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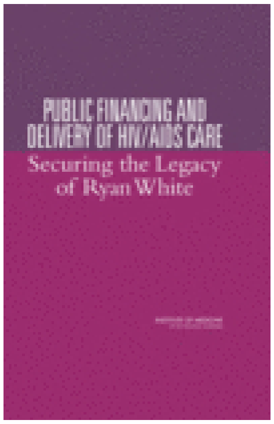

Public Financing and Delivery of HIV/AIDS Care: Securing the Legacy of Ryan White

Committee on the Public Financing and Delivery of HIV Care

ISBN: 0-309-65541-2, 364 pages, 6 x 9, (2005)

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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

INSTITUTE OF MEDICINE
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THE NATIONAL ACADEMIES PRESS
Washington, D.C.
www.nap.edu

THE NATIONAL ACADEMIES PRESS 500 Fifth Street, N.W. Washington, DC 20001

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This study was supported by Contract No. 231-01-0061 between the National Academy of Sciences and the Health Resources and Services Administration. Any opinions, findings, conclusions, or recommendations expressed in this publication are those of the author(s) and do not necessarily reflect the view of the organizations or agencies that provided support for this project.

Library of Congress Cataloging-in-Publication Data

Public financing and delivery of HIV/AIDS care : securing the legacy of Ryan White / Committee on the Public Financing and Delivery of HIV Care, Board on Health Promotion and Disease Prevention.
p. ; cm.
"Supported by Contract No. 231-01-0061 between the National Academy of Sciences and the Health Resources and Services Administration."
Includes bibliographical references and index.
ISBN 0-309-09228-0 (hardcover)
1. AIDS (Disease)—Patients—Care—Government policy—United States. 2. AIDS (Disease)—Patients—Care—United States—Finance. 3. HIV infections—Patients—Care—Government policy—United States. 4. HIV infections—Patients—Care—United States—Finance.
[DNLM: 1. HIV Infections—therapy—United States. 2. Delivery of Health Care—standards—United States. 3. Financing, Government—United States. WC 503.2 P9756 2005] I. Institute of Medicine (U.S.). Committee on the Public Financing and Delivery of HIV Care.
RA643.83.P83 2005
362.196′9792—dc22
2005010580

Additional copies of this report are available from the National Academies Press, 500 Fifth Street, N.W., Lockbox 285, Washington, DC 20055; (800) 624-6242 or (202) 334-3313 (in the Washington metropolitan area); http://www.nap.edu.

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> *Willing is not enough; we must do."*
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This report has been reviewed in draft form by persons chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards of objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following for their review of this report:

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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.

Acknowledgments

This report represents the collaborative efforts of many organizations and individuals, without whom this study would not have been possible. The Committee extends its most sincere gratitude to those mentioned below.

The Committee thanks the sponsor of the study, the Health Resources and Services Administration (HRSA), especially the project officer Richard Conviser. All of the staff at HRSA were very gracious in handling the Committee's requests for information, for which we are very grateful. The Committee would especially like to thank Steven Young, Jill Ashman, Douglas Morgan, Deborah Parham, Kathy Marconi, and Faye Malitz for their help.

The Committee greatly appreciates the input of speakers whose presentations informed their thinking, including:

David M. Abramson, Columbia University
Casey S. Blass, Texas Department of Health
Glenn Clark, Whitman-Walker Clinic
Richard Conviser, Health Resources and Services Administration
Susan Dooha, Gay Men's Health Crisis
Geno Dunnington, Whitman-Walker Clinic
Ruth Finkelstein, New York Academy of Medicine
Julia Hidalgo, The George Washington University
Jennifer Kates, Kaiser Family Foundation
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Matt Salo, National Governor's Association
Bruce Schackman, Cornell University
Wayne Smith, Centers for Medicare and Medicaid Services
Tim Westmoreland, Georgetown University
Steven Young, Health Resources and Services Administration

The work of this Committee has been informed by several high-quality Institute of Medicine (IOM) reports on relevant topics, including *To Err Is Human: Building a Safer Health System* (2000); *Crossing the Quality Chasm: A New Health System for the 21st Century* (2001); *Care Without Coverage: Too Little, Too Late* (2002); *Fostering Rapid Advances in Health Care: Learning from Systems Demonstration* (2002); *Priority Areas for National Action: Transforming Health Care Quality* (2003); and *Insuring America's Health: Principles and Recommendations* (2004). We acknowledge our indebtedness to the committees and staffs of these reports.

The Committee commissioned work from a number of authors. Jennifer Kates provided an invaluable update of her comprehensive paper on the financing of HIV/AIDS care; Ruth Finkelstein and Rebecca Tiger's work on HIV and substance abuse and Miriam Davis's analysis of HIV and serious mental illness greatly added to the Committee's knowledge; Christine Lubinski provided an in-depth analysis of Medicaid programs in five states; Jeffrey Levi examined the changes in the Ryan White CARE Act since its inception; and John Palen wrote a legislative history of the Ryan White CARE Act. All of this work was extremely helpful and added to the Committee's understanding of this complex topic. The Committee would also like to thank the consultants who provided valuable information, analysis, and support—Constance Currier, Kathryn Ikard, and Mark Polston. The Committee would like especially to thank Barbara M. Smith for her contribution to the development and analysis of the various public financing options.

The Committee wishes to thank the liaison panel members: Terje Anderson, A. Cornelius Baker, Christopher Bates, Ignatius Bau, Guthrie Birkhead, G. Stephen Bowen, Mary Ann Chiasson, Richard Conviser, Gene Copello, Sharen Duke, Helen Fox Fields, Debra Frazer-Howze, Robert Fullilove, Kenneth T. Jones, Jennifer Kates, Seth Kilbourn, Monina Klevens,

Christopher Labonte, Miguelina I. Leon, Marsha Martin, Jean McGuire, Jesse Milan, Thomas L. Milne, Murray Penner, Kees Reitmeijer, Matt Salo, Jane Silver, Paul Simon, Wayne Smith, Tim Westmoreland, Joy Johnson Wilson, David Wunsch, and Steven Young. The Committee is grateful for their guidance.

In particular, the Committee would like to recognize two of its members, Jim Kahn and David Holtgrave, for their enormous contribution in developing the model used to predict the results of the Committee's recommendations. Dr. Kahn would like to acknowledge the inspiration and support that his father Stephen M. Kahn (deceased January 2003) offered for his work in HIV prevention and care policy. The Committee also gives a special thanks to Andy Schnieder for patiently guiding the Committee through the analysis of program options.

The Committee would also like to thank the numerous staff members of the Institute of Medicine, the National Research Council, and the National Academies Press who contributed to the development, review, production, and dissemination of this report. The Committee is grateful to Douglas Weil, who directed this study from its inception until July of 2003, and to Rose Marie Martinez, who provided guidance and oversight as Board Director and directed the study from July 2003 forward. The Committee extends its thanks to Melissa French for her outstanding research and writing, and assistance with model building. The Committee is also thankful for the administrative assistance provided by Gina Bata, Rita Gaskins, and Lori Young. Assistance with references and formatting of the report was provided by Hope Hare, Peter James, and Deepali Patel. IOM's research librarian, William McLeod, was enormously helpful in gathering and organizing the vast amounts of literature available on HIV/AIDS.

Contents

APPENDIXES

PUBLIC FINANCING AND DELIVERY OF HIV/AIDS CARE

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

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[1] Under 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 though 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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1

Introduction: Securing the Legacy of Ryan White

As the nation enters its third decade of the HIV/AIDS[1] epidemic, it faces a future of both promise and complex challenges. The advances and accomplishments in prevention and treatment of the disease have made an astonishing difference in health and well-being for those with access to the treatments and the ability to adhere to the regimens. At the same time, the changing demographics of the population affected by the epidemic have raised new challenges that the current system of care is less equipped to address. Transmission rates in the United States leveled in the late 1990s, but there have not been further reductions in new infections since then. Furthermore, many who could benefit from current treatment and care methods do not receive them. As a result, the disease remains a key public health problem for the nation.

In 2000, the Kaiser Family Foundation conducted a national survey of American views on HIV/AIDS. The survey revealed that Americans considered HIV/AIDS one of the most urgent health concerns facing the nation, second only to cancer. Eighty percent believed that access to care and treatment for HIV/AIDS is a problem in this country and that access is influenced by income, race, and gender (Kaiser Family Foundation, 2001).

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[1] Human Immunodeficiency Virus (HIV) is the virus that causes acquired immune deficiency syndrome (AIDS). The Committee uses HIV to refer to the virus and AIDS or HIV disease to refer to the illness it causes. The Committee uses HIV/AIDS as a global term to refer to the spectrum of issues surrounding the epidemic, from prevention to care and treatment.

Among minorities, who are disproportionately affected by the epidemic, the disease was ranked as the top national health concern.

In this context of changing demographics, improved treatment options, and continued widespread public concern, Congress passed the 2000 reauthorization of the Ryan White Comprehensive AIDS Resource Emergency (CARE) Act (CARE Act). The issues before legislators as they contemplated the future of the federal response to the HIV/AIDS epidemic included equitable resource allocation, reliable disease surveillance, and disparities in access to care and life-saving medications for the poor and uninsured. In the text of the reauthorization, the Institute of Medicine was charged to form two expert Committees to look at the future of the federal response to the HIV/AIDS epidemic. The two Committees—the Committee on Public Financing and Delivery of HIV Care and the Committee on the Ryan White CARE Act: Data for Resource Allocation, Planning and Evaluation—were intended to work independently but in parallel and to release their findings within months of one another. One report, from the Committee on the Ryan White CARE Act, addresses several specific questions raised by Congress about the current allocation formulas, the determination of resource needs in different jurisdictions, and the assessment of care quality. Although it addresses some long-range issues, it is intended to provide guidance on issues currently faced by Congress, the Health Resources and Services Administration (HRSA), and grantees in the administration of the CARE Act. This report, from the Committee on Public Financing and Delivery of HIV Care, is intended to provide a vision of the HIV care system necessary to meet the challenges of the third decade of the AIDS epidemic and beyond.

THE RYAN WHITE CARE ACT

Ryan White died 4 months before the legislation that bears his name was signed into law. The teenager, who had contracted the virus through blood products used to treat his hemophilia, had become the face of the epidemic for the nation in 1985, when he began his successful fight to be allowed to attend school with his classmates in Indiana. He had been ostracized, bullied, and threatened because he was infected with HIV, and his struggle to restore dignity to those living with the disease touched the nation (Johnson, 1990; GPO, 2000).

The CARE Act (see Box 1-1) bears the following stated purpose:

> [T]o provide emergency assistance to localities that are disproportionately affected by the Human Immunodeficiency Virus epidemic and to make financial assistance available to States and other public or private nonprofit entities to provide for the development, organization, coordination

BOX 1-1
The Ryan White CARE Act

The Ryan White CARE Act funds outpatient care and support services, including medical care, dental care, case management, and prescription drugs through the AIDS Drug Assistance Program (ADAP). In some cases it can also be used to fund insurance continuation. CARE Act funds do not pay for inpatient care or long-term institutional care. CARE Act-funded services are provided to more than half a million individuals each year, making it the federal government's largest HIV-specific care program. The CARE Act is organized into four titles and three targeted components:

Title I

Title I provides emergency assistance to the Eligible Metropolitan Areas (EMAs) that are most severely affected by the epidemic. There are currently 51 EMAs in 28 states and territories including Puerto Rico and the District of Columbia. Title I funds are used to provide medical and ancillary/support services. To receive Title I funds, an EMA must establish an HIV Health Services Planning Council representing various stakeholders within the community to allocate funds.

Title II

Title II provides grants to all states and eligible territories and funds the ADAP. Title II funds health care and support services, as well as health insurance continuation. Prescription drugs are funded under ADAP, which constitutes well over half of total Title II funds.

Title III

Title III grants are provided directly from the federal government to the eligible organization, which must be a public or private nonprofit entity that is currently providing or intends to provide comprehensive HIV primary care. There are three grant programs under Title III: Capacity Building Grant Program, Planning Grant Program, and Early Intervention Services.

Title IV

Title IV provides medical care as well as social, outreach, and prevention services to children, youth, and women living with HIV and their families.

Special Projects of National Significance (SPNS)

SPNS grants are provided to eligible entities to establish innovative models of care. The purpose of the SPNS program is to evaluate the effectiveness of programs and foster the development of new ideas.

The AIDS Education and Training Centers (AETCs)

AETC grants support a network of 11 regional centers plus associated sites that provide education and training to health care providers serving people living with HIV/AIDS.

continued

BOX 1-1 Continued

Dental Reimbursement Program and Community-Based Dental Partnership Program

The Dental Reimbursement Program provides reimbursement to dental schools, postdoctoral dental education programs, and dental hygiene education programs for nonreimbursed costs of providing dental care to people living with HIV/AIDS. The Community-Based Dental Partnership program provides funds to increase access to oral health care among rural and urban HIV-positive communities.

SOURCE: HRSA, 2001.

> and operation of more effective and cost efficient systems for the delivery of essential services to individuals and families with HIV disease (P.L. 101-381).

The dry words of the legislation belied the desperate need for these "systems for the delivery of essential services." AIDS is a disease that impoverishes and disables before it kills, leaving the individuals who have it disproportionately reliant on the public sector for care. The CARE Act grew from the realization in Congress that a coordinated federal response to the AIDS care crisis was necessary. The testimony of overwhelmed state and city government officials, public hospital administrators, people living with the disease, and their families had convinced members of both chambers of Congress that emergency relief was warranted.

The CARE Act provides funding for primary medical care and support services for low-income, uninsured, and underinsured populations with HIV disease. Though exact client counts are impossible, HRSA estimates that more than half a million individuals each year receive medical care, prescription drugs, and ancillary services paid for with CARE Act funds. This makes the CARE Act the federal government's largest HIV-specific care program, representing 22 percent of federal spending on health care for individuals with HIV/AIDS (Kates, 2004).

When the CARE Act was authorized in 1990, the experience of treating and living with HIV/AIDS was different than it is today. Treatment options were few, and the only antiretroviral medication approved for use (AZT) was of limited effectiveness. The focus of care, out of necessity, was on very expensive inpatient hospital and end-of-life care along with the social services that supported individuals and their families through progressively worse illness and disability.

Today the treatment outlook for HIV has changed dramatically. In 1996, highly active antiretroviral therapy (HAART) became the standard of treatment.[2] When used appropriately, HAART can delay disability and death indefinitely for a significant proportion of individuals using it. The focus of care has moved from inpatient services to outpatient services as HIV has begun to look more like a serious but chronic illness for those in treatment and less like a debilitating, fatal illness.

These changes have had a profound impact on individuals infected with HIV, providers of HIV/AIDS care, and the care system itself. Individuals infected with HIV have greater opportunities to remain healthy than ever before, provided they have access to appropriate treatment, can manage the disease, and adhere to treatment regimens. Providers enjoy the possibility of improved outcomes for their patients, but must face the pressures of providing care for the chronically ill in a system that was not designed to meet those needs. The interrelated structure and financing of the care system must be reassessed and modified where necessary to allow adaptation to the changing needs of the population served as well as changing treatments.

The CARE Act has been responsive to changes in the epidemic. Since its inception the CARE Act has been reauthorized twice, in 1996 and again in 2000. Congress has used the reauthorization process to evaluate the CARE Act and amend it as necessary to focus, refine, and evaluate the impact of the legislation and the policies to implement it. The General Accounting Office (GAO) has studied CARE Act programs since their inception, examining funding formulas, equity, use of funds, and access to services that Congress has used to guide changes to the legislation (GAO, 1995, 2000; Heinrich, 2000; Nadel, 1995). The GAO found inequities in funding allocations across geographic locations in both 1995 and 2000, but also that women and minorities were using CARE Act programs in numbers proportionate to the disease's impact on these populations. Congress used the GAO's finding to address the unintended consequences of policies stemming from earlier legislation and to assess how well the CARE Act fulfills

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[2] The Committee uses the acronym HAART throughout the report to mean multidrug antiretroviral therapy. This regimen typically consists of a combination of the three classes of antiretroviral drugs that are effective against HIV: nucleoside reverse transcriptase inhibitors (nRTIs), non-nucleoside reverse transcriptase inhibitors (nnRTIs), and HIV-specific protease inhibitors (PIs). Essentially all regimens use at least two nRTIs, typically combined with one nnRTI or one to two PI. Some regimens use three or four nRTIs without an nnRTI or a PI. One-drug antiretroviral therapy, or monotherapy, is obsolete and not recommended by current treatment guidelines. Though the more accurate term, combination antiretroviral therapy—CART—is coming into wider usage, the Committee believes that the term HAART will be familiar to the broadest audience.

its mission, along with whether this mission reflects the current needs of an evolving epidemic.[3]

THE CHARGE TO THE COMMITTEE

Though framed within the text of the CARE Act, the congressional charge specifically directs the Committee to assess the role of other programs and payers, particularly Medicaid, in providing care for those infected with HIV. The Synopsis of the Charge to the Expert Panel from the Health Resources and Services Administration—the agency tasked by Congress with oversight of this inquiry—reads, in part:

"The panel is being asked to examine the feasibility of creating a publicly funded system of care that is accessible, equitable, cost-effective, of high quality, comprehensive, and easily negotiable. One option specifically identified in the legislation is to extend Medicaid coverage to people in early stages of HIV infection. The panel is also to look at the costs stemming from current barriers to care as well as the costs and savings for affected programs from proposed changes in public financing for HIV care (HRSA, 2001)."

HRSA identifies three broad challenges to the system: (1) changes in the epidemic and increasing needs for support services, (2) state-to-state variability in access to publicly funded care, and (3) disparities in access to optimal treatment regimens. In addition, HRSA identifies a dozen issues to which the Committee should pay "particular attention," including reducing disparities in access to care and health outcomes and improving coordination in the delivery of services. Finally, HRSA states that the agency is "seeking solutions that will allow for the creation of an easily negotiable system of care that is equitable, cost-effective, of high quality, and comprehensive."

The Committee interpreted this broad charge as a challenge to set out a vision of a care system that meets the needs and makes the most of the opportunities presented by the third decade of the HIV/AIDS epidemic and beyond. Accordingly, the Committee's recommendations outline a program that is sweeping and comprehensive.

Early in the process, the Committee determined that one of the great challenges of defining a vision of an HIV care system would be ensuring

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[3] For example, the first reauthorization, in 1996, addressed differences in funding levels by modifying the allocation formula. The first reauthorization also contained revisions to planning council membership and administration after conflict of interest issues were raised regarding the selection of contractors and identification of priorities. The second reauthorization, in 2000, responded to treatment advances (HAART) and new research that showed a significant proportion of those with HIV were not in care by emphasizing HIV surveillance and outreach programs (Palen, 2003).

that the recommendations were developed within the broader context of the American health care system. It is, perhaps, instructive that in other developed countries with significant HIV-infected populations—such as the United Kingdom and Canada—national health insurance programs pay for most or all necessary medical care for residents, and do not require disease-specific programs. In those countries, the Committee is not aware of—and there would be little need for—large HIV-specific care programs that seek to "fill the gaps" in existing insurance systems.

In this country, different segments of the population obtain health insurance through a variety of public and private programs. Private health insurance is provided primarily through employers. Medicare, Medicaid, and the Department of Veterans Affairs (VA) fill significant (but not all) gaps in coverage for the elderly and poor. Many workers lack coverage, and the number of uninsured continues to grow. Even in this context, however, the political consensus necessary to create more comprehensive health insurance solutions has not emerged. Given these circumstances, it is a subpopulation of the uninsured and underinsured—those who are HIV infected—who are the intended beneficiaries of the CARE Act and the focus of the Committee's charge. The Committee accepted the earlier decision by Congress to create and sustain HIV-specific programs as the starting point and framework for its work.

There are both humanitarian and public health reasons for a program targeted to help those infected with HIV. First, the human tragedy of people in large numbers unable to work, impoverished by the disease, and dying painfully and rapidly led Congress originally to pass and fund the CARE Act. Second, because HIV is a transmissible illness, providing care also provides opportunities to arrest the spread of the virus at the population level. In this way, a narrowly targeted program serves the interest of the public at large and justifies the dedication of public money to that purpose, a decision made by Congress in 1990.

The conclusions and recommendations presented in this report represent the Committee's effort to develop a comprehensive vision of a system of care that will improve the quality and duration of life for those with HIV and promote effective management of the epidemic by providing access to comprehensive care to the greatest number of low-income individuals with HIV infection. Throughout its deliberations, the Committee sought the strongest evidence available for its conclusions and carefully weighed the feasibility of its recommendations.

The Committee gathered and analyzed information from a variety of sources. During public meetings, it heard testimony from many individuals, including advocates, policy makers, federal and state officials, and people living with HIV/AIDS. In addition, the Committee solicited the input and advice from a liaison panel made up of representatives of the HIV/AIDS community. Several papers were commissioned from experts on topics including the current system of financing care, HIV and comorbid substance abuse, and the efficacy and financing of ancillary services. Published findings provided additional evidence for conclusions and recommendations. Input from administrators of HIV care systems and providers of HIV care enhanced the Committee's understanding of the daily operations of the publicly funded system of care. Finally, the Committee relied on the individual and collective expertise of its members to make informed judgments where data were scarce and to weigh the various policy options under consideration.

The report is organized into six chapters, including this introduction. Chapter 2 addresses the changes in the epidemic over the past two decades in terms of treatment options and affected populations and the challenges posed by these changes. Chapter 3 examines the current financing and delivery system for HIV care. Portions of this chapter are taken from a paper commissioned by the Committee, "Financing HIV/AIDS Care: A Quilt with Many Holes," and included in the report as Appendix D. This paper is an update of a comprehensive overview of federal financing of HIV/AIDS care published by the Kaiser Family Foundation in 2000. Chapter 4 addresses barriers and problems faced by the individuals attempting to access and navigate this system. As part of its work, the Committee examined several policy options as vehicles for improving the current system of care to meet the standards of a desirable system. This examination is presented in Chapter 5. All of the options provide, to varying degrees, ways for expanding access to HIV care and the opportunity to eliminate disparities and discontinuities. The Committee's recommendations are contained in Chapter 6 along with the estimated budget and health impact of the proposed changes. The Committee developed an HIV care cost model to determine these estimates; a complete description of the model is presented in Appendix A. Appendix B provides a brief overview of Ryan White CARE Act fund allocation formulas. Because of the substantial impact of HIV on individuals with mental illness and substance abuse disorders, as well as the impact of these illnesses on the treatment of HIV, the Committee has included more in-depth examinations of these topics as Appendixes C and E.

The federal response to the needs of low-income individuals with HIV disease has grown from small, isolated grants into a $2 billion-a-year comprehensive program that provides care to those most in need. But this is not enough, given the changes in the epidemic, the promise of improved treatment on the one hand, and the challenges of increasingly vulnerable infected populations on the other. A key question for the third decade is this: How can the publicly funded HIV/AIDS care system operate more equitably and efficiently to fulfill the promise and mission of the Ryan White CARE Act?

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.

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2

HIV/AIDS Care in the Third Decade: Opportunities and Challenges in the Changing Epidemic

The year 2001 marked the beginning of the third decade of the AIDS epidemic. In just over 20 years, HIV/AIDS had changed the landscape of medicine, public health, and health care in the United States and the world. The rapid changes in treatments, however, threaten to outpace the design of the health care delivery system for individuals with HIV and AIDS. In 1996, the introduction of effective new antiretroviral therapies changed the clinical course and outcome of this illness. Until the introduction of highly active antiretroviral therapy (HAART), AIDS was associated with an inevitable functional deterioration and death. Acute illness brought people into the care system, clinical care occurred in a hospital setting with intense outpatient follow-up, and prevention was focused on those at risk of becoming infected.

The third decade of the HIV/AIDS epidemic offers a remarkable opportunity to extend the productive years of life of people living with HIV/AIDS (PLWH/A). The challenge will be to restructure the public health care financing and delivery system so that uninsured and underinsured PLWH/A have access to appropriate treatments without disparity, to offer the comprehensive set of services required to promote adherence to their medications to individuals affected by co-morbid conditions, and to prevent new infections by making prevention a routine part of care.

In the United States, 816,149 AIDS cases and 467,910 AIDS-related deaths have been reported as of December 2001 (CDC, 2002a). It is estimated that approximately 40,000 people in this country are newly infected with HIV each year, and the disease remains an imminent and serious threat to public health (Karon et al., 2001). Globally, the picture is starker. The Centers for Disease Control and Prevention (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, 2002a). Although the epidemic had slowed until recently in most of the developed world, the National Intelligence Council (2002) predicts that by 2010 the numbers of those infected with the virus could reach 75 million in Nigeria, Ethiopia, Russia, India, and China alone (NIC, 2002). In 2002, the United Nations Population Division lowered its estimate of the world's population for 2050 by 400 million people, largely because of the effect of HIV/AIDS (United Nations, 2003).

If the epidemic has maintained a staggering pace, so too has the fight against it. Scientific discovery has resulted in a rapid gain in knowledge about the disease, dissemination of prevention and treatment information, and changes in expectation and outcomes. The first widely distributed reports of the disease occurred in 1981 and concerned homosexual men (CDC, 1981). Over the next two years, at-risk populations were further defined to include injection drug users, individuals with hemophilia and others who had received blood products, and Haitians; universal precautions for health care workers and other professionals whose work put them in contact with blood and other bodily fluids had been published; and the virus that caused the disease had been identified (CDC, 1982a,b,c,d,e, 1983; Barre-Sinoussi et al., 1983). Advances in knowledge and treatment options continued throughout the eighties and early nineties, and by 1996 combination antiretroviral therapy became (and remains) the standard of care for those infected with HIV. The impact of HAART was dramatic—the number of deaths from AIDS fell by 43 percent between 1995 and 1997 (Figure 2-1) (CDC, 2002a). In all, it took only 15 years from the first noted incidence of this new disease to the development of therapies that can be effective against it.

The rapid pace of the development of new technology to fight the disease continues. In January 2003 the Food and Drug Administration (FDA) announced the expansion of availability of a rapid HIV test, which returns results in a matter of minutes rather than days or weeks. The FDA approved the expansion in the hopes that combining administration and results of the test into one clinic visit would increase the numbers of people seeking the test and entering the care system if testing positive (FDA, 2003a). In March 2003, the first in a new class of drugs called fusion inhibitors was granted accelerated approval, expanding the options of those for whom other treatments have failed (FDA, 2003b).

This promising evolution of treatment does not, however, mean that the HIV epidemic is over or that it soon will be. The decrease in deaths brought about by new treatments, coupled with the steady number of new

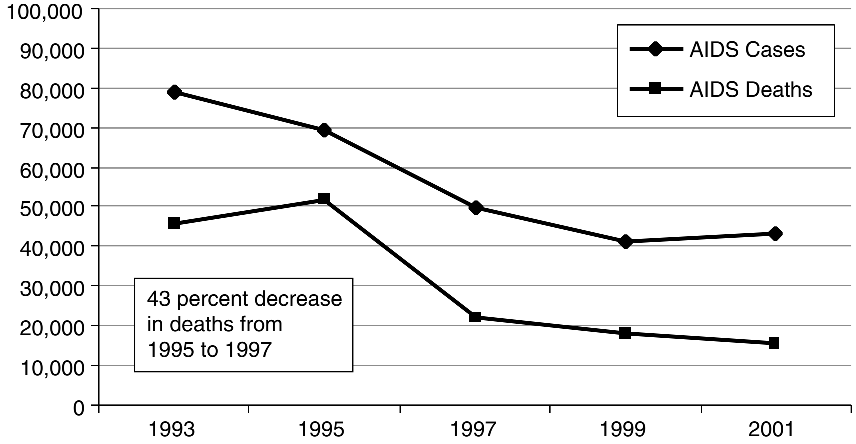

FIGURE 2-1 Numbers of AIDS cases diagnosed and AIDS deaths reported, 1987 through 2001.
SOURCE: CDC, 2002a.

infections, indicates that more people than ever are living with HIV and AIDS (CDC, 2002a). As a consequence, the population at risk for transmitting the disease—those already infected—continues to grow (Figure 2-2). In 2003, CDC released preliminary data showing an increase in the number of AIDS cases reported in 2002 over 2001 (CDC, 2003). Though the increase was small (2.2 percent), it was the first since 1993 and could be an early warning that the system is missing opportunities to prevent those with HIV infection from progressing to AIDS. The loss of these opportunities, both for treatment to prevent disease progression and for intervention to reduce risky behaviors and promote prevention, occurs when infected individuals remain outside the care system, and eventually results in a greater burden to the system. Furthermore, those newly infected with HIV are more likely than in the past to be poor, members of a racial/ethnic minority group, and uninsured or publicly insured (Levi and Hidalgo, 2001). Those groups that traditionally have been at high risk, such as men who have sex with men (MSMs) and injection drug users (IDUs), have been joined by the seriously mentally ill, women of color, and the homeless.

The third decade of the HIV/AIDS epidemic presents great opportunities and challenges for care providers and policy makers. Treating this deadly disease effectively is now possible for many individuals. But treatment regimens can be complex and expensive. The epidemic also continues its entrenchment in vulnerable populations suffering from co-morbid con-

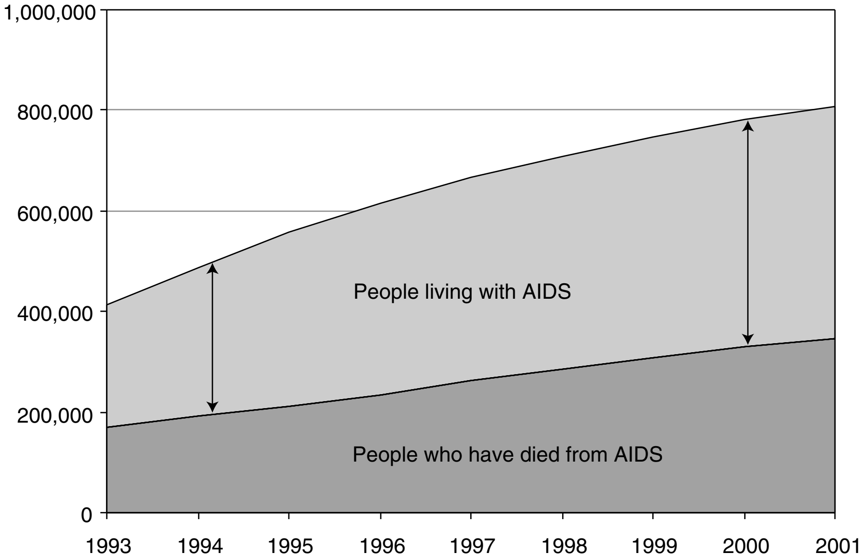

FIGURE 2-2 People living with AIDS as a proportion of cumulative AIDS cases.
SOURCE: CDC, 2002a.

ditions that can complicate their seeking and obtaining care. The ability of new therapies to slow the disease, both at an individual and a population level, is determined both by their availability to those who need them and the ability of recipients to follow complex regimens. Even then, it is possible that the treatment will fail and drug resistance will develop. Given the continuing shifts in the epidemic, the care system's ability to provide treatment in a timely manner to save lives, avert disability, and prevent the spread of the disease is increasingly challenged. This, in turn, challenges policy makers at all levels to ensure that programs meant to support the care system do so in a way that facilitates the mission of that system.

The following sections discuss the changing elements of the epidemic that require consideration in a restructured HIV care delivery system: the effect of HAART on the course of the disease, as well as the risk of toxicities and resistance with HAART; the central role of adherence to therapy; the changing demographics of the epidemic and the challenges they present; and the increasing incidence of both medical and social co-morbid conditions among PLWH/A. To provide the background for these discussions, however, it is necessary to understand the natural history of the individual HIV infection.

THE NATURAL HISTORY OF INDIVIDUAL HIV INFECTION

HIV is believed to have entered human populations from chimpanzees in Africa in the first half of the 20th century. Comparisons with closely related viruses in chimpanzees show that this crossover was likely made on multiple occasions (Korber et al., 2000; Hahn et al., 2000). In the United States, there is evidence the virus was present as early as 1977, though its long latency period rendered it invisible (Gottlieb, 2001).

The course of HIV disease varies by individual and is not fully predictable, and the full effects of current antiretroviral management on the natural history of the disease remain uncertain. Still, the scientific and medical communities have learned a great deal in the past 20 years, and the natural history of HIV infection is now better understood (Polk et al., 1987; Mellors et al., 1996, 1997; Vlahov et al., 1998; Pezzotti et al., 1999). This understanding is important to the care system because it indicates when care will be needed and which services will be necessary and appropriate at each point in the disease process.

Initial/Primary HIV Infection

The majority of newly infected individuals develop what is known as primary HIV infection or acute retroviral syndrome. Acutely infected persons are symptomatic, often sufficiently so to seek medical care. These symptoms—fever, rash, fatigue, generalized lymphadenopathy, and nausea among others—are flu-like and appear within days to several weeks of the moment of infection. Primary HIV infection usually resolves in a matter of weeks and is not life threatening. Because the symptoms are characteristic of infection by less serious viruses, the opportunity to identify HIV infection is often missed at this stage (Quinn, 1997; Kahn and Walker, 1998).

During the symptomatic phase of acute infection, virus replication is unchecked by the immune system. Individuals in this disease stage are highly infectious. This is of great importance from a public health perspective because unsafe behavior in this phase may readily lead to transmission. It is estimated that more than half of all HIV infections may be transmitted during this stage of infection (Schacker et al., 1998). Therefore, increasing the identification of HIV during this silent phase of the disease and providing prevention counseling to infected individuals are key strategies for managing the progression of the epidemic.

Asymptomatic HIV Infection

After full antibody reaction to HIV infection is established (typically within three to six months), the infection is said to be in the "chronic" or "established" stage (Fauci, 1993; Levy, 1993; Pantaleo et al., 1993). Symptoms of acute infection have resolved by this point. The term "asymptomatic HIV infection" applies to this phase when the person is unaware of any symptoms of infection. This phase may last for 1 to 10 or more years, even without antiretroviral therapy (Haynes et al., 1996). During this period, however, the virus is still actively replicating and the infected individual may unknowingly transmit the virus. Also, the infection is gradually changing the individual's complex immune system, most notably by causing a reduction in the number of CD4+ T-lymphocytes (CD4 cells) in the peripheral circulation.[1] Even though there are no clinical manifestations of the disease, the immune system begins to deteriorate (Pantaleo et al., 1993). As the CD4 cell count begins to decline, individuals who are asymptomatic, or have nonacute conditions such as chronic fatigue, may meet the established treatment guidelines criteria to receive HAART. The challenge with many HIV-infected individuals in this stage who are focused on more immediate needs, such as housing and employment, is to engage them in treatment and promote retention in care and adherence to therapy.

Eventually, the CD4 cell count falls from above 500 cells/ml, the threshold of a normally functioning immune system, to 200 cells/ml, an indicator of severe immune suppression, and can fall even lower. This drop in the CD4 cell count is significant because it increases the risk of serious and potentially fatal opportunistic infections or cancers (Polk et al., 1987; Mellors et al., 1996, 1997; Vlahov et al., 1998; Pezzotti et al., 1999). Antiretroviral therapy applied during the asymptomatic phase of disease can raise CD4 cell counts predictably and durably, preventing or delaying the stage of life-threatening immune deficiency commonly referred to as AIDS (Detels et al., 1998).

Symptomatic HIV Disease/AIDS

Advances in treatment have changed the ways in which the clinical stages of HIV disease are viewed. The difference between asymptomatic and symptomatic HIV disease is less obvious than the terms imply. With progressive immune depletion—perhaps especially if the plasma viral load[2]

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[1] CD4+ T-lymphocytes or CD4 cells are a type of white blood cell responsible for signaling other cells in the immune system to perform their specific functions, providing protection against viral, fungal, and protozoal infections. These cells are HIV's preferred targets, and their destruction is the primary cause of immunodeficiency. A decrease in CD4 cells is the best known risk indicator for developing opportunistic infections; thus, an individual's CD4 cell count is an important measure of disease progression (HIV/AIDS Treatment Information Service, 1999).

[2] Viral load, also known as viral burden, is the amount of HIV circulating in an individual's blood. The amount of virus in the blood is related to the overall health of the infected

is very high—patients may begin to note fatigue and malaise. Minor infections such as oral candidiasis are seen frequently and the risk of more serious complications rises as the CD4 cell count falls below 200 cells/ml. Some of these infections, notably *Pneumocystis carinii* pneumonia, can be prevented with prophylactic antibiotics, while others cannot (CDC, 2002a). Along with antiretrovirals, these prophylactic antibiotics, as well as certain vaccines that can prevent complicating infections, are essential components of medications that must be provided to maintain the health of the individual infected with HIV (USPHS/IDSA, 2001).

Death from HIV Disease

Prior to the availability of current effective antiretroviral therapy, development of AIDS and death were predictable outcomes among HIV-infected patients (Polk et al., 1987; Mellors et al., 1997; Vlahov et al., 1998; Pezzotti et al., 1999). Death usually followed several months of progressive debilitation, wasting, and often, dementia. Many suffered blindness from cytomegalovirus retinitis or endured intractable diarrhea.

Today, the pattern is more complex and not as predictable (Pezzotti et al., 1999). Antiretroviral therapies can continue at least partially to suppress viral replication and to maintain some integrity of the immune system. Although HAART options can be exhausted, and some individuals still die of AIDS, it is increasingly likely that the cause of death for an HIV-infected person will be tuberculosis or hepatitis C virus (CDC, 1999, 2002b).

EFFECT OF HAART ON HIV PROGRESSION AND CARE

The impact of antiretroviral therapy on the outcome of HIV infection is one of the most dramatic developments in medical history. Therapies for treating HIV have come so far that it is possible to forget the bleak outlook of the early to mid-eighties, when the best that medical technology could offer was palliative care that only delayed death for a short time. Once a retrovirus was established as the cause of the disease, researchers were able to focus their efforts on blocking the replication of the virus in the body. In 1986, the National Institutes of Health (NIH) organized the AIDS Clinical Trials Group (ACTG), which has studied dozens of therapies and continues to do so today. The findings from this research group provide the foundation of the current guidelines for antiretroviral therapy (Sepkowitz, 2001).

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individual—the higher the viral load, the sicker the patient. Measuring viral load is an important part of gauging a treatment regimen's effectiveness (HIV/AIDS Treatment Information Service, 1999).

In 1987, AZT became the first drug approved for the treatment of AIDS based on the interim results of a randomized clinical trial. Its introduction raised the hopes of the HIV-positive community. In 1989, however, the results from the completed ACTG trial showed that AZT could slow disease progression, but did not impact survival rates (Volberding et al., 1990; Sepkowitz, 2001; Bartlett et al, 2001). Subsequently, the results of the Concorde trial in Europe showed that long-term disease progression rates were also unaffected by AZT (Seligmann et al., 1994).

Seven years would pass before breakthrough research on viral load measurements and the efficacy of triple-drug therapy was first reported (Bartlett et al., 2001). A longitudinal study on viral load as an indicator of disease stage revealed that by monitoring the amount of the virus present in the plasma, therapeutic benefit of drug therapy could be assessed in days or weeks rather than the months required by monitoring CD4 cell counts (Mellors et al., 1996). The results of a trial of triple-drug therapy were equally exciting and some believed that eradication of the virus was close at hand (Bartlett et al., 2001).

Unfortunately, that was not the case, but morbidity and mortality did decrease sharply after the introduction of HAART therapy (Figure 2-3) (Palella et al., 1998; Detels et al., 1998; Chiasson et al., 1999). By 1998, the number of individuals receiving HAART therapy had risen dramatically,

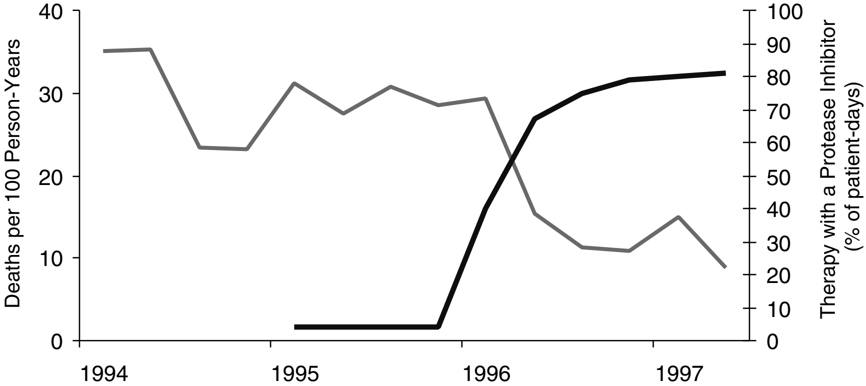

FIGURE 2-3 Mortality and frequency of use of combination antiretroviral therapy including a protease inhibitor among HIV-infected patients with fewer than 100 CD4 cells per cubic millimeter, according to calendar quarter, from January 1994 through June 1997.
SOURCE: Palella et al., 1998, Copyright 1998, Massachusetts Medical Society. All rights reserved.

and the number of deaths had fallen just as dramatically (Palella et al., 1998). Even those with severely weakened immune systems (indicated by a CD4 cell count of less than 50 cells/ml) had significantly fewer opportunistic illnesses when taking potent drug regimens (Miller et al., 2000).

The results to date in clinical practice remain impressive. In fact, it is no longer possible to give an evidence-based estimate of the median survival of those with HIV disease who are treated with appropriate drugs because not enough time has elapsed. Opportunistic infections, previously common, are now less so (USPHS/IDSA, 2001). Opportunistic malignancies—especially Kaposi's sarcoma and non-Hodgkins lymphoma of the central nervous system—have all but disappeared in those receiving effective antiretroviral therapy (Jacobson et al., 1999; Pezzotti et al., 1999). The success of HAART is tempered by its challenges, however. All antiretroviral medications carry the risk of side effects and adverse reactions, ranging from transient nausea and headache to serious or even fatal metabolic disorders (Montessori et al., 2004; Nolan, 2003). These adverse reactions can force a change in drug regimen and limit future treatment options (Ledergerber et al., 1999; Lucas et al., 1999). In addition, chronic conditions that develop as a result of the medications, such as diabetes and heart disease, must be treated along with the HIV infection in the long term (Carr et al., 1999).

To promote the adoption of the new therapies as quickly as possible, NIH sponsored a Panel to Define Principles of HIV Therapy (Box 2-1) that released its first report in 1998. Among other things the principles stressed the importance of individualized care, adherence to treatment regimens, and continuous monitoring and contact with the care system (CDC, 1998a).

Current Treatment Guidelines

The U.S. Department of Health and Human Services' (DHHS) Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents generally recommend HAART when the CD4 cell count falls below 350, although for individuals with CD4 cell counts of 200 to 349 other factors are considered. These include the individual's willingness and ability to begin therapy, current state of immunodeficiency and risk of progression, and the potential for adverse reactions and side effects. Combination regimens of three drugs are most commonly used, and one-drug regimens (monotherapy) are never recommended (DHHS, 2004).

The goal of therapy is durable suppression of HIV replication so that measured levels in the peripheral blood fall below the sensitivity levels of assays, usually below 50 HIV copies/ml. Therapy is monitored to follow the expected rise in CD4 cell counts and the fall in plasma viral load. All patients also require laboratory and clinical assessment for disease or drug-related toxicity (DHHS, 2004). For individuals who do not respond as

BOX 2-1
Principles of Therapy of HIV Infection

1. Ongoing HIV replication leads to immune system damage and progression to AIDS. HIV infection is always harmful, and true long-term survival free of clinically significant immune dysfunction is unusual.
2. Plasma HIV RNA levels indicate the magnitude of HIV replication and its associated rate of CD4+ T cell destruction, whereas CD4+ T cell counts indicate the extent of HIV-induced immune damage already suffered. Regular, periodic measurement of plasma HIV RNA levels and CD4+ T cell counts is necessary to determine the risk for disease progression in an HIV-infected person and to determine when to initiate or modify antiretroviral treatment regimens.
3. As rates of disease progression differ among HIV-infected persons, treatment decisions should be individualized by level of risk indicated by plasma HIV RNA levels and CD4+ T cell counts.
4. The use of potent combination antiretroviral therapy to suppress HIV replication to below the levels of detection of sensitive plasma HIV RNA assays limits the potential for selection of antiretroviral-resistant HIV variants, the major factor limiting the ability of antiretroviral drugs to inhibit virus replication and delay disease progression. Therefore, maximum achievable suppression of HIV replication should be the goal of therapy.
5. The most effective means to accomplish durable suppression of HIV replication is the simultaneous initiation of combinations of effective anti-HIV drugs with which the patient has not been treated previously and that are not cross-resistant with antiretroviral agents with which the patient has been treated previously.
6. Each of the antiretroviral drugs used in combination therapy regimens should always be used according to optimum schedules and dosages.
7. The available effective antiretroviral drugs are limited in number and mechanism of action, and cross-resistance between specific drugs has been documented. Therefore, any change in antiretroviral therapy increases future therapeutic constraints.
8. Women should receive optimal antiretroviral therapy regardless of pregnancy status.
9. The same principles of antiretroviral therapy apply to HIV-infected children, adolescents, and adults, although the treatment of HIV-infected children involves unique pharmacologic, virologic, and immunologic considerations.
10. Persons identified during acute primary HIV infection should be treated with combination antiretroviral therapy to suppress virus replication to levels below the limit of detection of sensitive plasma HIV RNA assays.
11. HIV-infected persons, even those whose viral loads are below detectable limits, should be considered infectious. Therefore, they should be counseled to avoid sexual and drug-use behaviors that are associated with either transmission or acquisition of HIV and other infectious pathogens.

SOURCE: CDC, 1998a.

expected to HAART, assays of genetic mutations associated with antiretroviral resistance are also commonly used, and some studies suggest an improved outcome if drug doses are adjusted for measured serum drug concentrations (DHHS, 2004). In many patients, antiretroviral therapy fails to fully suppress the virus either immediately or after a period of success. In this event, altering some or all of the drugs in the prescribed regimen may be required (DHHS, 2004).

Adherence

The central challenge of HAART is adherence, or the ability of an individual to consistently follow the prescribed treatment regimen. Adherence is crucial in the treatment of any illness; however, its importance is magnified in the treatment of HIV for two reasons. First, fully successful suppression of the virus in the blood requires very high levels of adherence. Second, poor adherence can contribute to the development of drug-resistant strains of the virus, which can then be transmitted to others. This results in reduced treatment effectiveness and options in those individuals who have never been treated for HIV before and thus constitutes a public health threat. The factors that influence an individual's ability to adhere to HAART include the regimen itself, an individual's personal characteristics, and the social environment of the patient (Ickovics and Meisler, 1997; Catz et al., 2000; Stone, 2002; Gebo et al., 2003).

The ability to fully adhere to a treatment regimen for any illness is almost never complete; in general, 80 percent compliance is considered adherent (Piliero and Colagreco, 2003; Rabkin and Chesney, 1999). Although rates of compliance of those with HIV on HAART are generally higher than those of individuals with other chronic illnesses, HAART requires unprecedented adherence of more than 90 percent to receive optimal benefit (Harrigan et al., 2003; Garcia de Olalla et al., 2002; Bangsberg et al., 2001; McNabb et al., 2001; Paterson et al., 2000). While adherence levels in clinical trials have been high, results in the clinical setting have not been as successful (Escobar et al., 2003). A number of studies using multiple methods to measure adherence in various settings and populations have indicated that patients' adherence to HAART averages 70 to 80 percent. Significantly, the studies show that few individuals are able to achieve the adherence levels required to receive the maximum benefit from the medication (Golin et al., 2002; Liu et al., 2001; Bangsberg et al., 2000). The inability of large numbers of patients to achieve the high levels of adherence required for complete viral suppression underscores the need to develop and provide appropriate adherence support as a routine part of HIV care.

The second factor that must be considered in any discussion of adherence is its role in the development of drug resistance. Drug resistance can lead to treatment failure, and resistance can develop across an entire class of drugs, not just the one currently prescribed, limiting future treatment options. Moreover, the development of drug resistance carries consequences beyond immediate treatment failure. Drug-resistant strains of the virus can be transmitted, compromising effective control of the epidemic and presenting a serious threat to public health. Emerging evidence indicates that the number of newly infected individuals who exhibit drug resistance is growing (Wensing et al., 2003; Grant et al., 2002; Little et al., 2002). Complete viral suppression, obtained through greater than 90 percent adherence, leaves little room for drug resistance to develop. In circumstances of less than total viral suppression, however, the virus begins to select for drug resistance as it replicates and evolves. If a drug-resistant virus is then transmitted, HAART regimens will not be as effective in the newly infected individual. Thus, the best opportunity for delaying development of AIDS will have been lost (Little et al., 2002).

Understanding the dynamics of adherence is an important part of HIV/AIDS care. The DHHS Guidelines list a number of factors that affect an individual's ability to adhere to a HAART regimen, including active alcohol and substance use and active mental illness (see Box 2-2). The transformation of HIV/AIDS to a chronic disease, which was brought about by the development of HAART, allows for useful comparisons to other chronic illnesses such as diabetes in terms of which factors influence adherence to treatment. The American Public Health Association highlights some of the lessons learned from the diabetes experience that may be useful in promoting adherence to HIV treatments in its *Adherence to HIV Treatment Regimens: Recommendations for Best Practices* (2002) (see Box 2-3). Among these lessons are that treatment is a collaborative process between patient and provider rather than a directive one from provider to patient, that

BOX 2-2
Predictors of Poor Adherence

- Poor clinician-patient relationship;
- Active drug and alcohol use;
- Active mental illness, particularly depression;
- Lack of patient education regarding treatment and inability of patients to identify their medications; and
- Lack of reliable access to primary medical care or medication.

SOURCE: DHHS, 2004.

BOX 2-3
Diabetes and HIV: Comparing and Contrasting Factors That Influence Adherence

Shared Factors

Individuals can remain largely asymptomatic for long periods of time.

Treatment can make the patient feel worse and can cause other serious health problems.

Treatment is lifelong, and the primary objective is to prevent deterioration in health as opposed to eliminating the disease.

Treatment is complex.

Dose–response relationship between adherence and benefit to the patient is particularly important but not always clear.

Patient must actively manage day-to-day treatment.

Both conditions occur disproportionately in populations underserved by the health care system.

Both conditions carry negative social stigma.

Factors other than adherence influence the course of the illness, even those with excellent adherence may experience disease progression and poor outcomes.

Differing Factors

HIV generally considered to be more deadly than diabetes, possibly leading to a sense of futility about treatment.

HIV generally associated with body wasting (being too thin) whereas diabetes is generally associated with obesity.

Treatment goals for diabetes are more flexible than for HIV.

The “window of opportunity” for beginning treatment and developing good adherence to achieve optimal outcomes for HIV is shorter than that for diabetes.

Side effects of HIV treatment are generally more severe than those stemming from treatment for diabetes.

SOURCE: APHA, 2002.

fostering adherence takes sustained time and effort on the part of both patient and provider, and that there is no single solution or strategy for success in adherence (APHA, 2002). Although, as noted earlier, adherence to HIV treatments is generally higher than for other chronic illnesses, these lessons learned over decades of diabetes treatment are applicable because HAART is much less forgiving than any other treatment regimen for any illness.

Medication regimen is the most common factor cited for nonadherence to HAART because of side effects and complexity of the drug regimen, which can require dosing up to three times a day and have dietary restrictions (Chesney, 2003; Bartlett et al., 2001). Nonadherence due to regimen complexity may be relieved somewhat as more antiretroviral medications are approved for once-daily dosing (Piliero and Colagreco, 2003). Other issues in adherence stem from the patient and the patient/health care provider relationship. Studies have shown that depression, lack of belief in the efficacy of the medicine, and lack of confidence in ability to adhere to the regimen predict nonadherence to HAART (Catz et al., 2000; Singh et al., 1999). There is a great deal of evidence that active alcohol or drug use contributes to nonadherence, although good adherence can be achieved among this population (Chesney, 2003; Escobar et al., 2003; Tucker et al., 2003; Lucas et al., 2002; Chesney et al., 2000). Lack of HIV-related knowledge and low literacy levels in general are also associated with poor adherence (Kalichman et al., 1999). One study of individuals with excellent adherence to HAART found that generally those with high adherence rates believed that the medication was and would continue to work and had trust and confidence in their primary care provider. They also were motivated by a strong desire to stay healthy that made taking their medications a priority, even when they were actively using drugs and alcohol (Malcolm et al., 2003).

Although these factors do predict poor adherence in overall study populations, it has also been shown that it is difficult for clinicians to predict adherence levels in individuals. In one study, physicians and clinic nurses were able to predict an individual's adherence less than half the time (Paterson et al., 2000). This is a significant issue when it concerns members of groups that are already highly stigmatized, such as those with a mental illness, because it could lead to the denial of therapy based on a presumption of the inability to adhere. Bogart and colleagues (2000) found in a 1998 survey that physicians relied on a variety of nonmedical factors in determining whether or not to prescribe HAART, including demographic and psychiatric factors such as homelessness, age, and history of psychiatric hospitalizations.

It is also important to note that many of the factors shown to inhibit an individual's ability to adhere are not immutable, but can be influenced with appropriate interventions. As noted earlier, there is evidence that even in populations where it is generally thought adherence will be low, such as individuals who are homeless, a significant proportion can attain high enough levels of adherence to realize some (though less than optimal) therapeutic benefit from the medication. From this evidence, it appears that certain interventions, such as treatment for depression, may increase adherence levels, allowing individuals to gain greater treatment benefit (Bangsberg et al., 2000). Appropriate adherence support provided as a routine part of HIV care offers the opportunity to get the most out of therapy and helps to reduce the likelihood that drug resistance will develop.

CHANGE IN AFFECTED POPULATIONS AND THE IMPACT ON TREATMENT

In 1993, the National Research Council's Panel on Monitoring the Social Impact of the AIDS Epidemic noted that "instead of spreading out to the broad American population, as was once feared, HIV is concentrating in pools of persons who are also caught in the 'synergism of plagues'," a situation in which "poverty, poor health and lack of health care, inadequate education, joblessness, hopelessness, and social disintegration converge" (NRC, 1993, p. 7). This trend has not reversed in the nearly 10 years since that report was released. HIV has continued its march into the most vulnerable populations in society: the uninsured, racial/ethnic minorities, those with substance use disorders and mental illness, homeless persons, and unsupervised youth (Karon et al., 2001; Levi and Hidalgo, 2001). These are the populations that publicly funded care is intended to help—individuals without financial, social, or personal resources upon which to draw in the event of a catastrophic illness such as HIV. In a move to offer these resources, in 1990 Congress enacted the CARE Act to provide safety net funds for health and supportive services for individuals living with AIDS and HIV infection who have either no or inadequate insurance.

The complex needs of the HIV population require provision of supportive services to overcome barriers to receiving primary care, including case management, housing, food, transportation, and mental health and substance abuse treatment. The greatest disparities in receiving care are manifest in these vulnerable populations, and providing access to HIV care clinicians is only part of what is needed (Shapiro et al., 1999).

This section discusses the demographic shifts of the epidemic and the co-morbidities faced by vulnerable populations that affect access to care, adherence to medications, and continuity of care. Mental health and drug dependence disorders and the effects of poverty disproportionately affect these groups and present challenges to them in meeting life's basic necessities, such as adequate food, housing, and health care. These populations are characterized further by being in transition between settings, for example, from the community, to the criminal justice system, to substance abuse and mental health facilities, and at times to homeless shelters. This complicates ensuring continuity of care for these individuals and requires communication and coordination between these settings. Finally, while the primary care setting is a focus for care provision, the delay between the time of a vulnerable patient's test results and entry into care can be long and retention in care can be difficult. Vulnerable patients need assistance that prepares them for entering and staying in primary care as well as assistance with navigating the health care system.

Demographics

In the United States, the epidemic grew rapidly through the mid-1980s before decreasing and then leveling off in 1998 through the present (CDC, 2002a). 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, 2002a).

Black[3] and Hispanic communities have been hit especially hard by this epidemic. Although blacks and Hispanics together accounted for 70 percent of all new AIDS cases in 2001, these groups made up only an estimated 26 percent of the total U.S. population (Figure 2-4) (CDC, 2002a; U.S. Census Bureau, 2000). In 2001, the AIDS case rate among blacks was nearly 10 times the rate among whites, while the AIDS case rate among Hispanics was nearly 4 times higher than for whites (CDC, 2002a). For the age group 25 to 44, AIDS remains 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). Blacks and Hispanics are also represented disproportionately compared with whites in the number of deaths related to AIDS. In 2001, out of 15,603 estimated total deaths of persons with AIDS, blacks accounted for 51.5 percent, Hispanics accounted for 18.4 percent, and whites accounted for 28.8 percent (CDC, 2002a).

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 25 percent in 2001 (CDC, 1994, 2002a). In 2001, 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, 2002a).

The geographic distribution of the epidemic is also shifting (Figure 2-5). The estimated incidence of AIDS in the South appears to be rising.[4] Seven of the 10 states with the highest AIDS case rates are located in this region. As in the United States as a whole, minority populations are disproportionately affected. Of people living with AIDS (PLWA) in the South, 53 percent are African American, although they make up only 19 percent of the total population of the region (Kaiser Family Foundation, 2002). HIV-infected

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[3] When referring to a specific racial or ethnic group, the Committee uses the term of the source cited.

[4] The source of this data, the Kaiser Family Foundation, defines the southern region of the United States as Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and West Virginia (Kaiser Family Foundation, 2002).

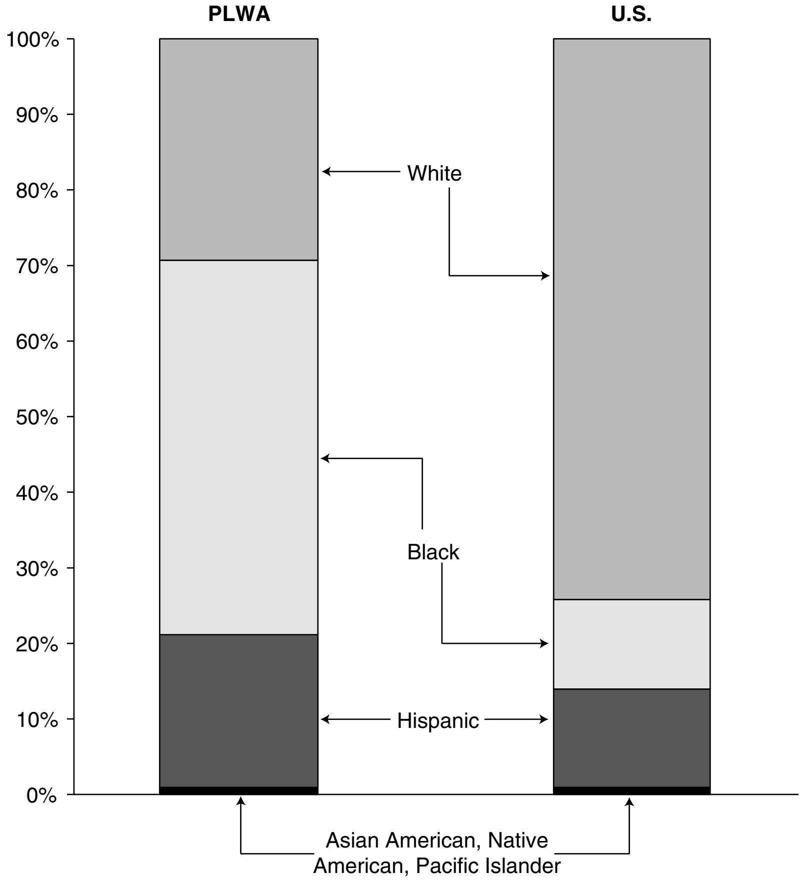

FIGURE 2-4 Proportion of people living with AIDS (PLWA) by race/ethnicity compared to total United States population.

individuals in the South are also more likely to be uninsured or publicly insured (Bozzette et al., 1998). These shifts both demographic and geographic represent the epidemic's move into populations that are traditionally underserved by the health care system and for whom current prevention messages are either inaccessible or lack resonance.

Co-Morbid Conditions

The rising prevalence of HIV/AIDS among individuals with co-morbid conditions adds another layer of complexity to the current state of the epidemic. These conditions can be medical in nature, such as existing

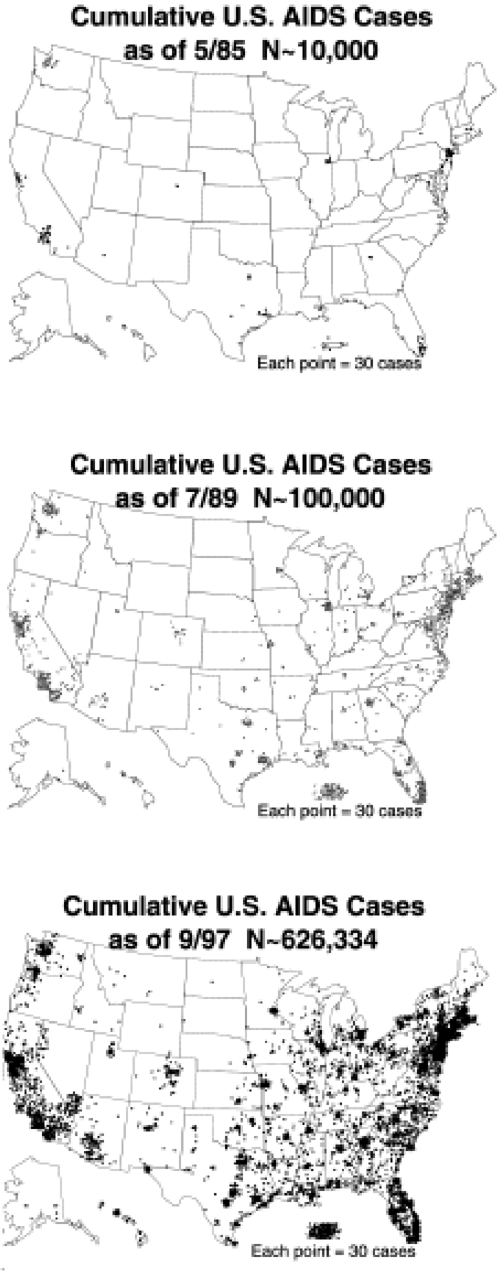

FIGURE 2-5 Cumulative AIDS cases for 1985, 1989, 1997.
SOURCE: CDC, 2004.

hepatitis or tuberculosis infection, or may involve substance abuse. They can also be what the Committee terms "social co-morbidities," that is, underlying social conditions that contribute to the complexities of care. Homelessness, for example, is not a disease process, but it is a definable state that affects the course of HIV infection. Often these co-morbidities occur in clusters as a mixture of existing, and preexisting, medical and social conditions that are both paths to infection and barriers to care. Co-morbidities and social conditions affecting HIV-infected individuals are not mutually exclusive, nor do they reside in well-defined populations; they often overlap with one another. Additionally, the extent to which someone is affected by co-morbid conditions, such as substance use disorder or mental illness, is episodic and dependent on a number of variables. An episode of binge substance use or severe mental illness, for example, can also result in a period of incarceration or homelessness.

Mental Illness[5]

Individuals with both mental illness and HIV represent a large and vulnerable segment of the HIV-infected population. The prevalence of mental illness among those infected with HIV has been estimated to be quite high: about 50 percent of those in HIV care have some form of a comorbid mental illness (Bing et al., 2001). In addition, people with mental illness are at higher risk for HIV than those without it (Cournos and McKinnon, 1997; Stoskopf et al., 2001). Among people with serious mental illness, the seroprevalence of HIV ranges from 4 to 23 percent, with an average of 7 percent, compared with prevalence of less than 1 percent in the United States population as a whole (Carey et al., 1997; Cournos and McKinnon, 1997).

Individuals who have a mental illness have been considered at increased risk of acquiring or transmitting HIV because they have a greater likelihood of high-risk sexual behavior or substance abuse (Cournos and McKinnon, 1997; Johnson, 1997; Carey et al., 1997; Sullivan et al., 1999). Underlying these concerns are the behavioral and cognitive manifestations of the disorders themselves—such as impaired decision making and perception of risks, low motivation, impulsivity, and vulnerability to sexual victimization. Recent studies that empirically examine whether the presence of mental illness can increase the risk of transmission of HIV give a more nuanced and complex portrait of the problem, however, suggesting variation in risk depending on the psychiatric diagnosis or nature of symptoms.

The evidence reveals that serious mental illness—but not depression

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[5] For an expanded discussion of HIV and mental illness, see Appendix C.

and anxiety—are associated with risky behavior, and that youth also increases risk. A meta-analysis of 34 studies investigated the impact of depression or anxiety on high-risk sexual behaviors, defined as having multiple partners and/or unprotected sex. The samples included individuals with mental illness alone, as well as those with mental illness and HIV. The study found little evidence that depression and anxiety are associated with more risky behavior (Crepaz and Marks, 2001).

Findings suggest that serious mental illness, without co-morbid HIV, does increase the likelihood of engaging in high-risk sexual behaviors (Carey et al., 1997; Cournos and McKinnon, 1997; Sullivan et al., 1999). Two relatively small studies have addressed the question of the impact on sexual behavior of having co-morbid mental illness and HIV. These studies have found an increased likelihood of engaging in high-risk sexual behaviors for those with more psychotic symptoms, those with problem drinking, and those not receiving HIV counseling (Tucker et al., 2003). Patients with serious mental illness were also found to have high rates of risky behavior, including sex with a known injection drug user, prostitution, and male–male sexual contact (Meyer et al., 1995).

Researchers at RAND, interviewing 159 treatment providers at 72 mental health and HIV treatment programs in New York City and Los Angeles, found that screening for HIV and risk behaviors in mental health agencies occurs haphazardly, given the range of clients' nonpsychiatric and other medical needs that compete for the attention of providers. In contrast, HIV treatment agencies tend to place high priority on screening and care for mental illness, as clinicians generally perceive the mental health of clients to be central to successful HIV treatment and adherence (Personal communication, P. Mendel, RAND Corporation, 2002). Nevertheless, because research has long established that depression is missed in 40 to 60 percent of patients in primary care (Hirschfeld et al., 1997; DHHS, 1999), it would not be surprising if depression often went undetected in HIV care. One of the few other studies of this problem found that community mental health clinicians in New Hampshire reported lack of specific knowledge about comorbid mental illness and HIV and reported interest in receiving training (Brunette et al., 2000).

Another study, which focused directly on the barriers to receiving HIV care for individuals whose co-morbid serious mental illness and HIV infection are already known, compared nearly 300 seriously mentally ill and HIV-positive patients in Los Angeles and New York City to patients from the HIV Cost and Services Utilization Study (HCSUS)[6] from the same geographic region and with HIV alone. It found that people with serious

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[6] The HCSUS study is a nationally representative study of HIV-positive adults receiving care in the contiguous United States.

mental illness and HIV were more likely to experience barriers to care than those with HIV alone (Personal communication, A. Fremont, RAND Corporation, 2002). Barriers to care were measured by a 3-item index—not getting needed medical care, going without care because of lack of money, or going without food in order to pay for care.

The relationship between mental illness and adherence to HAART has been investigated in several studies, most of which relied on measures of depression or anxiety symptoms or distress rather than psychiatric diagnoses per se. Although not all studies have found a relationship between adherence and psychological well-being, a number of studies have found depressive symptoms, hopelessness, psychological distress, and overall stress to be associated with lower antiretroviral adherence.

Paterson and colleagues (2000) studied 81 HIV patients, and tracked adherence with a microelectronic monitoring system. The study found that active psychiatric illness, primarily depression, was an independent risk factor for nonadherence, and that nonadherence was significantly associated with treatment failure. Catz and colleagues (2000) also found that depression was a risk factor for self-reported nonadherence in a sample of 72 patients at a teaching hospital. A study in Spain by Gordillo and colleagues (1999) of 366 patients also found that depression was a risk factor for poor adherence. Chesney and colleagues (2000), studying 75 patients at 10 United States sites, determined that nonadherent patients reported higher levels of perceived stress. Singh and colleagues (1999), using the Beck Hopelessness Scale and other measures, found that hopelessness and loss of motivation were associated with nonadherence.

