

TOWARD COMPREHENSIVE
HIV PREVENTION
SERVICE DELIVERY IN
THE UNITED STATES

AN ACTION PLAN

JUNE 2015

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About TAG and amfAR

amfAR, The Foundation for AIDS Research, is one of the world's leading nonprofit organizations dedicated to the support of AIDS research, HIV prevention, treatment education, and the advocacy of sound AIDS-related public policy. Since 1985, amfAR has invested \$415 million in its programs and has awarded more than 3,300 grants to research teams worldwide.

Treatment Action Group (TAG) is an independent AIDS research and policy think tank fighting for better treatment, a vaccine, and a cure for AIDS. TAG works to ensure that all people with HIV receive lifesaving treatment, care, and information. We are science-based treatment activists working to expand and accelerate vital research and effective community engagement with research and policy institutions. TAG catalyzes open collective action by all affected communities, scientists, and policy makers to end AIDS.

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Introduction

An objective of the National HIV/AIDS Strategy (NHAS), released by the White House in July 2010, is to lower the annual number of new infections in the United States by 25 percent by the end of 2015. Yet it is unclear if we will succeed in meeting this arguably unambitious target: 36,400 estimated new infections in 2015, compared with the 48,600 new infections estimated for the baseline year of 2006.¹

Our collective national prevention efforts have been unable to rein in an epidemic among gay and bisexual men and transgender women that, according to many indicators, is out of control.^{2,3} Available statistics are testaments not only to the severe shortcomings of U.S. prevention efforts, but also to the experience of individuals in vulnerable communities who live with the knowledge that many of their peers have a stigmatized and potentially lethal disease that is entirely preventable.

At the same time, there has never been greater potential for preventing new infections. The advent of biomedical tools to sharply curtail new HIV infection rates, along with emerging possibilities to more fully integrate HIV prevention services into systems of comprehensive primary care through provisions of the Affordable Care Act (ACA), presents tremendous opportunities to curtail new HIV infections, both generally and in vulnerable populations. The simultaneous arrival of new prevention science and a generally more favorable policy climate brings us to a long-awaited watershed—a time of unprecedented progress in national HIV prevention efforts.

There is, however, a great deal of work to be done. After nearly three decades of antiretroviral therapy (ART) development and refinement—including the emergence of data demonstrating that ART can nearly eliminate the risk of secondary transmission of the virus—less than half of all U.S. residents with the virus are fully engaged in clinical care, and only one-third have suppressed viral loads.⁴

While an effective HIV care continuum has been developed to help identify gaps in the HIV response for people living with HIV, there are no similar population-based metrics or best practices in place to ensure that people who are HIV-negative—particularly those most vulnerable to the infection—remain so. Despite scientific evidence and expert opinion that pre-exposure prophylaxis (PrEP) can substantially reduce the risk of primary infection among vulnerable HIV-negative individuals, PrEP remains underpromoted and underused. Wraparound health strategies to minimize health disparities among key U.S. populations have developed as a result of the ACA; however, PrEP continues to be largely disconnected from these efforts. In states that continue to oppose Medicaid expansion, the challenges of receiving comprehensive preventive care are even more significant.

Treatment Action Group (TAG) and amfAR, The Foundation for AIDS Research, convened two consultations in 2014 to explore research and implementation priorities to expand comprehensive HIV prevention service delivery for vulnerable HIV-negative individuals and populations. In May, nearly 40 representatives from government, academia, service agencies, and affected communities gathered to review the current prevention tools for HIV-negative people and to identify priorities for successful access, uptake, and use under the ACA. A larger consultation of 60 leaders, nearly half representing vulnerable populations and subpopulations, focused on specific challenges and opportunities and worked to more clearly define a community-based research and implementation agenda.

This action plan, based primarily on the proceedings of the two consultations, seeks to define a community-focused national strategy for integrating historically separate HIV prevention interventions and services—many with established positive effects on individual health outcomes—into needs-driven components of population-based care and support programs. Central to this effort has been the ongoing development of a comprehensive HIV prevention service delivery continuum to help galvanize stakeholders in much the same way that the continuum of care has done. Additionally, numerous research and implementation priorities of this plan were identified and discussed by consultation participants and are reviewed here.

THE PREVENTION TOOLBOX

Treatment as prevention (TasP)—maximizing viral-load suppression rates among people living with HIV to reduce further transmission of the virus—is now a primary focus of federal HIV prevention efforts and the cornerstone of the High-Impact Prevention (HIP) initiative at the U.S. Centers for Disease Control and Prevention (CDC). TasP’s effectiveness in reducing the number of new infections in the real world, at least in some regions, has been documented.^{5,6} However, to what extent TasP will reduce HIV incidence in the United States, particularly in heavily affected communities, is not clear.

Major reductions in funding for HIV prevention efforts directed toward vulnerable HIV-negative individuals, in favor of TasP strategies, are problematic. With the advent of PrEP, an effective solution is available for vulnerable people who have not benefited from condoms or behavioral interventions. In the absence of national budget increases for HIV prevention, and with the bulk of existing funds going to HIV care continuum efforts, we are significantly underinvesting in effective prevention options for vulnerable populations. On a population level, it will take several years for TasP alone to end the epidemic. Understanding how to better balance our investments in prevention for people with and without HIV will allow us to greatly improve the lives of people right now while also hastening an end to the epidemic.

The services and interventions available to vulnerable individuals and populations are varied, notably in their efficacy and acceptability. Yet even some for which the supportive evidence base is, at best, mixed, have the potential to be reevaluated and redeveloped as components of strategies to improve health outcomes in vulnerable populations. The following sections review essential interventions that not only have been shown to potentially lower HIV transmission but also have the potential to reduce other morbidities and disparities among vulnerable individuals, as part of packages of comprehensive primary and supportive care prevention services.

HIV Testing and Counseling

Testing and counseling have long been considered essential components of the national HIV response. While testing is critical, findings from a key 2013 study have called into question the added effectiveness of screening-based behavioral counseling on HIV acquisition.⁷

In light of evolved public health initiatives—examples include CDC recommendations for regular testing of high-risk individuals, access to PrEP and laboratory follow-up through licensed health care providers, and the ACA mandate that all individuals have health insurance coverage and be engaged in some form of comprehensive care—a more structural, and less behavioral, approach to counseling may be warranted.

HIV testing is a critical point of contact to link individuals to health insurance and culturally competent care and serves as a gateway to other prevention interventions, including PrEP. In turn, new approaches to pre- and post-test counseling that include referrals (either passive or active) to health insurance and comprehensive care should be explored and validated.

Educational and Behavioral Interventions

A substantial body of literature exists describing the methodology and outcomes of educational and behavioral interventions to minimize sexual and drug-use behaviors that increase risk of HIV transmission. Though some data, including those from the group-based Many Men, Many Voices (3MV) program, have been encouraging,⁸ other data supporting the efficacy of these educational and behavioral interventions are inconclusive.

However, all interventions, including biomedical methods, require some sort of behavioral modification in order to be successful, particularly in terms of adherence. Drawing from the substantial existing literature on behavioral interventions, newer educational and behavioral programs that introduce health care engagement and biomedical prevention strategies to vulnerable populations and focus more on assisting people in identifying and overcoming barriers to successful use of comprehensive prevention services should be developed and assessed in an implementation context.

Syringe-Exchange Programs

Evidence-based syringe-exchange programs (SEPs) have long been considered cost-effective in reducing transmission via injection drug use.^{9,10,11}

Moving forward, SEPs will continue to be critical in preventing the transmission of HIV and other bloodborne pathogens such as hepatitis C virus. Considering that injection drug use may be tied to greater sexual transmission risk of HIV as well as several other mental and physical health problems, SEPs have the potential to serve as gateways to sexual health services, primary care, and new biomedical interventions.¹²

Drug and Alcohol Use Counseling

Substance use has been associated with HIV incidence, including among men who have sex with men. Alcohol, erectile dysfunction drugs, amyl nitrates, and methamphetamines have all been linked to higher self-reported risk behaviors in this population.^{13,14,15} Harm reduction can be effective, but the results are inconsistent or not durable over time.¹⁶ Additionally, each substance has different effects and, as a result, may require a tailored intervention.

Addressing substance use in conjunction with interventions to minimize other health risks may have an important synergistic effect on reducing an individual's vulnerability to infection as well as improving his or her overall quality of life.¹⁷ Determining comprehensive prevention programming that addresses needs around substance and alcohol use for all key populations is essential.

Prevention and Treatment of Sexually Transmitted Infections

The presence of sexually transmitted infections (STIs) has been shown to increase the risk of acquiring HIV; however, the impact of screening and treatment of STIs on rates of new HIV infection is inconclusive.^{18,19,20,21}

STI testing and screening will be natural additions to comprehensive prevention services that require linkage to medical care such as PrEP and post-exposure prophylaxis (PEP). Conversely, programs providing STI testing, such as reproductive health clinics, will continue to be gateways to HIV prevention services for highly vulnerable individuals.

Housing, Case Management, and Ancillary Services

Providing social and structural support for people living with HIV has been a central component of many treatment and care programs. This has included case management, peer navigation, legal assistance, nutritional support, and housing assistance (including subsidies) to support clinical care engagement and treatment adherence.

Case management may be beneficial for many mental and physical health conditions; for people living with HIV, case management has been associated with improved linkage to and use of care as well as increased use of treatment.^{22,23} Case management may also prove to be an important component of comprehensive HIV prevention services, ensuring that people vulnerable to infection are adequately linked to affordable health

insurance, culturally competent care, and ancillary services. Additionally, housing is a particularly important area of focus for improving HIV prevention outcomes. A 2005 study found that improved access to stable housing greatly decreased HIV-related risk behaviors.²⁴

Evidence to support the role of case management, housing, and other ancillary services, including cost-effectiveness analyses to confirm the utility and value of these programs, is essential and should be a research priority.

