Post - Exposure Prophylaxis (PEP)

Philana Liang, PA-C, MPH

Washington University Infectious Disease Clinic

Core Program Manager, St. Louis STI/HIV Prevention Training Center

No Disclosures

PEP Panel Questions

- What are the best practices for ensuring a client gets access to PEP as soon as possible?
- How do you determine who receives a PEP prescription or not?
- What are some challenges you have faced as a provider and what solutions did you use to overcome them?
- What are some common misconceptions you hear about PEP? How do you discuss these with clients?
- How can providers and other staff address the gap or lack of PEP in rural areas?
- What can providers and other staff do to create a welcoming environment?
- What are some barriers you have run into while linking your clients to PEP?
- How can we ensure our clients have access to PEP services in our communities?
- What other conversations should be had when discussing PEP eligibility?
- How can PCPs and PrEP providers outside the ED assist in PEP provision?

A Fireside Chat with Philana

"What are some common misconceptions you hear about PEP?"

"How do you discuss these with clients?"

What is PEP?

- Taking antiretrovirals after a single and specific exposure with increased likelihood of HIV transmission to stop HIV infection in people who are HIV-negative.
- Exposure occurs typically through sex or sharing syringes (or other injection equipment) with someone who has or might have HIV.
- PEP must be started as soon as possible to be effective – always within 72 hours of a possible exposure – and continued for 4 weeks (HIV can establish infection within 24 to 36 hours after exposure)
- It's different from PrEP
- Some patients who need PEP can and should consider PrEP

So, what is PrEP?

Pre-exposure Prophylaxis

- Taking antiretroviral medication before sexual contact or injection drug use to prevent HIV from establishing infection
- For people who inject drugs and experience more frequent exposures, PrEP is probably a better prevention strategy than PEP.
- There is not enough evidence about PEP's effectiveness to prevent HIV infection from nonsterile injection drug use.

ORIGINAL ARTICLE

A Case–Control Study of HIV Seroconversion in Health Care Workers after Percutaneous Exposure

Denise M. Cardo, M.D., David H. Culver, Ph.D., Carol A. Ciesielski, M.D., Pamela U. Srivastava, M.S., Ruthanne Marcus, M.P.H., Dominique Abiteboul, M.D., Julia Heptonstall, M.R.C.Path., Giuseppe Ippolito, M.D., Florence Lot, M.D., Penny S. McKibben, David M. Bell, M.D., and the Centers for Disease Control and Prevention Needlestick Surveillance Group

- Reported effect of occupational PEP (prescribed as ZDV monotherapy) on HIV seroconversion.
- Identified risk factors for the transmission of HIV to health care workers (HCWs) from the U.S., France, Italy, and the UK who had experienced exposure to HIV-infected blood.
- Cases included those who had HIV seroconversion temporally associated with the exposure, and no other reported exposures to HIV.
- Controls were HIV negative at the time of exposure, and for at least six months after.
- No difference in the rate at which PEP was offered to cases or controls after controlling for HIV transmission risk.
- HIV seroconversion among HCWs who had received PEP after occupational exposure was reduced by approximately 81%, compared to those who did not receive PEP.
- This study is considered the strongest example of the benefit of PEP in humans.

N Engl J Med 1997; 337:1485-1490

Sexual Assault and HIV Postexposure Prophylaxis at an Urban African Hospital

Eric Munene Muriuki, MBChB, MSc,[1,,2] Joshua Kimani, MBChB, MPH,[2,,3] Zipporah Machuki, BS, MSc,[2] James Kiarie, MBChB, MMed, MPH,[1,,4,,5,,6] and Alison C. Roxby, MD, MSc[4,,7]

Reviewed hospital charts of survivors of sexual violence attending the Gender Based Violence Recovery Center between 2009 and 2012 in Nairobi, Kenya.

Survivors were mainly female, and 16% were children under 10 years old.

Of 385 survivors, 207 initiated PEP (ZDV/3TC plus LPV/r).

Only 70 completed the full 28-day course and 21 returned for a three-month follow up.

