

# Expert Panel: Access to Evidence-based Therapies Is Necessary to Support Individualized Treatment of HIV

## Expert Panel Members

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## Introduction

Tremendous progress has been made in the fight against HIV/AIDS. Advancement in antiretroviral (ARV) treatments and a better understanding of the prevention of HIV transmission have contributed to reducing AIDS-related morbidity and mortality and improving long-term outcomes for people living with HIV.<sup>1</sup>

Still, ending the HIV epidemic in the United States requires lifelong individualized treatment because HIV remains a complex, chronic disease.<sup>2,3</sup> Further, certain populations and geographic areas continue to bear a disproportionate burden of HIV, highlighting uneven progress.<sup>3</sup>

A multidisciplinary panel of HIV experts gathered in January 2019 to discuss the evolving landscape of HIV care. The panel reached consensus on recommendations for various stakeholders who work to improve HIV care, including population health decision-makers (such as formulary committees, pharmacy benefit managers, and clinical advisors), advocacy organizations, and local, state, and federal policy makers. This paper presents the panel's discussion, consensus opinion, and conclusions.

## Current Snapshot of HIV in the United States

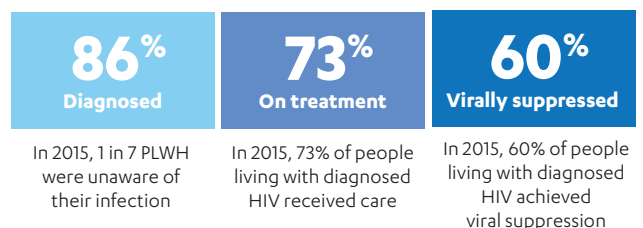
Substantial progress has been made in the fight against HIV since the early days of the epidemic.<sup>3</sup> However, comparing the current HIV epidemiology in the United States against HIV treatment goals—known as the 90-90-90 goals—reveals remaining opportunities to address the epidemic.<sup>4,5</sup>

The 90-90-90 goals are that by 2020, 90% of people living with HIV (PLWH) will know their HIV status, 90% of people with diagnosed HIV will receive sustained antiretroviral therapy (ART), and 90% of people receiving ART will achieve viral suppression.<sup>4</sup>

The latest estimates from the Centers for Disease Control and Prevention (CDC), however, show that we are falling short of these goals: 86% of PLWH are aware of their HIV status, 73% are receiving care, and 60% are virally suppressed.<sup>5</sup>

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## Diagnosis-based HIV Epidemiology in the United States<sup>5</sup>



The United States now aims to leverage ongoing efforts toward achieving the 90-90-90 goals with a new initiative. In January 2019, the Department of Health and Human Services (DHHS) proposed plans to end the HIV epidemic in the United States by reducing the number of new HIV infections by 90% in 10 years.<sup>6</sup>

## Ending the HIV Epidemic in the United States

The expert panel agreed that we have the necessary tools—such as effective ARVs—to end the HIV epidemic in the United States. However, we need open access to a diverse set of evidence-based therapies to meet the individualized treatment needs of PLWH because HIV is a complex disease with a wide range of individuals who are affected by various social and economic forces.

***“It’s everything except the drugs getting in the way of ending the HIV epidemic. While effective treatments are available, not enough people have access to them.”***

—Carl Schmid, MBA, Deputy Executive Director,  
The AIDS Institute

The panel emphasized that open access to effective treatments is necessary to activate key strategies that support ending the HIV epidemic in the United States, such as 1) preventing HIV transmission through treatment; 2) increasing HIV testing in high-risk populations; 3) connecting newly diagnosed individuals to HIV care through rapid initiation; 4) encouraging greater collaboration with high-quality HIV programs; and 5) promoting greater use of single-tablet regimens (STRs).

