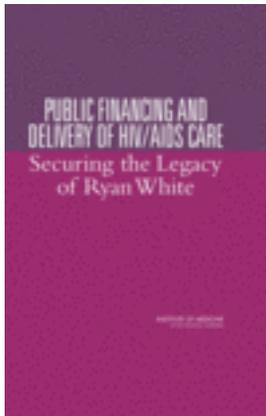




Free Executive Summary



Public Financing and Delivery of HIV/AIDS Care: Securing the Legacy of Ryan White

Committee on the Public Financing and Delivery of HIV
Care

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Each year it is estimated that approximately 40,000 people in the U.S. are newly infected with HIV. In the late 1990s, the number of deaths from AIDS dropped 43% as a result of highly active antiretroviral therapy. Unfortunately, the complex system currently in place for financing and delivering publicly financed HIV care undermines the significant advances that have been made in the development of new technologies to treat it. Many HIV patients experience delays in access to other services that would support adhering to treatment. As a result, each year opportunities are missed that could reduce the mortality, morbidity, and disability suffered by individuals with HIV infections.

Public Financing and Delivery of HIV/AIDS Care examines the current standard of care for HIV patients and assesses the extent the system currently used for financing and delivering care allows individuals with HIV to actually receive it. The book recommends an expanded federal program for the treatment of individuals with HIV, administered at the state level. This program would provide timely access and consistent benefits with a strong focus on comprehensive and continuous care and access to antiretroviral therapy. It could help improve the quality of life of HIV/AIDS patients, as well as reduce the number of deaths among those infected.

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Prologue

The Committee on Public Financing and Delivery of HIV Care was convened to develop a framework for a system of public financing and delivery of HIV care capable of meeting the current and future challenges of the HIV/AIDS epidemic. The charge to the Committee was guided by Section 501(b)(1) of P.L. 106-345, which directs the Secretary of the Department of Health and Human Services to request the Institute of Medicine (IOM) to conduct a study “concerning . . . the financing and delivery of primary care and health-related support services for low-income, uninsured, and underinsured individuals with HIV disease.” Further guidance on the study charge was provided by the study sponsor, the Health Resources and Services Administration (HRSA). The only specific programmatic reference in the charge directed the Committee to consider “modifying Medicaid to establish eligibility for medical assistance under such title on the basis of infection with HIV. . . .”

Given the broad scope of the Congressional language and the complexity of the issues, when interpreting the charge the Committee made several observations that were critical in shaping its work. First, the Congressional language is targeted; it refers to individuals with HIV disease. HIV disease combines a complex range of factors—an infectious agent; potentially fatal consequences; rapid spread in vulnerable, hard-to-insure populations; and the real potential for the development of drug-resistant strains of the virus. In addition, it is treatable with highly active antiretroviral therapy (HAART), and such treatment can substantially reduce mortality and morbidity from HIV. Second, the Congressional language does not refer to all

individuals with HIV; it specifically refers to those who are low-income, uninsured, or underinsured. Third, the authorizing language and direction from HRSA do not place limits on the range of financing and delivery options the Committee could consider, nor do they place limits on the amount of new public expenditures or the time frame that the Committee should keep in mind in developing its recommendations.

It might be appropriate for readers of this report to ask why those with HIV/AIDS should be provided public financing for care and services when those with other chronic conditions are not? This is a fair question. The IOM, in its recent report, *Insuring America's Health: Principles and Recommendations*, recommended moving toward some form of universal health insurance. Under such a model, it would not be necessary to link an HIV/AIDS diagnosis to an entitlement to services; all citizens would share in the same entitlement. Until a model of universal insurance is adopted, however, the Committee believes that the combination of factors mentioned above results in the potential for a far more catastrophic epidemic and public health threat, which in turn justifies a special program for those who are infected.

In this report, the Committee recommends the establishment of a new federally-funded program for low-income, HIV-infected persons that provides early access, continuous coverage, and uniform benefits to best meet the needs of those with HIV/AIDS. The HIV Comprehensive Care Program is designed with a strong focus on comprehensive and continuous primary care, substance abuse treatment, and mental health services to support adherence to HAART. The Committee took a holistic approach when considering the delivery of services to its targeted group because HIV/AIDS is a complex, multi-system illness that is heavily influenced by other aspects of the individual—general health, behaviors, and state of mind. In particular, the co-occurrence of HIV, substance abuse, and mental illness poses unique challenges for the management and treatment of the disease. When considering the types of services that should be delivered to people with HIV, therefore, the Committee acknowledged the large body of literature demonstrating that substance abuse and mental health are treatable conditions as well as the federal efforts in treating these diseases. The Committee agrees with the Substance Abuse and Mental Health Administration that individuals with and without HIV who have substance abuse problems or mental illness should be treated for those conditions. That such services may also help stabilize a patient and contribute to better adherence to HAART is an added benefit. In the Committee's view, not including such services in the benefit package would lower the standard of care for individuals with HIV.

Much of the Committee's recommended program is not entirely new. In many ways, this Committee's work is a logical application of the pertinent findings of other IOM Committees to the relatively narrow subject the



Committee was tasked to evaluate. Past IOM Committees have made recommendations for universal health-care coverage, and for specific types of services that should be covered (e.g., primary care services and public and private insurance coverage of evidence-based mental health and substance abuse treatment services). What is new in this report is the tying together of those services for individuals with HIV under the umbrella of a federally-supported entitlement.

With respect to the financing of services, the Committee considered expanding Medicaid to include low-income individuals with HIV, but rejected that approach in favor of a new federally-funded entitlement. The Committee is not breaking new policy ground by recommending this entitlement, but rather is in concordance with current policies because the Congressional language that discusses “eligibility for medical assistance under such title [Medicaid]” refers, by definition, to an individual entitlement. Further, had the Committee decided to recommend an expansion of the Medicaid program to cover individuals with HIV, that recommendation would not have been free to either the federal government or the states; thus, the Committee’s recommendation for additional funding is consistent with the financial implications of that financing option. Finally, it is worth highlighting that the Committee’s cost–benefit analysis demonstrates that the program would be cost-effective.

