

# EXHIBIT 30

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

AMERICAN PUBLIC HEALTH  
ASSOCIATION, *et al.*,

*Plaintiffs,*

v.

NATIONAL INSTITUTES OF HEALTH, *et  
al.*,

*Defendants.*

Case No. 1:25-cv-10787-BEM

**DECLARATION OF APHA MEMBER 4**

I, Sereno “Sari” Reisner, pursuant to 28 U.S.C. § 1746, depose and say as follows:

1. My name is Sari Reisner and I am an adjunct associate professor with tenure in the Department of Epidemiology at the University of Michigan School of Public Health, as well as an adjunct associate professor in the Department of Epidemiology at Harvard T.H. Chan School of Public Health. I am a transgender population health researcher and have been working in this field since 2009, with a focus on infectious diseases and mental health. My research aims to address health inequities among underserved communities, particularly in relation to mental health, substance use, HIV, and access to high-quality healthcare.

2. I am offering this declaration in my individual capacity and not on behalf of my employer.

3. I received my Doctor of Science from the Harvard T.H. Chan School of Public Health in 2013 and completed two years of post-doctoral training in infectious disease epidemiology in the Department of Epidemiology at the same institution. I have led a range of community-engaged research projects, and am a longtime collaborator with Fenway Health, an LGBT healthcare, research, and advocacy organization, where I have overseen major grants with a team made up largely of transgender research staff.

4. Disenfranchised communities continue to face systemic barriers that lead to persistent health disparities, limiting their ability to thrive. My work is motivated by a desire to understand and help address these challenges. I focus on improving health and wellbeing in underserved populations, with the goal of supporting more effective and inclusive health systems that provide *everyone* with the opportunity to achieve their best possible health.

5. This work addresses a critical gap in public health research. HIV continues to be a major societal and economic burden, and transgender people and men who have sex with men are among the most affected. By focusing research on these communities, my work not only improves individual and community health outcomes but also advances the national public health goals laid out in the National HIV Strategy for the United States 2022-2025. That Strategy was published in 2021 by the White House as part of the Ending the HIV Epidemic in the U.S. (EHE) initiative launched by President Trump in 2019. A true and correct copy of this report is attached hereto as Exhibit A.

6. I have received NIH funding for my research for more than a decade, and I have applied for and received over a dozen grants from the NIH over the course of my career.

7. Each application has involved months—sometimes years—of work, from conducting background research and refining the study design to collaborating with colleagues across disciplines and gathering community input. The grant review process is highly rigorous, and securing funding has become increasingly competitive over time, with many successful proposals scoring in the top tenth percentile or better. One of my current projects, for example, was ranked in the first percentile, reflecting its strength and scientific rigor. Despite the challenges and competitiveness, I value this process for helping to ensure that the most rigorous and impactful research is conducted to advance the scientific evidence-base to improve health outcomes.

8. I am a member of the American Public Health Association (APHA) and pay \$245 in annual dues.

9. The NIH has terminated five grants that supported my research, including four R01 grants and one U01 grant. I was the Principal Investigator for four of the projects these grants supported.

10. Among these terminated grants was an R01 grant (5R01MH129175) of approximately \$4 million awarded by the National Institute of Mental Health (NIM) on August 19, 2022, titled *Strategies to Prevent HIV Acquisition Among Transgender MSM in the US*. A true and correct copy of my NOA is attached hereto as Exhibit B.

11. Transgender men who have sex with men (MSM) are a critical population for this work, as they have an 11-fold higher risk of HIV transmission than transgender men who do not have sex with men. The project was a randomized controlled trial with 375 participants using peer intervention to encourage the use of pre-exposure prophylaxis (PrEP) in order to address these higher rates of HIV in transgender MSM. There are no evidence-based interventions to address HIV risk in this population, and the study aimed to fill that gap. The study focused on the 57 U.S. jurisdictions with the highest rates of new HIV cases, as identified and prioritized by the White House Office of National AIDS Policy. Ex. A at 16. Reducing infections in these areas not only helps this specific population, but it also has the potential to significantly reduce the burden of care nationwide.

12. This study also utilized peer-delivered digital interventions, a model that could be adapted and applied to a wide range of populations and thereby open new avenues for future research and public health efforts. It used a digital randomized trial to test two peer-delivered HIV prevention strategies—one-on-one peer navigation and a small group program—either on their own or combined. The 375 participants, all HIV-negative trans MSM eligible for PrEP, were randomly assigned to one of four groups (each receiving different peer-delivered HIV prevention strategies designed to increase PrEP uptake) and studied over 21 months. Every three months, participants completed surveys, did at-home HIV testing, and submitted samples to measure PrEP use. The study also included interviews to better understand how participants make decisions about PrEP and what their experiences were like in the program. The goal of the project was to evaluate the effectiveness of digitally delivered, peer-based HIV prevention strategies in increasing PrEP uptake. By engaging transgender MSM as active partners in the research process, the project aimed to develop culturally tailored, community-informed approaches to HIV prevention. Ultimately, the study seeks to fill critical gaps in HIV prevention for this underserved population, with implications for other at-risk population, and contribute to national efforts to end the HIV epidemic.

13. In filling that critical gap, the research directly contributes to reducing infectious disease disparities and promoting health equity. It also fills a critical gap in biomedical HIV prevention research, an area long prioritized by NIH due to the disproportionate burden of HIV among marginalized communities. The study also supports NIH's commitment to community-engaged research and inclusive public health innovation, and advances national efforts outlined in the



2021–2025 U.S. National Strategic Plan to End the HIV Epidemic, reinforcing NIH’s broader public health mission. Ex. A.

14. The application for this grant was the culmination of over a decade of research, beginning with a formative study in 2009 and followed by multiple qualitative, quantitative, and intervention studies that informed the final design. Developing the application took nearly a year and involved close collaboration with a team of six co-investigators from different institutions. The process was intensive, with significant time devoted to refining the proposal—including 50 to 60 hours in the final week alone. The application underwent two rounds of rigorous NIH peer review; while the first submission scored well, it was not initially funded. After careful revision and resubmission, it ultimately received a highly competitive score (scoring in the first percentile), reflecting both the quality of the science and the depth of preparation behind it.

15. By year three of the five-year project, we had hired a team of six staff members and four consultants, and were actively running a randomized controlled trial with 96 participants receiving intervention. Intervention was delivered by peers whom our team had trained, and was built on two years of collaboration with a national community advisory board to ensure materials were implementation-ready. Preparing for launch involved extensive groundwork, including over six months of staff training in facilitation, motivational interviewing, and crisis response, and work on branding and development of recruitment advertisements with a community artist. The project also included HIV testing, PrEP adherence monitoring through remote biospecimen collection, and coordination with an external laboratory. We had established a comprehensive study protocol, safety procedures, IRB approvals, and data management systems, and were six months into the 15-month observation period.

16. On March 21, 2025, NIH issued a termination notice, which stated that the award for this grant “no longer effectuates agency priorities.” A true and correct copy of my termination notice is attached hereto as Exhibit C. Three days later, on March 24, 2025, NIH issued a revised notice of award (NOA) reflecting the termination of the grant and echoing the language included in the termination notice. A true and correct copy of the revised NOA is attached hereto as Exhibit D.

17. I was never given any previous indication that my grant was in jeopardy, including when NIH twice approved my annual renewal request.

18. Neither the revised NOA nor the termination notice includes any individualized explanation for why the grant was cancelled, and both fail to discuss any of the data or analysis

from our application, annual progress reports, or other related material. Instead, the termination notice includes the following language about its decision:

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Ex. C at 2; *see also* Ex. D at 5.

19. I don't understand what the termination notice means by "gender identity" in relation to my project, nor did I understand how my project was "based on" "gender identity." I received no communication following up with clarification. While the project did involve transgender participants, the research ultimately centered on examining sexual risk behaviors for HIV and biomedical prevention, which is based in biological and anatomical sex. The primary focus was on encouraging the use of PrEP, which is a biomedical intervention aimed at reducing HIV acquisition risk.

20. Our project targeted enrollment to include 50% people of color, with a geographic focus on areas experiencing the highest rates of new HIV diagnoses in alignment with the White House Office of National AIDS Policy's national strategy. Ex. A at 16. We also worked with transgender men who have sex with men, the group with the highest HIV risk. While we included diverse populations in our research, the study itself was not centered around gender identity but rather on addressing the biomedical aspects of preventing HIV acquisition.

21. My other grant terminations were communicated in nearly identical ways, with no individualized explanations as to why the awards were canceled. In total, four of my other grants were terminated with references to "gender identity," with identical (or nearly identical) language as the termination notice discussed above. One grant was terminated with reference to "DEI." Across all of these grant terminations, key terms like "gender identity" were never defined, and their relevance to the specific canceled projects were unclear.

22. Generally, grant projects are required to submit annual progress reports. It is my understanding that it is extremely rare for a grant to be terminated or not renewed mid-project, especially after several years of work. To my knowledge, the only reasons for such a drastic action

would typically involve research misconduct or harm to participants. In my multi-decade career, I had never personally encountered a grant being terminated in the middle of a project before now.

23. The impacts of the grant termination have been severe. I cannot pay my staff of six people and have lost three months of my own salary.

24. I will be restricted in my ability to work on a project that took years to develop and receive funding for. Further, the early termination of the program with active participants will certainly damage the trust I have built with this community.

25. At the time of termination, we were only about halfway through the 15-month intervention period for our participants. The data we have collected will now be unusable for analysis to achieve the project aims, and the biospecimen samples collected have been discarded.

26. At the time of termination, we were approximately halfway through the 15-month observation period with our study participants. The sudden halt means that the data collected to date—midpoint data from an incomplete intervention—cannot be meaningfully analyzed and will not support valid conclusions. Similarly, the biospecimen samples collected under the study protocol have been discarded, representing a permanent loss of both scientific and financial investment. Because of the tightly controlled experimental design, pausing the study mid-course breaks the protocol's integrity—making it difficult to resume the study in an acceptable way.

27. The termination of this grant additionally raises serious ethical concerns due to the lack of a clear process for participants actively involved in the trial. Without the ability to bill or invoice, and with no plan for study close-out activities, participants—who were receiving an intervention as part of the study—are left in an uncertain and unsupported position. As a highly marginalized and at-risk population with mistrust of healthcare and research settings, the abrupt termination of the project may not only cause immediate harm and distress, but may also have long-term consequences. Research has found that stigma in healthcare settings, including interruptions in continuity of care, results in future avoidance of healthcare; thus, the immediate termination may adversely impact this population's future engagement in healthcare and research settings.

28. Typically, a study termination involves a plan to safely transition participants off the intervention, notify Institutional Review Boards, and ensure no harm. The abruptness of this termination, without a mission plan or proper procedures in place, is highly unusual—such actions are generally reserved for cases involving participant harm or researcher misconduct.

29. About 80 former participants in the study reached out to share their gratitude for the researchers' work contributing to health efforts relating to transgender populations and express dismay at the news that the project would be terminated. I am concerned that these former participants, who entrusted us with their stories and experiences, will feel abandoned—and that the trust we built with a highly marginalized population may now be irreparably damaged. Many of them described the study as one of the few times they felt seen and valued in a healthcare or research setting. At the very least, this termination cuts short a vital opportunity to extend the insights and positive outcomes experienced by those participants to the broader transgender community.

30. This grant supported predominantly transgender staff, meaning that the loss of this funding not only disrupts critical work but also undermines the capacity of a workforce that is both uniquely qualified and deeply connected to the populations they serve. The staff has also experienced severe emotional harm—many have expressed feelings of being devalued or targeted, and some are now questioning their place in public health entirely.

31. The termination of this portfolio of grants has left me uncertain about how to proceed, and it threatens my professional trajectory, ability to contribute to my field, and options for future career opportunities.

32. I worked with my university to file an appeal which was submitted April 18, 2025. Still, I do not know whether the appeal has any chance of success, given the termination notice's statement that modification of the project could align the project with agency priorities, and therefore no corrective action is possible. Ex. C at 2. I also did not know how to recharacterize my project in my appeal to fit within the asserted new agency priorities because I do not understand the terms used as the basis for termination.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 21st day of April, 2025.

A handwritten signature in black ink, appearing to be 'Sari Reisner', written over a horizontal line.

Sari Reisner

# EXHIBIT A

# NATIONAL HIV/AIDS STRATEGY



for the **United States**  
**2022–2025**





**Acknowledgments:** The National HIV/AIDS Strategy (NHAS or Strategy) was developed by the White House Office of National AIDS Policy (ONAP) in collaboration with federal partners and with input from the HIV community across the country. Interested parties and organizations throughout the federal government and those engaged in work in many different communities have helped shape the goals, objectives, and strategies in the Strategy. ONAP extends the gratitude and appreciation of the White House to everyone who made thoughtful recommendations and recommitted to the Strategy’s vision and goals. ONAP also offers thanks to the team at the Office of Infectious Disease and HIV/AIDS Policy in the U.S. Department of Health and Human Services for its many contributions to developing the Strategy.

**Language used in the National HIV/AIDS Strategy:** The Strategy honors the lived experiences and choices of all people, regardless of age, sex, gender identity, sexual orientation, race, ethnicity, religion, disability, geographic location, or socioeconomic circumstance. To reflect this, authors made a concerted effort to use inclusive and person-first language throughout the strategy. Evidence-based, contemporary terminology is also used to convey respect and to reduce stigma faced by communities and populations disproportionately impacted by HIV. This approach is intended to reflect the administration’s vision for a collective, inclusive, and respectful national response. Despite these efforts, in certain instances, for example to accurately convey scientific meaning, specific terminology or language may be unintentionally offensive or stigmatizing to some individuals or populations.

Additional information regarding the Strategy and associated activities may be accessed at the [White House website](#).

**Suggested citation:** The White House. 2021. *National HIV/AIDS Strategy for the United States 2022–2025*. Washington, DC.

The National HIV/AIDS Strategy is not a budget document and does not imply approval for any specific action under Executive Order 12866 or the Paperwork Reduction Act. The Strategy will inform the Federal budget and regulatory development processes within the context of the goals articulated in the President’s Budget. All activities included in the Strategy are subject to budgetary constraints and other approvals, including the weighing of priorities and available resources by the Administration in formulating its annual budget and by Congress in legislating appropriations.



# VISION ★ ★ ★ ★ ★

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*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, lives free from stigma and discrimination, and can achieve their full potential for health and well-being across the lifespan.*

*This vision includes all people, regardless of age, sex, gender identity, sexual orientation, race, ethnicity, religion, disability, geographic location, or socioeconomic circumstance.*

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# EXECUTIVE SUMMARY

Building on lessons learned and progress made in the past 40 years, the United States now has the opportunity to end the HIV epidemic. This opportunity has been made possible by tireless advocacy, determined research, and dedicated delivery of diagnostic, prevention, care, treatment, and supportive services.

The nation's annual new HIV infections have declined from their peak in the mid-1980s, and people with HIV in care and treatment are living longer, healthier lives. In 2019, the estimated number of new HIV infections was 34,800 and 1.2 million people were living with HIV in the United States. However, not all groups have experienced decreases in HIV infections or improvements in health outcomes. Centers for Disease Control and Prevention data show that new HIV infections fell 8% from 2015 to 2019, after a period of general stability in new infections in the United States. This trend represents a hopeful sign of progress. But gains remain uneven, illuminating opportunities for geographic- and population-focused efforts to make more effective use of the powerful HIV prevention, care, and treatment tools now available.

This National HIV/AIDS Strategy (the Strategy), the nation's third national HIV strategy, updates the HIV National Strategic Plan (2021). The Strategy sets forth bold targets for ending the HIV epidemic in the United States by 2030, including a 75% reduction in new HIV infections by 2025 and a 90% reduction by 2030. For interested parties and organizations across the nation, the Strategy articulates goals, objectives, and strategies to prevent new infections, treat people with HIV to improve health outcomes, reduce HIV-related disparities, and better integrate and coordinate the efforts of all partners to achieve the bold targets for ending the epidemic. The Strategy also establishes evidence-based indicators to measure progress, with quantitative targets for each indicator, and designates priority populations.

The Strategy establishes the following vision:

*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, lives free from stigma and discrimination, and can achieve their full potential for health and well-being across the lifespan.*

*This vision includes all people, regardless of age, sex, gender identity, sexual orientation, race, ethnicity, religion, disability, geographic location, or socioeconomic circumstance.*

The vision, goals, objectives, and other components of the Strategy were developed and approved by a dedicated Steering Committee, composed of subject matter experts from across the federal government, with input from numerous and varied interested parties and organizations in the field. The Strategy is designed to be accessible to and useful for a broad audience, including people working in public health, health care, government, community-based organizations, research, private industry, and academia. It serves as a roadmap for all sectors of society to guide development of policies, services, programs, initiatives, and other actions to achieve the nation's goal of ending the HIV epidemic by 2030.

The Strategy is designed to facilitate a whole-of-society national response to the HIV epidemic in the United States that accelerates efforts to end the HIV epidemic in the United States by 2030 while supporting people with HIV and reducing HIV-associated morbidity and mortality. While not every objective or strategy will speak to or be actionable by all readers, the intent is that individuals and organizations from all sectors of society can find opportunities

where they can support necessary scale-up, expansion, and refinement efforts. All communities, regardless of HIV prevalence, are vital to ending the HIV epidemic in this country and private- and public-sector partners must work together with community-based, faith-focused, and advocacy organizations; governmental public health; mental health and substance use disorder treatment services; the criminal justice system; and providers of housing, food and nutrition, education, and employment services because we all have a role in reducing new HIV infections, improving outcomes and quality of life for people with HIV, and eliminating HIV disparities.

Interwoven throughout the Strategy are approaches to address the individual, community, and structural factors and inequities that contribute to the spread of HIV, such as stigma and social determinants of health. The Strategy highlights opportunities to integrate HIV prevention, care, and treatment into prevention and treatment for sexually transmitted infections, viral hepatitis, mental health and substance use disorders, and other public health efforts by leveraging capacity and infrastructure across the domains and breaking down operational and funding silos. A recurring theme is the need to bring to scale innovative solutions and data-driven approaches to address the ongoing and emerging challenges to HIV prevention, care, and treatment, including expanding the types of community and clinical sites that address HIV to help reach and engage people in need of services; supporting retention in HIV prevention and care services; continuing research into development of better prevention tools, therapeutics, and vaccines; and understanding how to make best use of available tools in real-world settings. Throughout this document, the term “care” is used as an umbrella term meant to encompass holistic services including treatment and supportive services.

To ensure implementation and accountability, a Federal Implementation Plan that documents the specific actions that federal partners will take to achieve the Strategy’s goals and objectives will be developed in early 2022. Progress toward meeting the Strategy’s goals will be monitored and reported annually.

The Strategy and the [\*Ending the HIV Epidemic in the U.S.\*](#) (EHE) initiative are closely aligned and complementary, with EHE serving as a leading component of the work by the U.S. Department of Health and Human Services (HHS), in collaboration with local, state, tribal, federal, and community partners, to achieve the Strategy’s goals. The EHE initiative focuses on scaling up four strategies in the communities most affected by HIV. The Strategy covers the entire country, has a broader focus across federal departments and agencies beyond HHS and all sectors of society, and addresses the integration of several key components that are vital to our collective work, including stigma, discrimination, and social determinants of health.

# NHAS AT-A-GLANCE

This At-A-Glance section briefly summarizes the Goals, Objectives, and Strategies that are discussed in detail in the narrative that follows.



## Goal 1: Prevent New HIV Infections

### 1.1 Increase awareness of HIV

- 1.1.1 Develop and implement campaigns, interventions, and resources to provide education about comprehensive sexual health; HIV risks; options for prevention, testing, care, and treatment; and HIV-related stigma reduction.
- 1.1.2 Increase knowledge of HIV among people, communities, and the health workforce in geographic areas disproportionately affected.
- 1.1.3 Integrate HIV messaging into existing campaigns and other activities pertaining to other parts of the syndemic, such as STIs, viral hepatitis, and substance use and mental health disorders, as well as in primary care and general wellness, and as part of annual reproductive health visits and wellness visits.

### 1.2 Increase knowledge of HIV status

- 1.2.1 Test all people for HIV according to the most current USPSTF recommendations and CDC guidelines.
- 1.2.2 Develop new and expand implementation of effective, evidence-based, or evidence-informed models for HIV testing that improve convenience and access.
- 1.2.3 Incorporate a status-neutral approach to HIV testing, offering linkage to prevention services for people who test negative and immediate linkage to HIV care and treatment for those who test positive.
- 1.2.4 Provide partner services to people diagnosed with HIV or other STIs and their sexual and/or syringe-sharing partners.

### 1.3 Expand and improve implementation of safe, effective prevention interventions, including treatment as prevention, PrEP, PEP, and SSPs, and develop new options

- 1.3.1 Engage people who experience risk for HIV in traditional public health and health care delivery systems, as well as in nontraditional community settings.
- 1.3.2 Scale up treatment as prevention (i.e., U=U) by diagnosing all people with HIV, as early as possible, and engaging them in care and treatment to achieve and maintain viral suppression.
- 1.3.3 Make HIV prevention services, including condoms, PrEP, PEP, and SSPs, easier to access and support continued use.
- 1.3.4 Implement culturally competent and linguistically appropriate models and other innovative approaches for delivering HIV prevention services.
- 1.3.5 Support research into the development and evaluation of new HIV prevention modalities and interventions for preventing HIV transmissions in priority populations.

- 1.3.6 Expand implementation research to successfully adapt evidence-based interventions to local environments to maximize potential for uptake and sustainability.

**1.4 Increase the diversity and capacity of health care delivery systems, community health, public health, and the health workforce to prevent and diagnose HIV**

- 1.4.1 Provide resources, incentives, training, and technical assistance to expand workforce and systems capacity to provide or link clients to culturally competent, linguistically appropriate, and accessible HIV testing, prevention, and supportive services especially in areas with shortages that are geographic, population, or facility based.
- 1.4.2 Increase the diversity of the workforce of providers who deliver HIV prevention, testing, and supportive services.
- 1.4.3 Increase the inclusion of paraprofessionals on prevention teams by advancing training, certification, supervision, financing, and team-based care service delivery.
- 1.4.4 Include comprehensive sexual health and substance use prevention and treatment information in curricula of medical and other health workforce education and training programs.



## **Goal 2: Improve HIV-Related Health Outcomes of People with HIV**

### **2.1 Link people to care immediately after diagnosis and provide low-barrier access to HIV treatment**

- 2.1.1 Provide same-day or rapid (within 7 days) start of antiretroviral therapy for persons who are able to take it; increase linkage to HIV health care within 30 days for all persons who test positive for HIV.
- 2.1.2 Increase the number of schools providing on-site sexual health services through school-based health centers and school nurses, and linkages to HIV testing and medical care through youth-friendly providers in the community.

### **2.2 Identify, engage, or reengage people with HIV who are not in care or not virally suppressed**

- 2.2.1 Expand uptake of data-to-care models using data sharing agreements, integration and use of surveillance, clinical services, pharmacy, and social/support services data to identify and engage people not in care or not virally suppressed.
- 2.2.2 Identify and address barriers for people who have never engaged in care or who have fallen out of care.

### **2.3 Increase retention in care and adherence to HIV treatment to achieve and maintain long-term viral suppression and provide integrative HIV services for HIV-associated comorbidities, coinfections, and complications, including STIs**

- 2.3.1 Support the transition of health care systems, organizations, and patients/clients to become more health literate in the provision of HIV prevention, care, and treatment services.
- 2.3.2 Develop and implement effective, evidence-based, or evidence-informed interventions and supportive services that improve retention in care.
- 2.3.3 Expand implementation research to successfully adapt effective evidence-based interventions, such as HIV telehealth, patient and peer navigators, accessible pharmacy services, community health workers, and others, to local environments to facilitate uptake and retention to priority populations.
- 2.3.4 Support ongoing clinical, behavioral, and other research to support retention in care, medication adherence, and durable viral suppression.

### **2.4 Increase the capacity of the public health, health care delivery systems, and health care workforce to effectively identify, diagnose, and provide holistic care and treatment for people with HIV**

- 2.4.1 Provide resources, value-based and other incentives, training, and technical assistance to expand workforce and systems capacity to provide or link clients to culturally competent and linguistically appropriate care, treatment, and supportive services especially in areas with shortages that are geographic, population, or facility based.
- 2.4.2 Increase the diversity of the workforce of providers who deliver HIV care and supportive services.
- 2.4.3 Increase inclusion of paraprofessionals on teams by advancing training, certification, supervision, reimbursement, and team functioning to assist with screening/management of HIV, STIs, viral hepatitis, and mental and substance use disorders and other behavioral health conditions.



## **2.5 Expand capacity to provide whole-person care to older adults with HIV and long-term survivors**

- 2.5.1 Identify, implement, and evaluate models of care that meet the needs of people with HIV who are aging and ensure quality of care across services.
- 2.5.2 Identify and implement best practices related to addressing psychosocial and behavioral health needs of older people with HIV and long-term survivors including substance use treatment, mental health treatment, and programs designed to decrease social isolation.
- 2.5.3 Increase HIV awareness, capability, and collaboration of service providers to support older people with HIV, including in settings such as aging services, housing for older adults, substance use treatment, and disability and other medical services.
- 2.5.4 Promote research, cross-agency collaborations, and sharing of research discoveries that address specific aging-related conditions in people with HIV, and other comorbidities and coinfections that can impact people with HIV of all ages.
- 2.5.5 Develop and optimize collaborative multi-agency and multi-sectoral approaches and strategies to address emergent and evolving challenges facing people living with HIV at various life stages to support healthy aging with HIV.

## **2.6 Advance the development of next-generation HIV therapies and accelerate research for HIV cure**

- 2.6.1 Promote research and encourage public-private partnerships to accelerate new therapies to achieve sustained viral suppression and to address drug toxicity, viral resistance, adherence, and retention in care and stigma associated with ART use.
- 2.6.2 Increase investment in innovative basic and clinical research to inform and accelerate a research agenda to discover how to sustain viral suppression, achieve ART-free remission, reduce and eliminate viral reservoirs, and achieve HIV cure.



## Goal 3: Reduce HIV-Related Disparities and Health Inequities

### 3.1 Reduce HIV-related stigma and discrimination

- 3.1.1 Strengthen enforcement of civil rights laws (including language access services and disability rights), promote reform of state HIV criminalization laws, and assist states in protecting people with HIV from violence, retaliation, and discrimination associated with HIV status, homophobia, transphobia, xenophobia, racism, substance use, and sexism.
- 3.1.2 Ensure that health care professionals and front-line staff complete education and training on stigma, discrimination, and unrecognized bias toward populations with or who experience risk for HIV, including LGBTQI+ people, immigrants, people who use drugs, and people involved in sex work.
- 3.1.3 Support communities in efforts to address misconceptions and reduce HIV-related stigma and other stigmas that negatively affect HIV outcomes.
- 3.1.4 Ensure resources are focused on the communities and populations where the need is greatest, especially Black, Latino, and American Indian/Alaska Native and other people of color, particularly those who are also gay and bisexual men, transgender people, people who use substances, sex workers, and immigrants.
- 3.1.5 Create funding opportunities that specifically address social and structural drivers of health as they relate to Black, Latino, and American Indian/Alaska Native and other people of color.

### 3.2 Reduce disparities in new HIV infections, in knowledge of status, and along the HIV care continuum

- 3.2.1 Increase awareness of HIV-related disparities through data collection, analysis, and dissemination of findings.
- 3.2.2 Develop new and scale up effective, evidence-based or evidence-informed interventions to improve health outcomes among priority populations and other populations or geographic areas experiencing disparities.

### 3.3 Engage, employ, and provide public leadership opportunities at all levels for people with or who experience risk for HIV

- 3.3.1 Create and promote public leadership opportunities for people with or who experience risk for HIV.
- 3.3.2 Work with communities to reframe HIV services and HIV-related messaging so that they do not stigmatize people or behaviors.

### 3.4 Address social and structural determinants of health and co-occurring conditions that impede access to HIV services and exacerbate HIV-related disparities

- 3.4.1 Develop whole-person systems of care and wellness that address co-occurring conditions for people with or who experience risk for HIV.
- 3.4.2 Adopt policies that reduce cost, payment, coverage, and/or access barriers to improve the delivery and receipt of services for people with or who experience risk for HIV.
- 3.4.3 Improve screening and linkage to services for people with or who experience risk for HIV who are diagnosed with and/or are receiving services for co-occurring conditions.

- 3.4.4 Develop and implement effective, evidence-based and evidence-informed interventions that address social and structural determinants of health among people with or who experience risk for HIV including lack of continuous health care coverage, HIV-related stigma and discrimination in public health and health care systems, medical mistrust, inadequate housing and transportation, food insecurity, unemployment, low health literacy, and involvement with the justice system.
- 3.4.5 Increase the number of schools that have implemented LGBTQ-supportive policies and practices, including (1) having a Gay/Straight Alliance (GSA), Gender Sexuality Alliance, or similar clubs, (2) identifying safe spaces, (3) adopting policies expressly prohibiting discrimination and harassment based on sexual orientation or gender identity, (4) encouraging staff to attend professional development, (5) facilitating access to out-of-school health service providers, (6) facilitating access to out-of-school social and psychological service providers, and (7) providing LGBTQ-relevant curricula or supplementary materials.
- 3.4.6 Develop new and scale up effective, evidence-based or evidence-informed interventions that address intersecting factors of HIV, homelessness or housing instability, mental health and violence, substance use, and gender especially among cis- and transgender women and gay and bisexual men.

### **3.5 Train and expand a diverse HIV workforce by further developing and promoting opportunities to support the next generation of HIV providers including health care workers, researchers, and community partners, particularly from underrepresented populations**

- 3.5.1 Promote the expansion of existing programs and initiatives designed to increase the numbers of non-White research and health professionals.
- 3.5.2 Increase support for the implementation of mentoring programs for individuals from diverse cultural backgrounds to expand the pool of HIV research and health professionals.
- 3.5.3 Encourage the implementation of effective recruitment of community partners through community-based participatory research and social networking approaches.

### **3.6 Advance HIV-related communications to achieve improved messaging and uptake, as well as to address misinformation and health care mistrust**

- 3.6.1 Develop and test strategies to promote accurate creation, dissemination, and uptake of information and to counter associated misinformation and disinformation.
- 3.6.2 Increase diversity and cultural competence in health communication research, training, and policy.
- 3.6.3 Expand community engagement in health communication initiatives and research.
- 3.6.4 Include critical analysis and health communication skills in HIV programs to provide participants with the tools to seek and identify accurate health information and to advocate for themselves and their communities.
- 3.6.5 Expand effective communication strategies between providers and consumers to build trust, optimize collaborative decision-making, and promote success of evidence-based prevention and treatment strategies.



## **Goal 4: Achieve Integrated, Coordinated Efforts That Address the HIV Epidemic among All Partners and Interested Parties**

### **4.1 Integrate programs to address the syndemic of HIV, STIs, viral hepatitis, and substance use and mental health disorders in the context of social and structural/institutional factors including stigma, discrimination, and violence**

- 4.1.1 Integrate HIV awareness and services into outreach and services for issues that intersect with HIV such as intimate partner violence, homelessness or housing instability, STIs, viral hepatitis, and substance use and mental health disorders.
- 4.1.2 Implement a no-wrong-door approach to screening and linkage to services for HIV, STIs, viral hepatitis, and substance use and mental health disorders across programs.
- 4.1.3 Identify and address funding, policy, data, workforce capacity, and programmatic barriers to effectively address the syndemic.
- 4.1.4 Coordinate and align strategic planning efforts on HIV, STIs, viral hepatitis, substance use disorders, and mental health care across national, state, and local partners.
- 4.1.5 Enhance the ability of the HIV workforce to provide naloxone and educate people on the existence of fentanyl in the drug supply to prevent overdose and deaths and facilitate linkage to substance use disorder treatment and harm reduction programs.

### **4.2 Increase coordination among and sharing of best practices from HIV programs across all levels of government (federal, state, tribal, local, and territorial) and with public and private health care payers, faith-based and community-based organizations, the private sector, academic partners, and the community**

- 4.2.1 Focus resources including evidence-based and evidence-informed interventions in the geographic areas and priority populations disproportionately affected by HIV.
- 4.2.2 Enhance collaboration among local, state, tribal, territorial, national, and federal partners and the community to address policy and structural barriers that contribute to persistent HIV-related disparities and implement policies that foster improved health outcomes.
- 4.2.3 Coordinate across partners to quickly detect and respond to HIV outbreaks.
- 4.2.4 Support collaborations between community-based organizations, public health organizations, education agencies and schools, housing providers, and health care delivery systems to provide linkage to and delivery of HIV testing, prevention, care, and treatment services as well as supportive services.

### **4.3 Enhance the quality, accessibility, sharing, and uses of data, including HIV prevention and care continua data and social determinants of health data**

- 4.3.1 Promote the collection, electronic sharing, and use of HIV risk, prevention, and care and treatment data using interoperable data standards, including data from electronic health records, in accordance with applicable law.
- 4.3.2 Use interoperable health information technology, including application programming interfaces (APIs), clinical decision support tools, electronic health records and health IT products certified by the Office of the National Coordinator's Health IT Certification Program, and health information exchange networks, to improve HIV prevention efforts and care outcomes.

- 4.3.3 Encourage and support patient access to and use of their individual health information, including use of their patient-generated health information and use of consumer health technologies in a secure and privacy supportive manner.

#### **4.4 Foster private-public-community partnerships to identify and scale up best practices and accelerate HIV advances**

- 4.4.1 Adopt approaches that incentivize the scale up of effective interventions among academic centers, health departments, community-based organizations, allied health professionals, people with HIV and their advocates, the private sector, and other partners.
- 4.4.2 Expand opportunities and mechanisms for information sharing and peer technical assistance within and across jurisdictions to move effective interventions into practice more swiftly.
- 4.4.3 Develop and optimize collaborative multi-agency and multi-sectoral approaches and strategies to address emergent and evolving challenges facing persons of all ages living with HIV.

#### **4.5 Improve mechanisms to measure, monitor, evaluate, and use the information to report progress and course correct as needed in order to achieve the Strategy's goals**

- 4.5.1 Streamline and harmonize reporting and data systems to reduce burden and improve the timeliness, availability, and usefulness of data.
- 4.5.2 Monitor, review, evaluate, and regularly communicate progress on the National HIV/AIDS Strategy.
- 4.5.3 Ensure that the National HIV/AIDS Strategy's goals and priorities are included in cross-sector federal funding requirements.
- 4.5.4 Strengthen monitoring and accountability for adherence to requirements, targets, and goals by funded partners.
- 4.5.5 Identify and address barriers and challenges that hinder achievement of goals by funded partners and other interested parties.

## INDICATORS AT-A-GLANCE

- Indicator 1:** Increase knowledge of status to 95% from a 2017 baseline of 85.8%.
- Indicator 2:** Reduce new HIV infections by 75% from a 2017 baseline of 37,000.
- Indicator 3:** Reduce new HIV diagnoses by 75% from a 2017 baseline of 38,351.
- Indicator 4:** Increase PrEP coverage to 50% from a 2017 baseline of 13.2%.
- Indicator 5:** Increase linkage to care within 1 month of diagnosis to 95% from a 2017 baseline of 77.8%.
- Indicator 6:** Increase viral suppression among people with diagnosed HIV to 95% from a 2017 baseline of 63.1%.
  - Indicator 6a:** Increase viral suppression among MSM diagnosed with HIV to 95% from a 2017 baseline of 66.1%.
  - Indicator 6b:** Increase viral suppression among Black MSM diagnosed with HIV to 95% from a 2017 baseline of 58.4%.
  - Indicator 6c:** Increase viral suppression among Latino MSM diagnosed with HIV to 95% from a 2017 baseline of 64.9%.
  - Indicator 6d:** Increase viral suppression among American Indian/Alaska Native MSM diagnosed with HIV to 95% from a 2017 baseline of 67.3%.
  - Indicator 6e:** Increase viral suppression among Black women diagnosed with HIV to 95% from a 2017 baseline of 59.3%.
  - Indicator 6f:** Increase viral suppression among transgender women in HIV medical care to 95% from a 2017 baseline of 80.5%.
  - Indicator 6g:** Increase viral suppression among people who inject drugs diagnosed with HIV to 95% from a 2017 baseline of 54.9%.
  - Indicator 6h:** Increase viral suppression among youth aged 13-24 diagnosed with HIV to 95% from a 2017 baseline of 57.1%.
- Indicator 7:** Decrease stigma among people with diagnosed HIV by 50% from a 2018 baseline median score of 31.2 on a 10-item questionnaire.
- Indicator 8:** Reduce homelessness among people with diagnosed HIV by 50% from a 2017 baseline of 9.1%.
- Indicator 9:** Increase the median percentage of secondary schools that implement at least 4 out of 7 LGBTQ-supportive policies and practices to 65% from a 2018 baseline of 59.8%.

In addition, quality of life for people with HIV was designated as the subject for a developmental indicator, meaning that data sources, measures, and targets will be identified and progress monitored thereafter.



# INTRODUCTION

## HIV EPIDEMIC: PROGRESS TO DATE

After nearly 40 years of tireless advocacy, determined research, and dedicated delivery of diagnostic, prevention, care, treatment, and supportive services, the United States now has the opportunity to end the HIV epidemic. Since it was first discovered in 1981, HIV has affected the lives of millions of people across the nation. Today, through the ongoing commitment of interested parties and organizations from many sectors, as well as landmark biomedical and scientific research advances, the nation has many effective HIV diagnostics, prevention strategies, and improved care and treatment models. New laboratory and epidemiological approaches enable us to identify where HIV is spreading most rapidly and to respond swiftly to stop the further spread of new HIV transmissions.