One study of serious mental illness and adherence to HAART conducted by investigators at RAND found that about 40 percent of subjects were adherent (more than 90 percent adherence), while 31 percent had very poor adherence (less than 50 percent) (Personal communication, D. Kanouse, RAND Corporation, 2002). The 47 participants in this study had bipolar depression (n=24), schizophrenia (n=12), schizoaffective disorder (n=5), or psychotic depression (n=6). The overall average adherence rate was 66 percent of prescribed doses, a rate similar to general clinic or community populations. The finding that a large percentage of participants were adherent to their drug defied conventional wisdom that individuals with serious mental illness lack the capacity to adhere to a complex dosing schedule. Still, a third of the sample had very poor adherence, a finding that prompted the investigators to suggest further research to identify barriers and inform the development of tailored interventions for those with serious mental illness to achieve greater adherence, and thus greater treatment benefits.

In summary, the research on mental illness and adherence to HAART indicates that symptoms of depression and psychological distress are associated with lower adherence. There is little research on the relationship between adherence and actual diagnoses of depression or anxiety. One study of serious mental illness finds, contrary to expectations, that people with one of the more serious diagnoses are not necessarily more likely to be nonadherent. Further research on the relationship between mental illness and adherence to HAART would help identify the specific causes of nonadherence in this population and the interventions and approaches that can help promote adherence.

Substance Use Disorders

Another serious challenge for HIV care involves individuals with substance use disorders; treating this population requires a range of services, including substance abuse treatment, linked to primary care. Injection drug use in particular was identified early in the epidemic as a route of transmission, and CDC has conducted public health surveillance on the population of injection drug users as a result. Of the 40,000 new HIV infections each year, an estimated 25 percent are directly attributable to injection drug use. In the eastern seaboard cities, injection drug use accounts for at least half of the AIDS cases. Injection drug use is associated with 26 percent of all AIDS cases among African Americans, 31 percent among Hispanics, and 19 percent among whites. Overall, CDC estimates that injection drug use, directly and indirectly, accounts for 36 percent of AIDS cases in men and 57 percent of cases in women (CDC, 2002a).

Because CDC surveillance only identifies the risk category for infection, it is difficult to determine current rates of substance abuse in HIV-infected populations. Federal data sources such as the National Household Survey on Drug Abuse or Monitoring the Future each estimate the prevalence of substance use, but do not collect information about HIV infection; therefore, the overall estimate of those infected with HIV who also have substance use problems is difficult to determine. From a summary of the published literature, Holmberg (1996) earlier estimated that there were 1.3 million injection drug users in the United States and that 30 percent were HIV infected; broad population-based estimates of HIV infection by different drug and different routes of administration (i.e., other than injection) are not available. One study found that nearly 40 percent of HIV-infected individuals in care reported using an illicit drug other than marijuana and that 12 percent screened positive for drug dependence (Bing et al., 2001). This same study also found that nearly 50 percent of the sample screened positive for mental health disorders and that screening positive for a psychiatric disorder was independently associated with screening positive for drug dependence.

Other data also suggest that substance abuse is common in HIV-infected or at-risk populations. Sullivan et al. (1998) found a high rate of drug use in a facility-based study of nearly 1,000 MSMs from 12 states and metropolitan areas—51 percent had used marijuana, 31 percent used noninjected cocaine, and 16 percent injected crack cocaine in the five years preceding the interviews. In a study of HIV-positive women, 19.7 percent reported using crack, 15.4 percent reported using cocaine, and 8.8 percent reported injecting drugs within the past six months (Wilson et al., 1999). These data suggest that substance use is a frequent issue in dealing with HIV-infected patient populations.

Despite the need for integrated care for HIV-infected individuals with comorbid substance abuse, there is little intersection, and often conflict, between the two treatment systems. Adding further complexity is the conflict between abstinence-based and harm-reduction treatment approaches within the substance abuse treatment system. The HIV care system, concerned principally with keeping the HIV-infected individual in contact with the system, can be at odds with the abstinence approach to substance abuse treatment, which expels anyone who does not meet the strict standards of a program (Hsu, 2001).

There are many barriers to accessing HIV care for an individual with active substance abuse. The greatest barrier—but certainly not the only one—is active substance abuse itself. Active substance abuse has a demonstrated association with delayed HIV care seeking, making it likely that substance users are overrepresented in the HIV-infected population that is outside of the care system. One study of outpatient visits in two urban hospitals found that 39 percent of patients entering HIV care for the first time had delayed care seeking for one year, 32 percent for more than two years, and 18 percent for more than five years (Samet et al., 1998). In this study, injection drug use was associated with delayed care seeking. In a study of IDUs, Celentano and colleagues (2001) found the delay in initiating HAART was less than one year for active versus former drug users. One study of HIV-positive crack cocaine smokers found that one-third of the study population had not seen a provider for HIV-related care in the past year.

In this context, access to substance abuse treatment is revealed as a priority for this population. There are significant barriers here as well, and it has been estimated that nearly three-quarters of those who need substance abuse treatment do not receive it (Amaro, 1999). One of the greatest barriers to substance abuse treatment is lack of capacity to provide services to all individuals seeking care due to inadequate funding. For PLWH/A seeking substance abuse treatment—a population with especially complex needs—this problem is particularly acute. Co-location of substance abuse treatment and HIV care is difficult because of financing and bureaucratic issues that occur at the institutional and governmental policy levels. Lack of health insurance coverage presents another barrier, particularly for minorities, recent immigrants, and people who are homeless (Hsu, 2001). Low-income women of color face multiple barriers in that they, too, are more likely to lack health insurance coverage and have dependent children. It is estimated that nearly two-thirds of women of color with HIV infection have at least one child under the age of 20, adding further complexity to their lives and their care (Hsu, 2001; HRSA, 1999).

Once in care, HIV-infected substance abusers face obstacles to staying in care and receiving quality care. Studies have shown that substance abusers are more likely to receive sporadic care in emergency departments. Chronic drug users are less likely to have a regular source of health care and are more likely than nondrug users to utilize emergency room and inpatient care (Markson et al., 1998; Laine et al., 2001; Welch and Morse, 2001). Other studies have shown that substance abusers are less likely to receive HAART than nonusers (Soloman et al., 1998; Celentano et al., 2001; Metsch et al., 2001; Turner et al., 2001). This is partly because of provider beliefs that substance abusers are less likely to adhere to treatment regimens and because of concerns surrounding interactions between HAART drugs and illicit drugs, psychotropic medications, and methadone.

Though active substance abuse is considered a predictor of poor adherence, the evidence indicates that the link is not always clear. Some studies have found an association between active substance use (particularly crack cocaine use) or heavy alcohol abuse and lower adherence (Cook et al., 2001; Hinkin et al., 2002; Mannheimer et al., 2002). Substance abuse, however, may also be associated with depression or other affective disorders that can affect adherence (Ekstrand et al., 2002; Mannheimer et al., 2002; Perry et al., 2002). This association may in turn further complicate adherence, while substance abuse symptoms may mask symptoms of depression or vice versa.

PLWH/A with co-morbid substance abuse and/or mental illness encounter many obstacles to accessing treatment, remaining in care, and adhering to treatment regimens. However, there are interventions that can improve utilization, retention, and adherence rates for these populations. Substance abuse and mental illness often co-occur with one another as well as HIV, and can be the underlying cause of other conditions that complicate HIV care, such as homelessness. Effective management of the HIV epidemic requires that the issues of substance abuse and mental illness be confronted by providing appropriate treatment to those who need it in care settings that are also equipped to provide HIV care.

Co-Morbid Infections

The most common medical co-morbidities associated with HIV are sexually transmitted diseases (STDs), hepatitis C virus (HCV) infection, and tuberculosis (TB). The presence of an STD as a preexisting condition can lead to heightened risk of HIV infection in three ways: (1) STDs increase the infectivity of HIV, (2) STDs increase susceptibility to HIV infection, and (3) behaviors that lead to increased risk are highly related for HIV and STDs (IOM, 1997). Epidemiological studies suggest that people may be two to five times more likely to become HIV infected when other STDs are present (Levine et al., 1998; Patterson et al., 1998; IOM, 1997). A study of eight United States STD clinics in the early to mid-1990s found an overall prevalence of STDs among HIV-positive individuals of 32.6 percent. Among HIV-infected females, STD prevalence was 25 percent; among males, 35.1 percent; among blacks, 35.1 percent; among whites, 37.8 percent; among Latinos, 20.3 percent; among individuals under age 30, 35.1 percent; and among those older than 30, 31.5 percent (Rothenberg et al., 2000).

Nationally, about 25 percent of all HIV-infected individuals are estimated to have co-morbid HCV infection (CDC, 2002b). The risk is particularly high for injection drug use, the most common means of HCV transmission in the United States (Estrada, 2002). In a study of six drug treatment sites located throughout the United States, rates of hepatitis B and C viruses were consistently about 90 percent for older injection drug users (Murrill et al., 2002). CDC estimates that the rate of coinfection with HIV and HCV among injection drug users ranges from 50 to 90 percent. Comorbid HIV infection is associated with a more swift progression of HCV-related liver disease and cirrhosis, which may lead to limited tolerance for antiretroviral therapy due to hepatic side effects (Sulkowski et al., 2002; Ostrow, 1999; Greenberg, 1999; CDC, 2002b).

Individuals with HIV are especially vulnerable to tuberculosis. Because HIV infection suppresses the body's immune system, HIV-infected persons are at increased risk of developing TB and, if infected, are 100 times more likely to progress to active TB than those not infected with HIV. CDC estimates that about 15 percent of all TB cases, and 30 percent of cases among individuals ages 25 to 44, occur among HIV-infected individuals (CDC, 1998b). Among injection drug users, CDC estimates that the TB incidence rate for those who are HIV positive is more than seven times that of those who are not (CDC, 1999). This is an area of particular concern because there is evidence that some common HIV and TB treatments may be incompatible and substitutions are cost prohibitive, thus complicating care (Spradling, 2000).

Social Co-Morbidities

As explained earlier in the chapter, the Committee uses the term social co-morbidity to describe an underlying social condition that affects the course of HIV disease in an individual. Social co-morbidities can be one cause of circumstances that lead to disruption of care or inability to maintain adherence to a treatment regimen.

Homelessness

Homelessness creates challenges to access, adherence, and continuity of care for individuals infected with HIV. Inability to store or access medications, lack of routine medical care, poor nutrition, even the stress of being unstably housed can affect the course of HIV disease.

The experience of 1,445 HIV-infected Medicaid recipients in New York state, where 6 percent were homeless; 24.5 percent were "doubled up," that is, staying with friends or relatives; and 69.5 percent were stably housed provides an example. The homeless and doubled up were less likely than the stably housed to have a regular source of care, a recent visit to a physician, and HIV-related medications. They were also more likely to use the emergency room for care (Smith et al., 2000). Once administrative databases for homeless shelters and AIDS case reporting were merged in Philadelphia, the incidence of AIDS was observed to be nine times higher in the shelters than the general population. The most predictive factors for AIDS within this homeless population were being male, being a minority (black), having a substance use disorder or mental illness, and lacking insurance (Culhane et al., 2001). In the same study, persons who were newly diagnosed with AIDS were three times more likely than the general population to become homeless during the follow-up period.

The overlap between homeless populations and populations with substance use disorders or mental illness that was demonstrated in the Philadelphia study also has been observed in multiple other studies (D'Amore et al., 2001; Martens, 2001; Rosenblum et al., 2001; Cheung et al., 2002; Kilbourne et al., 2002). Where it was measured, individuals in these studies were also more likely to have HIV, TB, and/or HCV (D'Amore et al., 2001; Rosenblum et al., 2001; Cheung et al., 2002).

Unsupervised Youth

Another group that faces challenges in receiving adequate care is HIV-infected unsupervised youth, usually homeless or runaways. In a Minnesota study of 201 street youth, 37 percent reported having 15 or more alcoholic drinks per week, 37 percent used marijuana three or more times a week, and 15 percent reported having used injection drugs at least once, including 6 percent who used injection drugs within the previous month (Lifson and Halcon, 2001). Underscoring the theme that there is considerable overlap across vulnerable populations, in a sample of HIV-infected adolescents in Washington, D.C., 53 percent had received psychiatric diagnoses prior to their treatment at the clinic, 50 percent had a documented history of sexual abuse, and 82 percent had a history of substance use (Pao et al., 2000).

Undocumented and Legal Immigrants

Undocumented workers and other immigrants also face barriers to accessing and maintaining continuity of care for HIV. These individuals are especially vulnerable to the barriers presented by language difference, lack of cultural competency, and lack of insurance or other means to pay for care. In a pilot study of undocumented immigrants in southern California, less than 8 percent of the sample accessed nonemergency health care, and high-risk behavior or HIV (although no HIV testing was done) suggested that this population requires closer attention for HIV-related services (Loue and Oppenheim, 1994). Although considerable attention has been paid to immigrants with tuberculosis in the previous decade, HIV infection identification and treatment have not received an equal amount of attention (Weis et al., 2001). A summary of a needs assessment of recent migrants into a Texas county indicated that migration was associated with knowledge barriers for all types of services. Results also showed that recent immigration was a significant predictor of failure to receive government-administered basic services such as food services, but was not a significant predictor of failure to receive community-based organization-administered "specialized" services targeted specifically to HIV-positive individuals (Montoya et al., 1998). This indicates that there are programs and interventions that can reach this population.

Incarcerated Populations

A study conducted by Hammett et al. (2002) used data from 1997 to estimate that up to one-fourth of the people living with HIV in this country pass through a correctional facility each year. A recent assessment of voluntary counseling, testing, and referral (VCTR) in 48 correctional facilities throughout the country resulted in an HIV prevalence of 3.4 percent (Sabin et al., 2001). In one study, 85 percent of HIV infection in prison was associated with injection drug use prior to incarceration (Vlahov et al., 1989). Transmission of HIV infection in prison is rare (Brewer et al., 1988; Horsburgh et al., 1990). Although screening and prevention is not the focus, VCTR illustrates that contact with the correctional health care system can give public health professionals an opportunity to diagnose HIV and provide therapy to a population that might prove difficult to reach otherwise (Hammett et al., 2002; Sabin et al., 2001; Rich et al., 2001).

Because the majority of persons who enter a correctional facility will eventually return to their communities, the manner in which correctional health services deal with the HIV-infected individual has important implications to the overall care of the HIV-infected population. Routine HIV testing is well accepted as a procedure offered to incoming prison inmates. Combination antiretroviral therapy has been associated with a reduction in mortality in prisons. A link between community HIV specialists and correctional health care providers is an important partnership for ensuring that HIV-infected patients have optimal care both inside prison and after release (Spaulding et al., 2002).

CONCLUSION

The current environment of HIV care is both more hopeful and more complex than it was 20 years ago. The early HIV care system was designed—consciously or not—to manage patients who entered with symptomatic, advanced disease and who died after several years of increasingly untreatable opportunistic diseases. A substantial portion of this time was spent in acute care hospitals and involved use of cumbersome, expensive, and invasive therapies. This model of care no longer applies. The changes in the treated natural history of HIV infection from an acute to a chronic disease model and the shift in populations most affected must be considered when crafting policies for the public financing and delivery of HIV care. The public care system must take advantage of the opportunities offered by effective treatments such as HAART while working to meet the challenges of the new epidemic.

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.
- Nearly complete adherence to the prescribed HAART regimen is crucial for both optimal treatment benefit and the prevention of drug resistance.
- The demographics of the HIV epidemic are shifting into populations that are highly vulnerable in terms of having access to care, continuity of care, and adherence to treatment, such as racial and ethnic minorities, low-income women, individuals who are mentally ill or have substance abuse disorders, and homeless individuals.

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3

Current Financing and Delivery of HIV Care

People living with HIV/AIDS rely on a variety of private and public payment mechanisms to obtain care. Thirty-one percent 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) (see Figure 3-1).[1] Programs such as the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act program, community and migrant health centers, private free clinics, and public hospitals provide a health care safety net for many individuals with HIV/AIDS who are uninsured and/or underinsured.

The federal programs that provide care to people living with HIV/AIDS operate through two financing mechanisms: mandatory spending programs, in the form of entitlements to the individual and to the states, and discretionary annual funding for specific services. These financing mechanisms have significant implications for individuals and governments in terms of stability of financing, access to care, durability of services, and costs. In 2002, 72 percent of the $8.7 billion spent on health care and related social support services for people with HIV/AIDS was spent under mandatory or entitlement programs. In fiscal year 2002, a total of $14.7 billion was spent by the federal government on HIV/AIDS medical care, research, prevention, and other activities (see Figure 3-2).

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[1] Portions of this chapter draw heavily from a paper commissioned by the Institute of Medicine Committee on Public Financing and Delivery of HIV/AIDS Care. The paper was written by Jennifer Kates, Kaiser Family Foundation, and is included in its entirety in Appendix D.

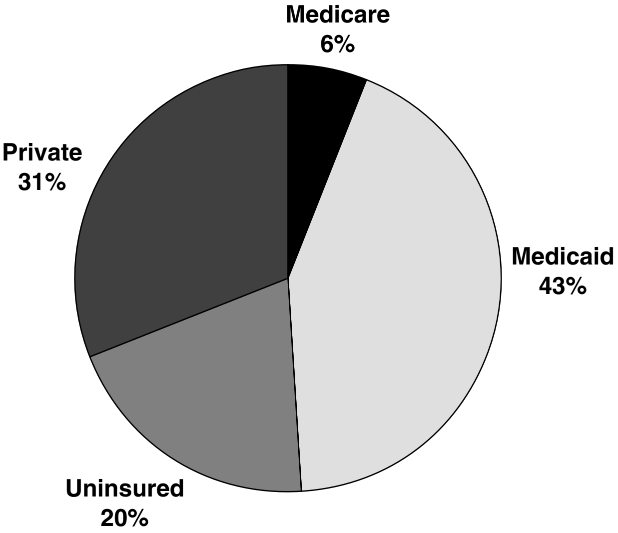

FIGURE 3-1 People living with HIV/AIDS in regular care: estimated insurance coverage, 1996.
SOURCE: Bozzette et al., 1998.

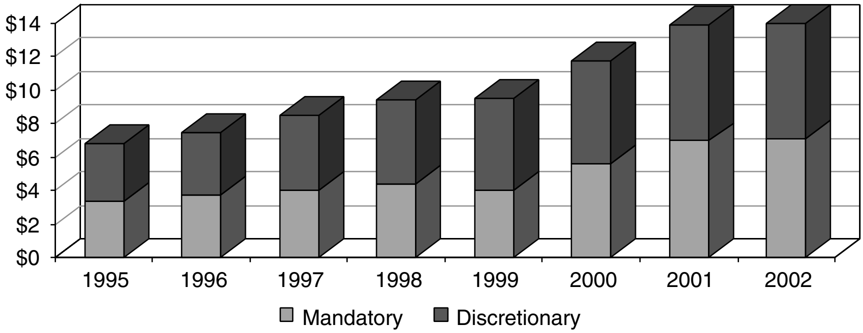

FIGURE 3-2 Federal spending on HIV/AIDS by type (mandatory or discretionary), 1995–2002.
SOURCE: Kates, 2004.

FEDERAL FINANCING OF HIV CARE

Medicaid

Medicaid, Title XIX of the Social Security Act, is the largest source of public financing for HIV/AIDS care in the United States. Created in 1965, Medicaid is a jointly funded, jointly administered federal–state health insurance program for low-income people who meet one or more of several categorical eligibility requirements, including disability. The program is administered through the Centers for Medicare & Medicaid Services (CMS). Through Medicaid, the federal government provides matching funds to states that meet certain minimum federal standards in operating their Medicaid programs. States have broad flexibility in designing their Medicaid programs, and consequently there is significant variation in eligibility, benefits, provider payments, and other aspects of the program at the state level (Westmoreland, 1999; Kaiser Commission on Medicaid and the Uninsured, 2001). State Medicaid policies vary considerably even among similar-sized and or adjacent states. Thus, a person who is eligible for Medicaid in one state might not be eligible in another state; and the services provided by one state may differ from those of another state.[2]

Because many people with HIV/AIDS are low income—or become low income—and disabled, Medicaid is an important source of coverage. In FY 2002, Medicaid spending on AIDS care totaled $7.7 billion, including $4.2 billion in federal dollars and $3.5 billion in state funds (see Figure 3-3). Overall, the program is estimated to cover approximately 44 percent of people with HIV and 55 percent of those living with AIDS (CMS, 2002). Medicaid is also estimated to cover the health care costs of up to 90 percent of children with AIDS (CMS, 2002).[3] Among those recently diagnosed with HIV (for whom coverage data were available), more than one-fifth (22 percent) were already covered by Medicaid at the time of diagnosis (Kates et al., 2002).

Eligibility

To be eligible for Medicaid, a person must meet the categorical and financial eligibility criteria in his or her state's Medicaid program. Most

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[2] Horizontal equity problems (across states) exist under the Medicaid program. Some federal policies have attempted to deal with this problem. Federal minimum-income eligibility thresholds for children in all states, for example, have increased interstate equity. However, some variation in eligibility criteria persist because some states exceed minimum standards while others do not (Pernice et al., 2001).

[3] Data on federal spending on HIV/AIDS are actuarial estimates developed by CMS.

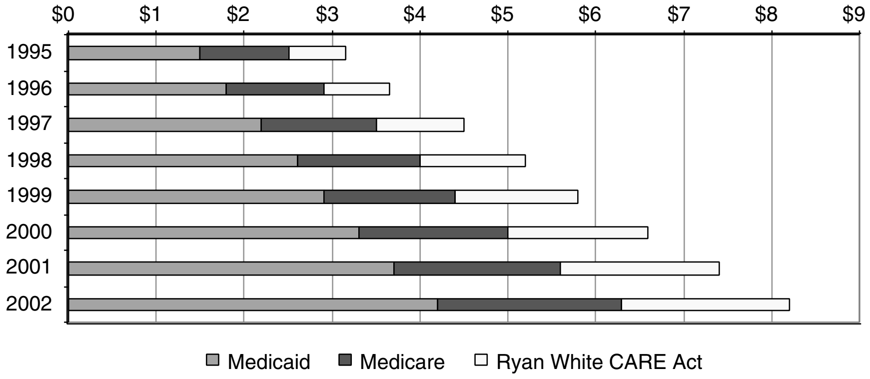

FIGURE 3-3 Federal spending on care: Ryan White CARE Act, Medicare, and Medicaid, fiscal years 1995–2002 (in billions).

adults with HIV/AIDS who qualify for Medicaid do so because they meet the disability and income and assets criteria of the federal Supplemental Security Income (SSI) program for persons who are aged, blind, or disabled. For purposes of SSI eligibility, a person is disabled if he or she is unable to engage in any gainful activity due to a medically determined physical or mental impairment expected to result in death or last for a continuous period of at least 12 months (Westmoreland, 1999).[4] Some states, known as 209(b) states,[5] may apply more restrictive eligibility rules under SSI.

People with HIV may also qualify for Medicaid through a state's medically needy program that enables those who meet categorical eligibility requirements, such as disability, to spend-down their incomes to meet their state's income eligibility threshold, which varies among states. Individuals must also meet a state's resource test.

Benefits

Federal rules require states participating in Medicaid to cover a set of mandatory services to eligible people in order to receive federal matching payments (Box 3-1). States may also choose to provide optional services

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[4] The Social Security Administration's (SSA) criteria for evaluating HIV infection are not linked to the Centers for Disease Control and Prevention's (CDC's) definition of AIDS. SSA determines disability by inability to work; thus, a person with symptomatic HIV infection who can still work may not be eligible for disability (SSA, 2004).

[5] States with a 209(b) designation may continue to use their pre-1972 eligibility standards rather than the current federal eligibility standards (Westmoreland, 1999).

BOX 3-1
Services Provided Under Medicaid

Mandatory Services States Must Provide to Qualify for Federal Matching Payments Under Medicaid and Selected Optional Services That May Be Provided

Mandatory Services

- Hospital services (inpatient and outpatient)
- Physician services
- Laboratory and X-ray services
- EPSDT (early and periodic screening, diagnosis and treatment services for those under 21 years)
- Federally qualified health center services
- Rural health clinic services
- Family planning services
- Nursing facility services
- Home health services
- Nurse-midwife services
- Certified pediatric or family nurse practitioner services

Selected Optional Services

- Prescription drugs
- Hospice services
- Case management services
- Clinic services
- Preventive services
- Tuberculosis-related services

SOURCE: Westmoreland, 1999.

and receive matching payments. Food and Drug Administration- (FDA) approved prescription drugs are an optional benefit that all states have chosen to provide. Medicaid coverage of prescription drugs includes all FDA-approved highly active antiretroviral therapy (HAART) drugs, but coverage of these drugs is at state option and subject to amount, duration, and scope limits (e.g., limit on the number of prescriptions), nominal copayments for adults, and prior authorization controls. Other optional services that can be important for people with HIV/AIDS include case management, prevention services, tuberculosis-related services, and hospice services.

States may also seek waivers to cover certain services that would not otherwise qualify for federal matching funds, and a number have done so (Kates, 2004).

Medicare: Coverage for Disabled and Elderly Persons with HIV/AIDS

Medicare (Title XVIII of the Social Security Act) is the nation's federal health insurance program for the elderly and disabled. It was established in

1965 and is also administered by CMS. Medicare is an important source of coverage for people with HIV/AIDS who are disabled, have sufficient work history to qualify for disability insurance, and live long enough to qualify for Medicare. Medicare covers an estimated 6 percent of people with HIV/AIDS who are in care (CMS, 2002; Kates, 2004; Bozzette et al., 1998).

As people with HIV/AIDS live longer, the number of people with HIV/AIDS on Medicare is expected to grow, and Medicare spending is also expected to increase. Today, Medicare is the second largest source of federal financing of HIV/AIDS care, accounting for $2.1 billion in FY 2002. Medicare spending on HIV/AIDS has roughly doubled since FY 1995, when it was $1 billion (IOM, 2001; CMS, 2002; Kates, 2004). Some individuals with Medicare coverage also qualify for Medicaid because they have low income levels; they are considered to be dual-eligible.[6] For these individuals, Medicaid provides varying levels of coverage, including payment of premiums, some cost sharing, coverage of services during the waiting period (for those under 65 years), and coverage of prescription drugs.

Eligibility

Most Americans ages 65 and older are entitled to Medicare as soon as they are eligible for Social Security payments. People under age 65 who receive Social Security Disability Insurance (SSDI) benefits and individuals with end-stage renal disease may also qualify for Medicare. People with HIV/AIDS who meet SSDI eligibility criteria are eligible for Medicare benefits. The Social Security Administration defines disabled to mean that an individual 18 years or older is unable to engage in any substantial gainful activity due to any medically determinable physical or mental impairment(s) that can be expected to result in death or that has lasted or can be expected to last for a period of not less than 12 months (SSA, 2004). In addition, individuals must have paid Social Security taxes through their workplace for a minimum number of fiscal quarters. Federal law, however, requires a 5-month waiting period after disability determination to receive SSDI benefits and then a 24-month waiting period before an SSDI beneficiary can join Medicare, resulting in a total of 29 months before receipt of health benefits (SSA, 2004; Schietinger and Schecter, 1998).

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[6] Qualified Medicare Beneficiaries, Specified Low-Income Medicare Beneficiaries, Qualified Individuals, Qualified Disabled and Working Individuals, and Consolidated Omnibus Budget Reconciliation Act (COBRA) Continuation Beneficiaries are dual-eligible for Medicaid.

Benefits

Medicare as it currently exists is composed of three parts (KFF, 2004):

- **Part A** covers inpatient hospital services, skilled nursing facilities, home health services, and hospice care.
- **Part B** helps pay for the cost of physician services, outpatient hospital services, medical equipment and supplies, and other health services and supplies.
- **Part C** allows beneficiaries to choose to enroll in a health maintenance organization or other managed care plan, a preferred provider organization or to chose a medical savings account.

Prescription drugs will not be a covered benefit under the Medicare program until January 1, 2006, when Medicare Part D takes effect as established by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MPDIM) (PL. 108-173). A number of questions and concerns have already been raised about certain provisions of the legislation, its implementation, and its costs, including particular concerns for individuals who receive services as "dually eligible." These concerns are related to the range of drugs offered, potential lapses in prescription drug coverage, difficulties navigating the enrollment process, out-of-pocket costs and the associated denial of prescription drugs if co-payment cannot be met. These issues are discussed in Kates (2004) in Appendix D.

Ryan White CARE Act

Administered by the Health Resources and Services Administration (HRSA), the Ryan White CARE Act was designed to address the gaps in financing care for people with HIV/AIDS and to provide financial support to cities that were bearing a disproportionate burden of the cost of care. The CARE Act is intended to function as payer of last resort—that is, to provide care to individuals who are uninsured or underinsured and cannot cover the costs of care on their own, and who do not have another source of payment for services, public or private, available to them (HRSA, 2002j). Through the CARE Act, cities, states, and other public and private nonprofit entities receive funds to develop, coordinate, and operate systems for the delivery of health and support services to medically underserved individuals and families affected by HIV disease.[7] The CARE Act has helped to create an AIDS care infrastructure across the country.

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[7] See Appendix B for an overview of CARE Act funding allocation formulas.

Ryan White CARE Act Title I and II

The CARE Act has several titles and components, which are described in Box 1-1. In FY 2003, federal spending for the CARE Act totaled $2.0 billion; it represents the third largest source of federal funding for HIV care in the United States (HRSA, 2003a). Title I ($626.7 million) and Title II ($1 billion) of the CARE Act provided the largest amount of grant funding to areas, states, and territories in FY 2003. The majority of Title I funds go to health care services, case management, and social support services (HRSA, 2002a). The majority of Title II funding is directed as an earmark to the AIDS Drug Assistance Progam (ADAP) ($714.3 million, a program that provides medications but can also be used to purchase private insurance with drug coverage benefits) (HRSA, 2002b). The remainder of ADAP funds is directed to states ($352.6 million) for services (HRSA, 2002c, 2003a). In recognition of the varying nature of the HIV/AIDS epidemic across the country, CARE Act grantees, including states and cities, are given broad discretion in designing local programs. As a result, there is significant variation in state funding, eligibility, services, and other aspects of CARE Act programs across the country.

Other Ryan White CARE Act Programs That Provide Care

Although much smaller in scope, three additional CARE Act programs provide funding for care services: Title III-Early Intervention Services, Planning and Capacity Grants (Title III); Title IV-Women, Children, Infants, and Youth (Title IV); and the HIV/AIDS Dental Reimbursement Program (Dental Reimbursement Program). In FY 2003, these programs had a cumulative appropriation of $288.8 million.

Title III of the CARE Act funds early-intervention HIV services provided by public and non-profit groups. Early-intervention services include counseling, testing, medical evaluation, primary care, antiretroviral therapies, medical and mental health care, case management, and other services. A smaller proportion of the Title III funds help such groups plan for the development of early-intervention services (one-year grants of $50,000) or build their capacity to provide services (up to $150,000 over a three-year period (HRSA, 2002d). In FY 2003, $200.9 million was appropriated for this program (HRSA, 2003a).

Title IV of the CARE Act addresses the specific needs of women, infants, and children and youth living with HIV. Title IV evolved from the Pediatric AIDS Demonstration Program which was established in 1988. The funds cover primary and specialty medical care, psychosocial services, logistical support and coordination, outreach, and case management (HRSA, 2002e). Title IV also provides clients with increased access to HIV/AIDS clinical trials and research. In FY 2003, $74.5 million was appropriated for this program (HRSA, 2003a).

The Dental Reimbursement Program was added to the CARE Act in 1996. The program provides funding to improve access to oral health care for people with HIV/AIDS by providing reimbursement to educational programs. The funds help to offset the cost of uncompensated dental HIV care provided by the programs (HRSA, 2002f). The program was appropriated $13.4 million in FY 2003 (HRSA, 2003a).

In addition to these programs, two additional Ryan White CARE Act programs are designed to assist in improving the quality of care provided by the Ryan White programs and to assist community providers in improving the delivery of care. A total of $60.6 million was appropriated to these programs in FY 2003.

The AIDS Education and Training Centers (AETC) programs fund a network of 11 regional centers and associated sites that conduct multidisciplinary education and training for providers who care for persons with HIV/AIDS. The centers are designed to expand the number of providers who can counsel, diagnose, treat, and medically manage individuals with HIV, and who can help prevent high-risk behaviors that transmit HIV (HRSA, 2002g). The program disbursed $35.6 million in FY 2003 (HRSA, 2003a).

The Special Projects of National Significance (SPNS) Programs were established to advance knowledge and skills needed to deliver health and support services to underserved populations with HIV infection. SPNS programs evaluate the effectiveness of models of care, support the design of innovative care programs, and help replicate effective models (HRSA, 2002h). Funding for this program is provided through a set-aside from Titles I–V that cannot exceed $25 million (HRSA, 2003).

Clients Served by the Ryan White CARE Act

CARE Act providers serve an estimated 533,000 individuals each year (HRSA, 2003a).[8] CARE Act providers, compared to non-CARE Act providers, typically serve more women, minorities (Ashman et al., 2000), and persons with no insurance (GAO, 2000). CARE Act providers also provide some services to Medicaid-only and dual-eligible beneficiaries whose needs are not met by these programs.

Data from HRSA's Client Demonstration Project present similar findings. The project uses unique identifiers to track the service use of all HIV-

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[8] It is impossible for HRSA to determine the exact number of clients served because individuals may receive care under several parts of the CARE Act and most grantees do not report unduplicated client-level data.

infected and -affected clients receiving services from Ryan White CARE Act-funded providers in specific Eligible Metropolitan Areas (EMAs) or states. More than 33,800 clients are tracked in five sites: Colorado; Michigan; Virginia; Orange County, CA; and Los Angeles, CA (HRSA, 2002i). Data from this tracking project indicate that the CARE Act served a much higher proportion of HIV-infected, African-American women than women from other racial/ethnic categories at these sites and that clients who received medical care services from Ryan White CARE Act providers were more likely to have no insurance coverage and less likely to have private insurance than clients who did not receive medical care from CARE Act providers.

Eligibility

CARE Act services are available to uninsured or underinsured individuals and families living with HIV/AIDS; states and municipalities determine eligibility for these services. Results from a 2000–2001 survey of Title I Planning Councils found that, in nearly all EMAs, medical eligibility required only that an individual be HIV positive. Some EMAs had additional medical eligibility criteria for specific services, for example, Social Security determination of disability to receive home health services. With respect to financial eligibility, at least 20 EMAs reported that they did not have income-related financial eligibility for Title I services. For those EMAs with financial eligibility criteria, the criteria tended to be higher than eligibility levels for Medicaid, and most were at least twice the federal poverty level (i.e., $8,980 for an individual in 2003). Some EMAs allowed client fees for some services. These were likely to be charged to individuals exceeding financial eligibility requirements. Client fees were typically based on a sliding-scale fee schedule (Buchanan, 2002).

Benefits

The CARE Act primarily funds outpatient care and support services and does not pay for hospitalizations and long-term institutional care (see Table 3-1). Services include outpatient medical and dental care, prescription drugs (through ADAP), case management, home health and hospice care, insurance continuation, and housing, transportation, and nutritional services.

Table 3-2 presents the distribution of dollars for CARE Act Titles I and II for Fiscal Years (FY) 1996, 1998, 2000, and 2001. The most notable trends in Title I spending are the level expenditures on health care since 1998 at 44 percent, and fairly level expenditures on case management and support services. Under Title II, spending on support services and case

TABLE 3-1 Services Available Through Ryan White CARE ACT Title I and II

Health Care Services Available Through CARE Act Titles I and II	Support Services Available Through CARE Act Titles I and II
Ambulatory medical care	Case management
Medications	Adoption/foster care assistance
Dental care	Buddy/companion services
Health insurance purchase	Client advocacy
Home health and hospice care	Counseling
Mental health therapy, counseling	Day/respite care
Nutritional services	Direct emergency assistance
Rehabilitation care	Food bank, home meals
Substance abuse treatment	Health education, risk reduction
Treatment adherence and counseling	Housing assistance
	Outreach
	Primary care referrals
	Transportation

TABLE 3-2 Percentage Distribution of CARE Act Title I and Title II Funds, FY 1996, 1998, 2000, 2001

Service	1996		1998		2000		2001[a]	
Ryan White Program	Title I	Title II	Title I	Title II	Title I	Title II	Title I	Title II
Funding ($ millions)	391.7	260.8	464.8	543.0	546.4	823.8	580.5	845.6
Percentage spent on service category								
Health care (outpatient medical, dental, home health, hospice care)	49	24	44	11	44	09	44	12
Case management	12	11	11	06	12	05	12	08
Support services	23	12	23	06	27	05	26	07
Medications/ADAP	07	46	12	67	07	71	07	68
Administration, planning, evaluation, and program support	09	07	10	10	10	09	11	07

[a] The most recent data available is for 2001 (Personal communication, Dr. Richard Conviser, HRSA, December 23, 2003).

management declined over the period, while spending on ADAP increased significantly, from 46 percent to 68 percent in response to the growing demand for antiretroviral therapy.

CARE Act Planning Bodies and Consortium

Title I funding is determined by a formula based on the estimated number of people living with AIDS in the EMA over the most recent 10-year period. Supplemental grants are awarded competitively by the U.S. Department of Health and Human Services (DHHS) on the basis of demonstrated severity of need and other criteria. Title II grants are also determined by a formula based on the estimated number of living AIDS cases in a state.[9] The allocation of CARE Act Title I funds is guided by local planning councils. Councils have responsibility for assessing an EMA's HIV/AIDS service needs, establishing priorities for the allocation of funds, developing a comprehensive plan for the organization and delivery of HIV services that is compatible with existing state and local plans, addressing the efficiency of the administering agency in rapidly allocating funds to areas of greatest need, and establishing operations to make planning tasks function smoothly (HRSA, 2003c). Planning council membership is determined by law and is intended to reflect the demographics of the population of individuals with HIV disease in the eligible area involved, with particular consideration given to disproportionately affected and historically underserved groups and subpopulations (HRSA, 2003c). It is required that 15 membership categories (see Box 3-2) be represented in the planning council.

CARE Act Title II funds are awarded to a state agency for administration. States use funds to provide services directly as well as through consortia. The Act defines consortia as "an association of one or more public, and one or more nonprofit private health care and support service providers and community based organizations operating within areas determined by the state to be most affected by HIV disease" (HRSA, 2003d). Consortia are responsible for assessing needs and contracting and coordinating a comprehensive continuum of outpatient health and related support services (HRSA, 2001). Furthermore, consortia are expected to promote the coordination and integration of available community resources, use case management to ensure continuity of services, and evaluate their effectiveness at meeting service needs. Consortia membership includes agencies with expe-

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[9] As part of the Ryan White CARE Act Reauthorization in 2000, Congress directed that the Title I and Title II formulas incorporate data on cases of HIV as well as AIDS in order to target funding to more accurately reflect the HIV/AIDS epidemic. The use of such data could take effect in FY 2005.

BOX 3-2
Ryan White Title I Planning Council Membership Categories

1. Health care providers
2. Community-based organizations
3. Social service providers
4. Mental health providers
5. Substance abuse providers
6. Local public health agencies
7. Hospital planning agencies
8. Affected communities
9. Nonelected community leaders
10. State agency administering Title II program
11. State Medicaid agency
12. Grantees under Title III
13. Grantees under Title IV
14. Grantees of other federal HIV programs
15. Representative of individuals who were released from the custody of the penal system during the preceding three years

rience in HIV/AIDS delivery and populations and representatives of those groups of persons living with HIV disease who reflect the local incidence of HIV. In conducting their work, consortia members must also demonstrate that they have consulted with people affected by the disease, the public health agency providing HIV/AIDS-related health care, at least one community-based AIDS service provider, other CARE Act grantees, and Title I planning councils.

Private Coverage for HIV/AIDS Care

Private insurance represents a significant source of coverage for individuals with HIV/AIDS. According to the HIV Cost and Services Utilization Study (HCSUS), an estimated one-third of people in HIV/AIDS care are covered by private health insurance obtained through their employers (Kates, 2004; Bozzette et al., 1998) (see Box 3-3). Those who are insured in the group market tend to have the most comprehensive coverage and have less difficulty obtaining and keeping that coverage. The insurance market is largely regulated at the state level; however, the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191), also known as HIPAA, established basic national standards for insurance regulation in the small-group market (firms with 2 to 50 workers) and, to a lesser extent, in the

BOX 3-3
HIV Cost and Services Utilization Study

The HIV Cost and Services Utilization Study (HCSUS) was the first major research effort to collect information on a nationally representative sample of people in care for HIV infection. HCSUS is sponsored by the federal government and is centered at RAND. The core study enrolled a national probability sample of 2,864 HIV-infected adults who were receiving ongoing or regular medical care in the first two months of 1996. Respondents were sampled from 28 urban areas and 24 clusters of rural counties in the continental United States. Patients receiving services in hospitals, clinics, and private staff model practice settings were enrolled. HCSUS oversampled women and members of health maintenance organizations to obtain more precise information on these specific populations. The HCSUS design includes a baseline in-person interview with sampled patients, two follow-up interviews scheduled for 6 months and 12 months after the baseline interview, and abstractions of data from patients' medical, pharmaceutical, and billing records. All baseline and followup interviews were completed as of January1998. In addition, a supplemental interview containing a standardized instrument to diagnose psychiatric disorders was administered to a subsample of approximately 1,500 HCSUS respondents in conjunction with the first followup interview. Additional blood samples have been collected from a majority of HCSUS respondents, and virological analyses are being initiated.

Supplemental studies are examining HIV care delivery in rural areas, prevalence of mental and substance abuse disorders, oral health of HIV-positive individuals, and issues related to HIV-infected persons over 50 years of age. A supplemental sample of persons receiving care in rural areas was obtained to augment the core rural sample and to provide a basis for studies focused on the rural population with HIV infection. Another supplemental project is collecting data from the providers of care to HCSUS respondents.

The study continues to add to our understanding of AIDS. Although the original data collection activities are now several years old, the point estimates for a large number of values are still robust. Values for social situations and access issues within subpopulations, for example, have not changed much: most of those in care now were in care then (because of longer survival), and most people entering care still enter care with advanced disease. Point estimates for changes in clinical practices resulting from new information such as the proportion of persons on four or more antiretroviral therapies are less robust. However, this study remains the most diverse cohort ever, and the relationships found between predictor variables (e.g., demographics, insurance, region, etc.) and status or outcomes are not only robust but very unlikely to have changed over time (Personal communication, Sam Bozzette). Results from the HCSUS appear in a number of peer-reviewed journal articles.

SOURCE: AHRQ, 2004.

individual market. Protections covered in HIPAA included the following (Pollitz et al., 2000; Kates, 2004):

- **Portability.** Exclusions of preexisting medical conditions are limited to a maximum of 12 months.
- **Nondiscrimination.** Insurers in the group market are prohibited from conditioning persons' eligibility for group coverage on their health status. This does not apply to individual policies.
- **Guaranteed issue.** Insurers must offer all of their small-group policies to any small employers that want to purchase coverage for their workers.
- **Guaranteed renewal.** Insurers must allow all policies—group and individual—to be renewed.

Although private insurance represents a significant source of coverage for individuals with HIV/AIDS, its importance as a source of coverage diminishes as the disease progresses. A recent analysis of HCSUS data found that private insurance covered 42 percent of individuals with HIV infection in the early asymptomatic stage of the disease. Medicare, Medicaid, or a combination of the two programs provided coverage for 31 percent of those with asymptomatic disease, and the remaining 26 percent of individuals were uninsured. During the symptomatic stage, private insurance coverage dropped to 31 percent, federal programs provided coverage for 44 percent of symptomatic individuals, and the percentage of uninsured individuals remained virtually unchanged (25 percent). In the most advanced stage of the disease—full-blown AIDS—private insurance bears a proportionately small burden for providing coverage. At this stage, private insurance covers 26 percent of individuals, federal entitlement programs cover 62 percent of individuals, and 12 percent are uninsured. The study authors note that there is a close link between insurance coverage and HIV disease progression. Patients with private insurance are able to start treatment early but tend to lose insurance coverage as their disease worsens, and the uninsured must delay treatment until their health deteriorates enough for them to be deemed disabled and eligible for public insurance coverage under Medicare or Medicaid (Goldman et al., 2003).

DELIVERY OF HIV/AIDS CARE SERVICES

During the first two decades of the epidemic, hospitals served as the backbone of the HIV/AIDS delivery system. At that time, AIDS patients required the expertise of hospital-based infectious disease specialists for the majority of their clinical care, including palliative medical interventions.

Organizations, some linked to hospitals and some not, provided AIDS patients with supportive and other palliative care services.

By the end of the epidemic's second decade (1990s), revolutionary and increasingly more simplified HAART medical therapy was successful in preventing disease progression, death, and disability. Today, patients who know their status, enter care, and stay in continuous care over their lifetime experience HIV/AIDS as a lifetime chronic disease that most often allows them to continue to make productive contributions to society (Gifford and Groessl, 2002). Changes in understanding of the disease and improvements in therapeutic technology have required significant changes in delivery system structure, moving the primary locus of care from the hospitals, hospital providers, and end-of-life social supports like buddy and nutrition services to outpatient medical care systems and medical providers supported by social services providers. While care still includes specialized inpatient care when needed, outpatient clinical services are now the backbone of the HIV/AIDS care system. Care services are organized and coordinated by outpatient infectious disease specialists, primary care physicians, or nonphysician case managers from community-based organizations that provide social support.

The shift from inpatient to outpatient care is consistent with the shift in the goals of therapy for HIV-infected patients. Until the advent of HAART, the goals of treatment were to manage the acute conditions associated with immune system deficiencies and provide supportive and palliative care services so as to minimize suffering and maximize functional status through a period of decline and ultimately death. With the introduction of HAART, survival times are longer and the primary treatment goals are to reduce viral loads to low levels, maintain immune system function, and delay or prevent the progression from HIV to AIDS. Today, HIV/AIDS is managed much like a serious chronic condition (e.g., diabetes, asthma) rather than a terminal disease such as cancer (Gifford and Groessl, 2002). The shift in care emphasis—from acute to chronic—has important implications for managing the condition. As discussed in the section on adherence in Chapter 2, diabetes in particular provides important lessons in the management of HIV. These lessons include the importance of developing a collaborative relationship between the patient and the health care provider and implementing financing mechanisms that allow for continuity of care and adequate reimbursement of time spent on the part of the health care provider (APHA, 2002). In addition, experience with the management of diabetes has highlighted the importance of provider training in promoting adherence to treatment (APHA, 2002).

The Committee reviewed current guidelines and standards of care for HIV-infected individuals to understand what an appropriate level of care would include. Eight broad areas of standard care surfaced that capture the critical components of HIV care. These critical components of HIV care will reduce mortality, extend the lives of people with HIV, and, when combined with prevention services, assist in controlling the epidemic. They include HAART, other drug therapies, primary care services, obstetrics and reproductive health services for HIV-infected women, substance abuse treatment, treatment for mental illness, case management services, and HIV prevention services.

Highly Active Antiretroviral Therapy

As noted in Chapter 2, access and adherence to life-sustaining comprehensive antiretroviral therapy is the cornerstone of HIV care. Without it, patients experience a rapid death. HAART is described as a standard of care in the Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents (DHHS, 2004). The guidelines recommend that HAART be offered to all patients with symptoms of HIV infection, especially those with with a CD4 cell count below 350 or viral load exceeding 55,000 copies/mL. To assist in managing the disease, the International AIDS Society-USA Panel developed new guidelines recommending antiretroviral resistance testing to better manage HAART therapy and minimize the risk of viral drug resistance (Hirsch et al., 2003).

Compelling cost-effectiveness evidence also supports the need to provide HIV-infected individuals with HAART. Studies by numerous researchers have demonstrated that HAART use is cost effective in that it significantly reduces hospital inpatient costs and community costs (Gebo et al., 1999; Bozzette et al., 2001; Moore, 2000; Keiser et al., 2001; Freedberg et al., 2001) and improves the health-related quality of life of patients with HIV infection (Hays et al., 2000).[10]

As noted earlier, HAART is available through Medicaid and the ADAP portion of the CARE Act programs. The extent to which individuals receive appropriate prescribed drugs, however, varies significantly for each program.

Other Drug Therapies That Prevent Complications and Support Retention in Care

Although antiretroviral therapy can reduce opportunistic infections in HIV-infected people, some will still develop a variety of infections that complicate their care. Many of these illnesses are very serious, and they

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[10] While HAART use is cost effective, it is important to note that it is not, overall, cost saving because life expectancy of individuals on HAART is increased and treatment is lifelong.

need to be prevented or, when they occur, treated. Opportunistic infections seen in individuals with HIV infection include those that are bacterial and mycobacterial (*Mycobacterium avium* complex or MAC, tuberculosis, syphilis), fungal (candidiasis, coccidioidomycosis, histoplasmosis), protozoal (cryptosporidiosis, cryptococcosis, toxoplasmosis), and viral (cytomegalovirus or CMV, herpes zoster). The U.S. Public Health Service and Infectious Diseases Society of America (2001) (CDC, 1998) have developed guidelines for preventing exposure to infections, disease, and recurrence of these opportunistic infections among HIV-infected persons. Specific guidelines for the prevention and treatment of tuberculosis in HIV patients have been published by CDC (1998, 2003d).

Obstetrics and Reproductive Health Services for HIV-infected Women and Pediatric Care for Infants with HIV

As stated in *Reducing the Odds: Preventing Perinatal Transmission of HIV in the United States* (IOM, 1999),"One of the most promising victories in the battle against AIDS was the finding in 1994 that administration of the antiretroviral drug zidovudine (ZDV) during pregnancy and childbirth could reduce the chance that the child of an HIV-positive mother would be infected by two thirds." Since then, epidemiologic data have since confirmed the efficacy of ZDV for reduction of perinatal transmission. In 1998, the Public Health Service Task Force recommended that all pregnant HIV-1 infected women should be offered HAART to maximally suppress viral replication, to reduce the risk of perinatal transmission, and to minimize the risk of development of resistant viruses. These recommendations were revised in June 2003 to update recommendations on antiretroviral chemoprophylaxis for reducing perinatal transmission. The recommendations also state that all women should receive comprehensive health care services that continue after pregnancy for their own medical care and for assistance with family planning and contraception (U.S. Public Health Service Task Force, 2003).

Similar guidelines for the use of antiretroviral agents for the treatment of pediatric HIV infection were developed by the Working Group on Antiretroviral Therapy and Medical Management (WGATMM) of HIV-Infected Children (revised June 2003). The guidelines provide the standard of care for the management of an estimated 300 infants who contract HIV from their mothers each year (CDC, 2003a; WGATMM, 2004). Supervising the HIV Perinatal and Pediatric guidelines is a new initiative launched by CDC and other DHHS agencies: *Advancing HIV Prevention: New Strategies for a Changing Epidemic* (CDC, 2003b). One of the initiative's four key strategies is to further decrease mother-to-child HIV transmission by incorporating HIV testing in the routine battery of prenatal tests (CDC, 2003b).

Care for Individuals with HIV/AIDS, Substance Abuse, and Mental Illness

Care of the HIV-infected individual requires specific attention to the interplay of co-occurring diseases of substance abuse and mental illness (Douaihy et al., 2003a, 2003b; Bruce and Altice, 2003; Bing et al., 2001; Altice and Friedland, 1998; CSAT, 1995, 2000). Several reasons support the need to provide care delivery strategies that are comprehensive and that meet the standards of care for these three diseases. First, adherence to antiretroviral treatment may be undermined by co-occurring substance abuse and mental illness and could lead to the development of drug resistance. Second, the clinical management of HIV-infected individuals must take into account the impact of substance abuse and mental illness and their treatment on the expression of symptoms, the development of drug interactions, progression of HIV disease, the utilization of care services, and high-risk HIV behaviors (see Box 3-4).

Drug treatment adherence. As noted in Chapter 2, adherence to antiretroviral therapy is critical for therapeutic effectiveness (Harrigan et al., 2003; Garcia de Olalla et al., 2002; Bangsberg et al., 2001; McNabb et al., 2001; Paterson et al., 2000). However, an individual's ability to adhere to a treatment regimen may be related to co-occurring substance abuse and mental illness (Ferrando et al., 1996; Sternhell and Corr, 2002; Starace et al., 2002). A longitudinal study of the effects of continued drug use on the treatment of HIV infection in patients who attend an urbanized HIV clinic (Lucas et al., 2002) found that switching from non-use to substance abuse was strongly associated with worsening antiretroviral therapy use and adherence, less frequent HIV-1 RNA suppression, and blunted CD4 cell increases. The researchers also found that switching from substance abuse to non-use was strongly associated with improvements in antiretroviral therapy use and adherence, and HIV-1 treatment.

Tucker and colleagues (2003) analyzed data from the HCSUS study to investigate the association of antiretroviral medication nonadherence with specific types of psychiatric disorders and drug use, and with varying level of alcohol use. The researchers found that patients with depression, generalized anxiety disorder, or panic disorder were more likely to be nonadherent than those without a psychiatric disorder. Nonadherence was also associated with use of cocaine, marijuana, amphetamines, or sedatives in the previous months. Moderate and heavy alcohol use compared with no alcohol use was also found to be associated with nonadherence (Tucker et al., 2003). Researchers in Canada (Palepu et al., 2003) made similar find-

BOX 3-4
Why Treat Three Conditions When It Is One Patient?

"Although discussions regarding triple diagnosis began more than 10 years ago, the interrelated nature of substance abuse, mental illness, and HIV infection has been highlighted in the last several years with the understanding that adherence to antiretroviral therapy must approach 100 percent to be most effective. Both active substance abuse and mental illness in a HIV infected persons make the attainment of high adherence difficult, though not impossible. Among substance abusers, especially injection users, there is a high prevalence of social instability, which exacerbates the effects of substance abuse on adherence. Poor adherence to antiretroviral may result in the development of drug resistance and poor virologic outcomes. In addition, persons with triple diagnosis, especially those not receiving treatment, are also more likely to engage in high risk behaviors and thus fuel the HIV epidemic through the transmission of the virus, particularly multidrug-resistant strains.

"Clinically, it is unrealistic to address each of these diagnoses individually. Because of the overlapping natures of these 3 diagnoses, triple diagnosis should be viewed as 3 overlapping spheres of influence, with each diagnosis affecting the others. Conceptually this is important because successful therapy will treat all spheres of influence rather than ignore any single area. Consider the case of the heroin-dependent woman with bipolar disorder and advanced HIV disease. It would not be feasible to expect that one condition must be treated before addressing the others. Such an approach would likely result in a stalemate in which none of the conditions would be adequately treated. While the psychiatrist might argue that her drug use must be stabilized first, the drug treatment provider might insist that her untreated bipolar disorder compromises successful drug treatment. The HIV clinician might fear poor adherence to HAART and forego treatment until both the mental illness and substance abuse are controlled. This approach might result in significant morbidity and mortality as a result of opportunistic infections.

"Recognition of the interplay between substance abuse and mental illness in HIV-infected patients remains a focal point for the organization of health care and public health services. Models of integrated health care must continually be developed using innovative approached to address this complex problem. . . ."

R. Douglas Bruce, M.D.
Fredrick L. Altice, M.D.

SOURCE: Bruce and Altice, 2003.

ings. In a study of injection drug use and virologic response to HAART, current injection drug users were significantly less likely to suppress their HIV-1 RNA while former injection drug users were not significantly different from non-drug users. The researchers also found a significant interaction between drug use and adherence. The adherence of former drug users and non-drug users was positively associated with HIV-1 RNA suppression, whereas for current drug users it was not. Enhancing adherence to HAART would require careful assessment and treatment of co-occurring drug use and mental illness.

Expression of symptoms. The differential diagnosis and treatment of individuals with HIV-infection, substance abuse, and mental illness is complicated by the overlap of some symptoms and medical complications associated with the three disease entities (CSAT, 2000). Anorexia and weight loss, for example, may be directly related to HIV infection or associated with cocaine and methamphetamine use. Similarly, neurological symptoms such as peripheral neuropathy can be associated with HIV infection, AIDS dementia complex, and with other opportunistic infections such as toxoplasmosis. Peripheral neuropathy is also associated with the abuse of alcohol (alcohol polyneuropathy). Similarly, altered mental states can be associated with mental illness, HIV infection, opportunistic infection with cryptococcosis, and with the use of methamphetamine and other recreational drugs.

Drug interactions. Treatment of HIV, substance abuse, and mental illness often require the use of prescription medication; thus, a clinician is faced with managing the potential of serious pharmacokinetic drug interactions (Faragon and Pilliero, 2003; CSAT, 2000). These interactions can affect absorption, distribution, metabolism, and elimination of concurrently administered drugs. The use of the recreational drug ecstasy (3,4 methylenedioxymeth; MDMA), for example, can lead to significant toxicity when combined with antiretroviral therapy. The combination of heroin and ritonar and nelfinavir may enhance the effect of heroin. The medical or recreational use of barbituates is also problematic because it can reduce the levels of protease inhibitors and increase the risk of virologic failure and/or resistance. Alcohol use by patients with HIV has been shown to alter drug metabolism and to increase the risk of drug-induced hepatotoxicity, especially in patients co-infected with hepatitis C.

Similarly, prescribed medications used in the treatment of substance abuse and mental illness can produce drug interactions with the medications used in the treatment of HIV infection. The concentration of methadone, used in the treatment of heroin addiction, has been found to be significantly reduced when combined with certain HAART drugs—efavirenz and nevirapine (Faragon and Pilliero, 2003). Medications used to treat psychiatric disorders such as benzodiazepines can interact with some antiretrovirals in a negative way. Antiretrovials may increase the risk of benzodiazepine toxicity. HIV disease management would require an assessment of potential drug interactions.

Complication and progression of HIV disease. The course of HIV disease can be mediated by state of mind. Researchers investigating depression as a risk factor in HIV disease found that among women whose CD4 was less than 200, HIV-related mortality of those with chronic or intermittent depressive symptoms was 54 percent and 48 percent compared with 21 percent for those with limited or no depressive symptoms. The study's findings provide evidence that depression may alter the function of killer lymphocytes in HIV-infected women and suggests that depression may decrease natural killer cell activity and lead to an increase in activated CD8 T lymphocytes, and that viral load may decrease natural killer cell activity and lead to an increase in activated CD8 lymphocytes and viral load (Evans et al., 2002).

Another study addressing the impact of depression and mortality among women with HIV found that women with chronic depressive symptoms were two times more likely to die than women with limited or no depressive symptoms. Women with chronic depressive symptoms also had a more rapid decline in CD4 counts compared with women with limited or no depressive symptoms (Ickovics et al., 2001). Additional research investigating whether psychological distress was independently associated with rapid progression to AIDS among HIV-infected injection drug users found similar results. Psychological distress was found to be associated with more rapid time to AIDS. The strongest association was observed in individuals with the lowest CD4 cell counts (Golub et al., 2003).

High risk behavior. As noted in Chapter 2, HIV-infected individuals who abuse substances or are mentally ill are at a higher risk of transmitting HIV infection to others. For some, substance abuse and mental illness placed them at risk for becoming infected with HIV. Use of injection drugs and associated practices such as the sharing of needles and other injection equipment is an efficient method for transmitting HIV. Similarly, the exchange of bodily fluids through unprotected sexual activity increases the risk of transmitting HIV infection to others (IOM, 2001; Friedman et al., 1999; CSAT, 2000). Individuals with mental illnesses—including mood disorders, schizophrenia, and personality disorders—are at higher risk of engaging in behaviors that increase HIV risk. Risky behavior has been noted to be related to illness severity and psychiatric symptoms (Otto-Salaj and Stevenson, 2001).

Utilization of services. In addition to reducing adherence to antiretroviral therapy, substance abuse may also impact the use of other medical services. Arici et al. (2002) found that HIV-infected active injection drug users tend to be less compliant with keeping medical appointments, taking medications, and obtaining regular laboratory testing. Depression may also interfere with treatment of HIV and utilization of care services. Depressed patients are often more difficult to engage in and maintain in treatment because of the associated anergy, hopelessness, and negativism associated with their disorder (Hsu, 2002).

The complex nature of treating individuals with co-occurring HIV, substance abuse and mental illness has given rise to rethinking the way care is provided. Consensus groups, researchers, care providers, and government officials have begun to consider integrated treatment approaches that integrate services of medical providers, psychiatrists, substance abuse counselors, therapists, and social workers. The Center for Substance Abuse and Treatment (CSAT), in its Treatment Improvement Protocol on Substance Abuse Treatment for persons with HIV/AIDS (CSAT, 2000), for example, notes that the treatment of substance abuse and HIV/AIDS should reflect the interconnected relationship they share and be coordinated as much as possible to maximize care for persons with both HIV/AIDS and substance abuse disorders. CSAT recommends that "integrated treatment is the best option" for this population and that substance abuse treatment programs should incorporate primary care. CSAT also recommends that substance abuse treatment centers screen for HIV (CSAT, 2000). Two federal programs that focus on this population, the HIV set-aside in Substance Abuse Prevention and Treatment Block Grants and the CARE Act, are mandated to seek collaboration between substance abuse treatment providers and medical care providers and to seek to establish service linkages between the two systems (CSAT, 1995). Both of these programs, however, are relatively small compared with other parts of the HIV care system. Medicaid, the care provider with which the majority of people with HIV/AIDS in care interact, provides highly variable and at times restricted access to substance abuse treatment and offers few incentives to integrate care (Lubinski et al., 2002).

The Substance Abuse and Mental Health Services Administration (SAMHSA) in collaboration with HRSA and the CDC have been working on developing more effective services to integrate HIV prevention and care, substance abuse prevention and treatment, and mental health services (SAMHSA Funding FY 2004 Budget Narrative). Integration of services is an important focus of HRSA projects under its SPNS program. The HIV/AIDS Treatment Adherence Health Outcomes and Cost Study, for example, is a collaborative effort of six U.S. Department of Health and Human Service components to study integrated mental health, substance use, and primary medical HIV treatment interventions.

The HIV/AIDS Mental Health Services Demonstration Program, a joint federal project that offered mental health care to PLWH/A, found that individuals with comorbid substance abuse disorders and HIV were more likely to seek primary health care if they received mental health services and that early intervention with mental health services can improve adherence to HIV medications (SAMHSA, 1997). In short, individuals with HIV infection and severe and persistent mental illness often are inhibited by their mental illness from seeking care and from adhering to medication regimens that could help them lengthen and improve the quality of their lives.

Case Management Services

While there is no set definition for "case management," the Ryan White CARE Act Title I Manual (HRSA, 2001) defines case management for the Title I and Title II programs as:

> A range of client centered services that link clients with health care, psychosocial and other services to insure timely, coordinated access to medically appropriate levels of health and support services, continuity of care, on-going assessment of the client's and other family members' needs and personal support systems, and inpatient case management services that prevent unnecessary hospitalizations or that expedite discharge, as medically appropriate, from inpatient facilities. Key activities include: initial comprehensive assessment of the client's needs and personal support systems; development of a comprehensive, individualized service plan; coordination of the services required to implement the plan; client monitoring to assess the efficacy for the plan; and periodic re-evaluation and revision of the plan as necessary over the life of the client. May include client-specific advocacy and/or review of utilization of services.

More simply put, the main purpose of case management is to coordinate care, decrease barriers to medical and support services, and increase quality of life (HRSA, 2001).

Growing evidence shows that HIV-positive individuals who have case managers are more likely to use life-prolonging HIV medications and to have their needs met for income support, health insurance, home health care, and emotional counseling than those without case managers (Katz et al., 2001; McKinney and Marconi, 2002). Specifically, case management was found to have a positive effect on retaining people in appropriate HIV medical care (Conviser and Pounds, 2002; Ashman et al., 2002; Sherer et al., 2002; Messeri et al., 2002; Magnus et al., 2002). In one study, individuals who received case management were more than twice as likely to be retained in appropriate medical care than were those who did not (Messeri et al., 2002).

A debate is ongoing, however, about how case management services are best delivered. In one delivery model, case management services are co-located or intensely related to medical care. In another model, services are established in community service organizations that lack tight ties to clinical providers. Many medical providers of HIV services prefer models in which case management services are closely related to primary care, so that these services can directly support treatment adherence.

Case management service visits account for the largest number of visits made by Ryan White CARE Act clients under Title I and Title II non-ADAP services (HRSA, 2002j). Case management services are optional services under Medicaid.

HIV Prevention Services

Antiretroviral therapy can help prevent transmission of HIV because it reduces a person's viral load and renders the person less infectious (Vernazza et al., 1999; Staszewski et al., 1999; Barroso et al., 2000). However, an HIV-infected person receiving antiretroviral therapy can still spread infection to others, thus risk reduction interventions among HIV-infected individuals is considered an important part of overall HIV prevention. The U.S. Preventive Services Task Force *Guide to Clinical Preventive Services* (1996) makes HIV prevention recommendations for providers in clinical care settings. Specifically, the task force recommends that clinicians take a complete sexual and drug history to help determine patient risk and the appropriate prevention intervention. The recommendations, though, do not target individuals who are already HIV infected and who may still engage in risky behavior. In 1997, a National Institutes of Health consensus statement concluded that there was a need to develop programs to help HIV-infected individuals avoid risky behavior over long periods of time (NIH, 1997). A 2001 Institute of Medicine report, *No Time to Lose: Getting More from HIV Prevention*, noted this deficiency and recommended that HIV prevention services for HIV-infected persons and those at high risk should be a standard of care in all clinical settings. There is no mandatory or optional Medicaid service category that specifically covers HIV prevention services in the clinical setting (IOM, 2001).

More recently, CDC's *Advancing HIV Prevention: New Strategies for a Changing Epidemic* identified preventing new infections among persons diagnosed with HIV and their partners as a key element of its new prevention strategy. CDC has made a commitment to publishing (along with other federal agency partners) *Recommendations Incorporating HIV Prevention into the Medical Care of Persons with HIV Infection* (CDC, 2003c).

The literature reports at least two randomized trials for a risk reduction intervention for HIV-positive injection drug users (Kalichman et al., 2001; Margolin et al., 2003). In the first study, HIV-infected individuals were randomly assigned to an intervention to reduce the risk of HIV transmission. The risk reduction intervention resulted in less unprotected intercourse and greater condom use at follow-up. Transmission-risk behaviors with non-HIV-positive sexual partners and estimated HIV transmission rates were also significantly lower for the behavior risk-reduction intervention group. Authors of the second study (Margolin et al., 2003) found that enhancing methadone maintenance with interventions targeting HIV-seropositive injection drug users increases both harm reduction and health promotion behaviors. HRSA, under its CARE Act SPNS program, has two studies underway exploring prevention with HIV-infected persons seen in primary care settings and a demonstration project on prevention for HIV-positive persons (HRSA, 2003a).

Primary Care Services

HIV/AIDS is a complex multi-system illness. Patients with HIV/AIDS require a broad range of services and care from a number of providers. A primary care services approach to managing the complexity of services and providers who provide care to people with HIV infection has been an important foundation of the CARE Act and the federal Medicaid program.

Generally, primary care is understood as the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community (IOM, 1996). The elements of primary care include first contact care, continuity of care or one individual or team of associated individuals serving as the source of care over a defined period of time, comprehensiveness of services and the need to provide them directly or arrange for their provision when needed, and coordination of providers and referral services. The value of primary care for individuals is that it provides a place to which patients can bring a wide range of health problems for appropriate attention, guides patients through the health care system, provides opportunities for disease prevention and health promotion as well as early detection of problems, and helps to build bridges between personal health care services and providers and patients' families and communities that can assist in meeting the health needs of the patient (IOM, 1996).

Under the CARE Act, the primary care approach is used to provide and coordinate providers and such services as diagnostic testing, early intervention and risk assessment, preventive care and screening, practitioner examination, medical history taking, diagnosis and treatment of common physical and mental conditions, prescribing and managing medication therapy, education and counseling on health issues, well-baby care, continuing care and management of chronic conditions, and referral to and provision of specialty care (includes all medical subspecialties) (HRSA, 2003b, 2003c).

Primary care services also include primary oral health care. The first signs of HIV infection are often found in the oral cavity. As the disease progresses and the immune system deteriorates, AIDS patients are more susceptible to mouth infections such as oral herpes, fungal diseases, and gum disease. Thus, primary oral care is a critical component of primary care for HIV/AIDS.

