



Friday
April 26
1pm ET

# We Can't End HIV in the United States Without Equitable PrEP Access Strategies for Success







HIV prevention research - a new forum for advocacy on the latest

avac.org/project/choice-agenda



We asked...

What are you and/or your organization doing to improve PrEP equity?

- Advocacy for access to new products
- Advocacy, PrEP distribution within HIV prevention research



- Advocating for a National PrEP Program
- Community outreach events w/discussions about safe, healthy sex. Engaging more youth, women of color
- Decentralizing PrEP and Demand Creation
- Ensuring cisgender women learn about PrEP, are supported by providers to access PrEP info and services
- Partnering with other orgs for comprehensive social services including partnering with foodbanks for food insecure communities
- PrEP drug assistance program, recruiting providers to participate in program who are in PrEP deserts/gap areas
- PrEP panel kits, PrEP education, collaboration with CBOs/HCOs
- Prioritizing street outreach in lower resourced neighborhoods; ensuring PrEP is free for all
- Raising awareness in the community and advocating, focus on Black and Brown gay/trans folx
- Rallying for a national prep program
- We have resources for uninsured individuals, doing lots of education around including PrEP discussions in routine visits for all





## Thank you to our co-sponsors





#### **Speakers**

- Dr. Patrick Sullivan, Rollins School of Public Health Emory University
- Dr. Rupa Patel, Centers for Disease Control and Prevention
- Dr. Lorraine Dean, Johns Hopkins University

Moderator
Dr. Greg Millett, amfAR



We Can't End HIV in the United States Without Equitable PrEP Access: Strategies for Success

## We Can't End HIV in the United States Without ... Coverage and Equity

Patrick Sullivan, DVM, PhD

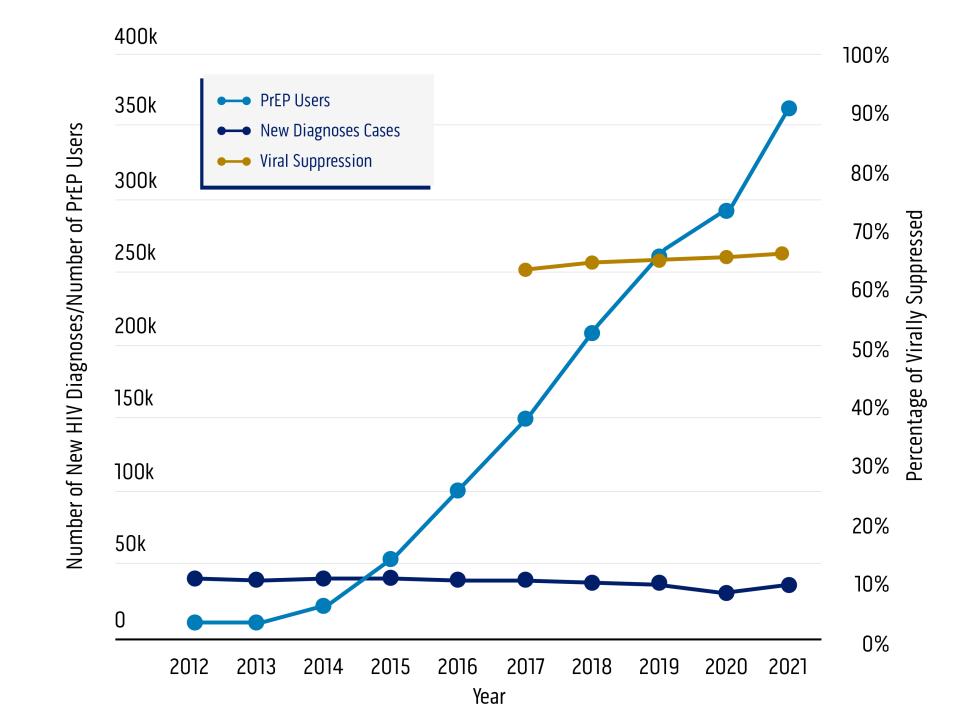
Emory University
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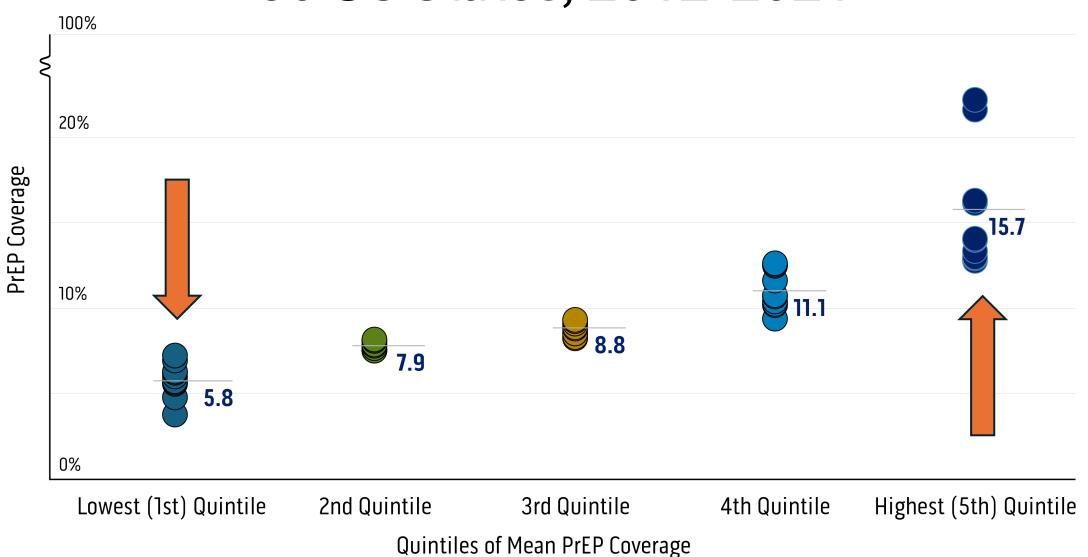


