PREP IN PRIMARY CARE

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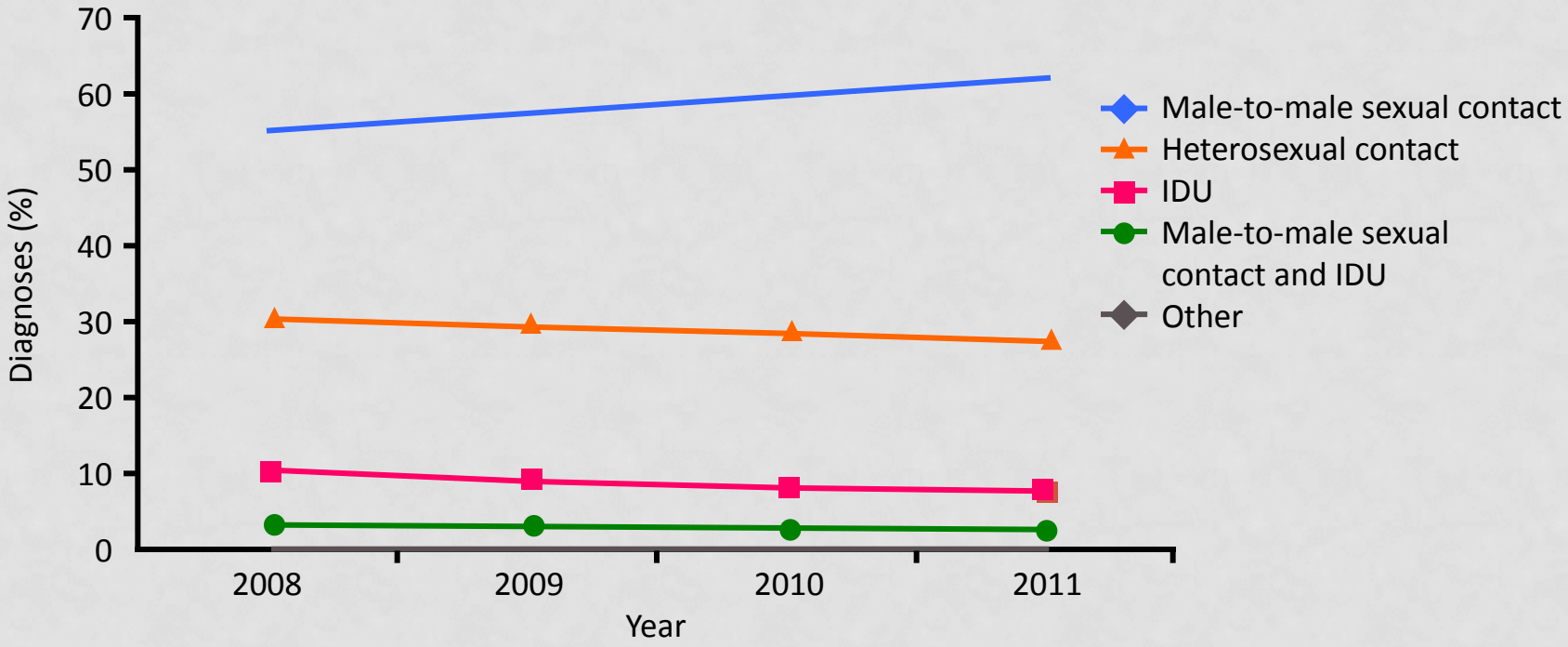
THE NEED FOR CONTINUED HIV PREVENTION

Estimated new HIV infections in the US for the most affected subpopulations, 2008-2011



CDC. HIV in the United States: 2013.

PROVEN HIV TREATMENT AS PREVENTION

- Prevention of mother-to-child transmission (PMTCT)
  - ARVs are given to mother during pregnancy, labor, and delivery and to infant postpartum; reduces the risk of transmission to 20-30% to <1%
- Postexposure prophylaxis (PEP)
  - ART taken within hours of a known or suspected HIV exposure (eg, needle stick injury, sexual exposure)
  - Since 1999, only 1 confirmed case of occupationally acquired HIV infection in the United States
- HPTN 052
  - First evidence from RCT showing early ART can reduce the risk of HIV transmission to a sexual partner

ART=antiretroviral therapy; HPTN=HIV Prevention Trials Network; RCT=randomized controlled trial.

CDC. Proven HIV Prevention Methods. Released December 2014. Available at: http://www.cdc.gov/nchhstp/newsroom/docs/HIVFactSheets/Methods-508.pdf; DHHS. Perinatal Guidelines, 2014. Available at: http://aidsinfo.nih.gov/education-materials/fact-sheets/24/70/preventing-mother-to-child-transmission-of-hiv-during-childbirth; Centers for Disease Control and Prevention. Preventing New HIV Infections. Available at: http://www.cdc.gov/hiv/guidelines/preventing.html; Kuhar DT, et al. Infect Control Hosp Edimeiol. 2013;34(9):875-892; Smith DK, et al. MMWR Recomm Rep. Jan 21 2005;54:1-20; Joyce MP, et al. CROI 2015. Abstract 1027; Cohen MS, et al. N Engl J Med. 2011;365(6):493-505.

TREATMENT AS PREVENTION

PRE-EXPOSURE PROPHYLAXIS (PREP)

What is PrEP?

- An individual who is not infected with HIV takes ARV agent(s) before potential HIV exposure
- In 2012, the FDA approved TDF/FTC as PrEP for uninfected individuals who are at high risk of HIV infection

Not a new concept

- Antimalarial agents before traveling to areas with malaria
- Antibiotics before dental procedures

FDA=Food and Drug Administration; TDF/FTC= tenofovir/emtricitabine.

CDC. Preexposure Prophylaxis for the Prevention Of HIV Infection in the United States -- 2014: A Clinical Practice Guideline. May 2014. www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf. Accessed 1/19/15.

CDC PREP GUIDANCE: WHO IS RECOMMENDED PREP?

