Guidelines for Blood-borne Pathogen Exposure and Post-Exposure Prophylaxis at Global Health Field Sites

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Purpose

The purpose of the guidelines are to delineate recommended actions that should be taken in case of an occupational exposure of any member of the Feinberg School of Medicine to infected or potentially infected bodily fluid while at a global health field site, i.e. off-campus, non-U.S. site. The policy extends to Feinberg School of Medicine students.

The guidelines outlines the recommendations of the Feinberg School of Medicine (FSM). It does not replace individual choice. Each exposed person has the right to weigh the risks and benefits and make their own choice about when to take post-exposure prophylaxis (PEP).

Policy

All students in FSM global health programs will be provided with a copy of these guidelines and should familiarize themselves with it prior to travel so that they are prepared in case a potential exposure should occur. Exposure to blood-borne pathogens should be avoided as much as is reasonably possible, as outlined by Universal Precautions policies. See OSHA website in appendix. In the event of a potential exposure, immediate action will be taken to protect the exposed person. A copy of these guidelines will be readily available to FSM students. An exposed individual should first consult an attending physician or clinical preceptor at the host institution and contact FSM as soon as possible for further advice – please see Emergency Contacts section of this document for more details. *The guidelines supplement rather than replace FSM's current needle-stick policy and apply only to global health sites. Link to FSM's current needle-stick policy is included in appendix.*

Reduction of Risk

All FSM global health program participants, i.e. all FSM graduate students, are required to have a full course of vaccination against hepatitis B virus prior to travel. If possible, antibody titers should be obtained to prove immunity. It is recommended that all members, including faculty, residents, and clinical volunteers, be tested for HIV at least once prior to travel regardless of personal risk factors. Individuals who engage in personal behaviors placing them at high-risk for HIV exposure should be tested more frequently, as needed based on risk exposure.

Background Information

Definition of Exposure

Occupational exposure is defined as any contact with an infectious body fluid as a result of an injury with a needle or any other sharp instrument, via mucous membranes or an existing cutaneous condition (wound, eczema, scratch, etc.). Non-occupational exposures to infectious body fluid may also occur, such as in the case of unprotected intercourse or blood exposure during a motor vehicle crash. A body fluid that comes from a person who carries an infection is termed infectious.

Potentially infectious body fluids include: blood, CSF, synovial fluid, pleural fluid, pericardial fluid, amniotic fluid, semen, or vaginal secretions.

Non blood borne pathogen transmitting body fluids include feces, nasal secretions, saliva, sputum, sweat, tears, urine, and vomit, as long as these are not visibly contaminated with blood.

Risk of Infection due to Exposure

People are considered to be at risk of infection from hepatitis B, hepatitis C, and HIV as the result of an occupational or non-occupational exposure.

The average risk for HIV transmission after a single percutaneous exposure to HIV-positive blood is low (see table 1) and this risk is considerably lower than that arising from hepatitis B and C viruses (100 times and 10 times less, respectively). The risk of transmission of HIV due to sexual intercourse is summarized in table 2.

There is also a risk, although a lower one, of transmission of any other infectious agent present in the blood (viruses that cause hemorrhagic fever, trypanosomiasis, etc.).

Factors of the exposure that are associated with higher risk of HIV transmission are a percutaneous injury with a needle that has been placed in a vein or artery of the source (infected) patient, a sharp that is visibly contaminated with HIV-positive blood, or an untreated source patient with primary HIV infection or end-stage HIV.

The HIV prevalence in some world regions is high. Estimates of HIV prevalence in sub-Saharan African countries range from approximately 3% to 30% depending on what population is considered. The hospitalized population is estimated to be roughly 50% HIV-infected (1). Hepatitis B and C prevalence rates are often unknown.

Definition of Post-Exposure Prophylaxis (PEP) Post-exposure prophylaxis refers to medications given to prevent infection after exposure. The prophylactic treatment(s) offer the benefit of preventing transmission, though may be associated with risk of adverse drug effects to the exposed person (see table 3). These guidelines provide a recommendation about when to take PEP and describe how PEP should be administered but does not mandate that PEP be taken when recommended, or not taken when not recommended. The exposed person must be advised of the risks and benefits and make their own decision whether or not to take PEP.

