Moving PrEP into Practice

Nursing Advocacy, Strategies and Policies for the Establishment of HIV Pre Exposure Prophylaxis (PrEP) Prevention Programs In Substance Abuse Treatment, Reproductive Health and Primary Care Settings

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Continuing Nursing Education

Upon full participation in this webinar & completion of an evaluation, participants will be awarded 1.0 contact hours.

The Association of Nurses in AIDS Care (ANAC) is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.
Disclosures

Faculty Conflict of Interest Disclosures

Joanne Phillips, Claire Simeone, Carole Treston have no actual or perceived conflicts of interest related to the content of this program.

Commercial Support Disclosures

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Agenda

- Overview & Resources
- Policy Implications
- PrEP & Women
- PrEP & People Who Use Drugs
- Q&A
Learning Objectives

At the end of this session participants will be able to:

• Describe the various roles of nurses in advocating for and establishing local PrEP programs.

• Discuss innovative nursing strategies for PrEP programs in substance abuse treatment and reproductive health settings.

• Identify local institutional and programmatic policies that are necessary for implementing effective PrEP programs that align with national HIV prevention policies and recommendations.
Moving PrEP into Practice

HIV Pre Exposure Prophylaxis (PrEP) Implementation Resources & Policy Overview

October 30, 2015

Carole Treston, RN MPH ACRN FAAN
Trials Guidelines & Approvals

• Nov 2010 IPREX Study
• Jan 2011 CDC Interim Guidance MSM
• July 2011 Partners PrEP TDF2
• July 2012 FDA Approval of PrEP
• Aug 2012 CDC Interim Guidance Hetero M/F
• May 2014 USPHS CDC Guidelines
• July 2014 IPREX Ole
• Sept 2015 WHO Recommendations
• 2015 SCALE-UP
CDC Guidelines

Daily oral PrEP with the fixed-dose combination of tenofovir 300 mgm/FTC 200 mgm (Truvada) has been shown to be safe and effective in reducing the risk of sexual HIV acquisition in adults; therefore PrEP is recommended as one prevention option for:

- sexually-active adult MSM at substantial risk of HIV
- adult heterosexually active men and women at substantial risk of HIV
- adult injection drug users
- In sero-discordant couples to protect the uninfected partner during conception and pregnancy
U.S. Cities Involved in Demonstration Projects

Demonstration and Implementation projects have a planned enrollment of approximately 8,000 participants.

* NYC = Manhattan, Harlem, Bronx and Brooklyn
Implementation Assistance

**PrEPline**: Peer to Peer Consultation:
Clinician Consultation Center UCSF, HRSA/HAB, AETC
Mon-Fri 11 a.m. – 6 p.m. EST 855-448-7737

**Drug Payment:**
MA & Pvt insurance coverage; Prior authorization
Gilead *Medication* Assistance Program
Insured & non-insured at 500% FPL = $58,344/year

**Provider & Lab Costs**
Insured
Uninsured****

[ANAC logo]
Access to PrEP

Current Status of State Medicaid Expansion Decisions

NOTES: Under discussion indicates executive activity supporting adoption of the Medicaid expansion; it requires federal waiver approval. *AR, IA, IN, MI, PA and NH have approved Section 1115 waivers. Coverage under the PA waiver went into effect 1/1/15, but it is transitioning coverage to a state plan amendment. Coverage under the IN waiver went into effect 2/1/15. WI covers adults up to 100% FPL in Medicaid, but did not adopt the ACA expansion.

Other Resources

What is PrEP.org
myprepexperience.com
Patient Experience/
PrEPWatch.org
ANAC website
Patient Video
Access
Trials & Global Advocacy
ANAC webinars
PrEPisms

- When ARVs – for treatment or prevention – are taken, they work
- PrEP is a Tool, but it is not forever, it is not for everyone. Useful during “Seasons of Risk”
- PrEP is a Program, not just a prescription
- Barriers are real, and sometimes they are us
Moving PrEP into Practice: Women’s Health

Joanne Phillips, RN, MS
## PrEP Guidelines

<table>
<thead>
<tr>
<th>Detecting substantial risk of acquiring HIV infection</th>
<th>Heterosexual Women and Men</th>
<th>HIV-positive injecting partner Sharing injection equipment Recent drug treatment (but currently injecting)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-positive sexual partner</td>
<td>HIV-positive sexual partner</td>
<td>Sharing injection equipment Recent drug treatment (but currently injecting)</td>
</tr>
<tr>
<td>Recent bacterial STI</td>
<td>Recent bacterial STI</td>
<td>Sharing injection equipment Recent drug treatment (but currently injecting)</td>
</tr>
<tr>
<td>High number of sex partners</td>
<td>High number of sex partners</td>
<td>Sharing injection equipment Recent drug treatment (but currently injecting)</td>
</tr>
<tr>
<td>History of inconsistent or no condom use</td>
<td>History of inconsistent or no condom use</td>
<td>Sharing injection equipment Recent drug treatment (but currently injecting)</td>
</tr>
<tr>
<td>Commercial sex work</td>
<td>Commercial sex work</td>
<td>Sharing injection equipment Recent drug treatment (but currently injecting)</td>
</tr>
<tr>
<td>In high-prevalence area or network</td>
<td>In high-prevalence area or network</td>
<td>Sharing injection equipment Recent drug treatment (but currently injecting)</td>
</tr>
</tbody>
</table>

### Clinically eligible
- Documented negative HIV test result 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 doses of TDF/FTC (Truvada), ≤90-day supply