- Daily oral PrEP is recommended for adults at substantial risk of acquiring HIV infection:
  - Sexually active MSM
  - Heterosexually active men and women
  - Injection drug users

	MSM	Heterosexual Women and Men	Injection Drug Users
Detecting substantial risk of acquiring HIV infection	▪ HIV-positive sexual partner ▪ Recent bacterial STI ▪ High number of sex partners ▪ History of inconsistent or no condom use ▪ Commercial sex work	▪ HIV-positive sexual partner ▪ Recent bacterial STI ▪ High number of sex partners ▪ History of inconsistent or no condom use ▪ Commercial sex work ▪ In high-prevalence area or network	▪ HIV-positive injecting partner ▪ Sharing injection equipment ▪ Recent drug treatment (but currently injecting)

MSM=men who have sex with men; STI=sexually transmitted infection.

CDC. Preexposure Prophylaxis for the Prevention Of HIV Infection in the United States -- 2014: A Clinical Practice Guideline. Section: Summary of Guidance for PrEP Use. May 2014. www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf. Accessed 1/19/15.

CDC GUIDANCE: CLINICAL ELIGIBILITY

Before prescribing PrEP, identify patients for whom it would be harmful or may present risks:

- Documented negative HIV test result
- No signs/symptoms of acute HIV infection
- No use of contraindicated medications
- Normal renal function
- Documented absence of HBV infection or immunity
  - (i.e., successful vaccination)

HBV=hepatitis B virus.

CDC. Preexposure Prophylaxis for the Prevention Of HIV Infection in the United States -- 2014: A Clinical Practice Guideline. May 2014. www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf. Accessed 1/19/15.

BEFORE PRESCRIBING PREP: HIV TESTING

Rule out acute and chronic HIV infection

- Document negative antibody test within the week before starting (or restarting) PrEP medication
- Perform testing by drawing blood and sending to lab for routine HIV EIA or rapid, point-of-care fingerstick blood test
  - Combination antibody and p24 antigen tests reduces false negative window after acute infection
- Avoid oral rapid HIV testing because of lower sensitivity
- Do not accept patient-reported results

EIA=enzyme-linked immunoassay

CDC. Preexposure Prophylaxis for the Prevention Of HIV Infection in the United States -- 2014: A Clinical Practice Guideline. May 2014. www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf. Accessed 1/19/15.

BEFORE PRESCRIBING PREP: IMPORTANT EVALUATIONS

- Required screenings
  - Renal function
    - Avoid PrEP with TDF/FTC in anyone with CrCl of < 60 mL/min
  - Hepatitis B infection
    - Document HBV negative and vaccinate patients who are HBV susceptible

- Recommended screenings
  - Metabolic panel
  - Urinalysis
  - STI (e.g., syphilis, gonorrhea, chlamydia, HCV)
  - Pregnancy

CrCl=creatinine clearance.

CDC. Preexposure Prophylaxis for the Prevention Of HIV Infection in the United States -- 2014: A Clinical Practice Guideline. May 2014. www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf. Accessed 1/19/15.

CDC GUIDANCE: RECOMMENDED ORAL PREP

- Fixed-dose TDF/FTC is the recommended PrEP regimen* for MSM, heterosexually active men and women, and IDU who meet prescribing criteria:
  - FDA approved indication
  - Dosed as a single pill (300/200 mg) once daily
  - Provide a prescription or refill authorization for no more than 90 days (until next HIV test)

***MSM, heterosexually active men and women, and IDU who meet PrEP prescribing criteria.**

CDC. Preexposure Prophylaxis for the Prevention Of HIV Infection in the United States -- 2014: A Clinical Practice Guideline. May 2014. www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf. Accessed 1/19/15.

CDC PREP GUIDANCE: FOLLOW-UP AND MONITORING

Follow-up	At Least Every 3 Months	At Least Every 6 Months	At Least Every 12 Months
All patients	▪ HIV testing ▪ Adherence assessment ▪ Side effect assessment ▪ Medication adherence counseling ▪ Behavioral risk reduction support ▪ Answer any new questions	▪ Assess renal function (CrCl) ▪ Test for bacterial STIs	▪ Evaluate need to continue PrEP
Women	▪ Pregnancy test		

***Many experts recommend more frequent follow-up (i.e., monthly) of patients on PrEP, especially after initiation of TDF/FTC, to assess adherence and monitor for STI including HIV.**

CDC. Preexposure Prophylaxis for the Prevention Of HIV Infection in the United States -- 2014: A Clinical Practice Guideline. May 2014. www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf. Accessed 1/19/15.

PREP AND PREGNANCY

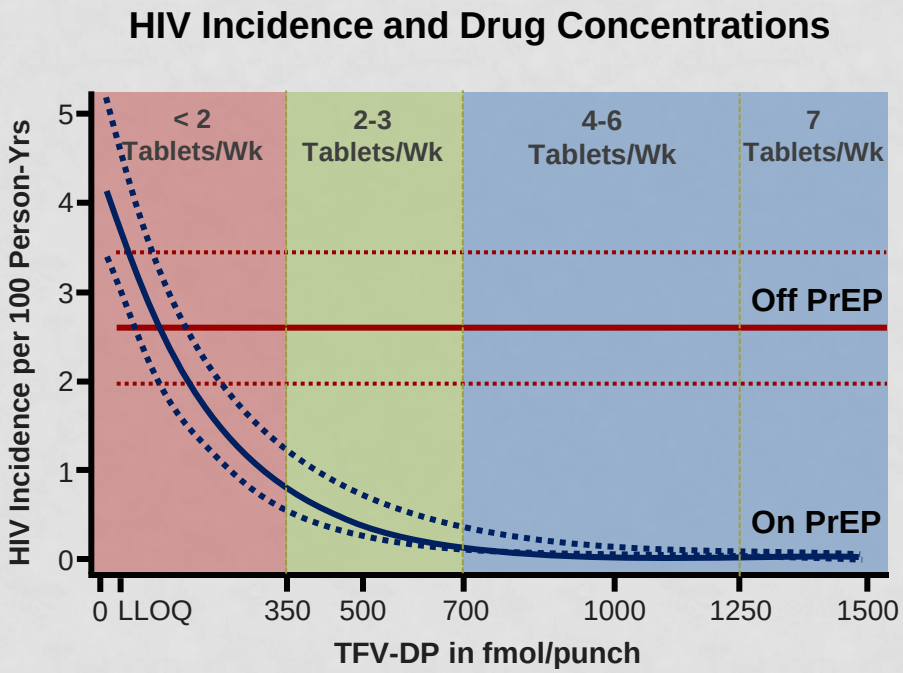
- Use at conception and during pregnancy can reduce the risk of HIV acquisition for uninfected partners
- Limited study on the use of PrEP during pregnancy
  - In one study, ART taken by uninfected women to prevent HIV transmission from infected male partners:
    - Did not result in significant fetal harm
    - Did not add risk to normal pregnancy
  - Extensive use of TDF/FTC in HIV+ pregnant women without evidence of fetal harm
- TDF and FTC are classified Category B
- Discuss the potential risks and benefits as well as limited information with the patient