No seroconversions were reported among those who came for a repeat HIV test

ONTARIO HIV TREATMENT NETWORK

The efficacy of post-exposure prophylaxis (PEP) for HIV

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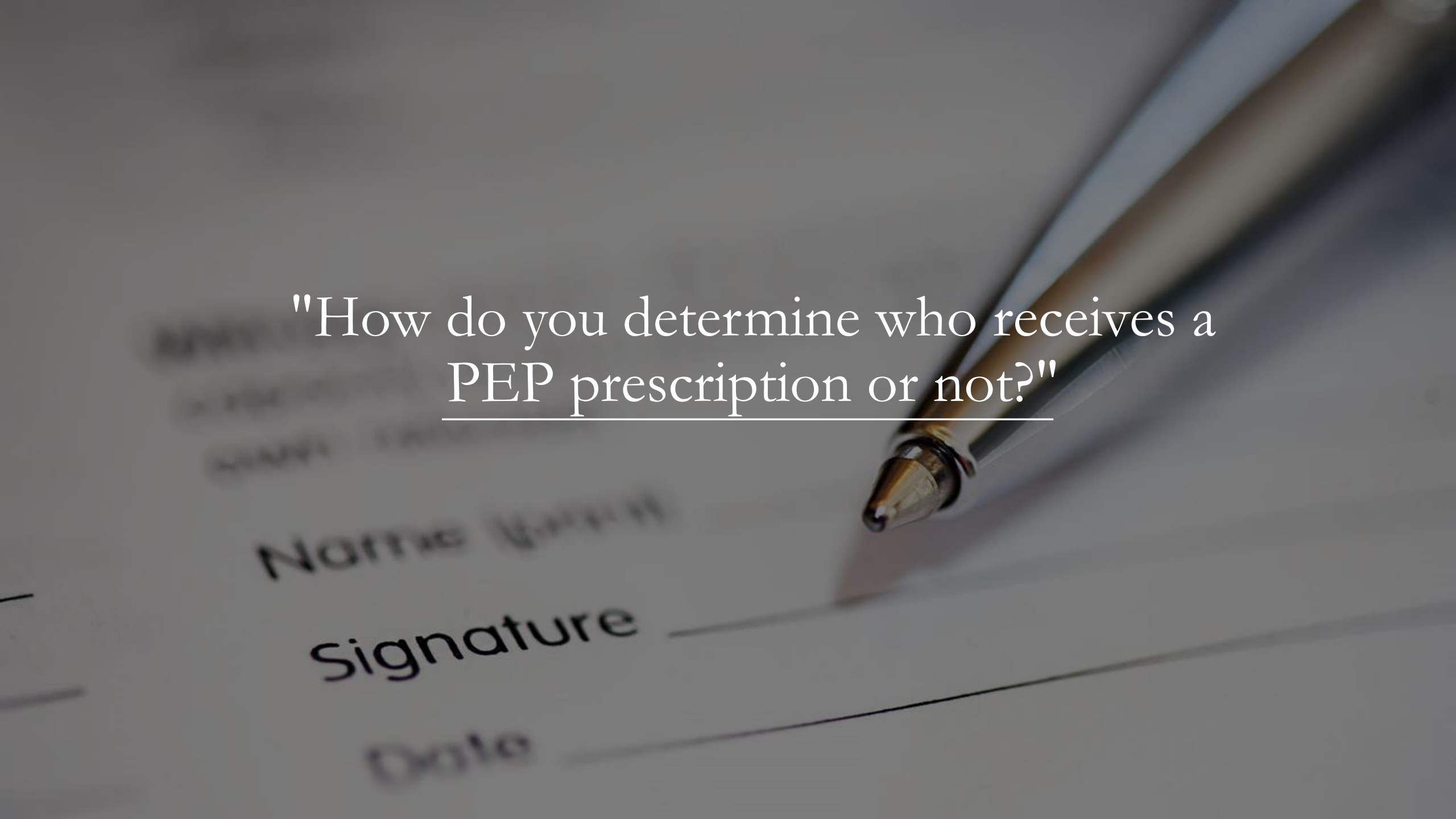
Keys to PEP Success

- The timing of initiation and the duration of treatment
- Adherence to the prescribed regimen to maintain sufficient antiretroviral drug levels is important in preventing replication of the HIV virus.
- Continued exposure to HIV while on PEP may also be a key determinant in its efficacy.

