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Investing in National HIV PrEP Preparedness

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The United States has failed to build and sustain public health infrastructure and rapid-response systems that can adequately reach vulnerable communities during public health crises.

Despite more than 40 years of responding to HIV and important breakthroughs in primary and secondary prevention, the rate of new infections is stuck at 35,000 per year, and racial disparities are worsening. Similar failures were apparent in the response to mpox last summer, with the most vulnerable communities once again bearing the brunt of a new viral threat. It is not too late to reverse course, but doing so will take political will and commitment. A new approach to accessing HIV preexposure prophylaxis (PrEP) could provide a blueprint for responding to other public health emergencies.

Over the past year and a half, health policy experts, community PrEP advocates, and health care service providers have laid the groundwork for scaling up innovative efforts in HIV prevention, as recommended by the Centers for Disease Control and Prevention (CDC). Advocates are calling for a program that empowers the federal government to secure fair public health prices for PrEP medications and related laboratory tests for uninsured persons; builds capacity throughout a PrEP-provider network, which encompasses clinical care providers as well as nonclinical community-based organizations and other partners that can reach people who aren't accessing traditional health care sites; and invests in community education efforts.

In July 2022, two of us and several other colleagues published a proposal for a national PrEP program, spearheaded by a group at Johns Hopkins; our article appeared alongside several others presenting expert analyses of approaches to equitable PrEP access.[1] An earlier version of our proposal was a key inspiration for the Biden administration's request in March for the "PrEP for All to End the HIV Epidemic" program as part of the fiscal year (FY) 2023 budget, which amplified advocacy that ultimately led Congress to call on the CDC to support PrEP uptake as part of the FY 2023 appropriations process. Building on the momentum of the President's request, the newly formed National PrEP Program Working Group, which consists of nearly 120 leading HIV/AIDS organizations, spent much of 2022 advocating for the immediate funding and implementation of such an initiative. In September, advocates held the "PrEP in Black America" summit, which contributed further expert recommendations for a truly effective national PrEP program.

The stage is set for innovative national PrEP access, but to make it happen, Congress and the administration would have to act. The limited funding allocated to the "Ending the HIV Epidemic in the U.S." initiative in the FY 2023 budget could be a first step toward building a national PrEP program for uninsured and underinsured people, but more action is needed.

We believe that federal negotiation of medication and laboratory-test prices for uninsured people would have to be central to a national PrEP program. For medications, the negotiation could start with generic tenofovir disoproxil fumarate–emtricitabine (TDF–FTC). The current list price of TDF–FTC is less than $20 per month, but programs that serve uninsured people are having difficulty consistently obtaining it at that price because of markups imposed by pharmacy benefit managers.[2] Moreover, generic PrEP is still woefully underutilized despite its excellent safety and efficacy profile, in part owing to a patchwork of inefficient and conflict-ridden coverage and drug-procurement systems that have been designed to give preference to higher-cost brand-name drugs. A national PrEP program could streamline access through one federal program and allow the federal government to negotiate a fair public health price with any generics manufacturer who wanted to participate. The program could then leverage willing pharmacies, using existing drug-procurement mechanisms that would allow pharmacies to be reimbursed for providing medications under the program. Generic TDF–FTC is not right for everyone, so a national PrEP program should eventually include negotiation of prices for brand-name drugs, including newer long-acting products that may increase adherence but are also expensive.

The problems with cost variability and unaffordability that we see with PrEP medications also apply to PrEP lab tests, whose prices vary considerably throughout the country and result in more than $1,000 in annual cash costs per person in many places.[3] A similar mechanism could allow federal negotiation of lab prices from participating commercial labs.

