HIV PREVENTION IN THE UNITED STATES

FEDERAL INVESTMENTS ARE SAVING LIVES AND STRENGTHENING COMMUNITIES



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OVERVIEW WHERE ARE WE HEADED WITH HIV PREVENTION IN THE UNITED STATES?

HIV remains a continuing serious public health threat.

DECLINING INFECTIONS AND DEATHS

The annual number of new HIV infections has declined from a peak of about 130,000 per year in the mid-1980s to 39,782 in 2016. Deaths (all causes) among people diagnosed with HIV have fallen from a high of 50,877 in 1995 to approximately 12,497 in 2015. In 2014, 6,721 deaths were attributed directly to HIV.

HIV TREATMENT PREVENTS HIV TRANSMISSION

Highly effective antiretroviral therapy (ART) suppresses the HIV virus so that people who remain suppressed do not transmit infection sexually to others.

PRE-EXPOSURE PROPHYLAXIS (PREP) PREVENTS HIV ACQUISITION

PrEP is a new, safe and highly effective way for HIV negative individuals to remain uninfected that provides a complementary boost to existing prevention tools.

To end the HIV epidemic, national policy needs to be geared toward ensuring that all people living with HIV know their status and support them to initiate and adhere to an ART regimen so that they maintain viral suppression. The Centers for Disease Control and Prevention (CDC) works with other federal agencies along with state and local health departments and community partners to support multi-faceted prevention programs. The CDC pursues a High Impact Prevention approach that uses combinations of scientifically proven, cost-effective, and scalable interventions targeted to the right populations in the right geographic areas. Essential components of High Impact Prevention are: surveillance and monitoring, integrated HIV prevention and care planning and community engagement, HIV testing and linkage, HIV treatment, biomedical prevention, male and female condoms and access to syringe services programs, and behavioral interventions.

FEDERAL INVESTMENTS MUST SUPPORT CONTINUING INNOVATION TO:

INTEGRATE SURVEILLANCE AND CLINICAL CARE DATA SYSTEMS

INTERRUPT HIV TRANSMISSION WITHIN SEXUAL AND DRUG-USING NETWORKS

IMPROVE THE TAILORING AND INTEGRATION OF SERVICES TO THE HIGHEST NEED COMMUNITIES

DEVELOP LONG-ACTING PREVENTION AND THERAPEUTIC OPTIONS

PROMOTE JURISDICTIONAL PLANS TO END HIV AS A PUBLIC HEALTH THREAT

AT A TIME WHEN MANY POLICY MAKERS ARE ASKING FUNDAMENTAL QUESTIONS ABOUT THE IMPACT OF PUBLIC INVESTMENTS ON VARIOUS **PROGRAMS, THIS ISSUE BRIEF** EXAMINES THE DYNAMIC NATURE OF THE HIV EPIDEMIC IN THE UNITED STATES TO ASSESS WHAT OUR COUNTRY HAS ACCOMPLISHED, WHERE THINGS STAND, AND WHERE CONTINUED FEDERAL LEADERSHIP AND FUNDING ARE NEEDED TO KEEP REDUCING THE SIZE AND SCOPE OF THE HIV EPIDEMIC.

HIV has been with us for more than 35 years. The newness has worn off and since we are accustomed to it being a public health threat, we risk losing sight of how far we have come. HIV remains a significant public health threat in the US. There are 1.1 million Americans living with HIV and more than 35,000 become newly infected each year.¹ By recognizing the progress we have made and by honestly assessing both what is working and what is not, we can keep delivering results for the American people. Our collective success will lead to healthier people, less risk for becoming infected with HIV, and ultimately it will save the Nation money from averting health care expenses that would have been devoted to providing lifelong HIV treatment and services. The lifetime cost to treat one person who becomes infected with HIV is \$466,000.²

HOW FAR HAVE WE COME? PROTECTING THE HEALTH OF THE AMERICAN PEOPLE

THE WORLD FIRST HEARD ABOUT what would later become known as HIV in 1981. The first federal funding for HIV care and prevention—\$8 million—was awarded in 1982; this funding nearly doubled each year over the decade and then increased more gradually.³ The first FDA-approved test for HIV infection became available in 1985.⁴ Since those early days, it is believed that nearly 2 million Americans have become infected with HIV and more than 700,000 Americans have died of AIDS.⁵

HIV went from an unknown condition to a serious and growing public health crisis in a matter of years. By 1990, the Centers for Disease Control and Prevention (CDC) estimated that more than 80,000 people were being infected each year. Retrospective analyses of historical trends indicate that new infections peaked in the mid-1980s at approximately 130,000 infections per year.⁶ Black and Latino Americans have long comprised the majority of HIV diagnoses in the United States. Collectively, they comprise 29% of the population and in 2016 accounted for 69% of new diagnoses. In response, in 1998, the Congress established the Minority AIDS Initiative. This led to a significant infusion of new resources for HIV programs at the CDC and elsewhere, focused on improving HIV-related outcomes for racial and ethnic minority communities disproportionately affected by HIV, with an emphasis on strengthening organizational capacity of minority community-based organizations. The disparities in infection rates have grown since this time, and the Minority AIDS Initiative remains an important component of the federal investment in HIV prevention and care funding.

