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# The Ending the HIV Epidemic in the U.S. Initiative

*An Interim Assessment and Policy Recommendations*

## AUTHORS

Jeffrey L. Sturchio  
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A report of the CSIS Global Health Policy Center

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CENTER FOR STRATEGIC &  
INTERNATIONAL STUDIES

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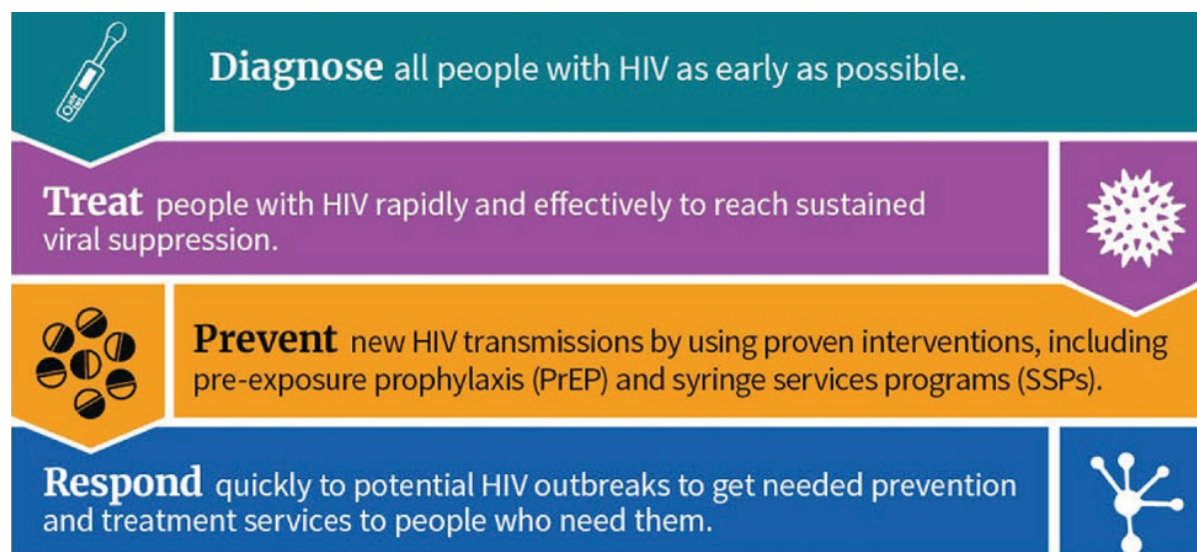
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# Introduction

The Ending the HIV Epidemic in the U.S. (EHE) initiative is a promising federal program launched by the U.S. Department of Health and Human Services (HHS) in February 2019 with the aim of reducing new HIV infections by 75 percent by 2025 and 90 percent by 2030 (from a baseline of more than 38,000 new diagnoses in 2017).<sup>2</sup> The roadmap for achieving the outlined goals of the EHE is based on four pillars: diagnose, treat, prevent, and respond (Figure 1).

Figure 1: EHE Pillars



Source: "What is the Ending the HIV Epidemic in the U.S. Initiative?" America's HIV Epidemic Analysis Dashboard, U.S. Department of Health and Human Services, <https://ahead.hiv.gov/about-ehe>.

While the EHE initiative set ambitious targets for ending the HIV epidemic in the United States in the context of a sound and sensible plan, it is at present off track. Now, three years in—at the midpoint of the first EHE phase, which has a target of reducing new HIV infections to 9,250 people or fewer by 2025—is an opportune moment to assess its status and the challenges it faces. After a review of progress to date, this report examines the collision between the logical plan behind the EHE initiative and the complicated patchwork of programs that provide HIV prevention, care, and treatment to the diverse communities affected across all EHE jurisdictions. The analysis is informed by several roundtable discussions convened by CSIS with the participation of a representative group of people living with HIV/AIDS (PLWHA), community advocates, physicians, service providers, researchers, and policymakers who are implementing the EHE initiative around the country.

The report concludes with policy recommendations in four areas: (1) meet people where they are by building programs that are centered on the needs of populations directly affected by the HIV epidemic; (2) address flexibility in design and implementation; (3) improve data, metrics, and accountability; and (4) heighten political advocacy to ensure future funding of the EHE initiative. A strong theme that runs throughout the report is that lessons from the global HIV response—the importance of building interventions from the ground up, of engaging with affected communities, and of taking an integrated approach across a spectrum of biomedical, clinical, social, behavioral, economic, and political dimensions—can inform and strengthen the U.S. domestic response to HIV/AIDS.

# Background

Organized on the four pillars of diagnose, treat, prevent, and respond, the EHE initiative is designed to address the health inequities based on geographic, racial, ethnic, and economic disparities that have persisted for far too long in the fight against HIV/AIDS. In announcing the new plan, Anthony S. Fauci, director of the National Institute of Allergy and Infectious Diseases at the U.S. National Institutes of Health (NIH); Robert R. Redfield, then director of the U.S. Centers for Disease Control and Prevention (CDC); Brett P. Giroir, then assistant secretary for health at the HHS; and their colleagues pointed to the opportunities now emerging from advances in research on both treatment and prevention of HIV infection. Powerful and well-tolerated new antiretroviral treatments make it possible for people properly treated and adherent to these regimens to live healthy lives and, if their viral load remains undetectable, to avoid transmitting HIV infection to others. In addition, HIV pre-exposure prophylaxis (PrEP) has also proved to be highly effective in preventing infection in at-risk individuals. “Collectively,” they wrote, “these advances suggest that, theoretically, the HIV epidemic in this country could be ended quickly by expanding access to treatment to all persons with HIV and PrEP to all those at high risk.” In particular, they pointed to the asymmetrical character of the HIV epidemic in the United States: “Demographic and geographic hotspots of HIV infection need a particular focus to interrupt or disrupt the kinetics of HIV spread in the United States.”<sup>3</sup>

Accordingly, the EHE initiative began with three proposed phases, the first one focusing on 57 jurisdictions.<sup>4</sup> This includes 48 counties plus San Juan, Puerto Rico, and Washington, D.C., which together account for more than half of new HIV diagnoses in the United States, and an additional seven states with a substantial rural HIV burden (Figure 2).



A map of the United States showing the distribution of priority states and priority counties. The map uses a color-coded system to highlight specific areas.

**Legend:**

- Priority U.S. counties, Washington, D.C., and San Juan, Puerto Rico
- Priority states

**Priority States (Light Blue):** The map shows several states highlighted in light blue, including California, Nevada, Arizona, Texas, Oklahoma, Kansas, Nebraska, Minnesota, Wisconsin, Illinois, Indiana, Michigan, Ohio, Pennsylvania, New York, Vermont, New Hampshire, Maine, Connecticut, Rhode Island, Massachusetts, New Jersey, Delaware, Maryland, Virginia, North Carolina, South Carolina, Georgia, Florida, Alabama, Mississippi, Louisiana, Arkansas, Missouri, Iowa, and Wisconsin.

