Policy Advocacy for PrEP Access: Lessons from the Field
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Presenters: Jeremiah Johnson, PrEP4All
Noelle Esquire, Elton John AIDS Foundation

Continuum 2024 • June 9-11, 2024 • Puerto Rico
Overview of Current PrEP Policy Priorities
SIGN ON: An Appeal to the Biden Administration Regarding Mpox Preparedness
About PrEP4All

• Mission: We ignite political action to put lifesaving medication into the hands of everyone who needs it. www.PrEP4All.org

• Jeremiah Johnson (He/Him), MPH, Executive Director. Jeremiah@PrEP4All.org
Some Current PrEP Policy Priorities

- A National PrEP Program for un- and underinsured
- Protecting our existing infrastructure (#SaveHIVFunding)
- *Braidwood v. Becerra*: Protecting PrEP coverage for the insured
- Improving coverage compliance among insurers
- Expanding access points through pharmacist-provided PrEP
PrEP use varies widely by region.

In 2022, there were only 11 PrEP users for every new new HIV diagnosis in the South, compared to 22 PrEP users for every new HIV diagnosis in the Northeast.

PrEP-to-Need Ratio (PNR) is the ratio of the number of PrEP users in 2022 to the number of people newly diagnosed with HIV in 2020. It is a measurement for whether PrEP use appropriately reflects the need for HIV prevention. A lower PNR indicates more unmet need.

Data not available.

PrEP Users | PnR
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West | 109,175 | 17.32
Midwest | 66,328 | 16.11
Northeast | 94,610 | 22.2
South | 165,115 | 10.54

Number of Persons Using PrEP, 2022

0 | 5 - 6 | 7 - 8 | 9 - 11 | 12 - 14 | 15 - 19 | 20 - 28 | 29 - 44 | 45 - 83 | 84 - 238 | 239+

SOURCE: AIDSVu
Jurisdictions with lowest PrEP uptake in the U.S. (AIDSVu 2022)

i. South Dakota – 41 in 100k
ii. Wyoming – 47 in 100k
iii. West Virginia – 61 in 100k
iv. Mississippi – 67 in 100k
v. Wisconsin- 67 in 100k

vi. Kentucky – 78 in 100k
vii. Alabama – 80 in 100k
viii. Michigan – 85 in 100k
ix. South Carolina – 86 in 100k
x. Maine – 89 in 100k
Increasing Urgency to Address Inequitable PrEP Uptake

A Cost Saving Intervention

• PrEP can be prescribed for as little as $26/month/per person averting an HIV infection with a lifetime cost of at least $500,000 per person

• In our 2022 proposal, we estimate that six thousand monthly prescriptions would cost less than $500,000.

• At 35,000 new infections per year, we add approx $17.5B in healthcare costs annually

• A recent analysis out of Mass General Hospital looking at costs of PrEP for young MSM found that “generic oral PrEP and every-3-month screening would be cost-saving compared with annual screening alone, even with high discontinuation and low adherence, over a range of HIV incidences.”

PrEP Prescribing in the United States

**186,367 persons were prescribed PrEP (Sept 2022):**

Generic FTC/TDF: 93,808 (50.3%)

*Of 186,367 PrEP users, 50% generic TDF/FTC and 0.5% CAB (Sept 2022, Source: IQVIA)*

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Table. Characteristics of persons prescribed long-acting cabotegravir, United States, January 2013 through September 2022

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<tr>
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<th>Oral PrEP</th>
<th>Injectable PrEP</th>
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<td>65+</td>
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A National PrEP Program: What are we asking for?

PrEP Pass

- Build simplified federal reimbursement mechanisms that leverage existing pharmacy supply and payment mechanisms and laboratory networks.
- The system needs to cover labs, medications, and provider visits related to PrEP.
- Help to save time for providers, pharmacies, and patients in navigating reimbursement for un- and under-insured individuals

Provider Network Expansion

- Need for additional prescribing sites: pharmacies, STD clinics, etc.
- Grant program that could establish “hub & spokes administrators”
- An expanded nonclinical network can leverage telePrEP in a way that allows immediate virtual access to a prescribing provider as well as act as a traditional referral system for patients who prefer in person clinical visits.