Stigma experienced by the people most affected by HIV has been part of our country's response to the epidemic from the beginning. Before it was even known to be caused by a virus, it was called GRID, for gay-related immune disorder and the first people recognized as being affected by HIV were known as the "4Hs", for homosexuals, hemophiliacs, Haitians, and heroin users. We have come a long way since then. The landmark civil rights law, the Americans with Disabilities Act of 1990 (ADA), was passed with the HIV crisis as its backdrop. It specifically includes people with HIV under its umbrella of protection. Today, many people are less fearful of HIV. More people recognize that with early and sustained treatment, people can live a full lifespan. Yet, stigma against people living with or perceived to be living with HIV remains rife. People with HIV still face discrimination in the workforce. Subtle biases pervade every day interactions in health care settings, in churches, and in homes. And, criminal laws that may have been intended to counter HIV are now used to prosecute and criminalize people with HIV for living their lives and create real barriers to getting people to take the steps needed to curb HIV transmission, including getting tested for HIV, getting and staying in care, and receiving ongoing treatment.⁷

Early progress involved the discovery of the HIV virus, which allowed for testing of individuals, but also screening of the blood supply. Over 10,000 people with hemophilia contracted HIV from blood transfusions during the early parts of the epidemic,⁸ but since effective screening was put in place, fewer than 10 transmissions from tainted blood or blood products have been documented in the United States over the past 18 years.⁹

As HIV spread, perinatal transmission (from mother to child) increased. In 1991, at the peak of perinatal transmissions, 1,760 babies were born with HIV in the United States each year. Research has documented the effectiveness of antiretroviral therapy (ART) at reducing the likelihood of perinatal HIV transmission to below 1%.¹⁰ For many years, the United States has said

SNAPSHOT OF US HIV EPIDEMIC

NEW HIV DIAGNOSES, BY TRANSMISSION CATEGORY (2016, N=39,782)

GAY AND BISEXUAL MEN REMAIN MOST AFFECTED 3% 6% GAY AND BISEXUAL MEN **PEOPLE WHO** wнo INJECT DRUGS INJECT DRUGS 2,224 DIAGNOSES 39,782 1.201 DIAGNOSES NEW HIV DIAGNOSES IN 2016 GAY AND BISEXUAL MEN **HETEROSEXUALS** 26,570 DIAGNOSES 9,578 DIAGNOSES 67% 24% **NEW DIAGNOSES BY RACE NEW DIAGNOSES BY RACE** BLACK GAY AND BISEXUAL MEN BLACK WOMEN, HETEROSEXUAL CONTACT 10,223 4.189 LATINO GAY AND BISEXUAL MEN BLACK MEN, HETEROSEXUAL CONTACT 1,926 7,425 WHITE WOMEN, HETEROSEXUAL CONTACT WHITE GAY AND BISEXUAL MEN 7,390 1.032 LATINO WOMEN, HETEROSEXUAL CONTACT 1.025

OTHER KEY FACTS

Southern US is disproportionately impacted: Half of all new HIV diagnoses occur in the southern US, even though this region contains only 38% of the US population.

Most diagnoses are in urban areas, yet many infections in the South and Midwest occur in suburban and rural areas: Nationwide, more than 80% of new diagnoses occur in large urban areas, but in the South 23% and in the Midwest 20% occur in suburban and rural areas.

HIV rates are falling in nearly all groups: New HIV infections fell by 18% from 2008 to 2014.

Disparities among gay and bisexual men are large: In 2014, Black and Latino men accounted for 38% and 28% of new HIV infections among these men, respectively. From 2008 to 2014, new infections increased by 20% among Latino gay and bisexual men, and HIV rates continue to rise for gay and bisexual men aged 25-34.

Source: Centers for Disease Control and Prevention. Diagnoses of HIV infection in the United States and dependent areas, 2016. *HIV Surveillance Report*. 2017;28.

that it has virtually eliminated perinatal transmission of HIV, but in a country with nearly four million live births annually, more than 200 babies were born with HIV each year into the 2000s. Recently, however, with expanded access to health care, more emphasis on getting all people with HIV onto ART, and a greater focus on screening pregnant women in the third trimester of pregnancy, there have been further declines in perinatal transmissions. Recent data show that in 2014, only 44 babies were diagnosed with HIV in the United States.¹¹ This is a remarkable, but fragile success. Notably, 80% of babies born with HIV in the United States are Black or Latino. underscoring the need for continued efforts to eliminate racial disparities in perinatal transmissions.¹² As with other HIV prevention activities, stopping such efforts (access to health care, routinely screening for HIV infection, and monitoring each case of perinatal HIV) would cause the numbers of new infections to rebound and racial disparities to remain or even widen.

One of the most striking successes in the fight against HIV has been in reducing the impact of HIV among people who inject drugs. While our public policy goals must remain focused on leading people away from substance abuse and into recovery, harm reduction models have proven their effectiveness. The provision of sterile syringes and related services to people who inject drugs has caused HIV infections among people who inject drugs to fall by 80% since the 1980s.¹³ These services also offer a pathway to treatment and recovery from substance abuse. While the data are clear on their effectiveness, there remain major gaps across the country, in both urban and rural areas, in access to comprehensive community-based programs to address drug use and infectious diseases. This includes a limited capacity to deliver syringe services programs—a deficit that is becoming increasingly apparent with the growing opioid crisis.¹⁴ Moreover, we likely need greater willingness to accept research findings from other countries and our

IN 2014, ONLY 44 BABIES WERE DIAGNOSED WITH HIV IN THE UNITED STATES. THIS IS A REMARKABLE, BUT FRAGILE SUCCESS.