CDC. Preexposure Prophylaxis for the Prevention Of HIV Infection in the United States -- 2014: A Clinical Practice Guideline. May 2014. www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf. Accessed 1/19/15; DHHS. HIV Perinatal Guideline. 2014; American College of Obstetricians and Gynecologists. Available at: http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Preexposure-Prophylaxis-for-the-Prevention-of-Human-Immunodeficiency-Virus. Accessed 1/19/15; Mugo NR, et al. JAMA. 2014;312(4):362-371.

PERFECT ADHERENCE TO DAILY PREP NOT REQUIRED FOR FULL BENEFIT

iPrEx OLE

- Open label extension study of daily oral PrEP (TDF/FTC) in MSM and transgender women (N=1603)
- PrEP provides protection even when adherence is less than 100%:
  - Efficacy of 4-6 tablets weekly similar to 7 tablets weekly (100% risk reduction)
  - 2-3 tablets weeks also associated with significant risk reduction (84%)
- Participants at highest risk had the greatest levels of adherence



Follow-up, %	26%	12%	21%	12%
Risk Reduction, %	44%	84%	100%	100%
95% CI, %	-31 to 77%	21 to 99%	86 to 100% (combined)	

Grant R, et al. Lancet Infect Dis. 2014;14(9):820-829; Grant RM, et al. 20th International AIDS Conference. July 20-25, 2014. Melbourne. Abstract TUAC0105LB.

BARRIERS TO PREP IN CLINICAL PRACTICE

Providers

- Unaware of intervention
- Uncertainty about complexity and monitoring time involved
- Uncomfortable assessing candidacy
- Uncertain how to bill for
- HIV providers have the expertise but primary care providers have the appropriate patients.

Patients

- Lack of awareness
  - Risk of HIV
  - PrEP availability
  - How to access it
- Lack of- or delayed access to preventive care
- Uninsured; cannot afford
- Adherence problems
- Concerns about disclosure
- Stigma

Liu A, et al. PLoS Med. 2014;11(3):e1001613; Krakower D, et al. Curr Opion HIV AIDS. 2012;7(6):593-599; Krakower D, et al. AIDS Behav. 2014;18(9):1712-1721.

DISCUSSING PREP WITH PATIENTS

- Adverse events will diminish soon after treatment
- Address issues related to medication access
- Provide adherence counseling
  - Identify barriers
  - Respond to missed doses with nonjudgmental
  - Emphasize the importance of adherence
  - Keep in mind that patient self-report may not reflect actual adherence

CDC. Preexposure Prophylaxis for the Prevention Of HIV Infection in the United States -- 2014: A Clinical Practice Guideline. May 2014. www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf. Accessed 1/19/15; Liu A, et al. PLoS Med. 2014;11:e1001613; Van Der Straten A, et al. CROI 2014. Abstract 44; Baxi SM, et al. CROI 2014. Abstract 953.

PATIENT INFORMATION FOR PREP

GETTING YOURSELF PREPARED FOR PrEP

It is not uncommon for people to face problems with their insurance covering the costs of Truvada for PrEP. This infographic provides details that may be useful to you. For help with troubleshooting, join **PrEP Facts on Facebook**: facebook.com/groups/PrEPFacts/

LEARN MORE ABOUT PrEP

- prepfacts.org
- myprepexperience.org
- hivwebline.org
- thewellproject.org/hiv-information/prep-women
- whatisprep.org

CHECK YOUR INSURANCE PLAN

Your costs

It's wise to check your insurance plan ahead of time to see what you may have to pay out of pocket while on PrEP:

- Find what your deductible is.
- Find what drug tier that Truvada is on.
- Figure out your total costs for medical visits, routine blood work, and the prescription.
- Ask for help from doctor's office, pharmacist, local case manager, or insurance plan rep.
- Avoid Bronze plans if you can (they generally have higher costs). Silver, Gold and Platinum plans offer better coverage if you can afford them.

FIND A MEDICAL PROVIDER WHO SUPPORTS YOUR DECISION TO PrEP

Schedule an appointment

Approach your medical provider about Truvada for PrEP prescription.

- If s/he will prescribe, CELEBRATE!
- If s/he doesn't know about PrEP but is willing to prescribe:
  1) S/he can consult the US PHS's prescribing guidelines, *Pre-Exposure Prophylaxis for the Prevention of HIV Infection* (www.cdc.gov/hiv/prevention/research/prep/), and/or
  2) You can take a copy of the guidelines with you, and/or
  3) S/he can consult the CDC's PrEP Line at 855-448-7737 during business hours (http://tinyurl.com/CDCprepline).
- If s/he isn't willing to prescribe:
  1) Avoid/utilize these resource materials:
     - CDC's "Talk to Your Doctor" pamphlet: http://tinyurl.com/CDCPrEPbrochure
     - Project Inform's "Working through a Difficult Doctor Visit": http://tinyurl.com/PrEPdocvisit
  2) Ask for a referral, or find another provider on your own:
     - your insurance plan's provider directory
     - public health and STD clinics
     - local, county and state health departments
     - provider searches on: hivma.org, aahivm.org, glma.org
     - http://accesstoprep.org/

MEDICAL VISITS, BLOOD WORK

If you encounter costs related to your medical visits and/or blood work, these options may help:

Public health clinics

- Some public health clinics offer sliding fee scale for medical visits and blood work.

