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HIV screening, PrEP & PEP

Objectives

1

Explain

HIV screening recommendations

2

Identify

Patients indicated for HIV PrEP and PEP

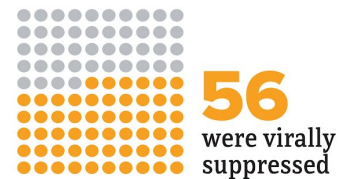
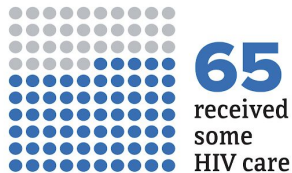
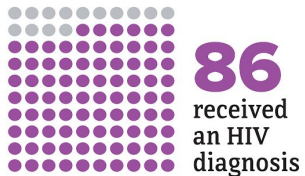
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Summarize

Appropriate medication options for HIV PrEP and PEP

HIV in the United States

Not all people with HIV are getting the care they need. An estimated **1.2 million people had HIV in the US in 2018**. For **every 100 people with HIV**:*



* Includes people with diagnosed or undiagnosed HIV.

www.cdc.gov/hiv | 1-800-CDC-INFO

Get Tested. Get in Care. Stay in Care. Stay Healthy.

Sources: CDC. Monitoring selected HIV prevention and care objectives using HIV surveillance data—United States and 6 dependent areas, 2018. *HIV Surveillance Supplemental Report 2020;25(2)*.
CDC. Selected national HIV prevention and care outcomes (slides).
Based on the most recent data available in December 2020.



Health Disparities - 2018 National Data

| | Blacks | Hispanics | Asians |
|---------------|--------|-----------|--------|
| New diagnoses | 42% | 27% | 2% |

2019 MN Data

- Cases remained stable with **275 cases** reported in 2019, compared to 286 in 2018
 - **72%** of all new HIV cases during 2019 were male
 - Male-to-male sex remains the main risk factor for males of all ages
 - **Over half (61%)** of new HIV cases are among communities of color



HIV Screening

Question 1: Which age group in the general population should receive HIV screening?

- A) 18+**
- B) 25+**
- C) 18-50 years old**
- D) 15-65 years old**

Screening Recommendations

| Population | Adolescents and adults aged 15 to 65 years | Pregnant Persons |
|----------------|--|---------------------------------------|
| Recommendation | Screen for HIV infection. Grade: A | Screen for HIV infection. Grade: A |

- **CDC has specific guidance for gay, bisexual and other men who have sex with men (MSM)**
 - **Asymptomatic sexually active MSM should be tested annually**
 - **Consider the benefits of more frequent screening (every 3-6 months) for individual MSM at increased risk**

UDS Clinical Quality Measure

- **Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV**
 - **Based on patients meeting this age criterion with at least one outpatient medical visit during the measurement period**
 - **Patients with HIV diagnosis prior to start of measurement period are excluded**

UDS Clinical Quality Measure

- **Percentage of patients newly diagnosed with HIV who were seen for follow-up treatment within 30 days of diagnosis**
 - **Patients need to have had at least one medical visit during the measurement period or prior year**

CUHCC Data

- New measure: **34.7%** of patients ages 15-65 years of age received HIV screening in 2020 (1843/5313)
- For timely follow-up within 90 days,
 - 2017: 50% (1/2)
 - 2018: 50% (1/2)
 - 2019: n/a (0/0)
 - 2020 measure changed to follow-up in 30 days: 100% (1/1)



HIV

**Pre-Exposure
Prophylaxis**



Starting PrEP

HIV PrEP- Who?

BOX B1: RECOMMENDED INDICATIONS FOR PREP USE BY MSM²

- Adult man
- Without acute or established HIV infection
- Any male sex partners in past 6 months (if also has sex with women, see Box B2)
- Not in a monogamous partnership with a recently tested, HIV-negative man

AND at least one of the following

- Any anal sex without condoms (receptive or insertive) in past 6 months
- A bacterial STI (syphilis, gonorrhea, or chlamydia) diagnosed or reported in past 6 months

HIV PrEP- Who?

