Pharmacist for HIV Pre-exposure Prophylaxis

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Prevention

- Risk Reduction
  - Condoms
  - Behaviors
- Testing
  - 1 in 7 do not know
- Treatment
## Treatment as Prevention

<table>
<thead>
<tr>
<th>Transmission Category</th>
<th>Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex (oral, anal, or vaginal)</td>
<td>Effectively no risk</td>
</tr>
<tr>
<td>Pregnancy, labor and delivery</td>
<td>1% or less</td>
</tr>
<tr>
<td>Sharing syringes</td>
<td>Unknown</td>
</tr>
<tr>
<td>Breastfeeding</td>
<td>Substantially reduces, but not eliminate risk</td>
</tr>
</tbody>
</table>
Prevention

- Risk Reduction
  - Condoms
  - Behaviors
- Testing
  - 1 in 7 do not know
- Treatment
- PrEP
PrEP: High Impact Prevention Measure

- NNT to prevent 1 HIV infection = 25\(^1\) (13 – 48)\(^{1,2,3}\)
  - Depended on the model used
  - If 40% of at risk MSM receive PrEP over the next decade (assuming 62% adherent), we would avert 1162 infections per 100,000 person-years, 33.0% of expected infections\(^1\)

1. Jenness JID 2016
Clinical Eligibility for PrEP

- Patients must meet the following criteria before PrEP is prescribed
  - Documented HIV-negative antibody test within 1 wk of initiating PrEP
  - No signs/symptoms of acute HIV infection in preceding month or on day of evaluation
  - Normal renal function (eCrCl\textsubscript{CG} ≥ 60 mL/min)
  - No documented contraindications to FTC/TDF
PrEP Treatment: FTC/TDF

- FTC/TDF 200/300 mg\[^1\]
  - **Only** drug approved for PrEP
  - Once-daily tablet, no food requirements
  - Not recommended in patients with CrCl < 60 mL/min
  - PrEP is contraindicated in patients with unknown or positive HIV status

- Prescribing\[^2\]
  - Provide prescription for no more than 90 days
  - Patient MUST be reassessed every 90 days for continued use

- Common adverse events\[^1\]
  - diarrhea, nausea, fatigue, headache, abdominal pain
## PrEP Monitoring Summary

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Initiation</th>
<th>At Least Every 3 Mos</th>
<th>At Least Every 6 Mos</th>
<th>At Least Every 12 Mos</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV test: signs/symptoms of acute HIV</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnancy test</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>STI assessment</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>STI testing</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Hepatitis B serology</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Renal function</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Asses HIV risk and PrEP indication*</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Counsel on adherence and behavioral risk reduction</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

*Based on provider discretion, can be done more frequently.*


Slide credit: clinicaloptions.com

AETC Southeast
HIV Risk and PrEP Conversations in the Pharmacy

- Stigma and shame related to PrEP use represents a considerable sociocultural barrier to PrEP uptake[1]
- Medical mistrust may also be an important barrier for racial minorities[4]
- Discussions of HIV risk and PrEP eligibility must take into account the sensitivity of these topics and the need for confidentiality
  - Important to use nonjudgmental, inclusive language, and gender-affirming pronouns

3. Calabrese SK. JAIDS. 2018;79:46. 4. Tekeste M. AIDS Behav. 2018;[Epub].
Reasons for Not Using PrEP Among US MSM

- N = 4698 survey respondents:
  - 85% had not used PrEP,
  - 22% unaware of PrEP
  - 83% reported ≥ 1 condomless anal intercourse in previous 3 mos

<table>
<thead>
<tr>
<th>Reasons for Not Using PrEP, %</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Concerned about cost</td>
<td>40.2</td>
</tr>
<tr>
<td>Concerned about potential AEs</td>
<td>31.4</td>
</tr>
<tr>
<td>Do not know where to access PrEP</td>
<td>30.6</td>
</tr>
<tr>
<td>Concerned about potential effects of insurance</td>
<td>19.5</td>
</tr>
<tr>
<td>Do not feel at risk</td>
<td>19.3</td>
</tr>
<tr>
<td>Concerned about medical provider’s reaction if I asked for it</td>
<td>18.1</td>
</tr>
<tr>
<td>I didn’t think it would be effective</td>
<td>5.3</td>
</tr>
<tr>
<td>Concerned about reaction of sexual partner(s)</td>
<td>5.3</td>
</tr>
</tbody>
</table>


