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## Call to Action: What is needed for the Ending the HIV Epidemic in the USA Initiative to Succeed?

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### Summary:

With over 1.2 million American currently living with HIV, a complex epidemic across this large, diverse country, and a fragmented health care system marked by widening health disparities, the U.S. HIV/AIDS epidemic requires sustained scientific and public health attention. With high incidence densities sustained over decades and an epidemic increasingly concentrated among racial, ethnic, and sexual and gender minority persons and communities, the U.S. epidemic has been stubbornly persistent. This has been true despite extraordinary scientific advances

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in prevention, treatment and care—advances which have been led to a significant degree by U.S. supported science and researchers. In this watershed year of 2020, and in the face of the COVID-19 pandemic, it is clear the U.S. will not meet the stated goals of our current National HIV/AIDS Strategy, particularly reductions in new infections, decreases in morbidity, and reductions in HIV stigma. The 6 papers in this *Lancet HIV in the USA* series have each examined the underlying causes of these challenges, and laid out paths forward for an invigorated, sustained, and more equitable response to the U.S. HIV epidemic. The current sciences of HIV surveillance, prevention, treatment, and implementation all suggest that the visionary goals of the *Ending the HIV Epidemic Initiative* in the US may be achievable—but fundamental barriers and challenges must be addressed, and the research effort sustained, if we are to succeed.

### Keywords

HIV; United States; Epidemic Control; pre-exposure prophylaxis; treatment as prevention; undetectable equals untransmittable; COVID-19

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### COMMENT

HIV has infected more than 75 million women, men, and children, killed at least 40 million, and caused immense suffering.<sup>1,2</sup> Slow to respond at first to its own epidemic, the U.S. emerged in the following decades as the largest funder of research on HIV/AIDS. This research effort was essential to the development of effective therapy for HIV disease in 1996, and to the development of potent prevention tools, including pre-exposure prophylaxis, in 2010.<sup>3,4</sup> HIV care in the US has been supported by The Ryan White Comprehensive AIDS Resource Emergency (CARE) Act of 1990 which has subsidized the health care and social service needs of hundreds of thousands of people with HIV in the US.<sup>5</sup> In addition to the research efforts and support for domestic HIV care, the U.S. government has been by far the largest donor to global AIDS programs, most notably PEPFAR and the concurrent U.S. contribution to the Global Fund to Fight AIDS, TB, and Malaria.<sup>6</sup>

This is an extraordinary record of success. Yet the U.S. itself continues to have higher burdens of HIV, higher rates of new infection, and an overall more severe HIV epidemic than any other member of the G7 group of industrialized countries.<sup>7,8</sup> Indeed, in 2019, the U.S. remained the only global north country among the 10 most HIV affected countries worldwide.<sup>8,9</sup>

The Obama administration was the first to establish a comprehensive national plan for the U.S. epidemic, The National HIV/AIDS Strategy (NHAS), in 2010, set to run through 2020.<sup>10</sup> Its vision was clear, compassionate, and evidence-based:

The United States will become a place where new HIV infections are rare and when they do occur, every person regardless of age, gender, race/ethnicity, sexual orientation, gender identity or socio-economic circumstance, will have unfettered access to high quality, life-extending care, free from stigma and discrimination.<sup>10</sup>

Several articles in this issue of the *Lancet* comprehensively review the current state of the HIV epidemic in the US. Sullivan et al describes the epidemiology of HIV in the nation. Adimora, Mayer, and Hodder, respectively, review HIV among women, MSM, and opioid users;<sup>11–13</sup> and Kates et al discuss health care financing systems as they relate to HIV in the US.<sup>14</sup> These articles confirm that the visionary goals of the 2010 NHAS have not been achieved by 2020. New infections at over 38,000/year in 2017, are not rare. And racial, ethnic, geographic, and sexual and gender minority disparities in HIV have worsened.<sup>15</sup> HIV, as Sullivan et al report, is increasingly concentrated in the U.S. South and Southeast, among racial/ethnic minority and sexual and gender minority communities,<sup>15</sup> and as Kates et al have noted, among lower income and under- or uninsured Americans.<sup>14</sup> Some have called for a “PEPFAR for the United States,” a bold and to-scale commitment to address the U.S. epidemic.<sup>16</sup> The announcement in early 2019 of the US government’s “Ending the HIV Epidemic Initiative,” EHE, has been seen as just such a response.<sup>17</sup> It calls for inter-agency cooperation, expanded resources, and an “all hands on deck” mobilization around the U.S. epidemic.<sup>17</sup>

