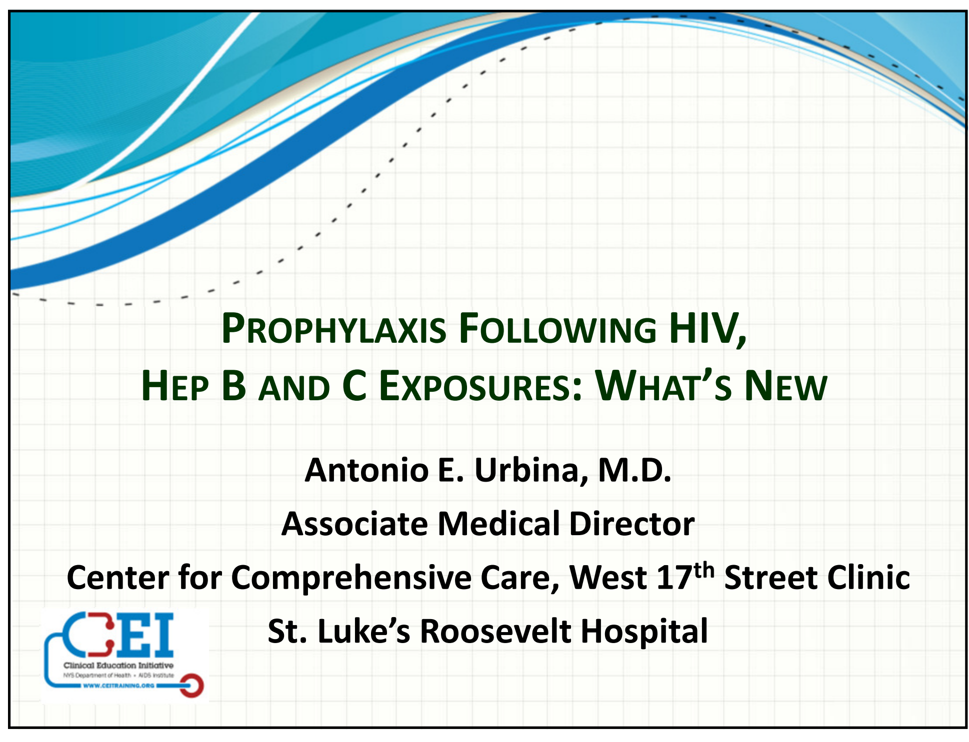
PROPHYLAXIS FOLLOWING HIV,
HEP B AND C EXPOSURES: WHAT'S NEW
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CEI
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DISCLOSURES
Speaker's Bureau: Gilead, Merck, BMS
Research Support: BMS
CEI
Clinical Education Initiative

Learning Objectives:

1. Describe the scientific rationale for how PEP works

2. Review the updated NYS DOH Guidelines for PEP

3. Review the guidelines for the management of exposure to hepatitis B and C

What is PEP?

- **Post-exposure prophylaxis** (**PEP**) is any prophylactic treatment started immediately after exposure to a pathogen (such as a disease-causing virus), in order to prevent infection by the pathogen and the development of disease
  - For exposures to HIV: 28-day (4 week) course of anti-retrovirals

A1

Treating HIV Is Hugely Expensive

- Lifetime Cost of HIV Care in the US in the Current Treatment Era $1.5 million [1,2]