Over the past decade, the HIV response in the United States has been guided by the National HIV/AIDS Strategy (NHAS or Strategy), first released in 2010 and updated in 2015. The Strategy has changed the way that Americans talk about HIV, prioritize and coordinate resources, and deliver prevention and care services along with other clinical and nonclinical services that support people with or who experience risk for HIV. It has also led to increased collaboration among federal agencies; people with or who experience risk for HIV; state, local, tribal, and territorial governments; health care providers; researchers; faith communities; and many other community partners. Since the release of those first national strategies, several important achievements have bolstered the nation's HIV response:

- **Population-level viral suppression has increased.** After the NHAS was released, the Centers for Disease Control and Prevention (CDC) published its first national estimates of the share of all people with HIV who have achieved viral suppression, finding that only about one in four people with HIV (27.9%) in the United States was virally suppressed in 2010.<sup>1</sup> By 2019, however, viral suppression rates in the United States had doubled to 57%.<sup>2</sup> Although still too low, these rates represent real progress.
- **HIV diagnoses have declined, especially in key groups.** HIV diagnosis rates were relatively stable for many years prior to the release of the NHAS. CDC data suggest that annual new diagnoses declined by 14.3% from 2010 (42,938) when the Strategy was released to 2019 (36,337).<sup>3, 4</sup> Large declines occurred in some groups, including women. Deaths declined by 7.6% from 2010 (16,726) to 2019 (15,463).<sup>3, 4</sup>
- **Outcome disparities within the Ryan White HIV/AIDS Program have decreased.** Nearly 9 in 10 clients of the Health Resources and Services Administration's (HRSA's) Ryan White HIV/AIDS Program (RWHAP) were virally suppressed in 2019, and the program continues to show progress at reducing disparities across groups.<sup>5</sup> From 2010 to 2019, the gap between male and female clients decreased from nearly 5 percentage points to <1 percentage point. Similarly, the difference between viral suppression rates in Black clients and White clients was 13 percentage points in 2010 but 7 percentage points in 2019.<sup>5, 6</sup>
- **Policy changes ensure that federal money follows the epidemic.** Earlier in the epidemic, federal HIV resources to states and local governments were either allocated via a discretionary manner or via a formula that relied on cumulative AIDS cases, skewing resources toward early epicenters of the epidemic and not reflecting the current burden of HIV across the country. Prior to release of the Strategy, Congress changed the formulas used by the RWHAP to be based on living HIV/AIDS cases. The Strategy's call for federal money to follow the epidemic spurred further action. In fiscal year 2012, CDC changed the formula for its major HIV prevention program for state and local health departments to be based on living HIV/AIDS cases, and, in 2016, Congress modernized the law that authorized the Housing Opportunities for Persons With AIDS (HOPWA) program to be based on living HIV/AIDS cases.
- **The advent of pre-exposure prophylaxis (PrEP) has increased options for HIV prevention.** The first randomized controlled trial of PrEP reported results in 2010, and the U.S. Food and Drug Administration (FDA) approved the first PrEP medication in 2012. Several federal actions embraced this new biomedical

tool as an important part of comprehensive HIV prevention: for example, CDC issued interim and then final prescriber guidance; the expansion of PrEP access was a central component of the 2015 update to the NHAS; and the *Ending the HIV Epidemic in the U.S.* (EHE) initiative further sought to remove barriers to PrEP uptake, including through the establishment of the Ready, Set, PrEP program, which makes PrEP available at no cost to individuals without prescription drug coverage. Although uptake remains too low and disparities are large, the adoption of new medical technologies often takes decades, and the goal is to expedite widespread adoption of PrEP for people who can benefit from it.

- **Health insurance coverage rates for people with HIV have increased to match the general population.** In 2018, just 1 in 10 (11%) nonelderly people with HIV were uninsured, a rate on par with that of the general population (10%).<sup>7</sup> An estimated 42% of the adult population with HIV is covered by Medicaid, compared to 13% of the overall adult population.<sup>8</sup> Medicaid is the largest source of insurance coverage for people with HIV, covering a broad range of services from inpatient and outpatient care, to prescription medications, to preventive services.<sup>9</sup>
- **Strategic investments by the National Institutes of Health (NIH) in research have advanced efforts toward new prevention tools, next-generation therapies, a vaccine, and a cure.** NIH discovery science has been newly complemented by a suite of NIH implementation science projects designed to meet EHE initiative goals through improved use of proven HIV strategies.
- **States, cities, tribes, and local communities have developed their own HIV strategies.** These strategies (e.g., plans to end the HIV epidemic or achieve zero new infections) aligned with the NHAS and resulted in increased coordination across government agencies, nongovernmental organizations, and the private sector.
- **Interested parties and organizations have enhanced the focus on supports and support services such as housing and employment, which play key roles in enabling economic self-sufficiency and improving health outcomes.** With the effectiveness of early antiretroviral treatment (ART), many people with HIV can (and do) participate in the country's workforce. Employment is associated with improved HIV health outcomes, notably testing, linkage to care, and adherence to medication.<sup>10</sup> Coordination and collaboration at all levels of government and across the public and private sectors have led to an increased awareness of these supports. Moreover, the COVID-19 pandemic has led communities across the nation to employ new strategies in providing support services, improving access to food, housing, and employment services.
- **The *Ending the HIV Epidemic in the U.S.* initiative was launched in 2019.** This bold plan aims to end the HIV epidemic in the United States by 2030. EHE is the operational plan developed by agencies across the U.S. Department of Health and Human Services (HHS) to pursue that goal. The initiative leverages critical scientific advances in HIV prevention, diagnosis, treatment, and outbreak response by coordinating the highly successful programs, resources, and infrastructure of many HHS agencies and offices. The initiative is focused on areas where data show the highest numbers of new HIV infections, providing 57 geographic focus areas with a rapid infusion of additional resources, expertise, and technology to develop and implement locally tailored EHE plans.
- **President Biden issued an Executive Order on preventing and combating discrimination on the basis of gender identity or sexual orientation.** This Executive Order aims to prevent and combat discrimination on the basis of gender identity or sexual orientation, and to fully enforce Title VII and other laws that prohibit discrimination on the basis of gender identity or sexual orientation.

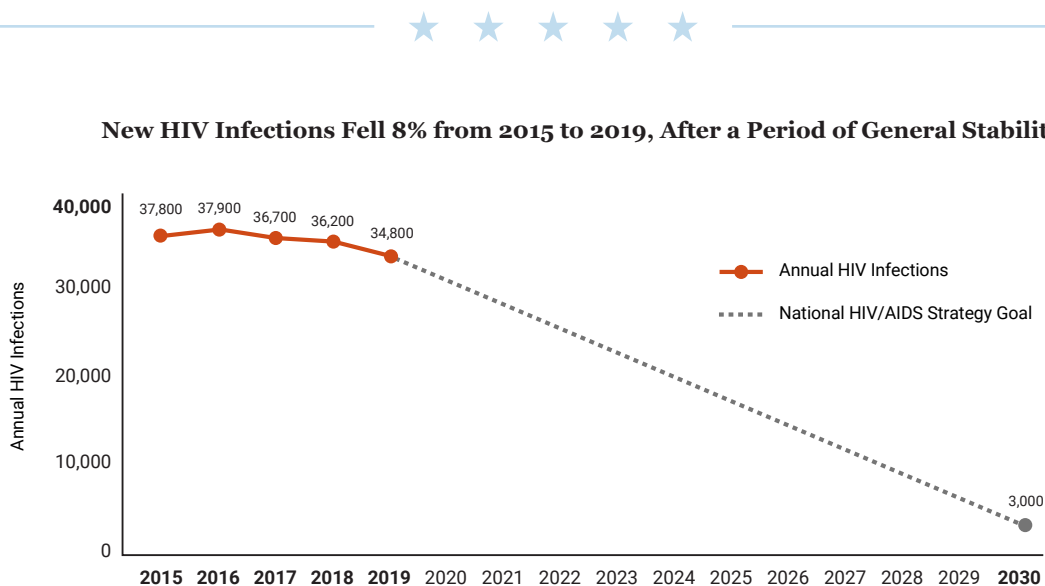
## HIV IN THE UNITED STATES TODAY

HIV persists as a serious public health challenge in the United States. An estimated 1.2 million people in the United States had HIV at the end of 2019, the most recent year for which this information is available.<sup>11</sup> National HIV prevention and care efforts have taken the nation from a peak of 130,000 HIV infections annually in the mid-1980s<sup>12</sup> to approximately 34,800 in 2019.<sup>10</sup> Although HIV infection rates have decreased in the United States, new infections continue in every U.S. state with 34,800 new infections occurring in 2019.



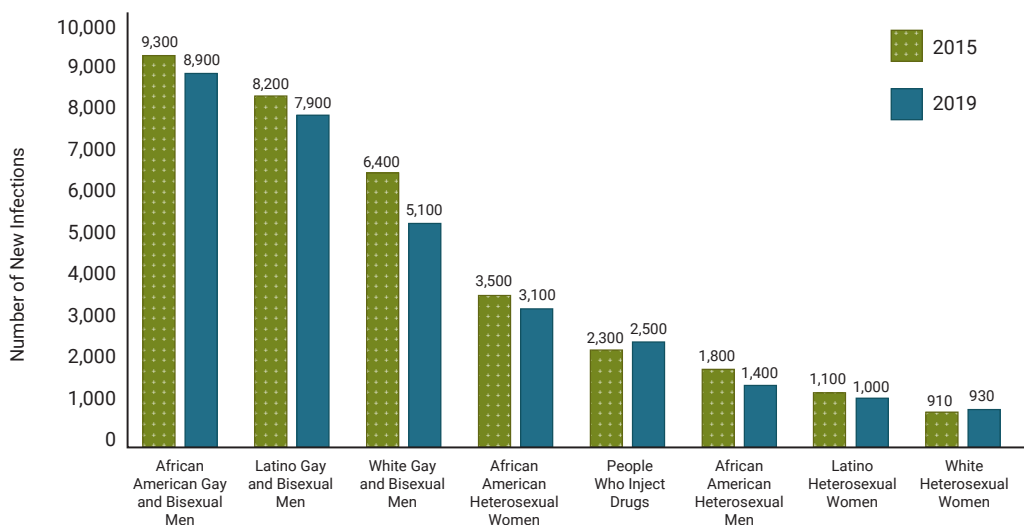
## HOPEFUL SIGNS OF PROGRESS EXIST.

The nation has seen hopeful signs of progress in recent years, but not everyone is benefiting equally from advances in HIV prevention and treatment. The latest CDC data show that new HIV infections declined by 8% from 2015 to 2019, after a period of general stability in new infections in the United States (see Figure 1). Much of this progress was due to larger declines among young gay and bisexual men in recent years.<sup>13</sup>



**Figure 1.** Annual HIV infections in the United States, 2015–2019

Despite this progress, important disparities persist. During this period, Black, Latino, and White gay and bisexual men and Black heterosexual women bore the greatest burden of new HIV infections.<sup>11</sup> (See Figure 2.)



**Figure 2.** New HIV infections by most impacted populations, United States, 2015 vs. 2019<sup>11</sup>

## EFFECTIVE TREATMENT AND PREVENTION ARE NOT ADEQUATELY REACHING PEOPLE WHO COULD BENEFIT MOST.

Although HIV remains a threat in every part of the United States, certain populations—and parts of the country—bear most of the burden, signaling where HIV prevention, care, and treatment efforts must be focused.

### HIV by Population

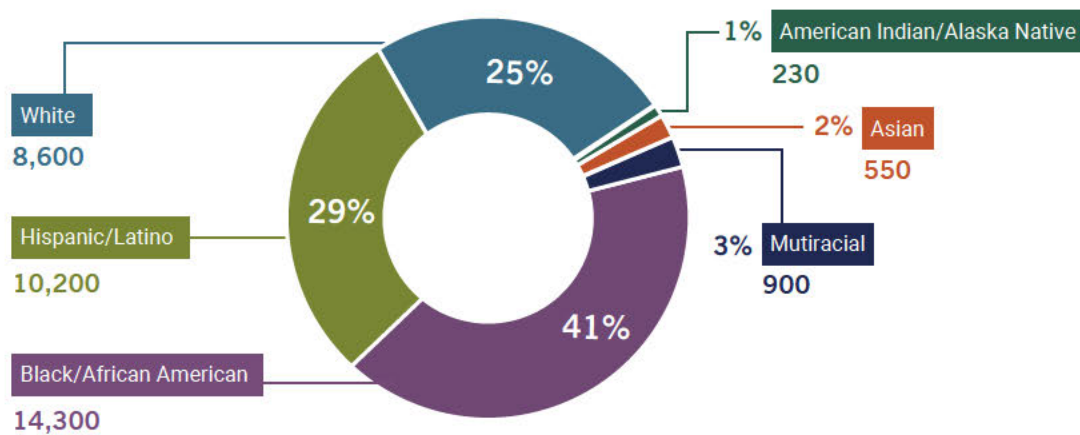
Black and Latino communities are disproportionately affected by HIV compared to other racial/ethnic groups (see Table 1).

**Table 1.** Proportion of People with HIV by Race/Ethnicity Compared to Proportion of U.S. Population, 2019

Race/Ethnicity	% of People with HIV, 2019 <sup>11</sup>	% of U.S. Population, 2019 <sup>14</sup>
<b>Black/African American</b>	<b>40.3%</b>	<b>13.4%</b>
White	28.5%	60.1%
<b>Hispanic/Latino</b>	<b>24.7%</b>	<b>18.5%</b>
Asian	1.5%	5.9%
American Indian/Alaska Native	0.3%	1.3%
Native Hawaiian and Other Pacific Islander	0.09%	0.2%

The disproportionate impact of HIV among Black and Latino communities is also evident in incidence (new infections). (See Figure 3.)

The latest incidence estimates indicate that effective **prevention and treatment are not adequately reaching people who could benefit most.**



**Figure 3.** HIV incidence by race/ethnicity, 2019<sup>11</sup>

In all regions of the United States, gay and bisexual men are the most disproportionately affected group. They account for about 66% of new HIV infections each year, even though they account for only 2% of the population, with the highest burden among Black and Latino gay and bisexual men and young men.<sup>14, 15</sup> In 2019, 26% of new HIV infections were among Black gay and bisexual men, 23% among Latino gay and bisexual men, and 45% among gay and bisexual men under the age of 35.



Disparities persist among women. Black women are disproportionately affected compared to women of other races/ethnicities. Although annual HIV infections remained stable among Black women from 2015 to 2019, the rate of new HIV infections among Black women was 11 times that of White women and 4 times that of Latina women.<sup>11</sup>

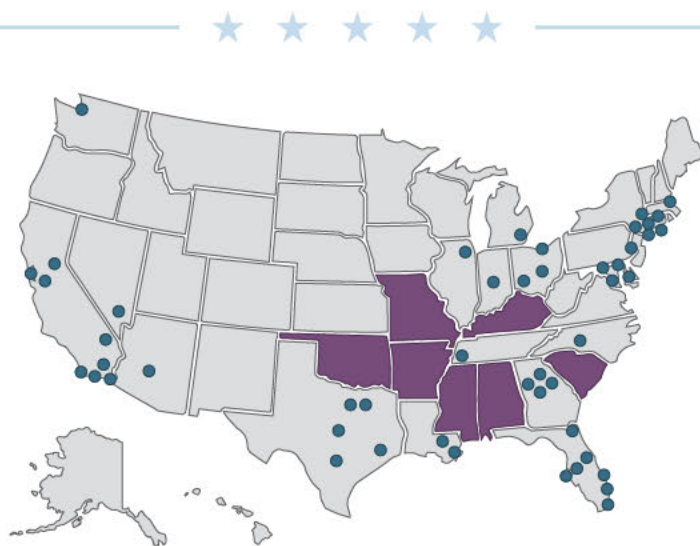
Over 1 million people identify as transgender in the United States.<sup>16</sup> Adult and adolescent transgender people composed 2% (669) of new HIV diagnoses in the United States and dependent areas in 2019. Most of those new HIV diagnoses were among Black/African American people. Compared to all adults and adolescents with diagnosed HIV in 2019, transgender women had almost equal viral suppression rates, while transgender men had higher viral suppression rates.<sup>2, 17, 18</sup>

In 2019, youth aged 13–24 years composed 21% of the 36,398 new HIV diagnoses in the United States. Youth with HIV are the least likely of any age group to be retained in care and have a suppressed viral load.<sup>3</sup> However, in a national survey of students in grades 9–12 in the United States, significantly fewer students reported being tested for HIV in 2019 (9.4%) than in 2009 (12.4%). In addition, trends over the past 10 years (from 2009 to 2019) indicate significant decreases in the percentage of sexually active high school students who used condoms during last sexual intercourse (61.1% vs. 54.3%), and only 8.6% of sexually active students reported being tested for sexually transmitted infections (STIs) during the past year.<sup>19</sup> This despite the fact that almost half of the 26 million new STIs were estimated to occur in youth ages 15–24 in the United States in 2018.

In 2019, 7% of new HIV infections in the United States were among people who inject drugs (PWID). Men who inject drugs accounted for 4% of new HIV infections, and women who inject drugs accounted for 3%. Long-term declining trends in HIV incidence among people who inject drugs have stalled. For example, from 2015 to 2019, the number of new HIV infections remained stable among people who inject drugs.<sup>11</sup> Localized outbreaks have contributed to this trend. People who inject drugs are at high risk for acquiring hepatitis C virus infection, and, in fact, 62–80% of people who inject drugs and have HIV experience coinfection with HIV and hepatitis C.

### HIV by Geography

Most of the nation's HIV diagnoses are concentrated in certain geographic areas, that is, urban areas and southern states. In 2016 and 2017, more than half of new HIV diagnoses were concentrated in geographic hotspots across the United States: 48 counties plus Washington, DC, and San Juan, Puerto Rico.<sup>4</sup> Seven states also have a substantial number of HIV diagnoses in rural areas.<sup>20</sup> These 57 jurisdictions are prioritized for the EHE initiative. Southern states account for 38% of the U.S. population but bear the highest burden of HIV infection with 53% of annual HIV infections, 46% of people with HIV, and 52% of people with undiagnosed infections.<sup>11</sup> (See Figure 4.)



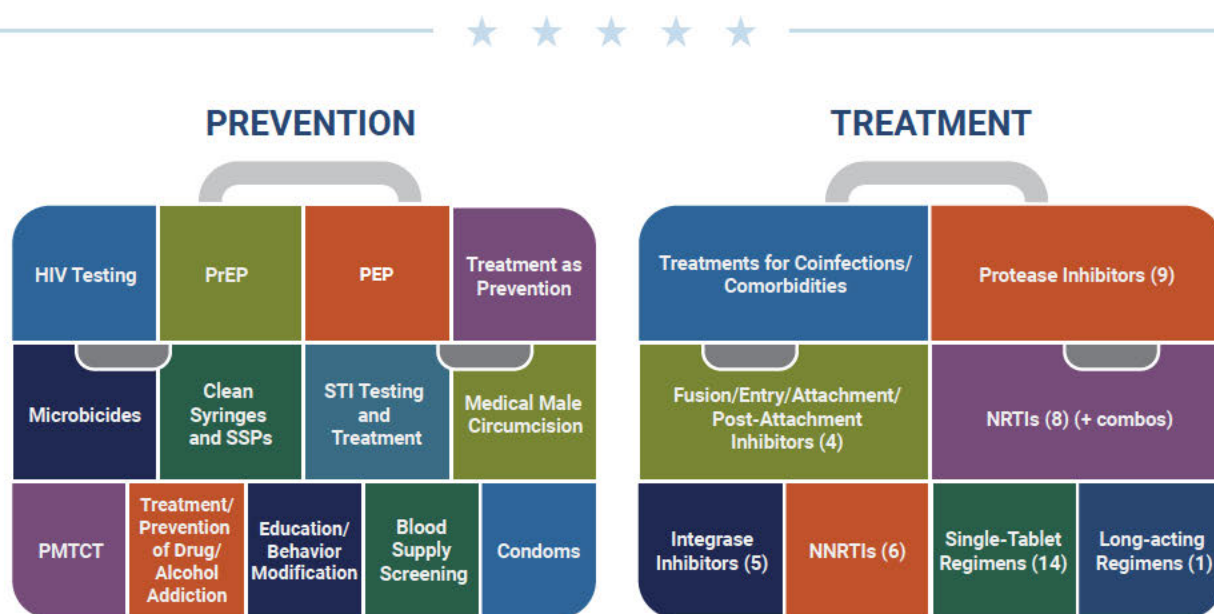
**Figure 4.** 57 jurisdictions prioritized in the *Ending the HIV Epidemic* initiative



This current landscape of HIV prevention, care, and treatment presents several opportunities and challenges that shape this 5-year Strategy.

## OPPORTUNITIES

More tools than ever before are available to end the HIV epidemic in the United States. People who initiate ART soon after diagnosis and remain adherent can live long, healthy lives.<sup>21</sup> In addition, people with HIV who take ART and achieve and maintain an undetectable viral load have effectively no risk of transmitting HIV through sex.<sup>22-25</sup> Thanks to a robust toolbox that includes syringe services programs (SSPs), PrEP, and post-exposure prophylaxis (PEP), and treatment as prevention, an individual's risk of acquiring HIV is significantly lower than ever (see Figure 5).



**Figure 5.** HIV prevention and treatment toolkits. Source: Eisinger et al.<sup>26</sup> Published by Oxford University Press for the Infectious Diseases Society of America 2019. This work is written by (a) U.S. Government employee(s) and is in the public domain in the U.S. Image modified with permission of authors.

To realize the full potential of these tools, several opportunities exist to expand the capacity of existing public health infrastructure, health care systems, and the health care and social service workforce. Engaging the diverse communities of people with and affected by HIV in planning for and delivery of HIV prevention and care services is essential. Further, expanding partnerships and training among traditional settings and parties, as well as identifying and working with nontraditional partners that are likely to engage people with or who experience risk for HIV, will better leverage the capacities of more interested parties and organizations to facilitate access to HIV diagnostics, prevention, care, treatment, and supportive services.

Importantly, the availability and use of data from a variety of sources, along with national, state, tribal, territorial, and local (and even clinic-level) indicators and targets, can help guide decision-making, service planning, and resource allocation.

Along with better use of data, ensuring that community-driven planning and decision-making include more diverse voices, expertise, and experiences can enhance how programs and services are tailored, implemented, and assessed to reach the populations that need them.

During the lifespan of this Strategy, other long-acting therapeutics and other simplified HIV drug regimens may become available. The overall value, potential impact, and cost-effectiveness of each new HIV testing, prevention, care, or treatment intervention must be demonstrated. Policy and program development should occur in parallel with the review and approval process for any new prevention or treatment options, such as long-acting injectable or implantable medications. These efforts should incorporate formative research and conversations with all relevant interested parties and organizations, especially patients, providers, and payers to identify challenges and opportunities to prevent gaps between the approval, implementation, and uptake stages.

Ongoing HIV research will facilitate progress toward HIV prevention and treatment, addressing of comorbid health conditions, and better understanding and addressing of HIV disparities and inequities, while advancing novel approaches toward long-term HIV remission and the ultimate goal of an HIV cure. Incorporating a strong implementation science framework in that research will support successful adaption and utilization of effective interventions that are acceptable to target communities.

These opportunities and developments, among others, will continue to transform and help guide the nation's approach to HIV through 2025.

## BIOMEDICAL HIV PREVENTION TOOLS

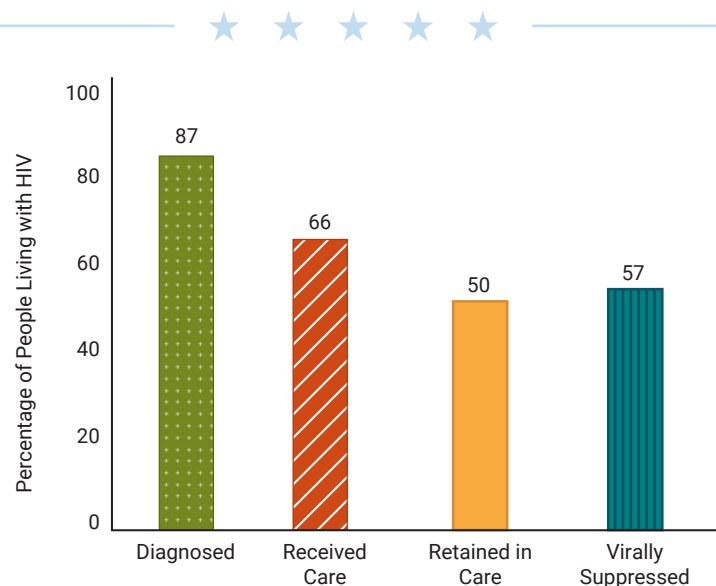
**PrEP** is medicine that people who experience risk for HIV take to prevent getting HIV from sex or injection drug use.

**PEP** is HIV medicine used in emergency cases for people who have possibly been exposed to HIV. People must start taking the pill within 72 hours of exposure.

**Treatment as Prevention** is a highly effective prevention method in which people with HIV take HIV medication daily as prescribed and get and keep an undetectable viral load. As a result, they have effectively no risk of sexually transmitting HIV to their HIV-negative partners. This is often referred to as U=U or "undetectable = untransmittable."

## CHALLENGES

Although the United States is making significant progress in improving HIV outcomes, significant challenges remain. Gaps in the HIV care continuum (see Figure 6) are driving HIV transmission. By ensuring that everyone with HIV is aware of their status, receives the treatment they need, and achieves and maintains viral suppression—key steps in the HIV care continuum—we can preserve the health of people with HIV, improve the quality of their lives, and drive down new HIV infections.



**Figure 6.** Prevalence-based HIV care continuum, United States, 2019<sup>2</sup>

The most recent data available (2019) show the following:

- Less than one-half (39%) of the U.S. population has ever been tested for HIV.<sup>27</sup> Of people with HIV, an estimated 158,500 (13%) were unaware of their status,<sup>11</sup> meaning they are not receiving the care they need to stay healthy and prevent transmission to others. The number unaware is especially high in the South, likely contributing to the high burden of HIV in the region.
- One in three people with HIV (34%) is not receiving needed HIV care.<sup>2</sup>
- Only 57% of people with HIV were virally suppressed, meaning that 43% are not receiving the benefits of HIV treatment.<sup>2</sup>

These gaps in the care continuum are challenges to be addressed because, according to a CDC transmission model based on 2016 data, approximately 80% of new HIV infections were transmitted from the nearly 40% of people with HIV who either do not know they have HIV or who received a diagnosis but are not receiving regular care (see Table 2).<sup>28</sup>

**Table 2.** HIV Transmissions in the United States, 2016

% of People with HIV	Status of Care	Accounted for X% of New Transmissions <sup>a</sup>
15%	Didn't know they had HIV	38%
23%	Knew they had HIV but weren't in care	43%
11%	In care but not virally suppressed	20%
51%	Taking HIV medicine and virally suppressed	0%

<sup>a</sup> Total does not equal 100% because of rounding. Source: CDC.<sup>29</sup>

In addition to these gaps in HIV diagnoses, care, and treatment, there are HIV prevention challenges. Only 23% of the approximately 1.2 million people indicated for PrEP are receiving it; in other words, about 3 in 4 people who could benefit from PrEP are not receiving it.<sup>30</sup> Further, significant disparities in PrEP coverage persist based on race/ethnicity, sex at birth, and age.<sup>31, 32</sup> Among those who initiate PrEP, daily pill adherence and long-term maintenance can be a challenge.<sup>33, 34</sup>

Although anyone can acquire HIV, the epidemic disproportionately affects specific populations, communities, and geographic areas across the United States. These disparities exist among gay, bisexual, and other men who have sex with men (MSM), especially Black, Latino,\* and American Indian/Alaska Native men. They also exist among Black women, transgender women, youth (particularly gay and bisexual young men and transgender youth), and people who inject drugs. These gaps remain particularly troublesome not only among disproportionately affected populations, but also in some rural areas and the South. In 2019, it was estimated that more than one-half of new HIV infections occurred in the South.<sup>11</sup>

Inequities in the social determinants of health are significant drivers and contributors to health disparities and highlight the need to focus not only on HIV prevention and care efforts, but also on the ways that programs, practices, and policies affect communities of color and other populations that experience HIV disparities.

Persons from racial and ethnic minority groups are more likely to be uninsured compared to non-Hispanic Whites,<sup>35</sup> limiting their access to health care. Barriers to health care access include lack of transportation and childcare, inability to take time off work, experiences with housing instability or homelessness, communication and language barriers, racism, discrimination, and lack of trust in health care providers.

\*For this Strategy, Black is defined as African American or Black, and Latino is defined as Latino or Hispanic.



Sexual and gender minorities also face health disparities.<sup>36-40</sup> Barriers to health care include stigma, discrimination, medical mistrust, safety, and lack of access to affirming mental health care.<sup>41</sup> Sexual and gender minorities face greater health challenges than heterosexual and cisgender people due in part to inequities such as stigma and discrimination.<sup>37</sup> Sexual and gender minority populations have lower levels of health insurance and access to regular health care compared to heterosexual/cisgender people.<sup>42, 43</sup>

Another threat to achieving national HIV prevention and care goals is the increase in drug use resulting from both the nation's opioid crisis and resurgent availability and use of methamphetamine and other stimulants among gay men and others who experience higher risk for HIV. Increases in drug use are linked to rising rates, and clusters, of several infectious diseases including hepatitis A, hepatitis B, hepatitis C, and HIV,<sup>44</sup> which threaten the progress to date to reduce HIV transmission, particularly among people who inject drugs. Recognizing this threat, in 2016 CDC identified 220 counties in 26 states that are vulnerable to HIV and viral hepatitis because of the opioid epidemic.<sup>45</sup> Many of those counties have taken steps to implement harm reduction services and strengthen their capacity to detect and respond to a potential outbreak. Half of the vulnerable counties were in the Appalachian region, where—along with other areas of the country—there have been multiple recent clusters and outbreaks of new HIV infections among people who inject drugs. Tailored technical assistance and support is needed to help these communities address the syndemic of HIV and hepatitis C virus fueled by substance use disorders. A particular focus should be on supporting them in resolving the local and state structural and systemic issues that get in the way of implementing evidence-based harm reduction and other services for the prevention of HIV and other infectious diseases and making best use of all available substance use disorder and infectious disease funding.

Using drugs or alcohol may lead to sexual behaviors (e.g., having sex without a condom, having multiple partners) that increase the risk of getting or transmitting HIV. In a recent large study of HIV-negative sexual and gender minorities who have sex with men, of whom a substantial proportion used crystal methamphetamine (crystal meth), this highly addictive drug emerged as the dominant risk factor associated with HIV seroconversion, with persistent methamphetamine users accounting for one-third of all observed HIV seroconversions in the study.<sup>46</sup> Further, a 2018 analysis of the National Notifiable Diseases Surveillance System found substantial overlap in reported substance use and sexual risk behaviors among primary and secondary syphilis cases.<sup>47</sup> For people with HIV, substance use can hasten disease progression and negatively affect care retention and treatment adherence.<sup>48</sup>

Rising rates of STIs also threaten efforts to reduce new HIV infections.<sup>49</sup> STIs are associated with a higher risk of transmitting or acquiring HIV.<sup>50</sup> A recent modeling analysis estimated that 7% of HIV infections were attributed to chlamydia, gonorrhea, syphilis, and trichomoniasis.<sup>51, 52</sup> Siloed program delivery leads to missed opportunities to screen, link, and provide navigation, care management, and treatment for people with HIV, STIs, viral hepatitis, and substance use and/or mental health disorders.

## **HIV, STIs, VIRAL HEPATITIS, AND SUBSTANCE USE DISORDERS—A HOLISTIC APPROACH TO THE SYNDEMIC**

A syndemic is a set of linked health conditions—such as HIV, viral hepatitis, STIs, and alcohol and substance use and mental health disorders—that adversely interact with one another and contribute to an excess burden of disease in a population. Addressing a syndemic can be challenging because it requires the implementation of integrated and sometimes simultaneous prevention, screening, diagnosis, and treatment efforts, as well as the rapid application of new scientific advances. To be successful, these efforts must go beyond disease-specific responses to identifying and

**Stigma** is an attitude of disapproval and discontent toward a person or group because of the presence of an attribute perceived as undesirable.

**Discrimination** is often a consequence of stigma, occurring when unfair and often unlawful actions are taken against people based on their belonging to a particular stigmatized group.

addressing root causes, with greater disease risk and poorer health outcomes often closely tied to employment, stable housing, access to health care and food, and other social determinants of health.

A holistic approach to addressing the syndemic of HIV, viral hepatitis, STIs, and substance use and mental health disorders can only be effective if we also continue to explore the connection between mental health, experience of violence and other types of traumas, substance use, and infectious diseases. Past and present trauma, including experience of violence, homo- and transphobia, discrimination, and racism, contribute to the excess burden of disease in many communities at risk for or diagnosed with these health conditions. This burden challenges our collective efforts to provide prevention and care services because models of trauma-informed care are often not fully developed within many health care settings. In addition, ready access to substance use and mental health care, or health care in general, is lacking in many communities, exacerbating existing health disparities in communities of color.

A **syndemic** is a set of linked health problems that interact synergistically and contribute to excess burden of disease in a population.

Social determinants of health and stigma also play a significant role in this syndemic.

The syndemic does not just appear in adulthood; the inter-relationship between sexual health, trauma, mental health, and substance use may have precursors in early childhood and coalesce in adolescence. Adverse childhood experiences have substantial effects on health and well-being through adolescence and into adulthood. In adolescence, sexual risk, substance use, experience of violence, and mental health problems co-occur and represent significant risk for STIs and HIV, particularly among sexual minority youth. The opportunity exists, however, to adopt trauma-informed approaches and bolster the coordination, capacity, and delivery of services to populations with and experiencing risk for these linked conditions.

To help drive a coordinated response to the syndemic, the Strategy complements the Viral Hepatitis National Strategic Plan (Viral Hepatitis Plan) and the Sexually Transmitted Infections National Strategic Plan (STI Plan), both released in early 2021. These plans mutually recognize that both the specific health conditions and the syndemic itself present opportunities to conduct relevant research and analyses, develop evidence-based interventions and policy options, and allocate resources to respond efficiently and effectively. The Strategy aligns with the Administration's statement of first-year drug control priorities and will also align with the comprehensive 2022 National Drug Control Strategy being developed by the White House Office of National Drug Control Policy.

## COVID-19 and the Syndemic

This Strategy is being released during the unprecedented COVID-19 pandemic. Since early 2020, SARS-CoV-2, the coronavirus that causes COVID-19 disease, has spread rapidly across the globe, causing more than 200 million confirmed cases worldwide and claiming the lives of more than 4 million individuals to date. The pandemic has caused great uncertainty, including for people with and who experience risk for HIV, STIs, viral hepatitis, and substance use and mental health disorders.

In the United States, the pandemic has exacerbated existing challenges in public health and health care systems, exposing longstanding and pervasive structural inequities. Many clinical and public health services focused on people with or who experience risk for HIV, viral hepatitis, STIs, and substance use and mental health disorders have been forced to reduce hours or close temporarily, with staff redeployed to address the public health emergency. These actions have particularly affected populations who are already disproportionately affected by these health conditions and who are most vulnerable to the economic and societal consequences of the pandemic, including loss of employment and insurance, the necessity to work in unsafe environments, housing and food insecurity, cutbacks to public transportation, lack of access to credible health information in multiple languages, and obstacles to practicing safe social distancing. Faced with these challenges, many individuals have not received necessary medical care or related services. Implementation of the Strategy should consider the potential long-term effects caused by these circumstances.



The Strategy accounts for the many lifesaving program innovations and policy changes that were developed to counteract the curtailment of in-person visits and other challenges posed by the COVID-19 pandemic. Examples include the use of telephone- and video-based telehealth visits to ensure that people who experience risk for HIV can access PrEP and that people with HIV can access ongoing care and treatment; exploration and implementation of tele-harm reduction approaches to substance use disorder treatment and HIV treatment; distribution of HIV self-tests and home specimen collection kits; multi-month dispensation of ART; condom delivery; and modification of policies to support mail order, home delivery, or curbside pick-up of medication. Further, community-based programs expanded their roles to ensure the safety of health care workers, clients, and community members by distributing timely and accurate information about COVID-19 testing and vaccinations; facilitating interactions with public health authorities; and serving as testing and vaccination sites.

These innovations in HIV prevention and care delivery prove that the nation can innovate and adapt to ensure that access to HIV prevention and treatment services continues uninterrupted—even in the presence of unprecedented circumstances. Although their outcomes must be studied, many of these innovations may prove worth sustaining as effective tools in our work to achieve our national HIV goals. Our tasks ahead are to carefully determine how to preserve these innovations over the long term for people who can benefit from them, adapt these innovations to achieve success with other populations, and leverage resources to deliver these innovations to larger audiences.

# NATIONAL HIV/AIDS STRATEGY 2022–2025

This Strategy, updated for 2022–2025, builds on the lessons learned and progress of previous iterations and seeks to leverage opportunities and address the challenges that remain. It provides a national roadmap for continuing the coordinated response to HIV and puts the country on the path to end the HIV epidemic in the United States by 2030. The Strategy is guided by this vision statement:

*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, lives free from stigma and discrimination, and can achieve their full potential for health and well-being across the lifespan.*

*This vision includes all people, regardless of age, sex, gender identity, sexual orientation, race, ethnicity, religion, disability, geographic location, or socioeconomic circumstance.*

## OVERVIEW

This Strategy includes the following:

- Four goals to achieve this vision, specific objectives for each goal, and strategies for each objective.
- Priority populations, identified by national-level data as being disproportionately affected by HIV, to help focus stakeholder efforts and resource allocation.
- Nine core indicators, one disparities indicator stratified for each priority population with quantitative targets to track progress toward achieving national HIV goals, and one developmental indicator to be established.