## Background

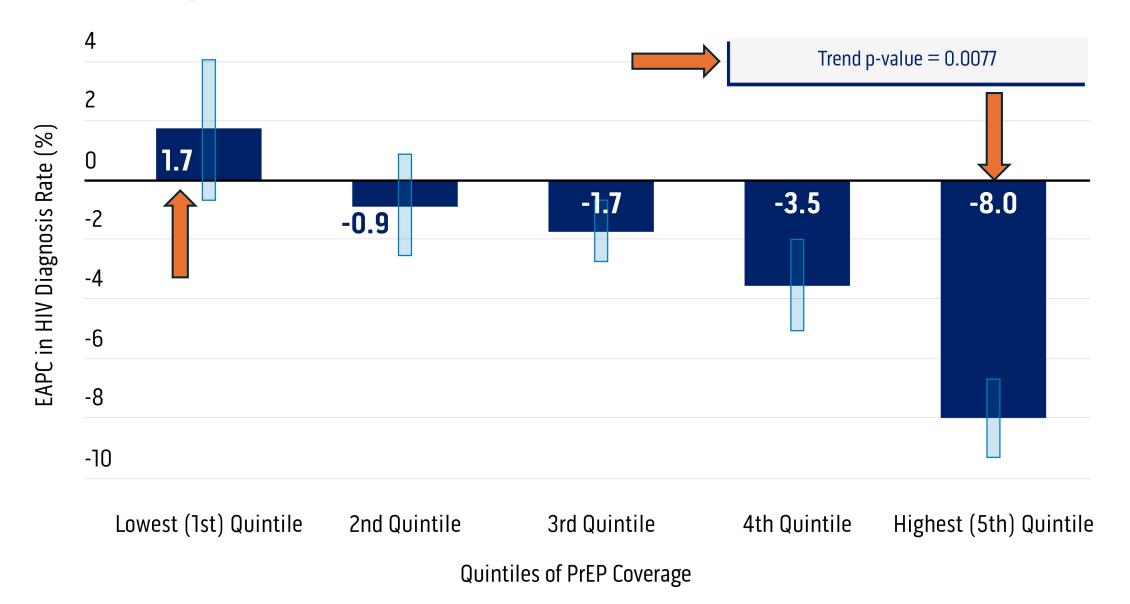
- Pre-Exposure prophylaxis was approved in 2012 for people at risk for HIV with an indication to reduce the risk of HIV acquisition
- Uptake of PrEP has increased steadily from 2012-2022, with an estimated 363,957 PrEP users in 2022
- However, PrEP uptake has not been equitable across the United States, across people of different races and enthicities
- Getting PrEP to the people who need it most will make the greatest impact on reducing new HIV infections



# Mean PrEP Coverage by PrEP Quintile of Use, 50 US States, 2012-2021



## Estimated Annual Percent Change in HIV Diagnoses, by State Quintile of PrEP Use, 2012-2021, United States





Contents lists available at ScienceDirect

#### Annals of Epidemiology



#### Original article

Policy- and county-level associations with HIV pre-exposure prophylaxis use, the United States, 2018



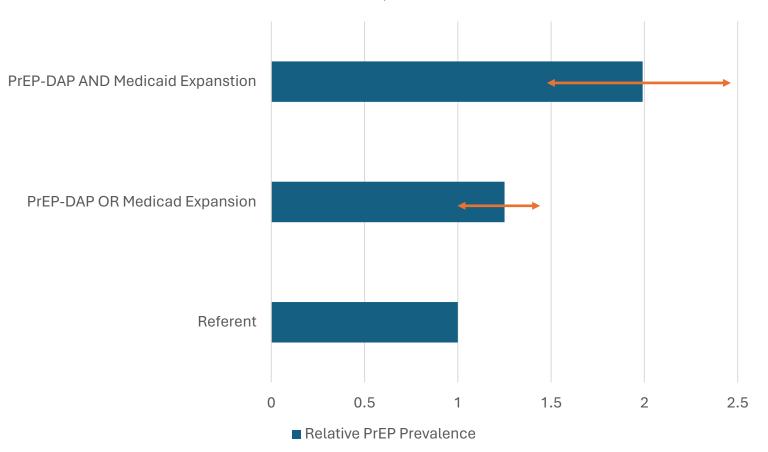
Aaron J. Siegler, PhD <sup>a, \*</sup>, C. Christina Mehta, PhD <sup>b</sup>, Farah Mouhanna, MS <sup>a, c</sup>, Robertino Mera Giler, MD, PhD <sup>d</sup>, Amanda Castel, MD, MPH <sup>c</sup>, Elizabeth Pembleton, MPH <sup>e</sup>, Chandni Jaggi, MPH <sup>e</sup>, Jeb Jones, PhD <sup>e</sup>, Michael R. Kramer, PhD <sup>e</sup>, Pema McGuinness, MPH <sup>d</sup>, Scott McCallister, MD <sup>d</sup>, Patrick S. Sullivan, DVM, PhD <sup>e</sup>

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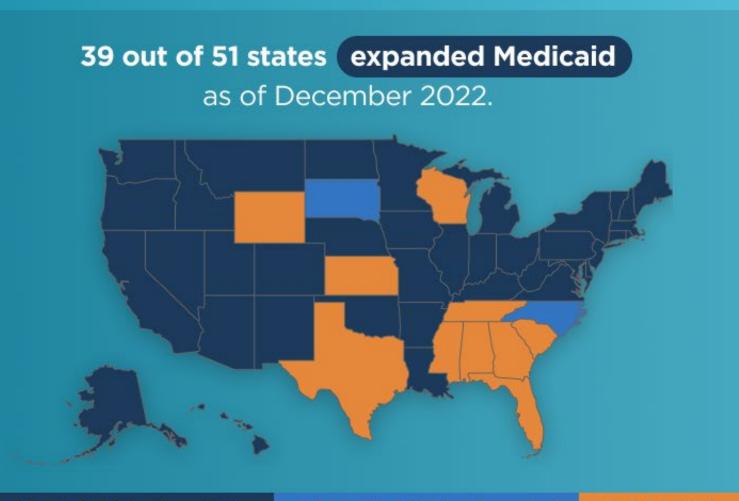
- PrEP Prevalence was higher in areas with PrEP-DAP alone, Medicaid alone, or both
- PnR (AKA more equitable PrEP use)
  was higher in areas with both PrEP
  DAP and Medicaid expansion
- Message: EITHER policy moves towards PrEP equality; COMBINED, they move towards PrEP Equity

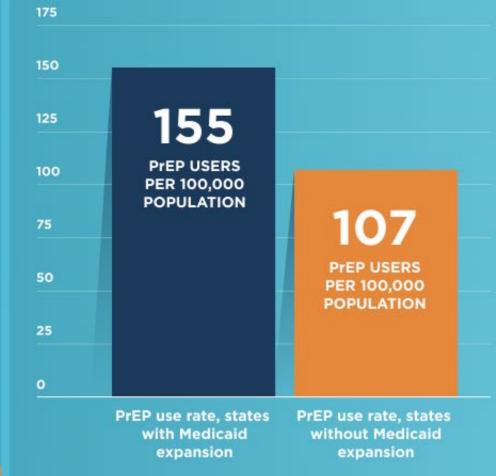
### Policy associations of PnR with State-level policy, United States, 2018



## In 2022, states that **expanded their Medicaid programs** had **PrEP use rates** that were **1.4X higher** than states that **did not expand Medicaid**.

\*For purposes of this analysis, District of Columbia is treated as a state.