**Priority Counties (Dark Blue):** The map shows numerous counties highlighted in dark blue, including counties in California, Nevada, Arizona, Texas, Oklahoma, Kansas, Nebraska, Minnesota, Wisconsin, Illinois, Indiana, Michigan, Ohio, Pennsylvania, New York, Vermont, New Hampshire, Maine, Connecticut, Rhode Island, Massachusetts, New Jersey, Delaware, Maryland, Virginia, North Carolina, South Carolina, Georgia, Florida, Alabama, Mississippi, Louisiana, Arkansas, Missouri, Iowa, and Wisconsin.

These high-priority jurisdictions were chosen using 2016 and 2017 data, targeting the regions that had the highest number of HIV diagnoses in those two years.<sup>5</sup> The second phase is slated to begin in 2026, when the initiative aims to have reduced new HIV infections by 75 percent, with a focus on expanding local and federal efforts to address prevention, treatment, and care for HIV across the United States. Phase III would ultimately provide intensive case management to keep the number of new transmissions below 3,000 per year. Since the announcement of the initial parameters of the initiative, the Biden administration has shifted its efforts from defined phases to focus instead on those areas of the country with the greatest need.

#### 4 | The Ending the HIV Epidemic in the U.S. Initiative

Partnerships are envisioned as central to the EHE initiative. As Brett Giroir noted in an early report in the *American Journal of Public Health*:

The initiative will include close partnerships with local entities—including city, county, tribal, and state public health departments; local and regional clinics and health care facilities; clinicians and providers of medication-assisted treatment of opioid use disorder; professional associations; advocates, and community- and faith-based organizations; and academic and research institutions—to develop or enhance jurisdictional-specific plans for ending the HIV epidemic.<sup>6</sup>

As Giroir rightly observed:

Different strategies will be needed in different communities. No one plan will work across every jurisdiction, and that is why this effort is so unique. Our funding and technical support will enable communities to develop and implement a plan that best fits their local needs. . . . This initiative should not be viewed solely as a federal effort or a state effort, but as a ‘whole of society’ collaborative effort.<sup>7</sup>

The EHE initiative is unusual—with respect to both its ambition and its emphasis from the start on health equity and on building community engagement—and has shown continued promise and resilience. The EHE initiative was also unexpected, arising as it did during the Trump administration, at a time when policies such as the Public Charge Final Rule, anti-immigrant crackdowns, decisions to permit discrimination against transgender people in healthcare settings, and workplace bias against LGBTQ+ people jeopardized access to HIV care and treatment and increased distrust of federal authorities in the LGBTQ+ community.<sup>8</sup> But the EHE initiative built on earlier efforts by community groups and advocacy organizations in cities such as Boston, New York, Seattle, and San Francisco and gained credibility both for these grassroots beginnings and for the expertise and standing of its early leaders, including Fauci, Redfield, and Giroir, who created a national initiative on these foundations.<sup>9</sup> It has had bipartisan support from the outset.

The Biden administration incorporated the EHE initiative into its renewed National HIV/AIDS Strategy (NHAS) for 2022–25 and has continued to support its goals.<sup>10</sup> The two are closely aligned and complementary, with the EHE initiative serving as a leading component of the work by HHS, in collaboration with local, state, tribal, federal, and community partners, to achieve the NHAS goals. The EHE initiative focuses on scaling up the four pillars in the communities most affected by HIV/AIDS. The NHAS is broader, covering the entire country and spanning federal departments, agencies, and beyond to all sectors of society—integrating several key components that are vital to the collective work of the domestic HIV response, including addressing stigma, discrimination, and other social determinants of health.

# Status of the EHE Initiative

In its first few years, the budget for the EHE initiative lagged behind the program's ambitions. In fiscal year (FY) 2019, roughly \$35 million was made available by reprogramming existing appropriations to jumpstart the initiative. Among the priority jurisdictions, major grants were made to DeKalb County, GA; East Baton Rouge Parish, LA; Baltimore City, MD; and the Cherokee Nation in Oklahoma, along with over 30 additional grants to other jurisdictions. FY 2020 brought an additional \$267 million in a new congressional appropriation, which increased to \$404.75 million in FY 2021 and \$473.25 million in FY 2022.<sup>11</sup> Most of the funds were allocated through the CDC and HRSA to primary HIV-prevention programs in the priority jurisdictions. Although these additional funds enabled those jurisdictions to expand their services to people living with or at risk for HIV, total EHE funding was always less than the administration requested and a small proportion of total federal funding for HIV/AIDS programs. The administration's FY 2023 request is for \$850 million, a \$377 million increase over the FY 2022 enacted level (an additional 80 percent).<sup>12</sup>

Although FY 2023 appropriations are not yet agreed, on June 22, 2022, the House Committee on Appropriations issued its funding bill for Labor, Health and Human Services, Education, and Related Agencies.<sup>13</sup> This bill included a total of \$422 million for the EHE initiative via HRSA (\$172 million for health centers and \$250 million for the Ryan White HIV/AIDS Program, increases of \$50 million and \$125 million, respectively, over the FY 2022 enacted levels) and \$245 million via the CDC (an increase of \$50 million over the FY 2022 enacted level). The Senate's Labor-HHS-Education appropriations bill included similar increase for the EHE initiative (with slightly more for RWHAP and the CDC).<sup>14</sup> These increases are an encouraging sign that Congress continues to support the initiative—but they are still modest compared to the scale of the need to achieve its ambitious goals.

Results to date for the EHE initiative are summarized in Table 1, drawn from the core indicators data reported by the CDC for 2019 and some preliminary data for 2021. These results reflect a complex mix of new and expanded programs across the 57 priority jurisdictions. Some jurisdictions have been able to build upon strong programs already in place, while others are just beginning to build out their response. As noted above, the first wave of funding targeted just a few places, and it took time for many jurisdictions to develop or refine plans, write proposals, and allocate funds to new programs. Much of the money has flowed through existing CDC and HRSA infrastructure, which enabled early wins.

