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The AETC's goal is to build the capacity of clinicians throughout their careers to care for people living with HIV/AIDS.

Skill building opportunities are available for pre-novice, novice and experienced providers. By increasing the HIV clinical competency of providers, outcomes along the HIV Care Continuum will improve with a greater number of patients diagnosed, engaged in care, on antiretroviral medications and virally suppressed.

Providing state-of-the-art HIV education, consultation, and resource materials to healthcare professionals throughout the region.	
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## **National HIV Consultation Services**

**Clinician Consultation Center** Online Consultation: nccc.ucsf.edu

# Pre-Exposure Prophylaxis 855.448.7737

Advice to clinicians on providing antiretroviral drug therapy to HIV uninfected persons to prevent HIV infection Call 9am-8pm EST, Monday - Friday

## Post-Exposure Prophylaxis 888.448.4911

Timely answers for urgent bloodborne pathogen exposure management Call 11am-8pm EST, 7 days a week or see the online PEP Quick Guide for urgent PEP decision-making

Perinatal HIV/AIDS 888.448.8765 Rapid perinatal HIV consultation Call 24 hours a day, 7 days a week

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Peer-to-peer advice on HIV/AIDS management Call 9 am - 8 pm EST, Monday - Friday Voicemail 24 hours a day, 7 days a week

## **AETC National Coordinating Resource Center**

www.aidsetc.org

Supporting HIV education for healthcare professionals

An up-to-date and downloadable PDF file is available online at www.SEAETC.com. To order additional printed copies, please email Jennifer Burdge at jennifer.burdge@vanderbilt.edu.

### Visit www.seaetc.com for additional resources on the following topics:

ARV Therapy in Adults & Adolescents

Hepatitis in HIV/AIDS

Oral Manifestations Associated with HIV/AIDS Non-Occupational Post-Exposure Prophylaxis (nPEP) and

Occupational PEP (oPEP) Treatment of Sexually Transmitted Diseases (STDs) in

**HIV-Infected Patients** 

# Report Adverse Events and Pregnancy Exposures

### FDA MedWatch

Report unusual or severe toxicity to antiretrovirals www.fda.gov/Safety/MedWatch/HowToReport/default.htm 800.FDA.1088 (332.1088)

## Antiretroviral Pregnancy Registry:

A voluntary prospective, exposure-registration, observational study designed to collect and evaluate data on the outcomes of pregnancy exposures to antiretroviral

Pre-Exposure Prophylaxis (PrEP), **Non-Occupational Post-Exposure Prophylaxis (nPEP) & Occupational PEP (oPEP)** 

	AETC AIDS Education & Training Center Program Southeast	May 2018
]	<b>Editors:</b> Jennifer Janelle, MD Joanne Orrick, PharmD, AAHIVP	Layout Editor: Clint Ribble, BS

This resource summarizes the guidelines for the management of occupational and non-occupational exposures to the human immunodeficiency virus (HIV), hepatitis B (HBV), and hepatitis C (HCV). This resource also summarizes recommendations for postexposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP) for the prevention of HIV in adults at high risk for acquiring HIV. This resource is intended to guide initial decisions about PrEP/PEP and should be used in conjunction with other guidance provided in the full reports available at websites listed throughout this resource.

### **Management of Non-Occupational Exposures**

Evaluate exposure - See inside of card

- · Start non-occupational post-exposure prophylaxis (nPEP) when indicated Sexual exposure requires evaluation for sexually transmitted infections (STIs)
- · For injecting drug users (IDUs), assess access to clean needles/syringes
- · Women at risk for unintended pregnancy should be offered emergency contraception
- · Refer as appropriate to counseling for risk-reduction, mental health, substance abuse, and domestic violence
- Victims of sexual assault should be referred for additional evaluation and counseling See the New York State Department of Health AIDS Institute guidelines for victims of sexual assault at http://www.hivguidelines.org/pep-for-hiv-prevention/after-sexualassault/
- National Sexual Assault Hotline 1800 656 HOPE (656 4673)

### **Management of Occupational Exposures**

Requires immediate reporting so exposed person can be evaluated, tested, and provided with appropriate occupational post-exposure prophylaxis (oPEP) if indicated Treatment (tx) of Exposure Site

- Wash wounds and skin sites with soap and water
- Flush mucous membranes with water
- Use of antiseptics-not contraindicated, but no evidence that it will further reduce
- risk of transmission. Avoid use of caustic agents (e.g., bleach).

