

Optimizing HIV Care: Policy Implications

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There are more than 1.1 million people living with human immunodeficiency virus (HIV) infection in the United States,¹ and every year, approximately 56,000 more people become infected.² With improvements in the treatment of HIV infection, the death rate has fallen to low numbers (about 14,000 deaths per year).³ Therefore, the prevalence of HIV is growing at a steady but predictable rate.⁴

The introduction of highly active antiretroviral therapy (HAART) has dramatically improved clinical outcomes in patients with HIV infection. HAART is defined as combination treatment with at least 3 active antiretroviral (ARV) medications. Over 25 approved ARV medications and fixed-dose coformulations in 6 mechanistic classes are available to design potent combination regimens.⁵ The impact of these treatments on reducing mortality has transformed HIV/acquired immunodeficiency syndrome (AIDS) from a rapidly progressing terminal disease to a chronic condition.^{6,7} However, HIV infection has also become a complex chronic condition that requires a high degree of specialized clinical skills among managing clinicians. This evolving infection requires a multidisciplinary approach, which links HIV treatment with prevention and traditional healthcare screening and management. HIV infection is a costly chronic condition with high expense for maintenance and the management of numerous potential comorbidities.^{8,9} This article proposes critical issues that policymakers must address to achieve optimal HIV care in the United States.

Expect to Initiate ARV Therapy Earlier in the Infection

The optimal time to initiate HAART remains uncertain. After the development of ARVs, there was a push toward earlier initiation of therapy.¹⁰ This was followed by the realization that ARV-related side effects, toxicity, and dosage inconvenience led to poor patient adherence, treatment failure, and the potential for drug resistance. A swing back toward delayed initiation of ARV treatment followed. Currently recommended HAART combinations, however, are easier to use, with fewer side effects, convenient dosing, and excellent efficacy.¹¹ Recent studies support a swing toward earlier initiation of treatment.

The landmark study by Egger et al demonstrated conclusively that mortality is higher in patients who begin HAART when their CD4 cell counts are less than 200 cells/ μ L compared with those who start HAART with higher CD4 cell counts.¹² The Antiretroviral Therapy (ART) Cohort Collaboration reported data from 13 North

Abstract

The introduction of highly active antiretroviral therapy (HAART) has dramatically improved clinical outcomes in patients with human immunodeficiency virus (HIV) infection. HIV infection has also become a complex chronic condition that requires a high degree of specialized clinical skills among managing clinicians. This evolving infection requires a multidisciplinary approach, which links HIV treatment with prevention and traditional healthcare screening and management. With improved immune function from HAART, non-acquired immunodeficiency syndrome-defining conditions are responsible for an increasing proportion of the morbidity and mortality experienced by HIV-infected patients. The focus of HIV care must shift from reducing short-term morbidity and mortality to maintaining long-term survival and quality-of-life goals. Reimbursement for HIV treatment is extremely low. The disconnect between treatment cost and reimbursement is not sustainable, and will become more acute as individual patient care needs begin to extend over multiple decades. Policy leaders must transition to a long-term view of HIV care and shift funding priorities to maintain a viable and engaged HIV workforce.

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American and European cohorts with 20,379 adults who initiated ART between 1995 and 2003. They found that the CD4 cell count at initiation was predictive of a 5-year risk of developing AIDS or death.¹³ Specifically, the risk of death was 1.4 times higher in patients who initiated ART with a CD4 cell count of 200 to 350 cells/ μ L compared with those who initiated ART with a CD4 cell count greater than 350 cells/ μ L.

With improved immune function from HAART, non-AIDS-defining conditions are responsible for an increasing proportion of the morbidity and mortality experienced by HIV-infected patients. The Strategies for Management of Antiretroviral Therapy (SMART) study provided relevant clinical trial data to address the question of the optimal CD4 cell count for initiation of HAART.¹⁴ A post hoc subgroup analysis was performed in adult subjects who entered the study naive to HAART ($n = 249$) or had discontinued HAART more than 6 months before randomization ($n = 228$).¹⁵ Subjects were randomized to start HAART immediately or to defer HAART until the CD4 cell count decreased to less than 250 cells/ μ L. In this analysis, the risk of fatal and nonfatal AIDS-defining and serious non-AIDS-defining events was 4 times higher in the deferred HAART group compared with the immediate HAART group (95% confidence interval, 1.69-10.39; $P = .002$). The risk of serious events was 75% lower among those randomized to receive HAART immediately.¹⁵

A major rationale for deferred HAART is avoidance of drug-induced side effects and toxicities. Investigators from the HIV Outpatient Study analyzed data in 2165 patients observed for at least 3 years. They found that initiation of HAART at a CD4 cell count greater than 350 cells/ μ L was associated with a reduced risk of peripheral neuropathy and anemia compared with initiation at a CD4 cell count of 200 to 350 cells/ μ L.¹⁶ Thus, these common side effects associated with ARV therapy were less likely to occur in patients who had earlier initiation of HAART.

