Bringing in New Settings and Workforce for PrEP Delivery: PrEP in Pharmacies and Other Models

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Objectives

• Provide an overview of pharmacy-based PrEP service delivery
  • Pharmacists delivering PrEP at an offsite pharmacy

• Identify challenges in implementing pharmacy-based PrEP

This presentation has been adapted from:
USCA Presentation 9.2017
CDC PrEP in Pharmacies Webinar 6.2017
Implementing care for the next generation of products
Introduction to PrEP Care

• Minimum PrEP care requirements:
  – Intake visit and testing
  – Prescription by prescribing provider (optimize task shifting here)
  – Follow-up visits and testing (optimize task shifting and settings here)

(Centers for Disease Control and Prevention [CDC] guidelines every 3 months)

• PrEP prescription filled at a pharmacy paid for by:
  – Public insurance (Medicaid/Medicare)
  – Commercial insurance
  – Manufacturer drug assistance and foundation programs

Pharmacies in the USA

- There are 67,753 estimated pharmacies in the USA in 2015 (Qato et al. PLOS One 2017)
  - Community pharmacies increased by 6.3% from 63,752 (2007) to 67,753 (2015)
  - Retail chain 40%
  - Independent pharmacies 35%
  - Food store 10%
  - Clinic-based 3%
  - Government <1
  - Mass retailer 12%
- Majority of pharmacy types allow for services access to individuals (except mass retailer)
- MISSED OPPORTUNITY to reach individuals and deliver services
Pharmacies and pharmacists’ roles in the PrEP health care system

Coordinated inter-organizational collaboration to address the PrEP Continuum of Care
In Missouri, this model has allowed clinics that cannot initiate PrEP services currently (e.g. staffing, costs, etc.) to initiate PrEP at their clinic and then allow patient to follow up at the pharmacy for office visits, labs, and other related services.
Traditional vs. Clinical Pharmacist Provider in Pharmacies

• **Traditional:** Provider is nurse practitioner (NP) or physician assistant (PA)
  – Performs initial medical consultation and follow up in the pharmacy
  – Requires a collaborative agreement between NP/PA and MD
  – Seen in retail pharmacies
  – Chronic care (Diabetes, Hypertension), HIV treatment, PEP, Vaccination
  – PrEP services in retail pharmacies

• **Clinical Pharmacist:** Provider is a clinical pharmacist
  – Responsible for initial (Washington State) and follow up medical consultations depending upon state laws
  – Requires a collaborative agreement between pharmacist and MD
  – Chronic care (Diabetes, Hypertension), HIV treatment, PEP, Vaccination
  – PrEP services in both retail and independent pharmacies

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Advantages of a Pharmacy Care Setting and for Pharmacists as Providers

- Potentially less stigmatizing than other locations
- Convenience with extended hours (weekend/evenings)
- Convenience as one-stop shop (food, meds, other)
- Convenience as location (in the neighborhood)
- Insurance billing and/or flat rate fee for service that meets the willingness to pay for PrEP seekers (Tung et al. CROI 2017)
- Pharmacists’ existing knowledge regarding 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 (Seattle; Tung et al. CROI 2017)
- Existing models support high patient retention (Seattle; Tung et al. CROI 2017)

The Required/Recommended Tools for the Pharmacy-Based Model of PrEP with a Clinical Pharmacist Provider

1. Legal authority for a pharmacist to implement PrEP services
   – Designating a medical doctor
   – Collaborative Practice Agreement
   – Practice protocol

2. 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

3. Adequate physical space – privacy, counseling, lab testing and processing

4. Medical Test Site Certificate for laboratory testing (recommended)
   – Clinical Laboratory Improvement Amendments (CLIA)-waiver
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”
    • Encompass initiation and continuation of PrEP by a pharmacist based on state regulations
    • PrEP protocols are a type of CPA

• Collaborative Drug Therapy Management (CDTM)
  – “legislation to allow pharmacists to participate in patient drug therapy management through collaborative arrangements with physicians and other health care providers”
    • CDTM is a type of CPA which pertains to drug therapy management

ABC’s of CPAs

• Use a simple medical protocol for follow up PrEP care that is used in the clinic
• May require lawyers from the 2 institutions since it is a contract
• Obtain sample templates and adapt to your setting
Map of CPA Laws by State

• Note heterogeneity of CPA laws in the United States

Figure: Map of States with Laws Authorizing Pharmacist Collaborative Practice Agreements, 2012

Washington University in St. Louis – Gateway Apothecary Collaboration for PrEP Delivery in St. Louis, Missouri

