

The AMERICAN ACADEMY of HIV MEDICINE

HIV SPECIALIST

PATIENT CARE, PRACTICE MANAGEMENT & PROFESSIONAL
DEVELOPMENT INFORMATION for HIV CARE PROVIDERS

Summer 2010

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the Battle
Continues

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Secretary Sebelius *and* President Obama Making a Commitment to the HIV Workforce

IN JUNE, Health and Human Services (HHS) Secretary Kathleen Sebelius and Health Resources and Services Administration Administrator Mary Wakefield announced a one-time investment of \$250 million to strengthen the primary care workforce. This new money came from a \$500 million Prevention and Public Health Fund which was a part of the new health reform law that passed this year (The Patient Protection and Affordable Care Act). This investment is not to be confused with the \$1.3 billion authorized over five years for the National Health Service Corps (also in the health reform bill), or the nearly \$300 million in the economic stimulus package for the National Health Service Corps.

Secretary Sebelius indicated that increasing the primary care workforce was a personal priority and that this money was a “quick but critical investment” in developing primary care. Yet there were some congressional leaders who were critical of the move, including Congressman Henry Waxman and Senator Tom Harkin (both longtime healthcare leaders on the Hill). While both indicated that they are supportive of increasing the primary care workforce, the \$500 million in the Prevention and Public Health Fund, they argued, was intended for other purposes.

I personally think Secretary Sebelius and her colleagues got it right. There is little more important to the cause of disease prevention than the primary care provider—the one who provides vaccinations, who counsels against smoking and drug abuse, who diagnoses serious illnesses, and who is more likely to routinely test for HIV. And the one who is more likely to become an HIV practitioner.

In the first edition of this magazine last year, we reported on an AAHIVM workforce survey that indicated nearly one-third of our current members plan to retire from the HIV field over the next decade. This trend, coupled with the increased patient load that is sure to come from ex-



James Friedman

panded routine testing, is a recipe for disaster. Additionally, the anticipated influx of patients resulting from the implementation of many of the health reform provisions in 2014 must be met with new and qualified providers.

HIV/AIDS workforce continues to be a high policy priority for the Academy. We have engaged Congress and advocated for the expansion of the National Health Service Corps, and are pleased to see that the new health re-

form law provides for growth in both funding and capacity of the Corps in the future—a move that will certainly help increase the number of HIV practitioners. The jumpstart that Secretary Sebelius provided by putting \$250 million directly into the U.S. health workforce was an essential boost.

On July 13, President Obama released the first ever U.S. National Strategy on HIV/AIDS at a briefing and reception at the White House. The release of the National Strategy included a 35-page Implementation Plan that identified organizational responsibilities and timeframes for specific actions. Director of the Office of National AIDS Policy, Jeff Crowley, and his staff did an excellent job of balancing numerous competing interests to provide a roadmap for HIV/AIDS in the United States.

An adequate supply of well-trained HIV practitioners is at the core of achieving virtually every aspect of the National Strategy. While the strategy discusses support for and an increase of the HIV workforce, it does not set quantified targets for expansion. The details of how an increase in the HIV workforce will be accomplished were left largely up to HHS and HRSA to determine.

Everyone can agree on the continued need to identify HIV infections, prevent transmissions, and to ensure all diagnosed HIV patients are properly linked to care. However, without a continued investment in the HIV workforce, these patients may be hard-pressed to find a quality care provider.

HIV

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340B Pharmacies Help Patients and Providers

THE FIRST TIME I HEARD about the concept of pharmacy care under the 340B program, I was incredulous. Could my clinic really receive revenue from processing our patients' prescriptions? There most certainly must be a catch: multiple forms to fill out, waiting endlessly on the phone to speak with a pharmacist, poor customer service for the patients.

But in an era where insurance company restrictions and hassles are the expectation not the exception, what a surprise to learn that there are programs available that not only make life easy for the patients, but for me as well—and provide financial rewards to our program.

To fully understand the concept probably requires a law degree, but basically Ryan White recipients have been granted status as a "Covered Entity" under Section 340B of the Public Service Health Act established by Congress in 1992.

This allows these organizations the right to buy pharmaceuticals at deeply discounted prices, on average at 40-50 percent of the average wholesale price. You may then bill the insurance at a standard price; profits must remain in the organization. Yes, it is legal and can be very financially beneficial. You may use any pharmacy to purchase and dispense the drugs, but there are special rules that must be followed. My clinic works with the Coordinated Care Network (CCN), a full service specialty mail order pharmacy with expertise in the complex 340B program.

We have all struggled to find ways to improve our patients' compliance with medications. Every additional voice in a patient's ear reinforcing adherence can make a difference. The sooner we are aware of a problem such as a patient not getting his or her medications, the quicker we can act to try and correct the situation.

Working with CCN has allowed our clinic to have an additional set of ears and eyes overlooking our patients. Once a patient is enrolled, CCN assigns a specific, dedicated representative to work directly with all of our patients. For our office, Stacey has been our contact. She has become a familiar voice for our patients. She contacts patients each month when their refills are due and makes sure they will be available for delivery. But more importantly, she is in constant contact with our office about any issue that is interfering with the patient's adherence. We can find out if patients are missing medications much earlier.

Enrolling patients for this program cannot be easier.

Once getting the patient's consent, I simply fax the list of meds to CCN. All meds, not just HIV treatment, can be filled. They take care of all the rest from contacting the patient directly, to discussing a delivery day and time, to coordinating with the patient's insurance to arrange billing. When a refill is needed, they fax a prescription to me.

The patients enrolled report back a very high satisfaction rate with the program. The few patients that disenrolled, did so mainly because they were not available for deliveries. What the patients appreciate the most is the personal service they receive. What I appreciate is having many patients being cared for by one pharmacy. This reduces calls to multiple pharmacies and the time and effort to make sure patients have their meds.

There are many obstacles that we face in trying to provide comprehensive care to our patients. The more partners we have working with the patient, the easier our job becomes. I have found by working with a partner pharmacy service like CCN, I am benefiting my practice as well as my patients. This is a winning program for all involved.

HIV




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Health Care Reform *and* HIV

In the 20th year
of the Ryan White
CARE Act, the nation
embarks on historic
health care reform

BY HOLLY A. KILNESS, MA



ON MARCH 23, 2010, President Obama signed the long-awaited health reform bill, the Patient Protection and Affordable Care Act of 2010 (ACA), into law, enacting the broadest reform to the United States' health care system since the 1960s. While the ACA does not include everything the HIV community had hoped for in terms of health care reform, it does create opportunities for expanding access to care and treatment for many people living with HIV/AIDS.

Although the ACA only specifically addresses HIV/AIDS a handful of times, there are many provisions that will have a direct impact on HIV care providers, the HIV workforce, and the federal programs which fund HIV care and practice in the U.S. today.



Medicare, Medicaid

The most prominent are the changes the ACA makes to the Medicaid and Medicare programs. The ACA eliminated the Medicaid disability requirement, the categorical eligibility requirement that restricted Medicaid coverage to “disabled” patients. This is good news for people with HIV, whose disease has not yet progressed to a state of disability, and who may now be eligible for coverage based solely on income.

Beginning in 2014, the new law also expands Medicaid eligibility to individuals and families with income below 133 percent of the federal poverty level (currently income below \$14,403 for an individual and \$29,326 for a family of four), which will increase the number of HIV patients eligible for the program. Many low-income uninsured people living with HIV will become eligible for



Medicaid services under the new change, but must wait until 2014 to gain access to the program.

