

A PROGRAM OF THE FENWAY INSTITUTE



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



Rupa R. Patel, MD MPH Founder & Director, PrEP Program Washington University in St. Louis



Our Roots

Fenway Health

- Independent 501(c)(3) FQHC
- Founded 1971
- Mission: To enhance the wellbeing of the LGBTQIA+ community as well as people in our neighborhoods and beyond through access to the highest quality health care, education, research, and advocacy
- Integrated primary care model, including HIV and transgender health services

The Fenway Institute

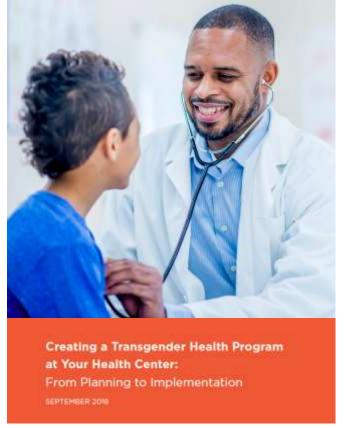
Research, Education, Policy



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The National LGBT Health Education Center offers educational programs, resources, and consultation to health care organizations with the goal of providing affirmative, high quality, cost-effective health care for lesbian, gay, bisexual, transgender, queer, intersex and asexual (LGBTQIA+) people.

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Other Health Professionals	Confirm equivalency of credits with relevant licensing body.

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Today's Faculty

Rupa Patel, MD

Founder and Director of the PrEP Program at Washington University in St. Louis's School of Medicine

Disclosure

Neither presenter has financial conflicts of interest.

Objectives

- Understand pharmacy-based PrEP service delivery
- Identify challenges in implementing pharmacy-based PrEP

Implementing care for the next generation of products







ESTIMATED NUMBER OF ADULTS WHO COULD POTENTIALLY BENEFIT FROM PREP, UNITED STATES, 2015

	Gay, bisexual, or other men who have sex with men	Heterosexually active adults	Persons who inject drugs	Total by race/ethnicity
Black/African American, non-Hispanic	309,190	164,660	26,490	500,340
Hispanic/Latino	220,760	46,580	14,920	282,260
White, non-Hispanic	238,670	36,540	28,020	303,230
Total who could potentially benefit from PrEP	813,970	258,080	72,510	1,144,550

Notes: PrEP=pre-exposure prophylaxis; data for "other race/ethnicity" are not shown









HIV prevention pill is not reaching most who could potentially benefit – especially African Americans and Latinos



of people who could potentially benefit from PrEP are African American – approximately 500,000 people...

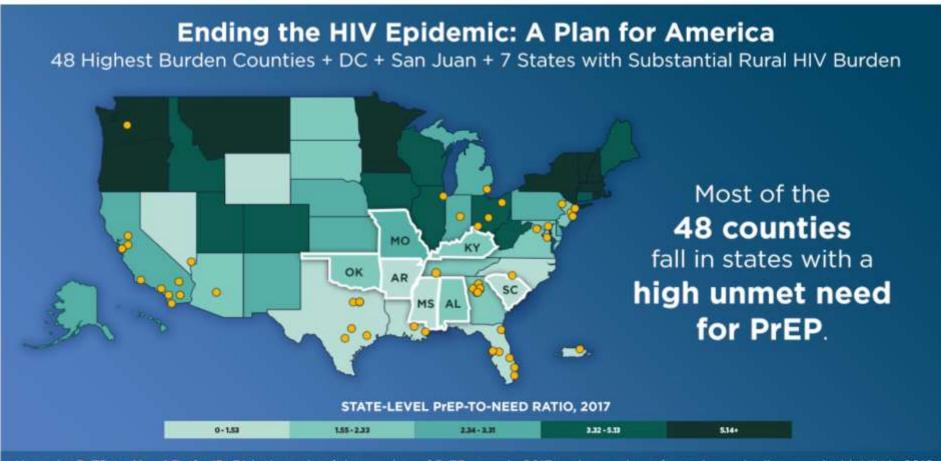




of people who could potentially benefit from PrEP are Latino – nearly 300,000 people...



