HIV PEP Guidelines after Sexual Assault

Harborview Medical Center April 2010

Initial risk assessment and discussion with patient about risk and PEP is by clinician who does exam (SANE, Ob-Gyn resident, pediatrics resident.)

ED Medicine attending meets with all patients in "Low to moderate risk" category, and with any patient in other risk categories who wishes to talk about or consider HIV PEP.

Follow-up: All patients who start PEP will have follow-up through Madison Clinic. Leave voice message with Madison Clinic PCC (744-5155) who will arrange appointment.

Medication: Patient needs 5 days of medication in hand when leaving ED. Dispense from Pyxis.

	Lowest risk HIV PEP not indicated	**Very low risk** Option of PEP should be discussed with patient by medical provider (SANE). PEP may be prescribed if patient wishes after full discussion of risks/benefits	**Low to moderate risk** Recommendation for PEP should be discussed with patient, with full discussion of risks and benefits
Risk factors of assailant		Assailant is: Man who has sex with women OR Unknown risk factors Note: man who has been in prison has same risk as general male population (1%)	Assailant is: Man known or suspected HIV positive (most important factor) Man who has sex with men (HIV prevalence 12-15%) Known IV drug use (HIV prevalence 2%)
Risk factors of contact	Prior recent unprotected sexual contact (e.g. intimate partner) No semen to mucosal or wound contact	Semen to mucosal contact, one assailant	Semen to mucosal contact, 2 or more assailants Victim is man assaulted by man Victim has grossly visible vaginal or anal tears Exposure semen to rectum Exposure blood to mucosa Exposure blood to open wound
Time since contact		**PEP must be initiated within 3 days of exposure**	
HIV PEP Regimen	PEP not indicated	**Basic regimen** Truvada x 5 days 1 tab po qd Full course is 28 days Reevaluate at Madison Clinic. Follow-up	**Basic Regimen** **Truvada x 5 days 1 tab po qd** **Expanded regimen** - primarily when assailant in high risk group (e.g. known HIV+ or MSM) Truvada x 5 days 1 tab po qd + Atazanavir 300 qd* x 5 days + Ritonavir 100 mg qd* x 5 days (see drug interactions next page) **Alternative expanded regimen** Truvada 1 tab bid + Kaletra 2 tab po bid Full course is 28 days Reevaluate at Madison Clinic follow-up
Patient Ed	Use "Information about HIV for Patients" attached Use condoms for consensual relations for 6 months		
Discussion with patient	Advise HIV serology may be obtained at f/u medical, 6 wks, 3 and 6 months	ED medicine attending meets patient to discuss PEP **if** patient is interested Advise: HIV serology should be obtained at 6 wks, 3 and 6 mo	ED Medicine Attending meets all patients in this risk category to discuss HIV PEP

If patient is appropriate candidate for medication, discuss:

□ 28 days medication course needed.

□ 5 days of medication will be provided in ED.

□ Must come to Madison Clinic appointment within 4 days for evaluation of medication and decision to complete course (see below for how to arrange appt)

□ Costs: Crime Victims Compensation may cover cost medication, but only if patient applies for CVC (to qualify pt must cooperate with law enforcement, assault must have occurred in Washington state.). Patient may qualify for charity care, or insurance may cover costs. Med should be obtained at HMC unless pt has insurance.

Baseline labs if patient starts PEP

- ✓ Pregnancy test – if positive, Truvada, Atazanavir, Ritonavir, and Kaletra are safe in pregnancy. Weigh the risks and benefits
- ✓ Urine NAAT for Chlamydia gonorrhea
- ✓ HIV serology
- ✓ CBC platelets
- ✓ Creatinine
- ✓ Liver function panel (Hepatic panel A)
- ✓ RPR

Medications

Prescribe usual post-exposure medications: Azithromycin 1 gm, Cefixime 400 mg, and Hepatitis B vaccine if not previously fully immunized. Levonorgestrel emergency contraception as indicated.

Basic regimen: Truvada 1 tablet daily (tenofovir 300 mg + emtricitabine 200 mg)

□ Generally well-tolerated

□ May cause nausea, vomiting, diarrhea, flatulence, headache, renal impairment

□ Rare but serious lactic acidosis and hepatic steatosis

✓ Safe in pregnancy (Category B)

Expanded regimen: Truvada 1 tablet daily + Atazanavir 300 mg qday + Ritonavir 100 mg qday)

□ Don't use with omeprazole, pantoprazole, lansoprazole, cisapride, or other PPI

□ Dose 12 hours apart from H2 blockers such as ranitidine

□ Don't use with midazolam, triazolam, ergots, cisapride, or pimozide St. John's Wort or lovastatin.