Coverage for primary care services is mandatory under Medicaid. Primary care services are supported by the CARE Act but are available in varying degrees; services vary significantly from state to state and city to city depending on local resource allocation decisions. Acknowledging that HIV/AIDS patients suffer a high incidence of oral disease and many low-income people with HIV need assistance covering their dental costs, the Ryan White HIV/AIDS Dental Reimbursement Program was established in 2000. The program is directed at dental institutions (dental schools, dental hygiene schools, and postdoctoral dental education programs) to cover their non-reimbursed costs of providing oral health care to individuals with HIV.

Where HIV/AIDS Patients Receive Care

The most comprehensive source of information on the delivery of HIV care comes from the HIV Costs and Service Utilization Study. The survey is based on a representative sample of individuals receiving medical care for HIV infection in January and February of 1996.[11] An analysis of survey data found that 30 percent of patients received care at major teaching hospitals, and the balance received care from office-based physicians and community hospitals and clinics. Data also show that one-third of patients made at least one visit to an emergency room and 20 percent were hospitalized every six months.

One of the survey's most disturbing findings underscored the lack of regular care by individuals with HIV infection. Survey results suggest that an estimated two-thirds of HIV-infected adults do not receive medical care on a regular basis. Furthermore, most infected adults who do not receive medical care on a regular basis are in the early stages of disease (Shapiro et al., 1999).

With the spread of HIV infection outside large metropolitan areas, the delivery of care in smaller cities and less urbanized areas has become a growing concern. HCSUS data were analyzed to assess the delivery of care in rural areas. Results of the analysis revealed significant disparities between rural and urban areas. Patients in rural HIV care were more likely than patients in urban care to receive care from providers seeing few infected patients, and were also less likely than urban patients to have taken HAART (Cohn et al., 2001). This finding is significant given the recognition that greater physician and hospital experience with HIV/AIDS treatment has been linked to improved outcome—that is, longer survival after AIDS diagnosis (Laine et al., 1998). Other study findings have shown that patients in clinics with HIV expertise rely less on the emergency department for care (Markson et al., 1998).

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[11] The sample does not include individuals who receive care in the military, prisons, or emergency room departments.

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 stage of the disease, but only 26 percent of individuals with full-blown AIDS.
- The Ryan White CARE Act Program provides coverage to individuals who are uninsured or underinsured in other public and private programs.
- 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.
- 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 and pediatric care for infants with HIV, primary care services, substance abuse and mental illness treatment, case management services directly related to clinical care, and HIV prevention services.
- Two-thirds of HIV care takes place in physician offices, community hospitals, and clinics.
- Many HIV-infected adults do not receive medical care on a regular basis, and many of them are in the early stages of disease.
- 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.

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4

Barriers to HIV Care

As noted in Chapter 3, people with HIV disease access HIV care through a number of federal programs (e.g., Medicaid, Medicare, and the Ryan White Comprehensive AIDS Resource Emergency [CARE] Act [CARE Act]), private insurance, or a combination of these programs. There is little question that these programs have provided coverage for services that have made the difference between extended life and rapid death for many with HIV/AIDS. However, several finance-related barriers associated with these sources of coverage encumber the ability of the system to respond to the HIV epidemic. In the next section, the barriers associated with each source of coverage are reviewed, and concluding observations are presented.

PRIVATE INSURANCE PROGRAMS

People with HIV/AIDS in the private insurance market face a number of obstacles in accessing and maintaining care. Even with the protections offered by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), people with HIV/AIDS face barriers to accessing private insurance, particularly in the individual insurance market. First, there are no limits on insurance rates, so people can be priced out of the market when they are asked to pay high premiums. To address this problem, some states have adopted community rating;[1] others have utilized

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[1] Community rating refers to premium rates that are set for the community as a whole. Rates cannot be set based on an individual's claim experience (experience rating), health status, or duration of coverage.

"rating bands"[2] to limit the size of premium increases.[3] Some states have also chosen to purchase new policies for people with HIV, using CARE Act funds or other programs that target low-income or uninsured people. Other features of private insurance plans that pose problems for individuals with HIV/AIDS are the annual or lifetime caps on benefits, copayments, and deductibles, and limits on services. Finally, the insurance market and insurance reforms vary significantly by state, thus presenting different options and limitations across the country (Kates, 2004; Levi et al., 1999). Results from the HIV Cost and Services Utilization Study (HCSUS), for example, indicate that private insurance coverage for HIV varied substantially by region. In the West, 51 percent of HIV patients had private insurance coverage, compared with only 19 percent in the Northeast (Shapiro et al., 1999).

HIPAA protections do not improve access to the individual market for those without prior group coverage. Many individual health insurance applications, for example, ask questions about HIV diagnoses, treatment, or medication for AIDS; other immunological deficiency disorders; and whether the individual has ever had a positive test for HIV antibodies. Most carriers in the individual market generally consider HIV/AIDS an "uninsurable" condition, and applications for coverage are routinely denied (Kates, 2004). Texas insurance law, for example, now allows state-regulated insurers to exclude or deny coverage or cancel a policy based on a diagnosis of AIDS, HIV, or HIV-related illness. If other states follow suit, federal programs such as Medicaid and the CARE Act could play an even more important role as a safety net insurer.[4]

As their illness progresses, individuals with HIV often face difficulties maintaining coverage if they become unemployed due to illness. The Health Insurance Program (HIP) under Title II of the CARE Act provides funding for health insurance coverage for people with HIV disease by purchasing insurance services or by extending an individual's existing health insurance coverage. This program, added under a provision to the CARE Act in 1996,

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[2] Rating bands are restrictions placed on the variation in premiums.

[3] The impact of these strategies is controversial; conventional wisdom suggests that community rating actually reduces insurance coverage because young healthy consumers react to the higher premiums (than expected for their risk status) by dropping coverage and thus stimulating further increases in premiums. A study by Buchmueller and DiNardo (1999) examined the effect of community rating by contrasting the different reform approaches in three states: New York with pure community rating, Connecticut with moderate restrictions on insurer premiums, and Pennsylvania with no reform. The study found no evidence that community rating leads to adverse selection and dropping of coverage, but did see evidence of marked shift away from indemnity insurance toward HMOs.

[4] Texas Consumer Choice of Benefits Health Insurance Plan Act, Health Maintenance Organizations. SB541, Legislative Session 78 (R).

allows states to use CARE Act funds to help people with HIV/AIDS who are eligible for Consolidated Omnibus Budget Reconciliation Act (COBRA)[5] health benefit provisions to pay their premiums or buy private insurance. Title II AIDS Drug Assistance Programs (ADAP) may also purchase health insurance services for clients that include a full range of HIV treatment and primary care services. HIP also allows funds to be used to pay family health insurance premiums to ensure insurance continuation for a family member and to pay for public or private copayments and deductibles for persons with HIV disease.

MEDICAID

Certain elements of the Medicaid program create access problems for people living with HIV/AIDS, most notably, the eligibility criteria (Boxes 4-1–4-5). Most adults, for example, are denied entry into the program until they become disabled, long after the standard of care would call for intervention and despite the availability of therapies that may prevent disability (Kates, 2004; Levi and Kates, 2000). To tackle this problem, some states have applied for a Medicaid research and demonstration waiver to expand Medicaid eligibility to low-income people with HIV prior to disability.[6] However, waivers must be budget neutral, meaning that programs conducted under a demonstration should not cost the federal government more than would have been spent under the program absent the demonstration. This criterion has been difficult for many states to meet (Kahn et al., 2001; Schackman et al., 2001). Also, federal consideration and approval of waivers may take years. For example, an HIV waiver submitted by the state of Georgia in 2000 had not been approved as of November 2003.

Medicaid beneficiaries often lose eligibility for Medicaid if they return to work. Access to life-saving antiretroviral therapy through the Medicaid program allows many HIV beneficiaries to feel well enough to return to work, but health improvement may be a double-edged sword. The return to work and income earned can place individuals at income levels above the Medicaid eligibility level for participation in the program. The Balanced Budget Act of 1997 gave states the option to allow low-income individuals to keep their Medicaid coverage while working and earning income up to 250 percent of poverty level. The Ticket to Work/Work Incentives Improvement Act (TWWIIA) of 1999 provides a similar option. TWWIIA expands

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[5] Enacted in 1986, COBRA amends the Employee Retirement Income Security Act, the Internal Revenue Code, and the Public Health Service Act to provide continuation of group health coverage that otherwise might be terminated.

[6] Section 1115 waivers allow states to experiment with how their Medicaid programs cover and deliver services.

BOX 4-1
Variation in Medicaid Programs: Joe and Nancy

As discussed in this chapter, Medicaid is an important vehicle for paying for care for people with HIV/AIDS. The variation among Medicaid programs, however, is a significant challenge to ensuring access to comprehensive care without disparities. The Centers for Medicaid & Medicare Services (CMS, formerly known as the Health Care Financing Administration), the federal agency that oversees Medicaid, states that there are “essentially 56 Medicaid programs—one for each state, territory, and the District of Columbia” (HCFA, 2000.) As might be expected, the differing economics, politics, and attitudes among states have produced widely varying Medicaid programs.

In general, individual states’ Medicaid policies have a profound impact on access to care for individuals with HIV/AIDS (Morin et al., 2002). In addition, if a state’s Medicaid program has narrow eligibility rules and a limited benefits package, other programs, particularly Ryan White, may be expected to fill the gaps in Medicaid coverage (Levi et al., 2000). Because Ryan White is allocated on a discretionary basis, the amount of funds does not expand automatically according to need; thus, the larger the gap, the more likely that Ryan White funds will not be adequate. When examined from a national perspective, these variations in policies create disparities and discontinuities in care that are at odds with the stated federal goal to reduce HIV infection (Kates, 2004).

To illustrate the implications of variations in state Medicaid programs at an individual level, a series of text boxes will run throughout this chapter on the experiences of Joe and Nancy, two fictional individuals with HIV. Their experiences in five states—Florida, Georgia, Illinois, New York, and Texas—as they move through the Medicaid system show the gaps and disparities in coverage caused by the variation among Medicaid programs.

Medicaid varies not just among the states but within them, sometimes from county to county. In addition, eligibility and benefits rules change from year to year, particularly during times of economic downturn. Therefore, any representation of the experience of accessing HIV health care through Medicaid, no matter how nuanced, would fall short. Unless otherwise cited, the information in these text boxes is drawn from an analysis of the five Medicaid programs contained in Lubinski et al. (2002). These scenarios were developed in 2003 and may not reflect recent changes in state Medicaid law or policies.

Meet Joe and Nancy

The characters of Joe and Nancy are representative of some individuals living with HIV/AIDS in the United States who do not have access to private insurance. Joe has developed AIDS and suffers from a serious mental illness, bipolar disorder. He is considered disabled, thus qualifying for a $546 per month Supplemental Security Income (SSI) payment. The SSI payment is his only income.

Nancy is a single mother of two with asymptomatic HIV and active substance abuse disorder. Nancy’s HIV diagnosis does not qualify her for Medicaid, although receiving care now could prevent progression of the disease. Because she is the mother of two children, however, she does qualify for Temporary Assistance to Needy Families (TANF), which makes her eligible for Medicaid under specific circumstances.

state options under Medicaid by creating new Medicaid buy-in options and extended Medicare coverage for working individuals with disabilities. The Act also authorized state demonstration programs to provide Medicaid to workers with potentially severe disabilities, including HIV/AIDS, who are not yet disabled but whose health conditions could be expected to cause disability. Few states have chosen to implement these options.

Once eligible for services, some Medicaid beneficiaries with HIV disease encounter difficulties finding providers—especially 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 more specifically to health care provider participation. By influencing provider participation, low reimbursement rates have been shown to affect access to care for Medicaid beneficiaries in particular (Perloff et al., 1995; Adams, 2001; Kaiser Commission on Medicaid and the Uninsured, 2001; Cunningham, 2002; GAO, 2002; Santerre, 2002). 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. The limitation on state discretion is that payments must be "sufficient to enlist enough providers so that care and services are available under [the state's Medicaid program] at least to the extent that such care and services are available to the general population in the geographic area" (CMS, 1999). Furthermore, reimbursement for HIV care in both fee-for-service and managed care settings does not always reflect the true cost of providing care that can be time consuming and resource intensive (Bartlett, 2002; Beronja et al., 2002; Norton and Zuckerman, 2000; Conviser and Murray, 2000). With the advent of more costly protease inhibitors as a mainstay of therapy for HIV, small managed care organizations have found it unprofitable to participate in Medicaid managed-care programs (Conviser et al., 1997). Low reimbursement rates have been suggested as a factor contributing to inferior patterns of care for some Medicaid enrollees with HIV/AIDS (Shapiro et al., 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).

In many states, Medicaid beneficiaries are enrolled in managed-care organizations (MCO) (Westmoreland, 1999; Kaye and Cardona, 2002). A number of concerns have been raised about enrolling individuals infected with HIV in MCOs (Levi and Kates, 2000). At issue is the adequacy of capitation rates necessary to ensure that MCOs are able to maintain an "adequate provider network" that "includes providers who have both

BOX 4-2
Variation in Medicaid Programs

Eligibility for Joe

Joe's AIDS diagnosis does not guarantee that he will qualify for Medicaid or Supplemental Security Income (SSI) disability payments. First, he must obtain a Social Security Administration (SSA) determination of disability through a complex system that involves multiple organizations in determining whether a claimant is eligible for benefits. The definition applied by the SSA when making this determination is "a physical or mental impairment that keeps a person from performing any 'substantial' work and is expected to last 12 months or result in death" (SSA, 2004). If he is dissatisfied with the SSA's initial decision, he can pursue a revised decision by appealing to three levels of administrative appeal that have their own procedures for evidence collection, review, and decision making. Once he has crossed this threshold, Joe is eligible for Medicaid in all five states. In Illinois, he would be allowed to earn up to 100 percent of the federal poverty level, or $738 per month in 2002. The other four states—Florida, Georgia, New York, and Texas—would require that he earn no more than the maximum disability payment, $546 per month.

Because Joe's Medicaid eligibility is based on receipt of SSI payments, he is required to enroll in managed care in Florida and Georgia. In New York, enrollment in managed care is voluntary. In Texas, managed-care enrollment is mandatory in Harris County (Houston), but voluntary where it is available throughout the rest of the state. If Joe were to enroll in managed care in Texas, he would not face the three-prescription drug limit that fee-for-service Medicaid beneficiaries do. Managed-care plans, however, are available in only 51 of the 254 counties in Texas.

Eligibility for Nancy

If Nancy qualifies for Temporary Assistance for Needy Families (TANF), she is automatically eligible for Medicaid. The income requirements for TANF vary; in Texas she must earn no more than $188 per month, while in New York she could earn up to $577 per month and still qualify. Federal law places a five-year lifetime limit on the receipt of TANF benefits; Florida and Georgia, however, impose a four-year limit. In addition, Florida limits TANF eligibility to two years within a five-year period for most individuals. This has serious implications for Nancy's ability to receive stable lifetime care for her HIV.

It is important to note that Nancy's HIV diagnosis does not guarantee her access to medical care in any of the five states. If she makes too much money, for example, by working full time earning the minimum wage, she is ineligible for Medicaid coverage even in the states with the most generous eligibility requirements.

experience with HIV and the capability to take new patients" (Ashman and Conviser, 1998; Kaye and Cardona, 2002).

At this time there are no formal guidelines for determining whether a physician is qualified as a specialist in HIV care, and there is substantial debate about whether a generalist or a specialist for HIV/AIDS provides higher quality care (Lewis, 1997; Zuger and Sharp, 1997; Laine and Weinberg, 1999; Valenti, 2002). However, it is widely accepted that experience counts. There is evidence that physicians with more experience treating HIV have better patient outcomes (Levi et al., 2003; Gerbert et al., 2001; Stone et al., 2001; Kitahata et al., 1996). Research also shows that more experienced providers are more likely to provide care that is in accordance with rapidly changing HIV treatment guidelines (Kitahata et al., 2000; Brosgart et al., 1999). Moreover, the longer a physician has been treating patients for HIV infection and the higher the volume of these patients in the physician's regular practice, the higher the physician's confidence in assessing patient status, prescribing treatment regimens, and inter-

BOX 4-3
Variation in Medicaid Programs: Prescription Drugs

Joe's bipolar disorder adds yet another dimension to his already complex AIDS care. It would not be unlikely that Joe would be prescribed three drugs for bipolar disorder as well as three antiretroviral medications and an opportunistic illness prophylactic. The three medications that Joe takes to control his bipolar disorder would be covered at various levels. In New York, Joe would face no copays and no limits on the number of prescriptions. In Florida, mental health drugs are excluded from the limit of four brand-name prescription drugs and there are no copays, so here Joe also would face no restrictions. If he lived in Georgia, Joe would be within the five-prescription drug limit (in treating only his bipolar disorder), but would face a copay of 50 cents to $3 per prescription, forcing him to spend as much as $9 a month on drugs. If Joe lived in Texas, there are two possibilities. If he lived in an area where managed care is available and he chose to enroll, then he would face no limits and no copays. If he lived in a county where managed care is unavailable—as it is in most counties—then prescription drug treatment for his bipolar disorder would exhaust his drug benefit of three prescriptions per month.

To receive all of his medications, Joe might have to find coverage from other sources. In Texas, Joe would need to rely upon the AIDS Drug Assistance Program (ADAP) to fill the gap between his needs and Medicaid coverage. In Georgia, Medicaid has a five-drug limit and ADAP has a waiting list; Joe would need to either pay for two of his prescriptions out-of-pocket—an unthinkable expense considering his income—or go without, choosing between treating his HIV infection or his bipolar disorder.

preting new research findings (Gerbert et al., 2001). To address the problem of access to experienced providers, the Health Care Financing Administration (which is now the Centers for Medicare & Medicaid Services, or CMS) issued guidance to state Medicaid directors to work to "ensure access to experienced HIV providers in both the fee-for-service program and managed care" (CMS, 1999).

Another concern associated with capitation rates centers on the extent to which rates meet the cost of providing care for HIV disease (Conviser et al., 2000; Kates, 2004). To address this problem, some states have begun to apply risk adjustment strategies in determining capitation rates for patients with HIV disease (Lubinski et al., 2002; Kaye and Cardona, 2002). An evaluation of Maryland's Medicaid HealthChoice Program, which pays managed-care organizations risk-adjusted capitation rates to ensure that plans are adequately compensated while serving a wide range of beneficiaries, provides some lessons from Maryland's experience. Evaluation findings indicate that the HealthChoice program greatly expanded eligibility and services to a larger and more diverse population than previously was served. Financial performance levels of the HealthChoice plans were consistent with commercial HMO performance. However, the evaluation left unclear whether differential enrollment based on patient risk would be sufficient to justify the resources needed to make such adjustments (Chang et al., 2003).

State Medicaid programs are also experimenting with other strategies to mitigate inadequate provider reimbursement, including health-based payment systems that set capitation rates based on health status and "carve-out" programs that exclude some expenses from the capitation rate (Conviser et al., 1998, 2000). In New York's Medicaid program, for example, those physicians who meet the state-set criteria as HIV specialists receive an enhanced Medicaid reimbursement rate that comes closer to covering the actual cost of care (New York State Department of Health, 2003).

Perhaps the most troubling aspect of the Medicaid program is the tremendous variation in state Medicaid programs, which in turn results in different levels of services for individuals with HIV disease (Table 4-1). States vary in income eligibility thresholds and in the existence of medically needy programs, home and community-based services (HCBS) waiver programs,[7] Section 1115 waiver programs, and Ticket to Work Programs that can help to expand access to services. States also vary tremendously in

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[7] Home and Community-Based Services Waivers (Section 1915(c)) allow states to bypass certain federal requirements that limit the development of Medicaid-financed, community-based treatment alternatives (Westmoreland, 1999).

BOX 4-4
Variation in Medicaid Programs: Treatment for Mental Illness

In each of the five states, Joe could see a psychiatrist at a mental health clinic. In Florida, he would have a copay of $2 for each visit. In Texas, he would be limited to 30 visits per year. To help him manage the requirements of treating his illness, Joe could also have access to case management services in Illinois and New York. In Florida and Georgia, Joe would have access to a case manager only if he were deemed to be at immediate risk for hospitalization or had just been released from a hospital. This service would be limited to 30 days, however. If Joe resided within the Dallas area in Texas and enrolled in the NorthSTAR Behavioral Pilot Program, it is possible, but not guaranteed, that he would receive some case management. If Joe were outside of the Dallas area but enrolled with one of the two health maintenance organizations in Texas's Medicaid program, he may be eligible for case management, but again this benefit is not automatic.

BOX 4-5
Variation in Medicaid Programs: Substance Abuse Treatment

Even though as a recipient of TANF Nancy is eligible for Medicaid, her active substance abuse presents a barrier to her seeking and remaining in HIV care. Not surprisingly, her opportunities to receive substance abuse treatment within the differing Medicaid programs would vary.

In Illinois and New York, Nancy would have access to substance abuse services, including outpatient visits (there is a limit to the number of visits covered per year) and inpatient detoxification. In Illinois, she would also receive priority admission to community-based substance abuse services as part of the program's target populations (TANF eligible, HIV positive, and a woman with children).

In Texas, if Nancy lived in Dallas or its surrounding counties, she would be eligible for a pilot program that provides a comprehensive set of services. These include

- Day treatment programs for acute needs and skills training,
- Intensive crisis residential services,
- Supportive housing,
- Medication services, and
- Specialized chemical dependency services for women with dependent children that includes child care.

If Nancy lived outside of the Dallas area, no substance abuse services would be covered under Medicaid.

TABLE 4-1 Select State Variation in Medicaid Coverage

State/ Territory	SSI Eligibility, % Federal Poverty Level, 2000[1]	Pregnant Women Eligibility, %FPL, 2000[1]	Medically Needy Program (Eligibility), 2001[1,2]	209(b) State, 2002[1,2]	Prescription Limitations Per Month: No. Per Month, 2001[3,4]	HIV-Specific Waivers: 1115, TWWIIA, HCBS, 2002[5,6]
California	74	300E	Yes (83%)	—	6	HCBS
District of Columbia	74	200	Yes (53%)	—	—	1115, TWWIIA, HCBS
Florida	74	185	Yes (25%)	—	4	HCBS
Georgia	74	235	Yes (44%)	—	5	—
Illinois	41	200	Yes (40%)	Yes	—	HCBS
Mass.	74	200	Yes (NA)	—	—	1115
New York	74	200	Yes (87%)	—	Yes: annual limit	—
Ohio	64	150	—	Yes	—	—
Texas	74	185	Not for disabled	—	3	—
West Virginia	74	150	Yes (28%)	—	10	—

SOURCE: Kates, 2004.

the benefits they provide under Medicaid. Across states, there are differences in the limits on some Medicaid services, such as the number of prescriptions allowed per month, the length of hospital inpatient services, the number of physician visits per month, and prior authorization requirements (however, these limits cannot be applied selectively to one group of beneficiaries). With respect to adults, states may also impose "nominal" cost-sharing requirements on mandatory or optional services (with the exception of emergency and prenatal care). States also vary in special provisions for HIV/AIDS; some states require access to experienced providers, targeted case management, dental care, transportation, and vision coverage, while others do not (Conviser, 2002; Kaye and Cardona, 2002).

MEDICARE

People with HIV/AIDS, as well as people with disabling conditions in general, face certain challenges in accessing Medicare or needed benefits through the Medicare program once they become eligible. Medicare has relatively high deductibles relative to Medicaid and no limits on out-of-pocket spending, which means that some individuals may not be able to afford services. Furthermore, at this time Medicare does not cover outpatient prescription drugs, so Medicare beneficiaries with HIV/AIDS must find other means to pay for highly active antiretroviral therapy (HAART), which is critical for the treatment and control of HIV/AIDS. Some individuals with HIV/AIDS may receive limited prescription drug benefits by enrolling in a Medicare managed-care plan. However, in recent years, reductions in managed-care plan service areas and plan withdrawals from the market have affected beneficiaries' access to Medicare services (Kaiser Family Foundation, 2002). Medicare is also quite limited in its support for nonmedical services that are important elements of HIV care (e.g., social case management, preventive services, and other support and enabling services) (Levi and Kates, 2000).

One option that may allow Medicare beneficiaries with HIV/AIDS to obtain prescription drugs is to purchase a private Medicare Supplemental Insurance policy—also referred to as a "Medigap" policy. However, these policies do not completely solve beneficiaries' problems in obtaining needed medications. Drug benefits under these policies generally have a deductible and may cover only a percentage (e.g., 50 percent) of the drug costs up to a maximum level per year. Furthermore, the premiums associated with these policies may place them out of reach for low-income beneficiaries and some create hardships for middle-income beneficiaries. People with HIV/AIDS who cannot afford prescription drugs must rely on Medicaid or ADAP to obtain medications (Kates, 2004).

RYAN WHITE CARE ACT

Although the CARE Act is designed specifically for people with HIV disease, clients face challenges in accessing CARE Act services. Access to life-extending comprehensive antiretroviral therapy and primary care, for example, varies significantly by state and city of residence (Table 4-2). In North Carolina, people with HIV and incomes up to 125 percent of the federal poverty level (FPL) are eligible for ADAP services, while residents in New Jersey may qualify with incomes up to 500 percent of the FPL. Other states have specific income eligibility limits, such as less than $50,000 in Massachusetts and less than $30,000 in Pennsylvania (Kates, 2004).

Primary care access may vary from city to city and state to state depending on planning council and state funding allocations. Likewise, substantial state variation occurs in the types of drugs covered, the number of prescriptions provided through ADAP, and the capacity of the ADAP program to assist individuals who need HAART. States such as Louisiana, Nebraska, and Utah provide access to fewer than 20 drugs. Other states—including New York (463 drugs), Missouri (270), Connecticut (170), and California (144)—provide access to a larger number of drugs through their ADAP formularies, while Massachusetts and New Jersey have open or unrestricted ADAP formularies.

Limitations in ADAP formularies may have important health consequences. The care of HIV disease often requires numerous medications for complicating conditions or symptoms, in addition to antiretroviral drugs. Ceilings on the number and type of prescription drugs allowed may force dangerous choices concerning this essential element of care. With antiretroviral drugs, effective continuation of clinical benefit often requires replacing drugs in the regimen because of complex patterns of resistance and intolerance. Optimum outcome can be seriously compromised if the provider is limited in choosing among these crucial drugs because delays in controlling viral growth can allow rapid resistance and, ultimately, clinical failure.

The number of people living with HIV/AIDS continues to grow, as does the cost of care and the demand for CARE Act services. As a discretionary grant program, the CARE Act depends on annual appropriations by Congress (and often by states and municipalities). CARE Act dollars do not necessarily match the need for services, and many grantees have been unable to serve all those in need. This is a particular problem for ADAP. In June 2003, many Ryan White-funded ADAP programs reported budget shortfalls and had to develop or implement plans to restrict access through waiting lists (nine states) or caps on enrollment (four states) and/or limit benefits available to individuals already in the program (three states) (NASTAD, 2003).

CARE Act programs and services vary across the country because of local flexibility in program design, different levels of CARE Act funding, and access to other programs such as Medicaid (see Table 3-2). All states receive Title II HIV Care formula grants for ADAP and health care and support services, but some states receive additional CARE Act funding through other CARE Act programs. Nearly all states also receive some Title III Early Intervention Services (EIS) discretionary grants to expand the service capacity of organizations providing primary care services, but some states have more than one grantee (New York, 41 grantees; California, 30; Florida, 19; Texas, 9; Michigan, 4). Twenty-eight states/territories have a number of Eligible Metropolitan Areas (EMAs) and receive additional funding under the Title I Emergency Relief Grant program. Some states are home to some of the 90 grantees who receive funding under Title IV for coordinated services and access to research for women, infants, children, and youth (not shown in Table 3-2). Furthermore, residents with HIV in 37 states have an opportunity to continue health coverage that otherwise might be terminated under the Ryan White Health Insurance Continuation Program (Kates, 2004).

Available CARE Act funds vary in different areas of the country; thus, there is wide variation in the state per capita allocation of CARE Act dollars, a variation that has raised important issues about funding equity. In 2000, a General Accounting Office study found substantial differences in funding among states. In particular, per capita allocations differed significantly between states with an EMA and those without one. States with no eligible EMA received an average of \$3,340 per capita for persons with HIV. States with more than 75 percent of their AIDS cases in an EMA averaged \$4,954 per AIDS case, nearly 50 percent more than those states without an EMA (GAO, 2000). States with even higher numbers of AIDS cases (more than 90 percent) in EMAs, such as California and New York, received nearly \$5,240 per case. States with EMAs receive more funding because AIDS cases are counted twice under Title I and Title II formulas. GAO called for Congress to phase out the "double counting" of EMA AIDS cases to improve equity in the distribution of CARE Act funds. Subsequent changes in the formula have reduced these inequities, but others remain.[8]

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[8] In allocating CARE Act funds, the Health Resources and Services Administration (HRSA) currently uses a "hold harmless" provision that curtails the extent to which CARE Act funds can decline from one period to the next within an EMA. Note that all funds retained by EMAs under such provisions are in effect funds denied to other EMAs and their HIV-infected populations. According to a recent Institute of Medicine (IOM, 2003) report, EMAs would observe a 2.6 percent increase in their allocation if the "hold-harmless" provision currently in effect for San Francisco was removed.

TABLE 4-2 State Variations in Ryan White Programs

State/ Territory	Eligibility, %FPL, June 2001	ADAP Number of Drugs on Formulary, June 2001	Waiting List or Other Restriction, June 2003, 16 states	Other Ryan White Title I EMA, 2001, 28 states, (51 EMAs)	Title III EIS Site, 2001, 50 States (310 EIS)	Health Insurance Program, 2001, 37 States
Alabama	250	26	Waiting list	—	Yes	—
Alaska	300	62	Capped enrollment	—	Yes	Yes
Arizona	300	27	—	Yes	Yes	—
Arkansas	300	43	Capped enrollment	—	Yes	—
California	400	144	—	Yes	Yes	Yes
Colorado	300	40	Waiting list	Yes	Yes	Yes
Connecticut	400	170	—	Yes	Yes	—
Delaware	500	137	—	—	Yes	Yes
District of Columbia	300	65	—	Yes	Yes	—
Florida	350	53	—	Yes	Yes	Yes
Georgia	300	47	—	Yes	Yes	Yes
Hawaii	400	85	—	—	Yes	Yes
Idaho	200	35	Capped enrollment	—	Yes	
Illinois	400	67	—	Yes	Yes	Yes
Indiana	300	67	Waiting list	—	Yes	Yes
Iowa	200	32	—	—	Yes	Yes
Kansas	300	47	—	Yes	Yes	Yes
Kentucky	300	30	Waiting list	—	Yes	Yes
Louisiana	200	18	—	Yes	Yes	Yes
Maine	300	38	—	—	Yes	—
Maryland	400	85	—	Yes	Yes	Yes
Massachusetts	<$50,000/yr	Open	—	Yes	Yes	Yes
Michigan	450	160	—	Yes	Yes	Yes
Minnesota	300	112	—	Yes	Yes	Yes

Mississippi	400	43	—	—	Yes	—
Missouri	300	270	—	Yes	Yes	Yes
Montana	300	49	Waiting list	—	Yes	Yes
Nebraska	200	18	Waiting list	—	Yes	Yes
Nevada	400	55	—	Yes	Yes	Yes
New Hampshire	300	32	—	Yes	—	Yes
New Jersey	500	Open	—	Yes	Yes	Yes
New Mexico	300	60	—	—	Yes	Yes
New York	<$44,000/yr	463	—	Yes	Yes	Yes
North Carolina	125	51	Capped enrollment	—	Yes	—
North Dakota	400	86	—	—	—	—
Ohio	300	69	—	Yes	Yes	Yes
Oklahoma	200	65	Other	—	Yes	—
Oregon	200	56	Waiting list	Yes	Yes	Yes
Pennsylvania	<$30,000/yr	69	—	Yes	Yes	—
Rhode Island	400	57	—	—	Yes	Yes
South Carolina	300	48	—	—	Yes	Yes
South Dakota	300	41	Waiting list	—	Yes	Yes
Tennessee	300	43	—	—	Yes	Yes
Texas	200	36	Antiretroviral restrictions	Yes	Yes	Yes
Utah	200	18	—	—	Yes	Yes
Vermont	200	69	—	—	Yes	Yes
Virginia	300/333	51	—	Yes	Yes	—
Wash.ington	300	137	Other	Yes	Yes	Yes
West Virginia	250	27	Waiting list	Yes	Yes	Yes
Wisconsin	300	43	—	Yes	Yes	Yes
Wyoming	200	51	Other	—	—	—
Puerto Rico	Certified as indigent	115	—	Yes	Yes	—
Virgin Islands	200	26	—	—	Yes	—
Guam	200	26	—	—	—	—

SOURCE: Kates, 2004 .

An Institute of Medicine (IOM) Committee on the Ryan White CARE Act: Data for Resource Allocation, Planning, and Evaluation, recently reported on the continuing inequities in Ryan White funding by state, as noted earlier by GAO (IOM, 2003). Based on an analysis of characteristics associated with Fiscal Year (FY) 2001 CARE Act funding, the Committee found that the presence of an EMA is associated with a significant reduction in Title II funding, but a significant increase in overall CARE Act funding. For example, a state with 1,000 estimated living cases entirely concentrated in an EMA receives approximately $1,814,000 more than an otherwise comparable non-EMA state with the same number of estimated living cases of HIV/AIDS. The Committee also found that Southern states receive about $318 less per case of HIV/AIDS than non-Southern states.

Because the Ryan White CARE Act program wraps around other federal and state programs, Medicaid in particular, CARE Act spending is highly influenced by state Medicaid programs. A review of the impact of state-by-state variability in entitlement programs on the CARE Act and access to services found that the relative generosity of a state's Medicaid program affects the spending priorities made by states with Title I programs. States with generous Medicaid programs tend to spend greater levels of CARE Act funds on support services and less on primary care than states with less generous Medicaid programs (Levi et al., 2000). Moreover, states with Medicaid programs that have restrictive eligibility and/or low generosity rankings were more likely to have non-income-related restrictions on access to ADAP. A correlation between ADAP income eligibility criteria and Medicaid income criteria was not found. The study also found that state Medicaid programs had little impact on Title II spending in part because ADAP funds dominate their grants.

Program Data and Accountability

One of the Committee's primary objectives was to understand the accomplishments of the Ryan White CARE Act program as it is currently configured, and to identify areas for improvement, such as gaps in ensuring medical care to persons living with HIV. However, the Committee found substantial difficulties in gaining an adequate level of understanding of the current program, especially for Title I spending. After nearly 15 years and billions of dollars spent in the program, an unduplicated count of beneficiaries does not exist except for HRSA's Client Demonstration Project, which collects unduplicated data for 33,000 of the 500,000 clients estimated to be served by the program. Current HRSA data collection efforts on EMA spending rely on broad categories of reporting (e.g., primary care, substance abuse services, case management services), which do not allow for a precise understanding of how Title I dollars are spent. In testimony before the Committee, it was noted that EMAs may not use consistent approaches in classifying service programs by these HRSA categories, thus frustrating attempts to compare spending priorities among EMAs. Furthermore, meaningful or systemic outcome measures have not yet been developed for the CARE Act program.

The IOM Committee on the Ryan White CARE Act: Data for Resource Allocation, Planning, and Evaluation explored a number of data issues as part of its review. Among its findings, the Committee noted that not all states were equally capable of providing high-quality data on HIV infection for planning purposes as required by the 2000 reauthorization of the CARE Act. The Committee also found significant variability in the data sources and measures, and the quality of those data sources and measures, used by grantees to describe their severity of need as part of the Title I Supplemental award application. This part of the application is intended to assist HRSA direct funds to areas in the greatest need of financial assistance. More troubling, however, was the Committee's finding that the Title I supplemental awards are highly correlated with their Title I formula base award, which is based on cumulative AIDS cases (87 percent correlation). The Committee recommended that the severity of need portion of the supplemental award application should be based primarily on a small number of quantitative measures and that the locally defined need be described in a short narrative by the applicant. The Committee also recommended that the quantitative measures receive greater weight.

As part of its review, the Committee also assessed data efforts to measure quality. Based on its review, the Committee found that HRSA and Ryan White CARE Act-funded clinics and programs are doing an admirable job defining, assessing, and attempting to improve the quality of care received by HIV-infected individuals. Some clinics had established quality management and improvement programs or were in the process of doing so. The Committee made a number of recommendations to further enhance these initiatives (IOM, 2003).

Challenges Faced by Ryan White Planning Bodies

Ryan White Planning Councils and Consortia, the bodies responsible for developing a comprehensive network of services for people with HIV/AIDS, face their own challenges in conducting comprehensive planning for allocating CARE Act funds (Box 4-6). Many of these challenges stem from the inherent difficulties in coordinating with external programs and providers, while others stem from factors intrinsic to the process (Meyerson et al., 2003). The Committee heard testimony on the experience of Ryan White planning bodies from a number of individuals reflecting numerous perspectives (HRSA, state AIDS directors, clients served, planning council

BOX 4-6
Observations on the Day-to-Day Planning Experience

"Replicate this room in your mind over and over and over with people who are very busy, whose pagers are going off constantly, consumers who are ill and have to trot off to the bathroom on a regular basis and so on. That is the environment, and there are always deadlines that have to be met. The needs assessment has to be approved. Has anyone read it? No. Well, let's go read it really quick. We have to find out the latest epidemiologic data so that we can make our decisions. A few slide shows, well, okay, we kind of think we understood what they said, but no one trained us in epidemiologic analysis, but tell us what we are supposed to do.

"We have to get the money out. It is going to take X number of weeks for a city to get the money through the pipeline. So, we have to hurry, hurry, hurry. Oh, we don't have enough money. We have to shift our priorities. Somebody didn't take the money we have offered. We have to realign everything quickly, a tremendous amount of deadlines. Lots of key representatives not showing up to help inform the process, to be able to say, oh, in Medicaid such and such is happening.

"That is the sort of normal day-to-day planning process. It is very time consuming. It has become increasingly politicized.

"I guess the other thing to know is, you [the Committee] heard about Title I principally, and some Title II planning. Many of those planning processes sort of run in parallel, but don't interconnect very well. Particularly in states with lots of Title I planning processes going on, it is very hard to coordinate that, to build a system that makes sense, [where] you can finance it with a public financing system that will work, that you can get funded in the larger legislative environment.

"So, as you can see, this sort of systemic planning process is complicated. What has resulted is an incredibly widely divergent patchwork soup, a conglomeration, muddle, of different priorities, allocation strategies from state to state, from city to city. Even adjoining and very closely located communities will set priorities for fairly similar populations that are widely divergent."

SOURCE: Researcher, Testimony before the Institute of Medicine, April 17, 2002.

members, and researchers).[9] Some of the key challenges raised included managing coordination among the various service providers and payers. Coordination with the state Medicaid program was identified as a specific problem, as was the coordination with substance abuse providers. Coordination among the different Ryan White program Titles (e.g., coordination between Title I and Title II) was also noted as difficult. Other areas that posed problems were the varying degrees of participation of planning body

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[9] Testimony was provided to the Committee on Public Financing and Delivery of HIV Care at an April 2002 meeting.

members, the choice by some planning bodies to allocate funds in areas that are not consistent with assessed needs, institutional inertia in changing a planning body's past allocation decisions, and perceived conflict of interest among planning council members whose agencies receive CARE Act funding.

Consistent with these challenges, the Committee notes that although the needs of people with HIV have changed dramatically, especially after the advent of HAART in 1996, the allocations by category of funds in the Title I program have largely remained the same. Health care services have not received a substantial increase in Title I funding, even though many people with HIV are not covered by Medicaid, Medicare, or private insurance and lack access to basic HIV primary care and medications. Title I funding for health care services actually decreased from 49 percent in 1996 to 44 percent in 2000, despite rapid advances in HIV care. The Title II ADAP has filled the need for prescription drugs, albeit with a thoroughness that varies among states. Antiretroviral therapy alone, however, is not helpful unless patients have access to experienced physicians who prescribe and manage the therapy. Illustrative comments on some of these challenges are included in the following testimony excerpts.

External Coordination

"Medicaid, the state substance abuse treatment agency, and the Title II consortia do not fully coordinate their programs or their funding as outlined in the EMA's plan. So, here we are, writing plans that are, I hope, realistic most of the time and evidence based, as much as we can, and calling for other systems and other players and other parties to do things. They say they will. We know they have the plan. We train them on it. We shared it with them and maybe trained them on it and maybe helped with it, but then nothing happens with it on their side" (planning council representative).

"Issues related to HIV service delivery and financing are not commonly a major consideration in the planning, design, and implementation of broader public financing. Broad policy issues are also not within the authority of HIV planning bodies or CARE Act grantees" (researcher).

Internal Planning Body Collaboration and Functioning

"They [council members] come to the table with varying degrees of planning experience. Some are quite sophisticated and professional and they do it every day. A third are consumers, who are living with HIV and have varying degrees of experience and exposure to planning, to all kinds of activities that are associated with this process" (planning council representative).

"Without levels of meaningful participation of all the mandated members, there are missed opportunities. Some voices aren't at the table that really should be. . . . By meaningful, I mean anything from like a government official who doesn't come to the meeting or [is] named to the planning council and [doesn't] show up ever, or meaningful meaning that the person isn't trained well enough and isn't comfortable enough to really bring [his or her] expertise into the situation. That, I think, is more solvable than the other. The other is sort of more difficult. Lack of time, lack of data, lack of data on time. We are always feeling the 'lack of data disease,' I call it. That is a challenge that seems to be quite pervasive" (planning council representative).

"Participation in HIV care planning efforts [is] reported to be extremely time consuming, politicized, polarizing, [and] of limited direct benefit to the operations of HIV care programs, and distracts care providers from their patient or client responsibilities" (researcher).

"HIV planning tends to be specific to individual Titles, sometimes with poor communication between grantees of various Titles" (researcher).

Evaluation of Processes and Outcomes

"We have seen some variation [in allocation of funds], what goes to primary care, for medication, for case management. We have seen over the years some changes in home and community-based services, dental care, and even substance abuse treatment services. There are some EMAs where primary care is primarily paid by another source. So, they have decided—rightly so—not to focus CARE Act dollars to support primary care, but to focus those dollars on other supportive services that aren't covered. Rightly or wrongly, the planning council has made those decisions to meet the needs of consumers. We have been, for the last several years, pushing people to provide more dollars toward primary care and medications because we now know they are a major benefit. That has met with some resistance from planning councils" (HRSA representative).

"We continue to look at what the results are [allocation decisions], and we will raise questions internally if we think that some of the results are way off base. Individual project officers who review applications on an annual basis, in fact, can and have gone back to planning councils and asked, 'Why did you make this decision or how did you get there?' When we have looked at some of our applications in a comprehensive way, we find that, even when there is a needs assessment and there are good epidemiologic data that say the epidemic is here, they [project officers] may see a result [an allocation decision] that is way out in left field. That may be simply because there is resistance to change the current system because of where dollars are flowing and who is getting what, and we recognize that that may be happening in several places" (HRSA representative).

Impact on Clients

"The biggest concerning gap is the disjointment in all services. Whenever I had to implement another service, if it wasn't through a case manager, it started a process all over again. Once into care, I think the system should be single access (via one case manager). Then I would have one case manager instead of 18" (client).

"Comorbidity factors, as far as people on drugs . . . one of the biggest things I can remember, even in mental health, is that I was going through the ads in the papers and tearing out all the pharmaceutical ads that showed side effects, to take this to my psychiatrist so that we didn't have a conflict between the medicines she was giving and my HAART medications. . . . She didn't know what HAART was. I had to literally make a scrapbook and take it to my psychiatrist and say, 'This is what I am taking.' Eventually, even that, getting those two connected [mental health and HIV care providers] is something that is very well needed, that all parties talk together and education in [vocational] rehab and all of those services. It would ease the system tremendously" (client).

COORDINATION OF CARE

Previous sections of this report described the various programs that finance the care of individuals with HIV/AIDS and their requirements for eligibility and benefits. Earlier sections of this chapter identify a number of barriers associated with each program. This section briefly describes how these programs interact in very complex ways that create barriers for coordination of services and care management.

Eichner (2001), a researcher at the National Academy of Social Insurance, conducted a case study analysis that described the complexity of coordinating health coverage for Medicare enrollees with HIV/AIDS in the state of California. Eichner identified the four most common ways (there were many permutations) Medicare enrollees pay for their health care.

Scenario 1: Medicare + Medi-Cal[10] (dual eligible)

Scenario 2: Medicare + Medi-Cal with share of cost[11] +Ryan White ADAP

Scenario 3: Medicare + Medi-Cal + Private Insurance[12] + Ryan White ADAP

Scenario 4: Medicare HMO[13] + Ryan White ADAP

Findings from Eichner's case study suggest that the multiple programs needed to provide complex health coverage result in a fragmented and complex conglomeration. From the standpoint of a Medicare beneficiary with HIV/AIDS, the Medicare benefit package is incomplete and services from other programs must be sought to build a more rounded package of benefits. However, lack of coordination can exacerbate the difficulties of navigating the "system." Coordination was hampered by the following: (1) multiple program administration agencies: two federal agencies (CMS and HRSA) and the state, (2) some programs are managed by separate divisions within an agency (Medicare and Medicaid), (3) programs lack coordination with regard to eligibility requirements and benefits, (4) the roles of agencies managing a single program lack clarity as in the case of SSA and CMS regarding Medicare, (5) some individuals move among programs as their circumstances change, and (6) health coverage options are intertwined with income and other related benefits (Social Security Disability Income and Social Security Income).

Interviews with program staff and others from 37 sites located in San Francisco, Los Angeles, and Kern counties noted that benefits counseling was a crucial service for coordinating access to programs. This service was primarily provided by AIDS organizations and was funded in part by AIDs organizations' general funds, Ryan White grants, and other grants.

The need for coordination is not a new issue for programs that provide service for individuals with HIV/AIDS. In 1996, amendments of the Ryan White CARE Act recognized that there was a need for coordination between the CARE Act program and Medicaid. Requirements for coordination were established that placed a representative from the state Medicaid agency on the Ryan White Planning Council associated with the Title I program. In a similar action to foster coordination, the Centers for Medicaid & Medicare (then the Health Care Financing Administration) directed a letter to State

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[10] California's Medicaid program.

[11] Medicare enrollees with incomes above the MediCal limits but who have high medical expenditures (within asset limits) must pay some share of cost.

[12] Private insurance associated with former employment or individually-purchased policy.

[13] Enrollees in a Medicare HMO that may provide limited HIV-related drugs or copayments for drugs.

Medicaid directors (CMS, 1998) to implement strategies to improve coordination between the two programs. As stated in the letter, "There are considerable opportunities for the Medicaid and CARE Act programs to work together to effectively coordinate the services each program provides. . . . Coordination between Medicaid and CARE Act programs and their providers can eliminate duplication of services, save the States' and the Ryan White Program's limited funds, and ultimately serve individuals with HIV more effectively and efficiently."

Since the promulgation of the CARE Act Amendments and the CMS directive to state Medicaid directors, individuals with HIV/AIDS continue to wrestle with the coordination of multiple systems, programs, and benefits.

ACCESS BARRIERS

Barriers that reduce or restrict access to care are created by the financing and organization of care, characteristics of the individuals including comorbidities, and characteristics of the providers. These problems were examined by the HIV Cost and Services Utilization Study (HCSUS) conducted in the late 1990s. HCSUS remains the only nationally representative sample of HIV-infected individuals that can provide an overview of the problems faced in accessing HIV care. A number of other studies also address barriers to care (Morin et al., 2002; Cook et al., 2002; Turner et al., 2001; Sambamoorthi et al., 2000).

The HCSUS study found large variations in insurance coverage for HIV infection, in part reflecting the relative restrictions on the Medicaid programs in different states. Overall, 20 percent of adults in care for HIV lacked health insurance, 50 percent received care through Medicaid and Medicare (about 15 percent of these had both Medicare and Medicaid), and 31 percent received care through private insurance. Geographic differences were also quite striking: the proportion uninsured was 11 percent in the Northeast, compared to 30 percent in the South. In the Northeast, 50 percent of patients had Medicaid as primary payer, compared to 28 percent in the South (Bozzette et al., 1998).

HCSUS also demonstrated that there were substantial disparities in treatment across affected groups. Although disparities decreased as the decade progressed, blacks, women, the uninsured, and Medicaid beneficiaries all were less likely to receive protease inhibitor therapy when it became the standard of care (Shapiro et al., 1999). Medicaid insurance also continued to predict a lower likeliness of receiving HAART more than two years into its availability (Cunningham et al., 2000). With respect to access to experimental drug therapy, Gifford et al. (2002) found that blacks and Hispanics were less likely to have received experimental HIV therapy or to have participated in an HIV clinical drug trial, and that these findings could not be explained by differences in the desire to receive such therapies (Gifford et al., 2002). Blacks, Hispanics, women, the uninsured, and Medicaid beneficiaries also had less favorable patterns of use of hospitals, emergency departments, and ambulatory office or clinic settings (Shapiro et al., 1999). Patients in rural areas were also less likely to receive antiretroviral therapy (Cohn et al., 2001).

Additional compelling evidence supporting the hypothesis that improved financing of HIV care would reduce disparities in access is offered in the recent study using HCSUS data conducted by Bhattacharya and Goldman (2003). Data from this study show that patients with public health insurance (Medicaid) have much lower death rates than uninsured patients (controlling for severity illness). The authors estimate that expanding public insurance coverage for HIV/AIDS patients could reduce HIV/AIDS-related deaths among the uninsured up to 66 percent. The researchers also found that states with Medicaid programs with less restrictive eligibility rules and more generous drug coverage had significantly lower death rates than states with more restrictive eligibility rules and less generous drug coverage.

Demographic variables and comorbidities also play an important role in accessing HAART. Additional HCSUS analyses found that women, blacks, those with less education, and injection drug users were least likely to have received early access to HAART (Andersen, 2000). The results of a study of service claims data from four states (California, New York, Florida, and Texas) supports racial and ethnic differentials found in the HCSUS study. Significant racial/ethnic disparities were found in the reduction of AIDS-related mortality and in reduction of AIDS-related mortality by state. AIDS-related mortality was reduced by 64 percent in California compared with 52 percent in Texas (Morin et al., 2002). Mortality reductions for Latinos and African Americans were found to be lower than for non-Latino whites. These disparities were associated in part with policy barriers, such as limits on Medicaid eligibility based on disability requirements and state-imposed income and benefit limits on ADAP, as well as social barriers (HIV-related stigma).

Marcus and colleagues (2000) analyzed HCSUS data to assess access to dental services. He found that perceived unmet need was greatest among those on Medicaid in states that did not provide dental coverage through the Medicaid program, and for others lacking dental insurance. Persons with low incomes (under $5,000) and those with less than a high school education also had higher odds of having perceived unmet needs (Marcus et al., 2000).

Case management services have been found to support individuals' access to care. Katz et al. (2000) found a high level of unmet need for supportive services among persons in care. Unmet need was significantly higher among nonwhites and persons with less education. Those with a case manager were less likely to have unmet needs in these areas (Katz et al., 2000). In a follow-up study, Katz and colleagues (2002) found that receipt of case management services was associated with a higher rate of HAART use, but not with increased inpatient or ambulatory services utilization. Cunningham et al. (1999) also found a high rate of competing subsistence needs among persons in care for HIV. More than one-third of subjects postponed care or went without it because of need for food, clothing, or housing; lack of transportation; or being too sick or unable to take off from work. In addition, nearly 8 percent went without food or appropriate clothing in order to pay for medical care. Delays of care for these reasons were greatest among those with less education, low income, and no health insurance and among nonwhites (Cunningham et al., 1999, 2000).

Other studies have shown that receiving treatment for mental illness is associated with a higher probability of receiving antiretroviral treatment; thus, the barriers to receiving care for mental illness are relevant when considering access to HIV care (Turner et al., 2001; Cook et al., 2002; Sambamoorthi et al., 2000). These barriers are substantial, as indicated by the high proportion of those who need treatment for mental illness but do not receive it. Many barriers to receiving treatment for mental illness are similar to those that are present for receiving treatment for HIV.

Two Surgeon General reports have analyzed the barriers that deter more than half of those with diagnosable mental disorders from receiving care (DHHS, 1999, 2001). Three overarching barriers to care were identified: the stigma attached to mental illness, the cost of mental health services, and the fragmentation of services. The third barrier refers to the patchwork of programs and settings of care (e.g., hospital, community clinic, private office, school) and the myriad of financing streams that make it difficult for people to obtain care and remain in care. Members of ethnic and racial minority groups face not only these three barriers, but also a host of others, including fear and mistrust of mental health care providers, providers' lack of awareness of cultural concerns, and language barriers for immigrants (DHHS, 2001). Rates of both access to and utilization of mental health care are lower for minorities than for whites (DHHS, 2001).

Individuals with comorbid mental illness and HIV can face additional barriers to receiving care for both illnesses even if they have been brought into the treatment system for one. The barriers stem partly from the complexity of coordinating care among overlapping yet distinct service systems—mental health, substance abuse, and general medical care. People with mental illness, regardless of severity, are seen by specialty mental health providers or by general medical providers (e.g., primary care) (DHHS, 1999). People with HIV are seen in primary medical care or by infectious disease specialists. To complicate matters, substance abuse treatment providers do not always diagnose mental disorders (Zweben, 2000).

Understanding Differences in Access to Care

Policy analysts and researchers posit that the combination of financing structures and individual characteristics such as race/ethnicity and low-income level interact to exacerbate disparities in health care. Rice (2003) and Rosenbaum (2003) identified a number of federal program elements that may contribute to racial and ethnic disparities in access to care. Rice (2003) explains that higher cost sharing requirements (a cost containment strategy designed to lower utilization of services) are a greater financial burden on those with low income because they result in more income being spent on services or fewer services being purchased. On average, racial and ethnic minorities have lower incomes than whites; thus, they tend to be more adversely affected. Rice supports this relationship with findings from the RAND Health Insurance Experiment (Manning et al., 1987; Newhouse and Insurance Experiment Group, 1993). Researchers from that study found that co-payments had a substantial impact on whether or not patients sought care for an illness, but little effect on how much care they received once they sought care. As Rice states more simply, ". . . its major impact is on reducing the number of episodes of care for which care is sought rather than the cost of care per episode" (Rice, 2003, p. 702). Rice notes that the RAND study also found some instances in which lower cost sharing (free care) improved health outcomes among low-income families and persons (Brook et al., 1983; Valdez, 1986; Shapiro et al., 1986).

Wong et al. (2001), using data from the Medical Outcomes Study, a study designed to examine the impact of different systems of care on health outcomes, found that in a chronically ill adult population, the low- and high-copayment groups were less likely to seek care for minor symptoms in comparison to a no copayment group, but only the high-copayment group had a lower rate of seeking care for serious symptoms. The study found no difference in follow-up physical and mental health status scores among the three groups.

Rosenbaum (2003) and Rice (2003) also considered the impact of administrative choices made in payment of Medicaid providers and racial and ethnic disparities in health care. According to Rosenbaum (2003), low payment rates (e.g., Medicaid payment rates) discourage all but core safety net provider participation because the loss of revenues as a result of steep contractual allowances cannot be supported by other small classes of providers. Rice (2003), on the other hand, draws upon the "price discriminating monopolist" model (Sloan et al., 1978) to explain provider behavior that has a disproportionate impact on minority patients. Under this model, physicians can receive different amounts of revenue from different groups of patients (e.g., private insurers, Medicare, Medicaid). Physicians would be more inclined to treat the most lucrative patients first, then those who are less lucrative. Physicians would tend not to treat those groups of patients whose costs exceed revenue. The differential coverage of whites and minorities under the Medicaid program places minority patients at a higher risk of having less access to providers, except for those minority patients who are heavily dependent on Medicaid revenues (Rice, 2003).

COMMITTEE OBSERVATIONS AND CONCLUSIONS

In assessing the current factors that affect access to HIV care, the Committee recognized that there are many actors in the care system—including people living with HIV, providers of medical care, Ryan White planning councils, and policy makers at the federal, state, and local levels—and these actors do not view themselves or act as interrelated elements of a complex whole. Each has different goals and objectives, which at times are complementary but often are conflicting.

At the most fundamental level, the goal of HIV therapy is to increase the level of functioning in the patient, or at least halt its decline, and to slow or halt the progression of the disease. Combination antiretroviral therapy accomplishes this by inhibiting viral replication, thereby maintaining effective immune system response for an indefinite period of time. The goal of providers caring for people living with HIV/AIDS is to provide effective HIV therapy, including HAART when appropriate, to maintain the patient's health for as long as possible, and to provide comfort and palliative care when necessary. But providers also face the pressures of maintaining an adequate income for themselves and the staff they employ; without adequate reimbursement they can be forced to curtail the services they offer or leave the practice of HIV care altogether.

At its simplest, the goal of people living with HIV is to obtain effective HIV therapy. However, complications abound in trying to achieve this simple goal. An untreated comorbidity, such as substance use disorder, can introduce a competing objective that is often at odds with receiving effective HIV treatment. An underlying social condition such as poverty can be the source of multiple competing objectives as the individual struggles to obtain necessities such as food and shelter.

As the circle of care widens, the actors and their goals grow even more complex. At the local level, Ryan White planning councils have the objective of appropriately and effectively allocating federal grant dollars to the areas of greatest need within the community. But existing recipients of funds may become entrenched interests who resist needed changes as the epidemic evolves, putting pressure on the planning councils to maintain the existing infrastructure within the care community.

Federal, state, and local government agencies are charged with serving the greatest number of people possible with limited resources. Often, however, and perhaps inevitably, they attempt to shift costs and responsibilities to one another in an effort to free up resources for other programs or priorities. Policy makers at every level are faced with developing and implementing fiscally responsible and politically viable policies that meet the needs of their constituencies.

That all of these various individuals and the organizational entities they represent would have differing goals is not always inappropriate. Each has a role to play and may be required to provide a balance to some other element of the system. However, it is important to remember that individual elements are parts of a whole. What are the goals of the whole—the publicly funded HIV/AIDS care system itself? Defining the goals of the HIV/AIDS care system is a crucial step toward improving it. There must be a system-level set of objectives that integrates the needs and interests of the various elements into a common cause, in order to provide rationality to the system.

Goals for the HIV/AIDS Care System

The Committee believes the primary goal of the publicly funded system of HIV care should be **to improve the quality and duration of life for those with HIV and promote effective management of the epidemic by providing access to comprehensive care to the greatest number of individuals with HIV infection.**

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

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

The financial portion of this goal will be discussed in Chapter 6.

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

With these goals and objectives as a backdrop, the Committee asked the following questions: Does the financing system described in this and previous chapters ensure access to the standard of care for HIV? Does the system promote delivery of high-quality services? Does the system facilitate efficiency and ensure accountability? Based on the data presented in previous chapters, the Committee offers the following observations and conclusions.

While the third decade of HIV/AIDS offers unprecedented technological and clinical advances in its treatment and epidemiological management, the structural barriers in the financing and delivery of care have undermined the effective application of these advances. As discussed in preceding chapters of this report, effective HIV/AIDS management results in (1) people with HIV/AIDS experiencing substantial reductions in mortality and disability, (2) people with HIV/AIDS experiencing improved quality of life, and (3) with continued HIV prevention, the rates of new infection declining significantly, protecting the health of the public. As a clinical and scientific matter, the improvement in the individual health of those with HIV/AIDS and the protection of the public's health are inextricably linked.

The link between individual health and the protection of the public's health is reflected in three overarching clinical and epidemiological realities. First, with sustained comprehensive treatment, mortality from the disease can be reduced significantly, with commensurate reductions in disability and health care costs. Second, receiving sustained comprehensive treatment can help to prevent transmission of HIV to others because drug therapies reduce viral load, thus potentially rendering the individual less infectious (Vernazza et al., 1999; Staszewski et al., 1999; Barroso et al., 2000). Yet there is some evidence that receiving HAART can cause an increase in unsafe behaviors, thus emphasizing the importance of prevention counseling as a routine part of clinical care (Katz et al., 2002). Third, people who receive drug therapies on a nonsustained or intermittent basis are more likely to develop and transmit resistant strains of HIV, creating substantial new risks for individuals and the community at large.

The Committee finds that the current system of HIV/AIDS care is characterized by substantial financial and structural barriers to critical elements of care, including HAART, and by interruptions in care and drug therapies that pose serious risks to both individual and community health. These barriers include limited access to private insurance and constrained eligibility for public programs with benefit packages that vary from state to state. The result is continued preventable death and disability and little decline in the rate of new infections each year (CDC, 2002).

Based on its analysis of the trends in HIV infection, demographics of the disease, treatment advances, and the current systems of financing and delivering care, the Committee concludes the following:

> **Conclusion 1: Current public financing strategies for HIV care have provided care and extended the lives of many low-income individuals.**

However, significant disparities remain in assuring access to the standard of care for HIV across geographic and demographic populations.

Conclusion 2: 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. State Medicaid programs that provide a significant proportion of coverage for HIV care are dependent upon widely varying resources and priorities that produce an uneven and therefore ineffective approach to managing the epidemic.

Conclusion 3: 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 prevent comprehensive and sustained access to quality HIV care.

Conclusion 4: 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.

Conclusion 5: Low provider reimbursement in Medicaid and managed-care delivery systems has the potential to discourage experienced physicians from treating patients with HIV infection and to undermine the quality of HIV care.

Conclusion 6: The lack of nationwide data on the unduplicated number of individuals served and the services they received under the Ryan White CARE Act hinders accountability, quality monitoring, and outcomes evaluation, and impedes the improvement of the program.

Conclusion 7: The majority of HIV care is publicly financed, providing a strong incentive and opportunity for the federal government to finance and deliver care more effectively.

The Committee's conclusions serve as the backdrop for considering a number of alternative options for the public financing and delivery of HIV care. These alternative options are discussed in Chapter 5.

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5

Options for Financing and Delivering HIV Care

Building on the findings and conclusions of previous chapters, the Committee considered a range of alternative approaches in developing its recommendations for improving the public financing of HIV care. This chapter presents the Committee's analysis of the different options, while focusing on the concept of "Centers of Excellence" as a recommended method for improving HIV care.

The Committee considered a range of alternative approaches in developing its recommendations for improving the public financing of HIV care. Most of the approaches build on existing financing programs. One approach would expand the Ryan White Comprehensive AIDS Resource Emergency (CARE) Act. Another would expand Medicare to cover individuals with HIV infection. Three approaches would give states options for expanding their Medicaid programs to cover low-income individuals who have HIV but are not currently eligible. One of these approaches would facilitate Medicaid coverage through Section 1115 demonstration waivers; the other two would create a new optional Medicaid eligibility category of individuals with HIV, but with varying federal matching rates. The remaining approaches would create new federal programs. One would establish a federal block grant to allow states to purchase services for individuals with HIV. The other would establish a federally funded, state-administered entitlement to care for low-income individuals with HIV.

Each of these seven approaches was considered in light of the Committee's goal to develop a comprehensive vision of a system of care that is accessible and efficient and that meets accepted standards of quality and accountability for individuals with HIV who rely on public programs. From this goal, the Committee derived five assessment criteria:

- Eligibility: Does the approach include a minimum, uniform standard for eligibility that ensures that low-income individuals with HIV (i.e., individuals with incomes at or below 250 percent of the federal poverty level, or FPL) have coverage for recommended services regardless of the state in which they reside?
- Benefits: Does the approach include a benefit package that meets the standard of care for HIV/AIDS and that is uniform for all eligible individuals?
- Provider reimbursement: Does the approach include payment rates that are adequate to enable providers to furnish services commensurate with the standard of care for HIV/AIDS?
- Financing: Does the approach include a financing mechanism that is capable of supporting eligibility, benefits, and provider payment elements that meet the Committee's criteria and that is stable over time?
- Integrated and coordinated services that foster accountability: Does the approach include the integration and coordination of services that allows for administrative arrangements that are efficient and that support program accountability and evaluation?

The Committee applied these assessment criteria to each of the alternative approaches. The Committee's findings are summarized in Table 5-1. The remainder of this chapter sets forth the Committee's analysis of the advantages and disadvantages of these alternative approaches in light of these criteria. The recommendations that flow from this analysis are set forth in Chapter 6.

In the Committee's judgment, the alternative that best fits the assessment criteria is a new federally funded, state-administered entitlement program for low-income individuals with HIV.

The Committee recognizes that the alternatives examined here do not represent the universe of policy options for financing and delivering HIV care. The Committee selected these particular options as broadly illustrative of the alternatives that federal policy makers are likely to explore given the current configuration of federal and state programs described in Chapter 3. For example, the most recent significant health care eligibility expansion at the federal level was the State Children's Health Insurance Program (SCHIP), enacted in 1997. Although this program is targeted at a much different population than that to which this report is addressed, the structural features of SCHIP reflect some important policy preferences. The Committee therefore modeled one of its illustrative approaches on SCHIP.

The Committee notes that, in each approach presented (excluding the Medicare option), state participation is optional. In theory, the federal

TABLE 5-1 Alternative Options for Financing HIV Care by Assessment Criteria

Option	Minimum Uniform Eligibility Rules for Individuals with HIV	Benefit Package Meets Standard of Care for HIV/AIDS	Provider Reimbursement Is Adequate to Standard of Care for HIV/AIDS	Financing Mechanism Is Adequate to Standard of Care for HIV/AIDS over Time	Integrated and Coordinated Services Fostering Accountability and Evaluation
1: Expand Ryan White CARE Act	No	No	—	No	No
2: Medicare Eligibility for HIV	Yes	No	Yes	Yes	Yes
3A: Medicaid Budget-Neutral Waiver Expansion	No	No	No	No	Yes
3B: Medicaid Optional Eligibility, Regular Match	No	No	No	No	Yes
3C: Medicaid Optional Eligibility, Enhanced Match	No	No	No	No	Yes
4: Block Grant to States	No	No	No	No	No
5: New Federally Funded, State-Administered Entitlement	Yes	Yes	Yes	Yes	Yes

government could attempt to require state participation in a program responding to a national epidemic, perhaps by conditioning the flow of federal grants-in-aid for highway construction or education upon state participation. However, the Committee believes such an approach does not merit consideration. Most states are currently experiencing substantial revenue shortfalls, and there is evidence that the imbalance between the demands on state budgets and available revenues is not temporary, but structural (Boyd, 2003). In these circumstances, reliance on any measure of required state financial participation seems to the Committee to be highly problematic. More fundamentally, forcing state participation would generate political tensions between federal and state governments that could compromise the accomplishment of the Committee's objective: the financing of an accessible, efficient system of care for low-income individuals with HIV that meets accepted standards of quality and accountability.

FINANCING OPTIONS

Option 1: Expand Ryan White CARE Act

Under this approach, the Ryan White CARE Act programs discussed in Chapters 1 and 3 would be continued as currently structured, but annual appropriations would be increased to enable all CARE Act programs, ranging from Title I to Title IV, to expand their capacity to meet the medical and support service needs of low-income individuals with HIV.

Advantages

The primary advantage of working through the existing CARE Act programs is that these programs are already operational and have a track record of providing access to care for the uninsured and the poor. Since 1990, CARE Act programs have played a pivotal role in developing and strengthening the health care delivery infrastructure for individuals with HIV/AIDS. Though a substantial proportion of CARE Act funding is spent on medical treatment and drugs, a large proportion (27 percent) is also spent on local-level support services that are critical for individuals with HIV (GAO, 2000) but are often not covered by other programs (Levi and Kates, 2000).

This approach also has administrative advantages. The planning process within the Ryan White CARE Act is designed to allow local level flexibility in determining where funding should be directed. Planning councils established under Title I of the CARE Act are charged with monitoring local trends and assessing annual funding needs. These administrative structures provide the opportunity to address population-level issues and build capacity for services such as substance abuse treatment or outreach to immigrants. The planning process also allows members of the local community to have a voice in how funds are allocated and services are delivered.