For instance, from March 2020 to December 2020, HRSA distributed \$63 million to 47 RWHAP Part A and Part B recipients in the EHE jurisdictions, together with grants to two technical-assistance providers and 11 RWHAP AIDS Education and Training Centers. Together, these organizations served 19,500 people who were newly diagnosed or recently reengaged in HIV care and treatment, exceeding original estimates that they would reach 18,000 people.<sup>15</sup> This is a remarkable achievement at a time when health workers were being diverted to Covid-19 care. Through HRSA's Bureau of Primary Health Care (BPHC) health center programs, over 389,000 patients received PrEP or PrEP-associated services. Additionally, 2.5 million clients received HIV tests, which was an increase of almost one million from the previous period.<sup>16</sup>

Table 1: EHE Indicator Data

Indicator	2017	2019	2021 (preliminary)	2025 goal	2030 goal
Incidence	37,000	34,800	–	9,250	3,700
Knowledge of status	85.8%	86.7%	–	95%	95%
Diagnoses	38,351	36,528	31,231	9,588	3,835
Linkage to HIV medical care	77.8%	81.3%	83.4%	95.0%	95.0%
Viral suppression	63.1%	65.5%	–	95.0%	95.0%
PrEP coverage	13.2%	22.5%	26.1%	50.0%	50.0%

Incidence: estimated number of new HIV infections nationwide

Knowledge of status: percentage of people aware of their HIV status nationwide

Diagnoses: number of people diagnosed with HIV for a given year nationwide

linkage to HIV medical care: percentage of people nationwide living with diagnosed HIV who have an amount of HIV less than 200 copies/ml of blood

PrEP coverage: percentage of people with indications of prep classified as having been prescribed PrEP nationwide

Note: Data for all 50 states with a focus on 57 priority areas. Data for 2021 are preliminary and may change.

Source: “National Progress,” EHE Dashboard, America’s HIV Epidemic Analysis Dashboard (AHEAD), accessed August 26, 2022, <https://ahead.hiv.gov>.

While all indicators are moving in the right direction, the pace of change appears to be too slow to reach the goals established for 2025 and 2030. (Modeling studies show that the lack of adequate funding for the EHE initiative helps explain why the 2025 and 2030 goals may be out of reach, as discussed in the “financing”

section below.) For instance, at the current rate, new HIV infections nationwide would still be around 30,000 in 2025, not the targeted 9,250. The situation appears to be similar for other core indicators—some improvement in knowledge of HIV status, linkage to HIV medical care, and viral suppression, but not at rates sufficient to meet the EHE goals. HIV diagnoses appear to be declining more rapidly (a decrease of 14 percent between 2019 and 2021), but this is likely to be due more to disruptions in HIV testing and diagnosis for people who were avoiding testing to comply with guidance on Covid-19 social distancing than to a decline in the overall rate of new HIV infection. Furthermore, the CDC reported sharp declines in HIV testing and other services between 2019 and 2020, which had an adverse impact on efforts to expand the EHE initiative.<sup>17</sup> Finally, PrEP coverage has remained more or less flat, with only around one in five people indicated for PrEP having begun this preventive regimen.



# Challenges and Opportunities for the EHE Initiative

The EHE initiative is designed to expand and improve upon the U.S. domestic response to the HIV epidemic, with an emphasis on health equity. After decades of programmatic interventions, featuring an ever-increasing and more effective array of biomedical tools, the benefits of HIV prevention and treatment efforts are still not available to everyone.<sup>18</sup> For instance, the prevalence of HIV infection among men who have sex with men (MSM) and transgender women is estimated to be 150 times that of heterosexual men and women. And HIV incidence in 2015 was 8 times higher among African-Americans and 3 times higher among Hispanic/Latinx individuals than among white people.<sup>19</sup> The EHE plan, as outlined above, was intended to address the needs of key populations (MSM, adolescent girls and young women, people who inject drugs, transgender individuals, and other vulnerable groups) by building programs with community input, providing flexibility to states and communities in how to use new federal funds, and using mandatory funding to try to improve national rates of PrEP coverage. In addition, the EHE initiative aimed to take into account not just biomedical dimensions of the HIV epidemic, but also the social, economic, and behavioral determinants of health that lead to persistent inequalities in access to care and treatment. These determinants include structural racism, poverty, stigma and discrimination, homelessness and housing insecurity, food insecurity, lack of access to transportation, lack of access to health insurance, and substance use and mental health disorders.

Translating this comprehensive strategy into reality has proved difficult since the EHE initiative got under way just as the coronavirus pandemic swept the United States. The same healthcare institutions, community organizations, government agencies, and healthcare workers that are dedicated to addressing the needs of people living with and at risk of HIV infection found themselves inundated with the acute Covid-19 crisis. The stresses and strains that Covid-19 has created in the U.S. healthcare system simply exacerbated underlying patterns of health disparities, with a disproportionate impact

on the same communities of color and vulnerable populations that had already been affected by the HIV epidemic. In a fascinating and powerful analysis, Greg Millett of amfAR, the Foundation for AIDS Research, showed how the Covid-19 and HIV responses are interrelated due to the same underlying pathways through which they affect communities of color across the United States. “For EHE to be successful and sustainable in racial and ethnic communities at greater risk of HIV,” he concludes, “we must address the structural issues at the root of HIV and other health disparities.”<sup>20</sup>

As Millett makes clear, business as usual will not get the United States to its EHE goals. What are some of the salient challenges that the EHE initiative faces now, and where will the necessary innovations be found to meet them? The series of roundtable discussions that CSIS hosted among PLWHA, community advocates, healthcare workers, service providers, and policymakers (including—from West to East—representatives from California, Texas, Louisiana, Mississippi, Alabama, Georgia, North Carolina, Virginia, the District of Columbia, and Massachusetts) offered important insights on both the challenges and opportunities. These observations are summarized below under the following categories: data and design; structural barriers to HIV prevention, care, and treatment; community engagement; implementation; financing; and metrics and accountability, followed by case studies of innovation using EHE funding at the community level that hold special promise for replication and scale-up.

## Data and Design

The jurisdictions chosen for the EHE initiative were based on 2016 and 2017 data, but the HIV epidemic continues to evolve in a dynamic way. This has led to challenges with pivoting to address outbreaks outside these jurisdictions. For example, the CDC reported an outbreak of HIV infection among a population of people who inject drugs in Kanawha County, WV, in 2019–21, which was due in part to sharing syringes when syringe-exchange programs closed, and the outbreak was exacerbated due to medical mistrust based on experiences of stigma and discrimination. This cluster of HIV infections also shows how the HIV epidemic interacts with the Covid-19 pandemic and the widespread incidence of substance use disorders. Local public health practitioners mobilized to address the outbreak, but because West Virginia is not a Phase I EHE jurisdiction, they had to do so without the benefit of any associated resources.<sup>21</sup> This raises the question of whether and when additional jurisdictions will receive EHE support in Phase II (and whether there should be funds earmarked for outbreak response before then) so that the initiative can follow the changing dynamics of the HIV epidemic in the United States.

The latest systematic data available for the EHE initiative overall are from 2019. Delays in providing updates are likely due in part to the impact of Covid-19 on data-collection processes for 2020 and 2021, but the lack of more robust data resources make it difficult for EHE jurisdictions to plan effectively and adjust their programs to make sure they are achieving optimum impact. In addition, two other issues came up in the CSIS roundtable discussions: (1) the need for better disaggregated data about minority populations and other vulnerable groups (including transgender individuals); and (2) the importance of avoiding imposing additional reporting burdens on jurisdictions when different federal entities require different metrics for projects that blend funds in an integrated implementation.

