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The Prospect Of A Generation Free Of HIV May Be Within Reach If The Right Policy Decisions Are Made

ABSTRACT Scientific advances have transformed HIV treatment and prevention, leading to the adoption of an approach that emphasizes broad testing and antiretroviral treatment at earlier stages in the disease, called “test and treat.” In addition to clinical benefits, early treatment generates considerable social and economic value. These changes raise the prospect that for the first time since the 1980s, an entire generation might be free of HIV. However, achieving such a goal will require continued scientific advances and the presence of policies and programs to ensure that people living with HIV/AIDS have access to health care and adhere to treatment regimens. This article explores the opportunities and challenges that the Affordable Care Act (ACA) presents for people living with HIV/AIDS and discusses how the act’s various components might interact with existing support for people with HIV/AIDS, such as the Ryan White Program. As the ACA’s reforms proceed, coordinated state and federal programs must make smart policy choices so that critical access to and affordability of comprehensive care are maintained in the fight against HIV/AIDS.

Since reports of the first AIDS cases in 1981,1 tremendous progress has been made in fighting HIV/AIDS. What was once a terminal condition is now, with proper treatment, a manageable chronic disease.2 As discussed below, recent major scientific discoveries have changed the approach to HIV/AIDS prevention, testing, and treatment, bringing into view—for the first time since the 1980s—the prospect of a generation free of HIV.

The achievement of this goal depends not only on continued scientific progress, but also on policies that influence the treatment and prevention decisions of patients, providers, and public health officials. In this period of great fiscal pressures as well as scientific optimism, the fluid policy environment presents many opportunities to improve access to treatment. However, it also presents numerous challenges. This commentary examines obstacles to achieving HIV policy goals in the United States, as the focus shifts to the prevention or near eradication of HIV/AIDS in America.

Progress Shifts The Focus From Treatment To Prevention

Scientific breakthroughs have led to a new understanding of how best to combat the HIV/AIDS epidemic. HIV testing continues to become faster, less expensive, and more reliable.24 Home testing kits that require only an oral sample and provide results in a matter of minutes are now
available, replacing lab tests that require blood serum or other fluid samples.5

The introduction of combination antiretroviral therapy (cART) in 1996 means that a diagnosis of HIV need no longer be a death sentence. Today, cART is increasingly effective, as regimens have become easier to tolerate and thus to follow.6,7

Long the standard treatment for people in advanced stages of HIV, cART is now also recommended for those in earlier stages of the disease.8-11 (Stages of HIV are defined by CD4 white blood cell counts, a key measure of the disease’s progression. CD4 cells are involved in the immune system’s defense against tumors and infection; the number of the cells in a cubic millimeter of blood is a standard measure of immune response to antiretroviral therapy.) Perhaps more important, recent research demonstrates the effectiveness of early treatment in preventing the transmission of the virus to uninfected partners.8,11,12

These scientific advances have led many policy makers and health care providers to adopt a “test and treat” strategy—that is, expansive testing for HIV and the immediate initiation of antiretroviral treatment among those diagnosed with the disease—to combat HIV/AIDS.12 This is reflected in recent changes to treatment guidelines that broaden recommendations for testing and call for the early initiation of cART for people at all CD4 cell counts who are willing and able to commit to the treatment.14,15

Although promising, these new strategies are resource intensive and are being implemented in a period of both fiscal and policy uncertainty. Calls for cost containment present an obstacle for policy makers who wish to invest in these strategies.

Fortunately, new research indicates that even under fiscal pressures, early cART treatment is a prudent policy option. Two articles in this issue of Health Affairs underscore the value of early treatment. In the first, John Romley and coauthors found that in the period 1996-2009, early treatment with cART generated more than $80 billion in value from reduced mortality among people living with HIV/AIDS.16 As the authors note, drug manufacturers received less than 40 percent of this value through increased revenues. This suggests that the benefits were greater than the cost of providing cART drugs.

The benefits from prevention of HIV transmission are also substantial. By suppressing viral load, early treatment reduces the likelihood of HIV transmission through sexual contact or drug use.17 In the second article, Dana Goldman and coauthors found that 188,000 infections were prevented by early treatment in the period 1996-2009.18 Totaling $128 billion, the value of the avoided losses in life expectancy was 60 percent larger than the value of the longevity gains experienced by those who had HIV/AIDS and initiated treatment early.

In addition, the preventive value includes only avoided loss of life from transmission by people already diagnosed with HIV. Each prevented transmission might prevent further transmissions through risky behavior on the part of people who avoided infection. As a result, the actual benefits from prevention are likely much larger than those estimated in the study.

