

DISCUSSING PREVENTION HELPS PROTECT YOUR PATIENTS AND THEIR PARTNERS

Although people living with HIV often adopt healthy behaviors upon initial diagnosis, many revert back to risky behavior after time. Risky behaviors can lead to acquiring an STD, which can jeopardize a patient's health, and untreated STDs increase the risk of transmitting HIV to partners. Research shows that integrating brief prevention transmission discussions into each patient visit helps reduce risky behaviors. The Centers for Disease Control and



Prevention created the *Prevention IS Care* campaign and Web site to support providers who treat people living with HIV. **To receive FREE materials** that translate scientific evidence into practical tools for providers and patients, visit www.cdc.gov/PreventionISCare or call I-800-458-523 I.





Integrating Prevention Messages into HIV Care

A Physician's Perspective

2006 STUDY BY MARKS ET AL ESTIMATED THAT, IN THE U.S., 46% OF NEW HIV INFECTIONS

acquired through sexual transmission come from people aware that they have HIV.1 This fact illustrates a continuing need to incorporate a brief discussion on preventing the spread of HIV into each patient visit.

My colleagues often agree that there is a need for prevention counseling, but many are unsure of how to integrate it into their busy schedules. From my own 20-plus years of experience in treating patients with HIV/AIDS, I offer the following thoughts.

Addressing New Research

Many of my patients keep up on the latest HIV news. They hear things, but are reluctant to mention them to me; so I have to be proactive. For example, when reports circulated that patients with undetectable viral loads might not transmit HIV, I asked my patients if A Final Thought they had heard those stories. They had—and wanted to know more, which gave me the perfect opportunity to discuss viral loads, transmission and the importance of keeping themselves healthy.

Spreading the Word

It's good for patients to hear about prevention from different providers because they have different relationships with their doctor, nurse, medical case manager, and pharmacist. And they may feel more comfortable talking about personal issues with one staff member over another. I find it doesn't matter who's saying it, as long as the message is getting across. I train all of my employees to deliver and reinforce prevention messages.

We're surrounded by HIV every day, so we may forget that there can still be a stigma associated with having HIV. That's why we always have to remember to be empathetic and nonjudgmental to-

To help integrate prevention messages into

patient care, check out the CDC Prevention IS Care Provider Resource Kit. To order free posters, screening

tools, a patient brochure, medical curriculum and

info@cdcnpin.org, or visit www.cdc.gov/PreventionISCare.

other materials, call 1-800-CDCINFO, e-mail

Displaying Visual Cues

We have plenty of visual reminders around the office to help spark prevention discussions with patients. There's a jar of condoms in every exam Screen for risky behavior. Prescribe healthy behavior.

room. And we display resistance and adherence messages and ward our patients if we expect posters around the office. The CDC's Prevention IS Care campaign is a good source for posters.

Integrating Prevention into Medical Records

There's so much to cover during an office visit that it's easy to forget about prevention. That's why I like the fact that our Progress Notes have a checkbox for prevention messages. It's a good reminder for me to bring the subject up during every visit. And it's easy to check past Progress Notes to see what we talked about before, so I can go at it from another angle.

Taking Advantage of Screening Tools

Patients' responses on screening tools provide us with a wealth of information, some of it unexpected, which can be a great starting point for a prevention discussion. We use the Global Appraisal of Individual Needs (GAIN)* but other screening tools are available, including one on the Prevention IS Care Web site.

them to listen to—and talk openly with—us. For some patients, their health care team is the only support system they have. I try never to forget this fact and it always helps me lead with empathy during every patient visit.



About the Author: J. Kevin Carmichael, MD is an AAHIVM-Credentialed HIV Specialist and Family Practice physician who works exclusively with patients with HIV and AIDS at EI Rio Community Health Cen-

ter in Tucson, Arizona which is funded in part by Ryan White Parts B and C. He is also co-chair of the Ryan White Medical Providers Coalition and former board member of the Southwestern Board of AAHIVM. He has been working with HIV patients since 1986.

1. Marks G, Crepaz N, Janssen RS. Estimating sexual transmission of HIV from persons aware and unaware that they are infected with the virus in the USA. AIDS 2006;20:1447-1450.

