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www.seaetc.com

SEAETC

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.

Alabama	Florida
Georgia	Kentucky
Mississippi	North Carolina
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National 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 11 am - 6 pm EST, Monday - Friday

Post-Exposure Prophylaxis 888.448.4911

Timely answers for urgent exposure management Call 9 am - 9 pm 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

HIV/AIDS Management 800.933.3413

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

National Resource Center

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An up-to-date and downloadable PDF file is available online at www.SEAETC.com.

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

-DA 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 products.

www.apregistry.com

800.258.4263

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

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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-sexual-
- assault National Sexual Assault Online Hotline 1.800.656.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.

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:

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

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

ence 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 field, clinicians are encouraged to consult with their local experts or research the literature for the most up-to-date information to assist with individual treatment decisions for their patient. If your patient should experience a serious adverse event, please report the event to the FDA (www.fda.gov/Safety/MedWatch/HowToReport/default.htm) to help increase patient safety.

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SPECIAL THANKS TO:

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 - 2014. Available at www.cdc.gov/hiv/pdf/PrEPguid CDC and DHHS. U.S. Public Health Service. Clinical Providers' Supplement: Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States - 2014. Available at <u>www.cdc.gov/hiv/pdf/PrEPProviderSupplement2014.pdf</u>. Both accessed April 12, 2017.

BEFORE INITIATING PrEP

Recommendations for PrEP

- PrEP is recommended for men who have sex with men (MSM), intravenous drug users (IDUs) and heterosexual 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):
- Any sex in past 6 months
- Not in a mutually monogamous partnership with a recently tested HIV-negative partner AND ≥ 1 of the following:
- Ongoing sex with HIV-positive partner or
- Any STI diagnosed or reported in past 6 months or
- High number of different 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:

- Sharing of injection or drug preparation equipment in the past 6 months or in a methadone, buprenorphine, or suboxone tx program in the past 6 months 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 antibody test 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 an HIV-infected person in the last 30 days and/or ongoing injection drug use. Delay initiating PrEP until pt is confirmed to be HIV-negative.
- See Figure on Documenting HIV Status in the PrEP Guidelines available at http://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf
- Assess for pregnancy or breastfeeding and discuss pregnancy plans so that an informed decision can be made regarding risks/benefits of PrEP exposure. Provide contraception if pregnancy is not desired while on PrEP.
- Confirm that pt is at substantial, ongoing, high risk for acquiring HIV infection

Provide pt with a medication fact sheet listing dosing instructions and side effects

Consider using TDF/FTC for both tx of active hepatitis B infection and HIV prevention

Review important prescribing considerations

Make sure pt has a follow up appointment

registry (www.apregistry.com)

chlamydia) without regard to symptoms.

- A sexual history is recommended for all pts. If sexual partner(s) are known HIV-positive, assess if they are in care and on antiretroviral (ARV) therapy and assist 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

uninfected

Accessed April 12, 2017.

PrEP use.

- Screen for hepatitis B infection; 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 sexually transmitted infections (syphilis serology and gonorrhea and chlamydia testing at all sites of exposure) and tx if
- 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 breastfeeding¹

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

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.

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-

. 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.

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

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

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

Document negative pregnancy test; if pregnant, discuss ongoing PrEP with pt and prenatal care provider and report exposure to antiretroviral pregnancy

STI symptoms assessment and testing and tx as indicated at each follow-up visit; at 6 month intervals screen for bacterial STIs (syphilis, gonorrhea and

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

ON DISCONTINUING PrEP

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

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

Assess side effects, adherence and HIV acquisition risk behaviors. Consider more frequent follow-up visits if inconsistent adherence is identified

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.

Assess pregnancy intent and perform pregnancy test. Assure the pt has been informed about the benefits and risk of use should pregnancy occur

2. Gilead Sciences, Inc. TRUVADA* for a Pre-exposure Prophylaxis (PrEP) Indication: Risk Evaluation and Mitigation Strategy (REMS). March 2016. Available at <u>www.truvadapreprems.com</u>. Accessed: April 12, 2017. 3. Gilead Sciences, Inc. Agreement Form for Initiating TRUVADA* for Pre-exposure Prophylaxis (PrEP) March 2016. Available at <u>www.truvadapreprems.com/Content/pdf/Agreement_Form.pdf</u>. Accessed: April 12, 2017.