FSAs

- FSAs (Flexible Spending Accounts) are accounts set up with pre-tax dollars to help pay for out-of-pocket health care costs.
- FSAs have an annual limit of $2,550, available through employers if offered.
- Enrollment is usually annual, so plan ahead.

GET YOUR PRESCRIPTION

Prior authorizations

Some insurance plans require a prior authorization (PA) for Truvada for PrEP.

- This is a normal process.
- May need extra paperwork.
- Your provider can use the codes found on p29 at www.cdc.gov/hiv/pdf/PrEPProviderSupplement2014.pdf.
- Re-submit paperwork until the PA is approved.

Denials

- Make sure your provider has coded paperwork correctly to insurance carrier. (Same Dx as above.)
- Work with your provider's office to submit challenge(s). It may take more than one time.

PICK UP PRESCRIPTION

Pharmacy refills

Plans vary in what they offer. Your plan may:

- Vary in how you get meds. (at pharmacy, mail order).
- Provide only 30-day refills.
- Offer 90-day refills.
- Make you initiate the monthly refill.
- Have an auto-send function for refills.
- Offer refills earlier than waiting 30 days.

ALSO:

- In-network pharmacies will reduce prior cost.
- Apply for Gilead's Co-Pay Card **before** going to pharmacy (URL over column).
- If pharmacy doesn't accept Co-Pay Card, keep pharmacy and sales receipts. Call the number on back of co-pay card. Submit

PAY FOR THE MEDICATION

Manufacturer programs

(www.truvada.com/truvada-patient-assistance)

Gilead Co-Pay Program

- covers up to $3,500/mo for out-of-pocket drug costs.
- for insured and uninsured individuals.
- cannot be used with Medicaid, Medicare, VA or other federal/state funded programs (apply to PAN Foundation).
- re-apply as needed.

Gilead Medication Assistance Program

- uninsured, income below 500% FPL (federal poverty level).
- re-apply as needed.

PAN Foundation Patient Access

PAN Foundation will help after all other sources are used.

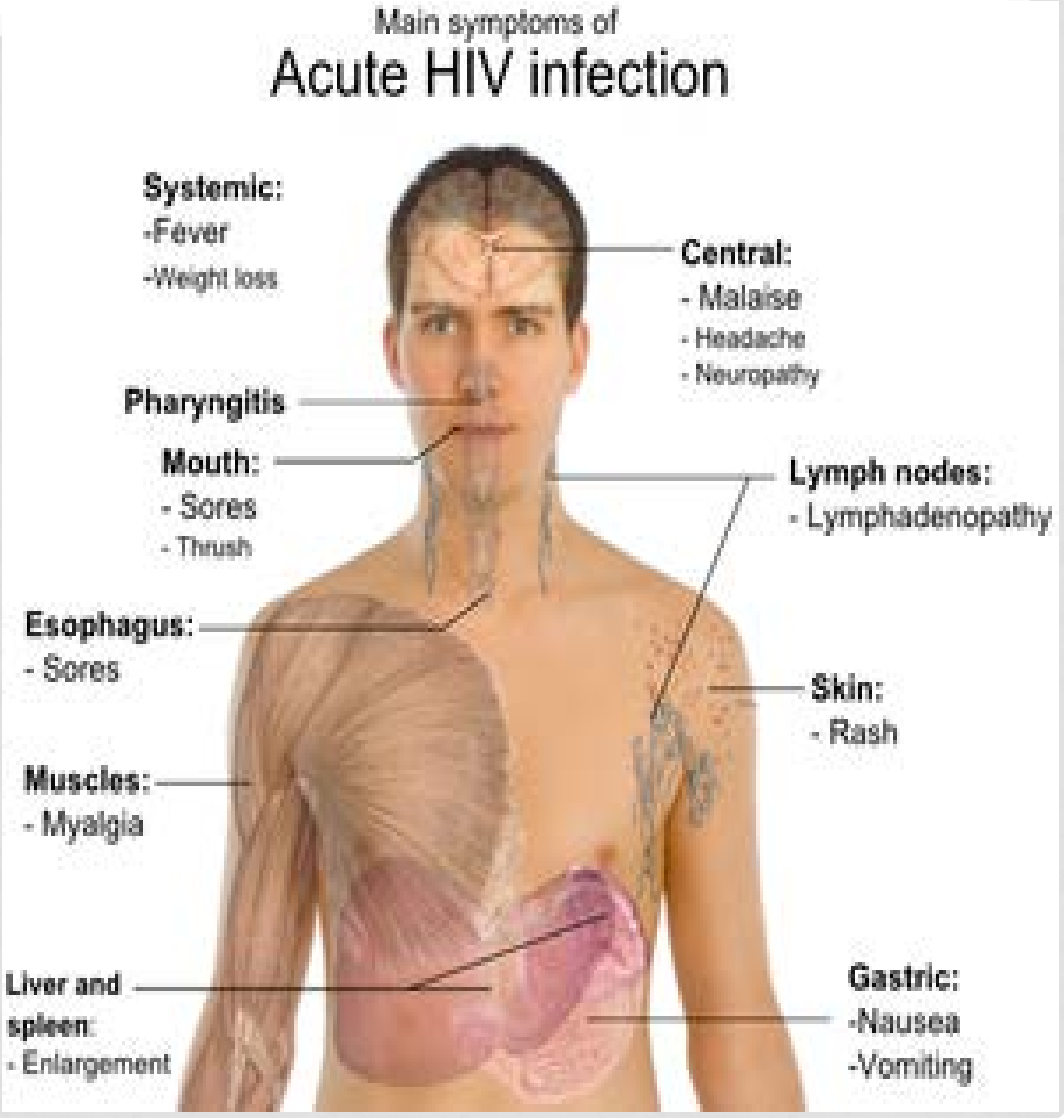
- Does not serve uninsured individuals.
- Income below 500% FPL (~$58,850).
- $4,000 maximum per year – may reapply.
- Covers co-pays, deductibles and co-insurance.
- Pharmacies can bill PAN Foundation directly.
- www.panfoundation.org, 866-316-7263.

