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SYMPOSIUM



Financing and Delivering Pre-Exposure Prophylaxis (PrEP) to End the HIV Epidemic

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and Joshua M. Sharfstein

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C O N T E N T S

SPECIAL SUPPLEMENT TO VOLUME 50.2 • SUMMER 2022

Symposium Articles

SYMPOSIUM

Financing and
Delivering
Pre-Exposure
Prophylaxis
(PrEP) to
End the HIV
Epidemic

Guest Edited by
Jeremiah Johnson,
Amy Killelea, Derek
T. Dangerfield II,
Chris Beyrer, and
Joshua M. Sharfstein

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Letter from
the Editor

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Introduction: Building Equitable Access to HIV Pre-Exposure Prophylaxis (PrEP) in the U.S. by Disrupting the Status Quo
Jeremiah Johnson, Amy Killelea, Derek T. Dangerfield II, Chris Beyrer, and Joshua M. Sharfstein

Pre-exposure prophylaxis — or PrEP — is an essential intervention for the prevention of HIV, and a key tool in reaching the goals and objectives of the National HIV/AIDS Strategy and the Ending the HIV Epidemic initiative in the U.S. However, as we head toward the 12th anniversary of the iPrEx findings that demonstrated the efficacy of PrEP and the 10th anniversary of the FDA approval, PrEP remains out of reach for most people who could best benefit. There are massive disparities in PrEP initiation and adherence by income, race and ethnicity, age, gender, and region. This special edition of the *Journal of Law, Medicine & Ethics* centers on a novel proposal for a national PrEP access program with the potential to break through a failed status quo. To help bring an end to the HIV epidemic, the proposed program would streamline access to PrEP medications for people covered by Medicaid or without insurance coverage, enhance clinical care for PrEP, and create a new network of PrEP access points in communities.

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Financing and Delivering Pre-Exposure Prophylaxis (PrEP) to End the HIV Epidemic

Amy Killelea, Jeremiah Johnson, Derek T. Dangerfield II, Chris Beyrer, Matthew McGough, John McIntyre, Rebekah E. Gee, Jeromie Ballreich, Rena Conti, Tim Horn, Jim Pickett, and Joshua M. Sharfstein

The U.S. has the tools to end the HIV epidemic, but progress has stagnated. A major gap in U.S. efforts to address HIV is the under-utilization of medications that can virtually eliminate acquisition of the virus, known as pre-exposure prophylaxis (PrEP). This document proposes a financing and delivery system to unlock broad access to PrEP for those most vulnerable to HIV acquisition and bring an end to the HIV epidemic.

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Pre-Exposure Prophylaxis for HIV Infection as a Public Health Tool

Chris Beyrer, Sheena McCormack, and Andrew Grulich

The efficacy of pre-exposure prophylaxis, PrEP, with antiviral agents for prevention of HIV infection has been demonstrated in multiple randomized controlled trials and demonstration projects. These trials have studied prevention at the individual level. The effectiveness of PrEP as a public health intervention to reduce HIV incidence at community and population levels is being actively evaluated but is less well described. In reviewing the available data on PrEP as a public health intervention, three significant examples have demonstrated success, and all have been among communities of gay, bisexual and other men who have sex with men (MSM). The communities include MSM in the UK, in Australia, and among white MSM in the U.S. In studies and surveillance reports in all three of these contexts there have been measurable declines in new HIV diagnoses among all MSM when there has been significant uptake and use of PrEP among community members. In the UK and Australia, PrEP is being provided as part of the national health schemes and is either free of charge or low cost. PrEP can be an effective public health tool for communities of MSM with good access, coverage, and low cost.

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From COVID Vaccines to HIV Prevention: Pharmaceutical Financing and Distribution for the Public's Health

Joshua M. Sharfstein, Rena M. Conti, and Rebekah E. Gee

The complexity and inefficiency of the US health care system complicates the distribution of life-saving medical technologies. When the public health is at stake, however, there are alternatives. The proposal for a national PrEP program published in this issue of the Journal applies some of the lessons of the national COVID vaccine campaign to HIV prevention. In doing so, it draws on other examples of public health approaches to the financing of medical technology, from vaccines for children to hepatitis C treatment.

Symposium articles are solicited by the guest editor for the purposes of creating a comprehensive and definitive collection of articles on a topic relevant to the study of law, medicine and ethics. Each article is peer reviewed.

Independent articles are essays unrelated to the symposium topic, and can cover a wide variety of subjects within the larger medical and legal ethics fields. These articles are peer reviewed.