Adopted and Implemented

Adopted but Not Implemented

**Not Adopted** 

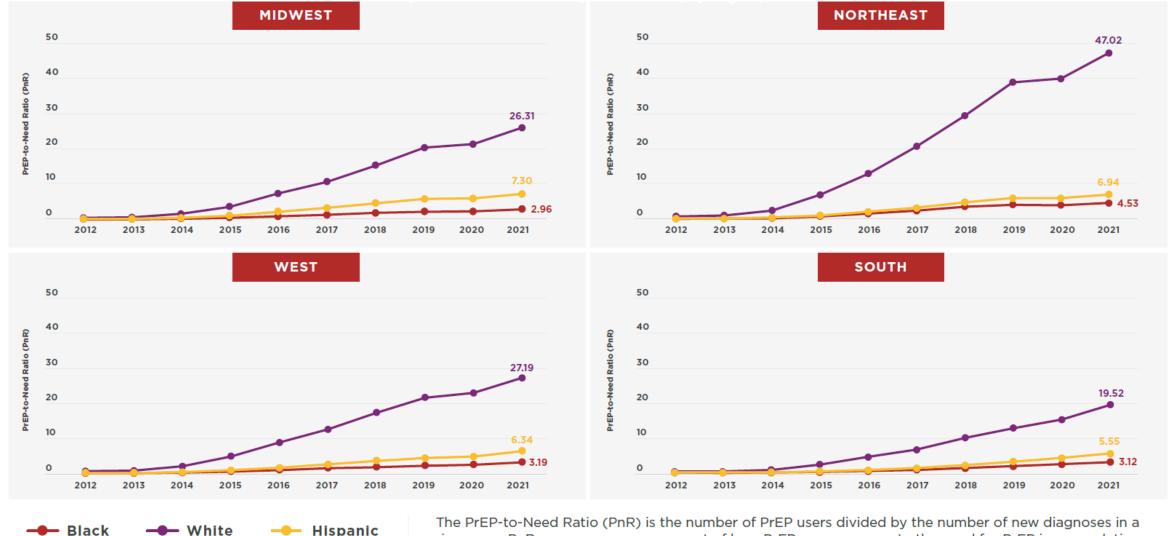


Black people
represented only
14% of PrEP users
(2022) but accounted
for 40% of new HIV
diagnoses (2021),
indicating a
significant unmet
need for PrEP.



SOURCE: AIDSVu

### PnR by Race/Ethnicity and US Region, 2012-2021



given year. PnR serves as a measurement of how PrEP use compares to the need for PrEP in a population.

#### Discussion

- A dose-response relationship exists between PrEP coverage and magnitude of declines in HIV diagnoses. Higher coverage is better.
- Combined approaches to HIV prevention including timely diagnosis and availability of effective treatments – play an additive role in realizing reductions in new HIV transmissions
- In addition to HIV testing and PrEP referral programs, Medicaid expansion and PrEP Drug Assistance Programs have been found to be associated with higher equity in PrEP use, which is important to maximize the prevention benefits of PrEP
- Equitable PrEP use is optimal prevention. We'll move faster towards ending the HIV epidemic when we get PrEP to the people who need it most.

## Funding and Acknowledgements

- National Institutes of Health
  - This work was supported by the Center for AIDS Research at Emory University (P30 AI050409)
  - This work was supported by R01Al143875, U01PS005244, UG3Al176853, R01MH122341
- AIDSVu, the source of PrEP data resources, is supported by a grant from Gilead Sciences



AIDSVu Resources





#### **Challenges in PrEP Delivery**

Rupa R. Patel, MD MPH FIDSA Clinical Biomedical Prevention Activities Lead HIV Research Branch, Division of HIV Prevention Centers for Disease Control and Prevention, USA

April 26, 2024



#### Disclaimer

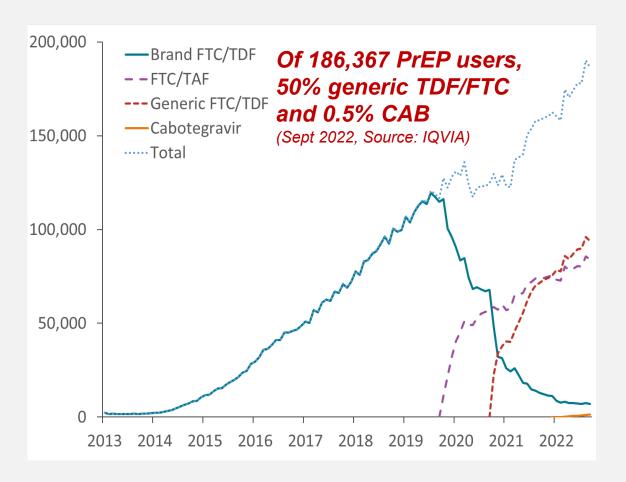
The findings and conclusions in this presentation are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

#### **Outline**

- Cost-related challenges to PrEP delivery
- Clinical challenges in PrEP delivery



#### **PrEP Prescribing in the United States**

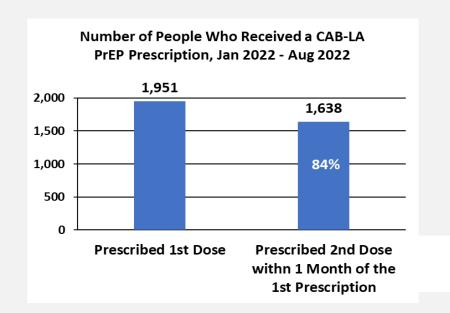


#### 186,367 persons were prescribed PrEP (Sept 2022):

Generic FTC/TDF:93,808(50.3%)FTC/TAF:84,141(45.1%)Brand FTC/TDF:7,065(3.8%)CAB-LA:1,353(0.5%)

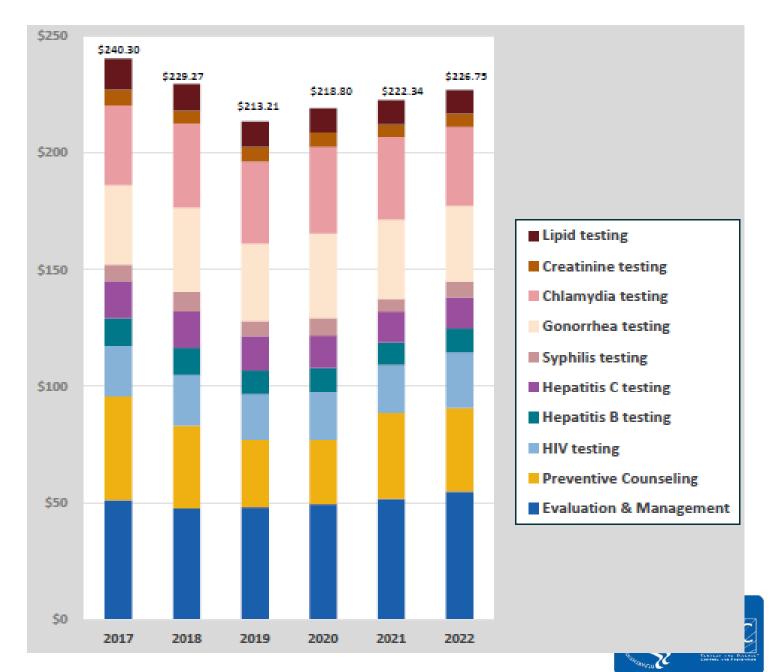
Table. Characteristics of persons prescribed long-acting of	cabotegravir,
United States, January 2013 through September 2022	

	Oral PrEP		Injectable PrEP	
	N	%	N	%
Total	381,883		2,695	
Sex				
Male	355,087	93.0	2,359	87.5
Female	26,697	7.0	336	12.5
Unknown	99	0.0	0	0.0
Age				
13-24	46,814	12.3	369	13.7
25-34	150,864	39.5	1,111	41.2
35-44	96,243	25.2	698	25.9
45-54	47,668	12.5	297	11.0
55-64	31,427	8.2	149	5.5
65+	8.867	2.3	71	2.6



#### **Cost-Related Challenges**

- 1 out of 3 people were charged cost sharing despite ACA financial protections
- Mean OOP annual payments for PrEP services 2017-2022 (\*\*)
   \$220.00)
- ~ 50% of costs were the provider visit



