PrEP and PEP for HIV Prevention is key

September 15, 2017

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Financial disclosures

- None

Goals

- Discuss how to use PrEP and in which high risk populations
- Recognize use of PrEP in pregnancy
- Understand the appropriate use and timing of non-occupational Post Exposure Prophylaxis (nPEP)

Case

- 30 yo woman had condomless intercourse with her new partner 2 weeks ago and one week ago.
- Found out he has HIV and made appt to see you
- At the visit she admits to condomless intercourse the evening before.

What is PrEP

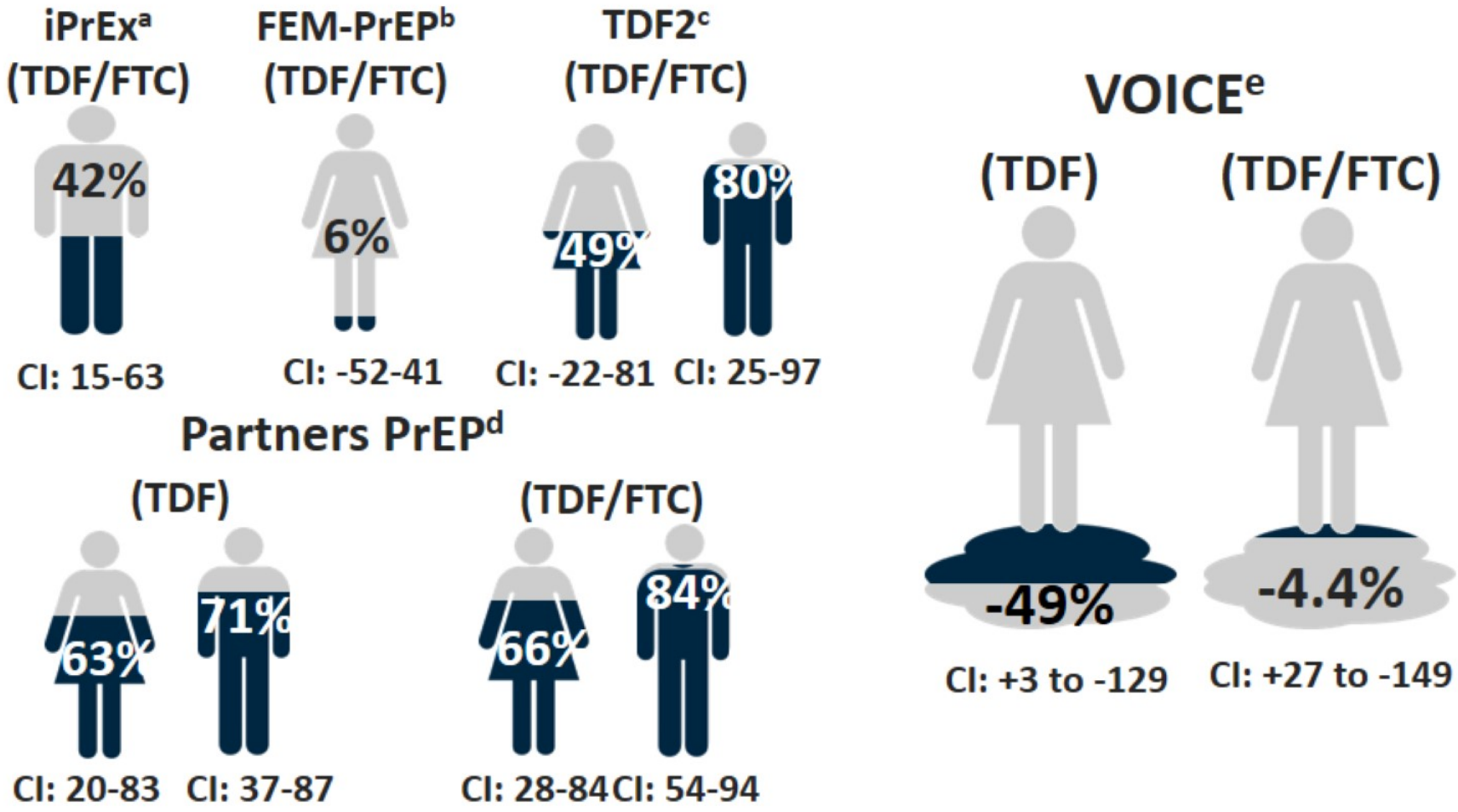
- Pre Exposure Prophylaxis for HIV prevention
- Single pill taken once daily
- Combination of 2 reverse transcriptase inhibitors:
  - Emtricitabine
  - Tenofovir disoproxil fumarate
  - (FTC/TDF)

Why PrEP?

- “HIV infection is preventable, yet every year we see some 50,000 new HIV infections in the United States,” said CDC Director Tom Frieden, M.D., M.P.H. “PrEP, used along with other prevention strategies, has the potential to help at-risk individuals protect themselves and reduce new HIV infections in the US.”
- The guidelines were developed by CDC in partnership with other federal health agencies, public health experts and community leaders.
- PrEP use began 2010, Initial guidelines May 2014

The time for debate on the effectiveness of PrEP is over.

PrEP Effectiveness



a. Grant RM, et al. *N Engl J Med*. 2010;363:2587-2599[1]; b. Van Damme L. *N Engl J Med*. 2012;367:411-422[2]; c. Thigpen MC, et al. *N Engl J Med.* 2012;367:423-434[3]; d. Baeten JM, et al. *N Engl J Med*. 2012;367:399-410[4]; e. Marrazzo J, et al. *N Engl J Med*. 2015;372:509-518.[5]

iPrEx Study

- Target populations: MSM
- Daily PrEP with TDF/FTC
- Overall relative HIV transmission reduction: 42%
- Participants with detectable drug levels showed reduction 92% (P<.001)
- Adherence is Key

Grant RM et al, NEJM 2010;363; 2587-2599.

