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THE PRESENTATION BEGINS

The HIV/STD/TB/Hepatitis Program, Division of Disease Control, conducts Lunch and Learn Webinars for health care professionals in North Dakota.

Each month a new topic will be held from 12:00 p.m. to 1:00 p.m. CST on the **fourth Wednesday of the month.**

Next L&L : October 26, 2016

Register: <http://www.ndhealth.gov/HIV/events.htm>

Please complete the post-test to receive CEU's for this presentation. You must score at least 70% to receive credit.

You can take the post-test up to two weeks after the presentation. Post-test, along with the slides and the recording of this presentation can be found at:

www.ndhealth.gov/HIV/Resources/resources.htm

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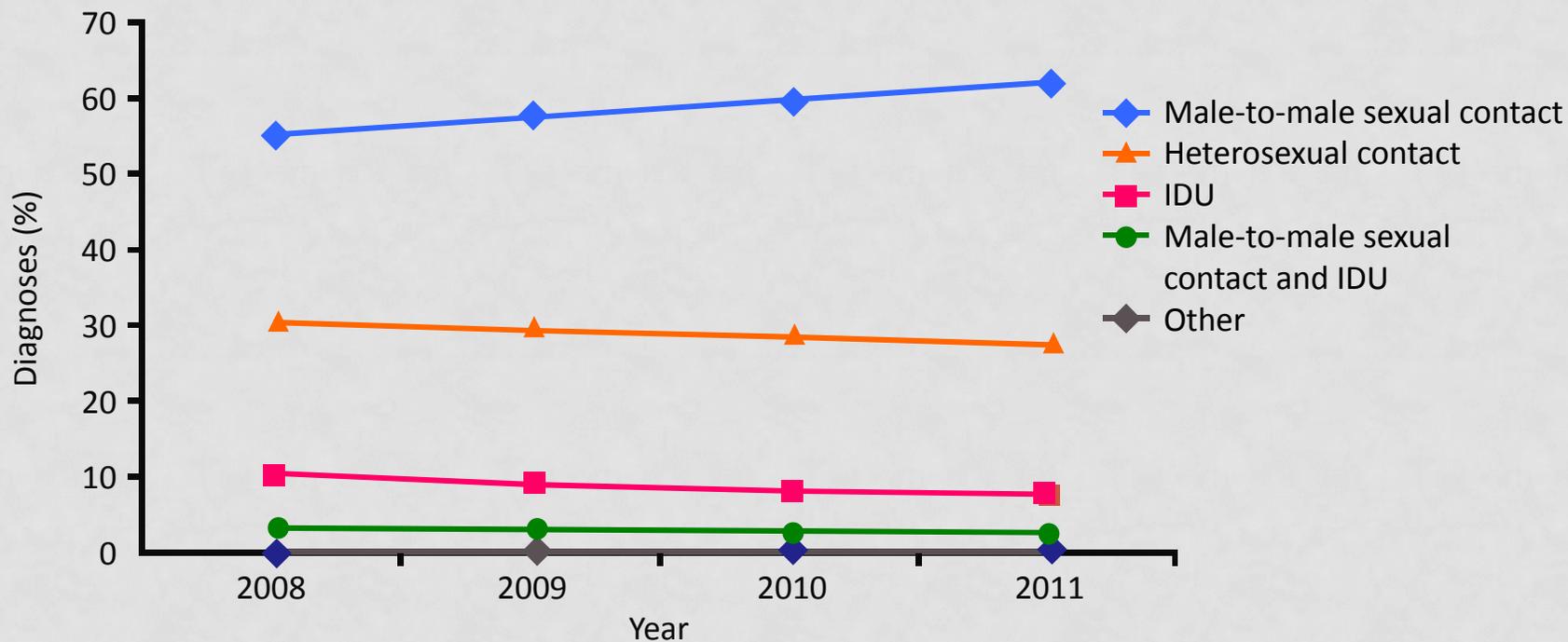
PREP IN PRIMARY CARE AND OCCUPATIONAL PEP

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THE NEED FOR CONTINUED HIV PREVENTION

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



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/nchstp/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



HIV STATUS?
UNDETECTABLE



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

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	<ul style="list-style-type: none"> ▪ HIV-positive sexual partner ▪ Recent bacterial STI ▪ High number of sex partners ▪ History of inconsistent or no condom use ▪ Commercial sex work 	<ul style="list-style-type: none"> ▪ 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 	<ul style="list-style-type: none"> ▪ 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.

