

**Webinar Public Engagement Responses to  
2014 nPEP Guidelines Recommendations, Tables and Figures**

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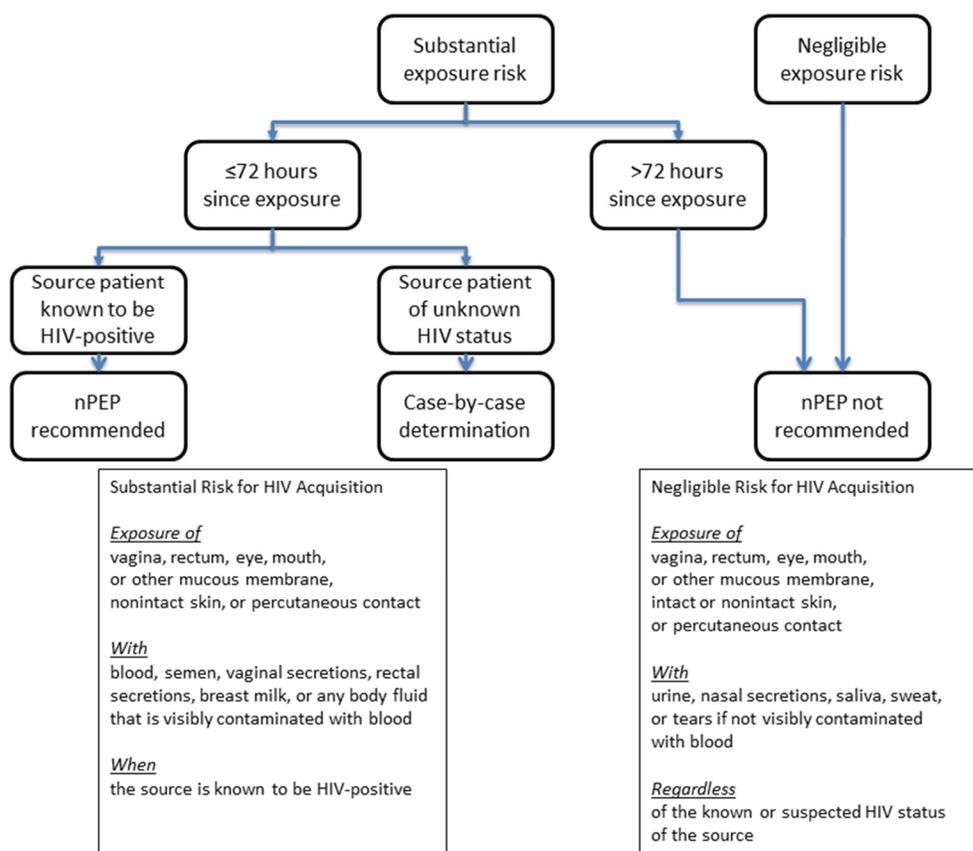
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## Draft Recommendations As Presented

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- 1) Healthcare providers should rapidly evaluate persons for nPEP when care is sought within 72 hours after a potential nonoccupational exposure that presents a substantial risk of HIV acquisition
  - a) All persons considered for nPEP should undergo HIV testing, preferably with a rapid HIV antibody test
  - b) If a rapid HIV test unavailable and nPEP indicated, nPEP should be initiated without delay and nPEP can be discontinued if the (source) patient is later determined to be HIV-uninfected
- 2) nPEP is recommended when
  - a) the source of the body fluids is known to be HIV-positive and
  - b) the reported exposure would present a substantial risk of transmission
- 3) nPEP is not recommended when the reported exposure presents no substantial risk of HIV transmission
- 4) nPEP is not recommended when care is sought more than 72 hours after potential exposure
- 5) a case-by-case determination about nPEP use is recommended when:
  - a) the HIV infection status of the source unknown and
  - b) the exposure would present a substantial risk of transmission if the source was HIV-infected
- 6) All persons offered nPEP should be prescribed a 28-day course of a three-drug antiretroviral regime
  - a) Preferred regimen for otherwise healthy adults and adolescents
    - i) tenofovir DF (300mg) with emtricitabine (200 mg) once daily plus
    - ii) raltegravir 400 mg twice daily or dolutegravir 50 mg once daily
  - b) Alternative regimen for otherwise healthy adults and adolescents
    - i) tenofovir DF (300mg) with emtricitabine (200 mg) once daily plus
    - ii) darunavir (800 mg) and ritonavir (100 mg) once daily
  - c) Regimens are also provided for children and persons with decreased renal function
  - d) Healthcare providers who plan to use other than the preferred or alternative nPEP regimens should consult an expert
- 7) All persons evaluated for possible nPEP should be provided any indicated prevention, treatment, or supportive care for other exposure-associated health risks and conditions such as
  - a) bacterial sexually transmitted infections
  - b) traumatic injuries
  - c) hepatitis, pregnancy
- 8) Provide risk-reduction counseling and intervention services to persons who report behaviors or situations that place them at risk for future HIV exposures such as
  - a) injection drug use
  - b) sex without condoms
  - c) receipt of one or more courses of nPEP

**Figure 1. Algorithm for evaluation and treatment of possible nonoccupational HIV exposures**



**Table 1. Estimated per-act risk of acquiring HIV from an infected source, by exposure act**  
(source: <http://www.cdc.gov/hiv/law/transmission.htm>)