Fem PrEP Study

- Target population: 2120 African Women
- Daily PrEP with TDF/FTC
- Study stopped early due to lack of efficacy
- 4.7 infections/100 person years vs. 5.0 infections/100 person years for placebo
- Poor adherence as measured by blood levels

Van Damme L, NEJM 2012;367:411-422.

PrEP in Women

Pharmacologic Measures of Exposure May Be Particularly Important

- Adherence may be more critical in women than in men because TDF concentrations are higher in rectal tissue than in vaginal tissue[a]
  - However, FTC levels were higher in vaginal and cervical tissue than in rectal tissue[a]
- Cumulative exposure of rectal tissue to TDF and tenofovir diphosphate was 30 and 120 times higher, respectively, vs vaginal tissue in the same group of women[b]

a. Patterson KB, et al. *Sci Transl Med*. 2011;3:112re4[19]; b. Louissaint NA, et al. *AIDS Res Hum Retroviruses*. 2013;29:1443-1450.[20]

Partners PrEP Study

- Target population: 4758 male-female couples with 1 HIV+ partner
- Relative Reduction of HIV transmission:
  - 67% with TDF
  - 75% with TDF/FTC

Baeten JM et al, NEJM. 2012;367:399-410

NATIONAL HIV/AIDS STRATEGY: UPDATED TO 2020

5 MAJOR CHANGES SINCE 2010

Since the first National HIV/AIDS Strategy was released in 2010, major advances have transformed how we respond to HIV, provided new tools to prevent new infections, and improved access to care. With a vision for the next five years, our National HIV/AIDS Strategy has been updated to leverage these achievements and look ahead to 2020.

Our prevention toolkit has expanded.

Pre-Exposure Prophylaxis (PrEP)

A daily pill to prevent HIV.

When taken consistently, can reduce the risk of HIV by up to **92%**

Treatment as Prevention

The risk of transmitting HIV is reduced by **96%** in those who start treatment early.

The Affordable Care Act has transformed health care access.

Millions more individuals now have **affordable, quality health coverage.**

There is **no denial of coverage for pre-existing conditions, like HIV.**

Preventive services, including HIV testing, are covered without co-pays.

Protections against sex or disability discrimination in health care.

HIV testing and treatment are recommended.

Federal Guidelines now recommend **routine HIV screening** for people aged **15 TO 65**

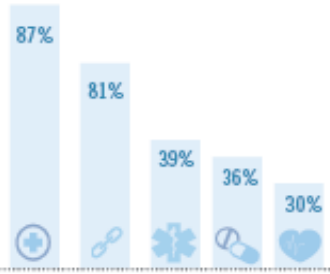
CDC updated recommendations for HIV testing to help labs **detect infections earlier.**

Federal HIV treatment guidelines now recommend **antiretroviral therapy for all people living with HIV.**

Improving HIV Care Continuum outcomes is a priority.

President Obama's **HIV Care Continuum Initiative** directed Federal departments to increase the number of people with HIV who are:

- **diagnosed** with HIV
- **linked** to HIV care
- **retained** in HIV care
- **prescribed** HIV treatment
- **virally suppressed** (having very low levels of HIV in their body).



Research is unlocking new knowledge and tools.

- Evidence that **starting HIV treatment early** lowers the risk of developing AIDS or other serious illnesses
- New **HIV testing technologies**, including new diagnostic tests
- New **HIV medications** with fewer side effects, less frequent dosing, and a lower risk of drug resistance
- **Continued investigation** of long-acting drugs for HIV treatment and prevention, an HIV vaccine, and, ultimately, a cure.

UPDATED 8.5.15

Learn more about the National HIV/AIDS Strategy: Updated to 2020 at **AIDS.gov/2020** **#HIV2020**

Summary of Guidance for PrEP Use

	Men Who Have Sex With Men	Heterosexual Women and Men	Injection Drug Users
Detecting substantial risk of acquiring HIV infection:	• Sexual partner with HIV • Recent bacterial STD • High number of sex partners • History of inconsistent or no condom use • Commercial sex work	• Sexual partner with HIV • Recent bacterial STD • High number of sex partners • History of inconsistent or no condom use • Commercial sex work • Lives in high-prevalence area or network	• HIV-positive injecting partner • Sharing injection equipment • Recent drug treatment (but currently injecting)
Clinically eligible:	• Documented negative HIV test before prescribing PrEP • No signs/symptoms of acute HIV infection • Normal renal function, no contraindicated medications • Documented hepatitis B virus infection and vaccination status		
Prescription	**Daily, continuing, oral doeses of TDF/FTC (Truvada), ≤90 day supply**		
Other services:	• Follow-up visits at least every 3 months to provide: • HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STD symptom assessment • At 3 months and every 6 months after, assess renal function • Every 6 months test for bacterial STDs		
	• Do oral/rectal STD testing	• Assess pregnancy intent • Pregnancy test every 3 months	• Access to clean needles/ syringes and drug treatment services

Source: US Public Health Service. Preexposure prophylaxis for the prevention of HIV infection in the United States —2014: a clinical practice guideline.