## Preventing HIV transmission through treatment

ART has transformed the HIV prevention landscape.<sup>1</sup> Known as “Undetectable = Untransmittable” or “U=U,” PLWH who take HIV medicine as prescribed and achieve and maintain an undetectable viral load have effectively no risk of transmitting the virus through sexual activity with their HIV-negative sexual partners.<sup>1,7</sup> A person’s viral load is considered durably undetectable when all viral load test results are undetectable (defined as <200 copies of HIV per milliliter of blood) for at least 6 months after the first undetectable test result.<sup>1,8,9</sup>

Several notable organizations—including the CDC and DHHS—actively communicate U=U as an important HIV prevention effort.<sup>1,2,7</sup>

The benefits of U=U extend beyond preventing HIV transmission. There can be psychosocial benefits in a stably suppressed individual by reducing internalized stigma, relieving guilt surrounding potential transmission, and enabling sex without fear. U=U can also reduce the community viral load, which supports public health goals to reduce population-level incidence.<sup>7</sup>

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***“U=U has been a game changer in terms of motivating patients to start HIV treatment and addressing internalized stigma. The U=U message must also be incorporated into our policy work to reduce external stigma.”***

—Kathie Hiers, Chief Executive Officer,  
AIDS Alabama

Despite the findings and benefits, many medical providers, PLWH, and individuals potentially at risk of acquiring HIV are unaware of or misinformed about U=U.<sup>2,10</sup> Expert panel members stressed that outreach efforts in key demographics, such as men who have sex with men (MSM), and individuals outside of the HIV community are necessary to increase knowledge about U=U.

However, PLWH who do not have affordable access to care lack the opportunity to engage in care and achieve and maintain viral suppression. Likewise, populations facing discrimination and stigmatization experience challenges to accessing ART safely and embracing U=U within their own lives.<sup>7</sup>

## Increasing HIV testing in high-risk populations

Despite the advances in HIV prevention, not everyone is benefitting equally. African American MSM accounted for 38% of all new HIV diagnoses among MSM in 2016. Of these men, 63% reside in the southern United States. Despite being a high-risk population, African American MSM who reside in a southern state received only 6% of HIV tests provided at community-based facilities in 2016.<sup>11</sup>

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***“It’s dangerous to cast an assumption that we’re all the same. Baton Rouge is not San Francisco, New York, or Chicago.”***

—Joseph Gathe, MD, Medical Director,  
Therapeutic Concepts

As of 2016, approximately 38% of new infections are transmitted by individuals who are unaware of their infection status.<sup>9</sup> Improving HIV testing is a crucial first step toward reducing HIV transmission in disproportionately affected populations.<sup>11</sup>

To increase HIV testing in high-risk populations, the expert panel recommended: 1) improving partnerships to target the right populations at the right time; 2) increasing the frequency of testing in high-risk populations; and 3) working to reduce the stigma around HIV testing.

The panel cited a pilot HIV testing program conducted by the Virginia Department of Health in partnership with Walgreens pharmacies as an example of improving HIV testing in high-risk populations. This pilot program offered a walk-in rapid HIV test at selected Walgreens retail pharmacies that serve low-income African American and Latino clients with disproportionately higher incidence rates of HIV in areas not served by other testing options.<sup>12</sup>

Through this program, retail pharmacists performed over 3200 HIV tests, including 25 positive tests; 46% of the clients had never been tested or were unsure; and 61% were African American or Latino. Clients who tested positive were referred to confirmatory testing at a local nonprofit organization or health department. The program showed cost savings per positive test compared with traditional community-based HIV testing programs (\$4300 versus \$14,900).<sup>12</sup>

## Connecting newly diagnosed individuals to HIV care through rapid initiation

Many individuals who are newly diagnosed fail to engage in HIV care, which can pose a serious public health risk. Approximately 43% of new infections are transmitted by individuals who are diagnosed with HIV but are not in care.<sup>9</sup>

Several barriers may prevent individuals with an HIV diagnosis from engaging in care. Commonly reported barriers include psychosocial factors (eg, stigma, disbelief of HIV serostatus, distrust of healthcare system), lack of transportation, unstable housing, and lack of health insurance.<sup>13</sup> Initiating ART in newly diagnosed patients entails multiple HCP appointments to complete medical evaluation and laboratory testing, which can be problematic for people who face these barriers.<sup>2</sup>

To help engage newly diagnosed individuals in care, several treatment guidelines recommend starting ART immediately following diagnosis—known as “rapid initiation,” “rapid start,” or “test and treat”—prior to the availability of baseline laboratory assessments.<sup>2,14,15</sup>

