Pre-Exposure Prophylaxis (PrEP) for HIV Prevention in Women

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Agenda
- HIV & PrEP uptake trends in the US
- Identifying PrEP candidates
- Clinical pearls for providing PrEP
- PrEP in pregnancy, lactation, and for safer conception

Disclosure
I have nothing to disclose

Lifetime risk of HIV in the US

A PrEP primer
Pre-exposure prophylaxis for HIV prevention
HIV-negative individuals take antiretroviral medications before and after exposure

PrEP eligibility in the US

PrEP utilization in women by race/ethnicity, 2013-16

White females were 3.8 and 4.4 times more likely to start PrEP than their Black or Hispanic counterparts
Identifying PrEP candidates

CDC: Indications for PrEP in women
Box B2: Recommended Indications for PrEP Use by Heterosexually Active Men and Women

- Adult person
- Without acute or established HIV infection
- Any sex with opposite sex partners in past 6 months
- Not in a monogamous partnership with a recently tested HIV-negative partner
  AND at least one of the following
  - Is a man who has sex with both women and men (behaviorally bisexual) [also evaluates indications for PrEP use by Box B1 criteria]
  - Infrequently uses condoms during sex with 1 or more partners of unknown HIV status who are known to be at substantial risk of HIV infection (IDU or bisexual male partner)
  - Is in an ongoing sexual relationship with an HIV-positive partner

CDC: Indications for people who inject drugs

Box B3: Recommended Indications for PrEP Use by Persons Who Inject Drugs

- Adult person
- Without acute or established HIV infection
- Any injection of drugs not prescribed by a clinician in past 6 months
  AND at least one of the following
  - Any sharing of injection or drug preparation equipment in past 6 months
  - Risk of sexual acquisition (also evaluate by criteria in Box B1 or B2)

CDC summary of indications for PrEP, 2017
Challenges of identifying at-risk women

- CDC criteria, based on partner-based risk factors, are problematic
- Screening in itself may be problematic
  - Stigma around sexual practices
  - Distrust of the medical system
  - Experiences of racism in medicine
  - Personal history of (other) trauma(s)
- Low levels of PrEP awareness among women

STIs as biomarkers for HIV vulnerability

FL, 2000-2009: surveillance data to estimate risk of HIV after syphilis, GC, CT

Offer universal education, then screen (or just offer!)

Lessons learned

When to offer?
- Any HIV test
- Any STI screen
- Any sexual history

Who is PrEP for?
- Use inclusive language
- Cast a broad net
- Trust women

What is PrEP?
- Compare to what women already know (birth control pills)

Why use PrEP?
- For independence
- For confidence
- For love

Clinical pearls
Approach to counseling about PrEP

Offer PrEP as part of an integrated strategy to prevent HIV

- PrEP is not a recommendation
- PrEP is not for everyone

PrEP is for seasons of vulnerability

Continually assess for
- Changes in risk
- Opportunities for new prevention strategies

HIV prevention options

- PEP and/or PrEP
- Condoms
- Partner testing
- Treatment as prevention of partner living with HIV
- Changing type, frequency of sex
- Screening & treating STIs

Counseling messages

Key messages
- Adherence = effectiveness
  - >90% effective for vaginal exposures
- Regular HIV testing is mandatory
- PrEP does not prevent against other STIs
- “Forgiveness” for nonadherence varies in vagina vs. rectum
- Review side effects: nausea, headache
- Contingency planning
- Assess pregnancy intentions – safety periconception, during pregnancy and lactation

Additional messages

Safety & side effects of PrEP

Serious adverse events are rare
- 1/200 risk renal dysfunction
- 1-2% change in bone mineral density; no risk of fracture over 1-2 years; reversible after discontinuation

PrEP is well tolerated
- Nausea in < 10% subjects; primarily during 1st month (PrEP “start-up” symptoms)

Risk of developing drug resistance is highest when PrEP is prescribed to individuals already infected with HIV
- Overall risk of resistance 0.1%

You think PrEP might be right for a patient. Now what?