Slide credit: clinicaloptions.com
PrEP barriers: 40.2% concerned about cost

- Patient Advocate Foundation
- Gilead Medication Assistance Program
  - http://www.gilead.com/responsibility/us-
<table>
<thead>
<tr>
<th>State</th>
<th>Drug Assistance</th>
<th>Clinical Visits &amp; Lab Test Assistance</th>
<th>Patient Income Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Copay Assistance</td>
<td>Medication Assistance</td>
<td></td>
</tr>
<tr>
<td>California</td>
<td>Yes</td>
<td>Yes</td>
<td>Any participating provider</td>
</tr>
<tr>
<td>Colorado</td>
<td>Yes</td>
<td>Yes</td>
<td>Any participating provider</td>
</tr>
<tr>
<td>District of Columbia</td>
<td>Yes</td>
<td>No</td>
<td>Health dept clinics</td>
</tr>
<tr>
<td>Florida</td>
<td>No</td>
<td>Yes</td>
<td>Health dept clinics</td>
</tr>
<tr>
<td>Illinois</td>
<td>Yes</td>
<td>No</td>
<td>Select Grantees</td>
</tr>
<tr>
<td>Massachusetts</td>
<td>Yes</td>
<td>No</td>
<td>Select Grantees</td>
</tr>
<tr>
<td>New York State</td>
<td>No</td>
<td>No</td>
<td>Any participating provider</td>
</tr>
<tr>
<td>Ohio</td>
<td>Yes</td>
<td>Yes</td>
<td>Any participating provider</td>
</tr>
<tr>
<td>Virginia</td>
<td>No</td>
<td>Yes</td>
<td>Health depts/contracted providers</td>
</tr>
<tr>
<td>Washington State</td>
<td>Yes</td>
<td>Yes</td>
<td>Any participating provider</td>
</tr>
</tbody>
</table>
Role of the Pharmacist: Dispensing PrEP - Medication Counseling

PrEP barriers: 31% concerned about potential adverse events

- Patients should be counseled that adverse effects typically resolve within 1 month of starting therapy (“start-up syndrome”)
  - Discuss OTC medications for headache, nausea, flatulence
  - Counsel patients regarding symptoms requiring urgent evaluation
- Drug–drug interactions
- Missed doses
- Remind the patient that PrEP does not prevent STIs!

Role of the Pharmacist: Adherence Support

- Stress the importance of adherence and coming to all recommended follow-up visits
- Discuss tools for adherence support: reminder apps, pill boxes, refill reminder calls, scheduling follow-up visits, etc
- Discuss behavioral risk reduction at every visit

Slide credit: clinicaloptions.com
Adherence to PrEP Is Key to Preventing HIV Acquisition

- Taking FTC/TDF once daily as directed is central to prevention efficacy
- Women may be more vulnerable to missed doses than men due to biological differences in drug absorption
- Patients who miss PrEP doses should be reminded of the need to adopt other HIV prevention strategies

Role of the Pharmacist: Patient Counseling and Education on HIV Risk

PrEP barriers: 19% do not feel at risk

- Important for both HIV-negative and HIV-positive individuals
- For HIV-negative individuals, counsel on HIV risk factors and PrEP eligibility
- Get to know your patients; are you comfortable asking the right questions? Are you comfortable answering PrEP questions?
- Counsel on consistent and correct condom use and other behavioral risk reduction
- Have patient education resources on hand
Transitioning From nPEP to PrEP

- Patients repeatedly seeking nPEP or who are at risk for ongoing HIV exposure should be evaluated for PrEP
- Eligible patients should be transitioned to PrEP at completion of 28-day nPEP regimen
- No gap is needed: Failure to immediately transition from nPEP to PrEP may put the patient at risk for HIV acquisition
- If PrEP therapy is not wanted, patient should at minimum receive behavioral risk reduction counseling and be reassessed for possible PrEP in the future


Slide credit: clinicaloptions.com
Role of the Pharmacist: Facilitating Linkage to Care

PrEP barriers: 31% do not know where to access PrEP

- If you provide care in a community pharmacy setting, you are likely the most accessible medical care provider for any given patient
  - This puts you in a critical position for reaching at-risk populations
- Prescribing PrEP in pharmacy settings
  - Collaborative practice agreements
  - Laboratory ordering and monitoring

Advantages of a Pharmacy Care Setting and for Pharmacists as Providers

- Potentially less stigmatizing than other locations
- Convenience on multiple levels
  - Extended hours (weekend/evenings)
  - One-stop shop (food, meds, other)
  - Proximity (in the neighborhood)
- Pharmacists’ existing knowledge of medication adherence counseling

- Pharmacists and staff are experienced with drug assistance paperwork
- Collaborative agreements can be made by providers in any setting
  - Can foster public–private partnerships
- Existing models support recouping start-up costs within a reasonable time
- Existing models support high patient retention
Pharmacy-Based PrEP Service Model: Necessary Elements