## OBJECTIVES AND STRATEGIES

The Strategy sets forth four goals, objectives for each goal, and strategies for each objective (see Table 3 for definitions). These objectives and strategies are designed to guide federal partners as well as nonfederal parties in achieving the Strategy’s vision and goals. The objectives provide direction for the attainment of each goal. The strategies recommend approaches to achieve the objectives. Numerous objectives and strategies could fit under more than one goal. However, each one has been placed under the goal with which it most closely aligns.

**Table 3.** Definitions of Elements of the Strategy

National HIV/AIDS Strategy	Federal Implementation Plan
<p><b>Goals:</b> Broad aspirations that enable a plan’s vision to be realized</p> <p><b>Objectives:</b> Changes, outcomes, and impact a plan is trying to achieve</p> <p><b>Strategies:</b> Choices about how best to accomplish objectives</p>	<p><b>Action Steps:</b> Specific activities that will be performed to implement the strategies and achieve the goals of the plan</p> <p><b>Progress Reports:</b> Reports on progress, successes, and challenges</p>

<sup>a</sup> Adapted from the HHS Office of the Assistant Secretary for Planning and Evaluation.

The Strategy’s objectives and strategies are intended to be implemented by a broad mix of interested parties and organizations at all levels and across many sectors, both public and private. They also serve as a tool to foster a shared focus, enhance coordination of efforts across agencies and programs, and identify areas of synergy and new opportunities to sharpen collective efforts. The strategies are intended to be scalable by implementer type and size of population to be served.

## INDICATORS

The Strategy adopts bold targets for ending the HIV epidemic in the United States by 2030, calling for a 75% reduction in new HIV infections by 2025 and a 90% reduction by 2030. The Strategy’s goals, objectives, and strategies focus on achieving national targets set for 2025, setting the stage to ultimately end the HIV epidemic by 2030. As such, the Strategy’s vision, goals, objectives, strategies, indicators, and quantitative targets align with the EHE initiative, which complements and will serve as one of many important implementation elements of the Strategy (see Box 1).

The Strategy includes indicators for measuring progress and quantitative targets for each indicator. There are nine core indicators, one of which is stratified to measure progress in addressing HIV disparities in the priority populations (i.e., disparities indicators). In addition, one key issue, quality of life for people with HIV, was designated as the subject for a “developmental indicator,” meaning that data sources, measures, and targets will be identified, and progress monitored thereafter. The Strategy’s indicators and quantitative targets also align with *Healthy People 2030*. A detailed discussion of the indicators, including methodology, and specifications is found in Appendix A.



## BOX 1

### THE NATIONAL HIV/AIDS STRATEGY AND THE *ENDING THE HIV EPIDEMIC IN THE U.S.* INITIATIVE

The Strategy and *Ending the HIV Epidemic in the U.S.* (EHE) initiative are complementary, with EHE serving as a leading component of the work by the U.S. Department of Health and Human Services (HHS), in collaboration with federal, state, tribal, territorial, and local partners, to end the HIV epidemic in the United States by 2030. Both the Strategy and the EHE initiative aim to reduce new HIV transmissions in the United States by 75% by 2025 and by 90% by 2030, which would mean fewer than 3,000 new HIV infections per year.

EHE efforts focus on 57 priority jurisdictions, including 48 counties, Washington, DC, and San Juan, Puerto Rico, where greater than 50% of new HIV diagnoses occurred in 2016 and 2017, as well as 7 states with a disproportionate occurrence of HIV in rural areas. With additional funding appropriated by Congress, HHS is providing the 57 geographic focus areas with an infusion of additional resources, expertise, and technology to develop and implement locally tailored EHE plans. Those plans, developed and being implemented with significant community involvement, focus on four pillars:

- Diagnose all people with HIV as early as possible.
- Treat people with HIV rapidly and effectively to reach sustained viral suppression.
- Prevent new HIV transmissions by using proven interventions, including preexposure prophylaxis (PrEP) and syringe services programs (SSPs).
- Respond quickly to potential HIV outbreaks to get prevention and treatment services to people who need them.

The scope of the Strategy extends to agencies beyond HHS and encompasses the entire nation. The Strategy presents a holistic approach to engaging a broad range of interested parties and organizations across many sectors of society to not only end the HIV epidemic by 2030, but also address other components of the syndemic, stigma, discrimination, and social determinants of health.

## PRIORITY POPULATIONS

Although HIV affects people from all social, economic, and racial and ethnic groups, and from all parts of the United States, it disproportionately affects certain populations. The disproportionate prevalence of HIV in specific populations increases the risk for HIV transmission with each sexual or injection drug use encounter within those populations. In addition, a range of social, economic, and demographic factors—such as stigma, discrimination, socioeconomic status, income, education, age, and geographic region—affect people's risk for HIV or their ability to access or remain engaged in prevention or care services.

To focus effort and resources for the greatest impact, the Strategy uses national-level HIV surveillance data to identify populations disproportionately affected by HIV. The following factors were considered: (1) incidence of new HIV infections and trends; (2) prevalence of HIV; (3) HIV diagnoses; (4) outcomes along the HIV care continuum; and (5) potential impact of other major public health threats (e.g., opioid epidemic). Based upon this analysis, the Strategy prioritizes efforts to reduce disparities and improve HIV outcomes among

- gay, bisexual, and other men who have sex with men, in particular Black, Latino, and American Indian/Alaska Native men;



- Black women;
- transgender women;
- youth aged 13–24 years; and
- people who inject drugs.

Focusing efforts on these five priority populations will reduce the HIV-related disparities they experience, which is essential if the nation is to succeed on the path toward ending the HIV epidemic by 2030.

To drive action and measure progress toward reducing health inequities and disparities among the priority populations, the Strategy uses viral suppression, stratified by population, as an indicator. Viral suppression was selected as the disparities indicator because increasing and maintaining viral suppression among priority populations will improve health outcomes, reduce HIV-related deaths, and prevent new HIV transmissions. Monitoring progress on these disparities indicators also helps ensure that the nation is making progress with all populations, leaving no groups behind.

This Strategy acknowledges that other populations with unique circumstances warrant specific attention, such as sex workers, immigrants, older adults, people experiencing housing instability or homelessness, individuals with disabilities, and justice-involved individuals. For example, the risk of HIV among people who exchange sex for money, drugs, food, or shelter is high; however, little data exist for this population. The illegal—and often criminalized—nature of exchange sex complicates the collection of population-wide data on HIV risk among this population. Nevertheless, the high prevalence of HIV and STIs among people who participate in exchange sex warrants attention. Sex work is largely performed by transgender women, cisgender women, and men who have sex with men, and is also heavily concentrated among Black and African Americans. The convergence of gender, poverty, and racial and ethnic discrimination as social determinants of health within exchange sex must be examined further to fully understand the HIV epidemic.

Similarly, some non-U.S.-born people with or experiencing risk for HIV face unique challenges when accessing prevention, care, and treatment services. Discrimination, lack of culturally and linguistically competent service providers, and fear of interacting with health care systems and other authorities are often barriers to accessing needed services.

People involved in the justice system face a confusing/disparate system of prevention and care services, often for short time periods. These individuals experience a disproportionately high risk of HIV, as well as risk factors associated with under-utilization of prevention and treatment options, including substance use, mental health issues, and poor access to care.<sup>53</sup> Improving HIV prevention and management among justice-involved people requires innovative approaches to integrating care. HIV programs must work with state and local facilities to ensure that care services are provided throughout the justice system, particularly to people upon release back to their communities; pre- and post-transition planning is critical to decreasing barriers to care.

More than one-half of people diagnosed with HIV in the United States today are over age 50. Although an indicator of the success of modern HIV treatment, this statistic signals the need to tailor services to individuals within this population not only to continue their engagement in care and viral suppression but also to address the comorbidities and psycho-social needs often associated with aging.

Evidence suggests that some people with disabilities may experience higher risk of acquiring HIV than people who are not disabled. Some of the factors associated with this risk include poverty, vulnerability to sexual violence and abuse, limited access to education and health care, and social marginalization. Some people with disabilities may experience barriers to accessing the HIV prevention, testing, or care and treatment services they need.

People with HIV often have other disabilities, and people with disabilities can be at higher risk for acquiring HIV than the general population. Adopting syndemic approaches that place HIV in the context of multiply marginalized

communities and that seek to comprehensively leverage a variety of health care, social services, and other community supports to improve overall community health offers an important opportunity to strengthen health care outcomes and improve the quality of life.

Local partners and interested parties should use local surveillance and program data on HIV—as well as on STIs, viral hepatitis, and social determinants of health—to identify the populations most affected in their communities and to understand the outcomes for each population along the continuums of HIV prevention and care. Each state, tribe, community, program, or clinic will make its own assessment of relevant priority populations so that programs and services can be tailored and focused accordingly. In some jurisdictions, local surveillance and program data may indicate that additional populations not mentioned here are experiencing persistent HIV disparities that require focus from local efforts.

In addition, some partners and organizations may work with specific populations or communities in a limited area with data that vary somewhat from the national data. For example, on a federal level, agencies such as the Indian Health Service, CDC's Division of Adolescent and School Health, Department of Veterans Affairs, Federal Bureau of Prisons, and Administration for Community Living serve distinct populations with or who experience risk for HIV. Likewise, state, tribal, territorial, and local jurisdictions, as well as schools and other institutions, may serve distinct populations. For these and other interested parties, efforts should be guided by an assessment of health disparities within their purview and/or jurisdiction to determine how best to focus available resources to achieve results with the greatest impact.

## **IMPLEMENTATION**

A separate NHAS Federal Implementation Plan will be developed in early 2022 and will detail federal partners' plans and activities to implement the strategies set forth in this document. During development of that plan, the federal partners involved will explore opportunities to engage other federal departments or agencies that could expand services or that administer programs or support delivery of services that address social determinants of health and reduce health disparities and, as such, could make vital contributions to national efforts to end the HIV epidemic.



## GOAL 1: PREVENT NEW HIV INFECTIONS

### THE OPPORTUNITY

The most effective ways to reduce new HIV infections are to ensure timely diagnosis and engagement in care and treatment for people with HIV so that they achieve and maintain viral suppression and therefore cannot transmit the virus; target prevention resources to the places with the largest disease burden and the populations experiencing greatest risk; and ensure that the most effective prevention strategies are prioritized and widely implemented. An array of HIV prevention options, for use in combination or on their own, is available to people with or experiencing risk for HIV.

- **HIV treatment as prevention.** Evidence has definitively shown that people with HIV who achieve and maintain an undetectable viral load by taking HIV medication as directed will not sexually transmit the virus to an HIV-negative partner.
- **HIV testing and engagement in care.** Nearly 40% of people with HIV are unaware of their status or are diagnosed but not receiving care. In 2016, people unaware or not receiving care accounted for nearly 80% of new HIV infections in the United States.<sup>28</sup>
- **PrEP.** Because of the 2019 USPSTF recommendation that clinicians offer PrEP with effective ART to persons who are at high risk of HIV acquisition, as of January 2021 HHS requires most insurance plans to cover PrEP without copay or cost-sharing as a result of the preventive care provisions of the ACA. Implementation guidance issued in July 2021 clarified that this coverage also includes a range of clinical services as part of PrEP clinical care.<sup>54, 55</sup> In addition, in 2019 FDA approved a second PrEP drug for people assigned male at birth. A generic version of the original drug became available, increasing options for people who wish to use PrEP. Researchers are investigating a variety of non-vaccine HIV prevention products including long-acting injectable antiretrovirals, long-acting oral pills, vaginal rings, vaginal and rectal gels, and more. If found safe and effective and approved by FDA, these products would further expand the options in the prevention toolbox.
- **SSPs, medication for treatment of opioid use disorder, and other harm reduction services.** Nearly 30 years of research shows that comprehensive SSPs are safe, effective, and cost-saving; do not increase illegal drug use or crime; and play an important role in reducing the transmission of HIV, viral hepatitis, and other infections.<sup>56</sup> FDA has approved several different medications to treat alcohol and opioid use disorders. Certain medications for opioid use disorder relieve the withdrawal symptoms and psychological cravings resulting from opioid dependence. Research also shows that these medications and certain behavioral therapies can contribute to lowering a person's risk of contracting HIV or hepatitis C by reducing the potential for relapse. Appropriations language from Congress permits the use of funds from HHS, under certain circumstances, to support SSPs with the exception that funds may not be used to purchase needles or syringes. [Multi-agency guidance](#) was issued on this opportunity, and in 2020 CDC published a [technical package](#) on effective strategies and approaches for planning, design, and implementation of SSPs. The White



### GOAL 1: PREVENT NEW HIV INFECTIONS

#### Objectives

- 1.1 Increase awareness of HIV
- 1.2 Increase knowledge of HIV status
- 1.3 Expand and improve implementation of safe, effective prevention interventions, including treatment as prevention, PrEP, PEP, and SSPs, and develop new options
- 1.4 Increase the diversity and capacity of health care delivery systems, community health, public health, and the health workforce to prevent and diagnose HIV



House Office of National Drug Control Policy also included several actions related to increasing access to SSPs in its first-year policy priorities, including authorizing the use of federal funds to purchase syringes and other supplies.<sup>57</sup> In addition, in October 2021, the HHS released the new HHS Overdose Prevention Strategy in which evidence-based harm reduction services, including SSPs, are prioritized as a key target area of action.<sup>58</sup>

- **PEP, condoms, and other effective prevention interventions.** PEP is a short course of HIV medicines taken very soon after a possible exposure to HIV to prevent the virus from taking hold in the body. PEP should be used only in emergency situations and must be started within 72 hours after a recent possible exposure to HIV. Correct condom use remains one of the most effective methods to reduce the risk of HIV transmission during sexual activity. The CDC and USPSTF recommend intensive behavioral counseling on ways to prevent STIs (including HIV) in all adolescents and adults at increased risk for STIs.

In addition, a range of HIV prevention or multipurpose prevention products are under development or regulatory review, which could result in even more HIV prevention tools becoming available within the 5-year span of this Strategy.

## CHALLENGES

The following challenges hinder efforts to reduce new infections:

- HIV awareness remains too low.<sup>59, 60</sup>
- HIV testing and diagnosis opportunities are being missed (see Box 2).<sup>61</sup>
- STIs are surging in the United States (see Box 3).<sup>62</sup>
- A significant number of people with HIV are unaware of their status or are diagnosed in the later stages of their HIV disease.<sup>3, 11</sup>
- Retention in HIV care is suboptimal.<sup>2</sup>
- Uptake of PrEP is too low.<sup>30, 63, 64</sup>
- There are a range of policy, legal, and resource barriers that limit full implementation of SSPs, especially in the most needed areas.<sup>65, 66</sup>



### BOX 2 MISSED OPPORTUNITIES FOR HIV DIAGNOSIS

Substantial numbers of people who are diagnosed with HIV and who had experienced high risk for HIV experienced missed opportunities for earlier diagnosis. For example, in one study, approximately one-half of newly diagnosed gay and bisexual men and people who inject drugs had been unaware of their infection until diagnosed during the study. They reported not being offered HIV testing by any health care provider despite having seen one within the past year.<sup>61</sup> Further, a retrospective study at an urban adolescent HIV clinic found that many youth recently diagnosed with HIV had prior primary and acute care encounters within the health care system but did not receive an HIV test.<sup>67</sup>

Other studies have highlighted missed opportunities by setting. For example, STI clinic patients experience increased risk for HIV, yet data from nine STI clinics across the United States revealed that three-quarters of STI clinic patients were not tested for HIV despite visiting the clinic within the past year.<sup>68</sup>





## BOX 2 MISSED OPPORTUNITIES FOR HIV DIAGNOSIS (CONTINUED)

Similarly, more than two-thirds of missed opportunities for HIV diagnoses in a Louisiana health care system occurred at health care visits outside the primary care setting, including inpatient care, specialty care clinics, surgical specialties, ob-gyn visits, and emergency care facilities.<sup>69</sup> In addition, an infectious disease practice in New Jersey found that hospital emergency departments and subspecialty clinics were the two most common settings for missed testing opportunities, with between 37% and 45% of patients presenting with a new HIV diagnosis with an encounter in the institution in the year prior.<sup>70</sup> Dental facilities present another opportunity to provide point-of-care HIV screening and testing.<sup>71</sup> Pharmacies and retail clinics represent a vast, largely untapped potential for the delivery of HIV testing in settings that are more accessible and, for some people, less stigmatizing than traditional settings.<sup>72</sup> Finally, the Centers for Disease Control and Prevention recommends that HIV screening be provided upon entry into and before release from correctional settings and that voluntary (opt-out) HIV testing be offered periodically during incarceration.<sup>73</sup> Studies have shown that opportunities for HIV diagnosis and linking HIV-positive individuals with justice system involvement to community care after release are being missed in the majority of prison systems and jails.<sup>74, 75</sup>

COVID-19 testing and vaccinations also present an opportunity to diagnose people who are unaware of their HIV status. One hospital in an urban setting saw a “considerable increase in acute HIV diagnoses” when it linked HIV screening with COVID testing in emergency departments.<sup>76</sup>

Missed opportunities for HIV testing result in diagnosis delays, disease progression, and lack of access to HIV care and treatment. They also prolong the time a person is unaware of their infection, increasing the potential for HIV transmission. For care and treatment to effectively reduce HIV incidence, improved testing coverage and frequency are needed to ensure that a large proportion of cases are diagnosed and treated soon after infection occurs.



### BOX 3

## OPPORTUNITIES FOR ENHANCED HIV PREVENTION SERVICES IN STI SPECIALTY CLINICS

STI specialty clinics have been an important health care setting for people who may not otherwise have access to health care services, including those who are uninsured, and for people seeking low-barrier (e.g., nontraditional hours, walk-in or express appointments, low or no cost), expert, and confidential services. STI clinics serve people who may not be engaged in HIV prevention programs or the primary health care system for their STI and HIV prevention, care, and treatment.<sup>77-79</sup> As such, they are suitable settings to (1) reach people who could benefit from HIV pre-exposure prophylaxis (PrEP) and nonoccupational post-exposure prophylaxis (PEP), including people diagnosed with an STI; and (2) identify people with HIV who are either unaware of their status or are not virally suppressed and could benefit from linkage to or reengagement in care.<sup>80</sup>

An evaluation of HIV testing events funded by the Centers for Disease Control and Prevention provided further evidence of STI clinics' important role in identifying people who experience increased risk for HIV. In 2019, STI clinics provided almost one-third of all CDC-funded HIV tests conducted among health care settings, and approximately 20% of all newly identified HIV-positive persons were diagnosed in STI clinics.<sup>81</sup>

## SUMMARY OF OBJECTIVES

The following objectives are critical to achieving the goal of preventing new HIV infections:

- 1.1 Increase awareness of HIV
- 1.2 Increase knowledge of HIV status
- 1.3 Expand and improve implementation of safe, effective prevention interventions, including treatment as prevention, PrEP, PEP, and SSPs, and develop new options
- 1.4 Increase the diversity and capacity of health care delivery systems, community health, public health, and the health workforce to prevent and diagnose HIV

## OBJECTIVES AND STRATEGIES

### Objective 1.1 Increase awareness of HIV

Nearly four decades into the HIV epidemic, too many people still lack essential information about HIV or hold misconceptions about the virus, including how it is prevented and transmitted. The resulting misperception of self-risk and perpetuation of HIV-related stigma and discrimination can deter people from learning their status, accessing prevention services, seeking or remaining in care, or supporting people who need diagnostic, prevention, care, or treatment services.

More must be done to increase HIV awareness among everyone, but especially among people, communities, and the health workforce where HIV is most heavily concentrated. Messaging must be clear, specific, consistent, and [culturally and linguistically appropriate](#) and must reflect today's scientific knowledge of HIV disease progression, its impact on community and individual health, the importance of early and sustained HIV treatment, and the health and prevention benefits of viral suppression. Once developed, the messaging should be broadly and persistently disseminated as educational campaigns using both traditional and social media delivered by trusted community members and community influencers.



School-based health programs that include sexual health education and connect youth to services serve to create safer and more supportive school environments, particularly for LGBTQI+ youth.<sup>82</sup> These environments help prevent HIV among adolescents by providing students with the knowledge and skills to help them be healthy and avoid HIV. Comprehensive school-based health programs ensure that students can access the services they need, and promote protective factors, such as school connectedness, that have long-term impact on risk for HIV. HIV prevention implemented in schools includes curricula that are medically accurate, developmentally appropriate, affirming, culturally relevant, accessible, and universally designed with content and skills that target key behavioral outcomes and promote healthy sexual development. Efforts to improve the safety and supportiveness of school environments include the provision of policies and practices that support LGBTQI+ students as well as activities that increase school connectedness and parent engagement.

Suitable primary prevention approaches focused on youth should be age-appropriate, linguistically and culturally informed, community-centered, accessible and universally designed, inclusive, stigma-reducing, and grounded in science and medicine. According to the American Academy of Pediatrics, developmentally appropriate and evidence-based education about human sexuality and sexual reproduction provided over time by pediatricians, schools, other professionals, and parents is important to help children and adolescents make informed, positive, and safe choices about healthy relationships, responsible sexual activity, and their reproductive health.<sup>83</sup> Similar recommendations were presented in a 2021 report issued by the National Academies of Sciences, Engineering, and Medicine, which called for the adoption of a holistic sexual health paradigm, among other actions, to reduce STIs.<sup>84</sup> School-based programs that use strategies to increase sexual health education, connect youth to needed services, and increase the safety and supportiveness of school environments have been demonstrated to reduce sexual risk behavior, experience of sexual violence, and substance use.<sup>83</sup> Primary prevention should be a part of comprehensive sexual education, particularly for youth, including delayed initiation of sexual activity for those who are not yet sexually active, and non-judgmental and affirming information about safer sexual activity for those who are sexually active.

These efforts must engage organizations and people who shape and influence knowledge, attitudes, beliefs, and behaviors, particularly among populations that experience risk of HIV, as well as leverage digital strategies and new technologies to reach the highest number of people at relevant access points.

### Strategies

- 1.1.1 Develop and implement campaigns, interventions, and resources to provide education about comprehensive sexual health; HIV risks; options for prevention, testing, care, and treatment; and HIV-related stigma reduction.
- 1.1.2 Increase knowledge of HIV among people, communities, and the health workforce in geographic areas disproportionately affected.
- 1.1.3 Integrate HIV messaging into existing campaigns and other activities pertaining to other parts of the syndemic, such as STIs, viral hepatitis, and substance use and mental health disorders, as well as in primary care and general wellness, and as part of annual reproductive health visits and wellness visits.

### Objective 1.2 Increase knowledge of HIV status

In addition to general knowledge about HIV, it is important for people with HIV to receive a diagnosis (also known as knowledge of HIV status), which would allow them to take control of their health. Full implementation of CDC and USPSTF screening and testing guidelines is critical to increasing knowledge of status (see Box 4). Innovative models and approaches that expand access to and availability of testing in various settings such as routine opt-out testing in clinical settings, testing in retail pharmacies, self-testing, testing in correctional facilities, mobile testing, and self-testing offered via social networks are required. Early detection coupled with prompt linkage to care and immediate initiation of treatment is also critical and can lead to improved individual and community

health outcomes. The U.S. Department of Veteran Affairs (VA) provides an innovative solution in which pharmacists developed a clinical dashboard that lists patients needing action, including a shared electronic medical record to span HIV, STI, viral hepatitis, and PrEP needs of VA patients. The dashboard enables staff to access quality improvement data, benchmarks against other comorbidities, and comparative analysis by year for improvement purposes.



## BOX 4 HIV TESTING RECOMMENDATIONS

**U.S. Preventive Services Task Force (USPSTF) Recommendation (2019)**—USPSTF recommends that clinicians screen for HIV in adolescents and adults aged 15–65 years. Younger adolescents and older adults who experience increased risk of infection should also be screened. USPSTF also recommends that clinicians screen for HIV infection in all pregnant women, including those who present in labor or at delivery with unknown HIV status. [Read the recommendation.](#)

**Centers for Disease Control and Prevention (CDC) Recommendations (2006)**—CDC recommends that everyone aged 13–64 years get tested for HIV at least once as part of routine health care. For those with specific risk factors, CDC recommends testing at least annually. [Read the recommendations.](#)

Expansion of the status-neutral approach to HIV care allows for ongoing engagement in HIV prevention, care, and treatment regardless of a person’s HIV status (see Box 5). Embracing a status-neutral approach helps improve care and service provision and eliminates structural HIV and other intersecting stigma by meeting people where they are, offering a “whole person” approach to care, and putting the needs of the person ahead of their HIV status. By embedding HIV prevention and care into routine care, this approach advances health equity by integrating HIV prevention and care with strategies that address social determinants of health and barriers to accessing and remaining engaged in care. HIV testing serves as the entry point to services—the pathway to prevention and treatment. In addition, people are assessed for and engaged in continuous care and supportive services if needed to improve health and prevent new infections (see Figure 7). Health care providers and public health partners play critical roles in a status-neutral approach.

### Strategies

- 1.2.1 Test all people for HIV according to the most current USPSTF recommendations and CDC guidelines.
- 1.2.2 Develop new and expand implementation of effective, evidence-based or evidence-informed models for HIV testing that improve convenience and access.
- 1.2.3 Incorporate a status-neutral approach to HIV testing, offering linkage to prevention services for people who test negative and immediate linkage to HIV care and treatment for those who test positive.
- 1.2.4 Provide partner services to people diagnosed with HIV or other STIs and their sexual and/or syringe-sharing partners.

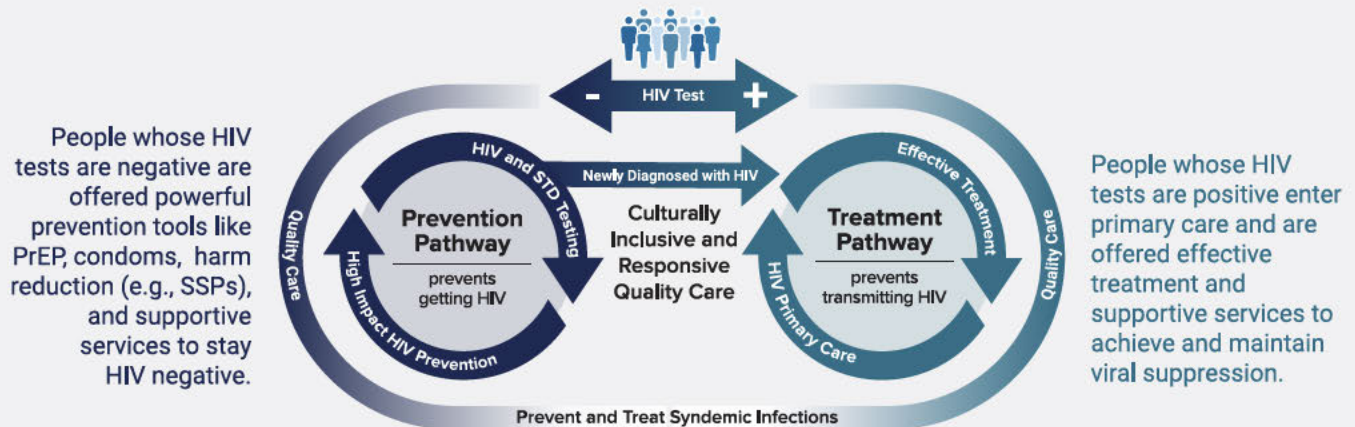




## BOX 5 STATUS-NEUTRAL APPROACH TO HIV SERVICES

Adoption of a status-neutral approach to HIV services—in which HIV testing serves as an entry point to services regardless of positive or negative result—can improve testing as well as prevention and care outcomes.

### Status-Neutral HIV Prevention and Care



Follow CDC guidelines to test people for HIV. Regardless of HIV status, quality care is the foundation of HIV prevention and effective treatment. Both pathways provide people with the tools they need to stay healthy and stop HIV.

**Figure 7.** CDC's HIV status-neutral approach to HIV services

People who receive a negative HIV test result are offered powerful tools that prevent HIV, which may include pre-exposure prophylaxis (PrEP) and information about access to condoms and sexual health and harm reduction services. The prevention pathway emphasizes a consistent return to HIV testing and facilitates seamless entry to treatment for people who later receive a positive test result.

People who receive a positive HIV test result should be quickly engaged in HIV primary care and prescribed effective treatment to help them achieve and maintain an undetectable viral load and to tend to their other non-HIV-related health care. An undetectable viral load essentially eliminates the risk of sexual HIV transmission and enables people with HIV to live long, healthy lives.

### Objective 1.3 Expand and improve implementation of safe, effective prevention interventions, including treatment as prevention, PrEP, PEP, and SSPs, and develop new options

Today, a range of highly effective prevention methods are available for use in combination or on their own. However, they do not yet reach everyone who needs them. Scaling up combinations of scientifically proven, cost-effective interventions targeted to the right populations in the right geographic areas is key to preventing new HIV infections. Especially important is scaling up highly effective, biomedical interventions: treatment as prevention (U=U), PrEP, and PEP, along with other highly effective prevention interventions including delayed initiation of sexual

activity, correct and consistent condom usage, HIV and viral hepatitis testing, STI testing and treatment, SSPs and harm reduction services, universal HIV testing and linkage to care in primary care settings, and behavioral health services.<sup>85-89</sup>

These interventions must be available to people who need them in a variety of traditional health care and public health settings as well as nontraditional settings. Public health and health care systems can better meet the HIV prevention needs of the people they serve by developing or adopting culturally competent, linguistically appropriate, and accessible approaches and policies for service design and delivery. Examples of interventions include models that allow for low-barrier access to prevention and supportive services such as expanded service hours, drop-in appointments, telehealth, peer navigators, community health workers, and co-located service delivery.<sup>90</sup>

Schools can offer on-site sexual health services through their own health care infrastructure, such as school-based health centers and school nurses, or can establish referral systems to community partners to provide services, such as periodic, school-wide HIV and STI screening events or mobile clinics. In addition, treatment for alcohol use disorder, other substance use disorders, and mental health conditions can also reduce HIV.<sup>91</sup>

Policy and other systemic changes can support the expansion or improvement of these prevention interventions and can often be cost-neutral or cost-saving, as resources are realigned and services are provided at focused hours and delivery is tailored to people seeking assistance.<sup>92</sup> For example, structural barriers such as state or local laws or policies may require review and revision to facilitate expanded access to HIV prevention services, such as permitting SSPs, working with law enforcement to strengthen training on harm reduction as an effective public health intervention, or expanding prescribing authority and reimbursement of services for PrEP and PEP to pharmacists and other providers.

Ongoing implementation research on how best to use new and existing HIV prevention tools is needed, as is continued research into new tools that make HIV prevention more convenient and accessible. Research must pursue biomedical interventions that simplify implementation, such as long-acting, extended-release tools that can protect against HIV infection without daily pills, as well as non-systemic tools that expand user options such as lubricant- or douche-based microbicides or multi-purpose tools that might protect women from both HIV and pregnancy. Research is needed to identify strategies to most effectively integrate such tools into HIV prevention services when they become available. Other prevention tools also warrant further investigation, including antibody-mediated protection strategies, effective vaccines, and behavioral and social-structural interventions.

## Strategies

- 1.3.1 Engage people who experience risk for HIV in traditional public health and health care delivery systems, as well as in nontraditional community settings.
- 1.3.2 Scale up treatment as prevention (i.e. U=U) by diagnosing all people with HIV, as early as possible, and engaging them in care and treatment to achieve and maintain viral suppression.
- 1.3.3 Make HIV prevention services, including condoms, PrEP, PEP, and SSPs, easier to access and support continued use.
- 1.3.4 Implement culturally competent and linguistically appropriate models and other innovative approaches for delivering HIV prevention services.
- 1.3.5 Support research into the development and evaluation of new HIV prevention modalities and interventions for preventing HIV transmissions in priority populations.
- 1.3.6 Expand implementation research to successfully adapt evidence-based interventions to local environments to maximize potential for uptake and sustainability.

#### **Objective 1.4 Increase the diversity and capacity of health care delivery systems, community health, public health, and the health workforce to prevent and diagnose HIV**

Expanding awareness, access, uptake, and adherence to effective HIV prevention interventions and improving availability of HIV testing for people with undiagnosed infection or ongoing risk of acquisition are actions that fall largely under the purview of the health care and public health systems. Therefore, steps must be taken to strengthen and expand capacity to ensure that these services are more commonly available in clinical and nonclinical settings including primary care, health centers, community-based organizations, emergency departments, pharmacies (see Box 6), Title X family planning sites, STI specialty clinics (see Box 3), substance use disorder treatment facilities, correctional settings, home- and community-based services, and other settings.

One step involves training all staff, ranging from those performing administrative duties to those delivering direct care, on trauma-informed care, cultural competency, stigma and discrimination, and unrecognized bias. Health care services that are respectful of and responsive to the health beliefs, practices, and cultural, developmental, and linguistic needs of diverse patients can also help bring about positive health outcomes.<sup>93</sup> Another step involves providing resources, incentives, training, and technical assistance to organizations to expand workforce and systems capacity especially in areas with limited availability of prevention and other health care and supportive services.<sup>94</sup> Available mechanisms to increase the number of HIV providers include health professions training grants, the National Health Service Corps Scholarship and Loan Repayment Programs, financial incentives to compensate providers for HIV care management, and program coordination so that providers who are not HIV specialists are adequately equipped to provide prevention services to high-risk populations and link patients who test positive to HIV clinical care providers.

These efforts must seek to expand the number, variety, diversity, and distribution of health care providers who routinely provide HIV testing, prevention counseling, and linkage to specialty care. A recent study showed that a low proportion of primary care providers were familiar with PEP and PrEP.<sup>95</sup> In some settings, these efforts require addressing the “purview paradox,” a contradiction in which primary care physicians and HIV specialists sometimes consider PrEP to be beyond their purview.<sup>96</sup> Thus, HIV prevention and testing must become the purview of providers of all types who care for patients who may experience risk. Further, health care providers in high HIV prevalence jurisdictions must understand the relationship of epidemiological context and HIV acquisition. In these jurisdictions, providers may be encouraged to offer universal opt-out HIV testing and integrate PrEP screening as a part of routine care for all clients.

The nation’s more than 13,500 health center service delivery sites span every U.S. state, U.S. territory, and the District of Columbia, and serve 1 in 11 people across the country. In 2020, health centers logged nearly 2.5 million visits for HIV tests and provided more than 389,000 people with access to PrEP.<sup>97</sup> Further strengthening and supporting the capacity of health centers to respond to the needs of individuals experiencing risk for HIV or living with HIV, including creating affirming and welcoming environments and providing HIV services with integrated behavioral health and family support models, is a promising approach to increasing availability of high-quality HIV prevention and care services for those who need them.





## BOX 6 PHARMACISTS' ROLES IN HIV PREVENTION AND CARE

Pharmacists' knowledge and accessibility in nearly every urban and rural community can be leveraged as part of a comprehensive HIV prevention and care strategy to expand access to care and improve population health. As trusted health care professionals, pharmacists develop a strong rapport with patients and may be the key to addressing current disparities in PrEP-prescribing patterns as well as serving as an essential liaison between patients and other members of the multidisciplinary care team.<sup>98</sup> Pharmacists and community pharmacies can also be utilized to expand rapid, point-of-care HIV testing in communities.<sup>72</sup> In addition, studies have shown that engaging pharmacists as key players in a care team can increase retention in care and adherence to ART and maintain viral suppression.<sup>99-101</sup>

### Strategies

- 1.4.1 Provide resources, incentives, training, and technical assistance to expand workforce and systems capacity to provide or link clients to culturally competent, linguistically appropriate, and accessible HIV testing, prevention, and supportive services especially in areas with shortages that are geographic, population, or facility based.
- 1.4.2 Increase the diversity of the workforce of providers who deliver HIV prevention, testing, and supportive services.
- 1.4.3 Increase the inclusion of paraprofessionals on prevention teams by advancing training, certification, supervision, financing, and team-based care service delivery.
- 1.4.4 Include comprehensive sexual health and substance use prevention and treatment information in curricula of medical and other health workforce education and training programs.

### Indicators of Progress

Working together to pursue these objectives, the nation can achieve the following targets by 2025:

- Indicator 1** Increase knowledge of status to 95% from a 2017 baseline of 85.8%.
- Indicator 2** Reduce new HIV infections by 75% from a 2017 baseline of 37,000.
- Indicator 3** Reduce new HIV diagnoses by 75% from a 2017 baseline of 38,351.
- Indicator 4** Increase PrEP coverage to 50% from a 2017 baseline of 13.2%.





## GOAL 2: IMPROVE HIV-RELATED HEALTH OUTCOMES OF PEOPLE WITH HIV

### THE OPPORTUNITY

Starting and staying on HIV treatment as soon as possible following HIV diagnosis is necessary for all people with HIV to improve health outcomes and to prevent HIV transmissions.<sup>102-104</sup> People who start HIV treatment early and remain adherent to antiretroviral medications can live a normal lifespan. Improving the health of people with HIV requires continued focus on the HIV continuum of care to identify gaps and disparities at each step of the continuum to target resources and interventions (see Figure 8). Increasing access to comprehensive health care through expansion of Medicaid programs, counseling about private insurance through the Affordable Care Act and the American Rescue Plan, and implementing programs to support maintaining insurance such as co-pay and premium assistance through the RWHAP will increase access.