Given the evidence,8 researchers, policy makers, and clinicians have devoted considerable attention to the concept of treatment as prevention. This is partly a result of ongoing challenges in the development of an HIV vaccine: the very narrow time frame in which the human body can clear HIV infection—that is, eradicate the virus before it is integrated into cell DNA and effectively becomes invisible to the immune system—and the tendency of HIV to mutate rapidly make creating a vaccine a constantly moving target.19

Until a vaccine is available, cART may be the most promising method for prevention. But new cases can also be prevented through the prophylactic use of antiretroviral therapies by the HIV-negative partners of people living with HIV/AIDS. This approach is known as pre-exposure prophylaxis (PrEP).20,21

The cost of cART is much higher than that of most vaccines.22 However, early initiation of that treatment and the use of PrEP are much more targeted strategies for prevention, compared to a typical vaccination program. US government spending on vaccination programs during the past century reflects the importance the country places on protecting public health.

Nonetheless, in the absence of a vaccine, the economic value of prevention through testing and treatment exceeds its cost. According to Elisa Long and coauthors, who modeled the cost-effectiveness of a national test-and-treat policy, this strategy would cost approximately $92.6 billion (discounted) over twenty years and would prevent 17.3 percent of 1.23 million projected new infections, at a cost of $21,580 per quality-adjusted life-year (QALY).23 From the societal perspective, the value of a QALY is between $50,000 and $300,000.24

Regardless of our assumptions about the value of QALYs, test and treat is a cost-effective strategy, and current HIV treatment guidelines reflect this understanding. However, because treatment is long term and ongoing, policy decisions that affect access and adherence to treatment will ultimately determine the extent to which potential benefits can be realized.
Access And Adherence To Early Treatment

The extent of the untapped benefits from current HIV treatment strategies is clear in the steady fall-off of patients at each step along the care continuum between testing and treatment (Exhibit 1). Of the 1.1 million people infected with HIV in the United States as of July 2012, only one in three are receiving antiretroviral therapy, and only one in four have suppressed viral loads—the most important indicator of response to antiretroviral therapy.25 The full benefits of treatment accrue only to patients who achieve viral load suppression. Thus, the downstream impact of improvements at earlier stages of the care continuum, such as testing, will be limited as long as rates of viral load suppression at later stages remain low. In fact, allocating more resources to viral load suppression may be more cost-effective than investing in other types of interventions.26

Paradoxically, advances in treatment pose their own challenges. As HIV becomes a manageable disease, people living with HIV will embark on a lifelong treatment plan. With time, they may become less compliant with relatively strict regimens and abandon treatment. In addition, many patients will begin treatment when they have no obvious symptoms. It may be harder to impress on these patients the need to remain adherent to therapy.

To realize the benefits of treatment with cART, efficient, comprehensive systems of care and support must be in place. Research shows that case management and supplemental services that address the social and environmental factors described above can sustain patients’ engagement in care.33 This form of care management is a central feature of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990, a critical part of the HIV/AIDS care delivery system.

The Ryan White Program serves more than 500,000 people annually and has helped create a medical home model for HIV/AIDS care.34 In addition to outpatient care and medical case management, the program provides key “wrap-around services,” including dental care, substance abuse treatment, mental health services, transportation assistance, and housing supplements. The program also supports access to cART regimens through state-level AIDS Drug Assistance Programs.

These services are critical for stabilizing both the disease and the lives of people with HIV/AIDS. As health reform unfolds, the role of the Ryan White Program is likely to change, though in what ways is yet to be determined.

The Promise And Risk Of Health Reform

With the enactment and implementation of the Affordable Care Act (ACA) and ongoing funding debates at all levels of government, established systems of HIV care delivery are now in flux. Whether or not this moment brings the goal of an HIV-free generation closer depends on careful coordination and implementation of health reform.

In 2010 nearly two-thirds of all Americans had some form of private health insurance,35 compared to just 17 percent of people living with HIV/AIDS.36 Medicaid is the most common source of coverage for HIV/AIDS patients, and
changes under the ACA will broaden the program’s reach in states that choose to participate. These changes include expanding eligibility for Medicaid to people with incomes of up to 138 percent of the federal poverty level and to childless individuals.

This Medicaid expansion, Julia Snider and co-authors note, has the potential to reach nearly 115,000 uninsured people living with HIV/AIDS, yet 51 percent of those 115,000 people live in states not currently moving forward with Medicaid expansion. However, these people will have access to insurance through a state or federal insurance exchange. This increasing access to insurance has the potential to make care more consistent for people living with HIV/AIDS, and it may consequently extend their lives.

Expansion of access, however, also raises concerns about transitions of care and the maintenance of existing safety nets. The experience of states such as California that have already expanded their Medicaid programs suggests that expansion might actually reduce access to important supplementary services in the Ryan White Program.