What is the PEP regimen?

- The preferred PEP regimen for otherwise healthy adults and adolescents is tenofovir disoproxil fumarate (TDF) (300 mg) + emtricitibine (FTC) 200 mg) once daily PLUS raltegravir (RAL) (400 mg) twice daily or dolutegravir (DTG) (50 mg) once daily).
- All persons offered PEP should be prescribed a 28-day course of a 3-drug antiretroviral regimen. Since adherence is critical for PEP efficacy, it is preferable to select regimens that minimize side effects, number of doses per day and the number of pills per dose.



"How do you determine who receives a PEP prescription or not?"

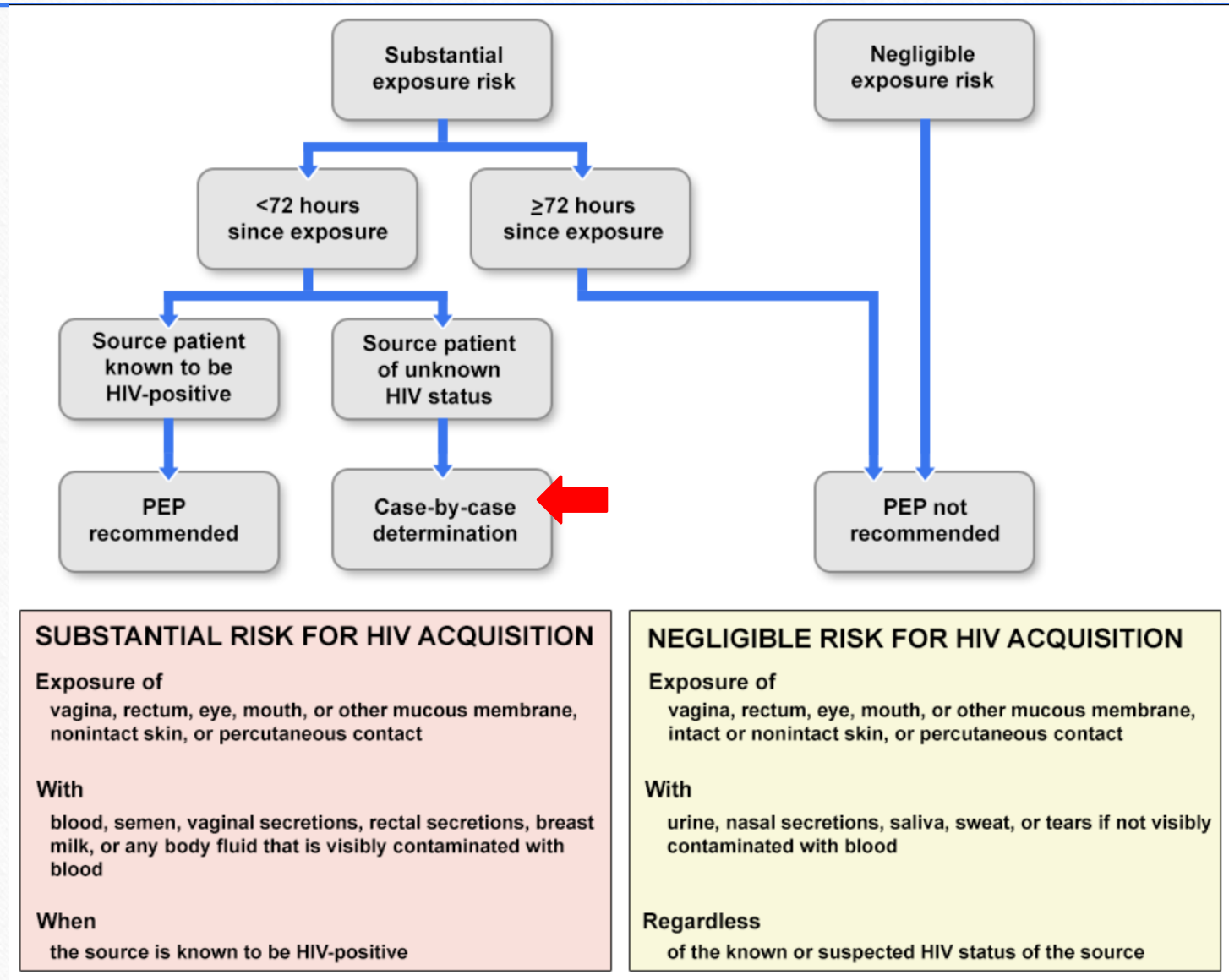
How do you define exposures?

