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PEP POCKET GUIDE

A GUIDE FOR POSTEXPOSURE PROPHYLAXIS RECOMMENDATIONS AND THE MANAGEMENT OF OCCUPATIONAL EXPOSURES

NORTH Dakota Be legendary. | Health & Human Services

About

This guide summarizes the U.S. Public Health Service and Centers for Disease Control and Prevention (CDC) recommendations for the management of health care personnel (HCP) who have occupational exposure to blood and/or other body fluids that might contain hepatitis B virus (HBV), hepatitis C (HCV) or human immunodeficiency virus (HIV).

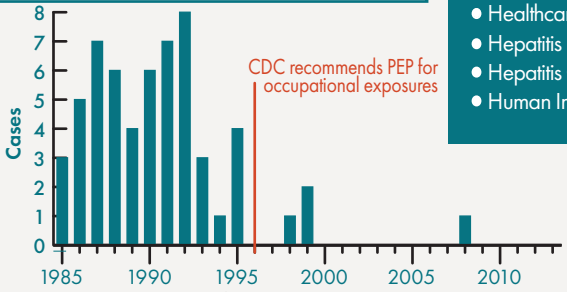
Note: This guide is a clinical aid that highlights the main action steps following a potential exposure to bloodborne pathogens in an occupational setting. Health care providers should refer to the references for the full-text versions of the guidelines for the management of occupational exposures to HBV, HCV, and HIV and recommendations for postexposure prophylaxis (PEP).

► How can I prevent occupational bloodborne pathogen exposures?

Follow standard precautions and primary prevention strategies at all times. Assume that blood and other body fluids are potentially infectious.

- Consistent use of personal protective equipment (PPE). Use gloves, goggles, and other barriers when anticipating contact with blood or body fluids.
- Wash hands and other skin surfaces immediately after contact with blood or body fluids.
- Be careful when handling and disposing of sharp instruments during and after use.
- Use safety devices to prevent needle-stick injuries.
- Dispose of used syringes/ sharp instruments in a sharps container.

Number of confirmed cases of occupationally acquired HIV infection among health care workers reported to CDC — U.S., 1985–2013



Source: Division of HIV/AIDS Prevention, National Center for HIV/AIDS,Viral Hepatitis, STD, and TB Prevention, CDC.

COMMON ABBREVIATIONS

- Source Person (SP)
- Exposed Person (EP)
- Healthcare Personnel (HCP)
- Hepatitis B virus (HBV)
- Hepatitis C virus (HCV)
- Human Immunodeficiency Virus (HIV)

STEP SUMMARY

These six steps are a guide to the appropriate management of occupational exposures to bloodborne pathogens.[1]

6 STEPS
TO MANAGE EXPOSURES

1 TREAT EXPOSURE SITE

Wash, flush, or irrigate exposed area.

2 REPORT AND DOCUMENT

Report immediately and describe the incident in detail.

3 EVALUATE THE EXPOSURE

Determine if exposure, infections of source and susceptibility of exposed.

4 EVALUATE THE EXPOSURE SOURCE

Test patient for HBsAg, HCV antibody and HIV antibody.

5 DISEASE-SPECIFIC PEP MANAGEMENT

Provide PEP to prevent infections as necessary

6 FOLLOW-UP

Monitor exposed persons with follow-up testing for several months after exposure.

STEP 1:TREAT EXPOSURE SITE[2]

Immediately after an exposure to potentially infectious fluids, those exposed should:

- **Wash** needlestick/cut exposed area with soap and water.
- **Flush** splashes to mucous membranes such as the inside the nose or mouth with water.
- **Irrigate** eyes with clean water, saline, or sterile irrigants.

No evidence exists that using antiseptics for wound care or expressing fluid by squeezing the wound further reduces the risk of bloodborne pathogen transmission. The application of caustic agents (e.g., bleach) or the injection of antiseptics or disinfectants into the wound is not recommended.

STEP 2: REPORT AND DOCUMENT[1]

Report occupational exposures immediately as they should be considered urgent medical concerns; circumstances of the exposure and PEP management should be recorded in the exposed person's confidential medical record. Include in the report:

- **Date and time of exposure.**
- **Details of the incident:** where and how the exposure occurred; if related to a sharp device, the type and brand of device and how and when in the course of handling the device the exposure occurred.
- **Details of the exposure:** type and amount of fluid or material, severity of exposure.
- **Details about the source person (SP):**
  - Whether the source material contained HIV, HBV or HCV.
  - If the (SP) is HIV-infected, determine stage of disease, viral load, history of antiretroviral therapy, and antiretroviral resistance information.
- **Details about the exposed person (EP):**
  - Hepatitis B vaccination and vaccine-response status.
  - Other medical conditions, current medications or drug allergies pregnancy or breast-feeding.
- **Documentation** of counseling, postexposure management and follow-up.