**Figure 8.** The HIV care continuum outlines the steps that people with HIV take from diagnosis to achieving and maintaining viral suppression. Source: HIV.gov.<sup>105</sup>

One common gap is the lack of understanding about the personal and public health benefits of entering treatment immediately and achieving and maintaining viral suppression. Increasing HIV education and available treatment along with strengthening relationships between patients and providers can play an even larger part in supporting people with HIV to begin, or reengage in, care and treatment and improve long-term health outcomes. Developing and expanding partnerships between providers of HIV specialty care and other providers (such as primary care and other health care providers as well as community organizations, health departments, community-based substance use and harm reduction programs, jails and prisons, and others) can leverage existing resources, allowing for seamless transitions between each step of the continuum from diagnosis to achieving and maintaining viral suppression. In addition, government, academic, and pharmaceutical industry research has provided simpler, more easily tolerated therapies than the initial generation of effective antiretroviral therapies. Continued advances such as long-acting injectables could result in the introduction of new HIV treatments during the course of this 5-year plan. These new options could help address challenges with adherence to a daily pill regimen.



Several approaches exist to support treatment initiation and adherence as well as retention in care across the continuum, including:

- **Rapid start programs.** Programs focusing on the immediate (ideally same day or within 7 days after diagnosis) initiation of ART have demonstrated success and are expanding in communities across the nation. Such “rapid start” or “red carpet” programs require structural or other changes to improve linkage to care, care coordination, patient navigation, adequate staffing, specialized services, and clinical provider evaluation.
- **Evidence-based strategies.** Every year evidence-informed best practices are added to the compendia of recommended interventions designed to improve treatment adherence and retention in care. Although interventions are often not a one-size-fits-all approach, health departments, clinics, and community organizations have additional tools to implement and receive a wide range of adaptations that have worked in different settings, in different population sizes, and for specific populations. Increasing the use of evidence-based strategies and best practices, coupled with community input, to reengage people who have fallen out of care, and people never in care, is necessary.
- **Health literacy.** Limited health literacy is associated with poorer health outcomes.<sup>106</sup> At all levels, further effort is needed to construct organizations, institutions, systems, and a workforce that embrace and implement the concepts and principles of health literacy. Efforts to create more health-literate public and private health systems at the federal, state, tribal, territorial, and local levels will help patients understand the health care system and the importance of HIV prevention, care, and treatment, and the benefits of viral suppression. Patient education is a necessary aspect of people-centered care, but it requires systems and providers to end the use of jargon, take the time to educate and explain in plain language, alter websites and brochures, proactively counter medical misinformation, use social media differently, and consider other culturally appropriate and accessible ways to deliver key information. Understanding HIV, the importance of treatment, and the risks of transmission to others can also lead to less stigma and shame, which in turn can lead to increased interactions with the health system and positive health outcomes.<sup>107</sup> Efforts to increase health literacy can also aid in addressing the mistrust of the medical system prevalent among many minority groups because of the historical systemic racism in many health care settings.
- **Comprehensive array of clinical and support services.** Current systems of HIV care and treatment have produced tremendous results, and the nation has more providers treating people with HIV than ever before. Today, people with HIV who are on treatment are living longer and healthier lives, and more than one-half of the people with HIV in the United States are over age 50. Researchers and clinicians are identifying and providing services to address the comorbidities experienced by people aging with HIV as well as people with HIV across the entire lifespan whose health can be impacted by noncommunicable comorbidities or coinfections. Other key



## GOAL 2: IMPROVE HIV-RELATED HEALTH OUTCOMES OF PEOPLE WITH HIV

### Objectives

- 2.1 Link people to care immediately after diagnosis and provide low-barrier access to HIV treatment
- 2.2 Identify, engage, or reengage people with HIV who are not in care or not virally suppressed
- 2.3 Increase retention in care and adherence to HIV treatment to achieve and maintain long-term viral suppression and provide integrative HIV services for HIV-associated comorbidities, coinfections, and complications, including STIs
- 2.4 Increase the capacity of the public health, health care delivery systems, and health care workforce to effectively identify, diagnose, and provide holistic care and treatment for people with HIV
- 2.5 Expand capacity to provide whole-person care to older adults with HIV and long-term survivors
- 2.6 Advance the development of next-generation HIV therapies and accelerate research for HIV cure

population groups, such as youth, transgender people, people with substance use disorders, justice-involved people, people with disabilities, or people experiencing homelessness, require different combinations of tailored services to help improve their health outcomes.<sup>108</sup> Work continues to scale up evidence-based and evidence-informed programs that provide enhanced case and care management for people with HIV specific to their comorbidities or co-occurring conditions such as homelessness, food insecurity, and lack of employment.

- **Capacity of the health care delivery system.** As providers engage and reengage people in care and implement rapid start models, the number of people in care will increase. However, workforce needs may not be able to keep pace. The existing highly skilled and dedicated workforce, combined with a growing number of federally funded health centers of all types treating people with HIV, are key to ensuring positive health outcomes. There is an opportunity to examine ways to restructure staff and clinic workflows, implement technological solutions, enhance quality improvement programs, consolidate paperwork requirements, and examine task sharing to create new efficiencies and revamp the ability to use peers in key places along the HIV care continuum. Continuing to find innovative ways to encourage clinical and nonclinical providers to specialize in HIV care and treatment and engaging primary care providers in care and treatment of HIV, viral hepatitis, and STIs will remain important.
- **Meaningful involvement of people with HIV in program design and implementation.** People with HIV are central to the response to the epidemic and must be included in all elements of programming and service delivery to achieve the Strategy's goals. People with HIV must be included in program design and implementation, quality improvement initiatives, and campaigns; engaged as peers in prevention and care services; employed in HIV service delivery organizations; and involved in large-scale structural and policy initiatives. COVID-19 has presented opportunities for engaging people with HIV and communities in new and different ways, and program implementers must continue to create mechanisms for the meaningful engagement of interested individuals.

## CHALLENGES

The following challenges hinder efforts to improve HIV-related health outcomes:

- Health care capacity and workforce shortages exist in critical geographic areas, particularly in the Southern United States.
- Services to address intersecting conditions of mental health, substance use disorders, homelessness or housing instability, and incarceration are limited and/or fragmented.
- HIV-related stigma, other forms of stigma associated with people with HIV, and discrimination continue to impede optimal health outcomes for people with HIV.
- There is a need for new and innovative health care delivery strategies and therapeutics to better support and retain people most vulnerable to not adhering to or dropping out of care.
- There is a lack of ongoing, diverse, meaningful, and engaged community input in some HIV programs and services.
- Medical mistrust and medical misinformation must be addressed.
- Lack of Medicaid expansion, particularly in Southern states disproportionately affected by HIV, limits access to HIV prevention and care services for many who need them.

## SUMMARY OF OBJECTIVES

A concerted national effort to engage people with HIV in care is essential to achieving the Strategy's vision. The following steps are critical to achieving success:

- 2.1 Link people to care immediately after diagnosis and provide low-barrier access to HIV treatment.
- 2.2 Identify, engage, or reengage people with HIV who are not in care or not virally suppressed.



- 2.3 Increase retention in care and adherence to HIV treatment to achieve and maintain long-term viral suppression and provide integrative HIV services for HIV-associated comorbidities, coinfections, and complications, including STIs.
- 2.4 Increase the capacity of the public health, health care delivery systems, and health care workforce to effectively identify, diagnose, and provide holistic care and treatment for people with HIV.
- 2.5 Expand capacity to provide whole-person care to older adults with HIV and long-term survivors.
- 2.6 Advance the development of next-generation HIV therapies and accelerate research for HIV cure.

## OBJECTIVES AND STRATEGIES

### Objective 2.1 Link people to care immediately after diagnosis and provide low-barrier access to HIV treatment

Achieving improved health outcomes for people with HIV begins with ensuring that they are promptly linked to effective HIV care and treatment upon diagnosis. Linkage to HIV care and treatment immediately or as early as possible following HIV diagnosis leads to faster time to viral suppression, increased rates of retention in care and ongoing viral suppression, and reduction in transmission risk.<sup>109-111</sup> Programs must continue to build capacity and shrink the amount of time between diagnosis and linkage to care so that immediate linkage to care becomes the standard across the United States, allowing people to begin receiving care and treatment within hours or days of their diagnosis no matter where they live. This effort may require that some clinics and health departments work to reduce facility-based, government-based, workforce, or administrative barriers to initiating care and treatment. Red carpet and warm-handoff programs provide low-barrier access by linking newly diagnosed people to care and treatment services, often within the same day.<sup>112, 113</sup> For example, these programs, which often integrate robust navigation services, may schedule medical appointments on behalf of the patient, drive newly diagnosed people who lack transportation from an HIV testing site to a trusted clinic, or help people who need assistance complete required forms and paperwork.

#### Strategies

- 2.1.1 Provide same-day or rapid (within 7 days) start of antiretroviral therapy for persons who are able to take it; increase linkage to HIV health care within 30 days for all persons who test positive for HIV.
- 2.1.2 Increase the number of schools providing on-site sexual health services through school-based health centers and school nurses, and linkages to HIV testing and medical care through youth-friendly providers in the community.

### Objective 2.2 Identify, engage, or reengage people with HIV who are not in care or not virally suppressed

Although improvements have been made over time, only 58% of people with diagnosed HIV were retained in care in 2019<sup>2</sup> and 81% of people with diagnosed HIV were rapidly linked to care within 1 month of diagnosis. In addition, 23% of people with HIV who are not receiving care account for 43% of new infections.<sup>28</sup> This population often needs highly tailored approaches to identify, conduct outreach, ascertain barriers to care, and create individualized care plans to facilitate entry into care, followed by navigation and other services to support retention in care, such as short- or long-term housing assistance, benefits counseling across the social services spectrum, and employment counseling. New solutions must be identified to engage and reengage populations that, to date, systems have been unsuccessful in reaching and retaining in care. Feedback and evaluations of services from people with HIV are critical to understanding and improving how services are received by those who need them the most. Attention should also be paid to eligibility and other requirements placed on people seeking care such as eligibility processes and duplicative paperwork requests.

Data-to-care models based on solid, interwoven data points, and other evidence-based interventions focused on finding people not in care and people who are not yet virally suppressed, are proven strategies to reengage people over the long term.<sup>114</sup> Disparate data systems must first be linked to identify people who have tested HIV positive but do not have recent indicators of quality care, people who have fallen out of care, people in care who lack timely prescription refills, and people in care who have not achieved or maintained viral suppression. Entering into formal data sharing agreements ensures that the uses of the data, responsibilities, and protections are clearly delineated for all parties. Such agreements are needed among state public health surveillance systems, state and local health departments, tribes, tribal organizations, urban Indian organizations, the RWHAP, federally funded health centers of all types, community-based organizations, STI specialty clinics, HOPWA programs, Medicaid, Departments of Corrections, pharmacies and pharmacy benefits managers, and other components of the health system serving people with HIV in a geographic area. A goal of data sharing agreements is to reduce administrative burden on providers as well as individuals, thereby avoiding redundant intakes, increasing efficiency, and preparing providers to work alongside clients to develop comprehensive treatment plans without delay.

### Strategies

- 2.2.1 Expand uptake of data-to-care models using data sharing agreements, integration and use of surveillance, clinical services, pharmacy, and social/support services data to identify and engage people not in care or not virally suppressed.
- 2.2.2 Identify and address barriers for people who have never engaged in care or who have fallen out of care.

### **Objective 2.3 Increase retention in care and adherence to HIV treatment to achieve and maintain long-term viral suppression and provide integrative HIV services for HIV-associated comorbidities, coinfections, and complications, including STIs**

People with HIV need ongoing support to stay in care and adhere to ART to achieve and maintain viral suppression.<sup>115</sup> Approaches to increase retention in care include higher levels of personal contact with a patient navigator or community health worker to ensure care receipt; reminders about appointments and calls to discuss why appointments were missed; patient navigation services designed to help patients identify, apply for, and receive necessary services to bolster medical care; medical case management; financial incentives; and low-threshold care including walk-in appointments and on-site pharmacies.<sup>116, 117</sup> Among adherence interventions are those designed to ensure the efficiency of receiving and taking medications such as 90-day prescriptions, options for medication pick-up or receipt by mail, use of technology such as medication reminder apps, and adherence counseling. Other interventions must address common barriers to adherence and retention, such as providing co-located treatment for HIV and mental health and substance use disorders.

Ongoing research in a variety of disciplines is also needed to improve care retention, medication adherence, and sustained viral suppression. Research topics include next-generation therapeutics that are longer-acting, less toxic, and have fewer side effects and complications, as well as behavioral and social sciences to better understand and address barriers to treatment uptake and adherence, as well as disparities. Biomedical, behavioral, and implementation research approaches can be combined to increase viral suppression, reduce HIV transmission, and improve health for all affected populations. Basic, translational, and clinical research can increase understanding of HIV-related comorbidities, coinfections, and complications, which can interfere with retention, adherence, or viral suppression.

New and differentiated models of care, especially those that integrate HIV prevention, care, and supportive services, alongside broader structural interventions, must be tailored and implemented for priority populations. Many populations such as youth transitioning from pediatric to adult care, people without consistent and stable housing, and people released from correctional facilities need well-coordinated interventions that span systems, providers, and payers and address structural, medical, behavioral, and support service concerns.

## Strategies

- 2.3.1 Support the transition of health care systems, organizations, and patients/clients to become more health literate in the provision of HIV prevention, care, and treatment services.
- 2.3.2 Develop and implement effective, evidence-based or evidence-informed interventions and supportive services that improve retention in care.
- 2.3.3 Expand implementation research to successfully adapt effective evidence-based interventions, such as HIV telehealth, patient and peer navigators, accessible pharmacy services, community health workers, and others, to local environments to facilitate uptake and retention to priority populations.
- 2.3.4 Support ongoing clinical, behavioral, and other research to support retention in care, medication adherence, and durable viral suppression.

## **Objective 2.4 Increase the capacity of the public health, health care delivery systems, and health care workforce to effectively identify, diagnose, and provide holistic care and treatment for people with HIV**

Increasing viral suppression requires expanded capacity of public health, health care and support service delivery systems, and the health workforce to be flexible and responsive to the needs of people with HIV. COVID-19 has strained HIV care and prevention systems and has highlighted gaps within our nation's response. Federal and state programs focused on HIV should work to identify opportunities to expand the HIV workforce, including partnerships with medical colleges, particularly Historically Black Colleges and Universities, and incentives for clinicians to provide HIV and related services. Increasing the diversity of providers offering HIV prevention and care services is one important capacity-building approach. In addition, publicly funded organizations can increase the diversity of their workforce and provide training to ensure culturally competent care and knowledge of best practices for caring for people from diverse backgrounds.<sup>118</sup> Health care and support systems can also take advantage of different types of health professionals such as nurses, advanced practice providers, pharmacists, and behavioral health specialists to ensure that any workforce shortages can be addressed. Innovative staffing models can also build capacity to better meet the needs of people with HIV including the use of community health workers, linkage to care and reengagement specialist teams, task sharing, integrated care teams, and use of peer mentors.<sup>119</sup> Organizations should also work to ensure that their staff represents the populations served, including hiring pathways for people with HIV and providing opportunities for leadership and leadership development. In addition, sustained continuous quality improvement programs must be utilized to ensure that up-to-date and high-quality care is being provided by integrated and diverse care teams.

In addition to the RWHAP, patient-centered medical homes and health homes create opportunities to address medical and support service needs of people with HIV through coordinated, team-based, and accessible programs including co-location of mental health, substance use, geriatric, reproductive, and other related health care services. Similar to HIV prevention, expanding care and treatment capacity must also include delivery of additional resources, incentives, training, and technical assistance to existing systems as well as development of new systems in areas with limited availability. For example, establishing new partnerships and advancing telehealth arrangements to expand access to professionals with specialized backgrounds should be explored to increase access to services in geographically underserved areas, as well as expanding broadband access, so that those in underserved and rural areas may have equitable access to telehealth arrangements. The design of programs to reach and engage people out of care, people never in care, and people who are challenged to stay in care may require novel approaches, services, and partnerships to address issues of trauma, poverty, and associated conditions that are obstacles to care. The creation and implementation of new programs should involve input and feedback from people with HIV because they have unique knowledge to share. Systems should also offer low-threshold capacity-building resources to organizations and retail health clinics led and staffed by local members of the priority populations to enhance their



ability to apply for and receive grants and foundation funds to increase the number of services being provided in and by affected communities.

In addition, to address the unique needs of people aging with HIV and long-term survivors, federal and state programs and community-based organizations must conduct analyses to identify gaps in service delivery for this population so that programs can be implemented to address shortfalls. This analysis should include federal programs such as Medicare and the RWHAP to ensure adequacy of care and support services, benefits, and policies.

### Strategies

- 2.4.1 Provide resources, value-based and other incentives, training, and technical assistance to expand workforce and systems capacity to provide or link clients to culturally competent and linguistically appropriate care, treatment, and supportive services especially in areas with shortages that are geographic, population, or facility based.
- 2.4.2 Increase the diversity of the workforce of providers who deliver HIV care and supportive services.
- 2.4.3 Increase inclusion of paraprofessionals on teams by advancing training, certification, supervision, reimbursement, and team functioning to assist with screening/management of HIV, STIs, viral hepatitis, and mental and substance use disorders and other behavioral health conditions.

### Objective 2.5: Expand capacity to provide whole-person care to older adults with HIV and long-term survivors

More than one-half (52%) of people in the United States with diagnosed HIV were aged 50 and older in 2019.<sup>3</sup> Of the more than 500,000 clients served by the RWHAP in 2019, 46.8% were aged 50 years and older—an increase from 31.6% in 2010. Of clients aged 50 years and older receiving RWHAP HIV medical care, 90.9% were virally suppressed, which was slightly higher than the national RWHAP average (88.1%).<sup>120</sup> The proportion of older adults with HIV is expected to continue to rise because of the effectiveness of ART, as well as new diagnoses within this age group, which accounts for approximately 17% of all diagnosed HIV in the United States.

People aging with HIV, many of whom are long-term survivors, have unique mental health and physical health needs.<sup>121</sup> Although people with HIV over age 50 have the highest viral suppression rates and the lowest incidence rates of any age group, the effects of aging, chronic inflammation, frailty, and distinctive behavioral health issues can compound the care and support service needs for this population.

Although modern antiretroviral therapies increase the life expectancy of people living with HIV, many challenges and opportunities for the treatment of HIV and HIV-associated comorbidities, coinfections, and complications across the lifespan persist. Even when long-term viral suppression is achieved, people living with HIV over age 50 are more likely than their peers without HIV to experience age-related complications such as cardiovascular disease, lung disease, infection-related and non-infection-related cancers, neurocognitive and neuropsychiatric disorders, osteopenia/osteoporosis, liver cirrhosis, and renal disease. In addition, people living with HIV infection may suffer from multiple morbidities, polypharmacy, declining physical and cognitive function, alterations in body composition, social isolation, and increased caregiver burden.

Older adults with HIV and long-term survivors of HIV often experience social isolation, loneliness, and a lack of social support, as well as HIV- and age-related stigma. These issues may prevent them from seeking or staying in care and can contribute to poor mental and physical health. The U.S. HIV care and treatment system must adapt to ensure that people aging with HIV can receive whole-person care that addresses their HIV- and aging-related health needs, along with support services such as mental health, transportation, housing, food and nutrition, and benefits counseling, among many others. Relatedly, our nation's programs designed to serve older adults—including Medicare, Medicaid, and programs supported through the HHS Administration for Community Living including

State Units on Aging, Area Agencies on Aging, and other community-based organizations and social service providers—must be prepared to meet the needs of people with HIV. Partnerships between HIV care providers and community-based organizations can greatly enhance the ability of people aging with HIV to maintain independence and experience improved quality of life (see Box 8 for a discussion of HIV Prevention and Care Across the Lifespan).

### Strategies

- 2.5.1 Identify, implement, and evaluate models of care that meet the needs of people with HIV who are aging and ensure quality of care across services.
- 2.5.2 Identify and implement best practices related to addressing psychosocial and behavioral health needs of older people with HIV and long-term survivors including substance use treatment, mental health treatment, and programs designed to decrease social isolation.
- 2.5.3 Increase HIV awareness, capability, and collaboration of service providers to support older people with HIV, including in settings such as aging services, housing for older adults, substance use treatment, and disability and other medical services.
- 2.5.4 Promote research, cross-agency collaborations and sharing of research discoveries that address specific aging-related conditions in people with HIV, and other comorbidities and coinfections that can impact people with HIV of all ages.
- 2.5.5 Develop and optimize collaborative multi-agency and multi-sectoral approaches and strategies to address emergent and evolving challenges facing people living with HIV at various life stages to support healthy aging with HIV.

### Objective 2.6: Advance the development of next-generation HIV therapies and accelerate research for HIV cure

Research and programmatic implementation of varied HIV therapeutic modalities that meet the needs of diverse communities of people with HIV is critical to reduce onward transmission and to achieve complete virus remission, eradication, and HIV cure. Collaboration must exist on a global scale, as much of the research on these new therapies is being done in highest incidence settings.

Novel ART classes and drugs that target the HIV lifecycle are in various stages of preclinical and clinical development and are under investigation in clinical trials. Next-generation therapeutics research includes basic and clinical studies to optimize efficient delivery of therapies and interventions that address drug toxicity, viral resistance, adherence, and retention in care and stigma associated with ART use.

Numerous novel diagnostic and delivery systems are similarly being developed and tested, including subcutaneous, intravenous, topical, implantable, and long-acting oral formulations. New delivery systems and technologies will improve adherence to drug regimens and reduce the burden on health systems.

Research toward safer, effective, and long-lasting therapeutics that successfully achieve viremic control in the absence of ART or completely eradicate the HIV infection (cure) must continue, and must seek a better understanding of the viral reservoir dynamics, persistent viral replication consequences, and the host immune system clearance capacity to remove residual infection.

In parallel to research efforts, safe, long-acting, more efficacious regimes must be rapidly approved and implemented to meet the needs of communities of people with HIV. Achieving these goals will benefit from robust public-private partnerships both in basic and clinical research as well as in implementation planning and delivery to ensure community involvement and advocacy.

## Strategies

- 2.6.1 Promote research and encourage public-private partnerships to accelerate new therapies to achieve sustained viral suppression and to address drug toxicity, viral resistance, adherence, and retention in care and stigma associated with ART use.
- 2.6.2 Increase investment in innovative basic and clinical research to inform and accelerate a research agenda to discover how to sustain viral suppression, achieve ART-free remission, reduce and eliminate viral reservoirs, and achieve HIV cure.

## INDICATORS OF PROGRESS

Working together to pursue these objectives, the nation can achieve the following targets by 2025:

- Indicator 5** Increase linkage to care within 1 month of diagnosis to 95% from a 2017 baseline of 77.8%.
- Indicator 6** Increase viral suppression among people with diagnosed HIV to 95% from a 2017 baseline of 63.1%.



## GOAL 3: REDUCE HIV-RELATED DISPARITIES AND HEALTH INEQUITIES

### THE OPPORTUNITY

Advances in HIV prevention, testing, care, treatment, and supportive services have led to significant declines in new HIV transmissions and deaths. They also make it possible for the nation to envision ending the HIV epidemic. However, realizing this vision requires that every person across the United States with or who experiences risk for HIV has access to high-quality and culturally competent prevention, diagnostic, care, treatment, and supportive services that are non-stigmatizing, non-discriminatory, inclusive, and responsive to their needs. Further, issues such as discrimination and systemic racism that contribute to differences in the quality of and access to health care and other necessities such as housing and behavioral and substance use services, and lead to ongoing disparities among racial, ethnic, and sexual and gender minority populations, must be addressed.

The Strategy recognizes racism as a serious public health threat that directly affects the well-being of millions of Americans. Racism is not only the discrimination against one group based on the color of their skin or their race or ethnicity, but also the structural barriers that impact racial and ethnic groups differently to influence where a person lives, where they work, where they play, and where they gather as a community. Over generations, these structural inequities have resulted in racial and ethnic health disparities that are severe, far-reaching, and unacceptable.<sup>122</sup> Across the country, federal, state, and local leaders are declaring racism to be a public health crisis, an important step in the movement toward equity.<sup>120</sup> This recognition comes with the need for a more equitable HIV response that focuses on populations with the greatest need.

Reducing these disparities entails focusing on the needs of disproportionately affected populations, supporting racial justice, combating HIV-related stigma and discrimination, providing leadership and employment opportunities for people with or who experience risk for HIV, and addressing social determinants of health and co-occurring conditions to reduce health inequities and disparities. Therefore, the Strategy fully recognizes that the national HIV goals can only be achieved through collaborative efforts at the federal, state, tribal, territorial, and local levels that focus on reducing HIV-related disparities and by ongoing commitment to understand and address the central factors that create HIV inequities.

In recent years, the nation and individual states have made progress in the area of HIV-related disparities. For example:

- **The RWHAP significantly reduced viral suppression disparities among client populations**, particularly women, transgender people, youth, Blacks, and people with unstable housing. Overall, 88% of clients receiving medical care in the RWHAP were virally suppressed in 2019.<sup>5</sup> From 2010 to 2019, the gap between male and female clients decreased from nearly 5 percentage points to <1 percentage point. In addition, the gap between male and transgender clients decreased from 9 percentage points to 5 percentage points. Similarly, the disparity between viral suppression rates in Black clients and White clients was 13 percentage points in 2010 but 7 percentage points in 2019.<sup>5, 6</sup> HRSA and its RWHAP recipients have continued to use these data to drive programs and decision-making.
- **Disparities in rates of new infections declined in some populations.** From 2015 to 2019 the United States saw reductions of disparities in the rates of new HIV infections among gay and bisexual men, Black gay and bisexual men, and Black women.<sup>11</sup>
- **Since 2014, at least nine states (CA, CO, IA, IL, MI, MO, NV, NC, VA) have modernized or repealed their HIV criminal exposure laws.** Changes have included removing HIV prevention issues from the criminal code and including them instead under disease control regulations, requiring intent to transmit or actual HIV transmission, or providing for defenses for taking measures to prevent transmission.



## CHALLENGES

The following challenges hinder efforts to reduce HIV-related disparities and health inequities:

- Disparities in HIV prevalence persist.<sup>124</sup>
- The South bears a disproportionate HIV burden.
- Disparities are also evident in the proportion of people with HIV with viral suppression.<sup>2</sup>
- Significant disparities exist in PrEP uptake by age, race, sex at birth, and geographic location.<sup>11, 63, 64</sup>

Research to better understand and address such disparities and inequalities—including through community-based participatory research methods—can help improve HIV testing and engagement and retention in prevention and care services and can enhance the health and well-being of people with or who experience risk for HIV in underserved and marginalized communities.

Also important is consideration of and appropriate and proportional response to HIV among groups that represent a small share of both the population and of HIV infections. Although it is vital to focus national efforts in communities with the highest burden, HIV prevention, care, and treatment must continue to be supported in localities with concentrations of groups such as Asian Americans and Pacific Islanders and American Indians/Alaska Natives, and informed by the best available data.

### *A Focus on Health Inequities*

Certain racial and ethnic minority groups have higher rates of HIV incidence, prevalence, poor health outcomes (lower viral suppression), and mortality, compared to non-Hispanic Whites.<sup>125</sup> Health disparities can stem from inequities in the social determinants of health and highlight the need to focus on not only HIV prevention and care efforts, but also how programs, practices, and policies affect racial and ethnic minority communities. Persons from racial and ethnic minority groups are more likely to be uninsured compared to non-Hispanic Whites,<sup>126</sup> limiting their access to health care. Sexual and gender minorities also face health inequities. Sexual and gender minorities have lower levels of health insurance and access to regular health care compared to their heterosexual counterparts.<sup>37, 38</sup> Barriers to health care access include lack of transportation and childcare, inability to take time off from work, communication and language barriers, racism, discrimination, and lack of trust in health care providers.<sup>127</sup> Further, CDC's 2019 Youth Risk Behavior Survey data show that substantial health disparities exist among an estimated 2.6 million sexual minority students, placing them at risk for negative health outcomes, including HIV infection.

The Strategy recognizes the importance of addressing social determinants of health to improve health outcomes for racial, ethnic, and sexual and gender minority groups. By working to establish policies and programs that positively



## GOAL 3: REDUCE HIV-RELATED DISPARITIES AND HEALTH INEQUITIES

### Objectives

- 3.1 Reduce HIV-related stigma and discrimination
- 3.2 Reduce disparities in new HIV infections, in knowledge of status, and along the HIV care continuum
- 3.3 Engage, employ, and provide public leadership opportunities at all levels for people with or who experience risk for HIV
- 3.4 Address social and structural determinants of health and co-occurring conditions that impede access to HIV services and exacerbate HIV-related disparities
- 3.5 Train and expand a diverse HIV workforce by further developing and promoting opportunities to support the next generation of HIV providers including health care workers, researchers, and community partners, particularly from underrepresented populations
- 3.6 Advance HIV-related communications to achieve improved messaging and uptake, as well as to address misinformation and health care mistrust



influence social and economic conditions and by supporting changes in individual behavior, health can be improved and sustained, and disparities reduced. Improving the conditions in which we live, learn, work, play, age, and worship and the quality of our relationships will create a healthier population, society, and workforce.<sup>128</sup> Application of a “health in all policies” strategy, a cross-sector collaborative approach to integrating health into policies and programs to close the health gaps,<sup>129-130</sup> can be implemented across all areas and levels of government and in the community to foster achievement of these aims.

## SUMMARY OF OBJECTIVES

The following objectives are critical to reducing HIV-related disparities and health inequities:

- 3.1 Reduce HIV-related stigma and discrimination
- 3.2 Reduce disparities in new HIV infections, in knowledge of status, and along the HIV care continuum
- 3.3 Engage, employ, and provide public leadership opportunities at all levels for people with or who experience risk for HIV
- 3.4 Address social and structural determinants of health and co-occurring conditions that impede access to HIV services and exacerbate HIV-related disparities
- 3.5 Train and expand a diverse HIV workforce by further developing and promoting opportunities to support the next generation of HIV providers including healthcare workers, researchers, and community partners, particularly from underrepresented populations
- 3.6 Advance HIV-related communications to achieve improved messaging and uptake, as well as to address misinformation and health care mistrust

## OBJECTIVES AND STRATEGIES

### Objective 3.1 Reduce HIV-related stigma and discrimination

Many people with HIV experience stigma and discrimination because of their HIV status. Stigma is an attitude of disapproval and discontent toward a person or group because of the presence of an attribute perceived as undesirable. Discrimination is often a consequence of stigma, occurring when unfair and often unlawful actions are taken against people based on their belonging to a particular stigmatized group. HIV stigma and discrimination can pose complex barriers for people with or who experience risk for HIV, preventing them from seeking prevention tools, learning their HIV status, and accessing medical care, treatment, and supportive services. Interested parties and organizations from all sectors of society, including government, faith communities, businesses, schools, and others, must work to combat stigma and discrimination in order to reduce new transmissions and improve health outcomes for people with HIV.

Ending the HIV epidemic requires addressing structural barriers to HIV prevention and care. HIV-specific criminal laws perpetuate HIV-related stigma, and discrimination can also deter individuals from getting tested. Some of these laws criminalize behavior that pose low or no risk for transmitting HIV and apply regardless of actual HIV transmission. These outdated laws do not reflect our current understanding of HIV and should be repealed or updated. At least nine states have done so since 2014. Such efforts must ensure that criminal laws and policies regarding HIV transmission are based on the latest scientific evidence and reflect effective public health strategies, and that legislators, prosecutors, and law enforcement officials have an accurate understanding of HIV transmission risks (see Box 7).

Discriminatory practices cause stress and play a role in the health outcomes of minorities.<sup>131</sup> Public health and health care systems should be respectful of and responsive to the health beliefs, practices, accessibility needs, and cultural and language needs of diverse patients.<sup>132</sup> At the community level, interested parties and advocates should

be equipped with knowledge and tools to address misconceptions and change norms that are associated with HIV-related stigma and discrimination. At the individual level, multiple approaches to address interpersonal and internalized stigma should be available to people with or who experience risk for HIV as well as their family, friends, health care providers, and others.

HIV-related stigma and discrimination and their effects on people with or who experience risk for HIV should not be viewed in a silo. Stigma and discrimination come in different forms and are often complicated when people also experience stigma and discrimination related to—among other identities or experiences—race and ethnicity, sexual orientation or sexual behavior, other STIs, gender identity, substance use, mental health, homelessness, socioeconomic circumstance, justice involvement, immigration status, age, disability, or sex work.<sup>108, 133</sup> Additional research, innovative solutions, and replication of global efforts, such as those from the President’s Emergency Program for Emergency AIDS Relief (PEPFAR), to address the drivers, facilitators, and manifestations of stigma are needed.<sup>134</sup> These solutions should be integrated into the delivery of services that are responsive and sensitive to the unique needs of populations that face intersectional stigmas and intersectional discrimination.

### Strategies

- 3.1.1 Strengthen enforcement of civil rights laws (including language access services and disability rights), promote reform of state HIV criminalization laws, and assist states in protecting people with HIV from violence, retaliation, and discrimination associated with HIV status, homophobia, transphobia, xenophobia, racism, substance use, and sexism.
- 3.1.2 Ensure that health care professionals and front-line staff complete education and training on stigma, discrimination, and unrecognized bias toward populations with or who experience risk for HIV, including LGBTQI+ people, immigrants, people who use drugs, and people involved in sex work.
- 3.1.3 Support communities in efforts to address misconceptions and reduce HIV-related stigma and other stigmas that negatively affect HIV outcomes.
- 3.1.4 Ensure resources are focused on the communities and populations where the need is greatest, especially Black, Latino, and American Indian/Alaska Native and other people of color, particularly those who are also gay and bisexual men, transgender people, people who use substances, sex workers, and immigrants.
- 3.1.5 Create funding opportunities that specifically address social and structural drivers of health as they relate to Black, Latino, and American Indian/Alaska Native and other people of color.



### BOX 7 STATE HIV CRIMINALIZATION LAWS

During the early years of the HIV epidemic, many states implemented HIV-specific criminal exposure laws to discourage behavior that they believed might lead to transmission, promote safer sex practices, and, in some cases, receive funds to support HIV prevention activities. These laws were passed at a time when very little was known about HIV, including how it was transmitted and how best to prevent or treat it. For example, many were enacted before the advent of pre-exposure prophylaxis (PrEP), which reduces the risk of acquiring HIV sexually by 99% when taken daily, or the availability of antiretroviral therapy (ART), which—when taken as prescribed—helps an individual with HIV achieve and maintain a suppressed viral load so that they have effectively no risk of transmitting HIV to sexual partners. As such, many of these state laws criminalize [behavior that cannot transmit HIV](#) and apply regardless of actual transmission.



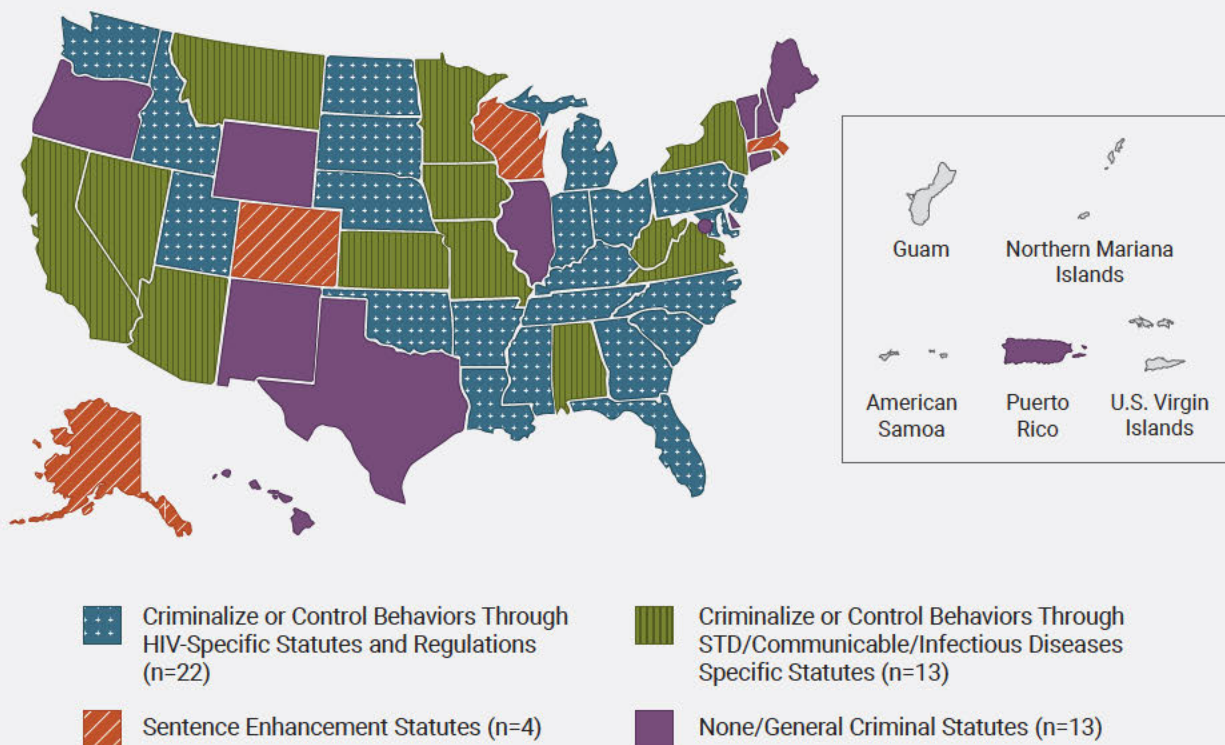


## BOX 7

### STATE HIV CRIMINALIZATION LAWS (CONTINUED)

Criminalization of potential HIV exposure is largely a matter of state law, with some federal legislation addressing criminalization in discrete areas, such as blood donation and sex work. In 2021, CDC assessed state laws and grouped them into four categories:

1. HIV-specific laws that criminalize or control behaviors that can potentially expose another person to HIV.
2. STI, communicable, contagious, infectious disease laws that criminalize or control behaviors that can potentially expose another person to STIs/communicable/infectious disease, perhaps including HIV.
3. Sentence enhancement laws specific to HIV or STI that do not criminalize a behavior but increase the sentence length when a person with HIV commits certain crimes.
4. No specific criminalization laws.



