



Pharmacist for HIV Pre-exposure Prophylaxis

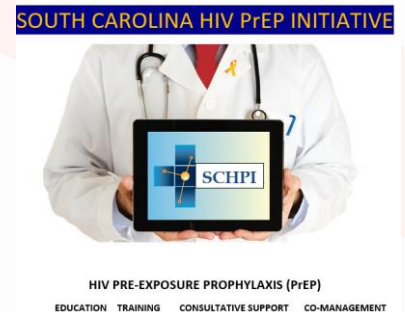
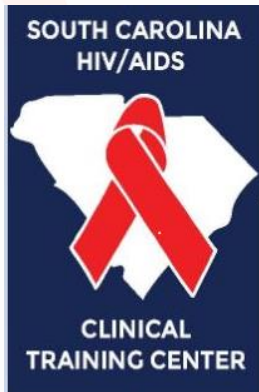
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Pronouns: he, him, his

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Prevention

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

Treatment as Prevention

Transmission Category	Risk
Sex (oral, anal, or vaginal)	Effectively no risk
Pregnancy, labor and delivery	1% or less
Sharing syringes	Unknown
Breastfeeding	Substantially reduces, but not eliminate risk

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 infections¹

1. Jenness JID 2016

2. McCormack S, et al. CROI 2015. Abstract 22LB (PROUD- NNT = 13)

3. Molina JM, et al. CROI 2015. Abstract 23LB. (IPERGAY – on demand – NNT 18)

4 Mascolini 2017- <http://www.thebodypro.com/content/79228/prep-coverage-of-40-would-prevent-one-third-of-hiv.html>

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 ($eCrCl_{CG} \geq 60$ mL/min)
 - No documented contraindications to FTC/TDF

CDC. PrEP Guidelines. 2017.



Slide credit: clinicaloptions.com

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

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

CDC. PrEP Guidelines. 2017.



*Based on provider discretion, can be done more frequently. Slide credit: clinicaloptions.com

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

1. Eaton LA. AIDS Behav. 2017;21:1236. 2. Dubov A. Am J Mens Health. 2018;12:1843.
3. Calabrese SK. JAIDS. 2018;79:46. 4. Tekeste M. AIDS Behav. 2018;[Epub].



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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

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

Mayer KE. IAS 2017. Abstr MOPEC0648.



Slide credit: clinicaloptions.com

Role of the Pharmacist: Patient Advocacy

PrEP barriers: 40.2% concerned about cost

- Patient Advocate Foundation
 - <https://www.patientadvocate.org/connect-with-services/copay-relief/>
- Gilead Medication Assistance Program
 - <http://www.gilead.com/responsibility/us->

State PrEP Assistance Programs

State	Drug Assistance		Clinical Visits & Lab Test Assistance	Patient Income Limit
	Copay Assistance	Medication Assistance		
California	Yes	Yes	Any participating provider	Up to 500%
Colorado	Yes	Yes	Any participating provider	Below 500%
District of Columbia	Yes	No	Health dept clinics	Up to 500%
Florida	No	Yes	Health dept clinics	None
Illinois	Yes	No	Select Grantees	None
Massachusetts	Yes	No	Select Grantees	Up to 500%
New York State	No	No	Any participating provider	Up to 435%
Ohio	Yes	Yes	Any participating provider	Below 300%
Virginia	No	Yes	Health depts/contracted providers	None
Washington State	Yes	Yes	Any participating provider	None

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!

Mayer KE. IAS 2017. Abstr MOPEC0648. CDC. PrEP Guidelines. 2017.

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

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



Slide credit: clinicaloptions.com

Mayer KE. IAS 2017. Abstr MOPEC0648.

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



Slide credit: clinicaloptions.com

Pate. IAPAC 2018. Tung. CROI 2017. Abstr 961.

