The HIV Landscape in a Managed Care Environment: Current Challenges and Potential Solutions

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ABSTRACT

OBJECTIVE: To review the current impact of human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) and its treatment on the population and on managed care.

SUMMARY: In 2006, HIV/AIDS remains as big a problem as ever, with many countries reporting an incidence of 40% or higher among intravenous drug users. While daunting, this does not detract from the many victories that have occurred over the HIV/AIDS landscape. Mortality has declined dramatically since 1995. Treatment with highly active antiretroviral therapy (HAART) has been simplified and offers substantial survivor benefits. The net effect of these advances has been to change the face of HIV/AIDS, from a fatal to a chronic illness. Accordingly, current and evolving management strategies need to encompass long-term care.

CONCLUSION: As people live longer, health care management organizations will be looking to balance good outcomes and successful long-term care with acceptable costs.

KEYWORDS: Human immunodeficiency virus (HIV), Acquired immunodeficiency syndrome (AIDS), Highly active antiretroviral therapy (HAART)

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More than 20 years have passed since the initial scattered reports of an unusual pneumonia and rare cancer—*Pneumocystis carinii* (since renamed *P jiroveci*) pneumonia and Kaposi's sarcoma—occurring in homosexual men provided the first whisperings of what was to become the human immunodeficiency virus (HIV) epidemic. Despite tremendous advances in our understanding and management of HIV and the acquired immunodeficiency syndrome (AIDS), the problem remains one of world-wide proportions. Today, the United States, Canada, Russia, and China as well as parts of Europe, Africa, the Pacific Islands, and South America have become deeply embedded in the HIV landscape, reporting a 40% or higher prevalence of HIV/AIDS among their intravenous drug users (Figure 1).¹

Population data from 2000 to 2004 in the United States shows a progressive increase in the incidence of AIDS among whites, blacks, Hispanics, Asians, Pacific Islanders, Alaskans, and American Indians (Table 1).² The number of AIDS cases continues to grow and is currently highest among non-Hispanic blacks and whites and lowest in American Indians and native Alaskans.²

Evolution of Drug Therapy

Treatment of HIV infection has always focused on effectiveness, which must be balanced with tolerability and patient adherence if highly active antiretroviral therapy (HAART) is to have any chance of working. With the development of drugs that are potent enough to keep the HIV virus in check, physicians are increasingly looking

FIGURE 1 Emerging HIV Epidemics: IVDUs

Source: WHO, UNAIDS. Beyrer C. 3rd IAS; Rio de Janeiro; 2005. #MoPI02. Worldwide prevalence of human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) among intravenous drug users (IVDUs).

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not only to prolong life but also to improve the quality of that life.

Many issues influence the quality of life for a patient being treated for HIV/AIDS. These include the regimen itself, dietary restrictions, and side effects. Adverse effects are a particular cause for concern because they contribute to other comorbidities and undermine adherence. Lipodystrophy, which causes disfiguring changes in body shape, is a major side effect of HAART that is distressing for patients. Anemia and fatigue are common as well. Metabolic abnormalities, such as hypercholesterolemia, cause concern about long-term cardiovascular health. All of these issues compound the risk and cost of care.

That is not to say that treatment has not improved—it has. Ten years ago, patients received a regimen of stavudine, lamivudine, and indinavir, 10 tablets or capsules every 8 hours for a total of 30 daily. Patients had to observe food restrictions and drink liquids frequently. This treatment was also plagued by short- and long-term toxicities that decreased tolerability. By 1998, the standard regimen was simplified to a lamivudine/zidovudine coformulation plus efavirenz, 5 tablets or capsules taken twice daily. Although clinicians and patients welcomed more simple dosing schedules, the side effects of the coformulation—gastrointestinal (GI) effects, anemia, neutropenia, central nervous system (CNS) toxicities, and mitochondrial-related toxicities—still hindered patient compliance. By 2002, this drug regimen was further refined to 3 tablets or capsules, twice daily, but issues of toxicity remained. Within 2 years, the HIV treatment paradigm changed again with the introduction of fully once-daily treatment options: efavirenz plus a coformulation of tenofovir disoproxil fumarate/emtricitabine or abacavir/lamivudine, both given as 2 tablets or capsules, once daily. These drug combinations help improve convenience and tolerability for the patient by offering treatments with less frequent daily dosing, reduced pill burden, minimal side effects, and no food restrictions. Moving forward, the goal is to develop a simple 1-tablet, once-daily regimen without side effects, allowing for optimal adherence and outcome despite the need for lifelong treatment.³

Mortality

The mortality rates from HIV have declined tremendously since 1995. Data from the Centers for Disease Control and Prevention show that, in 1995, 16 out of 100,000 persons in the United States died from AIDS.² By 2003, that figure had declined to roughly 4.4 per 100,000 population.²

The death rate has dropped as the percentage of patients receiving HAART has increased. In the second quarter of 1992, for instance, there were no patients on HAART, and the number of deaths per 100 person years averaged just over 11. By the second quarter of 2005, 80% of patients were receiving HAART, and the mortality rate was less than 1 per 100 person years (Figure 2).⁴

HAART also offers significant survival benefits. Walensky and colleagues⁵ examined surveillance data from 1989 to 2003 in patients receiving treatment for HIV/AIDS in the United States.