*Global Appraisal of Individual Needs (GAIN) is a product of Chestnut Health Systems, Bloomington, IL

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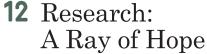
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EXECUTIVE DIRECTOR
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DIRECTOR OF COMMUNICATIONS ROBERT BANASZAK

EDITOR

ROBERT GATTY

G-Net Strategic Communications

E: BOB@GATTYEDITS.COM

PUBLICATION DESIGN & ART DIRECTION

BonoTom Studio, Inc. E: INFO@BONOTOM.COM

ROGER O. SELVAGE JR., ART DIRECTOR

ADVERTISING

JANE DEES RICHARDSON, PRESIDENT

AD MARKETING GROUP, INC. P: 703-243-9046 Ext. 102

E: JRICHARDSON@ADMARKETINGGROUP.COM

PUBLISHER

THE AMERICAN ACADEMY OF HIV MEDICINE

1705 DESALES ST., NW, SUITE 700
WASHINGTON, D.C. 20036
P: 202-659-0699 • F: 202-659-0976
E: NPO@AAHIYM.ORG • W: WWW.AAHIYM.ORG

EDITORIAL ADVISORY GROUP

CHAIR

JEFFREY T. KIRCHNER, DO, AAHIVS

MEDICAL DIRECTOR
COMPREHENSIVE CARE CENTER FOR HIV
LANCASTER GENERAL HOSPITAL
LANCASTER, PA

JEFF BERRY, EDITOR
POSITIVELY AWARE MAGAZINE

Positively Aware Magazine Chicago, IL

$\begin{array}{c} {\rm Joseph~S.~Cervia,\,MD,\,MBA,\,FACP,} \\ {\rm FAAP,\,AAHIVS} \end{array}$

CLINICAL PROFESSOR OF MEDICINE & PEDIATRICS ALBERT EINSTEIN COLLEGE OF MEDICINE ROSLYN, NY 11576

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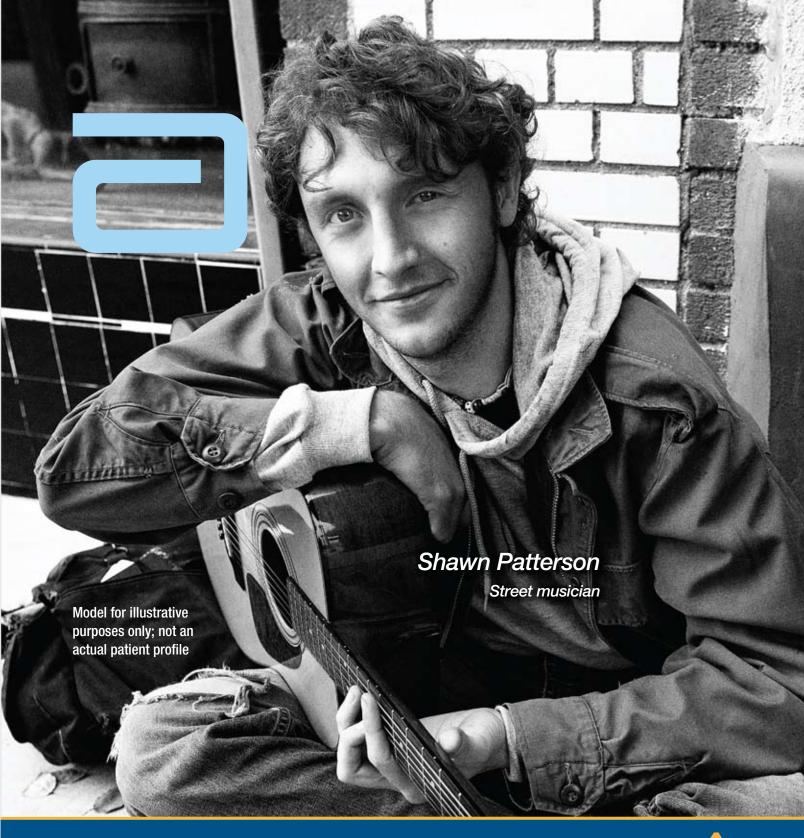
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A Look Inside...

T'S THE ECONOMY..." Since late last year, we have been hearing or talking of nothing else. We hear stories of financial chaos, the mortgage crisis, and soaring unemployment. We wait to see if bailouts and stimulus programs work, and wonder how these gargantuan efforts will affect our lives, personally and professionally.