Finally, recent research suggests that the rate of comorbidities among patients with HIV but not directly related to HIV infection may be higher than expected. Researchers and clinicians have observed increased rates of hepatic, cardiovascular, metabolic, renal, neurologic, and pulmonary events and non-AIDS-defining malignancy among HIV-infected patients.¹⁷⁻²³ If the risk of these comorbidities is increased because of progressive HIV-induced immunosuppression or HIV-associated chronic inflammation, then early initiation of HAART may prevent the occurrence of these complications. Although cohort and clinical trial analyses are not definitive, they are highly supportive of earlier initiation of

HAART. Policymakers and clinical leaders should plan for this earlier treatment trend, and expect a higher percentage of patients to initiate HAART much sooner after infection.

Maintain the Benefits of ARV Treatment for the Long Term

People infected with HIV are living longer and feeling better, with fewer AIDS-related complications. Numerous studies have confirmed the dramatic decline in AIDS-related deaths since the introduction of HAART.^{6,7,24,25} The survival benefit is likely to be maintained for decades. Harrison et al used US national HIV surveillance data (cases ≥ 13 years old) to model life expectancy after HIV diagnosis using the life table approach.²⁵ Average life expectancy after HIV diagnosis increased from 10.5 to 22.5 years from 1996 to 2005. Lohse et al presented a simulation model of survival and age-specific mortality among the entire HIV-infected population of Denmark.²⁶ The study team demonstrated that a 25-year-old individual infected with HIV from 2000 to 2005 is likely to live an additional 39 years on average. This compares with a projected survival of 51 additional years for a 25-year-old person who is not infected with HIV. Based on survival projections such as these, the focus of HIV care must shift from simply reducing short-term morbidity and mortality to maintaining long-term survival and quality of life.⁵

The focus of HIV management must now emphasize promoting and maintaining adherence to treatment, minimizing treatment and infection-related morbidities, and optimizing health outcomes over several decades. The cost of this approach is significant. Hutchinson et al estimated that 40,000 new patients with HIV infection in 2002 will accrue a total of \$6.7 billion in direct medical costs over their lifetime.⁸ However, the financial, medical, and social costs are likely to be much higher if we do not support this approach.

Adherence to HAART is critical to long-term success; however, many clinicians may defer therapy if nonadherence is a significant concern. To illustrate the importance of adherence, Wood et al calculated the mortality rates in 1422 HIV-infected patients given HAART. They observed that patients nonadherent to medication had higher mortality rates than adherent patients with similar CD4 cell counts.²⁷ If patients adhere to their ARV regimens, viral suppression is generally achieved in 16 to 24 weeks.⁵ Unfortunately, there are many HIV-infected patients who do not seek treatment or do not adhere to treatment. A French study noted that 30% of HIV patients who entered a hospital due to an opportunistic infection knew they

had HIV but did not seek treatment, and another 36% of patients knew they had HIV but were nonadherent to treatment.²⁸

Potential problems resulting from nonadherence include both patient-specific concerns, such as development of drug-resistant infection and loss of future treatment options, and public health concerns, such as the potential for transmission of drug-resistant HIV. Despite these issues, deferral of HAART because of adherence concerns may lead to worse patient outcomes.²⁹ There are many studies examining the reasons why patients do not adhere to HAART treatment. In a systematic review of patient-specific adherence barriers from 84 clinical studies, Mills et al cited the following frequent “barriers” to adherence: fear of disclosure, concomitant substance abuse, forgetfulness, suspicions of treatment, regimens that were too complicated, too many pills required, decreased quality of life, work and family responsibilities, falling asleep, and access to medication.³⁰ In the same review, common facilitators to treatment adherence included having a sense of self-worth, seeing positive effects of ARV therapy, accepting their seropositivity, understanding the need for strict adherence, making use of medication reminders, and having a simple regimen.

Finally, effective long-term HIV management must emphasize the importance of adherence to therapy, both at initiation and at each follow-up visit. Aberg et al recently provided additional primary care HIV recommendations for improving patient adherence to treatment³¹:

1. All patients with HIV should be provided timely access to routine and urgent primary medical care. This may involve improving insurance coverage in hard-to-treat patients, which has been associated with adequate treatment adherence.³²
2. All patients with HIV should be evaluated for depression and substance abuse, and if present, a management plan should be implemented in collaboration with appropriate providers.
3. HIV clinicians should utilize a multidisciplinary model but identify a primary provider for each patient and support the development of trusting long-term patient-provider relationships.
4. HIV clinicians should make every effort to provide care that is linguistically and culturally appropriate.

Screen Earlier for HIV and Screen Everyone

Since 2006, the Centers for Disease Control and Prevention (CDC) recommends that all patients (13-64 years of age) in healthcare settings be screened for HIV infection, and that persons at high risk for HIV infection be screened at least annually.³³ Furthermore, the CDC advocates HIV screening

as a routine part of medical practice, no different from testing for any other chronic condition, such as cancer, cardiovascular disease, or diabetes.³³

The rationale for the CDC’s recommendations was simply to identify HIV-positive individuals as quickly as possible to reduce transmission risk and begin earlier treatment. Hall et al estimated that up to one quarter of patients with HIV may be unaware of their infection.² A similar percentage was noted by the CDC—in 2006, an estimated one fifth (232,700) of the approximate 1.0 million to 1.2 million persons living with HIV in the United States were unaware of their infection.¹ Until now, progress in earlier HIV diagnosis has been insufficient. Between 1990 and 1992, 51% of patients who were first tested for HIV died from AIDS within a year.³³ During 1993-2004, that percentage only dropped to 39%. As such, the CDC recommended a more proactive approach to HIV testing. Furthermore, by testing all patients, the stigma and exceptionalism associated with the HIV test can be reduced.