STEP 3: EVALUATE THE EXPOSURE

The exposure should be evaluated for the potential to transmit HBV, HCV, or HIV based on the body substance involved and the type of exposure. Also, the SP's infection status and EP's susceptibility, including necesssary baseline testing, should be determined as soon as possible after an incident.

► Identify Exposure

For transmission of bloodborne pathogens (HIV, HBV and HCV) to occur, an exposure must include both of the following.

- **Infectious body fluid[2]:** Blood, semen, vaginal fluid, amniotic fluid, breast milk, cerebrospinal fluid, pericardial fluid, peritoneal fluid, pleural fluid and synovia fluid

  Note that saliva, vomitus, urine, feces, sweat, tears and respiratory secretions do not transmit HIV (unless visibly bloody). The risks of HBV and HCV transmission from non-bloody saliva is considered to be negligible[2].

- **A portal of entry:** Percutaneous injury, mucous membrane exposure, nonintact skin exposure, bites resulting in blood exposure to either person involved.

  Nonintact skin: exposed skin that is chapped, abraded or afflicted with dermatitis.

If both of these factors are not present, there is no risk of blood borne pathogen transmission and further evaluation is not required.

► Infection Status of Source Patient

At the time of the incident, the source should have baseline testing for:

- **HIV** - **HCV** - **HBV**

Note: Step 4 has more information on baseline testing for SP.

► Susceptibility of Exposed Person

If no bloodborne pathogen exposure occurred or the SP is confirmed negative on baseline testing, no baseline testing is clinically indicated for the EP. If indicated, the exposed person should have the following testing as soon as possible (preferably within 48 hours):

- **HIV Ag/Ab or HIV Ab**
- **HCV Ab, Follow-up with HCV RNA testing if Ab positive**
- **HBV testing: HBcAb, for anyone who is not a known responder to Hep B.**

Note: See page 7 for Hep B PEP

STEP 4: EVALUATE THE EXPOSURE SOURCE [3,4,5]

The source patient (SP) of an occupational exposure should be evaluated for HBV, HCV, and HIV infection.

► **When SP is KNOWN,** test source patient (SP) for:

- **HIV Ag/Ab or HIV Ab** (rapid HIV testing preferred if accessible)*
  - If SP's rapid HIV test is positive, assume this is a true positive for purposes of initial PEP decision-making, and send confirmatory/ supplemental testing
  - investigation of whether a source patient might be in the "window period" is unnecessary unless acute retroviral syndrome is clinically suspected.
- **HCV Ab or HCV RNA** ("HCV viral load")
  - Other option, but not preferred: Test the source patient for antibodies to hepatitis C virus (anti-HCV), then if positive, reflex test for HCV RNA.
- **HBsAg** (HBV surface antigen) or a hepatitis panel including HBsAg, HBsAb and HBcAb

If the source person is NOT infected with a bloodborne pathogen, baseline testing or further follow-up of HCP is not necessary.

There are exceptions to testing source patients if consent is not obtained. Refer to ND Century Code, CHAPTER 23-07.5, for more information on testing of source patients, informed consent, result disclosure and confidentiality.

► **When source patient is NOT known:**

- **For patients who cannot be tested, consider medical diagnoses, clinical symptoms, and history of risk behaviors.**
- **Evaluate the likelihood of high risk exposure:**
  - Consider the possiblity of bloodborne pathogen infection among patients in the exposure setting, e.g., what is the community infection rate? Does the clinic/hospital unit care for a large number of HIV-,HBV-, or HCV-infected or at-risk patients?

Do not test discarded needles for bloodborne pathogens; the reliability of these findings is not known.

STEP 5: DISEASE SPECIFIC PEP MANAGEMENT

To prevent the development of infections, PEP is available after exposure to hepatitis B and HIV. Unfortunately, there is no current PEP available for exposures to HCV.