Evaluate Exposure - See inside of card

Start oPEP when indicated

Exposure to other blood-borne pathogens (e.g., hepatitis B and C) should be considered in addition to HIV. See sections on hepatitis B and C provided in this resource. Patients should be counseled to initiate or resume preventive behaviors to prevent additional exposure and to prevent possible secondary transmission while receiving PEP.

**ARV Therapy in Pediatrics** 

Opportunistic Infections (OIs) in HIV/AIDS

Pre-Exposure Prophylaxis (PrEP)

Post-Exposure Prophylaxis (PEP) in

Pediatrics/Adolescents

Treatment of Tuberculosis (TB) in Adults with HIV Infection

Pre-Exposure Prophylaxis for the Prevention of HIV Infection

Centers for Disease Control and Prevention (CDC) and Department of Health and Human Services. U.S. Public Health Service. Clinical Practice Guideline: Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States - 2017. Available at www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guide CDC and DHHS. U.S. Public Health Service. Clinical Providers' Supplement: Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States - 2017. Available at https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2017.pdf. Both accessed April 22, 2018.

**BEFORE INITIATING PREP** 

## **Recommendations for PrEP**

- · PrEP is recommended as one prevention option for adults who do not have acute or established HIV infection, but are at high risk for acquiring HIV infection Risks and benefits of PrEP for adolescents should be weighed carefully in the context of local laws and regulations as the data on efficacy and safety of PrEP for adolescents are insufficient
- Sexual PrEP Indications (men who have sex with men and/or women, heterosexual men or women, transgender men or women):
  - Not in a mutually monogamous partnership with a partner who is has recently tested negative for HIV AND ≥ 1 of the following: Sex with person known to have HIV infection or
  - Sexually transmitted infection (STI)<sup>1</sup> diagnosed or reported in past 6 months or
  - High number of sexual partners or
  - History of inconsistent or no condom use or
  - Commercial sex work

NOTE: Sexual activity in high HIV prevalence areas may increase risk of HIV acquisition (see http://www.AIDSvu.org or http://www.cdc.gov/nchhstp/ atlas/).

IDUs indications

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- Injecting partner with HIV or sharing injection equipment
- and/or Risk of sexual acquisition (see above)
- Tenofovir disoproxil fumarate/emtricitabine (TDF/FTC, Truvada®) is the only agent that is FDA-approved for prevention of HIV via PrEP for all populations at risk listed above
- Tenofovir disoproxil fumarate (TDF, Viread\*) alone is an alternative option for heterosexual or IDU's but not for MSM, as efficacy has not been studied in the MSM population. See guidelines for more information.

#### Determine Eligibility

- Negative HIV test (antigen/antibody laboratory test preferred) within one week before starting PrEP medication. Anonymous tests, patient-self reported test results or oral rapid tests (less sensitive than blood based tests) should not be used to screen for HIV infection when considering PrEP.
- Obtain HIV viral load if symptoms of acute HIV infection are present or if patient (pt) has had at-risk sexual exposure with person living with HIV in the last 30 days and/or ongoing injection drug use. Delay initiating PrEP until pt is confirmed to be HIV-negative.
- See Figure Clinician Determination of HIV Status for PrEP Provision in the PrEP Guidelines. Assess for pregnancy or breastfeeding and discuss pregnancy plans so that an informed decision can be made regarding risks/benefits of PrEP exposure.<sup>2</sup> Provide contraception if pregnancy is not desired while on PrEP.
- Confirm that pt is at substantial, ongoing, high risk for acquiring HIV infection
- A sexual history is recommended for all pts. If sexual partner(s) are known to have HIV infection, assess if they are in care and on antiretroviral (ARV) therapy and assist with linkage or re-engagement if needed.
- Perform estimated creatinine clearance (CrCL). Do not initiate if estimated CrCL is < 60 mL/min. If pt has mild renal insufficiency or risk factors for renal dysfunction obtain CrCL, phosphorus, urine glucose and urine protein prior to initiating PrEP to evaluate for renal disease/Fanconi syndrome. See Box C of the PrEP guidelines for the Cockcroft-Gault formula for CrCL estimation.
- Consider bone mineral density in pts with risk factors for osteoporosis or bone loss or history of pathologic fracture

