all negative.

Audience Response Question

What is the next step for this patient?

1. Refill TDF/FTC and make follow up visit for 3 months
2. Refill TDF/FTC and order further work-up
3. Switch daily TDF/FTC to TAF/FTC on-demand PrEP
4. Stop TDF/FTC and make follow up for 3 months to re-assess
5. Stop TDF/FTC and order further work-up
6. Other

When to Stop HIV PrEP

- Renal dysfunction
  - Creatinine increase >0.5 not due to other causes
  - CrCl <50
  - New proteinuria not due to other causes
- HIV seroconversion
- Allergic reaction
- Severe intolerance
- Non-adherence to medications or visits
- No longer at risk

Note: Protection will wane 7-10d after ceasing daily PrEP

Insurance Coverage for PrEP

- The Patient Protection and Affordable Care Act (ACA) now requires qualified health plans to cover PrEP as a preventive service at no cost to patients

- Steps to verify PrEP coverage: **https://www.nastad.org/sites/default/files/Uploads/2021/prep_specialenrollmentperiod-final.pdf**

Conclusion & Clinical Pearls

- HIV prevention methods can be used in combination to reduce HIV transmission risk.
- Knowledge about when the last potential high risk exposure happened, and the interpretation of the HIV screening test are important to determine if a patient is a candidate for HIV PEP or HIV PrEP.
- HIV PrEP is effective at reducing HIV transmission but not enough patients at high risk have access.
- Patients on HIV PrEP require screening every 3 months for adherence, toxicities, STIs, and HIV.

Educational Resources

- Questions about HIV PEP or HIV PrEP
  - Case presentations during PrEP TeleECHO Sessions
  - Clinical Consultation Center HIV PrEP line (855-448-7737)
  - Clinical Consultation Center HIV PEP line (888-448-4911)
  - AETC National HIV Curriculum https://aidsetc.org/nhc
  - Medscape Online trainings
    - Kelley: Advancing PrEP in Practice https://www.medscape.org/viewarticle/880821
    - Saag: Preventing HIV Infection in the Primary Care Setting

References

- www.cdc.gov/hiv
- https://aidsvu.org/preptoolkit2018/
- https://primeinc.org/hiv?s=aetc
- US Public Health Service. *PreExposure Prophylaxis for the Prevention of HIV Infection in the United States-2017 Update: A Clinical Practice Guideline*. https://www.cdc.gov/hiv/pdf/guidelines/cdc-hiv-prep-guidelines-2017.pdf
- Marrazzo et al., *HIV Prevention in Clinical Care Settings 2014 Recommendations of the International Antiviral Society–USA Panel* JAMA. *July* 2014;312(4):390.
- Katz, D et al. *HIV Incidence among MSM after dx with STI*. Sexually Transmitted Diseases. 2016;43(4):249-254.

Resources

- National Clinician Consultation Center
  http://nccc.ucsf.edu/
  - HIV Management
  - Perinatal HIV
  - HIV PrEP
  - HIV PEP line
  - HCV Management
  - Substance Use Management
- Present case on ECHO
  http://echo.unm.edu
  hivecho@salud.unm.edu

- AETC National HIV Curriculum
  https://aidsetc.org/nhc
- AETC National Coordinating Resource Center
  https://targethiv.org/library/aetc-national-coordinating-resource-center-0
- Additional trainings
  scaetcecho@salud.unm.edu
- www.scaetc.org

Prescribing HIV PrEP

- ICD-10 Codes:
  - Z20.6 Contact with and (suspected) Exposure to HIV
  - Z20.2 Contact with and (suspected) Exposure to infections with a predominantly sexual mode of transmission
- If insured, may require prior authorization
- TDF/FTC now generic through Teva Pharmaceuticals
  - Co-pay assistance card no longer available as of 4/1/21
- If no insurance or large copay:
  - Medication Assistance Program: 1-855-330-5479; http://www.gilead.com/responsibility/us-patient-access/truvada%20for%20prep%20medication%20assistance%20program
  - Patient Advocate Foundation: https://www.copays.org/diseases/hiv-aids-and-prevention