The efficacy of PEP options for hepatitis B and HIV are time sensitive. Optimal time to start PEP is within hours of exposure, rather than days. PEP for hepatitis B is considered effective if given within 7 days after an exposure. HIV PrEP should be started immediately or within 72 hours. The effectiveness of HIV PrEP started after 72 hours is believed to be reduced. After a longer interval (e.g., 1 week), initiating therapy might still be considered for exposures that represent an extremely high risk for transmission. If there is reason to suspect an HIV exposure, do not wait for SP test results (unless results will be available within an hour or two) to proceed with a PEP decision and initiation, when indicated.

Exposure Risks of Transmission

HBV

The risk of HBV transmission from an occupational percutaneous exposure ranges from 1% to 31% depending on the presence of hepatitis B e antigen (HBeAg), a marker of active replication [Schillie, et al. 2013]. Average risk of HBV transmission after needlestick [CDC 2001; Schillie, et al. 2013]:

HBV: 1.0% to 31.0%.
HBeAg+: 22% to 31%.
HBeAg-: 1.0% to 6.0%

HCV

For **percutaneous** exposure to anti-HCV–positive blood or body fluids, the estimated risk for HCV infection was reported as approximately **0.2%.** With **mucocutaneous** exposure, the risk for HCV infection was **0%.**[4]

HIV

The average risk for HIV transmission after a **percutaneous** exposure to HIV-infected blood has been estimated to be approximately **0.3%** (and after a **mucous membrane** exposure, approximately **0.09%.**

Transmission risk might be higher for EP with exposure to hollow-bore needles.[4,5] Increased risk for HIV infection was associated with exposure to a large quantity of blood from a SP as indicated by 1) a device visibly contaminated with the SP's blood, 2) a procedure that involved a needle being placed directly in a vein or artery or 3) a deep injury. The risk also was increased for exposure to blood from a SP with terminal illness, likely reflecting the higher titer of HIV in blood.[5]

STEP 5: PEP for HBV Exposures

HBV PEP should be initiated IMMEDIATELY, preferably within 24 hours. PEP for hepatitis B is considered effective if given within 7 days after an exposure. The following table summarizes HBV PEP.

RECOMMENDED PEP FOR EXPOSURE TO HBV[6] [a]

Exposed Individual Vaccination Status	Source is HBsAg Positive	Source is HBsAg Negative or Not Available	Source is Not Availabe; Known High-Risk [b]
	Indicated treatment for EXPOSED individual:		
Unvaccinated/ non-immune	• Administer HBIG 0.06 mL/kg IM. • Initiate HBV vaccine series.	Initiate HBV vaccine series.	Treat as if source is HBsAg positive.
Previously vacccinated with completed HBV series; known responder [c]	No treatment.		
Previously vaccinated with completed HBV series; known nonresponder [c]	• Administer HBIG 0.06 mL/kg IM. • Initiate revaccination [d] or administer second dose of HBIG 1 month later.	No treatment.	Treat as if source is HBsAg positive.
Previously vacccinated with completed HBV series; unknown antibody response	• Administer single dose of vaccine. • Check titer. If low, complete 3-dose vaccine series.	No treatment.	Treat as if source is HBsAg positive.
Undergoing vaccination at time of exposure	• Administer HBIG 0.06 mL/kg IM. • Complete 3-dose vaccine series.	Complete vaccine series.	

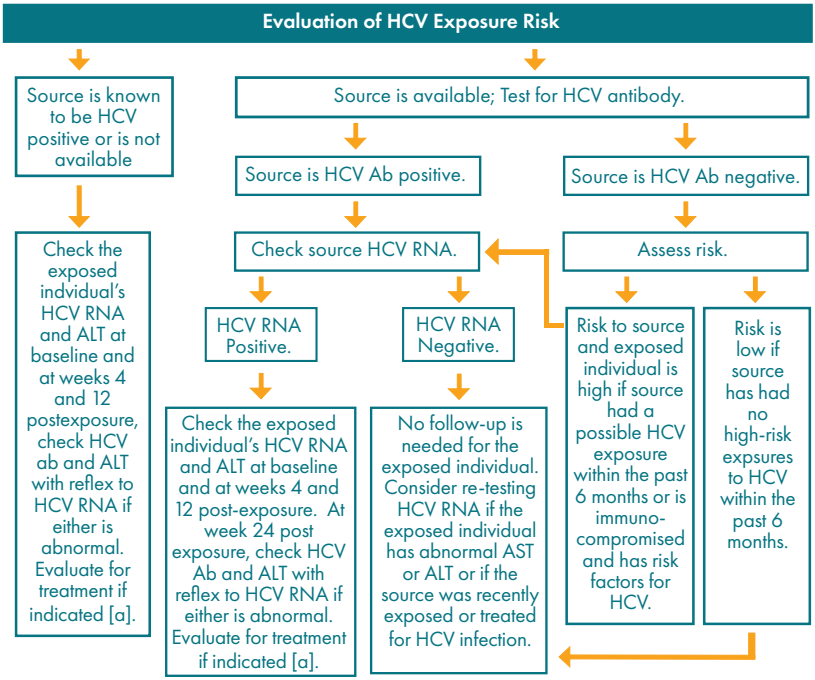
Abbreviations: anti-HBs, hepatitis B surface antibody; HBIG, hepatitis B immune globulin; HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; IM, intramuscular.

