

Post-exposure prophylaxis: The PEPLine, expert consultation and systems for managing exposures to blood-borne pathogens

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National Clinicians' Post-Exposure Prophylaxis Hotline (PEPline)

For questions about occupational exposures to HIV & other blood-borne pathogens (e.g., needlesticks, splashes, etc.)

**National HIV/AIDS Clinicians' Consultation Center
HIV/AIDS Bureau
Health Resources and Services Administration**

San Francisco General Hospital, University of California San Francisco

Objectives

- Review principles of managing occupational exposures
- Describe PEPLINE services and experiences
- Identify components essential to managing blood-borne pathogen exposures within health care facilities

Occupational HIV exposures are crisis situations demanding immediate, decisive action.

Henderson, Emerg Infect Dis 2001; 7:254-8.

Extent of the problem

600,000 - 800,000 exposures annually

Underreporting

Nurses most common:

One exposure/year

HIV, hepatitis B and C infections

Enormous emotional impact

Goals in Post-Exposure Care

Prevent transmission

Avoid unnecessary PEP and PEP toxicity

Provide counseling and follow-up

Managing BBP Exposures

Assessing injury/exposure risk

Assessing source patient risk

Determining whether to offer PEP

Selecting PEP drugs

Counseling the HCW or treating clinician

Follow-up

Phases in Managing BBP Exposures

Phase One

First Aid

Triage

Crisis Management

Phase Two

Exposure Risk Assessment

Source Patient Evaluation

PEP Decision

Initiating Treatment

Phase Three

Post-Exposure Follow-up

Source Patient Follow-up

ARV Toxicity Monitoring

Case 1

- Phlebotomist had superficial injury through glove last night.
- Couldn't sleep last night - worried

What else do we need to know?

- ?
- ?
- ?
- ?
- ?

First aid

- Soap and water for percutaneous exposures
(not antiseptic solutions)
(no back-bleeding)

Counseling Exposed HCP

- Non-judgmental understanding; acknowledge the value of their call
- Joining
- Statement about competence/expertise
- Calm control
- Facts: gain perspective

<Note: Treating Clinicians may need the same>

Risk of Transmission

Overall risk, percutaneous: 0.3% (3 per 1000)

Henderson, Tokars, Ippolito, Gerberding, Bell

Risk Factors

Visibly blood device

Device used in artery or vein

Deep injury

End-stage AIDS

Decreased risk of transmission 80% w AZT PEP

Cardo, et al. N Engl J Med 1997;337:1485-90.

Exposure Risks

HIV

0.3 % percutaneous

0.09 % mucous membrane

- Hepatitis B without immunity

Serologic evidence of infection 22-62 %
depending on e-antigen

800/year

- Hepatitis C

1.8 %

Timing of PEP

- 1-2 hours
 - 24 hours
 - 72 hours
 - 1 week (or more?)
-
- Start as soon as possible
 - Efficacy decreases as time passes
 - Do not delay pending test results

Case 1

- Phlebotomist had superficial injury through glove last night.
- Couldn't sleep last night - worried
- Noted tiny puncture wound on finger after she took gloves off; doesn't remember if there was blood under her glove
- Needle used to draw blood
- Possibly visibly bloody
- SP not known to be HIV positive – status unknown

Updated US Public Health Service Guidelines
for the Management of Occupational Exposures
to HBV, HCV, and HIV and Recommendations
for Postexposure Prophylaxis

MMWR, June 29, 2001

www.cdc.gov
www.hivatis.org

Percutaneous Exposures

Exposure type	Infection status of source				
	HIV-Positive Class 1*	HIV-Positive Class 2*	Source of unknown HIV status†	Unknown source‡	HIV-Negative
Less severe§	Recommend basic 2-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP for source with HIV risk factors¶	Generally, no PEP warranted; however, consider basic 2-drug PEP in settings where exposure to HIV-infected persons is likely	No PEP warranted
More severe#	Recommend expanded 3-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP for source with HIV risk factors¶	Generally, no PEP warranted; however, consider basic 2-drug PEP in settings where exposure to HIV-infected persons is likely	No PEP warranted