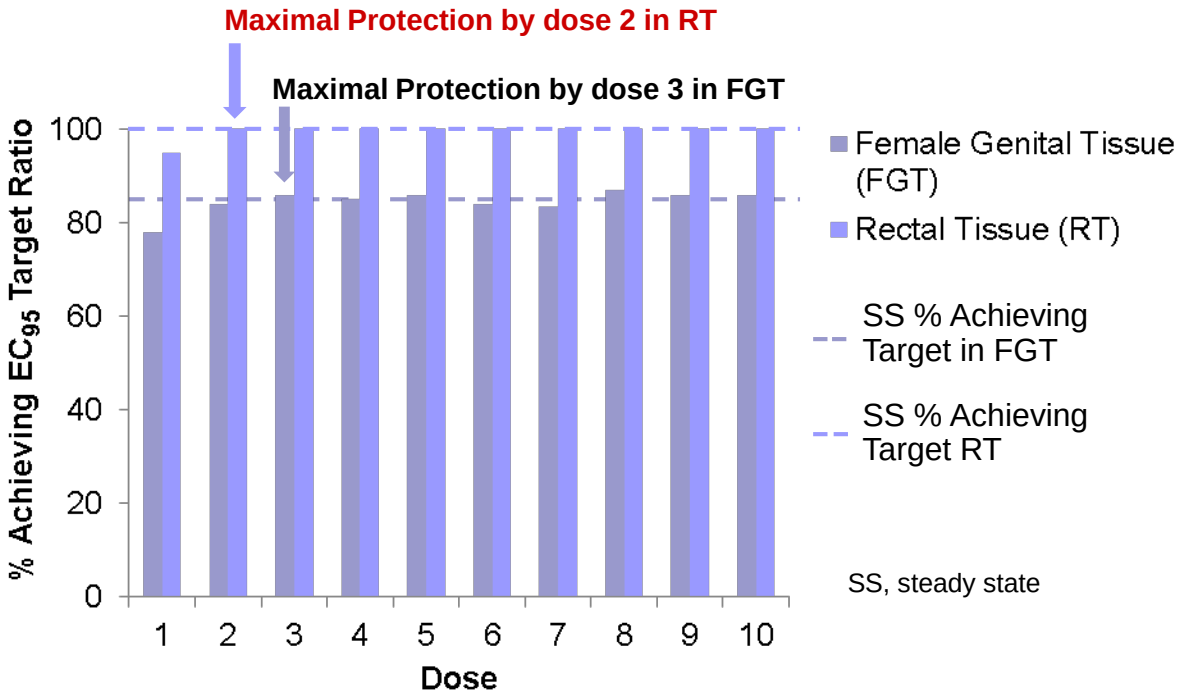
Essential Lab Tests for PrEP Candidates

- HIV
  - Prescribe PrEP for HIV-negative patients
  - Fourth-generation HIV tests preferable to assure HIV-negative status
- Hepatitis B virus
  - Document patient's HBV status
  - PrEP agents are active against HBV; discontinuation of PrEP necessitates a change in treatment
  - Recommend HBV vaccination
- Creatinine clearance
  - Order with standard metabolic panel
  - TDF has the potential for renal toxicity
  - Creatinine clearance must be > 60 mL/min

CDC website.[6]

Time to Protection with Daily Dosing of TDF/FTC for PrEP

- WHO recommends additional HIV prevention measures should be used for 7 days after starting daily PrEP[1]
- Target ratios have been defined for TFV and FTC for adequate cellular protection in genital tissue[2]



- Time to maximal protection is achieved by 3rd dose in FGT and by 2nd dose in RT[3], well within the WHO recommendation of 7 days post-PrEP initiation

1. WHO Implementation tool for pre-exposure prophylaxis (PrEP) of HIV infection. Module 1: Clinical.Geneva: World Health Organization; 2017 (WHO/HIV/2017.17)
2. Cottrell M, et al J Infect Dis. 2016 Jul 1;214(1):55
3. Kashuba A, IAS 2017, France, Paris. Symposium #MOSY0803

Vaginal Microbiome and PrEP

- Of 1450 women in Partners PrEP study(1) from Kenya and Uganda, 357 had BV.
- No difference in seroconversion in those with healthy microbiota vs. BV.
- No effect of the 1% TFV gel in the presence of non-lactobacillus dominant microbiota (2)

(1) Efficacy of oral pre-exposure prophylaxis for HIV among women with abnormal vaginal microbiota: a post hoc analysis of the randomized, placebo controlled Partners PrEP Study. Heffron R et al. Lancet HIV 2017:Jul 18.

(2) The vaginal Microbiome and its potential to impact efficacy of HIV Pre-Exposure Prophylaxis for Women. Velloza J, Heffron R. Curr HIV/AIDS Rep 2017 Aug 15.

Annals of Internal Medicine ORIGINAL RESEARCH

Safety and Tolerability of Maraviroc-Containing Regimens to Prevent HIV Infection in Women

A Phase 2 Randomized Trial

Roy M. Gulick, MD, MPH; Timothy J. Wilkin, MD, MPH; Ying Q. Chen, PhD; Raphael J. Landovitz, MD, MSc; K. Rivet Amico, PhD; Alicia M. Young, MS; Paul Richardson, MSc; Mark A. Marzinke, PhD; Craig W. Hendrix, MD; Susan H. Eshleman, MD, PhD; Ian McGowan, MD; Leslie M. Cottle, BA; Adriana Andrade, MD; Cheryl Marcus, BSN; Karin L. Klingman, MD; Wairimu Chege, MD, MPH; Alex R. Rinehart, PhD; James F. Rooney, MD; Philip Andrew, RN; Robert A. Salata, MD; Marc Siegel, MD; Yukari C. Manabe, MD; Ian Frank, MD; Ken Ho, MD; Jorge Santana, MD; Joanne D. Stekler, MD; Shobha Swaminathan, MD; Marybeth McCauley, MPH; Sally Hodder, MD; and Kenneth H. Mayer, MD

- August 22, 2017
- HIV-uninfected women reporting condomless vaginal or anal intercourse with at least 1 man with HIV Infection or unknown serostatus within 90 days.
- MVC only, MVC–emtricitabine (FTC), MVC–tenofovir disoproxil fumarate (TDF), and TDF–FTC (control).
- Among 188 participants, 85% completed follow-up, 11% withdrew early, and 4% were lost to follow-up; 19% discontinued their regimen prematurely. The number discontinuing and the time to discontinuation did not differ among regimens.
- Participants were not necessarily at high risk for HIV infection
- Maraviroc-containing PrEP regimens were safe and well-tolerated compared with TDF–FTC in U.S. women

Adolescent PrEP

- Safety and acceptability of daily oral emtricitabine/tenofovir as a PrEP solution in 148 HIV-free adolescents aged 15-19 years from two study sites in South Africa over a span of 12 months
- majority female (99 girls/49 boys),
- sexually transmitted infections were present in 40% of participants, a level that remained constant throughout the study.
- One instance of HIV infection was reported, although the patient in question dropped out of the program 24 weeks before diagnosis.
- plasma tenofovir levels detectable in 57% of participants after 12 weeks, 38% after 24 weeks and 38% at the end of the study
- International AIDS Society Conference on HIV Pathogenesis and Treatment in Paris.