BOX B2: RECOMMENDED INDICATIONS FOR PrEP USE BY HETEROSEXUALLY ACTIVE MEN AND WOMEN

- Adult person
- Without acute or established HIV infection
- Any sex with opposite sex partners in past 6 months
- Not in a monogamous partnership with a recently tested HIV-negative partner

AND at least one of the following

- Is a man who has sex with both women and men (behaviorally bisexual) [also evaluate indications for PrEP use by Box B1 criteria]
- Infrequently uses condoms during sex with 1 or more partners of unknown HIV status who are known to be at substantial risk of HIV infection (PWID or bisexual male partner)
- Is in an ongoing sexual relationship with an HIV-positive partner
- A bacterial STI (syphilis, gonorrhea in women or men) diagnosed or reported in past 6 months

HIV PrEP- Who?

BOX B3: RECOMMENDED INDICATIONS FOR PREP USE BY PERSONS WHO INJECT DRUGS

- Adult person
- Without acute or established HIV infection
- Any injection of drugs not prescribed by a clinician in past 6 months

AND at least one of the following

- Any sharing of injection or drug preparation equipment in past 6 months
- Risk of sexual acquisition (also evaluate by criteria in Box B1 or B2)

Identifying Indications for PrEP

Risk assessment-MSM

- Have you had sex with men, women or both? If men/both, how many men?
- How many times without a condom?
- How many HIV-positive partners?
- Methamphetamine use?

Risk assessment-heterosexual men and women

- Have you had sex with men, women or both? If opposite or both sexes, how many?
- How many times without a condom?
- How many partners were HIV positive?