[1] B R Schackman, et al. Journal of Medical Care, 2006

[2] Antiretroviral Therapy Cohort Collaboration, Lancet, 2008

Support for PEP Treatment Guidelines

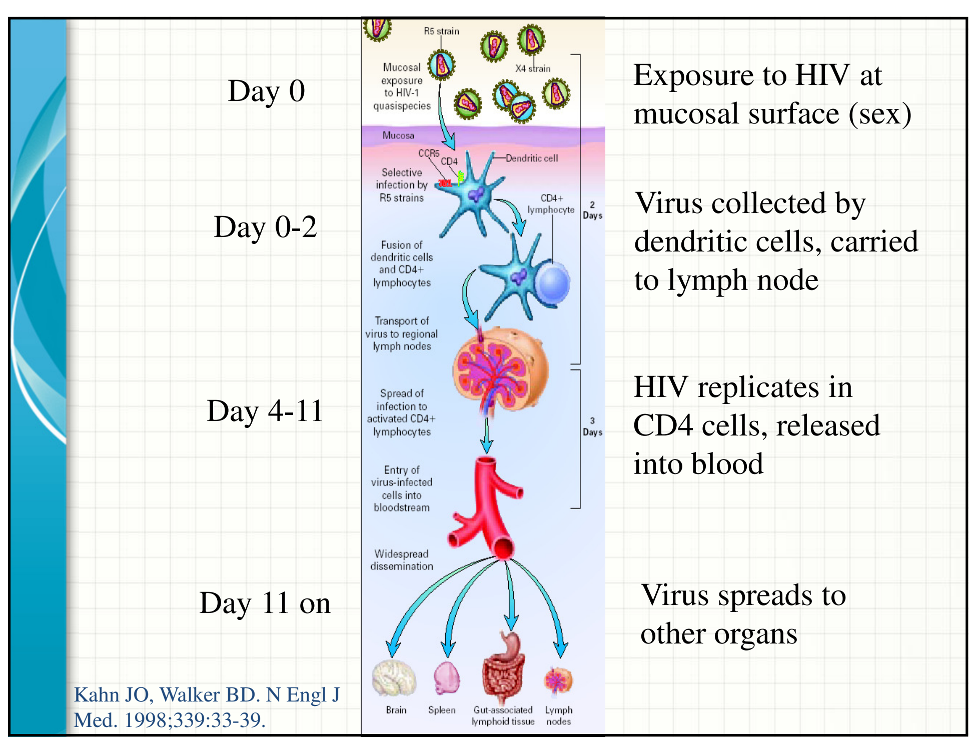
- **ACTG 076 Study (MTCT)**
  - Decreased transmission by 67%
- **CDC International Case Control Study**
  - **Use of AZT by HCW decreased risk of HIV acquisition by 81%**
- **Laboratory and animal models**
  - **No adequate human data on nPEP efficacy**
  - **Shortened courses (10 day vs 28) not as effective**

Slide 5

A1 Wow, seems high! The Schackman article is more like $360K.
Author, 5/15/2013

NON-OCCUPATIONAL ESTIMATED TRANSMISSION RISK

Exposure Type if Source HIV-infected	Estimated Risk of Single Exposure
Needle-sharing	0.67% (1/150)
Receptive anal intercourse	0.5%-3% (1-6/200)
Receptive vaginal intercourse	0.1% (1/1000)
Insertive anal intercourse	0.065% (1/1500)
Insertive vaginal intercourse	0.05% (1/2000)
Receptive oral sex with ejaculation	0.005-0.01% *(conflicting data but low risk)*



Slide 7

A2 Great!
Author, 5/15/2013

A2 Consider changing the font in the table to a sans serif font (i.e., arial, calabri) to make it easier to read. I changed to arial but please feel free to disregard.
Author, 5/15/2013

PEP Guidelines

NYS DOH Guidelines	CDC Guidelines
• oPEP (occupational) – Jan 2008 – Oct 2012 • nPEP (non-occupational) – Jan 2008 – Updated guidelines expected in 2013 • Link: www.hivguidelines.org	• oPEP (occupational) – Sept 2005 – Updated guidelines expected 2013 • nPEP (non-occupational) – Jan 2005 – Updated guidelines expected in 2013 • Link: www.cdc.gov/hiv/resources/guidelines

Exposure Management

- Wash immediately with soap and water
- Flush mucous membranes with water
- No evidence that use of antiseptics or expressing fluid reduces transmission
  - Antiseptics not indicated; caustic agents (bleach) not recommended
  - "Milking the wound" may increase risk
    - increases local inflammation

