



NORTHWEST AIDS EDUCATION AND TRAINING CENTER

Post-Exposure Prophylaxis - HIV and HBV

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Overview & Objectives

Occupational Exposures

- Resources & Definitions
- Classifying types of exposures (HBV and HIV)
- Best estimates for transmission

HIV PEP

- Practical management considerations
 - Timing & Duration of PEP
 - Choosing a regimen
 - Laboratory Monitoring

HBV PEP

- Use of HBIG and HBV vaccine



MMWR™

Morbidity and Mortality Weekly Report

Recommendations and Reports

September 30, 2005 / Vol. 54 / No. RR-9

**Updated U.S. Public Health Service Guidelines
for the Management of Occupational Exposures
to HIV and Recommendations
for Postexposure Prophylaxis**

MMWR Sept 30, 2005 54(RR-9):1-17



MMWR™

Morbidity and Mortality Weekly Report

Recommendations and Reports

January 21, 2005 / Vol. 54 / No. RR-2

**Antiretroviral Postexposure Prophylaxis
After Sexual, Injection-Drug Use,
or Other Nonoccupational Exposure
to HIV in the United States**

Recommendations from the U.S. Department
of Health and Human Services

MMWR January 21, 2005 54(RR-2)

Postexposure Prophylaxis for Occupational Bloodborne Exposure



A MANUAL FOR HEALTH CARE PROVIDERS

Kathy Hall, PA-C
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and

The Northwest AIDS Education and Training Center

INSTRUCTIONS FOR HEALTH CARE WORKERS

1. In the Event of An Exposure

In the event of a possible exposure to a bloodborne pathogen, the health care worker (HCW) should act promptly to carry out the steps listed below.

2. Decontaminate the Area of the Exposure

72 HOUR FOLLOW-UP VISIT

Instructions for the Managing Clinician

1. Address HCW Questions or Concerns

At this visit address any questions or concerns the exposed HCW may have about the exposure or PEP recommendations to date. **Form 9: 72 Hour Follow-up Visit** provides a template that can be used to record details of this and subsequent follow-up visits. Offer psychological counseling referral if indicated.

TWO WEEK FOLLOW-UP VISIT (FOR HCWs WHO INITIATED ANTIRETROVIRAL PEP)

1. Address HCW Questions or Concerns

Address any questions or concerns the exposed HCW may have about the exposure or PEP recommendations to date. Use **Form 11: Two Week Follow-up Visit: Recommendations for HCW** to record details of this and subsequent steps. Offer psychological counseling referral if indicated.

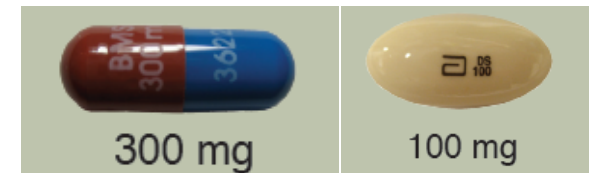
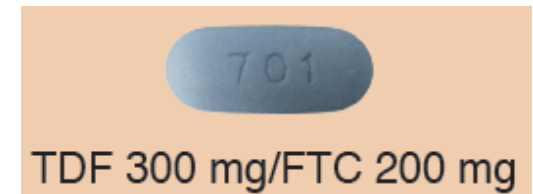
SIX WEEK FOLLOW-UP VISIT

1. Address HCW Questions or Concerns

Address any questions or concerns the exposed HCW may have about the exposure. Offer psychological counseling referral if indicated.

Post-Exposure Prophylaxis (PEP)

- The use of therapeutic agents to prevent infection **following** exposure to a pathogen
- For health-care workers, PEP commonly considered for exposures to HIV and Hepatitis B



Exposures...What Counts?

Exposures:

- Transfusions
- IV, IM, SQ needle injury w/ potentially infectious fluid*
- Mucus Membrane/skin break splash w/ potentially infectious fluid*
- Human Bites (if bleeding present in mouth & at bite)

Non-Exposures

- Intact Skin splash w/ potentially infectious fluid*
- IV, IM, SQ needle injury w/ no infectious fluid
- Mucus Membrane/skin break splash w/ no infectious fluid
- Human Bites (non-bloody)

SEX!