**Figure 9.** State criminal HIV exposure laws, as of 2021

As shown in Figure 9, these laws vary as to what behaviors are criminalized or what behaviors result in additional penalties. Several states criminalize one or more behaviors that pose a low or negligible risk for HIV transmission. Only 9 of the 35 states with HIV criminalization laws account for HIV prevention measures that reduce transmission risk, such as condom use and ART.





## BOX 7 STATE HIV CRIMINALIZATION LAWS (CONTINUED)

Since 2014, at least nine states have modernized or repealed their HIV criminal laws: California, Colorado, Illinois, Iowa, Michigan, Missouri, Nevada, North Carolina, and Virginia. Changes have included removing HIV prevention issues from the criminal code and including them under disease control regulations, requiring intent to transmit or actual HIV transmission, or providing defenses for taking measures to prevent transmission such as viral suppression or being noninfectious, condom use, and partner PrEP use.

**After more than 30 years of HIV research and significant biomedical advancements to treat and prevent HIV transmission, many state laws are still outdated and do not reflect our current understanding of HIV.** In many cases, this same standard is not applied to other treatable diseases. Further, these laws have not increased disclosure and may discourage HIV testing, increase stigma against people with HIV, and exacerbate disparities. To end the HIV epidemic, public health, criminal justice, and legislative systems must work together to ensure that laws protect the community, are evidence-based and just, and support public health efforts. When a law meant to protect the public is not working as intended, is unjust, and may be hurting efforts to keep communities healthy, common solutions must be found to better meet public health and public safety goals. States should repeal or update these outdated laws and practices.

Source: CDC<sup>135, 136</sup>

### Objective 3.2 Reduce disparities in new HIV infections, in knowledge of status, and along the HIV care continuum

Monitoring of progress toward HIV targets should identify, raise awareness of, and inform appropriately tailored interventions to respond to ongoing and emerging disparities among various populations and in geographic areas. With improved mechanisms to measure, monitor, and report data in a timely manner and enhanced quality, accessibility, sharing, and use of data (see Goal 4), governments and organizations can more quickly identify disparities and direct resources appropriately.

When disparities are identified, tailored interventions must be developed in partnership with the affected populations. Specific populations may have unique or specialized needs and face challenges that require more tailored approaches based on sociodemographic, geographic, cultural, and other characteristics that may be associated with HIV risk or health-promoting behaviors.

#### Strategies

- 3.2.1 Increase awareness of HIV-related disparities through data collection, analysis, and dissemination of findings.
- 3.2.2 Develop new and scale up effective, evidence-based or evidence-informed interventions to improve health outcomes among priority populations and other populations or geographic areas experiencing disparities.

### Objective 3.3 Engage, employ, and provide public leadership opportunities at all levels for people with or who experience risk for HIV

Achieving the goals of this Strategy and ending the HIV epidemic demand a whole-of-society effort that must include and elevate the diverse voices and experiences of people with or who experience risk for HIV, as well as



their partners, families, and communities. Jurisdictions and organizations must meaningfully engage and employ people with or who experience risk for HIV in the development, implementation, monitoring, and assessment of policies, programs, and services. This includes creating opportunities for employment and advancement, as well as fair compensation, wherever possible, particularly for individuals from the priority populations identified in this Strategy. Their experiences and expertise can inform efforts to remove barriers that hinder access to needed information or services and to design services that meet unique needs as well as enhance cultural competency. Governments and other institutions working to meaningfully engage people with or who experience risk for HIV must develop partnerships with networks of people with or who experience risk for HIV and other organizations that engage and serve populations most affected by HIV in each community, thereby identifying ways to optimize messages and services and to combat stigma and discrimination. This includes meaningful engagement of Black, Latinx, American Indian/Alaska Native, and other people of color communities—especially people with or experiencing risk for HIV, people who inject drugs, people with a history of justice involvement, immigrants, sex workers, transgender people, and gay and bisexual men—in HIV planning, service delivery, program monitoring/assessment, research, and policymaking.

### Strategies

- 3.3.1 Create and promote public leadership opportunities for people with or who experience risk for HIV.
- 3.3.2 Work with communities to reframe HIV services and HIV-related messaging so that they do not stigmatize people or behaviors.

### Objective 3.4 Address social and structural determinants of health and co-occurring conditions that impede access to HIV services and exacerbate HIV-related disparities

Addressing social determinants of health and co-occurring conditions, such as noncommunicable comorbidities and coinfections, is essential to reducing HIV-related health disparities and inequities. For many people with or who experience risk for HIV, addressing basic and immediate needs, such as safety and/or shelter, takes precedence over HIV testing, prevention, care, or treatment. Lack of continuous health insurance coverage, inability to pay for care and treatment, inadequate housing, food insecurity, under- and unemployment, medical mistrust, provider misconceptions and bias, low health literacy, language barriers, and involvement in the justice system all act as barriers to improved HIV outcomes.

In other cases, people may be interested in HIV services, but shortages of a skilled and competent workforce or lack of nearby HIV services hinder their ability to access them. These limitations are made worse by inadequate infrastructure, including limited or no broadband internet services and lack of public transportation.<sup>94</sup> Structural barriers such as laws or policies can also impede the availability of or access to HIV services. For example, support for the legalization or expansion of SSPs is needed in many jurisdictions, particularly in areas with a significant population of people who inject drugs.

Ending the HIV epidemic requires recognition of the need for interventions and pooled resources to address upstream factors often rooted in racism and other social and structural barriers.<sup>137</sup> Programs could destigmatize HIV services, increase service utilization, address social determinants of health, and improve health outcomes by integrating them in multi-disease, community-based testing, care, and treatment models.<sup>138</sup> Ultimately, the success of biomedical and behavioral interventions may be directly impacted by whether structural interventions are effectively integrated to support them. Such integration supports person-centered care that considers all of the patient's needs and lived experiences, including those separate from HIV that vary across the lifespan (see Box 8). Integration also includes establishing additional opportunities to engage in partnerships that make it possible to address clients' unmet needs, maximize reach, and promote efficiency and sustainability.



## BOX 8

### ADDRESSING HIV PREVENTION AND CARE ACROSS THE LIFESPAN

Responsive services that recognize and support variable and episodic needs across the lifespan are necessary to best support people with or who experience risk for HIV.

Much progress has been achieved in preventing perinatal transmission of HIV in the United States; only 65 HIV infections were attributed to perinatal transmission in 2018.<sup>139</sup> Although rare, perinatal transmission of HIV still occurs in the United States but disproportionately impacts Black children.<sup>139</sup> Limited antiretroviral therapy (ART) formulations for infants and children make HIV management in these age groups challenging. Questions remain about the impact of HIV and ART exposure in utero, as well as HIV infection and long-term ART on the growing and developing child. While early treatment reduces morbidity and mortality from HIV, whether very early ART can ameliorate complications of HIV and preserve neurodevelopment, optimal cognitive functioning, and mental health in children with HIV is unclear. Preventing mother-to-child transmission requires intensive case management and coordination across many systems and payors.

Youth experience worse HIV outcomes on status awareness, pre-exposure prophylaxis uptake, and health outcomes. Children and young adults with HIV need tailored and often more intensive medical and support services to support them as they grow and become young adults. Schools play an important role in the primary prevention of HIV in youth by offering comprehensive sexual health education and on-site sexual health services through school-based health centers and school nurses, or in collaboration with community partners that provide services, such as periodic, school-wide HIV and STI screening events or mobile clinics. Schools that cannot provide direct sexual health services can establish integrated referral systems that link students to youth-friendly providers in the community. There is a need for both primary prevention approaches and HIV care models that are tailored to groups of youth at disproportionate risk of HIV, including young gay, bisexual, and other men who have sex with men and people who inject drugs.

Across the lifespan, individuals with HIV will also experience a spectrum of non-HIV-specific needs, which may require coordination across various health and social services systems, such as sexual and reproductive health or transition-related care for transgender individuals, in order to ensure affirming whole-person care.

Similarly, tailored approaches are required to meet the HIV prevention, testing, and care needs of older adults. Older Americans are more likely than younger Americans to be diagnosed with HIV infection late in the course of their disease, meaning they get a late start to treatment and possibly experience more damage to their immune system. Thanks to effective HIV care and treatment, people with HIV who are diagnosed early in their infection, and who get and stay on ART, can keep the virus suppressed and live long and healthy lives. Therefore, the number of older adults with HIV is growing; more than one-half of people with diagnosed HIV in the United States were aged 50 and older in 2018.<sup>125</sup>

Older people with HIV, especially long-term survivors, face different health and psychosocial issues than their younger counterparts and thus require appropriately tailored HIV care and treatment services. These unique needs include screening for, assessment of, and treatment of HIV-associated, non-AIDS conditions as well as age-associated diseases for which people with HIV experience increased risk, and addressing social challenges such as social isolation or depression faced by many people aging with HIV and especially those who are long-term survivors of the disease. As this population continues to age, it will be necessary to research, develop, and implement effective interventions, and adapt and appropriately fund systems of care, with attention to comorbidities related to aging.



**BOX 8****ADDRESSING HIV PREVENTION AND CARE ACROSS THE LIFESPAN  
(CONTINUED)**

HIV systems of care must incorporate and form partnerships with service providers for older adults, including local Area Agencies on Aging and housing for older adults, to ensure that older people with HIV can also access social services as well as qualified mental health and substance use services that are provided by people experienced in elder care and HIV. Ensuring that agencies focused on elder services can provide age-friendly, affirming care to LGBTQI+ individuals and those with HIV is imperative as the population in need of those services continues to grow.

There is a clear need for both primary prevention approaches and HIV care models tailored to different life stages. Cross-agency efforts are needed to develop, adapt, and implement treatments and interventions specific for the different life stages in order to improve and sustain HIV health outcomes.

Sources: Mandsager et al.<sup>6</sup>, McNeil and Rowe<sup>40</sup>

**Strategies**

- 3.4.1 Develop whole-person systems of care and wellness that address co-occurring conditions for people with or who experience risk for HIV.
- 3.4.2 Adopt policies and laws that reduce cost, payment, coverage, and/or access barriers to improve the delivery and receipt of services for people with or who experience risk for HIV.
- 3.4.3 Improve screening and linkage to services for people with or who experience risk for HIV who are diagnosed with and/or are receiving services for co-occurring conditions.
- 3.4.4 Develop and implement effective, evidence-based and evidence-informed interventions that address social and structural determinants of health among people with or who experience risk for HIV including lack of continuous health care coverage, HIV-related stigma and discrimination in public health and health care systems, medical mistrust, inadequate housing and transportation, food insecurity, unemployment, low health literacy, and involvement with the justice system.
- 3.4.5 Increase the number of schools that have implemented LGBTQ-supportive policies and practices, including (1) having a Gay/Straight Alliance (GSA), Gender Sexuality Alliance, or similar clubs, (2) identifying safe spaces, (3) adopting policies expressly prohibiting discrimination and harassment based on sexual orientation or gender identity, (4) encouraging staff to attend professional development, (5) facilitating access to out-of-school health service providers, (6) facilitating access to out-of-school social and psychological service providers, and (7) providing LGBTQ-relevant curricula or supplementary materials.
- 3.4.6 Develop new and scale up effective, evidence-based or evidence-informed interventions that address intersecting factors of HIV, homelessness or housing instability, mental health and violence, substance use, and gender especially among cis- and transgender women and gay and bisexual men.

**Objective 3.5: Train and expand a diverse HIV workforce by further developing and promoting opportunities to support the next generation of HIV providers including healthcare workers, researchers, and community partners, particularly from underrepresented populations**

Continuous building of a diverse HIV workforce is critical to achieve HIV epidemic control. Supporting and promoting equity and diversity is fundamentally important to adequately and effectively advance research and

enhance innovation. Diversity, inclusion, and community representation are key to achieving creative problem-solving perspectives, and to ensuring the comprehensive cultural spectrum necessary to understand epidemic dynamics.

Multiple obstacles, including the lack of opportunity for minority institutions and communities, paucity of adequate mentorship, and resource limitations, impede achieving equity and diversity in the health workforce. Such structural barriers create challenges at all levels of the workforce development ladder, from recruitment to education, promotion, and retention of HIV providers including researchers, community health workers, and other health care providers.

Together with the development of a diverse health workforce, research that effectively reduces and eliminates health disparities in HIV will require the participation of all sectors of the community. Inclusion of all sectors is fundamental to better understand current needs and develop effective actions to mitigate existing gaps in HIV research and service delivery.

A multipronged approach will be necessary to achieve the interrelated goals of a more diverse and appropriately trained research and health workforce and improved community engagement. Successful approaches should address both individual factors and social factors and involve funding agencies, academic institutions, professional societies, and peer collaboration.

### **Strategies**

- 3.5.1 Promote the expansion of existing programs and initiatives designed to increase the numbers of non-White research and health professionals.
- 3.5.2 Increase support for the implementation of mentoring programs for individuals from diverse cultural backgrounds to expand the pool of HIV research and health professionals.
- 3.5.3 Encourage the implementation of effective recruitment of community partners through community-based participatory research and social networking approaches.

### **Objective 3.6: Advance HIV-related communications to achieve improved messaging and uptake, as well as address misinformation and health care mistrust**

Accurate and accessible health communication is essential to ending the HIV epidemic. Communication science provides the tools and strategies for developing communications tailored to the needs of people with HIV and experiencing risk for HIV. Effective HIV communication science involves best practice principles applied to communicator choice and the design, content, tone, and timing of messages. Communications must be responsive to life contexts, community circumstances and feedback, and changes over time.

The U.S. Surgeon General’s “Advisory on Building a Healthy Information Environment” states that the nation has the power to build a healthier information reality.<sup>141</sup> Such an environment improves health by enabling informed decision-making and bolsters trust. Dissemination of accurate and accessible health information has been pivotal in the success of HIV prevention and treatment strategies. HIV health communication plays a significant role in decreasing transmission, increasing treatment, and reducing stigma.

Health communication science is a key to understanding and addressing inaccurate health information, whether unintentional misinformation or deliberate and strategic disinformation. Increased investment in new communication implementation research will improve HIV-related health communication strategies and decrease vulnerability to misinformation and disinformation. Addressing communication challenges requires a sustained whole-of-government approach and engagement with multi-sector partnerships and communities.



## Strategies

- 3.6.1 Develop and test strategies to promote accurate creation, dissemination, and uptake of information and to counter associated misinformation and disinformation.
- 3.6.2 Increase diversity and cultural competence in health communication research, training, and policy.
- 3.6.3 Expand community engagement in health communication initiatives and research.
- 3.6.4 Include critical analysis and health communication skills in HIV programs to provide participants with the tools to seek and identify accurate health information and to advocate for themselves and their communities.
- 3.6.5 Expand effective communication strategies between providers and consumers to build trust, optimize collaborative decision-making, and promote success of evidence-based prevention and treatment strategies.

## INDICATORS OF PROGRESS

Working together to pursue these objectives, the nation can achieve the following targets by 2025:

**Indicator 7** Decrease stigma among people with diagnosed HIV by 50% from a 2018 baseline median score of 31.2 on a 10-item questionnaire.

**Indicator 8** Reduce homelessness among people with diagnosed HIV by 50% from a 2017 baseline of 9.1%.

**Indicator 9** Increase the median percentage of secondary schools that implement at least 4 out of 7 LGBTQ-supportive policies and practices to 65% from a 2018 baseline of 59.8%

In addition to these indicators, the Strategy identifies a disparities indicator to measure progress toward reducing significant HIV-related disparities. Core indicator 6 on viral suppression serves as this disparities indicator and is stratified by each of the priority populations identified in the Strategy:

**Indicator 6a** Increase viral suppression among MSM diagnosed with HIV to 95% from a 2017 baseline of 66.1%.

**Indicator 6b** Increase viral suppression among Black MSM diagnosed with HIV to 95% from a 2017 baseline of 58.4%.

**Indicator 6c** Increase viral suppression among Latino MSM diagnosed with HIV to 95% from a 2017 baseline of 64.9%.

**Indicator 6d** Increase viral suppression among American Indian/Alaska Native MSM diagnosed with HIV to 95% from a 2017 baseline of 67.3%.

**Indicator 6e** Increase viral suppression among Black women diagnosed with HIV to 95% from a 2017 baseline of 59.3%.

**Indicator 6f** Increase viral suppression among transgender women in HIV medical care to 95% from a 2017 baseline of 80.5%.

**Indicator 6g** Increase viral suppression among people who inject drugs diagnosed with HIV to 95% from a 2017 baseline of 54.9%.

**Indicator 6h** Increase viral suppression among youth aged 13–24 diagnosed with HIV to 95% from a 2017 baseline of 57.1%.



## GOAL 4: ACHIEVE INTEGRATED, COORDINATED EFFORTS THAT ADDRESS THE HIV EPIDEMIC AMONG ALL PARTNERS AND INTERESTED PARTIES

### THE OPPORTUNITY

Since the NHAS was first published in 2010, it has inspired all sectors of society—including government agencies, nongovernmental organizations, and the private sector—to better coordinate the nation’s response to the HIV epidemic. This iteration of the Strategy continues to recognize the importance of more integrated, coordinated efforts.

Even greater coordination is possible and essential to ending the HIV epidemic in America. Opportunities include partnerships to meet unmet needs, maximize reach, share best practices to overcoming common challenges, leverage available data, use new and evolving technologies, and promote efficiency and sustainability. Greater integration of services is crucial to meeting the nation’s HIV testing, prevention, care, treatment, and supportive service needs, especially for people living in under-resourced areas and/or who are not effectively reached and engaged by existing programs and services.

It is also essential to address the syndemic of HIV, STIs, viral hepatitis, and alcohol and substance use and mental health disorders. Collaborative efforts cannot be a one-way street, only benefiting the goals of HIV programs; rather, they should address how HIV programs can facilitate the attainment of other programs’ goals that contribute to the overall health and well-being of the populations served.

Activities that exemplify improved integration and coordination of efforts include the following:

- **CDC and HRSA’s joint guidance to health departments and planning groups about single, multi-year Integrated HIV Prevention and Care Plans.** In June 2021, CDC and HRSA issued Integrated Plan Guidance for CY 2022–2026, which intends to accelerate progress toward meeting national goals while allowing each jurisdiction to design an HIV services delivery system that reflects local vision, values, and needs. This guidance built on the first such guidance issued in 2015;<sup>142</sup> reduced duplicative planning and reporting for grantees; streamlined the work of health department staff and HIV planning groups; and promoted improved collaboration and coordination in the use of data to inform HIV prevention and care program planning, resource allocation, evaluation, and continuous quality improvement.
- **Integration of CDC funding for health department HIV surveillance and prevention.** In 2018, CDC renewed and strengthened its flagship funding program to support HIV surveillance and prevention efforts led by state, territorial, and local health departments with 5-year funding awards that integrated HIV surveillance and prevention programs for the first time. Integration helps health departments plan and execute more efficient, coordinated, and data-driven prevention efforts.
- **Pilot programs that have demonstrated the effectiveness of collaborative data-to-care (D2C) approaches.** Using HIV surveillance and other data to improve continuity of HIV care, these CDC-supported pilot programs integrated data from public health and health care delivery to identify people with an HIV diagnosis who were not engaged in medical care and facilitated linkage to care. The pilots demonstrated effectiveness in achieving their goal of increasing the number of people with HIV who are reengaged in care and virally suppressed.<sup>143</sup>
- **Integration of data across programs to improve design and delivery of services.** HRSA and the Department of Housing and Urban Development collaborated to better coordinate HIV care and housing services for people with HIV through data integration and to ultimately improve health outcomes along the HIV care continuum.<sup>144</sup>



- **HRSA, NIH, and CDC Implementation Science**

**Workgroup.** In 2018 the HRSA HIV/AIDS Bureau began a close collaboration with the CDC Division of HIV/AIDS Prevention and the National Institutes of Health's National Institute of Mental Health to create a platform for dialogue across federal agencies working to apply implementation science in HIV, establishing the Federal Implementation Science Workgroup. The resulting funding opportunity announcements seek to strengthen research/service delivery collaborations between NIH investigators and implementers such as sites funded by CDC, HRSA, the Indian Health Service (IHS), the Substance Abuse and Mental Health Services Administration (SAMHSA), and other providers of HIV prevention and care services. Applicants develop creative, locally defined, and culturally sensitive concepts that align with the EHE jurisdictional plans.<sup>145</sup>

- **A growing awareness of the need to better integrate services for populations vulnerable to multiple health concerns.**

For example, a 2019 National Academies of Sciences, Engineering, and Medicine workshop highlighted the importance of addressing infectious diseases as part of an improved, comprehensive opioid response and noted that separately administered substance use disorder treatment and infectious disease services often inhibit comprehensive care.<sup>146</sup> In addition, in 2020 SAMHSA published [Prevention and Treatment of HIV Among People Living with Substance Use and/or Mental Disorders](#), a guide that addresses the co-occurrence of HIV and mental illness and/or substance use disorders and reviews effective programs and practices to prevent HIV and, for people with HIV, to increase linkage and retention in care in order to improve health outcomes.

- **Use of new HIV surveillance techniques.** CDC has supported several jurisdictions to detect possible HIV infection clusters more quickly and then coordinate swift responses across programs to deliver needed prevention and treatment services to people who need them. As work continues to expand the ability to identify and quickly respond to new HIV infections, health departments and communities must work together to collectively address the consent, privacy, and data use concerns.

- **Provisions in the 21st Century Cures Act on the interoperability of health information.** These provisions, including those related to social determinants of health, put the patient at the center of care and promote secure health information exchange to enable improved coordination, targeting of resources, and research that can support achieving the Strategy's goals. In March 2020, the Office of the National Coordinator for Health IT (ONC) issued a final rule to implement key interoperability provisions of the 21st Century Cures Act, including promoting patient access to their electronic health information, supporting provider needs, advancing innovation, and addressing industry-wide information blocking practices.<sup>147</sup>



#### **GOAL 4: ACHIEVE INTEGRATED, COORDINATED EFFORTS THAT ADDRESS THE HIV EPIDEMIC AMONG ALL PARTNERS AND INTERESTED PARTIES**

##### **Objectives**

4.1 Integrate programs to address the syndemic of HIV, STIs, viral hepatitis, and substance use and mental health disorders in the context of social and structural/institutional factors including stigma, discrimination, and violence

4.2 Increase coordination among and sharing of best practices from HIV programs across all levels of government (federal, state, tribal, local, and territorial) and with public and private health care payers, faith-based and community-based organizations, the private sector, academic partners, and the community

4.3 Enhance the quality, accessibility, sharing, and uses of data, including HIV prevention and care continua data and social determinants of health data

4.4 Foster private-public-community partnerships to identify and scale up best practices and accelerate HIV advances

4.5 Improve mechanisms to measure, monitor, evaluate, and use the information to report progress and course correct as needed in order to achieve the Strategy's goals

- **Partnerships with Medicaid programs.** Through these partnerships, several state HIV programs have been able to implement performance measures that reward providers who have increased the numbers of patients who have achieved and maintained viral suppression.
- **Enhanced efforts to integrate services and disciplines in health care delivery.** In recent years, greater emphasis has been placed on integrating behavioral health (mental health and substance use disorder) services and primary care and vice versa. Expanding availability of medications for treatment for substance use disorders in primary care settings is one example. Similarly, to serve the growing population of people with HIV over age 50, more clinics are adopting a geriatric multidisciplinary approach to health care, addressing the domains of medical problems, cognitive and functional abilities, psychiatric disorders, and social circumstances.<sup>148</sup>
- **Updating the United States Core Data for Interoperability (USCDI) as a Foundation for Interoperability.** In July 2021, ONC released version 2 of the USCDI. The update expands the standardized set of health data classes and elements for nationwide, interoperable health information exchange. The new data elements support efforts to advance health equity by addressing sexual orientation, gender identity, and social determinants of health.<sup>149</sup>

## THE CHALLENGES

The following challenges hinder efforts to achieve more integrated and coordinated efforts that address the HIV epidemic among all partners and interested parties:

- Rising rates of substance use have resulted in concurrent infectious diseases epidemics.
- Coordination at the federal, state, and local levels has not expanded to include other necessary government, community-based, and civic partners.
- Data sharing and integration is not timely across programs.
- Local HIV plans are not adequately supported.
- The COVID-19 pandemic continues to divert resources.
- Legislation, budget allocations, and payment systems are not aligned with models of integrated care.

## SUMMARY OF OBJECTIVES

The following objectives are critical to achieving integrated, coordinated efforts that address the HIV epidemic among all partners and interested parties:

- 4.1 Integrate programs to address the syndemic of HIV, STIs, viral hepatitis, and substance use and mental health disorders in the context of social and structural/institutional factors including stigma, discrimination, and violence.
- 4.2 Increase coordination among and sharing of best practices from HIV programs across all levels of government (federal, state, tribal, local, and territorial) and with public and private health care payers, faith-based and community-based organizations, the private sector, academic partners, and the community.
- 4.3 Enhance the quality, accessibility, sharing, and use of data, including HIV prevention and care continuum data and social determinants of health data.
- 4.4 Foster private-public-community partnerships to identify and scale up best practices and accelerate HIV advances.
- 4.5 Improve mechanisms to measure, monitor, evaluate, and use the information to report progress and course correct as needed in order to achieve the Strategy's goals.



## OBJECTIVES AND STRATEGIES

### Objective 4.1 Integrate programs to address the syndemic of HIV, STIs, viral hepatitis, and substance use and mental health disorders in the context of social and structural/institutional factors including stigma, discrimination, and violence

The syndemic of HIV, STIs, viral hepatitis, substance use and mental health disorders in the United States highlights overlapping risk factors as well as associations with social determinants of health such as poverty, lack of health insurance, housing instability, and other related inequities. An effective response to the syndemic requires integration of programs to enable increased flexibility in utilization of allocated resources; better coordinated policy and program planning, development, and delivery; and rapid adjustment to new data or scientific advances. For such integration to occur, major shifts in policy, systems, and societal norms and attitudes must occur, and the willingness to explore new and nontraditional approaches and strategies must increase.

A National Academies report recommends that the syndemic be addressed via integrated medical services in place of often siloed services.<sup>146</sup> Opportunities are missed every day to test people for multiple infections and to scale up HIV services in settings where people who experience risk receive other services. For example, in 2019 among health care settings and non-health-care settings, only 34% of CDC-funded HIV tests had at least one STI or hepatitis C test conducted concurrently.<sup>150</sup> These missed opportunities translate directly into lost time and resources and may result in harm to people who remain undiagnosed, untreated, and at risk of severe outcomes or of transmitting the infection to others. A reciprocal, integrated approach in responses to infectious diseases, the opioid crisis, and substance use and mental health disorders that puts patients first through a status-neutral and no-wrong-door approach will maximize their ability to access services that meet their health needs. In addition, creating a system that focuses on a whole-health approach and one that considers a myriad of needs can lead to enhanced life experiences for people living with HIV. For example, HIV testing programs can identify opportunities to screen for other STIs, viral hepatitis, substance use, and intimate partner violence. Similarly, STI, substance use disorder treatment, and viral hepatitis programs can integrate HIV testing and linkage to relevant HIV prevention or care services, as appropriate.

#### Strategies

- 4.1.1 Integrate HIV awareness and services into outreach and services for issues that intersect with HIV such as intimate partner violence, homelessness or housing instability, STIs, viral hepatitis, and substance use and mental health disorders.
- 4.1.2 Implement a no-wrong-door approach to screening and linkage to services for HIV, STIs, viral hepatitis, and substance use and mental health disorders across programs.
- 4.1.3 Identify and address funding, policy, data, workforce capacity, and programmatic barriers to effectively address the syndemic.
- 4.1.4 Coordinate and align strategic planning efforts on HIV, STIs, viral hepatitis, substance use disorders, and mental health care across national, state, tribal, territorial, and local partners.
- 4.1.5 Enhance the ability of the HIV workforce to provide naloxone and educate people on the existence of fentanyl in the drug supply to prevent overdose and deaths and facilitate linkage to substance use disorder treatment and harm reduction programs.

### Objective 4.2 Increase coordination among and sharing of best practices from HIV programs across all levels of government (federal, state, tribal, local, and territorial) and with public and private health care payers, faith-based and community-based organizations, the private sector, academic partners, and the community

Ending the HIV epidemic requires a whole-of-society approach. Increasing coordination across all sectors of society enables better delivery of services and resources to people with or who experience risk for HIV. Likewise,

establishing trusted partnerships enables coalitions to develop, implement, and regularly evaluate and update policies and programs that address the social, economic, and political environments that shape and constrain individual, community, and societal outcomes.

Increased coordination at the federal level includes expanding the partners engaged in the nation's HIV response. This effort includes leveraging existing programs whose primary purpose may not be HIV services, but that could provide supportive services such as employment training or nutrition assistance to people with or who experience risk for HIV. Such coordination helps to ensure that resources are allocated according to current burden of disease and that the most effective prevention and care strategies are tailored to local community needs to achieve maximal results.

Better coordination involves fostering strong linkages among community-based organizations, health departments, other public programs and services, education agencies, pharmacies, health care providers and systems, and community leaders. Collaboration with community partners is particularly important to developing locally relevant plans for providing testing, prevention, care, treatment, and supportive services, including those that engage people not yet reached by existing programs and services. Collaboration also involves engaging and building capacity and competencies among partners and communities that are interested in providing HIV services but may not have had the opportunity or resources to do so. Expanded and strengthened partnerships can better equip communities to respond swiftly and effectively to identified outbreaks of HIV, STIs, and/or viral hepatitis. Greater involvement by our nation's technology and other business communities can boost efforts to provide accurate information, reach key populations, and develop innovative tools.

Attention must also be focused on service delivery and payment methods. Fee-for-service and other payment models do not adequately support integrated, comprehensive health care delivery models, such as behavioral health and medical care integration, patient-centered medical homes, services provided by pharmacists in nontraditional roles, integration with support services, oral health care, and care coordination. Grant funding to support pilots or demonstrations of such integrated models is limited and time-bound. Scaling up and sustaining these effective care delivery models require evolutions in public and private payer systems.

### Strategies

- 4.2.1 Focus resources including evidence-based and evidence-informed interventions in the geographic areas and priority populations disproportionately affected by HIV.
- 4.2.2 Enhance collaboration among local, state, tribal, territorial, national, and federal partners and the community to address policy and structural barriers that contribute to persistent HIV-related disparities and implement policies that foster improved health outcomes.
- 4.2.3 Coordinate across partners to quickly detect and respond to HIV outbreaks.
- 4.2.4 Support collaborations between community-based organizations, public health organizations, education agencies and schools, housing providers, and health care delivery systems to provide linkage to and delivery of HIV testing, prevention, care, and treatment services as well as supportive services.

### Objective 4.3 Enhance the quality, accessibility, sharing, and uses of data, including HIV prevention and care continua data and social determinants of health data

High-quality data are essential to increasing coordination, integration, and seamless delivery of services that are required to end the HIV epidemic. The appropriate collection and use of data can inform efforts to focus prevention and testing services on populations that need them most, can help ensure that people newly diagnosed with HIV are promptly linked to care, and can facilitate retention in effective HIV care. However, jurisdictions need resources, guidance, and support to strengthen HIV surveillance systems and activities, in accordance with applicable law, to

obtain the data needed to improve our response to the HIV epidemic, including viral load reporting and disparities data to ensure that populations or communities are not being left behind.

Appropriate use of secure electronic health information exchange can help to engage and retain or reengage people in care and to facilitate transitions across care and community settings. Further, sharing of treatment and outcome data can drive the science needed to develop new and better treatments, approaches to retention in care, and prevention interventions. Better use of data on social determinants of health can optimize prevention and testing efforts for groups experiencing greater risk of acquiring HIV, engage and retain people with HIV in care, support adherence to treatment, and inform ongoing research efforts to develop better treatment and prevention. Use of modeling and other analytical approaches may yield novel insights and inform planning.

### **Strategies**

- 4.3.1 Promote the collection, electronic sharing, and use of HIV risk, prevention, and care and treatment data using interoperable data standards, including data from electronic health records, in accordance with applicable law.
- 4.3.2 Use interoperable health information technology, including application programming interfaces (APIs), clinical decision support tools, electronic health records and health IT products certified by the Office of the National Coordinator's Health IT Certification Program, and health information exchange networks to improve HIV prevention efforts and care outcomes.
- 4.3.3 Encourage and support patient access to and use of their individual health information, including use of their patient-generated health information and use of consumer health technologies in a secure and privacy-supportive manner.

### **Objective 4.4 Foster private-public-community partnerships to identify and scale up best practices and accelerate HIV advances**

Effective private-public-community partnerships are necessary to enhance responses to critical implementation challenges. Partnerships should ensure local relevance and emphasize the leadership role of community members, academic investigators, public health departments and other collaborators through intentional involvement in all stages of research, from conceptualization of the research question to dissemination of results.

There is growing interest in developing closer partnerships among the private sector to increase the appropriate application of evidence in policy and practice. Private-sector resources and approaches that integrate multidisciplinary HIV prevention and treatment service delivery in different settings can reach communities in ways that government cannot. Emphasis on cross-disciplinary collaboration and input by allied health and community service providers as partners with the private sector in HIV research, prevention, and care will optimize program acceptability, uptake, and rollout; improve outcomes; and maximize the impact of translation of research results.

The response to the HIV epidemic has generated significant scientific advances and best practices. Implementation science provides a framework to identify factors that facilitate application of relevant and effective public health interventions and services. Community-centric implementation research is one important approach to rapidly and effectively translate new discoveries into practice at the local level, with fidelity. Effective partnerships can achieve an impact at the population level, to efficiently disseminate evidence-based interventions at scale through culturally appropriate public health initiatives and clinical practice (see Box 9).

There is a need to develop more opportunities and mechanisms for timely information sharing and peer technical assistance to support replication of best practices and use of lessons learned to address common barriers within and across jurisdictions. Activities supporting replication and scale-up of proven interventions should address infrastructure needs and include intentional sustainability planning to ensure continuity of care and services across all participating service settings.



## Strategies

- 4.4.1 Adopt approaches that incentivize the scale up of effective interventions among academic centers, health departments, community-based organizations, allied health professionals, people with HIV and their advocates, the private sector, and other partners.
- 4.4.2 Expand opportunities and mechanisms for information sharing and peer technical assistance within and across jurisdictions to move effective interventions into practice more swiftly.
- 4.4.3 Develop and optimize collaborative multi-agency and multi-sectoral approaches and strategies to address emergent and evolving challenges facing people of all ages living with HIV.



### BOX 9

## LEVERAGING TECHNOLOGY INNOVATIONS TO IMPROVE HIV PREVENTION AND TREATMENT

Technological innovations have rapidly altered many aspects of life in the past decade. Many Americans have transformed their digital toolbox to include systems such as Zoom or FaceTime, email, and other applications to stay informed on their health and connected to health care systems. These innovations prove the potential to leverage technology in the HIV response.

Telehealth has proven to be a reliable resource for reaching populations experiencing risk or who are living with HIV and can address many of the factors identified as barriers to retention in HIV care. Telehealth can also broaden access to pre-exposure prophylaxis (PrEP), HIV care and treatment, and mental health and substance use treatment in rural areas, which often face workforce shortages and transportation challenges.<sup>154</sup> Refining and sustaining telehealth services that were implemented in response to the COVID-19 pandemic will allow organizations to use these technological advances to improve the HIV response.

Expanded use of the internet and social media can help people involved in HIV prevention and treatment use mobile devices, websites, and applications as hubs for HIV information and collaboration to ensure that scientifically and medically accurate information is prioritized, and misinformation is combated. At the same time, these websites and applications can also make accessing information on HIV prevention, testing, and treatment more accessible and discrete. Wearable technology such as smartwatches can use health applications to provide real-time insights on an individual's health status and empower people to personalize and monitor their own health data. Electronic health records strengthen the HIV care continuum by providing accurate and timely information. Electronic health records can also use clinical decision support tools to help improve screening by identifying patients for whom an HIV test or PrEP might be recommended or facilitating reengagement in HIV care for those who may have left but present for other health care services elsewhere. Further advancements in the use of technology to improve HIV care could also be used to streamline patient pathways including enhanced remote patient monitoring techniques and other engagement opportunities made available through emerging fields such as digital therapeutics and at-home testing. Policymakers, clinicians, and private-sector partners must collaborate to uncover solutions and further innovation to leverage technology in the HIV response and improve patient engagement.