Case 1

- Counsel phlebotomist that “Generally, no PEP warranted; however, consider for source with HIV risk factors.” Beyond window for starting with optimal efficacy, although efficacy still possible
- If SP has risk factors
 - Consider (offer) basic PEP regimen – her decision

Case 1

- Decided to take AZT/3TC pending test results

PEP selection

- 28-day treatment course
- Basic 2-drug regimen
 - AZT + 3TC
 - Alternatives – ddI/d4T; d4T/3TC; +/- AZT/ddI

Default: can treat and stop

- Can be reassuring
- Allows time for test results
- Allows time for HCP reconsideration

Phases in Managing BBP Exposures

Phase One

First Aid

Triage

Crisis Management

Phase Two

Exposure Risk Assessment

Source Patient Evaluation

PEP Decision

Initiating Treatment

Phase Three

Post-Exposure Follow-up

Source Patient Follow-up

ARV Toxicity Monitoring

Source Assessment: Laboratory Testing

- Testing options
 - Rapid vs standard HIV antibody test
 - SUDS- almost no false negatives; few false positives
 - (Negatives reassuring)
 - (True positives – treat)
 - (False positives – treat & discontinue in a few days)
 - Antibody testing vs direct virus assay
 - (false positives; may help in window period)
- Testing discarded needles is not an option

Post-Exposure Follow-Up

- HIV Antibody Testing:
 - Baseline, 6 wks, 3 mos, 6 mos
 - Consider 12 month for co-exposures to HIV/HCV
- HCV Antibody Testing & ALT:
 - Baseline, 6 wks, 3 mos, 6 mos
 - Confirm positives
- HCV RNA testing
 - Consider at 4-6 weeks if earlier diagnosis needed
- HBV testing – as clinically indicated

Antiretroviral Toxicity Monitoring

- Symptoms/Signs – GI intolerance, rash, etc
- Laboratory
 - Baseline: LFTs, CBC w/diff + platelets
 - Consider renal panel, amylase
 - Repeat at 2 weeks
 - Repeat at 4 weeks if any abnormalities

Case 1

- Decided to take AZT/3TC pending test results
- Developed some headache and nausea in first day; resolved with acetaminophen and taking meds with food
- Results of ELISA @ day 3: Negative

Case 2

- HIV patient spat in the eye of a medical assistant in your urgent care clinic
- Medical assistant had previous evidence of response to hepatitis B immunization series

What else do we need to know?

- ?
- ?
- ?
- ?
- ?

Infectious Fluids

Considered Infectious

Blood, tissue

Cerebrospinal, amniotic, pericardial, peritoneal,
pleural, synovial fluids

Semen, vaginal secretions

Considered Non-infectious (Unless visibly bloody)

Urine, feces, nasal secretions, saliva, gastric fluid,
sputum, tears, sweat

Case 2

- HIV patient spat in the eye of a medical assistant in your urgent care clinic
- Medical assistant had previous evidence of response to hepatitis B immunization series
- Patient had been in a fist-fight and was bleeding from the mouth – saliva was visibly bloody

Mucous Membrane & Non-Intact Skin Exposures

Exposure type	Infection status of source				
	HIV-Positive Class 1 [†]	HIV-Positive Class 2 [†]	Source of unknown HIV status [‡]	Unknown source [§]	HIV-Negative
Small volume	Consider basic 2-drug PEP [¶]	Recommend basic 2-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP [¶] for source with HIV risk factors ⁷	Generally, no PEP warranted; however, consider basic 2-drug PEP [¶] in settings where exposure to HIV-infected persons is likely	No PEP warranted
Large volume ^{**}	Recommend basic 2-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP [¶] for source with HIV risk factors ⁷	Generally, no PEP warranted; however, consider basic 2-drug PEP [¶] in settings where exposure to HIV-infected persons is likely	No PEP warranted

Guideline Definitions

- HIV + Class 1: Asymptomatic or Viral load <1500
- HIV + Class 2: symptomatic, AIDS, known high VL, acute seroconversion illness

- Small volume: a few drops
- Large volume: a major splash

- Eye exposures same as other mucous membrane exposures?