Medicaid reimbursement rates for some primary care providers are increased under the new law for the years of 2013-14. This provision applies to family physicians, general internists, and pediatricians and pertains to evaluation and management services as well as immunization administration. However, the increased reimbursement does not apply to specialists, which unfortunately excludes infectious disease doctors.

For the Medicare program, perhaps the biggest accomplishment of the ACA is closing the so-called Part D prescription drug “donut hole” by 2020. The new law also provides a \$250 rebate for patients who fall into the donut hole in 2010.

The law also changes a provision that previously penalized patients who received AIDS Drug Assistance Pro-

gram (ADAP) coverage for their drugs. Under prior law, patients who fell into the Medicare Part D “donut hole” were eligible to receive their drugs through state ADAPs. However, the ADAP expenditure did not count towards the Medicare Part D’s “True Out-of-Pocket Spending Limit” (TrOOP). This meant that those who fell into the donut hole, and received ADAP funding, were never able to get back out. Under the new law, ADAP coverage costs will count towards TrOOP expenditures starting in 2011—good news for both state ADAP programs and for patients.

Private Insurance Requirements

In addition to the Medicare and Medicaid program improvements, a number of changes were mandated for private health insurance plans.

The ACA prohibits health insurance discrimination based on health status or gender and lifetime limits on coverage starting in 2010. Beginning in 2014, the new law prohibits pre-existing condition exclusions and charging higher premiums based on gender or health status. There are new mandatory benefits package requirements for health insurance in 2014 including, among other benefits, prescription drugs, mental health and substance abuse treatment, preventive care and chronic disease management. Consumers in new plans also will have access to an effective internal and external appeals process to appeal decisions by their health insurance plan.

The law requires all individuals to purchase insurance beginning in 2014. It also creates government subsidies for people with incomes up to 400 percent of the federal poverty level to purchase insurance. Until the 2014 provisions take effect, an additional provision of the bill—establishment of a temporary national high-risk insurance pool to provide health coverage to individuals with pre-existing conditions—should cover many HIV patients.

Funding

It is important to note that although these programs were authorized in the new law, funding levels ultimately will be decided by Congress. A program can be authorized, but if money is not appropriated, it cannot be carried out.

One key example of federal budget constraint is the Ryan White program. Demand for Ryan White Program-provided care and treatment is far outpacing federal and state funding. All Ryan White Program funding, including ADAP funding, is discretionary and subject to annual appropriations by Congress. Many provisions of the ACA, including the workforce-

related provisions, also fall under the category of discretionary spending, and will be subject to Congressional approval in the years to come.

The federal government is facing stark financial realities. There is much need for federal programs like Ryan White in times of economic downturn, and yet voters demand that the rapidly ballooning federal deficit be reduced. In January, President Obama announced a three year cap on all domestic non-defense spending, which meant that many HIV programs received no new funding in the President's FY 2011 budget request. Congress, for its part, has not yet been able to pass a budget, and may wait to do so until after the fall elections.

Implementation

Despite the progress that passage of the ACA represents to HIV health care providers and people living with HIV and AIDS, its implementation will bring continued challenges. Many of the fine details are left to federal agencies, like the Department of Health and Human Services (HHS), to decide through regulatory and rule-making processes.

A few such provisions for the HIV community to note: Regulators must determine what is covered in the annual Medicare wellness visit benefit, a provision of the ACA that requires that a yearly visit to the doctor be covered by Medicare with no co-payment or deductible. If the annual wellness visit and essential benefits packages are both determined to include, for example, HIV testing and sexual health screening, that would be a huge step towards ensuring that many Americans are tested once a year for HIV and other STDs.

The ACA also requires a minimum “benchmark benefits” package for those individuals who become newly eligible

The Workforce

The ACA also contains many provisions aimed at increasing the provider workforce. The law authorizes increased funding or expansion of many existing workforce programs, and creates a plethora of new programs, including:

- **Funding for Federally Qualified Health Centers:** \$11 billion over a five-year period to hire staff and add new sites
- **Funding to Community Health Centers:** an additional \$10 billion over five years
- **Nurse-led Health Care:** a new \$50 million grant program for “nurse-managed health clinics”
- **School-Based Health Centers:** a new \$50 million grant program for “School-Based Health Centers”
- **National Health Service Corps/Scholarships:** new funding for the National Health Service Corps program as well as an additional \$4 billion over the next 5 years for scholarships and loan repayment
- **Primary Care and Dentistry:** a new student loan program for health professions students to practice in primary care for 10 years, and also grants for training programs in primary care and dentistry



- **Nurses and Nurse Practitioners:** funding for grant and scholarship programs for graduate and undergraduate nursing education including new “nurse retention grants”



for Medicaid in 2014. This “benchmark” level of benefits is the same package of essential benefits as will be required for most new health insurance plans (including individual and small group plans, but excluding employer-sponsored plans) in the insurance exchanges. Some of these essential benefits are spelled out in the law, such as laboratory services, preventive and wellness services, and chronic disease management, but other essential benefits can be defined by HHS. At a minimum, it is crucial that the HIV community work to ensure that HHS defines the essential health benefits package to provide the level of care and treatment needed by individuals living with HIV.

The federal high-risk insurance pools are another example of an area of the new law where the HIV community must continue to monitor and comment on regulations as they are developed.

High-risk insurance pools are state programs designed to provide health coverage to otherwise “uninsurable” individuals, like some HIV patients, whose care and treatment costs are prohibitively expensive. Thirty-five states already operate some type of high-risk insurance pool program, but the ACA creates a new federal pool until 2014.

For individuals living with HIV who are unable to obtain private insurance or meet current Medicaid/Medicare eligibility requirements, enrollment in these high risk pools could provide health care until the Medicaid expansion in 2014. However, HIV advocates need to work with regulators to ensure HIV is classified as a “presumed eligible” disease within the defined pre-existing conditions that make individuals automatically eligible for the pools. In addition, regulations should designate Ryan White Program resources as eligible to help enrollees meet high-risk pool premiums and co-payment obligations.

Reimbursement Rates

Another area that will require continued advocacy efforts is reimbursement rates for Medicare and Medicaid. Current Medicaid payments for medical services average only 72 percent of Medicare (or private sector) payments for the same services. These reimbursement rates leave many HIV providers unable to provide adequate care to HIV patients.

While the ACA included federal funding to increase primary care reimbursement rates for 2013 and 2014, the increase is temporary and does not extend to specialists. Advocacy efforts must continue to press for a permanent reimbursement rate repair; otherwise providers will be unable or unwilling to meet the increased need for care, especially after the coverage expansion in 2014 brings thousands of new patients into the system.

The ACA will provide unprecedented opportunities to improve health care access, affordability, and quality for the HIV/AIDS community. It is important that providers fully take advantage of the ACA and make sure their patients do so as well. However, advocacy will be necessary to monitor and shape the implementation of the law, in order to ensure inclusion of HIV providers and patients in these crucial programs, and to secure funding for the programs that will build the HIV workforce for decades to come.

HIV



ABOUT THE AUTHOR: Holly A. Kilness, MA is Director of Public Policy at the American Academy of HIV Medicine.