### Objective 4.5 Improve mechanisms to measure, monitor, evaluate, and use the information to report progress and course correct as needed in order to achieve the Strategy's goals

There is a continued need to streamline and harmonize data reporting to reduce reporting burden and produce more regular, timely, and useful data. Support is also needed to adopt new analytic methods and approaches to

increase the timeliness of data, enhance the ability to characterize the burden of HIV across the nation, and use that information to allocate resources to achieve the greatest impact. In addition, complementary data sources such as health care payer databases, surveys, and linkages to electronic health records are necessary to ensure that robust information that can guide decision-making.

Timely data will improve accountability among federally funded organizations as they set and make progress toward measurable goals and targets aligned with this Strategy. Data for the indicators at the local, state, and national levels should be regularly and publicly reported and reviewed to identify successful efforts, indicate challenges, and facilitate ongoing dialogue about ways to continue moving forward. Such reporting and review require a monitoring plan that evaluates the implementation of the Strategy. A system of regular public reporting will help to sustain public attention and support at the national level. Organizations that struggle to engage new parties and organizations or fall short of expected outcomes should receive intensive capacity-building assistance and other supportive measures as a condition of continued funding. The nation can thus direct its funds to entities and initiatives that demonstrate the highest level of performance and accountability for high-impact HIV prevention.

### **Strategies**

- 4.5.1 Streamline and harmonize reporting and data systems to reduce burden and improve the timeliness, availability, and usefulness of data.
- 4.5.2 Monitor, review, evaluate, and regularly communicate progress on the National HIV/AIDS Strategy.
- 4.5.3 Ensure that the National HIV/AIDS Strategy's goals and priorities are included in cross-sector federal funding requirements.
- 4.5.4 Strengthen monitoring and accountability for adherence to requirements, targets, and goals by funded partners.
- 4.5.5 Identify and address barriers and challenges that hinder achievement of goals by funded partners and other interested parties.

# IMPLEMENTATION AND ACCOUNTABILITY

## FEDERAL PARTNERS

The Strategy provides a framework for ending the HIV epidemic in the United States. Development of the Strategy was a collaborative process led by the White House that engaged federal partners across multiple departments and agencies with input from a diverse range of interested parties and organizations from across the nation.

Federal partners will collaborate to develop an implementation plan to pursue the Strategy goals, objectives, and strategies. The NHAS Federal Implementation Plan will set forth federal partners' commitments to policies, initiatives, and activities to meet the goals of the Strategy and will be published for transparency and accountability.

As part of their ongoing commitment to reduce HIV in this nation, federal partners have committed to serve on a Strategy implementation working group. This working group will collaborate to address HIV in an integrated fashion by including other infectious diseases as components of the syndemic. The working group will meet regularly to coordinate activities across agencies and departments, apply lessons learned from epidemiological data and research findings, monitor progress toward the indicator targets, course correct as needed, and report on national progress. As scientific, medical, and public health advances and challenges emerge, new and innovative policies will be developed to complement the existing Strategy.

## NONFEDERAL PARTNERS

Addressing HIV is not solely a federal activity. Success depends on coordinated action by state, tribal, territorial, and local governments; community-based organizations and faith-based organizations; health plans and payers, health care providers, and other health-related organizations; private-sector partners; the criminal justice system; universities, schools, education agencies, and other venues for educational activities; researchers; families; and patients and their partners. Its success also depends on a holistic approach to the various parts of the syndemic, including STIs, viral hepatitis, substance use and mental health disorders, stigma and discrimination, and social and structural determinants of health.

Each community and stakeholder brings a unique perspective and plays a critical role in preventing and responding to HIV. Over the past several years many states and localities have engaged in community-wide efforts to develop their own plans to end the HIV epidemic. Interested parties and organizations are encouraged to use this Strategy to engage with others and build or update their own roadmap to reduce HIV and end the HIV epidemic among the populations and communities they serve. Interested parties and organizations should consider adopting the vision and goals of this Strategy; pursuing the objectives and implementing the strategies relevant to their role(s), populations served, and community circumstances; and identifying opportunities to adopt and use the Strategy's indicators and targets to measure their own progress. In doing so, communities and interested parties and organizations can also apply other evidence-based strategies that are appropriate for responding to HIV in their area and use all available data to identify where their resources and effort will have the most impact. A data-driven strategy will help interested parties and organizations focus efforts and efficiently and effectively use available resources. Integrating HIV testing, prevention, care, and treatment efforts with other components of the syndemic is also strongly encouraged.



# APPENDIX A: PROCESS FOR DEVELOPING THE STRATEGY

On June 5, 2021, the Biden-Harris administration re-established the Office of National AIDS Policy (ONAP) within the White House. After discussions with staff of the White House Domestic Policy Council, it was agreed that the HIV National Strategic Plan (HIV Plan) released in January 2021 provided a strong foundation for ending the HIV epidemic but required updates to reflect Administration priorities, the latest data and research, and community feedback specific to the HIV Plan.

ONAP consulted with the federal department and agency representatives who served on the interagency Steering Committee that developed the HIV Plan (see Table A.1) to obtain recommendations to fulfill this mandate. In addition, ONAP received feedback from a variety of parties from the HIV community that could strengthen the Strategy to end the HIV epidemic by 2030. ONAP reviewed, considered, and integrated much from these various inputs into this Strategy, with support from the White House Office of National Drug Control Policy and the Office of Infectious Disease and HIV/AIDS Policy (OIDP), within the Office of the Assistant Secretary for Health at the Department of Health and Human Services (HHS). Drafts were refined through successive rounds of review by the Steering Committee, Domestic Policy Council, inter-departmental clearance, and the White House.

**Table A.1.** Composition of NHAS Federal Steering Committee

Federal Departments and Agencies	HHS Agencies/Offices	
<ul style="list-style-type: none"> <li>• Department of Agriculture</li> <li>• Department of Defense</li> <li>• Department of Education</li> <li>• Department of Justice</li> <li>• Equal Employment Opportunity Commission</li> <li>• Department of Health and Human Services</li> <li>• Department of Housing and Urban Development</li> <li>• Department of Labor</li> <li>• Department of Veterans Affairs</li> </ul>	<ul style="list-style-type: none"> <li>• Administration for Community Living</li> <li>• Agency for Healthcare Research and Quality</li> <li>• Centers for Disease Control and Prevention</li> <li>• Centers for Medicare &amp; Medicaid Services</li> <li>• Food and Drug Administration</li> <li>• Health Resources and Services Administration</li> <li>• Indian Health Service</li> </ul>	<ul style="list-style-type: none"> <li>• National Institutes of Health</li> <li>• Office for Civil Rights</li> <li>• Office of the Assistant Secretary for Health</li> <li>• Office of the National Coordinator for Health Information Technology</li> <li>• Substance Abuse and Mental Health Services Administration</li> </ul>

## IDENTIFICATION OF PRIORITY POPULATIONS BASED ON NATIONAL-LEVEL DATA

ONAP maintained in this Strategy the priority populations designated in the HIV National Strategic Plan. Priority populations are disproportionately affected populations, which are defined as groups of people with a higher burden of disease than others. HIV testing, prevention, care, and treatment interventions and resources can be delivered to priority populations for the greatest impact. An Indicators Subcommittee of the Steering Committee that developed



the HIV National Strategic Plan reviewed national HIV surveillance data available in 2020 to identify priority populations. In developing this Strategy, ONAP reviewed the most recent data and determined that it continued to support the designation of the identified priority populations.

**Table A.2.** Priority Populations and Summary National-Level Data, Calendar Year 2019 (unless otherwise indicated)

### Gay, Bisexual, and Other Men Who Have Sex with Men (MSM)

- Gay, bisexual, and other men who have sex with men are the population most affected by HIV in the United States. At the end of 2019, an estimated 1,189,700 people had HIV in the United States. Of those, 692,900 (58%) were gay and bisexual men.<sup>11</sup>
- In 2019, adult and adolescent gay and bisexual men represented 66% (23,100) of the 34,800 new HIV infections in the United States.<sup>11</sup>
- The incidence of many STIs in gay, bisexual, and other men who have sex with men—including primary and secondary syphilis and antimicrobial-resistant gonorrhea—is greater than that reported in women and men who have sex with women only.<sup>152</sup> Having another STI can greatly increase the chance of getting or transmitting HIV. Of new HIV infections among men who have sex with men, 10% are estimated to be attributable to gonorrhea and chlamydia, equating to 2,600 HIV infections each year.<sup>51</sup>

### Black MSM

- Black gay, bisexual, and other men who have sex with men are more affected by HIV than any other group in the United States.
- In 2019, Black gay and bisexual men accounted for 26% (8,900) of the 34,800 new HIV infections and 39% of the 23,100 new infections among all gay and bisexual men in the United States.<sup>11</sup>
- Of the 36,337 new HIV diagnoses among adolescents and adults ≥13 years in the United States and dependent areas in 2019, 25% were among Black gay and bisexual men.<sup>3</sup>
- From 2015 to 2019, HIV infections remained stable among Black gay and bisexual men overall. By age group, the annual number of new HIV infections declined in Black gay and bisexual men aged 13–24, while the number of new infections remained stable among all other age groups of Black gay and bisexual men.<sup>11</sup> In 2019 the largest percentage of new HIV infections among Black/African American gay and bisexual men was among those aged 25–34 years (46%), followed by those aged 13–24 years (33%).<sup>11</sup>
- Along the HIV care continuum, compared to all people with diagnosed HIV in 41 states and the District of Columbia, Black gay and bisexual men have lower viral suppression rates.<sup>7</sup> (See Figure A.1.)

### Latino MSM

- Latino gay, bisexual, and other men who have sex with men are heavily affected by HIV. In 2019, adult and adolescent Latino gay and bisexual men comprised 23% (7,900) of the 34,800 new HIV infections in the United States and 34% of 23,100 new HIV infections among all gay and bisexual men in the United States.<sup>11</sup>
- Of the 36,337 new HIV diagnoses among adolescents and adults ≥13 years in the United States and dependent areas in 2019, 22% were among Latino gay and bisexual men.<sup>3</sup>
- From 2015 to 2019, the annual number of new HIV infections declined in Hispanic/Latino gay and bisexual men aged 13–24, while the number of new infections remained stable among all other age groups of Hispanic/Latino gay and bisexual men.<sup>11</sup> In 2019 the largest percentage of HIV infections among Hispanic/Latino gay and bisexual men was among those aged 25–34 years (44%), followed by those aged 13–24 years (23%).<sup>11</sup>

### American Indian/Alaska Native MSM

- American Indian/Alaska Native men who have sex with men are disproportionately affected by HIV. In 2019, 62% (126/209) of diagnoses among adolescents and adults ≥13 years occurring among American Indian/Alaska Native people were among men who have sex with men.<sup>3</sup>
- HIV diagnoses among American Indian/Alaska Native gay and bisexual men increased 15% between 2015–2019, while diagnoses among gay and bisexual men of other races/ethnicities were either stable or declined.<sup>125</sup>

### Black Women

- Although data show a 22% decrease in new HIV infections among Black women between 2010 and 2019, among all women in the United States, Black women account for the largest share of 6,400 new HIV infections (3,400 or 53%) in 2019.<sup>4, 11</sup>
- The rate of new HIV infections among Black women (18.9 per 100,000) is nearly 11 times as high as the rate among White women (1.8 per 100,000) and nearly 4 times as high as the rate among Latinas (4.9 per 100,000).<sup>11</sup>

### Transgender Women

- A 2019 systematic review and meta-analysis found that an estimated 14% of transgender women have HIV.<sup>14</sup>
- By race/ethnicity, an estimated 44% of Black transgender women, 26% of Latina transgender women, and 7% of White transgender women have HIV.<sup>2, 3, 153</sup>
- Among the 3 million HIV testing events reported to CDC in 2017, the percentage of transgender people who received a new HIV diagnosis was three times the national average.<sup>154</sup>

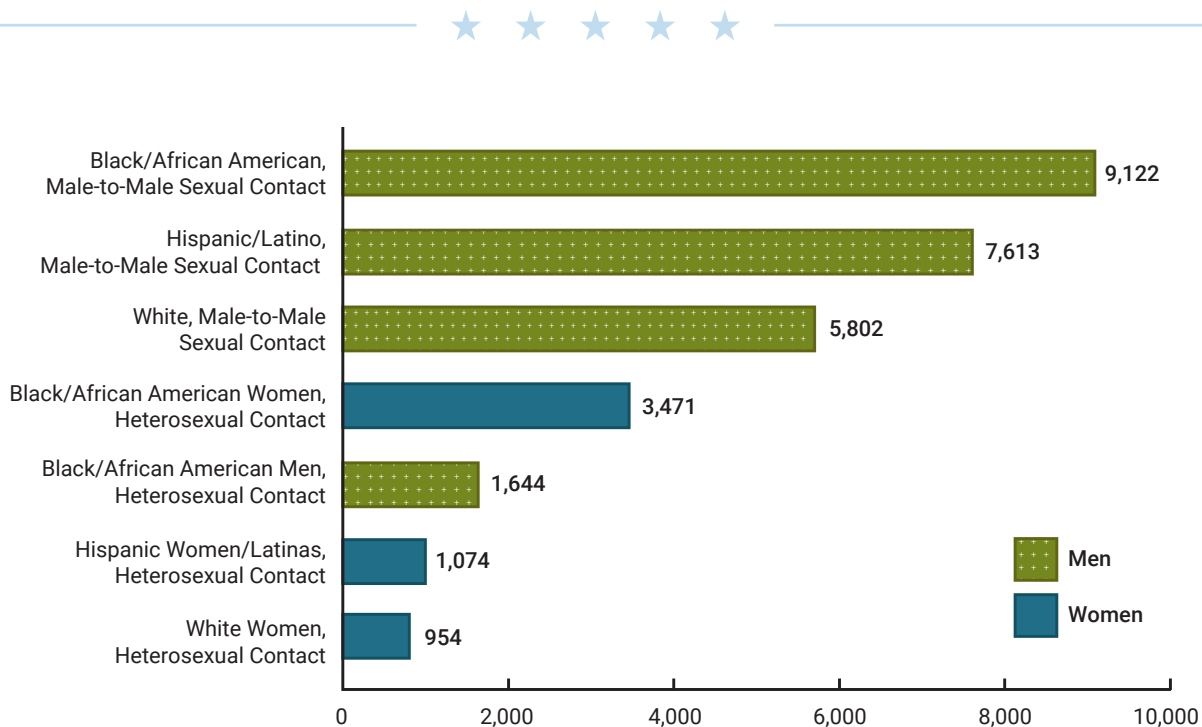
### Youth Aged 13–24 Years

- In 2019, youth aged 13–24 years accounted for 21% (7,200) of the 34,800 new HIV infections in the United States and dependent areas. Most new HIV diagnoses among youth were among young gay and bisexual men.
- Only 9% of high school students have been tested for HIV and therefore do not know their HIV status. Among male students who had sexual contact with other males, only 15% have ever been tested for HIV.<sup>155</sup>
- In 2019, youth with diagnosed HIV were also the least likely of any age group to be linked to care within 1 month of diagnosis (79%).<sup>2</sup> Further, compared to all people with HIV, youth have the lowest rates of viral suppression. For every 100 youth with HIV, 45 received some HIV care, 33 were retained in care, and 35 were virally suppressed.<sup>2</sup>
- People aged 15–24 years account for approximately 50% of the 20 million new STIs in the United States each year, yet approximately 25% of the sexually active population.<sup>152</sup> Having another STI can greatly increase the chance of getting or transmitting HIV.

## People Who Inject Drugs (PWID)

- People who inject drugs are at high risk for getting HIV and/or HCV if they use and share needles, syringes, or other drug injection equipment that someone with HIV has used.
- New HIV infections among people who inject drugs have increased 8.7% in recent years (from 2,300 infections in 2015 to 2,500 infections in 2019) in the United States and dependent areas.<sup>11</sup>
- Although HIV incidence among people who inject drugs has declined substantially over many years, the ongoing use of opioids and other frequently injected substances including cocaine and methamphetamine are threatening this HIV prevention success. HIV diagnoses among people who inject drugs increased by 11% nationally from 2016 to 2018, with more pronounced increases among adults younger than age 40 and non-Hispanic White adults.<sup>125</sup> Injection drug use has contributed to multiple recent clusters and outbreaks of new HIV infections among people who inject drugs.<sup>156</sup>
- Among people with HIV who inject drugs, 62–81% were also living with hepatitis C.<sup>157</sup> People with HIV also living with hepatitis B or hepatitis C have higher liver-related morbidity and mortality, and higher overall mortality than patients only living with hepatitis B or hepatitis C.<sup>158-160</sup>

Figure A.1 depicts the subpopulations (defined by race, ethnicity, and gender) with the most new HIV diagnoses in 2019.



**Figure A.1.** New HIV diagnoses in the United States and dependent areas for the most-affected subpopulations, 2019

Notes: Black refers to people having origins in any of the Black racial groups of Africa. African American is a term often used for Americans of African descent with ancestry in North America. Hispanics/Latinos can be of any race. Subpopulations representing 2.0% or less of all people who received an HIV diagnosis in 2018 are not represented in this chart. Source: Centers for Disease Control and Prevention.<sup>161</sup>

The Strategy recognizes the importance of providing HIV services to all populations with or who experience risk for HIV. Therefore, even though they were not designated as priority populations, the Strategy discusses the importance of addressing the unique needs of other groups, such as long-term survivors and older people with HIV or people experiencing unstable housing or homelessness.

## INDICATORS TO MEASURE PROGRESS FOR THE NATIONAL HIV/AIDS STRATEGY

The Strategy includes 9 core indicators to monitor annual progress toward achieving Goals 1, 2, and 3. In addition, one of the core indicators is stratified by each of the priority populations to measure progress toward reducing disparities.

For each indicator, baseline measurements (2017) and targets for 2025 are provided. Indicators 1–6 are aligned with the EHE initiative and *Healthy People 2030* objectives. Alignment of the indicators between the HIV Plan and EHE allows for consistency and reduced burden on local and state health departments that report data as well as on federal partners who monitor and report on progress in measuring and reporting results across the indicators.

The methods for measuring progress and specifications for each of the indicators is detailed below.

### METHODS

CDC's National Center for Health Statistics describes the “percent of targeted change achieved,” which quantifies progress for *Healthy People 2020* indicators that are moving toward their targets. The methods are described in full by Talih and Huang<sup>162</sup> and may be used for measuring progress in *Healthy People 2030*. To align methods for measuring progress across HHS, the percentage of targeted change achieved method is adapted for use to measure national progress annually for the National HIV/AIDS Strategy.

### METHODS

The “percent of targeted change achieved” used in *Healthy People 2020* is the difference between the baseline and the midcourse value as a percent of the targeted change between the baseline value and the *Healthy People 2020* target. To adapt for use in the National HIV/AIDS Strategy, annual results and National HIV/AIDS Strategy targets are used. This method also provides a way to compare percent of targeted change achieved by National HIV/AIDS Strategy indicator and highlights areas on which to focus. The formula is as follows:

$$\text{Percent of targeted change achieved} = \frac{\text{Annual result} - \text{Baseline result} \times 100}{2025 \text{ target} - \text{Baseline result}}$$

The magnitude of change for percent of targeted change achieved may be evaluated using statistical significance testing for indicators that are estimated.



An *example* using hypothetical data is provided below to illustrate the calculations for the percent of targeted change achieved for linkage to care within 1 month and viral suppression.

**Table A.3.** Hypothetical Data for Linkage to Care and Viral Suppression Calculations

Indicator	2017	2023	2025 Target
Linkage to Care within 1 Month	78.4%	82.3%	95%
Viral Suppression	54.4%	65.5%	95%

Percent of targeted change achieved for *linkage to care within 1 month*:

$$= \frac{82.3\% - 78.4\%}{95\% - 78.4\%} = \frac{3.9}{16.6} = 23.5\%$$

Achieving the 95% target for linkage to care within 1 month is 100% of the targeted change needed by 2025.

*Interpretation:* By 2023, almost one-quarter or 23.5% of the targeted change has occurred for linkage to care within 1 month.

Percent of targeted change achieved for *viral suppression*:

$$= \frac{65.5\% - 54.4\%}{95\% - 54.4\%} = \frac{11.1}{40.6} = 27.3\%$$

Achieving the 95% target for viral suppression is 100% of the targeted change needed by 2025. *Interpretation:* By 2023, a little more than one-quarter or 27.3% of the targeted change has occurred for viral suppression.

### Indicators that met or exceeded their targets

When the desired direction is increase, an indicator has met or exceeded the target if the annual result is greater than or equal to the 2025 target.

$$\text{Annual result} \geq \text{2025 target}$$

When the desired direction is a decrease, an indicator has met or exceeded the target if the annual result is less than or equal to the 2025 target or the 2030 target.

$$\text{Annual result} \leq \text{2025 target}$$

Statistical significance is not factored into the determination of the target met or exceeded status.

### Indicators moving toward their targets

For indicators that had not already met or exceeded their targets at baseline and are *moving toward* their 2025 targets, the percent of targeted change achieved measures the extent of movement toward the target. The formula is the same as that presented above and is calculated by:

$$\text{Percent of targeted change achieved} = \frac{\text{Annual result} - \text{Baseline result} \times 100}{2025 \text{ target} - \text{Baseline result}}$$

When the desired direction is an increase (i.e., increase to 95%), an indicator is *moving toward* its target when the most recent *annual result is higher than the baseline value but less than the 2025 target*.

#### Baseline result < Annual result < 2025 target

When the desired direction is a decrease (i.e., decrease by 75%), an indicator is *moving toward* its target when the most recent *annual result is less than the baseline value but greater than the 2025 target*.

#### Baseline result > Annual result > 2025 target

### Indicators moving away from their targets

For indicators that had not already met or exceeded their targets at baseline and are moving away from their 2025 targets, the percent of targeted change achieved measures the extent of movement away from the target and is calculated by:

$$\text{Magnitude of percent change from baseline} = \frac{|\text{Annual result} - \text{Baseline result}| \times 100}{\text{Baseline result}}$$

The absolute value of the percent change from baseline is used to measure movement in this instance. When indicator results are moving away from the 2025 targets, the indicator results will need to make up the deficit from the baseline (i.e., get back to baseline value). Additional work would be needed to see desired targeted change once the baseline value is regained.

## INDICATOR SPECIFICATIONS FOR THE NATIONAL HIV/AIDS STRATEGY

### Indicator 1: Increase knowledge of status

- Definition:
  - ◊ Numerator: Number of persons aged ≥13 years living with diagnosed HIV at end of a measurement year.
  - ◊ Denominator: Estimated number of persons aged ≥13 years living with diagnosed or undiagnosed HIV at the end of a measurement year.
- Baseline year: 2017
- Baseline result: 85.8%
- Target: By 2025, increase to 95%.
- Data source: National HIV Surveillance System (NHSS).<sup>11</sup> NHSS is the primary source for monitoring trends in HIV in the United States. It is the data source for incidence, diagnoses, and other HIV care continuum data.
- Data availability: Data are published annually.

**Indicator 2: Reduce new HIV infections**

- Definition: Incidence is the estimated number of new HIV infections among persons aged  $\geq 13$  years that occurred in the measurement year and includes diagnosed and undiagnosed infections.
- Baseline year: 2017
- Baseline result: 37,000
- Targets: By 2025, reduce incidence by 75% from baseline. By 2030, reduce incidence by 90% from baseline.
- Data source: National HIV Surveillance System (NHSS).<sup>11</sup> NHSS is the primary source for monitoring trends in HIV in the United States. It is the data source for incidence, diagnoses, and other HIV care continuum data.
- Data availability: Data are published annually.

**Indicator 3: Reduce new HIV diagnoses**

- Definition: Number of persons  $\geq 13$  years who have received laboratory or clinical confirmation of HIV in a measurement year.
- Baseline year: 2017
- Baseline result: 38,351
- Targets: By 2025, reduce diagnoses by 75% from baseline. By 2030, reduce diagnoses by 90% from baseline.
- Data source: National HIV Surveillance System (NHSS). NHSS is the primary source for monitoring trends in HIV in the United States. It is the data source for incidence, diagnoses, and other HIV care continuum data.<sup>3</sup>
- Data availability: Data are published annually. Preliminary data are also available quarterly.
- Notes: Provisional annual data (annual data with  $\geq 12$  months of reporting delay) will be used to measure progress.

**Indicator 4: Increase PrEP coverage**

- Definition:
  - ◊ Numerator: Number of persons  $\geq 16$  years who were classified as having been prescribed PrEP in a measurement year.
  - ◊ Denominator: Estimated number of persons with indications for PrEP in a measurement year.
- Baseline year: 2017
- Baseline result: 13.2%
- Target: By 2025, increase to 50%.
  - ◊ Numerator: IQVIA Real-World Longitudinal Prescriptions database
  - ◊ Denominator: Uses three data sources:
    1. The American Community Survey from U.S. Census is used to estimate the number of men who have sex with men (MSM) in a jurisdiction.<sup>163</sup>
    2. Behavioral data from the National Health and Nutrition Examination Survey (NHANES) are used to estimate the proportion of HIV-negative MSM with indications for PrEP.<sup>164</sup>
    3. The National HIV Surveillance System (NHSS) diagnoses data are used.<sup>2</sup> The number of HIV-negative MSM with indications for PrEP are multiplied by the ratio of percentage of HIV diagnoses during the specified year attributed to persons who inject drugs (PWID) and heterosexual transmission risk groups compared to the percentage among MSM. The estimated number of persons with indications

for PrEP in the three major transmission risk groups (MSM, heterosexuals, PWID) in each jurisdiction are then summed to yield national estimates.

- Data availability: Data are published annually. Preliminary data are also available quarterly.
- Note: Prescriptions for PrEP or having indications for PrEP are not reportable conditions and therefore are not reported through the National HIV Surveillance System. Annual data will be used to measure progress.

### Indicator 5: Increase linkage to care

- Definition:
  - ◊ Numerator: Number of persons aged  $\geq 13$  years with HIV diagnosed in a measurement year and who had  $\geq 1$  viral load (VL) or CD4 test  $\leq 1$  month after HIV diagnosis.
  - ◊ Denominator: Number of persons aged  $\geq 13$  years with HIV infection diagnosed during a measurement year.
- Baseline year: 2017
- Baseline result: 77.8%
- Target: By 2025, increase to 95%.
- Data source: National HIV Surveillance System (NHSS). NHSS is the primary source for monitoring trends in HIV in the United States. It is the data source for incidence, diagnoses, and other HIV care continuum data.<sup>2</sup>
- Data availability: Data are published annually. Preliminary data are also available quarterly.
- Notes: Data are reported for jurisdictions with complete laboratory reporting of CD4 and viral load test results to CDC. The number of jurisdictions may vary each year. Provisional annual data (annual data with  $\geq 12$  months of reporting delay) will be used to measure progress.

### Indicator 6: Increase viral suppression

- Definition:
  - ◊ Numerator: Number of persons aged  $\geq 13$  years living with diagnosed HIV and have a viral load test result  $< 200$  copies/mL at the most recent viral load test during a measurement year.
  - ◊ Denominator: Number of persons aged  $\geq 13$  years living with diagnosed HIV by the end of the year prior to the measurement year and alive at the end of the measurement year.
- Example: Denominator for 2019 viral suppression is the number of persons aged  $\geq 13$  years living with diagnosed HIV by the end of 2018 and alive at the end of 2019.
- Baseline year: 2017
- Baseline result: 63.1%
- Target: By 2025, increase to 95%.
- Data source: National HIV Surveillance System (NHSS). NHSS is the primary source for monitoring trends in HIV in the United States. It is the data source for incidence, diagnoses, and other HIV care continuum data.<sup>2</sup>
- Data availability: Data are published annually.
- Note: Data are reported for jurisdictions with complete laboratory reporting of CD4 and viral load test results to CDC and with complete death ascertainment. The number of jurisdictions may vary each year.

### Indicator 7: Decrease stigma

- Definition: The median score of a 10-item stigma scale, ranging from 0 (no stigma) to 100 (high stigma), measured among persons aged  $> 18$  years living with diagnosed HIV infection living in the United States and Puerto Rico.



- Note: The stigma scale was revised for the 2018 data collection cycle and includes three questions with a 12-month reference period to allow participants to provide experiences in a defined and more recent period of time for one domain of stigma (personalized stigma).
- Baseline year: 2018
- Baseline result: 31.2 median score
- Target: By 2025, decrease by 50%.
- Data source: Medical Monitoring Project (MMP). MMP is a cross-sectional, nationally representative, complex sample survey that assesses the behavioral and clinical characteristics of adults with diagnosed HIV infection in the United States. MMP also provides information on behaviors and clinical outcomes affecting the risk of HIV transmission, morbidity, and mortality. In 2015, MMP sampling and weighting methods were revised to include all adults with diagnosed HIV infection regardless of HIV care status.
- Data availability: Data are published annually.

### Indicator 8: Reduce homelessness

- Definition:
  - ◊ Numerator: Number of persons aged  $\geq 18$  years living with diagnosed HIV in a measurement year and report having been homeless during the 12 months prior to interview. Homelessness is defined as living on the street, living in a shelter, living in a single-room-occupancy hotel, or living in a car.
  - ◊ Denominator: A sample of persons aged  $\geq 18$  years living with diagnosed HIV in a measurement year, as documented in the medical record.
- Baseline year: 2017
- Baseline result: 9.1%
- Target: By 2025, reduce by 50%.
- Data source: Medical Monitoring Project (MMP). MMP is a cross-sectional, nationally representative, complex sample survey that assesses the behavioral and clinical characteristics of adults with diagnosed HIV infection in the United States. MMP also provides information on behaviors and clinical outcomes affecting the risk of HIV transmission, morbidity, and mortality. In 2015, MMP sampling and weighting methods were revised to include all adults with diagnosed HIV infection regardless of HIV care status.
- Data availability: Data are published annually.

### Indicator 9: Increase LGBTQ-supportive school policies and practices

- Definition: This indicator is the median percentage of secondary schools that are implementing at least four of seven school policies and practices that are known to improve health outcomes for both LGBTQ youth and all students: (1) having a Gay/Straight Alliance (GSA) or similar club, (2) identifying safe spaces, (3) prohibiting harassment based on sexual orientation or gender identity, (4) encouraging staff to attend professional development; (5) facilitating access to out-of-school health service providers, (6) facilitating access to out-of-school social and psychological service providers, and (7) providing LGBTQ-relevant curricula or supplementary materials.
- Baseline year: 2018
- Baseline result: 59.8%
- Targets: By 2025, increase the median percentage of secondary schools that are implementing at least four of seven LGBTQ-supportive policies and practices to 65% from a 2018 baseline of 59.8%. By 2030, increase the median percentage of secondary schools to 68.7%.

- Data source: CDC School Health Profiles. The School Health Profiles is a system of surveys assessing school health policies and practices in states, large urban school districts, and territories.
- Data availability: Data are published bi-annually.

## Disparities Indicators

To monitor our progress in addressing HIV disparities, the viral suppression indicator is monitored for the following priority populations.

### MSM

- Definition:
  - ◊ Numerator: Number of persons with male-to-male sexual contact (MSM) aged  $\geq 13$  years living with diagnosed HIV and have a viral load test result  $< 200$  copies/mL at the most recent viral load test during a measurement year.
  - ◊ Denominator: Number of persons with male-to-male sexual contact (MSM) aged  $\geq 13$  years living with diagnosed HIV by the end of the year prior to the measurement year and alive at the end of the measurement year.
- Baseline year: 2017
- Baseline result: 66.1%
- Target: By 2025, increase to 95%.
- Data source: National HIV Surveillance System (NHSS).<sup>2</sup> NHSS is the primary source for monitoring trends in HIV in the United States. It is the data source for incidence, diagnoses, and other HIV care continuum data.
- Data availability: Data are published annually.
- Note: Data are reported for jurisdictions with complete laboratory reporting of CD4 and viral load test results and with complete death ascertainment. The number of jurisdictions may vary each year.

### Black/African American MSM

- Definition:
  - ◊ Numerator: Number of Black/African American persons with male-to-male sexual contact (MSM) aged  $\geq 13$  years living with diagnosed HIV and have a viral load test result  $< 200$  copies/mL at the most recent viral load test during a measurement year.
  - ◊ Denominator: Number of Black/African American persons with male-to-male sexual contact (MSM) aged  $\geq 13$  years living with diagnosed HIV by the end of the year prior to the measurement year and alive at the end of the measurement year.
- Baseline year: 2017
- Baseline result: 58.4%
- Target: By 2025, increase to 95%.
- Data availability: Data are published annually.
- Data source: National HIV Surveillance System (NHSS).<sup>2</sup> NHSS is the primary source for monitoring trends in HIV in the United States. It is the data source for incidence, diagnoses, and other HIV care continuum data.
- Note: Data are reported for jurisdictions with complete laboratory reporting of CD4 and viral load test results and with complete death ascertainment. The number of jurisdictions may vary each year.

### Hispanic/Latino MSM

- Definition:
  - ◊ Numerator: Number of Hispanic/Latino persons with male-to-male sexual contact (MSM) aged  $\geq 13$  years living with diagnosed HIV and have a viral load test result  $< 200$  copies/mL at the most recent viral load test during a measurement year.
  - ◊ Denominator: Number of Hispanic/Latino persons with male-to-male sexual contact (MSM) aged  $\geq 13$  years living with diagnosed HIV by the end of the year prior to the measurement year and alive at the end of the measurement year.
- Baseline year: 2017
- Baseline result: 64.9%
- Target: By 2025, increase to 95%.
- Data source: National HIV Surveillance System (NHSS).<sup>2</sup> NHSS is the primary source for monitoring trends in HIV in the United States. It is the data source for incidence, diagnoses, and other HIV care continuum data.
- Data availability: Data are published annually.
- Note: Data are reported for jurisdictions with complete laboratory reporting of CD4 and viral load test results and with complete death ascertainment. The number of jurisdictions may vary each year.

### American Indian/Alaska Native MSM

- Definition:
  - ◊ Numerator: Number of American Indian/Alaska Native persons with male-to-male sexual contact (MSM) aged  $\geq 13$  years living with diagnosed HIV and have a viral load test result  $< 200$  copies/mL at the most recent viral load test during a measurement year.
  - ◊ Denominator: Number of American Indian/Alaska Native persons with male-to-male sexual contact (MSM) aged  $\geq 13$  years living with diagnosed HIV by the end of the year prior to the measurement year and alive at the end of the measurement year.
- Baseline year: 2017
- Baseline result: 67.3%
- Target: By 2025, increase to 95%.
- Data source: National HIV Surveillance System (NHSS).<sup>2</sup> NHSS is the primary source for monitoring trends in HIV in the United States. It is the data source for incidence, diagnoses, and other HIV care continuum data.
- Data availability: Data are published annually.
- Note: Data are reported for jurisdictions with complete laboratory reporting of CD4 and viral load test results and with complete death ascertainment. The number of jurisdictions may vary each year.

### Black Women

- Definition:
  - ◊ Numerator: Number of Black/African American females aged  $\geq 13$  years living with diagnosed HIV and have a viral load test result  $< 200$  copies/mL at the most recent viral load test during a measurement year.
  - ◊ Denominator: Number of Black/African American females aged  $\geq 13$  years living with diagnosed HIV by the end of the year prior to the measurement year and alive at the end of the measurement year.
- Baseline year: 2017
- Baseline result: 59.3%

- Target: By 2025, increase to 95%.
- Data source: National HIV Surveillance System (NHSS).<sup>2</sup> NHSS is the primary source for monitoring trends in HIV in the United States. It is the data source for incidence, diagnoses, and other HIV care continuum data.
- Data availability: Data are published annually.
- Note: Data are reported for jurisdictions with complete laboratory reporting of CD4 and viral load test results and with complete death ascertainment. The number of jurisdictions may vary each year.

### Transgender Women in HIV Medical Care

- Definition:
  - ◊ Numerator: Number of transgender women living with HIV  $\geq 13$  years who received from a Ryan White HIV/AIDS Provider at least one outpatient ambulatory health care (OAHC) visit and had at least one viral load test during the measurement year who was virally suppressed. Viral suppression was defined as the most recently reported HIV test result of  $< 200$  copies/mL.
  - ◊ Denominator: Number of transgender women living with HIV  $\geq 13$  years who received from a Ryan White HIV/AIDS Provider at least one outpatient ambulatory health care (OAHC) visit and had at least one viral load test during the measurement year.
- Baseline year: 2017
- Baseline result: 80.5%
- Target: By 2025, increase to 95%.
- Data source: Ryan White HIV/AIDS Program Services Report<sup>5</sup>
- Data availability: Data are published annually.

### People Who Inject Drugs (PWID)

- Definition:
  - ◊ Numerator: Number of persons who inject drugs aged  $\geq 13$  years living with diagnosed HIV and have a viral load test result  $< 200$  copies/mL at the most recent viral load test during a measurement year.
  - ◊ Denominator: Number of persons who inject drugs aged  $\geq 13$  years living with diagnosed HIV by the end of the year prior to the measurement year and alive at the end of the measurement year.
- Baseline year: 2017
- Baseline result: 54.9%
- Target: By 2025, increase to 95%.
- Data source: National HIV Surveillance System (NHSS).<sup>2</sup> NHSS is the primary source for monitoring trends in HIV in the United States. It is the data source for incidence, diagnoses, and other HIV care continuum data.
- Data availability: Data are published annually.
- Note: Data are reported for jurisdictions with complete laboratory reporting of CD4 and viral load test results and with complete death ascertainment. The number of jurisdictions may vary each year.

### Youth 13–24 years

- Definition:
  - ◊ Numerator: Number of persons aged 13–24 years living with diagnosed HIV and have a viral load test result  $< 200$  copies/mL at the most recent viral load test during a measurement year.
  - ◊ Denominator: Number of persons aged 13–24 years living with diagnosed HIV by the end of the year prior to the measurement year and alive at the end of the measurement year.