own medical practitioners even when they may be counter-intuitive and potentially controversial. In particular, to further reduce HIV and hepatitis infection rates among people who inject drugs, we need to keep expanding our models for harm reduction. Specifically, we should be open to exploring models for medically-supervised safe injection or other drug consumption called safe consumption services (SCS) that have demonstrated impressive results in Canada and elsewhere at reducing overdose deaths, reducing HIV and Hepatitis C transmission, and creating a new pathway to substance use disorder treatment, including medication-assisted therapy.¹⁵ Several US jurisdictions are considering moving forward to implement safe consumption spaces in their communities, although to date, these efforts have been limited to progressive urban communities, and we have not yet seen similar leadership in rural communities that are being overwhelmed responding to the opioid crisis.¹⁶

WHERE ARE WE NOW? SAVING LIVES AND STRENGTHENING COMMUNITIES

WHEN HIV FIRST APPEARED, highly effective tools to prevent transmission did not exist. Now, we have an array of biomedical and behavioral tools that,

MAJOR GAPS REMAIN IN BOTH URBAN AND RURAL **AREAS IN ACCESS** TO COMPREHENSIVE COMMUNITY-BASED PROGRAMS TO ADDRESS DRUG USE AND INFECTIOUS DISEASES. THIS INCLUDES A I IMITED CAPACITY TO DELIVER SYRINGE SERVICES PROGRAMS-A DEFICIT THAT IS BECOMING **INCREASINGLY APPARENT WITH** THE GROWING OPIOID CRISIS.

together, have the potential to end the HIV epidemic. Our goal is to support early diagnosis of HIV infection and create easy ways to seamlessly link people into systems of care that provide effective ART and other services that promote health. Since most HIV transmissions in the US arise from sexual activity, encouraging regular condom use for a long time was at the center of our prevention strategy. Early on, condoms and behavior change were all that we had. Condoms, when used consistently and correctly, are highly effective. But, decades of experience have shown that many people struggle with consistent condom use for many reasons. Moreover, changing behavior is hard and sustaining behavior change is harder. While these remain essential components of our overall approach to preventing HIV, today we have more highly effective tools to prevent transmission.

The US has been making steady progress at increasing the share of all people with HIV who have been diagnosed. Currently, only one in seven people living with HIV are unaware that they are infected.¹⁷ Most people with HIV, on learning their status, actively work to prevent transmitting infection to others. Therefore, even though they comprise a relatively small share of the HIV population, undiagnosed persons account for an estimated 40% of HIV transmissions.¹⁸ This underscores the importance of continuing to improve diagnosis rates and decrease the length of time from infection to diagnosis.

Once diagnosed, people need individualized and culturally appropriate care to help them remain engaged in care. When people are on an appropriate ART regimen, they become virally suppressed. This means that the amount of HIV virus circulating in their blood falls to extremely low levels. Diagnostic advances mean that we can now measure HIV virus below the former limits of detection. Therefore, federal policymakers have established a standardized definition of fewer that 200 copies/mL of blood to indicate viral suppression.¹⁹

Persons who achieve and maintain viral suppression are called "undetectable." In the last few years, there has been a consumer-led campaign, called U=U, for "undetectable means untransmittable."²⁰ The campaign underscores that a person who maintains viral suppression cannot transmit HIV sexually. Scientific evidence supports this position.^{21, 22, 23}

DURABLE VIRAL SUPPRESSION

AMONG PERSONS AGED 13 YEARS OR OLDER DIAGNOSED THROUGH 2013 AND ALIVE AT THE END OF 2014

SUSTAINED SUPPRESSION TOO LOW IN ALL GROUPS; INEQUITIES PERSIST



Source: Crepaz N, Dong X, Wang X, Hernandez AL, Hall HI. Racial and ethnic disparities in sustained viral suppression and transmission risk potential among persons receiving HIV care—United States, 2014. *MMWR Morb Mortal Wkly Rep.* 2018; 67(4): 113-118. Sustained viral suppression was defined as viral load test results of <200 copies of HIV RNA/mL for all tests in 2014.

The opportunity for public health officials is to diagnose every person with HIV, get them into HIV care, and support them to stay on ART and remain virally suppressed.

Ensuring that all diagnosed people are engaged in care and on ART is a continuing challenge. More work is needed to build systems and approaches for identifying and linking people to HIV care who are not receiving it. We also must build real-time systems for intervening with people with HIV who miss medical appointments or stop filling prescriptions for their ART medications.²⁴ Skipping doses of ART could cause mutations that can lead to resistant strains of HIV virus and will cause viral rebound in which circulating virus rises in the body to the point where individuals can transmit infection to others. Data from the CDC released in 2017 examined durable viral suppression IF ALL PEOPLE LIVING WITH HIV WERE ON ART AND DURABLY VIRALLY SUPPRESSED, HIV TRANSMISSION WOULD END.

in 33 jurisdictions in the US.²⁵ The study found that in 2014, only about half (48%) of people living with diagnosed HIV had durable viral suppression, i.e., all viral load measures were suppressed during the defined time period. Both the CDC and the Health Resources and Services Administration (HRSA, the federal agency that administers the Ryan White HIV/AIDS Program) have been supporting critical efforts to assist state and local health departments to improve their monitoring of engagement in care.