Slide 11

JE1

??HIV RNA or delayed PrEP for high risk patients with symptoms consistent with acute infection??

Joseph Eron, 3/23/2015

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.

Slide 13

JE2

Should level of risk be mentioned here??

Joseph Eron, 3/23/2015

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	<ul style="list-style-type: none"> ▪ HIV testing ▪ Adherence assessment ▪ Side effect assessment ▪ Medication adherence counseling ▪ Behavioral risk reduction support ▪ Answer any new questions 	<ul style="list-style-type: none"> ▪ Assess renal function (CrCl) ▪ Test for bacterial STIs 	<ul style="list-style-type: none"> ▪ Evaluate need to continue PrEP
Women	<ul style="list-style-type: none"> ▪ 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

JE3

Slide 15

JE3

Not sure how to deal with this but this is not true given the results of the PROMIS study. This may be due to use in developing nations or perhaps interaction with LPV/r but probably cannot go unmentioned.

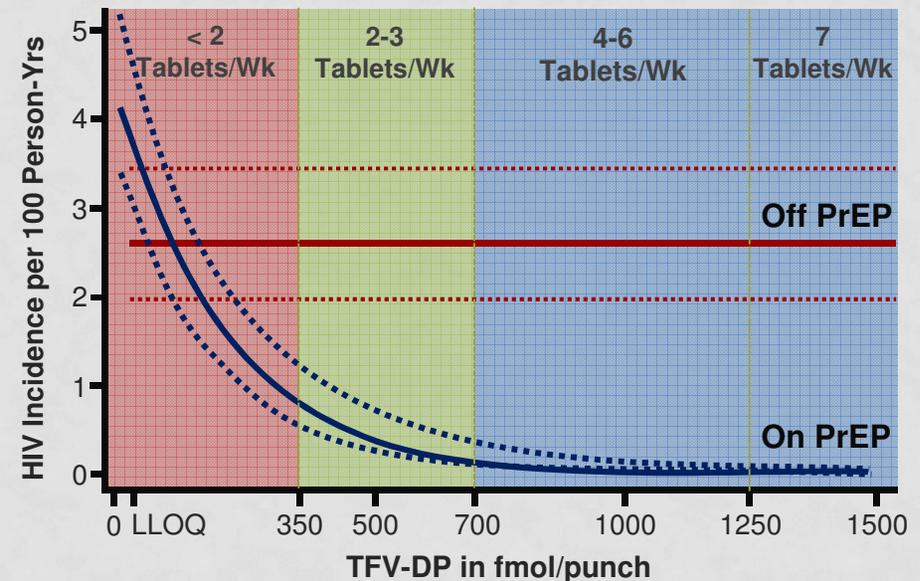
Joseph Eron, 3/23/2015

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

HIV Incidence and Drug Concentrations



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

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

PATIENT INFORMATION FOR PREP



GETTING PrEPped

Some people may 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

- projectinform.org/prep
- prepfacts.org
- myprepexperience.org
- hiveonline.org
- thewellproject.org/hiv-information/prep-women
- whatisprep.org
- [pleasepreme.org \(CA\)](http://pleasepreme.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, GREAT NEWS!
- If s/he doesn't know about PrEP but is willing to prescribe:
 - 1) S/he can consult the US PHS's prescribing guidelines: www.cdc.gov/hiv/pdf/prepguidelines2014.pdf, and/or
 - 2) Take a copy of the guidelines with you, and/or
 - 3) S/he can consult the CCC's PrEPLine at 855-448-7737 during business hours (<http://tinyurl.com/CCCprepline>), and/or
 - 4) S/he can consult NASTAD's *Billing Coding Guide for HIV Prevention* (<http://tinyurl.com/NASTADguide>).
- If s/he isn't willing to prescribe:
 - 1) Read/utilize these resource materials:
 - "Talk to Your Doctor": <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/STD clinics; local, county and state health depts
 - search: greaterthan.org/get-prep/, accesstoprep.org, hivma.org, aahivm.org, glma.org
 - CA: pleasepreme.org. IL: tinyurl.com/ILPrEPdocs. NY: tinyurl.com/NYPrEPdocs. OH: ohioprep.org/get-prep/. OR: tinyurl.com/ORPrEPdocs. WA: tinyurl.com/WAPrEPdocs.



MEDICAL VISITS, BLOOD WORK

If you encounter uncovered 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 URL as above.)
- Work with your provider's office to submit challenge(s). It may take more than once.

Nurx.co/prep

- This online source may be able to provide a prescription to you without a doctor's visit.



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 your cost.
- Apply for Gilead's Co-Pay Card **before** going to pharmacy (URL next column).
- If pharmacy doesn't accept Co-Pay Card, keep pharmacy and sales receipts. Call the number on back of co-pay card. Submit paperwork for payment.



PAY FOR THE MEDICATION AND OTHER COSTS

Manufacturer assistance

www.gileadadvancingaccess.com, 800-226-2056 (18 years old or older)

Co-Pay Assistance

- covers up to \$3,600 per calendar year, out-of-pocket costs
- for insured individuals, re-apply as needed
- not used w/ Medicaid, Medicare, VA or other federal/state programs

Medication Assistance

- uninsured, insurance declined payment, or no pharmacy benefits
- US resident (SSN not required) and family income < 500% FPL (federal poverty level, <http://tinyurl.com/FPLincome>)
- eligibility confirmed every 6 months by provider, re-apply as needed

Patient Access Network Foundation

PAN Foundation has temporarily stopped enrolling new applicants.

- Insured individuals only; family income below 500% FPL
- \$7,500 max per year, may reapply
- Covers co-pays, deductibles and co-insurance
- panfoundation.org/hiv-treatment-and-prevention, 866-316-7263

Patient Advocate Foundation

- Insured individuals only; family income below 400% FPL
- \$7,500 max per year for co-pay/deductible costs, may reapply
- <https://www.copays.org/diseases/hiv-aids-and-prevention>

Other assistance for residents of:

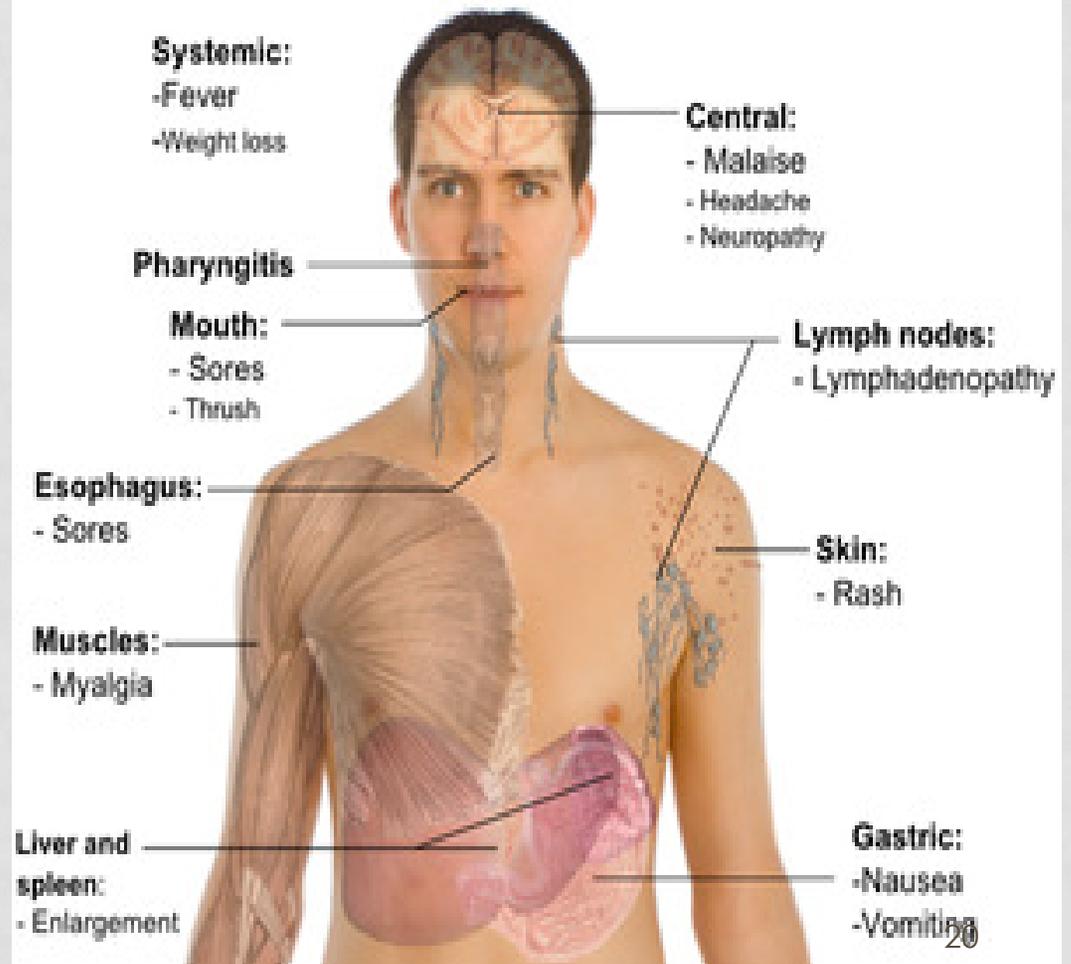
- NEW YORK: <http://tinyurl.com/NYprepAP> (only cost of services)
- WASHINGTON: <http://tinyurl.com/WAprepDAP> (only cost of drug)

Source: http://www.projectinform.org/pdf/PrEP_Flow_Chart.pdf

