

MASSACHUSETTS SEXUAL ASSAULT NURSE EXAMINER PROGRAM
PROTOCOL FOR ADULT/ADOLESCENT SANES

SECTION VIII

SEXUALLY TRANSMITTED INFECTIONS (STIs)

A primary concern for most patients who have experienced a sexual assault is contracting Sexually Transmitted Infections (STIs). SANES should provide anticipatory guidance and education about testing and treatment for STIs as recommended by the MA Department of Public Health (MDPH), Division of STI Prevention 2016 Sexually Transmitted Diseases Treatment Guidelines.

Patient Education

- Educate the patient about the possibility and risks of disease transmission as indicated by the specific details of the assault described by the patient.
- STI testing within 5 days of a sexual assault may be testing for exposure to an STI that occurred before the incident of the assault.
- STI testing is offered to all patients presenting post-sexual assault.
- Site-specific STI testing is recommended **ONLY** if the patient exhibits physical signs and symptoms of current infection.

STI Testing

All Patients with Mucosal Exposure to Blood/Hazardous Bodily Fluids:

- STI Testing offered
- STI Prophylaxis recommended
- Verbal patient consent should be obtained

Patient Declines Prophylaxis:

- STI Testing recommended
- Verbal patient consent should be obtained

Patient with Signs and Symptoms of Genital Infection:

Management to be discussed with ED physician; consider all STI testing suggested below as well as other testing deemed necessary.

Lab Testing Recommended if STI Prophylaxis (including HIV nPEP) Declined:

1. Urine NAAT (First-catch)
 - Gonorrhea
 - Chlamydia
 - Trichomoniasis
2. Serology
 - HIV -1/2 antigen/antibody combination immunoassay (4th generation) testing preferred. Antibody only if antigen/antibody not available.
 - Syphilis serology (as per individual hospital protocol)
 - Hepatitis C antibody
 - Hepatitis B surface antibody

Lab Testing if nPEP is Administered:

1. Must obtain:
 - Serum creatinine
 - ALT/AST
2. Recommend:

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- HIV: 1/2 antigen/antibody combination immunoassay (4th generation) testing preferred. Antibody only if antigen/antibody not available.
 - Hep B: Surface Antigen, Surface Antibody, Core Antibody
3. Offer (in addition to above):
- Urine gonorrhea, chlamydia, and trichomoniasis (First-catch urine)
 - Hep C antibody
 - Syphilis serology

Site Specific STI Testing (Oral, Anal, Vaginal) – see Appendix 5: STI Testing Algorithm

Not recommended during acute timeframe. Discuss with ED physician if STI symptoms are present

Medication Recommendations for STI Prophylaxis

Sexual assault patients should be offered STI prophylactic medications for **Gonorrhea, Chlamydia, Trichomonas, Hepatitis B and HIV**.

- If the patient declines STI prophylaxis, the patient should be advised to obtain STI testing 2 – 6 weeks after the ED visit at a public community testing center or with their Primary Care Physician (Refer patient to MSAECK Form 6).

The SANE should ensure that the patient has been educated about STIs and prophylaxis, assessed for any allergies and has been advised of the signs and symptoms of medication side effects. The SANE should collaborate with ED physician and make recommendations for STI testing and STI prophylaxis based on the patient's assault and the associated risk factors of the assault. The SANE should communicate their recommendations to the MD provider. The physician is responsible for ordering medication(s) and the patient's primary nurse is responsible to obtain and administer the medication(s) in a timely manner. The ED staff is responsible for providing follow-up medical referrals.

The MA Department of Public Health, Division of STI Prevention Guidelines for the Treatment of Sexually Transmitted Diseases Guidelines are intended to serve as a recommendation and are not intended to be a comprehensive list of all effective treatment regimens. These medications may not be appropriate for all patients and the choice of medications may differ depending on the patient's needs. This information does not replace, and is not intended to replace, the full description of these medications. Consult with the Emergency Department Physician about indications and contraindications of these medications.