The World Health Organization (WHO) recommends that rapid ART initiation, defined as starting ART within 7 days of HIV diagnosis, be offered to all PLWH following a confirmed HIV diagnosis and clinical assessment and on the same day to people who are ready to start.<sup>14</sup>

The latest DHHS guidelines state that in persons with acute or recent (early) HIV infection, in pregnant people with HIV, or in people who will initiate ART on the day of or soon after HIV diagnosis, ART initiation should not be delayed while awaiting resistance testing results. Once results are reported, the regimen can be modified if warranted.<sup>2</sup>

Despite the robust support for rapid initiation, the expert panel noted that some providers are hesitant to prescribe ARVs before having all necessary baseline laboratory results. They highlighted that the delay in initiating ART while waiting for these results remains another significant barrier to connecting individuals to HIV care immediately following HIV diagnosis.

Further, a study by Raper et al<sup>16</sup> found that the mean number of days required for an HIV outpatient clinic to process a prior authorization (PA) through commercial plans was 6.3 days. Given that WHO defines rapid initiation as starting ART within 7 days of HIV diagnosis, this finding suggests utilization management strategies, such as PAs, are an additional barrier to rapid initiation.<sup>14,16</sup>

A recent retrospective, longitudinal study by Benson et al<sup>17</sup> showed that less than 20% of commercially insured patients with HIV-1 who initiated treatment within the first 60 days of diagnosis followed current WHO guidelines of initiating ART within 7 days.

The total accumulated all-cause healthcare costs in patients who initiated ART within 7 days (RI cohort) were consistently lower than in those who initiated treatment within the first 60 days (mRI cohort) over follow-up periods of 6, 12, 24, and 36 months. Total per-person-per-month (PPPM) all-cause healthcare costs were also lower for the RI cohort but decreased over time in both study cohorts at the same follow-up periods, demonstrating cost savings associated with rapid initiation in general.<sup>17</sup>

The expert panel agreed that rapid initiation is an important model of care for helping engage newly diagnosed individuals in care. The DHHS guidelines suggest specific regimens that have high barriers to resistance for this use.<sup>2</sup> To help reduce barriers for providers and patients, the expert panel advocated for open access to these evidence-based regimens recommended for rapid initiation without requiring PAs and improved knowledge about the model through robust clinical trials data.

### Encouraging greater collaboration with high-quality HIV programs

Once patients are on treatment, achieving and maintaining viral suppression requires strict lifelong adherence to the prescribed ARV regimen.<sup>2</sup> However, retrospective studies found (using healthcare claims) that suboptimal adherence was common across payer types in the United States.<sup>18,19</sup> Real-world factors, such as those listed below, can lead to adherence challenges for PLWH.<sup>2,13,20-25</sup>

The expert panel cited the Ryan White HIV/AIDS Program as an exemplary model of HIV care that could address these challenges. The program provides a comprehensive system of HIV medical care, essential support services, and medications to low-income PLWH who are uninsured or underserved.

The program has achieved noteworthy success in implementing high-quality HIV care. In 2017, 85% of individuals in the program who had at least 1 medical visit had achieved viral suppression, which nearly meets the 90-90-90 goals. Further, the program increased the rate of viral suppression in key populations, including women, African American individuals, adolescents and young adults, and those with unstable housing.<sup>4,6</sup>

Given this success, the panel advocated for 1) the expansion of the Ryan White HIV/AIDS Program and 2) a partnership between the program and local and federal agencies to leverage its expertise in identifying the groups most in need and effectively directing resources.

### Promoting greater use of STRs

Suboptimal adherence can increase the risk of developing drug resistance and impact future treatment options, which in turn can lead to higher costs of care.<sup>26-28</sup> A Canadian study by Krentz et al,<sup>29</sup> which aimed to retrospectively measure and compare the direct costs of HIV-related care, found a 22% increase in mean PPPM costs for patients who developed HIV drug resistance compared with patients who did not.

In addition, the total treatment cost per patient increased on later lines of ART. A study by Solem et al<sup>28</sup> found that the average per-patient-per-year cost was 24% higher with a second-line treatment and 41% higher with a third-line treatment than with a first-line treatment.