Type of Exposure for Person Without HIV Infection	Risk of HIV acquisition per 10,000 Exposures
<b>Parenteral</b>	
Blood Transfusion	9,000
Needle-sharing during injection drug use	67
Percutaneous (needle-stick)	30
<b>Sexual</b>	
Receptive anal intercourse	50
Receptive penile-vaginal intercourse	10
Insertive anal intercourse	6.5
Insertive penile vaginal intercourse	5
Receptive oral intercourse	Low
Insertive oral intercourse	Low
<b>Other</b>	
Biting	negligible
Spitting	negligible
Throwing body fluids (including semen or saliva)	negligible

**Table 2. Recommended schedule for laboratory evaluations of source and exposed persons for providing nPEP**

		For all persons considered for or prescribed nPEP			
	Source	Exposed Persons			
Test	Baseline	Baseline	4-6 weeks after exposure	3 months after exposure	6-12 months after exposure
HIV antibody testing <sup>1</sup>	✓	✓	✓	✓	✓ <sup>8</sup>
HIV antigen testing <sup>2</sup>	-	-	✓ <sup>1</sup>	✓ <sup>1</sup>	-
Serum creatinine <sup>3</sup>	-	✓	✓	-	-
Hepatitis B serology	✓	✓	-	✓ <sup>4</sup>	-
Hepatitis C serology	✓	✓	-	✓ <sup>5</sup>	-
Syphilis serology	✓	✓	✓	-	✓
Gonorrhea <sup>6</sup>	✓	✓	✓ <sup>9</sup>	-	-
Chlamydia <sup>6</sup>	✓	✓	✓ <sup>9</sup>	-	-
Pregnancy <sup>7</sup>	-	✓	✓	-	-
HIV viral load	✓ <sup>10</sup>	✓ <sup>10</sup>	✓ <sup>10</sup>	✓ <sup>10</sup>	✓ <sup>10</sup>
HIV genotypic resistance	✓ <sup>10</sup>	✓ <sup>10</sup>	✓ <sup>10</sup>	✓ <sup>10</sup>	✓ <sup>10</sup>

- 1 Any positive or indeterminate HIV antibody test should undergo confirmatory testing of HIV infection status
- 2 If signs or symptoms consistent with acute HIV infection
- 3 If placed on tenofovir-containing preferred regimen
- 4 If exposed person susceptible to hepatitis B at baseline
- 5 If exposed person susceptible to hepatitis C at baseline
- 6 If oral or rectal sexual exposure, test for gonorrhea and chlamydia at those sites; if penile-vaginal exposure, test for gonorrhea and chlamydia at those sites
- 7 If woman of reproductive age, not using effective contraception, and with vaginal exposure to semen
- 8 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.
- 9 If not provided presumptive treatment at baseline, or if treated and symptomatic at follow-up visit
- 10 At first visit where determined to have HIV infection

**Recommendation 1-b**

Looks like you would stop nPEP if the exposed patient's baseline tests comes back negative

*We will edit the recommendation and the text to clarify that if the source person is determined to be HIV uninfected after the exposed person were started on nPEP, nPEP would be discontinued*

**Recommendation 6**

Considering referencing brand names as well as generic names

*Both brand and generic names are ncluded in drug tables in the guidelines document, but not in recommendation statements*

Discussion of atazanavir (rather than raltegravir) in pregnancy?

*Subject matter experts considered a range of option before choosing preferred regimens. No change will be made.*

**Recommendation 6a**

Did you consider Stribild as a first line agent?

*Subject matter experts considered a range of option before choosing preferred regimens. No change will be made.*

Why not Truvada alone, given its effectiveness for PrEP? Why are 3 drugs preferred?

– expert opinion, treatment potency

*Subject matter experts considered a range of option before choosing preferred regimens. No change will be made.*

**Figure 1      Algorithm for evaluation and treatment of possible nonoccupational HIV exposures**

Why doesn't the algorithm distinguish between levels of risk within routes of transmission higher (anal sex) and lower risk events

*This algorithm is streamlined to assist busy clinicians in making a rapid determination about the level of risk for a reported exposure. Table 1 and guidelines text do discuss these additional factors to be considered*

**Table 1 Estimated per-act risk of acquiring HIV from an infected source, by exposure act**

Why not distinguish between HIV+ positive source patients on ART and those not

*This additional information will be considered in the final guideline.*

What about persons on PrEP with possible exposure (e.g., rape), do they need nPEP? Will consider addressing this in the final guideline.

*This additional information will be considered in the final guideline.*

**Table 2 Recommended schedule for laboratory evaluations of source and exposed persons for providing nPEP**

Consider reformatting lab table to clarify that 12 month HIV testing is only for persons infected with hepatitis C

*The table will be reformatted to clarify this and other concerns raised by reviewers*

Reconsider the value of repeat creatinine and pregnancy testing at 4 weeks?

*Considered but no change made.*

If you're using a 4<sup>th</sup> generation antigen-antibody test for HIV, can you stop repeat HIV testing at 4 months [after exposure event]?

*Follow-up testing can be stopped after 3-4 months if an antigen/antibody assay is used for prior nPEP-related HIV testing. Revisions to Table 2 will indicate that.*

Should 4<sup>th</sup> gen be a secondary option?

*We will indicate in the guidelines that 4<sup>th</sup> generation HIV tests are preferred in the context of nPEP.*

Why is HIV testing added at 6-12 months (not in 2005 guidelines)?

*The recommendation for HIV antibody testing during 6-12 months is only if hepatitis C infection was acquired during the original exposure. This is indicated in a footnote to the table and in the text of the guideline. Delayed HIV seroconversion has been documented in persons who simultaneously acquire HIV and hepatitis C infection. The recommendation does not apply to all exposed persons.*