Other pharmacy-based PrEP models:
- One-Step PrEP® at Kelley-Ross Pharmacy in Seattle, WA (Elyse Tung, PharmD)
- Scales Pharmacy in Denver, CO (Dan Scales, PharmD)
- Roseman University of Health Sciences in Las Vegas, NV (Christina Madison, PharmD)
- University of New Mexico Truman Health Sciences in Albuquerque, NM (Keenan Ryan, PharmD)
• Gateway Apothecary is an independent specialty pharmacy with HIV certified staff
• Patient-focused, adherence-driven pharmacy model
• LOCATION: near a metro and bus stop
• SERVICES:
  • PrEP Clinic (Same Day PrEP)
  • Free Home Delivery
  • Medication Therapy Management
  • Specialty Pharmacy Services
  • Extended hours: evenings and weekends
  • Injection Services
  • Onsite free rapid HIV and Hep C testing
  • Extended Clinical Services
  • Strip Packaging – Blister Packaging
  • Reminder Calls – Refill Medications
  • Interpreter Services
  • Personalized Service
  • Patient Assistance Programs
  • Home Visits
  • Community Education Sessions

Choose elements of a pharmacy that can promote ease of care and access

www.rx-gateway.com
4473 Forest Park Avenue
St. Louis, MO 63108
Phone: 314-381-1818
Fax: 314-667-3202
Gateway Apothecary PrEP Services

- Program created in December 2016
- Protocol and CDTM (between medical doctor and pharmacist) are based on the CDC PrEP Clinical Guidelines (2014)

- **Physician role:**
  - Initial visit, determine PrEP eligibility, prescribe, and referral to pharmacy
  - Initial visit must occur in the physician office for CPA in Missouri

- **Pharmacist role:**
  - Conduct all follow-up visits, refill medications, counseling
  - Perform paperwork, dispense PrEP, monitor refills (can identify clients who do not refill on time), notify physicians, perform HIV rapid testing, and STI treatment

- **Nurse role (unique to Gateway Apothecary):**
  - Follow-up history, draws labs and uses i-STAT handheld machine (CLIA-waived) to process results, and offers counseling (risk reduction) and referrals (mental health, substance use, STI testing)
Gateway Apothecary PrEP Services

Private room to provide PrEP care

Point-of-care (POC) creatinine (Cr) test device to assess kidney function
Gateway Apothecary
PrEP Follow-up Form

- PrEP follow-up form aids in the efficiency of clinic flow
- Scanned into patient’s chart at the doctor’s office.
- Main components:
  - STI symptoms
  - PrEP adherence and side effects
  - Drug use history
  - Sexual history
  - Mental health assessment
Patient arrives in waiting room → Check-in at front desk → Patient sees PrEP counselor and gets rapid HIV test → HIV test result → Negative → See prescriber for PrEP

While waiting for result, perform HIV risk assessment and counseling on risk reduction

Obtain Creatinine, Hep B surface antigen, & pregnancy test per CDC guidelines

Obtain Hep C and STD testing (RPR, gonorrhea, chlamydia)

Same day PrEP: prescribe PrEP for 30-90 days while waiting for lab results

Follow-up appointment at 1 month. Obtain HIV, STD (RPR, gonorrhea, chlamydia), & pregnancy tests. Perform medication adherence and risk reduction counseling.

Follow-up appointment at 3 months. Obtain HIV, Creatinine, STD (RPR, gonorrhea, chlamydia), & pregnancy tests. Perform medication adherence and risk reduction counseling.

Follow-up appointment at 6 months. Obtain Creatinine, HIV, STD (RPR, gonorrhea, chlamydia), & pregnancy tests. Perform medication adherence and risk reduction counseling.

Follow-up appointment at 9 months. Obtain HIV, STD (RPR, gonorrhea, chlamydia), & pregnancy tests. Perform medication adherence and risk reduction counseling.

Follow-up appointment at 12 months. Obtain Creatinine, HIV, STD (RPR, gonorrhea, chlamydia), & pregnancy tests. Perform medication adherence and risk reduction counseling.
# PrEP in Gateway Apothecary