Disadvantages

There are several disadvantages to an approach that relies on an expansion of the CARE Act. The first relates to eligibility for services, which now varies significantly from one state to the next and from one city to the next. As a "safety net program," the CARE Act supplements other HIV/AIDS programs in a state or locality, most notably Medicaid; in practice, this results in CARE Act programs with widely different eligibility criteria. This variation is inconsistent with a uniform, minimum standard of eligibility.

Similarly, CARE Act benefits vary substantially from state to state, for many of the same reasons that eligibility standards vary. Access to life-extending comprehensive antiretroviral therapy also varies significantly by state. Individuals in one state may be ineligible because of income level or have access to a fewer number of drugs or types of drugs than an individual with the same disease status in another state. This variation is also inconsistent with access to the standard of care for HIV/AIDS regardless of state of residence.

Another disadvantage of this approach concerns financing. As a discretionary program, the CARE Act program is subject to the uncertainties of the annual congressional appropriations process. States, localities, and private providers cannot predict with any confidence that the funds required to meet the standard of care for those with HIV in need of program assistance will be available in any given fiscal year. Currently, CARE Act dollars do not match the need for services, and some grantees have been unable to serve all those in need. Budget shortfalls for the AIDS Drug Assistance Program (ADAP) in particular have resulted in waiting lists, caps on enrollment, and/or limitations on benefits available to individuals already in the program. Although an expansion of federal appropriations consistent with this proposed approach could, if enacted, annually address these shortfalls, this would not resolve the related problem of allocation.

The community planning process associated with CARE Act Title I funds has provided important community input into how funds are allocated at the local level. This process does not, however, necessarily result in funding allocation decisions that reflect the greatest areas of need over time. This is partly because of inadequate and inconsistent data sources and measures used to describe severity of need for the Title I Supplemental Application (IOM, 2003b). Furthermore, current program data collection activities do not adequately support accountability or evaluation. It is currently impossible to determine national estimates of the number of clients served or the types of services received because programs do not provide unduplicated counts of clients and the services they receive. In short, there is no guarantee, even if the necessary funds were actually appropriated each year, that these funds would be allocated in a manner that enables the standard of care for HIV/AIDS for all those in need of public program assistance in each state.

Option 2: Extend Medicare to Individuals with HIV

Under this approach, individuals found to be infected with HIV would be eligible for Medicare coverage, subject to the same premium, deductible, and coinsurance requirements as other Medicare beneficiaries. This approach would parallel the current coverage of individuals with end-stage renal disease (ESRD), who qualify for Medicare benefits even though they do not otherwise meet the Medicare eligibility requirements applicable to the aged (i.e., 65 or over and 40 quarters of payroll tax contributions) or the disabled (have received Social Security Disability Insurance payments for 24 months due to total and permanent disability) (CMS, 2003).

Advantages

This approach has four principal advantages. First, because Medicare is a national program, and because the presence of HIV infection is a standardized medical determination, this approach would ensure coverage of individuals with HIV infection regardless of the state in which they reside. Moreover, this approach would qualify an individual for coverage upon a medical determination of HIV infection, without a waiting period and without a disability determination or a financial means test.

Second, while the adequacy of Medicare payment rates for hospital, physician, and laboratory services is the subject of continuous analysis and political debate, there is little question that most providers participate in the program (MedPAC, 2003). In the Committee's judgment, Medicare payment rates, as a general matter, would be adequate to enable providers to furnish services commensurate with the standard of care for HIV/AIDS.

Third, this approach offers sources of financing—federal payroll tax revenues (Medicare Part A), federal general revenues (Medicare Part B), and beneficiary premiums (Medicare Part B)—that are as broad in scope as the epidemic itself. These financing sources, while not without their challenges, are substantially more stable than the revenue bases of individual states, many of which are ill-equipped to absorb their portion of the costs of a national epidemic.

Finally, this approach relies on existing administrative structures that, while not without their shortcomings, are relatively efficient and have created a high level of uniformity in how the program is operated. The program's national data collection requirements also allow for tracking, monitoring, and reporting on the program. To supplement the data systems and administrative capacity of the Centers for Medicare and Medicaid Services (CMS), the Congress has established an independent agency, the Medicare Payment Advisory Commission (MedPAC), the mission of which is to monitor, evaluate, and report on the operation of the Medicare program on a continuous basis. Program accountability is promoted by oversight from the Government Accountability Office (GAO) and the Office of Inspector General (OIG) of the Department of Health and Human Services (DHHS).

Disadvantages

Extending Medicare eligibility to individuals infected with HIV has two major disadvantages. First, because Medicare is a social insurance program and not a means-tested entitlement, it does not lend itself to a national program that focuses on low-income individuals with HIV. Just as Medicare now covers all individuals determined to have ESRD without regard to income or resources, so under this approach would Medicare cover all individuals with HIV without regard to income or resources. While the Committee does not object to universal eligibility in principle, the Committee recognizes that federal resources are limited, and that in the long run Medicare's ability to finance current benefits is questionable (as of this writing the Medicare Part A Trust Fund is projected to remain solvent through 2026). In the Committee's judgment, the federal resources potentially available to address the national HIV epidemic cannot realistically sustain an approach that offers universal eligibility of infected individuals through Medicare.

The second major disadvantage relates to Medicare's benefits. As currently configured, Medicare's benefits package does not include a number of services that are essential to the standard of care for HIV/AIDS, including outpatient prescription drugs and case management services. The current lack of coverage for HAART is especially problematic. As the Committee deliberated and reached its conclusions, the President signed into law the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MPDIM) (P.L. 108-173). One of the major features in the law is a prescription drug benefit (Medicare Part D, planned to take effect January 1, 2006) that allows beneficiaries to choose a drug benefit plan (the number of plans to choose from will vary by region). The standard benefit package of a Medicare Part D plan requires a $250 deductible, an average premium of $35 per month, and copayments. It offers coverage of 75 percent of prescription drug costs up to $2,250, no coverage for the next $3,600 in drug costs, and 100 percent coverage of costs above $5,850. Deductibles, premiums, copayments, and coverage thresholds are linked to inflation and will rise as time goes on. For individuals whose incomes are below 150 percent of FPL, cost-sharing and premium assistance is available and the $3,600 gap in coverage does not apply. This assistance does not reach those with incomes between 150 and 250 percent of FPL, however, leaving them with out-of-pocket drug costs that the Committee believes to be unacceptably high for individuals with HIV/AIDS. In addition, the new legislation requires that plans offer medications from each class of drugs, but state plans do not have to offer every drug within a class. Since treatment for HIV requires multiple drugs within a class and treatment regimens must be altered with some frequency, this leaves individuals with HIV vulnerable to high, uncovered costs if all of the required drugs are not on the plan's formulary (Kates, 2004).

Even with Medicare Part D supplying coverage of prescription drugs, the Medicare benefits package remains inadequate to the task of providing the standard of care for HIV/AIDS for low-income individuals. HAART therapy alone is not sufficient. The management of HIV/AIDS requires not only therapeutic services but also attention to the patient's social and environmental circumstances to conserve levels of independence and slow the progression of disease and disability. Patients with HIV/AIDS, especially those with co-morbid conditions, require care from multiple clinicians and multiple systems. In addition to HAART and other drug therapies, a number of adjunct services and interventions have been identified as essential to the care process and necessary for optimal reductions in the rates of infection of HIV/AIDS. These services include but are not limited to primary medical care services (Ashman et al., 2002), substance abuse treatment (Turner et al., 2001), mental health services (Ashman et al., 2002; Davis, 2002), prevention counseling for the infected population (IOM, 2001a), and medical and social case management services (Laine et al., 1999; Ashman et al., 2002; Lo et al., 2002; Levi, 2002).

The current Medicare benefits package does not incorporate all of these services. Expanding the Medicare benefits package to include these services for all beneficiaries would represent a historic program expansion. Restructuring the benefits package just for one group of beneficiaries defined by HIV infection would represent a fundamental break from the Medicare program's long-standing commitment to offering a uniform national benefit to all eligible individuals.

Option 3: Extend Medicaid to More Individuals with HIV

As discussed in Chapter 3, Medicaid is currently the nation's largest source of public financing for HIV/AIDS care. The Committee considered three approaches to extending Medicaid to other individuals with HIV who are not currently eligible for the program. All three of these approaches are optional with the states, in recognition of the strong opposition on the part of many state policy makers to federal requirements. The approaches vary significantly in terms of potential cost to the federal government. The first is budget-neutral, the second would apportion the costs of HIV/AIDS care between federal and state governments as under current law, and the third would increase the federal financial responsibility. A discussion of each approach follows.

Option 3A: Budget-Neutral Medicaid Expansion

Under Section 1115 of the Social Security Act, the Secretary of Health and Human Services (the Secretary) has the authority to waive certain requirements of federal Medicaid law to enable states to engage in demonstrations that are likely to assist in promoting the objectives of the Medicaid program while continuing to receive federal Medicaid matching funds. Currently, Massachusetts, Maine, and the District of Columbia have been granted Section 1115 demonstration waivers to provide coverage to low-income individuals in the early stages of HIV disease, although Maine has not yet implemented its waiver (Shirk, 2003; Kates, 2004). Under this approach, the Secretary would set forth specifications for a national Section 1115 demonstration initiative to cover low-income individuals with HIV who otherwise would not be eligible for Medicaid prior to the onset of disability. The specifications would provide for uniform eligibility standards and a benefit package that meets the standard of care for HIV/AIDS, as well as a budget-neutrality test less stringent than applied currently (e.g., rather than focusing solely on federal Medical savings, the Secretary in applying the budget neutrality test could also consider savings to other federal programs). States seeking to operate a demonstration program consistent with the specifications and able to demonstrate budget neutrality would have their waiver applications processed and approved on an expedited basis. As under current law, the demonstrations would be subject to independent evaluation.

Advantages

The primary advantage to this approach is administrative. It would streamline the process of applying for and approving Section 1115 waivers, at least insofar as it applies to demonstrations involving low-income individuals with HIV who are not disabled by the disease and therefore ineligible for Medicaid. Making these waivers more readily available to states would in effect make federal Medicaid matching funds more available to assist them in meeting the treatment costs of this population. This approach would also allow for the addition of ancillary services such as substance abuse treatment and case management that would not necessarily be offered under a straight Medicaid expansion. In addition, because Section 1115 waivers by definition involve demonstrations, this approach maximizes the opportunity for the comparative evaluation of state coverage initiatives for this population.

Disadvantages

This approach has a number of disadvantages. First, although it specifies a uniform eligibility standard for state demonstrations, it does not ensure that all states would implement such waivers and adopt such eligibility policies. Similarly, although this approach specifies a uniform benefits package that meets the standard of care for HIV/AIDS, it does not ensure that all states would implement such waivers and establish such benefit packages. This approach is silent on the issue of provider reimbursement rates, which tend to be low in relation to the cost of caring for individuals with complex conditions like HIV/AIDS. In states where rates are low, however, raising them significantly would likely make it difficult for the state to satisfy the budget-neutrality requirements. Finally, this approach leaves Medicaid's current federal–state financing arrangements in place. Thus, the federal government's share of any state's cost of treating individuals with HIV would vary inversely with the state's per capita income, from a minimum of 50 percent to a maximum of 77 percent. State per capita income has no apparent relationship to the demands that the HIV epidemic places on any given state or to a state's fiscal capacity to respond to the epidemic. Moreover, while Section 1115 demonstration projects must be budget neutral from the federal government's standpoint over a five-year period, this does not necessarily ensure budget neutrality in state expenditures in any given year. In light of the current fiscal circumstances of most states, it seems unlikely that a majority of states would be willing to assume the risk that these demonstration projects might require additional state funds, at least in the short run.

Option 3B: Optional Medicaid Eligibility Group

Another approach would allow states to extend Medicaid coverage to low-income individuals with HIV who otherwise would not be eligible for Medicaid without obtaining a demonstration waiver or maintaining budget neutrality. Instead, states would be allowed to amend their state Medicaid plans to cover a new optional category of low-income individuals infected with HIV. (Conceptually, this parallels the current state option to cover individuals infected with tuberculosis.[1]) A minimum eligibility standard

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[1] In 1993, Congress created an optional Medicaid eligibility group for individuals infected with tuberculosis (Section 1902(a)(10)(A)(ii)(XII) of the Social Security Act, 42 U.S.C. 1396a(a)(10)(A)(ii)(XII)). States opting to cover this group may receive federal Medicaid matching funds for the cost of providing to eligible individuals the following defined set of tuberculosis-related benefits: prescribed drugs, physician services, outpatient hospital services, laboratory and x-ray services, clinic services, case management services, and services designed to encourage completion of prescribed drug regimens (directly observed therapy). States' costs are matched at a state's regular Medicaid matching rate (50 to 77 percent, depending on the state's per capita income).

would be established at 250 percent of the federal poverty level. The costs of this eligibility expansion would be matched by the federal government at the same rate as the costs of most other eligibility groups (e.g., 50 percent to 77 percent depending on state per capita income). States electing this option would be required to offer the full range of current Medicaid benefits to individuals enrolling under the expansion. Current Medicaid rules governing provider reimbursement rates would continue to apply.

Advantages

Relative to Option 3A, this option would make it significantly less difficult for states interested in expanding coverage for low-income individuals with HIV to obtain federal Medicaid matching funds to defray the costs of such coverage. States would not have to demonstrate to the Secretary of HHS that the federal government would not spend more over a five-year demonstration period than it would if the expansion did not occur. Instead, this option would make additional federal matching funds available to states willing to put additional funds of their own into such an expansion. In those states electing the option, a uniform standard for eligibility could be achieved, and the benefits provided to individuals with HIV would at least meet the standard of care offered currently under Medicaid programs.

Disadvantages

As in the case of Option 3A, this approach has a number of disadvantages that stem from its optional nature and the current fiscal pressures on the states. If all states were to elect this option, a minimum uniform standard of eligibility would be achieved but variations in the scope of benefits would continue. However, given the revenue shortfalls being experienced by most states, widespread state participation in an option that involves the outlay of additional state funds seems unlikely. Even in those states that elect to cover this optional group, low provider reimbursement rates may constrain provider capacity to meet the standard of care and may limit participation by providers qualified to do so. Moreover, individuals enrolled under this expansion would have access only to those benefits offered under the state's existing Medicaid program, which may not provide coverage for the ancillary services necessary for optimal HIV care. Finally, this option does not alter the current distribution of financial responsibility between the federal government and the states. Although the HIV epidemic is national in scope, the federal government's share of the costs of treating individuals infected with HIV under this approach would vary from state to state, from a low of 50 percent to a high of 77 percent, depending on the state's per capita income. Many states, regardless of their relative per capita incomes, will find it difficult to generate their share of the costs of an eligibility expansion in the face of revenue shortfalls.

Option 3C:
Optional Medicaid Eligibility Group with Increased Federal Match

This approach follows Option 3B, with one exception. As in Option 3B, states would be allowed to amend their state Medicaid plans to cover a new optional category of low-income individuals infected with HIV. States electing this option would be required to cover individuals with incomes up to 250 percent of the FPL and to furnish benefits to such individuals that meet the current scope of benefits offered under Medicaid. States could continue to use their existing provider reimbursement rates. Unlike Option 3B, however, the costs of covering this new optional group would be matched by the federal government at an enhanced rate ranging from 65 to 84 percent, depending on state per capita income. (In this regard, this approach parallels the current law option for covering uninsured women diagnosed with breast or cervical cancer.[2])

Advantages

This approach has the same advantages compared with Option 3A as does Option 3B. States would be able to obtain federal matching funds for the costs of covering low-income individuals with HIV who are currently ineligible for Medicaid without having to satisfy the Secretary that their eligibility expansion would be budget neutral to the federal government over a five-year period. Additionally, as in the case of Option 3B, this approach would ensure that, in states electing the option, the minimum eligibility standard would be uniform although variations in the scope of benefits would remain.

This approach would have one additional advantage. By increasing the federal financial share of the costs of coverage, this approach would reduce the state share of costs for treating individuals with HIV, both those newly eligible and those already covered by Medicaid under existing rules. In all likelihood, state participation in this option would be greater than state participation under either Option 3A or 3B, resulting in the coverage of a greater number of low-income individuals with HIV.

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[2] Under Section 1902(a)(10)(A)(ii)(XVIII) of the Social Security Act, 42 U.S.C. 1396a(a)(10)(A)(ii)(XVIII), states may extend Medicaid coverage to uninsured women diagnosed with breast or cervical cancer through a Centers for Disease Control and Prevention early detection program. The federal matching rate available for the costs of treatment is the same enhanced rate available to a state under the State Children's Health Insurance Program, which reduces each state's own-source contribution by 30 percent.

Disadvantages

This approach has the same generic disadvantages as Options 3A and 3B, but they are somewhat mitigated by the enhanced federal matching rate feature. The Committee's criteria of a minimum uniform standard of eligibility would be achieved only if all states participated. The enhanced federal matching rate would increase state participation compared with the other Medicaid options, but universal state participation still seems a remote possibility in light of the revenue pressures under which most states are operating. Even in those states that choose to participate, there would be no requirement that provider reimbursement rates be adequate for maintaining appropriate levels of provider participation. In states with low rates, this would limit the ability or willingness of providers to deliver covered services. Finally, although this option recognizes that the federal government has a greater financial responsibility for the costs of responding to a national epidemic, it still requires a significant state contribution, ranging from 17 to 35 percent, depending on state per capita income. Many states, particularly those hard hit by the epidemic, will have difficulty sustaining their state contribution toward the costs of an eligibility expansion over time, regardless of their relative per capita incomes.

Option 4: Federal Block Grant to States for HIV Care

Under this approach, the federal government would establish a block grant to states for HIV care modeled on the State Children's Health Insurance Program block grant. SCHIP was enacted in 1997 as a means of providing health benefits coverage to uninsured children living in families whose incomes exceed their state's eligibility limits for Medicaid, but do not exceed 200 percent of the FPL.[3] The SCHIP block grant is a federal entitlement to states subject to a cap; that is, federal matching funds are made available to participating states based on costs incurred up to the state's allocation for a given fiscal year. The state's allocation, in turn, is determined under a statutory formula that distributes a fixed federal dollar amount for a fiscal year among states based on the number of low-income children with and without health insurance coverage, as well as geographic variations in health care costs. The rate at which the federal government matches state costs up to the allocation varies from 65 to 84 percent, depending on the state's per capita income. Uninsured children have no individual entitlement to a defined package of services; instead, states have

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[3] Title XXI of the Social Security Act as established by P.L 105-33, SCHIP is codified as 42 U.S.C.§§ 1397aa-1397jj:chapter 7, Title 42.

discretion to limit enrollment of otherwise eligible children (GAO, 2001). States also have discretion, within broad federal guidelines, to design their own SCHIP benefits packages, which may be less generous than those available to children enrolled in their Medicaid programs. States have complete discretion with respect to provider reimbursement rates; they can pay more or less than their state Medicaid program pays for comparable services. They may administer SCHIP through their Medicaid program, through a separate free-standing program, or through a combination of the two (Lambrew, 2001).

Following this model, a federal HIV block grant would make matching funds available to each state opting to participate, up to a specified dollar amount each fiscal year. The allocation to each state would be determined by distributing the fixed federal amount for a fiscal year among participating states based on the estimated number of individuals with HIV and the costs of health care services. The federal matching rate would be the same as that under the SCHIP block grant, a reduction of 30 percent in the state share under the Medicaid matching rate formula. States could use the funds to purchase services for individuals with HIV who are ineligible for Medicaid and have incomes up to 250 percent of the FPL. States would be able to offer benefits that meet the standard of care for HIV/AIDS, but would have the discretion to design their own alternative benefits package. States would have complete discretion in setting provider payment rates and in establishing their own administrative structures.

Advantages

The principal advantage to this approach is that it makes additional federal resources available to states to furnish the standard of care for HIV/AIDS to low-income individuals infected with HIV who cannot now qualify for Medicaid. Because of the enhanced federal matching rate, states would be required to contribute a significantly smaller share of the costs of caring for these newly eligible individuals with HIV than the proportion that they contribute to the costs of caring for Medicaid patients with HIV/AIDS. In addition, a state would have broad flexibility to design its own benefits package and to establish its own provider payment levels, allowing for innovation in the design of an HIV delivery system. Finally, states would have the discretion to cap enrollment of otherwise eligible individuals in the event that their expenditures exceed the available federal funds. For all of these reasons, participation in such a block grant might be more attractive to some states than participation in an optional Medicaid expansion of the kind described in Option 3C. To the extent that more states participate, more state resources would be brought to bear on the epidemic and its victims.

Disadvantages

This approach has a number of disadvantages, most of which stem from the inherent structural characteristics of a block grant approach. The total federal financial contribution in any given fiscal year would be fixed in advance (the total funding levels for the SCHIP block grant were specified in 1997 for each fiscal year through 2007). This fixed total amount must be allocated among states each year based on a formula rather than on the basis of actual costs incurred by states in treating eligible individuals. Because the federal funds available to any given state in a fiscal year are fixed, each state that elects to participate is given broad discretion in determining eligibility, benefits, and provider reimbursement.

This approach would not ensure the adoption of a minimum standard of eligibility for low-income individuals with HIV from state to state. Not all states would necessarily participate, and those opting to participate would be likely to set different eligibility thresholds. Even among states with comparable eligibility thresholds, some states might impose enrollment caps, leaving some eligible individuals without coverage, while other states might not. In short, considerable variation in eligibility would be likely from state to state.

A recent report from the Kaiser Commission on Medicaid and the Uninsured (Ross and Cox, 2003) on strategies states are implementing under SCHIP found that enrollment freezes in six states (Alabama, Colorado, Florida, Maryland, Montana, and Utah) have resulted in tens of thousands of eligible children going without health insurance. These enrollment freezes are creating inequities among children eligible for health coverage programs. In some states, inequities relate to policies that bar newborn children from the program (Alabama, Florida, Maryland, and Utah), such as an age-based eligibility structure for health coverage programs that puts young children enrolled in Medicaid at increased risk of becoming uninsured if a SCHIP enrollment freeze is in effect. In Alabama and Montana, children who are subject to the freeze may lose the value of 12-month “continuous eligibility” and remain uninsured for part of the year (Ross and Cox, 2003).

The same can be said with respect to benefits. Some participating states would likely adopt a benefit package that meets the standard of care for HIV/AIDS. Others might design a less comprehensive package or might offer different packages in different parts of the state. In short, this approach would not ensure the use of a benefits package that meets the standard of care for HIV/AIDS and that is uniform for all eligible individuals. In addition, because the new HIV block grant would affect benefits only for low-income individuals not eligible for Medicaid, the benefits available to individuals with HIV/AIDS enrolled in Medicaid would be likely to remain the same as under current policy, often departing from the standard of care for HIV/AIDS.

Under this approach, states would have even more discretion in establishing provider reimbursement rates than the considerable discretion they are currently allowed under Medicaid. Some states would likely set payment rates that are adequate to enable providers to furnish services consistent with the standard of care for HIV/AIDS. Other states would likely set payment rates that are not adequate, potentially undermining provider participation in the program and patient access to services. The rates set by a state under its HIV block grant program may or may not be the same as the rates used by the state under its Medicaid program. If the rates under the HIV block grant program are significantly higher (or lower) than those under the state's Medicaid program, providers may have an incentive to favor the treatment of those individuals covered by the higher paying program.

As discussed earlier, the availability of federal matching funds to states on an entitlement basis has advantages over funding that is subject to annual appropriations. However, the signature feature of the block grant is that this federal funding would be subject to a limit in each state for each fiscal year, regardless of the number of uninsured low-income individuals infected with HIV or the actual cost of providing the standard of care for HIV/AIDS to these individuals through qualified providers. These annual limits would be determined 5 to 10 years in advance and likely would be based not just on projections of the epidemic and its costs, but also on competing federal budget priorities (the SCHIP block grant was enacted as part of the deficit reduction agreement in the Balanced Budget Act of 1997). Multiple factors—not the least of which is the difficulty in developing accurate population estimates of HIV—make predicting what resources each state will need in any given year particularly daunting. As noted previously, up to one-third of the HIV-infected population is unaware of their HIV status, and as many 30 percent of those people with HIV who are aware of their status are not in care. Because of the difficulties in developing information for allocation formulas, block grants have not been found to be effective in achieving equity among states (NRC, 2001; IOM, 2003b). Thus, the annual limits on federal funds might or might not be capable of supporting, over time, the eligibility, benefits, and provider payment policies that meet the Committee's criteria for the financing of HIV care.

A related disadvantage has to do with the differential federal matching rates that this approach implies. Under this block grant, state expenditures would be matched (up to each state's allocation for the fiscal year) at an enhanced rate compared with the matching rate under Medicaid. Thus, in a state with a relatively high per capita income, the federal government would pay 50 percent of the costs of treating Medicaid beneficiaries with HIV/

AIDS, but 65 percent of the costs of treating individuals with HIV who are eligible for the block grant. Similarly, in a state with relatively low per capita income, if the federal government paid 70 percent of the costs of treating Medicaid beneficiaries, it would pay 79 percent of the costs of treating individuals with HIV who are eligible for the block grant. These differential matching rates are difficult to justify: Why should the federal government assume a greater share of the cost of treating individuals with HIV who are less poor than those eligible for Medicaid? In addition, differential matching rates create a risk of manipulation of the system by fiscally pressed states seeking to maximize federal revenues.

Finally, the block grant approach has potential administrative disadvantages. States that opt to participate by establishing a new program separate from their Medicaid program will incur some administrative costs that duplicate those already assumed by their Medicaid programs. In addition, because of the emphasis on state flexibility under a block grant, obtaining comparable, accurate, and timely program data is likely to be more difficult for the federal government than it would be under Medicaid or another entitlement program, where reporting is tied to state claims for federal matching funds for costs incurred on behalf of specific individuals. Difficulty in tracking how federal block grant funds are being spent or even how many individuals are being served would be particularly counterproductive in a program designed to control the proliferation of infection and achieve specified targets in reduced mortality.

Option 5: New Federal HIV Entitlement Program Administered by States

The final approach the Committee considered is the implementation of a federally funded, state-administered program for the coverage of HIV/AIDS care. Under this option, the federal government would establish eligibility requirements, specifications for benefits, and standards for provider reimbursement designed to ensure that individuals with HIV and family incomes at or below 250 percent of the FPL receive the services needed to meet the standard of care for the treatment of HIV infection. State participation would be optional; however, all costs incurred by a state in furnishing covered services to eligible individuals, including reasonable administrative expenses, would be reimbursed by the federal government at a 100 percent matching rate.[4] Federal funding for this program would be available to states on an entitlement basis and would not be subject to annual appropriation or to an upper limit in any fiscal year. Individuals eligible under the

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[4] A 100 percent matching rate means that the state spends the money and is reimbursed, dollar-for-dollar, by the federal government on a quarterly basis.

federal standards who reside in participating states, including individuals currently eligible for Medicaid or for Ryan White CARE Act services, would have an individual entitlement to the federally defined set of benefits under the new program. States electing to participate would have the option of administering the new national program as a free-standing program or through their Medicaid program, so long as they meet the federal requirements relating to eligibility, scope of benefits, and adequacy of provider reimbursement.

The Committee also considered a similar program that was not only federally financed but also federally administered—a program that did not rely on any state Medicaid or other administrative structures. In states with dysfunctional administration, the creation of new beneficiary enrollment and provider claims processing capacity through federal contracting with private entities could potentially improve program implementation and outcomes. However, the Committee determined that a new "stand-alone national program" would create administrative challenges not presented by other alternatives. For example, a new, separate administrative structure would be required to receive and disburse program funds, determine eligibility, certify and contract with providers, and monitor quality. The creation of a new structure would unnecessarily duplicate costs built into the management of existing programs. The Committee did not pursue this option.

Advantages

This approach has a number of advantages. First, of all the approaches considered by the Committee, this approach has the greatest likelihood of ensuring that all individuals with HIV and family incomes below 250 percent of the poverty level have coverage for services that meet the standard of care for HIV/AIDS, regardless of the state in which they reside. As will be noted, this approach does not guarantee this result because it does not compel state participation; however, the incentives for state participation are quite powerful.

With respect to benefits, this approach would give federal policy makers the ability to design a comprehensive benefit package that includes the necessary mix of medical and social services for effective HIV/AIDS management. Federal policy makers would also set minimum payment standards to ensure participation by qualified providers to an extent sufficient to meet the demand for services by eligible individuals. Because participating states would be reimbursed for the full cost of paying qualified providers adequate rates for furnishing the specified benefits to eligible individuals, there is a strong likelihood that most low-income individuals with HIV would have access to the standard of care for HIV/AIDS.

Another advantage of this approach lies in its financing mechanism.

Currently, the costs of treating individuals with HIV/AIDS are paid for in significant part by those states (and localities) in which large numbers of individuals with HIV/AIDS are concentrated. Under this federally funded approach, the scope of the revenue base would be aligned with the scope of the epidemic. The federal government's national revenue base is not limitless, but it is significantly more capable of supporting an effective program of care for HIV/AIDS over the course of the epidemic than are the revenue bases of individual states.

This approach also offers two significant advantages with respect to administration. First, rather than creating a new and potentially redundant set of federal administrative structures, this approach would rely on participating states to select the most effective set of administrative arrangements. Some states may elect to use their Medicaid agencies and program administrative contractors; others may decide to establish a new program, either using another state agency or contracting out to a private vendor (or both). Because the federal government would pay 100 percent of the administrative costs incurred by states, it could specify reporting requirements that would ensure program accountability and facilitate evaluation, regardless of the particular administrative arrangement a state chooses to put in place.

Second, because the federal government would finance the entire cost of covered services for all eligible individuals in participating states, it would have purchasing leverage that could be used to generate considerable efficiencies in the purchase of prescription drugs used in highly active antiretroviral therapy (HAART). As discussed in Chapter 6, the Medicaid program, ADAP, and the Veterans Administration (VA) all obtain discounts on HIV/AIDS drugs. These discounts vary from program to program and, in the case of ADAP, from state to state. The creation of a national program that entitles more individuals with HIV to HAART would provide an opportunity for the federal government to achieve greater program efficiencies by negotiating lower prices with manufacturers in exchange for the increased volume of sales that the new program will bring.

Disadvantages

This approach is not without its disadvantages. First, as in the case of all the approaches considered by the Committee, participation in this new program would be optional on the part of the states. Thus, there is no guarantee that the Committee's criteria of a national, uniform standard of eligibility and a national, uniform benefits package meeting the standard of care for HIV/AIDS will be met in practice. However, the availability of federal matching funds for 100 percent of the costs of covered services and administration would be a powerful incentive for every state to participate, particularly in the cases of those states that currently spend significant amounts of state funds purchasing services for individuals with HIV/AIDS through their Medicaid programs. By participating in this new program, these states would be able to replace these state dollars with federal funds without simultaneously incurring any additional state costs for expanding eligibility to individuals with incomes at or below 250 percent of the FPL.

A related disadvantage arises from the strong financial incentive for states to participate: federal expenditures for HIV/AIDS care will increase substantially. This increase has two principal sources. First, the federal government will be paying 100 percent of the costs of covering all the newly eligible individuals with HIV in those states electing to participate. Second, the federal government will also be paying what is currently the state share of the cost of treating Medicaid beneficiaries with HIV/AIDS (on average, 43 percent of the costs). The federal government can realize some offsetting savings by redirecting the federal Medicaid funds and a portion of the Ryan White CARE Act funds now being spent on individuals who qualify under the new program. Nonetheless, a significant net increase in federal spending will occur. There are three broad options for addressing this net increase in federal outlays: reducing other entitlement programs, increasing federal revenues, or further increasing the federal budget deficit.

Another disadvantage is that any state funds now being applied to the provision of services for low-income individuals with HIV that are replaced by the new federal funds would not necessarily remain available to combat the epidemic. This option does not contain a maintenance of effort (MOE) requirement under which states would have to continue their current level of spending on HIV/AIDS care. Although the absence of an MOE requirement makes participation in the program considerably more attractive to the states, and although there is a strong logic to the federal government's assumption of the costs of a national epidemic, the disadvantage remains that significant public resources now being applied to HIV/AIDS care would be applied to other purposes.

A final disadvantage arises from the federal–state nature of this program. Because the federal government would match state rather than local expenditures for covered services on behalf of eligible individuals, there would be less opportunity for local policy makers to address issues specific to providing services in their communities. The role of Ryan White Planning Councils, in particular, would be reduced, and the program would likely require the redistribution of dollars in ways that may reduce funding for certain community-based services.

IMPROVING THE DELIVERY OF HIV CARE

In addition to considering options to improve the public financing of HIV care, the Committee was asked to consider what improvements could be made in the delivery of HIV care. In this section, the Committee provides a framework for redesigning an improved health care system for people with HIV.

The complexity of HIV disease—lifelong need for treatment and prevention, coordination of medical treatment with social support and mental health and substance abuse services, and chronic care management requirements—calls for the development of an improved HIV/AIDS care delivery structure. This is essential if the goals of preventing death and disability associated with HIV infection, controlling the epidemic spread of HIV, and improving quality of life for those affected by the disease are to be achieved. These goals can be accomplished within the broader context of care systems that are organized to provide effective and efficient services that are accessible, comprehensive, and coordinated, with high quality maintained within an environment of accountability. The Committee drew from two bodies of literature—chronic disease and quality care—to develop a framework for considering ways to improve the delivery of HIV care. The concepts and principles supported in this literature guided the Committee to examine the concept of "Centers of Excellence" as a means to improve the delivery of HIV care.

HIV/AIDS as a Chronic Condition

Chronic illnesses, as defined by the National Center for Health Statistics of the Centers for Disease Control and Prevention, are "illnesses that are prolonged, do not resolve spontaneously, and are rarely cured completely" (McKenna et al., 1998). There is no cure for HIV disease; however, as noted earlier, access to HAART early in the course of HIV disease has been shown to delay the onset of AIDS and is associated with decreased mortality from HIV disease (Palella et al., 1998, 2003; Moore and Chaisson, 1997, 1999; DHHS, 2004). Once treatment has begun, an individual can expect to be on antiretroviral medication for the remainder of his or her life. Under these conditions, HIV/AIDS squarely meets the definition of a chronic illness (Gifford and Groessl, 2002).

As noted in Chapter 2, HAART requires a high level of management to ensure adherence (Garcia de Olalla et al., 2002; Bangsberg et al., 2001; McNabb et al., 2001; Paterson et al., 2000). However, HAART alone is not sufficient. The management of HIV/AIDS requires not only therapeutic services but also attention to the patient's social and environmental circumstances to conserve levels of independence and slow the progression of disease and disability and the prevention of new infections. Patients with HIV/AIDS, especially those with co-morbid conditions, require care from multiple clinicians and multiple systems. In addition to HAART and other drug therapies, a number of adjunct services and interventions have been identified as essential to the care process and necessary for optimal reductions in the rates of infection of HIV/AIDS. These services include, but are not limited to, primary medical care services (Ashman et al., 2002), substance abuse treatment (Turner et al., 2001), mental health services (Ashman et al., 2002; Davis, 2002), prevention counseling for the infected population (IOM, 2001a), and medical and social case management services (Laine et al., 1999; Ashman et al., 2002; Lo et al., 2002; Levi, 2002).

To fully support the management of chronic illnesses, a "chronic care model" has been developed and described more fully by Wagner (2001), Wagner et al. (1996, 2001), and Bodenheimer et al. (2002). In this model, chronic care takes place within three spheres: the community, the health care system, and the provider organization. The workings of each sphere can help or hinder optimal care. In the community sphere, community-based resources such as community support, social service resources, and policies provide critical linkages to provider organizations. In the health care system and provider spheres, the structure, goals, and values of the provider organization and its relationship with purchasers, insurers, and other providers are established. These spheres support critical dimensions of chronic care, including recognition of the patient and family as the source of control with the practice team collaborating and providing expertise and tools, the creation of a care delivery structure that is appropriate to the planned management of patients with chronic illness with clear roles for all staff, the integration of evidence-based guidelines into daily practice, and the development of clinical information systems that allow clinicians to plan care for both individuals and whole populations of patients and to monitor and receive appropriate feedback (Bodenheimer et al., 2002; IOM, 2002).

The management of HIV/AIDS is very similar to that of other chronic diseases. It requires coordination of care, clinical integration of services, and development of delivery system and community relationships. The management of HIV/AIDS also differs in important ways from the management of other chronic diseases. In this section, the Committee illuminates some of the similarities and differences in the managing adherence to diabetes and HIV/AIDS treatment.

In 2003, the American Public Health Association developed a comparison of the management of diabetes and HIV/AIDS as part of a Web-based document on *Treatment Adherence to Antiretroviral Therapies: Recommendations for Best Practices* (APHA, 2003). The comparison highlighted shared features and influences that influence adherence or utilization of treatment and features that distinguish between the two diseases that may complicate adherence. Table 5-2 provides an overview of these similarities and differences.

Experiences in promoting adherence in diabetes provide some lessons for promoting treatment adherence in HIV. The report identifies several

TABLE 5-2 Managing Adherence Case Study Contrasting Diabetes and HIV/AIDS

Shared Features	Distinguishing Features
• Early stages of disease are asymptomatic. • Treatment may cause symptoms or increase the risk of other serious problems. • Treatment is life long and aimed at preventing deterioration of the patient's health. • Treatment regimen is complex including multiple and concurrently used drugs; timing and dosing is important, coordinated with food intake. • Treatment is secondary prevention. • Patients must actively participate in treatment. • Motivation and adherence vary over time. • Patients are disproportionately underserved by health care system and face substantial social and economic stressors that maintain patterns of behavior that place them at risk. • The conditions are associated with negative social stigma that pose barriers to adherence. • Treatment is costly.	• HIV is considered a more serious disease or "death sentence." • Treatment goals in diabetes are more flexible than in HIV. • Biomarkers of disease control differ with respect to risk; HIV should be undetectable; biomarkers in diabetes are based on a continuum of values. • Window of opportunity for beneficial treatment for achieving health benefits from adherence in HIV treatment is shorter than that for diabetes. • Side effects of treatment are more of a barrier to HIV adherence than for diabetes.

conditions of care management that support treatment adherence. Especially important among these conditions is care that is based on a collaborative model where the provider's role is to apply technical knowledge and skill, and to assist patients to develop self-management skills. Continuing contact and support is another critical condition of care that supports sustained adherence. Well-trained providers organized in multidisciplinary teams and skilled to deal with adherence problems are other conditions that support treatment adherence.

Lessons learned from the broader chronic care management literature highlight five important elements of chronic care programs. These elements include evidenced-based planned care, a multidisciplinary team approach, systematic approaches to providing patient information (counseling, education, information feedback), clinical knowledge and expertise (available to both patients and clinicians), and supportive information systems that allow sharing of information among team members and between patients and team members (IOM, 2003a). Chronic disease management programs have been implemented by a number of health care providers, states, and public health agencies for a number of disease states; common among these are programs for asthma, diabetes, and hypertension (Wheatley, 2002). The Task Force on Community Preventive Services (CDC, 2001) strongly recommended disease and case management as an effective strategy for reducing morbidity and mortality from diabetes. The Committee concludes that the chronic care model is an appropriate framework for redesigning an improved delivery system for HIV care.

Quality Care

In 2001, an Institute of Medicine (IOM) study committee charged with "developing a strategy that would result in a substantial improvement of health care over the next 10 years" issued its report, *Crossing the Quality Chasm: A New Health System for the 21st Century* (IOM, 2001b). This report followed that of a 2000 IOM study, *To Err Is Human: Building a Safer Health Care System*, which focused on a specific quality concern—patient safety. These two reports have focused significant attention on organizational management issues related to improving the health care sector.

In *Crossing the Quality Chasm* (IOM, 2001b), the Committee on Quality of Health Care proposed specific aims for health care system improvement and for meeting patient needs. Several of these aims are consistent with the chronic care model—providing care that is patient centered, effective, safe, and timely. The Committee on Quality of Health Care also recognized that the challenge health care organizations face is fundamentally an issue of the current failings of systems of providers; and hence, the need to redesign the process of clinical care delivery. To this end, the Committee identified specific challenges for the design of health care organizations and systems that are also challenges for care provided under a chronic care model. These challenges include redesigning care processes based on best practices; making effective use of information technologies; managing clinical knowledge and skills; developing effective teams; coordinating care across patient conditions, services, and settings over time; and incorporating performance and outcome measurements for improvement and accountability.

The Committee on the Public Financing and Delivery of HIV Care fully embraces the principles of quality and strategies for quality improvement as outlined in the previous IOM reports and believes that publicly funded programs of HIV care should support delivery system redesign in order to improve the quality of the services they provide. Some of these steps are being taken already. The Health Resources and Services Administration (HRSA) and CMS have been working to improve the quality oversight of their programs and to support quality improvement programs. In particular, HRSA's HIVQUAL Continuous Quality Improvement Program seeks to improve quality of care for people with HIV by building knowledge, skills, and capacity through system improvement, information management, and performance measurements (New York State Department of Health, no date).

Delivery System for HIV/AIDS Care

Drawing from the review of the chronic care literature and the *Quality Chasm* report in particular, the Committee acknowledges that the HIV/AIDS care system—like the American health care delivery system in general—is in need of fundamental redesign, not just minor correction. When applied to HIV/AIDS care, that idea suggests that allocating new funds to the current system will not necessarily achieve better results; what is needed is fundamental change in the design of the delivery system and a redesigned financing system. Toward that end, the Committee is convinced that HIV/AIDS patients need to be cared for in a system that is specifically designed around the core concepts of the chronic care model and of the *Quality Chasm* report. That system does not exist today. In the next section, the Committee discusses the characteristics of a delivery system that would better integrate these two conceptual areas for HIV/AIDS care (Figure 5-1).

Figure 5-1 provides a broad overview of the Committee's view of the logic of integrated and coordinated care for individuals with HIV. If HIV-infected patients know their status, enter care, and stay in continuous care over their lifetime, a previously fatal disease is converted into a lifetime chronic disease, allowing those afflicted to maintain productive contributions to society. Appropriate medical management of the disease requires coordinated and integrated expert care. Such medical care may be more effectively provided through organized and accountable systems of care such as Centers of Excellence. Early infection status determination rather than AIDS determination leads to early therapy and prevention of both epidemic spread and progression to serious disability for those infected. Changes in the understanding of the disease and improvements in therapeutic technology also require significant changes in delivery system structure such as moving the primary locus of care from social settings and providers supported by medical providers to medical care systems, settings, and providers supported by social systems and providers. The integrated and coordinated model also acknowledges that the development of "rapid testing" technology and availability of newer and easier to use HAART thera-

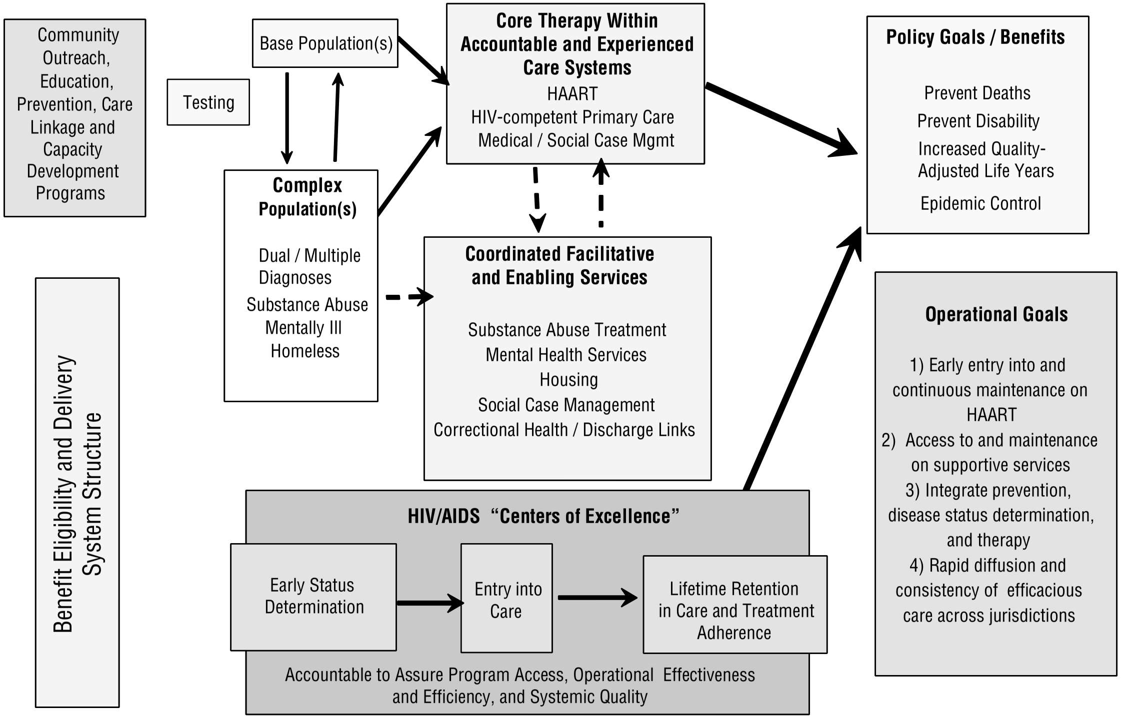

FIGURE 5-1 The logic of integrated and coordinated HIV care.

pies, combined with a significant number of HIV-positive individuals who do not know their disease status, creates an increased need for community outreach to achieve early status determination and referral to care.

Delivery System Functions

The Committee identified two key functions of an HIV/AIDS care system: (1) the provision of HAART in order to delay or prevent progression of the disease and minimize infection of others, and (2) the provision and coordination of other medical care and ancillary support services necessary to ensure that patients adhere to HAART. The evidence reviewed by the Committee in earlier chapters and much of the public testimony heard by the Committee indicate that the delivery of services for patients with HIV/AIDS falls far short of optimal. Many patients do not have a regular "medical home"; many (particularly those in rural areas) receive care from physicians with little experience in treating HIV (Cohn et al., 2001); coordination of care plans and other information among medical, mental health, and substance abuse providers is often minimal or nonexistent; and many patients face significant barriers in trying to make and keep appointments with multiple providers in multiple organizations with multiple medical records systems and phone numbers to remember. The need for medical or social case management systems comes largely from the administrative complexity of the current "system" for providing HIV/AIDS care.

Boiled down to its administrative essentials, an improved delivery system for HIV/AIDS care in the public sector must have the ability to engage experienced HIV/AIDS providers and coordinate their activities in service of the two key functions described above. More specifically, the system should be made up of entities capable of

- identifying highly qualified, experienced providers of HIV-related services and entering into contracts with those providers for the provision of care to a defined set of patients;
- managing patients' clinical information (i.e., medical records) and making that information available as needed to the range of health care providers involved in patient care;
- measuring and monitoring access to care, quality of care provided, and outcomes of care, and reporting that information to the public entities providing funds for HIV-related services; and
- receiving and managing public funds allocated for HIV/AIDS care and distributing those funds to individual providers and provider organizations in exchange for services rendered.

The Committee considered several types of delivery models, and heard testimony from a number of organizations that have done exemplary jobs of providing and/or coordinating HIV-related services. No single organizational model has become clearly established as superior to all others. There is great variety in the organizational structure of those models—some are large integrated medical care systems such as the VA; others are smaller, HIV/AIDS-focused organizations whose roots are in social services rather than medical care. Successful organizations have all, to some extent, adapted themselves to local and geographic circumstances that are unique and therefore not precisely replicable elsewhere.

Centers of Excellence

In spite of this variety in current models, the Committee remains convinced that some modification to the current system for delivering HIV/AIDS services would be essential to ensure that patients receive the maximum possible benefit of the enhanced financing being recommended. The Committee focused its discussion on the concept of Centers of Excellence (CoEs) to provide high-quality, chronic care services to patients with HIV/AIDS.

The CoE concept implies a system of care that offers access to clinical and support services that are comprehensive, integrated across providers, and seamless. Centers of Excellence generally include clinicians who are highly trained and experienced in providing care to a specific set of patients. Typically, CoEs focus on particular diseases that are high cost or high volume (cancer) or affect a specific population (e.g., women). CoEs often integrate or bridge the multiple services and multidisciplinary providers whose services are not necessarily coordinated. CoEs, as part of their responsibility to recruit and maintain a highly trained and experienced staff (physicians, mental health and substance abuse providers, case managers, etc.), often implement strategies for training and continuing education. Through these strategies, staff are kept abreast of changing therapies and evolving knowledge on HIV and care for HIV patients. Some CoEs are also organized to conduct research to improve the care delivery system for their target population. An administrative structure assumes responsibility for ensuring access to services and for the quality, outcomes, and cost of services provided. CoEs may receive special reimbursement consideration and/or may be involved in reimbursing participating providers through a salary or other mechanisms.

The Medicaid program has some experience with disease-focused CoEs, but not with CoEs for HIV care. The state of New York, however, has been experimenting with the CoE concept since 1986 through its Designated AIDS Center Program (DACs). The 44 centers designated under the program are hospital based and state certified. These centers serve as the hub for a continuum of hospital- and community-based care for persons with HIV infection and AIDS. DACs provide multidisciplinary inpatient and outpatient care coordinated through hospital-based case management. The centers are held to HIV-specific care standards to ensure uniform and quality care, and an AIDS Intervention Management System is used to collect, organize, and evaluate data for utilization monitoring and quality of care reviews. Enhanced funding is provided for services delivered through the program. The program, originally established when hospital-based care was the norm, is in the process of review now that the hub of care is no longer hospital based (New York State Department of Health, 1993, 2003).

CoEs for chronic conditions such as HIV/AIDS will have to be different in some respects from those for acute illnesses. The need to coordinate services from many different providers over extended periods of time, to maintain patient tracking systems and promote adherence to therapy, and to integrate with community-based programs and services will all require somewhat different organizational forms than those found in hospital-based CoEs for acute conditions.

Organizing Centers of Excellence

The Committee discussed a variety of structural models that a CoE might adopt. The Committee chose not to recommend one specific model over the others, recognizing that local circumstances (e.g., existing organizations, community preferences, geographical considerations) will favor one model over another in those circumstances. Furthermore, current models have not been specifically designed with the needs of individuals with HIV in mind. The Committee recognizes that testing and experimentation will need to occur before the best ways to serve people with HIV are identified. Thus, the committee remains open to different approaches for providing the most appropriate and feasible care for people with HIV/AIDS. Testing of these alternatives will require mechanisms for ensuring accountability. Experimentation with alternatives will require data collection, especially analysis and reporting related to assessing access, cost, quality, and patient satisfaction.

The range of potential structural models for a CoEs is quite broad. Models can range from highly integrated systems exemplified by the VA or Kaiser Permanente to very loosely structured organizations in which there is no central administrative entity. In the former model, a single organization provides the entire range of medical and support services and receives payment for that entire range of services. The organization may occasionally contract with outside providers for a limited set of highly specialized services, but for the most part services are provided by employees of the integrated system. It is likely, but not guaranteed, that each patient will have a single medical record (perhaps in electronic form) and a care plan that is shared among all types of service providers. In some instances, the entire range of medical, mental health, substance abuse, and social services will be available at a single physical facility; in other instances, the organization may have multiple physical facilities that are closely linked in terms of medical records, appointments, and billing systems.

In the latter model, the CoE concept comes to life primarily through a process of selecting only high-quality, experienced providers to participate in the public financing system. There would not be a mechanism for formally assigning patients to individual providers or to the system as a whole, but only designated providers would be able to receive payment for services to individuals with HIV/AIDS. Structurally, there is no distinction between this model and an unstructured fee-for-service delivery system. Payment in this model is made directly by the public entity (e.g., Medicaid program) to individual providers, including providers of case management or care coordination services. Payment for services may be made on the basis of fee-for-service, capitated, or any other model mutually agreeable between the provider and the payer.

There are other models in the middle of this continuum of administrative integration. For example, there could be a "managed care model," exemplified by many health maintenance organizations (HMOs) and other forms of managed-care or "carve-out" plans. In this model, a single entity would receive payment (almost always on a capitated basis) for the entire range of necessary services. That entity would generally not provide services directly, but would contract with a network of medical and social service providers to ensure that members/patients receive necessary services in a timely fashion. In many state Medicaid programs, individuals with HIV/AIDS are assigned to managed-care plans and receive services through this model.

One might also envision a "care coordination model," in which a defined entity is responsible for providing case management/care coordination services in the context of a loosely connected network of medical and social services providers. The care coordination entity would not receive payment for the complete range of medical and social services, though, and would not pay the other providers. An outside entity (e.g., state Medicaid program) would pay the other providers on the basis of whatever payment model(s) it can negotiate with each type of provider. In this model, the case management/care coordination entity can be (but does not have to be) given authority to set quality standards, develop and enforce coordinated care plans for individual patients, collect and analyze data on quality of care, and select the members of the provider network.

Regardless of the specific organizational form used in a given area, though, the Committee believes that the key functions for CoEs are those identified earlier in this section: assembling a set of highly trained, experienced HIV/AIDS providers; coordinating their activities in order to achieve the highest possible levels of adherence to HAART; and providing necessary medical and nonmedical services to complement and support HAART. The Committee assumes that a wide range of providers, including community-based providers who have experience and expertise in working with the new populations affected, will be considered when organizing Centers of Excellence.

Mechanisms of Accountability

Any of the potential structural models for an HIV/AIDS Center of Excellence can support mechanisms of accountability to the public funders of HIV/AIDS care. That is, there can be mechanisms to collect, analyze, and report data related to standards for access, cost, quality, and patient satisfaction.

Each CoE would be organized as an accountable health enterprise. Individual providers within each designated CoE would be reimbursed at a level to attract and retain the complete range of excellent providers required to meet the comprehensive service needs of the eligible HIV/AIDS population. Each designated CoE would be responsible for assuring that individual providers meet ongoing quality and service standards to maintain their individual eligibility to participate in the CoE. The designated CoE organization, itself, would receive compensation from the state Medicaid agency to support network management, quality management, and network care coordination expenses required to assure long-term efficacy and cost effectiveness of care services.

Each designated CoE would be accountable for assuring appropriateness of fund expenditures and for the cost and quality of services rendered. Expenditures, service levels, and quality levels would be reported to the state Medicaid agency by each designated CoE on an annual basis. The national Medicaid program would assume responsibility for compiling and reporting program access, cost, and quality results to all participants, to the Centers for Disease Control and Prevention, and to Congress on a regular basis. Where deficiencies are deemed to exist, the national Medicaid program would ensure that plans are placed in effect to correct the deficiencies at the state level. A general overall program accountability concept is summarized in Figure 5-2.

For true accountability to exist in the system, though, there must be consequences for good or poor performance that have the net effect of improving quality and efficiency. Most systems of accountability in health care involve consequences in either "market share" or funding. The former involves incentives that move members/patients to better performing orga-

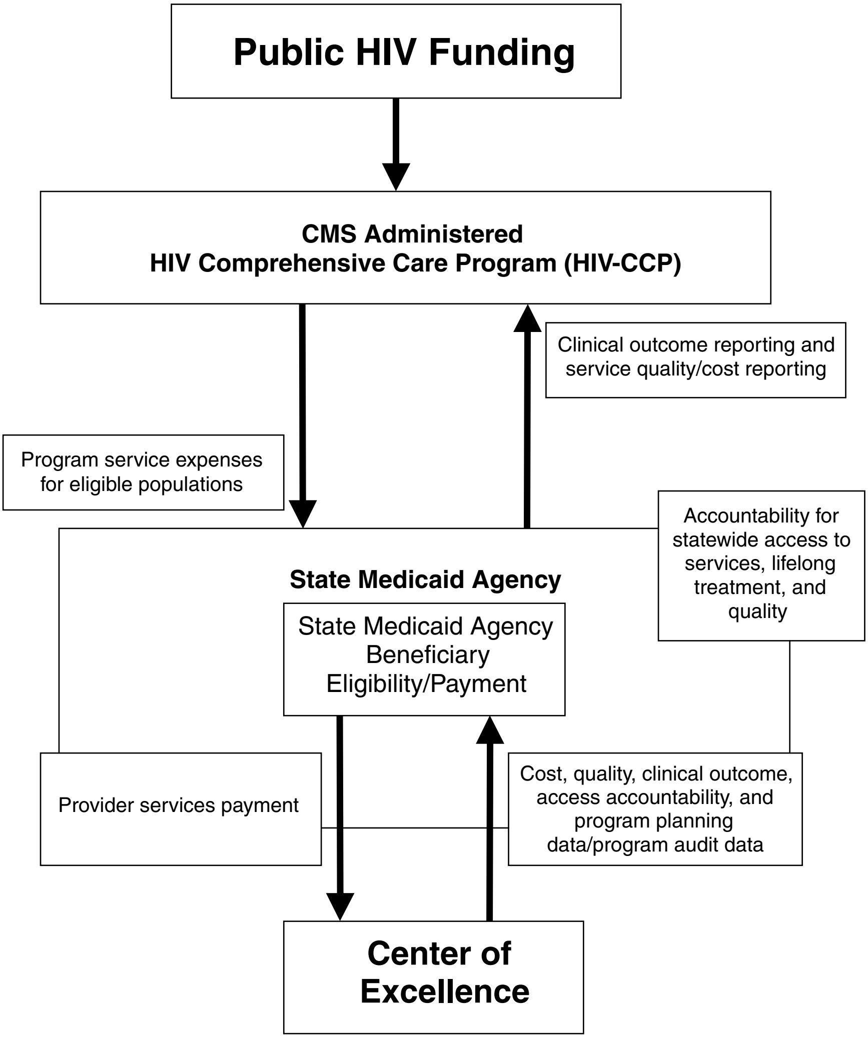

FIGURE 5-2 Overall program accountability concept.

nizations or away from poorer performing organizations. The latter involves financial rewards (either supplemental payments or higher rates of basic payment) to better performing organizations and financial disincentives (e.g., no return of "withholds") for poorer performing organizations or individual providers.

In the context of a CoEs model for HIV/AIDS care, both types of approaches can be used within states, but each will have a mix of strengths and weaknesses. Reward in the form of increased market share can be effective for CoEs that are performing well, but only if those organizations have room to grow and the payment system is set so that the CoE at least breaks even on additional patients. If the CoE is already at capacity in terms of its providers or inpatient capacity, additional patients are a problem rather than a reward. If the payment model produces a predictable loss for each new patient seen, more patients are not a reward. This type of reward is also not effective in a region or community with only one CoE and a fixed number of HIV/AIDS patients to see. There is no way of increasing market share over 100 percent.

Disincentives in the form of reduced (or possibly completely eliminated) market share are generally more effective because organizations typically depend on a predictable flow of patients to keep providers busy and facilities full. A mechanism through which patients can be reassigned from one CoE to another as a consequence of poor performance (or if patients are allowed to choose among competing CoEs) can provide a strong incentive for improvement in poor-performing organizations. This mechanism would work more effectively in moderate to large urban areas where more than one CoE is possible. A similar incentive can be provided through fixed-term contracts between individual providers and CoEs, or between competing CoEs and the state, if the contracts involve a reassessment of performance and the tangible prospect of nonrenewal. These types of incentives and disincentives, however, may not be implementable in some areas, for example rural areas, because the poor-performing entity may be the sole provider in that area.

Financial rewards for excellent performance can be effective, but rarely have been used in health care, particularly in the context of HIV/AIDS care or Medicaid (IOM, 2003a). Potential models can take the form of either "bonus payments" at the end of a period of time if certain quality or efficiency targets are achieved, or higher fee-for-service or capitation payments in future time periods if performance targets are reached in a current period. These models can only be implemented if the state or other public payer has funds available that are not already committed to the basic payment model for services and if clear performance measures, data collection, and analysis systems are available to assess performance on a regular basis (Kates et al., 2001). Some models may also require an amendment of legislation or regulation that defines levels of provider payment and the extent that payment can vary from provider to provider.

Financial disincentives for poor performance are typically the mirror image of financial rewards—they either involve a "take-back" of funds on the basis of poor performance or a lower rate of payment in the future if performance is poor in the recent past. These models have been implemented in the context of "withholds" in the payment agreements between HMOs and physicians, but have not been widely used in the context of publicly financed HIV/AIDS care. If base reimbursements are already low, any form of take-back or lower payment may have the effect of driving a particular provider out of the program entirely. In some instances, this may be an acceptable consequence of a financial disincentive system, but it will not allow poorer performing providers time or opportunity to improve and remain in the system. This may be a significant concern in situations where many of the HIV/AIDS service providers are not financially stable and not able to withstand any cuts in payment levels or are unable to meet all performance criteria because of having to make tradeoffs among different aspects of care (e.g., good care is provided when the patient sees the physician, but a waiting time may not meet standards because of budget constraints).

At a higher level of oversight, the federal government, through CMS, can define standards of performance for the state Medicaid programs (or other public entities) that will be asked to administer the new HIV/AIDS care program. Theoretically, the federal government can create a system of accountability by providing more or less funding to states with better or poorer performance according to those standards. In practice, though, this ability is limited by the language of legislation and regulation that sets rates of federal payments to states, and by the ability of CMS staff to make and enforce decisions that would be highly visible and strongly opposed by elected officials from adversely affected states.

A system of accountability based on market share is essentially impossible to implement in the context of federal–state relationships because the population of HIV/AIDS patients in a given state is essentially fixed in the short run, and it is unlikely that patients would ever be asked to travel to a different state to receive services. It is conceivable that in some regions, with large metropolitan areas that cross state boundaries, the federal government could encourage individuals to seek care in one state rather than another and allocate funds accordingly, but the Committee views this as not being feasible.

SUMMARY

The Committee is convinced that implementing a redesign of the HIV delivery system would result in an improved system of HIV care based on the chronic care model and driven by the six aims for health system improvement: safe, effective, patient centered, timely, efficient, and equal. The Committee also recognizes that it is almost certainly impossible to create systems of care with all these attributes in all regions of the country in a short time frame. However, the Committee believes it is possible to modify current relationships among providers of services in order to create systems of care that have more of these attributes than are currently experienced by most patients.

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6

Recommendations

The Committee reiterates that the primary goal of a publicly financed program for HIV/AIDS care is to improve the quality and duration of life for those with HIV and promote the effective management of the epidemic by providing access to comprehensive care to the greatest number of individuals with HIV infection. As discussed in Chapter 4, the existing public and private programs do not achieve this goal. In Chapter 5, the Committee set forth criteria for a financing program that would be more likely to achieve this goal. After assessing seven different approaches, the Committee concluded that the approach most closely aligned with the Committee's criteria is a federally funded, state-administered program that purchases a uniform benefits package meeting the standard of care for HIV/AIDS on behalf of low-income individuals with HIV.

In this chapter, the Committee puts forth its vision for an improved public financing and delivery system for HIV care and examines the cost and health implications of such a program. For expository convenience, the Committee has named its proposal the HIV Comprehensive Care Program (HIV-CCP). The Committee anticipates that the vast majority of individuals with HIV/AIDS currently receiving care financed through state Medicaid programs would be eligible for and would enroll in the HIV-CCP. This shift will cause an increase in federal expenditures on HIV/AIDS care but is offset by substantial savings by the states. In all, the Committee estimates that approximately 400,000 individuals would be eligible to enroll in the HIV-CCP in the first year of the program and that approximately 280,000 of these individuals would enroll and remain in care. Of these, the Committee estimates that 58,697 individuals with HIV who are in need of but are not receiving highly active antiretroviral therapy (HAART) would begin antiretroviral therapy. As a direct result of receiving HAART, the Committee predicts that premature deaths among this cohort of individuals would fall over a 10-year period by more than half (55.9 percent). Put another way, an estimated 19,825 lives would be saved. The Committee estimates that the incremental cost of providing HAART to these individuals for 10 years in 2002 dollars is $2.65 billion, discounted (over 10 years). In the judgment of the Committee, this investment would be cost effective for the nation, yielding an estimated cost per quality-adjusted life year (QALY) saved of $42,972, less than one-fourth of the estimated cost per QALY of an annual mammography for women ages 55–65.

These estimates, combined with its analysis of current public programs and alternative options, persuade the Committee that establishment of a new federally funded, state-administered program for low-income individuals with HIV is the most appropriate policy direction at this stage of the epidemic. The Committee therefore makes a number of specific recommendations regarding the major structural elements of such a program: eligibility, benefits, provider payment, financing, administration, and cost containment. The Committee recognizes that these recommendations do not constitute a detailed set of specifications from which implementing legislation could be drafted. Instead, the Committee intends that its recommendations serve as a framework for a complete program design by policy makers.

The recommendations are:

Recommendation 6.1: The federal government should establish and fully fund a new entitlement program for the treatment of individuals with HIV that is administered at the state level.

Recommendation 6.2: 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 (FPL). 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.

Recommendation 6.3: 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.

Recommendation 6.4: The new program should reimburse providers who elect to participate at rates comparable to those paid by Medicare for comparable services.

Recommendation 6.5: 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.

Recommendation 6.6: 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.

Recommendation 6.7: 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.

The Committee acknowledges that the group of recommendations it makes to redesign the way HIV care is financed and delivered is a bold response to its charge. In formulating its response and recommendations, however, the Committee conducted extensive modeling and analysis of the program before deciding to move forward. In the next section, the committee presents the results of its analyses, including the anticipated impact of the program on HAART use, the expected health benefits associated with the program, the cost and cost effectiveness of the program, the program's overall budget impact, and the prevention benefits associated with the program. Finally, the committee presents an outline of the program it recommends.

COST AND HEALTH IMPLICATIONS OF THE HIV COMPREHENSIVE CARE PROGRAM[1]

The Committee's recommendations were guided by an assessment of the financial implications, health benefits, and relative cost per health benefit gained of increased access to HAART under the HIV-CCP. In the next section, the analysis and results of the assessment are presented.

In its approach to making calculations of cost and benefits, the Committee first identified access to HAART as its primary indicator of receiving appropriate and quality HIV care. This decision was based on the centrality of HAART to treatment for HIV infection. Second, the Committee made

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[1] For a complete discussion of the methods used to derive the cost and health outcome estimates reported here, see Appendix A. The numbers presented in the Cost and Health Implications section are estimates derived from data on current HIV population size and care patterns, and assumptions regarding program rules, eligibility, enrollment, and care seeking. Therefore, these numbers are subject to two types of imprecision. There is rounding error because in the tables we round calculated values to whole numbers of individuals. More importantly, the estimates are subject to uncertainties in inputs; we address this issue in the sensitivity analyses.

two assumptions in estimating the benefits and costs of the program. The first assumption is that the implementation of the HIV-CCP would not have the effect of providing incentives for the privately insured to discontinue their coverage and enroll in the program, resulting in "crowd-out" and an increase in the publicly insured population. This assumption is based on recent findings indicating that subsidized health insurance for low-income persons did not result in crowd-out in four state programs among adults with incomes below 100 percent of poverty. Some crowd-out did occur among person with incomes of 100 to 200 percent of poverty in two states (Kronick and Gilmer, 2002). Though it is reasonable to expect there will be some level of crowd-out if the program is implemented, any estimation of its potential effects was deemed too unreliable to be included in the Committee's calculations. Thus, an estimated 167,500 individuals who are aware of their infection and privately insured are not included in the policy changes being modeled. The second assumption is that the creation of a health care entitlement will not increase enrollment in care or increase HAART use among individuals who are unaware of their HIV status.[2] Thus, the estimated 280,000 individuals who are unaware of their HIV serostatus are also not included in the modeling.

Anticipated HAART Use Gain and Program Enrollment of HIV-CCP

As discussed previously, 670,000 individuals are aware of their positive HIV serostatus; of these, the Committee estimates that 69 percent (463,070) are in need of HAART as determined by treatment guidelines (Table 6-1). Evidence from Kahn and colleagues (2002) indicates that slightly less than half of those who need HAART (230,000 individuals) receive it, leaving 233,070 individuals with an unmet need for HAART. Among those on HAART, the Committee estimates that 73 percent (167,650) are publicly insured through Medicaid, Medicare, or both, or are uninsured and rely on a public program to finance their care. Of those who need HAART but do not receive it, the Committee estimates that 77 percent (180,314) are publicly insured or uninsured.

Program Eligibility and HAART Gain for the HIV-CCP

Using the federal poverty level of $8,860 for an individual in 2002, and extrapolating from the HIV Cost and Services Utilization Study (HCSUS)

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[2] This assumption underlies the Committee's base case analysis and results. A univariate sensitivity analysis was performed, however, for 36 model input values, including total population estimates. The sensitivity analysis produced results for values of ±20% of the base case. These results are presented in Appendix A.