Jeffrey T. Kirchner

It only follows that this issue of *HIV Specialist* addresses which includes continued vaccine research. what is happening in our country financially, and examines how the current situation may be affecting the practice of HIV medicine. After all, it is all about the economy, isn't it?

A recent survey of AAHIVM members revealed that a staggering 85% of HIV care providers report feeling the impact **of the current economic crisis.** You will see from our report

in this issue that the impact is being felt by doctors, nurse practitioners and physician assistants, in a variety of health care settings around the nation. And, what may be no surprise to those in the trenches, but is nonetheless troubling to see in print, is how this economic downturn is affecting the lives of our patients. Loss of medical insurance and mounting prescription co-pays are something we hear in our center daily. As we struggle to maintain capacity to provide the highest quality care with static or diminishing re-

sources, our patients struggle to maintain or gain access to the very care we are working hard to sustain. If they are unable to see us because they can't pay for their visit or medications, how can we help them? If we can't get in for a follow up visit because our schedules are inundated with new patients whose federally-funded clinics have closed, how can we help them?

In our challenging economy, we see that when it comes to looking at the impact on HIV medical practice, it **REALLY** is all about our patients.

Fortunately there is room for hope based on the commitment to domestic HIV/AIDS issues that President Barack Obama has declared since taking office. In this issue you'll see that commitment reflected in the words of **Jeffrey Crowley**, recently appointed by President Obama as the **Director of the** Office of National AIDS Policy. You will also hear from Dr. Anthony S. Fauci, director of the National Institute of Allergy and Infectious Diseases (NIAID), on the expected boost in Federal funding for HIV prevention research,

The Academy has worked hard over the years to combat HIV/ AIDS complacency, especially as it seeks to educate and credential MDs, DOs, PAs, NPs as HIV Specialists. This issue features an overview of how **AAHIVM's credentialing program** works. We note its value to providers who continue to maintain their **HIV Specialist**[™] certification and promote its significance to colleagues

> and patients. Also included is an update to our premiere issue's piece on timing of ARV treatment based on the NA-ACCORD study. The "when to start" ARV therapy question continues to be a major issue for patients, providers, and payers.

> We continue our series on converting your practice to an electronic medical records system, offering a checklist for your planning before moving ahead with your EMR conversion. You will also find a first-person essay from one of our Editorial Advisory Group members that offers a real-life ex-

ample of the impact of the economy on one patient's ability to access the necessary care after his move to another state.

Finally, I would like to say what a privilege it is to chair the Editorial Advisory Group of HIV Specialist. We have a dedicated Academy staff in Washington, DC and an enthusiastic team of AAHIVM-affiliated HIV clinicians, who continue to shape and improve this magazine with each issue. Please consider sending me any suggestions you have to make HIV Specialist even better. We also welcome first-person HIV-related pieces or letters to the editor commenting on the magazine's content. Our goal is to make HIV Specialist another resource that all AAHIVM-affiliated providers can use to advance excellence in HIV care. HIV

Sincerely.

Jeffrey T. Kirchner, DO, AAHIVS Chair, Editorial Advisory Group

Restless Shifting

HEN BEATING THE ODDS to survive HIV meant the opportunity to retire to the warm, sunny home of her dreams, Violet had every reason to be hopeful. Closer to friends and family, and away from inhospitable northeastern winters, a more affordable and welcoming lifestyle appeared within reach. What could shatter such an idyllic vision? Violet's experiences outline some of the challenges faced in reforming 21st century U.S. health care.

Embracing at the office doorway for what was likely to be the conclusion of our last visit, Violet whispered words of thanks. Diagnosed with AIDS nearly two decades earlier, she had beaten the odds, surviving the evolution of antiretroviral therapy with faith, hard work, and strict adherence to medical visits and prescribed treatment. Retirement to the Sunbelt home of her dreams, closer to old friends and family promised a well-deserved and affordable respite from the often harsh northeastern climate. The vision of a warmer and more welcoming lifestyle appeared within reach.

My vicarious indulgence in that idyllic vision was shattered with a telephone call some three months later.