## Structural Barriers to HIV Prevention, Care, and Treatment

As Greg Millett and others have demonstrated, structural racism and other barriers to HIV prevention, care, and treatment are creating systemic barriers to equitable access for populations at risk in many

areas of the United States. These structural barriers came up again and again in the CSIS discussions. For example, some states still have laws on the books that criminalize HIV infection, which—by reinforcing stigma and discrimination, as well as homophobia—make it difficult for people to access available resources for HIV treatment and care or to protect themselves against infection by obtaining PrEP.<sup>22</sup> In some jurisdictions, immigration status becomes a barrier to obtaining prevention, care, and treatment because of fear that health workers may be required to inform authorities about the status of their clients.

Despite the passage of the Affordable Care Act in 2010, the United States still has a bewilderingly complex landscape of payers, providers, and financing mechanisms for insurance coverage, creating a decidedly unlevel playing field for people living with HIV.<sup>23</sup> Insurance regulations vary from jurisdiction to jurisdiction, and a number of those given priority by EHE are in states that opted out of Medicaid expansion, which leads to further misalignment of policies and makes it difficult for people to gain access to resources that should be available to help them. For example, while PrEP may be theoretically available in clinics, in some jurisdictions prior authorization requirements make it much more difficult for people to obtain access. Kathleen McManus and colleagues have documented up to a 16-fold difference in such requirements by region, with the South—the region with the lowest PrEP uptake and the slowest growth in PrEP uptake—disproportionately affected.<sup>24</sup> Rather than making PrEP and, more recently, long-acting antiretroviral medications easier to get, bureaucratic hurdles (such as discriminatory benefit designs for formularies on insurance policies or other onerous administrative requirements for enrollment) may hinder uptake.

## Community Engagement

There is a strong consensus that although the EHE initiative contemplated stakeholder engagement at the community level, the reality of rollout has not always met expectations. First, there is a continuing need for training in cultural competency by health workers at all levels—physicians, nurses, community health workers, case managers, and any client-facing staff—to ensure that their interactions with people living with and at risk of HIV infection do not reflect racism, gender or ethnic stereotypes, or unconscious biases that perpetuate stigma and discrimination as well as racial, ethnic, and gender disparities in HIV prevention, care, and treatment.<sup>25</sup> An important corollary to this point is the need to ensure that representatives of key populations are very much engaged in planning, communicating, and implementing HIV responses at the community, state, tribal, and federal levels.

Second, there are still too many cases where the best intentions of those planning programs conflict with obvious and overlooked needs—for instance, the scarcity of interpreters or translated documentation in monolingual communities who speak languages other than English, or of adequate numbers of community health workers to help potential clients of EHE programs navigate the fragmented network of healthcare institutions to obtain services successfully and sustainably. In other instances noted by people engaged on the front lines of implementing EHE programs, community engagement may have been planned—with community advisory boards and committee membership, for instance—but there has been a lack of continued engagement or follow-through as programs were implemented. As a result, communities often feel shut out of decisionmaking, which has had the unintended consequence of driving people away from available services rather than encouraging them to take advantage of them. Finally, there is an

opportunity to engage private providers, along with other stakeholders, in planning to implement the EHE mission and activities; not to do so would be missing a key cohort with the expertise and resources to help achieve EHE goals at the local level.

## Implementation

The examples of successful implementation practices that participants shared in the CSIS EHE roundtable discussions ranged widely, with several common threads. First, there is a recognition that different EHE jurisdictions come from different starting points (e.g., those with Medicaid expansion funds versus those without) and that there is a continuing need to integrate HIV/AIDS services with the Covid-19 response since this has obvious implications for the deployment and availability of the healthcare workforce. A related issue is that the lack of public health funding in many jurisdictions has exacerbated provider fatigue from dealing with a succession of epidemics and pandemics—HIV/AIDS, other sexually transmitted infections, Covid-19, and now monkeypox. EHE implementation plans should have specific action steps for addressing structural barriers and access issues for HIV prevention, care, and treatment so that progress can be measured and shared across the initiative. There is also consensus that more could be done to disseminate the HRSA Best Practices Compilation across all EHE jurisdictions to encourage learning by doing.<sup>26</sup> There is considerable interest in making better use of telemedicine, at-home testing, and virtual online pharmacies as ways to reach people who might not be willing—or able—to come to the clinic physically (see the “tele-PrEP” section below).

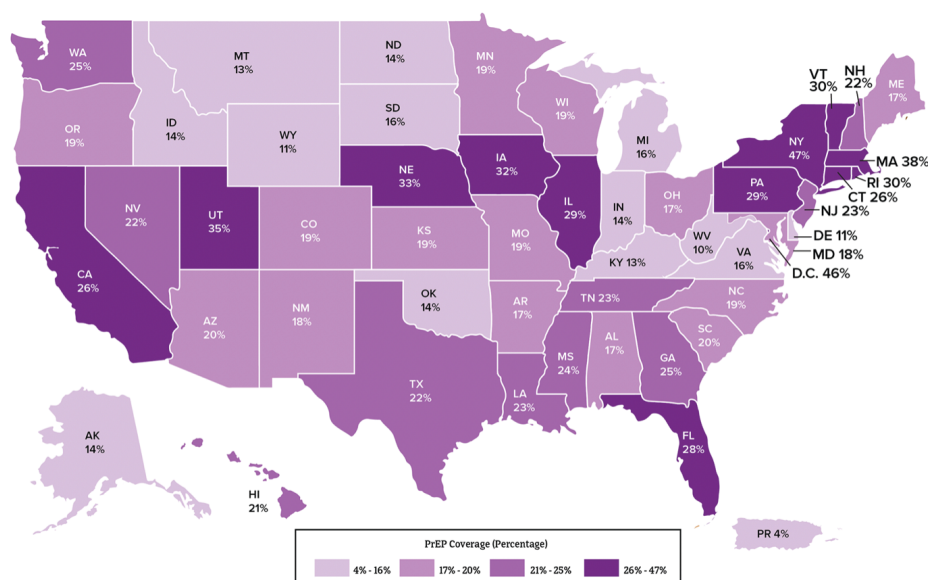
The two most important observations are that it is imperative to focus on keeping people in HIV care, not just making PrEP available and initiating treatment, to achieve long-term improvement of population health. And the best way to do this, as representatives from East Baton Rouge Parish in Louisiana emphasized, is to have “boots on the ground.” That is, to have an adequate number of trained and properly resourced community health workers who can extend the reach of the clinic and maintain engagement with the patient population.

