

AIDS Drug Assistance Programs: Highlighting Inequities in Human Immunodeficiency Virus–Infection Health Care in the United States

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The AIDS Drug Assistance Programs (ADAPs) were founded in 1987 to pay for human immunodeficiency virus (HIV)–related medications in the United States and to help provide prescriptions for HIV-infected patients ineligible for Medicaid who have no private health insurance. As HIV care has shifted from the inpatient to the outpatient arena and as patients live longer because of more-effective antiretroviral therapy, medication costs have increased, and ADAPs have increasingly been operating under emergency measures, with coverage limitations and eligibility restrictions. Because these programs operate at the state level, inequalities in resource distribution to those in need are manifest and appear to contribute to differences in disease outcomes that are based solely on patients' place of residence. Cost-effectiveness analysis would offer a more informed basis for distribution of ADAP resources in an efficient and equitable manner, leading to a standardized national structure.

The optimism resulting from recent clinical advances in treatment for HIV infection has been dampened by the challenge of working with limited resources. In the United States, the savings associated with lower costs for inpatient care have been outpaced by the growing costs of highly active antiretroviral therapy (HAART) [1, 2]. Moreover, increasing duration of survival among HIV-infected people means that the higher monthly costs of care are incurred for a longer time. These increasing costs of care have strained individual, state, and federal budgets. The state-operated AIDS Drug Assistance Programs (ADAPs) that provide HIV medications to low-income,

uninsured individuals under Title II of the federal Ryan White Comprehensive AIDS Resources (CARE) Act are a compelling example.

The ADAPs were originally established to assist states in paying for prescription coverage for the increasing number of HIV-infected patients who are not covered by Medicaid or private insurance. Since late 1995, with the introduction of protease inhibitors and the advent of HAART, ADAPs have struggled with explosive growth in budgets, expenditures, and numbers of clients served. Indeed, the national ADAP budget has increased almost 4-fold, from \$188.5 million in fiscal year 1996 to \$724.5 million in fiscal year 2000, and combination antiretroviral drug regimens account for ~90% of total ADAP spending [3]. Meanwhile, the ADAPs have failed to realize the savings associated with reduced inpatient expenditures. By 1997, 35 of the 54 ADAPs (including those in all 50 states, the District of Columbia, Puerto Rico, Guam, and the Virgin Islands) were operating under emergency measures: transferring funds from other health programs, instituting waiting lists for access, restricting eligibility, and limiting the number of drugs covered [3].

Infectious diseases clinicians can learn from the financial and managerial challenges currently facing the ADAPs. These chal-

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Challenges offer useful case studies in the allocation of scarce resources and the practical difficulties of making appropriate use of limited information to determine both what is fair and what is best for our patients. The costs of caring for patients with HIV/AIDS will continue to grow in the years to come [1, 3]. Moreover, emerging infections—most notably, infection with hepatitis C virus—will place additional strain on the nation's already overcommitted health budgets. In this article, we review the current structure of and rationale behind ADAPs, survey the challenges that new scientific developments create for future ADAP financing, and offer means by which their economic and political security can be strengthened to meet these emerging demands.

FEDERAL FUNDING FOR AIDS TREATMENT

The Ryan White CARE Act. In August 1990, Congress passed the CARE Act to provide funding to states and other nonprofit entities to develop, organize, coordinate, and operate more effective and cost-efficient systems for the delivery of essential health care and support services to medically underserved individuals and families affected by HIV disease [4]. The CARE Act provides assistance under 4 titles, as follows: Title I provides for distribution of funds to eligible metropolitan areas hardest hit by the epidemic, Title II provides for distribution of funds to all states to improve the quality of care for HIV-infected patients, Title III provides for direct funding of public and nonprofit agencies dedicated to early HIV interventions, and Title IV provides for direct funding of public and nonprofit agencies providing comprehensive care to women, children, and families affected by the epidemic. Eleven years after the Ryan White CARE Act was passed, \$9.8 billion in federal funds have been appropriated under its provisions (\$1.6 billion in 2000 alone), making it the largest single source of federal funds designated specifically for the health and social care of patients infected with HIV.