[A] Individuals who have previously been infected with HBV with HBsAb positivity are immune to re-infection and do not require post-exposure prophylaxis.
[B] Individuals at high risk are those who engage in needle sharing or high-risk sexual behaviors or were born in geographic areas with HBsAg prevalence of >2% [Weinbaum, et al. 2008].
[C] Based on info available at presentation. Responder is an individual with previously documented adequate levels of serum antibody to HBsAg (serum anti-HBs >10 mIU/mL); a nonresponder is an individual with previously documented inadequate response to vaccination (serum anti-HBs <10 mIU/mL). The decision to vaccinate shouldn't be delayed while testing for anti-HBs at presentation.
[D] The option of giving 1 dose of HBIG and reinitiating the vaccine series is preferred for nonresponders who have not completed a second vaccine series. For individuals who previously completed a second vaccine series but failed to respond, 2 doses of HBIG are preferred, given 1 month apart.

STEP 5: PEP for HCV Exposures

Currently, research has identified no effective prophylaxis for HCV infection. Immunoglobulin and antiviral agents are not recommended for HCV PEP. In contrast with other bloodborne pathogens for which PEP is recommended, curative DAA therapy is reserved for treatment if HCV transmission does occur. If an individual becomes acutely infected with HCV and is diagnosed at that time, immediate referral to a clinician experienced in the treatment of HCV is strongly recommended.

Utilize the below figure after an exposure to HCV for a summary of exposure risk and recommended follow-up. Persons with recently acquired acute infection typically have detectable HCV RNA levels as early as 1–2 weeks after exposure.



Abbreviations: ALT, alanine aminotransferase; AST, aspartate aminotransferase.
a. If at any time the serum ALT level is elevated, repeat HCV RNA testing to evaluate for acute HCV infection. If HCV infection is identified, refer to a clinician with experience in treating HCV for medical management.

STEP 5: PEP for HIV Exposures

A rapid and effective response to a reported HIV exposure may lead to the successful prevention of HIV infection. PEP has been established to effectively prevent HIV infection in an EP when initiated within 2 hours (ideal) and no later than 72 hours after an exposure.

► HIV PEP Key Facts

- Three drug PEP regimens are recommended for all exposures. PEP regimen is for 28 days.
- PEP is associated with side effects, severe toxicity and drug interactions.
- Unless active HIV is clinically suspected or recent (within previous 1 to 2 months) high risk exposure has occured, investigation of whether a SP is in the window period is unnecessary for determining if HIV PEP is indicated.

► PEP is typically recommended when an exposure to an HIV positive patient has occurred.

- Exposure to a SP with an undetectable serum viral load does not liminate the possibility of HIV transmission or the need for PEP. PEPline does not recommend following exposure from a person with a recent undetectable viral load, as the risks may be greater than benefits.

► PEP is generally not warranted in cases when the source has a unknown HIV status or when the source is unknown.

- However, consider PEP for exposures from a source with HIV risk factors. The decision to take PEP should be individualized following a shared decision-making process based on accurate risk assessment, the treating clinician's recommendations, and patient preferences.