Condoms

Male and female condoms are the mainstay of HIV prevention. They are effective against sexual transmission of the virus, along with various other STIs, provided that they are used correctly and consistently.

Male and female condoms will remain an important component of HIV and STI prevention strategies; however, there are strong indications that prevention programs focused on condom use will not be effective for many people, particularly in communities with high HIV prevalence.

Post-exposure Prophylaxis (PEP)

Since 1988, antiretroviral medications have been prescribed to prevent infection following possible occupational—and, more recently, non-occupational—exposure to HIV. Supporting data are primarily from case-controlled studies;^{25,26} placebo-controlled trials have long been considered an unethical method for evaluating PEP's efficacy.

PEP, however, remains very much underutilized. Greater use and, with it, meaningful population-level outcomes will require overcoming a number of barriers to timely access, including low levels of community and health care provider knowledge, barriers related to cost and coverage, and stigmatization of HIV-related behaviors and medications. Support related to adherence and completion of treatment must also continue to improve, possibly through innovative use of new technologies.

Pre-exposure Prophylaxis (PrEP)

The evaluation and ultimate approval of co-formulated tenofovir DF and emtricitabine (Truvada) as PrEP has generated a lot of hope for those working in HIV prevention.^{27,28,29,30} Despite highly variable intention-to-treat results in clinical trials completed to date,^{35,31,32,33,34,35,36} numerous analyses confirm that it is highly efficacious on an individual level if it is used at least four times a week or on a strict as-needed dosing schedule.

However, PrEP's population-level potential—specifically, its ability to reduce new infections in key populations, in tandem with TasP and other prevention efforts—will require that a substantial number of barriers to effective uptake and use be addressed. These include, but are not limited to:

- variable levels of awareness and knowledge across key populations;
- limited patient risk perception;
- concerns about side effects and drug resistance;
- unfamiliarity, unwillingness, and limited prescribing/follow-up resources among health care providers;
- medication and follow-up care affordability;
- poor coordination between social and behavioral service providers and licensed prescribers;
- medication and follow-up adherence challenges; and
- various social obstacles, notably stigma.

Adherence and Technology-Based Interventions

Outside of a vaccine, adherence will always remain a challenge with any HIV prevention intervention. Even promising PrEP modalities in the development pipeline, such as long-acting injectable drug formulations, will require individuals to get health care services consistently every three to four months. Therefore, interventions to improve adherence to prevention are critical. While systematic analyses of adherence to medications for other health conditions have found successful interventions, they have also shown that HIV is still different from, and trickier than, other diseases.³⁷ Still, the development of effective adherence interventions will be necessary for successful implementation of many new tools.

A great deal of literature exists on adherence interventions within HIV and broader health care research, which should inform the creation of new interventions. In terms of PrEP, Next Step Counseling, an adherence intervention used in the iPrEx trial, could be a useful technique to evaluate in other settings and with other populations.³⁸ The use of text message reminders has been found to be effective with ART adherence, and the ongoing CCTG 595 study is currently evaluating the effectiveness of text messaging for men who have sex with men and are taking PrEP.³⁹

Considering PrEP and PEP specifically, feedback from several focus groups and surveys of potential users of these interventions indicates that many of the best interventions for adherence will be structural.⁴⁰ In particular, simplifying paths to access and reducing cost will be crucial. For individuals, technology platforms—such as Medication Event Monitoring System caps, text messaging, and interactive apps—may play a uniquely valuable role in adherence interventions due to affordability and easy scalability, but are unlikely to be able to replace face-to-face interventions and case management.

BARRIERS TO AND OPPORTUNITIES FOR HIV PREVENTION SERVICE ENGAGEMENT

Efforts to scale up HIV prevention services, whether used alone, in combination with, or as a component of comprehensive primary, sexual health, or family planning care, require a nuanced understanding of the social, structural, and behavioral barriers to uptake that exist in the most marginalized and, by extension, HIV-affected populations in the United States.

Descriptions of key populations outlined here do not necessarily reflect the demographic diversity within each population. There are also many individuals with overlapping marginalized identities who experience barriers characteristic of several different communities.

Cross-population Barriers

A number of barriers highlighted are relevant for several key populations.

Access to Appropriately Trained, Culturally Competent, and Sex-Positive Service Providers

There are indications that many health care workers are not prepared to address HIV testing and comprehensive prevention.^{41,42} Many medical professionals are also unprepared to discuss human sexuality with patients.^{43,44} For members of LGBT communities, effective engagement with health care providers may be even more unlikely.

Mistreatment, particularly of transgender men and women, and racial discrimination are other barriers to overcome.^{45,46}

Systems Navigation Complexities

Navigating complex systems can hinder effective use of comprehensive HIV prevention services. Different prevention services are often not housed within a single center, with many AIDS service organizations (ASOs) and community-based organizations (CBOs) unable to provide services (such as PrEP and PEP) that require a clinician with prescribing privileges. Even within a single establishment, not all services may be available at the same time; a follow-up appointment to get PrEP may not happen on the same day as an HIV test, with little linkage coordination available to streamline this process. Costs associated with PrEP and PEP care and follow-up, along with paperwork and delays associated with insurance coverage and medication assistance programs, are also deterrents when systems of coverage are overly complex.⁴⁷

Promoting Pleasure and Health Versus Disease Avoidance

A singular focus on avoiding HIV by health care providers and public health officials is a barrier for effectively engaging many vulnerable individuals in prevention conversations. Individuals who are vulnerable to HIV often have many different health-related goals and priorities, and HIV may or may not be a top concern. For this reason, attempting to address HIV without addressing the whole person may be less effective.

Additionally, discussing sex only within the context of disease—as opposed to wellness, intimacy, and pleasure—may not be the most effective way to engage vulnerable individuals in discussions of comprehensive prevention.

Lack of Comprehensive Sex Education and Community HIV Knowledge

Schools have direct contact with millions of students for at least 13 critical years of their social, physical, and intellectual development and serve as a key setting in which students' behaviors and ideas are shaped. And despite data indicating that roughly one-quarter of HIV infections are occurring in young U.S. residents under the age of 24, sexual health (including LGBT topics) and HIV prevention education is far from standard or comprehensive.^{48,49,50}

Population Barriers

Blacks/African Americans

Black communities continue to be disproportionately affected by HIV.⁵¹ A higher background prevalence of HIV, including untreated infection, is a major factor.⁵² Thus, increasing viral suppression among black persons living with HIV is a critical component of improving HIV prevention outcomes in the United States.

Resource scarcity is a major barrier to comprehensive prevention for black communities. African Americans are more likely to experience poverty and housing instability.⁵³ Many have routinely had lower rates of health insurance, which greatly complicates access to PrEP, PEP, STI screening and testing, and other health care services.⁵⁴ With so many black individuals living in the South and in states that are currently not expanding Medicaid, the ACA has had a limited effect on addressing this barrier. Structural unemployment and limited availability of providers in black communities also lead to resource scarcity and its challenges relating to fuller access to PrEP, PEP, and other health care services.

A history of discrimination within health care systems may also pose a major barrier to black men who have sex with men engaging with their clinicians.⁵⁵ Community-based prevention services are also not necessarily accessible to black Americans. A recent systematic review of funded primary HIV prevention interventions for youth from 1991 to 2010 found that none focused specifically on young black gay men.⁵⁶ While other HIV prevention programs exist, men of color who are gay, bisexual, or other men who have sex with men are frequently misrepresented in larger discussions of HIV prevention.

Figure 1. Diagnoses of HIV Infection among Men Who Have Sex with Men Ages 13–24 Years, by Race/Ethnicity, 2009–2013—United States and 6 Dependent Areas