The Committee emphasizes that it has not gone beyond its charge in its recommendations in this report. As requested by Congress the Committee focused on a specific population and disease: low-income, uninsured, and underinsured individuals with HIV. The Committee’s recommendation for a new entitlement at a cost of \$7 billion is also within its purview given its charge to consider all financing options. The Committee is firm in its conviction that this nation can do more to treat individuals with HIV and to reduce the risk of HIV transmission. The HIV Comprehensive Care Program, if implemented, would secure the legacy of Ryan White and would indicate a continued federal commitment to address the financing and delivery of care for people with HIV/AIDS.



Executive Summary

ABSTRACT

The current financing and delivery system for publicly financed HIV care is complex and undermines the significant advances made in the development of new technologies to treat HIV/AIDS, such as highly active antiretroviral therapy (HAART). Many individuals experience delays in treatment access or are provided only limited options for specific drugs or important laboratory monitoring. As a result, each year there are missed opportunities to reduce mortality, morbidity, and disability among individuals with HIV infection. It is not uncommon for patients to receive care for the first time only at advanced disease stages. The fact that about 40,000 new AIDS diagnoses and 16,000 deaths occur each year further indicates that our current system is failing to ensure adequate health care for persons living with HIV infection. A similar number of new HIV infections each year indicates that the threat to the public's health from HIV continues.

The current system is not without success, most notably the development of HAART, its adoption as the standard of care, and its wide use. As a result of this new therapy, the number of deaths from AIDS dropped by 43 percent over a two-year period (1995–1997). But new and difficult challenges have emerged, including the central role of adherence to the therapeutic regimen and the attendant risk of drug resistance to HAART, the changing demographics of the epidemic and the challenges presented by those changes, and the increasing incidence of both medical and social

co-morbid conditions among people living with HIV/AIDS. Most importantly, the course of the illness has changed. Individuals with HIV are living longer and require care appropriate for a chronic illness rather than for an acute terminal illness.

The shift from acute-care needs to chronic-care needs has not been adequately accounted for by changes in the HIV care delivery system. Initially, the HIV care system developed in response to AIDS, the final stage of HIV infection. In the early days of the epidemic, little could be done for an individual ill with AIDS except to treat opportunistic infections and cancers as aggressively as possible and provide palliative care to ease suffering. As a result, hospitals and community groups were the backbone of a care system that relied heavily on inpatient and end-of-life care rather than on continuous primary medical care and drug treatment. The development of HAART allows for the suppression of the virus, which can prevent or delay the consequences of AIDS. That therapy, consisting of a number of prescription drugs, is delivered primarily in outpatient settings and requires access to high-quality primary care. In addition to HAART, many individuals require a variety of other services, including substance abuse and mental health treatment, case management, and prevention services. The care delivery system, and the financing that supports it, has struggled to adapt to the shift in the locus of service delivery and to integrate HIV care among numerous and multidisciplinary providers.

In assessing the current system, the Committee identifies the current standard of care for HIV and then assesses the extent to which the current financing and delivery system allow individuals with HIV to receive such care. The Committee's assessment leads to several conclusions. First, although current public financing strategies for HIV care have provided care to, and extended the lives of many low-income individuals, significant disparities remain in assuring access to the standard of care for HIV across geographic and demographic populations. As a result, many individuals have no access or limited access to the standard of care for HIV. Second, certain characteristics of the system (e.g., fragmentation of coverage, multiple funding sources with different eligibility requirements, and significant variations in the type of HIV services offered) do not allow for comprehensive and sustained access to quality HIV care. In many respects, this system, conceived in the early epidemic, is inadequate to meet current needs. Third, the current federal-state partnership for financing HIV care is unresponsive to the fact that HIV/AIDS is a national epidemic with consequences that spill across state borders. Finally, the Committee concludes that the large federal investment in HIV care presents a strong incentive and opportunity to finance and deliver care more effectively.

The Committee's principal recommendation to address system deficiencies is the establishment of a new federal program for financing HIV

care. The goal of the program is to provide timely access and consistent benefits to individuals with HIV, with a strong focus on comprehensive and continuous primary care and access to antiretroviral therapy. The program supports this goal by expanding program eligibility to persons with HIV infection rather than only those with AIDS, and by specifying a set of benefits that meet the standard of care for HIV. In formulating its recommendations, the Committee considered several alternative options, which are described in the report. The Committee further recommends that Centers of Excellence for HIV Care be created to demonstrate methods for improving the HIV care delivery system. Finally, the Committee recommends that the federal government seek opportunities to reduce the price of prescription drugs purchased on behalf of the new program.

This report presents the results of an assessment of the public financing and delivery of HIV care. The study was initiated in response to the second reauthorization of the Ryan White CARE Act (CARE Act), which occurred in 2000. In the text of the reauthorization, the Institute of Medicine was charged to convene an expert committee to look at the future of public financing and delivery of HIV care. Though framed within the text of the CARE Act, the Congressional charge specifically directs the Committee to assess the possible role of Medicaid in providing care for those infected with HIV. Moreover, the Health Resources and Services Administration (HRSA)—the agency tasked by Congress with oversight of this inquiry—stated in its expanded “Charge to the Expert Panel” that in the Committee’s evaluation “particular emphasis should be placed on the expansion of Medicaid eligibility to cover persons with HIV disease prior to developing AIDS, and the role of other State and Federally funded programs.” HRSA identified two broad challenges to the system:

- changes in the epidemic and increasing need for support services,
- state-to-state variability in access to publicly funded care, and disparities in access to optimal treatment regimens.