Actions to Follow in Case of an Exposure:

1. Stop what you are doing immediately and rinse/disinfect the exposed area. Percutaneous injuries should be allowed to bleed, and rinsed thoroughly in running water for five minutes. Mucous membranes including the eyes should be rinsed with saline or with water for five minutes.

2. Evaluate the type of exposure. If exposure was to potentially infectious body fluids (see above) via percutaneous injury, mucus membranes, cutaneous lesion or sexual contact then consider initiation of PEP. If exposure was to non-infectious fluids (i.e. non-bloody sputum, vomit or feces) then you do not need to take PEP.

3. Briefly evaluate the source patient. In these settings, the HIV status of patients may be unknown or recent testing unavailable at the time of exposure. If the current HIV status for the source patient is not known, have someone help you with obtaining consent from the source patient or family for immediate testing for HIV, Hepatitis B and Hepatitis C, if available.

At the time of exposure, if the patient: a) is known to be HIV infected, b) has an unknown HIV status, or c) if there is uncertainty about whether the patient could be acutely infected with HIV and in a "window" period, then ***immediately initiate HIV PEP***.

4. Initiate HIV PEP as soon as possible after the exposure. Do not delay the administration of PEP more than 2 hours post-exposure. If more than 72 hours have passed since the exposure (usually in the setting of sexual exposure), PEP may not be recommended. In this case, seek consultation with the Northwestern Infectious Diseases specialist assigned to you prior to your departure at the debriefing (see below #5).

Recommended HIV PEP regimens
The recommended regimens for HIV PEP are the following regimens for **28 days:**
Truvada® (tenofovir 300 mg/emtricitabine 200 mg) one tab PO once daily
And raltegravir 400mg po twice daily or dolutegravir 50mg po once daily
(Note: dolutegravir has been associated with possible increase in neural tube defects inpregnancy, dolutegravir 50mg once daily can be used as alternative agent to raltegravir if no concern for first term pregnancy or pregnancy in next 28 days)

Alternative options that may be found at international sites are below: (Pick one drug/drug pair from <u>each</u> bulleted section below; the regimen should contain three full-dose antiretroviral drugs. Either the brand name or generic products are acceptable):

- **(Pick one drug/drug pair):**
  Preziata® (darunavir 800mg po once daily and Norvir® (ritonavir) 100mg po once daily
  OR
  Reyataz® (atazanavir) 300 mg one tab PO daily + Norvir® (ritonavir) 100 mg one tab PO daily with food
  OR
  Kaletra® or Aluvia® (lopinavir 200 mg/ritonavir 50 mg) two tabs by mouth (PO) twice daily with food

  PLUS

- **(Pick one drug pair):**
  Combivir® (zidovudine 300 mg/lamivudine 150 mg) one tab PO twice daily
  OR
  Truvada® (tenofovir 300 mg/emtricitabine 200 mg) one tab PO once daily
  OR
  tenofovir 300 mg/lamivudine 300 mg one tab PO once daily.

Note: although other combinations of antiretroviral medications may be appropriate for PEP, nevirapine (NVP) is **contraindicated** for use as PEP and should **never** be used.

If the affiliated FSM global partner is designated in these guidelines under "HIV PEP Kit Access" as having a policy in place and HIV PEP kit available, the HIV PEP medication regimen should be obtained from the local healthcare facility or clinic. Otherwise, consult the section on "Unaffiliated FSM Partner Institutions." Exposed individuals are encouraged to assure local health care providers that all expenses for medication and lab tests will be reimbursed promptly by Northwestern University.

People taking HIV PEP may experience uncomfortable side effects and choose to discontinue before the 28 days are complete. *Discontinuation is highly discouraged* without first consulting your Infectious Diseases (ID) specialist. Many side effects can be managed symptomatically, so a person taking HIV PEP and experiencing side effects is encouraged to seek medical consultation in order to consider options before self-discontinuing HIV PEP.