Other sources for residents of:

- NEW YORK, http://tinyurl.com/NYgreatRX (only cost of services)

ACUTE HIV INFECTION

- Short, flu-like illness - occurs one to six weeks after infection
- Mild symptoms
- Infected person can infect other people



PRIMARY INFECTION: BETWEEN 2003 AND 2005

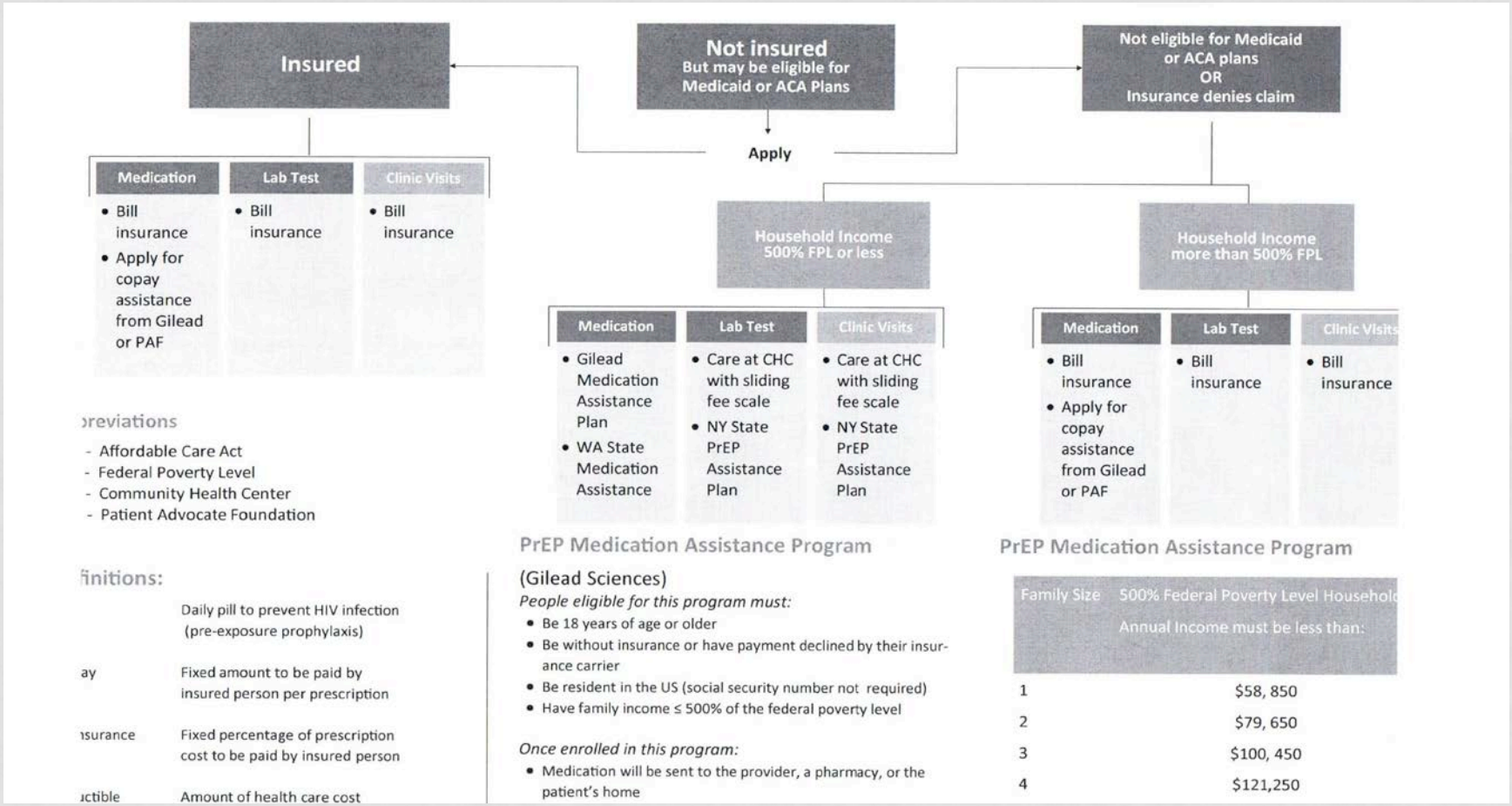
- Recent infection (<18 months) was diagnosed in 108 persons.

Of these:

- 93 (86%) were MSM
- 76 (70%) reported seroconversion symptoms
  - 55% fever
  - 37% rash
  - 33% pharyngitis
  - 28% diarrhea
  - 21% lymphadenopathy

Source: The AIDS Reader, April 2008, pg 163

PROVIDER INFORMATION REGARDING BILLING AND ASSISTANCE FOR PATIENTS NEEDING PREP



QUESTIONS?

Contact information:
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(605)940-8098
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POST EXPOSURE PROPHYLAXIS AND HIV

TRACY SALAMEH MSN, APRN, FNP-BC

POST EXPOSURE PROPHYLAXIS (PEP)

- Nonoccupational exposure and PEP (nPEP)
- Victims of sexual assault and PEP
- Occupational exposure and PEP

POST EXPOSURE PROPHYLAXIS (PEP) GENERAL INFORMATION

- Evaluation should occur as soon as possible
  - Wound and skin exposure sites should be washed with soap and water
  - Needlestick injuries should not be squeezed
- Source Person is Unavailable or Unwilling
  - If nPEP is indicated, initiate and complete a 28-day course
- Source Person is Known to be infected
  - Obtain information regarding his/her last viral load, antiretroviral medication history, and history of resistance, if possible. The first dose of nPEP should NOT be delayed while awaiting this information