### Other Recommended Actions

- Screen for hepatitis B infection and immunity; vaccinate if appropriate, or treat if active infection identified whether or not PrEP prescribed. Because TDF/ FTC treats hepatitis B, it is important to recognize if this infection is present as flare of hepatitis B is possible if infection is not recognized and TDF/FTC is discontinued.
- Screen pt for alcohol and illicit drug use, including the use of injectable drugs as these substances may affect sexual risk behavior. Refer for substance abuse tx if indicated. For IDUs, assess access to clean needles/syringes.
- Perform screening for bacterial STIs (syphilis serology and gonorrhea and chlamydia testing at all sites of exposure) and tx if indicated<sup>1</sup>
- Educate all pts on the importance of practicing safer sex consistently, using condoms correctly, need to avoid sharing injection equipment and the need for 100% adherence to PrEP medications if prescribed. Educate women on the following:
- PrEP has not been associated to date with adverse events in pregnancy or when breastfeeding<sup>2</sup>
- 1. Gonorrhea, chlamydia and syphilis testing for MSM including those who inject drugs. 2. Center's for Disease Control and Prevention. Provider Information Sheet-PrEP During Conception, Pregnancy, and Breastfeeding. Available at http://www.cdc.gov/hiv/pdf/prep\_gl\_clinician\_factsheet\_pregnancy\_english.pdf.

Accessed April 22, 2018.

### See the Guidelines for a complete discussion of laboratory tests and monitoring. http://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf#page=30 **BEGINNING PREP MEDICATION REGIMEN**

- Pts taking PrEP should be informed of side effects of these medications and possible signs and symptoms requiring urgent medical evaluation
- Provide pt with a medication fact sheet listing dosing instructions and side effects
- Reinforce the fact that PrEP is not always effective in preventing HIV infection particularly if used inconsistently. The consistent use of PrEP together with other prevention methods (consistent condom use, discontinuing drug injection or never sharing injection equipment) confers very high levels of protection.
- Review important prescribing considerations<sup>3</sup>
- Review "Agreement Form for Initiating TRUVADA® for Pre-Exposure Prophylaxis (PrEP) of Sexually Acquired HIV-1 Infection" with your pt4
- Prescribe Truvada® (300 mg tenofovir [TDF]/200 mg emtricitabine [FTC]) po once daily and educate pt on proper use of medication Prescribe no more than a 90-day supply, and renew only if HIV antibody test or fourth generation antigen/antibody test confirms that pt remains HIV-
- uninfected Assess pregnancy intent and perform pregnancy test. Assure the pt has been informed about the benefits and risk of use should pregnancy occur<sup>2</sup> Consider using TDF/FTC for both tx of active hepatitis B infection and HIV prevention
- Make sure pt has a follow up appointment

PrEP use

3. Gilead Sciences, Inc. TRUVADA<sup>+</sup> for a Pre-exposure Prophylaxis (PrEP) Indication: Risk Evaluation and Mitigation Strategy (REMS). Available at <u>www.truvadapreprems.com</u>. Accessed: April 22, 2018. 4. Gilead Sciences, Inc. Agreement Form for Initiating TRUVADA<sup>+</sup> for Pre-exposure Prophylaxis (PrEP) Available at <u>www.truvadapreprems.com/Content/pdf/Agreement\_Form.pdf</u>. Accessed: April 22, 2018.

## NOTE: 100% adherence is essential for PrEP to be effective.

Provide support for risk-reduction strategies and the consistent and correct use of condoms. Respond to new questions and provide any new information about

At 3 month intervals, STI testing and tx as indicated for pts with signs or sx of STI and STI screening of asymptomatic MSM. Every 6 mos, screen all sexually

Three months after PrEP initiation, and at least every 6 months thereafter, evaluate serum creatinine and estimated creatinine clearance. If pt has mild renal

insufficiency or risk factors for renal dysfunction obtain CrCL, phosphorus, urine glucose and urine protein. If CrCL falls to < 60 mL/min while on PrEP, re-assess

# PrEP is not always effective in preventing HIV infection particularly if used inconsistently.

FOLLOW-UP AT LEAST EVERY 90 DAYS WHILE PATIENT TAKING PREP

Assess for signs/symptoms of acute HIV infection and if present, discontinue PrEP until testing confirms that pt is HIV-negative.