## Financing

While the early results of the EHE initiative are encouraging, how likely is it that the 2025 and 2030 goals of the program will be met if the current approaches and resources are maintained? Evin Jacobson and colleagues at the CDC and RTI Health Solutions have looked at this question by modeling different scenarios that optimized or reallocated funding (including new EHE funding) among various interventions (including HIV testing for different population groups, HIV care continuum interventions, PrEP, and syringe-services programs) to minimize new infections and analyzing the projected impact from 2021–30. The good news is they found an increase in resources alone could lead to an 80 percent decrease in the annual incidence of HIV infections within 10 years. The bad news is the level of new resource commitments is already lagging behind the level assumed in their analysis (\$500 million per year for 2021–22, \$1.5 billion per year for 2023–25, and \$2.5 billion per year for 2026–30). As noted above, the FY 2023 appropriation of \$850 million is less than 60 percent of the projected amount needed for next year. While President Joe Biden’s FY 2023 budget request and the House Appropriations Committee’s action on June 22, 2022, are important steps in the right direction, Jacobson’s analysis suggests that without stepped-up levels of funding in future years and optimization of those resources to prevention services, it is unlikely the EHE initiative will reach its targets on HIV incidence in 2025 and 2030.<sup>27</sup>

Another financing challenge for EHE comes from existing regulations that provide “perverse incentives” to use available resources in ways that limit how many people in need are reached. The first oral HIV medication for PrEP was authorized by the Food and Drug Administration (FDA) a decade ago, yet the national coverage of PrEP is only 23.4 percent, ranging from 10.2 percent in Idaho to 50.0 percent in New York (Figure 3). Only 15 states, most of them clustered in the Northeast, exceed the national average. What is the cause of this patchwork of different policies and degrees of access to PrEP?<sup>28</sup> As noted above, the United States has a complicated mix of private and public sources of coverage and financing for HIV care and treatment, with a significant number of affected individuals still uninsured or underinsured. One attempt to plug some of the holes in this coverage net is the 340B Drug Pricing Program, which requires pharmaceutical companies to sell drugs at a highly discounted rate to entities that see many low-income or uninsured patients.<sup>29</sup> These entities are then reimbursed by insurance providers for an amount often closer to the list price of the medication, which provides them extra income that can then be reinvested in their programs. This aids many clinics and hospitals, buoying their finances. However, an unintended consequence of the 340B program was the creation of perverse incentives that push providers to prefer high-cost drugs, as the reimbursement is higher the more expensive a drug is. This has caused many entities to prioritize more expensive PrEP options rather than low-cost generics.<sup>30</sup> At the same time, some analysts argue, healthcare providers ineligible for the 340B program struggle to finance the full array of PrEP services for uninsured patients. This leads to widespread disparities in access to PrEP, illustrated in Figure 3. These disparities will only be exacerbated as long-acting injectable PrEP medicines such as cabotegravir become available, with a list price for injections about 87 times the cost of generic oral PrEP.<sup>31</sup>

Figure 3: PrEP Coverage in the United States and Puerto Rico



Data for 2020 should be interpreted with caution due to the impact of the COVID-19 pandemic on access to HIV testing, care-related services, and case surveillance activities in state and local jurisdictions.

Source: “PrEP Coverage,” CDC, accessed September 20, 2022, <https://www.cdc.gov/hiv/statistics/overview/in-us/prep-coverage.html>.



## Metrics and Accountability

The EHE initiative has striven to be as transparent as possible with data on the six core indicators (HIV incidence, HIV diagnoses, knowledge of HIV status, linkage to care, viral suppression, and PrEP coverage). Anyone interested can review and download the data in both aggregated and disaggregated form. These data derive from extensive reports from the CDC, HRSA, and other agencies at the federal, state, tribal, and local levels.<sup>32</sup>

There are also helpful discussions of the methods used to collect the data and their limitations, especially regarding transgender individuals. As the CDC notes, “In May 2013, CDC issued guidance to state and local programs on methods for collecting data on transgender persons and working with transgender-specific data. Information on gender identity is still not consistently collected or documented in the data sources used by HIV surveillance reporting jurisdictions. Thus, HIV data by gender remain limited.”<sup>33</sup> This is a data gap that should be addressed.

The other major limitation of the EHE data is that it focuses on a standard set of HIV-related indicators. Critics have pointed out that there are other dimensions of the HIV epidemic in the United States that will also affect the success and sustainability of the EHE initiative. These include such factors as policy and legislation, socioeconomic metrics, service availability, and overlapping epidemics and social determinants of health (e.g., HIV, Covid-19, substance use disorders, and mental health, along with well-being and quality of life). As Jennifer Kates and colleagues observe, “The EHE-targeted areas represent a diverse set of geographies that, in addition to being hard hit by HIV, face other barriers and challenges that could affect the implementation and reach of the initiative. These go beyond the standard HIV-specific measures the government will use to assess the EHE yet are integral to its success.”<sup>34</sup>

# Innovations in EHE: Learning from the Front Lines

Three interesting and innovative approaches to addressing the needs of key communities living with and at risk of HIV infection present models the EHE initiative could incorporate to adjust its priorities and programs in the months and years ahead to optimize its impact and increase the prospects of achieving its overall goals. These case studies are illustrative, not comprehensive, but they show the range of innovations that is happening among jurisdictions currently engaged in EHE implementation.

## Financial Incentives for HIV Prevention and Care in East Baton Rouge Parish

Providing financial incentives to encourage health behavior change has been met with varied success and remains controversial among the health community for ethical and sustainability reasons. However, there have been documented successes with using financial incentives in targeted formats to increase viral suppression of HIV-positive patients, especially in some of the most at-risk and vulnerable groups. In a study led by Wafaa El-Sadr published in *JAMA Internal Medicine*, financial incentives were found to have significantly increased viral suppression (by 3.8 percent) among people with HIV compared to among people with HIV receiving care with no financial incentives.<sup>35</sup> Despite this success, the same study showed that financial incentives did not have a statistically significant impact on linkage to care for people with HIV. Therefore, financial incentives for HIV prevention and care need to be implemented in a strategic manner with the sole purpose of increasing viral suppression among targeted populations. The success of financial incentives cannot be extrapolated and used for other purposes within HIV prevention and care. This is an area for continued research on how financial incentives can be used appropriately in an evidence-based way to help reach EHE goals.