Slide 10

A6 with
Author, 5/15/2013

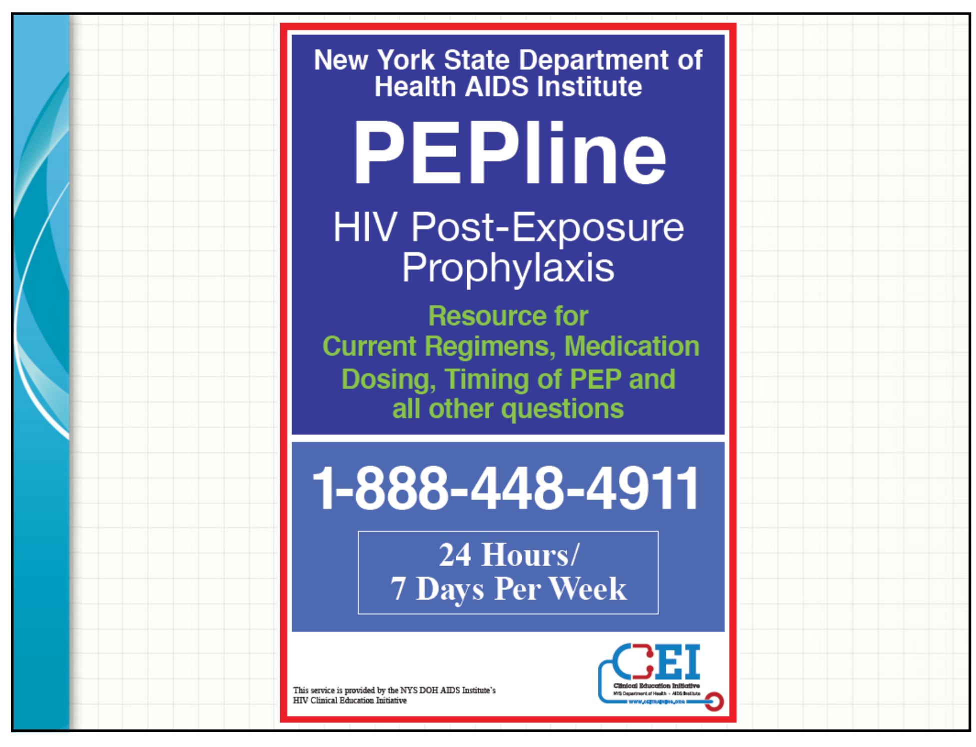
A7 Add "that" between "evidence" and "use"
Author, 5/15/2013

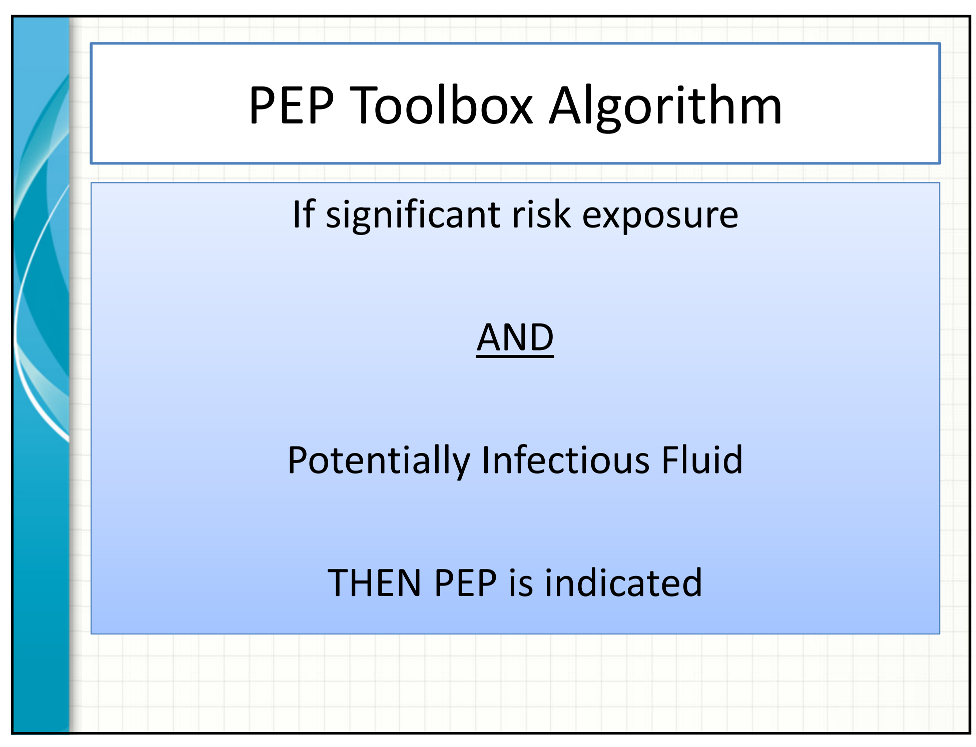
Assess Risk Exposure:

- Percutaneous injury
- Contact of mucous membrane
- Contact non-intact skin

Risk and PEP of Non-Occupational Exposures

PEP recommended, if source HIV + or at risk of HIV	PEP *NOT* recommended
* Unprotected receptive & insertive vaginal/anal intercourse * Unprotected receptive penile-oral contact with ejaculation * Oral-vaginal contact with blood exposure * Needle-sharing * Injury with blood exposure - needlestick, bite, accident	* Kissing, or oral-oral contact & no mucosal damage * Bites without blood * Needles/sharps exposure not in contact with HIV + or at-risk person * Mutual masturbation – intact skin * Oral-anal contact * Receptive penile-oral contact without ejaculation * Insertive penile-oral contact * Oral-vaginal – no blood exposure


New York State Department of Health AIDS Institute
PEPline
HIV Post-Exposure Prophylaxis
Resource for Current Regimens, Medication Dosing, Timing of PEP and all other questions
1-888-448-4911
24 Hours/ 7 Days Per Week
This service is provided by the NYS DOH AIDS Institute's HIV Clinical Education Initiative
CEI
Clinical Education Initiative


PEP Toolbox Algorithm
If significant risk exposure
AND
Potentially Infectious Fluid
THEN PEP is indicated

Community Needlestick Injuries

- Consider:
  - HIV prevalence in the community or facility
  - Surrounding prevalence of injection drug use
- Do not test discarded needles for HIV

Key Updates

A8

- Tenofovir/Emtricitabine + Raltegravir is now the preferred regimen for all exposures of significant risk
  - AZT is no longer recommended in the preferred PEP regimen
- Occupational and non-occupational exposure require ***urgent medical evaluation***
  - Initiate PEP as soon as possible, *ideally within 2 hours of exposure*
    - First dose of PEP should be offered while evaluation is underway
    - PEP should not be delayed while awaiting information about the source patient or the results of the exposed patient baseline HIV test

Slide 16

A8 Font is kind of small here and this is KEY content.
Author, 5/15/2013

KEY UPDATES

A9

- If source patient is HIV negative and has had risks in the last 6 weeks, HIV RNA testing of source patient is also recommended
  - PEP should be initiated and continued until results of viral load come back

A10

- Baseline HIV test should be conducted on exposed worker whether or not they take HIV PEP
- If PEP indicated, follow-up HIV serology for exposed worker at 4 weeks and 12 weeks

A11

TIMING OF PEP INITIATION

- Decisions regarding initiation of PEP beyond 36-72 hours post exposure should be made on a case-by-case basis with the realization of diminished efficacy when timing of initiation is prolonged. (AII)
  - An absolute elapsed time after which PEP should not be administered cannot be stated with certainty.

A12

Slide 17

A9 I think SP refers to the case which will be presented AFTER this talk. Can you substitute something else here?
Author, 5/15/2013

A10 EP and EW are also not abbreviations I know well. Wondering if you might consider subbing them out?
Author, 5/15/2013

A11 I think we shouldn't assume tthat people will know the old guidelines. No need to mention anything that is no longer recommended.
Author, 5/15/2013

Slide 18

A12 I'm wondering whether we should say that the NYC DOHMH only funds people with exposure in the 36 hour window?
Author, 5/15/2013

PREFERRED PEP REGIMEN

Truvada [TRV] (tenofovir [TDF] 300 mg/emtricitabine [FTC] 200 mg) one tablet daily

+

Isentress (raltegravir [RAL]) 400 mg BID

Duration X 28 days (or until source patient ruled out fo A13 HIV)

Alternative PEP Regimen

Preferred Alternative

- TRV (one tablet) PLUS
  - Darunavir (DRV) 800 mg
    OR
  - Atazanavir (ATV) 300 mg
    OR
  - Fosamprenavir (FPV) 1400 mg
    PLUS
  - Ritonavir (RTV) 100gm
  - All once daily