5. **Alert your local direct clinical supervisor and your assigned Northwestern Infectious**

Diseases faculty specialist as soon as possible. ***Do not delay the steps listed above while waiting to contact your supervisor or faculty member.*** The Northwestern ID faculty member will initiate an incident report. If you have any medical conditions, are taking medications, if the source patient is currently on antiretrovirals, or if there are any other questions, concerns, or ambiguities that come up when considering PEP, then notify the ID faculty consultant of these issues at the initial communication. ***Do NOT delay initiation of HIV PEP while awaiting consultation and communication.***

6. You must have the following laboratory tests performed at your local healthcare facility as soon as possible after the exposure and initiation of PEP (see table 4): HIV Rapid Test, hepatitis B surface antigen, hepatitis C antibody, complete blood count, creatinine, ALT, and Urine HCG (for females only). In the event that these tests are not available, get all the testing that you can and proceed with initiation of PEP. Again, do not delay the administration of PEP more than 2 hours post-exposure while obtaining laboratory testing. If you decide not to take PEP, then you should still be evaluated and have the following laboratory testing: rapid HIV test, ALT, hepatitis C antibody, hepatitis B surface antigen, and urine HCG (for females only).

Considerations for hepatitis B PEP: At your visit to the local healthcare facility post-exposure, they will assess your need for hepatitis B PEP. You do NOT need hepatitis B PEP if you have received the HBV vaccine within the last five years AND have had antibody testing to prove response with anti-HbS level >10 IU/L. If you have ever had an antibody anti-HbS >100IU/L, then there is no need for hepatitis B PEP regardless of when the last vaccine was given. These assessments should have been performed prior to your departure by student health services. In the case that you do not fulfill the criteria above, then you should initiate hepatitis B revaccination as PEP, if available at the local healthcare facility. If you have *never* been vaccinated against hepatitis B, the vaccine should be given and the option to travel and obtain immune globulin treatment should be considered.

There is no post-exposure prophylaxis for hepatitis C, and often no readily available laboratory testing in many low resource settings. Exposed persons should seek medical attention immediately if they experience any symptoms of hepatitis. One hepatitis C antibody test should be performed at the time of exposure and six months after exposure to evaluate for hepatitis C infection, and hepatitis C viral load should be done at 6 weeks.

6. You must complete an incident report according to the policy of the training site where the incident has taken place. The ID faculty consultant to whom the exposure is reported will also fill out an incident report to be kept on file. The incident report will contain your name, the date, a narrative of the details of the exposure, the type of exposure and the source patient, and a record of whether you decided to take PEP. The case will be reviewed by clinical faculty in six months and the ultimate outcome will be recorded in the report, including any changes in the PEP plan, and final HIV and hepatitis B and C results, if you consent to providing this information. The disclosure of information about test results or the course of PEP is completely voluntary. Disclosure of this information is requested in order to help the program to assess the utility and efficacy of the PEP policy.

7. You should follow up with your local healthcare facility or your assigned faculty ID specialist for clinical visits and blood work according to the schedule in table 4. You should not engage in unprotected sex or donate blood during the first six months after exposure in order to prevent the possible spread of HIV or hepatitis B or C. If you have side effects or problems with taking PEP then immediately discuss these issues with your local clinical advisor as well as your assigned Northwestern ID faculty specialist.

HIV PEP Kit Access

Affiliated FSM Partner Institutions: Many affiliated FSM global partners have their own policies on needle stick protocol and visiting trainees should familiarize themselves with local policies and how to access the HIV PEP kit upon arrival. If trainees plan on training at rural district hospitals/clinics for an extended period of time or plan on spending time on rotations where access to the HIV PEP kit would be limited or unavailable, students should ask the attending on day one of the rotation what PEP resources are available in the case of an exposure and take proper precautions regarding occupational hazards.

Affiliated Partners that have needle-stick policies in place and offer HIV PEP Kits on-site to international students:

- Asociacion Civil Impacta Salud y Educacion - Peru
- Centro Medico Humberto Parra - Bolivia
- Charite University – Germany
- Child Family Health International – Various locations
- Clinica de Familia – Dominican Republic
- Hillside Health Care Clinic – Belize
- Karolinska Institute – Sweden
- Keio University – Japan
- Makerere University – Uganda
- Peking University – China
- Royal College of Surgeons in Ireland
- Stellenbosch University
- Tel Aviv University – Israel
- Trinity College Dublin – Ireland
- Universidad Panamericana – Mexico
- Universite Cheikh Anta Diop – Senegal
- Universite de Strasbourg – France

Short-term visits to rural community-based clinics, including but not limited to the COBES program at Makerere University, the Hope/Kid Cru program at Stellenbosch, and the social service program at Panamericana may involve visits to facilities that do not have PEP kits available. Students should be aware of the risk involved.