### Other services
- Follow-up visits at least every 3 months to provide the following:
  - HIV test, medication adherence counseling, behavioral risk reduction support,
  - side effect assessment, STI symptom assessment
  - At 3 months and every 6 months thereafter, assess renal function
  - Every 6 months, test for bacterial STIs
- Do oral/rectal STI testing
- Assess pregnancy intent
- Pregnancy test every 3 months
- Access to clean needles/syringes and drug treatment services
## Current Evidence

### Among Heterosexual Men and Women

<table>
<thead>
<tr>
<th>Study</th>
<th>Phase</th>
<th>Treatment</th>
<th>Control</th>
<th>Conclusion</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partners PrEP</td>
<td>Phase 3</td>
<td>TDF (n = 1589)</td>
<td>Placebo (n = 1586)</td>
<td>Minimal</td>
<td>High</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TDF/FTC (n = 1583)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>TDF2</td>
<td>Phase 2</td>
<td>TDF/FTC (n = 611)</td>
<td>Placebo (n = 608)</td>
<td>High loss to follow-up; modest sample size</td>
<td>Moderate</td>
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### Among Heterosexual Women

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<thead>
<tr>
<th>Study</th>
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<th>Conclusion</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEM-PrEP</td>
<td>Phase 3</td>
<td>TDF/FTC (n = 1062)</td>
<td>Placebo (n = 1058)</td>
<td>Stopped at interim analysis, limited follow-up time; very low adherence to drug regimen</td>
<td>Low</td>
</tr>
<tr>
<td>West African Trial</td>
<td>Phase 2</td>
<td>TDF (n = 469)</td>
<td>Placebo (n = 467)</td>
<td>Stopped early for operational concerns; small sample size; limited follow-up time on assigned drug</td>
<td>Low</td>
</tr>
<tr>
<td>VOICE</td>
<td>Phase 2B</td>
<td>TDF (n = 1007)</td>
<td>Placebo (n = 1009)</td>
<td>TDF arm stopped at interim analysis (futility); very low adherence to drug regimen in both TDF and TDF/FTC arms</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TDF/FTC (n = 1003)</td>
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PrEP Considerations for Women

• Risk
  – Partner status
    • Estimated 140,000 serodifferent couples in the US (Lampe, 2011)
    • Study of 181 WLWH of child bearing age in 2 US clinics in Baltimore:
      – 62% have a negative partner
      – 11% have a partner whose HIV status was unknown (Finocchiaro-Kessler, 2010)
  – Residing in a high-prevalence area
PrEP Considerations for Women

• Plans for conception, especially if partner HIV-positive
  – Barriers identified by the Expert Panel
    • Conducting semen analysis
    • Coordination of couples counseling
    • Access to both partner’s medical records
• Continuation of PrEP during pregnancy or breastfeeding
Accessing PrEP

Primary Care

Reproductive health clinic

ID clinic

OB/GYN
Barriers

• Lack of clarity on where to access PrEP
• Reaching clients “at-risk” for HIV but otherwise healthy
• Cost
  – Insurance co-pays can be very expensive
  – Time-consuming process for clinic staff and client to obtain insurance approval or complete drug company assistance paperwork
• Stigma
• Lack of provider knowledge
• Lack of Patient knowledge
  – About PrEP
  – About risk for HIV
PrEP Implementation

- Recommendations from the Expert Panel on Reproductive Health and Preconception Care for Persons Living with HIV
  - Work with key clinic stakeholders to obtain buy-in in the clinical setting
  - Develop and train a group of “PrEP Champions”
    - Providers who see PrEP as a priority, feel comfortable prescribing and monitoring those on PrEP
  - Educate patient navigators about PrEP so they can be the ones sharing the information with patients – peer-to-peer
  - Use a team-based approach
PrEP Implementation (Cont.)

• Recommendations from the Expert Panel on Reproductive Health and Preconception Care for Persons Living with HIV
  – Develop models of identifying candidates for PrEP
  – Utilize a reproductive justice framework when training about PrEP
    • Train providers to empower women to decide her level of acceptable risk and take control of PrEP and other reproductive health decisions
  – Educate patient navigators about PrEP so they can be the ones sharing the information with patients – peer-to-peer
  – Identify & fund support staff and/or automated reminder systems for monitoring, assessment and HIV testing and adherence counseling
Moving PrEP into Practice:
PrEP for People Who Use Drugs

Claire Simeone, FNP, MSN
ANAC Annual Conference
Chicago, IL
October 30, 2015
CDC Recommendation

Any non-prescription IDU in past 6 months

AND at least one:

Shared equipment in past 6 months
Participated in medication assisted treatment in past 6 months
Risk of sexual acquisition

CDC, 2014
What does the research say?

- One RCT: “the Bangkok study”
- Clients attending drug treatment services
- TDF vs placebo
- 17 vs 33 new infections in treatment vs placebo
- 48.9% reduction in HIV incidence, 73.5% if TDF detected

Choopanya et al. 2013
Questions to Answer

• Can we predict adherence?

• What is the added value of PrEP to other risk reduction strategies?

• What is the driver of risk? (paraphernalia or sex)

• Diversion?
Implementation Challenges

• Aligning medical and behavioral health cultures

• Funding

• Staff knowledge/skills

• Leadership support and prioritization

• Work flow

• Confidentiality
OUT OF THE MOUNTAIN OF DESPAIR,
A STONE OF HOPE

Questions