The Committee on Public Financing and Delivery of HIV Care was formed to respond to this study request. The Committee interpreted its charge as a challenge to set out a forward-looking vision for HIV care that meets the needs and makes the most of the opportunities presented by the third decade of the HIV/AIDS epidemic and beyond.

BACKGROUND

The enormity of the HIV/AIDS problem is familiar. In the United States alone there have been 816,149 AIDS cases and 467,910 AIDS-related deaths reported as of December 2001 (CDC, 2002). In 2001, the Centers for

Disease Control and Prevention (CDC) estimated that 43,158 individuals were newly diagnosed with AIDS and that between 15,000 and 16,000 individuals die from it each year (CDC, 2002). It is estimated that approximately 40,000 people in this country are newly infected with HIV each year (Fleming et al., 2000). Outside the country's borders, the problem is even more stark. The CDC estimates that the number of people living with HIV/AIDS worldwide is 40 million and that during 2001 the world's death toll from AIDS reached 3 million (CDC, 2002).

In 1990—almost a decade after the first widely distributed reports of the disease in the United States—a clear consensus had emerged in Congress to address the tragedy of large numbers of people, many of them young, dying impoverished from the disease, and to address the financial burden of AIDS on the nation's health care system and on states, cities, and hospitals. Congress passed the CARE Act, an HIV-specific federal grant program. This program funds care for uninsured or underinsured individuals who have no other resources to pay for care, and has helped create a major infrastructure for delivery of HIV/AIDS care. Other federal programs, most notably Medicaid and Medicare, along with private insurance, also provide health coverage to individuals with HIV infection.

Findings:

- Congress, through legislative action, distinguished HIV/AIDS as a disease warranting focused attention and resources.
- Through the Ryan White CARE Act, the federal government provides funding for primary medical care and support services for low-income, uninsured, and underinsured populations with HIV disease.

In 1996, HAART became (and remains) the standard of care for those infected with HIV. The impact of HAART has been dramatic—the number of deaths from AIDS in the United States fell by 43 percent between 1995 and 1997 and continued to decline at a slower pace until leveling off at the end of the decade (CDC, 2002). The discovery of an effective treatment does not, however, mean that the HIV epidemic is over or that it soon will be. HIV therapy is not a cure; it only controls the infection when potent combinations of medications are prescribed correctly, monitored closely, and taken as prescribed. The decrease in deaths brought about by new treatments—coupled with the steady number of new infections—indicates that more people than ever are living with HIV and AIDS (CDC, 2002). As a consequence, the population at risk for transmitting the disease—those already infected—continues to grow.

Findings:

- Despite remarkable advances in the treatment of HIV, the epidemic remains a threat to public health.
- Access to HAART is the cornerstone of HIV care. Without it, individuals face increased illness, disability, and death.

HAART presents its own challenges, as well. To receive optimal benefit, individuals must achieve 90 percent or higher rates of adherence to the treatment regimen, which can involve multiple pills taken at multiple times throughout the day (Paterson et al., 2000; Bangsberg et al., 2001; McNabb et al., 2001; Garcia de Olalla et al., 2002; Harrigan et al., 2003). Poor adherence also carries with it the risk of the development of drug resistant strains of the virus, dangerous not only because drug resistant strains contribute to treatment failure in the individual, but also because they can be transmitted to others. Emerging evidence indicates that the number of newly infected individuals who exhibit drug resistance is growing and that this resistance decreases treatment response, making the epidemic ever more difficult to control (Grant et al., 2002; Little et al., 2002).

Finding: Nearly complete adherence to the prescribed HAART regimen is crucial for both optimal treatment benefit and the prevention of drug resistance.

Persons newly infected with HIV are more likely to be poor, members of a racial/ethnic minority, and uninsured or publicly insured than in the past (Levi and Hidalgo, 2001). Whereas HIV was once considered a disease of white men who have sex with men, people of racial and ethnic minority groups now represent the majority of Americans in the categories of new AIDS cases, new HIV cases, people living with AIDS, and AIDS-related deaths (CDC, 2002). Although blacks and Hispanics together accounted for 70 percent of all new AIDS cases in 2001, these groups comprised only an estimated 26 percent of the total United States population (CDC, 2002; U.S. Census Bureau, 2000). For the age group 25–44, AIDS is the leading cause of death for blacks, the third leading cause of death for Hispanics, and the fifth leading cause of death for whites (NCHS, 2001).

The disease also increasingly affects women. The proportion of annual new AIDS cases represented by adult/adolescent women rose from 16 percent in 1993 to one quarter in 2001 (CDC, 1994; CDC, 2002). That same year women also accounted for 32 percent of new HIV cases. The growing

number of HIV and AIDS cases among the general population of women follows a growing trend in the heterosexual transmission rate. The proportion of AIDS cases linked to heterosexual transmission accounted for 6.4 percent in 1993 and 16 percent in 2001 (CDC, 1994, 2002).

Finding: The demographics of the HIV epidemic are shifting into populations that are highly vulnerable in terms of having access to care and continuity of care: racial and ethnic minorities, low-income women, individuals who are mentally ill or have substance abuse disorders, and homeless individuals.

In addition, HIV is a complex, multi-system illness that is heavily influenced by other aspects of the individual—general health, behaviors, and state of mind. The number of individuals with HIV who have a co-occurring condition—either medical, such as co-infection with hepatitis C virus, or social, such as homelessness, or both—is rising. In particular, the co-occurrence of HIV, substance abuse, and mental illness poses unique challenges to HIV-infected individuals in that these conditions often delay entry into care or undermine an individual’s ability to adhere to a treatment regimen. Basic primary care service, substance abuse services, and mental health services are critical for managing the complexity of HIV disease. Access to these services, as well as food, transportation, and housing assistance, has been shown to positively affect entry and retention in care (Messeri et al., 2002; Lo et al., 2002; Cunningham et al., 1999; Wells et al., 2001).