Document reasons for discontinuing PrEP. PrEP should be discontinued upon any positive test result suggesting HIV infection.

Repeat HIV test every 3 months. In women of childbearing potential, perform pregnancy testing every 3 months.

the risk vs. benefits of PrEP and dose adjust TDF/FTC per package insert if PrEP continued.

At least every 12 months, evaluate the need to continue PrEP as a component of HIV prevention

- Document negative (blood or serum) HIV antibody test or fourth generation antigen/antibody test (preferred)
- Document negative pregnancy test; if pregnant, discuss ongoing PrEP with pt and prenatal care provider<sup>2</sup> and report exposure to antiretroviral pregnancy registry (www.apregistry.com) Assess side effects, adherence and HIV acquisition risk behaviors. Consider more frequent follow-up visits if inconsistent adherence is identified

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should any endorsements be interred by HKSA, HHS, and the U.S. Government.

#### **SPECIAL THANKS TO:**

ion contained in this publication is intended for medical professionals, as a

ield, clinicians are encouraged to consult with their local experts or research the literature for the or, on one of the second of th

note to the national guidelines. This resource does not replace nor represent the sive nature of the published guidelines. Recognizing the rapid changes that occur in this

Colorado AIDS Education and Training Center for medication images (images are not actual size and colors may vary) and www.poz.com for phonetic pronunciation

ation HIV antigen/ar Perform blood (or serum) HIV antibody test or fourth gen

**ON DISCONTINUING Prep** 

- If HIV-positive, convert PrEP regimen to an HIV treatment regimen recommended by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents. See Section 8 of the PrEP Provider Supplement.
- If HIV-negative, assure continued risk-reduction support services as indicated
- If active hepatitis B is diagnosed, assure continued hepatitis B tx

active pts for bacterial STIs even if asymptomatic.

If pregnant, inform prenatal care provider of TDF/FTC use in early pregnancy

## Post-Exposure Prophylaxis (PEP) for Hepatitis B Virus (HBV)

CDC. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. MMWR, 2001;50(RR-11): 1-53. Available at www.cdc.gov/mmwr/pdf/rr/rr5011.pdf. CDC. CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management. MMWR, 2013;62(RR-10); 1-19. Available at http://www.cdc.gov/Mmwr/preview/mmwrhtml/rr6210a1.htm?s\_cid=rr6210a1.btm?s\_cid=rr621

#### Management of Exposures to HBV

- · See Table on Recommended Schedule for Laboratory Evaluation for Source and Exposed Persons
- Any blood or body fluid exposure to an unvaccinated person should lead to the initiation of the hepatitis B vaccine series, unless they have not responded after a second complete vaccination series (after two 3-dose series)
- Recombivax HB® 10 mcg or Engerix-B® 20 mcg IM at 0, 1, and 6 months (Consider 40 mcg dose or alternate dosing strategies such as intradermal route if exposed person is on dialysis, is immunocompromised, or is a nonresponder)<sup>5</sup>
- When Hepatitis B Immune Globulin (HBIG) is indicated, it should be administered as soon as possible after the exposure (preferably within 24 hours, but is recommended up to 1 week following an occupational exposure)
- HBIG can be administered simultaneously with the Hepatitis B vaccine, but at a separate site
- Test for Hepatitis B surface antibody (HBsAb) 1-2 months after last dose of vaccine series or booster, adequate if HBsAb ≥ 10 mIU/mL (>0.99 index value)