MDPH SANE Protocol for Gonorrhea, Chlamydia, and Trichomonas Prophylaxis*

- Ceftriaxone 250mg IM x 1 dose
- Azithromycin 1 gm orally x 1 dose
- Metronidazole 2mg orally x 1 dose

(See Below for Additional medication information)

Depending on the patient circumstances, prophylaxis may also include:

- Hepatitis B vaccine
- Human Papilloma Virus (HPV) vaccine
- HIV prophylaxis

*These medical regimens are standard choices but do not take in to consideration allergies, pregnancy status, or ages other than adolescents/adults. **For patient allergies or other contraindications to these medications**, please see the Massachusetts Department of Public Health Treatment Guidelines for alternatives (www.mass.gov/eohhs/docs/dph/cdc/std/ma-std-tx-guidelines-2016.pdf).

Antiemetic Medication

The combined administration of multiple STI medications may cause patients to become nauseous. The SANE and the Primary Nurse should consider the need for an antiemetic, to be provided 30 minutes prior to 1st medication administration, to minimize nausea and the risk of vomiting.

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Additional Medication Prophylaxis Information

Gonorrhea Prophylaxis

Medication: Ceftriaxone (Rocephin)
Dosage: 250 mg I.M., single dose
Indicated for Rx of: Uncomplicated Gonococcal infections at all sites (genital, anal, and pharyngeal).
Safe for: Pregnant women and adolescents
Contraindications: Allergy to penicillin/cephalosporins

AND

Medication: Azithromycin (Zithromax)
Dosage: 1 Gm, P.O., onedose
Indicated for Rx of: Uncomplicated gonococcal infections at all sites (genital, anal pharyngeal sites)
Safe for: Pregnant women and adolescents
Contraindications: Previous hypersensitivity to Azithromycin
Notes: If treating for BOTH gonorrhea and chlamydia, only one gram of azithromycin (Zithromax) is required.

Chlamydia Prophylaxis

Drug of choice where available

Medication: Azithromycin (Zithromax)
Dosage: 1 Gm, orally single dose
Indicated for Rx of: Chlamydial infection at all sites
Safe for: Adults, pregnant women, adolescents, and children at least 45kg
Contraindications: allergy to erythromycin, azithromycin, and other macrolide antibiotics
Notes: Single dosage is important for patients at risk for poor adherence to multi-dose regimens. If treating for BOTH gonorrhea and chlamydia, only one gram of azithromycin (Zithromax) is required.

Trichomoniasis Prophylaxis

Medication: Metronidazole (Flagyl)
Dosage: 2 Gm, orally single dose
Indicated for Rx of: Trichomoniasis
Safe for: Adults, pregnant women and adolescents
Contraindications: Allergy to metronidazole

**METRONIDAZOLE HAS AN ANTABUSE EFFECT.
DO NOT ADMINISTER IF PATIENT HAS CONSUMED ALCOHOL!
COUNSEL THE PATIENT NOT TO CONSUME ALCOHOL DURING TREATMENT.**

Hepatitis B Prophylaxis

For Ages 11-19

Medication: Hepatitis B Vaccine [Engerix Bor Recombivax]
Adolescents Engerix B: 10 mcg/0.5 mL IM
OR
Recombivax: 5 mcg/0.5 mL IM

Adults over age 19

Engerix B: 20 mcg/1 mL IM OR
Recombivax: 10 mcg/1 mL IM
Indicated for Rx of: Hepatitis B prophylaxis after potential exposure d/t sexual assault
Safe for: Adults and children

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Contraindications: Allergy to yeast (very rare)

Notes: Administer if the patient is known not to be immune or if the patient's status is unknown; patients should be informed of the need for follow-up for completion of the vaccination series for Hepatitis B immunization

For full treat guidelines please see link:

www.mass.gov/eohhs/docs/dph/cdc/std/ma-std-tx-guidelines-2016.pdf

HUMAN IMMUNODEFICIENCY VIRUS (HIV)

Sexual assault patients often have concern about their risk of contracting HIV from the assault. SANES/clinicians should provide patients with information to help them make informed choices regarding HIV prophylaxis and testing. All patients presenting within 5 days following a sexual assault should be offered **prompt** HIV/ STI testing and prophylaxis.

