HIV: Are You PrEPared?

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Speaker conflicts: nothing to disclose

Pre Exposure Prophylaxis

Survey Question 1

What is your practice setting?

A. Community
B. Specialty
C. Hospital
D. Ambulatory clinic
E. Academia
F. Student

*If you are a resident or fellow, select your primary training site
Survey Question 2
How comfortable are you providing PrEP care?

A B C D E
Not at all Neutral Very

Survey Question 3
What is your level of experience with PrEP care?

A B C D E
Novice Neutral Expert

Pharmacist Objectives
At the conclusion of this program, the pharmacist will be able to:

- Recognize PrEP uptake and utilization gaps nationally and in the State of Illinois
- Describe pharmacotherapy agents and guidelines for the prevention of HIV infection
- Discuss pharmacist roles in PrEP care
Technician Objectives

At the conclusion of this program, the technician will be able to:

- List medications used for the prevention of HIV infection
- Describe the role of the pharmacy technician in PrEP care
- Discuss lessons learned and best practices for preventing HIV

Pre-Test Question 1

This group is at the highest risk of acquiring HIV, but has had low uptake of PrEP:

A. White heterosexual males
B. Black men who have sex with men
C. Any race/gender living in the Midwest
D. Women with controlled HIV+ partners

Pre-Test Question 2

In the “One Step-PrEP” program in Seattle, pharmacists provide PrEP care in this setting:

A. Emergency room
B. Telemedicine
C. Hospital-based clinic
D. Community pharmacy
Pre-Test Question 3

This medication combination is approved by the Food and Drug Administration (FDA) for HIV PrEP in persons at high risk for infection:

A. Emtricitabine / tenofovir (FTC/TFV)
B. Darunavir / cobicistat (DRV/c)
C. Cabotegravir / rilpivirine (CAB/RPV)
D. Dolutegravir / lamivudine (DTG/3TC)

Pre-Test Question 4

The best way for pharmacy technicians to help increase access to PrEP is:

A. Educating patients on their PrEP prescriptions
B. Monitoring patient’s lab results
C. Facilitating patient assistance program applications
D. Collecting swabs for STI tests

Patient Cases

• 26 year old Black heterosexual woman who is being treated for chlamydia but is otherwise healthy. On oral hormonal contraception.

• 47 year old white man with renal disease secondary to uncontrolled hypertension. 8 male sexual partners in the last month with inconsistent condom use.
Uptake and Utilization

Lifetime Risk of HIV Diagnosis by Race/Ethnicity, US

HIV Incidence by Geographic Location


http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html

Slide credit: clinicaloptions.com
Effective HIV Prevention

PrEP

Biomedical Interventions

Behavioral Interventions

Structural Interventions

PrEP Indication vs. Utilization

70,395 PrEP Users

1,232,000 Indicated

5%

PrEP Utilization in Illinois
Barriers to PrEP Uptake and Utilization

- Providers not familiar or comfortable
- Not enough service providers
- Lack of patient education
- Patient concerns

Patient Cases

- What factors contribute to these patients' HIV risk?
  - 26 year old Black heterosexual woman who is being treated for chlamydia but is otherwise healthy. On oral hormonal contraception.
  - 47 year old white man with renal disease secondary to uncontrolled hypertension. 8 male sexual partners in the last month with inconsistent condom use.

Pharmacotherapy
PrEP Medications: F/TDF and F/TAF

TDF vs. TAF

F/TDF vs. F/TAF
F/TDF vs. F/TAF (cont.)

<table>
<thead>
<tr>
<th></th>
<th>F/TDF</th>
<th>F/TAF</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General Safety</strong></td>
<td>Low overall side effects; usually improve over time</td>
<td>Boxed warnings: hepatitis B exacerbation, confirm HIV negative</td>
</tr>
<tr>
<td><strong>Bone Density</strong></td>
<td>More decline</td>
<td>Less decline</td>
</tr>
<tr>
<td><strong>Kidney</strong></td>
<td>More effects</td>
<td>Less effects</td>
</tr>
<tr>
<td>&amp; not for existing kidney disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Weight</strong></td>
<td>Small weight loss</td>
<td>Small weight gain</td>
</tr>
<tr>
<td><strong>Cholesterol</strong></td>
<td>Small decreases</td>
<td>Small increases</td>
</tr>
</tbody>
</table>

Which One?!

Patient Cases

**F/TDF or F/TAF?** Education?

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• 47 year old white man with renal disease secondary to uncontrolled hypertension. 8 male sexual partners in the last month with inconsistent condom use.
Long-Acting Agents for PrEP

- Intravaginal ring
- Implant
- Injectable
- Antibody

PrEP Guidelines

US Public Health Service

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES – 2017 UPDATE

A CLINICAL PRACTICE GUIDELINE

Candidates for PrEP

<table>
<thead>
<tr>
<th>MSM</th>
<th>Heterosexual Persons</th>
<th>PWID</th>
</tr>
</thead>
<tbody>
<tr>
<td>- HIV+ sexual partner</td>
<td>- HIV+ sexual partner</td>
<td>- HIV+ injecting partner</td>
</tr>
<tr>
<td>- Recent bacterial STI</td>
<td>- Recent bacterial STI</td>
<td>- Sharing injection equipment</td>
</tr>
<tr>
<td>- High number of sex partners</td>
<td>- High number of sex partners</td>
<td></td>
</tr>
<tr>
<td>- Inconsistent or no condom use</td>
<td>- Inconsistent or no condom use</td>
<td></td>
</tr>
<tr>
<td>- Commercial sex work</td>
<td>- Commercial sex work</td>
<td></td>
</tr>
</tbody>
</table>