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Details</th>
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<tbody>
<tr>
<td>Patient number</td>
<td>&gt; 70</td>
</tr>
<tr>
<td>Start date</td>
<td>December 2016</td>
</tr>
<tr>
<td>Onsite service fees</td>
<td>None</td>
</tr>
<tr>
<td>Billing to insurance</td>
<td>Prescriptions; billing for services not performed by pharmacists is not allowed in Missouri</td>
</tr>
<tr>
<td>Pharmacy type</td>
<td>Independent, community</td>
</tr>
<tr>
<td>HIV specialty</td>
<td>Yes</td>
</tr>
<tr>
<td>Target patients</td>
<td>Uninsured/underinsured</td>
</tr>
<tr>
<td>Intake visit requirement</td>
<td>At the collaborating WashU clinic</td>
</tr>
<tr>
<td>Lab testing onsite (Lab source)</td>
<td>Rapid HIV, Rapid Hep C, pregnancy (State Health Dept); POC Cr and other (Abbott i-STAT),</td>
</tr>
<tr>
<td>Main PrEP staff</td>
<td>PharmD (5) [AAHIVP 2], RN (1), Social Worker (1), Pharmacy Techs (8)</td>
</tr>
<tr>
<td>CPA collaborators/settings</td>
<td>Academic clinic, public STI clinic, private providers</td>
</tr>
<tr>
<td>Referrals</td>
<td>Mental health, STIs, substance use, social services</td>
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</table>
PrEP with Comprehensive Services

• **At the pharmacy, services that are offered are:**
  – Condom distribution
  – Mental health and substance abuse referral (private, talk therapy, support groups)
  – STI testing at county health department and community-based organizations
  – Social service referrals (e.g. CAASTLC for workplace and home support)
  – Onsite social worker support
  – Onsite risk reduction counseling
  – Preventive services (e.g. vaccines)
  – Primary care referrals
  – Onsite insurance health literacy and navigation
  – PrEP navigators and linkage to care specialists (in collaboration with CBOs)
  – Events
  – **Same-day PrEP re-starts and assistance with same-day PrEP prescribing & medication dispensation on the initial visit**
  – PrEP Education and HIV testing at CBO events
Key Lessons Learned from Missouri

• Pharmacy-based PrEP care can provide services for the uninsured and underinsured in many instances, in addition to the insured
  – Helps with individual insurance coverage interruptions

• Onsite HIV (and other) testing and protocols that take into account starting-stopping-restarting is important to address insurance interruptions for PrEP users

• Given state regulations, the protocol for care must have a smooth transition from clinic intake to pharmacy follow-up to minimize loss to follow up

• Intake forms and social work services from the clinical care site (with whom the pharmacy is collaborating with) is important for promoting comprehensive PrEP care

• HIV testing onsite in the pharmacy has promoted same-day prescribing, minimized missed refills and medication interruptions during PrEP care, and reduces the potential to restart PrEP in HIV-infected individuals
  – Requires communication with prescribing doctor as well
Key Lessons Learned from Missouri

• Replicating the model beyond St. Louis for PrEP in non-retail pharmacies (Cape G and Springfield):
  – **Practical issues with obtaining labs (and related staffing)**
  – **Buy in from administration**
  – Comfort to change the scope of work
  – **Enough revenue to meet overhead costs** in the context of lower volume of PrEP users compared to programs in large urban areas

• More discussions generated about onsite HIV testing and PrEP, in general, and can change what the standard of services offered in a pharmacy in the future

• Highlights the discussion of HIV testing which is beneficial by itself but substantially benefits **PrEP follow up care and monitoring** for the community and affiliated clinics
  – Can help detect HIV infection in those who miss refills
  – Can identify insurance changes during refill dispensation and refer to navigators
Key Lessons Learned from Missouri

• **Maximizing lab testing with staff phlebotomy certification and onsite testing promotes one-stop services**

• Pharmacy staff may need extensive *training on sexual health* and creating a physical and emotional inclusive environment
  – Other training includes: mental health, substance use, social work referrals
  – Training every 6 months provided

• **Having a private space** is important for consultation
  – Not having a bathroom limits STI testing

• Marketing pharmacy-based PrEP services among certain communities may motivate consultations compared to traditional clinic settings *(perceived reduced stigma)* (Patel RR et al. IAPAC 2018)
<table>
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<tr>
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<th>Location</th>
<th>Pharmacy/Pharmacist Services</th>
<th>Additional Information</th>
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<tbody>
<tr>
<td>Virginia DoH in collaboration with Walgreens Pharmacy (32 locations) (Elaine Abrahms)</td>
<td>West Virginia</td>
<td>HIV POC rapid testing Walk-in services during all pharmacy hours</td>
<td>Performed 3200 tests June 2014-June 2016 Reported 0.8% positivity rate</td>
</tr>
<tr>
<td>Kelly-Ross Pharmacy “One-Step PrEP” (Elyse Tung, PharmD)</td>
<td>Seattle, Washington</td>
<td>PrEP assessment and initiation Pharmacist run HIV PrEP clinic: assess PrEP eligibility, order and perform lab tests, prescribe and dispense medication, billing and assistance, routine follow-up care, STI testing and treatment</td>
<td>Began March 2015 In first 3 years, 714 patients evaluated; 97% started PrEP Collaborative practice agreement with physician medical director</td>
</tr>
<tr>
<td>Scales Pharmacy (Dan Scales, PharmD)</td>
<td>Denver, Colorado</td>
<td>PrEP follow-up (not initiation) – counseling, prescribing, and dispensing Draws labs STI testing and treatment</td>
<td>Began December 2015 Pharmacist trained in phlebotomy Collaborative practice agreement with medical director</td>
</tr>
<tr>
<td>UNMH Outpatient Pharmacy (Keenan Ryan, PharmD)</td>
<td>Albuquerque, New Mexico</td>
<td>PrEP initiation and monitoring</td>
<td>EMR retrospective review 7/2015-7/2017 136 attended first PrEP appointment 127 patients started PrEP Patients average &lt; 1 missed dose per mo</td>
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## Examples of PrEP Services in Community Pharmacies