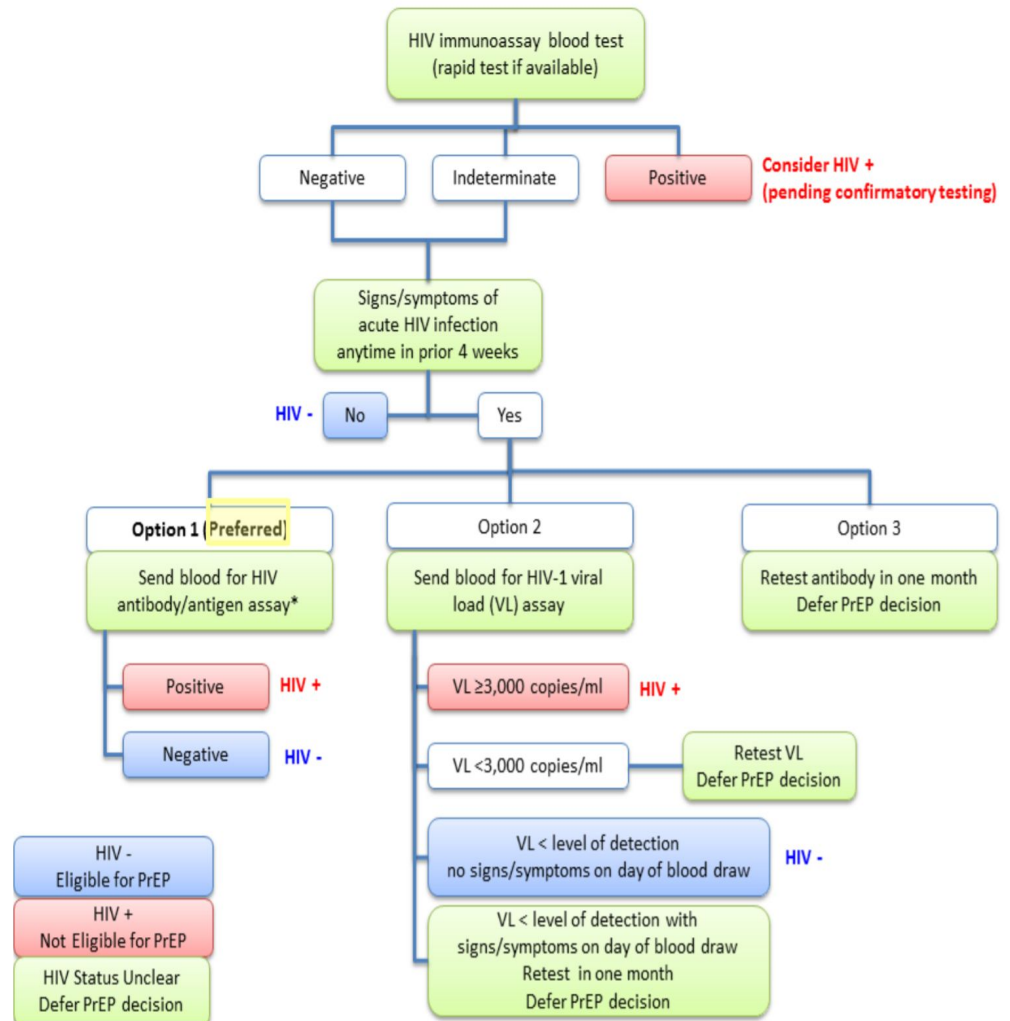
Identifying Indications for PrEP

Risk assessment-Persons who inject drugs (PWID)

- Have you ever injected drugs that were not prescribed to you by a clinician?
- If yes, when did you last inject unprescribed drugs?
- In the past 6 months, have you used equipment that had already been used by someone else?
- In the past 6 months, have you been in a methadone or other medication-based drug treatment program?

Prior to Starting Treatment

- Laboratory testing
 - Documented negative antibody test result within the one week before starting medication
 - Renal function
 - Hepatitis B coinfection



Additional Considerations

Hepatitis C

- Hepatitis C (HCV) testing at baseline is recommended for:
 - Persons who have ever injected drugs
 - MSM
 - All sexually active persons
- If HCV positive, patients should be evaluated for treatment as Truvada does not treat HCV

STIs

- Syphilis and gonorrhea screening at baseline and semi-annual visits
- Chlamydia is very common, therefore does not strongly correlate with risk of HIV acquisition

Question 2: Which of the following is NOT part of baseline testing a sexually active patient should receive before starting PrEP?

- A) Syphilis and gonorrhea**
- B) Liver function**
- C) Renal function**
- D) HIV testing**



Medication Options

PrEP Options



Truvada

(emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg)