The EHE targets are ambitious. Arguably the most difficult to realize will be the goal of reducing new HIV infections in the US by 75% in 5 years, and by 90% in 10. HIV infections in the US have been overall falling at a relative 2% per year for the past several years, but have been increasing among Latinx MSM and among clusters of people who inject drugs.<sup>18</sup> Success will likely demand that we better understand the persistence of the US epidemic and the unresolved inequities which drive it. The COVID-19 pandemic has had explosive and devastating impacts on the US just as the EHE initiative was to be underway, and the US remains the most COVID affected country globally. The new pandemic brought into sharp relief the limitations of our patchwork of health systems, and with remarkable speed the same health inequities that have bedeviled the response to HIV in the US, most notably the profound racial and ethnic disparities, were being seen in COVID-19 infections and deaths among African Americans, Latinx persons, and Native Americans.<sup>19–22</sup> Our still-struggling and uncertain response to COVID-19 underscores that while success against HIV in the U.S. *may* be achieved, it is not at all certain in 2020 that by 2030 it *will* be achieved.

Among the biggest challenges we face as a nation is lack of health care access due in large part to inadequate health insurance systems and to the lack of national health system for all Americans. Following implementation of the Affordable Care Act (ACA) with enrollment of millions of people in new coverage options, the nation’s uninsured rate dropped to its lowest levels in 2013 through 2016.<sup>23</sup> However, efforts to limit the affordability and availability of coverage have caused the US uninsured rate to rise again.<sup>24</sup> By 2019 the number of uninsured nonelderly adults had risen to 27.9 million.<sup>23</sup> In response to COVID-19, the current administration closed new enrollments to the ACA in early 2020.<sup>25</sup>

As Kates, et al, show, the U.S. healthcare system(s) with its patchwork of uneven coverage and access to HIV prevention and treatment services itself presents significant barriers to success.<sup>14</sup> The ACA significantly expanded health insurance for many millions of Americans, yet it remains politically vulnerable. The decision of many state governments not to expand health coverage through the Medicaid expansion provisions of the ACA, has limited coverage where it is needed most for both HIV and COVID-19.<sup>14</sup>

In understanding the many barriers to achieving progress against the HIV epidemic in the U.S., a social ecological model may help unpack the multi-level challenges we face. [See Online Appendix I]. At the individual level these include substance use, mental health, poverty, sexual and gender minority status, and untreated STI.<sup>11,12,15</sup> Network-level factors have been important for heavily burdened groups, such as Black and Latinx MSM, who are much more likely to be in social and sexual networks with viremic men, newly HIV infected men, and men with untreated STI.<sup>26–28</sup> Anticipated discrimination and microaggressions may impact Black Americans' engagement in HIV services.<sup>29,30</sup> Community-level factors, most notably HIV stigma and intersectional stigma, can play powerful potentiating roles.<sup>31</sup> Racism and racist policies must be included in these community level risks.<sup>32</sup> Limits on harm reduction and drug treatment programs for substance users have also proven to be potent barriers to controlling HIV outbreaks.<sup>33,34</sup> This has been particularly challenging as the geography of opiate use has shifted to rural and suburban communities; and to Appalachia and the Midwest, where services have been lacking and more socially and politically fraught.<sup>13</sup>

We now have several models of progress in overcoming these many barriers, such as the Getting to Zero Initiative in San Francisco, the Washington State efforts, and Ending the Epidemic in New York State.<sup>35–37</sup> However, we have many more counter examples where HIV burdens remain high, treatment coverage too low, and many or most of these multi-level barriers remain. Among the 48 jurisdictions in the EHE initiative “hot spots” for new HIV infections, many of the focus counties in Florida, Texas, Georgia, Mississippi, Alabama, and the Carolinas share these challenging characteristics.<sup>14,15</sup>

Achieving success against HIV/AIDS in the U.S. will call for both reform and innovation. With tools as potent as the current generation of antivirals for treatment and prevention, enhanced implementation and expansion of access to essential services will both be key. This means we must ensure universal access to quality health care, reduce geographic, racial and ethnic disparities in HIV services, and address discrimination and racism in health care.

