Series

HIV in the USA 6

Call to action: how can the US Ending the HIV Epidemic initiative succeed?

Chris Beyrer, Adaora A Adimora, Sally L Hodder, Ernest Hopkins, Greg Millett, Sandra Hsu Hnin Mon, Patrick S Sullivan, Rochelle P Walensky, Anton Pozniak, Mitchell Warren, Bruce Richman, Raniyah Copeland, Kenneth H Mayer

With more than 1·2 million people living with HIV in the USA, a complex epidemic across the large and diverse country, and a fragmented health-care system marked by widening health disparities, the US HIV epidemic requires sustained scientific and public health attention. The epidemic has been stubbornly persistent; high incidence densities have been sustained over decades and the epidemic is increasingly concentrated among racial, ethnic, and sexual and gender minority communities. This fact remains true despite extraordinary scientific advances in prevention, treatment, and care—advances that have been led, to a substantial degree, by US-supported science and researchers. In this watershed year of 2021 and in the face of the COVID-19 pandemic, it is clear that the USA will not meet the stated goals of the National HIV/AIDS Strategy, particularly those goals relating to reductions in new infections, decreases in morbidity, and reductions in HIV stigma. The six papers in the *Lancet* Series on HIV in the USA have each examined the underlying causes of these challenges and laid out paths forward for an invigorated, sustained, and more equitable response to the US HIV epidemic than has been seen to date. The sciences of HIV surveillance, prevention, treatment, and implementation all suggest that the visionary goals of the Ending the HIV Epidemic initiative in the USA might be achievable. However, fundamental barriers and challenges need to be addressed and the research effort sustained if we are to succeed.

Introduction

HIV has infected more than 75 million women, men, and children, killed at least 40 million people, and caused immense suffering.12 Slow to respond at first to its own epidemic, the USA has emerged in the following decades as the largest funder of research on HIV and 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 2010.3,4 HIV care in the USA has been supported by the Ryan White HIV/AIDS Program, which has subsidised the health-care and social service needs of hundreds of thousands of people with HIV.5 In addition to the research efforts and support for domestic HIV care, the US Government has been by far the largest donor to global AIDS programmes, most notably the President's Emergency Plan for AIDS Relief (PEPFAR) and the concurrent US contribution to The Global Fund to Fight AIDS, Tuberculosis, and Malaria.6

This is an extraordinary record of success. Yet the USA continues to have higher burdens of HIV, higher rates of new infections, and an overall more severe HIV epidemic than any other member of the G7 group of industrialised countries.^{7,8} Indeed, in 2019, the USA remained the only high-income country among the ten most HIV-affected countries worldwide.^{8,9}

The Obama administration was the first to establish a comprehensive national plan for the US epidemic in 2010, the National HIV/AIDS Strategy, set to run up to 2020.¹⁰ Its vision was clear, compassionate, and evidence-based: "The United States will be a place where new HIV

infections are prevented, every person knows their status, and every person with HIV has high-quality care and treatment and lives free from stigma and discrimination."¹⁰

Several papers in this Lancet Series comprehensively review the state of the HIV epidemic in the USA. Patrick Sullivan and colleagues describe the epidemiology of HIV in the country.11 Adaora Adimora and colleagues review HIV in women,12 Kenneth Mayer and colleagues review HIV in men who have sex with men,13 Sally Hodder and colleagues review HIV in opioid users,14 and Jennifer Kates and colleagues discuss health-care financing systems as they relate to HIV in the USA.15 These articles show that the visionary goals of the 2010 National HIV/AIDS Strategy were not achieved by 2020. New infections, at more than 38 000 per year in 2017, are not rare. And racial, ethnic, geographical, sexual, and gender minority disparities in HIV have worsened.11 HIV, as Sullivan and colleagues report, is increasingly concentrated in the US South and southeast, among racial, ethnic, sexual, and gender minority communities,11 and, as Kates and colleagues have noted, among lowincome and underinsured or uninsured people in the USA.15 Some have called for a similar programme to PEPFAR for the USA, a bold and to-scale commitment to address the US epidemic.16 The announcement in early 2019 of the US Government's Ending the HIV Epidemic: A Plan for America (EHE) initiative has been seen as just such a response.17 The initiative calls for interagency cooperation, expanded resources, and a fullscale mobilisation around the US epidemic.17