PREFERRED 3-DRUG HIV PEP REGIME

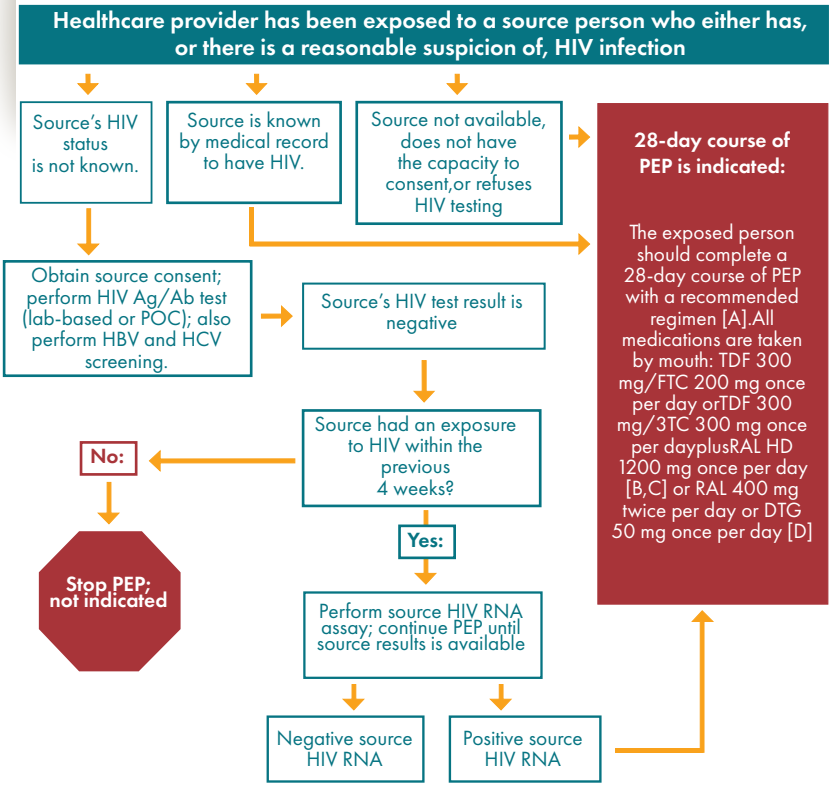
Truvada™ 1 PO Once Daily
[co-formulated Tenofovir DF (Viread®; TDF) 300mg + emtricitabine (Emtriva™; FTC) 200mg]

PLUS

Raltegravir (Isentress®; RAL) 400mg PO Twice Daily

Alternative PEP regimens are available and the preferred regimen should be reevaluated and modified when additional information is obtained about the SP (e.g., possible treatment history or antiretroviral drug resistance). Given the complexity of choosing and administering HIV PEP, consultation with an infectious diseases specialist or another physician who is an expert in the administration of antiretroviral agents is recommended. Such consultation should not, however, delay timely initiation of PEP.

STEP 5: PEP for HIV Exposures



Abbreviation key: Ag/Ab, antigen/antibody; CrCl, creatinine clearance; HBV, hepatitis B virus; HBsAg, hepatitis B surface antigen; HCV, hepatitis C virus; PEP, post-exposure prophylaxis; POC, point-of-care. Drug name abbreviations (brand name): 3TC, lamivudine (Epivir); DTG, dolutegravir (Tivicay); FTC, emtricitabine (Emtriva); RAL, raltegravir (Isentress); TDF, tenofovir disoproxil fumarate (Viread); TDF/FTC (Truvada)

Notes: a. See Management of Potential Exposure to Hepatitis B Virus and Management of Potential

[A]. Do not use fixed-dose combination tablet forpatients who require dose adjustment for renal failure. Adjustdose of TDF/FTC or TDF/3TC for patients with CrCl < 50mL/min. See NYSDOH AI guideline Recommended Dose Adjustments for Use of Selected Fixed-Dose Combination ARVs in Patients with Hepatic or Renal Impairment. [B]. RAL HD maybe prescribed for patients who weight>40kg. [C]..RAL HD should not be prescribed for pregnant individuals. [D]. See Use of Dolutegravir in Individuals of Childbearing Capacity.

STEP 6: FOLLOW-UP

Individuals who have experienced occupational exposures should receive follow-up counseling, postexposure testing, and medical evaluation regardless of whether they take PEP. A follow-up appointment after the initial PEP assessment may provide another (and perhaps less anxiety-ridden) opportunity to allow the EP to ask questions and for the counselor to make certain that the EP has a clear understanding of the risks for infection and the risks and benefits of PEP.

Exposed personnel should be advised to use precautions (e.g., use of barrier contraception, avoid blood or tissue donations) to prevent secondary transmission, especially during the first 6-12 weeks postexposure. Individuals should also be advised to avoid pregnancy and if possible, breastfeeding if exposed to HIV. Individuals should be aware of the potential maternal to child transmission of HCV. Providing individuals with psychological counseling should be an essential component of the management and care of those exposed to bloodborne pathogens.