The use of financial incentives has been an integral part of the EHE initiative in East Baton Rouge Parish in Louisiana. This locale was chosen as an EHE jurisdiction due to a high concentration of new HIV diagnoses: The rate of people living with HIV is three times the national average.<sup>36</sup> East Baton Rouge Parish has unique demographics of people living with HIV. Overall, 37 percent of people living with HIV in the parish are women. Black people make up a majority of the new HIV diagnoses (84 percent), new AIDS diagnoses (89 percent), and total persons living with HIV (86 percent), despite only accounting for 47 percent of the parish population. Additionally, heterosexual individuals comprise a significantly larger proportion of new HIV diagnoses and PLWHA than in other regions in Louisiana, with 41 percent of new HIV diagnoses being among heterosexual individuals in 2019.<sup>37</sup>

In the EHE five-year plan for East Baton Rouge Parish, financial incentives are built into the second pillar (treatment) as part of efforts to reach some of these at-risk populations.<sup>38</sup> As seen in El-Sadr's study, these incentives aim to keep patients in care and maintain viral suppression. Clients receive monetary benefits in the form of reloadable gift cards when they (1) achieve viral suppression, (2) maintain viral suppression, (3) adhere to medical and laboratory appointments, and (4) attend referral appointments recommended by the health workers. In an analysis of the Health Models program piloted by the Louisiana Department of Health, which uses this incentive structure, the share of enrolled patients who were virally suppressed increased from 57.7 percent to 82.7 percent after 12 months. Additionally, the rate of engagement in care across the program was at least 90 percent between the first 12 and 24 months of enrollment.<sup>39</sup>

While there is evidence demonstrating the beneficial use of incentives for HIV prevention, questions have also been raised about the long-term sustainability of incentive programs, both in terms of being able to continuously fund them and whether the intended behavior changes are short-lived or indicate long-term health behavior modifications. In a qualitative case study looking at the use of incentives for people at risk of or living with HIV in British Columbia, Canada, the definition of success was unclear.<sup>40</sup> While the incentives brought "people through the door," they failed to address the social and structural barriers that inhibited HIV prevention within the most at-risk populations, therefore providing "superficial, short-lived and one-dimensional" outcomes. If financial incentives are to be implemented across all EHE jurisdictions, they should be paired with social and behavioral change campaigns, shifting the incentive from a transactional intervention to a transformational one.<sup>41</sup> While financial incentives alone will not address the structural and social barriers to HIV prevention and care, when used at the community level in cases like East Baton Rouge Parish, they can be a powerful tool to increase viral suppression among at-risk populations.

## **Meeting PLWHA Where They Are: Ward 86's POP-UP Initiative in San Francisco**

A cornerstone of HIV prevention and care is meeting at-risk communities and PLWHA where they are, both geographically and in their treatment methods. One innovative approach toward providing HIV care for PLWHA who are experiencing homelessness or unstable housing came out of Ward 86 at the San Francisco General Hospital, which was the first HIV/AIDS specialized clinic in the world and has subsequently been at the forefront of HIV/AIDS care and research.<sup>42</sup>

This specialized initiative, known as POP-UP (Positive-health On-site Program for Unstably-housed Populations), is a low-threshold model of comprehensive care that allows patients to have drop-in visits without scheduled appointments, includes financial incentives, and provides increased outreach

to help patients obtain access to care, apply for Medicaid, and make appointments.<sup>43</sup> The POP-UP team includes not just physicians and nurse practitioners who are HIV specialists, but also a pharmacist, a pharmacy technician, a social worker, and a linkage-to-care navigator. Through POP-UP, patients can obtain access to same-day antiretroviral-therapy reactivation, substance use treatment and counseling, and comprehensive primary care. This one-stop-shop for PLWHA who are experiencing homelessness or unstable housing significantly reduces barriers to care and viral suppression.

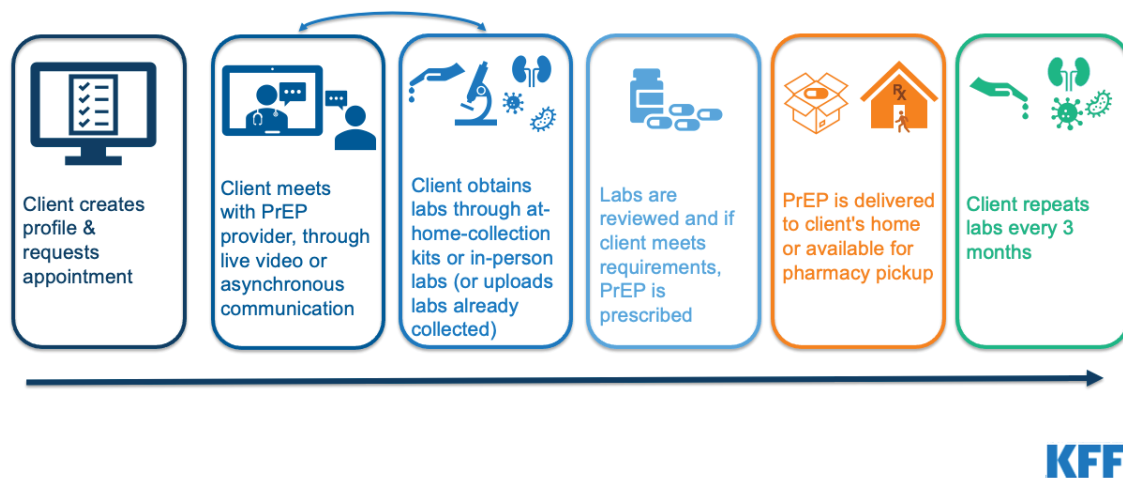
The POP-UP initiative had great initial success that continued after the onset of the Covid-19 pandemic, which further worsened HIV outcomes for PLWHA experiencing homelessness or unstable housing. In 2018, 33 percent of PLWHA experiencing homelessness or unstable housing in San Francisco were virally suppressed, compared to 75 percent of housed PLWHA in the city. However, out of 75 eligible patients enrolled in the POP-UP program at its outset, more than three-quarters restarted antiretroviral therapy within a week of enrollment and 91 percent returned for follow-up consultations within 90 days. After six months, the cumulative incidence of viral suppression was 55 percent, much higher than the San Francisco average among PLWHA experiencing homelessness or unstable housing.<sup>44</sup> Another study found that for the 112 patients subsequently enrolled in POP-UP—individuals living with overlapping barriers to HIV care engagement, including homelessness/unstable housing, substance use disorders, and mental health diagnoses—the share who achieved viral suppression improved from 0 to 44 percent after 12 months.<sup>45</sup> When the Covid-19 pandemic placed even more barriers on access to medical care, housing resources, and social services due to prolonged shutdowns and shelter-in-place orders, the POP-UP clinic continued to provide in-person low-threshold care to this at-risk population even as telehealth began to replace face-to-face care.<sup>46</sup> Lessons from Ward 86's POP-UP initiative should be scaled up across other EHE jurisdictions, pairing low-threshold comprehensive care with related social services and financial incentives informed by the target population's needs.