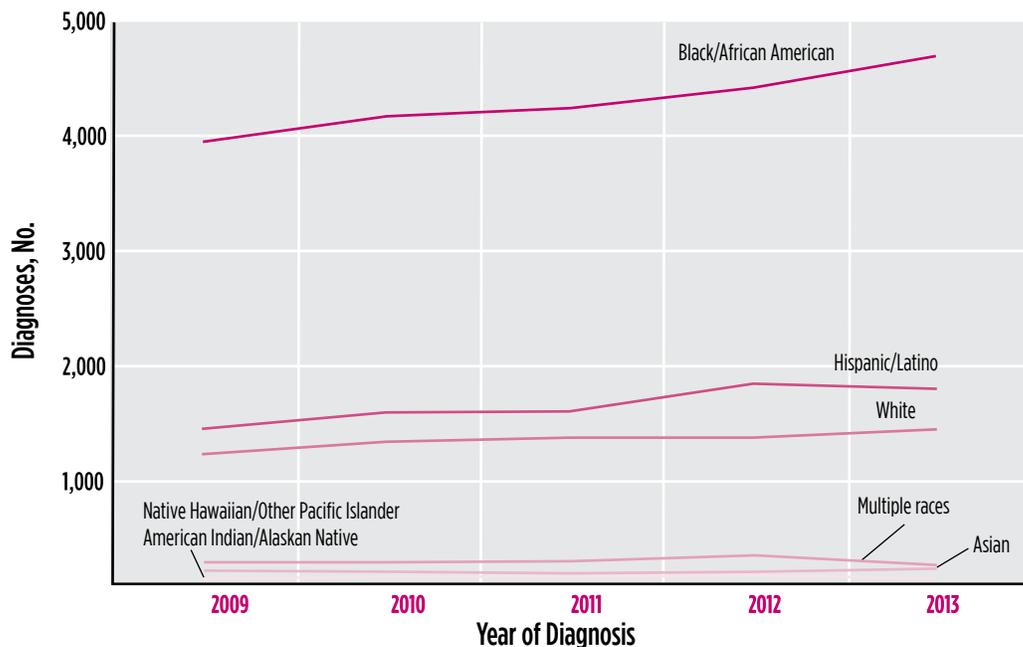
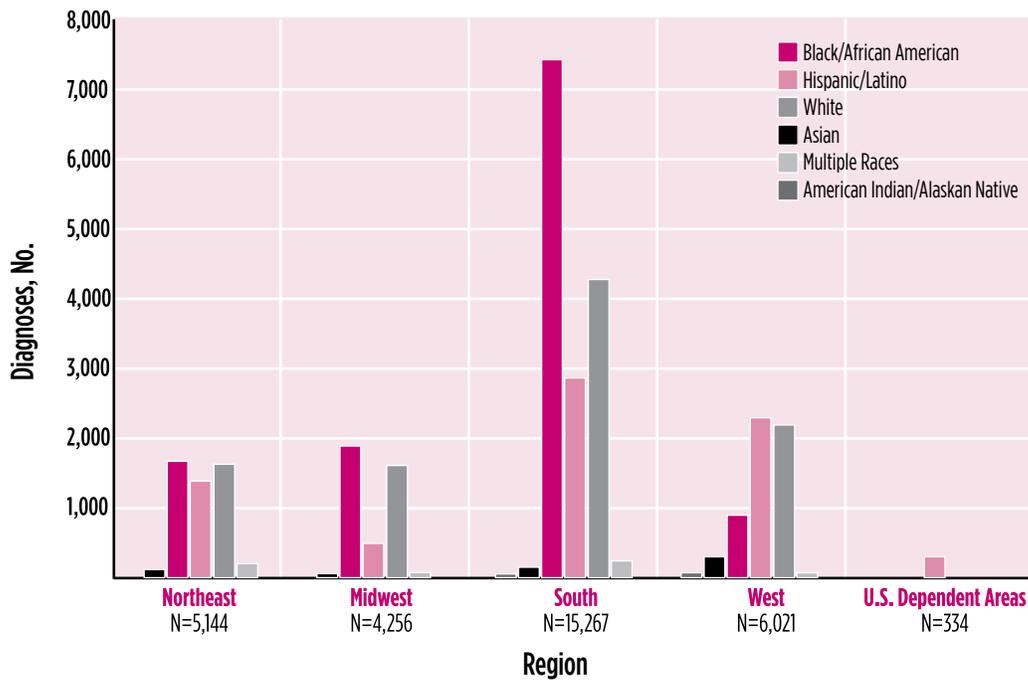


Figure 2. Diagnoses of HIV Infection among Men Who Have Sex with Men, by Region of Residence and Race/Ethnicity, 2013—United States and 6 Dependent Areas



Adapted from: Centers for Disease Control and Prevention (U.S.). HIV surveillance—men who have sex with men. Atlanta: Centers for Disease Control and Prevention; 2013.

Hispanic/Latino and Latina Populations

Hispanics/Latinos and Latinas are also disproportionately affected by the HIV epidemic in the United States.^{57,58} Late diagnosis and linkage to care are a major problem, with HIV/AIDS being the eighth leading cause of death for Hispanics/Latinos and Latinas between the ages of 25 and 34 and the ninth leading cause of death for those ages 35 to 44.⁵⁹ As in black communities, high background prevalence of HIV and community viral load present enormous challenges for prevention efforts.

Inadequate attention to language and cultural differences has limited the effect of national prevention efforts for Hispanic/Latino and Latina communities. Best practices for providing comprehensive services often differ according to country of origin, yet these nuances are inadequately addressed in prevention campaigns. Greater work must be done to change HIV-related stigmas in Hispanic/Latino and Latina communities, including homophobia and transphobia.

Figure 3. Lifetime Risk of HIV Diagnosis by Race

	Men	Men Who Have Sex with Men	Non-transgender Women	Transgender Women
Black/African American	1 in 16	1 in 3	1 in 30	1 in 2
Hispanic/Latino/Latina	1 in 35	1 in 5	1 in 114	1 in 3-6
White	1 in 104	1 in 6	1 in 588	1 in 6

Adapted from: Millett G. Defining HIV prevention research and policy priorities for at risk individuals in the U.S. Paper presented at: Minding the Gaps consultation; 2014 December 11; Washington, D.C.

Undocumented Immigrants

Undocumented immigrants—particularly those who are gay, bisexual, or other men who have sex with men; injection drug users; and transgender women—are frequently underrepresented in epidemiological data and federal HIV prevention planning efforts and excluded from health programs expanded by the ACA.

Lack of health insurance and fear of deportation greatly limit access to prevention services that require a physician. Systemic racism, xenophobia, competing priorities, and significant language and cultural barriers may also deter immigrants from seeking and obtaining services.

There are key opportunities within undocumented communities. Frequently ignored and poorly treated, these communities need and deserve well-planned, culturally respectful messaging. Additionally, huge networks of activists have formed as part of the Dreamer movement, with many LGBT immigrants at the forefront. Learning how to connect with these networks around health and wellness, including HIV, may prove very productive.

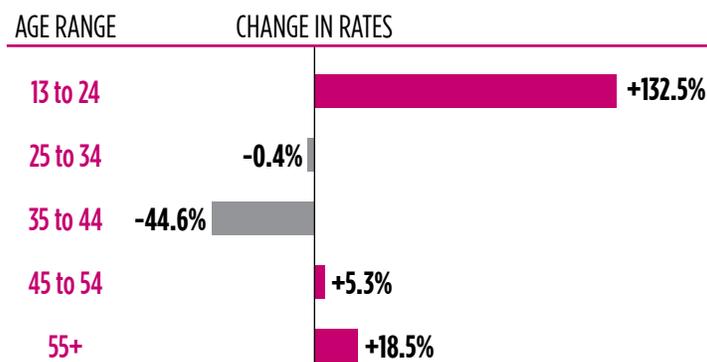
Gay, Bisexual, and Other Men Who Have Sex with Men

For decades, gay and bisexual men have mobilized to address HIV in their communities. From early in the crisis, these communities built powerful grassroots efforts to prevent infections during a time of government negligence. Thus, robust community involvement continues to be a major strength within this population.

Still, HIV remains endemic among gay and bisexual men. With indications from the 2011 National HIV Behavioral Surveillance (NHBS) data that as many as 18 percent of men who have sex with men living in urban areas are HIV-positive, background prevalence is a major challenge.^{60,61} The same NHBS data also suggest that one-third of HIV-positive gay and bisexual men do not know they have the virus, further complicating harm reduction practices.

Homophobia remains a major driver of the epidemic for gay and bisexual men. In particular, stigmatization of gay male sex continues to hinder open conversation about sexual well-being and HIV. Gay and bisexual men also struggle with certain types of invisibility within the epidemic. The ubiquitous use of the epidemiological term “men who have sex with men” homogenizes a very diverse population. Young gay men of color are also frequently underrepresented in HIV prevention discussions; bisexual men and men who do not identify as either gay or bisexual are even less visible.

Figure 4. Changes in Diagnosis Rates between 2002 and 2011 among Men Who Have Sex with Men in the U.S. by Age Range



Adapted from: Johnson AS, Hall HI, Hu X, Lansky A, Holtgrave DR, Mermin J. Trends in diagnoses of HIV infection in the United States, 2002–2011. JAMA. 2014 Jul 23-30;312(4):432–4.

Transgender Men and Women

Many transgender individuals experience uniquely intense barriers to obtaining comprehensive HIV prevention services. Transgender people are often invisible, as evident in the paucity of reliable incidence and prevalence rates for transgender women and men. When transgender women and men are included in epidemiological data—they are missing from the NHBS data—they are often incorrectly categorized as men who have sex with men. Also, many gender-nonconforming individuals do not identify as transgender, leading to further miscategorization. The inadequate data we do have indicate that transgender women are likely the group most disproportionately affected by HIV in the United States.^{62,63}

The tendency to ignore the specific needs of transgender people extends to community prevention services. Few transgender-focused CBOs receive stable funding. Additionally, transgender individuals experience uniquely intense social stigma and face high rates of poverty, unemployment, and homelessness.⁶⁴

With so much injustice, transgender individuals have many competing priorities in addition to HIV—not least of them being gender-affirming therapies and surgeries—so programs and facilities that focus on HIV may not address their primary needs. Additionally, being identified with such a stigmatized condition as HIV may also deter transgender people from using these services.

Figure 5. Transgender Discrimination in Health Care Survey (N=6,450) HIV rates: **Four times the national average** (higher in people of color)

- 19%** Experienced **refusal of care** due to gender identity.
- 50%** Reported having to teach **untrained medical providers** about transgender care.
- 28%** Reported **delaying care** due to fear of discrimination.
- 48%** Reported **postponing care** due to affordability.

Adapted from: Grant JM, Mottet L, Tanis JE, Harrison J, Herman J, Keisling M; National Center for Transgender Equality. Injustice at every turn: a report of the National Transgender Discrimination Survey. Washington, D.C.: National Center for Transgender Equality; 2011.