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



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Collaborative Agreements

- **Collaborative Practice Agreement (CPA)**

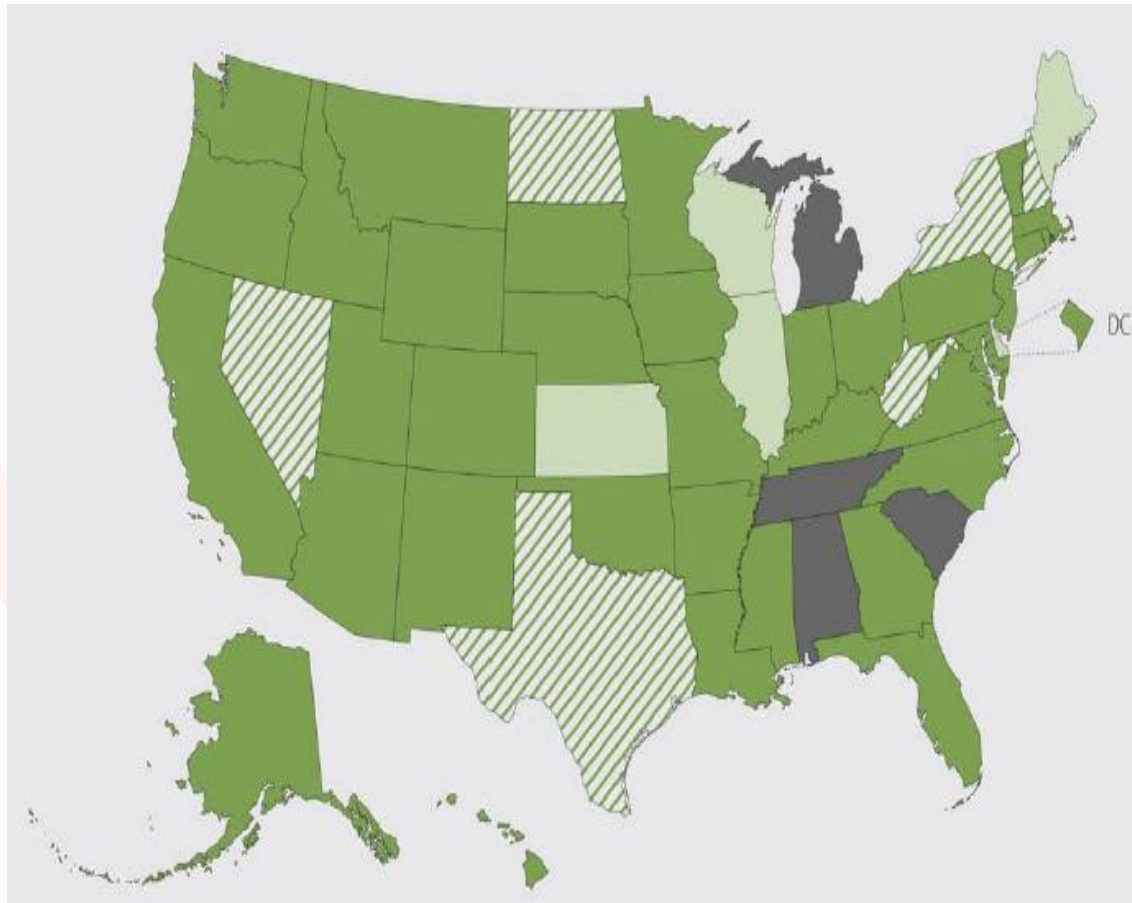
- *“Between one or more physicians and pharmacists wherein qualified pharmacists working within the context of a defined protocol are permitted to assume professional responsibility for performing patient assessments; ordering drug therapy-related laboratory tests; administering drugs; and selecting, 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

https://www.cdc.gov/dhdsp/pubs/docs/pharmacist_state_law.pdf



Slide credit: clinicaloptions.com

Examples of PrEP Services in Community/Outpatient Pharmacies

Pharmacy	Location	Pharmacy/Pharmacist Services
Gateway Apothecary Pharmacy/ Washington University Clinic ^[1]	St Louis, Missouri	PrEP follow-up care by appt only: medication refills, counseling, HIV rapid testing, STI treatment Collaborative Practice Agreement
Kelly-Ross Pharmacy “One-Step PrEP” ^[2]	Seattle, Washington	Pharmacist-run HIV PrEP clinic: assess PrEP eligibility, order and perform lab tests (pharmacist trained in phlebotomy), prescribe and dispense PrEP medication, billing and assistance, routine follow-up care, STI testing and treatment Collaborative practice agreement
Scales Pharmacy ^[3]	Denver, Colorado	PrEP follow-up care: counseling, prescribing, dispensing, blood draws for lab testing (pharmacist trained in phlebotomy), STI testing and treatment Collaborative practice agreement
University of New Mexico Hospitals Outpatient Pharmacy ^[4]	Albuquerque, New Mexico	PrEP initiation and monitoring

1. <https://infectiousdiseases.wustl.edu/patient-care/prep/>. 2. Tung. Sex Health. 2018;15:556.
3. <https://www.scalespharmacy.com/services/>. 4. Ryan. IDWeek 2018. Abstr 1293.