Interested in PrEP
Clinical Eligibility

At Baseline

Required:
- Documented negative HIV test
- No signs/symptoms of acute HIV infection
- Obtain baseline laboratory tests
  - Serum creatinine (eGFR>60)
  - Hepatitis B serologies
  - Pregnancy testing, if applicable

Additional Labs to Optimize Care:
- STI testing, genital/oral/rectal
- Other hepatitis serologies
- Vaccination history

Monitoring and Follow-Up

Every 3 Months
- Repeat HIV testing
- Assess for signs/symptoms of acute HIV infection
- Pregnancy testing, if applicable
- Assess side effects, adherence, and HIV risk behaviors
- Provide support for adherence and risk reduction
- Review new questions and provide any new information about PrEP use
- Refill T/FTC for no more than 90 days

Every 6 Months
- STI testing, genital/oral/rectal
- Monitor CD4

Every 12 Months
- Evaluate continued need for PrEP

Time to Protection

Rectal Tissue
7 days

Vaginal Tissue
20 days
Patient Cases

Baseline tests? Monitoring & follow-up?

• 26 year old Black heterosexual woman who is being treated for chlamydia but is otherwise healthy. On oral hormonal contraception.

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Pharmacist & Technician Roles

PrEP Care Continuum
University of Illinois at Chicago

- Multidisciplinary clinic model, including clinical pharmacists
- PrEP management protocol for clinical pharmacists
  - Under supervision of primary care provider
  - Screening, monitoring, and medication management
- Order and note templates

One-Step PrEP (Seattle)

- Independent community pharmacy
- Collaborative drug therapy agreement
- Pharmacists complete all aspects of care, including phlebotomy
- Pharmacists bill insurance for services
  - Washington State requires commercial insurances to recognize pharmacists as providers

Additional Examples

- Miami Veteran Affairs Health System
- Washington University & Gateway Apothecary (St. Louis)
- Iowa Tele-PrEP
- Scales Pharmacy (Denver)
- Kansas City CARE Clinic
- Brooklyn Hospital Center
- University of New Mexico
Brainstorm

What can you / your practice site do to help increase PrEP uptake and utilization?

Pharmacist & Technician Roles

- Advocate
- Educate
- Support retention
- Obtain accurate history
- Facilitate financial assistance
- Dispense
- Provide PrEP fact sheets
- Support adherence
- Monitor
- Keep a list of PrEP providers
- Prescribe
- Listen

Resources – Informational

Providers

- CDC PrEP Guidelines
- CDC PrEP Guidelines – Provider Supplement
- US Preventive Services Task Force PrEP Recommendation Statement
- CDC Taking a Sexual History

Patients

- CDC
  - https://www.cdc.gov/hiv/basics/prep.html
- PrEP4Love
  - https://prep4love.com/
Resources – Financial
- Gilead Advancing Access
  - https://www.gileadadvancingaccess.com/
- IL PrEP Assistance Program
  - https://www.prep4illinois.com/
- PAN Foundation
- Good Days
- PAF
  - https://www.copays.org/diseases/hiv-aids-and-prevention

Brainstorm
What barriers do you think you / your practice will face in implementing efforts to increase PrEP uptake and utilization?

Considerations
- Scope
- Legal
- Funding
- Support
- Time
- Space
- Training
- Labs
- Documentation
Post-Test Question 1

This group is at the highest risk of acquiring HIV, but has had low uptake of PrEP:

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Questions???

Take Home Points

- PrEP uptake and utilization is lowest among populations at greatest risk for HIV infection
- FTC/TDF & FTC/TAF are currently approved for PrEP and additional agents are in the pipeline
- Expanding pharmacist/technician roles in PrEP represents one approach to increase PrEP use and decrease new HIV infections
Ending the Epidemic by 2030 in Illinois

1. Zero new HIV transmissions
2. Zero people living with HIV who are not receiving treatment

“Through increasing access and uptake of PrEP, retaining more people living with HIV in care, and the continued funding of ongoing supportive services, we can get to zero.”

References

- https://gtzillinois.hiv/ (accessed 6/14/19)
- https://www.avert.org/professionals/hiv-programming/prevention/overview (accessed 6/14/19)
- https://aidsvu.org/resources/deeper-look-prep/ (accessed 6/14/19)
- https://map.aidsvu.org/map?prep=1 (accessed 6/14/19)
- MMWR. 2018;67(41);1147–1150.
- Misra et al. CROI 2019. Seattle, WA. Poster 107
- Patel R, et al. HIVR4P 2018, Madrid, Spain. PD08.03
- Grant R et al, CROI 2016. Boston, MA, Oral #48LB
- https://giveprepashot.org/sites/ (accessed 6/14/19)
- https://giveprepashot.org/sites/ (accessed 6/14/19)
- https://www.hptn.org/research/studies/hptn083 (accessed 6/14/19)
- https://chicago.medicine.uic.edu/departments/academic-departments/medicine/infectious-diseases/research/project-wish/ (assessed 6/14/19)
- Sexually Transmitted Diseases. Epub Ahead of Print. DOI: 10.1097/OLQ.0000000000001017.
- https://gtzillinois.hiv/ (accessed 6/14/19)

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