## Tele-PrEP

One of the most interesting new developments in administering PrEP has been the advent of using telehealth to extend the reach of PrEP programs. A recent analysis by Lindsey Dawson, Brittni Frederiksen, and Ivette Gomez of the Kaiser Family Foundation examines the variety and extent of such “tele-PrEP” programs in the United States.<sup>47</sup> They surveyed 12 tele-PrEP providers in four categories: (1) national telehealth companies, some of which focused primarily on PrEP; (2) tele-PrEP programs located within clinics or hospital systems; (3) state-run tele-PrEP programs in California and Iowa; and (4) a laboratory company that, among other services, provides most major tele-PrEP companies with home collection kits and lab services. In some cases, the tele-PrEP services began before Covid-19 but were accelerated by the disruptions in healthcare services during the pandemic, when people were not able to visit clinics in person. The typical steps for people to obtain PrEP via one of these telehealth programs is depicted schematically in Figure 4.

Tele-PrEP is one method to expand uptake of PrEP significantly, though it would need to overcome certain potential problems. For instance, rules on insurance coverage for associated laboratory services or multi-month dispensing of antiretrovirals should be aligned to support tele-PrEP. Introducing multi-state licensing of telehealth practitioners to enable them to provide PrEP services in multiple jurisdictions would also be an important enabling policy change. As Dawson and her colleagues report, the active experimentation with tele-PrEP is likely to solve these problems, and this practice has the potential to expand PrEP services within the EHE initiative significantly.<sup>48</sup>

Figure 4: Typical Process for Accessing Tele-PrEP



Source: Lindsey Dawson, Brittini Frederiksen, and Ivette Gomez, "Prep Access in the United States: The Role of Telehealth," Kaiser Family Foundation, May 3, 2022. <https://www.kff.org/report-section/prep-access-in-the-united-states-the-role-of-telehealth-issue-brief/>.



# Policy Recommendations

The Ending the HIV Epidemic initiative is off to a good start, but as with any ambitious public health program, there is an opportunity to learn by doing. The Biden administration's expanded budget request for FY 2023—and Congress's willingness to provide the necessary appropriations—signal that the EHE initiative remains a vital element of the HIV policy agenda in the United States. As this review has shown, there are elements of the initiative that are clearly working well, while others would benefit from a course correction. There is a need for realism and patience in assessing what it can achieve and by when. The overall goals are important and achievable if coordination and implementation are improved across the EHE jurisdictions and lessons learned from those efforts are shared with other, non-EHE jurisdictions nationwide. The following recommendations will aid that process of reconsideration and refinement.

- *Meet people where they are.* Working with all stakeholders who are directly affected by the HIV epidemic in local contexts is critical to ensure that the needs and insights of those at the community level are central to the strategy, planning, and implementation of the EHE initiative. Community engagement should be adopted in all EHE jurisdictions; it builds directly on the long-standing belief among HIV community members that there is “nothing for us without us,” which has informed successful HIV interventions for decades. The power of “meeting people where they are” was clear in the examples of East Baton Rouge Parish's financial incentive program and Ward 86's POP-UP clinics. One way to operationalize this insight would be to provide targeted funding for making community outreach—through community representatives, community health workers, social workers, and other key stakeholders—an integral part of planning and design of all EHE implementation.

- *Address flexibility in design and implementation.* It is also important to respond flexibly to program requirements and find ways to shape implementation so that bureaucratic rules do not get in the way. The goal of the EHE initiative, after all, is to deploy federal resources efficiently and creatively to effect a radical decline in new HIV infections nationally by 2025—and doing so requires rethinking the usual assumptions about what works or might work. For example, rather than maintain separate silos for HIV care, HIV prevention, substance use interventions, mental health treatment, and primary care, why not move toward more integrated models of HIV prevention, treatment, and care that address the lived experiences of clients? Federal agencies can provide guidance on minimum program standards based on the best clinical and scientific evidence, then encourage EHE jurisdictions to innovate as they implement.

Opportunities to redesign approaches and priorities can range from simple tactics—for instance, not distributing funds proportionate to population size in EHE jurisdictions, which may perpetuate the resource constraints smaller counties face—to more ambitious innovations such as using AIDS Drug Assistance Program (ADAP) money to subsidize health insurance, rather than just medications, a policy that has been a cost-effective way to expand healthcare access for PLWHA in Virginia.<sup>49</sup> Additionally, financial incentives, which have helped improve access to HIV prevention, care, and treatment in both East Baton Rouge Parish and Ward 86 in San Francisco, may well be adaptable to other jurisdictions, so long as they are monitored for long-term positive improvements in retention of care and health outcomes.

To capture the social determinants of health that affect the lives of people living with and at risk of HIV infection, EHE jurisdictions—and the federal agencies supporting them—should be willing to try new approaches to improving wraparound services to vulnerable populations (including offering housing stability, food security, transportation, education, and childcare) to get people to clinics. For example, housing stability has been shown to have a positive correlation with HIV outcomes. But because of limitations in housing stock for EHE beneficiaries, available support from the Housing Opportunities for Persons with AIDS (HOPWA) program of the U.S. Department for Housing and Urban Development might be more useful if used as capital to finance new housing, but this would require changes in program requirements.<sup>50</sup> Another creative application of program rules has been used by SAMHSA, which has begun to require that HIV grant program applicants show how they will use support for substance use disorders and mental health services to enroll people in PrEP.<sup>51</sup>

This suggests another experiment that EHE could implement, drawing on the experience of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) in encouraging countries through the Country Operating Plan (COP) process to address structural barriers to HIV response such as homophobia or criminalization of sex work.<sup>52</sup> Although PEPFAR cannot force countries to change their laws or policies, it can provide incentives to do so by making operational support contingent on certain policy outcomes. PEPFAR's success in its partner countries can be attributed in part to this use of strategic leadership to design services that can reach lower-income people at scale. What if a similar process were applied to a certain amount of EHE funding each year? Rather than just providing money to EHE jurisdictions in the usual way and letting them spend it as they see fit, the federal government could earmark part of the budget to create pilot programs—such as the POP-UP clinic in San Francisco or the incentives-based approach used in East Baton Rouge Parish—to encourage adoption of proven innovations shown

in other environments to improve health outcomes in measurable ways. The federal government could work with certain EHE jurisdictions to launch such pilot programs and provide dedicated technical assistance. These rapid starts could then serve as models for other EHE jurisdictions facing similar challenges.<sup>53</sup> Such pilots could build upon the experience already gained through the CDC's Enhance Comprehensive HIV Prevention Planning Program (ECHPP) and Care and Prevention in the U.S. Demonstration Project (CAPUS).<sup>54</sup>

- *Improve data, metrics, and accountability.* “What gets measured, gets done.” This commonplace observation is apposite to the question of how the EHE initiative can put data to better use in guiding programmatic design and making adjustments to ensure it reaches its goals by 2025 and 2030. Three recommended actions will help ensure that the EHE initiative can be held more accountable for results.