Adolescent PrEP

- Dapivirine vaginal ring
- 15-17 y.o. sexually active young woman in the US
- 73 randomized to ring, 23 to placebo.
- Well tolerated
- International AIDS Society Conference on HIV Pathogenesis and Treatment in Paris July 2017

The Journal of Infectious Diseases

MAJOR ARTICLE

IDSA Infectious Diseases Society of America

hivma hiv medicine association

OXFORD

Low Risk of Proximal Tubular Dysfunction Associated With Emtricitabine-Tenofovir Disoproxil Fumarate Preexposure Prophylaxis in Men and Women

Kenneth Mugwanya,[1,2,10] Jared Baeten,[1,2,3] Connie Celum,[1,2,3] Deborah Donnell,[4] Thomas Nickolas,[5] Nelly Mugo,[2,11] Andrea Branch,[7] Jordan Tappero,[9] James Kiarie,[12] Allan Ronald,[13] Michael Yin,[6] and Christina Wyatt[8]; for the Partners PrEP Study Team[a]

Departments of [1]Epidemiology, [2]Global Health, and [3]Medicine, University of Washington, and [4]Vaccine and Infectious Disease Division, Fred Hutchinson Cancer Research Center, Seattle, Washington; Department of Medicine, Divisions of [5]Nephrology, and [6]Infectious Diseases, Columbia University Medical Center, Department of Medicine, Divisions of [7]Liver Diseases, and [8]Nephrology, Icahn School of Medicine at Mount Sinai, New York, New York; [9]Division of Global Health Protection, Center for Global Health, Centers for Disease Control and Prevention, Atlanta, Georgia; [10]Division of Disease Control, School of Public Health, Makerere University, Kampala, Uganda; [11]Kenya Medical Research Institute, and [12]Department of Obstetrics and Gynecology, University of Nairobi, Kenya; and [13]Department of Medicine, University of Manitoba, Winnipeg, Canada

- TDF is associated with proximal tubular dysfunction when used to treat HIV infection
- Subgroup of Partners PrEP
- 24 month follow up
- Tubulopathy 1.7% for FTC/TDF vs. 1.3% for placebo

Seidman DL, et al. *Am J Obstet Gynecol*. 2016;215:632.e1-632.e7. doi: 10.1016/j.ajog.2016.06.020

Use of HIV pre-exposure prophylaxis during the preconception, antepartum and postpartum periods at two United States medical centers.

- Study at Bronx and San Francisco
- Identified 27 high risk women desiring pregnancy (8), pregnant (18) or lactating (1).
- 50% unstable housing
- 22% experiencing partner violence
- 22% engaged in substance abuse
- 26/27 had a partner with HIV, 1 had an MSM partner
- Of male partners, only 42% had documented viral suppression
- 67% of women offered PrEP chose to initiate it.

Conception with HIV infected Men

Original guidelines published in 1990, CDC recommended against insemination from HIV + men

The process of sperm washing was developed to be used with IUI or IVF, first in Italy, and in a few research centers in the US. Expensive.

Update: **Strategies for Preventing HIV Infection Among HIV-Uninfected Women Attempting Conception with HIV-Infected Men — United States** *Weekly* / June 2, 2017 / 66(21);554–557. Discusses IUI/IVF data with approx. 11,500 assisted conception cycles using sperm washing, with no conversion in the women or positive children. Last + was in 1990.

Morbidity and Mortality Weekly Report

Effects of Antiretroviral Therapy to Prevent HIV Transmission to Women in Couples Attempting Conception When the Man Has HIV Infection — United States, 2017

John T. Brooks, MD[1]; Jennifer F. Kawwass, MD[2,3]; Dawn K. Smith, MD[1]; Dmitry M. Kissin, MD[2,3]; Margaret Lampe, MPH[1]; Lisa B. Haddad, MD[2,3]; Sheree L. Boulet, DrPH[2]; Denise J. Jamieson, MD[2,3]

The risk for male-to-female sexual transmission of HIV in the absence of any prevention measures is estimated to be approximately 8 per 10,000 episodes of condomless intercourse

August 18, 2017 / 66(32);859–860, update

Studies

- HPTN 052, PARTNER, and Opposites Attract followed 3000 sexually active mixed HIV-status couples over many years while they did not use condoms.
- All 3 studies observed no HIV transmission to the uninfected partner while the partner with HIV was virologically suppressed with HAART.

Infect Dis. 2016 Jul 15;214(2):212-5. doi: 10.1093/infdis/jiw131. Epub 2016 Apr 6.

Seminal HIV-1 RNA Detection in Heterosexual African Men Initiating Antiretroviral Therapy.

Mujugira A[1], Coombs RW[2], Heffron R[1], Celum C[3], Ronald A[4], Mugo N[5], Baeten JM[3]; Partners PrEP Study Team

- HIV RNA found in semen of Virologically suppressed men up to 25% of the time
- Seminal HIV-1 RNA was detected in 24% (37 of 155), 10% (5 of 49), and 11% (8 of 70) of samples collected 0-3, 4-6, and >6 months after ART initiation. When blood HIV-1 levels were suppressed, seminal HIV-1 RNA was detected in 8% (16 of 195)

What to offer?