*Prescription data in this analysis limited to those filled at retail pharmacies or mail order services from September 2015 – August 2016; racial and ethnic information not available for one-third of the prescription data



Here, the **PrEP-to-Need Ratio (PnR)** is the ratio of the number of PrEP users in 2017 to the number of people newly diagnosed with HIV in 2016. States in the bottom two quintiles were considered to have high unmet need for PrEP.

AIDSVu.ORG

SOURCE: U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION







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

Preexposure prophylaxis for the prevention of HIV infection – 2014: A clinical practice guideline. Available at: https://stacks.cdc.gov/view/cdc/23109

Centers for Disease Control and Prevention. Pharmacy-Based Preexposure Prophylaxis for the Prevention of HIV: Innovative Service Delivery Models. Webinar presented on June 22, 2017.





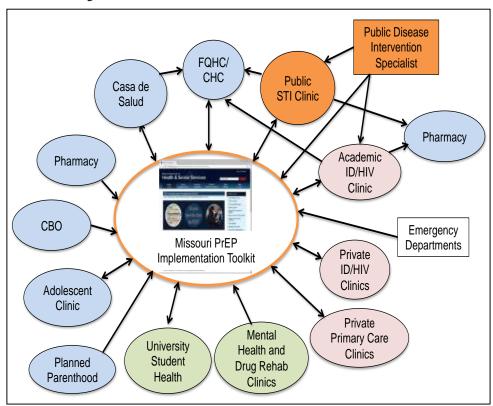
Pharmacies in the USA

- 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

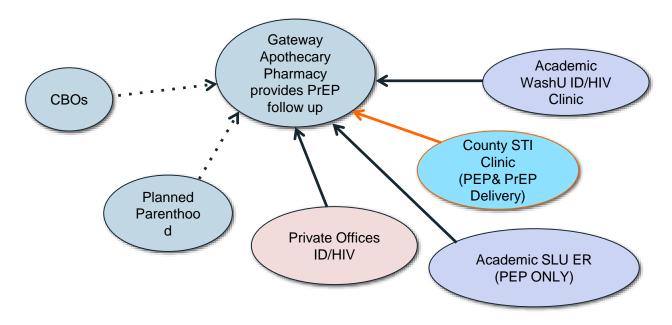


Coordinated inter-organizational collaboration to address the PrEP Continuum of Care





Pharmacy-Based PrEP Generates Access Points for Uninsured/Underinsured in St. Louis



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 PrEP users to follow up at the pharmacy for office visits, labs, and other related services.





<u>Traditional</u> vs. <u>Clinical Pharmacist</u> 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

Centers for Disease Control and Prevention. Pharmacy-Based Preexposure Prophylaxis for the Prevention of HIV: Innovative Service Delivery Models. Webinar presented on June 22, 2017.





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 PrEP user retention (Seattle; Tung et al. CROI 2017)

Patel RR et al. Reduced stigma in pharmacies for PrEP services among Black MSM. IAPAC oral presentation. Miami, Florida. June 2018.

Tung E, Thomas A, Eichner, A, et al. Feasibility of a pharmacist-run HIV PrEP clinic in a community pharmacy setting [961]. Oral presentation at: the Conference on Retroviruses and Opportunistic Infections; 2017; Seattle, Washington.





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

Centers for Disease Control and Prevention. State Law Fact Sheet: Select Features of State Pharmacist Collaborative Practice Laws. 2012. Available at: https://www.cdc.gov/dhdsp/pubs/docs/pharmacist_state_law.pdf