"Dr. Cervia I need your help. I am in trouble," Violet pleaded. She recounted that upon arriving for her first scheduled appointment at her new center, Violet was told that the visit had been cancelled as the practice no longer accepted her coverage. Moreover, as she did not own a car and public transportation in her new hometown was virtually non-existent, there were no reachable providers who would accept that coverage. To make matters worse, Violet had run out of medication, and had fallen into the "doughnut hole" of her prescription drug plan.

After several hours of discussions with members of our care team and with pharmaceutical patient assistance plan representatives, we were able to get Violet back on her prescribed medications. Unfortunately, finding a willing and able local provider was not as easy. Violet eventually scheduled return visits at our center, commuting over one thousand miles quarterly before finally giving up and moving back north for good. Sadly, experiences such as Violet's are not unique, nor do they represent worse case scenarios.

Healthcare economists refer to the phenomenon of cost

shifting as the allocation of unpaid costs of care delivered to one patient or population through above-cost revenue collected from other patient populations. Yet, as Violet's story illustrates, with the U.S. healthcare reimbursement structure as fragmented as it is, cost shifting assumes other dimensions as well.

As the nation now faces unprecedented fiscal challenges, it would appear that this restless shifting of the financial burdens of healthcare goods and services will likely grow even more common, especially among our most vulnerable populations. Older Americans like Violet are finding their dreams of retirement fading; and, record unemployment with resulting losses in employer-sponsored heath benefits is contributing to growing numbers of uninsured and underinsured.

According to U.S. Bankruptcy Court, Chapter 7 personal bankruptcy filings, which discharge most unsecured debt, including medical bills, were up 40% in fiscal year 2008. Yet few experts have even speculated about how lengthy or severe the current economic recession may ultimately prove. We can only imagine the vast cost shifting to follow in its wake. Nevertheless, with healthcare reform high on the domestic policy agenda, there remain important opportunities for providers, patients and payers to collaboratively fashion a system that will finally put an end to this restless shifting and assure universal access to high quality, cost-effective care.

The problem and its ultimate resolution are not unique in my experience, and highlight some of the challenges that we face in ensuring broader access to high-quality, cost-effective care for individuals living with HIV. HIV



About the Author: Dr. Joseph S. Cervia is Clinical Professor of Medicine and Pediatrics, Albert Einstein College of Medicine. He is Attending Physician, The Center for AIDS Research and Treatment, The North Shore/Long Island

Jewish Health System, and Medical Director and Senior Vice-President, Pall Medical, East Hills, NY 11548 **Contact: cervia@lij.edu**, **joe_cervia@pall.com**. The author has no conflicts. Patient names and identifying information have been altered to protect confidentiality.

THE STRUGGLE TO HELP THE STRICKEN CONTINUES, BUT HOPE IS ON THE HORIZON...

ACROSS THE NATION, PATIENTS WITH HIV AND AIDS

are facing a new threat, as if their life-threatening disease was not serious enough. It is the possible loss of access to the continuum of care that is so essential to their survival and to the lifesaving, although exceedingly expensive, drugs that allow them to live productive and relatively normal lives.

The threat has been building as the nation's economy has worsened. Patients who once had insurance at work are losing their jobs—and their coverage—and so they skip appointments and checkups, try to make their drugs last longer—or stop taking their meds altogether—only worsening their conditions and making treatment even more difficult.

Many patients whose employers provide coverage are seeing their co-payments skyrocket to the point where they have no means of covering those costs. They have too many resources for publicly-supported care, but they are too poor to provide it themselves.

Then, there are the patients who are unemployed and rely on Ryan White-funded clinics for their care and

for their drugs. Now, they are seeing that safety net jeopardized as grant money is slow

to arrive and clinics are forced to cut costs to even stay open.

But there is a glimmer of hope stemming from the new Obama Administration, which has already committed large sums for HIV/AIDS, from research, to programs, to even a new public relations campaign to remind Americans of the seriousness of the HIV/AIDS crisis in the United States.

Following is an examination of this crisis from the voices of the dedicated men and women who treat HIV/AIDS patients in every corner of America, as well as two key Administration officials responsible both for the nation's research initiatives and the development of policy within the White House itself.

N CONNECTICUT, A NURSE PRACTITIONER, winner of a prestigious award for excellence in clinical practice in HIV, is considering a new job because of the instability of federal funds that support her position and provide resources for patient care. She is devastated at the thought of leaving HIV care, and knows many of her patients—and the clinic where she works—will suffer as a result.