- **Fertility care interventions should be provided as the first line options for HIV + serodiscordant couples who desire children in settings with affordable access to care, regardless of their fertility status**. Safier LZ, Sauer MV. J Int AIDS Soc. 2017;20(Suppl 1):21294.

vs.

- **HIV-affected couples and individuals who desire children should be offered options for safer conception.** Lealah C Pollock[1,§], Shannon Weber[1], Angela Kaida[2], Lynn T Matthews[3] and Dominika L Seidman

Conception with HIV+ Men: CDC Guidelines

- Man must be on HAART to achieve undetectable viral load
- Woman takes daily oral TDF/FTC for one month before conception attempt and continue for one month after
- Limit sex without a condom to peak fertility periods
- Sperm washing can be offered

Conception in HIV+ women: CDC Guidelines

- Safest option is intravaginal insemination
- Limit sex without a condom to peak fertility times
- Woman must be on HAART with undetectable viral load
- Man should be on PrEP

Register patients

- The CDC encourages those physicians who prescribe PrEP to a woman while pregnant to prospectively and anonymously submit information about the pregnancy to the Antiretroviral Use in Pregnancy Registry.[1] (http://www.apregistry.com/)

Newly Acquired Infection with Multi-Drug Resistant HIV-1 in a Patient Adherent to Pre-Exposure Prophylaxis

Martin Markowitz1, Howard Grossman2, Peter L. Anderson3, Robert Grant4, Monica Gandhi4, Howard Horng4 and Hiroshi Mohri. JAIDS, 2017 published online ahead of print

- 26 yo MSM. Started on PrEP 1/2016
- At follow up 5/2016, he reported insertive and receptive condomless anal intercourse (ICAI and RCAI) with his regular partner and 2 separate episodes of ICAI with 2 different partners of unknown HIV status, 11 and 5.5 weeks prior to presentation
- He reported high level of compliance with PrEP- skin and hair samples confirmed.
- Acquired high level drug resistant HIV- different from regular partner whose HIV was undetectable.

PrEP Summary

- TDF/FTC one pill daily, 30 pills, 2 refills
- Baseline HIV 1,2 Ag/Ab, creatinine, syphilis IGG, GC/chlamydia, pregnancy, hepatitis B
- Every 3 month appointment for counseling, HIV 1,2 Ag/Ab and refill of meds if appropriate
- Every 6 month labs for STI screen, creatinine, pregnancy

iPERGAY Trial: On-Demand PrEP

- TDF/FTC before and after sex
  - 2 tabs from 2 to 24 hours before sex
  - 1 tab 24 hours after
  - 1 tab 48 hours after
- 400 MSM enrolled- 199 PrEP, 201 placebo
- Averaged 15 pills per month each group
- 2 HIV + in TDF/FTC, 14 in Placebo

Molina JM et al. N Engl J Med 2015; 373:2237-2246

IPERGAY results- 86% risk reduction- CDC Dr. Mermin still cautions:

- Since available data suggest that men in this study were taking PrEP an average of three to four days per week, CDC cautions that researchers do not yet know if this regimen will work among MSM who have sex less frequently and would therefore be taking PrEP less often.
- It is not known whether the regimen will work if taken only a few hours or days before sex, without any buildup of the drug from prior use. Studies suggest that it may take days, depending on the type of sexual exposure, for the active drug in PrEP to build up to an optimal level for preventing HIV infection.
- There are also no data on how effective this regimen would be for heterosexual men and women and injection drug users or on adherence to this relatively complex PrEP regimen outside a trial setting. CDC continues to recommend only daily use of PrEP, as approved by the FDA. IPERGAY findings combined with other recent research suggests that even with less than perfect daily adherence, PrEP may still offer substantial protection if taken consistently.

Efficacy, safety, and effect on sexual behaviour of on-demand pre-exposure prophylaxis for HIV in men who have sex with men: an observational cohort study.

Molina JM[1], Charreau I[2], Spire B[3], Cotte L[4], Chas J[5], Capitant C[2], Tremblay C[6], Rojas-Castro D[7], Cua E[8], Pasquet A[9], Bernaud C[10], Pintado C[11], Delaugerre C[12], Sagaon-Teyssier L[3], Mestre SL[13], Chidiac C[4], Pialoux G[5], Ponscarme D[11], Fonsart J[11], Thompson D[14], Wainberg MA[15], Doré V[13], Meyer L[16]; ANRS IPERGAY Study Group. Lancet HIV. 2017 Jul 21. [Epub ahead of print]

- Follow up to iPERGAY, offering open –label
- 361 participants
- Participants used a median of 18 pills of study drug per month
- One participant who discontinued PrEP seroconverted (0.19 per 100 person-years) versus 6.60 per 100 person years in the original placebo control arm
- Report of condomless sex increased from 77% at baseline to 86% at 18 months “High rates of STIs resulting from low condom use did not undermine PrEP efficacy, but warrant frequent testing.

PrEP for IV drug users

- Bangkok Tenofovir Study 2005-2013. Randomised, double-blind, placebo controlled phase 3 trial, enrolling from 17 drug treatment clinics.
- Reported in The Lancet Volume 381, No. 9883, p2083–2090, 15 June 2013
- 2413 participants
- 17 became HIV infected in the tenofovir group
- 33 became HIV infected in the placebo group
- 48.9% reduction

Young Black, MSM

Arrington-Sanders R, et al. *J Adolesc Health*. 2016 Oct 5. pii: S1054-139X(16)30245-2. doi: 10.1016/j.jadohealth.2016.08.006

- Johns Hopkins and University of Maryland
- 66% engaged in anal sex without condoms
- 54% had recently visited a healthcare provider
- 62% revealed their sexual orientation to that provider
- 62% were willing to take PrEP
- Only 8% were currently on PrEP