ACUTE HIV INFECTION

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

Main symptoms of Acute HIV infection



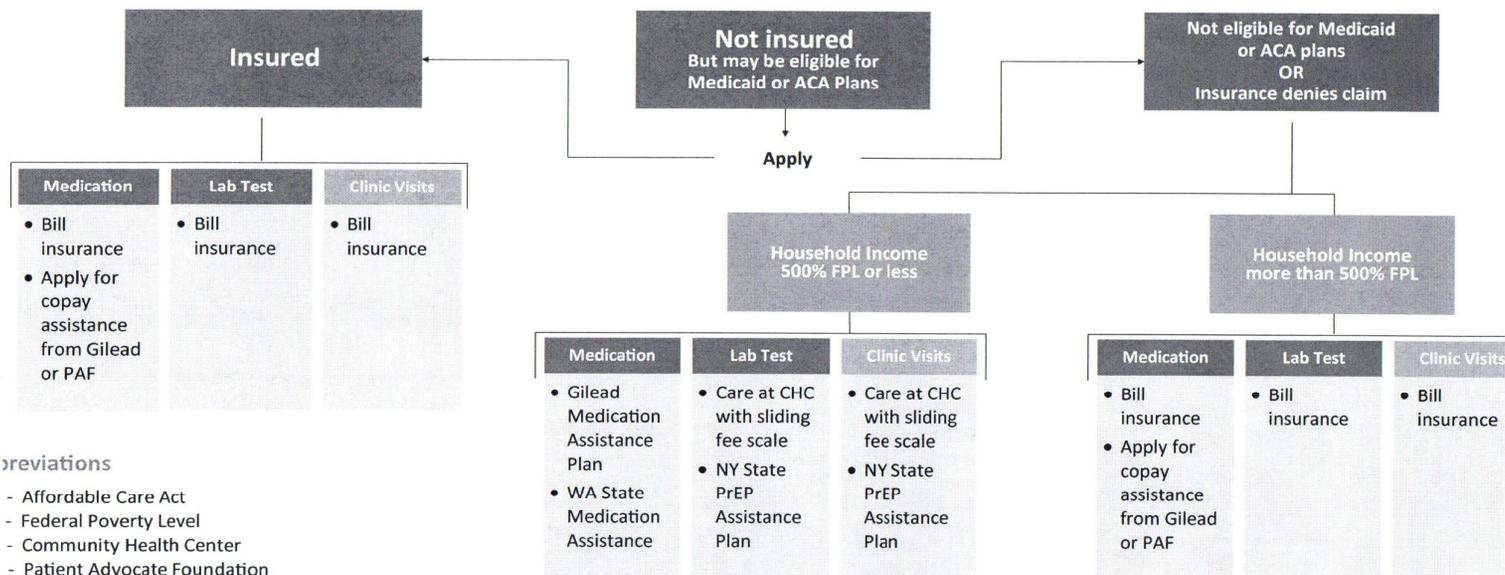
PRIMARY INFECTION: BETWEEN 2003 AND 2005