Demand Creation

- A need for several novel approaches to awareness and demand creation. Pharmacies can do a lot here.
- For community-led messaging, contract with an experienced PR/marketing firm that specializes in deep partnership with communities most in need of PrEP
- National and locally-tailored campaigns
Progress Towards National Access

- July 2018- PrEP4All releases white paper
- Dec 2021- JHU releases policy proposal
- Mar 2022- Biden FY23 Budget Request released (includes $9.8B mandatory spending “PrEP for All” program)
- June 2022- NPP Working Group sends letter for $400M discretionary ask
- Sept 2022- PrEP in Black America summit
- Dec 2022- $25M increase for CDC/DHP Ending the HIV Epidemic funding secured + report language
- Feb 2023- PIBA releases the Roadmap
- Feb 2023- follow up call with CDC, and letter on additional specificity sent

- Mar 2023- FY24 Budget Request released
- May 2023- WH surprises us with a hard push for a revised "NP3" proposal, first publicly presented at PIBA Summit N.O.
- June 2023- We receive slides and a handout on revised proposal; work with coalition to coordinate discretionary request
- July 2023- Major FY24 HIV cuts proposed in the House, Senate reverses and mentions NPP
- Sept 2023- PrEP4All, AVAC, HIVMA, and PrEP In Black America meet with Neera Tanden at White House
Recent Work with the Biden Administration

- September meeting with Neera Tanden
  - Emphasis on existing resources
- November meeting with OMB
  - Inclusion of $9.8B, 10-year NPP in FY25
- December meeting with Dr. Cohen
- February and April meetings with CDC
  - Commitment to an NPP pilot in two jurisdictions
  - Data transparency
  - Additional meetings to be had, incl with other HHS agencies
    - What to do about Ready, Set, PrEP?
Sign on to our FY25 Funding Request Letter [For Organizations]

- Calling for $100M in FY25 discretionary funding to continue to develop a National PrEP Program

[Link to sign on](bit.ly/npp-orgs2024)
#SaveHIVFunding Campaign

- PrEP4All initiated campaign, close coordination with AVAC, HIVMA, and PrEP in Black America
- Funding from Elton John AIDS Foundation
- Expanded by Federal AIDS Policy Partnership, further funding from BC/EFA
- Sept Press Conference
- World AIDS Day Ad Buys/Campaign
- February/March Ad Buys

Visit: bit.ly/savehivfundingnow
Basic Facts (From Lambda Legal)

- The plaintiffs are Braidwood Management, a for-profit closely held organization, owned by a trust, with Dr. Hotze, a religious Christian, as the sole trustee and beneficiary.
  - Braidwood is self-insured and provides health insurance to its 70 employees.
- The other plaintiff is Kelley Orthodontics, a Christian professional association owned by plaintiff John Kelley
- 6 private individuals who purchase insurance – some with religious objections, some who don’t have religious objections
- The plaintiffs claim that requiring them to purchase insurance covers preventative health services violates various rights.
- The US Dept of Health and Human Services and Health Secretary are the defendants.
• ACA § 2713 requires full coverage of preventive services recommended by USPSTF, ACIP, and HRSA.

• Plaintiffs challenged mandate to cover all services.

• District Court held:

  1) Requirement to cover services recommended by USPSTF on or after March 23, 2010, violates the Appointments Clause

Both sides appealed to the Fifth Circuit.

- Defendants want to reverse the lower court’s two main rulings—but the Plaintiffs want a decision that does more damage to the ACA.

- Bottom line: appeal could impact coverage of USPSTF, ACIP, and HRSA recommended services.

- Next steps: Waiting to see outcomes from briefing and March 2024 oral arguments at the Fifth Circuit, possibly followed by appeal to Supreme Court.
Insurer Compliance

The AIDS Institute examined insurance plan documents for insurance plans available on the 2024 Health Insurance Marketplace to determine how insurance plans are communicating their coverage of PrEP and its related services.