In recent years, once-daily STRs have become an integral part of ART. They have been proven to improve adherence by reducing pill burden and may also decrease healthcare costs.<sup>30</sup> In a study by Cohen et al,<sup>31</sup> STR use was associated with significantly lower pharmacy costs than multiple-tablet use (\$1593 vs \$1779,  $P < 0.0001$ ) and showed a decrease in hospitalization costs (\$834 vs \$1152,  $P = 0.0203$ ).

The expert panel urged population health decision-makers to consider the economic consequences of HIV drug resistance and disease progression as a result of suboptimal adherence and the compelling data associated with STR use. The panel recommended open access to STRs for all PLWH based on evidence that supports their long-term cost-effectiveness.

The panel also noted that STRs help ensure that patients are taking a complete regimen as recommended by treatment guidelines at every dose. Multiple-tablet regimens (MTRs), on the other hand, likely require multiple co-pays and off-cycle prescription fulfillment, both of which can lead to partial dosing and increase the risk of developing drug resistance.

In addition, market entrance of generic ARVs may increase the use of MTRs because US patent laws currently limit the coformulation of generic alternatives to branded drugs.<sup>2</sup> MTRs increase pill burden and, in turn, lead to lower adherence (Spearman correlation = -0.45,  $P = 0.004$ ) and worse virologic suppression rates (Spearman correlation = -0.70,  $P < 0.0001$ ), as observed in a meta-analysis of 19 randomized controlled trials.<sup>32</sup>

Further, prescribing individual generic components of a branded coformulated product may lead to higher co-pay under some insurance plans, which may increase patient out-of-pocket costs and reduce medication adherence as a result.<sup>2</sup>

## Real-world Factors That Can Lead to Adherence Challenges<sup>2,13,20-25</sup>

### Personal Barriers

- Complex regimen
- Low levels of health literacy
- Treatment-naïve
- Busy or irregular lifestyle
- Current substance abuse
- Mental health issues (eg, stress, depression)
- Psychosocial issues (eg, low social support, stigma of HIV)
- Young age

### Systemic Barriers

- Nondisclosure of HIV status
- Nonadherence to clinical appointments
- Difficulty with taking medication
- Absence of HIV-1 symptoms
- Transition from jail/prison
- Lack of access to transportation
- Homelessness/unstable housing
- Fallen out of care
- Lack of robust care network
- Cost and insurance issues
- Co-pays and prior approval of medications
- Maintaining pharmacy benefit

## Containing the Cost of HIV Care

As PLWH are living longer and aging with the disease, patients and payers face a considerable financial burden related to the lifelong management of HIV and treatment of HIV-related comorbidities. For example, a 2018 Express Scripts report found that the average all-cause healthcare cost per patient between 2014 and 2017 was 6.5 times higher among PLWH (\$38,905) than among people living without HIV (\$6226).<sup>33</sup>

The additional costs associated with HIV care have led some commercial payers to look for ways to start managing the category through utilization management strategies and cost sharing.<sup>34,35</sup> As more therapeutic options and generics enter the market, payers may look to further manage this category in the future.

With Medicare Part D plans, the overall increase in drug spending across all therapeutic areas has led the Centers for Medicare and Medicaid Services to propose a change in rules on protected classes, which include ARVs. While the current Medicare Part D policy requires plan sponsors to include all drugs in protected classes on formulary, the proposal would allow these plans to implement utilization management strategies, such as PA and step therapy (among others), for the first time.<sup>36</sup>

However, payer policies that limit treatment options could be counterproductive; for example, switching ARV regimens requires careful consideration of each patient's ARV history, past ARV-associated toxicities and intolerances, and cumulative resistance test results.<sup>2</sup> While cost may be one factor to consider, the goal should be to maintain viral suppression without jeopardizing future treatment options.<sup>2</sup>

## Conclusion

Although the expert panel recognized that containing the cost of HIV care remains a necessity for payers and patients, it emphasized that HIV is a complex disease that requires individualized therapy to address the unique treatment needs of each patient. In order to meet these needs, the panel advocated for access to a diverse set of evidence-based treatments and programs that support lifelong viral suppression and a high quality of life for all PLWH.

The panel urged population health decision-makers to consider the expansive evidence that supports the long-term and population-wide benefits of individualized therapy. By preventing HIV transmission through treatment, connecting diagnosed patients to care through rapid initiation, and improving adherence through STR use, the United States can meet and maintain its HIV treatment goals.

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