How do you quantify risk?

Contact with potentially contaminated body fluids from an HIV-infected source in the vagina, rectum, eye, mouth or other mucous membrane, non-intact skin, or perforated skin (eg, needle stick)

If the source is of unknown HIV status, a **case-by-case determination may be made regarding the use of PEP.**

Algorithm for evaluation and treatment of possible HIV exposures



Updated Guidelines for Antiretroviral Postexposure Prophylaxis after Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV – United States, 2016. MMWR Morb Mortal Wkly Rep, 2016. **65**(17): p. 458.

Estimated Per-Act Probability of Acquiring HIV from an Infected Source, by Exposure Act*

Type of Exposure	Risk per 10,000 Exposures
Parenteral	
Blood Transfusion	9,250
Needle-Sharing During Injection Drug Use	63
Percutaneous (Needle-Stick)	23
Sexual	
Receptive Anal Intercourse	138
Insertive Anal Intercourse	11
Receptive Penile-Vaginal Intercourse	8
Insertive Penile-Vaginal Intercourse	4
Receptive Oral Intercourse	Low
Insertive Oral Intercourse	Low
Other^	
Biting	Negligible
Spitting	Negligible
Throwing Body Fluids (Including Semen or Saliva)	Negligible
Sharing Sex Toys	Negligible

* Factors that may increase the risk of HIV transmission include sexually transmitted diseases, acute and late-stage HIV infection, and high viral load. Factors that may decrease the risk include condom use, male circumcision, antiretroviral treatment, and pre-exposure prophylaxis. None of these factors are accounted for in the estimates presented in the table.

^ HIV transmission through these exposure routes is technically possible but unlikely and not well documented.

Source:

- Patel P, Borkowf CB, Brooks JT. Et al. Estimating per-act HIV transmission risk: a systematic review. AIDS. 2014. doi: 10.1097/QAD.0000000000000298.
- Pretty LA, Anderson GS, Sweet DJ. Human bites and the risk of human immunodeficiency virus transmission. Am J Forensic Med Pathol 1999;20(3):232-239.

CLINICAL GUIDELINES PROGRAM

HIV and Sexual Assault

Increased risk of HIV infection in sexual assault has been associated with

Trauma at the exposure site

- Genitorectal trauma - 50% to 85% [Sachs and Chu 2002; Jones, et al. 2009; Sommers, et al. 2012]
- Anogenital trauma - 20% to 85% [Riggs, et al. 2000; Grossin, et al. 2003; Jones, et al. 2003; Sugar, et al. 2004; Laitinen, et al. 2013; Larsen, et al. 2015]

Absence of barrier protection

- High rates of unprotected receptive anal intercourse (88%) and vaginal penetration (>60%) [Draughon Moret, et al. 2016]
- Perpetrators of intimate partner violence

➢ Unlikely to use condoms (or use condoms inconsistently)

➢ Likely to force sexual intercourse without a condom

➢ Likely to have sexual intercourse with other partners [Raj, et al. 2006; Casey, et al. 2016; Stephenson and Finneran 2017].