#### **Cost-Related Challenges**

 Mean OOP payment for PrEP medications per month were estimated to be \$839 in 2021

Table. Number of PrEP prescriptions, tablets, and payments represented in the IQVIA database, January 2019 – September 2021

	2019	2020	Q1-Q3 2021
PrEP users*, n	183,274	211,924	231,787
PrEP prescriptions*, n	916,864	1,027,398	923,556
PrEP tablets*, n	32,666,301	36,495,127	33,155,114
F/TDF, n (%)	31,040,704 (95%)	19,271,043 (53%)	4,032,403 (12%)
F/TAF, n (%)	1,625,597 (5%)	14,750,036 (40%)	15,246,675 (46%)
Generic F/TDF, n (%)	NA	2,474,048 (7%)	13,876,036 (42%)
Mean total payments per 30 tablets, \$ (SD)	1,644 (304)	1,686 (364)	1,365 (732)
Mean OOP payments per 30 tablets, \$ (SD)	90 (239)	85 (250)	63 (255)
Drug type			
F/TDF	91 (240)	86 (255)	113 (364)
F/TAF	86 (228)	96 (257)	102 (297)
Generic F/TDF	NA	13 (105)	7 (86)
Payer type			
Commercial	108 (248)	103 (258)	72 (264)
Medicaid	2 (38)	4 (70)	6 (106)
Medicare	83 (191)	99 (226)	120 (248)
Cash	1,762 (703)	1,725 (922)	839 (1,019)
Gilead MAP	1 (40)	5 (96)	17 (183)
Ready, Set, PrEP	NA	4 (92)	0 (0)
lote: O1-O3=January to Sentember: E/TDE=tenofovir (	disoprovil fumarate and a	emtricitabine: E/TAE=ter	ofovir alafenamide and

Note: Q1-Q3=January to September; F/TDF=tenofovir disoproxil fumarate and emtricitabine; F/TAF=tenofovir alafenamide and emtricitabine; OOP=out-of-pocket; MAP=medication assistance program; SD=standard deviation; NA=not applicable.



<sup>\*</sup>Based on PrEP prescriptions with complete payment data in the IQVIA database.

#### **Cost-Related Challenges**

- States that expanded Medicaid had the highest PrEP to diagnosis ratios (PDRs)
  - Medicaid expansion may be an effective intervention to increase PrEP use
- In 2021
  - PDRs were highest for Hispanic Medicaid beneficiaries
  - Disparities in PDRs were small between Black and White Medicaid beneficiaries

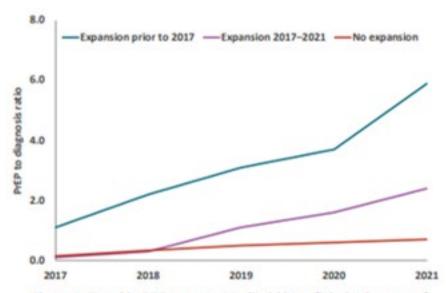


Figure 1. Trend in PDRs among Medicaid beneficiaries by year of Medicaid expansion — United States, 2017–2021

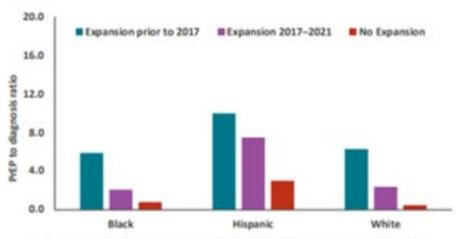


Figure 2. PDRs among Medicaid beneficiaries by year of Medicaid expansion and race and ethnicity — United States, 2021

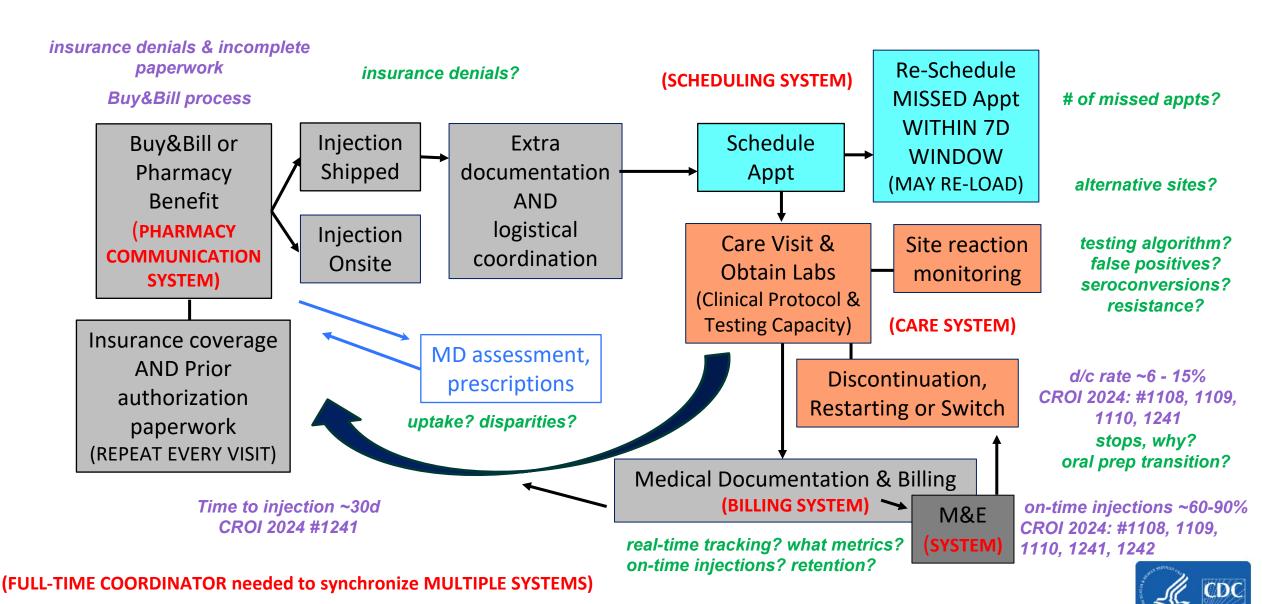


#### The Challenges/Knowledge Gaps for Equitable & Sustainable Injectable PrEP Rollout

Intervention (LAI CAB PrEP Q2M)	Outer Setting (Policy Level)	Inner Setting (Organization Level)	Individuals (i.e., Providers)	Process
<ul> <li>Re-medicalization</li> <li>Alternative inj. sites^</li> <li>Populations         Pregnancy, Chestfeeding     </li> <li>Pharmacokinetics</li> </ul>	<ul> <li>Cost, Insurance, Financing</li> <li>Denials, prior authorizations ("failed oral therapy"), med acquisition (Buy&amp;Bill)</li> <li>No financing program</li> <li>Clinical guidance (HIV testing*)</li> <li>Legal framework for LGBTQIA+ and women</li> <li>Healthcare regulation: injection administration</li> </ul>	<ul> <li>Funds</li> <li>Staff for pre-planning, coordination, care, documentation</li> <li>Space and appointment slots</li> <li>Real-time monitoring capacity</li> <li>Non-clinic based care**</li> <li>HIV testing capacity</li> <li>Culture and climate: readiness for change, take risk</li> </ul>	<ul> <li>Providers: time, awareness, comfort</li> <li>PrEP Users awareness, comfort, access, time, medical mistrust, stigma</li> <li>Leadership: take risks and competing priorities</li> </ul>	• Complex workflow