Transgender and PrEP

Anderson PL, et al. *J Acquir Immune Defic Syndr*. 2016;72(Suppl 3):S230-S234

- Male to Female Transgender PrEP has not been extensively studies
- Questions regarding possible interactions of TDF/FTC and transgender hormones including estradiol, progestins or spironolactone
- PrEP adherence is high in transgender women
- Group with one of the highest HIV incidence and prevalence rates

PrEP and insurance

- Covered by Medicaid and most major insurance companies

ICD-10	Description
Z72.5	High-risk sexual behavior
Z20.82	Contact with and (suspected) exposure to other viral communicable diseases
Z20.6	Exposure to HIV

CPT	Description
99401	Preventive counseling (15 minutes)
99402	Preventive counseling (30 minutes)
99403	Preventive counseling (45 minutes)
99404	Preventive counseling (60 minutes)

PrEP Consultation Service for Clinicians

(1-855 HIV-PREP)

11 a.m. – 6 p.m. ET , Monday-Friday

For more information on the services offered through the PrEPline, visit the **National Clinicians Consultation Center**

PEP, Post Exposure Prophylaxis

Definitions

- Sexual assault includes rape, unwanted genital touching, and forced viewing of or involvement in pornography
- Rape is a legal term describing any penetration of a body orifice involving force or the threat of force or incapacity (ie associated with young or old age, cognitive or physical disability, or drug or alcohol intoxication) and nonconsent

Care of the Adult Patient after Sexual Assault. Linden JA. N Engl J Med 2011;365:834-41

Sexual assault

- Lifetime prevalence 13-39% for women, 3% for men
- Only 16-38% of rape victims report the rape to law enforcement
- 17-43% present for medical evaluation after rape
- Fewer than half of reported rape cases are successfully prosecuted

SANE

- Sexual Assault Nurse Examiner
- Examines the victim for injuries
- Provides objective documentation
- Collects evidence while maintaining chain of custody
- Offers support and community referrals
- 650 SANE or SART (Sexual Assault Response Team) programs across the US

Data Collection

- Process can take 6 hours or more
- Detailed 17 step process
- Must be performed within 72 hours of assault to be effective and legal.
- Costs covered under the Ohio Victims of Crime Compensation Program

Testing pre-treatment

- NAATs for *C. trachomatis* and *N. gonorrhoeae* at the sites of penetration or attempted penetration
- NAATs from a urine or vaginal specimen or point-of-care testing (i.e., DNA probes) from a vaginal specimen for Trichomonas and Bacterial Vaginosis.
- A serum sample for evaluation of HIV, hepatitis B, hepatitis C and syphilis infections.

STI treatment

- All patients should be offered prophylaxis for:
  - Gonorrhea (ceftriaxone and azithromycin)
  - Chlamydia (azithromycin or doxycycline)
  - Bacterial vaginosis (metronidazole)
  - Hepatitis B (vaccine if not immunized)
  - Tetanus booster (if indicated)

Pregnancy

- Risk of pregnancy after rape is approximately 5%
- Baseline urine pregnancy test should be obtained, and if negative
- Female rape victims should be offered progestin-only emergency contraception (Plan B) within 120 hours of assault
- 98.5% effective

HPV- Human Papillomavirus

- HPV vaccination is recommended for female survivors aged 9–26 years and male survivors aged 9–21 years.
- For MSM with who have not received HPV vaccine or who have been incompletely vaccinated, vaccine can be administered through age 26 years.
- The vaccine should be administered to sexual assault survivors at the time of the initial examination, and follow-up dose administered at 1–2 months and 6 months after the first dose.

Preventing HIV Transmission

Lacking in our sexual assault protocols until recently…

Risk of HIV transmission

- Unprotected vaginal intercourse with known HIV + partner is 0.3%
- Unprotected receptive anal intercourse with known HIV+ partner is 1.43%
- Depends on infectiousness of the host

HIV transmission in sexual assault

- Transmission dependent on the likelihood of the perpetrator(s) having HIV
- The number of perpetrators
- Anal penetration
- Whether ejaculation occurs
- Presence of STIs (esp genital ulcers)
- Occurrence of injury

Rape Survivors

- Study of rape survivors in South Africa, of 480 initially seronegative survivors
- Begun on AZT and lamivudine and followed up for at least 6 weeks,
- 1 woman seroconverted. She had started taking medications 96 hours after the assault.
- 1 additional woman, who sought treatment 12 days after assault, was seronegative at that time but not offered nPEP. At retesting 6 weeks after the assault, she had seroconverted