There are published reports of HIV seroconversion following sexual assault [Murphy, et al. 1989; Claydon, et al. 1991; Albert, et al. 1994; Myles, et al. 2000]

PEP is the only proven method of reducing HIV acquisition after exposure, and it should be offered in cases of sexual assault.

https://www.hivguidelines.org/pep-for-hiv-prevention/pep/risk/#tab_2

"What are some challenges you have faced as a provider and what solutions did you use to overcome them?"

A Recent Case

22 year old transgender male at a local college reports unprotected sex with multiple partners two nights ago, involving oral, anal, and vaginal intercourse.

He was previously on PrEP, but stopped a week ago because he was trying to make his prescription last.

He is on his parents' insurance, but does not want them to find out about his situation.

He is not having any symptoms. He had a recent HIV test that was negative.

Barriers to PEP

- Cost
- Access
- Time Limitations
- Stigma
- Fear
- Side effects

ONTARIO HIV TREATMENT NETWORK

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Barriers to PEP

- "Medication costs have limited the feasibility and acceptability of biomedical strategies like PEP in Canada."
- "Programs offering PEP have been slow to appear in the United States as well, mainly due to a lack of awareness in both providers and potential consumers".
- "Expanding knowledge on biomedical interventions like PEP will contribute to the current efforts to eliminate new HIV infections."

https://www.ohtn.on.ca/rapid-response-the-efficacy-of-post-exposure-prophylaxis-pep-for-hiv/

- What are the best practices for ensuring a client gets access to PEP as soon as possible?
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Accessing PEP

- Establish relationships with pharmacies, local hospitals/EDs
- Patient assistance programs
- Hotlines (DC PEP Hotline, NYC/NYS PEP Hotline)
- Planned Parenthood
- Grants/Foundations

What about cost?

- One month supply of tenofovir disoproxil fumarate (TDF) is about $2000 without insurance.
- The average retail price of raltegravir is around $2,214.81.
- The cost for dolutegravir is around $429 for a supply of 30 tablets, depending on the pharmacy.

$2000 + $2,214.81 + $429 = $4,643.81

340B Drug Program

Section 340B(a)(4) of the Public Health Service Act specifies which covered entities are eligible to participate in the 340B Drug Program. These include qualifying hospitals, Federal grantees from HRSA, the Centers for Disease Control and Prevention (CDC), the Department of Health and Human Services' Office of Population Affairs, and the Indian Health Service.

Covered entities are only allowed to provide 340B drugs to certain eligible patients. **Entities dispense 340B drugs through in-house pharmacies or contract pharmacies**, which are outside pharmacies entities contract with to dispense drugs on their behalf.

Health Centers

Federally Qualified Health Centers
Federally Qualified Health Center Look-Alikes
Native Hawaiian Health Centers
Tribal / Urban Indian Health Centers

Ryan White HIV/AIDS Program Grantees

Ryan White HIV/AIDS Program Grantees

Hospitals

Children's Hospitals
Critical Access Hospitals
Disproportionate Share Hospitals
Free Standing Cancer Hospitals
Rural Referral Centers
Sole Community Hospitals

Specialized Clinics

Black Lung Clinics
Comprehensive Hemophilia Diagnostic Treatment Centers
Title X Family Planning Clinics
Sexually Transmitted Disease Clinics
Tuberculosis Clinics

CDC Provided Links

How can I pay for PEP?

Depending on the reason you are prescribed PEP, you may qualify for free or low-cost PEP medicines.

Paying for PEP After a Sexual Assault

- You may qualify for partial or total reimbursement for medicines and clinical care costs.
- Find resources available in your area .

Paying for PEP After an Exposure at Work

- Your workplace health insurance or workers' compensation will usually pay for PEP.