- History
- Testing
- Prescribing PrEP
- Follow-up
- Discontinuing PrEP

Take a history

- Determine timing of last exposure
  - If <72 hours, offer PEP
- Assess for signs/symptoms of acute HIV in prior month
- Determine pregnancy/breastfeeding status and fertility desires

Laboratory testing

- HIV testing
  - Document negative HIV test before starting PrEP (within the week)
    - Do NOT use oral rapid test
  - If recent exposure & symptoms: test for acute HIV infection with 4th generation test or viral load (RNA PCR)
  - Cr clearance (ineligible if <60 mL/min)
  - Hep B S Ag & Hep B S Ab (immunize if titer<10, discuss with hepatologist if HBV positive)
  - HCV Ab
  - Screen for and treat STIs

Establishing HIV status before PrEP initiation
Prescribing PrEP

- Tenofovir/Emtricitabine (300/200 mg): 1 tablet by mouth daily
- Rx < 90-day supply
- Refill only after confirming patient remains HIV-negative

ICD-10 codes
- V01.79: Contact with or exposure to HIV/AIDS
- V01.89: Exposure to an STI

Follow-up care for patients on PrEP

Every visit
- Assess risk behaviors, provide counseling & condoms
- Evaluate adherence
- Assess pregnancy intentions

Baseline & every 3 months
- HIV testing

Baseline, 3 months, then every 6 months
- Bun/CR

Baseline & every 6 months
- STI testing regardless of symptoms
- Consider more frequent testing


Patient Assistance Program

http://www.gilead.com/responsibility/us-patient-access/truvada-for-prep-medication-assistance-program

Follow-up care for patients on PrEP

Discontinuing PrEP

Perform HIV test(s) to confirm HIV status
- Establish linkage to risk-reduction support services
- Consider completion of 28 day PEP course and confirmatory testing 6 & 12 weeks after last exposure

If active HBV infection
- Discuss with hepatologist

Prescribing PEP
Emtricitabine/tenofovir (Truvada) 1 pill PO QD x 28 days
AND
Raltegravir (Isentress) 400 mg PO BID x 28 days OR
Dolutegravir (Tivicay) 50 mg PO QD x 28 days

PrEP in pregnancy, lactation & for safer conception

Why are pregnancy intentions critical to HIV prevention decisions?

- Pregnancy is associated with ~2X increased risk of HIV acquisition
- Acute HIV during pregnancy associated with ~8X increased risk of perinatal transmission
- Acute HIV during breastfeeding associated with ~4X increased risk of lactational transmission

PrEP in pregnancy: data from women living with HIV

APR: adequate 1st trimesters exposures to detect 1.5X risk of overall birth defects
Systematic review of TDF in pregnancy (26 studies of women with HIV and with hep B): no differences in
  - pregnancy loss
  - preterm birth (<37 weeks)
  - low birth weight infants (<2500 g and <1500 g)
  - small for gestational age infants
  - birth defects
  - infant or maternal mortality
One small study (n=30) of women on PrEP in pregnancy: no differences in preterm birth, pregnancy loss or birth defects


PrEP during lactation

TDF/FTC is secreted in breast milk, but infant levels are extremely low
- 50 mother/infant pairs, exclusively breastfeeding, DOT with TDF/FTC PrEP x 10 days
- TDF not quantifiable in 94% of infant serum samples
- FTC quantifiable in 96% of infant serum samples
- Drug levels <1% those of therapeutic infant dosing


PrEP & pregnancy take-aways

Offering PrEP in pregnancy is supported by data & guidelines
- CDC, WHO suggest offering PrEP in pregnancy and lactation
- ACOG: TDF/FTC has “reassuring” safety profile and providers should be “vigilant” for seroconversion during lactation

Safer conception options

- Treatment as prevention
  - Monitor partner’s virologic control, screen for STIs, semen analysis
  - Timed condomless intercourse +/- PrEP
- IUI +/- PrEP
- IVF
- Sperm donor
- Adoption

Resources
Guidelines

CDC

DHHS

ACOG Committee Opinion
https://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Preexposure-Prophylaxis-for-the-Prevention-of-Human-Immunodeficiency-Virus

Provides clinicians of all experience levels with cost-free, confidential, timely, expert responses to questions on:
- HIV/AIDS management
- Occupational and non-occupational exposure management
- Management of HIV in pregnant women and their infants
- Providing PrEP as part of HIV prevention

HIV Management: 800.933.3413
7 am – 8 pm EST, M-F
PEPline: 888.448.4911
9 am – 2 am EST, every day
Perinatal HIV Hotline: 888.448.8765
PrEPline: 855.448.7737

Online Consultation: nccc.ucsf.edu

The CCC at UCSF/SFGH is a project of the HRSA AETC Program & the CDC

PrEP for Women Resource Page
www.hiveonline.org/PrEP4Women

PrEP for Family Planning Providers Toolkit
- Collaboration: HIVE, San Francisco DPH Center for Learning and Innovation (CBA), National CBA Provider Network Resource Center, National Clinical Training Center for Family Planning
- Published at: www.hiveonline.org/PrEP4FamilyPlanning
- Disseminated to: Various stakeholders nationwide. The page has been viewed over 700 times in the first 2 months
- Simultaneously gathered feedback from providers, advocates and consumers
Questions?

Thank-you!

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