- **Pediatric and Adolescent**

Care: new pediatric specialty loan repayment programs for pediatric, child and adolescent medical specialties, including mental health

- **Capacity-Building:** grants for training programs in primary care

- **Teaching Health Centers:**

grants to health centers, FQHCs, community health centers, etc. to establish primary care residency programs

- **Public Health Work Force:** grants for increasing the Public Health Workforce, and the Community Health Workforce

- **Disadvantaged Health Care Workers:** new loan repayment for students from disadvantaged backgrounds

- **Disparities:** new grants for programs that reduce disparities in health outcomes and provide culturally competent health care



- **Geriatric Education and Training:**

grants for geriatric workforce development, and provider training in geriatrics, chronic care management, long-term care, mental health and medication safety among the elderly



“The United States will become a place where new HIV infections are rare and when they do occur, every person, regardless of age, gender, race/ethnicity, sexual orientation, gender identity or social-economic circumstance, will have unfettered access to high quality, life-extending care, free from stigma and discrimination.”

—The National HIV/AIDS Strategy for the United States

On July 13, 2010, President Obama rolled out the new National HIV/AIDS Strategy for the United States. One of the President's top HIV/AIDS policy priorities since his election, the strategy was developed with three stated goals in mind: reducing HIV incidence, increasing access to care and optimizing health outcomes, and reducing HIV-related health disparities.

Under the direction of Jeffrey Crowley, Director of the Office of National AIDS Policy, the strategy has been under development virtually since President Obama assumed office. The White House indicated, prior to the release of the document, that the strategy would be a concise plan, building on what the federal government was already doing, not rewriting it.

The White House also indicated it would identify specific action steps that must be taken by the Federal Government and specific targets for measuring progress toward achieving the President's goals. Some of the goals included in the document are reducing new infections by 25 percent over the next five years, cutting the rate of the virus' spread by 30 percent, and increasing the percentage of HIV-positive people who know they're infected with the virus to 90 percent so they can get treatment. Other goals are getting treatment for 85 percent of patients within three months of their diagnosis, and increasing education about the virus, even in communities with low rates of infection.

The document says that a renewed sense of urgency is needed, and specifies steps to be taken by federal agencies, as well as the private sector, including:

- Intensify HIV prevention efforts in the communities where HIV is most heavily concentrated
- Reduce HIV-related mortality in communities at high risk for HIV infection
- Adopt community-level approaches to reduce HIV infection in high-risk communities
- Reduce stigma and discrimination against people living with HIV
- Educate all Americans about the threat of HIV and how to prevent it
- Establish a seamless system to immediately link people to continuous and coordinated quality care when they are diagnosed with HIV
- Take deliberate steps to increase the number and diversity of available providers of clinical care and related services for people living with HIV
- Support people living with HIV with co-occurring health conditions and those who have challenges meet-

The National HIV/AIDS Strategy

A Significant Step Forward

BY HOLLY A. KILNESS, MA

ing their basic needs, such as housing

- Increase the coordination of HIV programs across the federal government and between federal agencies and state, territorial, tribal, and local governments
- Develop improved mechanisms to monitor and report on progress toward achieving national goals

Redirecting Resources

The federal government currently spends more than \$19 billion annually on domestic AIDS programs. Under significant pressure from voters to slow government spending and reduce the deficit, President Obama announced in January a three year spending cap on all domestic non-defense spending. However, some were surprised that that the strategy included no request for additional funding from Congress.

As a down payment on some of the goals of the plan, Health and Human Services Secretary Kathleen Sebelius announced \$30 million will be released to develop better prevention methods using a combination of approaches. This money comes from the Prevention and Wellness Fund in the health reform law passed earlier this year.

Although the White House strategy acknowledges that “increased investments in certain key areas are warranted,” it does not propose increased federal spending. It relies instead on redirecting money to areas with the greatest need and populations at greatest risk, primarily gay and bisexual men and African-Americans, but also including Latinos and substance abusers.

Additionally, it seeks better coordination among the HIV/AIDS programs that currently focus on the disease. HIV/AIDS programs are a somewhat fractured web of resources and responsibilities, ranging across multiple federal agencies, including Health and Human Services (HHS), Housing and Urban Development (HUD), Justice, Veterans



Affairs (VA), USAID and Department of Defense. Within HHS, responsibility for HIV programs is spread across multiple agencies including the Centers for Medicare & Medicaid Services (CMS), the Health Resources and Services Administration (HRSA), Centers for Disease Control and Prevention (CDC), the Indian Health Service (IHS), the Food and Drug Administration (FDA), National Institutes of Health (NIH), the Office of HIV/AIDS Policy, the Office of Minority Health, and others.

This is not news to HIV services providers, who, as the strategy noted, “Often receive funding from multiple sources with different grant application processes and funding schedules, and varied reporting requirements.” Overlapping and competing programs can be burdensome, and there is a distinct lack of efficient coordination across programs. The strategy notes the “need to integrate services and reduce redundancy, encourage collaboration across different levels of government,” and calls this “both the simplest and hardest task ahead of us.”

In this regard, the White House relied heavily on the federal agencies to determine how to accomplish the strategy’s goals through implementation. HHS is designated with the chief goal of coordinating HIV/AIDS programs with other departments. A Presidential memo directs relevant departments to provide a report to the President within 150 days of the strategy’s release outlining the steps they will take to implement the recommendations in the strategy.

Workforce Issues

One key area where it will be interesting to see what the departments and agencies recommend is in the strategy’s workforce provisions.

The strategy takes much note of the shortages of physician supply in the HIV care universe. It cites both primary care and specialties like infectious disease as requiring an

“urgent response.” It refers to the provisions contained in the new health reform law that are aimed at bolstering the primary care workforce generally, such as increases to the National Health Service Corps scholarship and loan repayment programs. However, unlike some of the other provisions, which had specific targets and goals (i.e. reduction of new infections by 25 percent over the next five years), many of the workforce provisions of the strategy were general and vague.

Under a section of the Implementation Plan citing the goals to strengthen the current provider workforce to improve quality HIV care, the following goal is listed by 2011:

HRSA, Agency for Healthcare Research and Quality, and Department of Labor will coordinate with HHS to work with states, local governments, and state health professions associations to implement their recommendations and guidance to strengthen the current HIV/AIDS provider workforce.

This seems like a responsibility transfer of epic proportions. Furthermore, HRSA is already tasked with strengthening the current provider workforce. One can only hope that the agency’s implementation plan will offer immediate and practical steps to encourage future growth of the HIV workforce.

However, other recommendations offer some hope of improvement in the daily work of HIV providers.

For instance, AHRQ will develop a plan for working with public and private insurers to establish common data collection and reporting systems across all health care provider settings to enable monitoring of clinical care utilization, quality indicators, and health outcomes for people living with HIV.

For Ryan White providers and others receiving government funding from several sources, inevitably coupled with multiple reporting requirements for each agency, a common data reporting system would represent a very welcome change.

However, much of the workforce sections of the strategy and implementation plan also delve into peripheral workforce issues such as diversity, stigmatization, cultural sensitivity/competency, patient trust, health literacy and quality of care. While certainly issues of interest to the HIV workforce, these issues are tangential to the simple yet pressing need for an increased supply of well trained practitioners.