The relationship between the HIV/AIDS care-delivery system and the HIV/AIDS care-financing system is such that financing mechanisms determine in a large part how care is delivered or whether it is delivered at all. People living with HIV/AIDS rely on a variety of private and public payment mechanisms to obtain care. Thirty-one percent of the estimated total of people living with HIV/AIDS are covered by private insurance; the remaining individuals are covered through federal programs such as Medicaid and Medicare or are uninsured (Kates, 2004). Programs such as the CARE Act program, community and migrant health centers, private free clinics, and public hospitals provide a care safety net for many HIV/AIDS-infected individuals who are uninsured and/or underinsured (20 percent).

Finding: The standard of care for HIV/AIDS includes HAART, other drug therapies that prevent complications and that support retention in care, obstetrics and reproductive health services for HIV-infected women, pediatric care for infants and children with HIV, primary care services, substance abuse and mental illness treatment, case management services directly related to clinical care, and HIV prevention services.

Furthermore, design aspects of the two federal programs that provide services to HIV-infected people—Medicaid and CARE Act—allow for a tremendous amount of variability in the benefits an HIV-infected person can receive. Benefits in one area often fall well below those considered standard in others. The federal–state partnership embodied in the Medicaid program, in particular, allows states to respond to the epidemic in significantly different ways that may not be the most efficient or effective in light of a nationwide epidemic. HIV-infected individuals living in one state may not be eligible for Medicaid services in another state because of differences in income thresholds, or they may receive fewer or more services because the benefit packages vary in each state (e.g., limitations on prescriptions drugs, or coverage of case management and hospice services). Life-saving drugs may be available only intermittently, and providers may not be allowed to use critically important laboratory tests needed to evaluate HIV treatment. Disparities and variations in access to care are the signs of a system that does not equitably meet the needs of the HIV-infected population.

Findings:

- Government, through public insurance programs, is responsible for covering the care for half of all individuals with HIV/AIDS.
- Private insurance provides coverage for 31 percent of all individuals with the disease.
 - A substantial proportion of all individuals with HIV/AIDS—20 percent—are uninsured.
 - Private insurance covers 42 percent of individuals in the early stages of the disease, but only 26 percent of those with full-blown AIDS.
 - The CARE Act provides coverage to individuals without insurance and those who are underinsured in other public and private programs.

The advent of HAART changed the goal of therapy to near-complete suppression of the virus in order to maintain immune system function and overall health while simultaneously preventing the emergence of drug resistance, an outcome that had not been possible previously (CDC, 1998). Today, when appropriately treated, HIV can be managed as a serious chronic illness. Appropriate treatment requires early and continuous access to HAART, which is expensive, and the ability to support adherence to a sometimes complex drug regimen.

Yet, studies have shown that two years after HAART became the standard of care only half of those in care were receiving it (Cunningham et al., 1999). Other studies have also provided evidence that minorities, women,

and individuals with substance abuse disorders and mental illness face unequal access to newer drug therapies (Andersen et al., 2000; Celentano et al., 2001; Palacio et al., 2002; Kahn et al., 2002). A delayed access to new standards for care is troubling because HIV therapies evolve rapidly. Any lag in the receipt of new therapies or adherence to new guidelines compromises the reduction in morbidity and mortality that access to appropriate medical care early in the disease can ensure.

Under Medicaid, two specific program elements—provider accessibility and reimbursement—interfere with access to quality care. Some Medicaid beneficiaries with HIV disease encounter difficulties finding providers and more specifically, experienced providers, who are willing to take them on as patients (Tuller, 2001; Levi and Kates, 2000; CMS, 1999). One reason is financial; adequate reimbursement has been consistently asserted as necessary to ensuring beneficiary access to health-care services, and low reimbursement rates have been shown to affect access to care for Medicaid beneficiaries. Federal law provides states with considerable discretion in determining the amount Medicaid will reimburse for services provided to beneficiaries on a fee-for-service basis (Kaiser, 2001). Reimbursement for HIV care in both fee-for-service and Medicaid managed care settings does not always reflect the cost of providing care that can be time consuming and resource intensive (Bartlett, 2002; Menges et al., 2002; Norton and Zuckerman, 2000; Conviser et al., 2000). Low reimbursement rates have been suggested as a factor contributing to inferior patterns of care for some Medicaid enrollees with HIV/AIDS (Shapiro, 1999). It is instructive that the Medicare program, where reimbursement rates are set nationally at a higher level than Medicaid rates, has consistently higher physician participation, better patient access, and easier patient referrals than Medicaid (MedPAC, 2003).

Findings:

- A major shift in the delivery of services, from inpatient hospital and end-of-life social support to outpatient and chronic care, occurred with the discovery of HAART and treatment of HIV/AIDS as a chronic disease.
- Two-thirds of HIV care takes place in physician offices, community hospitals, and clinics.
- The delivery of HIV care in rural areas may be compromised if physicians lack the expertise that comes with providing care to greater numbers of HIV patients.

CARE Act programs, specifically designed to serve those with HIV disease and to fill the gaps left by Medicaid programs, also encounter difficulties in providing care. Access to HAART and primary care, for

example, varies significantly by state and city of residence, in part due to varying income eligibility requirements for the AIDS Drug Assistance Program (ADAP) under Title II of the CARE Act and in part due to the varying resource allocation decisions made by localities. Substantial state variation also occurs in the types of drugs covered and number of prescriptions allowed (Morin et al., 2002). Budget shortfalls can also lead to further restrictions in the ADAP program, such as enrollment caps or benefits limitations, as they did in June 2003.

Finding: A significant proportion of HIV-infected adults do not receive medical care on a regular basis, and many of those not receiving care are in the early stages of the disease.