Acceptable Alternative

- TRV + FTC + Zidovudine
- TRV + FTC + Lopinavir/ritonavir
- Zidovudine + lamivudine (Combivir) PLUS
  - DRV 800 mg and RTV 100 mg
  - ATV 300 mg and RTV 100 mg
  - FPV 1400 mg and RTV 100 mg
  - Lopinavir/ritonavir

Slide 19

A13 Again, spell out SP?
Author, 5/15/2013

A17

PEP Follow-Up Schedule

Table 6: Monitoring Recommendations After Initiation of PEP Regimens Following Occupational Exposure[a]						
	Baseline	**Week 1**	**Week 2**	**Week 3**	**Week 4**	**Week 12**
Clinic Visit	√	√ Or by telephone	√ Or by telephone	√ Or by telephone	√	
Pregnancy Test	√					
Serum liver enzymes, BUN, creatinine, CBC[b]	√		√		√	
HIV test [c]	√				√	√

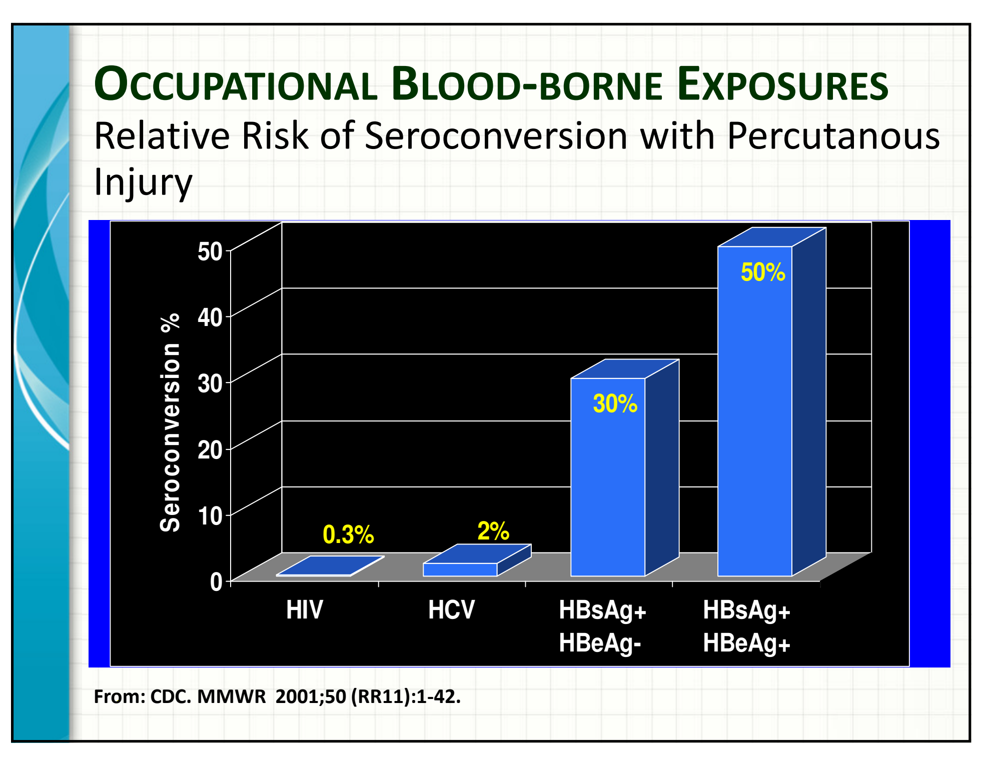
[a] For post-exposure management for hepatitis B and C, see *Section XI: Occupational Exposures to Hepatitis B and C*

[b] CBC should be obtained for all exposed workers at baseline. Follow-up CBC is indicated only for those receiving a zidovudine-containing regimen.

[c] Recommended even if PEP is declined.

OCCUPATIONAL BLOOD-BORNE EXPOSURES

Relative Risk of Seroconversion with Percutanous Injury



From: CDC. MMWR 2001;50 (RR11):1-42.