- Baseline year: 2017
- Baseline result: 54.9%
- Target: By 2025, increase to 95%.
- Data source: National HIV Surveillance System (NHSS).<sup>2</sup> NHSS is the primary source for monitoring trends in HIV in the United States. It is the data source for incidence, diagnoses, and other HIV care continuum data.
- Note: Data are reported for jurisdictions with complete laboratory reporting of CD4 and viral load test results and with complete death ascertainment. The number of jurisdictions may vary each year.

***Developmental Indicator—Quality of life for people with HIV***

In addition, one key issue, quality of life for people with HIV, was designated as the subject for a “developmental indicator,” meaning that data sources, measures, and targets will be identified, and progress monitored thereafter. Potential data sources and measures exist for this indicator, but further work must be done to assess them and craft the specifications for this developmental indicator. Working with parties and organizations, the federal government will develop an indicator.

# APPENDIX B: ACRONYMS

AIDS	acquired immune deficiency syndrome
ART	antiretroviral therapy
CDC	Centers for Disease Control and Prevention (HHS)
COVID-19	coronavirus disease 2019
EHE	Ending the HIV Epidemic in the U.S.
FDA	Food and Drug Administration (HHS)
HHS	U.S. Department of Health and Human Services
HIV	human immunodeficiency virus
HOPWA	Housing Opportunities for Persons With AIDS
HRSA	Health Resources and Services Administration (HHS)
IHS	Indian Health Service (HHS)
MSM	men who have sex with men
NHAS	National HIV/AIDS Strategy
NIH	National Institutes of Health
OASH	Office of the Assistant Secretary for Health (HHS)
OIDP	Office of Infectious Disease and HIV/AIDS Policy (HHS)
ONAP	Office of National AIDS Policy (White House)
PEP	post-exposure prophylaxis
PrEP	pre-exposure prophylaxis
PWID	people who inject drugs
RWHAP	Ryan White HIV/AIDS Program (HRSA)
SAMHSA	Substance Abuse and Mental Health Services Administration (HHS)
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SSP	syringe services program
STI	sexually transmitted infection
U=U	Undetectable = Untransmittable
USPSTF	U.S. Preventative Services Task Force

# APPENDIX C: REFERENCES

- 1 Centers for Disease Control and Prevention. [Vital Signs: HIV prevention through care and treatment—United States. \*Morb Mortal Wkly Rep.\* 2011 \(December 2\);60\(47\):1618-1623. <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6047a4.htm>](https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6047a4.htm)
- 2 Centers for Disease Control and Prevention. [Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas, 2019. \*HIV Surveillance Supplemental Report\* 2021;26\(2\). Accessed October 30, 2021. <https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-26-no-2/index.html>](https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-26-no-2/index.html)
- 3 Centers for Disease Control and Prevention. [Diagnoses of HIV infection in the United States and dependent areas, 2019. \*HIV Surveillance Report\* 2019;32. Accessed October 30, 2021. <https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-32/index.html>](https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-32/index.html)
- 4 [NCHHSTP AtlasPlus: HIV, hepatitis, STD, TB, social determinants of health data](https://www.cdc.gov/nchhstp/atlas/index.htm). Centers for Disease Control and Prevention. Accessed September 23, 2021. <https://www.cdc.gov/nchhstp/atlas/index.htm>
- 5 [Ryan White HIV/AIDS Program annual client-level data report 2019](https://hab.hrsa.gov/sites/default/files/hab/data/datareports/RWHAP-annual-client-level-data-report-2019.pdf). Health Resources and Services Administration. Accessed September 23, 2021, <https://hab.hrsa.gov/sites/default/files/hab/data/datareports/RWHAP-annual-client-level-data-report-2019.pdf>
- 6 Mandsager P, Marier A, Cohen S, et al. [Reducing HIV-related health disparities in the Health Resources and Services Administration's Ryan White HIV/AIDS Program. \*Am J Public Health.\* Nov 2018;108\(S4\):S246-S250. doi:10.2105/AJPH.2018.304689](https://doi.org/10.2105/AJPH.2018.304689)
- 7 Dawson L, Kates J. [Insurance coverage and viral suppression among people with HIV, 2018](https://www.kff.org/hivaids/issue-brief/insurance-coverage-and-viral-suppression-among-people-with-hiv-2018/). Kaiser Family Foundation. September 24, 2020. Accessed September 29, 2021. <https://www.kff.org/hivaids/issue-brief/insurance-coverage-and-viral-suppression-among-people-with-hiv-2018/>
- 8 [Medicaid and HIV](https://www.kff.org/hivaids/fact-sheet/medicaid-and-hiv/). Kaiser Family Foundation. Updated October 1, 2019. Accessed October 1, 2021. <https://www.kff.org/hivaids/fact-sheet/medicaid-and-hiv/>
- 9 Adamson B, Lipira L, Katz AB. [The impact of ACA and Medicaid expansion on progress toward UNAIDS 90-90-90 goals. \*Curr HIV/AIDS Rep.\* Feb 2019;16\(1\):105-112. doi:10.1007/s11904-019-00429-6](https://doi.org/10.1007/s11904-019-00429-6)
- 10 Rajabiun S, Tryon J, Feaster M, et al. [The influence of housing status on the HIV Continuum of Care: Results From a multisite study of patient navigation models to build a medical home for people living with HIV experiencing homelessness. \*Am J Public Health.\* Dec 2018;108\(S7\):S539-S545. doi:10.2105/AJPH.2018.304736](https://doi.org/10.2105/AJPH.2018.304736)
- 11 Centers for Disease Control and Prevention. [Estimated HIV incidence and prevalence in the United States, 2015–2019. \*HIV Surveillance Supplemental Report\* 2021;26\(1\). Accessed October 30, 2021. <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-supplemental-report-vol-26-1.pdf>](https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-supplemental-report-vol-26-1.pdf)
- 12 Hall HI, Song R, Rhodes P, et al. [Estimation of HIV incidence in the United States. \*JAMA.\* 2008 \(August 6\);300\(5\):520-529. doi:10.1001/jama.300.5.520](https://doi.org/10.1001/jama.300.5.520)

- 13 [2019 National HIV Surveillance System Reports](https://www.cdc.gov/nchhstp/newsroom/2021/2019-national-hiv-surveillance-system-reports.html). Centers for Disease Control and Prevention. May 27, 2021. Accessed October 1, 2021. <https://www.cdc.gov/nchhstp/newsroom/2021/2019-national-hiv-surveillance-system-reports.html>
- 14 [Quick facts—United States](https://www.census.gov/quickfacts/fact/table/US/PSTo45219#PSTo45219). U.S. Census Bureau. Accessed September 29, 2021. <https://www.census.gov/quickfacts/fact/table/US/PSTo45219#PSTo45219>
- 15 Centers for Disease Control and Prevention. [Sexual Orientation Information Statistics. Sexual Orientation and Health among U.S. Adults: National Health Interview Survey, 2018](https://www.cdc.gov/nchs/nhis/sexual_orientation/statistics.htm). Accessed November 13, 2021. [https://www.cdc.gov/nchs/nhis/sexual\\_orientation/statistics.htm](https://www.cdc.gov/nchs/nhis/sexual_orientation/statistics.htm)
- 16 A.R. F, Herman JL, Gates GJ, Brown TNT. [How Many Adults Identify as Transgender in the United States?](https://williamsinstitute.law.ucla.edu/wp-content/uploads/Trans-Adults-US-Aug-2016.pdf); 2016. Accessed November 14, 2021. <https://williamsinstitute.law.ucla.edu/wp-content/uploads/Trans-Adults-US-Aug-2016.pdf>
- 17 Centers for Disease Control and Prevention. [Estimated HIV incidence and prevalence in the United States, 2014–2018. HIV Surveillance Supplemental Report](https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-supplemental-report-vol-25-1.pdf). 2020;25(1). Accessed November 14, 2021. <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-supplemental-report-vol-25-1.pdf>
- 18 [Annual estimates of the resident population: April 1, 2010 to July 1, 2019](https://www.census.gov/quickfacts/fact/table/US/PSTo45219#PSTo45219). U.S. Census Bureau. Accessed September 29, 2021. <https://www.census.gov/quickfacts/fact/table/US/PSTo45219#PSTo45219>
- 19 Szucs LE, Lowry R, Fasula AM, et al. [Condom and contraceptive use among sexually active high school students—Youth Risk Behavior Survey, United States, 2019](https://doi.org/10.15585/mmwr.su6901a2). *MMWR Suppl*. 2020(August 21);69(1):11-18. doi:10.15585/mmwr.su6901a2
- 20 Custom data analysis. Centers for Disease Control and Prevention.
- 21 Antiretroviral Therapy Cohort C. [Survival of HIV-positive patients starting antiretroviral therapy between 1996 and 2013: a collaborative analysis of cohort studies](https://doi.org/10.1016/S2352-3018(17)30066-8). *Lancet HIV*. 2017(August);4(8):e349-e356. doi:10.1016/S2352-3018(17)30066-8
- 22 Bavinton B, Grinsztejn B, Phanuphak N, et al. HIV treatment prevents HIV transmission in male serodiscordant couples in Australia, Thailand and Brazil. Presented at: 9th IAS Conference on HIV Science; July 25, 2017; Paris, France.
- 23 Cohen MS, Chen YQ, McCauley M, et al. [Prevention of HIV-1 infection with early antiretroviral therapy](https://doi.org/10.1056/NEJMoa11052438). *N Engl J Med*. 2011(August 11);365(6):493-505. doi:10.1056/NEJMoa11052438
- 24 Cohen MS, Chen YQ, McCauley M, et al. [Antiretroviral therapy for the prevention of HIV-1 transmission](https://doi.org/10.1056/NEJMoa1600693). *N Engl J Med*. 2016(September 1);375(9):830-839. doi:10.1056/NEJMoa1600693
- 25 Rodger AJ, Cambiano V, Bruun T, et al. [Sexual activity without condoms and risk of HIV transmission in serodifferent couples when the HIV-positive partner is using suppressive antiretroviral therapy](https://doi.org/10.1001/jama.2016.5148). *JAMA*. 2016(July 12);316(2):171-181. doi:10.1001/jama.2016.5148
- 26 Eisinger RW, Erbedding E, Fauci AS. [Ending the Human Immunodeficiency Virus pandemic: Optimizing the prevention and treatment toolkits](https://doi.org/10.1093/cid/ciz998). *Clin Infect Dis*. 2019(November 27);69(12):2212-2217. doi:10.1093/cid/ciz998
- 27 [National HIV Testing Day - June 27, 2019](https://doi.org/10.15585/mmwr.mm6825a1). *Morb Mortal Wkly Rep*. 2019(June 28);68(25):561. doi:10.15585/mmwr.mm6825a1



- 28 Li Z, Purcell DW, Sansom SL, et al. [Vital Signs: HIV transmission along the continuum of care - United States, 2016](#). *Morb Mortal Wkly Rep*. 2019;68(11):267-272. doi:10.15585/mmwr.mm6811e1
- 29 [Vital Signs](#). Centers for Disease Control and Prevention. Accessed 2021. [https://www.cdc.gov/nchhstp/newsroom/images/2019/hiv/hiv-transmissions-in-2016\\_highres.png](https://www.cdc.gov/nchhstp/newsroom/images/2019/hiv/hiv-transmissions-in-2016_highres.png)
- 30 Centers for Disease Control and Prevention. [National HIV Surveillance System data reported through March 2021; and preexposure prophylaxis \(PrEP\) data reported through December 2020](#). *HIV Surveillance Data Tables* 2021;2(3). Accessed October 30, 2021. <https://www.cdc.gov/hiv/library/reports/surveillance-data-tables/vol-2-no-3/index.html>
- 31 Centers for Disease Control and Prevention. [Core indicators for monitoring the Ending the HIV Epidemic initiative: HIV diagnoses and linkage to HIV medical care, 2019 \(preliminary data, reported through December 2019\); pre-exposure prophylaxis \(PrEP\)—2018, updated](#). *HIV Surveillance Data Tables* 2020;1(2). Accessed October 30, 2021. <https://www.cdc.gov/hiv/library/reports/surveillance-data-tables/vol-1-no-2/index.html>
- 32 Harris NS, Johnson AS, Huang YA, et al. [Vital Signs: Status of Human Immunodeficiency Virus testing, viral suppression, and HIV preexposure prophylaxis - United States, 2013-2018](#). *Morb Mortal Wkly Rep*. 2019(December 6);68(48):1117-1123. doi:10.15585/mmwr.mm6848e1
- 33 Dodge B, Ford JV, Bo N, et al. [HIV risk and prevention outcomes in a probability-based sample of gay and bisexual men in the United States](#). *J Acquir Immune Defic Syndr*. Dec 1 2019(December 1);82(4):355-361. doi:10.1097/QAI.0000000000002151
- 34 Rolle CP, Onwubiko U, Jo J, et al. [PrEP implementation and persistence in a county health department setting in Atlanta, GA](#). *AIDS Behav*. 2019(October);23(Suppl 3):296-303. doi:10.1007/s10461-019-02654-x
- 35 Artiga S, Hill L, Orgera K, et al. [Health coverage by race and ethnicity, 2010-2019](#). Kaiser Family Foundation. July 16, 2021. Accessed October 1, 2021. <https://www.kff.org/racial-equity-and-health-policy/issue-brief/health-coverage-by-race-and-ethnicity/>
- 36 Buchmueller T, Carpenter CS. [Disparities in health insurance coverage, access, and outcomes for individuals in same-sex versus different-sex relationships, 2000-2007](#). *Am J Public Health*. 2010(March);100(3):489-495. doi:10.2105/AJPH.2009.160804
- 37 [Lesbian, gay, bisexual, and transgender health](#). HealthyPeople.gov. Accessed September 29, 2021. <https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health?topicid=25>
- 38 Operario D, Gamarel KE, Grin BM, et al. [Sexual minority health disparities in adult men and women in the United States: National Health and Nutrition Examination Survey, 2001-2010](#). *Am J Public Health*. 2015(October);105(10):e27-34. doi:10.2105/AJPH.2015.302762
- 39 National Institutes of Health. [Strategic Plan to Advance Research on the Health and Well-Being of Sexual & Gender Minorities: Fiscal Years 2021-2025](#). Accessed October 30, 2021. [https://dpcpsi.nih.gov/sites/default/files/SGMStrategicPlan\\_2021\\_2025.pdf](https://dpcpsi.nih.gov/sites/default/files/SGMStrategicPlan_2021_2025.pdf)
- 40 [Trans 101: Transgender people in everyday work and life](#). UCSF Prevention Science. Accessed September 29, 2021. <https://prevention.ucsf.edu/transhealth/education/trans101#Who-Are-Transgender-People>
- 41 [How COVID-19 impacts sexual and gender minorities](#). American Psychological Association. Accessed September 29, 2021. <https://www.apa.org/topics/covid-19/sexual-gender-minorities>

- 42 Cicero EC, Reisner SL, Silva SG, et al. [Health care experiences of transgender adults: An integrated mixed research literature review](#). *Adv Nurs Sci*. 2019(April/June);42(2):123-138. doi:10.1097/ANS.000000000000256
- 43 National Center for Transgender Equity. *The Report of the U.S. Transgender Survey*; 2015. Accessed October 30, 2021. <https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf>
- 44 National Academies of Sciences, Engineering, and Medicine. *Integrating Responses at the Intersection of Opioid Use Disorder and Infectious Disease Epidemics: Proceedings of a Workshop*. The National Academies Press; 2018. Accessed October 31, 2021. <https://www.nap.edu/catalog/25153/integrating-responses-at-the-intersection-of-opioid-use-disorder-and-infectious-disease-epidemics>
- 45 Van Handel MM, Rose CE, Hallisey EJ, et al. [County-level vulnerability assessment for rapid dissemination of HIV or HCV infections among persons who inject drugs, United States](#). *J Acquir Immune Defic Syndr*. 2016(November 1);73(3):323-331. doi:10.1097/QAI.0000000000001098
- 46 Grov C, Westmoreland D, Morrison C, et al. [The crisis we are not talking about: One-in-three annual HIV seroconversions among sexual and gender minorities were persistent methamphetamine users](#). *J Acquir Immune Defic Syndr*. 2020(November 1);85(3):272-279. doi:10.1097/QAI.0000000000002461
- 47 Copen CE, Brookmeyer KA, Haderxhanaj LT, et al. [Sexual risk behaviors among persons diagnosed with primary and secondary syphilis who reported high-risk substance use: Data from the National Notifiable Diseases Surveillance System, 2018](#). *Sex Transm Dis*. 2021(August 31). doi:10.1097/OLQ.0000000000001546
- 48 [HIV and substance use](#). Centers for Disease Control and Prevention. Accessed September 29, 2021. <https://www.cdc.gov/hiv/risk/substanceuse.html>
- 49 Centers for Disease Control and Prevention. *Sexually Transmitted Disease Surveillance 2019*. U.S. Department of Health and Human Services; 2021. Accessed October 30, 2021. <https://www.cdc.gov/std/statistics/2019/default.htm>
- 50 Bernstein KT, Marcus JL, Nieri G, et al. [Rectal gonorrhea and chlamydia reinfection is associated with increased risk of HIV seroconversion](#). *J Acquir Immune Defic Syndr*. 2010(April 1);53(4):537-543. doi:10.1097/QAI.ob013e3181c3ef29
- 51 Chesson HW, Song R, Bingham A, et al. [The estimated number and lifetime medical cost of HIV infections attributable to sexually transmitted infections acquired in the United States in 2018: A compilation of published modeling results](#). *Sex Transm Dis*. 2021(April 1);48(4):292-298. doi:10.1097/OLQ.0000000000001358
- 52 Jones J, Weiss K, Mermin J, et al. [Proportion of incident Human Immunodeficiency Virus cases among men who have sex with men attributable to gonorrhea and chlamydia: A modeling analysis](#). *Sex Transm Dis*. 2019(June);46(6):357-363. doi:10.1097/OLQ.0000000000000980
- 53 Westergaard RP, Spaulding AC, Flanigan TP. [HIV among persons incarcerated in the USA: a review of evolving concepts in testing, treatment, and linkage to community care](#). *Curr Opin Infect Dis*. 2013 (February);26(1):10-16. doi:10.1097/QCO.ob013e32835c1dd0
- 54 Department of Labor. *FAQS About Affordable Care Act Implementation Part 47*. Accessed October 31, 2021. <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-47.pdf>

- 55 U.S. Preventive Services Task Force. *Final Recommendation Statement: Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis*. June 2019. Accessed October 30, 2021. <https://www.uspreventiveservicestaskforce.org/uspstf/document/RecommendationStatementFinal/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis>
- 56 [Summary of information on the safety and effectiveness of syringe services programs \(SSPs\)](#). Centers for Disease Control and Prevention. Accessed September 30, 2021. <https://www.cdc.gov/ssp/syringe-services-programs-summary.html>
- 57 Office of National Drug Control Policy. *The Biden-Harris Administration's Statement of Drug Policy Priorities for Year One*. 2021. Accessed October 30, 2021. <https://www.whitehouse.gov/wp-content/uploads/2021/03/BidenHarris-Statement-of-Drug-Policy-Priorities-April-1.pdf>
- 58 [Overdose Prevention Strategy](#). U.S. Department of Health and Human Services. Accessed November 13, 2021. <https://www.hhs.gov/overdose-prevention/>
- 59 Southern AIDS Coalition and GLAAD. *2021 State of HIV Stigma*. Accessed October 30, 2021. [https://www.glaad.org/sites/default/files/HIV-StigmaStudy\\_2021\\_081621%20%281%29.pdf](https://www.glaad.org/sites/default/files/HIV-StigmaStudy_2021_081621%20%281%29.pdf)
- 60 Kirzinger A, Lopes L, Wu B, et al. [KFF Health Tracking Poll – March 2019: Public opinion on the domestic HIV epidemic, Affordable Care Act, and Medicare-for-all](#). March 26, 2019. Accessed September 30, 2021. <https://www.kff.org/hiv/aids/poll-finding/kff-health-tracking-poll-march-2019/>
- 61 Wejnert C, Prejean J, Hoots B, et al. [Prevalence of missed opportunities for HIV testing among persons unaware of their infection](#). *JAMA*. 26 2018(June 26);319(24):2555-2557. doi:10.1001/jama.2018.7611
- 62 [The state of STDs—infographic](#). Centers for Disease Control and Prevention. Accessed September 30, 2021. <https://www.cdc.gov/std/statistics/2019/infographic.htm>
- 63 Huang YA, Zhu W, Smith DK, et al. [HIV preexposure prophylaxis, by race and ethnicity - United States, 2014-2016](#). *Morb Mortal Wkly Rep*. 2018(October 19);67(41):1147-1150. doi:10.15585/mmwr.mm6741a3
- 64 Sullivan P, et al. [The impact of pre-exposure prophylaxis with TDF/FTC on HIV diagnoses, 2012-2016, United States](#). Presented at: 22nd International AIDS Conference (AIDS 2018); July 27, 2018; Amsterdam, Netherlands. Accessed October 30, 2021. [https://www.natap.org/2018/IAC/IAC\\_17.htm](https://www.natap.org/2018/IAC/IAC_17.htm)
- 65 Canary L, Hariri S, Campbell C, et al. [Geographic disparities in access to syringe services programs among young persons with hepatitis C virus infection in the United States](#). *Clin Infect Dis*. 2017(August 1);65(3):514-517. doi:10.1093/cid/cix333
- 66 Sharp A, Jones A, Honermann B, et al. [220 Vulnerable Counties: One year later](#). presented at: Conference on Retroviruses and Opportunistic Infections; March 4-7, 2018; Boston, MA. Accessed October 30, 2021. <https://www.croiconference.org/abstract/220-vulnerable-counties-one-year-later/>
- 67 Lazar NR, Salas-Humara C, Wood SM, et al. [Missed opportunities for HIV screening among a cohort of adolescents with recently diagnosed HIV infection in a large pediatric hospital care network](#). *J Adolesc Health*. 2018(December);63(6):799-802. doi:10.1016/j.jadohealth.2018.07.010
- 68 Traynor SM, Rosen-Metsch L, Feaster DJ. [Missed opportunities for HIV testing among STD clinic patients](#). *J Comm Health*. 43(6):1128-1136. doi:https://doi.org/10.1007/s10900-018-0531-z

- 69 Downing A, Garcia-Diaz JB. [Missed opportunities for HIV diagnosis](#). *J Int Assoc Provid AIDS Care*. 2017(Jan/Feb);16(1):14-17. doi:10.1177/2325957416661423
- 70 DeRose J, Zucker J, Cennimo D, et al. [Missed testing opportunities for HIV screening and early diagnosis in an urban tertiary care center](#). *AIDS Res Treat*. 2017;5708620. doi:10.1155/2017/5708620
- 71 Parish CL, Siegel K, Liguori T, et al. [HIV testing in the dental setting: Perspectives and practices of experienced dental professionals](#). *AIDS Care*. 2018(March);30(3):347-352. doi:10.1080/09540121.2017.1367087
- 72 Weidle PJ, Lecher S, Botts LW, et al. [HIV testing in community pharmacies and retail clinics: a model to expand access to screening for HIV infection](#). *J Am Pharm Assoc (2003)*. 2014(September-October);54(5):486-492. doi:10.1331/JAPhA.2014.14045
- 73 Branson BM, Handsfield HH, Lampe MA, et al. [Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings](#). *MMWR Recomm Rep*. 2006(September 22);55(RR-14):1-17; quiz CE1-4. Accessed October 30, 2021. <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm>
- 74 Flanigan TP, Zaller N, Beckwith CG, et al. [Testing for HIV, sexually transmitted infections, and viral hepatitis in jails: Still a missed opportunity for public health and HIV prevention](#). *J Acquir Immune Defic Syndr*. 1999;55(2):S78-S83. doi:10.1097/QAI.0b013e3181fbc94f1
- 75 Solomon L, Montague BT, Beckwith CG, et al. [Survey finds that many prisons and jails have room to improve HIV testing and coordination of postrelease treatment](#). *Health Aff (Millwood)*. 2014(March);33(3):434-442. doi:10.1377/hlthaff.2013.1115
- 76 Stanford KA, McNulty MC, Schmitt JR, et al. [Incorporating HIV screening with COVID-19 testing in an urban emergency department during the pandemic](#). *JAMA Intern Med*. 2021(July 1);181(7):1001-1003. doi:10.1001/jamainternmed.2021.0839
- 77 Barrow RY, Ahmed F, Bolan GA, et al. [Recommendations for providing quality sexually transmitted diseases clinical services, 2020](#). *MMWR Recomm Rep*. 2020(January 3);68(5):1-20. doi:10.15585/mmwr.rr6805a1
- 78 Hoover KW, Parsell BW, Leichliter JS, et al. [Continuing need for sexually transmitted disease clinics after the Affordable Care Act](#). *Am J Public Health*. 2015(November);105 Suppl 5:S690-S695. doi:10.2105/AJPH.2015.302839
- 79 Seth P, Wang G, Sizemore E, et al. [HIV testing and HIV service delivery to populations at high risk attending sexually transmitted disease clinics in the United States, 2011-2013](#). *Am J Public Health*. 2015(November);105(11):2374-2381. doi:10.2105/AJPH.2015.302778
- 80 Cuffe KM, Esie P, Leichliter JS, et al. [HIV services provided by STI programs in state and local health departments — United States, 2013–2014](#). *Morb Mortal Wkly Rep* 2017;66:355-358. doi:http://dx.doi.org/10.15585/mmwr.mm6613a2
- 81 Centers for Disease Control and Prevention. [CDC-Funded HIV Testing in the United States, Puerto Rico, and the U.S. Virgin Islands, 2019](#). Accessed November 14, 2021. <https://www.cdc.gov/hiv/pdf/library/reports/cdc-hiv-annual-HIV-testing-report-2019.pdf>
- 82 Robin L, Timpe Z, Suarez NA, et al. [Local Education Agency impact on school environments to reduce health risk behaviors and experiences among high school students](#). *J Adolesc Health*. 2021(September 13). doi:10.1016/j.jadohealth.2021.08.004



- 83 Breuner CC, Mattson G. [Sexuality education for children and adolescents](#). *Pediatrics*. 2016(August);138(2). doi:10.1542/peds.2016-1348
- 84 National Academies of Science, Engineering, and Medicine. [Sexually Transmitted Infections: Adopting a Sexual Health Paradigm](#). The National Academies Press; 2021. Accessed October 30, 2021. <https://www.nap.edu/catalog/25955/sexually-transmitted-infections-adopting-a-sexual-health-paradigm>
- 85 [Preventing sexual transmission of HIV](#). HIV.gov. Accessed September 30, 2021. <https://www.hiv.gov/hiv-basics/hiv-prevention/reducing-sexual-risk/preventing-sexual-transmission-of-hiv>
- 86 [MAT medications, counseling, and related conditions](#). Substance Abuse and Mental Health Services Administration. Accessed September 30, 2021. <https://www.samhsa.gov/medication-assisted-treatment/medications-counseling-related-conditions>
- 87 [Male condom use](#). Centers for Disease Control and Prevention. Accessed September 30, 2021. [https://www.cdc.gov/hiv/risk/estimates/preventionstrategies.html#anchor\\_1562942368](https://www.cdc.gov/hiv/risk/estimates/preventionstrategies.html#anchor_1562942368)
- 88 Satcher D. *Evidence-Based Findings on the Efficacy of Syringe Programs: Analysis from the Assistant Secretary of Health and Surgeon General of the scientific research completed since April 1998*. 2000.
- 89 Marks G, Crepaz N, Janssen RS. [Estimating sexual transmission of HIV from persons aware and unaware that they are infected with the virus in the USA](#). *AIDS*. 2006(June 26);20(10):1447-1450. doi:10.1097/01.aids.0000233579.79714.8d
- 90 Rothman J, Rudnick D, Slifer M, et al. [Co-located substance use treatment and HIV prevention and primary care services, New York State, 1990-2002: a model for effective service delivery to a high-risk population](#). *J Urban Health*. 2007(March);84(2):226-242. doi:10.1007/s11524-006-9137-3
- 91 Centers for Disease Control and Prevention. [Sexual assault and abuse and STIs – adolescents and adults](#). *Sexually Transmitted Infections Treatment Guidelines, 2021*. Accessed October 30, 2021. <https://www.cdc.gov/std/treatment-guidelines/sexual-assault-adults.htm>
- 92 AIDS Education & Training Center (AETC) Program Rural Health Committee. [HIV/STI Post-Sexual Exposure Prophylaxis: Policy and Procedure Template](#). 2018. Accessed October 30, 2021. [https://cdn.ymaws.com/www.safeta.org/resource/resmgr/forms\\_library/npepsexualexposuretemplate\\_f.pdf](https://cdn.ymaws.com/www.safeta.org/resource/resmgr/forms_library/npepsexualexposuretemplate_f.pdf)
- 93 Agency for Healthcare Research and Quality. [2009 National Healthcare Quality Report](#). March 2019. Accessed October 30, 2021. <http://archive.ahrq.gov/research/findings/nhqrd/r/nhqro9/Key.html>
- 94 Douthit N, Kiv S, Dwolatzky T, et al. [Exposing some important barriers to health care access in the rural USA](#). *Public Health*. 2015(June);129(6):611-620. doi:10.1016/j.puhe.2015.04.001
- 95 Henny KD, Duke CC, Geter A, et al. [HIV-related training and correlates of knowledge, HIV screening and prescribing of nPEP and PrEP among primary care providers in Southeast United States, 2017](#). *AIDS Behav*. 2019(November);23(11):2926-2935. doi:10.1007/s10461-019-02545-1
- 96 Pleuhs B, Quinn KG, Walsh JL, et al. [Health care provider barriers to HIV pre-exposure prophylaxis in the United States: A systematic review](#). *AIDS Patient Care STDS*. 2020(March);34(3):111-123. doi:10.1089/apc.2019.0189
- 97 Macrae J. [HRSA releases 2020 data on HIV prevention and treatment in health centers](#). HIV.gov. September 1, 2021. Accessed October 31, 2021. <https://www.hiv.gov/blog/hrsa-releases-2020-data-hiv-prevention-and-treatment-health-centers>

- 98 Farmer EK, Koren DE, Cha A, et al. [The pharmacist's expanding role in HIV pre-exposure prophylaxis](#). *AIDS Patient Care STDS*. May 2019(May);33(5):207-213. doi:10.1089/apc.2018.0294
- 99 Cantwell-McNelis K, James CW. [Role of clinical pharmacists in outpatient HIV clinics](#). *Am J Health Syst Pharm*. 2002(March 1);59(5):447-452. doi:10.1093/ajhp/59.5.447
- 100 Byrd KK, Hou JG, Bush T, et al. [Adherence and viral suppression among participants of the patient-centered Human Immunodeficiency Virus \(HIV\) Care Model Project: A collaboration between community-based pharmacists and HIV clinical providers](#). *Clin Infect Dis*. Feb 14 2020;70(5):789-797. doi:10.1093/cid/ciz276
- 101 Byrd KK, Hardnett F, Clay PG, et al. [Retention in HIV care among participants in the Patient-Centered HIV Care Model: A collaboration between community-based pharmacists and primary medical providers](#). *AIDS Patient Care STDS*. Feb 2019;33(2):58-66. doi:10.1089/apc.2018.0216
- 102 TEMPRANO ANRS Study Group, Danel C, Moh R, Gabillard D, et al. [A trial of early antiretrovirals and isoniazid preventive therapy in Africa](#). *N Engl J Med*. 2015(August 27);373(9):808-822. doi:10.1056/NEJMoa1507198
- 103 INSIGHT Start Study Group, Lundgren JD, Babiker AG, Gordin F, et al. [Initiation of antiretroviral therapy in early asymptomatic HIV infection](#). *N Engl J Med*. 2015(August 27);373(9):795-807. doi:10.1056/NEJMoa1506816
- 104 U.S. Department of Health and Human Services. [Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents in HIV](#). 2018. Accessed October 30, 2021. <https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/initiation-antiretroviral-therapy>
- 105 [What is the HIV Care Continuum](#). HIV.gov. Accessed September 30, 2021. <https://www.hiv.gov/federalresponse/policies-issues/hiv-aids-care-continuum>
- 106 Osborn CY, Paasche-Orlow MK, Davis TC, et al. [Health literacy: An overlooked factor in understanding HIV health disparities](#). *Am J Prev Med*. 2007(November);33(5):374-378. doi:10.1016/j.amepre.2007.07.022
- 107 Hutchinson P, Dhairyan R. [Shame and HIV: Strategies for addressing the negative impact shame has on public health and diagnosis and treatment of HIV](#). *Bioethics*. 2018(January);32(1):68-76. doi:10.1111/bioe.12378
- 108 Griffin A, Dempsey A, Cousino W, et al. [Addressing disparities in the health of persons with HIV attributable to unstable housing in the United States: The role of the Ryan White HIV/AIDS Program](#). *PLoS Med*. 2020(March);17(3):e1003057. doi:10.1371/journal.pmed.1003057
- 109 Bacon O, Chin JC, Hsu L, et al. [The Rapid Art Program Initiative For HIV Diagnoses \(RAPID\) in San Francisco](#). Presented at: Conference on Retroviruses and Opportunistic Infections; March 4-7, 2018; Boston, MA. Accessed October 30, 2021. [https://www.natap.org/2018/CROI/croi\\_51.htm](https://www.natap.org/2018/CROI/croi_51.htm)
- 110 Colasanti J, Sumitani J, Mehta CC, et al. [Implementation of a rapid entry program decreases time to viral suppression among vulnerable persons living with HIV in the southern United States](#). *Open Forum Infect Dis*. 2018(June);5(6):ofy104. doi:10.1093/ofid/ofy104
- 111 Halperin J, Butler I, Conner K, et al. [Linkage and antiretroviral therapy within 72 hours at a federally qualified health center in New Orleans](#). *AIDS Patient Care STDS*. 2018(February);32(2):39-41. doi:10.1089/apc.2017.0309

- 112 [Red carpet](https://www.whitman-walker.org/careprogram/hiv-care). Whitman-Walker Health. Accessed September 30, 2021. <https://www.whitman-walker.org/careprogram/hiv-care>
- 113 Ruria EC, Masaba R, Kose J, et al. [Optimizing linkage to care and initiation and retention on treatment of adolescents with newly diagnosed HIV infection](#). *AIDS*. 2017(July 1);31 Suppl 3:S253-S260. doi:10.1097/QAD.0000000000001538
- 114 Centers for Disease Control and Prevention. [Compendium of Evidence-Based Interventions and Best Practices for HIV Prevention](#). June 28, 2021. Accessed October 30, 2021. <https://www.cdc.gov/hiv/research/interventionresearch/compendium/index.html>
- 115 Yehia BR, French B, Fleishman JA, et al. [Retention in care is more strongly associated with viral suppression in HIV-infected patients with lower versus higher CD4 counts](#). *J Acquir Immune Defic Syndr*. 2014(March 1);65(3):333-339. doi:10.1097/QAI.0000000000000023
- 116 Dombrowski JC, Galagan SR, Ramchandani M, et al. [HIV care for patients with complex needs: A controlled evaluation of a walk-in, incentivized care model](#). *Open Forum Infect Dis*. 2019(July);6(7):ofz294. doi:10.1093/ofid/ofz294
- 117 El-Sadr WM, Beauchamp G, Hall HI, et al. Brief report: [Durability of the effect of financial incentives on HIV viral load suppression and continuity in care: HPTN 065 Study](#). *J Acquir Immune Defic Syndr*. 2019(July 1);81(3):300-303. doi:10.1097/QAI.0000000000001927
- 118 Saha S, Korthuis PT, Cohn JA, et al. [Primary care provider cultural competence and racial disparities in HIV care and outcomes](#). *J Gen Intern Med*. 2013(May);28(5):622-629. doi:10.1007/s11606-012-2298-8
- 119 [Target HIV](#). Accessed September 30, 2021. <https://targethiv.org/>
- 120 [Older Adult Clients: HRSA's Ryan White HIV/AIDS Program, 2019](#). Accessed October 30, 2021. <https://hab.hrsa.gov/sites/default/files/hab/Publications/factsheets/population-factsheet-older-adults.pdf>
- 121 HRSA Ryan White HIV/AIDS Program. [Addressing the Health Care and Social Support Needs of People Aging with HIV](#). Accessed October 30, 2021. <https://hab.hrsa.gov/sites/default/files/hab/Publications/factsheets/hrsa-aging-tep-summary.pdf>
- 122 [Director's Commentary](#). Centers for Disease Control and Prevention. Accessed October 1, 2021. <https://www.cdc.gov/healthequity/racism-disparities/director-commentary.html>
- 123 [Racism is a Public Health Crisis](#). American Public Health Association. Accessed October 1, 2021. <https://www.apha.org/topics-and-issues/health-equity/racism-and-health/racism-declarations>
- 124 Crepaz N, Hess KI, Purcell DW, et al. [Estimating national rates of HIV infection among MSM, persons who inject drugs, and heterosexuals in the United States](#). *AIDS*. 2019(March 15);33(4):701-708. doi:10.1097/QAD.0000000000002111
- 125 Centers for Disease Control and Prevention. [Diagnoses of HIV Infection in the United States and Dependent Areas, 2018 \(Updated\)](#). *HIV Surveillance Report* 31. Accessed October 30, 2021. <https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-31/index.html>
- 126 Berchick ER, Barnett JC, Upton RD. [Health Insurance Coverage in the United States: 2018](#). Current Population Reports, P60-267(RV). U.S. Government Printing Office; 2019. Accessed October 30, 2021. <https://www.census.gov/content/dam/Census/library/publications/2019/demo/p60-267.pdf>