Non-transgender Women

Rates of HIV infection in the United States have been declining significantly among non-transgender women, including a 21 percent decrease among black women between 2008 and 2010.⁶⁵ However, many women remain vulnerable to infection, particularly those with a history of trauma and those who have access to fewer resources.^{66,67,68}

Assumptions that HIV does not affect women create unique challenges for women who are vulnerable to the disease, including low testing rates and late HIV diagnoses.^{69,70} Negotiating condom use has also been consistently challenging for many women, making condom-centric prevention services less effective.⁷¹

There is hope that a number of women may be more likely than other key populations to quickly adopt new prevention options such as PrEP. An assessment by Gilead of PrEP prescriptions in 55 percent of U.S. pharmacies indicated that about half of these early adopters were women, though in more recent data, scale-up has greatly increased amongst men.^{72,73} Ongoing partnership with other preventive health services, such as reproductive health, may be a particularly useful opportunity for women in the United States.

People Who Use Drugs

There has been a great deal of success with HIV prevention among people who inject drugs. SEPs, along with the availability of opioid substitution therapy (OST) and buprenorphine, have likely played a major part in a substantial decline in the number of new infections attributable to sharing injection equipment, although declines have also taken place in areas without wide availability of these services.⁷⁴

Still, ongoing challenges remain in providing comprehensive prevention services to individuals who use injection and non-injection drugs. Specific challenges moving forward include removal of the ban on the use of federal funding for SEPs, increased access to OST and other recovery services, and greater linkage between wellness services for people who inject drugs and comprehensive prevention services. Sustained efforts to control the epidemic among people who inject drugs will be of even greater importance as we continue to see a rise in opioid injection in the United States, particularly among new, inexperienced individuals. We also continue to see higher mortality among those who are HIV-positive.⁷⁵

Sexual transmission is frequently linked to substance use as well, but not enough is being done to provide comprehensive prevention for sexual transmission for users of various substances.

People Who Are Homeless and Transitionally Housed

According to the U.S. Department of Housing and Urban Development, on any given night in January 2013, over 600,000 Americans were homeless, with nearly a quarter of those individuals under the age of 18.⁷⁶ Several studies have shown a link between homelessness and vulnerability to HIV infection.^{77,78,79}

Access to testing and comprehensive prevention services is frequently limited for marginally housed individuals. Many homeless individuals are transient or unconnected to housing services of any kind, making it difficult to reach them consistently. Shelters often do not provide testing and linkage to prevention services, or such services are not safely accessible in those environments due to stigma. Challenges with mental health and addiction are also more common among people experiencing homelessness.

Stigmatization of homelessness and homeless individuals makes the needs of this population invisible and complicates efforts to house them. Modeling has indicated that housing HIV-positive homeless individuals would ultimately save money by cutting down on health-related expenses, yet many still perceive housing to be too expensive an intervention for people living with HIV or those who are vulnerable to it.⁸⁰ Not enough research has been done to assess the prevention needs of HIV-negative homeless individuals, particularly outside of urban areas. Discussions of how to get PrEP and PEP to homeless populations are only beginning.

People Who Have Been Incarcerated

Addressing the HIV-related needs of individuals who have been incarcerated is of critical importance in the U.S. epidemic, yet this population continues to face significant challenges in getting testing and comprehensive prevention services. The United States currently imprisons over 2 million of its citizens, with communities of color disproportionately represented.⁸¹ Incarcerated individuals are at an increased risk of acquiring HIV and are frequently associated with other vulnerable groups, including people who inject drugs, people with mental illness, and individuals of lower socioeconomic status.

Testing practices vary greatly between prisons, with many locations afraid to take on medical or legal liabilities related to an HIV diagnosis. Sexual and drug-use practices of incarcerated individuals are typically not officially recognized in the prison system, often leading to limitations in availability of condoms and other key prevention options. Discussions about PrEP and PEP availability appear to be lacking at present, and risks associated with tattoos acquired in prison remain inadequately addressed.

In leaving the prison system, individuals face enormous stigma, joblessness, homelessness, and resource scarcity, making HIV prevention only one priority among many. Individuals have limited access to HIV prevention interventions as they transition out of incarceration. Greater surveillance of incidence, prevalence, and provision of HIV prevention services is needed. Incarcerated individuals are also not adequately included in many HIV prevention discussions.

American Indians/Alaska Natives

American Indian/Alaska Native (AI/AN) communities in the United States are proportionately affected by HIV.⁸² However, certain subpopulations may be disproportionately affected within those communities, including gay and bisexual men (culturally self-identified as “two spirit” individuals) and transgender women. The percentage of new infections attributed to injection drug use is also higher among Native Americans than in those with other racial and ethnic identities.⁸³

Ongoing efforts dictated by the NHAS for all federal agencies, like the CDC and the National Institutes of Health (NIH), to improve data collection and research on risk in AI/AN communities and relevant subpopulations must continue. High levels of migration and misclassification in data create challenges in ensuring accuracy, as does historical mistrust of government agencies and researchers.

For vulnerable AI/AN people living on reservations, there are a number of barriers to obtaining comprehensive prevention services. In recent years there has been an increased push for testing and biomedical prevention access through the Indian Health Service (IHS), the federal government’s health agency for federally recognized AI/AN people.

Sex Workers

There are some indications, especially anecdotally, that many sex workers have adapted to the epidemic by using condoms consistently with clients. The creativity, adaptability, and resilience of sex workers from working without legal protection should not be underestimated.

Despite this resilience, sex workers are in dire need of greater visibility and support. Very few epidemiological studies have been conducted regarding HIV among sex workers.⁸⁴ More information is needed to understand prevalence, incidence, and HIV-related risks and behaviors among male, female, and transgender sex workers of all ages and races.

The criminalization of sex work and HIV, as well as prosecution for condom possession as evidence of criminal activity, creates enormous barriers for sex workers seeking comprehensive prevention care. Such policies heavily discourage testing and condom use for individuals who depend financially on sex work. While PrEP and PEP might be particularly useful options for sex workers facing challenges with condom use, very little has been done to explore or promote these options in this population, and community efforts to help link sex workers to services, when they exist, are frequently underfunded. Additionally, many sex workers may also be mistrustful of public clinics and other health care services due to legal concerns, leaving them with few options for comprehensive prevention services. Open conversations about HIV may still be stigmatized among sex workers, leading to even less understanding of available prevention options.

IDENTIFYING STRATEGIES TO IMPROVE HIV PREVENTION SERVICE ENGAGEMENT

Toward Comprehensive HIV Prevention Service Delivery: A Double-Helix Continuum

HIV care continua—metrics-driven pillars reflecting rates of testing, engagement in care, and treatment that have been developed nationally, for several states and metropolitan areas, and for key populations—are cornerstones of research and policy discussions about improved population-based health and prevention outcomes in the United States. Though questions remain regarding the quality and linearity of metrics used to define outcomes along these continua, they remain highly visual, accessible, and reproducible models; they have been critical in efforts to galvanize advocacy and funding; and they continue to lead to better implementation of sound research, policies, and best practices.

Similar models have been proposed for vulnerable HIV-negative populations. These include expanded cascades describing the number of individuals both at risk for and living with HIV who are receiving the full benefits of prevention, care, and treatment services;⁸⁵ PrEP-specific cascades;^{86,87} and population-based cascades underscoring the need for counseling and risk stratification, provision of tailored prevention services, retention in services, and adherence support.^{88,89}

A variation on a population-based, comprehensive HIV prevention service delivery model is being proposed by Treatment Action Group: a “double-helix” continuum that seeks to complement and replicate the outcomes-driven individual and public health pillars of the HIV care continuum.

The TAG double-helix continuum is based on the following principles:

1. People who test negative for HIV, particularly through screening programs targeting vulnerable populations, may still be at considerable risk for HIV infection and may therefore require engagement in culturally competent care providing comprehensive risk assessments and either the coordination or direct provision of services—including PrEP—to minimize infection risk.
2. Testing for HIV should be considered a critical point of contact with the health care system and an opportunity to link people to health insurance coverage and culturally competent care.
3. Linkage to, and ongoing engagement in, culturally competent care—including primary care, sexual health clinics, and reproductive health services—serves as an opportunity to screen for and address not only HIV risk factors, but (sometimes overlapping) risk factors for other diseases that disproportionately affect vulnerable populations.
4. To expand the HIV prevention tool box by increasing the use of PrEP and emerging biomedical prevention methods among vulnerable individuals and populations, process models and best practices for comprehensive HIV prevention service delivery should include definitive roles for health care providers and systems.
5. Comprehensive HIV prevention service delivery will require collaboration between, and coordination among, health departments, medical facilities, policy makers, and nonmedical CBOs to ensure that structural, social, behavioral, and biomedical needs are met.