Because sexual and gender minority persons, including men who have sex with men and transgender women who have sex with men, now account for the majority of new HIV infections in the U.S., advancing and protecting LGBTQ rights, access to services, and engagement in the response is essential, as is the training of health care workers and systems to provide culturally congruent and competent care.

Protecting and advancing women's access to sexual and reproductive health services, including contraceptive services, is essential.<sup>11</sup> It is also imperative to include US women in HIV prevention and treatment trials. Pharmaceutical companies, the FDA, and the NIH should ensure that women are appropriately represented in all trials of drugs that may be used by women.<sup>38</sup> The recent studies demonstrating a possible association of dolutegravir use in early pregnancy and neural tube defects among newborns strongly suggest that trials which exclude or under-enroll women of child bearing age risk limiting key findings.<sup>39</sup>

Enabling drug policy environments have all been shown to reduce the harms of substance use, including HIV infection.<sup>40</sup> Laws criminalizing HIV transmission also continue to

stigmatize and criminalize persons living with HIV.<sup>41,42</sup> Finally, as Mayer, et al make clear, training of health care providers in cultural competency to provide quality care to racial, ethnic, sexual, gender minority people and people who use drugs is an essential component of an enabling environment.<sup>12</sup>

There is a truly remarkable range of new HIV prevention and treatment technologies and platforms under development, including injectables, longer-acting agents, depo formulations, implants, vaginal rings and broadly neutralizing antibodies, bNabs. The toolkit for HIV control may look strikingly different by 2030. They are likely to also be prohibitively expensive; we will then need a rapid mechanism to use them to do the most individual and public health good.<sup>43</sup> And we must acknowledge that the current toolkit lacks both preventive vaccines, and curative or long-term remission therapies, meaning we may achieve gains against clinical AIDS, but will continue to have over a million HIV infected citizens for many decades.

What will it take to achieve success? The science, policy, implementation and financing challenges raised in this series suggest many simultaneous efforts and advances will be necessary, but are achievable. The U.S. could indeed become a place where new HIV infections and AIDS deaths are rare, and where people at risk for either are provided the services they need in safety, dignity, and with compassion.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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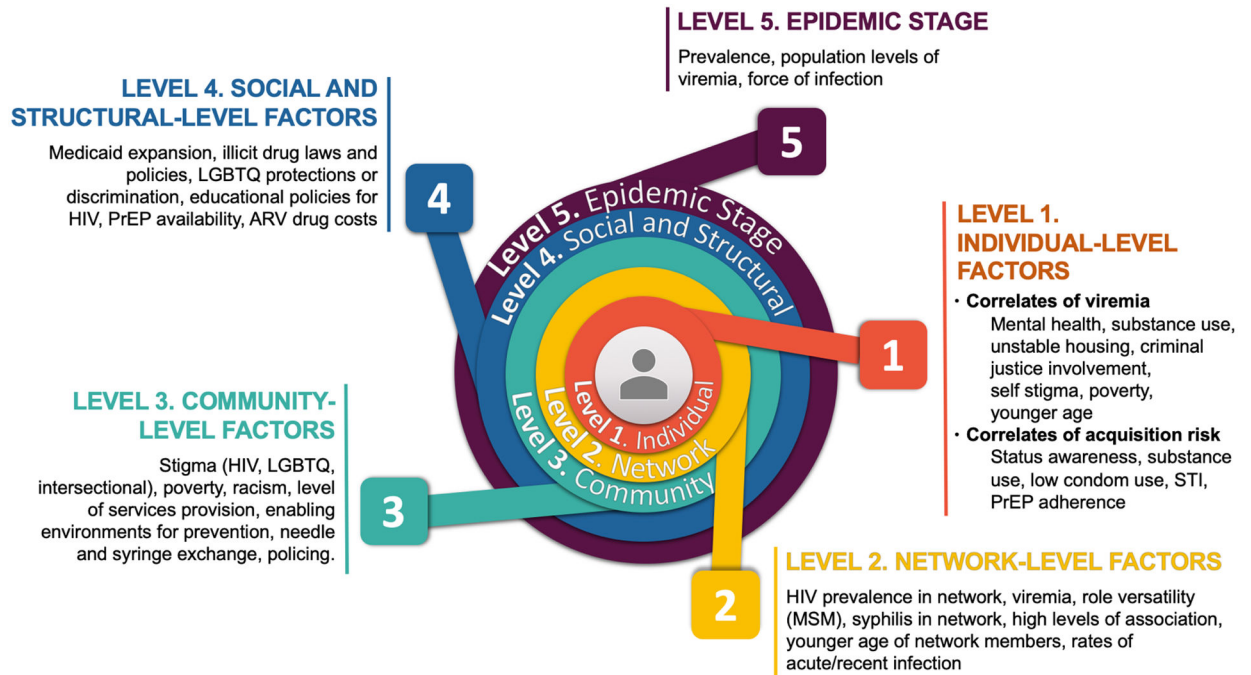
### TEXTBOX 1: CALLS TO ACTION FOR ENDING THE EPIDEMIC OF HIV IN THE USA