**Consolidated Framework for Implementation Research (Five Domains)** 

#### Injectable PrEP Workflow Challenges Foster <u>Disparities</u> and <u>Unsustainability</u>



#### **Finding Answers: Policy Implications**

#### Delivery

- Staff Task Shifting\*
- Where (i.e., mobile units, homes)
- Syndemics (syphilis & HIV prevention)
- Policy examples (i.e., family planning, COVID)

#### Financing and insurance coverage

- Medicaid expansion to enable primary care
- Other avenues for insurance coverage
- State-level public health and PrEP programs
- Dedicated PrEP coverage programs (local, state and federal levels)

#### 2. High-priority recommendations that require policy change or new action

- 2.1 Mandate syphilis testing on all stillbirths.
- 2.2 Allow medical assistants (MAs) with telehealth access to a supervising clinician to provide intramuscular injections in the field.
  2.3 Allow disease intervention specialists to give intramuscular injections under the
- standing order of a local health office Office Legis Report to the Le

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#### PrEP CHW Program Model: Washington, D.C.

#### **Hands-On Provider Training for PrEP Specialists**

- Videotape and in-clinic observation feedback
- Surveys every month on injection comfort level
- Written and video assessments
- Weekly review of cases; and refresher trainings
- Created checklists, client scripts, and work aids simultaneously
- Phlebotomy and rapid testing training

**PrEP Specialists & Navigators** 



#### **WWH PrEP Services Pathway**





#### **Summary**

- Out-of-pocket individual costs post-2021-ACA mandates remain an issue for medications and ancillary services
- Clinical workflow challenges, which include staffing and systems coordination issues, contribute to inaccessible and inequitable care
- Policies need to expand the prevention workforce, foster non-clinic delivery, expand healthcare insurance coverage for primary care with PrEP, and earlier and more options for generic medication production







# Cost **Still** Matters to HIV PrEP Uptake in the US

Lorraine T. Dean, ScD

Associate Professor of Epidemiology

Johns Hopkins Bloomberg School of Public Health



### Why are PrEP costs *still* important?

- USPSTF "A" rating in 2020 means private insurers and Medicaid expansion programs complying with the Affordable Care Act should be offering PrEP and related services with no cost-sharing
  - Yet, recent legal challenges threaten to upend the ACA and \$0 PrEP
  - 2023 Braidwood vs Becerra challenges requiring preventive care for STI unconstitutional and violation of religious rights
- Further, insurers have used various means to circumvent \$0 PrEP
  - Limiting formularies
  - Listing PrEP drugs on the wrong tiers to discourage use
- Manufacturer reimbursement for 340-B safety net clinics ends

# Predicting the Impact of Cost on HIV PrEP Uptake and Racial/Ethnic Disparities among MSM

Pls: Chan, Raifman, Dean

NIH R21MH118019

### Team



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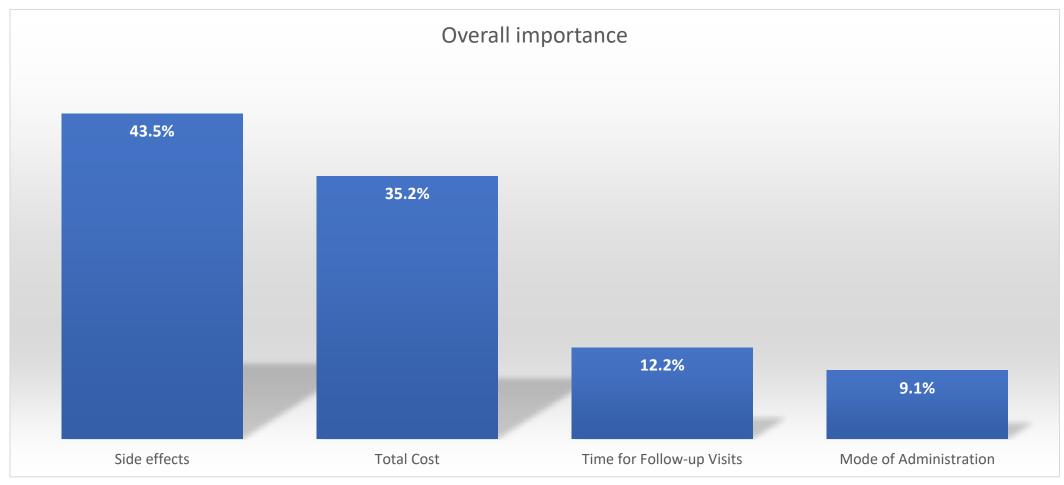
Alexandra Skinner, MPH Kristen Nocka, MPH

# Preference Elicitation Example

(1/8) Choose your preferred option below:

Attributes				
7 Teel 15 di ees	PrEP Option 1	PrEP Option 2		
Total cost (average per month)	\$10	\$200		
Time for follow-up visits (travel time and clinic time, every 3 months)	30 minutes	1 hour	Levels	
Side effects	Some side-effects on starting (headaches and nausea) which persist while on PrEP	Some longer-term side-effects (be and kidney problems) in later year PrEP		
Mode of administration	Small implant every few months	Small implant every few months		

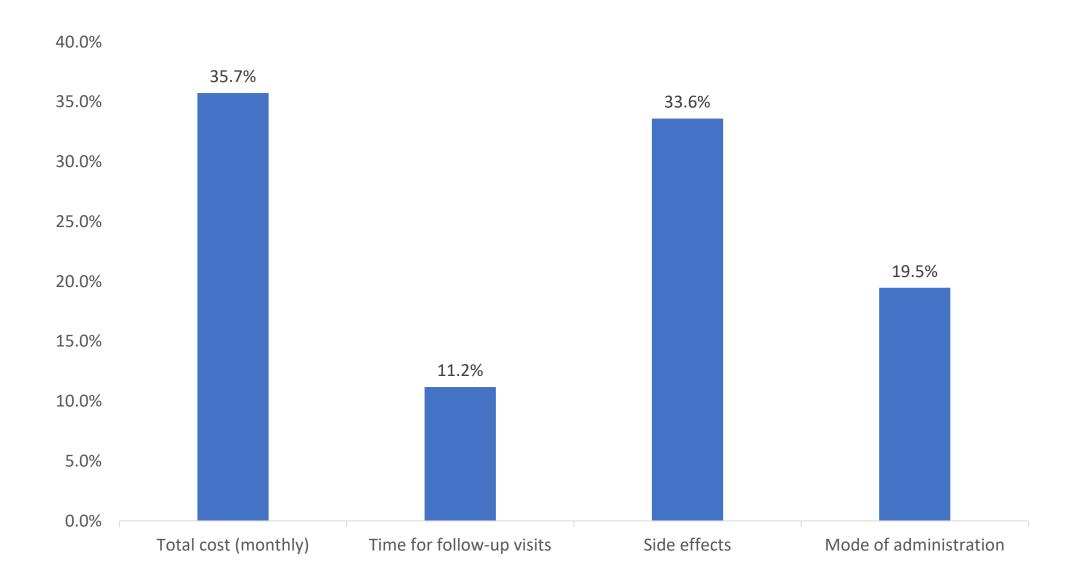
## Side effects and cost are top concerns