As a locally controlled, discretionary program that relies on annual appropriations by Congress, CARE Act programs cannot ensure continuity of care from year to year, nor can they ensure that all eligible individuals infected with HIV will receive a minimum basic set of services, thus leading to access issues within the program. In addition, while the community planning process for CARE Act Title I funds has provided important community input into how funds are allocated at the local level, the current process has resulted in funding allocation decisions that have not reflected the greatest areas of need. Perhaps the clearest evidence of this is that the advent of highly effective HIV therapies has produced no meaningful shift of Title I funds to primary care and medications. In part, this is due to significant variability in data sources and measures (and the quality of those data sources and measures) used to describe severity of need for the Title I Supplemental Application (IOM, 2003). Furthermore, current program data collection activities do not support accountability or evaluation. It is currently impossible to make national estimates of the number of clients served by the program or the types of services received because programs do not provide unduplicated counts of clients and the services they receive. As a result, it is difficult to appropriately evaluate the prioritizing of services and allocation of funds within the programs that are so important to providing access to care. There are also lingering conflict of interest concerns about local planning councils because many of their members are service providers who receive CARE Act funds.

CONCLUSIONS

After examining the current direction of the epidemic, the advances in treatment, and the status of the current system of financing and delivery of HIV care, the Committee reached a number of conclusions.

Current public financing strategies for HIV care have provided care and extended the lives of many low-income individuals. Significant disparities remain, however, in assuring access to the standard of care for HIV across geographic and demographic populations. The current federal–state partnership for financing HIV care has been unresponsive to the fact that HIV/AIDS is a national epidemic with consequences that spill across state borders. State Medicaid programs that provide a significant proportion of coverage for HIV care have widely varying resources and priorities, which in turn produce an uneven and therefore ineffective approach to managing the epidemic.

Under the current patchwork of public programs that finance HIV care, many HIV-infected individuals have no access or limited access to the standard of care for HIV. Fragmentation of coverage, multiple funding sources with different eligibility requirements that cause many people to shift in and out of eligibility, and significant variations in the type of HIV services offered in each state do not allow for comprehensive and sustained access to quality HIV care. The lack of sustained access to HAART, in particular, is an indicator of poor quality care. Without access to HAART, individuals face increased illness, disability, and death. Moreover, low provider reimbursement in Medicaid (including Medicaid managed care) delivery systems can discourage experienced physicians from treating patients with HIV infection.

The Committee also concludes that the lack of nationwide data on the unduplicated number of individuals served and the services they received under the CARE Act hinders accountability, quality monitoring, and outcomes evaluation, and impedes the improvement of the program. The fact that the majority of HIV care is publicly financed provides a strong incentive and opportunity for the federal government to finance and deliver care more effectively.

IMPROVING THE FINANCING AND DELIVERY OF HIV CARE

The review of the evidence also led the Committee to determine that a systemwide set of objectives was necessary to improve the financing and delivery of HIV care. There are many actors in the current system and little recognition that each is an interrelated part of a complex whole. The Committee believes that defining the goals of the publicly funded HIV care system would help each part of the system to balance competing needs and priorities.

The Committee believes the primary goal of the publicly funded system of HIV care for low-income individuals should be to *improve the quality and duration of life for those with HIV and to promote effective manage-*

ment of the epidemic by providing access to comprehensive care to the greatest number of low-income individuals with HIV infection.

The Committee defined four secondary objectives of the system around the essential concepts of access, quality, accountability, and efficiency.

- Ensure low-income HIV-infected individuals early and continuous access to an appropriate, comprehensive set of medical and ancillary services that meet the standard of care.
- Promote the delivery of high-quality services.
- Facilitate the provision of services with a minimum of administrative costs (for payers and providers) and a minimum of duplication of effort.
- Ensure financing system and service delivery accountability for meeting established standards of treatment and health outcomes for all eligible individuals.

Those four objectives define the goals of an integrative chronic care system that can appropriately meet and weigh the needs of both individuals with HIV/AIDS and the providers who serve them.

The Committee also reviewed the literature on quality of care and strategies for quality improvement as outlined and recommended in past IOM reports (IOM, 2000, 2002, 2003). It embraces those recommendations and believes that publicly funded programs to provide HIV care should make every effort to improve the quality of services they provide. As one way to meet systemwide goals and objectives, the Committee also examined the concept of Centers of Excellence: systems of care that emphasize access to clinical and supportive services that are clinically appropriate, comprehensive, integrated across providers, and seamless.

ALTERNATIVE STRATEGIES

In developing its recommendations, the Committee considered a variety of alternative approaches for improving the financing of HIV care and reducing service gaps. These approaches included entitlement programs, block grants, and discretionary programs.

The Committee considered the following seven alternative approaches:

- Expand the Ryan White CARE Act
- Provide Medicare coverage to all HIV-infected individuals
- Expand the use of the 1115 Waiver for HIV care
- Create an optional Medicaid eligibility category for people with HIV
- Expand Medicaid coverage for HIV-infected individuals via enhanced federal match

- Create a federal block grant for HIV care
- Create a federally funded state-administered HIV program

Each approach was considered in light of the Committee’s goals for the public HIV care financing and delivery system: to improve the quality and duration of life for those with HIV and to promote effective management of the epidemic by providing access to comprehensive care to the greatest number of low-income individuals with HIV infection. More specifically, the Committee considered whether each option provided (1) uniform access to services, (2) a benefit package that meets the standard of care for HIV/AIDS, (3) a financing structure that ensures continuity of care, (4) reduced barriers to access services, and (5) administrative structures that support program accountability and evaluation.