Nevertheless, the strategy represents a significant step forward in the America’s fight against the disease. It’s been nearly 30 years since the CDC Morbidity and Mortality Weekly Report first documented five cases of an illness that would come to be known as HIV/AIDS. Presidential administrations have set various priorities in the battle against AIDS, but this is the first effort to create a cohesive coordinated national strategy against the disease. The Obama Administration deserves recognition for this accomplishment. Let’s hope its agencies are up to the task of implementing the plan.

HIV





Ryan White

The Guiding Force

Ryan White Administrator Deborah Parham Hopson
Values Partnerships with Providers

BY BOB GATTY

“The biggest contribution, I think, that Ryan made is, and I didn’t know it at that time, that his legacy would be that people are getting their drugs and their treatment and that people are living with AIDS.”

—Jeanne White Ginder, Ryan White’s mom

THIS AUGUST, THE NATION MARKS THE 20TH ANNIVERSARY of the Ryan White CARE Act, the federal program created by Congress to provide primary medical care and essential support services to patients who do not have sufficient health care coverage or financial resources to cope with HIV disease.

Last October, President Obama signed the Ryan White HIV/AIDS Treatment Extension Act of 2009, extending for four years the program that is administered under the care of Deborah Parham Hopson, PhD, RN, FAAN, Associate Administrator for HIV/AIDS at the Health Resources and Services Administration (HRSA).

Dr. Parham Hopson, who holds the rank of Assistant Surgeon General and Rear Admiral in the Commissioned Corps of the United States Public Health Service, has been working in HIV/AIDS care since 1994. She recognizes the critical role that health care providers play in caring for HIV/AIDS patients and in making certain that Ryan White funds are used efficiently and effectively.

“It is because of the excellent care that so many of these providers give to people living with HIV that many of them are alive today,” she said in an exclusive interview with *HIV Specialist*. “If it hadn’t been for them out there providing that care, many of those patients would be dead. So I am honored to work with, and for, the providers of care as they work on behalf of people living with HIV.”

Dr. Parham Hopson, a proponent of



Dr. Parham Hopson

SJLOCKE / ISTOCK

health care teams, emphasized the important contributions made by every team member in providing care for people with HIV, from the physician, to physician assistants, nurse practitioners, and pharmacists.

"The pharmacist is an integral part of the health care team," she said. "They work with the clinical staff for coordination of medication and clinical care. They provide guidance regarding drugs and drug interaction and patient adherence. They also provide a lot of drug education regarding uses and requirements."

A National Strategy

On July 13th, the White House released the first ever National HIV/AIDS Strategy for the United States. Under the leadership of the White House Office of National AIDS Policy (ONAP), Dr. Parham Hopson co-chaired one of the interagency work groups involved in developing the strategy.

Interviewed prior to the release of the document, Dr. Parham Hopson provided some insight into her role in the process. One of her objectives, she said, was to make certain that the important contributions of providers were understood and considered as the strategy was developed.

"One of the things that I was able to bring to the table, in particular as co-chair of the financial working group, was the perspective of my program—basically, I provide grant funding to providers who actually care for people living with HIV," she said. "So I brought the message that as we think about the HIV/AIDS strategy, there will be people in government implementing this strategy that are at a policy level, but it is at the provider level where the strategy will actually come to life. I have made it abundantly clear in the meetings that I've participated in, and others have as well, that the providers of care are critical for the success of any national AIDS strategy."



Reauthorized Ryan White

In fact, providers will play a critical role by helping to implement new HIV testing and linkage to care requirements for Ryan White Part A and Part B grantees contained in the new reauthorization law, Dr. Parham Hopson explained.

For Part A, grantees are required to develop a comprehensive plan for the organization and delivery of health and support services and for identifying individuals with HIV/AIDS who are unaware of their HIV status—and a plan for providing services to them. One-third of the grant applicant's score under Part A is now based on how well that task is accomplished.

Under Part B, grantees must also develop a similar comprehensive plan, but there is no specific percentage of their score that is tied to the plan.

"The goal," Dr. Parham Hopson explained, "is that we want to tighten up that link between finding people and getting them tested, and for those who test positive, getting them into care. Because we all know that if you get people into care earlier in the course of their disease, then we can provide appropriate treatment and people can live longer, healthier lives."

While the requirements are placed on Ryan White Part A and B grantees, Dr. Parham Hopson explained that all Ryan White-supported providers would feel the impact. "At a minimum, the service providers, both Ryan White-funded and beyond, will be encouraged to help in the integration of outreach, testing, referral and linkage to care," she said.

The ADAP Crisis

In April, HRSA released more than \$1.84 billion for Ryan White grants, which the agency says helps more than half a million individuals every year obtain clinical care, treatment and social support services. A total of \$652 million will pay for primary care and support services for individuals living with HIV/AIDS under Part A, and \$1.145 billion was sent to states and territories under Part B, with \$841 million of that total designated for the AIDS Drug Assistance Programs (ADAPs).

On June 29, the Presidential Advisory Council on HIV/AIDS adopted a resolution urging the White House and Congress to approve another \$126 million in emergency funds for ADAPs, which provide subsidies for the anti-retroviral drugs needed by low-income people with HIV and AIDS who lack health insurance. Because of sharp budget cuts by states, Dr. Parham Hopson said 1,924 people in 11 states were on waiting lists for ADAP assistance—an increase of 184 people in just one week, and up from 1056 reported on May 6 to be on waiting lists in 10 states.

In her interview with *HIV Specialist* in late May, Dr. Parham Hopson pointed to the ADAP funds that were provided in April. "The money went from us to the states and now they have to get the money into the proper places to actually start spending it, and hopefully some of the waiting list will decrease," she said, explaining that her agency is working with state ADAP directors, some new on the job, to help them effectively manage their ADAP funds.

"Some of it will just be assessing their current drug purchasing method making sure they are getting their drugs through the 340B drug pricing program. Some states still do rebate purchasing. It might be more beneficial to do direct purchasing," she explained.

For people on waiting lists, Dr. Parham Hopson said her office wants to make sure they receive antiretrovirals if a physician indicates they are needed.

The patient assistance programs provided by the pharmaceutical companies are an important source for those drugs, she said. Most pharmaceutical companies offer some sort of assistance for individuals who cannot afford their medications. However, this can be a time-consuming process for the providers to register patients into these programs, depending on how many companies need be contacted, and programs applied for.

"So we do pay more case managers to work with these pharmaceutical companies to get drugs for individual clients," she explained. "It's very time consuming, but it's something that we are committed to doing to make sure that



The pharmacist is an integral part of the health care team,” she said. “They work with the clinical staff for coordination of medication and clinical care. They provide guidance regarding drugs and drug interaction and patient adherence. They also provide a lot of drug education regarding uses and requirements.”

people who are on the waiting list for ADAP are not necessarily without medication.”

Even so, Dr. Parham Hopson acknowledged that those combined resources are insufficient. “I think some states will continue to have waiting lists,” she explained, “but we are committed to making sure that people who are still on the waiting list for ADAP and are appropriately and clinically indicated, do have access to medication,” whether it is through PAPs or Ryan White funding. “We do not want them to fall through the cracks,” she said, pointing out that some states use money from other sections of the Ryan White program to purchase medication. Providers play an important role in helping their patients obtain their lifesaving drugs.

Caseloads and Funding

HRSA is aware that most providers’ HIV and AIDS caseloads have dramatically increased in recent years, while Ryan White funding has remained constant, according to Dr. Parham Hopson.