ALL people at risk through sex or injection drug use



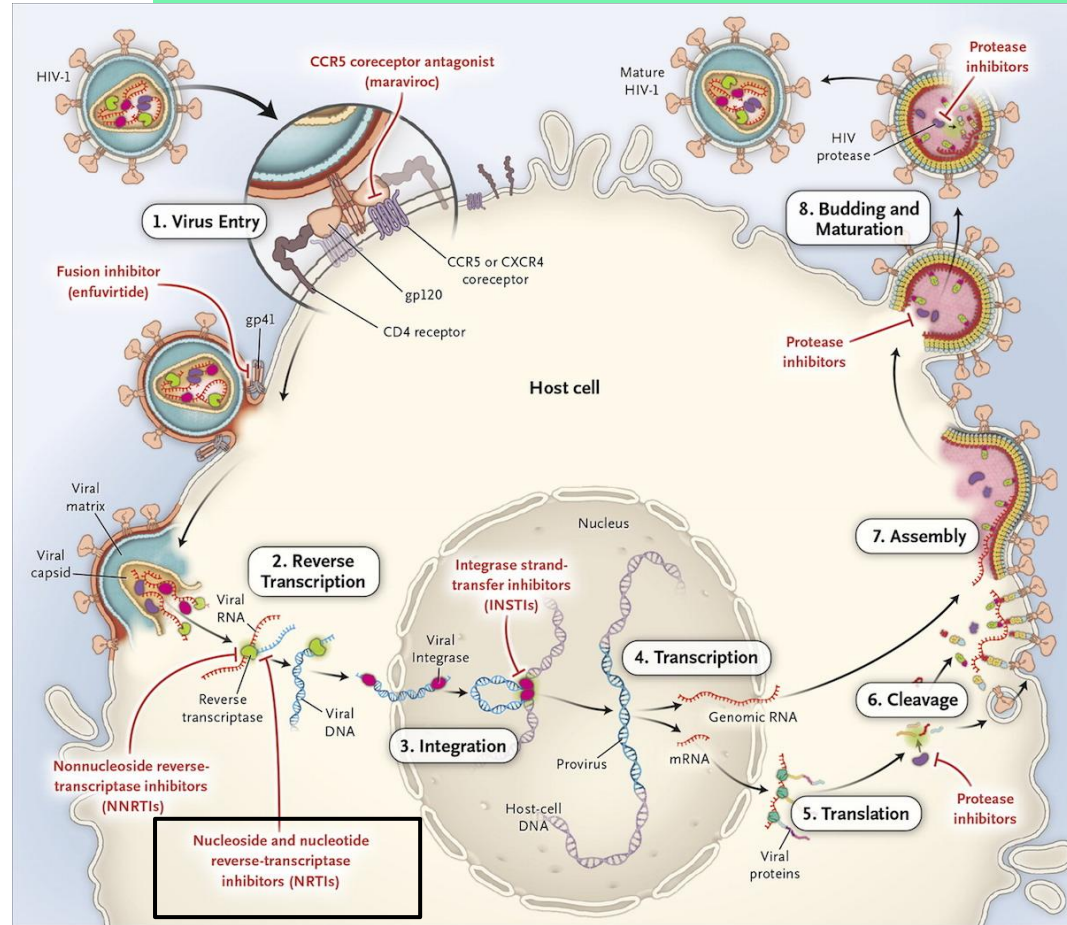
Descovy

(emtricitabine 200 mg/tenofovir alafenamide 25 mg)

People at risk through sex, EXCEPT for people who are at risk of getting HIV from receptive vaginal sex

Mechanism of Action

- Emtricitabine is a nucleoside reverse transcriptase inhibitor (NRTI)
- Tenofovir disoproxil fumarate and tenofovir alafenamide are nucleoside reverse transcriptase inhibitor (NRTI)



Truvada

- Take 1 tablet by mouth once daily, with or without food
- Should be dispensed in the original container and kept tightly closed
- Do not use for PrEP with CrCl <60 mL/min
- Side effects: dizziness, depression, insomnia, abnormal dreams and decreased weight
- Precautions: concomitant use with other nephrotoxic agents, decreases in bone mineral density and lactic acidosis and severe hepatomegaly with steatosis have been reported

Descovy

- Take 1 tablet by mouth once daily, with or without food
- Store in original container with lid closed tightly
- Use not recommended with CrCl <30 mL/min or ESRD not on hemodialysis
- Side effects: nausea, diarrhea, headache, fatigue, abdominal pain
- Precautions: redistribution of body fat, lactic acidosis and severe hepatomegaly with steatosis, bone loss and mineralization defects, autoimmune disorders

Drug Interactions

- Truvada
 - Drugs that are eliminated by active tubular secretion or decrease renal function
 - Certain NRTIs, HIV protease inhibitors, Hepatitis C antiviral agents
- Descovy
 - Drugs that are eliminated by active tubular secretion or decrease renal function
 - Drugs that affect P-gp and BCRP activity can change absorption
 - Certain PIs, anticonvulsants, antimycobacterials, and herbal products

Additional Safety Considerations

- Truvada generally considered safe in pregnancy/lactation
 - Risk/benefit discussion
- Contraindications
 - Patients who are HIV+
 - Patients with renal insufficiency

Monitoring

| | |
|--|---|
| HIV testing | At first 3 month visit and every 3 months thereafter |
| Measure creatinine and estimate CrCl | At first 3 month visit and every 6 months thereafter |
| Medication adherence and behavioral risk reduction support | At first 3 month visit and every 3 months thereafter |
| Screen for bacterial STIs | MSM: at first 3 month visit and every 3 months thereafter All sexually active patients: every 6 months after first 3 month follow-up |
| Specific populations | Pregnancy test at first 3 month visit and every 3 months thereafter PWID: access to sterile equipment and substance use disorder treatment services at first 3 month visit and every 3 months thereafter |

Effectiveness Estimates

MSM

~99% effective with
daily oral use

Heterosexual men & women

~99% effective with
daily oral use

PWID

74-84% effective
with daily oral use

Access

- Many insurance plans cover PrEP
- Co-pay cards from Gilead
- Patient Assistance Programs
- MnDOH

Pre-Exposure Prophylaxis (PrEP)

On this page:

[Overview](#)

[Who can take PrEP](#)

[PrEP Navigation](#)

[Paying for PrEP](#)

[Finding a PrEP Provider](#)

Overview

PrEP is a daily pill that you can take to prevent HIV infection.

When taken as prescribed, PrEP can reduce someone's risk of HIV infection when exposed by up to 99%.