RECOMMENDATIONS

Each of the seven options has certain advantages for improving access to HIV care. The Committee chose the option that creates a new federal program administered by states as the one with the greatest potential to achieve the goals of a publicly financed system of HIV care. In the Committee’s view, other options continue to perpetuate major deficiencies in the current financing system and fail to provide for uniform and consistent access to care and the comprehensive set of benefits necessary to meet the standard of HIV care that will extend lives and reduce illness and disability. The Committee is aware that its recommendations mark a radical departure from the way that public financing and delivery of HIV care is currently organized. It believes, however, that in light of the dramatic developments in treatment and troubling demographic trends in the HIV epidemic this departure is warranted and necessary. In supporting its decision to recommend a new federal program, the Committee examined carefully the cost and health implications of what it is proposing. Through extensive modeling of program impact and costs, presented below, the Committee concluded that its recommended program will significantly reduce premature deaths from HIV/AIDS, will add a substantial number of quality-adjusted years of life to those individuals who gain access to HAART under the program, and is cost effective; that is, the benefits of the program warrant the level of expenditure required.

The Committee determined that the best option for improving the financing of HIV treatment would be to formulate a new program that is unencumbered by existing programs that provide coverage for HIV care. The Committee formulated its program in five recommendations; the first recommendation establishes the program, and the remaining recommendations address major features of the program, including (1) eligibility,

(2) benefits, (3) provider reimbursement, and (4) possible cost saving measures. Two additional recommendations address integration and coordination of services within the program and with CARE Act funded services.

Recommendation 1: The federal government should establish and fully fund a new entitlement program for the treatment of low-income individuals with HIV that is administered at the state level.

To assist states in implementing the program, the federal government should pay for costs directly attributable to efficient administration of the program. To receive federal funding, states must ensure compliance with federal standards and operate programs according to principles of accountability and transparency. Under the federally sponsored program, the federal government would relieve the states of the full cost of providing care to HIV-infected individuals through their Medicaid programs.

The program has several primary design features that are critical to achieving the goals of the program. These features focus on eligibility requirements, benefits, access to experienced providers and provider reimbursement, quality and program management efficiencies, and interaction with other programs.

Eligibility

Most people receiving care for HIV/AIDS do so through Medicaid programs and the CARE Act program. In Medicaid, most states limit eligibility to those with HIV/AIDS who otherwise meet Medicaid disability standards. As a practical matter, this means that people only become eligible once they have advanced AIDS—resulting in disability and serious illness—and have low income. The benefits of HIV therapy are compromised by such delayed access. Therefore, people cannot get Medicaid coverage upon diagnosis with HIV, which would enable access to care that would prevent the costly onset of active disease and disability-related health costs. Eligibility for the CARE Act programs is usually based on HIV diagnosis. The program, however, varies by state and locality, as do the services available. Eligibility for ADAP within the program is generally offered to individuals with HIV infection with incomes typically under 300 percent of the federal poverty level (FPL) although a few states set eligibility at under 500 percent of FPL. Because ADAP operates under a defined appropriation with limited funding, many localities have waiting lists for eligible people to receive medication. Limiting eligibility to persons with AIDS disability and maintaining waiting lists for the commencement of drug therapies fundamentally contradicts the need for early and continuous access to care.

The Committee concludes that the income eligibility threshold should be higher than those typically represented in Medicaid (thus, it should be at 250 percent of FPL). This standard is higher than the minimum Medicaid eligibility standard for disabled Supplemental Security Income recipients but is consistent with the standard applicable to working disabled individuals eligible for Medicaid at state option under the Balanced Budget Act (BBA) of 1997 (1902(a)(10)(A)(ii)XIII of the Social Security Act added by section 4377(3) of the BBA, P.L. 105-33). In recognition of the burden care imposes, the income limit should also include a spend-down provision for those whose medical expenses for HIV/AIDS reduce their incomes to 250 percent of the FPL.¹ The current Medicaid program includes spend-down eligibility as a state option. Some 39 states have taken advantage of Medicaid medically-needy options with spend-down provisions to extend eligibility to higher income levels than basic Medicaid covers (Etheredge and Moore, 2003). In addition, those not otherwise financially eligible should be able to buy into the program on a sliding scale basis to ensure that their lack of access to private insurance is not a barrier to participating in a system of care. The Committee is concerned that the absence of spend-down and buy-in provisions would leave too many people outside the program to meet its objectives to reduce morbidity, mortality, and disability. Accordingly, the Committee considers these provisions essential.

Recommendation 2: The new program should extend coverage for treatment to individuals determined to be infected with HIV whose family incomes do not exceed 250 percent of the federal poverty level. Individuals with HIV infection whose family incomes exceed this standard should be allowed to establish eligibility for coverage by spending down or by buying in on a sliding scale basis.

Benefits

To be clinically effective, HIV/AIDS treatment requires comprehensive care. Most notably, timely initiation of HAART and maintenance of therapy are critical elements of care. Because of the complexity of the disease process and the susceptibility of those with HIV to opportunistic

¹Under the Medicaid program individuals may qualify for coverage even through their countable incomes are higher than the specified income standard by “spending down.” Under this process, the medical expenses that an individual incurs during a specified period are deducted from the individual’s countable income during that period. Once the individual’s income has been reduced to a state-specified level by subtracting incurred medical expenses, the individual qualifies for Medicaid for the remainder of the period (Kaiser Commission on Medicaid and the Uninsured, 2001).

infection, primary care services, case management, and prevention services are essential. To prevent HIV transmission from pregnant women to their newborn children, which is virtually completely avoidable with appropriate drug therapy during pregnancy, obstetric and reproductive health services must be included. Finally, many people with HIV/AIDS suffer from co-morbid conditions such as mental illness or substance abuse disorders that interfere with compliance with treatment regimens. The inclusion of services to address mental illness and substance abuse is fundamental to the continuation of therapies essential to disease management. Accordingly, the Committee recommends:

Recommendation 3: The new program should entitle each eligible individual with HIV to a uniform, federally defined benefit package that reflects the standard of care for HIV/AIDS.

Provider Payment

Even where programs exist for HIV/AIDS care, such as Medicaid and the Ryan White CARE Act program, access to sustained care has been undermined by erratic and uncertain provider participation in the programs. In most cases, this is attributable to inadequate provider reimbursement, specifically under Medicaid. In fact, Medicaid reimbursement to HIV/AIDS providers historically has been so low that in many states access to care for people with HIV/AIDS in Medicaid is the same as for those who are uninsured (Shapiro et al., 1999).

