PrEP and PEP

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PrEP: *Pre-exposure prophylaxis*

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- Prescription medication taken by those at risk of getting HIV from sex or injection drug use to prevent the spread of the disease

- PrEP reduces the risk of getting HIV from sex by about 99% and from injection drug use by at least 74%

- Medications approved for use as PrEP:
  - **Truvada** (emtricitabine 200mg/tenofovir disoproxil fumarate 300mg)
  - **Descovy** (emtricitabine 200mg/tenofovir alafenamide 25mg)

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PrEP: *Truvada*

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- Truvada is typically the drug of choice for PrEP in most patients
- Has been studied more than any other PrEP medication

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PrEP: *Descovy*

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- Not studied as much as Truvada
- Should not be used for those who main risk for HIV is receptive vaginal sex
- Has shown to have less bone and renal toxicity compared to Truvada

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PrEP: *Treatmenet*

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- Initial treatment choice is typically ***Truvada:***
    - Emtricitabine 200mg/tenofovir disoproxil fumarate 300mg daily

- ***Descovy*** is typically used for patients with renal insufficiency or issues with bone health
    - emtricitabine 200mg/tenofovir alafenamide 25mg PO daily

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PrEP: *Monitoring*

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- Patients should be seen 1 month after starting therapy and then every 3 months
- Every 3 months:
    - HIV testing
    - screen for symptoms of acute HIV infection
    - perform routine STI screening
    - pregnancy testing (if applicable)
    - creatinine in all patients with risk factors for renal disease
- Every 6 months:
    - serum creatinine in all patients
    - urinalysis in patients with risk factors for kidney disease
    - Hep C screening every 6-12 months in high-risk populations or sooner if LFTs are elevated

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PrEP: *Counseling*

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- Importance of adherence to daily medication regimen should be discussed.
- Daily reminders or alarms can be helpful to minimize barriers.
- Risk reduction counseling should be discussed:
    - consistent condom use and/or reducing drug use

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PrEP: *Renal Abnormalities*

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- Consider discontinuing Truvada if eGFR <60
- If eGFR is >30 it is reasonable to switch from Truvada to Descovy
- If eGFR >60 but there has been a significant decrease since initiation of Truvada, Descovy is a reasonable alternative.

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PrEP: *Side Effects*

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- Side effects are not common when taking PrEP, but some patients do experience the following:

    - Upset stomach
    - Headache
    - Vomiting
    - Loss of appetite

*These should improve after the first month of taking PrEP

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PEP: *Post-exposure prophylaxis*

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- Antiviral medications taken to stop HIV seroconversion after a possible exposure
- Must be started within 72 hours of possible exposure (the sooner the better!)
- Taken daily for 28 days
- PEP given to HIV-negative people reduces likelihood of HIV seroconversion by approximately 80%

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PEP: *Post-exposure prophylaxis*

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- ***Preferred treatment regimen:***
  - Tenofovir disoproxil fumarate 300mg/emtricitabine 200mg once daily x 28 days
    PLUS
    - Dolutegravir 50 mg daily x 28 days
      OR
    - Raltegravir 400 mg PO BID x 28 days
- ***Patients with renal dysfunction:***
  - Zidovudine + lamivudine x 28 days
    PLUS
    - Dolutegravir 50 mg PO daily x 28 days
      OR
    - Raltegravir 400 mg PO BID x 28 days

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PEP: *Side Effects*

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- The most common side effects are nausea/upset stomach and fatigue

- Consider concurrent prescribing of Zofran for patients who experience negative side effects

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HIV: *Moderna HIV vaccine trials*

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The Phase I trial, IAVI G002, is designed to test the hypothesis that sequential administration of priming and boosting HIV immunogens delivered by messenger RNA (mRNA) can induce specific classes of B-cell responses and guide their early maturation toward broadly neutralizing antibody (bnAb) development. The induction of bnAbs is widely considered to be a goal of HIV vaccination, and this is the first step in that process.

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HIV: *Moderna HIV vaccine trials*

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In 2021, Dr. Schief announced results from the IAVI G001 clinical trial, showing that an adjuvanted protein-based version of the priming immunogen (eOD-GT8 60mer) induced the desired B-cell response in 97% of recipients. IAVI G002 not only tests priming of the desired immune response using mRNA delivery of eOD-GT8 60mer, but also assesses the ability of a boosting immunogen to induce further maturation of B cells.

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HIV: *Moderna HIV vaccine trials*

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The Schief lab has been a pioneer of the vaccine design approach known as germline targeting. Naive B cells display antibodies encoded by unmutated, or "germline" genes. A series of vaccines, which would begin with the prime-boost immunogens tested here, may be able to target specific naive B cells and induce them to mature into bnAb-producing ones. In the lab, bnAbs have been shown to neutralize a broad range of HIV variants, and one bnAb, VRC01, was recently shown to be capable of protecting humans against infection by neutralization-susceptible HIV strains. VRC01 is a member of the class of bnAbs targeted in IAVI G001.

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[For IAVI G002] the sites (GWU School of Medicine and Health Sciences, Hope Clinic of Emory Vaccine Center, Fred Hutchinson Cancer Research Center, and University of Texas–Health Science Center at San Antonio) will enroll 56 healthy, HIV-negative adult volunteers. Forty-eight participants will receive one or two doses of eOD-GT8 60mer mRNA Vaccine (mRNA-1644), with 32 of them receiving the boost Core-g28v2 60mer mRNA Vaccine (mRNA-1644v2-Core). An additional eight volunteers will receive the boost immunogen alone. Participants will be monitored for safety for six months after last vaccination. Participants' immune responses to the vaccine candidates will be examined in molecular detail to evaluate whether the targeted responses were achieved.

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