The EHE targets are ambitious. Arguably the most difficult to realise will be the goal of reducing new HIV



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This is the sixth in a **Series** of six papers on HIV in the USA

Center for Public Health and Human Rights, Department of Epidemiology, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD, USA (Prof C Beyrer MD, S H H Mon MSPH); Department of Epidemiology, Gillings School of Public Health, University of North Carolina, Chapel Hill, NC, USA (Prof A A Adimora MD): Section of Infectious Diseases, School of Medicine, West Virginia University, Morgantown, WV, USA (S L Hodder MD); San Francisco AIDS Foundation San Francisco, CA, USA (F Hopkins BA): Foundation for AIDS Research (amfAR), Washington, DC, USA (G Millett MPH): Department of Epidemiology, Rollins School of Public Health, Emory University, Atlanta, GA, USA (Prof P S Sullivan DVM): Division of Infectious Diseases Massachusetts General Hospital, Boston, MA, USA (Prof R P Walensky MD): Department of HIV, Chelsea and Westminster Hospital NHS Trust, London, UK (Prof A Pozniak FRCP); AIDS Vaccine Advocacy Coalition (AVAC), New York, NY, USA (M Warren BA); Prevention Access Campaign, New York, NY, USA (B Richman ID): Black AIDS Institute. Los Angeles, CA, USA (R Copeland MPH); Beth Israel Deaconess Medical Center. Harvard Medical School Fenway Health, Boston, MA, USA (Prof K H Mayer MD)



Correspondence to: Prof Chris Beyrer, Center for Public Health and Human Rights, Department of Epidemiology, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD 21205, USA cbeyrer@jhu.edu

Key messages

- Although the new Ending the HIV Epidemic: A Plan for America (EHE) 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, government entities, community organisations, and advocates, and should be used to drive and focus the EHE initiative efforts
- The US HIV epidemic is most intense in the South, which represents 37% of the US population but 51% of people living with HIV and 47% of new HIV diagnoses in the USA in 2018
- The drivers of HIV transmission are diverse, including social or structural, network, biological, and individual behavioural factors, necessitating multifaceted approaches to HIV prevention
- The ability to curb the national HIV epidemic will require universal access to quality health care, safety net programmes, and curtailing high HIV drug costs
- The demographic and gender diversity of people living with HIV in the USA requires tailored approaches; the disproportionate HIV epidemic among Black and Latino men who have sex with men is potentiated by poverty, racism, and assortative mixing, requiring culturally appropriate engagement
- All clinical trials for prevention and treatment of HIV infection should enrol women—including US women—in sufficient numbers to permit meaningful analysis by sex and gender
- Ending the HIV epidemic among women in the USA will require universal access to health care, housing, and other supportive services, and will also require eliminating the race, class, and gender inequities, as well as the discrimination and structural violence, that have promoted and maintained the disparate distribution of HIV in the country
- In the era of the undetectable equals untransmittable (U=U) campaign and pre-exposure prophylaxis (PrEP), health-care professionals can play a unique role in providing supportive and informed care, as well as preventive services, for people living with or at risk of the virus
- A national culturally competent effort is needed to raise awareness of the U=U campaign as a promising approach to reduce HIV stigma, which has a powerful potentiating role in both acquisition risks and treatment challenges
- Health-care professionals need to 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 might greatly improve the social and emotional wellbeing of people living with HIV, reduce HIV stigma, reduce anxiety associated with HIV testing, and help motivate treatment uptake, treatment adherence, and engagement in care

- Advocates should be equipped to use the so-called public health argument from U=U in advocacy to increase access and remove barriers to quality health care; ensuring people with HIV have the treatment and services they need to achieve and maintain an undetectable viral load not only saves lives, but also is an effective way to prevent new transmissions
- Access to PrEP needs to be enhanced for primary prevention and made available at a considerably lower cost than it is currently or at no cost at all for individuals most in need
- Syndemic factors associated with HIV spread and non-adherence (eg, depression and substance use) must be addressed and integrated into clinical care programmes; further research into the optimal ways to provide culturally competent evidence-based care and preventive services should be supported
- Although delivering the current tools for prevention, treatment, and care at scale and across all populations 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 crucial gaps in knowledge about the HIV epidemic, particularly regarding data on HIV infections among transfeminine and transmasculine people; despite the development of population-based denominators for men who have sex with men, people who inject drugs, and transgender men and women, up-to-date and better estimates of HIV diagnoses in transgender men and women are still needed to fully depict the impact of HIV in these communities
- Exciting trends are present in the data tools to help respond to the HIV epidemic in the USA, locally and nationally; there is increased public availability of data about the 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 should be used with attention to confidentiality and human rights
- To end HIV in the USA and globally, a vaccine or a curative strategy, or both, are needed, which means the HIV research effort must be sustained by the next generation of researchers, advocates, funders, and other stakeholders