EXPOSED PERSON'S	TREATMENT		
IMMUNE STATUS	Source HBsAg (+), HBsAg (unknown) or Not Available for Testing	Source HBsAg (-)	
Unvaccinated or Incomplete Vaccination	HBIG (0.06 mL/kg IM) x 1 and complete vaccination	Vaccinate	
Vaccinated-responder (HBsAb $\geq$ 10 mIU/mL)	No PEP	No PEP	
Vaccinated-nonresponder	After first vaccination series- HBIG (0.06 mL/kg IM) x 1 and revaccinate <sup>6</sup>	Revaccinate <sup>6</sup>	
(HBsAb < 10 mIU/mL)	After second vaccination series- HBIG (0.06 mL/kg IM) x 2 doses (one at time of exposure and one 1 month after exposure)	No PEP	
Vaccination Completed	Test exposed person for HBsAb. If HBsAb ≥ 10 mIU/mL, no PEP necessary.	No PEP	
(HBsAb response unknown)	Test exposed person for HBsAb. If HBsAb < 10 mIU/mL, administer HBIG x 1 and revaccinate. <sup>6</sup>	Revaccinate <sup>6</sup>	
5. Filippelli M, Lionetti E, Gennaro A, et al. Hepatitis B vaccine by intradermal route in non responder patients: An update. World J Gastroenterol 2014; 20(30): 10383-10394. Available at http://www.yignet.com/1007-9327/full/v20/i30/10383.htm. 6. Give vaccine booster dose; check antibody response (HBsAb guantitative) 1-2 months later; give additional 2 doses (for total of 6 doses) if HBsAb remains < 10 mIU/mL and repeat HBsAb 1-2 months later.			