In Los Angeles, patients who have lost jobs and/or insurance are skipping appointments and checkups, and the number of uninsured patients seeking treatment and medication has increased.

In Atlanta, some co-pays have skyrocketed and patients who can't afford their drugs try to stretch them out. Their choices: shelter, food, or life-saving medication.

In Maryland, a physician has become so concerned about the lack of funding to help HIV/AIDS patients

pay for their meds that she's established a special fund to help, and is soliciting donations.

America's economic crisis is difficult for the healthy, but for those with HIV/AIDS whose survival depends upon regular treat-

Struggle

BY BOB GATTY, EDITOR, HIV SPECIALIST

ment and costly medication, it is a life-threatening crisis.

Meanwhile, many physicians, physician assistants, and nurse practitioners who treat HIV/AIDS patients, struggle with declining financial support from cash-strapped governments. It is a growing crisis that threatens to further increase the nation's health care burden as patients grow sicker and the cost of their care increases exponentially.

Impact in the Trenches

STORY

COVER

According to an internet survey of members and credentialed HIV Specialists™ of the American Academy of HIV Medicine (AAHIVM) taken in March, 85.6% of the 291 respondents said the current U.S. economic situation is affecting the day-to-day operations of their HIV practices, with 57.5% reporting reduced or flat public funding and 74.1% reporting an increase in the number of patients unable to pay for their care. Nearly 30% said their facility had to layoff staff or reduce hours, while 16.5% reported reduced patient services.

Meanwhile, 85.3% said the poor economy has made it more difficult

for patients to access care in their communities.

"As more and more patients come into our public health clinic undetectable on their ARVs, but with a limited supply and no payer source, we are providing a great deal of 'emergency' prescriptions in order not to interrupt their therapy until their ADAP (AIDS Drug Assistance Program) comes through," one survey respondent said. "More uninsured patients (are) accessing our indigent funding," said another.

Chicago

Corinne Blum, M.D, AAHIVS, works at the STI/HIV Prevention & Control Services Section at the Chicago Department of Health. A supervising physician, she oversees clinical care in five STI/HIV clinics where patients can be tested and receive care through a Ryan Whitefunded program.

"I expect the number of people seeking care with us will increase as folks lose their insurance," Dr. Blum said. "My patients have been talking a lot about the stresses associated with job loss, unemployment, lack of money for housing, food, and other necessities, which definitely impacts their ability to make it to their appointments and their overall health and well-being. In addition, our city's health department has been forced to layoff workers, which impacts our program's ability to provide efficient and expanded care."

Fortunately, Dr. Blum's agency has seen a fairly steady

tion to get to the clinic, and are asking for help. But much worse is the impact of increased homelessness in her community.

"A lot more people tell me they don't have access to food, or they are homeless and don't have a refrigerator to keep their food in, and a lot of HIV medicine needs to be taken with food," Dr. Blum reported. It is heartening, she said, when the clinic can help provide support for these patients and their families. "It's very rewarding if we can connect them to help, but frustrating when there are not enough resources out there."

Hartford.

For Seja Joyce Fishman, APRN, AAHIVS, delays in the dispersal of Ryan White funds by the Health Resources and Services Administration (HRSA) in the U.S. Department of Health and Human Services may force her to leave her contract position at the Burgdorf Clinic, a satellite of St. Francis Hospital in Hartford, CT, where she serves 195 patients as a nurse practitioner.

Pointing out that funding delays directly affect patients, Fishman said if she leaves her agency, it will be difficult for many patients to find another provider.

tients Cope Even Survive

stream of funding, but she is concerned, aware that many facilities in other areas have not been so fortunate. For now, her patients are most affected by the nation's economic crisis.

"People have been losing their jobs, so if they had insurance, they lose it," she said. "To access their medication, they need to apply for ADAP, which then can delay their treatment."

Dr. Blum says many patients are experiencing dramatic co-payment increases as employers reduce the cost of employee health insurance benefits.

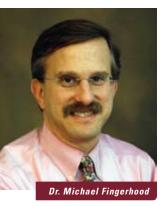
"What's happened to a couple of my patients," she explained, "is that they have a huge bill and the pharmacy won't provide any more medicine until it is paid. They don't have a job, so they can't pay. They are really in trouble."