Case 2

- HIV patient spat in the eye of a medical assistant in your urgent care clinic
- Medical assistant had previous evidence of response to hepatitis B immunization series
- Patient had been in a fist-fight and was bleeding from the mouth – saliva was visibly bloody
- Patient is heavily ARV-experienced, currently on d4t/ddI/Kaletra with poor viral control. He is hepatitis B and hepatitis C co-infected.

Phase 1 Actions

- First aid: Water or saline for mucous membrane exposures
- Triage- to designated clinician, ER, employee health, etc
- Crisis management- make concerns realistic through data, understanding concerns, acting promptly

Post-Exposure Prophylaxis for Hepatitis B

Vaccination And antibody Response status of exposed workers*	Treatment		
	Source HbsAG [†] positive	Source HbsAG [†] negative	Source Unknown or not available for testing
Unvaccinated	HBIG [‡] x 1 and initiate HB vaccine series [§]	Initiate HB vaccine series	Initiate HB vaccine series
Previously vaccinated			
Known responder	No treatment	No treatment	No treatment
Known nonresponder [¶]	HBIG x 1 and initiate revaccination or HBIG x 2 [#]	No treatment	If known high risk source, treat as if source were HbsAg positive
Antibody response unknown	Test exposed person for anti-HBs** 1. If adequate, no treatment is necessary 2. If inadequate, [¶] administer HBIG x 1 and vaccine booster	No treatment	Test exposed person for anti-HBs 1. If adequate, [§] no treatment is necessary 2. If inadequate, [§] administer vaccine booster and recheck titer in 1-2 months

Hepatitis C

- HCV
- No prophylaxis
- Early treatment vs. careful follow-up (may clear the infection or have no clinically important sequelae; 20+ years' latency; continually improving antiviral drugs)
- Need to give HCP the options to make informed decision

Rationale for Expert Consultation

Ready access to expert consultation is especially important:

- for clinicians with limited experience in managing occupational exposures
- when clinical scenarios do not fit into the Guidelines
- complicated exposures (e.g., S/P on ARVs, pregnancy, drug toxicity, etc.)

Objectives

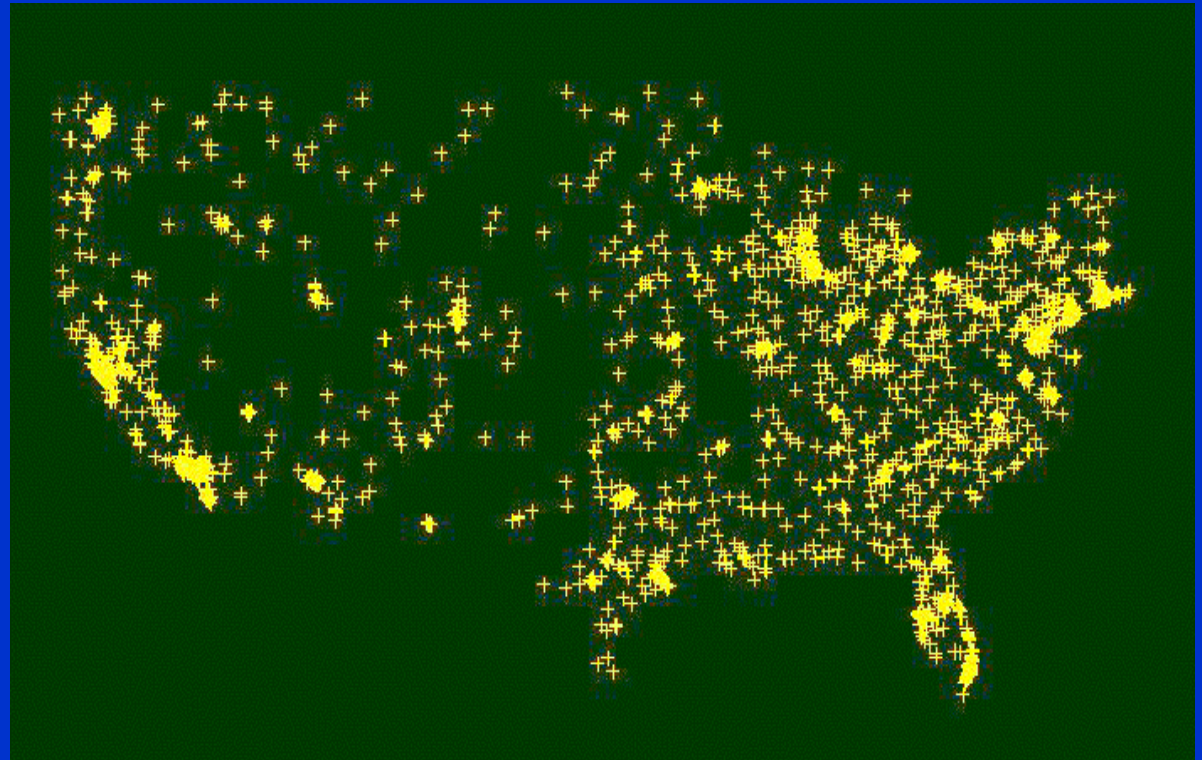
- ✓ Review principles of managing occupational exposures
- Describe PEpline services and experiences
- Discuss components of systems to manage blood-borne pathogen exposures within health care facilities