***Potentially Infectious Fluid (HIV/HCV)**

YES

- **Blood**
- **Semen**
- **Vaginal Fluid**
- **Pus**
- **Amniotic Fluid**
- **Spinal, Pleural, Synovial, Peritoneal Fluid**
- **Breastmilk**

NO

- **Saliva/Sputum**
- **Urine**
- **Feces**
- **Vomit**
- **Sweat**
- **Tears**
- **Nasal Secretions**
(unless visibly bloody)

*Potentially Infectious Fluid (HBV)

YES

- Saliva/Sputum
- Blood
- Semen
- Vaginal Fluid
- Pus
- Amniotic Fluid
- Spinal, Pleural, Synovial, Peritoneal Fluid
- Breastmilk

NO

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

Hepatitis/HIV – Relative Risk of transmission

- **‘The rule of three’**
- Needlestick transmission rates:
 - HBV – 30 of every 100
 - HCV – 3 of every 100
 - HIV – 0.3 of every 100

Percutaneous (blood)	0.3%
Mucocutaneous (blood)	0.09%
Receptive anal intercourse	1 - 2%
Receptive vaginal intercourse	0.1 – 0.2%
Insertive vaginal intercourse	0.03 – 0.14%

HIV PEP

Evidence of Efficacy of HIV-PEP

- Animal models: high level of protection when started within 24 hours¹, 28 days more effective than 3 days or 10 days
- OR = 0.19 for zidovudine (AZT) use in case-control study² (81% decrease in risk of HIV acquisition)
- Two drugs vs. three drugs:
 - no direct evidence that more drug = more effective
 - cases of seroconversion despite 3-drug PEP imply efficacy less than 100%^{3,4}

1. Tsai C-C et al. J Virol 1998;72:4265-73

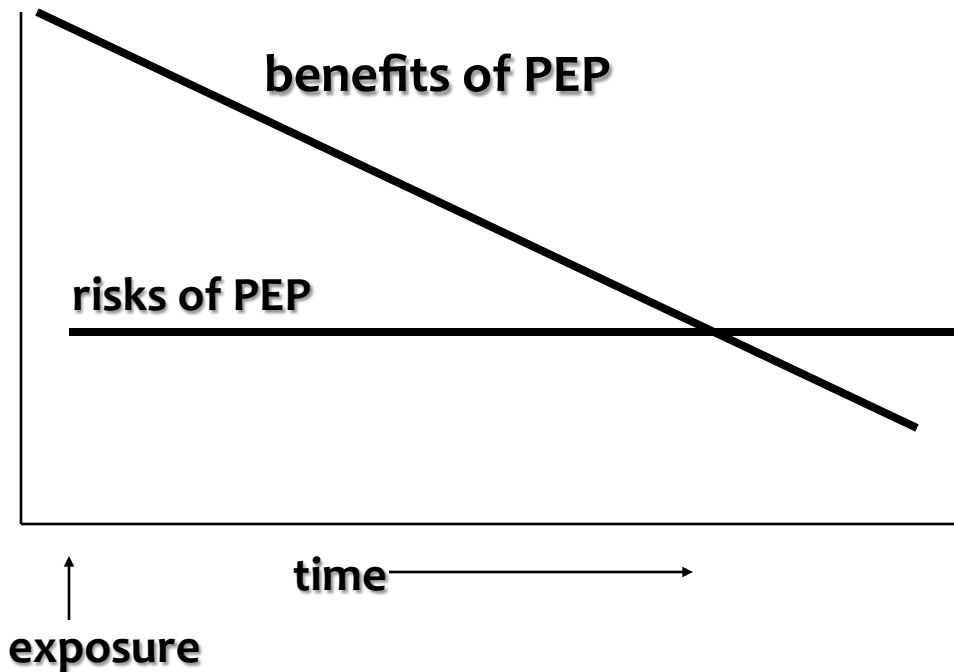
2. Cardo DM et al. NEJM 1997;337:1485-90.

3. Jochimsen EM et al. Arch Int Med 1999;159:2361-3.

4. MMWR June 29, 2001 / 50(RR11);1-42

When should PEP be started?

- Efficacy of PEP thought to wane with time
- at what point is PEP “no longer worth it”?



CDC language:

“...as soon as possible, preferably within hours rather than days...”