Unaffiliated FSM Partner Institutions: It is the responsibility of FSM students who independently identify international host-institutions to inquire prior to travel whether an HIV PEP kit is available for visiting international trainees. See the Institute for Global Health's Approval Form for Unaffiliated Sites. If students plan on visiting rural district hospitals and/or

plan on spending time on rotations where access to the PEP kit designated would be limited or unavailable, students will be traveling and training at their own risk.

Communication Protocol

FSM trainees and/or faculty who have been exposed should first consult the local attending physician and/or local medical director about PEP protocol at the local, host-institution. Next, trainees should contact FSM's emergency contacts in the Institute for Global Health as soon as they are reasonably able. ***Do NOT delay initiation of PEP while awaiting consultation and communication with FSM.***

Trainees should email ALL emergency contacts listed below after an exposure. If no local physician or medical director is available students should contact FSM faculty by email, phone and/or Skype. Trainees should schedule a consult with an FSM faculty member in the Division of Infectious Disease upon their return to FSM.

Emergency FSM Contacts

1. Dr. Shannon Galvin, Associate Professor, Division of Infectious Disease; Institute for Global Health
    - Email: s-galvin@northwestern.edu
    - Cell: 1-312-613-8161
2. Dr. Chad Achenbach, Associate Professor, Division of Infectious Disease; Institute for Global Health
    - Email: c-achenbach@northwestern.edu
    - Cell: 1-773-251-6970
    - Skype: chad.achenbach
3. Dr. Robert Murphy, Professor, Division of Infectious Disease; Institute for Global Health
    - Email: r-murphy@northwestern.edu
    - Cell: 1-312-404-1352

Students should also CC the following Deans in the office of Medical Education:

1. Dr. Susan Goldsmith, Associate Dean for Student Affairs
    - Email: s-goldsmith@northwestern.edu
2. Dr. Sandy Sanguino, Senior Associate Dean, Medical Education
    - Email: ssanguino@northwestern.edu

The exposure and subsequent lab results and treatment should be documented in an incident report (described above in Action #7) and shared with both FSM and the medical director at the host institution.

TABLES:

Table 1. Risk of transmission after occupational exposure to infected blood

Virus	Exposure Type	Risk of Infection
HIV	Percutaneous	0.3%
HIV	Mucocutaneous*	0.09%
HBV	Percutaneous	10-30%
HCV	Percutaneous	0-10%

*Exposure to mucus membranes or cutaneous cuts or abrasions

Table 2. Risk of HIV transmission after a single event of sexual activity

Exposure Type	Risk of Infection
Receptive anal intercourse	1.38%
Insertive anal intercourse	0.11%
Receptive vaginal intercourse	0.08%
Insertive vaginal intercourse	0.04%
Receptive or insertive oral sex	Low, but not zero

Table 3. Description of different forms of post-exposure prophylaxis (PEP)

Virus	PEP Options	Benefit	Risk
HIV	28 days of combination (3-drug) antiretroviral therapy	80% reduction of risk of transmission	Medication side effects depending on PEP regimen
Hepatitis B	Hepatitis B vaccine Hepatitis B immune globulin	No good data as an occupational form of PEP, but when combo given in perinatal situation, transmission from mother to child is prevented in 85-95% of cases	Allergic reaction, pain at infection site
Hepatitis C	None		

Table 4. Recommended clinic visit and laboratory monitoring follow-up after exposure.

Time since exposure	Taking PEP	Not taking PEP
Initial visit as soon as possible after exposure	Rapid HIV test, Hepatitis C antibody, Hepatitis B surface	Rapid HIV test, Hepatitis C antibody, Hepatitis B surface

	antigen, creatinine, ALT, Complete Blood Count (CBC), and urine HCG (if applicable)	antigen, ALT and urine HCG
2 weeks	Rapid HIV test, creatinine, ALT and CBC	None
6 weeks	Rapid HIV test and ALT	Rapid HIV test and ALT
12 weeks	Rapid HIV test and ALT	Rapid HIV test and ALT
6 months	Rapid HIV test, Hepatitis C antibody, Hepatitis B surface antigen and ALT	Rapid HIV test, Hepatitis C antibody, Hepatitis B surface antigen and ALT

Appendix:

1. **Occupational Safety & Health Administration Universal Precautions:**

https://www.osha.gov/SLTC/etools/hospital/hazards/univprec/univ.html

2. **Feinberg's Needle Stick policy:**

http://www.feinberg.northwestern.edu/education/current-students/policies/needle-stick.html

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