□ There are potential significant interactions with rifampin, lovastatin, simvastatin, fluticasone, anticonvulsants, and garlic (not a comprehensive list)

□ May cause diarrhea, nausea, vomiting

✓ Safe in pregnancy

Consult with infectious disease specialist to choose alternate meds if source patient is taking antiretroviral.

Alternative Expanded regimen: Truvada 1 tablet daily + Kaletra 2 tablets bid (lopinavir 400 mg + ritonavir 100 mg bid)

□ Don't use with midazolam, triazolam, ergots, cisapride, or pimozide St. John's Wort or lovastatin.

□ There are potential significant interactions with rifampin, lovastatin, simvastatin, fluticasone, anticonvulsants, and garlic (not a comprehensive list)

□ If using oral contraceptives, use back-up barrier birth control till 2 weeks after stopping Kaletra
□ May cause diarrhea, nausea, vomiting
✓ Safe in pregnancy

Consult with infectious disease specialist to choose alternate meds if source patient is taking antiretroviral.

Providing initial doses

□ Provide initial 5-day supply from ED Pyxis. Both basic and expanded regimen are stocked there.

Follow-up

For sexual assault patients only

□ HCSATS PCC will coordinate Madison and HCSATS follow-up visits
□ Medical follow-up will be at Madison (initially in 2-4 days, and then 2, 6, 12, and 24 weeks)
□ All patients will get social work outreach call from HCSATS
□ Counseling follow-up will be at HCSATS (if patient wishes)

Resources on drug interactions: Harborview Madison Clinic Pharmacy (206-744-5151)
http://depts.washington.edu/madclin/pharmacy/drugs/index.html, and
http://www.hiv-druginteractions.org/

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Information for Providers

Risk of Transmision

Do not over-prescribe HIV PEP

Do not prescribe PEP if blood contacted only intact skin.

Do not prescribe PEP for exposures to:

- Saliva (unless visibly bloody)
- Tears
- Feces
- Nasal secretions
- Sweat
- Vomit
- Urine

…even if these contacted mucous membrane or non-intact skin.

Do not prescribe PEP for bites, unless source person's mouth was bloody AND exposed person's skin was visibly broken.

Estimated per-act for acquisition of HIV from HIV + source, by exposure route [1]

Action	Predicted conversions per 10,000 acts	
Blood transfusion	9000	
Needle sharing	67	(0 .67 per 100 exposures with HIV+ source)
Receptive anal intercourse	50	
Needle stick	30	
Receptive penile- vaginal intercourse	10	(0.1 per 100 exposures with HIV + source)
Blood to mucous membranes	9	
Insertive anal intercourse	6.5	
Insertive penile vaginal intercourse	5	
Receptive oral intercourse	1	(.01 per 100 exposures with HIV+ source)
Man receiving oral sex	0.5	

Risk that source patient is HIV+ (for King County)

- General population: < 1%
- Incarcerated men ~ 1%
- Injection drug users 2-3%
- Men who have sex with men: 12-15%
- Man who has sex with men and and injection drug use: 25%

References

1. CDC Antiretroviral Postexposure Prophylaxis after sexual, injection-drug use, or other nonoccupational exposure to HIV in the United States. MMWR Reports and recommendations 2005; 54 (No. RR-2).
2. CDC Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures
3. to HIV and Recommendations for Postexposure Prophylaxis 2005 ; Vol. 54 (No. RR-9)
4. Garcia MT, Figueriredo RM, Moretti ML, Resende MR, Bedoni AJ, Papaiordanou. Postexposure prophylaxis after sexual assaults: a prospective cohort study. Sex Transm Dis. 2005 Apr; 32(4):214-9.
5. Wiebe ER, Comay SE, McGregor M, Ducceschi S. Offering HIV prophylaxis to people who have been sexually assaulted: 16 months' experience in a sexual assault service. CMAJ. 2000 Mar 7;162(5):641-5.

Case Examples

1. Woman assaulted by male acquaintance, risk factors of male unknown. Penile-vaginal and penile-oral contact, no condom, no visible genital anal injuries.
   Assessment: Very low risk
   Action: Option of PEP should be discussed with patient
   Who: By medical provider (SANE), ED medicine attending if patient wishes medication.
   Treatment: PEP may be prescribed if patient wishes after full discussion of risks/benefits. Basic regimen.