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

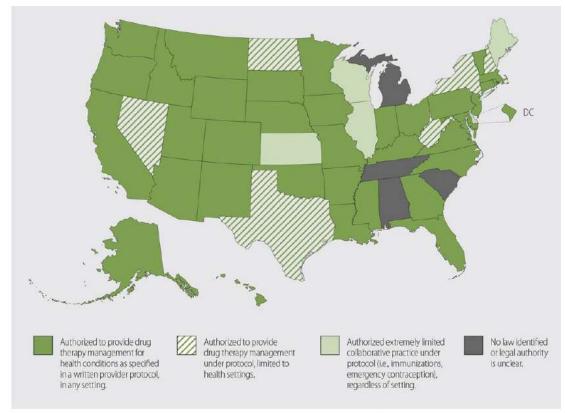


Figure: Map of States with Laws Authorizing Pharmacist Collaborative Practice Agreements, 2012

Centers for Disease Control and Prevention. State Law Fact Sheet: Select Features of State Pharmacist Collaborative Practice Laws. 2012. Available at: https://www.cdc.gov/dhdsp/pubs/docs/pharmacist_state_law.pdf





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)

Centers for Disease Control and Prevention. Pharmacy-Based Preexposure Prophylaxis for the Prevention of HIV: Innovative Service Delivery Models. Webinar presented on June 22, 2017.

- Gateway Apothecary is an independent (non-retail) community pharmacy
- LOCATION: near a metro and bus stop
- SERVICES:
- PrEP Clinic (Same Day PrEP)
- Free Home Delivery
- Medication Therapy Management
- Specialty Pharmacy Services (AAHIVP certified staff)
- Extended hours: evenings and weekends
- Injection Services
- Onsite free rapid HIV and Hepatitis C testing
- Located in a zip code with substantial HIV incidence
- Strip Packaging Blister Packaging
- Reminder Calls Refill Medications
- Interpreter Services
- Medication Patient Assistance Programs
- Home Visits
- Community Education Sessions

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





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





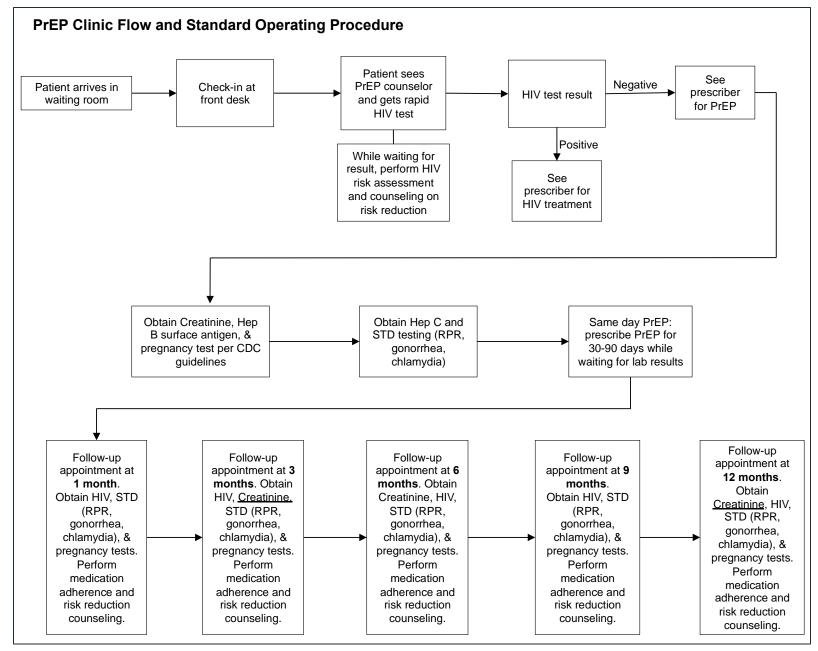
PrEP Follow-up Form

- PrEP follow-up form aids in the efficiency of clinic flow
- Scanned into the PrEP user's chart at the doctor's office
- Main components:
 - STI symptoms
 - PrEP adherence and side effects
 - Drug use history
 - Sexual history
 - Mental health assessment
- Any issues arising are communicated with the doctor and Wash U clinic staff