Paying for PEP for Another Reason

- If you cannot get insurance coverage, your health care provider can apply for free PEP medicines through the medication assistance programs run by the manufacturers.
- These requests for assistance can be handled urgently in many cases to avoid a delay in getting medicine.
- Enrollment applications, such as Gilead's Advancing Access form or NASTAD's Patient Assistance tool , can be completed online, over the phone, or by fax.

https://www.cdc.gov/hiv/basics/pep/paying-for-pep.html

Resources by State

North Dakota	CAWS North Dakota/Coalition on Abused Women's Services 521 East Main Ave., Suite 320 Bismarck, ND 58501 Phone: 701-255-6240 Toll Free: 1-888-255-6240 Website: www.ndcaws.org	First Nations Women's Alliance P.O. Box 107 1222 HIghway 2 E Devils Lake, ND 58301 Phone: 701-662-3380 Toll Free: 1-877-286-3692 Website: www.nativewoman.org	CAWS North Dakota/Coalition on Abused Women's Services 521 East Main Ave., Suite 320 Bismarck, ND 58501 Phone: 701-255-6240 Toll Free: 1-888-255-6240 Website: www.ndcaws.org
South Dakota	South Dakota Network Against Family Violence and Sexual Assault 2520 E River Ridge Pl., Suite 200 Sioux Falls, SD 57103-3903 Phone: 605-731-0041 Website: https://sdnafvsa.com	Native Women's Society of the Great Plains P.O. Box 638 Kyle, SD 57752-0638 Phone: 605-455-2290 Website: http://nativewomenssociety.org	South Dakota Coalition Ending Domestic & Sexual Violence 122 E Sioux Ave., Suite D Pierre, SD 57501 Phone: 605-945-0869 Website: www.sdcedsv.org

Crime Victims Compensation

NORTH Dakota | Corrections and Rehabilitation
Be Legendary.™

What Help Is Available?

- Reasonable medical and mental health treatment and prescribed medication.
- Wage loss.
- Replacement services loss (expenses incurred for services the claimant would normally have performed).
- Funeral expenses.
- Dependent's economic loss (loss of deceased's wages).

What Are The Limits On Awards?

- Wage loss is limited to an award of not more than $300.00 per week.
- Allowable funeral expenses are limited to $5,000.00.
- Total recovery may not exceed $25,000.00.

What Other Resources Are Considered?

- This fund is a secondary source which pays only for loss not paid by other sources, such as, but not limited to: medical insurance, medical assistance, medicare, sick leave or annual leave paid by the employer, social security, workers compensation or other disability benefits.

CRIME VICTIMS' COMPENSATION PROGRAM

SOUTH DAKOTA DEPARTMENT OF PUBLIC SAFETY

Allowable Expenses and Available Benefits

The South Dakota Crime Victims' Compensation (CVC) Program provides monetary assistance to victims of violent crimes. This program, administered by the Department of Public Safety, can pay victims of state, tribal, or federal crimes, a maximum of $15,000 for expenses incurred as a direct result of personal injury or death.

Please call (605) 773-6317 for more information or assistance.

Expenses must be reasonable in amount and may include:

- Medical expenses
- Mental health counseling expenses
- Mileage
- Funeral and burial expenses
- Loss of earnings or support
- Dental and prosthetic devices
- Eyeglasses or corrective lenses
- Homicide scene cleanup expenses
- Replacement costs for personal property used as evidence
- Other similar expenses

Requirements & Limitations

The program is a last resort for payment. In most cases, payments can only be made if there is no other source of payment including private health insurance for the victim or other public programs such as Medicaid or Medicare, etc. However, there are no income requirements. Compensation cannot be paid for property losses, attorney's fees, or pain and suffering. There may be limitations to the amount of compensation for the expenses listed above.

Back to the case

22 year old transgender male at a local college reports unprotected sex with multiple partners two nights ago, involving oral, anal, and vaginal intercourse.....

1. Baseline testing was arranged at the student health center.
2. PEP was provided free of charge and delivered to patient's home before 8:00PM the day he called clinic.
3. Zofran was prescribed in case of nausea
4. Follow up was arranged in the Clinic in 2 weeks.

When the patient returned for follow up:

1. He reported 100% adherence (no missed pills).
2. The patient reported no issues with side effects.
3. He had no STI or systemic symptoms.
4. Follow up labs were arranged through student health.
5. Follow up HIV testing, STI testing, and STI treatment was done through the health department STI clinic (to avoid billing)
6. The patient resumed PrEP through the student health center, but was also provided information on injectable PrEP through the ID clinic.