Only 25% of the 1.2 million people in the United States who would benefit from PrEP are actually using it. Though a national PrEP program would provide services only for those who are uninsured, that group accounts for a large proportion of the at-risk population. Advocates are calling for a $400 million investment to create a nationwide program, which could be scaled up over time. Expanding PrEP use in this way would avert new HIV infections and the high lifetime expenses that go with them, which the CDC estimates to be $501,000 per infection. Several studies have found that PrEP could be a cost-effective intervention if directed toward people at highest risk for HIV infection, but only if the cost of the drugs were set low enough.[4]

A national PrEP program would also have to invest in other direct services, including expansion of PrEP-provider networks and telehealth, and in creating demand and building awareness in key populations. Given its critical role, investment in these components could account for as much as half of a $400 million budget. Advocates for a national PrEP program recommend funding so-called hub-and-spoke delivery models within key geographic areas to connect experienced PrEP prescribers with nonclinical service providers using telehealth technologies, in order to dramatically expand the number of PrEP touchpoints for marginalized communities. Such expansion is essential for high-priority populations that cannot always access traditional pathways to preventive services owing to geographic, cultural, stigma-related, and other barriers. A hub-and-spoke model could build on existing efforts to educate clinicians about PrEP and integrate them into a larger state or local PrEP network.

At the same time, innovative national and locally tailored campaigns could inform communities about the availability of PrEP under the national program. Critically, they could reach out to vulnerable communities that have been largely neglected in national discussions about PrEP, such as Black cisgender women.

Without timely investment, growing disparities in PrEP access have the potential to leave historically marginalized communities perpetually behind in efforts to end the HIV epidemic. In 2021, Black people and Latinx people represented 14% and 17% of PrEP users, respectively, even though these groups accounted for 42% and 27% of new diagnoses, respectively, in 2020.[5] These extreme disparities in uptake lead to diverging epidemic trajectories: as the rate of new HIV infections declines in White communities, it stagnates in Black and Latinx communities. Nearly 10 years and 400,000 new infec-

tions after the Food and Drug Administration approved TDF–FTC as PrEP, we believe investment in an expert-driven, equitable national PrEP program is overdue.

A coherent, efficient response to PrEP could also guide the U.S. response to other public health crises that disproportionately affect marginalized communities. The discussion about a national PrEP program has already informed calls for a similar national program to address hepatitis C, another condition for which treatment access has been limited by the high prices of drugs and near-exclusive reliance on a patchwork of manufacturers' assistance programs for access by uninsured patients. Establishing a federal role in coverage of direct services and negotiation of public health prices for medications, diagnostics, and other key interventions could greatly facilitate an effective response to a reemergence of mpox, for example, or broadened availability of naloxone to avert opioid overdose deaths.

An audio interview with Jeremiah Johnson is available at NEJM.org

Ending the U.S. HIV epidemic requires systemic reforms that center health equity, efficiency, and innovative delivery models. We believe Congress and the Biden administration should support a national PrEP program to shift our federal public health paradigm in a way that improves responses to other health concerns, especially for marginalized communities.

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Health Care Reform and Equity for Undocumented Immigrants — When Crisis Meets Opportunity

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Reliable and equitable access to effective treatment for cancer and other serious medical conditions remains elusive in the United States. Although the Inflation Reduction Act is poised to lower prescription-drug prices for Medicare beneficiaries, basic, high-value medical care is still largely inaccessible to undocumented immigrants, who are categorically excluded from major forms of federal health insurance coverage under the Affordable Care Act.

As the United States faces the daunting task of economic recovery on the heels of a pandemic, and amidst high inflation rates, the dual challenges of health care reform and immigration reform are once again at the forefront of national policy debates. Over the past year, a record 2.4 million encounters have been reported at the U.S.–Mexico border, and at least 1 million people have been awaiting asylum since 2020. Recent state-of-emergency declarations in Illinois and New York City highlight the inability of public systems to accommodate the needs of a rapidly growing immigrant population. As U.S. officials contend with this impending humanitarian crisis, they must also consider its implications for domestic policy — including the potential need for expansion of the public health insurance system to narrow gaps in health care.

Of the 20.8 million noncitizens living in the United States in 2021, approximately 25% of nonelderly lawfully present residents and 46% of nonelderly undocumented immigrants were uninsured.[1] With the exception of refugees and asylees — who are eligible for Medicaid or other forms of public insurance coverage on arrival in the United States — immigrants who are