These access barriers are incompatible with the Committee's objective of achieving reduced morbidity, mortality, and disability. Of the public insurance programs, Medicare has achieved a noteworthy record of improving access to care, and provider participation remains very high (around 96 percent). While recent budget reductions may threaten the level of provider participation and may affect beneficiary access, Medicare still represents a model for improving access to care. Accordingly, the Committee recommends:

Recommendation 4: The new program should reimburse providers who elect to participate at rates comparable to those paid by Medicare for comparable services.

Cost Offsets

Drug manufacturers sell the same product at different prices to different purchasers. Under current law, the price drug manufacturers can charge the Department of Veterans Affairs (VA), the Department of Defense (DOD), the Public Health Service (PHS), and the Coast Guard for products

(brand name drugs) listed on the Federal Supply Schedule (FSS) is capped at the Federal Ceiling Price (FCP). That price is at least 24 percent less than the average price paid to a manufacturer (AMP) by wholesalers for drugs distributed to nonfederal purchasers (NFAMP). The NFAMP is not publicly available (GAO, 2000). The VA manages the FSS, another cost containing measure. The schedule specifies the quantities of and prices paid by the federal government for a wide range of medical goods including drugs. Competitive procedures are used to award contracts to companies to provide drugs at “the most favored customer price.”

Under the Medicaid program, state agencies are allowed to purchase drugs at a lower cost for the treatment of HIV/AIDS through a rebate program. Other entities, including ADAP, are eligible to purchase pharmaceuticals under the 340B Drug Discount Program. This program allows for these entities to purchase drugs directly from manufacturers through a centralized mechanism at a lower price or to obtain rebates under the state Medicaid rebate program. Twenty-two state ADAPs obtain drugs at the 340B discount price and 26 state ADAP programs take advantage of their states’ Medicaid unit rebates on a quarterly basis (Aldridge and Doyle, 2002).

In a report released in 2001, the Office of the Inspector General for the Department of Health and Human Services (OIG) estimated that state Medicaid programs in 1999 paid 33 percent more than the FCP for antiretroviral medications (DHHS, 2001). The OIG also estimated that Medicaid’s price for antiretroviral drugs was 10 percent higher than the FSS, and 5 to 15 percent higher than the price paid by state-administered ADAPs (depending on how the programs were organized). In its report, the OIG recommended that Medicaid be given access to the FCP for antiretroviral drugs (DHHS, 2001). In a separate report, the OIG has also recommended that ADAP also be given access to the FCP (DHHS, 2000). The Committee finds that the OIG analysis has merit and that it should apply with equal force to the new federal HIV program. By replacing and expanding upon both Medicaid and ADAP, the new federal HIV program would be this country’s single largest purchaser of the prescription drugs that make possible effective HAART therapy.

The Committee recognizes that pricing policy of public programs can affect the research and development investment decisions of pharmaceutical manufacturers, particularly when, as in this instance, the public program is a dominant purchaser. There is a risk that, if the new program purchases antiretroviral drugs at the FCP, manufacturers may be less willing to invest significant resources in research and development for HIV therapies because they project a reduction in potential revenues for new drugs in this class. There are also concerns that manufacturers will raise prices for other purchasers to offset revenue losses resulting from the lower reimbursement

for HIV/AIDS drugs (GAO, 2000). The Committee takes this matter seriously—research and development of antiretroviral therapies by pharmaceutical manufacturers have made fundamental contributions to our understanding of HIV and the dramatic change in the clinical course and outcome of HIV infection brought about by HAART. These concerns led the Committee to conduct an analysis (presented in Chapter 6) that suggests that there is substantial room for lowering prices for HAART obtained through the HIV-CCP while still increasing manufacturer net revenues. The Committee is firm in asking the federal government to be a prudent purchaser and to explore ways that would reduce the cost of pharmaceuticals in the new program, while recognizing that the steps taken should not undermine research and development of new HIV/AIDS drugs. Accordingly, the Committee recommends:

Recommendation 5: To ensure that the new program is a prudent purchaser of drugs used in the treatment of HIV/AIDS, the Congress should implement measures that lower the cost of these drugs such as applying the Federal Ceiling Price or the Federal Supply Schedule price currently used by some major federal programs. Implementation of this recommendation would lead to an estimated discount off of Medicaid antiretroviral prices of 9 percent to 25 percent.

Improving Quality and Programmatic Efficiencies

Consistent with past Institute of Medicine reports (IOM, 2000, 2001, 2003), the Committee asserts that HIV care delivery systems must provide medical management that is coordinated and integrated. The Committee acknowledges that a system of HIV care needs to (1) ensure effective treatment and efficient resource utilization, (2) coordinate care and social support across a number of providers within any given community, and (3) require a focused organization and management effort. The Committee believes that access to required services could take place within care networks that are comprehensive, coordinated, and accountable. Accordingly, the Committee recommends:

Recommendation 6: The new program should adequately fund a nationwide demonstration of the effectiveness of Centers of Excellence in delivering covered services to eligible individuals with HIV.

Coordination with Other Programs

The Committee emphasizes that the creation of a new federal HIV program for low-income individuals with HIV would not eliminate the need for the CARE Act. It would, however, alter the role of the CARE Act,

particularly with respect to funding drug therapies and other services that would be covered by the new federal program. Many of the individuals with HIV who are now served by the CARE Act would be eligible for the new federal program. As an entitlement, the new federal program would have more funds with which to address the treatment needs of these individuals than the CARE Act programs, which are subject to the annual appropriations process. In the case of individuals eligible for both programs, the new federal program should be the first dollar payer for the services that it covers. This would free up remaining CARE Act funds for other purposes, such as assisting individuals in enrolling in the new federal program, filling in any remaining service gaps, and supporting delivery system improvements. Accordingly, the Committee recommends:

Recommendation 7: The new program should coordinate closely with the Ryan White CARE Act, which should be refocused to meet the needs of low-income individuals who are not eligible to be served by the new program.