PrEP does not protect against pregnancy or other sexually transmitted diseases (STDs), so it is best to use PrEP with other risk reduction methods such as condoms and not sharing injection equipment.

- [PrEP Fact Sheet \(PDF\)](#)

Who Can Take PrEP

Question 3: Which option for HIV PrEP would be appropriate for a female patient at high risk?

- A) Descovy**
- B) Truvada**

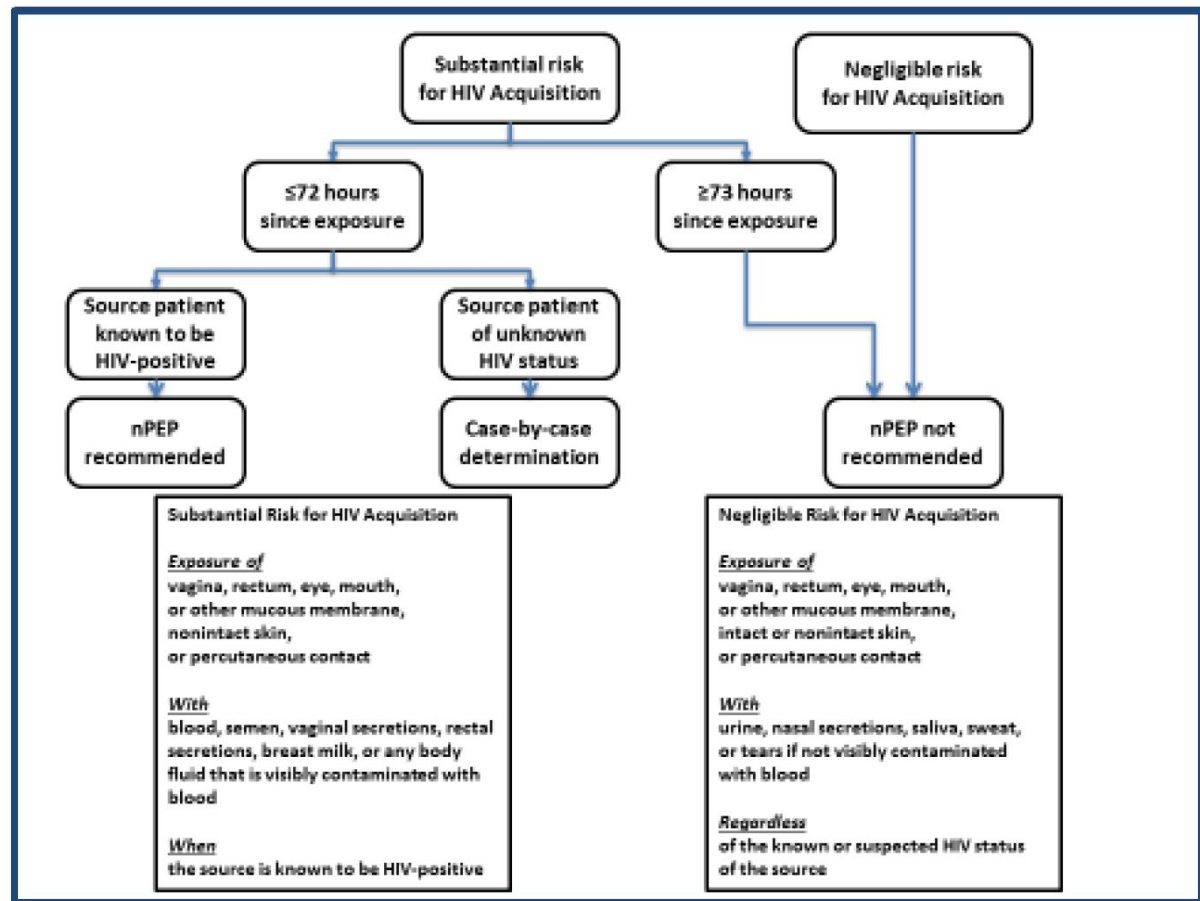


HIV

**Post-Exposure
Prophylaxis**

HIV PEP- Who?

Figure 1. Algorithm for evaluation and treatment of possible nonoccupational HIV exposures



HIV PEP- Who?