A highly effective regimen also exists for HIV negative individuals at high risk for HIV infection to remain uninfected. Preexposure prophylaxis (PrEP), as used in the US, involves taking a daily pill containing two antiretrovirals (ARVs) to prevent individuals from becoming infected with HIV, whereas the treatment of HIV infection typically involves regimens of three or more ARVs.²⁶ PrEP is safe and numerous well-designed research studies have proven PrEP to be highly effective when adherence is maintained. Indeed, PrEP effectiveness likely exceeds that of condoms and offers an important complementary approach to preventing infection. The US Preventive Services Task Force (USPSTF), which conducts evidence-based reviews of prevention interventions and whose ratings can lead to better and cheaper access to effective interventions, is currently assessing the evidence for PrEP.

PrEP remains a new technology and, as a Nation, we remain in the early phases of implementation. There is currently only one approved agent for PrEP, although it is anticipated that other products may receive FDA approval for use in the near future. There remain guestions over accessibility of PrEP, especially among some of the groups who stand to benefit the most, such as young gay and bisexual men of color and women of color. Barriers to PrEP access include the cost of PrEP and related monitoring services, insurance coverage, the willingness of insurers to provide appropriate and non-discriminatory access to PrEP, and longstanding inequities in the health system that prevent some people of color and other groups from accessing technologies such as PrEP. PrEP currently requires daily pill taking, and some challenges to a daily regimen include potential pill-taking fatigue and potential issues with taking PrEP when not having sex. Although the CDC recommends daily PrEP, research in France shows that among gay and bisexual men taking PrEP before and after sex is as effective as taking PrEP daily and may provide an option for users not to have to take PrEP every day for an extended period of time.27

A related prevention intervention is postexposure prophylaxis (PEP), which involves taking a 28-day course of ART following a potential exposure to HIV (whether through a sexual encounter, drug use, or an occupational exposure). Clinical guidelines require PEP to be initiated within 72 hours of the exposure, but ideally as early as possible. While the application of PEP is relatively small, it can be highly important in specific circumstances. Unfortunately, the uptake of PEP is quite low in the US, suggesting that we are missing opportunities to prevent infection following known exposures to HIV.

All of these biomedical tools highlight the centrality of health care services and the role of insurance and health coverage in preventing HIV infection. The increase in biomedical tools for prevention must lead

BUILDING BLOCKS OF EFFECTIVE PREVENTION SYSTEMS

Surveillance and monitoring: Being able to count and monitor all cases of HIV infection in the US, including new cases, is the central underpinning of our national HIV prevention effort. All 50 states, plus the District of Columbia and US territories, report HIV cases to the CDC.

Integrated HIV prevention and care planning and community engagement:

The allocation of funding at the state and local level must be consistent with the local epidemiology, but since jurisdictions receive separate funding for prevention and care services, it is increasingly important that jurisdictions have a unified plan to utilize all of their HIV prevention and care resources. Additionally, CDC funding supports the engagement of people living with HIV and other critical stakeholders in setting priorities for prevention services within individual jurisdictions. Community and health department partnerships strengthen the effectiveness of federal investments in HIV prevention.

HIV testing and linkage: From 2010 to 2014, the percentage of people with diagnosed HIV infection rose from 82.7% to 85%. This resulted from strategic investments targeting testing within certain communities and partner services that link the sex and drug using partners of diagnosed individuals to HIV screening and other prevention services, along with federal policy changes that have facilitated more routine, population-based screening for HIV in clinical settings.

HIV treatment: People with HIV benefit from the earliest possible initiation of antiretroviral therapy (ART) after diagnosis. We also know that people who achieve and maintain effective viral suppression do not transmit HIV infection to others. Securing stable access to health care and supporting people with HIV to adhere to their ART regimens are perhaps the most important actions that federal policy can support to stop HIV transmission.

Biomedical prevention: Just as HIV treatment reduces the risk of people living with HIV transmitting infection, biomedical prevention tools (pre-exposure prophylaxis or PrEP and post-exposure prophylaxis or PEP) are safe and highly effective options that enable HIV negative individuals to avoid acquiring HIV infection.

Condoms and syringe services: Male and female condoms are safe, effective, and relatively inexpensive options for preventing HIV infection. Even as we scale up treatment and biomedical prevention, retaining easy and free or affordable access to condoms must remain a priority. Further, syringe services programs are a highly effective and relatively low-cost package of services for preventing HIV and hepatitis transmission that also can link persons to substance abuse treatment.

Behavioral interventions: Behavioral interventions take a variety of forms that help to support HIV positive and negative individuals adhere to ART for treatment or prevention and also help individuals to reduce their risk behaviors for acquiring HIV infection.

to new and strengthened interactions and partnerships between health departments and insurers. While the health system can and must play the primary role in financing and delivering biomedical prevention and treatment services, their roles do not diminish the central role of the CDC. health departments, and community-based organizations in advancing prevention. Whereas insurers and health care providers have historically focused on individuallevel outcomes, the CDC, HRSA, health departments, and community-based organizations bring a population-level orientation that is essential to ensuring that biomedical prevention and treatment are maximally effective. Moreover, the CDC and HRSA (and other federal agencies) have essential expertise and resources to assist the health system in improving prevention outcomes. These resources include data sets from the HIV surveillance system and the Medical Monitoring Project (MMP) that is a primary source of nationallyrepresentative data on the clinical care experience of people with HIV. Moreover, the CDC and HRSA have expertise needed by the health system to strengthen the identification and monitoring of diagnosed persons with HIV not in care.

THE INCREASE IN BIOMEDICAL TOOLS FOR PREVENTION MUST LEAD TO NEW AND STRENGTHENED INTERACTIONS AND PARTNERSHIPS BETWEEN HEALTH DEPARTMENTS AND INSURERS.