When California officials prepared to expand the state’s Medicaid program, Medi-Cal, in 2010, they assumed that participants in the Ryan White Program would continue to receive care through the program. However, because the Ryan White Program is restricted to serving as the payer of last resort, the program was no longer allowed to pay for services if Medi-Cal covered them, which disrupted the continuity of care for many people living with HIV/AIDS.

Additional implementation issues arose from a lack of communication across the different state departments administering Medi-Cal and the Ryan White Program. More broadly, the experience in California raises questions about the program’s ability and authority to maintain continuity of patient care during implementation of the ACA in the coming years.

Massachusetts provides another important case study. In theory, the shift to universal coverage in Massachusetts in 2007 should have created pathways to more comprehensive care for people with HIV/AIDS who were using the Ryan White Program to fill gaps in coverage. However, the program remains a critical link in the care continuum for many in the state. As coverage was expanded, Ryan White resources were increasingly devoted to assistance with insurance premiums, covering copayments, and strengthening case management and support services not always covered by traditional insurance.

These experiences highlight issues that are likely to arise in other states. Other potential ACA implementation issues also raise concern. For example, the need to designate a primary care provider may place many people living with HIV/AIDS in the care of physicians with little experience in managing the scope of social and environmental issues that such patients face.

Providers are also concerned that funding for important services such as AIDS Drug Assistance Programs, which provide free HIV drugs to low-income patients under the Ryan White Program, will be terminated or cut back after the ACA is fully implemented. Certain vulnerable populations, such as undocumented immigrants and people with mental health issues, might fall through the cracks if future policy changes do not take account of the ongoing need for the Ryan White Program.

Indeed, most people who were clients of the Ryan White Program before passage of the ACA were enrolled in some form of insurance and depended on the program to fill gaps in coverage. Thus, the need for a safety-net program such as Ryan White to fill gaps in existing coverage is unlikely to disappear. Even as the gaps in coverage shrink for many people living with HIV/AIDS, the specialized case management and wrap-around services of the Ryan White Program, which are designed to increase adherence to treatment, can continue to contribute to the effective management of HIV.

**Looking To The Future**

As medical advances reshape the treatment and care of people living with HIV/AIDS, policies must be adapted to promote cost-effective solutions. Implementation of the ACA is continuing, and reauthorization of the Ryan White CARE Act is pending. For people living with HIV/AIDS, the key to successful treatment will be carefully coordinated design and implementation of expanded coverage and access that helps limit disruptions in existing and future care relationships and nonmedical support services.

Policy makers must consider a number of issues in formulating and implementing new policies and programs. The issue of patients’ copayments and other out-of-pocket costs are an area of concern, particularly for the working poor who earn too much to be eligible for Medicaid yet who are unable to afford premiums or copays.

Maintaining stability in care will require that mechanisms be in place to ensure that patients whose coverage alternates between Medicaid, private insurance, and the Ryan White Program can continue to see their usual provider. Otherwise, they risk having their treatment interrupted.
To realize the benefits of treatment with cART, efficient and comprehensive systems of care delivery and support must be in place. New insurance coverage under the ACA, whether Medicaid or private coverage, should address the needs of the HIV-positive population through the creation of open provider networks—such as a preferred provider organization model with wide flexibility in choosing providers—that ensure access to physicians experienced in the care and treatment of people with HIV/AIDS.

Coverage of antiretroviral drugs should be generous, to ensure that patients are able to maintain treatment without interruptions. This is particularly important since advances in treatment allow more people with HIV/AIDS to live longer and healthier lives.

In 2012 antiretroviral drugs cost, on average, $12,151 annually per patient, and longer life expectancies and expanded recommendations for cART initiation may lead to increasing costs to payers. Disruptions in treatment, however, reduce the clinical and public health benefits of cART. This not only makes today’s spending on HIV drugs less cost-effective, but it also reduces future cost savings from reduced HIV incidence resulting from the preventive benefits of cART.

To maximize these benefits, treatment adherence must be supported in other ways. Programs such as Ryan White—or at least essential elements of these programs, such as case management and wrap-around services supporting access and adherence to cART—must be preserved to ensure that these people’s lives remain stable enough to maintain adherence to cART.

Conclusion

The policy arena currently offers many opportunities to better serve people living with HIV/AIDS and to capitalize on the major medical advances in their treatment. However, turning these opportunities into successes will depend upon careful and strategic policy decisions, which should be made with all stakeholders at the table. How the ACA continues to be implemented, and how the Ryan White Program fits into that implementation, will be key not only to the future of the more than one million people in the United States living with HIV/AIDS but also to that of the thousands of people who stand to be infected if prevention benefits are left on the table. The possibility of a generation of Americans free of HIV may be in sight for the first time since the 1980s, but policy decisions today will determine whether it can become reality.

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