National Clinicians' Post-Exposure Prophylaxis Hotline (PEPline)

888 / HIV-4911

888 / 448 - 4911

24-hours/day



PEPline Methodology

- Toll-free number
- Clinicians available 24 hours
 - 9 am – 8 pm EST clinicians answer directly
 - Off hours: answering service pages clinicians
 - respond within 15 minutes
- Clinicians UCSF faculty, HIV experienced
- Intensive PEP training (didactic and mentoring)
- Confidential documentation of caller information, exposure characteristics, and recommendations
- CQI

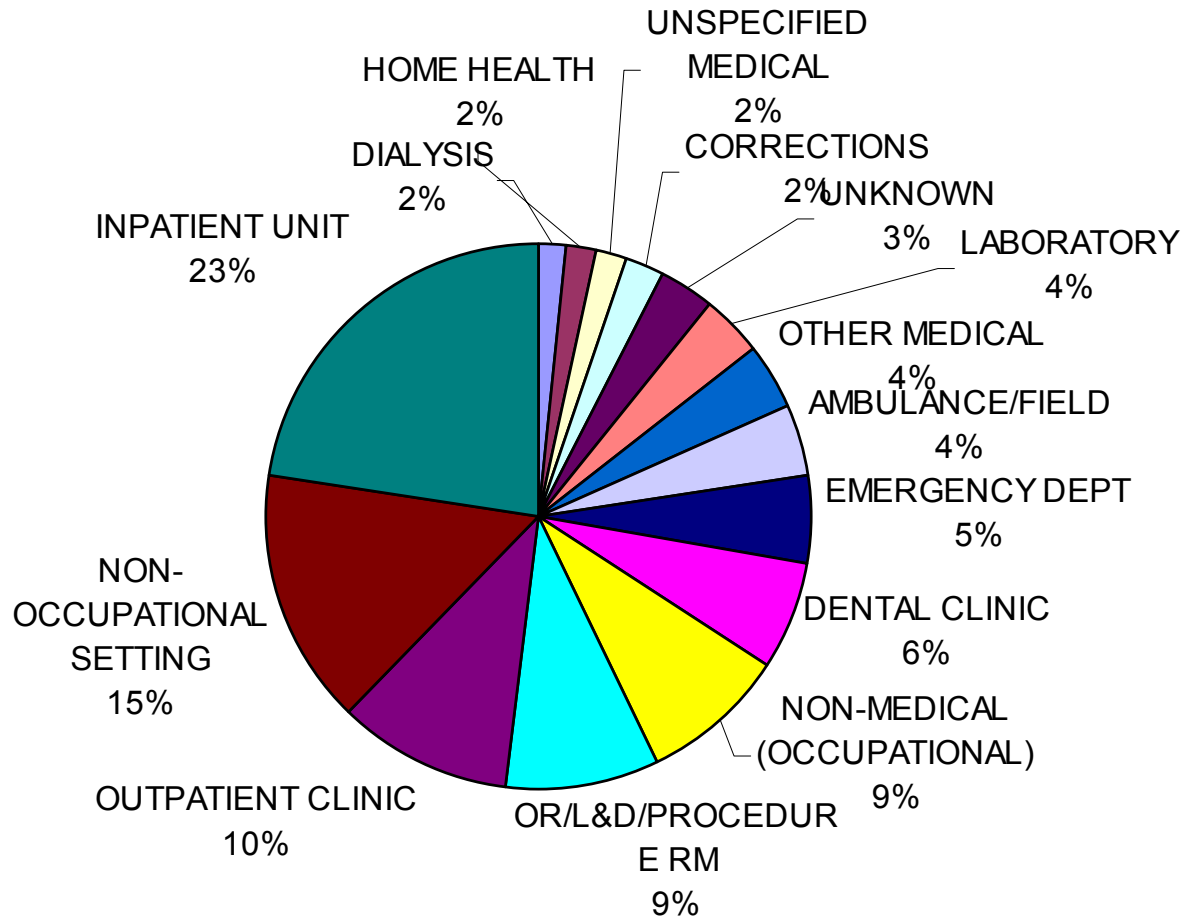
PEPlineVolume

- Call volume: 550/month
- Approaching 25,000 total calls since October 1997

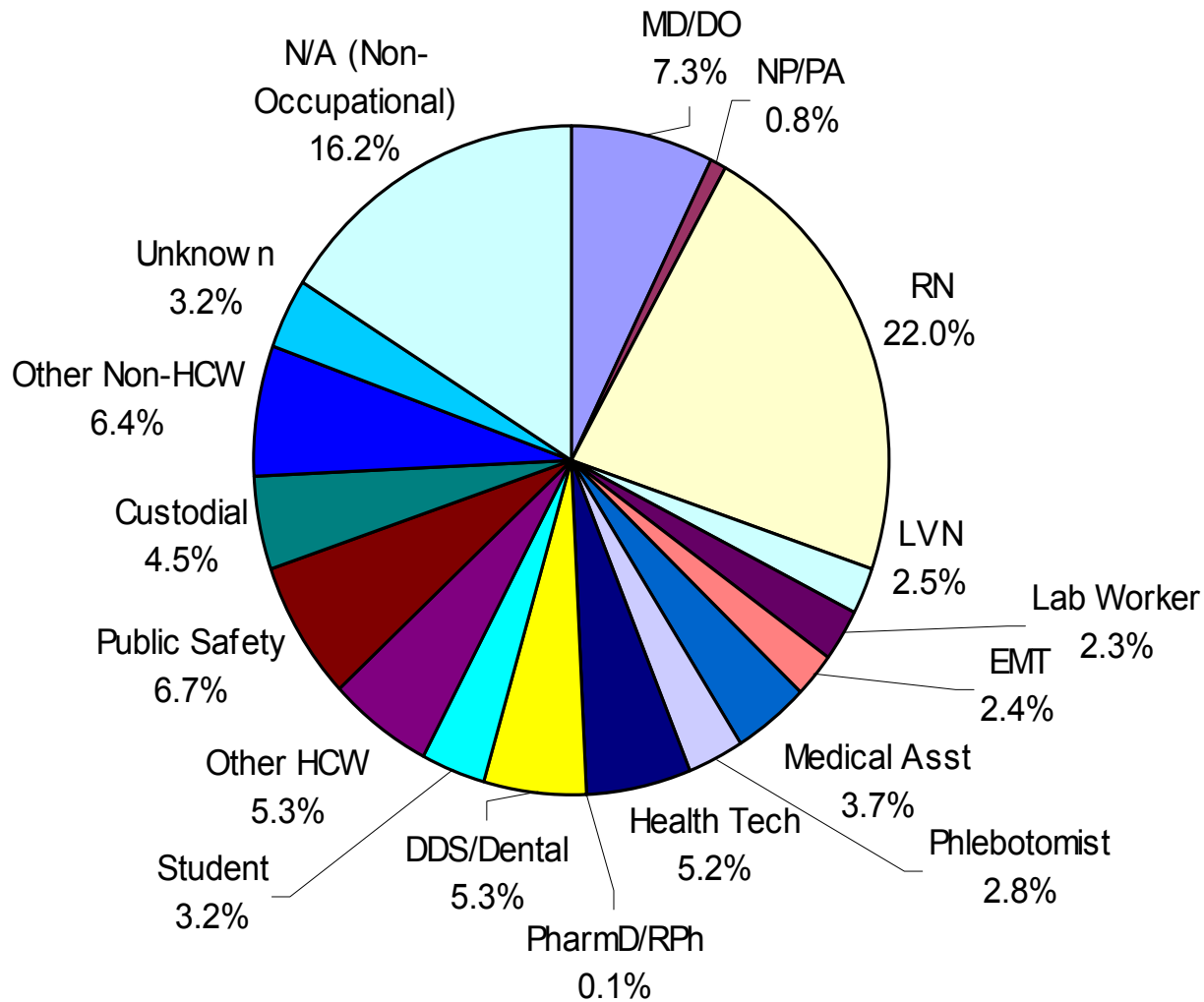
Callers to PEPLine

<u>Treating Clinicians</u>	78%
MD	62 %
NP, RN, PA, LVN	36 %
Other	2 %
<u>Exposed HCPs</u>	22%

Where Exposure Occurred



Profession of Exposed HCP



Exposed HCWs

Female 67.6 %

4.8 % pregnant

Pregnancy

- Recommendations same, except:
 - Avoid efavirenz: teratogenic
 - Avoid ddI/d4T combination: lactic acidosis

(Note: recommend discontinuing breast feeding while taking ARVs)

Exposure Type

- Percutaneous 78 %
- Mucous Membrane 15 %
- Cutaneous 5 %
- Other/Unknown 2 %

Exposure Fluids

Blood	71.2 %
Other	28.8 %
Infectious	9.6%