CDC'S VISION FOR HIGH IMPACT PREVENTION

High Impact Prevention is the current framework that guides federal HIV prevention efforts. It was issued following the release of the National HIV/AIDS Strategy for the United States in 2010 and was developed to align CDC prevention activities with the latest evidence about which interventions are most effective and scalable. Concurrently, the CDC updated its formula for allocating funding to health departments based on persons living with HIV. The adoption of this new formula ensures that funding better matches the burden of the epidemic across the country. Moreover, the funding announcement included new guidance that not only permits health departments to support a range of prevention activities, but also requires them to develop and implement plans that are epidemiologically sound and prioritize core prevention activities.

The most recent funding announcement for health departments was issued in 2017. It provided the latest iteration of CDC's guidance to help health departments strengthen their HIV prevention efforts. One of the most notable changes is that the CDC has taken steps to more closely align its HIV prevention and surveillance programs to foster greater integration of these activities at the state and jurisdictional level and to give health departments greater flexibility in tailoring their programs to meet their needs. Additionally, funding allocations will now be based on prevalence of HIV using current residence, a shift from using prevalence data relying on place of diagnosis.

EVIDENCE OF PROGRESS: For many years, the number of new HIV infections in the US was stable at around 50,000 per year. In early 2017, the CDC published an analysis showing that new infections have declined by 18% between 2008 to 2014.²⁸ Within this overall decline, new infections among people who inject drugs declined

by 56%, highlighting the potential for further declines among drug users if access to syringe services programs could be expanded to more needy communities, as well as a 36% decline among heterosexuals. Of note, while heterosexuals as a whole are at relatively low risk of HIV infection, Black women are at higher risk for infection compared to women of other races. From 2005 to 2014, the number of HIV diagnoses among Black women fell by 42%, although their diagnosis rate is still higher than women of other races and ethnicities.²⁹

These data also highlight areas where more urgent attention is needed. Gay and bisexual men comprise roughly two-thirds of all HIV infections in the US. New infections among Latino gay and bisexual men rose 20% during this period. While new infections are declining among gay and bisexual men overall, they also continue to rise among these men aged 25-34. Moreover, while not included in these data, transgender people, most especially transgender women, are often at extraordinarily high risk for HIV infection.³⁰ Therefore, more effective prevention efforts will only be successful when they effectively and sufficiently reach and meet the needs of these underserved, high-need communities.

POLITICAL AND POLICY CHALLENGES TO EFFECTIVE HIV PREVENTION: The

disparities in HIV prevention rates observed by some communities are among the most stark seen in modern medicine. Sadly, the CDC has estimated that the lifetime risk for Black gay and bisexual men becoming infected with HIV is one in two, an astonishing statistic that demands an urgent and focused response.³¹ Disparities among transgender women are equally or more stark.³² The most effective HIV prevention plan to lower the risk of HIV for all Americans would carefully articulate which services are needed for the general population, while preserving the vast majority of resources and attention to those communities with the greatest needs.33 For example, while the CDC recommends

INEQUITIES IN HIV INFECTION ARE LARGE

GAY AND BISEXUAL MEN ARE NEARLY 90 TIMES MORE LIKELY

TO BECOME INFECTED WITH HIV THAN HETEROSEXUAL MEN.³¹

BLACK WOMEN ARE NEARLY 20 TIMES MORE LIKELY

TO BECOME INFECTED WITH HIV THAN WHITE WOMEN.³¹

BLACK GAY AND BISEXUAL MEN ARE NEARLY 25 TIMES MORE LIKELY

TO BECOME INFECTED WITH HIV THAN BLACK WOMEN.³¹

TRANSGENDER WOMEN ARE NEARLY 50 TIMES MORE LIKELY

TO BE LIVING WITH HIV THAN THE GENERAL ADULT POPULATION.³²

80 PERCENT OF BABIES

BORN WITH HIV IN THE UNITED STATES ARE BLACK OR LATINO.¹²

that all persons are tested for HIV at least once in their lives, more frequent testing is warranted for individuals and groups with greater risk profiles. Focusing more resources on those at highest risk of infection will produce better results.

Unfortunately, the very marginalization and stigmatization faced by these communities often have been the biggest obstacles to effectively serving them. The politically easiest approach to HIV prevention, at all levels of government, typically has been to respond as if the US has a generalized epidemic (wherein the risk for infection is roughly the same across the population), as opposed to several overlapping concentrated epidemics within certain communities. Whether it is focusing on gay and bisexual men who account for roughly two-thirds of new HIV cases, serving transgender people, working with people who use drugs, or taking steps to reduce the large racial disparities and inequities in access to services and prevention outcomes, politics, not science, often has been our biggest obstacle.

A related challenge has been to maintain an appropriate balance to federal-statelocal-community partnerships upon which effective prevention depends. Indigenous community-based organizations that are led by and comprise groups at highest risk of HIV infection have an essential role in providing HIV prevention services. This includes organizations by and for various underserved groups such as people of color, Native Americans, immigrants, transgender people, gay and bisexual men, people who use drugs, and others. State and local health departments know their health systems and the local prevention and health care infrastructure and have the responsibility to both listen to their communities and administer federal grants appropriately to deliver the best prevention outcomes for their jurisdictions. The CDC and other federal agencies, however, are responsible to all of the American people to ensure that public resources are optimized by funding high priority activities or by

preventing the maintenance of the status quo that may further health inequities that federal policy is intended to reduce.