Columns are written or edited by leaders in their fields and appear in each issue of *JLME*.

Next Issue:

A Critical Moment for Transgender Health Equity
A Symposium Guest Edited by Heather McCabe

32 Opportunities and Challenges of Generic Pre-Exposure Prophylaxis Drugs for HIV
Jeromie Ballreich, Timothy Levensgood, and Rena M. Conti

Antiretroviral pre-exposure prophylaxis (PrEP) is protective against HIV. Low utilization rates amongst HIV vulnerable populations are due in part to the high cost of PrEP. Generic PrEP offers the potential to improve health at significantly reduced costs. In this study, we examine early utilization patterns and prices for generic PrEP. We discuss the opportunities and challenges for generic PrEP to improve health among HIV vulnerable populations.

40 The PrEP Laboratory Service Gap: Applying Implementation Science Strategies to Bring PrEP Coverage to Scale in the United States
Aaron Siegler and Patrick Sullivan

Using an implementation science framework, we detail how a national system for covering both standard and telemedicine laboratory testing would support a national PrEP program. Implementation strategies that will facilitate success include minimizing provider burden through uncomplicated billing systems and minimizing patient burden through centralized, online access systems. We anticipate that providing telemedicine and in-person laboratory testing options will optimize PrEP care by making it less burdensome, leading to cost-effective healthcare and improved population health.

47 The Downstream Impacts of High Drug Costs for PrEP Have Hindered the Promise of HIV Prevention
Kenyon Farrow

Prior to the recent introduction of generic TDF/FTC in the U.S., access to pre-exposure prophylaxis (PrEP) for HIV was greatly limited due to the downstream effects of the high cost of the medication. This article argues that despite drug copy cards and patient assistance programs, the promise of drastically reduced HIV diagnoses has never been fully realized, and more policy reforms on drug pricing are needed to make ending the HIV epidemic a reality.

51 Implementing a National PrEP Program: How Can We Make It Happen?
David Malebranche, Ariel Watriss, and Derek T. Dangerfield II

Inequities in HIV pre-exposure prophylaxis (PrEP) use persist in the United States. Although scientific advancement in delivery options and social acceptance of PrEP has occurred in the past decade, gaps remain in ensuring that this sexual health program is available to all. Components of what a national PrEP program for all would look like are discussed.

55 Building Racial and Gender Equity into a National PrEP Access Program
Jeremiah Johnson, Asa Radix, Raniyah Copeland, and Guillermo Chacón

Transgender and gender diverse (TGD), Black, and Latinx communities have long borne a disproportionate share of the U.S. HIV epidemic, yet these same key demographics are continually underrepresented in national PrEP prescriptions. Black, Latinx, and TGD individuals are also more likely to be uninsured, meaning that a proposed federal program to cover PrEP for people without insurance could provide significant benefit to potential PrEP users from these populations. However, coverage of PrEP costs alone will not end disparities in uptake. This commentary provides additional context and recommendations to maximize effectiveness of a national PrEP program for TGD, Black, and Latinx populations in the U.S.

60 Navigating the Intersection of PrEP and Medicaid
Naomi Seiler, Claire Heyison, Gregory Dwyer, Aaron Karacuschansky, Paige Organick-Lee, Alexis Osei, Helen Stoll, and Katie Horton

The proposed national PrEP program would serve people who are uninsured as well as those enrolled in Medicaid. In this article, the authors propose a set of recommendations for the proposed program's implementers as well as state Medicaid agencies and Medicaid managed care organizations to ensure PrEP access for people enrolled in Medicaid, addressing gaps without undermining the important role of the Medicaid program in covering and promoting PrEP.

64 Health Departments and PrEP: A Missed Opportunity for Public Health
Carri Comer and Ricardo Fernández

The paper identifies common barriers and challenges to Pre-Exposure Prophylaxis (PrEP) uptake and offers considerations for state and local public health departments to address barriers and retool infrastructure to increase access to PrEP to new users. The authors identify synergistic opportunities with federal agencies and funders to advance PrEP-related HIV prevention efforts that prioritize strategies and investments to provide PrEP to people who could benefit from the intervention but are unaware of PrEP or struggle to access it. Barriers discussed and examined include financing strategies to reduce financial burden of PrEP medication, expanding PrEP access and outreach beyond clinical settings, and increasing the network and reach of the provider community to serve people we oppress through policy choices and discourses of racial and socioeconomic inferiority.