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

Disclosures
I have nothing to disclose

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

Lifetime risk of HIV in the US

- African American Men: 1 in 24
- African American Women: 1 in 64
- Hispanic Men: 1 in 107
- Hispanic Women: 1 in 129
- White Men: 1 in 362
- White Women: 1 in 880

A PrEP primer

Pre-exposure prophylaxis for HIV prevention

HIV-negative individuals take antiretroviral medications **before and after** exposure

**PrEP** is taken **BEFORE & AFTER** exposure

**PEP** is taken **AFTER** exposure

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PrEP eligibility in the US

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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.
**CDC: Indications for PrEP in 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) who meets the criteria for PrEP prevention as defined in Box B1
  - Is an injection drug user or with a sex partner who injects drugs
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**CDC: Indications for people 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 criteria in Box B1 or B2)

**CDC summary of indications for PrEP, 2017**


- 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

**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
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- 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 for seasons of vulnerability
- PrEP is not a recommendation
- PrEP is not for everyone
- Continually assess for
  - Changes in risk
  - Opportunities for new prevention strategies
HIV prevention options

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

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

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%


Oral pre-exposure prophylaxis (PrEP) for all populations: a systematic review and meta-analysis.

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

- 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

When was last exposure?

- <72 hours, offer PEP

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

Prescribing PEP

Emtricitibine/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
PrEP: 855.448.4911
Perinatal HIV Hotline: 888.448.8765
PrEPline: 855.448.7737

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 U.S. Women: A collection of resources

Resources for Women:
- Private information on PrEP for Women
- Resources to help providers improve their care
- Risk assessment tools for PrEP
- PrEP guidelines
- PrEP effectiveness data

Resources for Advocates:
- Information on expanding PrEP coverage for all women
- Information on the role of PrEP in reducing HIV transmission in women
- Information on PrEP use among women
- Information on PrEP adherence

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PrEP for Family Planning Providers Toolkit

- Collaboration: HIVE, San Francisco DPH Center for Learning and Innovation (CSIA), National CSA 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

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Thank-you!

Dominika.seidman@ucsf.edu