This multi-faceted relationship is always fraught and requires careful tending. Too many federal requirements can stifle effective programs. Likewise, passing a blank check or hoping that states and local iurisdictions overcome the aforementioned political challenges to deliver services to the populations with the greatest needs has proven ineffective. At a time when the science of what works is clearer than ever, there should be an alignment of prevention services nationwide, while retaining flexibility to adapt to variation in local prevention and care delivery systems. For the most part, the tough alliance among governmental and community stakeholders is working, and policy makers need to support efforts to build health department capacity and to enable effective federal oversight, while insisting that the voices of people with HIV and affected communities formally remain part of the policy process.

WHERE ARE WE HEADED? CURBING HIV AS A PUBLIC HEALTH THREAT

AS WE EMBRACE THE IDEA that it is possible to end HIV as a public health threat, it can be helpful to be mindful both of the simplicity of the task and the complexity of achieving it. We need to get all people with HIV diagnosed, into care, and on ART. And, we need to get PrEP and other effective prevention interventions to the people who need them. The CDC has conducted an HIV Prevention Modeling Study to explore the potential payoffs from greater success at strengthening diagnosis and treatment to achieve higher rates of viral suppression, as well as to estimate how much of an impact PrEP could have at reducing HIV transmission. Importantly, their work underscores that all of these interventions are necessary and synergistic. But, their data also show the fundamental

IMAGINING FUTURE PROGRESS

CDC'S HIV PREVENTION MODELING PROJECT (2015-2020)

TESTING, TREATMENT, AND PrEP ARE A POWERFUL COMBINATION

New infections

HIV infections prevented due to expanded testing and treatment

HIV infections prevented due to PrEP (assumes PrEP use among high-risk populations = 40% MSM; 10% PWID; 10% HET)



Source: Centers for Disease Control and Prevention. Four Scenarios of the Potential Impact of Expanded HIV Testing, Treatment and PrEP in the United States, 2015-2020. February 24, 2016. https://www.cdc.gov/nchhstp/newsroom/images/2016/CROI_Four_Scenarios_Graph.jpg.

importance of getting people on ART and supporting viral suppression.

The last mile of a marathon is always the hardest. While we may not yet be in sight of the finish line, it is important to recognize that preventing each new case of HIV infection becomes increasingly difficult. The large disparities in who is benefitting from our prevention efforts expose longstanding political, economic and social barriers. Therefore, policy makers must embrace the reality that the communities who continue to be at highest risk of HIV infection may need the most intensive services and supports WE HAVE THE COMMITMENT AND CAPACITY TO KEEP IMPROVING, BUT THE NATION NEEDS TO CONSCIOUSLY KEEP INVESTING IN INNOVATION.

to enable them to benefit from the tools we have. For example, HIV rates are high and until recently have been increasing rapidly among young Black and gay and bisexual men. Thus, they are a primary focus population for tailored services to facilitate access to health care, as well as prevention services, such as PrEP. Yet, because of a history of marginalization and fewer efforts to even tell these young men that services are available and there are places that want to serve their health care and prevention needs appropriately, more work is needed by service providers to establish trust and prove their commitment to continually respecting them by providing high quality services. We have the commitment and capacity to keep improving, but the Nation needs to consciously keep investing in innovation.

The following five areas are where innovation is most needed and where the field is poised to move us forward:

1) INTEGRATING DATA SYSTEMS TO PROMOTE REAL-TIME INTERVENTION FOR PEOPLE FALLING OUT OF CARE:

Exciting work is being done with CDC and HRSA leadership, and active partnerships with state and local health departments and their clinical and community partners, to integrate HIV surveillance information (counts of new diagnoses and longstanding prevalent cases in a state or jurisdiction), in real time, with clinical care data to intervene with people with HIV who are not actively engaged in care. This is a complex endeavor as state and local laws, health systems, and staffing and technical capacity vary. But successful integration of these disparate data sources enables resources to be precisely focused in communities or neighborhoods where infections are occurring. Further expanding the CDC Data to Care Initiative and using it with HRSA's Ryan White client-level data (a data set that provides critical clinical indicators that can shape policy),³⁴ as well as Medicaid, Medicare, and health plan data, can provide a platform for data integration and more effective public health interventions. The immediate obstacle is providing sufficient resources and technical expertise to uniformly expand the data management capacity within more health departments to achieve this vision.

A notable source of progress has involved CDC's work with HRSA and state and local jurisdictions to facilitate greater integration of HIV prevention and care funds. Whereas in the past, many places operated separate planning bodies for their prevention and care programs, as of January 2018, 85% of states operate integrated prevention and care planning groups.³⁵

2) INTERRUPTING HIV TRANSMISSION WITHIN SEXUAL AND DRUG-USING

NETWORKS: Building on integrated data systems, a related idea is to focus more intensely on interrupting HIV transmission within clusters of people. There is an emerging field of molecular epidemiology that is using phylogenetic analysis to examine mutations in HIV strains to identify transmission patterns within communities and sexual and drug-using networks. The application of these tools offers an exciting way to effectively identify and intervene in places where HIV transmission is occurring.

The use of this technology, however, raises critical and urgent questions around privacy and consumer protection. Many jurisdictions already have criminal laws that are used to prosecute people living with HIV for engaging in sexual activity in circumstances that are considered by many to be both discriminatory and inconsistent with current science. Such laws and prosecutorial practices are believed to undermine public health effectiveness by creating fear for people to be tested for HIV or to initiate HIV treatment. The CDC is funding and providing technical assistance for molecular surveillance and transmission cluster detection and investigation. NIH also has a significant role to play in funding the development and evaluation of this emerging field. Additionally, the CDC and other federal agencies are needed to work with providers, community, law enforcement, and others to develop legal safeguards. An appropriate investment in policy development to protect individuals will be critical to effectively using this technology to more effectively prevent HIV transmission.