"What can providers and other staff do to create a welcoming environment?"

A Trauma-Informed Approach

- Awareness of the prevalence and impacts of trauma
- Emphasis on creating safety and trust
- Facilitating opportunities for choice, collaboration, and connection

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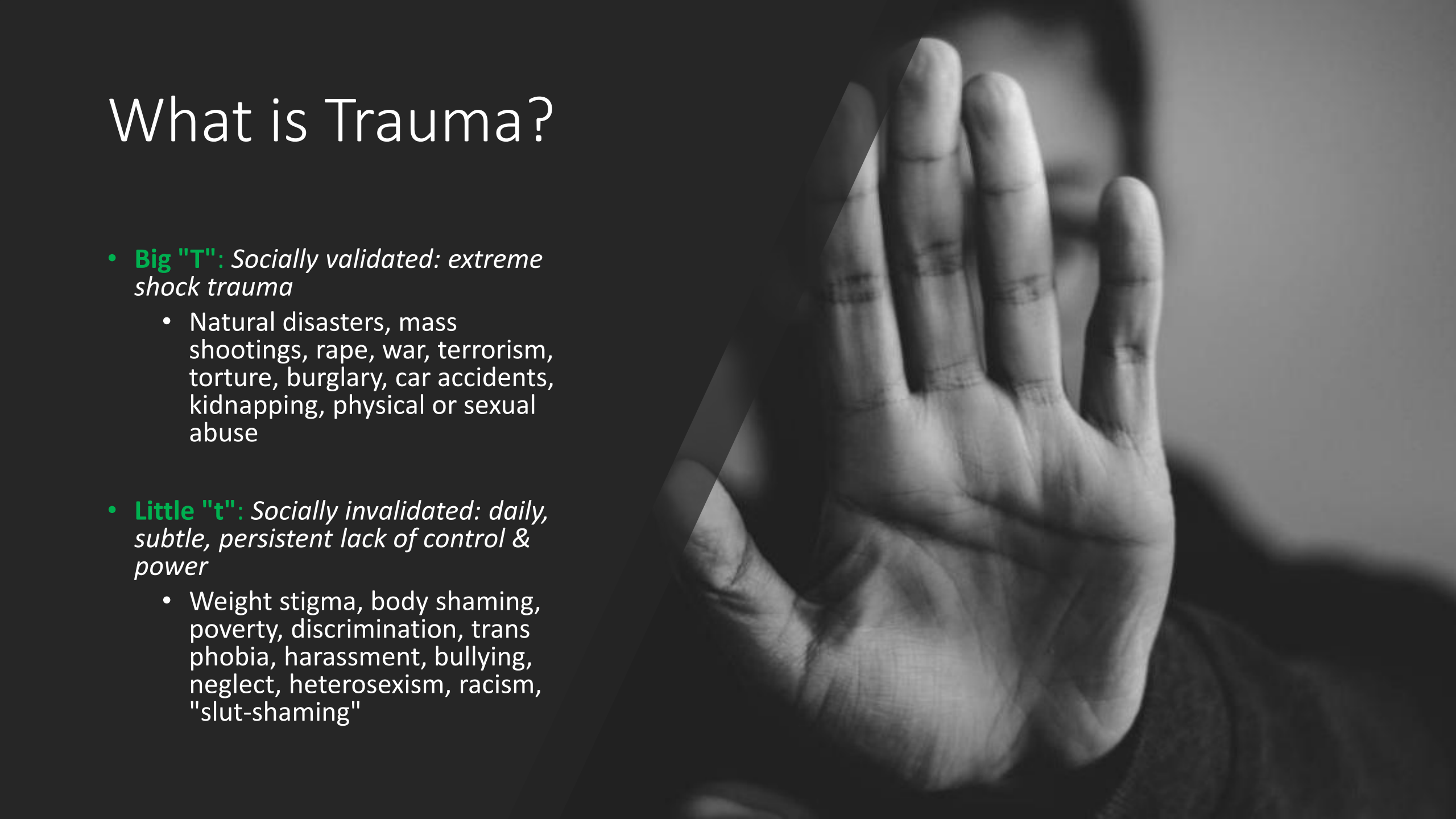
What is Trauma?