2. Woman assaulted by male acquaintance, risk factors of male unknown. Penile-vaginal, penile-oral, and penile-anal contact, no condom, no visible genital anal injuries.
   Assessment: Low to moderate risk.
   Action: Recommendation for PEP should be discussed with patient, with full discussion of risks and benefits.
   Who: Initial discussion by primary examiner, ED Medicine attending should meet with patient to discuss.
   Treatment: Basic regimen is appropriate, depending on clinician judgment and patient preference.

3. Woman assaulted by male acquaintance, Man thought to be an IV drug user, unknown other risk factors. Penile vaginal contact only
   Assessment: Low to moderate risk
   Action: Recommendation for PEP should be discussed with patient, with full discussion of risks and benefits.
   Who: Initial discussion by primary examiner, ED Medicine attending should meet with patient to discuss.
   Treatment: Basic regimen OR expanded regimen may be appropriate, depending on clinician judgment and patient preference.

4. Woman assaulted by 2 males 4 days prior to exam
   Assessment: outside of time frame for HIV PEP
   Action: Discuss with patient
   Who: Initial discussion by primary examiner, ED Medicine attending should meet with patient to discuss if further questions
   Treatment: No HIV PEP medication. Recommend baseline, 6 weeks 3 months and 6 month HIV serology. Baseline serology can be done at HCSATS follow-up.

4. Woman assaulted by male 24 hours ago. Penile-oral and penile-vaginal contact, condom used. Visible posterior fourchette tear.
   Assessment: Low to moderate risk
   Action: Recommendation for PEP should be discussed with patient, with full discussion of risks and benefits.
   Who: Initial discussion by primary examiner, ED Medicine attending should meet with patient to discuss.
   Treatment: Basic regimen appropriate,

5. Male assaulted by male stranger. Unknown other risk factors. Penile-oral contact only. No mouth lesions.
   Assessment: Low to moderate risk (although contact is very low risk, but assailant is likely MSM, risk of HIV in assailant is higher than average)
   Action: Recommendation for PEP should be discussed with patient, with full discussion of risks and benefits.
   Who: Initial discussion by primary examiner, ED Medicine attending should meet with patient to discuss.
   Treatment: Basic regimen OR expanded regimen may be appropriate, depending on clinician judgment and patient preference.

5. Male assaulted by male stranger. Risk factors unknown. Penile-oral and penile-anal contact.
   Assessment: Low to moderate risk.
   Action: Recommendation for PEP should be discussed with patient, with full discussion of risks and benefits.
   Who: Initial discussion by primary examiner, ED Medicine attending should meet with patient to discuss.
   Treatment: Basic regimen OR expanded regimen may be appropriate, depending on clinician judgment and patient preference.

INFORMATION ABOUT HIV FOR PATIENTS

HIV (human immunodeficiency virus) is the virus which can cause AIDS. Getting HIV is often a fear that people have after a sexual assault. For most individuals the risk of getting HIV from a sexual assault in Washington State is extremely low.

- **For women** the risk is less than 1 in 1000.
- An assailant must be infected with HIV in order to transmit it. If the assailant were HIV-infected, it is estimated that there is a less than 3% chance of transmitting it during sexual assault.
- In the Pacific Northwest, the rate of HIV infection in the male population is about 1 to 2 %. Most men who have HIV are homosexually active. The rate of HIV infection in injection drug users is 3-4%.
- Medicines are available which can decrease the risk of acquiring HIV. The medicines must be started within 72 hours of the exposure and taken for 28 days month in order to be effective. These medications can cause mild gastrointestinal symptoms (nausea, diarrhea, fatigue, and muscle aches) and are not recommended in very low risk situations.
- **For men** who have been sexually assaulted by men there is a higher, although still small chance of getting HIV. About 1 in 7 gay men in Seattle are HIV+, but the risk of HIV transmission, even without condoms is around 1%. Under these circumstances, the risks and benefits of preventive medicine should be discussed with a health care provider.

The risk of HIV infection is quite low. But this was not a risk that you chose to take.

If you wish, you can get blood testing for HIV at your follow-up appointment. A repeat test is needed 6 weeks and 3 months later in order to know for certain that you have not been infected, and a final test can be done 6 months after the assault. During this time, it is important to use condoms for all voluntary sexual relations.