“From a public health perspective, it is imperative that we identify people who are infected and link them to care. We also have to link those who know their status, but are not in care. We have to get them into care as well,” she said. Testing and linkage to care efforts bring more patients into the health system, which is good from a patient perspective, but creates additional burdens on provider resources.

“We also recognize that Ryan White funding is not the only source of funding for the uninsured. It’s critical that Ryan White-funded programs examine all the potential source of uncompensated care funding in their areas. This is particularly true as patients live longer and have greater primary care needs, as well as AIDS-related conditions,” noted Dr. Parham Hopson.

“We do realize that there are parts of the country where the epidemic is increasing and the Ryan White dollars are not, so we encourage people to look for other sources of funding,” Dr. Parham Hopson advised. “Make sure that you tap into both the private and public insurance that people might have,” as well as resources from community health centers that might be available.

Taking stock of the situation, she summarized, “We must realize that the Ryan White dollars are still, and always have been, the payers of last resort. But there are other dollars available, and more dollars, I anticipate, will be available in the future for people living with HIV as part of health care reform.”

Impact of Health Care Reform

The Patient Protection and Affordable Care Act (the new health reform law) provides for investments in prevention, public health, disease research, and prescreening. “So I anticipate there will be an impact on people living with HIV, as well as the providers who provide care for them,” she said.

Dr. Parham Hopson emphasized the important role that HIV/AIDS health care providers will play as the health reform law is implemented, and predicted that because of improvements that it will bring, providers will have an even larger patient base in the future than they do now.

She acknowledged that the Ryan White program might undergo some changes as health care reform is implemented—in ways we cannot currently anticipate.

“I can’t predict the future,” she said. “But what I can tell you is that we are aware that there are and remain high rates of HIV and AIDS in many communities, and that for many of the people we see in the Ryan White program, they lack access to needed HIV care.”

“Regardless of what the future holds, we can’t forget this, and we are committed to providing the access to care and the treatment they need,” she stressed. “We’ve coupled that with a new push on HIV testing, and identifying them early and linking them to care. I think there are lots of people who have HIV who will continue to need services that are provided by the Ryan White program providers. So, we will see what happens in the future.”

As for the continued role of the specialists who focus their care and practice on treating HIV/AIDS patients, Dr. Parham Hopson said, “They are the experts who provide care to poor people living with HIV and AIDS in this country. So even if they have insurance, there will still be poor and vulnerable populations living with HIV, and they need providers to provide the care. So I think that there is work for all of us to do, including current Ryan White providers.”

HIV



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Ryan White

The Inside

How two Congressional staffers worked behind the scenes to help pass the Ryan White CARE Act 20 years ago

From the Health Resources and Services Administration's website posting, "Living History:"

On the morning of May 16, 1990, as the Senate prepared to debate S. 2240, the Senate Chaplain, Reverend Richard C. Halverson, DD, noted in his morning prayer that rarely will the Senate be called upon to deal with an issue more complicated by prejudice, fear, and emotion, nor more presently or potentially destructive, than the issue of AIDS.

Debates on procedural matters during the previous two days highlighted the intensity of emotions on the issue. Whatever the tenor of the debate, the outcome that morning was a forgone conclusion—even to the bill's strongest opponent, Senator Jesse Helms of North Carolina. In speaking against the bill the day before, he noted that Yes, this bill will pass, no question about it.

That a bill on such a heated topic would pass the Senate by the large margin of 95 to 4 was the result of successful efforts to build strong bipartisan support over the preceding weeks and months and the wise strategy of creating legislation that provided resources to every state. The bill came to the floor with 66 co-sponsors, more than enough to block a filibuster attempt by Helms.

Just the day before, the Senate had also voted to name the bill in honor of Ryan White, an Indiana teen who had died of AIDS just five weeks before (on April 8, 1990). Ryan White's fight to go to school after his AIDS diagnosis gained him national and international attention. His grace and positive outlook throughout his struggle made him a hero to many.

In speaking of Ryan White on the Senate floor, Senator Edward Kennedy (D-MA), the bill's lead author, said, One thing that was extraordinary, and there are many things about this remarkable young man, was after he received that tainted blood

transfusion, to the moment he drew his last breath here on Earth, he never condemned anyone. He was not looking for the scapegoats. . . What he was doing was reaching out in the true spirit of the American character to recognize that there were people who were suffering.

Just two weeks after Ryan's death, his mother Jeanne had come to Capitol Hill to recruit Senate co-sponsors for and urge the passage of the bill that was to be named in honor of her son.

Like the appearance of actress Elizabeth Taylor at the Senate bill's introduction in early March, Jeanne White's involvement drew media attention and helped generate broad support for the legislation. Their involvement was the very public face of a much larger effort to strengthen the Federal response to AIDS as the epidemic neared the end of its first decade.

*The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act came to life at a time of despair and hope among those who were on the frontlines of the epidemic. Urban hospitals were overcrowded, and community-based models of care were collapsing under the weight of increasing caseloads and diminishing resources. With the advent of meaningful treatments—AZT (zidovudine) to fight the virus and aerosolized pentamidine to prevent *Pneumocystis carinii* pneumonia (PCP)—there was hope that change was in sight.*

That hope was tempered by the lack of resources to provide care and treatment. In January 1990, a task force of the House Budget Committee held field hearings in Los Angeles and San Francisco. The witness testimony and statements of House members gave voice to both the possibilities and the frustration.

Story

BY BOB GATTY

IT WAS AGAINST THAT BACKDROP

of overcrowded hospitals, overflowing emergency rooms with patients on hallway gurneys, and thousands dead from AIDS that Michael Iskowitz and Tim Westmoreland found themselves working on Capitol Hill.

Iskowitz, as Sen. Edward M. Kennedy's staffer charged with working on AIDS, and Westmoreland, in the same position with Rep. Henry Waxman, both played important roles in bringing the Ryan White CARE Act to life, and in the process changed their own lives.

Westmoreland, now a visiting professor of law and a research professor of public policy at Georgetown University, recalled the historic event. "It was gratifying because the CARE Act was the biggest piece of legislation to come out. Before, it was the power of the bully pulpit, but this was creating something new out of the work that the committee had been doing since 1982."

For Iskowitz, his work for Sen. Kennedy on the Ryan White CARE Act was the highlight of his career on Capitol Hill. "1990 was a landmark year for AIDS in Congress," he said. "In 1987, the fight against AIDS drafted me. I went to work for Kennedy to do a 10-week fellowship on children and poverty. At the end of 10 weeks, I met with him and said, 'You need to have someone to work full time on AIDS and to crank up the Congressional response.' He said, 'That would be you.'"

Kennedy's quest to provide help for people suffering from AIDS began when he became chairman of the Senate Labor and Human Resources Committee in 1987, when the Democrats took over the Senate.

"Thirty thousand Americans had already died; Reagan was President, the Surgeon General's AIDS report had been stuck in clearance for two years, and the ap-

propriation (for AIDS) was in the single digits," recalled Iskowitz, now an attorney, clinical psychologist and policy/strategy consultant engaged in the fight against AIDS. He also served as senior advisor to the White House Office of National AIDS Policy during the Clinton Administration and Director of UNAIDS-USA.