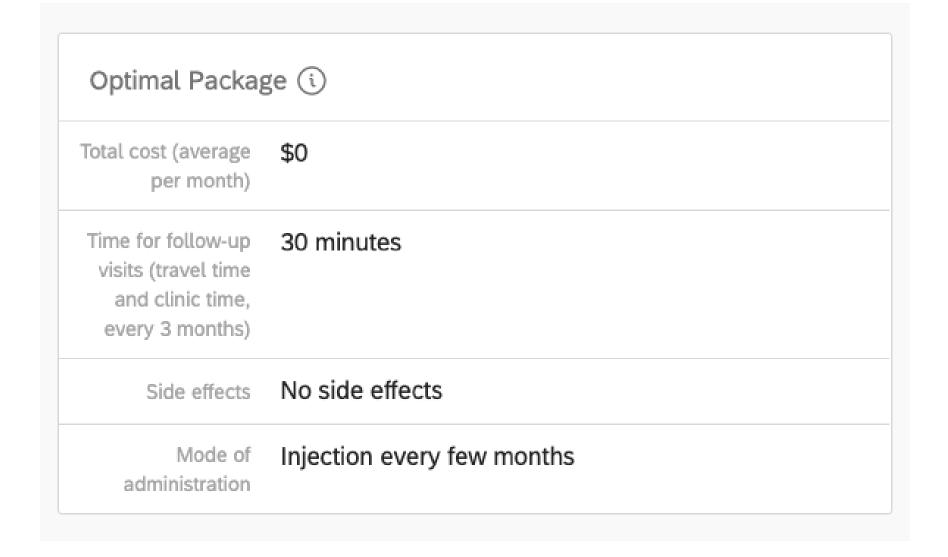
#### N=688 GBMSM across 6 New England States

Dean, LT, Predmore, Z, Skinner, A, Napoleon, S, Chan, PA, & Raifman, J. (2023). Optimizing Uptake of Long-Acting Injectable Pre-exposure Prophylaxis for HIV Prevention for Men Who Have Sex with Men. AIDS and Behavior. DOI:10.1007/s10461-023-03986-5

### Cost is critical for those with low PrEP interest



### Best Case Scenario

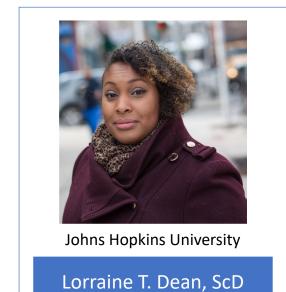


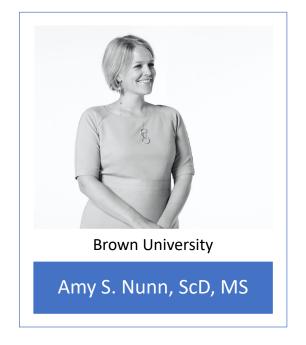
Assessing Gaps in HIV Pre-Exposure Prophylaxis (PrEP) Initiation and Retention using Pharmacy Claims Data

Pls: Dean, Nunn

R21NR018387

#### Team





Collaborators:
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Shivani Bakre, ScM
Rahel Dawit, PhD
Parya Saberi, PhD





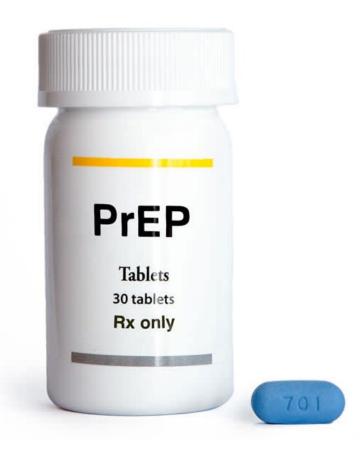






## Methods: Claims Data

- Data were provided for pharmacy claims for oral PrEP from October 1, 2015 to September 30, 2019
  - Symphony Health Solutions' Integrated Data Verse by Source Healthcare Analytics, LLC
  - 80-85% of active HIV PrEP prescriptions in the US
  - Across most public and private payers
  - Includes demographics and health outcomes
- Newly prescribed: No HIV diagnosis or PrEP use as of 2015
- Claims for Descovy were <u>not</u> included as it was FDA approved in October 2019



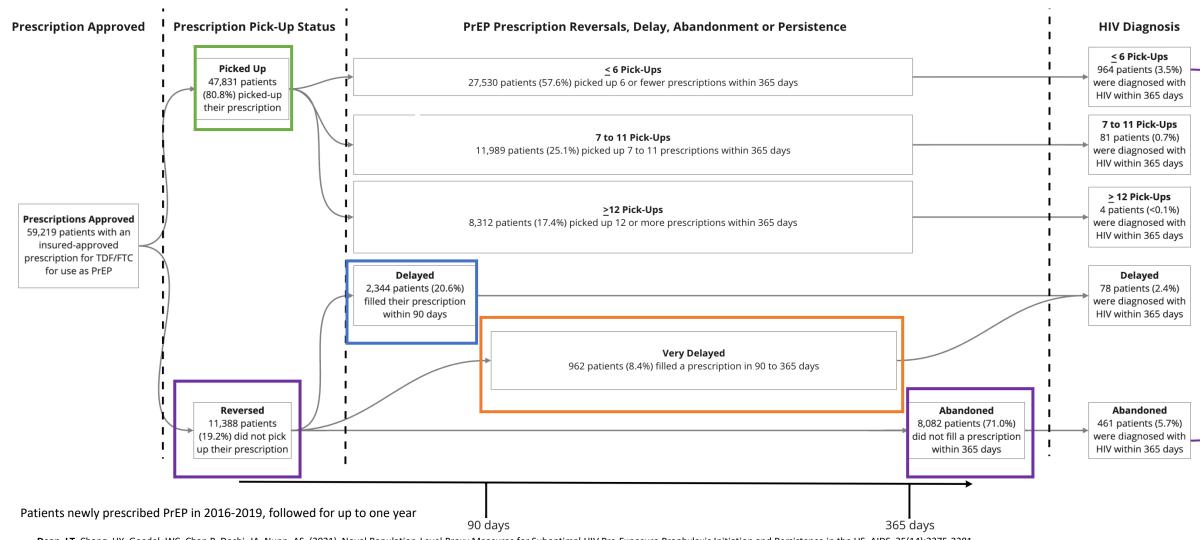
# Demographics: Newly Prescribed PrEP (N=58,529)

(14 33)323 j	00.00/
Male	88.8%
Age Group	
<24	9.2%
25-34	39.8%
35-44	24.3%
45-54	15.3%
55+	11.5%
Race/Ethnicity	
NH Black	11.1%
NH White	44.0%
Hispanic	11.1%
Other/Unknown	34.4%
Education	
High School or Less	16.6%
Some college	25.7%
Associates or more	27.4%
Unknown	30.3%