TABLE 6-1 Estimated HAART Need Use and Deficit by Insurance Status

	Private	Public	Uninsured	Public/ Uninsured Subtotal	Total
Total aware of HIV status	167,500	335,000	167,500	502,500	670,000
Need HAART	115,106	247,766	100,198	347,964	463,070
Receive HAART	62,350	123,024	44,626	167,650	230,000
HAART deficit	52,756	124,742	55,572	180,314	233,070

data presented by Bozzette and colleagues (1998), the Committee estimates that about 80 percent of publicly insured and uninsured individuals (400,975) who are aware of their positive status would meet the HIV-CCP income eligibility requirements (250 percent of FPL, or $22,150 for an individual in 2002; see Table 6-2). The Committee further estimates that about 71 percent (285,503) of those eligible would enroll and receive care, and that about 78 percent (222,681) of those enrolled and in care need HAART. Estimates of enrollment were derived using the Committee's expert judgment assessment of the likely enrollment rates across four subpopulations of those infected with HIV who are aware of their infection: those publicly insured and in care (90 percent), publicly insured and not in care (40 percent), uninsured and in care (90 percent), and uninsured and not in care (30 percent). The result equaled 71 percent of the total population that the Committee estimates is publicly insured or uninsured and aware of their

TABLE 6-2 HIV-CCP by Eligibility, Enrollment, and Care Status, HAART Need and HAART Gain

Eligibility, Enrollment, and Care Status	HIV-CCP
Individuals eligible to enroll in program	400,975
Individuals predicted to enroll in program and remain in care	285,503
Individuals enrolled and in care who need HAART	222,681
Individuals who will receive HAART through the program	181,848
Individuals receiving HAART through the program who received HAART prior to enrolling in the program	123,151
Individuals who will continue to receive HAART through a public program such as Medicaid or ADAP[a]	44,499
Total gain in HAART use as a result of the program	58,697

[a] These individuals represent a small percentage of individuals in public programs who may not transition into the new program because of imperfect outreach and awareness of the program, imperfectly implemented enrollment procedures, or personal choice.

TABLE 6-3 Comparison of Total HAART Use Estimated as a Result of the HIV-CCP by Insurance Status Prior to Implementation (new program numbers are in bold)

Insurance Status Prior to the Implementation of Alternative Financing Option	Current	HIV-CCP
Public	123,024	**169,868**
Uninsured, in care	44,626	**56,480**
Subtotal	167,650	**226,348**
Continued private insurance	62,350	62,350
Total	230,000	**288,697**
Total HAART Gain	n/a	**58,697**

HIV-positive status. See Appendix A for a complete discussion. Taking into account the increased likelihood of receiving HAART through insurance coverage and comprehensive support services, the Committee predicts that nearly 82 percent (181,848) of those in need of HAART will receive antiretroviral therapy paid for by the program. In addition, the Committee estimates that a small number of individuals (44,499) will continue to receive publicly funded HAART without enrolling in the program. Of 181,848 receiving HAART through the program, approximately 68 percent, or 123,151 individuals, were previously on HAART financed through public programs, largely Medicaid, but also programs for the uninsured such as the AIDS Drug Assistance Progra (ADAP). The Committee estimates that the implementation of the HIV-CCP will result in 58,697 individuals gaining access to HAART, or approximately one-third of those publicly insured or uninsured who are aware of their infection and need HAART but are not currently receiving it (Table 6-3).

Health Benefits of the HIV-CCP

Although the increase in HAART use is one measure of the benefit of implementing the Committee's policy recommendations for public financing of HIV care, it is an intermediate outcome that relates to but is not a direct measure of the likely impact of the Committee's recommendations on life expectancy or the quality of life of those living with HIV. To estimate the health impact of providing greater access to antiretroviral therapy, the Committee used a model of HIV disease states to conduct a computer simulation of HIV disease progression.

The model, adapted from Kahn et al. (2001), was used to estimate the number of lives saved (or, more precisely, premature deaths averted) and gain in life expectancy (life years) and quality-adjusted life-years[3] for those likely to receive HAART assuming the Committee's recommendations are implemented. The model is also used to estimate health care costs, the cost per life year gained, and the cost per QALY gained. These cost-effectiveness ratios can be compared with cost-effectiveness ratios for other health care investments to establish the relative value of providing greater access to antiretroviral therapy. All estimates for the HIV-CCP assume full participation occurring at the time of implementation, are calculated only for individuals who enter the program in the first year, and are based on a 10-year time horizon.

Preventing Deaths and Adding Years of Life

The Committee estimates that, of the initial cohort of 58,697 individuals who would not otherwise be taking HAART but who will receive it under the HIV-CCP, most are likely to have AIDS or symptomatic HIV disease, reflecting both current population distribution and evidence of substantial barriers to HAART. Without access to antiretroviral drugs, the model predicts 35,489 individuals from this cohort (60.1 percent) would die from an AIDS-related illness over a period of 10 years[4] (Table 6-4). Providing immediate access to antiretroviral medications would prevent an estimated 19,825 deaths among the initial cohort of 58,697 individuals receiving HAART through the first 10 years that the program is in place; this is a 55.9 percent reduction in mortality. With each additional year, the number of HIV-infected individuals who will benefit from the program will grow along with the number of lives that are "saved."

Adjusting for quality of life, the life-year gain as a result of the HIV-CCP is equivalent to 129,385 QALYs. This adjustment assumes that, in addition to extending life, there are benefits associated with HAART that improve quality of life (e.g., from reduced morbidity due to fewer opportu-

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[3] A quality-adjusted life year is a measure that takes into account both life expectancy and the quality of life, and is based on the notion that many people value a year of life lived in perfect health more highly than a year of life lived in less than perfect health. QALYs can be used to assess the relative benefits of alternative investments in health.

[4] The estimate is based on a computer simulation of disease progression that accounts for the current distribution of HIV disease by stage of illness, insurance, and financial status of the infected population. If no changes are made to the current system of public financing of HIV care, some of the initial cohort of 58,697 individuals who would not otherwise be on HAART at the time they would qualify for the program recommended by the Committee would eventually receive antiretroviral therapy as a result of a worsening in their disease status and/or finances.

TABLE 6-4 Premature Deaths Prevented Among the Year One Cohort (58,697) in the HIV-CCP

	Deaths in a Period of 10 Years
Without access to HAART	35,489
With access to HAART	15,664
Premature deaths prevented	19,825

nistic infections and less HIV disease progression). These benefits are greater than the negative impacts of HAART, including the burdens associated with the side effects of taking antiretroviral medications.

Cost and Cost Effectiveness

The Committee recognizes that there are competing demands for society's health care resources. One way to determine whether or not the Committee's recommendation to increase the level of HIV care funding is an efficient use of those dollars is to compare the incremental cost effectiveness of increased HIV care funding to the cost effectiveness of alternative uses of the same dollars.

The Committee estimates that the incremental cost of providing antiretroviral therapy to 58,697 individuals for 10 years in 2002 dollars is \$2.65 billion, discounted. Adding in the cost of the complete benefits package (including case management, substance abuse treatment, and mental health care services), and setting the rate of reimbursement for outpatient services at the Medicare rate and at Medicare plus 5 percent for services provided through Centers of Excellence, the incremental cost from a societal perspective associated with implementation of the HIV-CCP is estimated to be \$5.6 billion, discounted over 10 years (Table 6-5).

The Committee estimates that the cost per QALY gained associated with the implementation of the HIV-CCP will be \$42,972. This figure is substantially higher than previously reported cost-utility ratios for expanding access to HAART, but is well within the range of what is considered to be a cost-effective investment in health. The difference is due largely to a disparity in the breadth of the policies studied, assumptions made about the timing of the initiation of HAART, and the impact of medical care inflation on the cost of care.

To generate its estimate, the Committee followed the recommendations of the U.S. Panel on Cost-Effectiveness in Health and Medicine. Specifically, the Committee adopted the Panel's recommendation that the "societal perspective" be used in developing reference case analyses rather than the

TABLE 6-5 Cost Effectiveness of HIV-CCP

	Gain in HAART Use	Gain in QALYs	Incremental Cost over 10 Years	Cost Effectiveness (cost per QALY gained)
HIV-CCP	58,697	129,385	$5.6 billion	$42,972

perspective of a particular set of beneficiaries or that of a specific payer—that is, to incorporate all costs and benefits (including adverse effects) associated with an intervention, regardless of who pays the costs or to whom the benefits (or harms) accrue (Russell et al., 1996). Recognizing that the benefits associated with an investment in health may accrue in different years than the costs are incurred, and that people have a time preference for money and health, the Committee also adopted the panel's recommendation that both benefits and costs be discounted to their present value (Weinstein et al., 1996). The recommended discount rate is 3 percent per year after adjusting all costs for inflation (Weinstein et al., 1996).

Previous analyses focus narrowly on providing access to HAART in the early stages of the disease. The program modeled by the Committee provides for comprehensive care and therefore has substantial costs and benefits beyond the costs and life-expectancy gains associated with HAART. For example, the Committee recommends that case management, substance abuse treatment, and mental health services be provided as part of the packet of services to which beneficiaries are entitled in order to support the goal of early entry into care, retention, and adherence. Each of these services is likely to benefit the health of enrollees in ways that are independent of life expectancy. Although quality of life gains are difficult to quantify precisely, the Committee incorporated conservative estimates into its cost-effectiveness analysis, partially capturing these effects.

The Committee's estimate necessarily overstates the true cost per QALY gain because it accounts for all the costs, but not all benefits. Still, even overstated, the creation of an HIV care entitlement appears to be "cost effective." Generally speaking, an investment of health care resources that can purchase an additional QALY for less than $50,000 is considered to be a "good buy" (Hirth et al., 2000), and many of the health care investments routinely made are considerably more expensive. Table 6-6 uses the Committee's estimate of the incremental cost per QALY gained for the creation of an entitlement to care based on HIV infection and places it in the context of other health care investments society has decided to make. The interventions and cost per QALY numbers were drawn from the Harvard Center for Risk Analysis (Graham, 1999) and are expressed in 2002 dollars.

Among current investments in health care that are somewhat less expen-

TABLE 6-6 Cost-effectiveness Ratios for Selected Life-saving Measures (2002 $)[a]

Intervention	Comparator	Target Population	Cost/QALY Saved
Annual colorectal screening	No screening	People ages 50 to 75	$23,000
Frontal airbags with manual belts	Manual belts (50% use)	Drivers of passenger cars	$31,000
HIV Entitlement	Current treatment context	HIV-infected individuals with incomes <250% of the federal poverty level ($)	$42,972
Radon mitigation in homes	No testing or mitigation	Home residents with radon levels above 20 pCi/liter	$74,000
Coronary angioplasty	No revascularization	Patients with mild angina and one-vessel disease	$143,000
Annual mammography	Annual clinical breast exam	Women ages 55 to 65	$194,000
Screening to prevent HIV transmission to patients	Universal precautions	Health care workers in acute care settings	$636,000
Lap/shoulder belts in rear center seat of car (9% use)	No restraints	Rear-center seats of cars	$3,100,000

[a] Figures were obtained from *Risk in Perspective* (Graham, 1999) and were adjusted to 2002 dollars using the Medical Care Consumer Price Index (CPI) from the Bureau of Labor Statistics.

sive than an HIV health care entitlement are annual colorectal screening for individuals ages 50 to 75 ($23,000 per QALY gained) and adding driver side airbags to passenger cars in combination with manual seat belts ($31,000/QALY). Investments that are significantly more expensive than implementation of the Committee's recommendations for public financing of HIV care are annual mammography (versus clinical breast exam) for women ages 55 to 65 ($194,000/QALY), coronary angioplasty (versus no revascularization) for patients with mild angina and one-vessel disease ($143,000/QALY), and installation of lap and shoulder belts in the rear-center seats of cars versus no restraints ($3,100,000/QALY).

Estimated Budget Impact

Data derived from the Committee's model suggest that implementation of an entitlement to care based on HIV infection is likely to produce considerable benefits at a cost that compares favorably to other investments in health. The Committee recognizes, however, that its recommendations will have a substantially different budgetary implication for the federal government relative to other public payers—particularly the states.

The Committee estimates current public spending on care for people with HIV disease, including the cost of care for the uninsured, to be $7.161 billion. If an entitlement to care were established as recommended by the Committee, an additional $574 million in public spending would be needed in the first year the program is operational (Table 6-7). The estimate collapses the budgetary impact on all public payers into a single, summary figure. It assumes no crowd-out of private insurance and does not take into account any cost savings, such as discounted drug costs or reductions in disability that might be found to offset the cost of an expansion of publicly financed HIV care. The estimate assumes that provider reimbursement is set at Medicare rates for outpatient services and at Medicare plus 5 percent for outpatient services provided through a Center of Excellence.

TABLE 6-7 Comparison of Estimated Year One Expenditures, Current and Anticipated, by Payer Associated with the HIV-CCP (in millions)

	Current	Year 1 of HIV-CCP	Incremental Costs/ (Savings)
Federal share of Medicaid/Medicare	$3,003	$5,610[a]	$2,607
State share of Medicaid	$2,138	$984[b]	($1,154)
Subtotal CMS-administered (federal/state Medicaid/Medicare)[c]	$5,141	$6,594	$1,453
Care for the uninsured[d]	$2,020	$1,140	($880)
Total public (includes Medicare and federal/state Medicaid and the uninsured)	$7,161	$7,734	$574

[a] The cost of the HIV-CCP ($4,408) is included in the federal share of Medicaid/Medicare.

[b] This reflects state spending on individuals with HIV who remain in the Medicaid program as well as incomplete adjustment for dual Medicaid and Medicare eligibility.

[c] This excludes the cost of care provided by the Ryan White CARE Act, which is included in "care for the uninsured". See text for discussion of potential CARE Act savings.

[d] The estimate of the cost of care for the uninsured includes care provided to veterans with HIV/AIDS by the Department of Veterans Affairs (VA) health care system. Though the VA is the largest single provider of HIV/AIDS care in the country, the amount of money it spends on HIV/AIDS care is small compared with other public programs, totaling less that $400 million in FY 2002. The VA does not cover care for veterans with private insurance, so in a sense it is a program for the uninsured.

The additional cost to the federal government, measured by expenditures for the new program, plus greater federal-share-of-cost spending for Medicaid and Medicare beneficiaries who are not enrolled in the new program, is estimated at $2.607 billion. Collectively, the states would realize a first year savings of $1.154 billion. This savings is the result of the transfer of the cost of care from Medicaid, for which the states share fiscal responsibility, to the HIV-CCP, which is funded entirely by the federal government. The Committee predicts that the cost of care for the uninsured, currently estimated at $2.02 billion, will fall to $1.140 billion, resulting in a net savings of $880 million shared by the federal government, states, counties, providers of uncompensated care, and other payers.

Budget Impact on the Ryan White CARE Act

The Committee found estimating the cost of care for the uninsured to be a difficult task due to the variety and complexity of payers and the lack of data on both services provided and individuals treated. It is not surprising, then, that estimating the impact of the HIV-CCP on the cost of care for the uninsured, particularly on the Ryan White CARE Act, was difficult to do precisely, and was thus approached by the Committee with great caution. The Committee estimates that the current cost of care to public payers for uninsured individuals with HIV/AIDS is just over $2 billion dollars (Table 6-7). This number includes costs borne by states and localities, as well as by the VA for costs incurred by otherwise uninsured veterans, and, finally, a substantial portion of the Ryan White CARE Act. It is important to note that although the Ryan White CARE Act provides services exclusively for the un- and underinsured, the Committee's estimated cost of care for the un- and underinsured does not include the entirety of funds allocated to the CARE Act. This is because the CARE Act funds many services that are not included in the HIV-CCP (e.g., housing support) and therefore are not included in the modeling. For this reason, the Committee concluded that estimates of the potential reduction to the funding allocation of the Ryan White CARE Act should be only a cautious adjunct to reporting the modeling results.

If the HIV-CCP is implemented as recommended, however, there would indeed be a reduction in need among those currently served by the CARE Act. This might, in turn, lead to the opportunity to reduce the funds allocated to the CARE Act, providing further savings to the overall cost of care. The Committee would like to stress that any reduction in the funding allocation for the Ryan White CARE Act must be undertaken with utmost care and deliberation, as the individuals served by the CARE Act after the implementation of the HIV-CCP program would remain the most vulnerable population with HIV/AIDS. In fact, since the Committee believes that there is currently substantial unmet demand for services, any adjustments in funding for the Ryan White CARE Act should allow for meeting some of the currently unmet needs. The following paragraphs estimate the upper bound of the potential reduction to the Ryan White CARE Act if the HIV-CCP were to be fully implemented. This upper bound represents the most that could be eliminated from the program, before allowing for meeting current unmet needs.

As discussed in Chapter 3 (Box 3-2), Titles I and II of the CARE Act cover a variety of support services, including housing and food assistance, transportation, and advocacy and outreach services. The need for these services among the populations served by the CARE Act would not be eliminated by the implementation of the HIV-CCP. The Committee also envisions that any overlap between the CARE Act and the HIV-CCP would almost certainly occur only with Titles I and II and the dental reimbursement program. Though the Committee does foresee a potential restructuring of Title III (discussed later in this chapter), Title IV, and the AIDS Education and Training Centers (AETC) and the Special Projects of National Significance (SPNS) programs, these funds are targeted toward unmet needs that would still exist even with the new program and are unlikely to be diminished.

Table 3-1 provides the percentage distribution of funds for Titles I and II through Fiscal Year (FY) 2001, the most recent year for which data is available. Using these percentages for FY 2001 and applying them to FY 2002 allocations, we were able to approximate what percentage of CARE Act funds would be spent on services covered by the HIV-CCP (Table 6-8).[5]

The amount of CARE Act funds spent in service categories covered by the HIV-CCP totals $1.261 billion. This does not mean, however, that all of these funds could be used to offset the cost of the HIV-CCP. Not all of those receiving services under the CARE Act will be eligible for the HIV-CCP. In the model the Committee estimates that only 53 percent of uninsured individuals in care will be eligible for the program, leaving 47 percent who would continue to rely on other payers to receive care. Of the 53 percent who are eligible for the program, the Committee estimates that 90 percent (48 percent of those eligible) will actually enroll due to barriers in switching programs and inefficiencies in outreach and enrollment mechanisms. Thus, we calculate that of services covered by the HIV-CCP no more than $602 million of the $1.261 billion in potential overlap may be realized

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[5] The percentage distribution of funds across service categories in Titles I and II does vary slightly from year to year; however, it has not varied by more than ±5 percent in any category since 1998. Therefore, the margin of error caused by applying the values from FY 2001 to FY 2002 is relatively small.

TABLE 6-8 Areas of Potential Overlap between the Ryan White CARE Act and the HIV-CCP

Ryan White Funding Category	Type of Service Covered under the HIV-CCP ($ in millions)	NotCovered under the HIV-CCP ($ in millions)
Title I		
Health care	$272	
Case management	$74	
Support services		$161
Medications/ADAP	$43	
Administration, planning, evaluation, and program support		$68
Title II		
Health care	$117	
Case management	$78	
Support services		$68
Medications/ADAP	$664	
Administration, planning, evaluation, and program support		$68
Title III		$194
Title IV		$71
Dental assistance	$13	
AETCs		$35
SPNS		$25
Total	$1,261	$690

as savings within the Ryan White CARE Act. Compared to the estimated savings for care of the uninsured in Table 6-7, no more than $602 million of the estimated $880 million would be realized within the CARE Act. It is worth noting again that this estimate represents the upper bound of potential savings. Because the CARE Act is a discretionary program limited by the funds allocated to it each year, there is almost certainly a level of unmet need that would become apparent should the current recipients of CARE Act services gain access to other resources. The Committee has no acceptable data with which to determine the level of this unmet need and therefore does not make the attempt. But it is likely that at least some of the $602 million in potential savings would be absorbed in meeting the needs of those who are currently outside the system but would enter it if there were room.

Prevention Benefit of the HIV-CCP

In developing the model, the Committee sought a clear evidence base for making its assumptions. Wherever there was uncertainty, the Committee chose to be conservative. For example, the model does not take into account a potential "prevention effect" in the base-case analysis, although prevention counseling is included in the package of benefits provided in the recommended program. This does not imply that the Committee believes there would be no positive prevention impact as a result of the program. Rather, the Committee, on the basis of the available data, was uncomfortable providing an estimate of this effect as part of the model results. Instead, the Committee chose to estimate the potential "prevention effect" in a separate analysis. The Committee estimated the possible prevention impact of the program using a linear calculation with four data inputs: (1) gain in individuals receiving ongoing intensive prevention counseling, (2) rate of disease transmission, (3) prevention effect of the program, and (4) estimated cost of care for those newly infected over the first 10 years of infection. The significant assumption underlying this calculation is that the prevention counseling received through the program would be a concerted and sustained effort using evidence-based prevention methods.

It is estimated that the program would enroll 285,503 individuals in the first year. This population is made up of individuals who were not previously in care as well as those who were enrolled in Medicaid or received care through programs for the uninsured. Through the program, these individuals would receive ongoing prevention counseling, which the vast majority of them would not have received even if they were previously in care. Based on expert judgment, we adjusted the total population size by -0.30 to exclude the small number of individuals already receiving ongoing prevention counseling and individuals who would not receive this service even if offered in the benefits package. Thus, the total population that we estimate would receive ongoing prevention counseling through the program is 199,852.

An average HIV transmission rate of 4 percent per year (i.e., four new HIV infections per 100 infected individuals per year) for all individuals infected with HIV, as reported in Holtgrave (2004), was used in the calculations. Sensitivity analyses were conducted around lower values because the program may enroll individuals who are less infectious and/or engage in less risky behavior than average. To be conservative, the Committee did not examine higher values.

Though several studies are currently examining the risk reduction effectiveness of prevention interventions for individuals who are HIV positive and aware of their status, few have published results. In time, it will be possible to use a more precise number for effect size in this calculation, but in the absence of a clear point estimate, we decided to use a range of effect sizes from 30 to 50 percent reduction in transmission. This is consistent with many studies on prevention in mixed-HIV status risk groups.

An estimate of the cost of care averted by the prevention impact of the program was based on the model developed to determine the cost of the program. This model predicts that the cost of HIV disease for one person will be $45,000 over 10 years and $164,000 over 30 years, discounted to the present at 3 percent. The cost includes current use of ancillary services, but not the cost of added ancillary services such as substance abuse treatment received as a result of being enrolled in the program. The predicted cost reflects the fact that many individuals with early HIV disease are unaware of their infection. If perfect HIV awareness is assumed from the time of infection, the predicted costs rise to $67,000 and $190,000, respectively.

The results of this calculation show that from the 199,852 individuals in the program, 7,994 new infections can be expected to occur per year in the absence of prevention counseling. Using the midpoint of the range of risk reduction effect sizes (40 percent), we estimate that through ongoing prevention counseling, 3,198 of these infections can be averted, at an estimated cost savings to the care system of $144 million over 10 years and $524 million over 30 years. This represents an 8 percent reduction in the estimated 40,000 HIV infections transmitted each year. Using the lower and upper end of the range of effect sizes, the reduction in new infections is 2,398 and 3,997, respectively. Using a 3 percent annual transmission rate generates an estimate of 2,398 new infections prevented.

Table 6-9 shows the estimated number of infections averted and cost savings over 10 years and 30 years for both imperfect awareness of new infection and perfect awareness of new infection. The transmission rate is first assumed to be 4 percent and then varied to 3 percent as a sensitivity analysis. As indicated in the table, the expected results of exposure to prevention counseling, in terms of both infections and costs averted, vary as a function of changes in input parameter values. Yet even with wide variation, the human and economic benefits that will be realized from implementing the Committee's recommendations are substantial. These benefits were not included in the base case modeling results. Had they been included, the estimated cost per QALY gained would have decreased.

RECOMMENDATIONS

The number of lives that could be saved by a new federal program for low-income individuals with HIV, and the estimated cost effectiveness of additional federal funding for such a program, persuade the Committee that establishment of such a program would represent an important

TABLE 6-9 Estimated Prevention Impact of the HIV-CCP

	Imperfect Awareness Infections Averted—Cost Savings in Millions (10 yr/30 yr)	Perfect Awareness Infections Averted—Cost Savings in Millions (10 yr/30 yr)
4 percent transmission rate (4 new infections per 100 infected individuals)		
30 percent risk reduction	2,398 ($108/$393)	2,398 ($161/$456)
40 percent risk reduction	3,198 ($144/$524)	3,198 ($214/$608)
50 percent risk reduction	3,997 ($180/$656)	3,997 ($268/$759)
3 percent transmission rate (3 new infections per 100 infected individuals)		
30 percent risk reduction	1,799 ($81/$295)	1,799 ($121/$342)
40 percent risk reduction	2,398 ($108/$393)	2,398 ($161/$456)
50 percent risk reduction	2,998 ($135/$492)	2,998 ($201/$570)

improvement over the status quo. The Committee deliberated the structural outlines of such a program and arrived at the following recommendations. While these recommendations do not address all of the design features of such a program, they offer a coherent framework upon which federal and state policy makers can build.

> **Recommendation 6.1: 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.**

As discussed in Chapter 4, the current public financing programs do not adequately address the barriers to HAART for low-income Americans with HIV. Despite the dramatic decline in the annual number of AIDS deaths due in large part to the advent of HAART, the number of new infections has remained constant at about 40,000 per year; new data indicate that the number of new infections is on the rise (CDC, 2003). In addition, the demographics of the epidemic have shifted to include more individuals who come from low-income communities and communities of color and who are more dispersed geographically throughout the United

States than in the past. Data also show that individuals cared for in the publicly financed HIV delivery system often receive inadequate or incomplete care because of variations in coverage and limitations on prescription drugs and other services. Simply stated, the nation's current approach, which provides limited federal funding for early treatment of HIV and relies on the federal–state Medicaid partnership to fund much of the care once an AIDS diagnosis is made, does not provide the fiscal or administrative resources necessary to finance timely, comprehensive, and consistent care to low-income individuals infected with HIV.

The Committee examined seven different alternatives to the existing public financing arrangements. These ranged from incremental approaches building upon the existing Ryan White CARE Act, Medicare, and Medicaid programs, to the establishment of new federal programs. As explained in Chapter 5, the Committee concluded that the approach that best fit the criteria for effective public financing of HIV care for low-income Americans was a federally funded, state-administered program (Option 7). Medicare's character as a social insurance program oriented toward acute care was felt by the Committee to be incompatible with the need for a program targeted at the chronic care needs of low-income individuals with HIV. While Medicaid, as the nation's largest health care program for the poor, would appear to be a logical program on which to build, the Committee concluded that options for expanding Medicaid would not provide adequate funding under current and foreseeable state budget constraints. Similarly, options that leave the states substantial discretion to limit eligibility, benefits, and provider payment levels in order to constrain costs would undermine the Committee's objectives of a national program addressed to a national epidemic.

Under the Committee's recommendation, state participation would be voluntary. The federal government would pay the costs of covering low-income individuals with HIV, as well as all costs incurred by participating states in connection with administration of the program. To eliminate any uncertainty on the part of states regarding the availability of federal funds, the Committee recommends that the program be funded as an open-ended entitlement to states and not be subject to annual appropriations. That is, the federal government would pay all allowable costs of providing covered services to eligible individuals through qualified providers. Because the federal government would guarantee the payment of the costs of treating low-income individuals with HIV that states and localities now incur under Medicaid or the Ryan White CARE program, as well as the new costs they could be exposed to as the epidemic proceeds, the Committee believes that all states would choose to participate.

As a condition of participation, the new program could apply minimum standards relating to eligibility, benefits, and provider payment so as to create a reasonably uniform national program. With respect to administration, states would have the flexibility to use their Medicaid agencies, their public health departments, or some other state agency, so long as they complied with the reporting requirements needed to ensure programmatic accountability. All costs reasonably incurred by states in administering the new program, whether through their Medicaid or other agencies, would be assumed by the federal government.

Privacy and confidentiality are a concern for many individuals who are HIV positive. The Committee expects that the program would be run in accordance with the national standards for protecting the privacy of health information set by the Health Insurance Portability and Accountability Act of 1996 or pertinent state standards that impose more stringent standards.

> **Recommendation 6.2: 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.**

While early and continuous access to HAART is demonstrably cost-effective, as shown in Appendix A, it does entail costs. The drug therapies themselves are expensive, and the providers of the medical and nonmedical services required to maximize the effectiveness of these therapies must be compensated. At the same time, the federal government's resources are not unlimited, and there are numerous competing claims for the federal health care dollar. The Committee therefore recommends that eligibility for the new federal program be limited to individuals who are medically determined to be infected with HIV and whose family incomes do not exceed 250 percent of the federal poverty level (FPL; $8,980 for an individual in 2003).

As discussed in Chapter 3, most low-income Americans receiving care for HIV/AIDS do so through Medicaid or the Ryan White CARE Act program. Most state Medicaid programs limit eligibility to those with HIV/AIDS who otherwise meet Medicaid disability standards. As a practical matter, this means that most low-income individuals with HIV infection only become eligible for Medicaid once they have advanced AIDS, which results in disability and serious illness. In a classic Catch-22, people diagnosed with HIV cannot get Medicaid coverage that would enable them to access care that would prevent the costly onset of AIDS, which Medicaid does recognize as a basis for eligibility. In contrast, eligibility for the Ryan White CARE Act program is usually based on HIV diagnosis rather than the onset of AIDS. In the view of the Committee, this approach is far superior. Limiting eligibility for coverage to individuals whose disease has advanced to AIDS is fundamentally at odds with the demonstrated value of early and continuous access to HAART therapy. The Committee therefore recommends that categorical eligibility for coverage be based upon a medical determination of HIV infection.

With respect to income eligibility, there is no commonly agreed-upon standard for "low-income." Different means-tested programs apply different tests. For example, the minimum Medicaid income eligibility standard for an individual with disabilities who qualifies on the basis of receiving Supplemental Security Income (SSI) cash assistance is 74 percent of the federal poverty level. State Medicaid programs have discretion to set higher income standards for individuals with disabilities, and many of them have, resulting in considerable variation from state to state. The Ryan White CARE Act program uses less restrictive standards. Reflecting the high costs of HAART, eligibility for the AIDS Drug Assistance Program (ADAP) is offered to individuals with HIV infection with incomes at least under 500 percent of the federal poverty level in two states (Delaware and New Jersey). The majority of ADAP clients (92 percent) have incomes below 300 percent of the federal poverty level. However, the ADAP income standard applies to coverage for prescription drugs only, not for the full range of medical and related services needed to manage HIV/AIDS.

Because of the high cost of HAART and the comprehensive care necessary for effective treatment of HIV/AIDS, the Committee concludes that the income eligibility standard for the new federal program should be 250 percent of the federal poverty level ($22,500 for an individual in 2003). This standard is higher than the minimum Medicaid eligibility standard for disabled SSI recipients but is consistent with the standard applicable to working disabled individuals eligible for Medicaid at state option under the Balanced Budget Act of 1997 (1902(a)(10)(A)(ii)(XIII) of the Social Security Act added by section 4733(3) of the Balanced Budget Act, P.L. 105-33). This is lower, however, than the standard commonly applied in the ADAP program. Unlike the new federal program recommended by the Committee, ADAP does not cover services other than prescription drugs and does not guarantee coverage of the prescription drugs it offers to each individual with HIV who qualifies under its income standard.

Notwithstanding the differences between ADAP and the new federal program, the Committee recognizes that the adoption of an income standard lower than that now in use under ADAP will potentially pose a hardship to many individuals now receiving ADAP assistance. The Committee therefore recommends that, in determining whether an individual meets the 250 percent income standard, a "spend-down" methodology be applied similar to that used by many state Medicaid programs in determining income eligibility for individuals with disabilities through the "medically needy" eligibility category. Under this methodology, an individual's incurred medical expenses are subtracted from the individual's income to determine whether the individual's income is at or below the eligibility standard. Once the individual has incurred sufficient medical expenses to reduce his or her income to the eligibility standard (in this case, 250 percent of FPL), the program would cover all additional costs of care and treatment over the remainder of the accounting period (e.g., six months, one year). At the end of the accounting period, the "spend-down" process would be repeated, and the individual would be responsible for medical expenses until he or she had once more incurred sufficient costs to reduce income to the 250 percent standard.

The Committee recognizes that there will be individuals with HIV who have no access to adequate private insurance coverage, whose incomes exceed 250 percent of the federal poverty level, and who will not be able to "spend down" into eligibility. For these individuals, the new federal program, as a practical matter, will be the only available source of coverage for HAART and related services. The Committee does not believe that any useful public purpose would be served by excluding these individuals from the new federal program if they are willing to contribute toward the costs of this coverage. The Committee therefore recommends that individuals with HIV who cannot purchase adequate private insurance coverage (either through their employers or in the individual insurance market), and who are financially ineligible for the new federal program, have the opportunity to purchase coverage through the program by paying a monthly premium that is reasonably related to their incomes.

The Committee recognizes that under current Medicaid law, some eligibility groups are subject only to income limitations, while others are subject to both income and assets limitations. (Kaiser Commission on Medicaid and the Uninsured Resource Book, 2002). While the Committee supports the application of an income test, it does not recommend the use of an assets test. Assets tests are commonly applied in determining Medicaid eligibility for individuals with disabilities; in general, these individuals may not qualify for coverage if they have countable assets (e.g., savings accounts, real property other than the home) of more than $2,000. In contrast, the amount of assets an individual has is generally not a consideration in determining eligibility for ADAP benefits. From the standpoint of an applicant, assets tests are significantly more intrusive than income tests and can deter individuals from seeking benefits to which they are entitled (Moon et al., 2002; Cohen-Ross and Cox, 2000). From the standpoint of the program agency, administering an assets test is very staff-intensive and significantly increases the complexity and welfare stigma of the program (Moon et al., 2002). Assets testing has two broad policy purposes: to limit program benefits to those perceived to be most deserving (as measured by the absence of countable resources), and to discourage application for program benefits through the establishment of paperwork barriers. The purpose of the Committee's recommendation is to target coverage on low-income individuals with HIV while at the same time minimizing administrative burden and cost. In the Committee's view, application of an assets test would add significantly to the complexity and administrative cost of the program and runs the risk of deterring low-income individuals with HIV from applying for, or qualifying for, the coverage they need. In the Committee's judgment, neither of these policy objectives is appropriate to a federal program intended to facilitate access to early and continuous treatment for low-income individuals with HIV.

The Committee considered a number of eligibility criteria other than HIV infection and financial ability (as measured by income). These other criteria were private insurance coverage, immigration status, and residence in a correctional facility. In each case, federal Medicaid law has established a policy, and in each case, the Committee has determined that this established Medicaid policy should apply to the new federal HIV program as well.

With respect to insurance status, current Medicaid (and Medicare) policy is not to disqualify individuals who have private insurance coverage. Instead, this coverage is viewed as a liability of a third party for the beneficiary's cost of care, and Medicaid pays only for the services that the insurer does not cover. There is only one Medicaid eligibility category to which this policy does not apply: women diagnosed with breast or cervical cancer. In this case, a woman can qualify only if she is not privately insured; however, unlike any other Medicaid eligibility group, these women are not subject to an income or resource test.[6] The goal of the new federal program is to ensure early and continuous access to treatment by low-income individuals with HIV. Because of their income and their HIV status, these individuals are less likely to have private insurance coverage. In these circumstances, screening all applicants to identify those individuals would unnecessarily complicate the application process. In the Committee's view, the more efficient course is that now used by the Medicaid (and Medicare) programs, in which any private insurance coverage a low-income individual with HIV may have should be looked to as the primary payer rather than as a disqualifier.

New public programs may cause a "crowd-out effect" or the substitution of public funds for private funds. A new public program may prompt

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[6] The Committee notes that the authorizing statute, section 1504(a) of the Public Health Service Act, prohibits the Secretary of Health and Human Services from making Breast and Cervical Cancer Screening program grants to a state unless the state agrees that "low-income women will be given priority in the provision of services and activities [under the program]." However, there is no prohibition against screening women who are not low income (a term which is not defined either by income or assets).

employers, for example, to contribute fewer dollars to employees' health insurance coverage, or to drop or reduce coverage to encourage individuals to enroll in the new program. There is no clear estimate of the extent of crowd-out associated with public programs. Estimates on the extent of crowd-out associated with Medicaid expansions vary considerably (see a review of the evidence by Dubay, 1999; Dubay and Kenney, 1997; Cutler and Gruber, 1996; Thorpe and Florence, 1998; Holahan, 1997), and states have implemented a number of strategies to deal with the risk of "crowd out." Under the State Children's Health Insurance Program (SCHIP), for example, states have implemented a number of strategies including: establishing a wait period, verification of insurance status, monitoring changes in employer contributions, and imposing obligations on employers and/or insurers to deter them from encouraging employees to enroll in the program (Wooldridge et al., 2003). The monitoring strategy is a first step in evaluating the extent to which the proposed program results in crowd-out and the imposing of obligations could be a further step if it is determined that crowd-out is occurring. Another policy question posed by some analysts is not how much crowd-out is taking place, but rather how much substitution is acceptable (Altera, 2001).

With respect to immigration status, under current law Medicaid covers immigrants who are otherwise eligible and who entered the country legally after August 16, 1996, only after five years of continuous residency. Otherwise eligible immigrants who are in the country illegally may qualify for Medicaid coverage only for emergency services. The Committee recognizes this as a policy area in which considerations other than health care are at play and on which the national debate is ongoing. The Committee therefore weighed in favor of following current Medicaid policy rather than reopening this debate. However, the Committee expects that a strongly refocused Ryan White CARE Act program will include these populations in care.

With respect to individuals in correctional facilities, federal Medicaid law denies coverage for otherwise eligible individuals who are inmates in state or local institutions. This reflects a long-standing federal policy that states and localities should bear the costs of providing health care to their correctional populations. Again, this debate goes well beyond health care policy to issues of fiscal federalism, and the Committee decided not to reopen this issue in connection with the new federal HIV program. The Committee cautions, however, that it is estimated that up to one-fourth (151,000–197,000 people) of the people living with HIV infection in the United States pass through a correctional facility each year (Hammett et al., 1998; Rich et al., 2001), and others become infected while in prison (Sabin et al., 2001). Most of these people return to the community. Developing more effective ways to manage HIV infection in prison and to promptly engage people in care upon release must become a higher priority for state and local officials.

> **Recommendation 6.3: The new program should entitle each eligible individual with HIV to coverage for a uniform, comprehensive package of services that reflects the standard of care for HIV/AIDS.**

In the view of the Committee, a new federally funded program that is structured as an individual entitlement is most likely to achieve the Committee's goal of extending coverage reflecting the standard of care for HIV/AIDS to low-income Americans with HIV regardless of the state in which they reside. Entitlement to a specified set of services is a defining characteristic of the current Medicare and Medicaid programs and distinguishes those programs from a federal block grant like SCHIP. In Medicaid, eligible low-income Americans are entitled to have certain services such as physician and hospital care paid for on their behalf when medically necessary, regardless of the state in which they live. In SCHIP, eligible low-income children have no such entitlement; a state may close new enrollment in the program or disenroll existing eligibles, or both, at any time. The use of enrollment caps or other techniques to terminate or limit benefits to otherwise eligible individuals is not consistent with an effective program of coverage for low-income individuals with HIV, which requires early and continuous access to HAART, without which they face increased illness, disability, and death.

As discussed in Chapter 2, nearly complete adherence to the prescribed HAART regimen is essential to securing optimal benefit from the treatment and to preventing drug resistance. This in turn requires services that support and promote early and continuous participation in care, particularly among populations with one or more co-morbidities. The Committee therefore recommends that the defined benefits package to which all eligible individuals with HIV would be entitled contain the following six elements:

1. antiretroviral therapy and other medications, including those that prevent complications and support retention in care;
2. obstetric and reproductive health services;
3. treatment for mental health and substance abuse problems on both an inpatient and outpatient basis;
4. case management services;
5. HIV prevention services (e.g., education regarding risk reduction in the clinical and community setting); and
6. primary care services.

The logic of this comprehensive benefits package is clinical efficacy. Timely initiation of HAART and maintenance of therapy are crucial to clinical effectiveness. Medications must include not just antiretroviral drugs but also drugs necessary to treat opportunistic diseases, such as antibiotics and antifungals. Because of the complexity of the disease process and the susceptibility of those with HIV to opportunistic infection, primary care services, case management, and prevention services are essential. To prevent HIV transmission from pregnant women to their newborn children, transmission that 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 for these conditions is fundamental to retention in care and continuation of therapies essential to disease management

The Committee acknowledges that the six core elements of the defined benefit package it recommends are not new. In fact, much of what is included in the benefit package can be found in some of the currently funded CARE Act programs. Title III-Early Intervention Services, Planning and Capacity Grants, for example, allow for coverage of medical evaluation, primary care, antiretroviral therapies, medical and mental health care, case management, screening and testing, and other services. Title IV of the CARE Act addresses the specified needs of women, infants, and children and youth living with HIV. It covers primary and specialty medical care, psychosocial services, logistical support and coordination, and outreach, and case management (HRSA, 2002) for this subpopulation of HIV-infected individuals. The HIV/AIDS Dental Reimbursement program acknowledges the need for well trained oral health providers to provide oral health services to clients with HIV. What is new about the Committee's recommendation is that it hopes to make these benefits available to all low-income individuals who need them, regardless of the state they live in.

Recommendation 6.4: The new program should reimburse providers who elect to participate at rates comparable to those paid by Medicare for comparable services.

As in the Medicare and Medicaid and CARE Act programs, the Committee suggests that provider participation in the new federal HIV program be voluntary. Whether an individual practitioner or clinic or hospital or other provider decides to participate would depend on a number of factors. One of these is the adequacy of reimbursement. This may be particularly important for services that are technically complex or are time- or resource-intensive, as are many of the services required for effective clinical management of individuals with HIV.

As discussed in Chapter 4, low reimbursement rates in many state Medicaid programs affect access to care for beneficiaries of that program.

In fact, Medicaid reimbursement to HIV/AIDS providers historically has been so low that in many states access to care for Medicaid beneficiaries with HIV/AIDS is the same as for those who are uninsured (Shapiro et al., 1999). Such access barriers are incompatible with the Committee's objective of reducing morbidity, mortality, and disability among low-income individuals with HIV. While reimbursement levels will not in and of themselves guarantee widespread participation by qualified providers, they are an important determinant. Perhaps the best illustration of this is the contrast between Medicare and Medicaid. Physician participation in Medicare, which sets reimbursement rates higher than those in most states, has been consistently higher than in Medicaid, resulting in better patient access to care and easier patient referrals (MedPAC, 2003). This is not to say that Medicare rates for every covered item or service are always optimal. However, a public program that relies on Medicare payment principles and rates is much more likely to succeed in attracting sufficient qualified providers than is a program that pays providers less.

> **Recommendation 6.5: To ensure that the new program is a prudent purchaser of drugs used in the treatment of HIV/AIDS, 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, as discussed below.**

Drug manufacturers sell the same product at different prices to different purchasers. The price established for the different segments of purchasers depends on the price sensitivity of each group or the extent to which the group would change the amount of a product it buys if the price increases or decreases. 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 off 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. Under this Medicaid Drug Rebate Program, established by the

Omnibus Budget Reconciliation Act of 1990, manufacturers must enter into rebate agreements with the Secretary of Health and Human Service and pay quarterly rebates to state Medicaid agencies. The amount of the rebate received by the State is calculated as the greater of 15.1 percent of the AMP or AMP per unit, or the difference between the AMP and the manufacturer's "Best Price" for brand-name drugs. The "Best Price" is the lowest price the manufacturers charge "best customers" other than Medicaid (e.g., wholesalers, retailers, non-profits, FSS, etc.). For generic drugs, state agencies are given a rebate of 11 percent of the AMP (DHHS, 2001).

Certain entities are eligible to purchase pharmaceuticals under the 340B Drug Discount Program, including ADAP programs. This program allows for these entities to purchase drugs directly from manufacturers though a centralized mechanism at a lower price or to obtain rebates under the state Medicaid rebate program. The 340B discount is roughly the AMP minus the Medicaid rebate amount. Twenty-two state ADAP programs that directly purchase pharmaceuticals through a centralized purchaser obtain drugs at the 340B discount price. Twenty-six state ADAP programs take advantage of their states' Medicaid unit rebates on a quarterly basis (Aldridge and Doyle, 2002). ADAP programs that use this method do not purchase drugs but reimburse retail pharmacies for prescriptions filled (DHHS, 2001).

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 ADAP programs (depending on how the ADAP 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 recommended that ADAP programs 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. As discussed earlier in this chapter, while the new federal program would be demonstrably cost effective, it would nonetheless impose a net new burden on the federal treasury. The incremental cost of providing antiretroviral therapy alone would be in the range of $2.65 billion over the next 10 years. At this projected level of expenditure, simple fiscal prudence requires that the new program use mechanisms currently in use by other federal purchasers to constrain its expenditures and give taxpayers confidence that it is paying for needed items and services in an efficient manner. The Committee estimates that purchasing antiretroviral drugs at the FCP would reduce the federal government's outlays by $419.3 million. It is also worth noting that further cost savings may be achieved by extending this policy to Medicaid Managed Care Organizations (MCOs), which currently must negotiate directly with pharmaceutical manufacturers to obtain discounts on drugs.

The Committee recognizes that pricing policies 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 to other purchasers to offset revenue losses resulting from the lower reimbursement for HIV/AIDS drugs (GAO, 2000). The Committee takes this matter seriously: after all, 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. However, 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.

The preceding concerns led the Committee to conduct the following analysis, which suggests that there is substantial room for lowering prices while still substantially increasing manufacturer net revenues with this initiative. Specifically, the added revenue associated with increasing the number of individuals on HAART by 58,697 should be compared with the decrease in revenue for 123,151 individuals already on HAART who switch to the new program and thus obtain drugs for a more discounted price. The Committee calculated the discount off of the current Medicaid price at which net revenue is zero. We conservatively assumed that the marginal cost of production is $1,500 per person year of HAART therapy. This is conservative because brand-name HAART is available for low-income countries at costs substantially less than this (Médecins Sans Frontières, 2003). With this assumption on marginal cost of production, a 27 percent discount leads to revenue neutrality. Thus, any discount less than 27 percent leads to increased revenue to manufacturers, further defraying the cost of research and development. While this quantitative analysis is not the final word on maintaining adequate profits for manufacturers, it suggests that there is room for price discounts while still increasing net revenue and profits and thus maintaining incentives for research and development. Ideally the Committee would prefer to rely on a formal analysis of the future costs of research and development for new ARV medications and their potential market. However, such an analysis would be based on hypothetical assumptions and is beyond the scope of the Committee's research resources. In the absence of such an analysis, the Committee believes that a discount that *increases* net revenues in association with a drug-benefits expansion should assure ARV manufacturers that the United States government is committed to allowing them to recover substantial research and development costs.

> **Recommendation 6.6: The new program should adequately fund a nationwide demonstration and evaluation of the effectiveness of Centers of Excellence in delivering covered services to eligible individuals with HIV.**

Consistent with past IOM reports (IOM, 2000, 2001, 2002, 2003a, 2003b), the Committee embraces a chronic care model for HIV care and recognizes the need for any new delivery system to be grounded in the tenets of quality care. Centers of Excellence (CoEs) surfaced as a concept that embodies these goals. In the Committee's view, 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) be accountable to patients and to the programs that are purchased on their behalf. As discussed in Chapter 5, one promising model for a system of care meeting these criteria is the CoEs. The Committee recognizes that this model is not currently operational in many communities, that CoEs can be structured in a number of ways, and that testing is required to see which model is feasible in different geographic areas and circumstances. However, the Committee believes that the new federal program offers an opportunity to test this model for the benefit of low-income individuals with HIV, providers, and public and private purchasers. The Committee therefore recommends that the new program include adequate funding for a nationwide, multiyear demonstration of the effectiveness of CoEs in delivering the standard of care for HIV/AIDS to eligible individuals. The demonstration should include an independent evaluation of the quality, cost, and outcomes of the services furnished. Positive evaluation results would provide support for a wider dissemination of the model and the possibility of incorporating other responsibilities such as research to improve care delivery.

> **Recommendation 6.7: 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.[7]

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 Ryan White 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.

The proposed program has significant implications for a number of CARE Act sub-programs, notably Title II and ADAP. As noted before, ADAP represents the majority of Title II expenditures. Under the new program, the majority of these expenditures would be covered. However, the Committee recognizes that low-income immigrants with HIV infection will not be eligible for the federal program. Thus, a percentage of current ADAP funds should continue to be available to address the needs of this population and the public health imperative to control the spread of this infectious disease.

Title I under the CARE Act would also be notably impacted by the new program. If implemented as recommended by the Committee, the new program would lessen the need for Title I. Title I funds are primarily, but not entirely, devoted to services included in the Committee's benefit package and, as an entitlement program, eligibility is triggered by HIV infection; thus, funds follow the individual. Under this scenario, planning bodies would be refocused, and Title I funding savings could be used to offset federal spending on the HIV-CCP or some portion of the funds shifted to Title III.

The Committee gave considerable attention to the need for continuing to allocate funds for Title III, Early Intervention Services discretionary grants. Current grantees include community and migrant health centers, hospitals or university-based medical centers, and city and county health

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[7] For a discussion on the new program's budget impact on the Ryan White CARE Act, please see the earlier section of this chapter.

departments. Grantees use these funds to conduct risk reduction, counseling, and testing, and to provide clinical care, medications, and case management (GAO, 2000). The Committee envisions two possible roles for Title III grantees under the new program. In one role, Title III grantees—community health centers, hospitals, or university-based medical centers—with high-quality services and accountability structures, are engaged to participate as part of CoEs since many of the services they provide are included in the proposed program. In the second role, the Committee envisions Title III grantees acting to address two specific groups with unmet needs under the new program: those populations ineligible for the program and vulnerable populations who are often unable to access formal systems of care. These populations require additional outreach and support, services which the CARE Act system provides. In addition, these programs are a means to provide voluntary counseling and testing that enables individuals to be made aware of their infection at an earlier disease stage and to enter care. Thus, a refocused Title III program could continue to fulfill the mission of the CARE Act by covering the much smaller gaps remaining in the new system and acting as a link to CoEs (assuming they are implemented) by guiding the most vulnerable persons into care.

CONCLUSION

The Committee's recommendation for the establishment of a federally funded, state-administered entitlement to care for low-income Americans with HIV may strike some as imprudent. After all, the federal government is already experiencing high budget deficits, and the Committee's recommendation would require increased federal spending. In addition, current notions of federalism assume the devolution of responsibility for social welfare functions from the federal government to the states, and the Committee's recommendation would elevate all financial responsibility for HIV care to the federal level. In short, the Committee's recommendation does not reflect conventional wisdom. Instead, it reflects the Committee's conviction that such a program is demonstrably the most effective way for the United States to respond to the HIV epidemic and the needs of those affected by it.

With the development of HAART and other tools, we now have the technology to extend life and reduce morbidity and disability among those Americans with HIV. The Committee's estimates indicate that the cost effectiveness of delivering these technologies to low-income individuals with HIV compares favorably with that of other common public health interventions, such as frontal air bags and radon mitigation. To possess a demonstrably life-saving and cost-effective technology but not make it available to

Americans with HIV who cannot otherwise afford it is, in the Committee's view, indefensible.

Making these technologies available to those in need will require additional resources from the public sector. While both the federal government and state governments face serious budgetary constraints, it is clear to the Committee that the federal government is the proper locus of financial responsibility for this purpose. The HIV epidemic is global in scope, not state-specific; the federal government's revenue base is broader and more structurally sound than that of the states; and uniformity of eligibility and benefits, essential to an effective treatment of HIV nationally, cannot be sustained over time if states are required to fund the program. Of course, federal financing does not necessarily imply the establishment of a new federal bureaucracy. Indeed, the Committee recommends that the new national program be administered by the states. But without additional federal resources, harnessed through a national program along the lines recommended by the Committee, low-income Americans with HIV will continue to suffer avoidable death and disability. Our nation can and must do better.

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Appendix
A

Technical Appendix: Estimating the Impact and Cost of Expanded HIV Care Programs

INTRODUCTION

The charge given the Committee on Public Financing and Delivery of HIV Care is to develop policy recommendations that would "mitigate the discontinuities and inefficiencies of current public funding systems" that support services for people living with HIV and "eliminate resulting disparities in access to care by filling identified financing and service gaps." The Committee was specifically directed to consider as an option (including determining the expected costs, savings, and overall financial impact of) modifying Title XIX of the Social Security Act (Medicaid) to create an eligibility category based on HIV infection.

To guide its deliberations, the Committee developed estimates of the likely impact (financial and on the health of the HIV-infected population) of alternative policy options. This appendix presents the methods and data the Committee used to model the impact of different financing options, and the results. Because of time constraints, the analysis was focused on the two financing options believed by the Committee to provide the best opportunity for meeting the goals it identified for a desirable system of care. Both of these options create an entitlement to care for those diagnosed with HIV who meet established income eligibility requirements. One option, the HIV Comprehensive Care Program (HIV-CCP), is a public insurance program funded entirely by the federal government and administered by the states. The other option, Optional Medicaid Eligibility Group with Increased Federal Match (Enhanced Medicaid), is a modification to the Medicaid program that provides for an enhanced federal match (70 percent on average) to states that extend eligibility to individuals in the early stages of HIV disease. Both options are described in detail in Chapter 5. For brevity, "the Committee" is replaced by "we."

METHODS

The approach to the analysis was to pose and then answer three broad questions for each option:

- What are the likely health benefits of implementing an alternative approach to public financing of HIV care in terms of mortality and life expectancy? In other words, what incremental gains in health does an additional investment in HIV care buy?
- What is the cost effectiveness of implementing an alternative approach?
- What is the cost of implementing the proposed alternative approach?

MODELING OVERVIEW

To answer these questions, we conducted an analysis that involved five steps:

1. Estimate the number of people not currently receiving highly active antiretroviral therapy (HAART) who are likely to begin HAART with alternative methods for financing care.
2. Estimate the cost and health implications over 10 years of each financing option, including the anticipated gain in life expectancy (adjusted for quality of life) and reduced mortality (premature deaths averted) among those who participate in the programs.
3. Estimate the cost per quality-adjusted life-year (QALY) gained associated with enrollment in each financing option and compare the estimates to other investments in health.
4. Estimate the short-term (first-year) cost implications for each public payer.
5. Compare the results for each option to one another.

Our approach was to gauge the potential increase in HAART use associated with a policy to expand access to HIV care by estimating how many individuals are currently in need of HAART and, of those, how many do not receive HAART. We refer to the number of people who need but do not receive HAART as the "HAART use deficit." Our estimates of current HAART use are based primarily on data collected between 1996 and 1998, the beginning of the HAART era, which presents a limitation to our analysis.

There is also data from 2000, however, that suggest that antiretroviral therapy (ART) (but not HAART) was used by about two-thirds of individuals with AIDS. This, along with unpublished data from a Kahn (2002) study on HAART use combined with ART use, suggests overall HAART use of approximately 45 percent. Recognizing that HAART use may have grown in the interim, especially for individuals with late-stage AIDS, we used a higher value of estimated HAART use (64 percent) based on an AIDS diagnosis by the 1987 definition.

We then estimated the number of people who would receive HAART assuming implementation of a proposed change in public financing of HIV care. This estimate was based on program eligibility and enrollment, as well as the association of insurance status and ancillary services covered with HAART use. Current and anticipated HAART use were then compared to calculate the incremental gain in HAART use expected as a result of the creation of a new entitlement to care.

We used a disease state-transition (Markov) model of HIV disease progression adapted from Kahn et al. (2001) to estimate the health and financial impact of providing greater access to HAART. This model portrays a population of individuals with HIV disease classified into five increasingly severe disease states: asymptomatic with a CD4 cell count >500, asymptomatic CD4 200–500, symptomatic CD4 200–500, AIDS by the 1993 definition only (including CD4 < 200), and AIDS by the 1987 clinical definition. The model specifies transition probabilities between disease states and to death, per time period. These probabilities are derived from published empirical studies. The model thus predicts how the mix of HIV disease states evolves over time for the specified infected population. The transition probabilities are reduced for individuals on HAART, based on a structured review of HAART clinical trials which used disease progression or surrogate markers as endpoints. Thus, increased insurance coverage, such as with HIV-CCP, slows disease progression by increasing the likelihood of HAART use.

The original model produced three clinical outcomes. New AIDS diagnoses represent the progression from any pre-AIDS state to AIDS (by the CDC's 1993 definition). Deaths include all causes, as generally reported. Life years are cumulative years of life for all HIV-infected individuals, unadjusted for quality of life. The model was updated by the Committee to calculate QALYs, based on the most recent reviews of the utility of HIV health states. The model also calculates the costs of providing HIV medical care, by assigning to each individual in each time period a set of costs reflecting the Committee's estimates of the costs of HIV medical care by severity of illness (see separate section on costs).

We also estimated the health and cost implications of ancillary services provided by one financing option (HIV-CCP). This financing option has a benefit package that includes case management, mental health care, and treatment of substance abuse. For each service, we estimated from previously reported estimates the unmet need, the costs of meeting that need, and, for the latter two, expected increases in quality of life.

We estimated the cost per QALY for each option using the standard cost–utility ratio. The numerator includes societal costs for medical care and ancillary services under each financing alternative, minus the same costs with current financing. In the denominator is the gain in QALYs as compared with the current situation.

We estimated the first-year financial impact on the budgets of the federal government, collectively on the budgets of the states, and on the cost of care for the uninsured. This was done based on how services are currently financed, expected increases in cost, and specified changes in federal matching rates.

Finally, we compared the financing options on key outcome measures. This comparison indicated the incremental differences in costs, health gains, and cost per health gain. All costs are adjusted to 2002 using the medical component of the United States consumer price index. All future costs and health outcomes are discounted to 2002 using a discount rate of 3 percent per year.

FINANCING OPTIONS

We defined three financing options: maintaining the system as it currently exists, a federally funded eligibility expansion with a comprehensive benefit package (HIV-CCP), and a state-option eligibility expansion with 70 percent federal match (Enhanced Medicaid). Descriptions follow of the three options that focus on characteristics that we explicitly modeled.

The “current” option is based on the most recent and representative data, as described in the Inputs section. To facilitate adjustment of costs for specific services for the alternative financing options, we characterized current costs by type of service. The services included HAART, viral resistance testing, HIV monitoring labs, outpatient visits (adjusted for specifically listed outpatient services), other medications, inpatient care, emergency care, substance abuse treatment, mental health care, case management, dental care, obstetrics/gynecology, home health/visiting nurse care, and prevention counseling. Although the list is extensive, we did not include services such as housing, food, transportation, child care, and legal advocacy, which can also be necessary depending on the circumstances of the individual. Utilization was set to levels reported in current literature (primarily the HIV Cost and Services Utilization Study [HCSUS]), and other sources as well, reflecting the current mix of insurance and associated benefits packages.

The HIV-CCP option is a highly incentivized expansion in eligibility, accompanied by a 100 percent federal financing match, a strengthened benefit package, and higher outpatient reimbursement rates. Eligibility is based on having an income that is below 250 percent of the federal poverty level (FPL)—$22,150 for an individual in 2002. Enrollment is assumed to be high due to incentives to both providers (higher reimbursement) and patients (better benefits and better paid providers). The benefits package is richer than current average Medicaid benefits because unrestricted coverage of three key ancillary services (case management, mental health, and substance abuse treatment) is included. Outpatient reimbursement is increased 20 percent as compared with Medicaid to be comparable to Medicare, plus 5 percent on average for Centers of Excellence.

For the HIV-CCP, increases in utilization are in three areas. First, there is an increase in ancillary services, due to improved coverage. Second, some individuals who were previously out of care enter into regular care. Third, HAART use (and viral resistance testing) increases because being insured is associated with higher HAART use. We assume that because of enhanced reimbursement, HAART use will equal that seen with private insurance. HAART use further increases because of the improved coverage of ancillary services, which have been independently associated with higher HAART use. Because these services largely help to address problems associated with poverty, and because low income is independently associated with lower HAART use, we refer to these gains as partially alleviating the poverty effect.

The Enhanced Medicaid option is a state-discretion expansion in Medicaid eligibility, accompanied by a 70 percent federal financing match, with no change in benefits or reimbursement. Eligibility is also based on having an income below 250 percent of the FPL. Enrollment is lower than with the HIV-CCP entitlement due to much lower incentives to providers and patients. Increases in utilization are just for individuals who begin to use HAART (and viral resistance testing) as a result of becoming insured. Without enhanced reimbursement, HAART use among enrollees is assumed to equal that reported for Medicaid.

INPUTS

We conducted extensive literature searches to identify inputs for this model of HIV disease and health services use, and consulted with a number of experts. For most inputs, data were available that directly provided input values or could be readily adapted for that purpose. All cost data were adjusted to 2002 dollars using the medical care consumer price index. For those inputs lacking data, we relied on expert judgment, including discussion within the Committee, and chose values that tended to understate the impact of the modeled policies. Due to uncertainty in inputs, we specified uncertainty ranges and conducted sensitivity analyses.

The following discussion is divided into four categories: HIV population characteristics, HAART use, HIV clinical services and costs, and effects of financing options. The text parallels Table A-1.

HIV Population and Characteristics

According to Fleming et al. (2002), approximately 950,000 individuals are infected with HIV. Among those infected, Fleming further estimates that approximately 670,000 are aware of infection. Of these, approximately 360,000 have AIDS (CD4 < 200, or AIDS-defining condition). Based on data from in-care populations, we assume that 150,000 of these have AIDS by clinical criteria and 210,000 by CD4 < 200 (Bozzette et al., 1998). As individuals are more likely to be aware of HIV infection later in disease (e.g., if infected for longer and/or symptomatic), we assumed a greater number of aware individuals in each more severe disease state.

Information regarding income level and insurance status of HIV-infected individuals was obtained from HCSUS, a national probability sample of people with HIV in care. According to Bozzette et al. (1998), the majority (72 percent) of those with HIV are low income (household income < $25,000). Among these low-income individuals, nearly 25 percent are uninsured and 61 percent rely on Medicaid or Medicare. In contrast, of those with incomes > $25,000, most (78 percent) rely on private insurance (Bozzette et al., 1998).

Information regarding disease stage and insurance status was also obtained from HCSUS (not shown in table). Individuals with clinical AIDS are about two-thirds as likely to have private insurance as are asymptomatic individuals, and are correspondingly more likely to have Medicaid. This reflects the impoverishing effects of severe AIDS as well as the AIDS disability requirement for HIV-associated Medicaid eligibility.

HAART Use and Need

Estimates of the current prevalence of HAART use are drawn from a number of sources. Studies of HIV-infected populations (AIDS and HIV non-AIDS) in New York State and in three metropolitan areas used local data sources (HIV/AIDS surveillance, lab reporting, Medicaid and AIDS Drug Assistance Program [ADAP] billing claims) from 2001 in a framework endorsed by the Health Resources and Services Administration (HRSA) to estimate participation in HIV care (Kahn, 2002). Studies of Medicaid and ADAP populations were conducted for 1998 in four heavily HIV-affected states (Kahn et al., 2002). Additional older estimates provide

TABLE A-1 Analysis Inputs

HIV Population	Baseline Estimate	Sources
Infected	950,000	Fleming et al., 2002
Aware	670,000	Fleming et al., 2002

HIV Population Characteristics	Baseline Estimate	Sources
By clinical stage (among aware)		
CD4 > 500	0.08	Bozzette et al., 1998; Expert Judgment
CD4 499—350	0.15	
CD4 349—200	0.24	
CD4 199—50	0.31	
CD4 < 50	0.22	
By income level		
Proportion <$25,000	0.72	Bozzette et al., 1998
Proportion >$25,000	0.28	
By insurance status, among aware		
Proportion Medicaid, other public (including Medicare)	0.50	Bozzette et al., 1998; Expert Judgment
Proportion uninsured	0.25	
Proportion private	0.25	

HAART Use	Baseline Estimate	Sources
Current use		
Total current antiretroviral (ARV) use	230,000	Kahn, 2002; Kahn et al., 2002; Moorman et al., 1998; Palella et al., 1998
By clinical stage		
ARV current use (CD4 50–200)	0.40	Kahn, 2002; Kahn et al., 2002; Moorman et al., 1998; Palella et al., 1998
By income		
odds ratio (OR) getting ARV if < $25,000	0.60	Andersen et al., 2002
By insurance status		
OR getting ARV if uninsured	0.74	Andersen et al., 2002
OR getting ARV if Medicaid alone	0.83	
OR getting ARV if Medicare—other	0.82	
OR getting ARV if HMO insurance	0.90	

continued

TABLE A-1 Continued

HIV Clinical Costs[b]	**Use**	**Cost per person year (ppy)**	**Sources**
HAART (CD4 50–200)		$9,222	Schackman et al., 2002; Expert Judgment
Other medicines	1.00	$3,980	Aldridge et al., 2002; Bozzette et al., 2001
Prevention counseling	1.00	$272	Holtgrave et al., 2002
Monitoring labs	1.00	$682	Schackman et al., 2002
Outpatient medical	1.00	$1,629	Bozzette et al., 1998; Bozzette et al., 2001; Shapiro et al., 1999
Sexually transmitted disease, tuberculosis, and hepatitis screening	1.00	$14	IOM, 1997; Gable et al., 1996; HepNet Hepatitis C InfoCenter, 2003
Inpatient medical	1.00	$4,246	Bozzette et al., 1998; Bozzette et al., 2001
Emergency department	0.33	$846	Bozzette et al., 1998
Dental	1.00	$513	Bozzette et al., 1998; Capilouto et al., 1991
Obstetrics/gynecology	0.20	$446	Bozzette et al., 1998
Home health/visiting nurses	0.20	$5,000	London et al., 2001; MetLife, 2002

	Baseline Use	**Gain in Use Due to Improved Coverage**	**OR for ARV Use**	**Cost ppy**	
Substance abuse treatment	0.075	0.075	1.700	$6,193	Ashman et al., 2002; Burnam et al., 2001; Conover and Whetten-Goldstein, 2002; Finkelstein and Tiger, 2002; Lo et al., 2002; Marx, 2002; Messeri et al., 2002; Sherer et al., 2002; Strathdee et al., 1998; Zaric et al., 2000
Mental health	0.220	0.09	1.400	$1,380	Ashman et al., 2002; Burnam et al., 2001; Lo et al., 2002; Messeri et al., 2002; Sambamoorthi et al., 2000; Sherer et al., 2002; Turner et al., 2001

TABLE A-1 Continued

	Baseline Use	Gain in Use Due to Improved Coverage	OR for ARV Use	Cost ppy	
Case management	0.600	0.15	1.500	$826	Katz et al., 2001; Lo et al., 2002; Magnus et al., 2001; Marx, 2002; Messeri, 2002; Sherer, 2002

Federal Matching Rates for Medicaid		Sources
Florida	58.83	DHHS, 2003
Georgia	59.60	
Illinois	50.00	
New York	50.00	
Texas	59.99	

Effects of Financing	Baseline Estimate	Sources
Proportion eligible		
Publicly insured/in care	0.92	Expert Judgment
Publicly insured/not in care	0.975	Expert Judgment
Uninsured/in care	0.53	Expert Judgment
Uninsured/not in care	0.50	Expert Judgment
Enrollment rates		
Publicly insured/in care	0.90	Expert Judgment
Publicly insured/not in care	0.40	Expert Judgment
Uninsured/in care	0.90	Expert Judgment
Uninsured/not in care	0.30	Expert Judgment
If enrolled, in care		
Publicly insured/in care	1	Expert Judgment
Publicly insured/not in care	0.75	Expert Judgment
Uninsured/in care	1	Expert Judgment
Uninsured/not in care	0.75	Expert Judgment
Enrollment rate adjustment, Enhanced Medicaid program	0.667	Expert Judgment

Health Effects	Baseline Estimate	Sources
Utility deficit due to advanced disease	0.12–0.24	Tengs and Wallace, 2000
Utility change (drop) for being on HAART	–.03	Expert Judgment

continued

TABLE A-1 Continued

Health Effects	Baseline Estimate	Sources
Utility gain for being on HAART (symptom reduction)	0.06–0.13	Expert Judgment; see text
Utility adjustment for receiving substance abuse treatment	0.1	Zaric, 2000; Expert Judgment
Utility adjustment for receiving mental health treatment	0.05	Simon et al., 2001; Wang et al., 2002; Expert Judgment
Increase in Service Utilization		
Substance abuse treatment	0.075	Zaric, 2000; Expert Judgment
Mental health treatment	0.09	Simon et al., 2001; Wang et al., 2002; Expert Judgment
Case management	0.15	Expert Judgment

nationally representative data of individuals in care (Bozzette et al., 1998) and individuals in private and public HIV specialty clinics (Moorman et al., 1998; Palella et al., 1998). Based on these data, we estimated that 230,000 individuals are on HAART, including 40 percent of those with a nadir CD4 count between 50 and 199.