- Potentially exposed persons without HIV infection within 72 hours of exposure
- Provided only for infrequent exposure
 - if patient engages in behaviors that put them at risk for recurrent exposures, offer PrEP
- Consider risk of acquisition based on type of exposure
- If exposure source's HIV status is unknown, availability for HIV testing should be determined and clinical evaluation visit that includes HIV testing should be arranged

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 |



Laboratory Evaluation

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 | |

Recommended Regimens

- 3-drug antiretroviral regimen for 28 days
 - Lack of RCTs, so recommendation is based on extrapolation of data showing maximal suppression of viral replication in HIV+ patients
 - Greater protection against resistant virus and increased likelihood of successful prophylaxis compared to 2-drug regimen
 - If infection occurs despite PEP, 3-drug regimen more likely to limit emergence of resistance
- Adherence is critical- choose combination that minimizes pill burden and side effects

PEP Options

| | Preferred | Alternative |
|---|--|--|
| Adults and adolescents 13+ with CrCl \geq 60 ml/min | Truvada daily with either raltegravir 400 mg BID OR dolutegravir 50 mg once daily | Truvada daily with both darunavir 800 mg daily AND ritonavir 100 mg daily |
| Adults and adolescents 13+ with CrCl <60 ml/min | zidovudine AND lamivudine renally dosed with either raltegravir 400 mg BID OR dolutegravir 50 mg daily | zidovudine and lamivudine renally dosed with both darunavir 800 mg daily AND ritonavir 100 mg once daily |

Preferred Regimens



OR



OR



PEP Efficacy

- No RCTs have been conducted
 - Ethical and operational challenges
- Strongest evidence comes from case-control study
 - 81% reduction in the odds of HIV transmission among health care workers with percutaneous exposure

PEP Safety

- Zidovudine
 - Side effects: nausea, vomiting, headache, insomnia, fatigue
 - Cautions: anemia and neutropenia
- Lamivudine
 - Side effects: headache, nausea, malaise and fatigue, nasal symptoms, diarrhea, cough
 - Contraindicated with emtracitabine
- Dolutegravir
 - Side effects: insomnia, headache
 - Many drug interactions
 - Separate administration from other antacids, laxatives, polyvalent cations
- Raltegravir
 - Side effects: insomnia, nausea, fatigue, headache, skin & hypersensitivity reactions
 - Separate administration from other antacids, laxatives, polyvalent cations

Medication Access

- Patient assistance programs
 - need to be handled urgently
- If paying for PEP after sexual assault, may qualify for partial or total reimbursement for medicines and clinical care costs

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If you are in immediate danger, call 911. The Office on Violence Against Women does not provide services directly to the general public.

To find help, click on your state to see who serves your local area, or call one of the national hotlines:

- Domestic Violence Hotline ☎ 1-800-799-SAFE (7233) 1-800-787-3224 (TTY)
- Sexual Assault Hotline ☎ 1-800-656-HOPE (4673)
- Teen Dating Abuse Helpline ☎ 1-866-331-9474, 1-866-331-8453 (TTY)
- Victim Hotline ☎ 1-855-4-Victim (855-484-2846)

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Washington Oregon Idaho Wyoming Montana North Dakota South Dakota Minnesota Wisconsin Michigan New Hampshire Vermont Massachusetts Maine New York Rhode Island

Follow-up Evaluation

- HIV and other indicated lab testing
- Consider changing regimen as indicated by side effects and results of initial testing
- Provide additional counseling and support for med adherence and HIV prevention if indicated
 - If patients engage in behaviors that would require sequential courses of PEP should be offered PrEP at the conclusion of PEP course
 - No gap necessary between ending PEP and starting PrEP
 - Still need documented HIV-negative status before starting PrEP



Summary



Screening

- **Patients aged 15-65 years old should be screened for HIV**
- **CUHCC 2020 UDS report showed 34.7% patients in this range were tested**

HIV PrEP Summary

- **Conduct risk assessments in patients who engage in risk behaviors**
- **Perform screening laboratory assessment and initiate Truvada or Descovy for PrEP as appropriate**
- **Regular laboratory monitoring must be completed**

HIV PEP Summary

- **Assess risk for HIV acquisition**
- **Initiate 28-day course of 3-drug antiretroviral regimen if indicated**
- **Consider offering PrEP if risky behaviors will continue**

Thanks!

Questions?

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