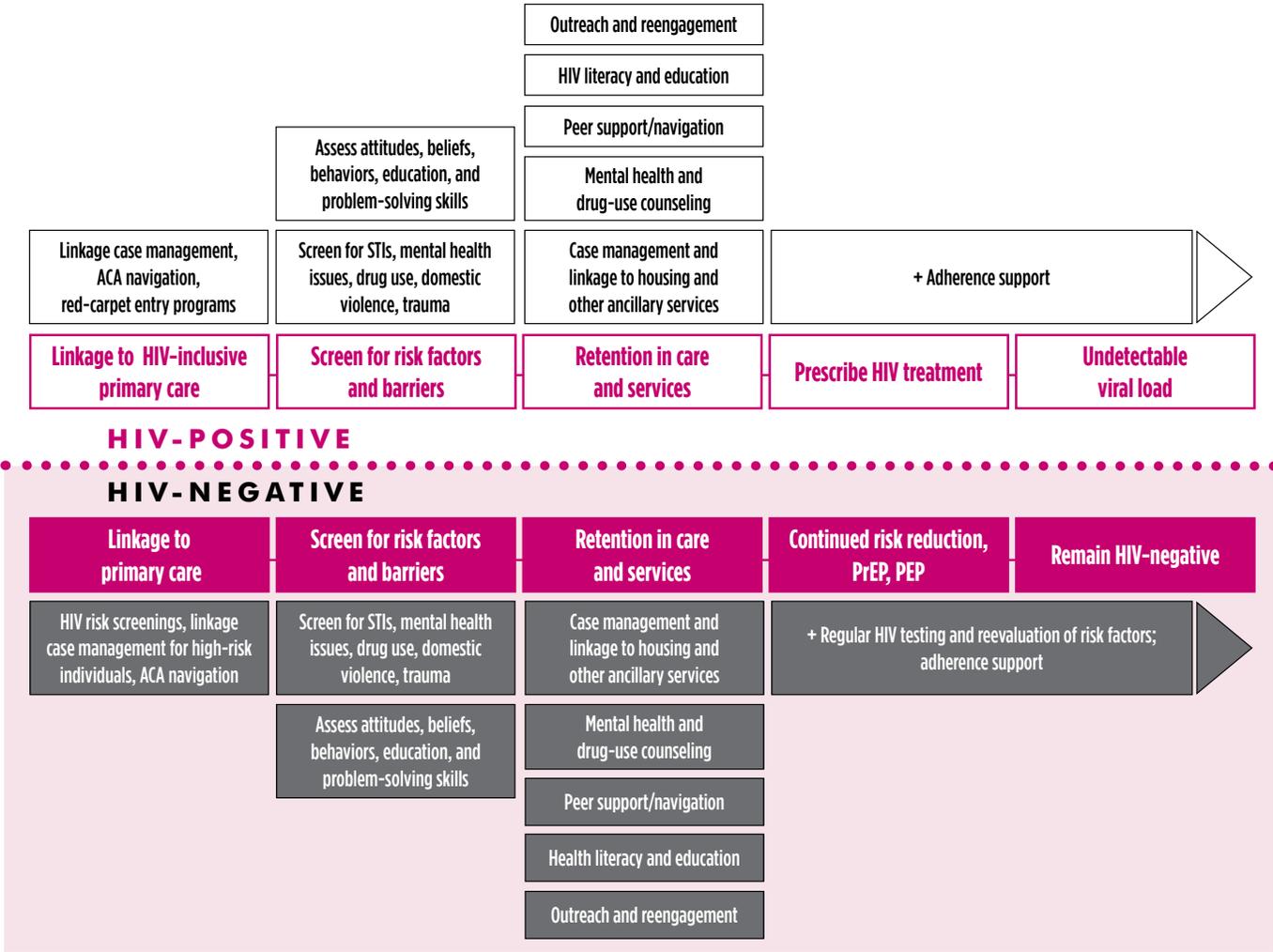
Reducing the complexities of HIV prevention into a simple model continues to prove challenging. Much like existing HIV care continua and cascades, a prevention continuum will, by necessity, oversimplify many aspects of prevention efforts in the United States.

In addition to questions and concerns that apply to both continua models, there are specific challenges facing the development of a prevention continuum. Whereas the HIV care continuum is outcomes-oriented and therefore dependent on an established denominator—the number of people estimated to be living with HIV, defined by geography or population—it remains unclear for whom an HIV prevention continuum is required.

And whereas the pillars of the HIV care continuum are essential to all people living with the virus, the needs of HIV-negative individuals are nonlinear, highly variable, and difficult to address through a centralized and standardized medical model, and therefore not best reflected in a bona fide continuum.

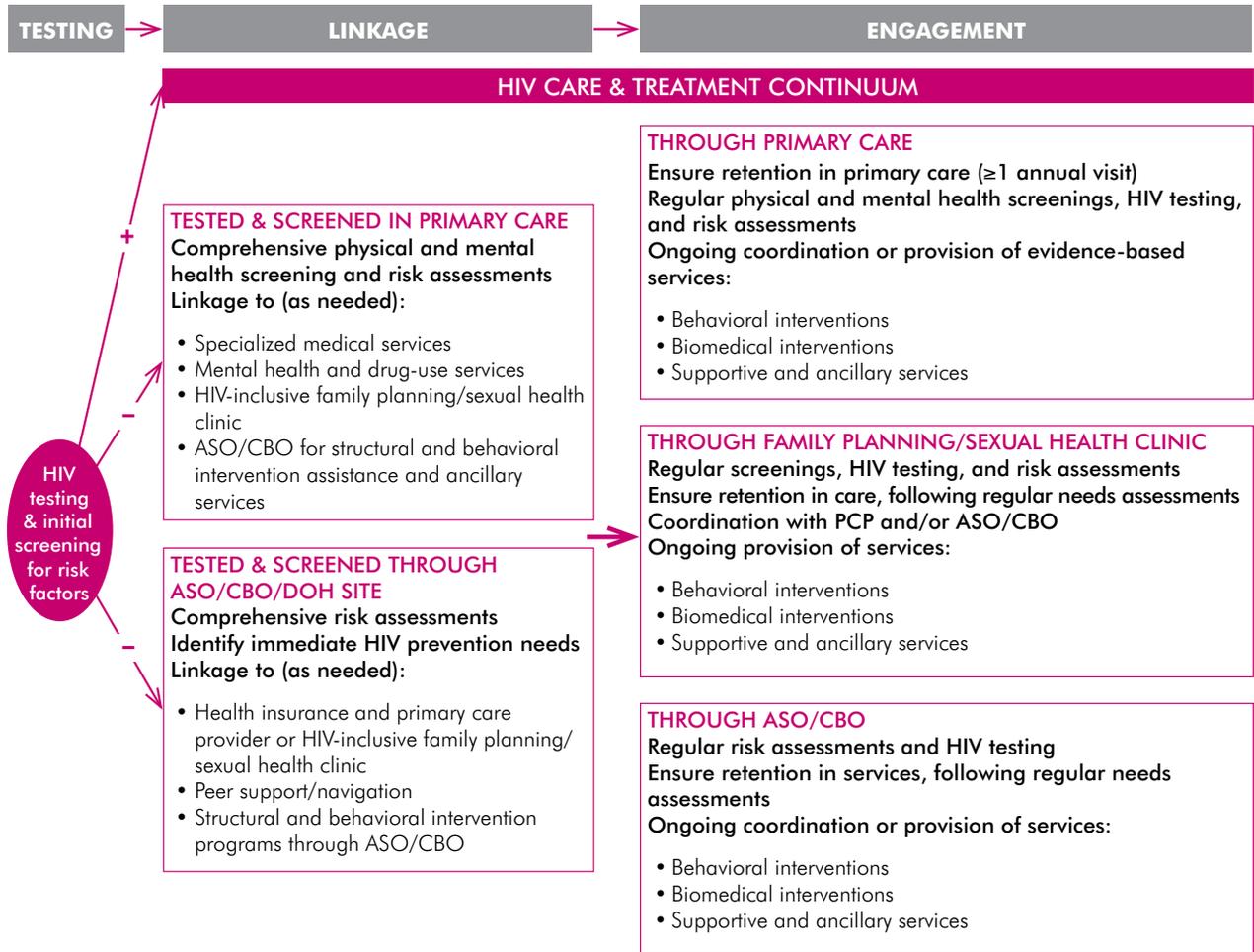
These concerns are valid and necessitate refinements to what must remain a simple and accessible outcomes-oriented process model to help define effective medical- and community-based prevention practices. The emergence of population-based strategies to reduce secondary transmission risk among people living with HIV, biomedical prevention tools to reduce primary infection risk among HIV-negative individuals, and preventive care mandates of the ACA provide us with a unique opportunity to reconfigure comprehensive HIV prevention service delivery as a central component of a much larger approach to preventive health care in the United States. In effect, continued development of continua that standardize HIV prevention service delivery as a core component of wellness outcomes, particularly for vulnerable populations, is warranted.

Figure 6. “Double Helix” Continuum: Concept One



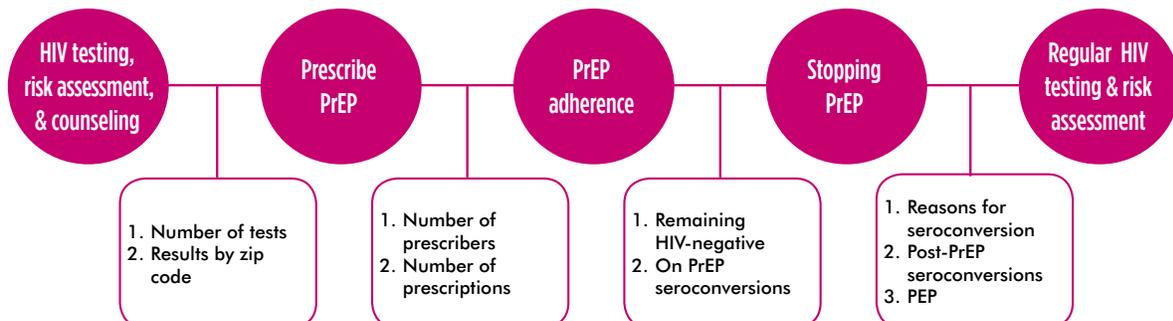
Mirroring the HIV care continuum (top), an HIV prevention continuum (bottom) details some of the core components of HIV risk reduction and maintained wellness made possible through engagement in care and the coordination of social support and other ancillary services. Strengths of this model include its accessibility and relatability across audiences; prioritizing linkage to insurance and care; and that it is not HIV-specific, but rather embodies HIV-inclusive risk screening and primary/preventive/whole health care. Limitations include pillars that are not 100% applicable to people with varying degrees of HIV risk; an overly restrictive reliance on primary medical care, given that many providers are largely unprepared, primary care is not a priority for some populations, insurance coverage is still fractured, and ASOs/CBOs remain critical to prevention work; and, importantly, a lack of a clear denominator and other metrics.