Pts taking PrEP should be informed of side effects of these medications and possible signs and symptoms requiring urgent medical evaluation

Review "Agreement Form for Initiating TRUVADA® for Pre-Exposure Prophylaxis (PrEP) of Sexually Acquired HIV-1 Infection" with your pt³

Prescribe Truvada® (300 mg tenofovir [TDF]/200 mg emtricitabine [FTC]) po once daily and educate pt on proper use of medication

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

Document negative (blood or serum) HIV antibody test or fourth generation antigen/antibody test

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

Perform blood (or serum) HIV antibody test or fourth generation HIV antigen/antibody test

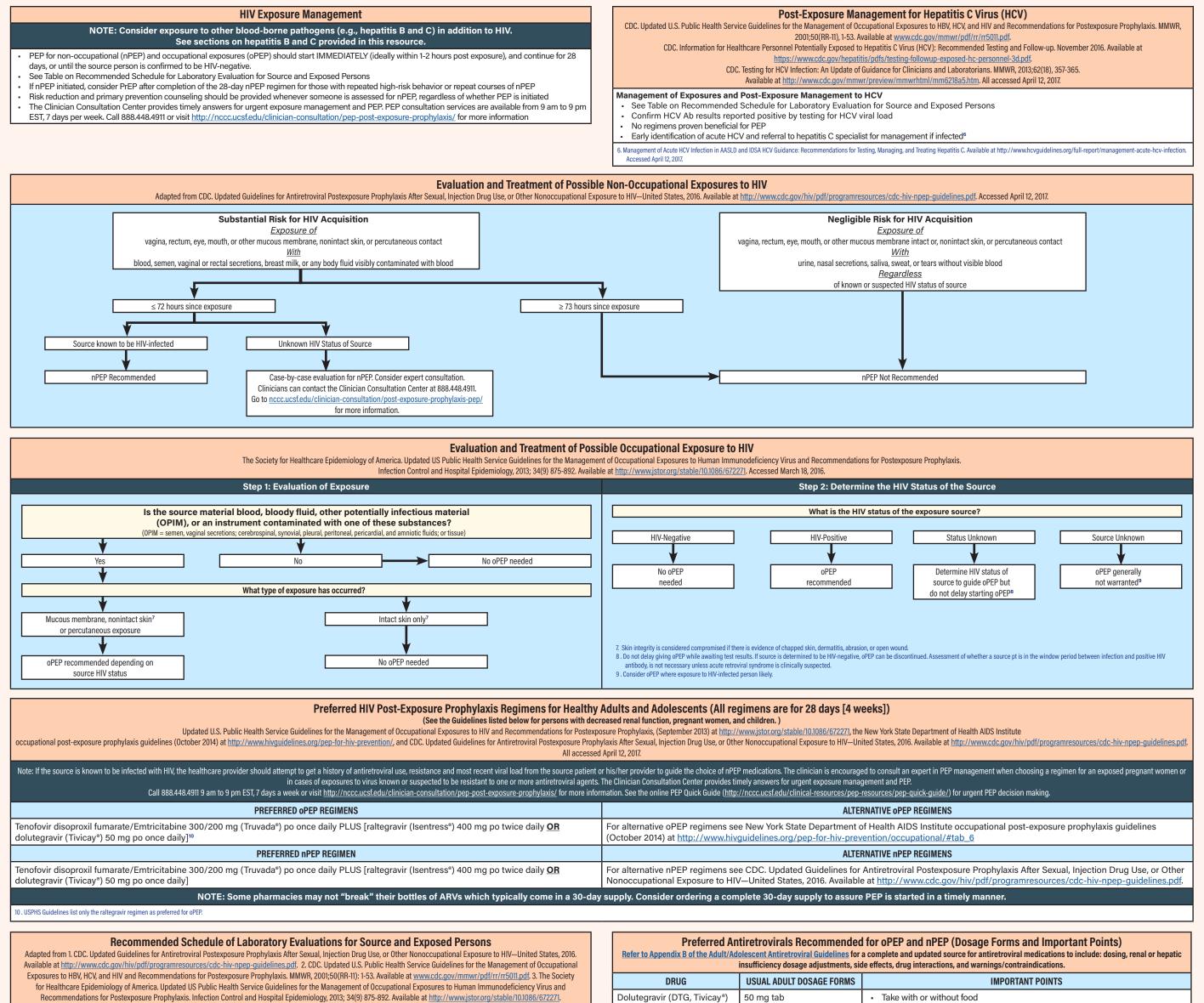
At least every 12 months, evaluate the need to continue PrEP as a component of HIV prevention

Colorado AIDS Education and Training Center for medication images (images are not actual size and colors may vary) and <u>www.poz.com</u> for phonetic pronunciations.