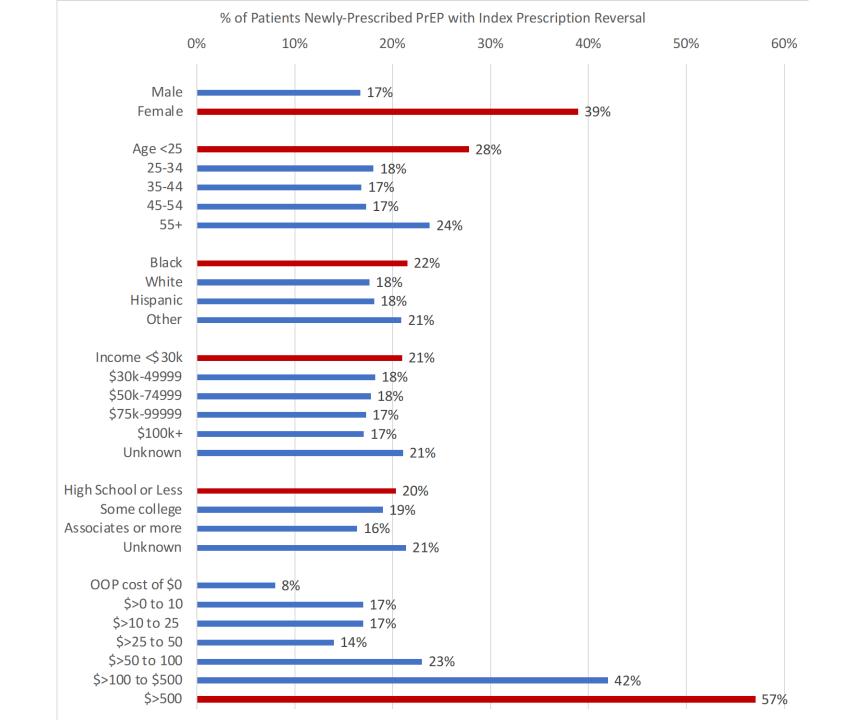
Household Income	
<\$30k	14.6%
\$30k-49999	15.5%
\$50k-74999	12.3%
\$75k-99999	8.8%
\$100k+	16.1%
Unknown	32.8%
Insurance Type	
Cash	3.5%
Commercial	78.0%
Medicaid	14.3%
Medicare	4.2%

Patients were the unit of analysis, followed for up to one year from 2016-2019

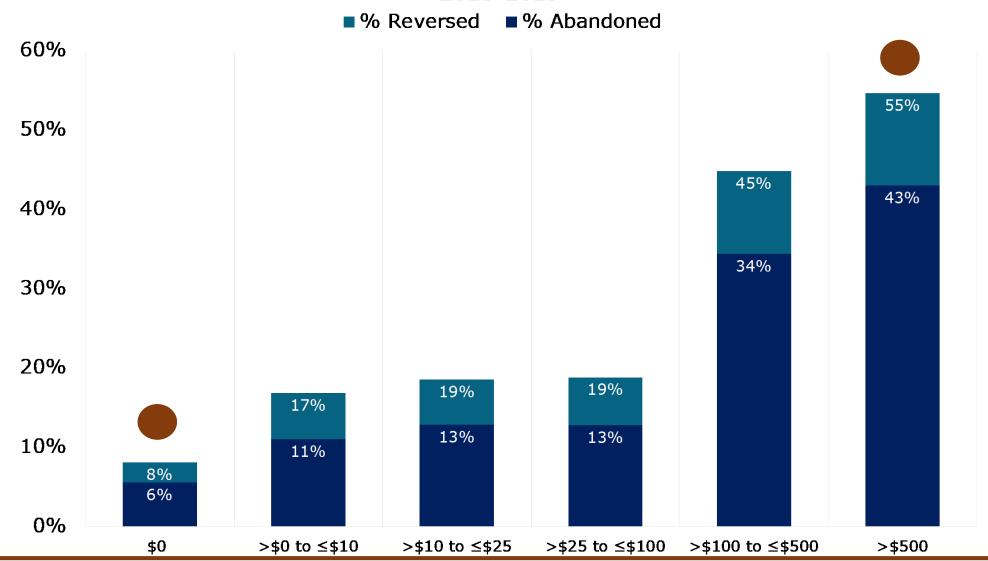
# 1 in 5 reverse -> Up to 5x higher HIV cases



Dean, LT, Chang, HY, Goedel, WC, Chan P, Doshi, JA, Nunn, AS. (2021). Novel Population-Level Proxy Measures for Suboptimal HIV Pre-Exposure Prophylaxis Initiation and Persistence in the US. AIDS, 35(14):2375-2381.



#### Adjusted Percent Reversal and Abandonment of HIV PrEP Prescriptions in the US by Patient Out-of-Pocket Cost 2015-2019



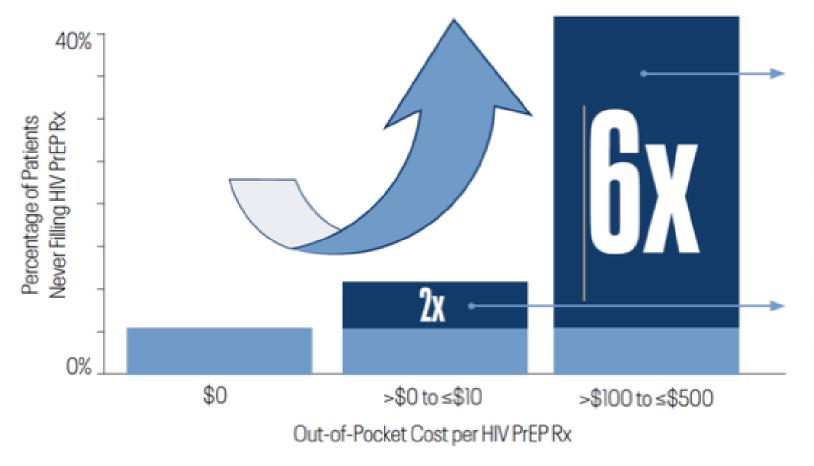
Key Finding: Relative to \$0, a cost of \$10 doubled the percent of patients who reversed or abandoned PrEP. At highest cost ranges, nearly half or more of patients reversed and over one-third abandoned PrEP.

#### Predicted PrEP Abandonment Rate (95% CI) by Hypothetical Out-of-Pocket Cost Category

Current Out- of-Pocket Cost Category	Patients (N)	<b>\$0</b>	> \$0 to ≤ \$10	>\$10 to ≤ \$25	>\$25 to ≤ \$100	> \$100 to ≤ \$500	> \$500
\$0	14,155	5.6 <b></b> (5.2 - 6.0)	11.1 (10.7 - 11.5)	12.9 (12.1 - 13.7)	12.8 (12.1 - 13.6)	34.7 (32.7 - 36.6)	42.9 (41.2 - 44.6)
>\$0 to ≤\$10	20,505	5.7 (5.4 - 6.1)	11.3 (10.9 - 11.7)	13.1 (12.3 - 13.9)	13.0 (12.3 - 13.7)	34.9 (33.0 - 36.8)	43.1 (41.5 - 44.8)
>\$10 to ≤\$25	7,437	4.8 (4.5 - 5.2)	9.8 (9.4 - 10.2)	11.4 (10.7 - 12.1)	11.3 (10.7 - 12.0)	32.3 (30.4 - 34.2)	40.5 (38.9 - 42.2)
>\$25 to ≤\$100	9,792	4.7 (4.4 - 5.1)	9.6 (9.1 – 10.0)	11.1 (10.4 - 12.0)	11.1 (10.5 - 11.7)	31.9 (30.0 - 33.8)	40.1 (38.5 - 41.8)
> \$100 to \$500	2,282	5.6 (5.2 - 6.0)	11.1 (10.6 - 11.6)	12.9 (12.1 - 13.6)	12.8 (12.1 - 13.5)	34.5 (32.7 - 36.4)	42.7 (41.2 - 44.3)
>\$500	4,358	7.3 (6.7 - 7.8)	14.0 (13.3 - 14.6)	16.0 (15.0 - 17.1)	16.0 (15.0 - 16.9)	39.8 (37.7 - 41.8)	48.0 (46.6 - 49.5)

Models adjusted for patient age, sex, race and ethnicity, household income, education level, US Census region, Charlson Comorbidity Index, year of the index PrEP prescription, and insurance type.