- 13% of marketplace health insurance plans in 2024 do not clearly indicate on their formulary that at least one PrEP drug is available without a copayment;
- 30% of plans do not include PrEP on a preventive service list;
- 66% of plans do not include any information about the availability of cost-free PrEP-related provider visits, labs, and screenings; and
- 71% of plans have no detail about which labs, screenings, or provider visits are covered without cost.

Read the full report here: https://bit.ly/3UCBCpv
Out-of-Pocket Payments

Payments have decreased over time

1 out of 3 commercially-insured persons were charged cost sharing for PrEP services despite ACA financial protections (2022)

~50% of service costs were for the provider visit (see red box)


Slide provided by Rupa Patel, MD, MPH
PrEP “abandonment rates” 5.5% at $0

Increase in cost from $0 to $10 doubled the rate of “abandonment”

HIV diagnoses 2 to 3 times higher among people who did not pick up their PrEP prescriptions than among those who filled them
Specific Challenges for Puerto Rico

Background

- 1 in 2 enrolled in *Plan Vital*
- Chaotic underfunding and reduced services
- Mandatory spending reductions implemented in 2018
- 72 of 78 municipalities “medically underserved areas”
- 32 “primary care shortage areas”
Draft Policy Priorities for Puerto Rico (courtesy of Latino Commission on AIDS)

- **Provider Education:** Require CME credits on PrEP for providers.
- **PrEP Access:** Eliminate cosignatory requirements to PrEP access.
- **PrEP Access:** Extend access to PrEP to the existing exclusion of parental consent for diagnosis and treatment of STI in minors.
- **PrEP Coverage:** Achieve Medicaid parity in Puerto Rico compared to U.S. States by eliminating funding caps
- **Prevention Focused Approach:** Expand the availability of evidence-based proven practices in HIV prevention.
#PrEPSaves PrEP Users’ Union

- **#PrEPSaves Storybank** to collect stories of members for use in future campaigns and news media to influence policymakers.

- **Direct Advocacy** to put members directly in communication with key stakeholders to discuss HIV policy issues.

- **Level-Setting Discussions** to ensure that PrEP4All and all P2U members are on the same page when it comes to the policy landscape for PrEP access and the barriers being faced by PrEP users around the nation.

PrEP4All is recruiting a diverse group of current and former PrEP users to join our #PrEPSaves PrEP Users’ Union to engage media and impact key HIV policy discussions!

Find out how to become a member at: prep4all.org/prepsaves

Contact: michael@prep4all.org
Funding Partner:

Core Partners:

Allied Partners:

• AIDS United
• The AIDS Institute
• Avita Care Solutions
• Frannie Peabody Center
• NASTAD
• NMAC
• Southern AIDS Coalition
• U.S. Business Action to End HIV
Elton John AIDS Foundation: U.S. Strategy Objectives

Enhance health workforce capabilities to provide compassionate care and support for people with HIV and people who want to prevent HIV infection.

Increase accessibility of and demand for commodities related to HIV prevention, care and treatment, sexual and reproductive health, and harm reduction.

Reduce stigma around HIV and discrimination against people with HIV, LGBTQ+ and people who use drugs.

Participate in opportunities for policy change to create a more supportive and enabling environment for priority populations to safely access the HIV prevention, care and treatment, sexual and reproductive health, and harm reduction services they need.
Our Goal: Accelerate Efforts to End the HIV Epidemic in the United States by 2030

- 1.2 million people in the US have HIV
- 13% of people do not know their status and need testing
- ~32,000 new HIV infections in 2021
- Lifetime medical costs for HIV range from the mid-$300,000 to $500,000
- Health Inequities Persist: Stigma, Access to Care, Racism, anti-LGBTQIA+ bias, Education
- 1.2 million people recommended for PrEP; ~250,000 people lack insurance, stark disparities
Opportunity

Address structural barriers to accessing HIV prevention and linkage to care services in communities that face highest risk.
Increase access to PrEP

- Access to PrEP providers is limited in areas of high need for prevention services.

- Proxy for understanding limitations for people to access HIV screening, PrEP, linkage to care, and more health services.