If HIV-negative, assure continued risk-reduction support services as indicated If active hepatitis B is diagnosed, assure continued hepatitis B tx If pregnant, inform prenatal care provider of TDF/FTC use in early pregnancy

If HIV-positive, baseline HIV genotype and linkage to care

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. 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. Updated U.S. Public 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/pdf/rr/rr5011.pdf . Both accessed April 12, 2017.				
 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)⁴ 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 ⁵	Revaccinate⁵		
(HBsAb < 10 mlU/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 (HBsAb response unknown)	Test exposed person for HBsAb. If HBsAb \geq 10 mIU/mL, no PEP necessary.	No PEP		
	Test exposed person for HBsAb. If HBsAb < 10 mIU/mL, administer HBIG x 1 and revaccinate. ⁵	Revaccinate⁵		
4. Filippelli M, Lionetti E, Gennaro A, et al. Hepatitis B vaccine by intradermal route in non responder pat 5. Give vaccine booster dose; check antibody response (HBsAb quantitative) 1-2 months later; give addi	atients: An update. World J Gastroenterol 2014; 20(30): 10383-10394. Available at http://www.wjgnet.com/1007-9327/full/v20/i30/10383.htm. ditional 2 doses (for total of 6 doses) if HBsAb remains < 10 mIU/mL and repeat HBsAb 1-2 months later.			



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

Take 2 hrs before or 6 hrs after certain medications (e.g. cation-containing

https://www.cdc.gov/hepatitis/pdfs/testing-followup-exposed-hc-personnel-3d.pdf. All accessed March 3, 2017.				
Note: See sections on HBV, HCV, and HIV of this resource for additional details including PEP				
Source				
HIV Ag/Ab ¹¹ , hepatitis B serology ¹² , hepatitis C antibody ¹³ (for sexual exposures also test for gonorrhea/chlamydia ^{14,15} , syphilis ¹⁵)				
Exposed Persons				
HIV Ag/Ab ¹¹ , hepatitis B serology ¹² , hepatitis C antibody ¹⁶ , pregnancy test ¹⁷ , serum creatinine ¹⁸ , AST/ALT ¹⁸ (for sexual exposures also test for gonorrhea/chamydia ^{14,15} and syphilis ¹⁵)				
HIV Ag/Ab ¹¹ , pregnancy test ¹⁷ , serum creatinine ¹⁸ , AST/ALT ¹⁸ , hepatitis C RNA ¹⁹ (for sexual exposures also test for gonorrhea/chamydia ^{14,15,20} and syphilis ¹⁵)				
HIV Ag/Ab ¹¹				
HIV Ag/Ab test ^{11,21} , hepatitis B serology ^{12,22} (for sexual exposure also obtain syphilis serology if indicated ^{15,23})				

determined to have HIV infection at any visit. Follow-up HIV testing should be done even if the exposed person declines PEP.

- 12. 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. 13. If source is IDU or is immunocompromised, consider adding HCV viral load testing
- 14. 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) 15. See the <u>Sexually Transmitted Diseases Guidelines, 2015</u> from the CDC for recommendations for treatment and follow-up if any STI is diagnosed.
- 16. If positive, reflex to HCV RNA viral load. If viral load positive, refer to care for pre-existing chronic HCV infection.
- 17 Woman of reproductive age, not using effective contraception, with vaginal exposure to semen
- 18. 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.
- 19. 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.
- 20. If not provided presumptive treatment at baseline or if symptomatic at follow-up visit
- 21. 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.
- 22. If susceptible to HBV at baseline. See Post-Exposure Prophylaxis for HBV section for testing following vaccination
- 23. 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.

		 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. Adverse Effects: headache and insomnia most common. Hypersensitivity reaction including rash, constitutional symptoms and organ dysfunction (e.g. liver injury) have been reported.
Emtricitabine (FTC, Emtriva®)	200 mg cap, 10 mg/mL oral solution (soln)	 Take with or without food Abrupt withdrawal can cause chronic active HBV flares Adverse effects: generally well-tolerated, ↑ pigmentation of palms/soles (> in black and Hispanic pts)
Raltegravir (RAL, Isentress®)	400 mg tab, 100 mg chewable tabs	 Take with or without food Avoid AI or Mg-containing antacids. No separation needed when given with CaCO³ 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, AI, Fe, Ca). 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
Tenofovir disoproxil fumarate (TDF, Viread®)	300 tab, 40 mg/1g oral powder	 Take tabs with or without food; take powder with food Abrupt withdrawal can cause chronic active HBV flares Do not use for PEP in pts with estimated CrCL < 60 mL/min Adverse effects: flatulence, headache, renal insufficiency, Fanconi Syndrome (rare), ↓ PO₄
Tenofovir disoproxil fumarate/Emtricitabine (TDF/FTC, Truvada®)	TDF 300mg / FTC 200 mg tab	See individual components