ADAPs. Title II of the CARE Act designates that funds be distributed to all states and US territories to assure that people infected with HIV have access to quality health care, regardless of their locale [4]. Under Title II, states are required to provide access to necessary HIV-related pharmaceuticals [4]. Indeed, in 1996, Congress appropriated funds directly to the ADAPs; this earmarked portion of the Title II award must be spent on US Food and Drug Administration (FDA)-approved, HIV-related medications for patients with limited insurance coverage. In fiscal year 2001, these earmarked funds totaled >\$589 million [5]. Thus, Title II specifically defines funds and the target population but delegates all further managerial and administrative responsibility to the individual states [6].

Patient enrollment qualifications in ADAPs vary widely from state to state. Minimal income eligibility ranges from

125% of the federal poverty level (North Carolina) to 500% of the federal poverty level (New Jersey and New York). Other states define eligibility according to maximum income levels (\$27,000–\$44,000) adjusted for the number of household members. Medical eligibility is most commonly based solely on HIV-infection status, but 4 states impose additional CD4 count and/or virus load criteria. Some states require an AIDS diagnosis [3].

States also vary widely in their own contributions to ADAPs. In 2000, 15 states provided no funding to supplement the federal ADAP contribution [3]. California contributes the most to its ADAP: \$44.6 million, or 34% of what it receives from the federal government. New York receives the most federal money for ADAP (\$95.8 million), but itself contributes only an additional \$9 million (7% of the federal contribution) [3].

Not surprisingly, antiretroviral therapy accounts for the bulk (87%) of ADAP expenditures: ~\$51.3 million is spent per month nationally. In 1997, states began diverging in their antiretroviral coverage, with some states approving payment only for individual drugs in each class and others eliminating expensive protease inhibitors from their formularies entirely. Largely because of the publication of new national guidelines [7, 8], efforts were extended to offer appropriate antiretroviral therapy to patients who met eligibility criteria. By 2000, all states except South Dakota, which still does not have sufficient funds for protease inhibitors, list all of the FDA-approved antiretroviral agents in their formularies [3].

However, success in providing state-of-the-art antiretroviral care for patients enrolled in ADAPs has come at the expense of other program attributes. For example, coverage of drugs for the treatment and prevention of opportunistic infections remains spotty. Four states have no coverage for any of the 16 recommended drugs used as prophylaxis or treatment for opportunistic infections; only 8 states cover all 16 drugs [3, 9]. Moreover, to limit consumption of expensive antiretroviral therapy, states have expanded the scope of eligibility restrictions. As of March 2001, 10 states had such program limitations in place, including capped enrollment, waiting lists, reduced formularies, and per capita expenditure caps [3].

CHALLENGES TO ADAPs

Three powerful forces will exacerbate the increased difficulties faced by the ADAPs in the next several years: (1) increased duration of survival of HIV-infected patients, (2) growing inequities in ADAP coverage between states, and (3) emerging infections.

Progress in HIV-infection care. The introduction of HAART in 1996 produced rates of virus suppression and immune reconstitution that changed HIV infection from a fatal disease to a treatable, chronic infection. Recent data from the

National State and Territorial AIDS Directors illustrate the financial crisis that has been fueled by the expanding number of HIV-infected patients and their longer survival. Between June 1999 and June 2000, there was a 12% increase in the number of ADAP clients [3]. ADAP expenses in June 2000 were \$1.2 million higher than they had been in June of the previous year—a 22% increase [3]. Meanwhile, the 2001 federal budget froze funds appropriated under the Ryan White CARE Act, offering no increases in allocation for the first time since its inception [10]. Because demand continues to outpace the allocation of dollars, many state-run ADAPs have been compelled to restrict eligibility and drug distribution. In 2000, 17 states reported further additions to their eligibility criteria. For example, 10 states had ADAP waiting lists. Although all states but 1 had protease inhibitors in their formularies, 5 states (1 more than in 1999) still restricted access to these medicines [3]. A Pennsylvania study surveyed both HIV-infected patients and a sample of shopping mall patrons to assess the acceptability of 5 current approaches to ADAP rationing, including limiting patient enrollment and restricting medicine availability. Although the study participants were aware of the ADAP budget constraints, neither group supported any of the rationing policies [11].