Figure 7. "Double Helix" Continuum: Concept Two



A more general framework embodying three core pillars of HIV-inclusive risk screening and primary/preventive/whole health care: testing, linkage, and engagement. CDC guidance recommends a one-time HIV test for all, and routine testing is advised for many. The linkage pillar accounts for different systems in which people are tested, at least initially. Critical to success in this pillar are two objectives: 1) comprehensive physical, mental health, and risk factor screenings; and 2) linkage to medical and support programs, as needed. The engagement pillar may be as straightforward as annual primary care visits, regular HIV testing, and routine risk screenings, or the provision or coordination of care and support interventions to help minimize risk of infection. Strengths of this model include that it is outcomes-oriented; all pillars should be 100%, in that they are applicable across the risk spectrum; it underscores testing (at least once), linkage and engagement in at least one HIV-inclusive program, and use of evidence-based and cost-effective interventions on an as-needed basis; and it demands bridging providers and coordination of services. Its limitations include a lack of readily identifiable metrics, including the denominator and numerators; it may also be too broad in its scope and best suited only for specific populations.

Figure 8. Key Metrics along the PrEP Continuum



The Need for an Implementation Science Agenda

In order to design any sort of successful national comprehensive prevention effort and make full use of a prevention continuum or similar heuristic, an implementation science agenda will be needed. As defined by the NIH's Fogarty International Center, "implementation science is the study of methods to promote the integration of research findings and evidence into health care policy and practice."⁹⁰ A more nuanced definition was offered in a recent article in the *Journal of Acquired Immune Deficiency Syndromes* discussing the use of implementation science:

"[I]mplementation science . . . aims to investigate and address major bottlenecks that impede effective implementation and to test new approaches to identifying, understanding, and overcoming barriers to the adoption, adaptation, integration, scale-up, and sustainability of evidence-based interventions."⁹¹

Examples of implementation science include, but are not limited to:

- dissemination research;
- cost-effectiveness, modeling, and economic evaluations;
- research syntheses to inform public health decision making;
- research to strengthen personnel and health systems;
- operations research;
- comparative effectiveness; and
- studies to analyze the impact of policy changes on public health outcomes.

Scattered implementation-related studies of HIV prevention for vulnerable people who are HIV-negative have emerged in recent years. However, much more needs to be understood if our intention is to reframe HIV prevention as a compendium of services and a component of wraparound care. It will be critical to learn how best to integrate comprehensive HIV prevention service delivery, both efficiently and effectively, in real-world communities and clinics and, importantly, to make better informed public-health decisions for intervention selection and delivery.

The PrEP demonstration projects and the 2014 Funding Opportunity Announcement, "Improving Delivery of HIV Prevention and Treatment through Implementation Science and Translational Research," sponsored by the National Institute of Mental Health and the National Institute of Allergy and Infectious Diseases (PA-14-131), are a step in the right direction. The CDC-led Sustainable Health Center Implementation PrEP Pilot (SHIPP) will also expand our knowledge of implementing PrEP in the real world. Many gaps remain, however. Notably, the PrEP demonstration projects seem to largely exclude implementation in rural areas of the United States, and while gay and bisexual men are widely represented, many other key populations are not being adequately assessed.

Greater coordination of implementation science research activities will be essential to identifying and addressing gaps in existing and ongoing implementation research. The development of a specific implementation science agenda for the provision of comprehensive domestic HIV prevention services is a necessary first step to understanding what key questions remain to be answered. Responsibility for addressing gaps identified in the agenda should also be determined; the NIH alone cannot conduct all necessary assessments for all populations. Where appropriate, other government agencies will need to take the lead in answering questions and providing funding. The establishment of an official agenda will also provide the opportunity to explicitly encourage the funding of more innovative forms of research. Despite the enormous demand for real-world implementation studies, current standards for scientific rigor often prevent such projects from being funded.

Research Priorities for HIV Prevention for Vulnerable People Who Are HIV-Negative

The field of HIV prevention has always been extremely complex. While research has provided valuable and enduring insights over the course of the epidemic, many questions remain about how to get the right set of interventions to the right people, in the right way, at the right time. Here, we identify some of the top priorities for HIV prevention research, as identified during breakout sessions at the December 2014 consultation. By working together to fill in some of these gaps, particularly through a lens of implementation science, we may better understand how to help vulnerable individuals throughout the United States.

Community-Level Research

ASO, CBO, and community mobilization outcomes and resources

Historically, CBOs have played a central role in addressing the prevention needs of constituents, through the direct provision of services, advocacy, and community mobilization. Yet the qualitative and quantitative outcomes of this work, including incidence and other metrics of health, along with the effects of inadequate funding and program closures on prevention goals, remain largely understudied. Investing in the development of standardized evaluation tools and the implementation of research to strengthen the evidence base for defining the utility and value of community-based prevention programming and community mobilization is therefore a priority.

Evaluating community involvement in research and decision-making processes

Community advisory boards are regularly part of both implementation and research processes. The level of involvement for community members can vary, however, with many community representatives underused or unprepared for meaningful engagement. Specific requirements for NIH-funded researchers to include community, beyond simply forming a community advisory board, should be established.

The development of standardized monitoring and evaluation measurements of community involvement may be useful here. Understanding to what extent researchers are prepared to work with community members via community-based participatory research may help us identify gaps in how we conduct research. Specific expectations, guidelines, and definitions for community-based participatory research and implementation science would bring greater uniformity across studies.

More needs to be understood about how to quickly disseminate key research findings and improve health and science literacy at the community level. Additionally, studies should be expected to develop and articulate transition plans that will specify what positive impact the findings will have on the community after the research is over, and how programs and resources will be leveraged to ensure continuity of care once research-related funds and intensive support services go away.

Community-level vulnerability and resilience

A detailed understanding of which populations and subpopulations are particularly vulnerable to HIV is crucial, particularly at a time when prevention resources remain scarce. The development of an index to quantitatively measure vulnerability may allow us to precisely determine where the greatest needs lie, especially in conjunction with qualitative research. Similarly, a community-resilience index would aid in gaining a clearer understanding of the intrinsic assets and strengths that communities possess. Such indices would help foster investments in community-based initiatives and support strategic planning in resource-limited settings.

Health Care Delivery Research

Gaps in the ACA

Assessments of health insurance coverage rates under the ACA, particularly in populations that have historically been uninsured or underinsured, must be a national priority. We also need a better understanding of the services people are actually receiving as part of coverage. In light of reports indicating that many medications for HIV are not adequately covered by insurance plans,⁹² it is important to identify other financial barriers to obtaining comprehensive prevention services such as PrEP. Understanding how the ACA can and cannot contribute to the provision of related services, including case management and housing support, will be essential. Addressing the large gaps in the availability of mental health and substance use services is also a high priority.

Capacity for HIV prevention to be better integrated into broader health care

Programs seeking to provide comprehensive prevention services, including PrEP and PEP, must, by necessity, link with mainstream health care services. Yet we have little knowledge of the capacity of health care systems to integrate these services or address related issues, including insurance billing and delivery and accessibility of medications. The frequently poor quality of patient-provider interactions in the context of HIV prevention also remains a major hurdle to comprehensive prevention in the PrEP era. By conducting research to identify the key skills and resources needed for successful provision of prevention services, as well as the best way to train future and current health care providers in those skills and to develop necessary infrastructure, we may advocate more precisely and with greater chances for successful outcomes. In particular, we need more information on how to encourage potential providers of HIV prevention services to actively participate in conversations related to sexuality and drug use.

Biomedical Research

Who is using PrEP and PEP?

Gilead has provided limited data on current uptake of PrEP: over 5,000 people, around one-third of them women, have been prescribed PrEP in 55 percent of U.S. pharmacies.⁹³ We are also gaining some insight into PrEP use through iPrEx OLE and domestic demonstration projects. However, we need a more comprehensive picture of PrEP and PEP uptake in the real world. The establishment of a longitudinal study, similar to the Multicenter AIDS Cohort Study and the Women's Interagency HIV Study, may provide insight into PrEP and PEP and the various factors associated with their use and discontinuation.

How do we ensure that all new biomedical interventions are easy for providers and communities to use?

We need more interventions that are acceptable to community members and easy for them to use. With future technologies, how do we incorporate real-world acceptability and uptake questions earlier on in the process to facilitate implementation and ensure that interventions are desirable? Simplicity of use and acceptability may also be key in getting providers of prevention services to recommend new tools to clients. Providers may be less likely to suggest interventions that they perceive to be too complex or to have potential drawbacks.

How do we ensure that youth and transgender women and men are included in biomedical research?

In May 2014, the CDC issued official clinical guidelines for the use of PrEP.⁹⁴ Notably, the CDC did not specifically recommend PrEP for transgender women, reflecting the lack of transgender-specific data

available. Despite the inclusion of some transgender women in the initial iPrEx trial, their involvement was too minimal to provide conclusive findings. There is still a paucity of data pertaining to PrEP safety and acceptability in the transgender community, including how tenofovir and emtricitabine interact with hormone therapies.

Although Truvada is approved for treatment of HIV in youth, the CDC guidelines specifically cite insufficient data for PrEP in adolescents under 18. The Adolescent Trials Network is currently looking at PrEP in men who have sex with men ages 15 to 17 to help change this (ATN Study 113), though the fact that Truvada's safety, acceptability, and feasibility are only now being studied in a key population, three years after its approval as PrEP, is shameful. We need to understand how to encourage research in adolescents and how to overcome the barriers to the inclusion of youth earlier in the process.