Many of Dr. Blum's patients can't even afford the cost of transporta-











"My attending physician will be burdened with a huge caseload and no consistent help from an HIV-specializing provider for some time," she said. "Some of my patients may follow me to another clinic and thus be a loss to the clinic. The interruption in substance abuse services, mental health services, and early intervention services is also a great setback for the community. Services that are already in great demand are cut back, delayed or altogether eliminated as the funding availability changes.

"I love HIV care," said Fishman, who has built her career on serving HIV/AIDS patients. "I've become an expert. I teach. I hope at some point I will be able to retain that."

Baltimore:

Michael Fingerhood, M.D., AAHIVS, associate professor of Medicine at Johns Hopkins University in Baltimore, MD, has noticed the sharp increase in co-pays since January. "Companies are making employees pay much more for their health care visits," he said. "Prescription costs have definitely gone up. For HIV patients, that's a huge outlay."

Dr. Fingerhood, like Fishman, reported delays in receiving Ryan White funding this year. "It was more than a month late, but the amount was a little more than last year, although we only received money for the first four months rather than the whole year. I expect we'll get the rest, but it's hard to plan that way."

Lori Fantry, M.D., M.P.H., AAHIVS, is medical director of the Institute of Human Virology/University of Maryland Infectious Diseases Clinic, which serves more than 1,800 patients. While her agency's Ryan White funding also was delayed this year, she expects to receive essentially the same amount as last year. "It never is adequate," she said, noting that the patient population her facility serves is 84% African American, mostly from Baltimore's inner city, with many unemployed.

"They rely on our services, including transportation and free meds," she said. "The HIV service is busier this year than last year. I think we are seeing people in total need."

Dr. Fantry said the clinic has been told to no longer cover patients' medications with Ryan White funds, so she has started a "special account" to accept donations to be used for HIV/AIDS medication. The seed money?

"My mother sent me \$100 and told me to use it to help my patients," she said. "So I started the fund with that. Now, we have a mechanism by which the money (\$20) that practitioners get for filling out Social Security disability medical forms will be directly deposited into the account to help patients. In addition, our Ryan White coordinator (a former social worker in our clinic) has decided to dedicate time to soliciting donations for this account."

Atlanta:

Alison Walter Kyle, NP, AAHIVS, is a family nurse practitioner at Atlanta's Grady Health System's Infectious Disease Program at the Ponce de Leon Center, which provides primary care and chronic disease management services for HIV/AIDS patients.

1. What is the impact of the current US economic situation on the day-to-day operations of your HIV care practice?

| | Response Percent | Response Count |
|--------------------------|---------------------|-------------------|
| A. No impact at all | 14.4% | 42 |
| B. Somewhat of an impact | 61.2% | 178 |
| C. Significant impact | 24.4% | 71 |
| | | |
| Number of Res | Other pondents | 47 291 |

There, more of the same – patients losing jobs, without health insurance, unable to afford COBRA, and desperate for help. "It's definitely a financial burden on our services, but we have a policy that if a patient is undetectable, we don't want to interrupt their ARVs. So we do whatever we can," she said.

2. Where is the impact seen or felt in your practice?

| | Response Percent | Response Count |
|---|---------------------|-------------------|
| A. Limited funds to recruit and/or retain clinical staff | 58.8% | 114 |
| B. Limited funds to recruit and/or retain admin. staff | 40.2% | 78 |
| C. Limited funds for professional development | 67.5% | 131 |
| D. Rising costs of medical equipment/supplies | 36.6% | 71 |
| E. Rising costs of office equipment/supplies | 29.9% | 58 |
| | | |
| Other Number of Respondents Number of Non-Respondents | | 31 194 97 |

"But there are patients who don't always get to us in time," Kyle said. "Then they come in and tell us, 'I used to be on meds, but I lost my job and don't have insurance, and I'm off my meds. Or we hear of people trying to stretch their drugs, which is the worst thing they can do."

Disheartening are the patients who finally get prescription drug insurance only to learn it is limited to perhaps \$2,000 a year. "The ARVs can cost \$2,000 a month or more. So the drug coverage is not enough and they don't qualify for ADAP because they have a job and make too much money. That is a serious problem," she explained.