Individual trauma results from an event, series of events, or set of circumstances that is experienced by an individual as physically or emotionally harmful or life threatening and that has lasting adverse effects on the individual's functioning and mental, physical, social, emotional, or spiritual well-being.

What is Trauma?

- **Big "T"**: *Socially validated: extreme shock trauma*
  - Natural disasters, mass shootings, rape, war, terrorism, torture, burglary, car accidents, kidnapping, physical or sexual abuse

- **Little "t"**: *Socially invalidated: daily, subtle, persistent lack of control & power*
  - Weight stigma, body shaming, poverty, discrimination, trans phobia, harassment, bullying, neglect, heterosexism, racism, "slut-shaming"



Sexual Violence is Common

1 out of every 6 American cisgender women has experienced attempted or completed rape in her lifetime (14.8% completed, 2.8% attempted).[4]

About 3% of American cisgender men—or 1 in 33—have experienced an attempted or completed rape in their lifetime.

10% of 27,715 respondents to the 2015 U.S. Transgender Survey reported being sexually assaulted in the 12 months prior to survey completion; 47% reported that they had experienced sexual assault during the course of their lives. [James, et al. 2016].

https://www.cdc.gov/violenceprevention/sexualviolence/fastfact.html

What is Trauma?

Traumatic experiences often involve a loss of power, control, or trust

People who experience trauma may feel a deprived sense of safety, autonomy and trust.

There are three main types of trauma:

Acute trauma results from a *single* incident.

Chronic trauma is *repeated* and *prolonged* such as domestic violence or abuse.

Complex trauma is exposure to *varied and multiple* traumatic events, often invasive and interpersonal in nature.

Trauma Changes the Brain

With chronic trauma, brain development is altered to survive high stress and remain alert. Neural pathways associated with fear are chronically activated so that the parts controlling fear and anxiety grow, while the parts controlling logical or more critical thinking shrink.

These two parts of the brain may conflict, resulting in flashbacks and difficulty interpreting or identifying emotional responses. The coping mechanisms used to survive traumatic experiences remain even after safety is established, resulting in unexpected or uncontrollable reactions to certain triggers.

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Triggers are Real

For people who experienced trauma, the brain connects certain sounds, smells, sights, touches, facial expressions and body movements, seasons, activities, and statements with traumatic incidents.

The brain continues to process specific stimuli as dangerous, and an emotional response is triggered.

A Trauma-Informed Approach

You can better respond to survivors in a person-centered, trauma-informed manner when you recognize and acknowledge the impact of childhood trauma and subsequent adult trauma.

Traditional	Trauma-Informed
Doing for people	Doing with people
What's wrong with you?	What happened to you?
Service provider as expert	Person as expert on own life
Symptoms and pathologies	Coping mechanisms
Treatment and cure	Healing and recovery
Non-compliant/disengaged	How can we better support you?
These are the service options	What might you need to live well?
Hierarchical	Sharing power

Shared Decision Making (SDM)

American College of Cardiology

"is an essential part of the clinician-patient relationship, improving accuracy of the patient's risk perception and clinician satisfaction. Done properly, it helps clinicians navigate patients' wide-ranging therapy options along with consideration of the patients' goals."

What other conversations should be had when discussing PEP eligibility?

When someone reports the need for PEP:

- Assess for the possibility of sexual assault or violence
- What kind of evaluation are you considering? (Forensic/Medical/Both)?
- When did it happen?
- What treatment are you interested in receiving? PEP (then PrEP), STI ppx, emergency contraceptive (then contraception)
- Which tests are you interested in?
  - STIs
  - HIV
  - Hepatitis B and C
- Can I provide you any resources
  - Mental health
  - Contraception/PrEP
  - Social Work
- Assess for IPV/power dynamics

Feel Free to Contact Me:

Email: phliang@wustl.edu

Office: 314-362-2439

I'd love to hear from you!