Slide 21

A17 FOnt is pretty small here...can you make it bigger? See my attempt (8 point to 16 point).
Author, 5/15/2013

HCV Exposures- Baseline Testing

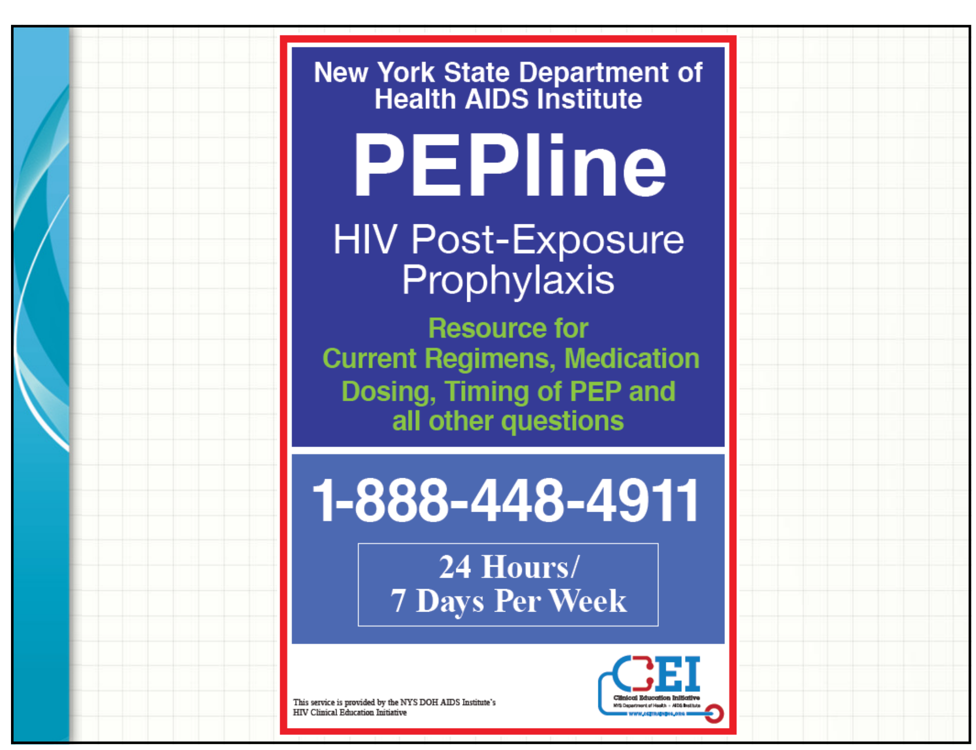
- Source Patient:
  - HCV antibody test (e.g., EIA/ELISA), and if positive, HCV RNA test or RIBA
- Exposed Worker:
  - Liver panel including liver enzymes
  - HCV antibody, and if positive, HCV RNA test

Recommended PEP for Hepatitis B Virus

Vaccination/Ab response status of exposed patient	Treatment when source patient is:		
	HBsAg positive	**HBsAg negative**	**Source unknown or not available for testing**
Unvaccinated/ non-immune	HBIG ×1; initiate HB vaccine series	Initiate HB vaccine series	Initiate HB vaccine series
Previously vaccinated, known responder	No treatment	No treatment	No treatment
Previously vaccinated, known non-responder	HBIG ×1 and initiate revaccination or HBIG ×2	No treatment	No treatment unless high-risk source; if high-risk source, treat as if source were HBsAg positive
Previously vaccinated, response unknown	Single vaccine booster dose	No treatment	No treatment unless high-risk source; if high-risk source, treat as if source were HBsAg positive
Still undergoing vaccination	HBIG ×1; complete series	Complete series	Complete series

Education and Counseling

- Relative risk of transmission by the exposure
  - Assess for factors that increase risk
- Risks and benefits of PEP including side effects
- Need to report any signs and symptoms of acute (primary) HIV infection
  - Need to prevent secondary transmission
- Acknowledge the fear/anxiety that commonly occur in exposed persons



A18
QUESTIONS?
CEI
Clinical Education Initiative
NYS Department of Health • AIDS Institute
WWW.CEITRAINING.ORG

Slide 27

A18 I wonder if you can mention financial issues (briefly)? As in, most insurance will cover this, correct? And also where uninsured person can get it (our 6 new sexual and behavioral health programs...I will get you more info to include)? Might also mention recent NYS law that states that sexual assault victims can get a free starter pack in EDs:
http://www.ceitraining.org/documents/31156-Dear%20Colleague%20letter_signed.pdf
Author, 5/15/2013