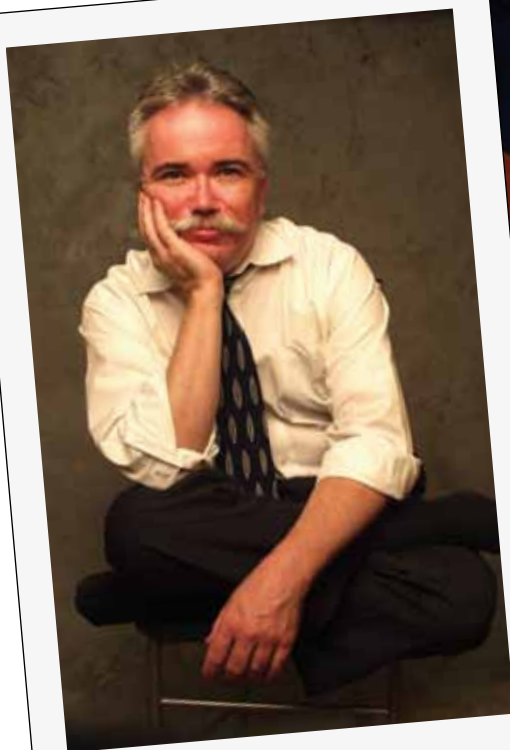
In order to bring more visibility to the issue of AIDS and to best educate both himself and his Senate colleagues, Kennedy began a series of dinners at his home showcasing experts in the AIDS field. He also began having one-on-one meetings with Members of Congress to pass along the latest scientific knowledge and the public health challenges to combating this disease.

But according to Iskowitz, Kennedy also wanted to see how AIDS was affecting our nation at the grassroots level. He conducted site visits and community meetings across the country in large cities—Washington, DC, New York City, Atlanta, Houston, Chicago, Los Angeles—as well as in small towns in rural America.

"We heard a lot of the same stories everywhere. There were some good community-based models pri-



Above: Senator Edward M. Kennedy and Michael Iskowitz
Left: Tim Westmoreland



vately funded, but urban public health systems were collapsing under the weight and almost nothing was being done in rural communities,” Iskowitz recalled.

“In New York, at NYU Hospital, despite their sophistication, they had a policy that people with AIDS had to be isolated in private rooms, and they didn’t have many private rooms. So hundreds of people were on gurneys in waiting rooms and in hallways, waiting for a private room. One person Kennedy spoke with had been on a gurney for 12 days, and he died shortly after that conversation. There was later a CBS special on him. It was symbolic of what was happening in big city hospitals everywhere.

“In places like Waycross, GA,” Iskowitz continued, “Kennedy sat for a day in a one room school house, and people came from hundreds of miles away with people with AIDS in the back seat of the car covered with blankets so that others would not see their sores and run them out of town. They told these horrific stories of how even local doctors would not see them; they were told to go to Grady Memorial Hospital in Atlanta. Local funeral homes would not bury their friends.”

Meanwhile in the US House of Representatives, Waxman, chairman of the House Subcommittee on Health and the Environment, was becoming a believer in the need to begin HIV testing, counseling, and to establish a system of early intervention.

“There were recommendations from the Reagan Commission and the National Commission on Acquired Immune Deficiency Syndrome warning that the situation would get worse,” Westmoreland said. “But very rarely are commission recommendations enough to get the political system to move. It took a perfect storm of a general collapse of the hospital system and the perceived need to do something good.”

Westmoreland recalled that in 1988 and 1989 Waxman’s subcommittee developed two bills—one to provide biomedical research and AIDS prevention and the other for testing. But in the Senate, Sen. Jesse Helms (R-NC) threatened to filibuster, so the confidentiality testing and early intervention measure was dropped. Lessons learned from working on these bills prepared Westmoreland and his team to craft the Ryan White CARE Act carefully, putting the legislation in the best position to succeed.

“When it came time to do the CARE Act, we were ready,” Westmoreland said.

Fear Factor

All of this was taking place in an atmosphere of fear within the gay community, as well as among many Americans who knew little about the disease other than the horror stories they had heard in the media. Thus resulted overt discrimination on the part of many Americans, such as those who said that young Ryan, diagnosed with AIDS at age 13, must have done something terrible to have contracted the disease.

The atmosphere of fear within the gay community was

heightened in 1985 with the advent of the ELISA test, for what was then called the HTLV3 virus. The “test” as it became known, was specifically designed to screen donated blood to keep the U.S. supply safe from the HTLV3 virus, and not as a clinical diagnostic test for AIDS, which was even printed as such on the test label.

Ryan White, like hundreds of his fellow hemophiliacs, became infected because the factor VIII he took daily to help stop bleeding was contaminated by the virus during its manufacture.

In 1985 there was such an intense association of AIDS with gay men that the test itself became a marker for sexual orientation. The logic was if you test positive for antibodies to the virus, you have AIDS and you must be a gay man.

With virtually no civil rights protections from employment discrimination, one’s positive test result could have serious, life long, non-health related consequences. At the first International AIDS Conference in Atlanta in 1985, the slogan “No Test is Best” was first displayed. With no anti-viral drugs yet invented and serious irregularities in the test itself, “No Test is Best” seemed the prudent course to the AIDS community and gay and lesbian civil rights organizations.

By 1990 however, testing was improved and there were more and more treatments available for people living with AIDS.

Why was Waxman so committed?

“He was chairman of the Health Subcommittee,” Westmoreland pointed out. “He was a dedicated public health advocate, and a strong antagonist of the Reagan and Bush administrations.”

In addition, Westmoreland explained, since Waxman represented West Hollywood in Congress, it was an important constituent issue for him. “He was not afraid of the question of gay men being involved. He was also an early supporter of gay civil rights issues.”

Once a TV crew came in to talk to Waxman, Westmoreland recalled. On camera, the reporter said, “Isn’t it true that you are only interested in this because you represent West Hollywood and it’s a gay man’s issue?”

Waxman replied, “No. And besides, would it be such a bad thing if I represented my constituents? When coal miners have health issues, their representatives speak out for them. What is wrong with me speaking out for gay men who also need health care? Also, I’m a Jew, and I know what it’s like when society doesn’t care what happens to you.”

Commitment Succeeds

And so, it was a committed, powerful team of lawmakers—one in the House and one in the Senate—who shepherded the Ryan White CARE Act through Congress.

For Kennedy, it was merging his two passions—public health and civil rights.

“A lot of people were saying those two things were in conflict,” said Iskowitz. “Some believed we were trying to protect



the rights of people with AIDS and therefore jeopardizing the public's health. But Kennedy took the opposite view—they were not in conflict, but in concert. He felt that if we didn't protect the rights of people with AIDS, that would drive the epidemic underground and we would have a public health disaster."

The CARE Act and the Americans With Disabilities Act (ADA) were moving through Congress at the same time. The ADA legislation was focused also on prejudices and how that negatively impacted people with AIDS. So during that time people with lots of personal experiences helped to shift that.

But public fear was a major barrier to mainstream education of AIDS. Kennedy and Waxman both understood that the key to public support was to put a real face on the issue.

"Kennedy said that as much as we could try to fight fear with facts, in the end the problem was a gut thing. People never heard the facts because their fear got triggered and they simply shut down. The public and policy makers both needed to connect—directly or indirectly—with people with AIDS. They needed real heroes to help them get past their fear and to open their hearts. Ryan White gave America a face of AIDS they couldn't turn away from, and one Americans didn't need to fear," Iskowitz said.