Non-infectious	19.2%

Source Patient Characteristics

Identity of Source Patient

Known	78 %
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Unknown	22 %
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Challenges in Implementing the Guidelines: The Role of Expert Consultation

Assessing actual risk of exposure

Questionable exposures (skin, oral, scratch, etc)

Unknown source (includes found needle,
sharps box)

Complicated exposures

Source Patient with prior or current ARV Rx

Pregnancy

Drug Toxicity

PEP Recommendations, Feb- July 2002

- Recommend 10 %
- Consider (benefits > toxicity) 4 %
- Consider (benefits:toxicity unclear) 11%
- Consider (benefits < toxicity) 25 %
- Not recommended 23 %
- Stop 2 %
- Unspecified, not discussed 29 %

PEPline Caller Survey - 2002

Timely response to caller's question	4.84
Information presented clearly	4.85
Recommendations useful in managing this exposure	4.87
Follow-up information received in a timely manner	4.85
Specific circumstances of the exposure incorporated into reply	4.74
Recommendations useful in managing subsequent exposures	4.87
Would call this service again	4.93

Objectives

- ✓ Review management of occupational exposures
- ✓ Review PEPline services and experiences
- Discuss components of response to occupational exposures

Institutions' key roles in organizing local systems for post-exposure care

- Establish organizational structure for exposure management
- OSHA Blood-Borne Pathogens Standards
- NIOSH Guidelines
- State Laws regarding reporting , etc.
- Hospital regulations
- Written policies and protocols for reporting, evaluating, counseling, treating, and follow-up.
- MMWR Guidelines
- Establish procedures to ensure confidentiality

Ensuring timely and accurate response

- Establish designated person(s) or team trained in prevention measures and response to exposure
- Availability of ARV medications
 - (emergency supply 24-hours; beware long weekends)

Who should provide post-exposure care?

On-site clinician

Knowledgeable

Can be expert

Connected to others with expertise

Familiar with PHS Guidelines

Who should not provide post-exposure care?

Friend/colleagues

Exposed HCP themselves

Bosses

Overinvolved

Inexperienced

Who should provide post-exposure care? (cont.)

Local/State/Regional Experts

PEPline

Consultative services are not a substitute for face-to-face evaluation, counseling, and follow-up

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