- 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

PROVIDER INFORMATION REGARDING BILLING AND ASSISTANCE FOR PATIENTS NEEDING PREP



Abbreviations

- Affordable Care Act
- Federal Poverty Level
- Community Health Center
- Patient Advocate Foundation

Definitions:

PrEP	Daily pill to prevent HIV infection (pre-exposure prophylaxis)
Copay	Fixed amount to be paid by insured person per prescription
Copay percentage	Fixed percentage of prescription cost to be paid by insured person
Total cost	Amount of health care cost

PrEP Medication Assistance Program

(Gilead Sciences)

People eligible for this program must:

- Be 18 years of age or older
- Be without insurance or have payment declined by their insurance carrier
- Be resident in the US (social security number not required)
- Have family income \leq 500% of the federal poverty level

Once enrolled in this program:

- Medication will be sent to the provider, a pharmacy, or the patient's home

PrEP Medication Assistance Program

Family Size 500% Federal Poverty Level Household Annual Income must be less than:

1	\$58,850
2	\$79,650
3	\$100,450
4	\$121,250

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

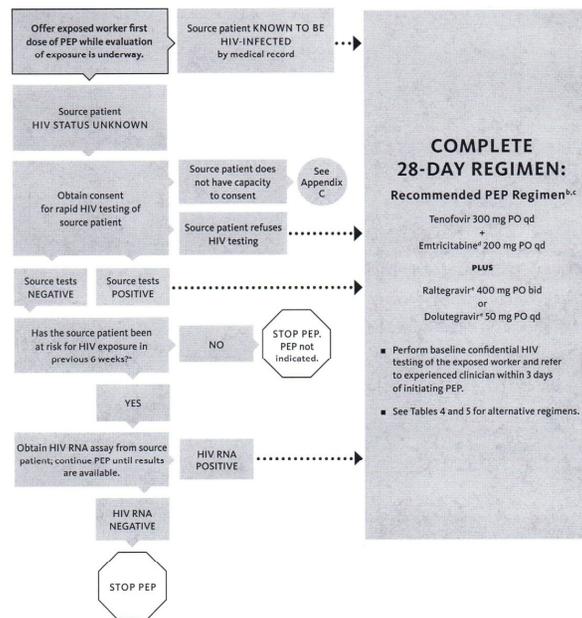
- Body sites exposed to potentially infectious fluid should be cleansed immediately
- Wash wound and skin exposure sites with soap and water
- Exposed mucous membranes should be flushed with water
- The exposed worker should not attempt to 'milk' the wound

EXPOSURE WHERE 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 exposure 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



¹ 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.

² 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.¹¹ 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.

³ See Appendix A for dosing recommendations in patients with renal impairment.

⁴ 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).

⁵ 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 PEP
- Duration of /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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