“Interval after which there is no benefit for humans is not known”

“Obtain expert advice when interval has exceeded 24-36 hours”

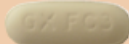
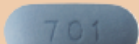
CDC PEP Guidelines: Known HIV+ Source

Exposure Type	Source Infection Status	
	HIV+ Class 1	HIV+ Class 2
Less Severe*	Basic (2 Drugs)	Expanded (≥ 3 Drugs)
More Severe^Δ	Expanded (≥ 3 Drugs)	Expanded (≥ 3 Drugs)

Exposure Type	Source Infection Status	
	HIV+ Class 1	HIV+ Class 2
Small Volume*	Consider Basic (2 Drugs)	Recommend Basic (2 Drugs)
Large Volume^Δ	Recommend Basic (2 Drugs)	Recommend Expanded (≥ 3 Drugs)

CDC-Recommended PEP regimens











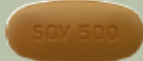
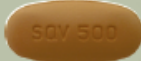

Basic:

Zidovudine + Lamivudine Combivir®	 AZT 300 mg/3TC 150 mg
Tenofovir + Emtricitabine Truvada®	 TDF 300 mg/FTC 200 mg

i tab PO BID*

i tab PO QD

Expanded = Basic PLUS:

Lopinavir/ Ritonavir (LPV/r) Kaletra®	 LPV 200 mg/RTV 50 mg	 LPV 200 mg/RTV 50 mg		
Atazanavir (ATV) Reyataz®	 300 mg	Ritonavir (RTV) Norvir®	 100 mg	
Fosamprenavir (FPV) Lexiva®	 700 mg	 700 mg	Ritonavir (RTV) Norvir®	 100 mg
Indinavir (IDV) Crixivan®	 400 mg	 400 mg	Ritonavir (RTV) Norvir®	 100 mg
Saquinavir (SQV) Invirase®	 500 mg	 500 mg	Ritonavir (RTV) Norvir®	 100 mg

ii tabs PO BID*

ii tabs PO QD

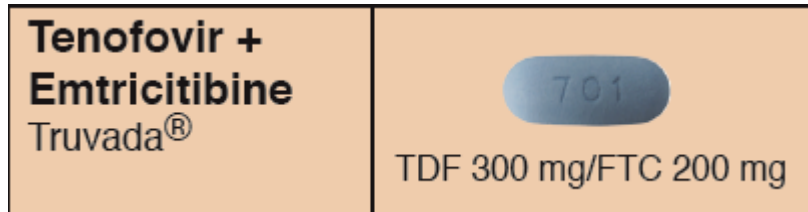
iii tabs PO QD

iii tabs PO BID

iii tabs PO BID

'Modern' PEP regimens

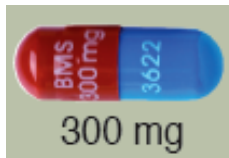
Basic:



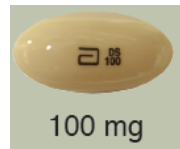
i tab PO QD

Expanded = Basic PLUS:

Atazanavir
(ATV)
Reyataz®



Ritonavir
(RTV)
Norvir®



ii tabs PO QD

Darunavir
(DRV)
Prezista®

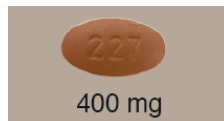


Ritonavir
(RTV)
Norvir®



iii tabs PO QD

Raltegravir
(RAL)
Isentress®

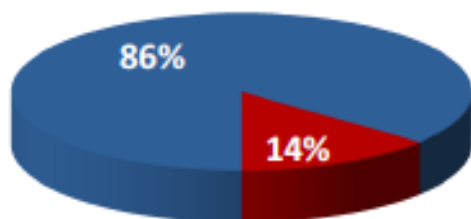


i tab BID

NCCC: Non-Guideline PEP Regimens

NCCC PEpline PEP Regimen Recommendations

N = 465 exposures, 638 HIV PEP regimens



■ CDC Guideline Preferred ARVs ■ Non-Guideline ARVs

Predictor Variables for Non-Guideline PEP Regimen Recommendation	Odds Ratio	P value	95% Confidence Interval
Known ARV Resistance	20.88	0.015	1.80 – 242.0
Viral Load >1500copies/mL	12.04	0.14	0.43 – 337.2
SP Clinical Status	4.67	0.38	0.15 – 143.1
NCCC PEpline Clinician Degree	1.03	0.98	0.12 – 8.54
SP Currently On ARVs	0.074	0.068	0.0045 – 1.21