infections in the USA by 75% in 5 years and by 90% in 10 years. HIV infections in the USA have been falling overall at 2% per year for the past several years but have been increasing among Latino men who have sex with men and among clusters of people who inject drugs.¹⁸

Success will probably demand that researchers better understand the persistence of the US epidemic and the unresolved inequities that drive it. Just as the EHE initiative was starting, the COVID-19 pandemic emerged, which has had explosive and devastating impacts; the USA remains the most COVID-19-affected country globally. The new pandemic brought into sharp relief the limitations of patchwork health systems; with remarkable speed, the same health inequities that have bedevilled the response to HIV in the USA—most notably the profound racial and ethnic disparities were being seen in SARS-CoV-2 infections and COVID-19 deaths among Black and Hispanic people, and among Native Americans.¹⁹⁻²² The struggling and uncertain US response to COVID-19 underscores that, although success against HIV in the USA might be achieved, it is not at all certain in 2021 that, by 2030, it will be achieved.

Outstanding barriers

Among the biggest challenges the USA faces is poor health-care access due in large part to inadequate health insurance systems and the absence of a national health system for all Americans. Following implementation of the Affordable Care Act, with enrolment of millions of people in new coverage options, the nation's uninsured rate dropped to its lowest level during 2013–16.²³ However, efforts to restrict the affordability and availability of coverage have caused the uninsured rate to rise again.²⁴ By 2019, the number of uninsured younger adults had risen to 27.9 million.²³ In response to COVID-19, the current administration closed new enrolments to the Affordable Care Act in early 2020.²⁵

As Kates and colleagues show, the US health-care system itself, with its patchwork system of uneven coverage and access to HIV prevention and treatment services, presents substantial barriers to success.¹⁵ The Affordable Care Act considerably expanded health insurance for many millions of people in the USA, yet it remains politically vulnerable. The decision of many state governments to not expand health coverage through the Medicaid expansion provisions of the act has restricted coverage for both HIV and COVID-19 where it is needed most.¹⁵

In understanding the many barriers to achieving progress against the HIV epidemic in the USA, a social-ecological model might help unpack the multilevel challenges (figure). At the individual level, these include substance use, mental health, poverty, sexual and gender minority status, and untreated sexually transmitted infections.¹¹⁻¹³ Network-level factors have been important for heavily burdened groups, such as Black and Latino men who have sex with men, who are much more likely to be in social and sexual networks with viraemic men, newly HIVinfected men, and men with untreated sexually transmitted infections.27-29 Anticipated discrimination and microaggressions might affect the engagement of Black people in HIV services.^{30,31} Community-level factors, most notably HIV stigma and intersectional stigma, can play powerful potentiating roles.32 Racism and racist policies need to be included in these



Figure: Social-ecological model of HIV risk and vulnerability in the USA

A social-ecological model to unpack the individual, network, community, and wider health factors and social justice challenges facing HIV epidemic efforts in the USA. Adapted from the modified social-ecological model to visualise multilevel domains of HIV risks developed by Baral and colleagues in 2013.²⁶ MSM=men who have sex with men. PrEP=pre-exposure prophylaxis. STI=sexually transmitted infection.

community-level risks.³³ Limits on harm-reduction and drug-treatment programmes for substance users have also proven to be potent barriers to controlling HIV outbreaks.^{34,35} These restrictions have been particularly challenging as the geography of opioid 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 than in other US regions.¹⁴