- 127 Institute of Medicine. *Care Without Coverage: Too Little, Too Late*. National Academies Press; 2002. Accessed October 30, 2021. <https://www.nap.edu/catalog/10367/care-without-coverage-too-little-too-late>
- 128 *Social determinants of health*. HealthyPeople.gov. Accessed September 30, 2021. <https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health>
- 129 European Observatory on Health Systems and Policies and Ministry of Social Affairs and Health (Finland). *Health in All Policies: Prospects and Potentials*. 2006. Accessed October 30, 2021. [https://www.euro.who.int/\\_data/assets/pdf\\_file/0003/109146/E89260.pdf](https://www.euro.who.int/_data/assets/pdf_file/0003/109146/E89260.pdf)
- 130 The National Prevention and Health Promotion Strategy. *The National Prevention Strategy: America's Plan for Better Health and Wellness*. June 2011. Accessed October 30, 2021. <https://www.hhs.gov/sites/default/files/disease-prevention-wellness-report.pdf>
- 131 Flentje A, Heck NC, Brennan JM, et al. [The relationship between minority stress and biological outcomes: A systematic review](#). *J Behav Med*. 2020(October);43(5):673-694. doi:10.1007/s10865-019-00120-6
- 132 Geter A, Herron AR, Sutton MY. [HIV-related stigma by healthcare providers in the United States: A systematic review](#). *AIDS Patient Care STDS*. 2018(October);32(10):418-424. doi:10.1089/apc.2018.0114
- 133 Galarraga O, Rana A, Rahman M, et al. [The effect of unstable housing on HIV treatment biomarkers: An instrumental variables approach](#). *Soc Sci Med*. 2018(October);214:70-82. doi:10.1016/j.socscimed.2018.07.051
- 134 Stangl AL, Earnshaw VA, Logie CH, et al. [The Health Stigma and Discrimination Framework: A global, crosscutting framework to inform research, intervention development, and policy on health-related stigmas](#). *BMC Med*. 2019(February 15);17(1):31. doi:10.1186/s12916-019-1271-3
- 135 [HIV and STD criminalization laws](#). Centers for Disease Control and Prevention. Accessed September 30, 2021. <https://www.cdc.gov/hiv/policies/law/states/exposure.html>
- 136 [HIV criminalization and Ending the HIV Epidemic in the U.S.](#) Centers for Disease Control and Prevention. Accessed October 1, 2021. <https://www.cdc.gov/hiv/policies/law/criminalization-ehe.html>
- 137 De Jesus M, Williams DR. [The Care and Prevention in the United States Demonstration Project: A call for more focus on the social determinants of HIV/AIDS](#). *Public Health Rep*. 2018(Nov/Dec);133(2\_suppl):28S-33S. doi:10.1177/0033354918801353
- 138 [Search: Sustainable East Africa Research in Community Health](#). Accessed September 20, 2021. <https://www.searchendaids.com/>
- 139 [HIV and pregnant women, infants, and children](#). Centers for Disease Control and Prevention. Accessed September 30, 2021. <https://www.cdc.gov/hiv/group/gender/pregnantwomen/index.html>
- 140 McNeil T, Rowe E. ["Looking after the survivors": the health of a cohort of long-term human immunodeficiency virus patients 25 years on](#). *Intern Med J*. 2019(May);49(5):592-597. doi:10.1111/imj.14165
- 141 Murthy VH. *Confronting Health MisInformation: The U.S. Surgeon General's Advisory on Building a Healthy Information Environment*. 2021. Accessed October 30, 2021. <https://www.hhs.gov/sites/default/files/surgeon-general-misinformation-advisory.pdf>



- 142 Division of HIV/AIDS Prevention NCfHA, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention and HIV/AIDS Bureau, Health Resources and Services Administration. *Integrated HIV Prevention and Care Plan Guidance, including the Statewide Coordinated Statement of Need, CY 2017- 2021*. June 2015. Accessed October 30, 2021. <https://hab.hrsa.gov/sites/default/files/hab/Global/hivpreventionplan062015.pdf>
- 143 Sweeney P, DiNenno EA, Flores SA, et al. *HIV data to care-using public health data to improve HIV care and prevention*. *J Acquir Immune Defic Syndr*. 2019(September 1);82(Suppl 1):S1-S5. doi:10.1097/QAI.0000000000002059
- 144 Towe VL, Stevens C, Fischer SH. *Sharing and integrating HIV client data across provider organizations to improve service coordination: A toolkit*. RAND Corporation; 2019. Accessed October 30, 2021. <https://www.rand.org/pubs/tools/TL344.html>
- 145 Psihopaidas D, Cohen SM, West T, et al. *Implementation science and the Health Resources and Services Administration's Ryan White HIV/AIDS Program's work towards ending the HIV epidemic in the United States*. *PLoS Med*. 2020(November);17(11):e1003128. doi:10.1371/journal.pmed.1003128
- 146 National Academies of Sciences, Engineering, and Medicine. *Opportunities to Improve Opioid Use Disorder and Infectious Disease Services: Integrating Responses to a Dual Epidemic*. The National Academies Press; 2020. Accessed October 30, 2021. <https://www.nap.edu/catalog/25626/opportunities-to-improve-opioid-use-disorder-and-infectious-disease-services>
- 147 HealthIT.gov. *ONC's Cures Act Final Rule supports seamless and secure access, exchange, and use of electronic health information*. Accessed October 29, 2021. <https://www.healthit.gov/curesrule/>
- 148 HRSA Ryan White HIV/AIDS Program. *Optimizing HIV Care for People Aging with HIV: Incorporating New Elements of Care Reference Guide for Aging with HIV*. Accessed October 30, 2021. <https://hab.hrsa.gov/sites/default/files/hab/clinical-quality-management/aging-guide-new-elements.pdf>
- 149 U.S. Department of Health and Human Services. *HHS updates interoperability standards to support the electronic exchange of sexual orientation, gender identity and social determinants of health*. Accessed October 29, 2021. <https://www.hhs.gov/about/news/2021/07/09/hhs-updates-interoperability-standards-to-support-electronic-exchange-of-sogi-sdoh.html>
- 150 Centers for Disease Control and Prevention. *PS18-1802: Integrated HIV Surveillance and Prevention Programs for Health Departments*. Monitoring and Evaluation Report; 2019. Accessed October 30, 2021. <https://www.cdc.gov/hiv/pdf/funding/announcements/ps18-1802/cdc-hiv-ps18-1802-monitoring-evaluation-report-2019.pdf>
- 151 Grove M, Brown LL, Knudsen HK, et al. *Employing telehealth within HIV care: advantages, challenges, and recommendations*. *AIDS*. 2021(July 1);35(8):1328-1330. doi:10.1097/QAD.0000000000002892
- 152 Centers for Disease Control and Prevention. *Sexually Transmitted Disease Surveillance 2018*. U.S. Department of Health and Human Services; 2019. Accessed October 30, 2021. <https://www.cdc.gov/std/stats18/STDsSurveillance2018-full-report.pdf>
- 153 Becasen JS, Denard CL, Mullins MM, et al. *Estimating the prevalence of HIV and sexual behaviors among the US transgender population: A systematic review and meta-analysis, 2006-2017*. *Am J Public Health*. 2019(January);109(1):e1-e8. doi:10.2105/AJPH.2018.304727

- 154 Centers for Disease Control and Prevention. [CDC-Funded HIV Testing in the United, States, Puerto Rico and the U.S. Virgin Islands, 2018 Annual HIV Testing Report](https://www.cdc.gov/hiv/pdf/library/reports/cdc-hiv-annual-HIV-testing-report-2018.pdf). Accessed November 14, 2021. <https://www.cdc.gov/hiv/pdf/library/reports/cdc-hiv-annual-HIV-testing-report-2018.pdf>
- 155 [Trends in the prevalence of sexual behaviors and HIV testing National YRBS: 1991–2019](https://www.cdc.gov/healthyouth/data/yrbs/factsheets/2019_sexual_trend_yrbs.htm). Centers for Disease Control and Prevention. Accessed September 30, 2021. [https://www.cdc.gov/healthyouth/data/yrbs/factsheets/2019\\_sexual\\_trend\\_yrbs.htm](https://www.cdc.gov/healthyouth/data/yrbs/factsheets/2019_sexual_trend_yrbs.htm)
- 156 [Recent HIV clusters and outbreaks across the United States among people who inject drugs and considerations during the COVID-19 pandemic](https://emergency.cdc.gov/han/2020/han00436.asp). Centers for Disease Control and Prevention. Accessed October 1, 2021. <https://emergency.cdc.gov/han/2020/han00436.asp>
- 157 Spradling PR, Richardson JT, Buchacz K, et al. [Trends in hepatitis C virus infection among patients in the HIV Outpatient Study, 1996–2007](https://doi.org/10.1097/QAI.0b013e3181b67527). *J Acquir Immune Defic Syndr*. 2010(March);53(3):388–396. doi:10.1097/QAI.0b013e3181b67527
- 158 Chen TY, Ding EL, Seage GR, et al. [Meta-analysis: Increased mortality associated with hepatitis C in HIV-infected persons is unrelated to HIV disease progression](https://doi.org/10.1086/644771). *Clin Infect Dis*. 2009(November 15);49(10):1605–1615. doi:10.1086/644771
- 159 Hoffmann CJ, Thio CL. [Clinical implications of HIV and hepatitis B co-infection in Asia and Africa](https://doi.org/10.1016/S1473-3099(07)70135-4). *Lancet Infect Dis*. 2007(June);7(6):402–409. doi:10.1016/S1473-3099(07)70135-4
- 160 Lo Re Vr, Kallan MJ, Tate JP, et al. [Hepatic decompensation in antiretroviral-treated patients co-infected with HIV and hepatitis C virus compared with hepatitis C virus-monoinfected patients: a cohort study](https://doi.org/10.7326/M13-1829). *Ann Intern Med*. 2014(March 18);160(6):369–379. doi:10.7326/M13-1829
- 161 [HIV in the United States and dependent areas](https://www.cdc.gov/hiv/statistics/overview/ataglace.html). Centers for Disease Control and Prevention. Accessed October 1, 2021. <https://www.cdc.gov/hiv/statistics/overview/ataglace.html>
- 162 Talih M, Huang DT. [Measuring Progress Toward Target Attainment and the Elimination of Health Disparities in Healthy People 2020](https://www.cdc.gov/nchs/data/statnt/statnt27.pdf). Accessed October 30, 2021. <https://www.cdc.gov/nchs/data/statnt/statnt27.pdf>
- 163 Smith DK, Van Handel M, Grey J. [Estimates of adults with indications for HIV pre-exposure prophylaxis by jurisdiction, transmission risk group, and race/ethnicity, United States, 2015](https://doi.org/10.1016/j.annepidem.2018.05.003). *Ann Epidemiol*. 2018(December);28(12):850–857, e9. doi:10.1016/j.annepidem.2018.05.003
- 164 [NHANES questionnaires, datasets, and related documentation](https://wwwn.cdc.gov/nchs/nhanes/Default.aspx). Centers for Disease Control and Prevention. Accessed October 5, 2021. <https://wwwn.cdc.gov/nchs/nhanes/Default.aspx>

# EXHIBIT B



## Recipient Information

### 1. Recipient Name

REGENTS OF THE UNIVERSITY OF  
MICHIGAN  
1109 GEDDES AVE, SUITE 3300  
ANN ARBOR, MI 48109

### 2. Congressional District of Recipient

06

### 3. Payment System Identifier (ID)

1386006309A1

### 4. Employer Identification Number (EIN)

386006309

### 5. Data Universal Numbering System (DUNS)

073133571

### 6. Recipient's Unique Entity Identifier

GNJ7BBP73WE9

### 7. Project Director or Principal Investigator

Sari Reisner, SCD  
Assistant Professor  
sreisner@umich.edu  
734-647-3737

### 8. Authorized Official

Shandra White  
cjharri@umich.edu  
734-763-3800

## Federal Agency Information

### 9. Awarding Agency Contact Information

Julie M. Bergerud  
Grants Management Officer  
NATIONAL INSTITUTE OF MENTAL  
HEALTH  
julie.bergerud@nih.gov  
301-827-6184

### 10. Program Official Contact Information

Michael J Stirratt  
Chief, Adherence To Treatment &  
Prevention Program And Hiv Small  
Business Program (sbir/sttr)  
NATIONAL INSTITUTE OF MENTAL  
HEALTH  
stirrattm@mail.nih.gov  
240-627-3875

## Federal Award Information

### 11. Award Number

7R01MH129175-03

### 12. Unique Federal Award Identification Number (FAIN)

R01MH129175

### 13. Statutory Authority

42 USC 241 42 CFR 52

### 14. Federal Award Project Title

Strategies to Prevent HIV Acquisition Among Transgender MSM in the US

### 15. Assistance Listing Number

93.242

### 16. Assistance Listing Program Title

Mental Health Research Grants

### 17. Award Action Type

Change of Recipient Organization

### 18. Is the Award R&D?

Yes

## Summary Federal Award Financial Information

### 19. Budget Period Start Date 08/12/2024 – End Date 06/30/2025

### 20. Total Amount of Federal Funds Obligated by this Action

\$676,347

20 a. Direct Cost Amount

\$635,010

20 b. Indirect Cost Amount

\$41,337

### 21. Authorized Carryover

### 22. Offset

### 23. Total Amount of Federal Funds Obligated this budget period

\$676,347

### 24. Total Approved Cost Sharing or Matching, where applicable

\$0

### 25. Total Federal and Non-Federal Approved this Budget Period

\$676,347

### 26. Project Period Start Date 05/15/2024 – End Date 06/30/2027

### 27. Total Amount of the Federal Award including Approved Cost

\$676,347

Sharing or Matching this Project Period

### 28. Authorized Treatment of Program Income

Additional Costs

### 29. Grants Management Officer - Signature

Heather Weiss

## 30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.



**RESEARCH**

Department of Health and Human Services  
National Institutes of Health

## Notice of Award



NATIONAL INSTITUTE OF MENTAL HEALTH

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**SECTION I – AWARD DATA – 7R01MH129175-03**
**Principal Investigator(s):**

Sari Reisner, SCD

**Award e-mailed to:** swhite-gov@umich.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of \$676,347 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to The Regents of the University of Michigan in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Mental Health of the National Institutes of Health under Award Number R01MH129175. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website <http://grants.nih.gov/grants/policy/coi/> for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Heather Weiss  
Grants Management Officer  
NATIONAL INSTITUTE OF MENTAL HEALTH

Additional information follows

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**Cumulative Award Calculations for this Budget Period (U.S. Dollars)**  
**Salaries and Wages**

\$47,562

<b>Fringe Benefits</b>	\$16,209
<b>Personnel Costs (Subtotal)</b>	\$63,771
<b>Subawards/Consortium/Contractual Costs</b>	\$571,239
<b>Federal Direct Costs</b>	\$635,010
<b>Federal F&amp;A Costs</b>	\$41,337
<b>Approved Budget</b>	\$676,347
<b>Total Amount of Federal Funds Authorized (Federal Share)</b>	\$676,347
<b>TOTAL FEDERAL AWARD AMOUNT</b>	\$676,347
<b>AMOUNT OF THIS ACTION (FEDERAL SHARE)</b>	\$676,347

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	THIS AWARD	CUMULATIVE TOTALS
3	\$676,347	\$676,347
4	\$652,603	\$652,603
5	\$617,515	\$617,515

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

**Fiscal Information:**

**Payment System Identifier:** 1386006309A1  
**Document Number:** RMH129175B  
**PMS Account Type:** P (Subaccount)  
**Fiscal Year:** 2024

IC	CAN	2024	2025	2026
MH	8472592	\$676,347	\$652,603	\$617,515

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

**NIH Administrative Data:**

**PCC:** 9A-ASGA / **OC:** 41025 / **Released:** 09/09/2024  
**Award Processed:** 09/10/2024 12:13:26 AM

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**SECTION II – PAYMENT/HOTLINE INFORMATION – 7R01MH129175-03**

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm>

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**SECTION III – STANDARD TERMS AND CONDITIONS – 7R01MH129175-03**

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- The grant program legislation and program regulation cited in this Notice of Award.
- Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- 45 CFR Part 75.
- National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm> for certain references cited above.)

**Research and Development (R&D):** All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that

some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See <http://grants.nih.gov/grants/policy/awardconditions.htm> for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01MH129175. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see <http://grants.nih.gov/grants/policy/awardconditions.htm> for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: <http://publicaccess.nih.gov/>.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of [Public Law 110-85](#)), the "responsible party" must register "applicable clinical trials" on the [ClinicalTrials.gov Protocol Registration System Information Website](#). NIH encourages registration of all trials whether required under the law or not. For more information, see [http://grants.nih.gov/ClinicalTrials\\_fdaaa/](http://grants.nih.gov/ClinicalTrials_fdaaa/)

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See <https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html> and <https://www.hhs.gov/>.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html> and <https://www.lep.gov>.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see <http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html>.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see <https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html>. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see <https://grants.nih.gov/grants/policy/harassment.htm>.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see <https://www.hhs.gov/conscience/conscience-protections/index.html> and <https://www.hhs.gov/conscience/religious-freedom/index.html>.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

**Treatment of Program Income:**

Additional Costs

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**SECTION IV – MH SPECIFIC AWARD CONDITIONS – 7R01MH129175-03**

Clinical Trial Indicator: Yes

This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

**CHANGE OF RECIPIENT:**

This award reflects an approved change of recipient organization for the above-named grant from **Brigham and Women's Hospital** in accordance with the relinquishing statement dated 2/8/24.

**AWARD NOTICE:**

This award has been made in response to the application submitted under the Funding Opportunity Announcement PA-21-268 which can be referenced at: [PA-21-268: Change of Recipient Organization \(Type 7 Parent Clinical Trial Optional\) \(nih.gov\)](#)

**BUDGET ADJUSTMENT:**

Inflationary increases have been discontinued for all competing and non-competing research grant awards (see NOT-OD-12-036). Therefore, this award is issued at the committed level but reflects a total rebudgeting of \$44 direct costs from the Research Assistant's salary (University of Michigan) category/categories to the Other Costs category in Year-05.

**CONSORTIUM / CONTRACTUAL COSTS:**

This award includes funds for consortium activity with:

**Johns Hopkins University  
Drexel University  
Fenway Community Health Center  
Duke University**

Each consortium is to be established and administered in accordance with the NIH Grants Policy Statement (<http://grants.nih.gov/grants/policy/nihgps/index.htm>). No foreign performance site may be added to this project without the written prior approval of the National Institute of Mental Health.

**PARTICIPANT RECRUITMENT - MILESTONES:**

Future NIMH support for this study is contingent upon adequate participant recruitment based on projected milestones as approved in the Recruitment Milestone Reporting



system (RMR) on 8/4/22. It is expected that **300** of the **300** total projected participants will be recruited by 4/1/25. This tri-yearly recruitment report should be submitted electronically to NIMH after each milestone period of April 1, August 1 and December 1 at: <http://wwwapps.nimh.nih.gov/rmr/displayHome.action>. In the event that actual recruitment falls significantly below projected milestones, NIMH may consider withholding future support and/or negotiating an orderly phase-out of this study. Information regarding the NIMH Policy for the Recruitment of Participants in Clinical Research is available at: <https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-027.html>.

#### **GCP TRAINING:**

NIH expects that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonization (ICH) as stated in NOT-OD-16-148.

#### **CLINICAL TRIAL DISSEMINATION PLAN:**

The clinical trial(s) supported by this award is subject to the plan within the competing application dated 1/6/2022 submitted to NIH and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. The plan states that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and primary summary results reported in ClinicalTrials.gov, not later than one year after the completion date. The reporting of summary results is required by this term of award even if the primary completion date occurs after the period of performance.

#### **CLINICAL TRIAL REQUIREMENTS:**

This award is subject to additional certification requirements with each submission of the Annual, Interim, and Final Research Performance Progress Report (RPPR). The recipient must agree to the following annual certification when submitting each RPPR. By submitting the RPPR, the AOR signifies compliance, as follows:  
In submitting this RPPR, the SO (or PD/PI with delegated authority), certifies to the best of his/her knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials are in compliance with the recipient's plan addressing compliance with the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded in whole or in part under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the completion date, even if the completion date occurs after the period of performance.

#### **DATA AND SAFETY MONITORING: Study ID 406698 and 514346**

This grant is subject to the clinical research policies outlined in NOT-MH-19-027. The recipient will adhere to the NIH (NIH GPS 4.1.15) and NIMH policies (NOT-MH-19-027) including appropriately providing adequate data and safety monitoring and timely reporting of key events as defined in the NIMH Reportable Events Policy. The level and frequency of human subject data and safety monitoring should always be commensurate with the risk and nature of the research.

This grant requires a Data and Safety Monitoring Board (DSMB). The recipient and Principal Investigator(s) should review the NIMH Policy Governing Independent Safety Monitors and Independent Data and Safety Monitoring Boards (cited in NOT-MH-19-027) for details regarding roles, independence, responsibilities, and review reports. Each RPPR submitted must include, in Section **G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS**, copies of all DSMB review determinations for all meetings/reviews conducted during the

reporting period since the last annual award. The RPPR is expected to also include the following information: (1) the dates that the DSMB convened and name(s) of the DSMB members; (2) a summary of key safety indices (e.g., cumulative rates of AEs/SAEs) during the reporting period and cumulatively over the course of the project; and (3) a summary of any recommendations from the DSMB and any actions taken based on the recommendations.

**OTHER SUPPORT TIME COMMITMENT:**

Commitment overlap is not permitted and occurs when an individual's time commitment exceeds 100 percent (i.e., 12 person months), whether or not salary is requested. Therefore, no individual's time commitment may exceed 100 percent. Reductions in NIH support due to commitment overlap must be made in accordance with NIH policy as outlined in the NIH Grants Policy Statement.

**SPREADSHEET SUMMARY**

**AWARD NUMBER:** 7R01MH129175-03

**INSTITUTION:** The Regents of the University of Michigan

Budget	Year 3	Year 4	Year 5
Salaries and Wages	\$47,562	\$48,882	\$45,967
Fringe Benefits	\$16,209	\$16,633	\$15,655
Personnel Costs (Subtotal)	\$63,771	\$65,515	\$61,622
Other			\$10,044
Subawards/Consortium/Contractual Costs	\$571,239	\$550,401	\$505,716
TOTAL FEDERAL DC	\$635,010	\$615,916	\$577,382
TOTAL FEDERAL F&A	\$41,337	\$36,687	\$40,133
TOTAL COST	\$676,347	\$652,603	\$617,515

Facilities and Administrative Costs	Year 3	Year 4	Year 5
F&A Cost Rate 1	56%	56%	56%
F&A Cost Base 1	\$73,816	\$65,513	\$71,666
F&A Costs 1	\$41,337	\$36,687	\$40,133

# EXHIBIT C



Sari Reisner <sreisner@umich.edu>

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## Fwd: Grant Termination Notification [AWD027880]

1 message

**Christy Bohensky** <cjharri@umich.edu>

Fri, Mar 21, 2025 at 12:52 PM

To: Ute Lowery <ulowery@umich.edu>, Sari Reisner <sreisner@umich.edu>, Cathy Howell <cmhowell@umich.edu>

Hi Sari and Cathy,  
I'm so sorry to be sharing unfortunate news. This just came in from NIH for AWD027880. Ute - please process the early termination mod.

Sincerely,  
Christy

### Christy J. Bohensky

Lead Sponsored Project Officer, Award Management

University of Michigan | [Office of Research and Sponsored Projects \(ORSP\)](#)

Phone: 734-763-3800 | Email: [cjharri@umich.edu](mailto:cjharri@umich.edu)

### U-M Personnel:

Help us deliver quality service by providing a PAF/AWD/UFA record number along with the PI's name whenever you contact ORSP. Up-to-date project status information is available in [eRPM](#).

----- Forwarded message -----

From: **Bulls, Michelle G. (NIH/OD) [E]** <[michelle.bulls@nih.gov](mailto:michelle.bulls@nih.gov)>

Date: Fri, Mar 21, 2025 at 12:38 PM

Subject: Grant Termination Notification

To: [cjharri@umich.edu](mailto:cjharri@umich.edu) <[cjharri@umich.edu](mailto:cjharri@umich.edu)>



**National Institutes of Health**  
*Office of Extramural Research*

3/21/2025

Bohensky, Christy

University Of Michigan At Ann Arbor

[cjharri@umich.edu](mailto:cjharri@umich.edu)

Dear Bohensky, Christy:

Effective with the date of this letter, funding for Project Number 7R01MH129175-03 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement, [\[1\]](#) and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination. [\[2\]](#)



The 2024 Policy Statement applies to your project because NIH approved your grant on 8/12/2024, and “obligations generally should be determined by reference to the law in effect when the grants were made.”[3]

The 2024 Policy Statement “includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]” According to the Policy Statement, “NIH may ... terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]” At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination “[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities.”

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although “NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,”[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget’s regulations to *USAspending.gov*. [8]

### Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed  
by Michelle G.  
Bulls -S

Michelle G. Bulls, on behalf of Theresa Jarosik, Chief Grants Management Officer, NIMH  
Director, Office of Policy for Extramural Research Administration  
Office of Extramural Research

[1] <https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] See 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] See 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

# EXHIBIT D



## Recipient Information

### 1. Recipient Name

REGENTS OF THE UNIVERSITY OF  
MICHIGAN  
1109 GEDDES AVE STE 3300  
ANN ARBOR, MI 48109

### 2. Congressional District of Recipient

06

### 3. Payment System Identifier (ID)

1386006309A1

### 4. Employer Identification Number (EIN)

386006309

### 5. Data Universal Numbering System (DUNS)

073133571

### 6. Recipient's Unique Entity Identifier

GNJ7BBP73WE9

### 7. Project Director or Principal Investigator

Sari Reisner, SCD  
Assistant Professor  
sreisner@umich.edu  
734-647-3737

### 8. Authorized Official

Shandra White  
cjharri@umich.edu  
734-763-3800

## Federal Agency Information

### 9. Awarding Agency Contact Information

Candace Renee Owens  
Grants Management Specialist  
NATIONAL INSTITUTE OF MENTAL  
HEALTH  
candace.owens@nih.gov

### 10. Program Official Contact Information

Michael J Stirratt  
Chief, Adherence To Treatment &  
Prevention Program And Hiv Small  
Business Program (sbir/sttr)  
NATIONAL INSTITUTE OF MENTAL  
HEALTH  
stirrattm@mail.nih.gov  
240-627-3875

## Federal Award Information

### 11. Award Number

7R01MH129175-03

### 12. Unique Federal Award Identification Number (FAIN)

R01MH129175

### 13. Statutory Authority

42 USC 241 42 CFR 52

### 14. Federal Award Project Title

Strategies to Prevent HIV Acquisition Among Transgender MSM in the US

### 15. Assistance Listing Number

93.242

### 16. Assistance Listing Program Title

Mental Health Research Grants

### 17. Award Action Type

Change of Recipient Organization (REVISED)

### 18. Is the Award R&D?

Yes

## Summary Federal Award Financial Information

### 19. Budget Period Start Date 08/12/2024 – End Date 03/21/2025

### 20. Total Amount of Federal Funds Obligated by this Action

\$0

20 a. Direct Cost Amount

\$0

20 b. Indirect Cost Amount

\$0

### 21. Authorized Carryover

### 22. Offset

### 23. Total Amount of Federal Funds Obligated this budget period

\$676,347

### 24. Total Approved Cost Sharing or Matching, where applicable

\$0

### 25. Total Federal and Non-Federal Approved this Budget Period

\$676,347

### 26. Project Period Start Date 05/15/2024 – End Date 03/21/2025

### 27. Total Amount of the Federal Award including Approved Cost

\$676,347

Sharing or Matching this Project Period

### 28. Authorized Treatment of Program Income

Additional Costs

### 29. Grants Management Officer - Signature

Theresa R. Jarosik

## 30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.



**RESEARCH**

Department of Health and Human Services  
National Institutes of Health

## Notice of Award



NATIONAL INSTITUTE OF MENTAL HEALTH

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**SECTION I – AWARD DATA – 7R01MH129175-03 REVISED**
**Principal Investigator(s):**

Sari Reisner, SCD

**Award e-mailed to:** swhite-gov@umich.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see “Award Calculation” in Section I and “Terms and Conditions” in Section III) to The Regents of the University of Michigan in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the “Terms and Conditions,” is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as “Research reported in this publication was supported by the National Institute Of Mental Health of the National Institutes of Health under Award Number R01MH129175. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.” Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator’s Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website <http://grants.nih.gov/grants/policy/coi/> for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Theresa R. Jarosik  
Grants Management Officer  
NATIONAL INSTITUTE OF MENTAL HEALTH

Additional information follows

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**Cumulative Award Calculations for this Budget Period (U.S. Dollars)**  
**Salaries and Wages**

\$47,562

Fringe Benefits	\$16,209
Personnel Costs (Subtotal)	\$63,771
Subawards/Consortium/Contractual Costs	\$571,239
 Federal Direct Costs	 \$635,010
Federal F&A Costs	\$41,337
Approved Budget	\$676,347
Total Amount of Federal Funds Authorized (Federal Share)	\$676,347
TOTAL FEDERAL AWARD AMOUNT	\$676,347
 AMOUNT OF THIS ACTION (FEDERAL SHARE)	 \$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	THIS AWARD	CUMULATIVE TOTALS
3	\$676,347	\$676,347

**Fiscal Information:**

**Payment System Identifier:** 1386006309A1  
**Document Number:** RMH129175B  
**PMS Account Type:** P (Subaccount)  
**Fiscal Year:** 2024

IC	CAN	2024
MH	8472592	\$676,347

**NIH Administrative Data:**

**PCC:** 9A-ASGA / **OC:** 41025 / **Released:** 03/24/2025  
**Award Processed:** 03/25/2025 12:23:42 AM

**SECTION II – PAYMENT/HOTLINE INFORMATION – 7R01MH129175-03 REVISED**

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm>

**SECTION III – STANDARD TERMS AND CONDITIONS – 7R01MH129175-03 REVISED**

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- The grant program legislation and program regulation cited in this Notice of Award.
- Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- 45 CFR Part 75.
- National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm> for certain references cited above.)

**Research and Development (R&D):** All awards issued by the National Institutes of Health (NIH) meet the definition of “Research and Development” at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See <http://grants.nih.gov/grants/policy/awardconditions.htm> for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01MH129175. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see <http://grants.nih.gov/grants/policy/awardconditions.htm> for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: <http://publicaccess.nih.gov/>.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of [Public Law 110-85](#)), the “responsible party” must register “applicable clinical trials” on the [ClinicalTrials.gov Protocol Registration System Information Website](#). NIH encourages registration of all trials whether required under the law or not. For more information, see [http://grants.nih.gov/ClinicalTrials\\_fdaaa/](http://grants.nih.gov/ClinicalTrials_fdaaa/).

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: <http://grants.nih.gov/grants/policy/policy.htm#gps>.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, <http://grants.nih.gov/grants/policy/policy.htm#gps>, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: <http://grants.nih.gov/grants/forms.htm>. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at:

[https://grants.nih.gov/grants/rppr/rppr\\_instruction\\_guide.pdf](https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf). Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience.*

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted

electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See <https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html> and <https://www.hhs.gov/>.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html> and <https://www.lep.gov>.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see <http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html>.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see <https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html>. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see <https://grants.nih.gov/grants/policy/harassment.htm>.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see <https://www.hhs.gov/conscience/conscience-protections/index.html> and <https://www.hhs.gov/conscience/religious-freedom/index.html>.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

#### **Treatment of Program Income:**

Additional Costs

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#### **SECTION IV – MH SPECIFIC AWARD CONDITIONS – 7R01MH129175-03 REVISED**

Clinical Trial Indicator: Yes

This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

#### **REVISION - TERMINATION**

It is the policy of NIH not to prioritize research activities based on gender identity no longer effectuates agency priorities. Therefore, this project is terminated. UNIVERSITY OF MICHIGAN may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within 120 days of the end of this grant.



NIH is taking this enforcement action in accordance with [2 C.F.R. § 200.340](#) as implemented in [NIH GPS Section 8.5.2](#). This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

SUPERSEDES NOTICE OF AWARD ISSUED 9/10/2024

**CHANGE OF RECIPIENT:**

This award reflects an approved change of recipient organization for the above-named grant from **Brigham and Women's Hospital** in accordance with the relinquishing statement dated 2/8/24.

**AWARD NOTICE:**

This award has been made in response to the application submitted under the Funding Opportunity Announcement PA-21-268 which can be referenced at: [PA-21-268: Change of Recipient Organization \(Type 7 Parent Clinical Trial Optional\) \(nih.gov\)](#)

**BUDGET ADJUSTMENT:**

Inflationary increases have been discontinued for all competing and non-competing research grant awards (see NOT-OD-12-036). Therefore, this award is issued at the committed level but reflects a total rebudgeting of \$44 direct costs from the Research Assistant's salary (University of Michigan) category/categories to the Other Costs category in Year-05.

**CONSORTIUM / CONTRACTUAL COSTS:**

This award includes funds for consortium activity with:

**Johns Hopkins University  
Drexel University  
Fenway Community Health Center  
Duke University**

Each consortium is to be established and administered in accordance with the NIH Grants Policy Statement (<http://grants.nih.gov/grants/policy/nihgps/index.htm>). No foreign performance site may be added to this project without the written prior approval of the National Institute of Mental Health.

**PARTICIPANT RECRUITMENT - MILESTONES:**

Future NIMH support for this study is contingent upon adequate participant recruitment based on projected milestones as approved in the Recruitment Milestone Reporting system (RMR) on 8/4/22. It is expected that **300** of the **300** total projected participants will be recruited by 4/1/25. This tri-yearly recruitment report should be submitted electronically to NIMH after each milestone period of April 1, August 1 and December 1 at: <http://wwwapps.nimh.nih.gov/rmr/displayHome.action>. In the event that actual recruitment falls significantly below projected milestones, NIMH may consider withholding future support and/or negotiating an orderly phase-out of this study. Information regarding the NIMH Policy for the Recruitment of Participants in Clinical Research is available at: <https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-027.html>.

**GCP TRAINING:**

NIH expects that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonization (ICH) as stated in NOT-OD-16-148.

**CLINICAL TRIAL DISSEMINATION PLAN:**

The clinical trial(s) supported by this award is subject to the plan within the competing application dated 1/6/2022 submitted to NIH and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. The plan states that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and primary summary results reported in ClinicalTrials.gov, not later than one year after the completion date. The reporting of summary results is required by this term of award even if the primary completion date occurs after the period of performance.

**CLINICAL TRIAL REQUIREMENTS:**

This award is subject to additional certification requirements with each submission of the Annual, Interim, and Final Research Performance Progress Report (RPPR). The recipient must agree to the following annual certification when submitting each RPPR. By submitting the RPPR, the AOR signifies compliance, as follows: In submitting this RPPR, the SO (or PD/PI with delegated authority), certifies to the best of his/her knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials are in compliance with the recipient's plan addressing compliance with the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded in whole or in part under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the completion date, even if the completion date occurs after the period of performance.

**DATA AND SAFETY MONITORING: Study ID 406698 and 514346**

This grant is subject to the clinical research policies outlined in NOT-MH-19-027. The recipient will adhere to the NIH (NIH GPS 4.1.15) and NIMH policies (NOT-MH-19-027) including appropriately providing adequate data and safety monitoring and timely reporting of key events as defined in the NIMH Reportable Events Policy. The level and frequency of human subject data and safety monitoring should always be commensurate with the risk and nature of the research.

This grant requires a Data and Safety Monitoring Board (DSMB). The recipient and Principal Investigator(s) should review the NIMH Policy Governing Independent Safety Monitors and Independent Data and Safety Monitoring Boards (cited in NOT-MH-19-027) for details regarding roles, independence, responsibilities, and review reports. Each RPPR submitted must include, in Section **G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS**, copies of all DSMB review determinations for all meetings/reviews conducted during the reporting period since the last annual award. The RPPR is expected to also include the following information: (1) the dates that the DSMB convened and name(s) of the DSMB members; (2) a summary of key safety indices (e.g., cumulative rates of AEs/SAEs) during the reporting period and cumulatively over the course of the project; and (3) a summary of any recommendations from the DSMB and any actions taken based on the recommendations.

**OTHER SUPPORT TIME COMMITMENT:**

Commitment overlap is not permitted and occurs when an individual's time commitment exceeds 100 percent (i.e., 12 person months), whether or not salary is requested. Therefore, no individual's time commitment may exceed 100 percent. Reductions in NIH

support due to commitment overlap must be made in accordance with NIH policy as outlined in the NIH Grants Policy Statement.

**SPREADSHEET SUMMARY****AWARD NUMBER:** 7R01MH129175-03 REVISED**INSTITUTION:** The Regents of the University of Michigan

Budget	Year 3
Salaries and Wages	\$47,562
Fringe Benefits	\$16,209
Personnel Costs (Subtotal)	\$63,771
Subawards/Consortium/Contractual Costs	\$571,239
TOTAL FEDERAL DC	\$635,010
TOTAL FEDERAL F&A	\$41,337
TOTAL COST	\$676,347

Facilities and Administrative Costs	Year 3
F&A Cost Rate 1	56%
F&A Cost Base 1	\$73,816
F&A Costs 1	\$41,337