Follow-up testing is recommended for exposed persons the based on a confirmed exposure and the infectious status of the source patient.

► **HBV exposure follow-up testing:**

- EP that are vaccinated should be tested for HBsAb to confirm immunity (HBsAb ≥10 mIU/mL). Test for anti-HBs 1-2 months after last dose of vaccine;
- EP with anti-HBs <10mIU/mL after complete vaccination series (or who are unvaccinated/incompletely vaccinated), and sustain an exposure to a source person who is HBsAg-positive or has unknown HBsAg status, should undergo follow-up testing for HBsAg and total anti-HBs approximately 6 months later.
- Passively acquired anti-HBs can be deteced for 4-6 months after administration of HBIG.

► **HCV exposure follow-up testing:**

- NAT for HCV RNA at 3–6 weeks after exposure.
- A final test for anti-HCV at 4–6 months with testing for HCV RNA if positive
- However, for those who had a negative anti-HCV result at 4–6 months and are immunocompromised or have liver disease, an additional test for HCV RNA can be considered

STEP 6: HIV FOLLOW-UP

► HIV exposure follow-up testing:

- If SP tests negative for HIV, follow-up testing isn't indicated for the EP.
- If SP is HIV positive or if the SP cannot be tested for HIV or SP is unknown, re-test the EP for HIV at 6 weeks and at 4 months.
- Extended HIV testing to 12 months is indicated only for HCP who acquire HCV infection after exposure to an HCV-HIV co-infected SP.
- Monitor for acute HIV symptoms (fever, chills, rash, night sweats, muscle aches, sore throat, fatigue, swollen lymph nodes, etc.)
- At a minimum, lab monitoring while on PrEP should occur at baseline and 2 weeks and should include complete blood count and renal and hepatic function tests.

► Final Follow-Up Testing at 4 Months

Current CDC guidelines recommend testing at 4 or 6 months. To conclude follow-up testing at 4 months, ***must use*** a U.S. Food and Drug Administration (FDA)-approved 4th-generation laboratory-based antigen/antibody (Ag/Ab) HIV screening test.

Note: The PEPline recommends final follow-up testing at 3 months. Delaying follow-up testing beyond 3 months is not necessary with the standard HIV test that is widely used at this time, and can add additional months of anxiety for exposed persons and their families. This PEPline recommendation is consistent with the USPHS non-occupational PEP Guidelines.

► Follow-up Care & Counseling for those on HIV PEP

Clinicians should follow up with the exposed individual within 48 hours, either by telephone call or in person, to assess PEP tolerability and adherence and to confirm access to the medications required to complete the full 28-day PEP regimen.

Providers should stress the importance of completing the prescribed regimen. Information should be provided about: potential drug interactions and prescription/nonprescription drugs and nutritional supplements that should not be taken with PEP or require dose or administration adjustments, side effects of prescribed drugs, measures (including pharmacological interventions) that may assist in minimizing side effects, and methods of clinical monitoring for toxicity during the follow-up period. EP should be advised that evaluation of certain symptoms (e.g., rash, fever, back or abdominal pain, pain on urination or blood in the urine, dark urine, yellowing of the skin or whites of the eyes, or symptoms of hyperglycemia (e.g., increased thirst or frequent urination) should not be delayed. Serious adverse events should be reported to FDA's MedWatch program.

RESOURCES

National Clinicans' Post expousre Prophylaxix Hotline (PEPline)	1-888-448-4911 https://nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis/
Mountain Plains E-mail Clinical Consultaion Services for HIV Infections	hivconsultation@UCHSC.edu
Centers for Disease Control and Prevention (CDC) Report occupationally acquired HIVinfections and failures of PEP	Cases of Public Health Importance (COPHI) Coordinator 404.639.2050
HIV Antiretroviral Pregnancy Registry	1-800-258-4263 apregistry.com
Food and Drug Administration Report unusual or severe toxicity to antiretroviral agents	1-800-332-1088 fda.gov/medwatch
HIVinfo	HIVinfo.nih.gov
AETC National HIV Curriculum	https://aidsetc.org/nhc
HIVdent	hivdent.org
National Clinician Consultation Center Hepatitis C Management	844-437-4636
North Dakota Department of Health - Divison of Sexually Transmitted and Bloodborne Diseases	800-472-2180 https://www.health.nd.gov/HIV

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