Harrington KRV, Chandra C, Alohan DI, Cruz D, Young HN, Siegler AJ, Crawford ND. Examination of HIV Preexposure Prophylaxis Need, Availability, and Potential Pharmacy Integration in the Southeastern US. JAMA Network Open. 2023;6(7).
Through community pharmacies*

- Over 70,000 community pharmacies in the U.S.
- 56% of community pharmacies are in Medically Underserved Areas/Populations
- 80% of U.S. counties lack an infectious disease doctor
- Majority of U.S. population lives within 5 miles of a pharmacy
- Many pharmacies have extended hours and are open on weekends

*Health Care Provider Taxonomy Code: A pharmacy where pharmacists store, prepare, and dispense medicinal preparations and/or prescriptions for a local patient population in accordance with federal and state law; counsel patients and caregivers (sometimes independent of the dispensing process); administer vaccinations; and provide other professional services associated with pharmaceutical care such as health screenings, consultative services with other health care providers, collaborative practice, disease state management, and education classes.
Opportunity: Mitigating stigma

- Mistrust of the medical community
  - U.S. history of medical mistreatment of people of color
  - Key populations disproportionately affected by HIV often experience discrimination from health care providers

- Pharmacies may offer a less-stigmatizing entry point for HIV prevention, and a neutral environment compared to traditional medical settings

- Pharmacies can also offer anonymity and discretion, compared to providers or clinics that are known in the community for HIV services

- Collaboration with medical providers is needed to ensure continuity of care beyond an initial HIV test or PrEP prescription from a pharmacist.
U.S. adults support expanding access to services

- 71% support pharmacists administering simple HIV tests at pharmacies.
- 65% support pharmacists prescribing PrEP
- 67% support pharmacists prescribing PEP
- 85% say pharmacists are easy to access

Data reflects results of a nationwide poll conducted online from October 25-30, 2023 among a sample of 10,031 adults. The poll was conducted by Morning Consult and commissioned by NACDS. State-level results are estimated by a multi-level regression and post-stratification (MRP) model weighted by age, race/ethnicity, gender, and educational attainment within each state. Results from the full survey have a margin of error of plus or minus 1 percentage points.
Why is HIV prevention not currently available in most U.S. pharmacies?

- In most U.S. states, pharmacists do not have the legal authority to conduct HIV testing or independently prescribe PrEP or PEP.

- In the U.S. states that do provide authority to pharmacists, very few state policies include the ability for pharmacists to get reimbursed by insurance for the service.

Dual Strategies: federal and state policy

**Federal:** Seeking modifications to expand coverage of HIV Prevention services to include community pharmacies

**Possible pathways:** Revising ACA Implementation Guidance and Medicare Benefit Policy Manual, National Coverage Determination for PrEP

**State:** State scope of practice policies through legislation, Board of Pharmacies, or other policy mechanism

**Authority:** Providing services (ordering, administering, consultation & management) and payment mechanism for services
Anticipated Challenges

- Some people who may want access to services through community pharmacies do not have insurance access.
- Ensuring no cost-sharing for USPSTF Grade A and B services: HIV screening and HIV PrEP.
- Determining availability of and reimbursement for point of care lab tests for PrEP recommended routine testing.
- Complicated and diverse state policies guide pharmacy practice.
- Ensuring effective collaborations across medical care disciplines.
- Incentivizing participation across commercial and public payors for community pharmacists as ‘providers’.
Support for U.S. State Action Planning
Policy component considerations

- **Scope of practice**: prescriptive authority, ordering and administering screening and counselling, removal of referral requirement
- **Payment and reimbursement**: comparable pay, medical benefit billing, flexible service setting
- **General prevention provisions**: Example – integrative health screening
- **Statewide protocols**
- **Training and education campaigns**
Get Involved

Engage with state and local initiatives working to increase access to HIV services through community pharmacies

Promote the value of collaborations across medical care disciplines incl. pharmacists, nurses, physicians, community health workers, patient navigators

Reach out to learn more: Noelle Esquire, noelle.esquire@eltonjohnaidsfoundation.org