3) IMPROVING THE TAILORING OF SERVICES FOR HIGHEST NEED

COMMUNITIES: HIV has never affected every community equally. At a time when our national politics are so turbulent, it is worth noting that many of the populations and communities at the center of national controversy around other policy issues transgender people, gay and bisexual men, immigrants, people who use drugs, and others-comprise those communities at highest risk of HIV infection. Therefore, to maximize the public investment and ensure the biggest payoff for the American people in terms of reducing HIV transmission, efforts must be redoubled to fund and support tailored interventions for specific populations and to address critical nonhealth care needs that may present barriers to care, such as lack of stable housing or food insecurity. Federal policy must continue to support community-based organizations who are often best situated to work in partnership with medical providers to effectively serve the varied needs of these communities.

4) DEVELOPING LONG-ACTING PREVENTION AND THERAPEUTIC

OPTIONS: HIV treatment and PrEP are safe and highly effective. For many reasons, however, not all people are able to adhere to daily pill taking. Research is underway that will likely deliver exciting and innovative new options both for HIV treatment and prevention that do not require daily pill taking. Developing such complex and ground-breaking technology requires much more than testing new drug products and getting them approved by the FDA. Significant work is needed to decide who should be prioritized for access to such products and to assess and monitor the impact of less frequent dosing on adherence to therapy. These new products have the potential to significantly increase viral suppression rates in communities of people at high risk for HIV infection. Federal investment in epidemiological and social and behavioral research, beyond strictly assessing safety and efficacy, is critically important.

5) PROMOTING JURISDICTIONAL PLANS TO END HIV AS A PUBLIC HEALTH

THREAT: Following the release of the National HIV/AIDS Strategy for the United States (released in 2010 and revised in 2015), an increasing focus has been placed on the importance of state and local leadership to actually implement the critical action steps called for by the Strategy. New York State's Plan to End AIDS is a prominent example of state-level leadership and at least 9 US cities have ioined the UNAIDS and IAPAC Fast-Track Cities Initiative to work toward the goals of 90% of people living with HIV (PLHIV) knowing their HIV status, 90% of PLHIV who know their HIV-positive status on antiretroviral therapy (ART), 90% of PLHIV on ART achieving viral suppression, and zero stigma and discrimination by 2020. These efforts need to be supported and greatly expanded to all highly burdened jurisdictions in the United States.

CONCLUSION

PREVENTING HIV INFECTION IS HARD.

Nonetheless, a fair assessment of our national success at HIV prevention should be applauded. There is still much more hard work to be done and a significant road ahead as we strive to get to no new HIV infections. For a country that often views its national attention span as fleeting, even as HIV has fallen from the front-pages of our newspapers, the steady investment in HIV prevention through the CDC and other federal agencies has been and remains critically important.

Despite all of our pressing national challenges, investing in ending the HIV epidemic remains strongly in the national interest. The record of success and the vision for future progress have us poised for exciting innovations that hold the potential to further reduce the number of new HIV infections and therein strengthen communities, states, and the Nation.

ENDNOTES

- HIV in the United States: At a Glance. Centers for Disease Control and Prevention website. https:// www.cdc.gov/hiv/statistics/overview/ataglance. html. Accessed January 31, 2018.
- Farnham PG, Gopalappa C, Sansom SL, et al. Updates of lifetime costs of care and quality-of-life estimates for HIV-infected persons in the United States: Late versus early diagnosis and entry into care. J Acquir Immune Defic Syndr. 2013;64(2):183-189. Estimates have been updated to 2016 dollars.
- Summers T, Kates J. Trends in U.S. Government Funding for HIV/AIDS Fiscal Years 1981 to 2004. March 2014. https://kaiserfamilyfoundation.files. wordpress.com/2013/01/issue-brief-trends-in-u-sgovernment-funding-for-hiv-aids-fiscal-years-1981to-2004.pdf. Accessed September 19, 2017.
- Kaiser Family Foundation. Global HIV/AIDS Timeline. November 29, 2016. http://www.kff.org/global-health-policy/timeline/global-hivaids-timeline/. Accessed September 19, 2017.
- Kaiser Family Foundation. The HIV/AIDS Epidemic in the United States: The Basics. February 2, 2017. http://www.kff.org/hivaids/fact-sheet/thehivaids-epidemic-in-the-united-states-the-basics/. Accessed September 19, 2017.
- Estimates of New HIV Infections in the United States. Centers for Disease Control and Prevention Fact Sheet. https://www.cdc.gov/nchhstp/ newsroom/docs/fact-sheet-on-hiv-estimates.pdf. Accessed September 19, 2017.
- Lehman JS, Carr MH, Nichol AJ. Prevalence and public health implications of state laws that criminalize potential HIV exposure in the United States. AIDS Behav. 2014;18(6):997-1006.
- Cichocki M. Hemophilia and HIV: What is Hemophilia and How Does it Intersect with HIV. September 7, 2016. https://www.verywell.com/hemophilia-andhiv-48852. Accessed September 19, 2017.
- "Hawaiian man says he got HIV from blood transfusion during bypass survey." New York Daily News. February 4, 2016. http://www.nydailynews.com/ news/national/hawaiian-man-hiv-blood-transfusion-article-1.2520226. Accessed September 19, 2017.
- HIV Among Pregnant Women, Infants, and Children. Centers for Disease Control and Prevention website. https://www.cdc.gov/hiv/group/gender/pregnant women/index.html. Accessed January 31, 2018.
- 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, 2015. *HIV Surveillance Supplemental Report*. 2017;22(2):49. This is an unadjusted number of perinatal transmission case reports from 2014 and may be adjusted upward by CDC as it analyzes the data and accounts for underreporting.
- 12. Ibid.