Social Behavioral Research

Real-world, community-driven research

A recent study released by the Kaiser Family Foundation has shed light on the knowledge and attitudes of gay and bisexual men related to HIV.⁹⁵ The study concluded that nearly half of those surveyed did not consider HIV to be a significant issue for them personally. More research of this kind for all key populations will be necessary for us to understand what HIV-related and non-HIV-related priorities are of greatest importance to communities. How important is HIV prevention to different key populations? What is their baseline knowledge? Conducting this research will require meaningful community leadership. One possible consideration is to change funding structures for community-focused research by disbursing grants to community organizations and having researchers apply to them for funding of projects.

Better understanding of the impact of trauma related to sexual abuse and sexual assault

Research has indicated that survivors of sexual abuse and sexual assault in key populations are especially vulnerable to HIV infection.^{96,97,98} We need to further clarify the link between the trauma associated with such events and its effect on HIV risk behaviors as well as overall sexual pleasure and wellness. The more we are able to develop successful interventions within the context of comprehensive prevention that address this underlying cause of increased vulnerability to HIV, the more success we may have with survivors of sexual violence and molestation.

Improved understanding of the impact of HIV-related stigma on vulnerable HIV-negative individuals

We know from several focus groups involving potential PrEP users that fear of being perceived as HIV-positive or as having engaged in stigmatized sexual acts (e.g., condomless sex) is a major deterrent to their using PrEP. While work is under way to understand stigma for people living with HIV, such as the Stigma Index being headed up domestically by the North American chapter of the Global Network for and by People Living with HIV, further understanding of how HIV-related stigma affects vulnerable HIV-negative individuals is critical. As we push to increase numbers of tests and the numbers of individuals who get prevention services, we also need to develop research to track the quality of the services being provided. To what degree are providers, particularly those operating outside the confines of traditional HIV service delivery, sex-negative or judgmental of drug use? To what degree are shaming and judgmental encounters a deterrent to future use of services?

Implementation Priorities for Comprehensive HIV Prevention Services

Thanks to changes in the prevention landscape over the past decade as well as the advent of the ACA, there are several opportunities readily available to drastically improve the uptake of prevention services in the United States.

Coordination of Services

Increased funding to develop systems and services to provide comprehensive prevention

Popular prevention discourse routinely emphasizes that new financial resources won't be available anytime soon. In terms of prevention for vulnerable HIV-negative individuals, the situation is worsening as the vast majority of CDC funding now goes to prevention for people who are HIV-positive. However, accomplishing the sorts of systems-level changes required would be challenging without greater investment. At a minimum, CBOs and ASOs will need funding to build capacity for wider prevention services. While some of the CDC's most recent HIP grant may be used toward this end, it is almost certainly not enough to facilitate the systems-level shift required across the country. The CDC's recent announcement of a \$185 million three-year investment in the prevention needs of men who have sex with men and transgender populations, which more prominently features PrEP, will improve existing funding imbalances. However, a major priority moving forward will be to develop a basic definition for "comprehensive prevention" and accurately estimate the financial resources needed to realistically scale up these services and then work to actually obtain those resources, either through reallocation of existing traditional or nontraditional funding sources or via advocacy.

Exploring the role of prevention case management and prevention navigators

At present, different prevention services are paid for in different ways and provided in different facilities all over the country. Gaining access to all of the tools is complex and varies tremendously by the community and individual. Just as case management has proven to be valuable for people living with HIV, we may find that the best option for the most vulnerable individuals traversing a complicated prevention landscape will be assistance from a professional or paraprofessional trained to navigate and access prevention services. Establishing the value of prevention navigators via nationwide pilot programs should be a priority, particularly as we try to build simplified systems for accessing comprehensive prevention. In addition, such programs could help link prevention services to other needs, including educational and employment services.

Putting forth prevention models and developing a standard of care

As discussed earlier, it is imperative to develop a prevention continuum and other models that help to establish a standard of care for highly vulnerable individuals. The field of prevention has changed dramatically over the past five years, and we need clearly defined general guidance from the Office of National AIDS Policy (ONAP) and U.S. Department of Health and Human Services (HHS) agencies on what comprehensive prevention should look like for vulnerable people in this country.

Monitoring and surveillance of PrEP and PEP use

Understanding the current uptake of PrEP and PEP was previously mentioned as a research priority. As a form of HIV-related surveillance, it is also an implementation priority for the CDC. The CDC must work closely with community members to develop systems of national surveillance for current and future biomedical interventions.

Improving the role of insurance in access to comprehensive prevention

Private health insurance or Medicaid under the ACA is not enough, especially considering the uneven expansion of Medicaid. Highly affordable prevention services available with minimal hurdles will be needed for all vulnerable populations, and discriminatory pricing policies for medications and prevention services will need to be remedied. Practices such as prior authorization for PrEP or PEP will need to be abolished. Ongoing advocacy to expand insurance access or develop alternative forms of service coverage to all vulnerable individuals, including undocumented immigrants, will also be essential. In some cases, the Washington State and New York State PrEP assistance programs may provide models of how to help individuals get services right now.

Improving coverage for mental health services, drug counseling, and even prevention case management will also be necessary for addressing HIV prevention needs as well as overall well-being and quality of life.

Best practices, technical assistance, and training for clinicians

The issuance of PrEP guidelines for clinicians by the CDC was a major step forward in 2014. The establishment of a national PrEPline (1.855.448.7737) by the University of California San Francisco's Clinician Consultation Center as a complementary and interactive resource is of tremendous benefit for clinicians. However, these and other prevention guidelines are not always on the radar for many primary care and nonspecialty clinicians.

Efforts by the CDC, state health departments, and medical societies to promote the PrEPline and provide opportunities for physicians to learn about the PrEP guidelines are essential. They will need to be maintained and even expanded to prepare more health care providers to offer comprehensive HIV prevention services. Trainings will also need to be focused on the many nonclinical aspects of HIV prevention in order to avoid the extremely negative interactions many members of key populations have had with physicians. Such trainings would also benefit midlevel providers and other clinic and office staff members who are often the primary contacts for clients.

Notifications via electronic records

Surveillance data-based notification programs, such as the Louisiana Public Health Information Exchange (LaPHIE), have helped reengage people living with HIV who fall out of care. Adapting such a notification system may help to engage highly vulnerable individuals in HIV prevention services. Testing this system in pilot programs may be helpful.

Accountability on stigma and discrimination

Stigmatizing interactions with health care providers create a major access barrier to comprehensive prevention services for many members of key populations. Merely getting individuals connected with health care providers is not enough; we need to ensure that they are receiving quality care. The CDC, health care providers, and community activists must push for ways to keep health care delivery services from providers and health systems accountable. We need to monitor and evaluate the behaviors of providers as comprehensively as we monitor the behaviors of vulnerable populations through the NHBS system.

Including the U.S. Department of Education in the NHAS

In recent years, the CDC has noted a decline in the number of elementary schools that are providing education on sexual health for students.⁹⁹ Very few LGBT students are receiving sexual education that covers all topics that are relevant to their health and well-being. This is contrary to the goals of the NHAS, which recommends that all Americans should be educated about HIV and how to prevent it, and it is completely unacceptable considering that youth remain the most vulnerable to HIV infection of all U.S. populations. Including the Department of Education (DOE) in the next incarnation of the NHAS will be a major priority in 2015 in order to empower that department to push for significant change across a highly fractured public education system.

The CDC's Division of Adolescent and School Health (DASH) is also a unique source of support for HIV prevention efforts in the nation's schools and should work closely with the DOE.

Expanding messaging to places where youth gather and meet

In focus groups with potential young PrEP users, many participants note that expanding prevention messaging outside of traditional venues into spaces where youth regularly gather in person or online may have greater success. We must make it a priority to take new or existing comprehensive prevention campaigns such as the CDC's "Start Talking. Stop HIV." into popular social venues for youth (and evaluate their efficacy) to increase the low levels of knowledge among youth. More recommendations on messaging for youth and other key populations can be found in TAG's recent report for the New York State Department of Health: *Toward Effective Pre-Exposure Prophylaxis, Post-Exposure Prophylaxis, and Comprehensive HIV Prevention Messaging in New York State*.

Addressing confidentiality complications for youth

Ensuring that youth are able to receive prevention services without parental notification is essential. For youth under the age of 18, establishing confidential and safe spaces within schools to receive comprehensive services and guidance on sexual health may have a significant impact on HIV in this critically vulnerable population. Pilot studies to establish the value of such services may be an easy first step in this controversial area of prevention work. For individuals under the age of 26 who are still on their parents' insurance, significant work needs to be done to ensure that rigorous medical confidentiality is maintained, particularly in terms of services related to drug use and sex. At present, many young people in the United States may underutilize insurance coverage for PrEP, PEP, and other treatments associated with stigmatized conditions for fear of parental notification.

Encouraging the collection of real, accurate data on youth

Frequently, in collecting health information or conducting surveillance, states can opt out of questions regarding youth sexual behaviors. HHS agencies and NIH-funded researchers looking into HIV risk behaviors and sexual habits of youth should make every effort to ensure that this information is obtained accurately and comprehensively, including through the use of incentives. In particular, it will be essential to have the CDC amend the School Health Policies and Practices Study to better assess whether the HIV prevention needs of LGBT students are being met. Precisely understanding all of the legal and procedural hurdles in obtaining this information and providing support for researchers may be helpful. For example, providing support and funding to make it through an arduous Internal Review Board process that is highly protective of youth may facilitate this critical research.