To determine the association of HAART use with income level and insurance status used data from HCSUS (Andersen et al., 2000). Though this data is from 1996, somewhat more recent nationwide data (from 1997–1998) and analyses of data from the state and local levels suggest the persistence of income and insurance effects found by Andersen et al. (Bhattacharya et al., 2003; Goldman et al., 2003; Kahn, 2002; Kahn et al., 2002; Goldman et al., 2001; Hsu et al., 2001). Low-income individuals (family income < $25,000) were less likely to be on HAART (odds ratio [OR] = 0.6). The odds of being on HAART also varied by insurance status, from 0.74 among those with no insurance, to 0.83 among Medicaid recipients, to 0.90 among those with health maintenance organization (HMO) insurance (reference group is those with private fee-for-service insurance) (Andersen et al., 2000).

We defined HAART need based on HIV disease stage. All those with AIDS "need" HAART. Although there are many legitimate reasons not to provide HAART when someone has AIDS, and many patients may decline HAART, clinical guidelines suggest offering and using HAART. Among those with HIV disease with a CD4 count of 200 to 350 (often symptomatic), we assume that half need HAART, consistent with the guidelines' suggestion for flexibility in this range. For those even earlier in disease, we define need as the small percentage estimated to be currently using HAART, which at that stage is not recommended (DHHS, 2003).

HIV Clinical Services and Costs

To determine HAART costs, estimates were reviewed from HCSUS data, state and territorial ADAPs, and the 1999 Red Book average wholesale price (AWP). We used the last of these, further adjusted to reflect Medicaid drug pricing (15 percent below average manufacturer price, which is 20 percent below AWP on average) (Schackman et al., 2002; DHHS, 2000). Thus, we estimated total per-person annual cost of HAART to be $9,222.

According to Committee estimates, individuals with HIV need a number of clinical services. Among individuals who have developed AIDS (CD4 < 199), in addition to benefiting from HAART, we estimate that all need the provision of medications beyond HAART as appropriate, such as opportunistic infection prophylaxis (DHHS, 2003). We also estimate that all individuals with HIV, regardless of disease stage, need prevention counseling, monitoring labs, inpatient and outpatient medical care, sexually transmitted disease (STD) screening and treatment, and dental care (100 percent need for each).

Among a smaller proportion of individuals with HIV, there is a need for additional clinical services. Based on estimates from HCSUS data, we estimate that a third of individuals with HIV need coverage for emergency department visits. Furthermore, we estimate that a fifth would benefit from obstetrics/gynecology services, home health/visiting nurses (according to data from HCSUS), and food services (based on data from a San Francisco study). A small percentage would also benefit from transportation services (also based on the data from San Francisco).

Utilization of case management, substance abuse treatment, and mental health treatment was estimated from published estimates of unmet need for care. We estimated an increase from 15 to 30 percent in use of substance abuse services among injection drug users (IDUs), who constitute half of individuals with HIV/AIDS, based on published data (Sherer et al., 2002) and expert judgment, including Committee member experience with offering substance abuse treatment to IDUs. We estimated an increase of 9 percent in mental health treatment, representing an estimated 18 percent unmet need and a 50 percent likelihood of seeking needed care (Burnam et al., 2001; Expert Judgment). We estimated a 15 percent increase in case management, based on expressed unmet need (Sherer et al., 2002). Costs for these services range from $852 per person per year for case management (Messeri et al., 2002) to $5,250 for treatment of substance abuse (Finkelstein and Tiger, 2002; Zaric et al., 2000).

In addition, we estimate that several of the services outlined would lead to a greater chance of receiving HAART. The provision of substance abuse treatment is associated with an OR for receiving HAART of 1.7 (Ashman et al., 2002; Messeri et al., 2002; Strathdee et al., 1998). Similarly, the receipt of mental health treatment is associated with a greater chance of receiving HAART (OR of 1.4) (Ashman et al., 2002; Magnus et al., 2001; Messeri et al., 2002), and case management services are associated with an OR for receiving HAART of 1.5 (Katz et al., 2001; Magnus et al., 2001; Messeri et al., 2002).

These estimates were formed based on a number of sources, including HCSUS data, data collected from HRSA's Client Demonstration Project sites (specifically, data on people living with HIV/AIDS collected from service providers in a delimited geographic area), an ongoing longitudinal study of HIV-infected individuals living in New York City, databases from a multiservice program in New Orleans, and a cohort study of IDUs in British Columbia.

Federal Matching Rates for Medicaid

We used the 2003 federal matching rates for Medicaid programs in five states—Florida, Georgia, Illinois, New York, and Texas—to estimate the cost of the Medicaid expansion options that were considered (DHHS, 2003).

Effects of Financing on Program Participation

The effects of financing mechanisms on insurance status and access to care depend on how many individuals are eligible for the program and what proportion chooses to enroll. We used HCSUS data on insurance status and income level to estimate the number of individuals who would be eligible for the program (Bozzette et al., 1998).

To determine the number of eligible persons who would enroll in the program, we attempted to find enrollment data on comparable public insurance programs. We found, however, that there were no public programs comparable to the recommended program, and little enrollment data exist from any public program. As a result, we relied on our consensus expert judgment as the basis for this assumption. We assumed that those currently in care, either publicly insured or uninsured, are highly motivated to seek care and that 90 percent of them would choose to enroll in the new program. Of those not currently in care who are publicly insured or uninsured, we assumed that much lower proportions would enroll in the new program—40 percent and 30 percent, respectively.

To estimate the enrollment rate for the Enhanced Medicaid program, we further reduced those numbers by a third to reflect the added barriers of a Medicaid program, such as lack of provider participation and the absence of benefits that might draw people into care. Again relying on expert judgment, we assumed that of those who enroll, 100 percent of those in care prior to enrollment would remain in care, but that just 75 percent of those who enroll and are not currently in care would enter care.

Health Status Effects of HIV Disease, HAART, and Ancillary Services

Using the quality of life adjustments from Tengs and Wallace (2000), we estimated a utility deficit for advanced disease of 0.12 to 0.24, depending on severity of illness. Because HAART is a complex regimen with multiple side effects, we used the Committee's expert judgment to assign a utility drop of –0.03 for being on HAART. To adjust for the symptom relief of HAART, we assigned a utility gain in the range of 0.06 to 0.13 for taking HAART, reflecting the product of efficacy (i.e., relative reduction in clinical events) and the utility deficit (above).

We used expert judgment to assign a utility gain of 0.1 for receiving substance abuse treatment and an increase in service utilization of 0.075 (Zaric et al., 2000). To determine the utility and service utilization adjustment for mental health treatment, we identified the health utility gain (0.4) from receipt of effective treatment for depression reported in Simon et al. (2001), and adjusted for estimates of the timeliness of care seeking, the imperfect effectiveness of mental health treatment, and the delay of symptom alleviation with effective treatment (Expert Judgment; Wang et al., 2002).[1] Thus, we conservatively estimate a utility gain of 0.05 for those seeking mental health care and an increase in service utilization of 0.09 as a result of receiving mental health treatment. Finally, we used expert judgment to estimate an increase of 0.15 in service utilization for receiving case management services.

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[1] "Service utilization" is defined as the prevalence of use of the specified service during one year, i.e., the percent of the population of interest using this service at least once. This is multiplied by the mean annual cost per user to estimate mean annual cost per person in the population of interest.

RESULTS

HAART Use Deficit

The estimates are based on an initial finding that there are 950,000 individuals living with HIV and that 670,000 individuals are aware of their HIV status, of whom 25 percent (167,500) are uninsured and 50 percent (335,000) are insured through a program financed with public dollars (Table A-2). Among those individuals who are aware that they are infected, we estimate that 69 percent (463,069) are in need of combination antiretroviral therapy and that slightly fewer than half in need of HAART (230,000 individuals) receive antiretroviral medications, leaving a deficit in HAART use of 233,069 for this cohort. We believe that an additional 82,000 individuals who are infected but unaware of their HIV status are also in need of HAART.

HIV-CCP HAART Use Gain

For the purpose of estimating the benefits and costs of its proposals, we assumed that the creation of a health care entitlement would not increase enrollment in care or HAART use among individuals who are unaware of their HIV status or who have private insurance. Of the estimated 502,500 individuals who are infected and aware of their HIV status, and who are either uninsured or have public insurance, 80 percent (400,975) would be eligible to enroll in the HIV-CCP program. The Committee estimates that 71 percent (285,503) of those eligible would enroll and receive care, that 78 percent (222,681) of those individuals enrolled and in care should be on HAART, and that 82 percent (181,848) in need of HAART would receive antiretroviral therapy paid for by the program.

We also estimate that there would be 106,849 individuals (uninsured or publicly or privately insured) who would not enroll in the program but would be on HAART. Therefore, the Committee predicts that the total number of individuals on HAART would be likely to rise from 230,000 to 288,697 with implementation of the HIV-CCP program, reducing the number of individuals in need of, but not receiving, HAART by 58,697 individuals (Table A-3). Of those 58,697 we estimate that less than two-thirds (57 percent) will receive HAART as a result of gaining access to insurance coverage or higher provider reimbursement (leading to a greater willingness to accept publicly insured patients). The remainder of those newly receiving HAART in the program will do so because of the enabling effects of ancillary services such as substance abuse and mental health treatment and case management (Table A-4). Almost all (98 percent) of enrollees starting HAART are symptomatic or have AIDS. Specifically, 34 percent have AIDS by the clinical

TABLE A-2 Estimate of Need for HAART, Current HAART Use, and HAART Use Deficit Given Existing System of Public Financing and Delivery of HIV Care

Population	**Estimate by Subpopulation**	**Estimate Total**
Infected with HIV		950,000
Aware of HIV status		670,000
Care status of those aware of HIV status		
In care		470,000
Not in care		200,000
Insurance and care status of those aware of HIV		
Private (31%)		
In care	117,500	
Not in care	50,000	
Public (47%)		
In care	235,000	
Not in care	100,000	
Uninsured (22%)		
In care	117,500	
Not in care	50,000	670,000
Those aware who need HAART by insurance and care status		
Private		
In care	88,821	
Not in care	26,285	
Public		
In care	191,187	
Not in care	56,579	
Uninsured		
In care	77,317	
Not in care	22,881	463,070
Those aware and in care who receive HAART by insurance status		
Private	62,350	
Public	123,024	
Uninsured	44,626	230,000
Those aware who need but do not receive HAART by insurance and care status (HAART use deficit)		
Private		
In care	26,471	
Not in care	26,285	
Public		
In care	68,162	
Not in care	56,579	
Uninsured		
In care	32,691	
Not in care	22,881	233,069

TABLE A-3 Increase in HAART Use Anticipated Given Implementation of HIV-CCP

Population	Estimate by Subpopulation	Estimate Total
Eligible		
Public		
Currently in care	216,200	
Currently not in care	97,500	
Uninsured		
Currently in care	62,275	
Currently not in care	25,000	400,975
Enroll, if eligible		
Public		
Currently in care	194,580	
Currently not in care	39,000	
Uninsured		
Currently in care	56,048	
Currently not in care	7,500	297,128
In care, once enrolled in the program		
Public		
Currently in care	194,580	
Currently not in care	29,250	
Uninsured		
Currently in care	56,048	
Currently not in care	5,625	285,503
Need HAART in the program		
Public		
Currently in care	158,303	
Currently not in care	23,797	
Uninsured		
Currently in care	36,880	
Currently not in care	3,701	222,681
Receiving HAART in the program		
Public		
Currently in care	129,275	
Currently not in care	19,433	
Uninsured		
Currently in care	30,118	
Currently not in care	3,023	181,848
Receiving HAART outside of the program (private and other public programs)		
Private (in care)	62,350	
Public (in care)	21,160	
Uninsured (in care)	23,339	106,849
Gain in HAART use		
Public		
Currently in care	27,411	
Currently not in care	19,433	
Uninsured		
Currently in care	8,831	
Currently not in care	3,023	58,697

TABLE A-4 Increase in HAART Use Anticipated Given Implementation of Enhanced Medicaid

Population	Estimate by Subpopulation	Estimate Total
Eligible		
Public		
Currently in care	216,200	
Currently not in care	97,500	
Uninsured		
Currently in care	62,275	
Currently not in care	25,000	400,975
Enroll, if eligible		
Public		
Currently in care	129,721	
Currently not in care	26,000	
Uninsured		
Currently in care	37,365	
Currently not in care	5,000	198,086
In care, once enrolled in Enhanced Medicaid program		
Public		
Currently in care	129,721	
Currently not in care	19,500	
Uninsured		
Currently in care	37,365	
Currently not in care	3,750	190,336
Need HAART in Enhanced Medicaid program		
Public		
Currently in care	105,536	
Currently not in care	15,864	
Uninsured		
Currently in care	24,587	
Currently not in care	2,468	148,455
Receiving HAART in Enhanced Medicaid program		
Public		
Currently in care	67,910	
Currently not in care	10,208	
Uninsured		
Currently in care	15,821	
Currently not in care	1,588	95,527
Receiving HAART outside of the Enhanced Medicaid program (private and other public programs)		
Private (in care)	62,350	
Public (in care)	55,114	
Uninsured (in care)	30,435	147,899
Gain in HAART use		
Public		
Currently in care	0	
Currently not in care	10,208	
Uninsured		
Currently in care	1,630	
Currently not in care	1,588	13,426

TABLE A-5 Derivation of Increase in HAART Use for 58,697 Individuals Estimated to Begin HAART Use as a Result of the HIV-CCP

Mechanism for Increase in HAART Use	Individuals Brought onto HAART
Moving from uninsured to insured (assumes publicly insured)	17,449
Enhanced reimbursement resulting in HAART use at private insurance levels	15,717
Enabling effects of ancillary services	25,531
Total	58,697

1987 definition, 49 percent have AIDS only by the 1993 definition (CD4 < 200), and 15 percent have symptomatic disease but not AIDS. This heavy contribution of individuals with more severe disease reflects several factors characterizing these individuals: higher awareness of infection, high levels of uninsurance and public insurance, low observed HAART use among individuals who are uninsured or publicly insured, greater likelihood of enrolling in HIV-CCP than less sick individuals, and clearer need for HAART. By way of comparison, the Committee estimates that implementation of the Enhanced Medicaid option would result in an increase of 13,426 individuals newly on HAART (Table A-5).

In the absence of HIV-CCP, some of the of the 58,697 individuals who start HAART because of this program would start HAART later in time, due to worsening of clinical condition. Specifically, the model estimates that 6 percent of survivors at 2 years would be on HAART, 15 percent at 5 years, and 30 percent at 10 years. These numbers should be considered in the context of estimates made by the Committee that currently only 45 percent of individuals with AIDS by the 1993 definition are on HAART, and only 64 percent of those with AIDS by the 1987 definition are on HAART. The model indicates that individuals who would go on HAART due to HIV-CCP are those, by definition, with no current HAART use due to not being in care, uninsurance and public insurance, and other factors. Thus, they are at high risk of not moving quickly to HAART without a change in the financing system.

Health Effects

Without implementation of the HIV-CCP program, the disease state-transition model predicts 35,489 deaths in a 10-year period among the 58,697 individuals likely to receive HAART given implementation of the program. With the program, the number of deaths is predicted to fall by

TABLE A-6 Premature Deaths Prevented Through HIV-CCP During a 10-Year Period (among those newly on HAART) (undiscounted)

	Deaths in a Period of 10 Years
Without access to HAART	35,489
With access to HAART	15,664
Premature deaths prevented	19,825

TABLE A-7 Life Expectancy and Quality-Adjusted Life Expectancy Gain Through the HIV-CCP During a 10-Year Period (among those newly on HAART) (undiscounted)

	Life Years	QALYs
Without access to HAART	385,180	299,516
With access to HAART	507,050	425,276
Gain	121,870	125,760

55.9 percent to 15,664 deaths, with 19,825 premature deaths prevented among the individuals who are enrolled in the program in its first year (Table A-6). In terms of life expectancy, the model predicts a gain of 121,870 life years and 125,760 QALYs in the same 10-year period (Table A-7). The quality of life adjustment assumes that in addition to extending life, there are benefits to antiretroviral therapy (e.g., reduced morbidity due to fewer opportunistic infections and slower progression of HIV disease) that outweigh the negative impacts associated with HAART (e.g., the side effects of treatment). By comparison, the Enhanced Medicaid option is predicted to prevent 4,537 premature deaths, resulting in a gain of 24,110 QALYs in the HIV-infected population.

Cost per QALY Gained

Discounting at an annual rate of 3 percent over a 10-year period to present value, implementation of the HIV-CCP would result in a quality-adjusted gain in life expectancy of 105,403 QALYs for the 58,697 individuals who would be newly on HAART (Table A-8). We conservatively estimate that the provision of substance abuse treatment, mental health services, and case management would result in an additional gain of 23,982 QALYs over the same time period, also discounted to present value, resulting in a total gain of 129,385 QALYs among those individuals likely to enroll in the

TABLE A-8 Expected Health and Economic Outcomes for the 58,697 Individuals Who Would Receive HAART as a Result of HIV-CCP, over 10 years*

	QALYs	**Deaths**	**Cost (millions)**
Current system	264,371	35,489	$6,889
HIV-CCP	369,773	15,664	$9,538
Difference	105,403	–19,825	$2,649

*QALYs and costs are discounted to present value at a rate of 3 percent per year. Costs reflect only the effects of increased use of HAART for these individuals. It excludes costs due to changes in Medicaid outpatient reimbursement; case management, mental health, and substance abuse care; and bringing individuals into care. These additional costs are reflected in the next table.

TABLE A-9 Estimated Cost per QALY Gained Associated with the HIV-CCP Program over a 10-Year Period for 297,128 Individuals Enrolled in the First Year (among those newly on HAART)*

Program Element	**QALY Gain**	**Cost ($)**	**Cost/QALY Gained**
HAART	105,403	2.648 billion	
Substance abuse treatment, mental health treatment, case management	23,982	1.750 billion	
Other services (additional costs associated with bringing people into care)	Assumed zero	775 million	
Outpatient reimbursement = Medicare or Medicare + 5%	Undetermined	387 million	
Total	129,385	5.560 billion	$42,972

*QALYs and costs are discounted to present value at a rate of 3 percent per year. No QALY gains are attributed specifically to changes in Medicaid reimbursement, being brought into care, or case management. These actions are portrayed as having health benefits only by increasing access to HAART. The QALY gains for mental health are 0.05 per year with mental services, and for substance abuse care 0.1 per year in substance abuse treatment (see text for discussion).

program in the first year. The estimate, from a societal perspective, of the 10-year incremental program as it applies to those initially enrolled is $5.56 billion, resulting in an estimated cost per QALY gained of $42,972. This is well within what is considered a “good buy” in terms of health care investment (Hirth et al., 2000) (Table A-9) (see Chapter 6).

Budget Impact

We estimate that public spending on care for people with HIV disease, including the cost of care for the uninsured, was $7.161 billion in 2002 (fiscal year 2001) and that an additional $574 million in public spending would be needed to fund the HIV-CCP program in the first year the program is operational (Table A-10). The estimate is a summary figure that collapses the budgetary impact on all public payers. It assumes no "crowd-out" of private insurance and does not take into account any cost savings such as discounted drug costs or reductions in disability payments that might be found to offset the cost of an expansion of publicly financed HIV care. The estimate assumes that all outpatient care will be delivered through a Center of Excellence and billed at Medicare rates plus 5 percent. Though it is highly unlikely that all care will be delivered through a Center of Excellence, the Committee attempted to model the optimal and most expensive scenario.

The incremental cost to the federal government is measured by expenditures for the new program, plus residual spending for Medicaid and Medicare recipients who are not enrolled in the new program. The new program is estimated to cost $4.408 billion. Overall federal Centers for

TABLE A-10 Comparison of Estimated Year One Expenditures, Current and Anticipated, by Payer Associated with the HIV-CCP (in millions)

	Current	Year 1 of HIV-CCP	Incremental Costs/(Savings)
Federal share of Medicaid/Medicare	$3,003	$5,610[a]	$2,607
State share of Medicaid	$2,138	$984[b]	($1,154)
Subtotal CMS-administered (federal/state Medicaid/Medicare)[c]	$5,141	$6,594	$1,453
Care for the uninsured[d]	$2,020	$1,140	($880)
Total public (includes Medicare and federal/state Medicaid and the uninsured)	$7,161	$7,734	$574

[a] The cost of the HIV-CCP ($4,408) is included in the federal share of Medicaid/Medicare.

[b] This reflects state spending on individuals with HIV who remain in the Medicaid program as well as incomplete adjustment for dual Medicaid and Medicare eligibility.

[c] This excludes the cost of care provided by the Ryan White CARE Act, which is included under care for the uninsured. See text for discussion of potential CARE Act savings.

[d] The estimate of the cost of care for the uninsured includes care provided to veterans with HIV/AIDS by the Veterans Administration (VA) health care system. Though the VA is the largest single provider of HIV/AIDS care in the country, the amount of money it spends on HIV/AIDS care is small compared with other public programs, totaling less that $400 million in FY 2002. The VA does not cover care for veterans with private insurance, so in a sense it is a program for the uninsured.

TABLE A-11 Comparison of Estimated Expenditures, Current and Anticipated, by Payer Associated with Enhanced Medicaid Expansion (in millions of dollars)

	Current	Year 1 of Enhanced Medicaid Program	Incremental Costs (Savings)
Federal share of Medicaid/Medicare	$3,003	$3,635[a]	$632
State share of Medicaid	$2,138	$2,225	$87
Subtotal public (Medicaid/Medicare)	$5,141	$5,859	$719
Care for the uninsured	$2,020	$1,433	($587)
Total public (includes Medicaid, Medicare, and the uninsured)	$7,161	$7,292	$132

[a] The cost of the Enhanced Medicaid program ($2,748) is included in federal share of Medicaid/Medicare.

Medicare & Medicaid Services (CMS) spending, when compared to existing federal Medicaid and Medicare spending on HIV, is estimated to rise by $2.607 billion. The states, which would shift much of the cost of their Medicaid expenditures for individuals with HIV to the federal government if the HIV-CCP were established, would collectively realize a first-year savings of $1.154 billion. The Committee predicts that care for the uninsured, currently estimated at $2.02 billion, would fall to $1.140 billion, resulting in a net savings of $880 million shared by the federal government, states, counties, providers of uncompensated care, and other payers.

Enhanced Medicaid

Implementation of the Enhanced Medicaid option would be less costly overall, requiring an estimated increase in public expenditures of $132 million in the first year of operation (Table A-11). The Enhanced Medicaid option would also require less of a financial commitment by the federal government. However, while the cost to the federal government would be considerably less ($632 million in additional spending by CMS versus $2.57 billion in the first year), collectively, the states would have to spend more ($87 million versus a savings of $1.16 billion).

Sensitivity Analyses

We performed univariate sensitivity analyses for 36 model input variables to the model (Table A-12), including HIV population estimates, cost

TABLE A-12 Univariate Sensitivity Analysis

	Values	Outcomes: QALYs Gained; Societal Cost; Cost/QALY	
Variable	Base Case (low, high)	Low Value[a]	High Value
Base case	NA	129,385 $5.56 billion $42,972	
HIV Population Characteristics			
Aware	670,000 (536,000; 804,000)[b]	103,508 $4.45 billion —[c]	155,262 $6.67 billion —
By clinical stage among aware			
Base case (CD4>500/CD4 499–350/CD4 349–200/ AIDS 93/AIDS 87)	0.07/0.15/0.24/0.31/0.22		
CD4 349–200 portion	(0.07/0.18/0.19/0.33/0.22, 0.07/0.12/0.29/0.29/0.22)	129,582 $5.60 billion $43,207	129,114 $5.51 billion $42,669
AIDS 93 portion	(0.07/0.15/0.27/0.25/0.25, 0.07/0.15/0.21/0.37/0.19)	131,256 $5.53 billion $42,122	127,514 $5.59 billion $43,808

continued

TABLE A-12 Continued

	Values	Outcomes: QALYs Gained; Societal Cost; Cost/QALY	
Variable	Base Case (low, high)	Low Value[a]	High Value
By insurance status, among aware Base case (public/uninsured/private)	0.50/0.25/0.25		
Low private High private	0.53/0.27/0.20 0.47/0.23/0.30	130,928 $5.72 billion $43,742	127,843 $5.39 billion $42,161
HAART Use			
Individuals currently on HAART—total	230,000 (184,000; 276,000)	108,141 $5.41 billion $50,031	150,627 $5.21 billion $34,601
Individuals currently on HAART—public and uninsured	167,650 (134,120; 201,180)	152,367 $6.72 billion $38,097	82,419 $4.40 billion $53,391
Relative risk of receiving HAART if family income <$25,000	0.60 (0.5; 0.7)	153,326 $5.94 billion $38,715	112,283 $5.26 billion $46,825

Relative risk of receiving HAART in program versus private insurance	1.0 (0.92, NA[d])	100,965 $5.05 billion $49,973	NA
Relative risk of getting HAART if receiving case management	1.5 (1.2, 1.8)	116,291 $5.33 billion $45,837	142,675 $5.78 billion $40,490
Relative risk of getting HAART if receiving mental health treatment	1.4 (1.2, 1.6)	124,108 $5.47 billion $44,607	134,662 $5.65 billion $41,944
Relative risk of getting HAART if receiving substance abuse treatment	1.7 (1.3, 3.0)	120,590 $5.41 billion $44,840	158,114 $6.00 billion $37,967
HIV Clinical Costs			
Clinical care, individuals not on HAART[e] (per person-year)	$18,705 ($16,834; $20,576)	— $5.51 billion $42,582	— $5.61 billion $43,361
HAART, in the program	$9,222 ($8,300; $10,144)	— $5.15 billion $39,830	— $5.97 billion $46,113
Non-HAART clinical care, individuals on HAART	$12,373 ($11,136; $13,611)	— $5.09 billion $39,340	— $6.03 billion $46,603

continued

TABLE A-12 Continued

	Values	Outcomes: QALYs Gained; Societal Cost; Cost/QALY	
Variable	**Base Case (low, high)**	**Low Value**[a]	**High Value**
Case management	$826 ($661; $991)	— $5.50 billion $42,452	— $5.62 billion $43,401
Mental health treatment	$1,380 ($1,104; $1,656)	— $5.50 billion $42,541	— $5.62 billion $43,402
Substance abuse treatment	$6,193 ($5,574; $6,812)[f]	— $5.46 billion $42,167	— $5.66 billion $43,777
Increase in Service Utilization			
Substance abuse treatment	0.075 (0.06; 0.09)	126,387 $5.35 billion $42,343	132,383 $5.77 billion $43,572
Mental health treatment	0.09 (0.07; 0.11)	127,387 $5.50 billion $43,160	131,384 $5.62 billion $42,789

Case management	0.15	—	—
	(0.12; 0.18)	$5.50 billion	$5.62 billion
		$42,542	$43,401
Eligibility and Enrollment			
Proportion Eligible			
By insurance status			
In care			
Public	0.92	121,393	137,378
	(0.87; 0.97)[g]	$5.24 billion	$5.88 billion
Uninsured	0.53	$43,176	$42,784
	(0.42; 0.64)		
Not in care			
Public	0.975	126,756	131,308
	(0.93; 1.0)[h]	$5.42 billion	$5.66 billion
Uninsured	0.50	$42,760	$43,139
	(0.4; 0.6)		
Enrollment Rates[i]			
In care			
Publicly insured	0.90 (0.45; 0.99)	84,518	138,358
Uninsured	0.90 (0.45; 0.99)	$3.77 billion	$5.92 billion
		$44,649	$42,773
Not in care			
Publicly insured	0.40 (0.20; 0.60)	109,559	149,211
Uninsured	0.30 (0.15; 0.45)	$4.57 billion	$6.55 billion
		$41,680	$43,927

continued

TABLE A-12 Continued

	Values	Outcomes: QALYs Gained; Societal Cost; Cost/QALY	
Variable	Base Case (low, high)	Low Value[a]	High Value
If enrolled, in care			
Not in care (previously)			
Publicly insured	0.75 (0.6; 0.9)	121,454	137,315
Uninsured	0.75 (0.6; 0.9)	$5.16 billion	$5.96 billion
		$42,503	$43,386
Health Effects			
Utility deficit due to advanced disease	0.12–0.24	127,128	131,642
	(–10%, +10%)	—	—
		$43,735	$42,235
Utility change (drop) for being on HAART	–0.03	141,340	117,430
(side effects, inconvenience)	(0.0; –0.06)[j]	—	—
		$39,337	$47,347
Utility gain for being on HAART	0.06–0.13	125,665	133,105
(symptom reduction)	(–10%, +10%)	—	—
		$44,244	$41,771

Utility adjustment for receiving substance abuse treatment	0.1 (0.08; 0.12)	126,387 — $43,991	132,383 — $41,999
Utility adjustment for receiving mental health treatment	0.05 (0.04; 0.06)	127,587 — $43,578	131,184 — $42,383

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[a] Low value/high value indicates the value of the input variable.

[b] Unless otherwise indicated sensitivity analyses were done using a range of ± 20%.

[c] A dash (—) indicates same value as base case.

[d] For HAART use in program, no upper bound is specified because use at the level of private insurance (base case) is considered a maximum.

[e] Cost of care not on HAART is for those individuals who would be on HAART with the program, to facilitate comparison with subsequent rows.

[f] A range of ± 10% was used for this variable.

[g] A range of ± 5% was used for this variable.

[h] A range of ± 5% was used for this variable.

[i] A range of ± 50% (with a maximum of 0.99) was used for all of the variables in this section.

[j] A range of ± 100% was used for this variable.

of care data, and estimated health utility gains from treatment. Generally, we used ranges of ±10 percent for the high/low values when the original input was from a well-done and directly relevant study or source, up to ±20 percent to determine the high/low values when the original input was from a published but less definitive source or sources, and ±50 percent or more when published data were scarce and we relied on expert judgment to estimate the input.

Each sensitivity analysis estimated three outputs (QALY gain, societal cost, and cost per QALY gained, all discounted) for the low and high input values. We found that no single variable had an unexpected impact on the results of the model and, in general, the variations in outputs resulting from the analyses were modest, especially for cost effectiveness. Predictably, total population with HIV along with HAART use and cost produced the widest range of results. Varying the total HIV population aware affected total program cost proportionately (i.e., ±20 percent) but did not affect cost per QALY gained. If, however, all newly aware were asymptomatic and not candidates for HAART over the five years, a 20 percent gain in awareness would generate much smaller gains in QALYs (to 134,181) and costs ($6.2 billion) and a small rise in cost per QALY gained (to $46,076) (not in table). Different disease distributions among the aware had little effect. Different insurance status distributions affected cost and QALYs gained a little, and cost per QALY gained almost not at all.

Varying current HAART use among those publicly insured or uninsured by ±20 percent produced relatively substantial changes in terms of both total cost and QALYs gained, and moderate variation in cost effectiveness ($34,000 to $54,000 per QALY gained). Variations in the relative risk of getting HAART due to use of ancillary services had only small effects.

HIV clinical costs had only modest effects on cost per QALY gained. The inputs with the greatest impact were cost of HAART per person-year and of non-HAART clinical costs for those on HAART. These sensitivity analyses by ±20 percent produced no change in QALYs and some variation in total cost. It produced one of the widest variations in cost effectiveness, however, from $39,000 to $46,000. Only non-HAART clinical cost for those on HAART had a greater variation in terms of cost effectiveness, from $39,340 to $46,603. Changes in utilization of ancillary services had very small effects.

For eligibility and enrollment, the largest variation in outputs resulted from inputs where the value was based on expert judgment. For example, uncertainty in enrollment led to variation in costs of $3.8 to $5.9 billion, though very little change in cost effectiveness due to similar changes in QALYs gained. This is essentially a program scaling effect.

Changes in health inputs had small effects due to fairly narrow uncertainty (e.g., for utility decrement due to disease status) or only limited impact on results (e.g., utility gain for one ancillary service). The largest effect was for the utility decrement associated with HAART use, due to complete lack of data, with variation in QALYs gained from 117,000 to 141,000, and for cost effectiveness from $39,000 to $47,000 per QALY gained.

Additional and more nuanced sensitivity analysis would be useful to explore the implications of variations of other assumptions, for example, differing distributions of HAART use by disease stage, particularly late AIDS. Time and resource constraints, however, dictated that we focus on those analyses where the outcomes could materially affect the findings of the model.

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Appendix
B

Overview of CARE Act Allocation Formulas[1]

Most allocation formulas include a measure of need, while some include measures of costs, fiscal capacity, and effort. Some formulas also contain special features such as floors and ceilings (minimum and maximum awards), "hold-harmless" provisions that prevent an area's funding from declining too rapidly from year to year, or eligibility thresholds (NRC, 2001, 2003).

Most formulas for Titles I and II of the Ryan White CARE Act (CARE Act) allocate funds based on a jurisdiction's disease burden, often defined as estimated living AIDS cases (ELCs). ELCs are calculated by applying annual national survival weights to 10 years of reported AIDS cases and summing the totals.[2] Most of these formulas also contain one or more features like hold-harmless provisions or thresholds.

TITLE I AWARDS TO ELIGIBLE METROPOLITAN AREAS

A metropolitan area becomes eligible for Title I if it has a population of 500,000 or more and has reported a cumulative total of more than 2,000

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[1] The material in this appendix is excerpted from *Measuring What Matters: Allocation, Planning and Quality Assessment for the Ryan White CARE Act*. Washington, DC: The National Academies Press, 2003.

[2] Both the survival weights and the most recent 10 years of reported AIDS cases are sent to Health Resources and Services Administration (HRSA) from the Centers for Disease Control and Prevention (CDC). The survival weights are updated and recalculated every two years.

cases of AIDS during the most recent five calendar years for which data are available from the CDC (HRSA, 2002a). A type of hold-harmless provision applies to Eligible Metropolitan Areas (EMAs) in that once a metropolitan area's eligibility is established, the area remains eligible even if the number of cases drops below the threshold in later years.

Base Award

An EMA's base award is determined by a formula based on its proportion of the total number of estimated living cases in all EMAs. The formula also includes a hold-harmless provision that limits the amount an EMA's funding can fall from year to year, according to a schedule specified in the legislation.[3] San Francisco is the only EMA that now benefits from the hold-harmless provision (HRSA, 2002c).

Supplemental Award

Supplemental awards are determined by a competitive application process, rather than by a formula. Reviewers score the application according to criteria laid out by HRSA. Either HRSA staff or external reviewers score applications. The supplemental award is divided among all EMAs, taking into account the score as well as the proportion of all ELCs that an EMA has. Three different "smoothing" algorithms are applied to see which distributes the money most appropriately. In general, no grantee is given less than 80 percent of its base formula award (HRSA, 2001).

Title I Minority AIDS Initiative

Minority AIDS Initiative (MAI) grant awards are divided among all EMAs according to a formula based on their proportion of racial and ethnic minorities AIDS cases—including African Americans, Hispanics, Asian/Pacific Islanders, and Native Americans/Alaska Natives—diagnosed during the most recent two years for which data are available, and adjusted for reporting delays. For instance, data from 1998 and 1999 were used to calculate the Fiscal Year 2001 MAI award (HRSA, 2001).

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[3] The hold-harmless award is subtracted from the total Title I supplemental funds before the latter are divided.

TITLE II AWARDS TO STATES AND TERRITORIES

Base Award

Title II base awards are determined by a formula. Eighty percent of the base grant is based on each state's proportion of the total number of ELCs. The remaining 20 percent is based on the number of ELCs in each state outside any EMAs, in proportion to the total number of such cases nationwide[4] (HRSA, 2001). The base award also includes a minimum award: \$200,000 for states with fewer than 90 ELCs, \$500,000 for states with more than 90 ELCs, and \$50,000 for all United States territories, regardless of the number of AIDS cases (HRSA, 2001). The base award formula includes a hold-harmless provision that declines annually according to a schedule established in the legislation.

States must match a portion of the Title II base award if they report more than 1 percent of the total number of AIDS cases for the two preceding fiscal years. The number of years that a state has been matching determines the percentage that it must match (20 percent the first year, 25 percent the second year, 33 percent the third year, and 50 percent in the fourth year). Puerto Rico is exempt from this requirement (HRSA, 2001).

AIDS Drug Assistance Program Award

The AIDS Drug Assistance Program (ADAP) award is based on a state's proportion of the total ELCs in all states and territories. Unlike the Title II base award, this award does not include an 80–20 split. The formula includes a hold-harmless provision that declines annually according to a schedule established in the legislation (HRSA, 2001).

ADAP Supplemental Award

Before the ADAP award is calculated, 3 percent of the appropriated earmark is set aside for the ADAP Supplemental Award, given to states in severe need (HRSA, 2002b). A state's supplemental ADAP award is based on its proportion of the total ELCs in qualifying states and territories. A state must match 25 percent of these federal funds to receive the award. If a qualifying state does not agree to do so, HRSA runs the formula again after deleting the nonparticipating states (HRSA, 2001).

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[4] This provision was enacted under the 1996 reauthorization to provide an extra boost to states without EMAs.

Title II Minority AIDS Initiative

This award is based on each state's proportion of all African Americans, Hispanics, Asian/Pacific Islanders, and Native Americans/Alaska Natives diagnosed during the previous two calendar years, adjusted for reporting delays. If a state or territory has no diagnosed non-white AIDS cases during the past two years, it does not receive an award (HRSA, 2001). Montana, North Dakota, American Samoa, Marshall Islands, Northern Marianas, Republic of Palau, and the Federated States of Micronesia did not qualify for this award in Fiscal Year 2002 (HRSA, 2002d).

Emerging Communities Award

Emerging communities are Metropolitan Statistical Areas (MSA—a community with a population greater than 50,000) that do not meet the eligibility criteria to qualify as a Title I EMA, but that have 500–1,999 reported AIDS cases in the most recent five-year period. Half the available funding goes to MSAs with 1,000–1,999 AIDS cases, while the other half is divided among MSAs with 500–999 AIDS cases. Each award is based on the area's proportion of the total number of AIDS cases among all qualifying MSAs (HRSA, 2001).

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Appendix
C

Mental Illness and HIV Comorbidity: A Large and Vulnerable HIV Subpopulation[1]

Individuals with both mental illness and HIV represent a large, vulnerable, and possibly growing segment of the HIV population. The prevalence of this comorbidity is exceedingly high: about 50 percent of those in HIV care have a comorbid mental illness (Bing et al., 2001). The mental illness (MI) can arise independently of HIV infection, can predispose to HIV (through risk-related behaviors), or can be a psychological consequence of HIV (e.g., depression).[2] Regardless of etiology, the comorbidity of MI-HIV poses special challenges for HIV care. Individuals with this comorbidity face even greater barriers to care than do those with HIV alone. Once in care, their treatment is more complex. Because MI can increase the risk of acquiring or transmitting HIV, responding to the barriers to, and complex needs in, care is imperative for both patients and the public health.

This appendix describes the impact of MI in terms of HIV acquisition or transmission, impact on the course of HIV disease, barriers to care, complexity of care, and outcomes of care. It begins, however, with an introduction to MI and the comorbidity of MI-HIV.

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[1] This appendix was primarily authored by Miriam Davis, Ph.D., Department of Epidemiology and Biostatistics, School of Public Health and Health Services, George Washington University, and independent medical writer.

[2] This section does not cover the neuropsychiatric manifestations of HIV itself, e.g., HIV dementia.

MENTAL ILLNESS

Mental illness is an umbrella term denoting any one or more of the mental disorders listed in DSM-IV or ICD-10.[3] The hallmarks of these disorders are abnormalities in mood, cognition, and the highest integrative aspects of human behavior, such as planning and social interactions. Mental illness is highly prevalent, with about 20 percent of the United States population (about 44 million) fulfilling criteria for one or more disorders in a given year (DHHS, 1999). Anxiety (16 percent) and depression (6–7 percent) are the most common, whereas bipolar disorder and schizophrenia affect about 1–2 percent of the population.

While overall rates of mental illness do not vary by gender, women have significantly higher rates of major depression: the 12-month rates are 13 percent of women versus 8 percent of men (Kessler et al., 1994). About half of people with a mental illness will also have a substance use disorder at some time during their lifetime (Kessler et al., 1994; DHHS, 1999). Comorbidity of MI and substance use disorders is the norm, rather than the exception.

People within the lowest socioeconomic status (SES) group are about two to three times more likely to suffer from mental illness than people in the highest group. Minorities, by virtue of lower SES, are disproportionately affected by mental illness (DHHS, 2001). After controlling for SES, mental illness is as prevalent in African Americans and Hispanic Americans as whites. The two main explanations for the link between poverty and mental illness are that (1) poverty causes exposure to more stressful environments (with fewer social supports), and (2) poverty is a consequence of having a mental illness that leads to unemployment or underemployment (DHHS, 2001). The fact that MI is more prevalent in minority populations is critical to understanding the shifting dynamics of the HIV epidemic, as explained later.

Mental illness is highly disabling, especially depression, bipolar disorder, or schizophrenia. A groundbreaking study by the World Health Association (WHO) ranked mental illness first in terms of causing disability in the United States, Canada, and Western Europe (WHO, 2001). It found that mental illness accounts for 25 percent of total disability, a rate higher than that for substance use disorders, which ranked second.

The disability toll of mental illness is high because mental illness is highly prevalent, often arises in childhood or adolescence, and carries a long-term (usually relapsing–remitting) course. Mortality is more commonly

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[3] *Diagnostic and Statistical Manual of Mental Disorders, DSM-IV*, 4th edition. Published by the American Psychiatric Association, 1994; *International Classification of Diseases,* 10th edition. Published by the World Health Organization.

from suicide, inadequately treated comorbid medical problems like diabetes (Dixon et al., 2000; Sullivan et al., 1999), or from physiological interrelationships between MI and comorbid medical conditions (see later section on depression). On a separate disability measure that includes both mortality and disability,[4] depression ranks directly behind HIV—yet both rank within the top ten (WHO, 2001). The loss of productivity to the United States economy from MI totals about $63 billion annually (DHHS, 1999). There are a range of effective treatments for most mental disorders—medications, psychotherapies, and other services and supports—but 50 percent of those with mental illness do not receive any treatment because of barriers to access (DHHS, 1999).

About 5–9 percent of United States adults and children have more severe forms of mental illness (Kessler et al., 2001; NHSDA, 2002; DHHS, 1999). For adults, the commonly used term is “serious mental illness.” Stemming from federal regulations, the term refers to a diagnosable mental disorder that impairs performance at work, home, or other area of social functioning. The analogous regulatory term for children is “serious emotional disturbance.” The disorders subsumed by either of these terms are typically severe depression, bipolar disorder, and schizophrenia. Their onset typically occurs in later adolescence or early twenties. Ninety percent of adults with serious mental illness are unemployed (DHHS, 1999).

This appendix focuses on the full range of mental disorders, from milder depression to serious mental illness, because most disorders are overrepresented in the HIV population, and the general barriers to MI or HIV treatment do not vary by mental disorder.

Mental Illness and HIV Comorbidity

People with MI are at higher risk for HIV than those without MI (Cournos and McKinnon, 1997; Stoskopf et al., 2001). The comorbidity of MI-HIV has been largely studied in two different ways—in samples either receiving mental health care, or in samples receiving HIV care. Neither sample type is representative of the population with MI-HIV comorbidity, partly because so many are not in treatment. Among people with serious mental illness (SMI), the seroprevalence of HIV ranges from 4 to 23 percent, with an average of about 7 percent (Carey et al., 1995; Cournos and McKinnon, 1997). That average is much higher than the rate of HIV in the general United States population (0.3–0.5 percent). Among people in HIV care, the prevalence of MI is at least 50 percent (Bing et al., 2001). This rate

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[4] Disability-adjusted life year (DALY), which expresses years of life lost to premature death and years lived with a disability of specified severity and duration (WHO, 2001).

TABLE C-1 Comorbidity of Mental Illness in Nationally Representative Sample of Patients in HIV care, HCSUS N=2,864

Condition	Percentage
Major depression	36.0*
Dysthymia	26.5
Generalized anxiety disorder	15.8
Panic attack	10.5
TOTAL	52.1

*These figures add up to more than 52.1 percent of the total sample because many had more than one mental disorder.
SOURCE: Bing et al., 2001.

is higher than that for illicit drug use (25 percent) or drug dependence (12.5 percent), according to the nationally representative HIV Cost and Services Utilization Study (HCSUS) (Bing et al., 2001). The investigators also screened HIV patients for the most common mental disorders using a brief screening instrument.[5] They found high rates of major depression (36 percent of the total sample), dysthymia (26.5 percent), generalized anxiety disorder (15.8 percent), and panic attack (10.5 percent) (Table C-1).[6] Because of resource constraints, they were unable to screen for less prevalent mental disorders, such as post-traumatic stress disorder (PTSD), schizophrenia, and bipolar disorder, which have been associated with HIV. Estimates are that 9.2 percent of those with schizophrenia have HIV (Cournos and McKinnon, 1997). One large, population-based study of all inpatient and emergency discharges from the state of South Carolina (n=379,000) found that MI-HIV comorbidity was highest for patients ages 18–25 and women (Stoskopf et al., 2001). Overall, the study found that people with MI were 1.44 times more likely to have HIV/AIDS than those without MI. The study did not find ethnic or racial differences in the risk of comorbidity, and it did not investigate SES as a risk factor.

While the prevalence of MI-HIV comorbidity is already high in clinical samples, is it likely to increase? This key question has not been formally addressed in any demographic projections. On the basis of existing data, it is reasonable to infer that rates of this comorbidity are destined to grow. Those at highest risk of comorbidity, as indicated above, are women and young people. Women and youth also account for a growing proportion of

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[5] The University of Michigan Composite International Diagnostic Interview, UM-CIDI.

[6] These figures add up to more than 50 percent of the total sample because many had more than one mental disorder.

new AIDS cases, as do racial and ethnic minorities (CDC, 2002). Minorities have higher prevalence of mental illness by virtue of lower SES, as explained above. Thus, because of shared demographic risk factors, the prevalence of MI-HIV comorbidity may climb. Put another way, HIV is rising in the same disadvantaged groups in which MI is concentrated.

Mental Illness and HIV Acquisition or Transmission

People with MI are considered at increased risk of acquiring or transmitting HIV for two reasons: (1) greater likelihood of high-risk sexual behavior or substance abuse and (2) poor adherence with the complex requirements of combination antiretroviral therapy (ARV), which can lead to the emergence and potential transmission of drug-resistant HIV (Cournos and McKinnon, 1997; Johnson, 1997; Carey et al., 1997; Sullivan et al., 1999). Underlying these concerns are the behavioral and cognitive manifestations of the disorders themselves—such as impaired decision making and perception of risks, low motivation, impulsivity, and vulnerability to sexual victimization.

This section summarizes recent studies that empirically examine whether MI can increase the transmission of HIV. The studies give a more nuanced and complex portrait of the problem, suggesting variation in risk depending on the psychiatric diagnosis or nature of symptoms. The findings have important implications for prevention and control of HIV. On the one hand, they suggest that targeted interventions are needed to help people with mental illness reduce risky behavior and improve adherence. On the other hand, they raise the possibility of discrimination against people with mental illness, not on the basis of their ability to adhere to treatment, but on the basis of their membership in a categorical group. There is some evidence that people with MI face discrimination in the form of physicians' withholding treatment for people with MI-HIV, as this section explains.

HIV Risk-Related Behavior

It has long been hypothesized that people with MI are more likely to engage in high-risk sexual behavior or injection drug use—behaviors that heighten the risk of acquiring or transmitting HIV. But research, when available, has given a mixed picture that varies by diagnosis, level or severity of symptoms, and age. The evidence reveals that serious mental illness—but not depression and anxiety—is associated with risky behavior, and that youth also increases risk. Depression and anxiety are the most common mental disorders among those in HIV care, as noted earlier.

A recent meta-analysis of 34 studies investigated the impact of depression or anxiety on high-risk sexual behaviors, defined as having multiple partners and/or unprotected sex. The samples included individuals with MI alone, as well as MI-HIV. The study found little evidence that depression and anxiety are associated with more risky behavior (Crepaz and Marks, 2001). Findings suggest that SMI, without comorbid HIV, does increase the likelihood of engaging in high-risk sexual behaviors (Carey et al., 1997; Cournos and McKinnon, 1997; Sullivan et al., 1999). In a recent and large study of 1,558 psychiatric outpatients, almost 70 percent were sexually active, and 23 percent engaged in risky sexual behavior (Carey et al., 2001). Younger age and having a diagnosis other than schizophrenia had the strongest associations with high-risk sexual practices. Adolescents with mental disorders are much more likely than peers to engage in unsafe sexual behavior, primarily because of impulsivity, self-destructive attitudes, cognitive immaturity, high rates of substance use, and sequelae of sexual abuse (Brown et al., 1997; Smith, 2001).

One causal pathway to HIV infection in adolescence or young adulthood is thought to begin with childhood sexual abuse, then development of SMI, a substance use disorder, and/or high risk sexual behavior, and culminating in HIV infection (Rosenberg et al., 2001). Childhood sexual abuse is often an antecedent to depression, PTSD, conduct disorder, or suicidal behavior (IOM, 2002). Adolescents with a history of sexual abuse are three times more likely than those without a history to report unsafe sexual behavior (Brown et al., 2000). Similarly, women with HIV, regardless of ethnicity, are about seven times more likely to have a history of sexual or physical abuse than women who are seronegative (Wyatt et al., 2002; see also references in Wyatt). Sexual abuse is also a strong predictor of becoming a victim of domestic abuse (physical, sexual, or psychological abuse by an intimate partner). Among almost 1,300 women with HIV or at risk for HIV, the prevalence of childhood sexual abuse was about 27–30 percent, and the lifetime prevalence of domestic violence was nearly 70 percent (Cohen et al., 2000). The study did not report on whether these women had mental disorders, but other studies indicate that PTSD is found in 33–86 percent of adult survivors of child sexual abuse (Follette et al., 1996) and often goes undiagnosed (Frueh et al., 2002).

What is the impact on sexual behavior of having comorbid MI-HIV? Does this comorbidity predict greater likelihood of high-risk sexual behaviors? There have only been two relatively small studies addressing this question. A study of 154 West Coast outpatients with comorbid SMI-HIV found increased likelihood of engaging in high-risk sexual behaviors for those with more psychotic symptoms, problem drinking, and not receiving HIV counseling (Tucker et al., 2003). The outpatients in this study had diagnoses of major depression with psychotic features, bipolar disorder, or schizophrenia/schizoaffective disorder. The only other relevant study was of 42 psychiatric inpatients in New York City at a late stage of HIV infection. It found that SMI-HIV patients had high rates of risky behavior, including sex with a known injection drug user, prostitution, and male–male sexual contact (Meyer et al., 1995).

There is a paucity of research on the impact of MI on risk of injection drug use. While comorbidity of MI and a substance use disorder is common, and lifetime rates of injection drug use are quite high among those with SMI, there is little information on whether injection drug practices are related to HIV transmission. For example, it is unknown whether persons with MI who engage in injection drug use participate in needle exchange programs or use bleach to clean needles (Sullivan et al., 1999).

Adherence to Antiretroviral Therapy

The relationship between mental illness and adherence to ARV has been investigated in several studies, most of which relied on measures of depression or anxiety symptoms or distress rather than psychiatric diagnoses per se. Although not all studies have found a relationship between adherence and psychological well-being, a number of studies have found that depressive symptoms, hopelessness, psychological distress, and overall stress are associated with lower antiretroviral adherence.

Paterson and colleagues (2000) studied 81 HIV patients, with adherence tracked by a microelectronic monitoring system. The study found that active psychiatric illness, primarily depression, was an independent risk factor for nonadherence, and that nonadherence was significantly associated with treatment failure. Catz and colleagues (2000) also found that depression was a risk factor for self-reported nonadherence in a sample of 72 patients at a teaching hospital. A study in Spain by Gordillo and colleagues (1999) of 366 patients also found that depression was a risk factor for poor adherence. Chesney and colleagues (2000), studying 75 patients at 10 United States sites, determined that nonadherent patients reported higher levels of perceived stress. Relatedly, Singh and colleagues (1999), using the Beck Hopelessness Scale and other measures, found that hopelessness and loss of motivation were associated with non-adherence.

One study of SMI and adherence to ARV conducted by investigators at RAND found that about 40 percent of subjects were adherent (>90 percent adherence), while 31 percent had very poor adherence (<50 percent). The overall average adherence rate was 66 percent of prescribed doses, a rate similar to general clinic or community populations. The fact that a large percentage was adherent defied the conventional wisdom that these individuals lack the capacity to adhere to a complex dosing schedule. Still, a third of the sample had very poor adherence, a finding that prompted the investigators to suggest further research to identify barriers and inform the development of tailored interventions for those with SMI to achieve greater adherence, and thus greater treatment benefits (Wagner et al., 2003).

In summary, the research on MI and adherence to ARV therapy indicates that symptoms of depression and psychological distress are associated with lower adherence. There is very little research on the relationship between adherence and actual diagnoses of depression or anxiety. The one study of SMI finds, contrary to expectations, that people with one of the more serious diagnoses are not necessarily more likely to be nonadherent. What is clear is that more research is needed on adherence across the entire spectrum of psychiatric diagnoses.

Mental Illness Impact on HIV Disease

The impact of MI on the course of HIV disease has drawn more attention because of longer survival with HIV. A nationally representative study of persons receiving HIV medical care determined that those with comorbid mood disorders had lower scores on health-related quality of life (Sherbourne et al., 2000). The authors interpret their findings to suggest that the comorbidity of HIV with mood disorders leads to greater disability and unnecessary utilization of other health services (Uldall et al., 1998).

An emerging area of inquiry is whether mental illness, particularly depression, has an effect on the actual course of HIV disease. This line of inquiry stems from the field of psychoneuroimmunology. It is now well established that depression, possibly through immune-mediated dysfunction, is a risk factor for early mortality from a variety of medical illnesses, including heart disease (Ford et al., 1998; DHHS, 1999). One longitudinal study of gay and bisexual men with HIV found that comorbid depression was associated with earlier mortality (Mayne et al., 1996). In another longitudinal study, women with chronic depressive symptoms were two times more likely to die than infected women with limited or no depressive symptoms (Iskovics et al., 2001). The underlying mechanisms were studied by examining immune functioning in HIV-seropositive versus HIV-seronegative women with depressive symptoms. While rates of depression diagnoses were similar, HIV-seropositive women had higher symptom scores. The investigators found that depression may alter the function of killer lymphocytes in HIV-seropositive women and yield an increase in activated CD8 T lymphocytes and viral load (Evans et al., 2002). The latter are associated with HIV disease progression. These findings, if confirmed, underscore the importance of recognizing and treating depression as a standard part of HIV care, considering that depression is the most prevalent mental disorder in those receiving HIV care (Bing et al., 2001).

Barriers to Care

Barriers abound with respect to access and treatment of both HIV and MI, given the findings that a large fraction of each population is not receiving any treatment. While many barriers are similar across diagnoses, this section focuses primarily on the barriers to care of MI—either alone or comorbid with HIV.

Two landmark reports of the United States Surgeon General have analyzed the barriers that deter more than half of those with diagnosable mental disorders from receiving care (DHHS, 1999, 2001). Three overarching barriers to care were identified: the stigma attached to mental illness, the cost of mental health services, and the fragmentation of services. The latter refers to the patchwork of programs and settings of care (e.g., a hospital, community clinic, private office, or school) and a myriad of financing streams that make it difficult for people to find care and remain in care. Members of ethnic and racial minority groups not only face these three barriers, but also a host of others, including fear and mistrust of mental health care providers, providers' lack of awareness of cultural concerns, and language barriers for immigrants (DHHS, 2001). Rates of both access and utilization of mental health care are lower for minorities than for whites, a striking finding considering the already low rate of service utilization for whites (<50 percent receives any treatment in a given year) (DHHS, 2001). Minorities are overrepresented in the most vulnerable groups of homeless and incarcerated persons (DHHS, 2001). While the HCSUS study of people in HIV care found relatively high rates of utilization of mental health services (61.4 percent used mental health services), it also uncovered regional variation and inequities among certain demographic groups. Access was lower by minority and low education, and income populations (Burnam, 2001).

Individuals with comorbid MI-HIV appear to face additional barriers even if they manage to reach care. The barriers include lack of detection of HIV and physician withholding HIV treatment. These barriers stem partly from the complexity of coordinating care among three overlapping, yet distinct service systems—mental health, substance abuse, and general medical care. People with mental illness, regardless of severity, are seen by specialty mental health providers or by general medical providers (e.g., primary care) (DHHS, 1999). People with HIV are seen in primary medical care or by infectious disease specialists. To complicate matters, care for substance abuse has its own treatment settings and treatment philosophies, and substance abuse providers do not always diagnose mental disorders (Zweben, 2000).

Inadequate Detection of HIV

A major barrier in mental health care is inadequate detection of the comorbid condition, although studies are few and samples are not necessarily representative. This barrier exists to various degrees in both HIV and mental health care settings, but research points to greater problems in the mental health setting. Mental health professionals may not adequately screen for HIV (Brunette et al., 2000; McKinnon et al., 2001), despite the public health recommendations to conduct routine HIV counseling and testing in settings with HIV prevalence of 1 percent or more (CDC, 2001). [7] This cutoff applies to most, if not all, mental health treatment programs, given prevalence figures cited earlier. Researchers at RAND, interviewing 159 treatment providers at 72 mental health and HIV treatment programs in New York City and Los Angeles, found that screening for HIV and risk behaviors in mental health agencies occurs haphazardly, given the range of clients' nonpsychiatric and other medical needs that compete for the attention of providers. In contrast, HIV treatment agencies tend to place high priority on screening and care for mental illness, as clinicians generally perceive the mental health of clients to be central to successful HIV treatment and adherence. Nevertheless, because research has long established that depression is missed in 40–60 percent of patients in primary care (Hirschfeld et al., 1997; DHHS, 1999), it would not be surprising if depression went undetected in HIV care.

One of the few other studies of this problem found community mental health clinicians in New Hampshire to report lack of specific knowledge about comorbid MI-HIV and to report interest in receiving training (Brunette et al., 2000).

One study that directly focused on the barriers to receipt of HIV care for individuals whose SMI-HIV comorbidity is already known compared nearly 300 SMI-HIV patients in Los Angeles and New York City to patients from the HCSUS cohort from the same geographic region and with HIV alone. It found that people with SMI were more likely to experience barriers to care (Allen M. Fremont, Personal communication, 2002). Barriers to care were measured by a three-item index—not getting needed medical care, going without care because of lack of money, or going without food because they needed the money for care.

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[7] Psychiatrists are urged to screen every patient for HIV risk factors to determine if counseling and testing are indicated—a targeted method of HIV counseling and screening (APA, 2001).

Withholding HIV Care and Discrimination Against Mental Illness

Persons with mental illness or HIV are highly stigmatized. Though empirical research is limited, it would hardly be surprising if stigma were not compounded for individuals with MI-HIV comorbidity. As expressed in *Mental Health Care for People Living with or Affected by HIV/AIDS: A Practical Guide*, "The HIV-infected client [of mental health services] often finds himself/herself stigmatized in many ways—for having a fatal, transmittable disease; for being 'crazy'; for being gay; for being sexual; for being a substance user; for being African-American; for being poor; for being Hispanic; for being an illegal immigrant; for being unemployed; for being homeless; or for being an ex-offender. HIV-related stigmatization constitutes an epidemic in itself—an epidemic of fear, prejudice, and discrimination" (Acuff et al., 1999).

A major concern is that identification of mental illness in HIV-infected individuals will lead to a particular form of medical discrimination: physicians' withholding HIV therapy in order to prevent possible transmission of multi-drug resistant HIV. A 1998 survey of 995 infectious disease physicians, responding to hypothetical scenarios, found that 57 percent of them were either "very much against" or "somewhat against" prescribing ARV for someone with prior psychiatric hospitalization (Bogart et al., 2000). A related survey found widespread use of nonmedical factors determining physician likelihood of starting someone on ARV, although questions did not specifically assess psychiatric history or current MI (Bogart et al., 2001). These studies underscore the problem that physicians may discriminate against patients on the basis of medical history or demographic group membership, rather than on the basis of their individual level of adherence. Patients' initial level of adherence is the strongest predictor of adherence (Sherbourne et al., 1992). Research reveals that physicians, typically using other factors, are unable to predict which of their patients will adhere to therapy (Sollitto et al., 2001).

Concerned about bias in treatment recommendations, a NIH panel alerted physicians in 1998: "No individual patients should automatically be excluded from consideration for antiretroviral therapy simply because he or she exhibits behavior or other characteristics judged by some to lend itself to noncompliance" (NIH, 1998). This precise wording was later adopted verbatim in the 2002 HIV treatment guidelines. With regard to initiating therapy, those guidelines explicitly rely on CD4 levels and viral load, as well as taking into account "the likelihood, after counseling and education, of adherence to the prescribed treatment regimen" (DHHS, 2004). An editorial review echoed the theme of unwarranted discrimination and urged physicians to work with potentially nonadherent patients until they achieve sufficient understanding and social support to maximize successful antiretroviral treatment (Sollitto et al., 2001).

TREATMENT ISSUES

The treatment of MI-HIV comorbidity is more complex than the treatment of HIV alone or MI alone. Both MI and HIV treatment require a wide array of long-term services, including medication, counseling, patient education, risk reduction strategies, and other supports and services. Monitoring and treatment of substance use are also vital. The care demands are so great that coordination of care and attention to social supports are essential. This section will draw attention to major issues in treatment, many of which are highlighted by the American Psychiatric Association in their recent Practice Guidelines for the Treatment of Patients with HIV/AIDS (APA, 2001).

Medication Complexity, Side Effects, and Costs

Treatment of HIV and SMI requires long-term reliance on multiple medications, alone or in combination with other therapies such as psychotherapy. The average patient with a serious mental illness, like schizophrenia or bipolar disorder, ingests two or three medications, some of which, like the mood stabilizer lithium, require blood monitoring of drug levels to avoid toxicity. Side effects of psychiatric medications, like those for ARV, can be highly debilitating and are highly prevalent. Some studies, for example, indicate that side effects occur in about 40 percent of those taking medication for schizophrenia (DHHS, 1999). People with MI also need frequent visits for medication adjustment. Pharmacotherapy of schizophrenia is a case in point: one-quarter of patients with stable antipsychotic drug regimens have their medications switched over the course of a year (Leslie and Rosenheck, 2002).

The complexity of medication dosing and the severity of side effects are some of the main determinants of adherence. Most studies of drug adherence for mental illness find average adherence rates of 58–65 percent, rates that are similar to those for HIV (see earlier discussion) and slightly but not significantly lower than those for other long-term physical disorders (Cramer and Roseheck, 1998). Even though adherence rates may be similar, that does not mean they are adequate, considering that minor deviations can lead to multidrug resistance to HIV.

Drug–drug interactions are another concern for MI-HIV comorbidity, although clinical experience does not suggest that these are major problems (APA, 2001). Some HIV medications are metabolized by the same liver enzymes that metabolize psychotropic medications. For example, non-nucleoside reverse transcriptase inhibitors (nevirapine and efavirenz) induce the cytochrome P450 isozymes 3A and 2B6, which in turn can decrease blood concentrations of psychotropic medications. Alternatively, various

HIV-psychotropic drug interactions may lower antiretroviral levels. The APA guidelines furnish the full range of possible interactions and provide guidance for clinicians.

Skyrocketing drug costs are another concern for MI-HIV comorbidity. The high cost of HIV drugs is well known, running about $12,000 per year. But not as well known is the high and rising cost of psychotropic medications. The introduction of new brand-name drugs has fueled large price increases in HIV antivirals as well as psychotropic medications (NIHCM, 1999). Prices have also risen as a result of increasing consumer demand, increased physician diagnosis, and managed care's emphasis on medications over psychotherapy, among other reasons (NIHCM, 2002). Price increases are reflected in expenditure figures. During 1993–1998, psychotropic drug expenditures rose 462 percent for antipsychotics and 241 percent for antidepressants (NIHCM, 1999). Increasing expenditures for medications have placed already strapped public mental health programs in financial jeopardy.

Utilization and Outcomes of Care

It is well established that individuals with MI have high rates of morbidity and mortality from comorbid medical illnesses (DHHS, 1999; Sullivan et al., 1999; Cradock-O'Leary et al., 2002). This awareness has prompted concerns that people with comorbid MI-HIV might receive suboptimal HIV care. One early indication was from a nationally representative study finding disparities in patterns of HIV care. While use of needed care was good for many HIV-infected patients, disadvantaged populations—blacks, Latinos, women, the uninsured, and Medicaid-insured—had the least favorable patterns of care (Shapiro et al., 1999). Most of these demographic groups are at higher risk of developing an MI.

The only study to have directly assessed problems in HIV care for mentally ill individuals focused on SMI. The study, by researchers at RAND, examined barriers to care,[8] problems with hospital care, functional health status, and disability days for nearly 300 patients with SMI-HIV compared with nearly 1,300 patients with HIV alone. The SMI-HIV patients (in Los Angeles and New York City) were more likely than HIV-only patients to have more problems with hospital care, poorer functional status, and more disability days (David E. Kanouse, Personal communication, 2002). The investigators concluded that, in light of these disparities, interventions are needed to enhance HIV care for those with SMI.

In an extremely large study from multiple cities, the receipt of mental

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[8] Study findings regarding barriers to care are reported earlier in this appendix.

health services and substance abuse services did increase the likelihood of using HIV medical care, of staying in care, and of receiving more medical visits (Ashman et al., 2002). In addition, several types of tailored interventions have been studied that are designed to reduce high-risk sexual behaviors among those with MI-HIV. A 1997 review found that intensive, small-group interventions did produce short-term reductions in high-risk sexual behavior (Kelly, 1997). Subsequent studies have identified effective programs for assertiveness training for women with SMI (Weinhardt et al., 1998), cognitive–behavioral training for men and women (Otto-Salaj et al., 2001), and educational intervention for out-of-treatment cocaine users with depression and anti-social personality disorder (Compton et al., 2000). The problem is that most interventions are costly, labor-intensive, require frequent "booster" sessions, and thus not widely used (Sullivan et al., 1999). In addition, these programs were add-on services rather than attempts at integration of mental health, substance abuse, and HIV care. Integrated care has the potential to be more cost effective.

In 1998, the Substance Abuse and Mental Health Services Administration (SAMHSA), in collaboration with several other federal agencies, began a five-year demonstration program to determine the effects of integrated mental health, substance abuse, and HIV/AIDS primary care services on the three major outcomes: treatment adherence, health outcomes, and cost of treatment. Each of the eight study sites approaches integration in different ways, but most use some variation of co-location of services or intensive case management. The results have not yet been reported.

CONCLUSIONS

This appendix has described a body of literature on the impact of MI on HIV disease. Studies have found that MI increases the risk of acquiring or transmitting HIV by virtue of high-risk behavior or lower adherence to ARV. There are, however, variations in risk depending on symptoms, diagnosis, and other factors. For those with comorbid MI-HIV, studies have found wide-ranging barriers to care, including stigma, cost, inadequate detection of comorbidities, and fragmentation of services. If individuals reach care, their treatment needs are broader and more complex. Physicians may discriminate against mentally ill patients by withholding or deferring HIV therapies because of concerns about nonadherence. This form of discrimination is unwarranted because it relies on group identification, rather than on each patient's own track record of adherence. All indications are that coordinated or integrated care—for the full range of comorbidities, including substance abuse treatment—is critical for improving adherence with HIV care, controlling the HIV epidemic, and for providing patients with the most comprehensive and effective array of health services.