Date					
10 ACC 10	Patient Name				
PrEP Patient Follow-Up					
Sexually Transmitted Diseases Symptoms					
Do you have any rectal, penile, or vaginal discharge, u	cers, or rashes right now? IYes No				
PrEP Use/Symptoms	Since your last visit, have you experienced:				
How many pills did you miss in the last 7 days?	☐ No symptoms				
How many pills did you miss in the last 50 days?	Stomach pain or discomfort				
	☐ Nausea or vomiting ☐ Headache				
	L) Readache				
Drug Use History					
Since your last visit, have you used the following?					
a. Intravenous drugs? Yes No					
b. cocaine? □Ves □No					
⊏ marijuana? □Yes □No					
f. crystal meth/speed? □Yes □No					
e. poppers (amyl nitrates)? Ves No					
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PrEP in Gateway Apothecary

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





PrEP with Comprehensive Services at the Pharmacy

- 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)
 - Same-day PrEP re-starts and assistance with same-day PrEP prescribing & medication dispension on the initial visit
 - PrEP Education and HIV testing at CBO events





Key Lessons Learned in 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-stoppingrestarting 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 in 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 dispension and refer to navigators





Key Lessons Learned in 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)





Examples of PrEP Services in Community Pharmacies

Pharmacy	Location	Pharmacy/Pharmacist Services	Additional Information
Virginia DoH in collaboration with Walgreens Pharmacy (32 locations) (Elaine Abrahms)	West Virginia	HIV POC rapid testing Walk-in services during all pharmacy hours	Performed 3200 tests June 2014- June 2016 Reported 0.8% positivity rate
Kelly-Ross Pharmacy "One- Step PrEP" (Elyse Tung, PharmD)	Seattle, Washington	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	Began March 2015 In first 3 years, 714 individuals evaluated; 97% started PrEP Collaborative practice agreement with physician medical director
Scales Pharmacy (Dan Scales, PharmD)	Denver, Colorado	PrEP follow-up (not initiation) – counseling, prescribing, and dispensing Draws labs STI testing and treatment	Began December 2015 Pharmacist trained in phlebotomy Collaborative practice agreement with medical director
UNMH Outpatient Pharmacy (Keenan Ryan, PharmD)	Albuquerque, New Mexico	PrEP initiation and monitoring	EMR retrospective review 7/2015- 7/2017 136 attended first PrEP appointment 127 individuals started PrEP PrEP Users average < 1 missed dose per mo





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





Contact

- **CDC Capacity Building** Provider's role in pharmacy-based PrEP training
- Washington University in St. Louis PrEP Program
- sites.wustl.edu/prep/cap acitybuilding.edu
- Rupa R. Patel, MD MPH
- rupapatel@wustl.edu
- 314-454-8293

The CBA Provider Network includes four major components:



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.

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

Regional Technical Assistance: To provide more personalized support and facilitate longterm 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

and HealthHIV

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:

	Funded Organizations			
	Northeast	South	Midwest	West
Track A: Clinical HIV Testing and Prevention for Persons with HIV	Primary Care Development Corporation	My Brother's Keeper	San Francisco Community Health Center (formerly Asian and Pacific Islander Wellness Center)	Denver Health and Hospital Authority (Denver Prevention Training Center)
Track B: Nonclinical HIV Testing and Prevention for HIV Negative People	University of Rochester	Latino Commission on AIDS		City & County of San Francisco Department of Public Health
Track C: Integrated HIV Activities and Structural Interventions	New York City Department of Health & Mental Hygiene	National Alliance of State & Territorial AIDS Directors	AIDS United	Public Health Foundation Enterprises, Inc. (California Prevention Training Center)



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

Asian and Pacific Islander American Health Forum

as peer-to-peer learning and support opportunities.



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.

University of Missouri - Kansas City





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





Ending the HIV Epidemic Resources

Ending the HIV Epidemic: A Plan for America

 https://www.hrsa.gov/ending-hivepidemic

HIV and Health Centers

 https://bphc.hrsa.gov/qualityimprove ment/clinicalquality/hivprimarycare.ht ml

HIV Testing Sites & Care Services Locator

https://locator.hiv.gov/

National LGBT Health Education Center at Fenway Health

https://www.lgbthealtheducation.org/





Integrating HIV Services through Partnerships for Care





Improvement

Questions?