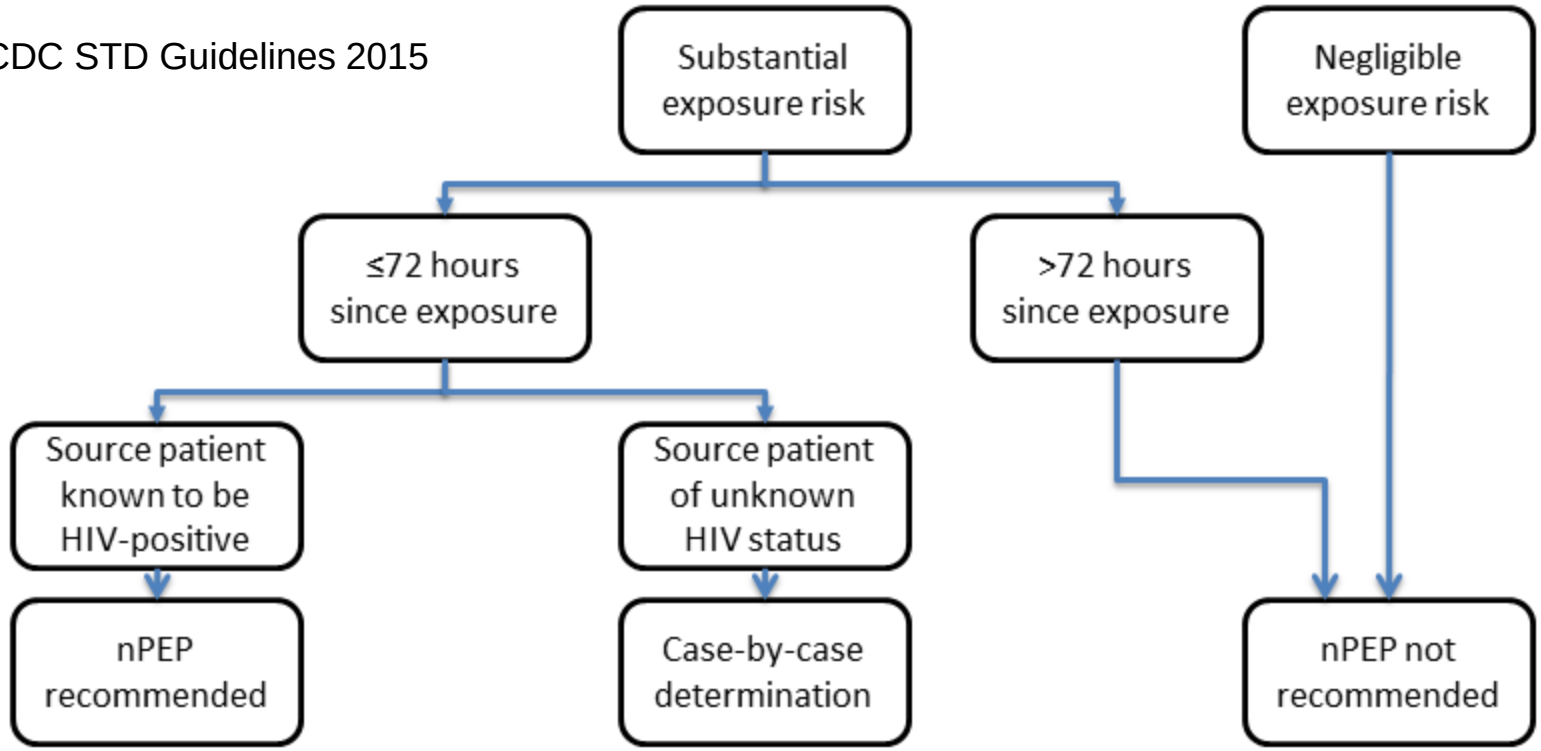
Sexual assault survivors

- Study of sexual assault survivors in Sao Paolo, Brazil, women who sought care within 72 hours after exposure were treated for 28 days with either AZT and lamivudine (for those without mucosal trauma) or AZT, lamivudine, and indinavir (for those with mucosal trauma or those subjected to unprotected anal sex) for 28 days.
- Women were not treated if they sought care >72 hours after assault, if the assailant was HIV-negative, or if a condom was used and no mucosal trauma was seen.
- Of 180 women treated, none seroconverted.
- Of 145 women not treated, four (2.7%) seroconverted

Recommendations for postexposure HIV risk assessment of adolescent and adult survivors within 72 hours of sexual assault

- Assess risk for HIV infection in the assailant, and test that person for HIV whenever possible.
- Use the algorithm to evaluate the survivor for the need for HIV nPEP. Consult with a specialist in HIV treatment if nPEP is being considered.
- If the survivor appears to be at risk for acquiring HIV from the assault, discuss nPEP, including benefits and risks.
- If the survivor chooses to start nPEP, provide enough medication to last until the follow-up visit at 3–7 days after initial assessment and assess tolerance to medications.

CDC STD Guidelines 2015



Substantial Risk for HIV Acquisition

Exposure of
vagina, rectum, eye, mouth, or other mucous membrane, nonintact skin, or percutaneous contact

With
blood, semen, vaginal secretions, rectal secretions, breast milk, or any body fluid that is visibly contaminated with blood

When
the source is known to be HIV-positive

Negligible Risk for HIV Acquisition

Exposure of
vagina, rectum, eye, mouth, or other mucous membrane, intact or nonintact skin, or percutaneous contact

With
urine, nasal secretions, saliva, sweat, or tears if not visibly contaminated with blood

Regardless
of the known or suspected HIV status of the source

FIGO Guidelines for the management of female survivors of sexual assault

- Report of FIGO working group on sexual violence/HIV in International Journal of Gynecology and Obstetrics. 2010
- PEP after rape is recommended as a routine part of post-rape care for survivors presenting within 72 hours of a rape in all countries with high prevalence rates of HIV.
- The risk of HIV transmission after rape is estimated to be relatively low, yet it is of grave concern to survivors

Offering HIV prophylaxis to people who have been sexually assaulted: 16 months' experience in a sexual assault service.

Wiebe ER, Comay SE, McGregor M, Ducceschi S. CMAJ. 2000 Mar 7;162(5):641-5.

-The sexual assault service at Vancouver General Hospital Emergency Department,

- 258 people were seen by the service, 71 accepted the offer of HIV prophylaxis.
- 29 continued with the drug treatment after receiving the initial 5-day starter pack,
- 8 completed the full 4-week treatment regimen
- Patients at highest risk for HIV infection (those who had penetration by an assailant known to be HIV positive or at high risk for HIV infection [men who have sex with men, injection drug users]) were more likely to accept prophylaxis and more likely to complete the treatment than those at lower risk.
- Compliance and follow-up were the main problems with implementing this service.
- Service providers found it difficult to give the information about HIV prophylaxis to traumatized patients.