Charlotte:

J. Wesley Thompson, PA-C, MHS, AAHIVS, a physician assistant at Carolina Medical Center in Charlotte, NC, provides care to the HIV/AIDS population of the region. "We are seeing more and more people lose their jobs, and CO-BRA is astronomical," he said. "It is a question of making a choice between health care, rent and food."

For many HIV/AIDS patients, there are more issues than obtaining care and medication, for as they live longer because of advances in medications, common co-morbidities related to aging emerge and must be treated.

"If we deem the condition is HIV-related, we have more leeway to help the patient through Ryan White," Thompson said. "But the patient will still get a bill. Ryan White is a band-aid over a very bad laceration in need of repair."

3. How much of an impact has the current state of the U.S. economy had on patient access to your practice?

| | Response Percent | Response Count |
|--------------------------|---------------------|-------------------|
| A. Significant impact | 24.1% | 70 |
| B. Somewhat of an impact | 61.2% | 178 |
| C. No impact at all | 14.8% | 43 |
| | | |
| Number of Respondents | | 291 |

Los Angeles:

In Los Angeles, Paul DenOuden, M.D., AAHIVS, medical director of the Westside Healthcare Center, agreed that "dealing with all of the normal medical problems of aging, plus all of the issues surrounding HIV," is difficult. "They have a longer sustained need," he said. "Maybe they take their HIV meds and let other things go. People are forgoing prescriptions, labs or screens."

Serving these patients with multiple needs, many uninsured, is a continuing challenge for a health system that must provide the optimal care possible with limited funds, said Dr. DenOuden.

"Many patients are skipping appointments, letting six months go by before labs are checked instead of three months," he said. "HIV patients need regular follow-up, and delays could cause HIV to progress and cause more resistance and more difficulty in controlling the disease. Some uninsured patients don't know where to go for help, so they stop their meds."

Washington State:

Ann Dreyer, M.D., AAHIVS, a physician who serves HIV/ tients have extraordinary needs," said Dr. Blum. "It will AIDS patients at the Everett Clinic, Mukilteo, WA, pointed take more (resources) for us to care for them in these ecoto a patient she diagnosed more than a decade ago and nomically stressful times." HIV

who has been doing well on a regimen she prescribed. "He is undetectable now, but it is \$8,000 a month. But he has coverage. He is fortunate. Not everyone is."

However, those who don't have insurance must still be treated, Dr. Dreyer said. "Because a lot of people we serve are Medicare and Medicaid patients, the clinic allows me to take them on. If I was in private practice, there would be no way I could stay in business."

Pittsburgh:

The Positive Health Clinic, a Ryan White-funded clinic at Pittsburgh's Allegheny General Hospital, serves about 600 patients - 93 of whom are uninsured and ineligible for Medicare, Medicaid or other governmentprovided coverage. According to Stacy Lane, DO, medical director, that number of uninsured has increased 340% since 2003 even as the clinic's Ryan White funding has been cut 2.5%.

Dr. Lane said the trend has worsened over the past year, adding that many patients work in low paying positions, often at retail firms that provide insurance but require copays of as much as 10% of the drug's cost.

"They're expected to come up with a co-pay of \$100 or more a month, and they can't do it," she explained. "So they fall between the cracks; they make too much to qualify for ADAP and they are not poverty level. For some, they would almost be better off if they had no insurance at all-because then they would have Ryan White and other options."

Dr. Lane's clinic is considering rewriting its policies to make it easier to help these patients. "Fortunately, we don't have a huge administrative structure here and we can do what's best for patient care," she explained, adding that she is thankful that Positive Health Clinic does not rely exclusively on Ryan White grants. Still, she said, the clinic has been forced to pare some of its services, principally dental, because of the poor economy.

"We have a lot of safety net funding available for folks," she said. "We are very fortunate that we have a separate pool of funding to rely on."

It's the Patients

Providers at many clinics report delaying expansion plans, forgoing acquisition of new equipment, and taking other steps to cut expenses because of the poor economy and funding uncertainties and difficulties.

But largely the impact is being felt by the patients, although it's putting additional stress on providers dedicated to helping them survive.