First, while America's HIV Epidemic Analysis Dashboard (AHEAD) presents key EHE indicator data, it is not fully integrated with other public data available from the federal government, such as the Atlas Plus database (maintained by the CDC's National Center for HIV, Viral Hepatitis, STD, and TB Prevention) or HRSA's Ryan White Compass dashboard.<sup>55</sup> Data from the latter two sources cannot be downloaded, which can make it challenging for researchers to obtain a comprehensive view of the issues they are studying. Providing more public de-identified data at all levels (federal, state, tribal, and local) is important for guiding work to end the HIV epidemic.

Second, under the auspices of the Office of National AIDS Policy, the EHE initiative should begin to convene semi-annual conferences to review the data, methodology, and potential ways to improve implementation, monitoring, and evaluation. These meetings should include not only the technical teams working on these issues at the federal, state, tribal, and local levels, but also representatives of the policy teams that work with them and the community-based stakeholder groups who have an interest in EHE outcomes. Building a culture of transparency and continuous improvement in understanding and refining the data at the core of the EHE initiative will help ensure that the results are more robust—and that lessons learned by the entire EHE community are used to improve monitoring and evaluation efforts. The NIH has made a strong start in supporting this approach to monitoring and evaluating the EHE initiative by sponsoring a portfolio of HIV implementation studies to inform EHE strategies.<sup>56</sup>

Third, monitoring and evaluation efforts could further build on learning from the global HIV movement, which has benefited from community-based reporting. For example, scholars at the Brookings Institution have argued that “no one is better placed to judge a government than those it governs, and no one is better positioned to monitor government services to ensure that they perform well and transparently than the citizens who use those services.”<sup>57</sup> In addition, the work of the World Health Organization's Independent Expert Review Group on Information and Accountability for Women's and Children's Health—which provided valuable critical feedback on the UN Every Woman, Every Child, Every Adolescent Initiative—is also instructive.<sup>58</sup> Such community-based independent monitoring and evaluation efforts would complement, enrich, and inform the formal data efforts already under way, as well as build transparency and trust among those affected by the EHE initiative's efforts.

- *Heighten political advocacy to ensure future funding.* Finally, to encourage the persistent efforts of the complex network of individuals and institutions required to see the EHE initiative through

to a successful conclusion, it will be critical to renew advocacy to raise visibility and awareness around the initiative and its goals. This advocacy agenda should begin with President Biden and Vice President Kamala Harris, each of whom has credibility in this area. But their advocacy alone is not enough. The EHE initiative will need the active engagement and support of governors, mayors, and state and federal legislators on a bipartisan basis. They will need to be educated, mobilized, and converted into active advocates.

Each new administration naturally wants to set its own priorities. The Biden administration has set a high bar in keeping a focus on HIV/AIDS—both domestically, through the EHE initiative and the National HIV/AIDS Strategy, and globally, through a renewed commitment to PEPFAR. Of course, Congress will need to do its part by fully funding the EHE initiative. So far, congressional appropriators have persistently underfunded it. Stronger and more energetic evidence-based advocacy can help change this and prevent the domestic and global HIV response from becoming a political football.

The EHE initiative should also provide earmarked funds for civil society organizations to build advocacy efforts that give voice to the needs of marginalized and vulnerable populations in EHE jurisdictions so no one is left behind. Celebrities and others who have credibility and trust with affected populations should also be enrolled in the advocacy efforts. Interested stakeholders—including professional groups, healthcare providers, and regional, state, and local NGOs—should let HRSA, the CDC, the Centers for Medicare and Medicaid Services, other federal agencies, and their elected representatives know that the EHE initiative is important to them and that they expect to see appropriate and timely action to provide the resources required to achieve its goals by 2030. Some obvious examples include expanding Medicaid by states that have not yet done so and adjusting the 340B Drug Pricing Program so it works more efficiently to provide treatment for more people. This is all the more important given the need for funding to make up for the disruptions caused by the Covid-19 pandemic.

# Conclusion

The EHE initiative still has the potential to transform the domestic HIV response, but it will require significant adjustments in policy, strategy, integration, inclusion, and resources to reach its goals of reducing HIV incidence by 75 percent by 2025 and 90 percent by 2030. The EHE initiative has strong leadership today in Harold Phillips, head of the Office of National AIDS Policy; Jonathan Mermin and John T. Brooks of the CDC; Laura Cheever and Heather Hauck of HRSA's HIV/AIDS Bureau; Jim Macrae of HRSA's Bureau of Primary Health Care; Kaye Hayes and Timothy Harrison of the HHS Office of Infectious Disease and HIV/AIDS Policy; and Dr. Carl Dieffenbach and Dr. Maureen Goodenow of the NIH, all working with state, tribal, community, and local leaders to implement programs. And it continues to have bipartisan congressional support, which remains a critical success factor.

There are four significant factors to emphasize in EHE's continued development:

- **Communities directly affected by HIV play a critical role** in planning and implementing programs that address their needs—and meet people where they are. Building trust with individuals living with and at risk of acquiring HIV infection and designing programs together that address their immediate needs and concerns will help ensure that the EHE initiative can achieve its goals.
- **Implementers can learn from the experience of the global HIV response**, in which many of the most effective ideas and interventions came from the bottom up and through unusual partnerships. PEPFAR's success, as noted above, has come through what Ambassador John Nkengasong, the U.S. global AIDS coordinator, calls “respectful partnerships” between the U.S. government and its counterparts in countries where PEPFAR operates, between public and private partners, and between each of these partners and civil society. Some ideas used successfully in PEPFAR programs overseas—such as multi-month dispensing of antiretroviral medications



and differentiated service delivery, as well as PEPFAR's extensive experience with public-private collaboration—could be applied usefully in some EHE jurisdictions.<sup>59</sup>

- **The EHE initiative should plan for a future in which an integrated policy strategy for pandemic preparedness and response is the norm**, given the complex challenges ahead of fighting concomitant epidemics of both HIV/AIDS and Covid-19, together with the need to prepare for unexpected new outbreaks such as monkeypox. For long-term sustainability of the EHE initiative, and to avoid internecine arguments over which infectious disease agenda should take priority, it is important to emphasize that breakthroughs in HIV/AIDS science in the past 40 years have led to breakthroughs in other areas of research, such as preventing the spread of Ebola and Covid-19.<sup>60</sup>
- **The EHE initiative needs to be funded fully.** Without the right level of resources to enable accelerated action, the EHE initiative will not be able to meet its 2030 goals. This funding can only come from Congress. The agreement and alignment regarding what needs to be done—among the Biden administration; federal, state, tribal, and local agencies; and affected communities—sends a strong signal in support of such funding. It is now up to Congress to act.

If these insights are translated into reality between now and 2030, in part by implementing the above recommendations, “the USA could indeed become a place where new HIV infections and AIDS deaths are rare, and where people at risk of either are provided with the services they need in safety and dignity, and with compassion,” as Chris Beyrer and colleagues note in a call to action published in *The Lancet*.<sup>61</sup> This vision of the future of the U.S. HIV/AIDS response is worth fighting for.

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