Slide credit: clinicaloptions.com

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

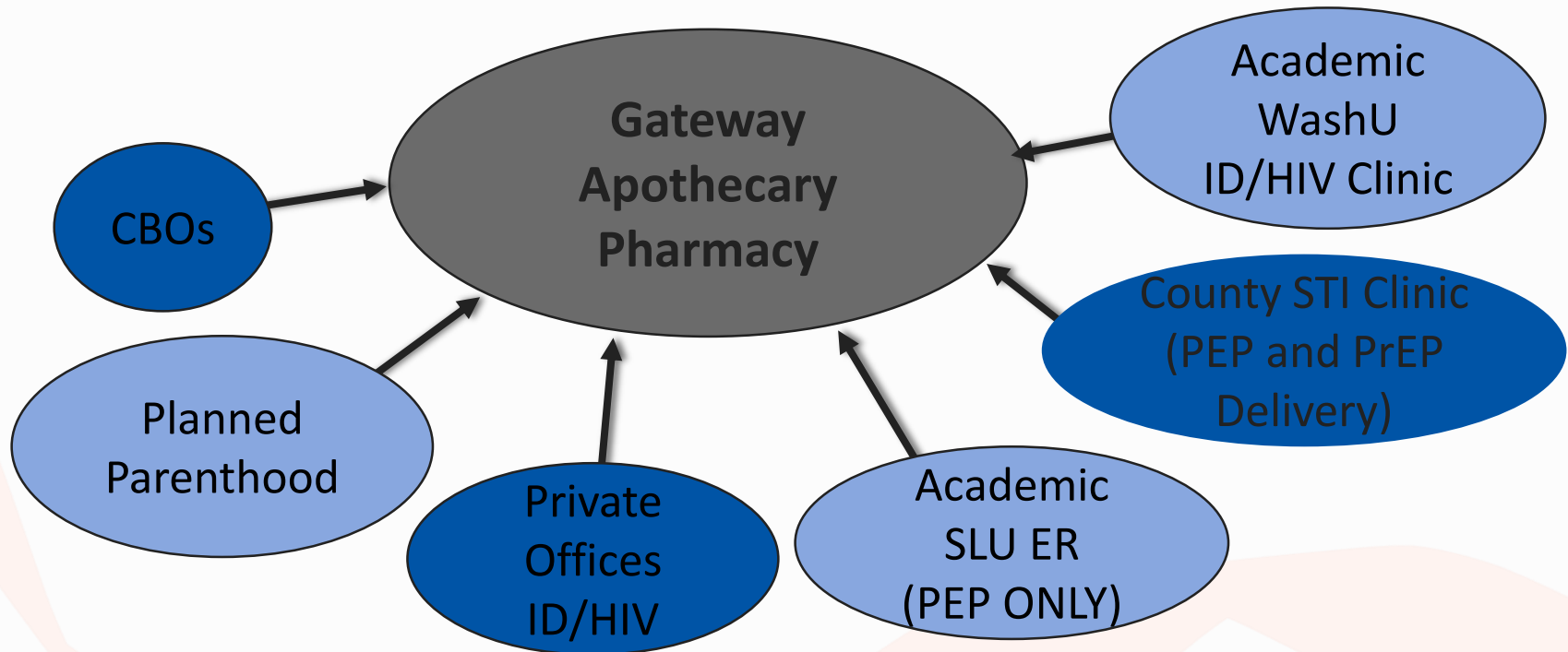
- Follow-up history
- Draw labs (process with CLIA-waived i-STAT handheld)
- Provide counseling (risk reduction)
- Provide referrals (mental health, substance use, STI testing)



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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)



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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

<http://www.vdh.virginia.gov/disease-prevention/walgreens-test-sites/>

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South Carolina

- CVS Minute Clinic
 - Test
 - Vaccinate
 - Prescribe
 - Treat
- Practice Act:
 - Practice & Technology Committee



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Any questions?