Several models of progress now exist in overcoming these many barriers, such as the Getting to Zero initiative in San Francisco (California), the Washington State efforts, and the EHE initiative in New York State.^{36–38} However, many more counterexamples exist, in which HIV burdens remain high, treatment coverage too low, and many or most of these multilevel barriers remain. Among the 48 jurisdictions in the EHE hotspots for new HIV infections, many of the focus counties in Florida, Texas, Georgia, Mississippi, Alabama, North Carolina, and South Carolina share these challenging characteristics.^{11,15}

Achieving success

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

Because sexual and gender minority individuals, including men who have sex with men and transgender

Panel: Stakeholder analysis for the Ending the HIV Epidemic call to action

Federal organisations

- Implement more rapid and real-time surveillance data for key Ending the HIV Epidemic (EHE) metrics
- Retain non-discrimination provisions in the Affordable Care Act to support engagement in care by transgender women, transgender men, and sexual and gender minorities
- Include questions on sexual orientation and gender identity in future US Census data collections
- Re-establish the Office of National AIDS Policy in the White House to coordinate EHE implementation
- Support continued innovation and key research into prevention, treatment, vaccines, remission, and cures
- Require appropriate representation of women in all trials of drugs for HIV prevention and treatment that might be used by women
- Include US women in phase 1, 2, and 3 trials of biomedical products for HIV prevention

State, local, or tribal organisations

- Develop and implement comprehensive EHE plans responsive to local contexts
- States that have not expanded Medicaid through the Affordable Care Act should do so immediately to reduce the numbers of underinsured and uninsured state residents and ensure universal access to high-quality health care
- States that have not established pre-exposure prophylaxis (PrEP) Drug Assistance Programs or other programmes to offset the costs of PrEP medication and clinical care should do so

women who have sex with men, now account for most new HIV infections in the USA, advancing and protecting LGBTQ rights, access to services, and engagement in the response are essential, as is the training of health-care workers to provide culturally congruent and competent care.

Protecting and advancing women's access to sexual and reproductive health services, including contraceptive services, is also essential.¹² US women need to be included in HIV prevention and treatment trials. Pharmaceutical companies, the Food and Drug Administration, and the National Institutes of Health should ensure that women are appropriately represented in all trials of drugs that might be used by women.³⁹ The studies showing a possible association of dolutegravir use in early pregnancy and neural tube defects among neonates strongly suggest that trials that exclude or underenrol women of childbearing age risk overlooking key findings.⁴⁰

Enabling drug policy environments have all been shown to reduce the harms of substance use, including HIV infection.⁴¹ Laws criminalising HIV transmission continue to stigmatise and criminalise people living with HIV.^{42,43} Finally, as Mayer and colleagues make clear, training of health-care providers in cultural competency

- Repeal harmful statutes that impede the EHE response, such as state laws criminalising non-disclosure of exposure; limits on harm-reduction services; and restrictions on opioid dependency treatments, including buprenorphine
- Eliminate barriers in state programmes, such as cumbersome AIDS Drug Assistance Program recertification requirements, that hinder access to antiretroviral therapy

Communities

- Engage in local planning activities and build community support for EHE
- Monitor and ensure that EHE funds are spent responsibly
 and reach individuals most in need
- Address community-level HIV stigma and intersectional stigma

Providers

- Include sexual health and sexual histories in clinical care
- Document sexual orientation and gender identity in medical records
- Get trained in reducing unconscious biases against racial, ethnic, sexual, and gender minority patients
- Advocate for use of the concept of undetectable equals untrasmittable in messaging and support all patients to remain virally suppressed

to provide quality care to racial, ethnic, sexual, and gender minority people and people who use drugs is an essential component of an enabling environment.¹³

There is a truly remarkable range of new HIV prevention and treatment technologies and platforms under development, including injectables, longeracting agents, depot formulations, implants, vaginal rings, and broadly neutralising antibodies. The toolkit for HIV control might look strikingly different by 2030. Future tools are likely to also be prohibitively expensive; a rapid mechanism will then be needed to use these technologies for the most individual and public health good.⁴⁴ It must be acknowledged that the current toolkit does not include preventive vaccines or curative or long-term remission therapies, meaning gains against clinical AIDS might be achieved, but more than a million citizens will continue to be infected with HIV 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 (panel), but these are achievable. 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.

Contributors

CB drafted the manuscript. All other coauthors contributed to the writing and editing of the manuscript, and approved the final version for publication.

Declaration of interests

We declare no competing interests.

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