<table>
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<tbody>
<tr>
<td>Roseman University of Health Sciences (Christina Madison, PharmD)</td>
<td>Las Vegas, Nevada</td>
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The CBA Provider Network includes four major components:

1. **National Training:** A standardized national training program will increase the knowledge, skills, and competencies of HIV prevention staff. Based on feedback from HIV prevention providers, web-based and classroom-based training will now be provided separately, though the eLearning and Classroom training providers will also collaborate to deliver trainings that blend online and classroom learning.

   - **Track A:** Electronic Learning (eLearning) Training Center
     - **Funded organizations:** ETR Associates, Inc. and HealthHIV

   - **Track B:** Classroom Learning Training Center
     - **Funded organization:** Cicatelli Associates, Inc.

2. **Regional Technical Assistance:** To provide more personalized support and facilitate long-term working relationships, technical assistance will now be tailored and delivered to meet capacity building needs within four geographic regions: Northeast, South, Midwest, and West. These providers will work together to develop and implement jurisdictional CBA plans for CDC-funded health departments and CBOs in each region. Each region will have a team of three technical assistance providers – one for each of the following three tracks:

   ![Regional Technical Assistance Table]

   - **Track A:** Clinical HIV Testing and Prevention for Persons with HIV
     - **Northeast:** Primary Care Development Corporation
     - **South:** My Brother’s Keeper
     - **Midwest:** San Francisco Community Health Center (formerly Asian and Pacific Islander Wellness Center)
     - **West:** Denver Health and Hospital Authority (Denver Prevention Training Center)

   - **Track B:** Nonclinical HIV Testing and Prevention for HIV Negative People
     - **Northeast:** University of Rochester
     - **South:** Latino Commission on AIDS
     - **Midwest:** Washington University
     - **West:** City & County of San Francisco Department of Public Health

   - **Track C:** Integrated HIV Activities and Structural Interventions
     - **Northeast:** New York City Department of Health & Mental Hygiene
     - **South:** National Alliance of State & Territorial AIDS Directors
     - **Midwest:** AIDS United
     - **West:** Public Health Foundation Enterprises, Inc. (California Prevention Training Center)

3. **Continuous Quality Improvement and Sustainability for CBOs:** This new distance-learning program, developed in response to input from CBOs, will help senior and mid-level program managers at CDC-funded CBOs improve the quality of their programs and the sustainability of their organizations. The program will include expert instruction, mentoring, and resource sharing as well as peer-to-peer learning and support opportunities.

   - **Funded organization:** Asian and Pacific Islander American Health Forum

4. **Marketing and Administrative Support for CBA Provider Network:** This provider will focus on marketing to increase awareness and utilization of the CBA program and administrative support to facilitate coordination, communication, and collaboration across the CBA Provider Network.

   - **Funded organization:** University of Missouri - Kansas City

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**Contact**

- CDC Capacity Building Provider’s role in pharmacy-based PrEP training
- Washington University in St. Louis PrEP Program
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  - 314-454-8293

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For more information, please visit: [www.cdc.gov/hiv/funding/announcements/ps19-1904/index.html](http://www.cdc.gov/hiv/funding/announcements/ps19-1904/index.html)
Summary

• Pharmacies and pharmacists are under-utilized for PrEP care
• This setting offers another access point to reach those who would benefit from services
• There are advantages and limitations to this service model to keep in mind
• Requires review of state laws and CPA
• Obtain sample agreements and speak to peer pharmacy networks in your region for practical implementation
• This model helps promote implementation of today’s and tomorrow’s PrEP products to help reduce HIV incidence
Acknowledgements

- Gateway Apothecary Pharmacy Leadership and Staff
- Washington University in St. Louis PrEP Program Staff
- Washington University in St. Louis ID Clinic Staff
- PrEP Users and the Community in Missouri
- NASTAD Staff