**HIV Exposure Management** Post-Exposure Management for Hepatitis C Virus (HCV) CDC. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Record mendations for Postexposure Prophylaxis, MMWR, NOTE: Consider exposure to other blood-borne pathogens (e.g., hepatitis B and C) in addition to HIV. 2001;50(RR-11), 1-53. Available at www.cdc.gov/mmwr/pdf/rr/rr5011.pdf See sections on hepatitis B and C provided in this resource. CDC. Information for Healthcare Personnel Potentially Exposed to Hepatitis C Virus (HCV): Recommended Testing and Follow-up. November 2016. Available at PEP for non-occupational (nPEP) and occupational exposures (oPEP) should start IMMEDIATELY (ideally within 1-2 hours post exposure), and continue for 28 https://www.cdc.gov/hepatitis/pdfs/testing-followup-exposed-hc-personnel-3d.pdf. days, or until the source person is confirmed to be HIV-negative. CDC. Testing for HCV Infection: An Update of Guidance for Clinicians and Laboratorians. MMWR, 2013;62(18), 357-365. See Table on Recommended Schedule for Laboratory Evaluation for Source and Exposed Persons Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6218a5.htm. All accessed April 22, 2018. If nPEP initiated, consider PrEP after completion of the 28-day nPEP regimen for those with repeated high-risk behavior or repeat courses of nPEP Management of Exposures and Post-Exposure Management to HCV Risk reduction and primary prevention counseling should be provided whenever someone is assessed for nPEP, regardless of whether PEP is initiated See Table on Recommended Schedule for Laboratory Evaluation for Source and Exposed Persons The Clinician Consultation Center provides timely answers for urgent exposure management and PEP. Call 888.448.4911 or visit http://nccc.ucsf.edu/clinician-Confirm HCV Ab results reported positive by testing for HCV viral load consultation/pep-post-exposure-prophylaxis/ for more information No regimens proven beneficial for PEP Early identification of acute HCV and referral to hepatitis C specialist for management if infected<sup>7</sup> 7. Management of Acute HCV Infection in AASLD and IDSA HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C. Available at http://www.hcvguidelines.org/full-report/management-acute-hcv-infection. Accessed April 22, 2018. Evaluation and Treatment of Possible Non-Occupational Exposures to HIV Adapted from CDC. Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States, 2016. Available at <a href="http://www.cdc.gov/hiv/pdf/program/esources/cdc-hiv-npep-guidelines.pdf">http://www.cdc.gov/hiv/pdf/program/esources/cdc-hiv-npep-guidelines.pdf</a>. Accessed April 22, 2018. Substantial Risk for HIV Acquisition **Negligible Risk for HIV Acquisition** Exposure of Exposure of vagina, rectum, eye, mouth, or other mucous membrane, nonintact skin, or percutaneous contact vagina, rectum, eve, mouth, or other mucous membrane intact or, nonintact skin, or percutaneous contact With <u>With</u> blood, semen, vaginal or rectal secretions, breast milk, or any body fluid visibly contaminated with blood urine, nasal secretions, saliva, sweat, or tears without visible blood **Regardless** of known or suspected HIV status of source ≤ 72 hours since exposure  $\geq$  73 hours since exposure Source known to be HIV-infected Unknown HIV Status of Source nPEP Recommended Case-by-case evaluation for nPEP. Consider expert consultation. nPEP Not Recommended Clinicians can contact the Clinician Consultation Center at 888.448.4911. Go to nccc.ucsf.edu/clinician-consultation/post-exposure-prophylaxis-pep/ Evaluate all pts with possible non-occupational HIV exposure for PrEP to start after nPEP course completion for more information Evaluation and Treatment of Possible Occupational Exposure to HIV The Society for Healthcare Epidemiology of America. Updated US Public Health Service Guidelines for the Management of Occupational Exposures to Human Immunodeficiency Virus and Recommendations for Postexposure Prophylaxis. Infection Control and Hospital Epidemiology, 2013; 34(9) 875-892. Available at http://www.jstor.org/stable/10.1086/672271. Accessed April 22, 2018 Step 2: Determine the HIV Status of the Source Step 1: Evaluation of Exposure Is the source material blood, bloody fluid, other potentially infectious material What is the HIV status of the exposure source? (OPIM), or an instrument contaminated with one of these substances? (OPIM = semen, vaginal secretions; cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids; or tis **HIV-Negative** HIV-Positive Status Unknown Source Unknown No oPEP needed Yes No No oPEF oPEP Determine HIV status of oPEP generally source to guide oPEP but needed recommended not warranted<sup>1</sup> What type of exposure has occurred? do not delay starting oPEP<sup>9</sup> Mucous membrane, nonintact skin<sup>3</sup> Intact skin only or percutaneous exposure 8. Skin integrity is considered compromised if there is evidence of chapped skin, dermatitis, abrasion, or open wound. 9. Do not delay giving oPEP while awaiting test results. If source is determined to be HIV-negative, oPEP can be discontinued. Assessment of whether a source pt is in the window period between infection and positive HIV oPEP recommended depending on No oPEP needed ntibody, is not necessary unless acute retroviral syndrome is clinically suspected. source HIV status 10. Consider oPEP where exposure to HIV-infected person likely. Preferred HIV Post-Exposure Prophylaxis Regimens for Healthy Adults and Adolescents (All regimens are for 28 days [4 weeks]) (See the Guidelines listed below for persons with decreased renal function, pregnant women, and children.) Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis, (September 2013) at http://www.jstor.org/stable/10.1086/672271, the New York State Department of Health AIDS Institute occupational post-exposure prophylaxis guidelines (October 2014) at <a href="http://www.hivguidelines.org/pep-for-hiv-prevention/">http://www.hivguidelines.org/pep-for-hiv-prevention/</a>, and CDC. Updated Guidelines for Antiretroviral Postexposure to HIV—United States, 2016. Available at <a href="http://www.cdc.gov/hiv/pdf/programmesources/cdc-hiv-npep-guidelines.pdf">http://www.cdc.gov/hiv/pdf/programmesources/cdc-hiv-npep-guidelines.pdf</a>. Available at <a href="http://www.cdc.gov/hiv/pdf/ All accessed April 22, 2018. Note: If the source is known to be infected with HIV, the healthcare provider to guide the choice of nPEP medications. The clinician is encouraged to consult an expert in PEP management when choosing a regimen for an exposed pregnant women or in cases of exposures to virus known or suspected to be resistant to one or more antiretroviral agents. The Clinician Consultation Center provides timely answers for urgent exposure management and PEP. Visit <a href="http://nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis/">http://nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis/</a> for more information. See the online PEP Quick Guide (<a href="http://nccc.ucsf.edu/clinician-resources/pep-resources/pep-quick-guide/">http://nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis/</a> for more information. See the online PEP Quick Guide (<a href="http://nccc.ucsf.edu/clinician-resources/pep-resources/pep-quick-guide/">http://nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis/</a> for more information. See the online PEP Quick Guide (<a href="http://nccc.ucsf.edu/clinician-resources/pep-resources/pep-quick-guide/">http://nccc.ucsf.edu/clinician-consultation/pep-quick-guide/</a>) for urgent PEP decision making. PREFERRED oPEP REGIMENS ALTERNATIVE oPEP REGIMENS Tenofovir disoproxil fumarate/Emtricitabine 300/200 mg (Truvada®) po once daily PLUS [raltegravir (Isentress®) 400 mg po twice daily OR For alternative oPEP regimens see New York State Department of Health AIDS Institute occupational post-exposure prophylaxis guidelines dolutegravir (Tivicay<sup>®</sup>) 50 mg po once daily]<sup>11</sup> (October 2014) at http://www.hivguidelines.org/pep-for-hiv-prevention/occupational/#tab\_6 PREFERRED nPEP REGIMEN ALTERNATIVE nPEP REGIMENS Tenofovir disoproxil fumarate/Emtricitabine 300/200 mg (Truvada®) po once daily PLUS [raltegravir (Isentress®) 400 mg po twice daily OR For alternative nPEP regimens see CDC. Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States, 2016. Available at http://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf. dolutegravir (Tivicay®) 50 mg po once daily] NOTE: Some pharmacies may not "break" their bottles of ARVs which typically come in a 30-day supply. Consider ordering a complete 30-day supply to assure PEP is started in a timely manner. . USPHS Guidelines list only the raltegravir regimen as preferred for oPEF Preferred Antiretrovirals Recommended for oPEP and nPEP (Dosage Forms and Important Points) **Recommended Schedule of Laboratory Evaluations for Source and Exposed Persons** Refer to Appendix B of the Adult/Adolescent Antiretroviral Guidelines for a complete and updated source for antiretroviral medications to include: dosing, renal or hepatic Adapted from 1. CDC. Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States, 2016.