POST EXPOSURE PROPHYLAXIS

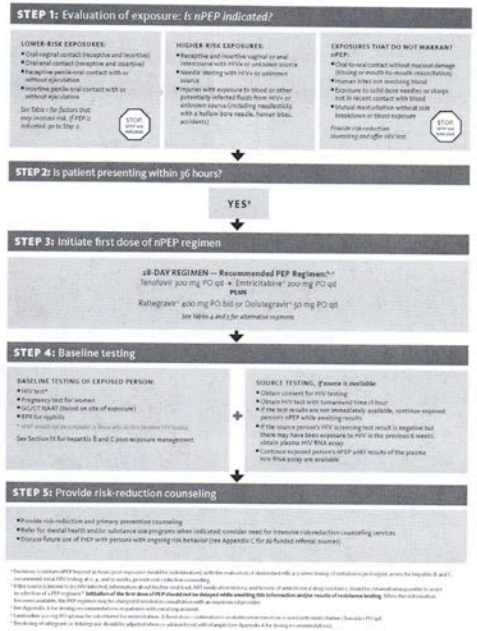
- Baseline HIV testing of the exposed person should occur within 3 days of the exposure
- If the exposed person declines testing, they should not receive nPEP
- For non-assault situations, clinicians should perform STI testing at baseline and treat as indicated
  - Gonorrhea, chlamydia, and syphilis
  - In addition, obtain baseline pregnancy testing for exposed women

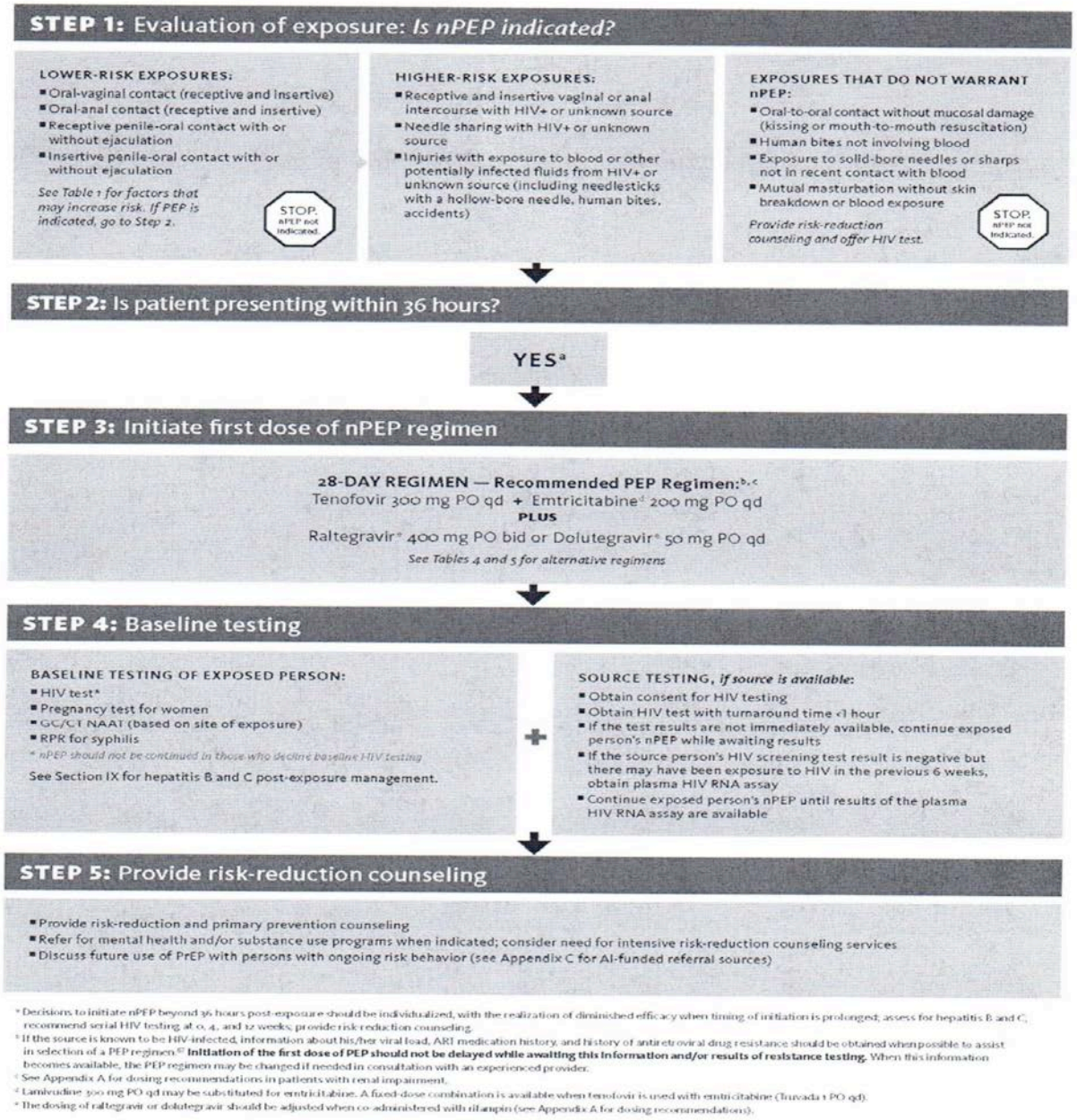
NONOCCUPATIONAL EXPOSURE TO HIV

- When a non-occupational exposure to HIV occurs, every effort should be made to initiate PEP as soon as possible, ideally within 2 hours
- Decisions regarding initiating beyond 36 hours post exposure should be made on a case-by-case basis
- How to decide if a patient requires nPEP?

HOW DO PROVIDERS EVALUATE THE NEED FOR NPEP?