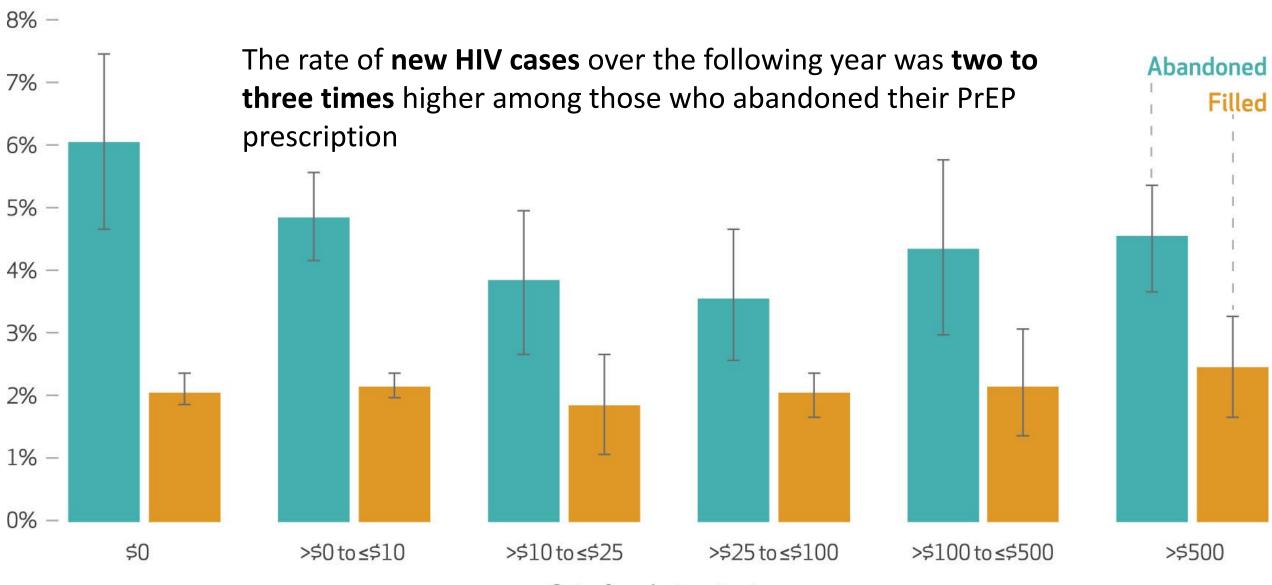
Dean, Lorraine T., et al. "Estimating The Impact Of Out-Of-Pocket Cost Changes On Abandonment Of HIV Pre-Exposure Prophylaxis: Study examines the impact of out-of-pocket spending changes on abandonment of HIV pre-exposure prophylaxis." *Health Affairs* 43.1 (2024): 36-45.



An increase from \$0 to between \$100 and \$500 in monthly PrEP out-of-pocket costs would increase PrEP abandonment rates by 6 times, resulting in more than 1 in 3 patients never filling their PrEP Rx

Even a small increase, from \$0 to \$10 in monthly PrEP out-of-pocket costs, would double the percent of patients never filling their PrEP Rx

Dean, Lorraine T., et al. "Estimating The Impact Of Out-Of-Pocket Cost Changes On Abandonment Of HIV Pre-Exposure Prophylaxis: Study examines the impact of out-of-pocket spending changes on abandonment of HIV pre-exposure prophylaxis." *Health Affairs* 43.1 (2024): 36-45.



Out-of-pocket cost category

Dean, Lorraine T., et al. "Estimating The Impact Of Out-Of-Pocket Cost Changes On Abandonment Of HIV Pre-Exposure Prophylaxis: Study examines the impact of out-of-pocket spending changes on abandonment of HIV pre-exposure prophylaxis." *Health Affairs* 43.1 (2024): 36-45.

## Opportunities

- Biden administration proposal to cover PrEP at no cost for people on Medicare
  - Currently awaiting a final decision from CMS

- PrEP Access and Coverage Act reintroduced in Congress in June 2023 which, if passed, will require all private and public insurers to cover PrEP at no cost
- National PrEP program to ease access and navigation

## Thank You!



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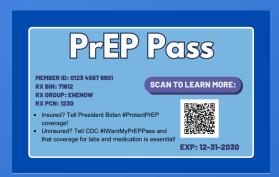
#### Support provided by

- NIH/National Institute for Minority Health & Health Disparities U54MD00214
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  - NIH/ National Institute for Mental Health R21MH118019
  - NIH/ National Institute for Allergy and Infectious Diseases R25AI154589
    - Johns Hopkins University Center for AIDS Research P30AI094189

# 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



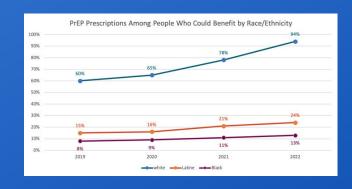
#### **Provider Network Expansion**

- 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



# 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

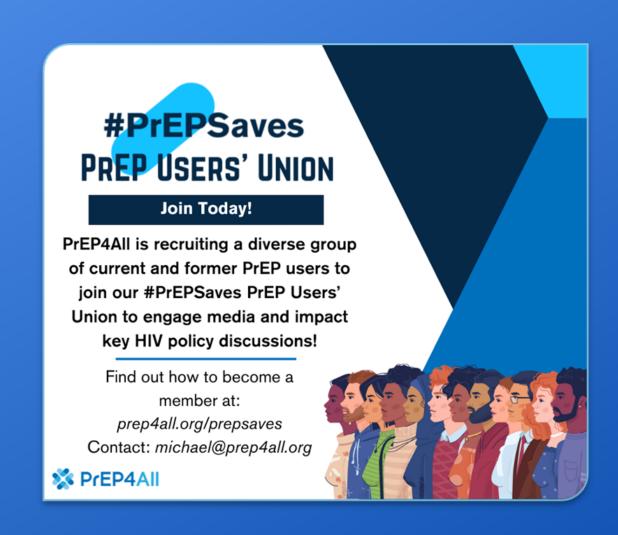
bit.ly/npp-orgs2024



## The #PrEPSaves PrEP Users Union

#### KEY COMPONENTS OF THE #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 P2U2 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.



## Download at: prep4all.org/publication/sac-report/

Available for Download

Toward PrEP Access for All

A report on the crucial steps needed to ensure everyone has equitable access to PrEP in the South.