Patient Education

- In collaboration with ED Provider, inform patient about estimated risk for acquiring HIV from an infected source (See Table 1 below).
- Provide patient with information so that they may make an informed choice about HIV testing and prophylaxis in the ED.
- Explain that the seroconversion period (the time it takes a person to develop HIV antibodies that may show up on an HIV test after exposure to HIV) varies from person to person:
 - Some people seroconvert as early as one to three weeks after exposure, with greater than 80% of the infected individuals testing positive for HIV antibodies by six weeks.
 - It could take as long as six months for seroconversion to occur in some people. Therefore, patients should be informed that the results of HIV testing in the ED indicate the **baseline** status of HIV infection, **not** the HIV status resulting from the sexual assault.

Risk of Seroconversion

Table 1. Estimated per-act risk for acquiring human immunodeficiency virus (HIV) from an infected source, by exposure act*	
Exposure type	Rate for HIV acquisition per 10,000 exposures
<u>Parenteral</u>	
Blood transfusion	9,250
Needle sharing during injection drug use	63
Percutaneous (needle stick)	23
<u>Sexual</u>	
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
<u>Other**</u>	
Biting	Negligible

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Spitting	Negligible
Throwing body fluids (including semen or saliva)	Negligible
Sharing sex toys	Negligible
<p>* Factors that may increase the risk of HIV transmission include sexually transmitted diseases, acute and late-stage HIV infection, and high viral load. Factors that may decrease the risk include condom use, male circumcision, antiretroviral treatment, and pre-exposure prophylaxis. None of these factors are accounted for in the estimates presented in the table.</p> <p>** HIV transmission through these exposure routes is technically possible but unlikely and not well documented.</p>	

Limits of Confidentiality

The limits of confidentiality of the HIV antibody test must also be discussed before the patient chooses to be tested in the ED setting. Patients should be informed the results of HIV testing in the ED indicate the **present** status of HIV infection, **not** the HIV status resulting from the sexual assault. Although conducted in a “confidential manner” according to hospital procedures, the results of the HIV test becomes a part of the medical record and may be subpoenaed in court proceedings.

The MDPH **strongly recommends** that patients receive pre-test and post-test education and counseling.

Additional Information Regarding ED-based HIV Testing

1. For all patients tested for HIV in a hospital: the hospital is responsible for compliance with Mass. General Laws c. 111, §70F and related policies in obtaining informed patient consent for HIV testing and for providing mechanisms for appropriate counseling, follow-up, and maintenance of HIV-related information contained in their records.
2. HIV testing is offered to all patients at the time of the sexual assault examination in the ED. If HIV post-exposure prophylaxis is started, baseline testing for HIV should be performed soon after the sexual assault examination. Patients who choose not to be tested but continue to have questions about their baseline HIV status may be referred to their primary care provider or to the AIDS Action Committee at 617-437-6200 (Mon-Fri) 9 AM-5PM to obtain HIV testing any time after the ED evaluation.

HIV Testing

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 ⁱ (or antibody testing if Ag/Ab test unavailable)	✓	✓	✓	✓	✓ ⁱⁱ
Hepatitis B serology, including: hepatitis B surface antigen hepatitis B surface antibody hepatitis B core antibody	✓	✓	—	—	✓ ⁱⁱⁱ
Hepatitis C antibody test	✓	✓	—	—	✓ ^{iv}
For all persons considered for or prescribed nPEP for sexual exposure					
Syphilis serology ^v	✓	✓	✓	—	✓
Gonorrhea ^{vi}	✓	✓	✓ ^{vii}	—	—
Chlamydia ^{viii}	✓	✓	✓ ^{ix}	—	—
Pregnancy ^x	—	✓	✓	—	—

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	For persons prescribed tenofovir DF + emtricitabine + raltegravir or tenofovir DF + emtricitabine + dolutegravir			
Serum creatinine (for calculating estimated creatinine clearance)	✓	✓	—	—
Alanine transaminase, aspartate aminotransferase	✓	✓	—	—
	For all persons with HIV infection confirmed at any visit			
HIV viral load	✓	✓ ^{x1}		
HIV genotypic resistance	✓	✓ ^{x11}		

HIV Non-Occupational Post-Exposure Prophylaxis (nPEP)

MA SANE Program Protocol recommends HIV nPEP administration **for up to 72 hours** following a sexual assault for all sexual assaults with a high risk of exposure to HIV. Sexual assaults with higher risk of exposure to HIV include situations with:

- Multiple assailants
- Known HIV-infected assailant(s)
- Known ejaculate or blood exposure
- Vaginal and/or anal assault
- Any disruption in skin integrity of the vaginal, anal, or oral mucosa

The SANE should notify the ED Attending Physician of the patient's risk factors to ensure timely administration of HIV nPEP. Current data analysis indicates that HIV nPEP is **less likely** to be effective if initiated more than 72 hours after an exposure. When a patient presents within 72 hours of an exposure, the use of HIV nPEP should be **initiated promptly** for the best chance of success. The sooner HIV nPEP is initiated after an exposure, the more likely transmission will be interrupted and viral replication suppressed.

2016 CDC Guidelines: Recommended HIV nPEP Medication Regime

Table 5. Preferred and alternative antiretroviral medication 28-day regimens for nPEP^{xiii xiv}

Age group	Preferred/ Alternative	Medication
Adults and adolescents aged ≥ 13 years including pregnant women with normal renal function (creatinine clearance ≥ 60mL/min)	Preferred	A 3-drug regimen consisting of: tenofovir DF 300mg and fixed dose combination emtricitabine 200mg (Truvada [®]) once daily with raltegravir 400mg twice daily or dolutegravir 50mg once daily
	Alternative	A 3-drug regimen consisting of: tenofovir DF 300mg and fixed dose combination emtricitabine 200mg (Truvada) once daily with darunavir 800mg (as 2, 400mg tablets) once daily and ritonavir ^{xvi} 100mg once daily
Adults and adolescents aged ≥ 13 years with renal dysfunction (creatinine clearance ≤ 59mL/min)	Preferred	A 3-drug regimen consisting of: zidovudine and lamivudine with both doses adjusted to degree or renal function with raltegravir 400mg twice daily

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		or dolutegravir 50mg once daily
	Alternative	A 3-drug regimen consisting of: zidovudine and lamivudine with both doses adjusted to degree or renal function with darunavir 800mg (as 2, 400mg tablets) once daily and ritonavir 100mg once daily
Children aged 2-12 years	Preferred	A 3-drug regimen consisting of: tenofovir DF, emtricitabine, and raltegravir with each drug dosed to age and weight
	Alternative	A 3-drug regimen consisting of: zidovudine and lamivudine with raltegravir and lopinavir/ritonavir with raltegravir and lopinavir/ritonavir dosed to age and weight
	Alternative	A 3-drug regimen consisting of: tenofovir DF and emtricitabine and lopinavir/ritonavir with each drug dosed to age and weight
Children aged 3-12 years	Alternative	A 3-drug regimen consisting of: tenofovir DF and emtricitabine and darunavir ^{xvii} /ritonavir with each drug dosed to age and weight
Age group	Preferred/ Alternative	Medication
Children aged 4 weeks ^{xviii} —<2 years	Preferred	A 3-drug regimen consisting of: Zidovudine oral solution and lamivudine oral solution with raltegravir or lopinavir/ritonavir oral solution (Kaletra ^{ix}) with each drug dosed to age and weight
	Alternative	A 3-drug regimen consisting of: Zidovudine oral solution and emtricitabine oral solution with raltegravir or lopinavir/ritonavir oral solution (Kaletra) with each drug adjusted to age and weight
Children aged birth-27 days	Consult a pediatric HIV-specialist	

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Follow-up Care

Concern about possible HIV infection as a result of sexual assault is common. Ideally, follow-up care—including HIV counseling and additional testing—is best done in the supportive, on-going relationship of the primary care provider. However, reluctance to disclose a sexual assault to the primary care provider may prevent this continuity of care. Therefore, options for confidential or anonymous HIV testing should be offered. The SANE/ED Clinician should be aware of confidential or anonymous HIV testing resources for survivors of sexual assault, available within the community and through the hospital. The following options for HIV testing can be provided as needed to the patient prior to discharge:

1. HIV and STI testing is provided at most private Physician's offices, community health centers, family planning agencies, and hospitals.
2. Local Sexual Assault Prevention and Survivor Services Programs generally can provide free sexual assault crisis counseling and referral to local HIV testing, counseling and treatment services.
3. The MDPH Office of HIV/AIDS funds numerous HIV Counseling, Testing, and Referral (CTR) sites throughout the state.
4. The MDPH and AIDS Action sponsor a website, <http://www.aac.org/> which gives HIV/STI/STI test site information and other resources in Massachusetts.
5. The hospital system may have other available services for HIV counseling as well as referral sources to meet the needs of the sexual assault patient.