Figure 1. Steps for Evaluating and Managing a Non-Occupational Exposure




STEP 1: Evaluation of exposure: Is nPEP indicated?
LOWER-RISK EXPOSURES:
Oral-vaginal contact (receptive and insertive)
Oral-anal contact (receptive and insertive)
Receptive penile-oral contact with or without ejaculation
Insertive penile-oral contact with or without ejaculation
See Table 1 for factors that may increase risk. If PEP is indicated, go to Step 2.
STOP. nPEP not indicated.
HIGHER-RISK EXPOSURES:
Receptive and insertive vaginal or anal intercourse with HIV+ or unknown source
Needle sharing with HIV+ or unknown source
Injuries with exposure to blood or other potentially infected fluids from HIV+ or unknown source (including needlesticks with a hollow-bore needle, human bites, accidents)
EXPOSURES THAT DO NOT WARRANT nPEP:
Oral-to-oral contact without mucosal damage (kissing or mouth-to-mouth resuscitation)
Human bites not involving blood
Exposure to solid-bore needles or sharps not in recent contact with blood
Mutual masturbation without skin breakdown or blood exposure
Provide risk-reduction counseling and offer HIV test.
STOP. nPEP not indicated.
STEP 2: Is patient presenting within 36 hours?
YES[a]
STEP 3: Initiate first dose of nPEP regimen
28-DAY REGIMEN — Recommended PEP Regimen:[b,c]
Tenofovir 300 mg PO qd + Emtricitabine[d] 200 mg PO qd
PLUS
Raltegravir[e] 400 mg PO bid or Dolutegravir[e] 50 mg PO qd
See Tables 4 and 5 for alternative regimens
STEP 4: Baseline testing
BASELINE TESTING OF EXPOSED PERSON:
HIV test*
Pregnancy test for women
GC/CT NAAT (based on site of exposure)
RPR for syphilis
* nPEP should not be continued in those who decline baseline HIV testing
See Section IX for hepatitis B and C post-exposure management.
SOURCE TESTING, if source is available:
Obtain consent for HIV testing
Obtain HIV test with turnaround time <1 hour
If the test results are not immediately available, continue exposed person's nPEP while awaiting results
If the source person's HIV screening test result is negative but there may have been exposure to HIV in the previous 6 weeks, obtain plasma HIV RNA assay
Continue exposed person's nPEP until results of the plasma HIV RNA assay are available
STEP 5: Provide risk-reduction counseling
Provide risk-reduction and primary prevention counseling
Refer for mental health and/or substance use programs when indicated; consider need for intensive risk-reduction counseling services
Discuss future use of PrEP with persons with ongoing risk behavior (see Appendix C for AI-funded referral sources)
[a] Decisions to initiate nPEP beyond 36 hours post-exposure should be individualized, with the realization of diminished efficacy when timing of initiation is prolonged; assess for hepatitis B and C, recommend serial HIV testing at 0, 4, and 12 weeks; provide risk reduction counseling.
[b] If the source is known to be HIV-infected, information about his/her viral load, ART medication history, and history of antiretroviral drug resistance should be obtained when possible to assist in selection of a PEP regimen.[6] Initiation of the first dose of PEP should not be delayed while awaiting this information and/or results of resistance testing. When this information becomes available, the PEP regimen may be changed if needed in consultation with an experienced provider.
[c] See Appendix A for dosing recommendations in patients with renal impairment.
[d] Lamivudine 300 mg PO qd may be substituted for emtricitabine. A fixed-dose combination is available when tenofovir is used with emtricitabine (Truvada 1 PO qd).
[e] The dosing of raltegravir or dolutegravir should be adjusted when co-administered with rifampin (see Appendix A for dosing recommendations).

PREFERRED NPEP REGIMEN

Tenofovir 300mg daily + Emtricitabine 200mg daily

PLUS

Raltegravir 400mg daily *or* Dolutegravir 50mg daily

When the source patient is known to be HIV infected:

Past and current ART therapy, viral load data, and genotypic or phenotypic resistance data (if available) may indicate the use of an alternative PEP regimen

Renal Insufficiency:

The dosing of tenofovir and emtricitabine should be adjusted in patients with a creatinine clearance of <50mL/min

WHAT ABOUT MANAGING A PATIENT ON PEP?

TABLE 7
MONITORING RECOMMENDATIONS AFTER INITIATION OF PEP REGIMENS FOLLOWING NON-OCCUPATIONAL EXPOSURES

	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[a]	√		√		√	
HIV test[b]	√				√	√
STI Screening *(for exposures unrelated to sexual assault)*[b]: • **GC/CT NAAT (based on site of exposure)** • **RPR** See *HIV Prophylaxis for Victims of Sexual Assault* for recommendations in cases of sexual assault.	√		√ (consider)			
Hepatitis B and C[a]	For post-exposure management for hepatitis B and C, see Section IX: *Non-Occupational Exposures to Hepatitis B and C*					

[a] CBC should be obtained for all exposed persons at baseline. Follow-up CBC is indicated only for those receiving a zidovudine-containing regimen.
[b] Recommended even if PEP is declined.

A. Adherence to the PEP Regimen

Follow-up care is necessary for patients receiving PEP to monitor for adverse effects of the PEP regimen and to maximize adherence to the prescribed regimen. Adherence to a 28-day PEP regimen has historically been modest (40-60%),[50-52] although newer studies using tenofovir + either lamivudine or emtricitabine as components for PEP regimens show increased rates of adherence.[40,41] Limited data show similar improved tolerability with tenofovir + emtricitabine plus raltegravir.[42,43]

HIV PROPHYLAXIS FOR VICTIMS OF SEXUAL ASSAULT

- Careful consideration should be given as to:
- Whether or not a significant exposure has occurred
- Knowledge of the HIV status of the alleged assailant
- Whether the victim is ready and willing to complete the PEP regimen

VICTIMS OF SEXUAL ASSAULT

- Significant exposure
  - Direct contact of the vagina, penis, anus or mouth with semen, vaginal fluids, or blood of the alleged assailant with or without physical injury, tissue damage, or the presence of blood at the site of the assault
- Broken skin or mucous membranes
  - Especially when in contact with blood, semen, or vaginal fluids of the alleged assailant

VICTIMS OF SEXUAL ASSAULT

- PEP should be initiated as soon as possible after exposure, ideally within two hours
- Initiation of PEP beyond 36 hours post exposure should be made on a case-by-case basis
- Baseline HIV testing of the victim should be completed before initiating PEP
- Prophylactic medication to prevent gonococcal and chlamydial infections should also be offered
- A baseline pregnancy test should also be completed

PREFERRED PEP REGIMEN FOR VICTIMS OF SEXUAL ASSAULT

Tenofovir 300mg daily + Emtricitabine 200mg daily

PLUS

Raltegravir 400mg daily *or* Dolutegravir 50mg daily

When the source patient is known to be HIV infected:

Past and current ART therapy, viral load data, and genotypic or phenotypic resistance data (if available) may indicate the use of an alternative PEP regimen

Renal Insufficiency:

The dosing of tenofovir and emtricitabine should be adjusted in patients with a creatinine clearance of <50mL/min

HIV PROPHYLAXIS FOLLOWING OCCUPATIONAL EXPOSURE

- Should be initiated as soon as possible, ideally within 2 hours of the exposure
- Occupational exposure requires urgent medical evaluation
- Baseline HIV testing of the exposed worker should always be obtained
- If PEP is indicated, repeat HIV testing at 4 weeks and 12 weeks should be obtained

OCCUPATIONAL EXPOSURE TO HIV

- Body sites exposed to potentially infectious fluid should be cleansed immediately
- Wash wound and skin exposure sites with soap and water
- Exposed mucous membranes should be flushed with water
- The exposed worker should not attempt to ‘milk’ the wound

EXPOSURE WHICH PEP IS INDICATED

- Splash of blood, visibly bloody fluid, or other potentially infectious material to a mucosal surface (mouth, nose, or eyes)
- A bite from a patient with visible bleeding in the mouth that causes bleeding in the exposed worker
- A non-intact skin expsoure to blood, visibly bloody fluid, or other potentially infectious material
- Break in the skin by a sharp object that is contaminated with blood, visibly bloody fluid, or other potentially infectious material
  - OR that has been in the source patient's blood vessel

FLOW CHART

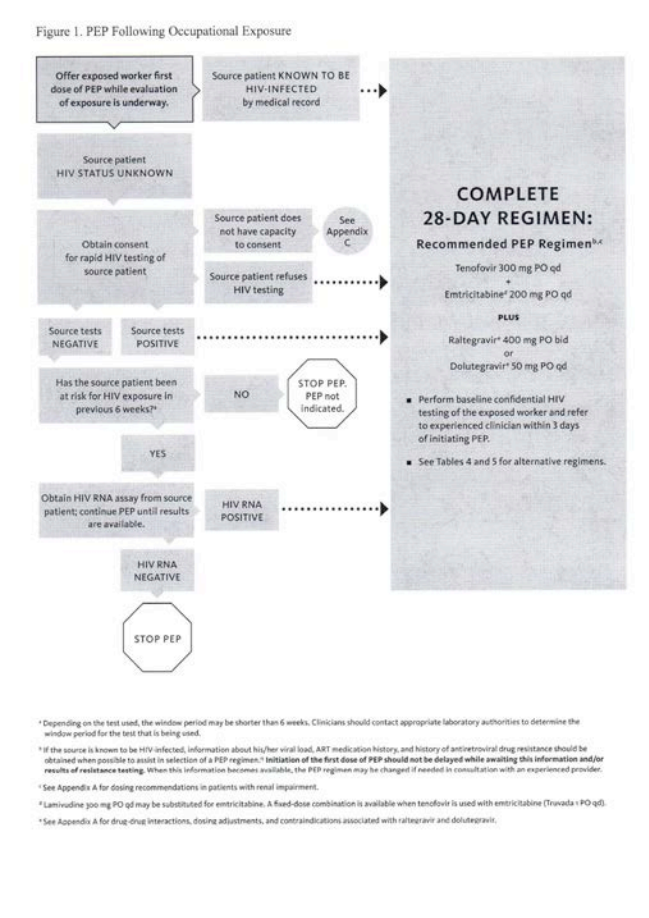


Figure 1. PEP Following Occupational Exposure
Offer exposed worker first dose of PEP while evaluation of exposure is underway.
Source patient KNOWN TO BE HIV-INFECTED by medical record
Source patient HIV STATUS UNKNOWN
Obtain consent for rapid HIV testing of source patient
Source patient does not have capacity to consent
See Appendix C
Source patient refuses HIV testing
Source tests NEGATIVE
Source tests POSITIVE
Has the source patient been at risk for HIV exposure in previous 6 weeks?a
NO
STOP PEP. PEP not indicated.
YES
Obtain HIV RNA assay from source patient; continue PEP until results are available.
HIV RNA POSITIVE
HIV RNA NEGATIVE
STOP PEP
COMPLETE 28-DAY REGIMEN:
Recommended PEP Regimenb,c
Tenofovir 300 mg PO qd
+
Emtricitabine[d] 200 mg PO qd
PLUS
Raltegravir[e] 400 mg PO bid
or
Dolutegravir[f] 50 mg PO qd
Perform baseline confidential HIV testing of the exposed worker and refer to experienced clinician within 3 days of initiating PEP.
See Tables 4 and 5 for alternative regimens.
a Depending on the test used, the window period may be shorter than 6 weeks. Clinicians should contact appropriate laboratory authorities to determine the window period for the test that is being used.
b If the source is known to be HIV-infected, information about his/her viral load, ART medication history, and history of antiretroviral drug resistance should be obtained when possible to assist in selection of a PEP regimen. Initiation of the first dose of PEP should not be delayed while awaiting this information and/or results of resistance testing. When this information becomes available, the PEP regimen may be changed if needed in consultation with an experienced provider.
c See Appendix A for dosing recommendations in patients with renal impairment.
d Lamivudine 300 mg PO qd may be substituted for emtricitabine. A fixed-dose combination is available when tenofovir is used with emtricitabine (Truvada = PO qd).
e See Appendix A for drug-drug interactions, dosing adjustments, and contraindications associated with raltegravir and dolutegravir.

COUNSELING AND EDUCATION BEFORE INITIATING NPEP OR PEP

- Potential benefit, unproven efficacy, and potential toxicity of nPEP/PEP
- Duration of nPEP/PEP regimen
- Importance of adherence to the treatment
- Need to reduce risk and prevent exposure to others
- Clinical and laboratory monitoring and follow-up schedule
- Signs and symptoms of acute HIV infection

RESOURCES

- Clinical Education Initiative (CEI PEP Line)
  1-866-637-2342

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