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Appendix
D

Financing HIV/AIDS Care: A Quilt with Many Holes[1]

Jennifer Kates
Kaiser Family Foundation

INTRODUCTION

There are multiple sources of insurance coverage and care for people with HIV/AIDS in the United States. Insurance coverage is important to help promote access to regular and high-quality care. Of those who are insured and in the care system, most are covered by public sector insurance programs (primarily Medicaid or Medicare or both). The uninsured and the underinsured rely on an array of safety net programs including the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, community and migrant health centers, private "free clinics," and public hospitals. Some people with HIV/AIDS have private insurance but may still need to rely on the Ryan White CARE Act to fill in the gaps.

These multiple sources of coverage and care for people with HIV, however, are not well coordinated across programs, making it difficult for patients, their advocates, and providers to navigate access. Moreover, these programs often vary by state, resulting in differential access across the country. As such, the current system of financing for HIV care represents a complex patchwork that leaves some outside the system and presents others with financial barriers to accessing needed care.[2,3,4,5]

Indeed, despite the existence of national treatment guidelines[6] calling for early access to medical care and treatment, including highly active antiretroviral therapy (HAART), an estimated 42% to 59% of the almost one million people living with HIV/AIDS in the U.S. are not in regular care[7] (see Figure D-1). While a proportion of these individuals may not know

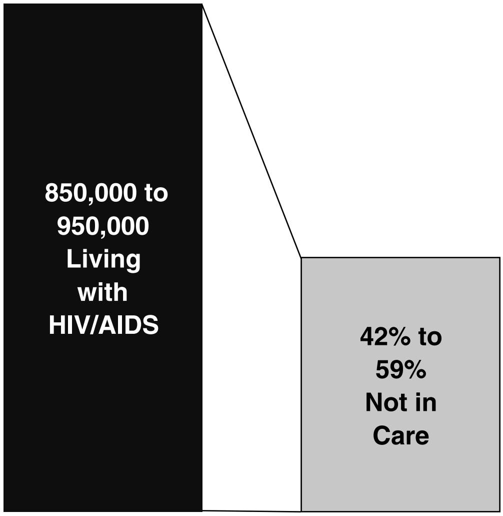

FIGURE D-1 Estimated number of people living with HIV/AIDS and proportion not in care, United States, 2000.
SOURCE: Fleming, P., et al., *HIV Prevalence in the United States, 2000*, 9th Conference on Retroviruses and Opportunistic Infections, Abstract #11, Oral Abstract Session 5, February 2002.

their HIV status (up to one-third of those living with HIV/AIDS[8]), others do not have access to insurance coverage (or face limits in their coverage) or care programs to help them afford the high cost of HIV treatment and services. The costs of HIV care present significant financial barriers to access for people with HIV/AIDS and strain the systems that serve them.

THE COST OF HIV CARE: A CONTINUING CONCERN

Financing care for people with HIV/AIDS has been of concern since early in the epidemic when people with HIV/AIDS often required expensive hospital inpatient and end-of-life care.[9,10,11] The introduction of antiretroviral drug treatment in 1987 did not allay cost concerns—the very first FDA-approved AIDS drug, AZT, carried an initial pricetag of $10,000 a year.[12] The current standard of care—combination antiretroviral therapy or HAART—calls for the use of expensive antiretrovirals in combinations of three, four, or even more medications.[6] HAART has been largely responsible for significant declines in HIV-related deaths and improved health status for many.[13,14] Combination therapy alone costs between $10,000 and $12,000 per patient per year depending on the regimen and payer (newer formulations of more than one antiretroviral drug may be priced as high as their component parts).[15,16,17,29] When additional medical expenses for doctor's visits, laboratory tests, and drugs to prevent or treat HIV-related opportunistic infections are taken into account, average annual costs rise to approximately $18,000 to $20,000 per patient, with even higher expenses for those with more advanced HIV-related illness.[17,18,19,20,21]

HIV is increasingly affecting people who are poor, outside the workforce, and have a history of barriers to access.[14,22] Even among those individuals who have resources, the costs of HIV care can quickly exhaust their assets and may leave them impoverished. In addition, despite improvements in treatment, HIV/AIDS is often a disabling condition that forces individuals to leave the workforce (or be unable to enter the workforce) thereby losing access to both income and, eventually, private insurance. Indeed, many people with HIV in care are low-income (an estimated 46% have incomes below $10,000 a year) and unemployed (63%).[19] Because of these factors, people with HIV rely heavily on the public sector for care.[11,23,24]

Expenditures for HIV/AIDS care, including public expenditures, have risen significantly over time.[23,24] Spending increases largely reflect growing numbers of people living with HIV/AIDS in need of services and increasing health care costs, particularly for prescription drugs. A recent analysis by the National Institute for Health Care Management (NIHCM) Foundation, for example, found that national retail drug expenditures for antiretrovirals totaled $2,572.4 million in 2001, representing an almost 21 percent increase over 2000, compared to a 17% increase for all retail prescription drug sales over the same period.[25] Analysis prepared for the Kaiser Family Foundation indicates that Medicaid spending on antiretrovirals increased significantly between 1991 and 1998, particularly after the introduction of HAART.[26] Spending on HIV/AIDS treatments by AIDS Drug Assistance Programs (ADAPs) has also increased significantly over time.[49]

Despite the high costs to patients and the payers and programs that serve them, spending on HIV care (an estimated $6.1 billion in 1998)[20] represents only a very small proportion—less than 1%—of estimated spending on overall direct personal health care expenditures in the United States.[27] In addition, several studies have demonstrated the cost effectiveness of HIV care when compared to the treatment of many other disabling conditions.[17,28,29,30] For example, a recent study found that the cost-effectiveness ratios of combination therapy for HIV infection ranged from $13,000 to $23,000 per quality-adjusted year of life gained (vs. no therapy) compared to $150,000 per quality-adjusted year of life gained for dialysis patients.[29]

INSURANCE COVERAGE OF PERSONS WITH HIV/AIDS

There are several challenges to assessing insurance coverage of persons with HIV/AIDS. These include difficulties in accessing the population of people with HIV/AIDS, given that a significant proportion is not in the care system and many do not know their HIV status, as well as limitations in data systems, methodological complexities, and the lack of capacity by major purchasers of care (e.g., state Medicaid programs) to perform client-level payer status analysis.

Coverage of Those in Care

The HIV Cost and Services Utilization Study (HCSUS), the only nationally representative study of people with HIV/AIDS in care, found that one-third to one-half of all people with HIV/AIDS were in regular care in 1996.[19,31] More recent estimates from the Centers for Disease Control and Prevention (CDC) place this range slightly higher, between 41% and 58%.[7]

Most of those in care rely on public sector insurance programs or are uninsured, estimated to range between approximately 70%[32] and 83%.[33] HCSUS found that one-half are estimated to depend on the Medicaid (44%) or Medicare (6%) programs for coverage and one in five (20%) are uninsured[32] (comparatively, among American adults overall, 6% are estimated to be covered by Medicaid, 2% by Medicare, and 19% are uninsured).[34] Almost one-third have private insurance, a much smaller percentage than the U.S. adult population overall (31% of people with HIV compared to 73% of American adults overall).[34] (See Figure D-2.) It is important to note that people with HIV/AIDS in care who are uninsured may be receiving care from Ryan White CARE Act programs or other safety net providers.

Many people with HIV/AIDS obtain their financing for care through multiple sources. For example, approximately 15% of those with Medicaid coverage also have other sources of coverage, primarily Medicare. About 12–13% of people with HIV/AIDS in care are estimated to be dual Medicaid and Medicare beneficiaries (called "dual eligibles" or "dual enrollees").[19,32,35] Viewed this way, Medicare covers approximately 19% of people with HIV/AIDS in care, including those also covered by Medicaid (6% with Medicare only and 12–13% with both Medicare and Medicaid).

More recent data on insurance coverage of people with HIV/AIDS in care are available from the HIV Research Network (HIVRN), a collaborative effort between the Agency for Healthcare Research and Quality (AHRQ), several other federal agencies, and the Johns Hopkins School of Medicine.[36] While not national in scope, the HIVRN includes data from 1999 for 15 medical practices around the country, representing approximately 9,500 patients. Insurance coverage data were available for 42% of

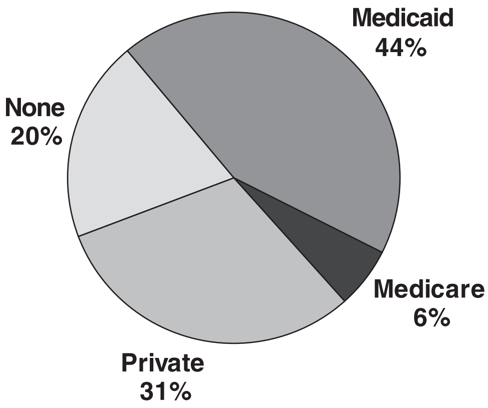

FIGURE D-2 Estimated insurance coverage of people living with HIV/AIDS in care, United States, 1996. Includes those with other coverage, primarily Medicare. SOURCE: Fleishman, J., Personal communication, Analysis of HCSUS Data, January 2002.

HIVRN patients. Of the full sample, including those for whom coverage data were not available, 30% had Medicaid coverage, 5% had Medicare coverage, 4% were uninsured, and 3% were privately insured. Of the 42% for whom coverage data were available, 70% were covered by Medicaid, 13% by Medicare, 10% were uninsured, and 7% were privately insured.[36]

There are important differences in coverage by race, ethnicity, and sex (see Figure D-3). HSCUS found[32] that African Americans and Latinos with HIV are much more likely to depend on Medicaid than whites (59% and 50% respectively, compared with 32% of whites). Minority Americans with HIV also are more likely to be uninsured than whites (22% of African Americans and 24% of Latinos compared with 17% of whites). Whites with HIV have the highest rate of private insurance across all racial and ethnic groups (44%). Women with HIV are also much more likely to rely on public insurance than their male counterparts, particularly Medicaid (61% of women compared with 39% of men), and less likely to be covered through the private sector (14% of women compared with 36% of men). This may be due in part to the fact that women are more likely to qualify for Medicaid as parents of dependent children or when pregnant. The intersection of race/ethnicity and sex is important here—most women newly infected with HIV and living with AIDS are women of color.[13,37]

Persons in care do not fare equally in the health care system. Analysis of data from HCSUS found that people with HIV who were covered by

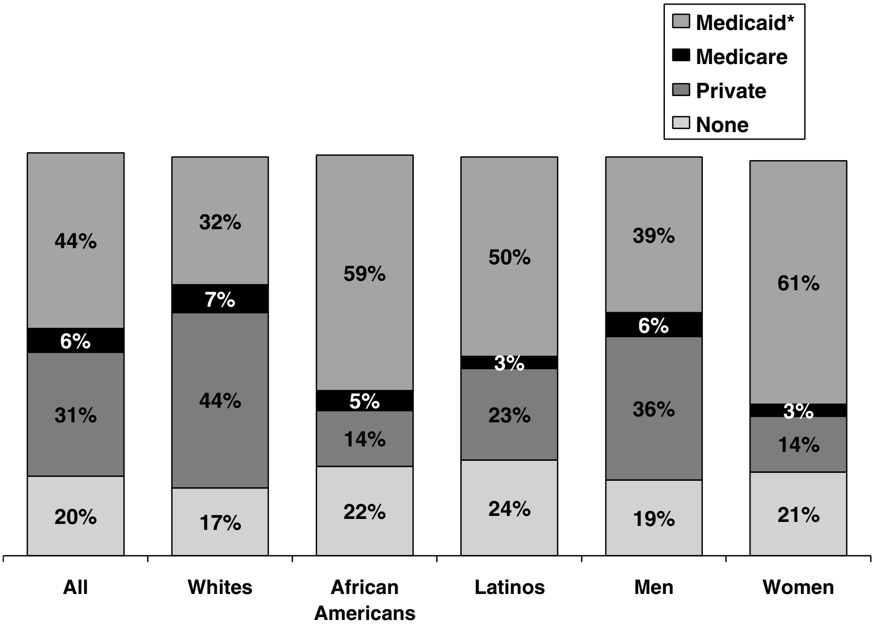

FIGURE D-3 Estimated insurance coverage of people living with HIV/AIDS in care by race/ethnicity and sex, United States, 1996. *Includes those with other coverage, primarily Medicare; May not total 100% due to rounding.
SOURCE: Fleishman, J., Personal communication, Analysis of HCSUS Data, January 2002.

Medicaid or were uninsured, and women and minority groups, fared more poorly on a range of access measures than those who were privately insured, male, and white.[38] Other studies have found disparities as well.[39,40,41,42] The reasons for this variation are not well understood but are likely due to a range of factors including the existence of historical barriers to access, disease stage at time of HIV diagnosis and at entrance into care, and HIV-related stigma.[40,43,44]

More recent analyses, including longitudinal analyses of the HCSUS national probability sample, have found that some of these differences have narrowed over time.[38,40,41,42] In addition, findings related to differences in care vary by type of access measure. For example, while HCSUS findings indicate that those covered by Medicaid did not fare as well as those who were privately insured according to some measures of access (e.g., receipt of combination therapy, hospitalization rates),[38] Medicaid coverage was also found to be a protective factor against delay in obtaining initial medical care after HIV diagnosis, compared to other payers.[45,46] Similarly, analysis of insurance coverage at time of initial HIV diagnosis indicates that those covered by Medicaid or by other public payers were less likely to be diagnosed late in illness than those who were privately insured (see discussion below).[47]

COVERAGE OF THOSE NOT YET IN CARE

Little is known about insurance coverage of people with HIV/AIDS who are not yet in regular HIV care. Recent analysis of the CDC's HIV/AIDS Surveillance System (HARS) database provides the first assessment of payer status at time of initial HIV diagnosis, before entrance into HIV care.[47] HARS data from 1994 through 1999 from 25 states with integrated HIV and AIDS surveillance were analyzed. Of the 104,780 persons diagnosed with HIV, data on insurance coverage were available for approximately half (52%). Of the full sample, including those for whom no coverage data were available, private coverage was the most common payer (17%); slightly more than one-third had public coverage or were uninsured—11% had Medicaid coverage, 10% had other public/government coverage, and 14% were uninsured. Of the 52% for whom insurance coverage data were available, 32% were privately insured, 22% had Medicaid coverage, 19% had other public coverage, and 27% were uninsured.[47,48] (See Figure D-4.)

Insurance coverage varied by race/ethnicity, sex, and exposure category at time of diagnosis. For example, while similar proportions of men and women were uninsured, women were more than twice as likely to be covered by Medicaid at time of diagnosis. African American and Latino women were more likely to be covered by Medicaid than white women. Latinos were least likely to be insured.[47]

In addition, insurance coverage and timing of initial HIV diagnosis (e.g., whether or not a diagnosis was "late," defined as having an AIDS diagnosis made within one year of the first reported HIV diagnosis) appear to be related. For example, between 34% and 54% were diagnosed late, depending on coverage. Those with private insurance were more likely to receive a late diagnosis (54%) than not (46%), while those with Medicaid, other public insurance, and the uninsured were more likely to receive an HIV diagnosis more than 12 months before their AIDS diagnosis.[47]

FEDERAL SPENDING ON HIV/AIDS CARE

Data on federal spending on HIV/AIDS care are derived from analysis of funds specifically earmarked in appropriations legislation for HIV/AIDS care and from agency estimates.[24] Actual HIV/AIDS care expenditures for the two largest care programs for people with HIV/AIDS, Medicaid and

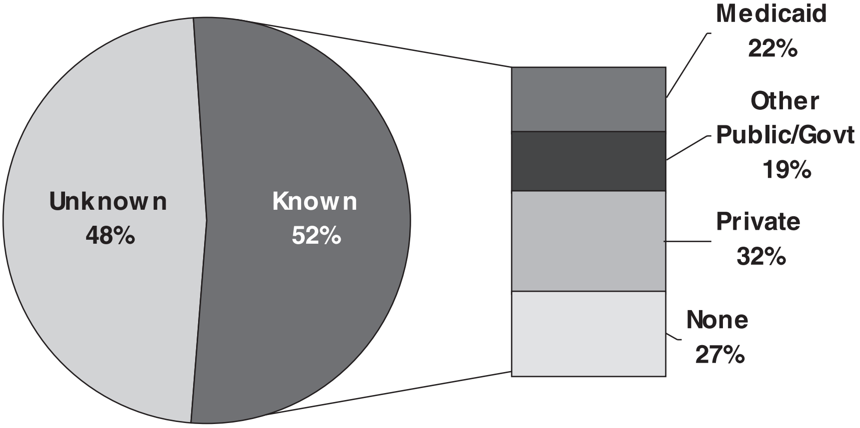

FIGURE D-4 Insurance coverage of persons with HIV/AIDS at time of diagnosis, 1994–1999.
SOURCE: Kates, J., Levi, J., Neal, J., Gallagher, K., "Learning More About the HIV-Infected Population Not IN Care in the United States: Using Public Health Surveillance Data to Inform Current Policy Challenges in Enhancing Access," Poster TuPeG 5690, XIV International AIDS Conference, Barcelona, Spain, July 2002.

Medicare, are not available, and data presented here are based on actuarial estimates provided by the Centers for Medicare and Medicaid Services (CMS), the Department of Health and Human Services (DHHS) Agency that has responsibility for the Medicaid and Medicare programs. This is primarily due to the difficulties of assessing actual expenditures for people with HIV/AIDS within these two programs, since such spending data are not routinely collected; rather, to assess actual spending for people with HIV/AIDS, Medicaid and Medicare claims data would need to be analyzed using an algorithm specifically designed to identify claims for HIV-related care. Such algorithms have been developed, but are expensive and complex to implement at a national level and most states do not have the capacity to carry out these analyses on their own for their Medicaid programs. The advent of managed care presents additional challenges to collecting and analyzing actual spending data for people with HIV/AIDS.

In FY 2002, federal spending on HIV/AIDS-related medical care, research, prevention, and other activities was estimated to total $14.7 billion.[23,24] Of that, more than half ($8.7 billion or 59%) was spent on health care and related support services for people with HIV/AIDS (an additional $1.6 billion was spent on disability income support provided through the Supplemental Security Income [SSI] and Social Security Disability Insurance

[SSDI] programs and housing assistance provided through the Housing Opportunities for Persons with AIDS [HOPWA] program). Not included in these care spending estimates is spending by state and local governments, although such spending represents an important component of public sector spending on HIV/AIDS care (for example, in FY 2002, the state share of Medicaid spending on AIDS was estimated by CMS to be $3.5 billion;[23,24] in addition, in FY 2002, states reported that they provided $160 million to their AIDS Drug Assistance Programs).[49]

Medicaid is estimated to account for the federal government's single largest expenditure on HIV/AIDS (29%). It also represents the largest amount of federal spending on health care for people with HIV/AIDS (48%), followed by Medicare (24%), and the Ryan White CARE Act (22%). The Department of Veterans Affairs accounts for another 4% of HIV/AIDS care spending, and remaining spending is spread among other agencies at the Department of Health and Human Services (e.g., the Substance Abuse and Mental Health Services Administration) and the Departments of Defense and Justice.[24] (See Figure D-5.)

More than two-thirds (72% in FY 2002) of estimated federal spending on HIV/AIDS care is entitlement or mandatory spending, through the Medicaid and Medicare programs. (See Figure D-6.) This is in large part because many people with HIV/AIDS become low-income (or are already low-income) and disabled and qualify for the nation's health insurance entitlement programs. Twenty-eight percent is discretionary spending, primarily through the Ryan White CARE Act, which is the third largest source of federal funding for HIV/AIDS care. These distinctions are important since most entitlement spending changes each year (increases or decreases) based on the need for and cost of services while discretionary spending is dependent on annual appropriations by Congress and may not correspond to the number of people who need care or the costs of that care.

Between FY 1995 and FY 2002, mandatory spending on HIV/AIDS care increased markedly (by 152%). Discretionary spending for HIV/AIDS care programs also increased significantly over this period (by 140%).[24] As mentioned above, these increases largely reflect the advent of antiretroviral combination therapy, the rising cost of prescription drugs, and the growing numbers of people living with HIV/AIDS in need of care. Between FY 2001 and FY 2002, estimated mandatory spending on AIDS care increased by approximately 13% percent; it grew by 14% between FY 2002 and FY 2003.[24,50,51] Federal funding for the Ryan White CARE Act increased by 6% between FY 2001 and FY 2002; it also grew by 6% between FY 2002 and FY 2003.[24,52]

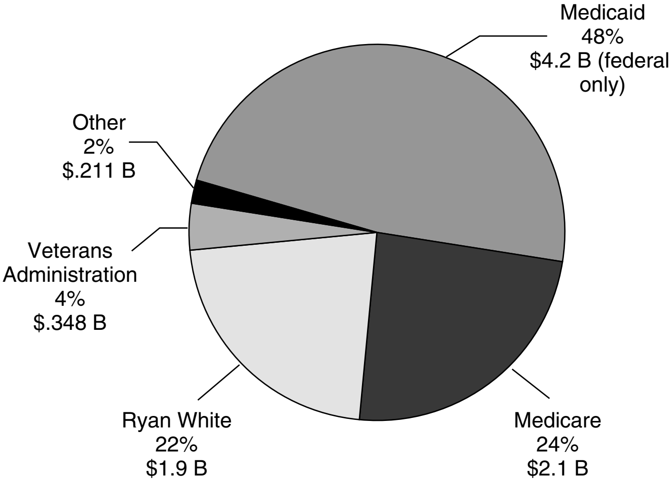

FIGURE D-5 Federal spending on HIV/AIDS care by program, FY 2002.
SOURCE: Kaiser Family Foundation, *Federal HIV/AIDS Spending: A Budget Chartbook, FY 2002*, September 2003.

FIGURE D-6 Federal spending on HIV/AIDS care by type (mandatory or discretionary), FY 2002.
SOURCE: Kaiser Family Foundation, *Federal HIV/AIDS Spending: A Budget Chartbook, FY 2002*, September 2003.

HOW IS HIV/AIDS CARE FINANCED: MAJOR SOURCES OF COVERAGE AND CARE

There are several sources of coverage and care for people with HIV/AIDS, including insurance mechanisms such as Medicaid, Medicare, and private insurance, and publicly supported sources of care, such as the Ryan White CARE Act, the Veterans Health Administration, and community health centers.

The availability and accessibility of these programs vary significantly across the country. Eligibility depends on a variety of factors—including an individual's health/disease status, family status, income, and assets—each of which may vary for a given individual over time. An individual may be eligible for more than one program in some states or none in others, and not all coverage and care programs are available in every state. Some programs are specifically designed for people with HIV/AIDS, such as those funded by the Ryan White CARE Act and HIV-specific Medicaid waivers. Others are more general coverage or care programs that are important for people with HIV/AIDS, particularly Medicaid and Medicare. Major sources of coverage and care are described below, and summary descriptions, as well as challenges, are provided in Table D-1. Table D-2 provides state-by-state data on variation in eligibility and other key characteristics for select programs.

Medicaid: Coverage for Low-Income Persons with HIV/AIDS

Medicaid (also known as Title XIX of the Social Security Act) is the largest source of public financing for HIV/AIDS care in the United States. Created in 1965, Medicaid is a jointly funded, jointly administered federal–state health insurance program for certain low-income people who meet one or more of several categorical eligibility requirements, including disability. Because many people with HIV/AIDS are low income—or become low-income—and disabled, Medicaid is a vital source of coverage for people with HIV. The program is estimated to cover approximately 44% of people with HIV, including those with AIDS, who are receiving care.[32] As people progress in their illness, it is more likely they will become eligible for Medicaid. Among persons living with AIDS, 55% are estimated to be enrolled in Medicaid. Medicaid is also estimated to cover the health costs of up to 90% of children with AIDS.[53] Among those recently diagnosed with HIV (for whom coverage data were available), more than one-fifth (22%) were already covered by Medicaid.[47]

CMS estimates that approximately 218,000 persons with AIDS were Medicaid beneficiaries in FY 2002 (due to the methodological challenges described above, the actual number of Medicaid beneficiaries with HIV/

AIDS is not currently known).[53] Medicaid spending on AIDS care in FY 2002 was $7.7 billion, including $4.2 billion in federal dollars and $3.5 billion in state funds. In FY 2003, CMS estimates that federal Medicaid spending on AIDS care totaled $4.8 billion.[50] Federal Medicaid spending on AIDS care more than tripled between FY 1995 and FY 2003, rising from $1.5 billion to $4.8 billion.[23,24,50]

At the federal level, the Medicaid program is administered by the Centers for Medicare & Medicaid Services of the Department of Health and Human Services. Through Medicaid, the federal government makes matching funds available to states that meet certain minimum federal standards in operating their Medicaid programs. Since 1982, all states have chosen to participate. States have broad flexibility in designing their Medicaid programs, and as a result there is significant variation in eligibility, benefits, provider payments, and other aspects of the program at the state level.[54,55]

Eligibility

To be eligible for Medicaid a person must have income, assets, and resources at or below a state's standard and generally meet one of several other eligibility criteria. There are certain categories of individuals that all states participating in Medicaid must cover, including the disabled. Most adults with HIV/AIDS who qualify for Medicaid do so because they meet the disability and income criteria of the federal SSI program for persons who are aged, blind, or disabled. For purposes of SSI eligibility, a person is disabled if they are unable to engage in any "substantial gainful activity by reason of a medically determined physical or mental impairment expected to result in death, or that has lasted or can be expected to last for a continuous period of at least 12 months."[54] There are eleven states, known as 209B states, however, that may apply more restrictive eligibility rules than those under SSI.[56]

Optional Medicaid eligibility categories are also important for people with HIV/AIDS, particularly the medically needy program. The medically needy program enables those who meet categorical eligibility requirements, such as disability, to spend-down their incomes on medical expenses to meet their state's income eligibility threshold; these income thresholds vary significantly across states.[56] Individuals qualifying as medically needy must also meet a resource test. Thirty-six states offer this optional program, 35 of which make it available to those who are disabled.[57] Given the high costs of HIV care, the medically needy program can be an important option available to people with HIV/AIDS.[54,57]

The Omnibus Budget Reconciliation Act of 1986 (OBRA 86) gave states the option to provide full Medicaid benefits to all aged and disabled persons with incomes up to 100% of the federal poverty level (FPL). Nine-

TABLE D-1 Major Sources of Coverage and Care for HIV/AIDS Financing, with Benefits and Challenges

Source of Coverage/Care (funding source)	Eligibility	Benefits
Medicaid (Federal and state funding)	Individuals must have income and assets at or below a state's standard and meet categorical eligibility criteria Mandatory groups include individuals who meet the disability and income criteria of the SSI program (some states use more restrictive criteria), certain low-income parents and children, low-income pregnant women, and certain low-income individuals who qualify for Medicare Optional groups include the medically needy and certain low-income working disabled Most people with HIV/AIDS who qualify for Medicaid meet income and disability criteria of the SSI program	Mandatory services include Inpatient/outpatient hospital care Physician visits Lab and x-ray services Home health care Long-term care Optional benefits include: Prescription drugs Case management Dental services
Medicare (Federal funding)	Age 65+ Under 65 disabled who receive Social Security Disability Insurance (SSDI) benefits Individuals with end-stage renal disease Most people with HIV/AIDS who qualify for Medicare are disabled SSDI beneficiaries	Part A Services include Inpatient hospital care Skilled nursing facilities Hospice care Home health care Part B Services include: Physician visits Outpatient hospital services Labs, x-rays, and medical equipment Medicare+Choice (M+C) plans contract with Medicare to provide both Part A and B services to enrolled beneficiaries. Part D adds outpatient prescription drug coverage, effective January 1, 2006. Beneficiaries entitled to Part A or enrolled in Part B are eligible to enroll in Part D.

Challenges
Eligibility “Catch-22” — SSI eligibility based on being disabled although therapies exist that can prevent disability, early care recommended Returning to work/entering workforce makes continuation of coverage uncertain Variation across states in eligibility, benefits, and other aspects of program Access to experienced HIV providers may be issue, particularly in Medicaid managed care context Need to ensure adequate capitation/reimbursement rates and services; historically low payment rates for providers and institutions HIV/AIDS drug prices higher than for other government purchasers
Eligibility “Catch-22” — SSDI eligibility based on being disabled although therapies exist that can prevent disability, early care recommended Must also have sufficient work history to be eligible 29-month waiting period from determination of SSDI eligibility before coverage begins High cost-sharing requirements No cap on out-of-pocket spending Lack of outpatient prescription drug benefit currently; prescription drug coverage benefit as of January 1, 2006 Prescription drug benefit may present new challenges, particularly to the dually eligible, for whom Medicaid prescription drug benefits will end. Challenges may include difficulty navigating the enrollment process; the potential for temporary lapse in coverage; variation and limitation in formularies; out-of-pocket expenses, which may be higher than those paid under Medicaid; and denial of prescription drugs if co-payment cannot be met

continued

TABLE D-1 Continued

Source of Coverage/Care (funding source)	Eligibility	Benefits
Ryan White CARE Act (Federal funding with some state and local funding)	Uninsured and underinsured individuals and families living with HIV/AIDS Eligibility set by states and municipalities	Primarily outpatient and related support services including Physician/clinic visits Prescription drugs (through ADAP) Case management Home health and hospice care Dental care Developmental and rehabilitation services Insurance continuation
Private Health Insurance (Employer, employees, individuals)	Group Coverage, primarily through an employer or association Individual coverage purchased through carrier/broker Most people with HIV/AIDS who are privately insured obtain group coverage through employer	Group plans tend to cover Inpatient and outpatient hospital care Physician visits Prescription drugs Lab tests, x-rays, and durable medical equipment Inpatient and outpatient mental health services Individual plans vary from policy to policy
Department of Veterans Affairs (Federal funding)	Any veteran of the armed services, including disabled veterans	Outpatient, inpatient, long-term care, prescription drugs, and range of other services VA operates AIDS service for veterans with HIV/AIDS
Community Health Centers and Other Safety Net Providers (Federal, state, and local funding)	Varies by type of provider Primarily serve low-income individuals, including uninsured or underinsured individuals and families; also serve many Medicaid beneficiaries	Services vary by type of provider but can include Physician/clinic visits Inpatient/outpatient hospital care Emergency care Some preventive services

Challenges
Discretionary grant program dependent on annual appropriations by Congress and in some cases, states and municipalities Funding does not necessarily match need for or cost of care Variation in programs and services across the country More CARE dollars needed to fill gaps in jurisdictions with less generous access to other programs Allocation of most CARE Act dollars based on AIDS cases, not HIV infection and may not reflect current burden and recent trends
Medical underwriting in the individual market may lead to denial of or limits on coverage—HIV generally considered uninsurable condition Premiums for individual policies often too high to afford Annual or lifetime caps on benefits may limit care for people with HIV/AIDS and other chronic conditions Limits may be placed on specific services (e.g., number of prescriptions filled, number of physician visits) May be other co-pays or deductibles
Disability must be service-related and/or veteran must be poor to receive subsidized care, otherwise must pay share of costs Not all veterans live near VA facilities
Most are discretionary grant funded and dependent on annual appropriations by Congress, states, and municipalities Funding does not necessarily match need for or cost of services Access to experienced HIV providers may be issue

TABLE D-2 State Variation in Insurance Coverage and Care Programs for People with HIV/AIDS: Select Programs, Both HIV-Specific and General

State/ Territory	SSI Eligibility %FPL, 2000[1]	Pregnant Women Eligibility, %FPL, 2000[1]	Medically Needy Program Eligibility, %FPL 2001[1,2]	209B States, 2002[1,2]	Prescription Limitations per Month # per month 2003[3]	HIV-Specific Waivers: 1115, TWWIIA, HCBS, 2002[4,5]
United States (Total number of states)	—	—	36 states (35 for disabled)	11 states	14 states	20 states (17 HCBW, 3 1115, 2 TWWIIA)
Alabama	74	133	—	—	—	—
Alaska	74	200	—	—	—	—
Arizona	74	140	—	—	—	—
Arkansas	74	133	Yes (15)	—	6	—
California	74	300[A]	Yes (83)	—	6	HCBS
Colorado	74	133	—	—	—	HCBS
Connecticut	69	185	Yes (80/66)	Yes	—	—
Delaware	74	200	—	—	—	HCBS
District of Columbia	74	200	Yes (53)	—	—	1115, TWWIIA, HCBS
Florida	74	185	Yes (25)	—	4	HCBS
Georgia	74	235	Yes (44)	—	5	—
Hawaii	Other	185	Yes (51)	Yes	—	HCBS
Idaho	74	133	—	—	—	—
Illinois	41	200	Yes (40)	Yes	—	HCBS
Indiana	76	150	—	Yes	—	—
Iowa	74	200	Yes (67)	—	—	HCBS
Kansas	74	150	Yes (66)	—	5	—

Eligibility, %FPL, June 2002[6]	Number of Drugs on Formulary, June 2002[6]	Waiting List or Other Restriction, September 2003[6,7]	Title I EMA(#), 2001[8]	Title III EIS Site (#) , 2001[8]	Ryan White Health Insurance Continuation Program, 2001[8]	State Pharmacy Assistance Programs for Non-Seniors—Subsidy (S) & Discount (D) Programs (not-HIV specific), 2002[9,10]	State-Sponsored High-Risk Pool, (not HIV-specific), 2001[11]
—	—	16 states	28 states (51 EMAs)	50 states (310 EIS)	37 states	14 states	29 states
250	26	Waiting List	—	Yes (9)	—	—	Yes
300	62	Capped Enrollment	—	Yes (2)	Yes	—	Yes
300	27	—	Yes (1)	Yes (3)	—	Yes (S)[C]	—
300	43	Capped Enrollment	—	Yes (3)	—	—	Yes
400	144	—	Yes (9)	Yes (30)	Yes	Yes (D)	Yes
300	40	Waiting List	Yes (1)	Yes (2)	Yes	—	Yes
400	170	—	Yes (2)	Yes (6)	—	Yes (S)	Yes
500	137	—	—	Yes (1)	Yes	Yes (S)	—
300	65	—	Yes (1)	Yes (5)	—	Yes (S)	—
350	53	—	Yes (6)	Yes (19)	Yes	Yes (D)	Yes
300	47	—	Yes (1)	Yes (13)	Yes	—	—
400	85	—	—	Yes (1)	Yes	—	—
200	35	Capped Enrollment	—	Yes (1)	—	—	—
400	67	—	Yes (1)	Yes (13)	Yes	Yes (S)	Yes
300	67	Waiting List	—	Yes (2)	Yes	—	Yes
200	32	—	—	Yes (4)	Yes	Yes (D)	Yes
300	47	—	Yes[B]	Yes (1)	Yes	—	Yes

continued

TABLE D-2 Continued

State/ Territory	SSI Eligibility %FPL, 2000[1]	Pregnant Women Eligibility, %FPL, 2000[1]	Medically Needy Program Eligibility, %FPL 2001[1,2]	209B States, 2002[1,2]	Prescription Limitations per Month # per month 2003[3]	HIV-Specific Waivers: 1115, TWWIIA, HCBS, 2002[4,5]
Kentucky	74	185	Yes (30)	—	—	—
Louisiana	74	133	Yes (14)	—	8	—
Maine	74	200	Yes (44)	—	—	1115
Maryland	74	200	Yes (49)	—	—	—
Massachusetts	74	200	Yes (NA)	—	—	1115
Michigan	74	185	Yes (57)	—	—	—
Minnesota	70	275	Yes (67)	Yes	—	—
Mississippi	—	185	—	—	5	TWWIIA
Missouri	74	185	—	Yes	5	HCBS
Montana	74	133	Yes (73)	—	—	HCBS
Nebraska	74	185	Yes (55)	—	—	—
Nevada	74	133	—	—	—	—
New Hampshire	76	185	Yes (76)	Yes	—	—
New Jersey	74	185	Yes (51)	—	—	HCBS
New Mexico	74	185	—	—	—	HCBS
New York	74	200	Yes (87)	—	Yes - Annual Limit	—
North Carolina	74	185	Yes (34)	—	6	HCBS
North Dakota	65	133	Yes (66)	Yes	—	—
Ohio	64	150	—	Yes	—	—
Oklahoma	74	185	Yes (36)	Yes	3	—
Oregon	74	170	Yes (58)	—	—	—
Pennsylvania	74	185	Yes (59)	—	—	HCBS

Eligibility, %FPL, June 2002[6]	Number of Drugs on Formulary, June 2002[6]	Waiting List or Other Restriction, September 2003[6,7]	Title I EMA(#), 2001[8]	Title III EIS Site (#) , 2001[8]	Ryan White Health Insurance Continuation Program, 2001[8]	State Pharmacy Assistance Programs for Non-Seniors—Subsidy (S) & Discount (D) Programs (not-HIV specific), 2002[9,10]	State-Sponsored High-Risk Pool, (not HIV-specific), 2001[11]
300	30	Waiting List	—	Yes (4)	Yes	—	Yes
200	18	—	Yes (1)	Yes (8)	Yes	—	Yes
300	38	—	—	Yes (2)	—	Yes (S, D)[C]	—
400	85	—	Yes (1)	Yes (3)	Yes	Yes (S,D)	—
less than $50,000 per yr	open	—	Yes (1)	Yes (16)	Yes	Yes (S)	—
450	160	—	Yes (1)	Yes (4)	Yes	—	—
300	112	—	Yes (1)	Yes (2)	Yes	—	Yes
400	43	—	—	Yes (7)	—	—	Yes
300	270	—	Yes (2)	Yes (4)	Yes	—	Yes
300	49	Waiting List	—	Yes (1)	Yes	—	Yes
200	18	Waiting List	—	Yes (2)	Yes	—	Yes
400	55	—	Yes (1)	Yes (2)	Yes	—	—
300	32	—	Yes[B]	—	Yes	—	Yes
500	open	—	Yes (5)	Yes (8)	Yes	Yes (S)	—
300	60	—	—	Yes (3)	Yes	—	Yes
less than $44,000 per yr	463	—	Yes (3)	Yes (41)	Yes	—	—
125	51	Capped Enrollment	—	Yes (9)	—	—	—
400	86	—	—	—	—	—	Yes
300	69	—	Yes (1)	Yes (7)	Yes	—	—
200	65	Other	—	Yes (2)	—	—	Yes
200	56	Waiting List	Yes (1)	Yes (1)	Yes	—	Yes
less than $30,000 per yr	69	—	Yes (1)	Yes (18)	—	—	—

continued

TABLE D-2 Continued

State/ Territory	SSI Eligibility %FPL, 2000[1]	Pregnant Women Eligibility, %FPL, 2000[1]	Medically Needy Program Eligibility, %FPL 2001[1,2]	209B States, 2002[1,2]	Prescription Limitations per Month # per month 2003[3]	HIV-Specific Waivers: 1115, TWWIIA, HCBS, 2002[4,5]
Rhode Island	74	250	Yes (87)	—	—	—
South Carolina	74	185	—	—	4	HCBS
South Dakota	74	133	—	—	—	—
Tennessee	74	185	Yes (34)	—	—	—
Texas	74	185	Not for disabled	—	3	—
Utah	74	133	Yes (53)	—	—	—
Vermont	74	200	Yes (111/102)	—	—	—
Virginia	74	133	Yes (47)	Yes	—	HCBS
Washington	74	185	Yes (78)	—	>4 brand review	HCBS
West Virginia	74	150	Yes (28)	—		—
Wisconsin	74	185	Yes (83)	—	—	—
Wyoming	74	133	—	—	—	—
Puerto Rico	—	—	—	—	—	—
Virgin Islands	—	—	—	—	—	—
Guam	—	—	—	—	—	—

NOTES:

[A] California's Medicaid program covers pregnant women with incomes up to 200%FPL; The Access for Infants and Mothers (AIM) program covers pregnant women between 200%FPL and 300%FPL.

[B] The Eligible Metropolitan Area (EMA) in this state is part of another state's EMA.

[C] Arizona program not yet operational. Maine discount program halted pending legal action. Vermont discount program not yet operational.

[D] Coverage for high-risk individuals is now provided under TennCare, the state's Medicaid program. The Tennessee Comprehensive Health Insurance Pool ceased operations on June 30, 1996.

Eligibility, %FPL, June 2002[6]	Number of Drugs on Formulary, June 2002[6]	Waiting List or Other Restriction, September 2003[6,7]	Title I EMA(#), 2001[8]	Title III EIS Site (#), 2001[8]	Ryan White Health Insurance Continuation Program, 2001[8]	State Pharmacy Assistance Programs for Non-Seniors—Subsidy (S) & Discount (D) Programs (not-HIV specific), 2002[9,10]	State-Sponsored High-Risk Pool, (not HIV-specific), 2001[11]
400	57	—	—	Yes (2)	Yes	—	—
300	48	—	—	Yes (7)	Yes	—	Yes
300	41	Waiting List	—	Yes (1)	Yes	—	—
300	43	—	—	Yes (4)	Yes	—	See note D
200	36	—	Yes (5)	Yes (9)	Yes	—	Yes
200	18	—	—	Yes (1)	Yes	—	Yes
200	69	—	—	Yes (1)	Yes	Yes (S,D)[C]	—
300/333	51	—	Yes (1)	Yes (5)	—	—	—
300	137	Other	Yes (1)	Yes (5)	Yes	—	Yes
250	27	Waiting List	Yes[B]	Yes (1)	Yes	—	—
300	43	—	Yes[B]	Yes (4)	Yes	—	Yes
200	51	Other	—	—	—	Yes (S)	Yes
certified as indigent	115	—	Yes (3)	Yes (9)	—	—	—
200	26	—	—	Yes (2)	—	—	—
200	26	—	—	—	—	—	—

SOURCES:

[1] Kaiser Family Foundation, *State Health Facts Online*, Medicaid & SCHIP, Eligibility Levels for Other Medicaid Enrollment Groups as Percent of Federal Poverty Level, www.statehealthfacts.org (Accessed January 18, 2003). See website for specific notes on state eligibility levels.

[2] Analysis prepared for the Kaiser Commission on Medicaid and the Uninsured by Jeff Crowley, Georgetown University, 2003.

[3] Kaiser Commission on Medicaid and the Uninsured, *Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey, 2003*, December 2003.

continued

TABLE D-2 Continued

[4] Centers for Medicare & Medicaid Services, Personal communication, August 2002

[5] Kaiser Family Foundation, *State Health Facts Online*, HIV/AIDS, Status of State Medicaid Expansion Efforts for People with HIV, www.statehealthfacts.org (Accessed January 18, 2003).

[6] National Alliance of State and Territorial AIDS Directors/Kaiser Family Foundation/AIDS Treatment Data Network, National ADAP Monitoring Project, Annual Report, April 2003.

[7] National Alliance of State and Territorial AIDS Directors, ADAP Watch, September 2003. Other restrictions include reduced formularies, annual expenditure caps, cost-sharing, and lowering financial eligibility criteria.

[8] Health Resources and Services Administration, HIV/AIDS Bureau, http://hab.hrsa.gov/ (Accessed August 30, 2002); Personal communication, HIV/AIDS Bureau, August and November 2002.

[9] Kaiser Family Foundation, *State Health Facts Online*, Medicare, State Pharmaceutical Assistance Programs, www.statehealthfacts.org (Accessed January 18, 2003).

[10] National Conference of State Legislatures, State Pharmaceutical Assistance Programs, http://www.ncsl.org/programs/health/drugaid.htm (Accessed January 18, 2003).

[11] Kaiser Family Foundation, *State Health Facts Online*, Managed Care and Health Insurance, State Sponsored High Risk Insurance Pools, www.statehealthfacts.org (Accessed January 18, 2003).

teen states use this option (17 have expanded Medicaid eligibility up to the poverty level and 2 have raised the income standard but not to the poverty level).[58]

Some children and adults with HIV/AIDS also qualify for Medicaid before they are disabled if they are poor and meet other program eligibility categories. The primary non-disabled categories are for low-income children and their parents and pregnant women. The income limits for each of these different eligibility criteria vary. Some Medicaid beneficiaries are also covered by Medicare, as discussed below.[19,32,54]

Benefits

Federal rules require states participating in Medicaid to cover a set of mandatory services to the categorically needy in order to receive federal matching payments. States may also choose to provide optional services and receive matching payments. One of the most important benefits for people with HIV/AIDS, prescription drugs,[59] is an optional benefit that all states have chosen to provide. Other optional services that can be important for people with HIV/AIDS include targeted case management, prevention services, and hospice services. Currently, 17 states have developed home and community based services (HCBS) programs for people with

AIDS using Section 1915(c) waivers. HCBS waiver programs are for individuals determined to be at risk for institutional care and have been used for people with AIDS to maximize their independence through the use of services such as case management, adult day health care, and hospice care.[60]

States may place limits on some Medicaid services, and several limit the number of prescriptions allowed per month, the length of hospital inpatient services, and the number of physician visits (these limits cannot, however, be applied selectively to one group of beneficiaries). In 2003, for example, 14 states limited the number of prescriptions per month or year.[61] States may also impose "nominal" cost-sharing requirements on most non-emergency mandatory or optional services with respect to adults (other than pregnant women and institutionalized patients). Emergency care, hospice care, and family planning services are excluded from cost-sharing.

Challenges

Certain aspects of the Medicaid program present challenges to people living with HIV/AIDS, as well as to low-income adults more generally (since low-income adults mainly qualify for Medicaid after they are disabled). These include the following:

Eligibility "Catch-22"

One main challenge facing low-income people with HIV/AIDS is a Medicaid eligibility "Catch-22"—many are not eligible for Medicaid until they become disabled, despite the availability of therapies that may prevent disability. Several options are being considered to address this, including:

- Section 1115 Waivers. Several states have applied for or are considering Medicaid Section 1115 waivers to expand Medicaid eligibility to low-income people with HIV prior to disability.[62] To date, three states—Maine, Massachusetts, and the District of Columbia—have received federal approval to operate such waivers. Only the Massachusetts and District of Columbia waiver is currently operational. A major barrier to the 1115 waiver strategy is that 1115 waivers must be "budget neutral" (i.e., the costs of the expansion over a designated period of time, usually 5 years, cannot exceed the costs to Medicaid in the absence of the expansion). This standard has been hard for states to meet. While analyses have shown that additional, non-Medicaid savings will accrue through such expansions (e.g., to SSI, SSDI, Medicare, and the Ryan White AIDS Drug Assistance Program), these savings cannot be included in budget neutrality calculations under current policy.[17,30]
- The Ticket to Work/Work Incentives Improvement Act of 1999.

The Ticket to Work/Work Incentives Improvement Act (TWWIIA) included an option for states to launch demonstration projects to provide Medicaid to workers with potentially severe disabilities, including HIV/AIDS, who are not yet disabled but whose health conditions could be expected to cause disability. This demonstration is funded at a total of $250 million over the FY 2001–2006 period. Mississippi and the District of Columbia have been awarded approval for HIV-related demonstrations under the Act.[62]

- The Early Treatment for HIV Act. Because of the many barriers faced by states through the 1115 process and the limited nature of the TWWIIA demonstration, Congress is considering the Early Treatment for HIV Act (ETHA). ETHA would create a new state option to expand Medicaid coverage to low-income people living with HIV who are not disabled, similar to legislation passed in 2000 by Congress that gave states the option to provide Medicaid coverage to women diagnosed with breast and cervical cancer.[63]

Returning to/Entering the Workforce

While new treatments are enabling more Medicaid beneficiaries with HIV to enter or return to the workforce, the continuation of their Medicaid coverage is uncertain. Current Medicaid rules do not allow beneficiaries to keep their health coverage when they earn income above the eligibility level. This may present a barrier to working since the cost of treatments that allow people with HIV to enter the workforce may be prohibitive without Medicaid coverage. In addition, people with HIV/AIDS who re-enter or enter the workforce for the first time may not be able to get insurance through the workplace. The Balanced Budget Act of 1997 gave states the option to allow low-income disabled individuals to keep their Medicaid coverage while working and earning income up to 250 percent of poverty. The TWWIIA also made several changes designed to encourage low-income individuals with disabilities to work while allowing them to keep their Medicaid coverage.[64] In both these cases, however, relatively few states have exercised these options.[65]

Variation in state Medicaid programs resulting in different levels of access across the states

In states with less generous Medicaid programs (e.g., states with limits on the number of prescriptions filled per month or states with lower income eligibility thresholds), low-income people with HIV may have to rely on other programs to fill the gaps or may not have access to needed services.[66]

Medicaid payment rates to providers and institutions

Historically low payment rates have been shown to affect access to care for Medicaid beneficiaries.[67]

Medicaid managed care

Medicaid managed care also presents new challenges to the financing and delivery of HIV care. These include the difficulties of developing adequate capitation and reimbursement rates in the context of rapidly changing standards of care; the need to ensure access to the continuum of care, including full access to prescription drugs within managed care plan formularies; and the need to ensure access to experienced HIV providers.[54,68]

Different prices paid by different government purchasers for the same medications

A recent analysis indicates that Medicaid, despite being the largest public purchaser of HIV/AIDS drugs, pays higher prices for these medications than other government purchasers, including the VA and ADAP programs.[69]

Finally, in addition to these challenges, states are experiencing increasingly difficult fiscal situations, with most facing budget shortfalls. As states struggle to balance their budgets, many are seeking ways to reduce their Medicaid spending, the second-largest expenditure in most state budgets, and the one that has grown faster than many other state programs. States are exploring or have already implemented several strategies for controlling Medicaid costs, including controlling pharmacy costs and provider payments, increasing cost sharing, eliminating optional benefits, and reducing eligibility. These strategies may limit beneficiary access to Medicaid, including for beneficiaries with HIV/AIDS, and limit the revenue flows to experienced HIV providers, including individual practitioners, clinics, and hospitals.[70,71]

Medicare: Coverage for Disabled and Elderly Persons with HIV/AIDS

Also created in 1965 and administered by CMS, Medicare (Title XVIII of the Social Security Act) is the nation's federal health insurance program for the elderly and disabled. Medicare is an important source of coverage for people with HIV/AIDS who are disabled, have sufficient work history to qualify for disability insurance, and live long enough to qualify for Medicare. Many of these individuals also qualify for Medicaid because they are low-income. Medicare is estimated to cover approximately 19% of people with HIV/AIDS who are receiving regular care, including an estimated 6% covered by Medicare alone and an additional 12–13% covered by both Medicare and Medicaid (a small percentage may also have private coverage).[19,32,35] CMS estimates that Medicare served approximately 44,000 persons with AIDS in 2001 and 46,000 persons with AIDS in 2002.[72]

Forecasting the growth in the number of Medicare beneficiaries with HIV/AIDS is difficult—on the one hand, the number of beneficiaries may grow as more people with HIV/AIDS live longer; on the other, the success of combination antiretroviral therapy may keep people with HIV from meeting the SSDI eligibility criteria needed to receive Medicare coverage. In addition, an increasing proportion of those becoming newly infected with HIV are estimated to be low income and may therefore be less likely to have sufficient work history to meet eligibility criteria.

Medicare spending on HIV/AIDS is estimated to have increased over time. Today, Medicare is the second largest source of federal financing for HIV/AIDS care, after Medicaid, accounting for an estimated $2.1 billion in FY 2002 and $2.4 billion in FY 2003, according to CMS.[50] Estimated Medicare spending on people with AIDS has more than doubled since FY 1995, when it was $1 billion.[23,24,50]

Eligibility

Most Americans ages 65 and older are entitled to Medicare as soon as they are eligible for Social Security payments. People under age 65 who receive SSDI benefits and individuals with end-stage renal disease may also qualify for Medicare. Most people with HIV/AIDS who receive Medicare benefits do so as a result of their SSDI status. Eligibility for SSDI, however, is limited to those who have sufficient work histories and who are permanently disabled. In addition, federal law requires a 5-month waiting period after disability determination to receive SSDI benefits and then a 24-month waiting period before an SSDI beneficiary can join Medicare, resulting in a total of 29 months before receipt of health benefits.[73]

For those Medicare beneficiaries with HIV who are low income, Medicaid coverage is critical, filling in the gaps in coverage for these beneficiaries. Depending on income, Medicaid provides varying levels of coverage to low-income Medicare beneficiaries including payment of premiums, some cost-sharing, and coverage of services during the 29-month waiting period. In addition, Medicaid has been a critical source of prescription drug coverage for dual beneficiaries because outpatient prescription drugs are not covered by Medicare.[65,74] With the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L. 108-173) in December 2003, the role of Medicaid as a provider of prescription drug coverage to the dually eligible will be eliminated when the new law goes into effect in 2006 (see discussion below).

Benefits

Medicare is comprised of the following parts:[75]

- Part A covers inpatient hospital services, skilled nursing facilities, home health services, and hospice care.
- Part B helps pay for the cost of physician services, outpatient hospital services, medical equipment and supplies, and other health services and supplies.
- Medicare+Choice (M+C) plans contract with Medicare to provide both Part A and B services to enrolled beneficiaries.
- Part D adds outpatient prescription drug coverage to the Medicare program, effective January 1, 2006. This new drug benefit would be delivered through private risk-bearing entities under contract with DHHS, and drug benefits would be provided through stand-alone prescription drug plans (PDPs) or comprehensive managed care plans, known as Medicare Advantage Plans. Beneficiaries entitled to Part A or enrolled in Part B will be eligible to enroll in Part D. The law establishes a new Medicare Prescription Drug Discount Card and Transitional Assistance Program to provide relief to beneficiaries before the benefit is fully implemented in 2006.[74,76]

Challenges

People with HIV/AIDS, as well as people with disabling conditions more generally, face certain challenges in accessing Medicare or needed benefits through the Medicare program. One such challenge is the 29-month waiting period for benefits. Early on in the AIDS epidemic, people with HIV who otherwise might have been eligible for Medicare benefits often did not live long enough to begin receiving them. Even though people with HIV are now living longer, the waiting period still presents a barrier to accessing Medicare coverage and during that 29-month period, they have to find care elsewhere. In addition, to be eligible for benefits, a person with HIV must have sufficient work history and, as with Medicaid, must meet federal disability criteria. In the case of the former, because HIV is increasingly affecting people who are poor and outside the workforce, it may be difficult for some to meet the work history requirements needed to access the program. In the case of the latter, even people with HIV who have sufficient work history may find themselves facing a similar “Catch-22” in eligibility that is encountered with the Medicaid program, since they cannot become eligible for SSDI benefits until they are disabled.

There are also limitations to the Medicare program that present particular problems to people with HIV/AIDS and others with serious illness and high care costs. Although Medicare provides broad coverage of basic health care services, it has high cost-sharing requirements, no cap on out-of-pocket spending, and does not cover outpatient prescription drugs, one of the most important benefits for people with HIV (this will change with the passage of the new Medicare prescription drug law). As a result, many Medicare beneficiaries have to rely on supplemental insurance or programs to fill in the gaps. For example, people with HIV/AIDS who cannot afford prescription drugs have had to rely either on Medicaid or the AIDS Drug Assistance Program of the Ryan White CARE Act in order to receive medications. Others may receive prescription drug benefits by purchasing a private "Medigap" policy or by enrolling in a Medicare managed care plan, although these benefits are severely limited and the recent withdrawals, service area reductions, and benefit limitations by Medicare plans in many markets have affected Medicare beneficiary access.[77,78]

While the recently enacted Medicare legislation adds a drug benefit for the more than 40 million seniors and people with disabilities who have Medicare, a number of questions and concerns have been raised about certain provisions of the legislation, its implementation, and its costs, including particular concerns for dual eligibles:[74,79]

- Range of drugs offered. Beneficiaries who participate in Part D will receive their drug coverage through private stand-alone drug-only plans or Medicare Advantage plans (offering comprehensive benefits). Plans can choose to establish formularies, and while they must follow certain rules to do so, they will have broad flexibility to determine formularies. A provision in the law allows plans to limit the number of drugs offered per therapeutic class to two. For people with HIV/AIDS who must rely on multiple medications, many of which are from the same therapeutic class (or could be depending on the definition used by the plan), this could present access and quality barriers. In addition, the range of drugs offered may vary by plan and could differ (be less or more generous) from that which beneficiaries may have had through prior coverage (e.g., what dual beneficiaries had under Medicaid).
- Potential lapse in prescription drug coverage. The new Medicare law eliminates prescription drug coverage for the dually eligible on January 1, 2006, regardless of whether they have actually enrolled in Part D. States can no longer receive Medicaid matching funds to provide any drugs that could be covered by a Medicare Part D plan, even if eligibles have not yet enrolled in Part D. While the law requires the Secretary of Health and Human Services to develop a plan to automatically sign up dual eligibles for Part D, that plan has not yet been formulated, and it is unclear how dual

eligibles will be identified for this purpose. This could mean that some dual eligibles might experience a lapse in prescription drug coverage if they have not yet enrolled in Part D, a situation that could be particularly problematic for people with HIV/AIDS on HAART regimens for which adherence is critical and for those fighting opportunistic infections.

- Difficulties navigating the enrollment process. It is also likely that the enrollment process for Part D will present challenges, particularly for low-income populations and this too could delay enrollment.
- Out of pocket costs. Co-payments may also pose barriers for some beneficiaries, particularly low-income beneficiaries, despite the law's provision for a low-income subsidy program. In some cases, co-payments may be higher under the new law than what dual beneficiaries were required to pay under Medicaid. In addition, beneficiaries will have to pay 100% of the costs of any drug not covered by their plan.
- Denial of prescription drugs if co-payment cannot be met. Under the new law, beneficiaries can be denied a prescription if they cannot meet the co-payment. This kind of restriction is barred under current Medicaid law.

Ultimately, how the new law will play out and what effect it will have on people with HIV/AIDS and the other programs that serve them (e.g., will it lead to increased demand for ADAP? increased costs? reduced access to prescription drugs?) remains unclear.

Ryan White CARE Act: A Payer of Last Resort for People with HIV/AIDS

First enacted in 1990 and reauthorized in both 1996 and 2000, the Ryan White CARE Act provides funding to cities, states, and other public and private nonprofit entities to develop, coordinate, and operate systems for the delivery of health and support services to medically underserved individuals and families affected by HIV disease. The Ryan White CARE Act is administered by the Health Resources and Services Administration (HRSA) of the Department of Health and Human Services. The CARE Act functions as the payer of last resort—that is, providing care to individuals who are uninsured or underinsured and cannot cover the costs of care on their own, and because no other source of payment for services, public or private, is available to them.[80]

The CARE Act was first designed to fill the gaps in financing care for people with HIV/AIDS and to relieve cities that were bearing a disproportionate burden of the cost of care. It has since grown into a major program that has helped create an AIDS care infrastructure across the country. In FY 2003, federal funding for Ryan White was approximately $2 billion, about three times its funding level in FY 1995 ($657 million), largely reflecting increases in funding for medications through the AIDS Drug Assistance Program.[23,24,52] The Ryan White program represents the third largest source of federal funding for HIV care in the United States.

Data on state-only spending for Ryan White programs are generally not available with the exception of state contributions to ADAP programs, which states report totaled $160 million in FY 2002, and state matching contributions to Title II HIV Care Grants, which are estimated to total approximately $400 million in FY 2002.[49,81]

HRSA's HIV/AIDS Bureau estimates that more than 500,000 people receive Ryan White-funded services each year, but it is impossible to obtain an unduplicated count of users, many of whom receive services from multiple parts of the CARE Act (unique client-level data are not reported for most parts of the CARE Act).[80]

In recognition of the varying nature of the HIV/AIDS epidemic across the country, Ryan White grantees, including states and cities, are given broad discretion in designing local programs. As a result, there is significant variation in state funding, eligibility, services, and other aspects of Ryan White programs across the country. For example, the number of drugs covered by state AIDS Drug Assistance Programs varies from a low of 18 to a high of 463. Another reason for variation across states is that Ryan White dollars are sometimes inadequate to fill the gaps in states with less generous Medicaid or other programs.[66]

Eligibility

CARE Act services are available to uninsured or underinsured individuals and families living with HIV/AIDS, and eligibility for services is determined by states and municipalities.

Benefits

The CARE Act primarily funds outpatient care and related support services and does not pay for hospitalizations and long-term institutional care. Services include outpatient medical and dental care, prescription drugs (through the ADAPs), case management, home health and hospice care, insurance continuation, and housing and transportation services. The CARE Act is comprised of several titles and components, including[82]

- Title I ($619 million in FY 2002) provides emergency assistance to eligible metropolitan areas (EMAs) most severely affected by the HIV/AIDS epidemic. Federal funding is awarded on a formula and supplemental basis to EMAs. Title I funds may be used to provide a wide range of services including outpatient medical and dental care and support services such as case management. Title I grantees must establish HIV Health Services Planning Councils to set service priorities for the allocation of funds. In FY 2001, there were 51 EMAs in 28 states/territories.

- Title II ($977 million in FY 2002, including ADAP funds) grants are awarded on a formula basis to states, the District of Columbia, Puerto Rico, and eligible U.S. territories and associated jurisdictions to provide health care and support services for people living with HIV disease, including home- and community-based services, continuation of health insurance coverage, prescription drugs (states receive earmarked funds to support ADAP), and direct health and support services. Some states are required to provide matching funds, depending on their AIDS case burden. In FY 2002, these matching funds are estimated to total close to $400 million.[81] As part of the year 2000 reauthorization, supplemental funds are also available through Title II for "emerging communities," urban areas within states that are not eligible for Title I funds but have a certain level of reported AIDS cases.
- AIDS Drug Assistance Programs ($639 million in FY 2002, included in Title II funding above). Title II funds also support ADAPs, which provide prescription medications to individuals with HIV disease who have limited or no coverage for medications through other insurance mechanisms. ADAPs began serving clients in 1987, when Congress first appropriated funds to help states purchase AZT, the only approved antitretroviral at that time. In 1990, Congress incorporated ADAP into Title II of the Ryan White CARE Act and, since 1995, Congress has specifically earmarked funding for ADAP, and states are permitted to spend some of their general Title II funds to support these programs. There are 56 ADAPs in all 50 states, the District of Columbia, Puerto Rico, Guam, the U.S. Virgin Islands, the Northern Mariana Islands, and the Marshall Islands. Each state administers its own ADAP program including establishing financial and clinical eligibility criteria and ADAP formularies.
- Title III ($194 million in FY 2002) supports early intervention services (EIS) for individuals who have been diagnosed with HIV disease. Currently, there are 310 Title III EIS-funded programs in 50 states/territories.
- Title IV ($71 million in FY 2002) provides community-based, and family centered services to children, youth, and women living with HIV and their families. Services include primary and specialty medical care, psychosocial services, and outreach and prevention services.
- Dental Assistance ($13 million in FY 2002). The dental reimbursement program assists accredited dental schools, post-doctoral dental programs, and dental hygiene education programs by reimbursing them for nonreimbursed costs incurred in the provision of oral health care to patients with HIV infection.

- AIDS Education and Training Centers (AETCs) ($35 million in FY 2002) support a network of 14 regional centers (and over 70 associated sites) that conduct targeted, multidisciplinary education and training programs for health care providers of clinical care for persons with HIV/AIDS.
- Special Projects of National Significance (SPNS) (funded through set-aside from Titles I–IV not to exceed $25 million annually; as of FY 2003, SPNS is being funded through DHHS evaluation set-asides) are funded to establish innovative demonstration projects that respond to the challenge of HIV/AIDS service provision to underserved and vulnerable populations.

Challenges

People with HIV also face challenges in accessing CARE services. As the number of people living with HIV/AIDS continues to grow and the cost of care increases, demand for CARE Act services is also increasing. Because the CARE Act is a discretionary grant program that depends on annual appropriations by Congress (and often by states and municipalities), CARE Act dollars do not necessarily match the need for services and some grantees have been unable to serve all those in need. For example, several state ADAP programs have had to place clients on waiting lists to access prescription drugs, or limit such access in other ways (16 as of September 2003)[83] and, as mentioned above, ADAP formularies vary significantly across the country—while almost all ADAPs cover all FDA-approved antiretrovirals, only 15 states cover the full set of drugs highly recommended for the prevention and treatment of opportunistic infections (OIs); 39 states cover 10 or more of these drugs.[49,84]

In addition, CARE Act programs and services vary across the country, due to local flexibility in designing programs, different levels of funding, and the CARE Act's role as gap filler. Much of the federal funding for the CARE Act is allocated by formula, based largely on local AIDS case burden. Yet health care system capacity and the availability of other programs vary across jurisdictions and more CARE dollars must be used to fill the gaps in jurisdictions with less generous access to other programs.[66] In addition, because the current allocation formula relies on AIDS cases, not HIV infection, allocations may not reflect recent trends in the epidemic and the full burden of affected individuals in all jurisdictions. The 2000 reauthorization of the CARE Act calls for the incorporation of reported HIV cases into the Title I and II formulas as early as FY 2005, if accurate and reliable data exist (a recently released Institute of Medicine report found, however, that HIV case reporting is not yet reliable enough for this purpose. See: Institute of Medicine, *Measuring What Matters: Allocation, Planning, and Quality Assessment for the Ryan White CARE Act*, 2004).

Private Health Insurance

Almost one-third (31%) of people with HIV/AIDS who are in care are estimated to be covered by private health insurance,[32] as are a significant proportion of those newly diagnosed with HIV.[47] As new treatments allow people with HIV to more fully participate in the workforce, private insurance will likely continue to play an important role in HIV/AIDS care.

Like most Americans, the vast majority of privately insured individuals with HIV obtain their insurance through their employers. Those who are insured in the group market tend to have the most comprehensive coverage and have much less difficulty obtaining and keeping that coverage. People with HIV/AIDS who must purchase coverage in the individual insurance market often face barriers to obtaining a policy. A recent study of the accessibility of the individual insurance market for those in less than perfect health found that people with HIV are generally considered "uninsurable" and are routinely rejected when they apply for coverage (some states require certain carriers in the individual market to offer coverage to all applicants).[85] Those who have limits in their private coverage may need to rely on safety net programs, such as the Ryan White CARE Act, to fill the gaps. Some states have implemented insurance reforms to enhance access to the individual insurance market, although these reforms vary and have different implications for people with HIV.[85,86] If recent trends indicating reductions in employer-sponsored health insurance coverage continue,[87] people with HIV/AIDS may increasingly need to rely on other safety net programs for care.

While the insurance market is largely regulated at the state level, the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191), also known as HIPAA, established basic national standards for insurance regulation in the small-group (firms with 2 to 50 workers) market and, to a lesser extent, in the individual market. Among the protections included in HIPAA were[88,89]

- Portability. Exclusions of pre-existing medical conditions are limited to a maximum of 12 months. In other words, if a person with HIV/AIDS changes jobs and insurers and has already experienced a 12-month coverage exclusion of that condition, the new insurer cannot exclude them again. Workers with previous coverage receive credit for each month of coverage to reduce the exclusion period. The portability protection only applies to group coverage and only if the period of time between coverage was less than 63 days.
- Non-discrimination. Insurers in the group market are prohibited from conditioning a person's eligibility for group coverage on their health status and worker contributions cannot be varied based on health status.

However, HIPAA does not prohibit an insurer from charging a higher premium to an employer based on the health status of workers. Nondiscrimination protections do not apply to individual policies.

- Guaranteed issue. Insurers must offer all of their small-group policies to any small employer that wants to purchase coverage for their workers. While HIPAA does not extend guaranteed issuance to the non-group market, it does require that each state have in place a policy that permits individuals losing coverage in the group market to get access to a non-group policy, either through an insurer or through another mechanism such as the state's high-risk pool. Although HIPAA does not limit the premiums that can be charged, many states do.
- Guaranteed renewal. Insurers must allow all policies—group and individual—to be renewed.

Those individuals who lose private group coverage in firms with more than 20 employees can continue that coverage for a specified period of time under the terms of the Consolidated Omnibus Budget Reconciliation Act of 1986 (P.L. 99-272), also known as COBRA. For those who are disabled, coverage can be extended for up to 29 months, designed to provide coverage until Medicare eligibility begins.[86,90] Employers are required to notify workers who are eligible for COBRA coverage and workers have 60 days to exercise their benefits. People who exercise their COBRA benefits must pay a monthly premium. A number of states apply COBRA-like laws to group plans that are exempt from COBRA.