The 'Ryan White' CARE Act

Adding Ryan White's name to the bill helped to achieve that. Iskowitz explains it this way:

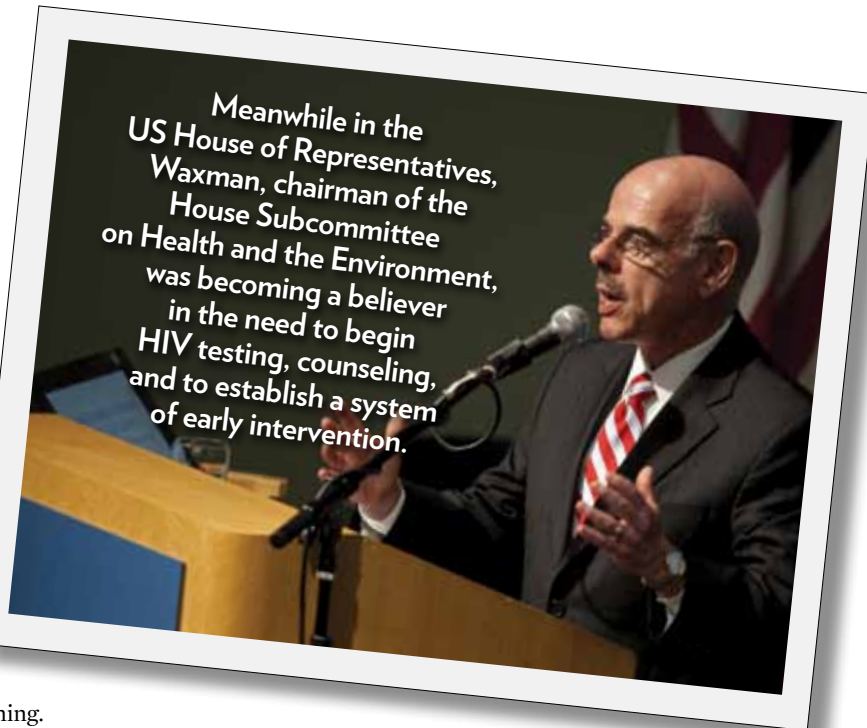
"The day the bill was being marked up in committee, Ryan was in the hospital. Kennedy and I called Ryan's room to see how he was doing. Elton John answered the phone. He said Ryan had gone into a coma. The senator talked briefly to Elton and to Jeanne, Ryan's mom. We hung up the phone and returned to the Committee room and just prior to the vote, Kennedy said, 'This one's for you, Ryan.' The next morning the press started calling it the Ryan White bill. The name wasn't officially changed until during the floor debate when Kennedy and (Sen. Orrin) Hatch (R-UT) offered an amendment to make it the Ryan White CARE Act."

There were stubborn opponents in both chambers whose objections had to be overcome. In the House, they included Rep. Bill Dannemeyer (R-CA), the ranking GOP member on Waxman's committee, and Rep. Bob Dornan (R-CA).

Dannemeyer, Westmoreland said, "was obsessed with gay men and HIV. He was relentless, so his Republican colleagues would not cross him for fear of having to spend weeks listening to his haranguing. If they had to cast a public vote, they would not cross him."

Dornan, Westmoreland added, "was as hard to the right as one could get. During some of the AIDS hearings, they had Republican witnesses who said AIDS was caused by spores in the workplace. Some Republicans were sympathetic (with the need to act), but they would not take Dor-

Meanwhile in the US House of Representatives, Waxman, chairman of the House Subcommittee on Health and the Environment, was becoming a believer in the need to begin HIV testing, counseling, and to establish a system of early intervention.



nan on because they didn't want to be perceived as pro-gay or pro-drug abuse."

In the Senate, Helms and his GOP colleague, Sen. Bill Armstrong (CO), fanned fear, Iskowitz recalled. "Helms always believed that everything the federal government did related to AIDS was part of a secret agenda to promote homosexuality," Iskowitz said, "so amendments were offered over and over to prevent anything from promoting homosexuality. It was a distraction strategy that sadly did real harm."

One of the amendments to the ADA was proposed by the National Restaurant Association (NRA) relating to people with AIDS working in eating establishments.

"It said antidiscrimination protections would not apply to HIV-positive people handling food," Iskowitz explained. "They said it would be unsafe, with people chopping in the kitchen and such; they might cut themselves. But Kennedy always said, 'Well if somebody bleeds on your salad, don't eat it!'"

The disability community went to the White House with the message that if people with AIDS were not fully protected, they would not support the ADA bill, Iskowitz explained. "Whatever the law was, it had to apply equally. That was a huge moment for the AIDS community and to the power of standing together as one."

Ultimately, the Ryan White CARE Act passed almost unanimously, with a vote of 96–4 in the Senate. Unlike the partisan atmosphere in Congress today, there was bipartisan support that was critical to the ultimate success of the legislation. However, this bipartisan support did not come easily.

It was only through the dedication of this superior team of Hill warriors that we are able to look back nearly 30 years later and recount the numerous obstacles, radical opinions and hard work that overcame them, resulting in a program that has helped thousands of HIV patients over the years, and literally saved lives.

HIV



Are We Now Back To “Hit Hard, Hit Early” for Our HIV-Infected Patients?

And can we afford to do this?

“Antiretroviral therapy for treatment of human immunodeficiency virus type 1 (HIV-1) infection has improved steadily since the advent of potent combination therapy in 1996. New drugs have been approved that offer new mechanisms of action, improvements in potency and activity even against multi-drug-resistant viruses, dosing convenience, and tolerability.”¹

THIS OPENING PARAGRAPH from the most recent version of the *DHHS Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents* provides a basis for the significant change in the guidelines regarding the initiation of combination anti-viral therapy. It is now recommended that clinicians treat all patients with CD4+ lymphocyte counts between 350-500 cells/mm³ and consider treating patients with CD4+ counts > 500 cells/mm³. Somewhat remarkably, we have returned to enact the mantra of “hit hard, hit early” from David Ho’s 1995 editorial in the *New England Journal of Medicine*.²

Why the change in 2010?

We now have convincing data from several controlled clinical trials that provide evidence of decreased morbidity and mortality from antiretroviral therapy in patients with CD4+ counts of 350 cells/mm³ or less. However, a comparable level of evidence showing benefit for patients with CD4 cell counts > 350 cells/mm³ is not yet available. The HHS panel based their decision on cumulative observational cohort data demonstrating benefits of antiretroviral therapy in reducing AIDS- and non-AIDS-associated morbidity and mortality. These two cohorts (NA-ACCORD and ART-Cohort) include about 35,000 total patients from

the United States and Europe.^{3,4} Based on these data, the panel now recommends antiretroviral therapy for patients with CD4+ count between 350 and 500 cells/mm³ (LOE: A-B/II). For patients with CD4+ count > 500 cells/mm³, the panel was divided in that 50 percent favored starting antiretroviral therapy at this stage of HIV disease (LOE: BIII); whereas, 50 percent viewed initiating therapy at this stage as optional (LOE: CIII).

Members advocating for earlier initiation of therapy based their recommendation on several recent developments: (1) data from the NA-ACCORD study noted above, (2) knowledge that untreated HIV infection appears to be

associated with development of many non-AIDS-defining diseases, including malignancies, cardiovascular disease, kidney disease, and liver disease; (3) availability of antiretroviral regimens that are more effective, easier to adhere to, and better tolerated than prior drug combinations; and (4) increasing evidence that effective antiretroviral therapy reduces HIV transmission (LOE: BIII).