- Centers for Disease Control and Prevention. HIV-associated behaviors among injecting-drug users—23 Cities, United States, May 2005-February 2006. MMWR Morb Mortal Wkly Rep. 2009;58:329-332.
- 14. Syringe Services Programs and the Opioid Epidemic. amfAR website. http://www.amfar.org/ssp-opioid-epidemic/. Published November 3, 2017. Accessed January 31, 2017. 93% of counties at high risk for an outbreak of HIV or hepatitis C among people who inject drugs do not have any syringe services programs.
- Kerr T, Mitra S, Kennedy MC, McNeil R. Supervised injection facilities in Canada: Past, present, and future. *Harm Reduct* J. 2017;14(1):28.
- Hodel D. The Case for Supervised Consumption Services. June 2017. http://opioid.amfar.org/amfAR%20 Supervised%20Consumption%20Services.pdf. Accessed January 31, 2018.
- HIV in the United States: At a Glance. Centers for Disease Control and Prevention website. https:// www.cdc.gov/hiv/statistics/overview/ataglance. html. Accessed January 31, 2018.
- Dailey AF, Hoots BE, Hall I, et al. Vital signs: Human immunodeficiency virus testing and diagnosis delays – United States. *MMWR Morb Mortal Wkly Rep.* 2017;66(47):1300-1306.
- Wolitski R. On track but continued progress needed on HIV viral suppression to achieve our nation's goal. HIV.gov Blog. https://www.hiv.gov/blog/trackcontinued-progress-needed-hiv-viral-suppressionachieve-our-nation-s-goal. Published November 15, 2017. Accessed January 31, 2018.
- Prevention Access Campaign. https://www. preventionaccess.org/undetectable. Accessed January 31. 2018.
- De Graff M. CDC declares that people on HIV medication cannot transmit the virus to sexual partners. *Daily Mail*. October 5, 2017. http://www.dailymail. co.uk/health/article-4953600/CDC-says-people-HIV-meds-transmit-virus.html. Accessed January 31, 2018.
- McCray E, Mermin J. Dear colleague letter. Centers for Disease Control and Prevention. September 27, 2017. https://www.cdc.gov/hiv/library/dcl/ dcl/092717.html. Accessed January 31, 2018.
- Fauci AS, Marston HD. Ending the HIV-AIDS Pandemic - Follow the Science. N Engl J Med. 2015;373(23):2197-2199.
- 24. Mugavero MJ, Westfall AO, Cole SR, et al. Beyond core indicators of retention in HIV care: Missed clinic visits are independently associated with all-cause mortality. *Clin Infect Dis.* 2014;59(10):1471-1479.
- 25. Crepaz N, Tang T, Marks G, Hall I. Viral-load dynamics among persons with diagnosed HIV: United States, 2014. Paper presented at: Conference on Retroviruses and Opportunistic Infections 2017; February 13-16, 2017; Seattle. Abstract 31.

- 26. US Public Health Service. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States - 2014: A Clinical Practice Guideline. https:// www.cdc.gov/hiv/pdf/prepguidelines2014.pdf. Accessed September 19, 2017.
- **27.** Molina JM, Capitant C, Spire B, et al. On-demand preexposure prophylaxis in men at high risk for HIV-1 infection. *N Engl J Med.* 2015;373(23):2237-2246.
- HIV Incidence: Estimated Annual Infections in the U.S., 2008-2014. Centers for Disease Control and Prevention Fact Sheet. https://www.cdc.gov/nchhstp/ newsroom/docs/factsheets/HIV-Incidence-Fact-Sheet_508.pdf. Accessed September 19, 2017.
- 29. HIV Among African Americans. Centers for Disease Control and Prevention website. https://www.cdc. gov/hiv/group/racialethnic/africanamericans/index. html. Accessed January 31, 2017.
- Poteat T, Malik M, Scheim A, Elliott A. HIV prevention among transgender populations: Knowledge gaps and evidence for action. *Curr HIV/AIDS Rep.* 2017;14(4):141-152.
- Hess KL, Hu X, Lansky A, Mermin J, Hall HI. Lifetime risk of a diagnosis of HIV infection in the United States. *Ann Epidemiol.* 2017;27(4):238-243.
- 32. Baral SD, Poteat T, Strömdahl S, Wirtz AL, Guadamuz TE, Beyrer C. Worldwide burden of HIV in transgender women: A systematic review and meta-analysis. *Lancet Infect Dis.* 2013;13(3):214-222.
- Hess KL, Hu X, Lansky A, Mermin J, Hildegard I. Lifetime risk of a diagnosis of HIV infection in the United States. Ann Epidemiol. 2017;27(4):238-243.
- 34. Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2015. December 2016. https://hab.hrsa.gov/ sites/default/files/hab/data/datareports/2015 rwhapdatareport.pdf. Accessed September 19, 2017.
- **35.** HIV planning group models noted by Natalie Cramer, NASTAD (email communication, January 2018).



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