Access to Prevention Services for Marginalized Populations

Providing better, clearer metrics and epidemiology, reported in a timely manner

We need to know the characteristics of the epidemic in each key population intimately in order to have real impact. Specific action plans to obtain clear, comprehensive, and accurate information on transgender women, undocumented immigrants, sex workers, and Native Americans must be top priorities. Collected information must also be reported in a timely manner in order to be truly useful. The current turnaround times by the CDC and other HHS agencies between data collection and reporting findings are entirely too slow. Many results of 2011 NHBS data for men who have sex with men were not made available until the very end of 2013, meaning that our understanding of the epidemic is nearly three years out of date. Establishing some sort of internal/external regulatory body to cut down on three-to-four-year periods of data processing would greatly improve the value of findings.

Providing clear guidelines on how to address structural barriers and social determinants of health at the programmatic level, including criminalizing policies

HIV prevention service providers require more specific steps for addressing the effects of structural barriers, social determinants of health, and criminalization on the vulnerable populations they serve. This will be even more urgent as prevention services expand and incorporate non-traditional providers who are less aware of how to work with marginalized populations. Providers will need clear understanding of how to address the individual needs arising from the many forms of social stigma experienced by the populations mentioned in this report. Specific recommendations on how to address structural barriers to comprehensive care such as homelessness and poverty will also be essential. Laws related to HIV transmission, drug use, sex work, and citizenship also play a huge role in the invisibility of many individuals in key populations and make them more vulnerable to HIV infection. There is a need for HIV prevention leaders in government to explicitly acknowledge that these laws and stigmas contribute to many health disparities, including HIV. Guidance on how to address them at all levels of prevention work in the United States is critical to help mitigate their impact.

Establishing an interagency working group on sexual health for transgender women and men

Considering the urgency of the HIV epidemic among transgender women and the glacial pace at which HHS agencies have moved to address their HIV prevention needs, an interagency working group that includes meaningful community leadership may significantly improve outcomes. Given that transgender individuals have many competing priorities, expanding the focus to general sexual health may be more in line with their needs while also addressing HIV.

Increasing leadership from priority populations at all levels

Providing sound guidance on how to increase the leadership of young gay and bisexual men of color and transgender women of color at all levels of HIV prevention is essential. While we need more reliable information on the demographic makeup of prevention service providers in the United States, it is highly likely that these populations are being excluded from leadership roles. Intimately understanding the barriers to obtaining leadership positions and providing solutions to facilitate involvement may help remedy this problem. We must also better document the true value of black leadership both in gay- and transgender-focused prevention programs and at the government level.

Developing programs that focus on top priorities of community members in addition to HIV

Marginalized communities have many competing priorities and interests outside of HIV; therefore, HIV prevention services and messaging may be more accessible within programming that also focuses on

the essential needs and interests of vulnerable individuals. This concept is not new; early community prevention efforts focused on sexual pleasure as a top priority rather than solely disease avoidance. Other natural partnerships may exist between HIV prevention and mental health services, treatment for addiction, and reproductive health. Programs focused on gender transitioning that also provide HIV prevention may be particularly helpful in attracting vulnerable transgender women. To be successful, such programs will require adequate and stable funding.

Exploring the use of technology to avoid subjective prevention counseling

Frequently, the prevention services provided to members of marginalized populations are tainted by various forms of stigma and discrimination. Negative perceptions of individuals based on their race, sexual orientation, gender identity, class, or other personal traits can lead to subjective withholding of comprehensive services and education. The use of computer-based interventions to enhance services is not new in the field of HIV, but more can be done to see how it may reduce subjectivity and possible discrimination in the provision of prevention services.

The Need for a Coordinated Federal Interagency Strategy

Following the example of the HIV Care Continuum Initiative, announced by President Obama in June 2013 to fortify the objectives of the NHAS, there is a need to mobilize and coordinate federal efforts to advance the research and policies required to address the comprehensive prevention needs of vulnerable populations in the United States.

There is a lack of cross-agency planning, development, and implementation to address complex biomedical, structural, behavioral, and social aspects of HIV prevention. Virtually all operating divisions of HHS—notably the Administration for Children and Families, the Administration for Community Living, the Agency for Healthcare Research and Quality, the CDC, the Centers for Medicare & Medicaid Services, the FDA, the Health Resources and Services Administration (HRSA), the IHS, the NIH, and the Substance Abuse and Mental Health Services Administration (SAMHSA)—along with the DOE, the National Science Foundation, and the U.S. Departments of Defense, Housing and Urban Development, Justice, Labor, and Veterans Affairs, as well as the Office of Minority Health, are responsible for strategic planning and resource allocations required to address at least one of the research and implementation issues outlined in this action plan.

The responsibility for coordinating a collaborative cross-agency response belongs to ONAP. As with the HIV Care Continuum Initiative, coordination of cross-agency efforts should begin with the formation of a working group consisting of representatives from all agencies specified above, in consultation with the Presidential Advisory Council on HIV/AIDS, as necessary. Functions of this working group would include but not be limited to:

- requesting and reviewing information from agencies describing efforts to improve frequency of voluntary counseling and testing, linkage to health insurance and primary/community-based care, and prevention outcomes, and determining whether there is appropriate emphasis on addressing comprehensive HIV prevention in relation to other health-related objectives, including the improvement of HIV care continuum outcomes;
- reviewing and recommending research, including the identification of implementation science gaps, aimed at improving HIV prevention outcomes;
- recommending ways to integrate efforts to improve HIV care continuum and primary prevention outcomes; and
- specifying how to better align and coordinate federal efforts, both within and across agencies, to improve both HIV care continuum and primary HIV prevention outcomes.

RECOMMENDATIONS

The priorities listed in this report can be grouped into the following recommendation areas:

Develop continua, process models, or similar heuristics to guide comprehensive HIV prevention service delivery research and implementation.

- The CDC, working in close collaboration with other HHS institutions, academics, and community stakeholders, should commit to the development of continua or similar process models required to more fully define critical HIV prevention outcomes—including testing, linkage to health insurance, engagement in culturally competent care, and routine screenings for HIV risk and other health disparities to assess service delivery needs—to complement the individual and public health goals of the HIV care continuum.
- This work should include rapid identification and validation of population denominators, numerators, and other metrics to define population-based service delivery needs and outcomes.
- This work should also ensure that models of comprehensive HIV prevention service delivery are age-appropriate, as adult models are not necessarily transferable to youth.

Strengthen surveillance to document HIV incidence, impact of prevention interventions and services, and progress toward reduced new infections and other health outcomes among all vulnerable populations

- The CDC, in close collaboration with science-based community organizations, should commit to addressing major gaps in HIV surveillance for key populations including incidence, prevalence, and behavioral measures. An action plan should be developed to list specific steps for the accurate collection, timely analysis, and comprehensive dissemination of information for transgender women and their sexual/drug-using partners, youth, sex workers, and Native Americans.
- Surveillance by the CDC regarding uptake, use, and complications related to new prevention and testing tools, including PrEP, PEP, fourth-generation testing, and at-home testing, should also be developed in collaboration with community organizations.

Identify and support research priorities to better define evidence-based prevention practices and implementation science

- The NIH's Office of AIDS Research (OAR), in collaboration with the CDC, should develop a community-inclusive working group to identify gaps in the prevention service delivery evidence base—including the potential utility of adapting older behavioral, structural, and social interventions in order to yield modernized, evidence-based interventions that better fit the proposed comprehensive care framework—and to recommend a research strategy and financial support.
- The OAR, in collaboration with other key government agencies, should develop an implementation science agenda and additional Funding Opportunity Announcements to identify and disseminate the most efficient and effective practices for delivering evidence-based interventions for the prevention of HIV in vulnerable populations.

- An effective implementation science strategy should include the establishment of best practices for maximizing community partnerships and meaningful participation in comprehensive HIV prevention service delivery strategies to ensure that research is relevant to community-based service and dissemination needs.
- An effective implementation science strategy should also include the establishment of a stigma index to track stigma and discrimination and more fully understand their impact on incidence and comprehensive HIV prevention service delivery outcomes.

Form a federal Comprehensive HIV Prevention Service Delivery Initiative, similar to the HIV Care Continuum Initiative, to identify and coordinate cross-agency responsibilities to address critical structural, social, and behavioral determinants of health and HIV risk reduction in key vulnerable populations.

- A Comprehensive HIV Prevention Service Delivery Initiative, headed by ONAP and actively supported by an interagency working group and stakeholder advisors, should be formed to better coordinate national HIV prevention efforts for vulnerable populations.
- Primary objectives of the Initiative should be to fully support and fund a two-pronged approach to prevention that fully addresses the needs of people living with, and vulnerable to, HIV infection.
- The initiative should focus on addressing many of the key implementation priorities highlighted in this report including, but not limited to, structural and social determinants of health at the policy and programmatic levels, easily accessible financial coverage of comprehensive prevention services, convenient and timely access to all prevention tools, culturally competent service delivery, and improved surveillance.

Develop, disseminate, and support best HIV prevention practices to facilitate comprehensive, culturally competent, streamlined, age-appropriate, and rapid uptake among non-HIV care and other service providers.

- ONAP and the CDC, in close collaboration with national and state health care trade associations, including student organizations, should establish core skills necessary for the provision of comprehensive HIV prevention services for vulnerable populations in order to better incorporate them into school curricula and continuing education classes for current and future providers.
- The CDC, in close collaboration with community-based organizations, should develop guidelines and suggestions for CBOs and ASOs to build capacity for comprehensive HIV service provision and provide funding for them to adapt to the changing prevention climate, including grants for pilot programs featuring prevention case management. Guidelines and financial assistance should specifically target organizations with a proven history of successful work with vulnerable black, Hispanic/Latino and Latina, and transgender communities.
- The CDC, in collaboration with HRSA, SAMHSA, and other relevant HHS agencies, should develop and disseminate guidelines for the integration of comprehensive prevention services into health care systems, substance use programs, jails and prisons, reproductive health clinics, and other community health clinics.

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