Most recently, the International AIDS Society—USA panel noted in their updated guidelines “there is no CD4 cell count at which initiating therapy is contraindicated.” They specifically recommend ARV treatment for all persons with CD4 count of < 500 cells/mm³ and that treatment should be considered for asymptomatic individuals with a CD count > 500 cells/mm³. This panel also listed several clinical conditions for which antiretroviral therapy is indicated.⁵

Regardless of how you feel about these recommendations, the guidelines do state that the risks and benefits of therapy should be discussed with all patients. Our patients should realize that they are potentially committing to lifelong therapy with medications they must take every day. Moreover, the HHS guidelines specifically note that patients and/or medical providers may elect to postpone therapy on a case-by-case basis, based upon clinical and psychosocial factors.

The physicians in our programs have been treating the majority of patients with CD4+ counts < 500 cells/mm³ for at least the past year. Some patients still prefer to defer therapy, and we discuss risks and benefits of doing so. For patients with > 500 CD4+ cells, we approach this on a case-by-case basis. Unfortunately, it may be about 5 years until we have data from the “START” trial which will randomize patients with CD4+ counts in this range to initiation or deferred therapy.

At a time when U.S. health care reform has captured the spotlight, renewing legitimate concerns surrounding the imperative for fiscal prudence, it is especially important to consider the expected impact of the new HIV treatment guide-

lines on the overall cost of care. Indeed, this issue has been studied in the past. In 2001, Freedberg and colleagues, analyzing data from major clinical trials, including the ACTG 320 Study, concluded that initial CD4+ cell counts and drug costs were the major determinants of cost-effectiveness.⁶

The investigators demonstrated that initiating three-drug therapy in patients presenting with a CD4+ count of 500 cells/mm³ or less increased total lifetime costs from just over \$64,000 to nearly \$91,000. Yet quality-adjusted life expectancy



was also increased from 5.1 to 6.9 years, resulting in an incremental cost of \$15,000 per quality-adjusted life year (QALY) gained compared to no therapy. A cost of \$50,000 per QALY gained is generally considered acceptable in Western society. Thus, early treatment was judged to be a more efficient use of resources than waiting to initiate therapy at a CD4+ count of 350 cells/mm³. Further, it was reported that with the improved efficacy of more recent regimens available by that time, costs were decreased to \$11,000 per QALY gained.

Later studies have examined cost-effectiveness implications with respect to the early initiation of antiretroviral therapy considering its possible impact upon coronary heart disease risk and fat redistribution,⁷ as well as with respect to implementation in resource-limited settings⁸ at CD4+ lymphocyte count thresholds of 350 cells/mm³ or less, and found them to be favorable. Though not directly addressing the issue of even earlier initiation, the accumulating data in aggregate point to the likelihood that antiretroviral therapy offers no exception to the general dictum that good medicine is cost-effective medicine.

On November 30, 2009, the World Health Organization (WHO) also updated its HIV treatment guidelines, which are widely utilized in developing nations. These guidelines raised the threshold for starting therapy from 200 to 350 CD4+ cells/mm³. While the global trend appears to be clearly toward earlier initiation of antiretroviral treatment, dramatically increasing the number of patients eligible for antiretroviral therapy will increase the strain on resources, both in poorer countries where millions of people lack access even using the older threshold, and in the U.S. where the recessionary economy is dampening support for AIDS Drug Assistance Programs (ADAPs). Although currently available evidence clearly justifies the recommendations for earlier therapy initiation, careful long-term outcome studies will be critical in monitoring the efficacy, safety, and cost-effectiveness

of this approach in the years to come.



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New drugs have been approved that offer new mechanisms of action, improvements in potency and activity even against multi-drug-resistant viruses, dosing convenience, and tolerability.



Needless Suffering, Needless Death

AM A PHYSICIAN in private practice, while my daughter, Bonnie, is a PGY2 in Internal Medicine at Emory. Even though we see patients in very different settings, we both have HIV/AIDS patients that owe their survival to the Ryan White program. For many of the uninsured, the Ryan White program represents the last option for life-sustaining treatment and medication that had otherwise been unavailable.

Due to expanded routine HIV testing, our patient load has increased—a positive result of better linkage to care for newly diagnosed patients. However, the number of patients in Georgia being placed on ADAP waiting lists has also increased. While this indicates that patients are learning where to seek help and are taking an active role in their care, the growing numbers greatly concern us.

The sheer volume of patients waiting for life-saving drugs also graphically illustrates a breakdown in our HIV care system. In an era where antiretroviral medications (ARVs) should be more accessible than ever before, why are our patients still suffering and even dying from HIV?

While much media and celebrity attention is focused on access to care for HIV positive patients in numerous countries throughout the world, especially in sub-Saharan Africa, many HIV positive patients in the United States have little means by which to afford care, including ARVs.

We see these patients everyday in the hospital and the clinics, each with a personal story that epitomizes the core challenges of a care system in disarray.

Tiffany, who acquired HIV congenitally, arrived at the hospital with severe candida esophagitis; she could not swallow medications or food. She was cachectic with a CD4 count of 10. Her mother, who had died of HIV, was never able to afford medications for herself or her daughter.

Tiffany was treated for her esophagitis, given information regarding enrollment in ADAP from a hospital representative, and soon after her discharge was able to begin antiretroviral therapy. She is currently in college and healthier than ever. Had she not been hospitalized at the large county hospital in Atlanta where there is a clinic representative to arrange for enrollment, she never would have known where to seek care. She would likely have succumbed to her virus like her mother, who was ashamed of her infected status and did not know where to turn to seek help.

Michael had an excellent job and medical insurance and was treated with HAART after initially presenting with

Pneumocystis jiroveci pneumonia and a CD4 count of 2. He was compliant with his medications and appointments and had full immune recovery and viral suppression. He even had to be placed on a weight reduction diet.

But Michael then missed several appointments after being extremely compliant for nearly ten years. When he was finally reached by phone, he said he had lost his job and insurance and was “too embarrassed to come in.” He had been off of his ARVs for eight months and was starting to feel “weak.”

Despite the fact that the practice tells all patients to inform their physicians immediately if there is a change in employment or insurance, it is more common for patients just to stop coming. Once the office was aware of Michael’s circumstances, he was granted access to the Ryan White program quickly. Michael was enrolled and restarted on ARVs and is now clinically doing well. This story, along with many others similar to it, easily could have had a different outcome.

Many Americans do not realize that here in the United States, a country with extreme wealth but also extreme poverty, people are still born with HIV; people are still dying of HIV, and, more importantly, people are unable to get care because they have no idea where to turn.

An ADAP waiting list in Georgia may be a reflection of the fact that many patients who were once insured and employed are now uninsured and unemployed. It may also indicate greater education regarding access to care that has spread throughout the HIV community. As providers, it is our responsibility to treat all patients equally, regardless of their socioeconomic status. Ryan White and the ADAP program grant us the avenue to do so.

Even in difficult economic times it is critical that the Ryan White funding continue and increase. Otherwise, patients that need treatment and cannot get it will end up costing the system much more than the price of the ARVs and the care they deserve—to say nothing of the needless suffering that they will endure. **HIV**



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