- While the new Ending the HIV Epidemic: A Plan for America Initiative promises to offer new resources, focus, and political will, an uneven playing field in treatment and prevention coverage threatens its progress.
- The epidemiology of HIV infections and the epidemiology of prevention, derived from surveillance and other data sources, is a roadmap to US HIV responses by local public health agencies, governmental entities, community organizations, and advocates and should be used to drive and focus the Ending the Epidemic initiative efforts.
- The US HIV epidemic is most intense in the South; the South represents 37% of the US population but 51% of people living with HIV and 47% of new HIV diagnoses in 2018.
- The drivers of HIV transmission are diverse, including social/structural, network, biological and individual behavioral factors, necessitating multi-faceted approaches to HIV prevention.
- The ability to curb the national HIV epidemic will require universal access to quality health care, safety net programs, and curtailing high HIV drug costs in the United States.
- The demographic and gender diversity of HIV in the US requires tailored approaches. The disproportionate HIV epidemic among Black and Latinx MSM is potentiated by poverty, racism, and assortative mixing, requiring culturally appropriate engagement.
- All clinical trials for prevention and treatment of HIV infection should enroll women – including US women – in sufficient numbers to permit meaningful analysis by sex and gender.
- Ending the HIV epidemic among women in the US will require universal access to health care, housing, and other supportive services – and will also require eliminating the race, class, and gender inequities; discrimination; and structural violence that have promoted and maintained the disparate distribution of HIV in the US.
- In the U=U and PrEP era, health care professionals can play a unique role in providing supportive and informed care, and preventive services, for those at risk and those living with the virus.
- A national culturally competent effort is needed to raise awareness of U=U as a promising approach to reduce HIV stigma, which has a powerful potentiating role in both acquisition risks and treatment challenges.
- Health care professionals must inform patients living with and affected by HIV about U=U to improve, first and foremost, personal health, as well as public health. Sharing this information may greatly improve the social



and emotional well-being of PWH, reduce HIV stigma, reduce anxiety associated with HIV testing, and help motivate treatment uptake, adherence and engagement in care.

- Advocates must be equipped to use the U=U “public health argument” in advocacy to increase access and remove barriers to quality healthcare. Ensuring people with HIV have the treatment and services they need to achieve and maintain an undetectable viral load not only saves lives, it is an effective way to prevent new transmissions.
- PrEP access must be enhanced for primary prevention, and made available at significantly lower cost or no cost for those most in need.
- Syndemic factors associated with HIV spread and non-adherence, e.g. depression and substance use, must be addressed and integrated into clinical care programs. Further research into the optimal ways to provide culturally competent, evidence-based care and preventive services, must be supported.
- While delivering the current tools for prevention, treatment and care at scale and across all population is key to progress, there remains the essential need to sustain investment in research and development of additional options to ensure a durable end to the epidemic.
- There are still critical gaps in knowledge about the HIV epidemic, especially data about HIV infections in transfeminine and transmasculine people. Despite development of population-based denominators for MSM, people who inject drugs, and transmen and transwomen recent, better estimates of HIV diagnoses in transmen and transwomen are still needed to depict a complete picture of the impact HIV in these communities.
- There are exciting trends in the data tools to help respond to the HIV epidemic, locally and nationally. There is increased public availability of data about the US epidemic, which are available through online data repositories and mapping portals. Data on the genetic traits of HIV viruses are available to health departments to better understand transmission clusters and improve programmatic responses but must be used with attention to confidentiality and protection of human rights.
- To actually “end” HIV in the US and globally, we need a vaccine and/or a curative strategy. This means the HIV research effort must be sustained by the next generation of researchers, advocates, funders, and other stakeholders.



**Figure 1.**  
Social-ecological Model of HIV risk and vulnerability in the US.