Program Cost and Health Benefits

As part of its charge the Committee was also instructed to develop estimates of the cost and impact of its recommendations. To do this, the Committee developed a model to estimate the cost and health impact associated with the implementation of the recommended program. Because the centrality of HAART to HIV care renders it a useful health outcome measure, the Committee focused on the number of people who would be newly prescribed antiretroviral medications. The Committee recognized the need to place HIV care in perspective with competing demands for society's health care resources and used the model to calculate the number of quality adjusted life years (QALYs) gained under the new program and the associated cost per QALY.

The Committee estimates that in the first year of implementation, the recommended program would enroll approximately 285,000 individuals with HIV/AIDS. The majority of these individuals' care is currently financed through state Medicaid programs; however, 58,697 people who currently need HAART but are not receiving it would gain access to the medication. All individuals enrolled in the program would gain access to a uniform, comprehensive set of services designed to help them remain in care and adhere to medication regimens. As a direct result of receiving HAART, the Committee estimates that premature deaths among those individuals will decline over a 10-year period by 55.9 percent, from 35,489 deaths to 15,664 deaths. The Committee also estimates a gain of 129,385 QALYs for those newly on HAART, when the entire set of services including substance

abuse and mental illness is accounted for, discounted to present value, over the 10-year period for those individuals enrolled in the first year.

The Committee estimates that the incremental cost of providing HAART to 58,697 individuals for 10 years in 2002 dollars is \$2.65 billion. Adding the cost of the other elements for comprehensive care that the Committee recommends—complete benefits package for all enrollees (including case management, substance abuse treatment, and mental health care services), Medicare rate for reimbursement for outpatient services, and Medicare plus 5 percent for services provided through Centers of Excellence—the incremental cost from a societal perspective is estimated to be \$5.56 billion, discounted, over 10 years.

The results of the Committee's analysis to determine whether the recommended program is cost effective indicates that cost per QALY gained of implementing the program is \$42,972 in 2002 dollars, an amount that is comparable to other widely accepted health care investments.

Final Observations

The Committee acknowledges that its recommendation to establish a new federal program will require new federal expenditures, and at a time of constrained fiscal resources, such a recommendation may appear irresponsible. The Committee struggled with the fiscal realities of the times but was not deterred from making its recommendations for several reasons. First, the HIV/AIDS epidemic in this country and in countries across the world reminds us every day that HIV/AIDS is a world tragedy. Left unchecked, it will continue to take the lives of millions of men, women, and children. The deaths, illness, and disability associated with HIV infection and its ability to spread insidiously through communities have led the leadership of our country and those in other countries to set HIV/AIDS apart from other infectious diseases for special attention and action.

Second, it was just 20 years ago that the United States experienced the exceedingly high rates of mortality that other countries face today. As a country we are fortunate relative to other nations; our investment in research and technology to fight AIDS has produced powerful results in the development of HAART and other tools. This technology has meant the difference between life and premature death for some individuals and has improved our ability to protect the health of the public. However, to possess tools that extend life, reduce illness, and reduce disability, while not making them available to those who need them is, in the Committee's view, indefensible. The program the Committee recommends provides access to the key technologies and tools our health system has to offer—HAART, primary care services, obstetric and reproductive health services, substance

abuse treatment, treatment for mental illness, and prevention services and case management.

Third, the Committee is reinforced in its decision to recommend a new comprehensive program by the positive results of the cost-effectiveness analysis. This type of an analysis is used by policy makers when tough decisions must be made regarding how best to allocate scarce resources; it evaluates the outcomes and costs of interventions designed to improve health. The Committee's recommended program, in addition to reducing deaths and improving the quality of life of those with HIV, is cost effective; it is also good social policy.

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PUBLIC FINANCING AND DELIVERY OF HIV/AIDS CARE

Securing the Legacy of Ryan White

Committee on Public Financing and Delivery of HIV Care

Board on Health Promotion and Disease Prevention

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*“Knowing is not enough; we must apply.
Willing is not enough; we must do.”*
—Goethe



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HERMINIA PALACIO, M.D., M.P.H., Assistant Professor of Medicine, Baylor College of Medicine, Houston Center for Quality of Care and Utilization Studies (until August 2002)

BENY PRIMM, M.D., Founder/Executive Director, Addiction Research and Treatment Corporation (until August 2003)

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Disease Prevention

Douglas S. Weil, Sc.D., Study Director (until July 2003)

Melissa G. French, M.A., Research Associate

Gina Bata, Sr. Project Assistant (until December 2002)

Lori Young, Project Assistant (until July 2003)

Rita Gaskins, Administrative Assistant, Board on Health Promotion and
Disease Prevention

Reviewers

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JOYCE ANASTASI, Ph.D., R.N., F.A.A.N., Columbia School of Nursing
CHRISTOPHER G. ATCHISON, M.P.A., University of Iowa
GORDON DEFRIESE, M.D., North Carolina Institute of Medicine, Inc.
MICHAEL V. DRAKE, M.D., University of California Office of the President
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WILLIAM G. POWDERLY, M.D., Barnes-Jewish Hospital
MICHAEL SAAG, M.D., University of Alabama at Birmingham



BRUCE SCHACKMAN, Ph.D., M.B.A., Weill Medical College of Cornell University
FRANK A. SLOAN, Ph.D., Duke University

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations, nor did they see the final draft of the report before its release. The review of this report was overseen by **Dr. Joseph Newhouse**, Harvard University, and **Dr. Fernando Guerra**, San Antonio Metropolitan Health District. Appointed by the Institute of Medicine, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the author committee and the institution.



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