TABLE 1 Number of HIV Diagnoses in the United States from 2000 to 2004

Race/Ethnicity	Year of Diagnosis					All Years
	2000	2001	2002	2003	2004	
White, non-Hispanic	11,378	11,052	11,604	11,657	12,013	375,155
Black, non-Hispanic	19,510	19,473	19,934	20,685	20,965	379,278
Hispanic	7,957	7,974	7,907	8,632	8,672	177,164
Asian/Pacific Islander	350	381	440	478	488	7,317
American Indian/Alaskan native	175	169	186	189	193	3,084

Data from Centers for Disease Control and Prevention, 2005.²

HIV=human immunodeficiency virus.

FIGURE 2 Mortality and HAART Use Over Time

Mortality from human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) and highly active antiretroviral therapy (HAART) use over time. As the percentage of patients receiving HAART has increased, deaths have declined dramatically. Reprinted with permission from Palella FJ et al. *J Acquir Immune Defic Syndr*. 2006;43(1):27-34.

As years progressed and treatment improved, patients lived longer. From 1989 to 2003, for example, antiretroviral treatment prolonged life by an average of 3 months. For the second (1993-1995) and third (1996-2003) periods of the study, antiretroviral therapy extended life by 2 and 11 to 13 years, respectively. The authors of this study concluded that the widespread availability of HAART has spared more than 3 million lives.

HIV Infection as a Chronic Disease

The impact of these treatments in reducing mortality has transformed HIV/AIDS from a terminal disease to a chronic disease. As a result, the focus of management shifts from mortality to promoting adherence, minimizing treatment- and disease-related

FIGURE 3 Specialty Pharmacy Trend vs. Average Pharmacy Trend (2004-2005)

Overall specialty pharmacy trend versus average pharmacy trend, 2004-2005. Spending, utilization, and unit cost are all higher for specialty pharmacy products. Adapted from Medco Health Solutions. Drug Trend Report: Managing Generation Rx. Copyright© 2005, Medco Health Solutions, Inc.

morbidities, optimizing outcome, and controlling the costs of ongoing treatment.

Medco Health Solutions tracked spending, utilization, and unit cost of specialty versus average outpatient prescription drugs for the period 2004 to 2005 (Figure 3).⁶ Specialty pharmacy is defined here as products used to treat chronic, high-cost, or rare diseases; injectable pharmaceutical and/or biologic products; products delivered through special delivery or requiring special handling; injectable and infusion therapies delivered in ambulatory settings and high-cost (\$5,000 and up per patient per year); and/or “high-touch” therapies (therapies requiring high levels of patient training and physician interaction). Spending, utilization, and unit cost were all higher for specialty drugs. The increased spending in the specialty drug category will be scrutinized closely by those involved in managing health care costs.

Looking Ahead

Currently, there are 197 specialty drugs on the market to treat various chronic conditions. However, there are more than 800 such drugs in various states of development. By 2010, 325 specialty drugs are projected to be available to physicians.⁷ Managed care organizations will be closely examining how physicians prioritize therapy expenditures and associated outcomes.

In 2005, the Health Strategies Group surveyed 60 pharmacy directors to determine how their managed care organizations handled various specialty therapies, including drugs for HIV/AIDS.⁸ Responses—specifically about their number of interventions and specialty formularies, use of direct contracting, and policies

mandating use of specialty pharmacy management for the various specialty therapies—ranked HIV/AIDS treatments, along with hemophilia and cancer supportive therapy, among medium priority specialties. Office and oral oncologic medications were low priority and medications for psoriasis, rheumatoid arthritis, multiple sclerosis, human growth hormone deficiency, and hepatitis were high priority. HIV/AIDS specialty medications are beginning to garner attention from managed care organizations concerned with ensuring that treatments are being prescribed appropriately. While there are no firm criteria for prioritizing specialties, managed care interests generally focus on areas with the potential to offer savings with management, i.e., multiple high-cost therapies available with high potential for unnecessary utilization.

Because so many AIDS victims are of working age, the business sector sees many of the effects of HIV/AIDS.⁹ Therefore, many employers are examining the impact of this disease on the workforce and total health-related costs. The Integrated Benefits Institute surveyed chief financial and executive officers about how HIV/AIDS affected their companies.¹⁰ The results showed that AIDS-related group health and workers’ compensation accounted for about 19% of total health care expenditures, while 10% of health costs went to disability coverage. Lost productivity consumed 71% of the health care budget. Studies are under way to further determine the impact of HIV-related health care costs and benefits on the workforce. This is something that will need to be examined when assessing the overall value and benefit of treatments prescribed for working adults who have HIV/AIDS.

Designing a Care Plan

The care plan for persons with HIV/AIDS is multifaceted and requires careful coordination. At the plan level, coverage, plan designs, and education programs need to be developed to promote appropriate access and adherence. In a managed care environment, the physician usually provides the initial point of care. Patients need to be educated about the disease and the treatment being offered to them. The pharmacist is another crucial point of care; he or she may provide specialty pharmacy management or direct the patient to an appropriate resource. All of these services need to be coordinated. It is also essential that the various caregivers involved in the treatment plan deliver a consistent message; patients who receive (or perceive) different messages from various caregivers can easily become confused, which detracts from their ability to fully adhere to treatment.

It is critical for care plans to be designed in consideration of appropriate access for patients to services. Optimal outcomes can only be achieved when patients can access appropriate care and comply with therapy.

Summary

While HIV/AIDS remains serious, treatment regimens are becoming progressively streamlined and oriented toward long-term care.

As people with HIV/AIDS continue to live longer, the financial burden of their care will continue to escalate. Managed care organizations will be studying these expenses and looking to develop strategies that optimize value by providing a practical, achievable balance of outcomes and cost.

DISCLOSURES

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