Inequalities between ADAPs. ADAP disparities between states make it clear that similar HIV-infected patients living in different states are not treated equally and cannot expect similar outcomes [12]. In a study by Johri et al. [13], our group used a mathematical simulation model of HIV disease to explore how state-to-state differences in ADAP policies alone could produce variation of up to 4.25 years in life-expectancy estimates for clinically similar patients. This difference was attributable only to the comprehensiveness of ADAP coverage in the states compared. Results from the HIV Cost and Services Utilization Study, which examined a national probability sample of people receiving care for HIV infection, also demonstrate disparate outcomes attributable to unequal access to care [1]. This study documents that overall access to care improved between 1996 and 1998, but that disadvantaged persons without public insurance continued to have inadequate access to outpatient resources and were, consequently, among those most frequently admitted to the hospital [1].

Emerging infections: hepatitis C. A new public health crisis threatens to send the system into further disarray. The story of the emergence of hepatitis C virus infection in many ways mirrors the HIV story, albeit 15 years later. First, there is a large and growing hepatitis C prevalence. Hepatitis C is already the most common chronic bloodborne infection in the United States, affecting at least 2.7 million people and accounting for 25,000 deaths annually [14, 15]. Second, a substantial number of people with hepatitis C infection remain unaware they are

infected and continue to transmit the virus to others [15]. Third, hepatitis C infection has a long, clinically silent period followed by considerable morbidity, mortality, and cost [14, 15]. Unlike HIV infection, however, liver transplantation further increases the cost of care for advanced hepatitis C infection. Hepatitis C infection is now the leading reason for liver transplantation nationally, accounting for 30% of all transplantation procedures (~1000 patients per year) [15, 16]. In 1997, the estimated total costs of medical treatment and lost work in the United States attributable to hepatitis C infection, including costs attributable to transplantation, primary liver cancer, and chronic liver disease, exceeded \$5 billion [14]. Finally, new and effective hepatitis C therapy carries substantial costs that cannot possibly be borne by uninsured patients. The hepatitis C nucleoside analogue, ribavirin, for example, has an average wholesale cost of ~\$1100 per month, which is ~3 times greater than the cost of the most expensive HIV nucleoside analogue [17]. Treatment with IFN- α also costs \$500–\$1000 per month [17]. Thus, combination medical therapy for hepatitis C infection carries a higher annual cost than does HIV therapy, even if the transplantation costs of >\$200,000 per patient are ignored [18].

As treatment for hepatitis C infection increasingly becomes standard, a need will emerge either for ADAP-like programs for hepatitis C infection to be instituted or for existing ADAPs to expand coverage for hepatitis C therapy. The challenge for infectious diseases physicians and public policy makers is to tackle the current inequalities, limitations, and budget constraints of ADAPs before they are further exacerbated by the hepatitis C epidemic.

COST-EFFECTIVENESS ANALYSIS

Discussions of the US health care delivery system and possible approaches to reform often focus on the question of rationing [19, 20]. Although both politicians and health care providers dislike the term, rationing (or distribution by supply) is an unavoidable reality when the claims on any constrained resource outstrip its availability. Implicit in the organization and delivery of health care in the United States is the premise that we cannot afford all that we would consume. Studies have repeatedly documented that uninsured patients have both major health risks and unmet health care needs [21, 22]. Difficult trade-offs in the distribution of health care resources will inevitably persist. The challenge is for us to agree upon a “fair” allocation process.