Effective counseling for PEP

- Victims must be negative for HIV to start PEP
- There is no guarantee PEP will be effective
- Need to start immediately
- Need to take for 28 days without missing any doses
- Possible side effects of PEP (worst in first few days)
- Importance of follow up testing
- Need for safe sex until all testing is completed at 3 months

Follow up testing

- HIV testing with Ag/Ab combination (alternative, Ab only) upon presentation and then at 4-6 weeks and 3 months
- Hepatitis B surface antigen (HBsAg) Hepatitis B surface antibody (HBsAb) and Hepatitis B core antibody (HBcAb) upon presentation and then at 6 months, if susceptible
- Hepatitis C testing: Surface antibody upon presentation and then at 6 months, if susceptible

Other follow up testing

- Other tests, if applicable, as follows:
- Syphilis serology upon presentation and then at 4-6 weeks and 6 months
- Gonorrhea (nucleic acid amplification) from all exposed sites (genital, pharyngeal, anal)
- Chlamydia (nucleic acid amplification) from all exposed sites (genital, pharyngeal, anal)
- Baseline laboratory tests for PEP medications, as follows:
- Urine human chorionic gonadotropin (HCG), if applicable, upon presentation and then at 4-6 weeks
- Complete blood cell (CBC) count
- Creatinine

Work Done in our Community

- Standardization of SANE protocol with regards to nPEP
- Presentation at National Conference
- Advocacy of Ohio Congress to provide funding for nPEP - enacted
- Continued work with Attorney General to assure funding provided.

Attorney General Proposal

- Proposing ER and hospitals accept payment of actual amount paid, not to exceed $2500, as payment for administration of HIV post-exposure prophylaxis protocol 109:7-1-01 OAC (Ohio Administrative Code)
- Covers: 28 days of meds, initial labs, physician charge, referral for follow-up

Costs (Not 340 B pricing)

- Truvada $1500 for 30 tablets
- Raltegravir $1300 for 60 tablets

Opportunities with meds

- ER should write for full 28 (30) day prescription, not 5 days
- Medicaid covers
- Get list of COPAY cards available (BCBS 28 days copay is $471
- Raltegravir (Merck) - https://www.activatethecard.com/7387/#
- Truvada (Gilead)- https://www.gileadadvancingaccess.com/copay-coupon-card

Gilead Advancing Access - uninsured

Truvada, Complera, Emtriva, Viread

- Fax letter of necessity stating sexual assault victim and needed for PEP to 1-800-216-6857.
- Wait 10 minutes, then
- Call 1-800-226-2056 between 9:00 a.m. and 8:00 p.m. (Eastern) Monday through friday
- Pt will be screened over the phone- no proof of income necessary.
- Immediate approval.

Resources

- **Assistance with nPEP-related decisions can be obtained by calling the National Clinician's Post Exposure Prophylaxis Hotline (PEP Line) (telephone: 888–448–4911).**

Limitations

- SANE nurses see patients >14 years of age(UH has pediatric nurses). Atlanta ER study: of 87 children and adolescents seen in the ED ≤ 72 hours after the assault, 23 had anogenital trauma or bleeding, and 5 were offered nPEP.
- No follow up clearly identified- ? Not comfortable with PCP discussing this or has no PCP
- Circle Health has obtained RFA through AIDS funding collaborative to get appts for this.

Victim Crime Compensation Program

- If you or your family members are innocent victims of a violent crime, financial assistance may be available. The following is a list of guidelines to help you determine whether you might be eligible for a payment. For specific questions, call the Attorney General's Office at (800) 582-2877.
- **Who may be eligible to receive a payment:**
  - Those injured during a violent crime.
  - Dependents of people killed in crimes.
  - Anyone responsible for a crime victim's finances, such as a parent or guardian.
- **Who may not be eligible receive a payment:**
  - Anyone convicted of a felony offense, child endangering or domestic violence within 10 years before the crime, or while the compensation application is pending.
  - Anyone who engaged in misconduct that caused or contributed to the injuries.

Victim Crime Compensation Program

- **Payments can cover:**
  - Medical and related expenses.
  - Counseling for immediate family members of victims of homicide, sexual assault or domestic violence.
  - Wages lost because of the crime.
  - Crime scene cleanup for personal security, such as doors and windows.
  - The cost to replace items taken as evidence.
  - Lost wages and travel expenses for family members of a deceased victim to attend court proceedings.
  - Financial support for dependents of a deceased victim.
  - Funeral and burial expenses.
- The maximum total payments are limited to $50,000, and several expenses have caps. Payments cannot be made for pain and suffering or for stolen, damaged or lost property.
- The Attorney General's Office will not pay victims for expenses that can be covered by any other available sources, such as insurance.

  Make sure to file an application for payment within two years, or by the 20th birthday of a minor victim or dependent.

Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States, 2016:

Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

- Same algorithm as with sexual assault
- Same timeline, <72 hours
- Same medication recommendations

MSM high risk exposure

- In a high-risk HIV incidence cohort in Brazil, nPEP instruction and 4-day starter packs of zidovudine and lamivudine were administered to 200 homosexual and bisexual men.
- Men who began taking nPEP after a self-identified high-risk exposure were evaluated within 96 hours
- 1 seroconversion among men who took nPEP
- 11 seroconversions among men who did not take

Why prescribers hesitate

- Concern for causing resistant HIV strains
- Lack of knowledge on prescribers part
- ? Other reasons

Non-assault nPEP, CDC 2016

- nPEP should be provided only for infrequent exposures.
- Persons who engage in behaviors that result in frequent, recurrent exposures that would require sequential or near-continuous courses of antiretroviral medications should not be prescribed frequent, repeated courses of nPEP.
- Instead, health care providers should provide persons with repeated HIV exposure events intensive sexual or injection risk-reduction interventions, and consider the prescription of daily oral doses of the fixed-dose combination of TDF and FTC (Truvada) for PrEP.
- However, if the most recent recurring exposure is within the 72 hours prior to an evaluation, nPEP may be indicated with transition of the patient to PrEP after completion of 28 days of nPEP medication.

Case

- 30 yo woman had condomless intercourse with her new partner 2 weeks ago and one week ago.
- Found out he has HIV and made appt to see you
- At the visit she admits to condomless intercourse the evening before.