Under a provision added to the Ryan White CARE Act in 1996, states can use Ryan White funds to help people with HIV/AIDS who are eligible for COBRA pay their premiums or buy private insurance. In addition, since 1993, Medicaid has given states the option to receive federal matching funds for the costs of COBRA premiums for individuals with incomes at or below 100 percent of the federal poverty level and countable resources under $4,000.

Challenges

Even with the protections offered by HIPAA, people with HIV face barriers to accessing private insurance, particularly in the individual insurance market. First, HIPAA does not include any limits on insurance rates and people can effectively be priced out of the market. Some states—most notably New York, New Jersey, Maine, and Vermont—have adopted community rating; others have utilized "rating bands" to limit the size of premium increases. Some states have also chosen to purchase new policies for people with HIV, using Ryan White CARE Act funds or broader programs that target low-income or uninsured people. Second, HIPAA does not improve access to the individual market for those without prior group coverage and, as noted above, HIV is generally considered an "uninsurable" condition by most carriers in the individual market. In addition, private insurance plans often have annual or lifetime caps on benefits, co-payments and deductibles, and limits on services that may limit access in the private market. Finally, the insurance market and insurance reforms vary significantly by state, presenting different options and limitations across the country.[85,86]

Department of Veterans Affairs

Acting as both insurer and provider of care, the VA is the largest single provider of comprehensive HIV/AIDS care in the United States. In FY 2001, the VA provided care to approximately 18,500 veterans with HIV/AIDS; since 1982, the agency has served a total of 50,000 persons with HIV/AIDS.[91,92] In FY 2002, the VA spent $348 million on HIV/AIDS care, representing 4% of federal spending on HIV care.[23,24] VA HIV/AIDS care is financed through annual appropriations out of general tax revenues. Any veteran of the armed services is eligible to receive HIV/AIDS care through the Veterans Health Administration. Under VA guidelines, private insurers must pay for care where appropriate, and veterans contribute based on a system of service-based ranking and means-testing screens. Disabilities, including HIV-related disability, must be service-related or a veteran must be low-income to receive subsidized care; otherwise, veterans must pay a share of costs.

HIV/AIDS care is provided at the VA's 163 hospitals, more than 850 primary care clinics, 137 nursing homes, 43 domiciliary centers, 73 home care programs, and 206 Vietnam Veteran Outreach Centers.[91,92,93] The VA has an HIV/AIDS Coordinator at every VA hospital and the VA's AIDS Service coordinates HIV/AIDS care throughout the VA system. In addition to providing care, the VA provides HIV prevention services to veterans, providing approximately 50,000 HIV tests per year, and conducts clinical research on HIV/AIDS.[92] Not all veterans, however, live near a VA facility, which could inhibit access.

Community Health Centers and Other Safety Net Providers

Those who are uninsured and underinsured also rely on an array of other safety net providers for care. These include community and migrant health centers, public hospitals, private "free clinics," and individual health care providers who offer free care. Services vary across these different types of providers.

Community health centers serve a large number of people living with

HIV, with both CARE Act dollars and community health center grant funding.[4] They can also directly bill Medicaid for eligible beneficiaries. In 2000, community health centers provided almost 250,000 HIV-related encounters to more than 48,000 people. In addition, they provided more than 270,000 HIV tests to approximately 231,000 people.[94]

Most of these safety net programs are funded through discretionary grants, and are dependent upon annual appropriations for funding. As such, funding does not necessarily match the need for or cost of care. In addition, people with HIV/AIDS may not always have access to experienced HIV providers through these mechanisms.

Other Sources of Coverage and Care

While there are several other mechanisms available for coverage and care, they provide access to only limited numbers of people with HIV/AIDS. These include high-risk pools, designed for people with significant health risks who have been denied coverage in the private market[85,86,95,96,97] and pharmacy assistance programs offered by states[98,99,100] and pharmaceutical manufacturers[101] to low-income individuals (with varying other eligibility requirements). Twenty-nine states currently operate high-risk pools[95] and 14 states have state pharmacy assistance programs available to non-seniors, either through subsidies or discounts.[99,100] Finally, the Department of Defense provides care to a small number of active duty service personnel[69] and the federal government, as an employer, provides care to federal employees with HIV/AIDS through the Federal Employee Health Benefits program.[24,51]

POLICY CHALLENGES

The patchwork of financing for HIV/AIDS care presents barriers to accessing care. As policymakers search for ways to improve access, they face several important challenges, many of which cut across the multiple sources of financing and care, including

Reaching Those Not in Care

A significant proportion (42% to 59%) of people living with HIV/AIDS are not in regular care. While some may not know their HIV status, many face financial and other barriers to access. More research is needed to identify the barriers to care. Outreach is also needed both to help bring people who know their HIV status into care early and to encourage others to get tested and learn their status. This will require better linkages between HIV testing and treatment facilities and services.

Enhancing Care for Those Who Are Uninsured or Publicly Insured, Minority Americans, and Women

Recent data indicate that although quality of HIV care has improved over time, there are still differences in quality and access by insurance status, race/ethnicity, and sex. These findings call for further research to understand better the underlying causes of these differences and identify ways to enhance access to and quality of care for different populations.

Improving Insurance Coverage

Current eligibility rules for Medicaid and Medicare make it difficult for many people with HIV to gain coverage before their health status worsens and they are disabled. Most people with HIV become eligible for Medicaid through SSI, after they are disabled, yet national treatment guidelines call for early access to treatment to prevent or delay disability (this eligibility limitation also present barriers to Medicare access, through SSDI). A few states are attempting to address this through Medicaid 1115 waivers and provisions of the TWWIIA, but most will need to continue to rely on discretionary grant funding, particularly the AIDS Drug Assistance Program and other parts of the CARE Act, to do so. Medicaid and Medicare eligibility may also be jeopardized for those beneficiaries with HIV who have benefited from new treatments and wish to enter or re-enter the workforce. The BBA and TWWIIA each had provisions designed to address some of these concerns, but challenges still remain and few states have exercised these options. The 29-month waiting period for Medicare eligibility also presents a challenge to coverage for people with HIV/AIDS. Finally, the current lack of a prescription drug benefit in the Medicare program and potential limitations of the new Medicare prescription drug law could present new challenges for people with HIV/AIDS.

Reducing Variation in Access Across States

Many of the programs that provide care to people with HIV have significant variation in eligibility, benefits, and other program components across states. This is particularly true for the Ryan White CARE Act and Medicaid, two of the most important sources of financing for HIV care. As a result, people with HIV face highly uneven access to coverage across the country.

Enhancing Coordination Across Programs

There is limited coordination across the multiple funding streams that finance HIV care. Yet these programs greatly impact one another and the level of access available to people with HIV across the country. More information is needed to understand how these financing systems interact and how they can better work together to increase program efficiency and enhance access to care for people with HIV. A recently proposed "HIV/AIDS Integrated Services Project," a joint initiative of HRSA, CMS, and CDC, will explore ways to blend federal funding streams and better coordinate care for people with HIV/AIDS on a demonstration basis; however, when exploring options to blend federal funding streams, it is important to maintain the level of individual entitlement to coverage for basic health services that each Medicaid or Medicare beneficiary now has.

Addressing the Cost of Prescription Drugs

Prescription drugs are one of the fastest growing components of health care spending. They also represent a key component of HIV/AIDS care. As such, rising prescription drug costs will continue to present challenges to people with HIV and the programs that provide for their care, especially Medicaid and the AIDS Drug Assistance Program, which have already seen sharp rises in expenditures for AIDS drugs. As a result, some state Medicaid programs and ADAPs have taken steps to control drug expenditures, which could limit access (e.g, Medicaid prescription drug limits and cost controls, ADAP waiting lists). Analysis indicating that Medicaid, the largest public purchaser of HIV/AIDS drugs, is paying higher prices for these drugs than other government purchasers also presents challenges for policymakers seeking to balance cost containment and access. It is also unclear how incentives in the new Medicare prescription drug law will impact drug prices over the long-term, particularly for breakthrough drugs for which there is little competition, and if the new law will affect the price paid for drugs by Medicaid (as it stands to lose purchasing power after prescription drug benefits for dual eligibles are transferred to Medicare in 2006).

Financing Prevention Services

Current care financing mechanisms do not offer clear incentives to provide prevention services in the clinical setting. Yet an estimated 40,000 people still become infected with HIV each year in the United States, indicating the importance of continued prevention efforts targeting those at risk. In addition, people already infected with HIV need access to prevention services to help prevent the further spread of HIV, which is the focus of the CDC's Serostatus Approach to Fighting the Epidemic (SAFE) and the CDC's new prevention initiative, Advancing HIV Prevention. A recent study showing that a significant proportion of people with HIV are already covered by Medicaid or other public payers at time of diagnosis underscores the important role public payers can play in the delivery of prevention services within the care setting.[47]

These policy issues are often heightened in the context of the HIV/AIDS epidemic due to shifting demographics and rapidly changing clinical standards of care. People with HIV/AIDS are increasingly likely to be members of already disadvantaged groups who are more likely to rely on the public sector for financing their care and face historical barriers to access. African Americans and Latinos, for example, represent the majority of new HIV infections and women now comprise almost a third (30%) of new HIV infections in the United States; most women newly infected are minority women.[37]

In addition, HIV care has grown increasingly complex, requiring rapid dissemination of new standards to diverse groups of providers. Moreover, to support receipt of and adherence to complex treatment and help them navigate the financing and health care delivery systems, people with HIV/AIDS need access to a comprehensive continuum of care and experienced providers. Yet some needed services, such as case management or prevention, are not always financed through the same mechanism as medical care or may not be financed at all. Together, these aspects of the epidemic mean that policymakers will be faced with continued challenges to financing HIV-related care in the future, particularly as the number of people with HIV/AIDS continues to grow, as do health care costs. These challenges may be exacerbated during tough economic times.

CONCLUSION

Despite the existence of multiple sources of financing, many people with HIV/AIDS are not in regular care and a significant proportion does not know they are infected. Even among those who are in care, numerous barriers may impede their access to needed treatments. The high cost of care poses challenges for individuals and caregivers, as well as state and federal governments. Eligibility rules create barriers to coverage and care. Existing programs vary significantly across the states and are often poorly coordinated. As the HIV epidemic continues to shift towards those who have always had a more difficult task gaining access to and paying for care, these policy challenges are certain to grow.

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Appendix
E

Towards an Understanding of Meeting HIV-Infected Substance Users' Needs[1]

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SYSTEMS DIVIDED

The epidemics of AIDS and substance abuse have been linked in the United States since long before identification of the HIV virus. The Centers for Disease Control's (CDC) June 1982 report that of 152 known cases of PCP, 21 percent involved drug users contributed to scientists' suspicion that the new condition was a blood borne disease (Altman, 1986). Despite the immediate inclusion of drug users among the infected and affected, homosexual men represented the largest number of early cases, and the gay community responded the most actively. Both the epidemiology and the response of gay activists helped to shape the policy issues surrounding AIDS (Watney, 1987).

Even though 17 percent of identified AIDS cases through the end of 1985 were among injecting drug users (CDC, 1986), very little research or programmatic attention had been directed to them. The barriers that had impeded societal response to the entire epidemic affected drug users particularly acutely. Among these were lack of knowledge about the affected populations; social distance between researchers and affected populations; and legal and institutional impediments to actions, including the initial resistance of the drug treatment system to do HIV education and the federal ban on funding syringe exchange (Des Jarlais and Friedman, 1988; Turner et al., 1989).

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[1] Paper prepared for the Committee on Public Financing and Delivery of HIV Care, Institute of Medicine, October 28, 2002. New York Academy of Medicine, Office of Special Populations.

Looking back, it is perhaps unfortunate that the first major drug abuse-related policy initiative advocated by the now mobilized "AIDS community" was syringe exchange. While of incontrovertible effectiveness in reducing the transmission of HIV and other blood borne infections among injecting drug users (see, for example, Jones and Vlahov, 1998), syringe exchange galvanized the opposition of drug treatment providers aligned with conservatives against the AIDS community. The same issue highlighted a second division—between some prominent African-American community leaders and the then predominantly white AIDS community.

This early fissure helped to allow the AIDS community to evolve into the AIDS services sector without inclusion of drug treatment providers (or, for many years, consideration of needs of drug users beyond sterile syringes). The largely abstinence-based substance abuse treatment system, in turn, found itself to be an isolated advocate for "drug treatment on demand" as an alternate approach to prevention of HIV transmission among injecting drug users. Some AIDS advocates responded hostilely to this call for enhanced drug treatment capacity as they viewed it as undermining advocacy for syringe exchange. This debate helped ossify two systems that were each already isolated from the mainstream health and social services system in opposition to one another.

While the field of HIV prevention has more explicitly addressed the prevention of transmission through injecting behaviors (though, not the integrated needs of injecting drug users for both syringe-related and sexual risk reduction), the HIV care system has remained far less responsive to the special needs of HIV-infected substance users than their prevalence would suggest. Examples abound: the first Ryan White Comprehensive AIDS Resources Emergency (CARE) Act authorized by Congress in 1990 mandated 11 categories of membership on the Title I planning councils, but did not include drug treatment providers, representatives from state substance abuse agency, or consumers who were substance users. In the 1996 reauthorization, a requirement for one representative of drug treatment providers was added. In the 2000 version, additional language was added about the need for the consumer representatives (as well as services allocations) to reflect the epidemiology in an area. As our past work has documented, Ryan White planning councils have largely not assessed, planned for, or allocated funds for the special needs of active substance users, including for substance abuse treatment, nor have they addressed particular barriers in receipt of HIV care (Finkelstein et al., 1999, 2001). As the following report will demonstrate, the conceptual divide between substance use and HIV has permeated research, data collection, planning, financing, and service delivery. Unfortunately, the place where complete integration and synthesis remains is within the estimated 360,000 individuals in the United States currently coping with both issues.

IDENTIFICATION OF THE AFFECTED POPULATION

Difference conceptualizations of the problems of HIV infection and substance abuse at the national level have resulted in no integration of data about HIV and substance use. As a result, gaining an accurate picture of the scope and nature of substance abuse among those with HIV is difficult.

Centers for Disease Control Surveillance

The national HIV surveillance system, with mode of transmission as its organizing principle, collects data on HIV related to injection drug use. As of 2002, the CDC estimates that approximately 800,000–900,000 people are living with HIV or AIDS in the United States, with 40,000 new infections occurring each year. Of these new infections, an estimated 25 percent (10,000 each year) are directly attributable to injection drug use. Of AIDS cases among women, 58 percent are related to injection drug use or sex with partners who inject drugs. Injection drug use is associated with 26 percent of all AIDS cases among African Americans, 31 percent among Hispanics, and 19 percent among whites. Overall, the CDC estimates that that injection drug use, directly and indirectly, accounts for 36 percent of AIDS cases in the United States. Because they are capturing transmission mode, CDC surveillance does not provide information on current drug use, and by focusing exclusively on injection drug use, these numbers do not reflect the extent to which non-injected substance use contributes to the spread of HIV/AIDS. As the CDC explains, "users trade sex for money or drugs, or they engage in risk behaviors when high." The CDC's observations have been confirmed by several studies of drug users' sexual risk behavior (Kra et al., 1998; Neaigus et al., 2001; Tun et al., 2002). Nor, obviously, are the CDC data on mode of transmission sufficient for answering the question of how many of the people currently living with HIV/AIDS are also current active substance users.

SAMSHA Substance Abuse/Use Data

While the CDC data are limited by their focus on transmission through injection drug use, national data on substance use from Substance Abuse and Mental Health Services Administration's (SAMSHA) National Household Survey on Drug Abuse (NHSDA) do not address HIV. The data do help illuminate the tremendous scope, variation and complexity of substance use in the United States. According to SAMSHA, an estimated 14 million Americans—6.3 percent of the population—use illicit drugs (SAMSHA, 2001a, 2001d). National data also reveal that drug use differs significantly by age, race, and gender (Office of National Drug Control

Policy, 2001; SAMSHA, 2001a) and is further complicated by overlapping issues, such as lack of access to welfare and health insurance benefits, unemployment, lack of education, and poverty (SAMSHA, 1998, 2001a, 2001b, 2001d; Tobias et al., 2002).

National data also indicate that type and rates of drug use vary significantly by geography. For example, even though metropolitan areas have higher rates of drug use overall, heroin use rates are increasing the fastest in non-metropolitan areas. While 97 percent of injection drug admissions in the Northeast were for opiates, primary methamphetamine injection was more prevalent in the Midwest and West, and primary cocaine injection was more prevalent in the Midwest and South (SAMSHA, 2002a). The variation in these numbers points to the fact that meaningful drug use data—useful for services and planning—must be local.

Nationally Representative Sample: HCSUS Study

Despite these indications that differences in locale and demographics are important to understanding substance use within a population, there is a dearth of national data that reflect the scope and variety of drug use among people with HIV/AIDS. The one nationally representative sample of people with HIV is the HIV Cost and Services Utilization Study (HCSUS)—a survey of people in care—that found that close to 40 percent of the sample reported using an illicit drug other than marijuana and that 12 percent screened positive for drug dependence (Bing et al., 2001). This same study also found that almost 50 percent of the sample screened positive for mental health disorders and that screening positive for a psychiatric disorder was independently associated with screening positive for drug dependence (Bing et al., 2001). This study was not designed for use in planning services and its usefulness for this purpose is limited because it obscures regional variations, not only in substance-using behavior, but also in systems of HIV care that are based on local financing and service capacity.

Inferences from Non-representative Samples

Other studies on HIV-infected substance users are not drawn from representative samples, so generalizations must be made cautiously, if at all. Nonetheless, these studies do suggest that drug use among those with HIV is both widespread and varied. One study of patients presenting for substance abuse treatment in an urban setting found that, of those who were HIV positive, 63 percent injected drugs, 17 percent used crack or cocaine, and 20 percent used alcohol (Samet et al., 1999). According to data from the Women's Interagency HIV Study, a longitudinal multi-site study, 19.7 percent of HIV positive women in the sample reported using crack within the last six months, 15.4 percent reported using cocaine, and 8.8 percent reported using injecting drugs—rates lower than those among HIV-negative women in the sample (Wilson, Massad et al., 1999). In a population- and facility-based study of 9,735 men who have sex with men (MSM) from twelve states and metropolitan areas, Sullivan et al. found that 51 percent had used marijuana, 31 percent non-injected cocaine, and 16 percent crack cocaine in the five years proceeding the interviews (Sullivan et al., 1998). They also found that white MSM were more likely than referent (mostly Hispanic) MSM to report using hallucinogens, marijuana, nitrites, methamphetamines and diazepam, while black MSM were more likely to report using non-injected crack cocaine. In addition, use of injected stimulants was higher among MSM residing in the West than in the East. While some studies have found that HIV-positive drug users are more likely to modify drug-related risk behaviors upon receiving their HIV test results than their HIV-negative counterparts (Celentano et al., 1994), others studies found no appreciable decrease in drug use or injection behaviors among recently tested injection drug users (IDUs) (Brogly et al., 2002).

Although HCSUS provides a representative sample of HIV-infected people in care, far less is known about HIV-infected substance users not in care. According to the CDC, close to 50 percent of (or 400,000) people with HIV/AIDS are not in care. If we apply the HCSUS finding that 40 percent of those in care are currently using substances to the 400,000 who are out of care, we estimate 160,000 HIV-infected substance users are out of care. However, this is likely to be an under-estimate of the numbers of HIV-positive drug users out of care because drug users face more barriers to care than other populations (as the following section describes) and are almost certainly over-represented among those out of care. Therefore, if we conservatively estimate that 50 percent of those out of care (vs. 40 percent of those in care) use drugs, 200,000 may be a more accurate estimate of the number of HIV-infected substance users not in care. Using the CDC and HCSUS date we derive an estimate that there are 360,000 people with HIV who actively use substances (of whom an estimated 200,000 are out of care and 160,000 are in care).

HEALTH CARE NEEDS AND BARRIERS FACING HIV-INFECTED SUBSTANCE USERS

Needs

HIV-infected substance users have multiple and complex needs that require services from a variety of sources. We conceptualize the HIV-related care needs of active users in three concentric circles, with the inner circle comprising HIV/AIDS medical care, the middle circle representing the continuum of available substance use services, and the outer circle comprised of ancillary services that enhance access to both HIV care and substance use treatment.

HIV care includes

1. primary care in which clients are supported to adhere to care and stay in care;
2. specialty care for HIV, Hepatitis C, tuberculosis (TB), and mental health services; and
3. on-going, intensive social services and case management to support treatment adherence and staying in primary and specialty care.

Substance use treatment services include

1. access to detox on demand;
2. access to a continuum of drug treatment modalities, appropriate for clients in various circumstances; and
3. harm reduction and recovery readiness services that link clients to entitlements, basic survival services, and primary care.

Ancillary services include

1. safe housing;
2. employment readiness assistance; and
3. services than enhance access, including transportation, childcare, and escort services if needed.

Barriers

HIV-infected substance users often face a health and social services system that stigmatizes them and erects multiple barriers to providing the care they require. As a consequence, their patterns of health care utilization and the quality and continuity of care they receive are far from optimal. In addition, public policies that penalize them because of their substance use serve as a barrier to the receipt of services that promote stability and can facilitate maintenance in substance abuse and healthcare treatment. While the following section is divided into barriers to HIV care and to substance use treatment, as will be clear, the crosscutting underlying barriers of poverty and lack of entitlements affect both.

Barriers to HIV Care

Knowing one's HIV status, seeking HIV care early, accessing continuous care from providers and in settings with HIV expertise, and receiving and adhering to a regimen of highly active antiretroviral therapy (HAART) all contribute to positive health outcomes for people with HIV/AIDS.

Delayed entry into HIV care

While access to HIV care enhances one's chances of survival, many people neither know their HIV status nor seek medical care when they do know their status. As discussed earlier, substance users are likely overrepresented in the estimated 50 percent of people with HIV/AIDS who are not in care. Substance use has a demonstrated association with delayed HIV care seeking. One study of an urban population found that the average duration between acquiring HIV and seeking primary HIV health care was 8.1 years (Samet et al., 2001). Another study of outpatient visits in two urban hospitals found that 39 percent of patients delayed care seeking for one year, 32 percent for more than two years, and 18 percent for more than five years (Samet et al., 1998). In these studies, injection drug use was associated with delayed care seeking. One study of HIV-positive crack cocaine smokers found that one-third of the study population had not seen a provider for HIV-related care in the past year (Metsch et al., 2001). Delayed care seeking could be prevented by increasing the availability of outreach services to substance users not in HIV, mental health, or substance abuse treatment (Raveis et al., 1998).

Setting

When substance users do access care, studies have shown that they are more likely to do so sporadically and in emergency rooms (ERs). Chronic drug users are less likely to have a regular source of health care and are more likely than non-drug users to utilize emergency room and inpatient care (Markson et al., 1998; Laine et al., 2001; Welch and Morse, 2001). Emphasizing the importance of setting for health outcomes, a recent longitudinal study of CDC data found that HIV-infected individuals who received a greater proportion of their care in the ER had a worse survival prognosis than those who received more of their healthcare in an outpatient clinic setting (Montgomery et al., 2002). Long waiting times and waiting lists for appointments are common in facilities where substance users receive care (Weissman et al., 1995; Weiss et al., 2000).

In these settings, substance users are less likely to encounter providers with HIV expertise, which has been shown to enhance health outcomes (Kitahata et al., 1996; Markson et al., 1998). Furthermore, provider inexperience poses a real problem to addressing substance users' needs and affects substance users' willingness to further seek health care. Overworked and under-trained physicians are often unable to give substance users the time that would be required to address their substance use, mental health, and health care needs (Weiss, Kluger et al., 2000).

Receipt of standard of care

The association of HAART with decreased morbidity and increased survival is clear. However, studies have shown that substance users are less likely to receive HAART than non-users (Solomon et al., 1998; Celentano et al., 2001; Metsch et al., 2001; Turner et al., 2001)—a clear marker that HIV-infected substance users are not getting the same level of care as their non-using counterparts. One such study found that only 34 percent of HIV-positive crack cocaine smokers in care received HAART (Metsch et al., 2001). ALIVE—a longitudinal study of the natural history of HIV infection in Baltimore—found that consistent drug use was associated with a 58 percent decrease in the probability of initiating HAART (Celentano et al., 2001).

One reason fewer substance users receive HAART is that many providers believe that substance users are less likely than non-users to appropriately adhere to medication regimes (Bamberger, Unick et al., 2000; Bogart, Kelly et al., 2000; Bogart, Catz et al., 2001; Ramos and Tiger, 2001). They may also be concerned about the interactions between HIV medication, illicit drugs, methadone, and psychotropic medications. While it is true that some HIV medications can increase the metabolism of methadone, causing opiate withdrawal symptoms (Munsiff, 2002), this issue can be addressed by adjusting dosages. However, medical care providers' fears about these interactions and uncertainty about how to address them often prevent them from prescribing HIV medication in the first place (Ramos and Tiger, 2001).

Substance use and adherence

Despite providers' concerns about substance users, the data on substance use and adherence point to a more refined approach than simply refusing HAART to all substance users. Some studies have, indeed, found an association between active substance use (particularly crack cocaine use) or heavy alcohol abuse and lower adherence (Cook et al., 2001; Hinkin et al., 2002; Mannheimer et al., 2002). Of note, however, substance abuse may also be associated with depression or other affective disorders that can affect adherence (Ekstrand et al., 2002; Mannheimer et al., 2002; Perry et al., 2002). This association may in turn further complicate adherence, while substance abuse symptoms may mask symptoms of depression or vice versa.

When discussing adherence, distinguishing between active and former substance use is important. While a few studies have shown a relationship between substance abuse history and adherence, most fail to demonstrate an association. (Many studies fail to distinguish between current and past substance use at all—e.g., those that employ "route of transmission" as a variable.) Importantly, substance abuse is often not a static phenomenon—on the contrary, many patients cycle between periods of heavy use and moderate use, or between use and no use. Among 685 patients in an inner-city HIV clinic followed over 30 months, 64 percent of those who reported heroin, cocaine, or heavy alcohol use at any semi-annual survey changed their substance use status (from use to non-use or vice versa) at least once during the study period. Moreover, such changes were temporarily associated with antiretroviral use, adherence, viral suppression, and CD4 counts (Lucas et al., 2002).

As Andrews and Friedland note, however, even with respect to current substance use, it is not merely its presence or absence but its severity that appears to be associated with adherence (Andrews and Friedland, 2000). Depending on individual patient dynamics, even current substance abuse does not preclude good adherence. With appropriate support, many substance users are perfectly capable of achieving high levels of adherence (Conway et al., 2002).

Provider attitudes

In addition to concerns about adherence, physicians hold other beliefs about substance users that may impact their quality of care. For example, studies have shown that inexperienced physicians commonly under-utilize pain medication for substance users despite its necessity for HIV-related conditions fearing that they will exacerbate their patient's drug dependence and/or attributing their patient's pain symptoms to drug-seeking behavior (Breitbart et al., 1999; Breitbart and Dibiase, 2002). Provider suspicion of "manipulative behavior" on the part of their substance using patients often affects both the level of trust between the provider and patient and the quality of care the patient receives (Munsiff, 2002). Perhaps the most telling indicators of provider bias is pervasive ignorance about the medical needs of substance users and/or an unwillingness to treat substance users (Ramos and Tiger, 2001). In recently-conducted interviews with primary care providers serving active substance users in New York City, one provider explained, "They [providers] are not used to the population and they have prejudices" (Ramos and Tiger, 2001).

Substance users' attitudes

Like providers' attitudes about substance users, substance users' attitudes about health care providers and the health care system may also impact the quality of their care. For example, some HIV-positive substance users, responding to long-standing community distrust of health care providers and/or individual negative experiences, may refuse prescriptions for HIV medications or modify the prescription regimen recommended by their primary care provider (Mantell and Cassidy, 2001). Negative experiences with the social service system also affect the level of trust and communication between healthcare providers and substance users. Fearing disapproval or even the loss of public assistance such as housing and income support, users are often unwilling to disclose their substance use to their providers (Weiss et al., 2000; Tiger and Finkelstein, 2002).

Systemic barriers

The attitudes and fears of substance users seeking care are grounded in the reality of systemic barriers. The 1996 welfare reform law allows the denial of benefits (including Medicaid) to recipients convicted of drug felonies; public housing is denied to convicted drug felons and their family members; and even liberal states, like New York, have enacted provisions where refusal of a referral to substance abuse treatment or unsuccessful completion of that treatment can result in loss of income support and Medicaid coverage. System level barriers play a significant role in preventing HIV-infected substance users from accessing, maintaining, and receiving optimal care. Even after substance users access care, barriers within the service system frustrate the efforts of even the most knowledgeable and well-intentioned providers. For example, providers' efforts to refer their substance using patients to additional sources of care are often met with institutional resistance from other health and social service providers (Stanton et al., 2000; Ramos and Tiger, 2001).

Barriers to Substance Abuse Treatment

The lack of supportive services in substance abuse treatment deters many of the populations most in need of treatment. For example, 75 percent of treatment facilities do not offer childcare—a factor which can have particularly troubling consequences for women mandated into treatment through the criminal justice system whose parental rights may be terminated if they are unable to care for their children (Tiger and Finkelstein, 2002). In addition, few programs offer services for pregnant women (Grella, 1997). This lack of supportive services is especially acute for HIV-positive clients, whose access to treatment is also restricted because of the dearth of treatment facilities equipped to address their medical needs (SAMSHA, 1999).

Funding constraints often prevent programs from focusing on substance users' multiple needs. Moreover, it is difficult to find staff who are knowledgeable about substance use, HIV, and mental health (Tobias et al., 2002). These barriers are especially acute in rural areas where long travel distances to medical facilities, a shortage of trained staff, transportation barriers, and community stigma toward HIV and substance abuse are common (Heckman et al., 1996; Heckman et al., 1998; Whetten-Goldstein et al., 2001). Furthermore, low-threshold harm reduction programs which can help link substance users to outpatient care and drug treatment are relatively scarce (Strathdee et al., 1999).

EXISTING SUBSTANCE ABUSE TREATMENT AND HIV CARE SYSTEMS: DO THEY MEET THE NEEDS?

Two key systems with which many HIV-positive substance users interact—the substance abuse treatment system and the HIV care system—are described below. In addition to being fragmented from one another, each has severe internal limitations in addressing the needs of this population.

Substance Abuse Treatment System

The substance abuse treatment system in the United States—a complex mix of services, settings, providers, and funding streams—has developed over the past 30 years in relative isolation from the health and social systems. Furthermore, deep divisions within the substance use treatment system, reflected in different paradigmatic approaches and program modalities, have resulted in fragmentation and little communication among the variety of programs and facilities serving substance users. A review of the data on the need for treatment and the system's capacity highlights the inadequacy of existing resources to meet HIV-infected substance users' substance abuse treatment needs.

Funding of Substance Abuse Services

To meet the need for substance abuse services, a complicated system of public funding has developed. In fact, many treatment programs are designed around the requirements and limitations of various funders (SAMSHA, 2000). Approximately $12.6 billion is spent per year on substance abuse treatment and prevention, $7.3 billion of which is publicly funded (SAMSHA, 2000). Overall, $3.6 billion of public funds are spent on substance abuse treatment (Office of National Drug Control Policy, 2002). The amount of substance abuse treatment covered by public funds has been steadily increasing since the 1980s, currently accounting for two-thirds of all treatment expenditures (Mark et al., 2000). In 1997, state substance abuse agencies paid for 31 percent and SAMSHA substance abuse block grants paid for 29 percent of treatment services. Other state agencies contributed 5 percent, county and local agencies 9 percent, other sources 18 percent, and other federal government agencies 7 percent, including Medicaid, Medicare, the Department of Veterans Administration, and the Department of Justice (NASADAD, 1999).

SAMSHA

Most funding for substance abuse treatment come from SAMSHA and is overseen by the Center for Substance Abuse Treatment (CSAT). In fiscal year 2002, close to $2 billion of SAMSHA's $3.1 million budget was spent on Substance Abuse and Prevention (SAPT) block grants to states, which are formula awards based on population size and augmented with matching funds. States may use up to 35 percent of their block grants for prevention and treatment of alcohol, 35 percent for the prevention and treatment of other drugs, and 20 percent for primary prevention activities. States must also use their block grants to serve pregnant injection drug users, pregnant substance users, and IDUs (National Alliance of State and Territorial AIDS Directors, n.d.). Beyond these stipulations, states have considerable discretion over how this money is spent. This discretion has resulted in wide variations in the substance abuse treatment systems among states.

Little information exists on the internal planning processes states use to determine how the block grant funding is allocated. In their annual plan submitted to SAMHSA, states are required to detail how they will spend their block grant funding. The federal government requires states to conduct an annual needs assessment and to report treatment need based on age, race, sex, and ethnicity. How the needs assessment is conducted and how it is used to develop the plan for spending the block grant funds is left to the discretion of individual states.

While SAMSHA has several funding streams dedicated to special populations, two in particular are related to HIV/AIDS. In 1992, SAMSHA initiated an HIV set-aside, requiring states with AIDS case rates of 10 per 100,000 to allocate 2–5 percent of their SAPT block grants to support HIV Early Intervention Services, including HIV counseling and testing for substance users and their partners in geographic areas with the greatest need (National Alliance of State and Territorial AIDS Directors, n.d.). Despite the potential of this set-aside to address injection drug use and HIV, a 1999 survey found that less than 50 percent of state AIDS directors knew about the set-aside and only 29 percent knew how the set-aside was being used in their particular states (National Alliance of State and Territorial AIDS Directors, n.d.).

Medicaid

Federal Medicaid dollars cover only 7 percent of substance abuse treatment expenditures. There are no substance abuse treatment services included in the federally mandated Medicaid benefit package, and while states may opt to add significantly to that, (expensive) residential drug treatment in drug treatment facilities is not covered. To fully understand Medicaid's role in financing substance abuse treatment services requires a separate analysis of each state's Medicaid eligibility requirements and benefits package (with corresponding amount, duration, and scope specification). This picture is further complicated by the widespread use of behavioral health managed care plans to deliver the substance abuse and mental health benefits, even in states without other Medicaid managed care. Such an analysis is beyond the scope of this paper, but can be found in C. Lubinski's paper (unpublished), which provides a picture of the categories of services covered as well as a detailed analysis of the variation among five example states in terms of services covered.

Medicaid is problematic as a source of substance abuse treatment for people with HIV because of eligibility requirements, restrictions on the types of services covered, and low reimbursement rates. To quality for Medicaid, individuals must meet financial and categorical requirements. Categories covered include beneficiaries of Supplemental Security Income (SSI), low-income parents and children, low-income pregnant women, the Medicare eligible who meet Medicaid income guidelines, and "medically needy" people who meet a categorical requirement but exceed the financial eligibility. Individuals in this latter category qualify by spending down their income on medical costs to levels set by the 35 states offering such programs. The numbers of people with HIV who qualify for SSI have decreased with the successes of the medical management of HIV (Westmoreland, 1999). In addition, SSI eligibility for individuals whose drug and alcohol addiction was the material factor for the determination of their disability ended in 1997 (Tiger and Finkelstein, 2002). Thus, many low-income substance users with HIV are ineligible for SSI, and, if not parents, are not included based on other Medicaid eligibility categories and are not, therefore, eligible for Medicaid no matter how poor they are. Despite the availability of "medically needy" eligibility, many substance users with HIV do not meet the necessary categorical requirements (Westmoreland, 1999).

The low reimbursement rates associated with Medicaid can affect a state's substance abuse treatment system by discouraging qualified providers from delivering services (American Academy of Pediatrics, 2001). These rates have contributed to the scarcity of Medicaid-funded treatment slots. The low reimbursement rates are especially problematic when providers must address their patients' need for a complex array of services including HIV care, substance abuse treatment, and mental health services (Gourevitch, 1996).

Variations in reimbursement rates, eligibility requirements, and funded services lead to differences between states (as to the Medicaid covered substance abuse services offered and for whom). As C. Lubinski's paper (unpublished) details, geography plays an important role in access to substance abuse treatment for people with HIV as demonstrated by differences in eligibility and covered services between the states she examined: Florida, Georgia, Illinois, New York, and Texas. For example, to qualify as medically needy an individual must spend her/his income down to 27 percent of the federal poverty level in Florida, 31 percent in Georgia, 42 percent in Illinois, and 87 percent in New York. Texas does not offer coverage under this category. Medicaid does not reimburse inpatient substance abuse treatment services in Georgia, outpatient treatment in Texas, and residential treatment in any of the five states. In all five states, Medicaid reimburses for clinic visits, day treatment, evaluation and testing, individual and family therapy, group therapy, and detoxification services. However, the scope and duration of these services differs considerably among states.

Lacking System Capacity

According to SAMSHA, there are an estimated 13 million substance abusers in the United States, 10 million of whom do not receive any treatment for their substance use (SAMSHA, 2000). The substance use treatment shortage is especially acute for people in prisons and jails, where only 15 percent of inmates receive treatment but where 30 percent of inmates in federal prisons and 70 percent in state prisons need such treatment (Schneider Institute for Health Policy, 2001). Close to half of existing treatment slots are filled by people referred through the criminal justice system, which is the largest single source of referrals to substance abuse treatment (SAMSHA, 2002c). Significantly, very few people are referred to treatment either through their health or mental health provider (9.4 percent), or through a welfare or social service agency (7.2 percent) (SAMSHA, 2000).

Because substance abuse treatment systems vary greatly from state to state, the gap between treatment availability and the need for treatment also varies. While waiting lists and treatment shortage are common, the dearth of services is particularly acute in rural and non-metropolitan areas where people may have to travel long distances for substance abuse treatment (SAMSHA, 2000; Whetten-Goldstein et al., 2001). The hours of treatment, as well as supportive services such as transportation, may be severely limited. The availability of methadone maintenance, widely considered an effective treatment for opiate addiction, varies considerably as does the availability of low threshold harm reduction services.

Urban areas also struggle with treatment shortages. For example, in New York traditional drug treatment serves only approximately 42,000 of the state's estimated 555,000 substance users. In addition, 30,000 of these treatment slots are for methadone maintenance, despite the fact that the majority of (non-marijuana) drug users in New York City are addicted to cocaine or a combination of drugs (Finkelstein and Vogel, 2000).

Further compounding the scarcity of appropriate treatment slots is the chronic, relapsing nature of substance abuse. In 1998, 58 percent of substance abuse treatment admissions had at least one prior treatment episode (SAMSHA, 2002b), and 13 percent were for people who had been in treatment five or more times previously (SAMSHA, 2002c). Therefore, simple comparisons between the numbers of active users in need of treatment and the number of treatment slots fail to account for the frequency of multiple drug treatment admissions.

Lack of Appropriate Capacity

Even when treatment slots are available, the treatment slot might not be appropriate for the person seeking treatment. Despite the existence of several treatment modalities, the bulk of state funds are used on outpatient treatment, which is provided in two-thirds of all publicly funded substance abuse treatment facilities. Residential rehabilitation is offered in 25 percent of facilities, partial hospitalization in 19 percent, and outpatient detoxification in 13 percent (SAMSHA, 1999). Since the 1980s, there has been a shift away from hospital-based services provided by medical professionals.

Furthermore, specialized services for people with mental illness and with HIV are limited, despite clear evidence that substance use, mental illness, and HIV commonly co-occur. According to SAMSHA's Uniform Facility Data Set, only 45 percent of programs surveyed indicated that they offered facilities for individuals dually diagnosed with a co-occurring mental illness, and only 22 percent said they offered programs for people with HIV/AIDS (SAMSHA, 1999). The majority of drug treatment programs for people with HIV/AIDS were offered in Veterans Administration facilities, reaching a small and circumscribed group of people with HIV/AIDS (Kates and Sorian, 2000).

Inadequate Funding

Obtaining information about resources expended for substance abuse treatment is difficult. Nonetheless, an examination of the available estimates points clearly to the need for augmented funds. CSAT estimates that the average cost per episode of outpatient treatment (excluding methadone) is $2,051 and $4,160 for short-term hospital treatment (Lundenberg, 1999).

Overall, an estimated $12.6 billion is spent on substance abuse treatment from public and private sources (SAMSHA, 2000). A crude calculation shows that just under $1,000 is available per person for treatment, less than half the cost of one outpatient treatment episode and less than a quarter needed for one inpatient episode. While in actuality most active users receive no treatment, this calculation illustrates the inadequacy of current resources.

HIV Care System

The HIV treatment system has developed independently from the substance abuse treatment system, despite the role that substance abuse has played in the epidemic. Like the substance abuse treatment system, HIV care is internally fragmented due to limited coordination among the various funding sources (Kates and Sorian, 2000). This internal fragmentation complicates the ability to plan for services across the HIV and substance abuse treatment systems.

Public funding for HIV care is provided predominately through Medicaid, Medicare, the Ryan White CARE Act, and the Veterans Administration. Medicaid is the largest single payer of HIV services, supporting care for the 40 percent of people living with HIV/AIDS who receive care. In 2000, Medicaid's HIV/AIDS expenditures exceeded $2 billion and were matched by states with another $1.7 billion. Medicaid funds a range of base services that states can augment, leading to widespread differences in the scope and availability of HIV services between states (Levi et al., 2000). While prescription drugs are not mandatorily covered, all states provide some sort of drug coverage for Medicaid recipients, although this coverage differs considerably between states. Medicare, serving 28 percent of people with HIV/AIDS and providing 23 percent of all governmental funding spent on AIDS care, funds hospital and outpatient care for some people with disabilities (after a 29-month wait) and the elderly (Alagiri et al., 2002).

Ryan White CARE Act

The Ryan White CARE Act is the third largest payer of HIV/AIDS services and the largest federal program geared solely towards HIV/AIDS in the United States. The total funding for the CARE Act has grown from $220,553,000 in its first year, 1991, to $1,910,587,000 in 2002, serving an estimated 533,000 people.

Despite the increase in funding, few Ryan White resources have been devoted to substance abuse treatment or to services targeted explicitly for substance users. An examination of funding allocations of Titles I and II to meet the needs of substance users with HIV shows the extent to which substance abuse has remained a relatively low priority for Ryan White funds despite its centrality to the epidemic.

The goal of the CARE Act's Title I—intended to provide "emergency relief" to eligible metropolitan areas (EMAs) hardest hit by HIV/AIDS—is to facilitate access to HIV/AIDS care by filling gaps in covered services, covering ineligible populations, and funding HIV-related support services. Funding allocation for Title I funds are determined on the local level by a community planning council comprised of consumers and providers of HIV and related services. The planning council prioritizes the EMA's service needs and allocates percentages of the EMA's Title I award toward these service categories. The local control afforded by Title I's structure gives planning councils the latitude to determine and prioritize the components of appropriate care for substance users and to address barriers to care. Title I's gap-filling function and the discretion afforded by local level control make it particularly suited to respond to the needs of substance users with HIV and to address gaps in the EMA's substance abuse treatment system.

Within Title II, the majority of the funds go towards supporting HIV medication through the AIDS Drugs Assistance Plan (ADAP), but Title II also funds home and community-based health care, health insurance continuation, and medical and support services. Medical and support services can be allocated by the state directly and/or through HIV care consortia that plan and deliver services. Services for substance users, when funded, come from this pool of money. The HIV care consortia, comprised of health and social service providers, are responsible for assessing needs and organizing, contracting, and delivering HIV services. Unlike Title I, a formalized planning mandate does not accompany Title II funding. However, both the state and/or the consortia must conduct needs assessments and develop plans for allocating funding based on this and other data.

Funding substance abuse treatment

Despite the local level control afforded by Title I and the regular assessment of need required by Titles I and II, both have been slow to respond to the needs of substance users. Title I planning councils often allocate funding with an incomplete understanding of substance users' needs or the substance abuse treatment system's capacity (Finkelstein et al., 1999; Finkelstein et al., 2001). Likewise, because of Title II's loose assessment and prioritization process, states and care consortia are not necessarily responsive to the changing epidemic (Levi et al., 2000). Based on 2001 allocation data compiled by HRSA, 6.9 percent of Title I funds and 1.5 percent of Title II's medical and support services funds are allocated to the "substance abuse treatment and counseling" category, which includes substance abuse treatment as well as supportive services. These numbers, however, do not reflect spending on services used by substance users that fall under other prioritized categories (e.g., mental health, case management, or primary medical care).

While a recent survey of Title I EMAs indicated that 88 percent allocated funding for some sort of substance abuse treatment, the type of services and amount of funds allocated to treatment vary considerably by EMA (Tobias and Drainoni, 2001a). The most common treatment funded is outpatient counseling followed by residential treatment and methadone maintenance. When allocated to substance abuse treatment, Title I funds are usually used to purchase existing treatment slots for targeted populations (e.g., African Americans, women, Latinos) (Tobias and Drainoni, 2001a). Few EMAs, however, use Title I funds to develop HIV-specific treatment programs, incorporate substance abuse treatment into primary care settings, or fund HIV primary care in substance abuse settings. Overall far fewer Title II funded programs (only 38 percent of those surveyed) provide any substance abuse treatment through Title II (Tobias and Drainoni, 2001b).

Planning process

To explain the lack of funding allocated to substance abuse treatment, states cite systematic barriers (e.g., lack of capacity) and programmatic barriers (e.g., lack of services for women with children) as the major obstacles. While many Title I grantees are able to identify barriers to care for substance users, few direct Title I funds to address these barriers (Tobias and Drainoni, 2001a). For example, 58 percent of grantees identified lack of residential treatment as a problem, but only 35 percent used Title I funds to augment this treatment (Tobias and Drainoni, 2001a).

In a 1999 study of five EMAs, reasons offered by grantees, planning council staff, and members for not funding more substance abuse treatment, despite its consistent identification as the biggest unmet need for active substance users, included that substance abuse treatment is (a) the responsibility of another funder; (b) subject to the "payor of last resort" rule, thus ineligible for Ryan White funding; (c) an expensive service without a guaranteed outcome; (d) like a bottomless pit that will drain all available funds; and (e) incorporated or accomplished by other services, such as harm reduction (Finkelstein et al., 1999). The same study suggested that outreach efforts to substance users were impeded by the perception that clients must have documented their HIV status before they are eligible for Ryan White funded services. As a result, the 2000 reauthorization of the Act explicitly allowed funds to be used for targeted outreach and case finding. However, less than 8 percent of the EMAs targeted Title I funds for such outreach to substance users in their 2003 applications.

In planning services, most EMAs rely heavily on local epidemiological data, which are helpful in illuminating the connection between injection drug use and HIV. However, these data do not provide information on the substance abuse services needs of drug users with HIV or how these services can be incorporated into a continuum of HIV care. Many Planning Councils rely almost exclusively on the perspectives of the substance abuse providers and consumers with a history of substance use on the Planning Council. While important, these perspectives often reflect one individual's experience or one programmatic perspective rather than the range of perspectives needed to create a continuum of HIV-related substance abuse treatment services. Moreover, planning councils rarely utilize information on models of integrated HIV and substance abuse treatment that have been shown to be effective in maintaining individuals in both substance abuse treatment and primary care.

Conclusion

The ability of both Title I and Title II to address substance use is limited by a specific locality's treatment infrastructure. Surveys of Title I EMAs and Title II programs found that lack of capacity was regularly cited as a systemic barrier to treating substance users (Tobias and Drainoni, 2001a; Tobias and Drainoni, 2001b). Programmatic barriers identified included few services for women with children, dearth of harm reduction services, lack of substance abuse providers with HIV training, lack of screening in primary care settings, and few linkages between social services, HIV medical care, and substance abuse treatment. Strikingly, despite their ability to identify these barriers, Title I and Title II planning bodies have not used the funds under their control to address them.

MODELS OF CARE

Barriers to meeting the needs of HIV-positive substance users exist on multiple levels. Systemic fragmentation in the HIV and substance abuse treatment systems often prevents the coordination of services. The capacity of the substance abuse treatment system is inadequate to meet the substance users' treatment needs. Barriers at the provider and client level impede substance users' receipt of optimal health care. Current planning for the substance abuse and HIV treatment systems do not, generally, address these issues.

While systemic level barriers are difficult to overcome, thoughtful, complex, and localized planning can address programmatic barriers and their implications for HIV-positive substance users. Ideally, this level of planning facilitates an in-depth examination of substance users' needs, barriers to care and the capacity of the local health care, substance abuse treatment, and social services infrastructure and allows planners to adopt programmatic models to address these needs and barriers.

Characteristics of Effective Programs

Existing research demonstrates that co-located health and substance abuse treatment are effective at maintaining substance users in care (O'Connor et al., 1992; Selwyn et al., 1993; Rompalo et al., 2001; Friedmann et al., 2001b). Flexible program hours and scheduling, services such as case management, and a multidisciplinary program staff are effective at meeting HIV-positive substance users' multiple needs (Weissman et al., 1995; Markson et al., 1998; Newschaffer et al., 1998; Tobias et al., 2002). Comprehensive models focus on integrating HIV and substance abuse treatment and have flexible approaches to meeting substance users' needs. They also contain program elements, such as housing, transportation services, case management, services for women with children, legal assistance, and benefits advocacy that help substance users to better access the health care system and to avoid penalties for their substance use. Broad models also focus on outreach to substance users at risk for HIV to engage them into care. In addition, models for skillfully blending the various funding sources available for health, substance abuse, and mental health services demonstrate the efficacy of and necessity for combining resources to address the gaps in allowable services from any single funding source.

Despite the proven effectiveness of these program features, comparatively few HIV-specific resources have been directed toward developing such broadly-focused programs for substance users. While many programs contain some of the elements proven successful, the ones highlighted below are noteworthy because they combine most, if not all, of the program features that have demonstrated efficacy at addressing HIV-positive substance users' needs.

Examples of Effective Programs

PROTOTYPES, Center for Innovation in Health, Mental Health and Social Services, located in California, serves over 10,000 women and children each year and provides a variety of integrated services for substance-using women with HIV/AIDS and their children. The services provided include residential, outpatient, and day treatment with specialized components for women with HIV/AIDS; residential and transitional services for women recovering from substance abuse; integrated substance abuse and mental health services; HIV/AIDS medical and social services; counseling and support groups; drop-in centers for homeless women; and job training. In addition, PROTOTYPES has extensive street outreach and intervention programs targeted to women at risk for HIV/AIDS and their children and partners. Through its outreach component, PROTOTYPES links with communities at high risk for HIV and links substance-using individuals to a broad range of health, substance abuse, and mental health care and necessary social services. By focusing specifically on providing services to women and their children, PROTOTYPES is able to eradicate one of the major barriers to care for this population.

Two programs located in areas of high prevalence of both drug use and HIV in the Bronx have developed to address the complex needs of their client population. Montefiore Substance Abuse Treatment Center provides primary medical care within its substance abuse treatment center. The drug treatment component focuses on multiple modalities, including methadone maintenance, individual counseling, group therapy, and 12-step programs. They are also in the process of establishing linkages with two local harm reduction programs and with pharmacies participating in the Expanded Syringe Access Demonstration Program (ESAP). HIV primary care is provided on-site, as are mental health and social support services. Reflecting the depth of service integration, center decisions are made jointly by providers from the substance abuse treatment and medical care components. VIP Community Services provides a broad range of services from street and community outreach programs that stress a low-threshold, harm reduction approach to drug use, methadone, outpatient day treatment, and residential treatment for women and men. VIP provides HIV primary medical care to substance users in the treatment programs as well as people not in treatment. VIP also provides HIV counseling and testing, case management, housing services, and specialized supportive services for women. They, too, have structured referrals to ESAP pharmacies for their injection drug using clients.

The Adult Day Health Program at Bailey Boushay House, located in Seattle, Washington, provides an array of services for people with HIV/AIDS including substance abuse and mental health treatment. The multidisciplinary staff, including nurses, social workers, substance abuse counselors and psychiatrists provides services seven days a week. Through funds from Housing Opportunities for Persons With AIDS (HOPWA), Bailey Boushay also has a housing program that helps its clients find and maintain housing in the community. Funding for Bailey Boushay comes from a broad range of private and public sources, including HRSA, Department of Housing and Urban Development (HUD), state, city, and county funds.

PROTOTYPES, VIP, Montefiore Medical Center, and Bailey Boushay House all utilize a broad range of services including health, substance abuse treatment, and harm reduction and are actively focused on providing care in communities of high need. By developing programs around a core set of medical and substance abuse treatment services, they are able to address substance abuse and HIV in one setting from a multidisciplinary perspective. Because of the lack of coordinated funding to provide this scope of services, these programs all piece together funding from disparate sources to provide comprehensive care.

A very different model of care entails integrating residential long-term HIV care with methadone maintenance, intensive mental health services, and harm reduction. New York State's HIV long-term care facilities include both inpatient (skilled nursing facility) and outpatient (AIDS day treatment) institutions. The inpatient facilities all offer HIV medical care as well as skilled nursing care and mental health services. Several, including Highbridge Woodycrest in the Bronx and Rivington House in Lower Manhattan, also offer onsite methadone maintenance. Similarly, in addition to ongoing HIV primary medical care, case management, and adherence support, several of the AIDS day treatment facilities offer additional services targeted especially for substance users ranging from methadone maintenance to on-site syringe exchange (at Housing Works) to 12-step meetings at several of the sites. These facilities also piece together their funding from multiple sources, anchored by enhanced Medicaid reimbursement for the HIV medical care provided. The inpatient facilities do not, of course, receive Ryan White funds.

Integration of funding streams at the systemic level is even rarer than comprehensive models of HIV and substance abuse treatment. Yet, it is at precisely this level that the combination of resources can have its most far-reaching effect. In an effort to achieve this integration, the state of Texas recently initiated NorthSTAR Behavioral Health Pilot Program, combining resources from the Texas Department of Mental Health and Mental Retardation, the Texas Commission on Alcohol and Drug Abuse, the Texas Department of Health, and the Texas Health and Human Services Commission. The funding was blended to provide integrated mental health and substance abuse treatment. While no HIV-specific resources have yet been allocated to this program, the inclusion of Ryan White funding could help develop a comprehensive system of substance abuse, mental health, and HIV treatment at the systemic, rather than programmatic, level.

Comprehensive, integrated services are required to fully address HIV-positive substance users' many needs. The flexibility of Ryan White funding, combined with its local-level distribution, makes it a potentially important vehicle for achieving this integration. Ryan White funding can be used to build new services for substance users with HIV and to enhance the infrastructure of existing substance abuse treatment and HIV programs to meet the needs of their HIV-infected substance using population. Moreover, the role of Ryan White funding could be expanded to help bridge gaps in integrating funding at the systemic level to facilitate cross-system programmatic integration.

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Appendix
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Committee on Public Financing and Delivery of HIV Care

Lauren LeRoy, Ph.D. (**chair**) is President and CEO of Grantmakers In Health, a non-profit education organization serving trustees and staff of foundations and corporate giving programs working in the health field. Previously, Dr. LeRoy served as Executive Director of the Medicare Payment Advisory Commission (MedPAC) and Executive Director of the Physician Payment Review Commission (PPRC). Dr. LeRoy's research interests include Medicare reform, the health workforce, health care for the elderly, reproductive health, and health philanthropy. Dr. LeRoy chaired the Institute of Medicine (IOM's) committee on Medicare payment methodology for clinical laboratory services. Dr. LeRoy received her Ph.D. in Social Policy Planning from the University of California, Berkeley.

David Holtgrave, Ph.D. is a Professor in the Department of Behavioral Sciences and Health Education at the Rollins School of Public Health of Emory University, and the Director of the Behavioral and Social Sciences Core in the Emory Center for AIDS Research. Dr. Holtgrave's interests include cost-effectiveness analysis methods and applications, HIV prevention intervention research, and the uses of prevention science in public health policy making. He formerly served as Director of the Division of HIV/AIDS Prevention-Intervention Research and Support at the Centers for Disease Control and Prevention. He received his Ph.D. from the University of Illinois in 1988, and was a member of the Wisconsin HIV Prevention Community Planning Council from 1996–-1997.

James G. Kahn, M.D., M.P.H. is a Professor at the University of California, San Francisco, in the Institute for Health Policy Studies, the Department of Epidemiology and Biostatistics, and the AIDS Research Institute. His major research interests are the HIV/AIDS treatment costs and the cost effectiveness of prevention and treatment, health care financing and reform, and international health. Dr. Kahn recently studied racial disparities in access to antiretroviral therapy in Medicaid and AIDS Drug Assistance Programs in four states; the health and financial implications of expanding national Medicaid to cover individuals with HIV; and techniques to measure unmet need for HIV primary care. Dr. Kahn received his M.D. at Albert Einstein College of Medicine and his M.P.H. in Epidemiology from the University of California, Berkeley.

Margaret A. Murray, M.P.A., is the Executive Director of the Association of Health Center Affiliated Health Plans. Her previous experience with healthcare finance includes serving as the Medicaid Director for the New Jersey Department of Human Services, as a Senior Program Examiner for the Office of Management and Budget, and as a Senior Associate at the Alpha Center. She has also held finance positions including Tax Legislative Analyst for Senator Bill Bradley, Revenue Director and Revenue Analyst for the Massachusetts House of Representatives Ways and Means Committee, and Financial Research Assistant for Cambridge Associates. She received her M.P.A. from the Woodrow Wilson School of Public and International Affairs.

David R. Nerenz, Ph.D. is a Senior Staff Investigator in the Center for Health Services Research at Henry Ford Health System in Detroit. Most of his current work is focused on the issue of racial and ethnic disparities in quality of care, and on the ways in which health care organizations can reduce or eliminate disparities. He is also Director of Outcomes Research for the Department of Neurosurgery and the Neuroscience Institute at Henry Ford, and is the site Principal Investigator for a national study of patterns and outcomes of care for patients with lung or colorectal cancer. Dr. Nerenz received his Ph.D. in Social Psychology from the University of Wisconsin-Madison in 1979.

Andy Schneider, J.D. is Principal of Medicaid Policy, LLC, a consulting firm he founded in Washington, D.C. that specializes in issues relating to Medicaid eligibility, benefits, and financing. His former positions include Counsel to the Subcommittee on Health and Environment of the House Energy and Commerce Committee, then chaired by Representative Henry A. Waxman (D-CA); Health Counsel to the Center on Budget Policy and Priorities in Washington, D.C.; and Staff Attorney to the National Health

Law Program in Los Angeles, California. Mr. Schneider received his J.D. from the University of Pennsylvania, School of Law.

Martin F. Shapiro, M.D. practices general internal medicine at the UCLA Medical Center. Dr. Shapiro obtained his undergraduate and medical education at McGill University. Subsequent to that he completed a residency in internal medicine at the Royal Victoria Hospital in Montreal and at UCLA, spent one year engaged in research in the Department of Epidemiology and Health at McGill, and completed a fellowship at UCLA as a Robert Wood Johnson Clinical Scholar. Dr. Shapiro received an M.P.H. in Health Services from UCLA, then a Ph.D. in history also from UCLA, conducting a dissertation on health care services in Portuguese Africa. Dr. Shapiro joined the UCLA faculty in the Division of General Internal Medicine and Health Services Research in 1980 and joined the Department of Health Services in 2000. He is Professor and Chief of the Division of General Internal Medicine and Health Services Research in the Department of Medicine. In 1988, he established the Primary Care Research Fellowship Program at UCLA, which he directed until 2003. He is Associate Director of the UCLA Clinical Scholars Program. Dr. Shapiro's scholarship has focused on the general theme of assuring that medical care is applied equitably and appropriately to the population and on health services research in the area of HIV disease. He has been the principal investigator on the HIV Costs and Services Utilization Study (HCSUS), a national study of AIDS costs and AIDS patients' access to and quality of care. Dr. Shapiro served on the Institute of Medicine's Committee on the Responsible Conduct of Research. He was President of the Society of General Internal Medicine from 2002–2003 and is an elected member of The American Society of Clinical Investigation and of the Association of American Physicians.

Janet L. Shikles, M.A., M.S.W. is a health care consultant who works with government agencies, associations, and foundations on projects involving health insurance, Medicare, Medicaid, and public health. She also chairs a multi-year project for the Robert Wood Johnson Foundation, which is designed to ensure the health and income of the older workforce. Previously, Ms. Shikles was a Vice President for Health Care Research and Consulting for Abt Associates Inc., a firm specializing in research and evaluation for government agencies and private center health care clients. She also served as the Executive Director of the Commonwealth Fund's Taskforce on the Future of Health Insurance. The goal of this taskforce was to conduct research and evaluations of different approaches to expand insurance coverage to the uninsured. Prior to this she was the Director of Public Policy and Government Relations for the firm Powers, Pyles, Sutter & Verville. Ms. Shikles also served as Assistant Comptroller General in charge of the Health Education and Human Services Division of the U.S. General Accounting Office (GAO), where she was responsible for GAO's work relating to health, education, labor, social security, veterans affairs and welfare programs. She was also the Director of Health Financing and Policy Issues at GAO. Prior to joining GAO, Ms. Shikles was an associate with Booz, Allen and Hamilton. She was also a senior analyst in health research with the Department of Health and Human Services. Ms. Shikles received a bachelor's degree in Government and holds an M.A. in Political Science from George Washington University and an M.S.W. in Research and Planning from Howard University.

Julie Sochalski, Ph.D., F.A.A.N, R.N. is an Associate Professor at the University of Pennsylvania, School of Nursing, where she teaches interdisciplinary courses in health policy and health services and outcomes research. She has held senior policy positions at the United Hospital Fund of New York and the Medicare Prospective Payment Assessment Commission in Washington, D.C., and was a 1992–1993 Robert Wood Johnson Health Policy Fellow. Her health services research portfolio includes strategies exploring quality of care and patient outcomes in hospital and community-based settings, Medicare payment policy and its impact on service use, and domestic and international trends in the health care workforce and their implications for public policy. She received her Ph.D. from the University of Michigan in 1988.

David Vlahov, Ph.D. is Director for the Center for Urban Epidemiologic Studies at the New York Academy of Medicine, Professor of Clinical Epidemiology Mailman School of Public Health at Columbia University, and Adjunct Processor in Epidemiology at the Johns Hopkins Bloomberg School of Public Health. Dr. Vlahov completed his BSN and M.S. in Nursing at the University of Maryland and a Ph.D. in epidemiology at the Johns Hopkins School of Public Health. He has developed extensive experience in the design, conduct, and analysis of infectious disease epidemiological studies. He has been Principal Investigator of the Natural History of HIV Infection among Injection Drug Users (the ALIVE study). Key collaborations have included joint investigations with the Multi-center AIDS Cohort Study, and internationally with cohort studies in Italy, France, and the Netherlands. For ALIVE, funded by the National Institute of Drug Abuse, the National Institues of Health recognized Dr. Vlahov with the MERIT Award. Dr. Vlahov was also a Principal Investigator of the CDC-funded HERS study to investigate gender specific factors associated with HIV progression in women. In addition, Dr. Vlahov has been involved with the evaluation of HIV prevention activities, including the Needle Exchange Programs in Washington, D.C., and Baltimore, Maryland. Dr. Vlahov has over 370 publications in peer-reviewed journals. Dr. Vlahov has been the primary advisor for twenty doctoral and post-doctoral students. He is the editor-in-chief of the Journal of Urban health and one of the founders of the International Society for Urban Health.

Paul A. Volberding, M.D. is a Professor and Vice-Chair in the Department of Medicine and the Co-Director of the Center for AIDS Research at the University of California, San Francisco (UCSF). He is the Chief of the Medical Service at the San Francisco Veterans Affairs Medical Center. He received his medical degree from the University of Minnesota and finished training at University of Utah and UCSF, where he studied for two years as a research fellow in the virology laboratory of Dr. Jay Levy, later a co-discoverer of HIV. Dr. Volberding's professional activities initially centered at San Francisco General Hospital, where he established a model program of AIDS patient care, research, and professional education. His research career began with investigations of HIV-related malignancies, especially Kaposi's Sarcoma. His primary research focus, however, shifted to clinical trials of antiretroviral drugs. He has been instrumental in testing many compounds, but is best known for groundbreaking trials establishing the benefits of treatment with antiretroviral drugs in asymptomatic HIV infection. Dr. Volberding has written many research and review articles. He is the Co-editor in Chief of the *Journal of Acquired Immune Deficiency Syndromes*, and is the founder and Chair of the Board of the International AIDS Society-USA and is a Past President of the International AIDS Society. He is the Vice President and President elect of the HIV Medicine Association of the Infectious Disease Society of America. He is a member of the IOM and has served on several committees addressing the HIV epidemic.

William E. Welton, Dr.P.H., M.H.A. is currently Senior Lecturer and M.H.A. Program Director in the Department of Health services at the University of Washington, Seattle. From 1994–1998, Dr. Welton served as Founding Dean of the newly developing School of Public Health within MCP Hahnemann University (Philadelphia, PA). In the capacity he led the planning and development of the school, including its innovative and highly successful problem-based learning (PHL) curriculum in public health—the first of its kind in the nation. In 1998, he was awarded the university's prestigious Founder's Award for his leadership role in the school's development. From 1996–2001, he served as Director of the MCP Hahnemann University School of Public Health's Center for Health Management and Policy and as Program Director of the school's part-time M.P.H. Program. Dr. Welton served as a Pew Health Policy Fellow (1994–1999) within the University of Michigan's Department of Health management and Policy, receiving his Dr. P.H. degree through its Pew Health Policy Program in1999.

From 1972–1994 Dr. Weldon served as a senior executive manager and governing board member within a variety of academic health systems and managed care organizations. From 1991–1994 he also served as Chairman Officer of the American Hospital Association's Health Care Systems Section Governing Council. Dr. Welton's academic and research interests focus on health policy and health services research with an emphasis on health economics, organizational strategy, and strategic and policy-oriented decision analysis.

Health Promotion and Disease Prevention Board Liaison

Joyce Seiko Kobayashi, M.D., is currently an Associate Professor in the Department of Psychiatry at the University of Colorado Health Sciences Center, and Associate Faculty Member of the Department of Healthcare Ethics, Humanities and the Law. Dr. Kobayashi received her undergraduate training at Stanford University, her M.D. from the University of Rochester School of Medicine, and completed her psychiatric training at Albert Einstein College of Medicine. She completed a subspecialty fellowship in Consultation/Liaison Psychiatry through Mt. Sinai College of Medicine, and has since specialized in the psychiatric treatment of people with HIV/AIDS. She was an American Psychiatric Association/National Institute of Mental Health (APA/NIMH) Minority Fellow and has served on a number of national Committees and Councils of the APA. During her tenure as Chairperson of the APA Committee of Asian American Psychiatrists, she organized the first International Symposium on Psychiatric Research in Asia. She has served for many years as a member of the National Commission on AIDS of the APA, where she was one of the authors of the needle exchange policy for the association. She served as a National Examiner for the Board of Psychiatry and Neurology. She has been the recipient of several awards, including the Dinkelspiel Award at Stanford, Colorado Woman of the Year in Health and Human Services from the Colorado Asian Pacific Women's Network, and Rocky Mountain Regional AIDS Conference Award for Service to People with AIDS. Dr. Kobayashi has published a variety of articles and chapters on HIV/AIDS, biomedical ethics, women's issues, and transcultural psychiatry and has given invited lectures at regional and national AIDS meetings.

Health Promotion and Disease Prevention Board Director

Rose Marie Martinez, Sc.D., is the Director of the Institute of Medicine's Board on Health Promotion and Disease Prevention. She has been with the IOM since November 1999. Prior to joining the IOM, Dr. Martinez was a Senior Health Researcher at Mathematica Policy Research, where she conducted research on the impact of health system change on the public health infrastructure, access to care for vulnerable populations, managed care, and the health care workforce. She is a former Assistant Director for Health Financing and Policy with the U.S. General Accounting Office, where she directed evaluations and policy analysis in the area of national and public health issues. From 1982 through 1988, she was Chief of Health Studies at the Regional Institute for Health and Social Welfare, the research arm of the Regional Ministry of Health in Madrid, Spain. Dr. Martinez received her B.A. from the University of Southern California and her Doctor of Science from the Johns Hopkins School of Hygiene and Public Health.

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