Non-Preferred Drugs	Number of Recommendations
Darunavir/Ritonavir (boosted)	37 (36%)
Raltegravir	32 (31%)
Atazanavir/Ritonavir (boosted)	19 (18%)
Maraviroc	6 (6%)
Atazanavir (unboosted)	2 (2%)
Etravirine	2 (2%)
Fosamprenavir (unboosted)	1 (1%)
Indinavir (unboosted)	1 (1%)
Nevirapine	1 (1%)
Efavirenz	1 (1%)
Atripla (Efavirenz/Tenofovir/Emtricitabine)	1 (1%)
Total	88 (100%)

Follow-up of HCW exposed to HIV

Test	Time Elapsed Since the Exposure Occurred				
	Baseline	2 Weeks	6 Weeks	3 Months	6 Months*
HIV antibody test	✓		✓	✓	✓
CBC with differential^	✓	✓			
Serum liver enzymes^	✓	✓			
Blood Urea Nitrogen^	✓	✓			
Pregnancy Test#	✓				

* HIV antibody testing should be performed at 12 months if the health care worker acquires hepatitis C virus from the occupational exposure

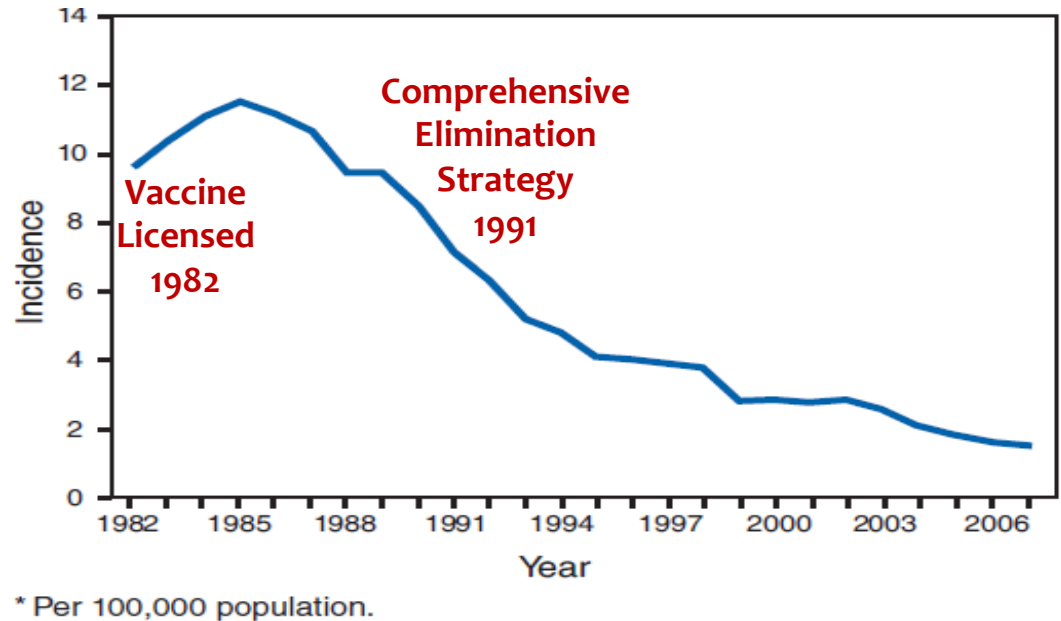
^ Only necessary to obtain these studies for health care workers who will receive postexposure prophylaxis to monitor for antiretroviral therapy toxicity

For women of reproductive age, especially if they will receive post-exposure prophylaxis

HEPATITIS B PEP

Hepatitis B PEP

- HBV prevalence in U.S. is low (0.1-2%)
- Most HCW are vaccinated against HBV



- Hepatitis B PEP: immunization + HBIG (HBV Immune Globulin – effective up to 1 week post exposure)

PEP: Summary

- HIV-PEP should be offered within **hours** from exposure and for 28 day duration
- Counseling is crucial to discuss true risks and benefits of PEP
- Providers should choose 2- or 3-drug HIV-PEP regimen based on exposure & source
- HBV PEP involves HBIG and HBV vaccination

Help is Available!!!

- PEPLine: 888-448-4911

www.ucsf.edu/hivcntr/Hotlines/PEPLine



9AM – 2 AM EST

- CDC/DHHS: 800-893-0485

- <http://aidsinfo.nih.gov>

- <http://depts.washington.edu/nwaetc/resources/pep.html>