The ADAP priority-setting challenge illustrates a general class of policy dilemmas that is often encountered in medicine—namely, the case of an identifiable decision maker who must allocate a limited resource to meet multiple competing claims and to maximize health and social objectives. These

so-called “constrained optimization” problems lend themselves to cost-effectiveness analysis, the systematic comparison of alternative social investments in terms of their ability to confer “value for money.” Cost-effectiveness analysis weighs a program’s total costs against the benefits (measured according to some yardstick of aggregate social utility) it produces. Benefits are typically expressed in natural units of health outcome, such as reduced morbidity or increases in life expectancy or quality-adjusted life expectancy.

Although cost-effectiveness analyses work to maximize efficiency (as measured by the total benefit conferred per unit of resource allocated), they do not focus on the equitable allotment of resources. Implicit in the cost-effectiveness framework is the belief that the value of a benefit is the same, regardless of who wins or loses or how that benefit is conferred. The greater gains of some can offset the lesser losses of others. Some segments of the population may be left underserved if doing so confers even a small incremental benefit on a sufficiently large number of people. The results could, on occasion, deprive large classes of the population (the very old or the extremely ill, for example) of resources in favor of other groups.

Cost-effectiveness analyses have been successfully used to evaluate most new developments in HIV clinical therapeutics, including HIV screening, opportunistic infection prophylaxis, antiretroviral therapy, and the use of diagnostic tests [2, 23–27]. These analyses have been used by HIV policy makers to help define the optimal use of HIV therapeutic resources in national guidelines [9]. Cost-effectiveness analyses examining the use of ADAP resources have shown explicitly that some state programs cost more but still deliver fewer benefits than do others. A simple redistribution of resources within some states would therefore confer additional health benefits with no net increase in resource consumption [13]. In addition, Johri et al. [13] found that, in almost every state, adding coverage for prophylaxis against opportunistic infections with *Pneumocystis carinii* pneumonia and *Mycobacterium avium* complex improved the efficiency of the ADAPs by providing the greatest possible gain in life-expectancy for any given level of expenditure.

Cost-effectiveness analyses have also demonstrated that even the most comprehensive ADAPs are a comparatively attractive use of HIV care resources. Multiple studies have shown that more-generous programs are more expensive but that even the most expensive programs deliver good value [2, 13, 27]. The cost-effectiveness of combination antiretroviral therapy (\$13,000–\$23,000 per quality-adjusted life-year [QALY] saved) repeatedly has been shown to compare favorably not only with other HIV patient-care interventions but also with other accepted medical investments, such as thrombolytic therapy for acute myocardial infarction (\$39,000 per QALY saved) and dialysis for seriously ill adults (\$147,000 per QALY) [2, 28, 29].

TOWARD AN INFORMED NATIONAL FRAMEWORK

Heeding the results of cost-effectiveness analyses of the ADAP budget will not fix all of the flaws in the provision of HIV health care in the United States. The funding of care for HIV-infected patients is achieved by way of a patchwork quilt of poorly coordinated, underfunded, predominantly public programs that are viewed more as safety nets than as essential components of an integrated, comprehensive whole. Moreover, analyses that restrict their attention to optimization of the existing ADAP budget ignore the greater issue: that the ADAP allowance may be altogether too small—and there is discussion of another frozen budget in 2003 [30]. However, cost-effectiveness analyses, if properly used in conjunction with input data from representative populations of infected persons, can provide a framework for more-informed ADAP policy. In the matter of ADAPs and HIV, considerations of justice, equity, and efficiency all point in the same direction: toward providing the current standard of HIV care for the prophylaxis and treatment of opportunistic infections and for antiretroviral therapy to all patients who would likely benefit [15, 31]. Logically, this policy should lead us to a national formulary. However, given the variable resources among states, some ADAPs may not currently be able to afford the national formulary. At a minimum, however, each state could aim to optimize its current budget, using a cost-effectiveness framework to confer the maximum possible benefit, subject to existing resource limitations, to all patients in need. Although this would not guarantee all patients the current standard of care nationwide, it would serve to clarify 2 things. First, states could be confident that they were making the best possible use of available funds to provide the greatest health benefit to their population. Second, states would be able to quantify the financial resources required to provide more-comprehensive ADAP coverage and the clinical implications of failing to adhere to existing guidelines.

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