- Legal authority for a pharmacist to implement PrEP services
  - Designating a medical doctor
  - Collaborative Practice Agreement
  - Practice protocol
- Adequate physical space: privacy, counseling, lab testing, and processing
- Medical Test Site Certificate for laboratory testing
  - CLIA waiver
- Systems needed for chart access, training, regular meetings; when building program, ideal to set up joint EHR at the beginning, standardize communications

- Trained and willing pharmacy staff
  - Medication dispensing, refill tracking, medication adherence counseling, insurance, prior authorization, patient assistance paperwork
  - Sexual history, injection drug use history, risk reduction counseling
  - Referral system for mental health, substance use, social services
  - Labs/phlebotomy: may require additional staff or licensing

Slide credit: clinicaloptions.com
Collaborative Agreements

**Collaborative Practice Agreement (CPA)**
- “Between one or more physicians and pharmacists wherein qualified pharmacists working within the context of a defined protocol are permitted to assume professional responsibility for performing patient assessments; ordering drug therapy-related laboratory tests; administering drugs; and selecting, initiating, monitoring, continuing, and adjusting drug regimens”

**Collaborative Drug Therapy Management (CDTM)**
- “Legislation to allow pharmacists to participate in patient drug therapy management through collaborative arrangements with physicians and other healthcare providers”
- CDTM is a type of CPA that pertains to drug therapy management
State Laws Authorizing Pharmacist Collaborative Practice Agreements, 2012

Authorized to provide drug therapy management for health conditions specified in a written provider protocol, in any setting

Authorized extremely limited collaborative practice under protocol (ie, immunizations, emergency contraception), regardless of setting

Authorized to provide drug therapy management under protocol, limited to health settings

No law identified or legal authority is unclear

# Examples of PrEP Services in Community/Outpatient Pharmacies

<table>
<thead>
<tr>
<th>Pharmacy</th>
<th>Location</th>
<th>Pharmacy/Pharmacist Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gateway Apothecary Pharmacy/ Washington</td>
<td>St Louis, Missouri</td>
<td>PrEP follow-up care by appt only: medication refills, counseling, HIV rapid testing, STI treatment Collaborative Practice Agreement</td>
</tr>
<tr>
<td>University Clinic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scales Pharmacy[3]</td>
<td>Denver, Colorado</td>
<td>PrEP follow-up care: counseling, prescribing, dispensing, blood draws for lab testing (pharmacist trained in phlebotomy), STI testing and treatment Collaborative practice agreement</td>
</tr>
<tr>
<td>University of New Mexico Hospitals Outpatient</td>
<td>Albuquerque, New Mexico</td>
<td>PrEP initiation and monitoring</td>
</tr>
<tr>
<td>Pharmacy[4]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Washington University ID Clinic Collaboration With Gateway Apothecary for Pharmacy PrEP Services

- **Collaborative Drug Therapy Management** agreement between physician and pharmacist with detailed practice protocols based on CDC PrEP guidelines

**Physician Roles**
- Initial visit (required to be in physician office per Missouri law)
  - Determine PrEP eligibility
  - Prescribe PrEP
  - Refer to pharmacy

**Pharmacist Roles**
- Conduct all follow-up visits
- Refill medications
- Provide counseling
- Complete paperwork
- Dispense medication
- Monitor refills (identify late refills, notify physician)
- Perform rapid HIV testing
- Provide STI treatment

**Nurse Roles**
- Follow-up history
- Draw labs (process with CLIA-waived i-STAT handheld)
- Provide counseling (risk reduction)
- Provide referrals (mental health, substance use, STI testing)

Slide credit: clinicaloptions.com
Pharmacy-Based PrEP Generates Access Points for Uninsured/Underinsured in St Louis

Model allows clinics not previously able to initiate PrEP (eg, staffing, costs) to now initiate PrEP at their clinic and have patients obtain follow-up at pharmacy (visits, labs, other related services)

Slide credit: clinicaloptions.com
HIV Example: Point-of-Care Screening in Retail Pharmacies

- Virginia Department of Health working in collaboration with retail pharmacy (32 locations) in Virginia
- Providing rapid HIV point-of-care testing as walk-in service during all pharmacy hrs
- Performed 3200 tests June 2014 - June 2016
- Subset of sites (~ 10) also providing HCV antibody testing

South Carolina

- CVS Minute Clinic
  - Test
  - Vaccinate
  - Prescribe
  - Treat

- Practice Act:
  - Practice & Technology Committee
Pharmacist for HIV Pre-exposure Prophylaxis

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Any questions?