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for Healthcare Epidemiology of America. Updated US Public Health Service Guidelines for the Management of Occupational Exposures to Human Immunodeficiency Virus and Recommendations for Postexposure Prophylaxis. Infection Control and Hospital Epidemiology, 2013; 34(9) 875-892. Available at http://www.jstor.org/stable/10.1086/672271. 4. CDC. Information for Healthcare Personnel Potentially Exposed to Hepatitis C Virus (HCV): Recommended Testing and Follow-up. November 2016. Available online at https://www.cdc.gov/hepatitis/pdfs/testing-followup-exposed-hc-personnel-3d.pdf.

Available at http://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf. 2. CDC. Updated U.S. Public Health Service Guidelines for the Management of Occupational

Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. MMWR, 2001;50(RR-11): 1-53. Available at www.cdc.gov/mmwr/pdf/rr/rr5011.pdf. 3. The Society

#### All accessed April 22, 2018.

Note: See sections on HBV, HCV, and HIV of this resource for additional details including PEP

Source		
Baseline       HIV Ag/Ab <sup>12</sup> , hepatitis B serology <sup>13</sup> , hepatitis C antibody <sup>14</sup> (for sexual exposures also test for gonorrhea/chlamydia <sup>15, 16</sup> , syphilis <sup>16</sup> )		
Exposed Persons		
Baseline	HIV Ag/Ab <sup>12</sup> , hepatitis B serology <sup>13</sup> , hepatitis C antibody <sup>17</sup> , pregnancy test <sup>18</sup> , serum creatinine <sup>19</sup> , AST/ALT <sup>19</sup> (for sexual exposures also test for gonorrhea/chamydia <sup>15, 16</sup> and syphilis <sup>16</sup> )	
4-6 weeks	HIV Ag/Ab <sup>12</sup> , pregnancy test <sup>18</sup> , serum creatinine <sup>19</sup> , AST/ALT <sup>19</sup> , hepatitis C RNA <sup>20</sup> (for sexual exposures also test for gonorrhea/chamydia <sup>15, 16, 21</sup> and syphilis <sup>16</sup> )	
3 months	HIV Ag/Ab <sup>11</sup>	
6 months	HIV Ag/Ab test <sup>11,22</sup> , hepatitis B serology <sup>13, 23</sup> (for sexual exposure also obtain syphilis serology if indicated <sup>16,24</sup> )	

12. Ag/Ab test preferred, antibody test can be used if Ag/Ab test not available; use of oral test is not recommended. If using Ag/Ab test, can consider discontinuing HIV testing at 3-4 months. Obtain HIV viral load and HIV genotype if determined to have HIV infection at any visit. Follow-up HIV testing should be done even if the exposed person declines PEP.

13. Hepatitis B serology: HBsAg, quantitative HBsAb, HBcAb Total or 1gG. Occupational exposure guidelines recommend only HBsAg testing in the source and all serologies listed for the exposed person.