Early detection and management of HIV infection has important public health benefits. Studies have reported a 50% reduction in high-risk behavior and a 30% reduction in transmission after HIV diagnosis.³⁴⁻³⁶ Furthermore, Porco et al interviewed HIV-positive patients about their sexual habits before and after HAART and noted a decline of 60% in HIV infectivity after HAART treatment, although the persons they interviewed continued to have unprotected sex.³⁷ Thus, earlier HIV diagnosis and earlier initiation of HAART in infected persons are critical HIV prevention tools.

Implicit in the recommendation to screen is the ethical prerequisite that the primary beneficiary of screening has to be those who are screened. Thus, not only is it imperative to avoid the stigma and discrimination associated with HIV diagnosis, but if we screen, we are ethically obligated to have resources to treat and manage every patient with a new HIV diagnosis. Since patients may be living several decades with HIV, we should plan for an increasing prevalence of HIV in the United States. Policy planners must address the future long-term clinical needs of this patient group.

Support the HIV Clinician Workforce

Since 2000, studies and reports by states, hospital associations, medical societies, researchers, and other professional organizations have concluded that there are serious shortages of clinicians in some specialties and in some geographic areas, especially among racial and ethnic minority communities.³⁸⁻⁴⁰ These reports warn of increasing national clinician shortages

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in the near future, with continued growth and aging of the US population and the potential retirement of a large cohort of physicians.

There are multiple factors affecting clinician shortages, including physician burnout, retirement, or physicians closing their practices due to financial considerations such as underfunding, poor reimbursement, and budget cuts. Similar factors are fueling a perceived decline in HIV clinicians. A majority of today's HIV clinicians entered the field early in the epidemic, as they were beginning their medical careers. At that time, AIDS was a terminal diagnosis for most patients. Although remarkable treatment advances are transforming HIV disease into a chronic condition, it is still deadly without appropriate treatment and access to continuity of care. As the first generation of HIV clinicians nears retirement, the demand for their services is increasing, leading to a serious HIV workforce crisis that is already evident in some areas of the United States.⁴¹

Policymakers must identify best practices to increase recruitment and retention of HIV healthcare professionals. Health systems must recognize and support the increased clinician time and effort needed to provide optimal care. HIV treatment is complex and HIV disease disproportionately affects minority and vulnerable populations.⁴² Finally, reimbursement for HIV treatment is extremely low—lower than the actual cost of providing care in many areas of the country.⁴³ This disconnect between treatment cost and reimbursement is not sustainable, and will become more acute as individual HIV patient care needs begin to extend over multiple decades. Policy and health system leaders must make appropriate interventions to avoid extending this scenario.

Conclusion

During the past decade, advances in HIV therapy have led to dramatic reductions in AIDS-related morbidity and mortality, transforming HIV infection into a chronic disease. The rapid pace of HIV clinical advances has generated a number of issues for US health policy leaders to consider as health systems focus on optimizing HIV care.

ARV treatment guidelines emphasize the importance of earlier initiation of HAART.⁵ Recent studies suggest that HAART not only reduces the rate of AIDS-defining illnesses, but can have a protective effect in reducing the high rates of non-AIDS-defining comorbidities, such as liver disease, cardiovascular disease, and cancers. Healthcare funders must plan for earlier and long-term treatment. Yet, despite the availability of effective treatments, many persons living with HIV are not engaged in medical care or receiving HAART. The reasons for poor treatment-seeking behavior are numer-

ous, but healthcare providers must recognize the risk factors for poor adherence and create an environment that is accessible, destigmatizing, and nonjudgmental.

Early initiation of HAART depends on earlier diagnosis of HIV infection. Earlier entry into care and treatment is also a critical preventive modality. Routine HIV screening associated with linkage to HIV care and treatment may be the best approach to achieve a reduction in new HIV infections. Prior risk-based HIV testing has not led to a decline in HIV incidence. However, this goal will not be achieved if only urgent care clinics, emergency departments, or community health centers participate in HIV screening. The responsibility for screening belongs to all public and private systems of healthcare.

The clinical workforce must be supported to provide lifelong care for HIV-infected patients. Although HIV diagnosis and treatment is cost-effective from a societal perspective, HIV care is costly over the short term as patients engage in care and initiate HAART earlier in the infection. Policy leaders must transition to a long-term view of HIV care and shift funding priorities to maintain a viable and engaged HIV workforce. Addressing these concerns will result in optimal HIV care and allow patients to live longer and healthier, while reducing the risk of transmitting infection to others.

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