Also, aftercare forms containing the names of ED providers, primary care or clinic networks, AIDS Action Hotline number, local Sexual Assault Prevention and Survivor Service Programs and Family Planning Clinic numbers will be provided.

Follow up HIV and STI testing should be encouraged at approximately 6 weeks, 3 months, and 6 months after the sexual assault. Patients should be advised to use prophylactics during sexual activity pending the results of their HIV and STI tests.

MA DPH educational brochures about HIV Counseling and Testing can be found at:

<http://files.hria.org/files/HA1656.pdf>

Abbreviations: Ag/Ab, antigen/antibody combination test; HIV, human immunodeficiency virus; nPEP, nonoccupational postexposure prophylaxis; tenofovir DF, tenofovir disoproxil fumarate.

ⁱ Any positive or indeterminate HIV antibody test should undergo confirmatory testing of HIV infection status.

ⁱⁱ Only if Hepatitis C infection was acquired during the original exposure; delayed HIV seroconversion has been seen in persons who simultaneously acquire HIV and hepatitis C infection.

ⁱⁱⁱ If exposed person susceptible to hepatitis B at baseline.

^{iv} If exposed person susceptible to hepatitis C at baseline.

^v If determined to be infected with syphilis and treated, should undergo serologic syphilis testing 6 months after treatment.

^{vi} Testing for chlamydia and gonorrhea should be performed using nucleic acid amplification tests. For patients diagnosed with a chlamydia or gonorrhea infection, retesting 3 months after treatment recommended.

- For men reporting insertive vaginal, anal, or oral sex, a urine specimen should be tested for chlamydia and gonorrhea.
- For women reporting receptive vaginal sex, a vaginal (preferred) or endocervical swab or urine specimen should be tested for chlamydia and gonorrhea.
- For men and women reporting receptive anal sex, a rectal swab specimen should be tested for chlamydia and gonorrhea.
- For men and women reporting receptive oral sex, an oropharyngeal swab should be tested for gonorrhea.

www.cdc.gov/std/tg2015/tg-2015-print.pdf

^{vii} If not provided presumptive treatment at baseline, or if symptomatic at follow-up visit.

^{viii} See point f.

^{ix} See point g.

^x If a woman of reproductive age, not using effective contraception, and with vaginal exposure to semen.

^{xi} eCrCl = estimated creatinine clearance calculated by the Cockcroft-Gault formula; eCrClCG = [(140-age) x ideal body weight] ÷ (serum creatinine x 72) (x 0.85 for females).

^{xii} At first visit where determined to have HIV infection.

Abbreviations: HIV, human immunodeficiency virus; nPEP, nonoccupational postexposure prophylaxis; tenofovir DF, tenofovir disoproxil fumarate.

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^{xiii} These recommendations to not reflect current Food and Drug Administration-approved labeling for antiretroviral medications listed in this table.

^{xiv} Ritonavir is used in clinical practice as a pharmacokinetic enhancer to increase the trough concentration and prolong the half-life of darunavir, lopinavir, and other protease inhibitors. Ritonavir is not counted as a drug directly active against HIV in the above "3-drug" regimens.

^{xv} Gilead Sciences, Inc., Foster City, California.

^{xvi} See note b.

^{xvii} Darunavir only FDA-approved for use among children aged ≥ 3 years.

^{xviii} Children should have attained postnatal age of ≥ 28 days and postmenstrual age (i.e., first day of the mother's last menstrual period to birth plus the time elapsed after birth) of ≥ 42 weeks.

^{xix} AbbVie, Inc., North Chicago, Illinois.

Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, (2016). Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV — United States. 2016 nPEP Guidelines update, 1-91. Retrieved from www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf

For additional clinical consultation regarding the administration of HIV nPEP, ED clinicians may call the National Clinicians PEP line at 888-448-4911, 9am-9pm 7 days/week.