14. If source is IDU or is immunocompromised, consider adding HCV viral load testing

15. Nucleic acid amplification test (NAAT) recommended. Men reporting insertive vaginal, anal, or oral sex (urine specimen), women reporting receptive vaginal sex (vaginal [preferred] or endocervical swab or urine specimen), men and women reporting receptive anal sex (rectal swab), men and women reporting receptive oral sex (oropharyngeal swab for gonorrhea) 16. See the <u>Sexually Transmitted Diseases Guidelines, 2015</u> from the CDC for recommendations for treatment and follow-up if any STI is diagnosed.

17. If positive, reflex to HCV RNA viral load. If viral load positive, refer to care for pre-existing chronic HCV infection.

18. Woman of reproductive age, not using effective contraception, with vaginal exposure to semen

19. If prescribed PEP, oPEP guidelines recommend repeating at 2 weeks and also recommend CBC even though current preferred oPEP regimens are not associated with hematologic toxicity. Further testing may be indicated if abnormalities are detected.

20. If positive, refer to care for Hepatitis C infection. If unable to do HCV RNA, check Hepatitis C antibody with reflex to HCV RNA at 6 months.

21. If not provided presumptive treatment at baseline or if symptomatic at follow-up visit

22. Delayed HIV seroconversion has been seen in persons who simultaneously acquire HIV and HCV infection. The oPEP guidelines recommend HCP undergo repeat HIV AG/AB testing at 12 months.

23. If susceptible to HBV at baseline. See Post-Exposure Prophylaxis for HBV section for testing following vaccination

24. If determined to be infected with syphilis and treated, should undergo serologic syphilis testing 6 months and 12 months after treatment. See the Sexually Transmitted Diseases Guidelines, 2015 from the CDC.

DRUG	USUAL ADULT DOSAGE FORMS	IMPORTANT POINTS
Dolutegravir (DTG, Tivicay®)	50 mg tab	<ul> <li>Take with or without food</li> <li>Take 2 hrs before or 6 hrs after certain medications (e.g. cation-containing antacids or laxatives, sucralfate, oral iron or calcium supplements, multivitamins with minerals) containing polyvalent cations (e.g. Mg, Al, Fe, Ca). DTG may be taken with calcium or iron supplements if taken together with food.</li> <li>Adverse Effects: headache and insomnia most common. Hypersensitivity reaction including rash, constitutional symptoms and organ dysfunction (e.g. liver injury) have been reported.</li> </ul>
Emtricitabine (FTC, Emtriva®)	200 mg cap, 10 mg/mL oral solution (soln)	<ul> <li>Take with or without food</li> <li>Abrupt withdrawal can cause chronic active HBV flares</li> <li>Adverse effects: generally well-tolerated, ↑ pigmentation of palms/soles (&gt; in black and Hispanic pts)</li> </ul>
Raltegravir (RAL, Isentress®)	400 mg tab, 100 mg chewable tabs	<ul> <li>Take with or without food</li> <li>Avoid Al or Mg-containing antacids. No separation needed when given with CaCO<sup>3</sup> antacids. Take 2 hrs before or 6 hrs after other medications (e.g., cation-containing antacids or laxatives, sucralfate, oral iron or calcium supplements, multivitamins with minerals) containing polyvalent cations (e.g. Mg, Al, Fe, Ca).</li> <li>Adverse effects: diarrhea, nausea, headache, and pyrexia; ↑ ALT, AST, creatine phosphokinase; myopathy and rhabdomyolysis have been reported, rare severe skin reactions (SJS/TEN) and systemic hypersensitivity reaction with rash, and constitutional symptoms +/- hepatitis</li> </ul>
Tenofovir disoproxil fumarate (TDF, Viread®)	300 tab, 40 mg/1g oral powder	<ul> <li>Take tabs with or without food; take powder with food</li> <li>Abrupt withdrawal can cause chronic active HBV flares</li> <li>Do not use for PEP in pts with estimated CrCL &lt; 60 mL/min</li> <li>Adverse effects: flatulence, headache, renal insufficiency, Fanconi Syndrome (rare), ↓ PO<sub>4</sub></li> </ul>
Tenofovir disoproxil fumarate/Emtricitabine (TDF/FTC, Truvada®)	TDF 300mg / FTC 200 mg tab	See individual components

insufficiency dosage adjustments, side effects, drug interactions, and warnings/contraindications.

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