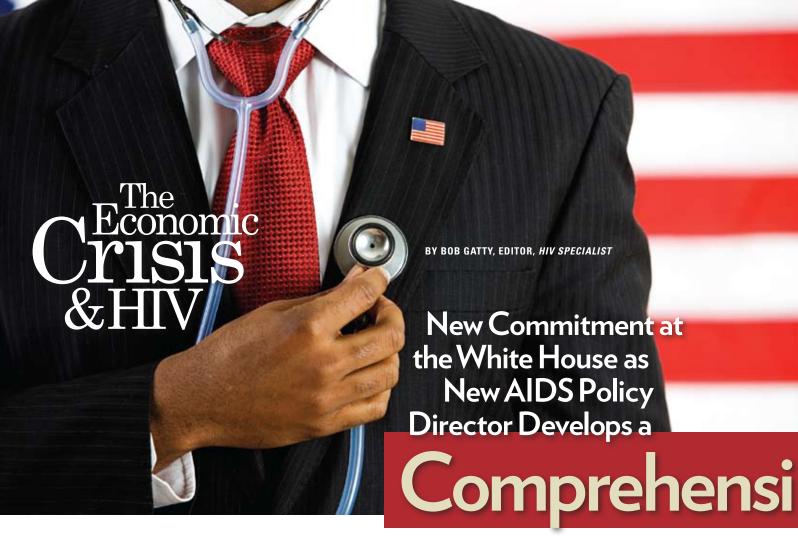
"We're doing the best with what we have, but our pa-











he Battle against hiv and aids in the United States has been waged
for many years now, but despite the efforts of dedicated researchers and treaters, the devastation of lives continues.

"In the United States, every 9½ minutes someone's brother, sister, best friend, father or moth-

New medicines now allow HIV patients to approach normalcy in their lives and there have been advances in federal support for research and funding. But budget pressures, the lack of a unified strategy, and the magnitude and complexity of the problem have resulted in a steady increase in newly-diagnosed domestic HIV/AIDS cases in recent years.

According to the Centers for Disease Control and Prevention (CDC), from 2004 through 2007, the estimated number of newly diagnosed HIV/AIDS cases in the 34 states with confidential name-based HIV infection reporting increased by 15 percent. In 2007, that rate was 21.1 per 100,000 people.

But there is reason to be optimistic that these cold numbers that represent so much human suffering may one day change, perhaps sooner than expected just a year or two ago.

The reason: President Barack Obama is committed to developing a unified national policy that will mobilize all relevant federal agencies to deal with this disease and its terrible toll on human lives, on our economy, our nation, and our society.

The Goal: A National AIDS Strategy

Leading that effort is Jeffrey S. Crowley, MPH, whom President Obama named in February as director of his Office of National Aids Policy. That office is charged with coordinating government efforts to reduce HIV infection in the U.S. and leading treatment of Americans with HIV/AIDS.

"The President is a strong supporter of the HIV/AIDS community," Crowley, former senior research scholar at Georgetown University's Health Policy Institute, told *HIV Specialist* in an interview. "In bringing me on, the primary task I've been given is developing a national AIDS strategy. He wants us to develop and begin to implement a comprehensive strategy including all agencies, with the goal of reducing HIV infection, increasing access to care, and reducing health disparities."

"In the United States, every 91/2 minutes someone's brother, sister, best friend, father or mother becomes infected with HIV," he said. "Yet, research shows that many of those becoming infected do not recognize their risk. This is a major concern, because lack of knowledge contributes to increased risk behaviors."

Crowley holds a master's degree in public health from Johns Hopkins University and previously served as the Deputy Executive Director for Programs at the National Association of People with AIDS (NAPWA). There, he helped implement several key initiatives including The National HIV Testing Day Campaign and the Ryan White National Youth Conference.

Crowley said he has been asked to focus on the "stigma" associated with HIV/AIDS. "We need to

do more to increase awareness and greater investment in the U.S.," he explained, saying there must be "measurable goals, a timeline, and real accountability mechanisms. Everything we do is to be grounded in science and what works."

His task at the Office of National AIDS Policy, will be formidable, but Crowley begins his work with the good will of the HIV/AIDS community.

Jim Friedman, executive director of the American Academy of HIV Medicine (AAHIVM), said President Obama's selection of Crowlev "signals a strong commitment from the Obama Administration to refocus the fight against HIV/AIDS here in the United States." Friedman said Crowley's positions at Georgetown in the Health Policy Institute and the O'Neill Institute for National and Global Health Law, combined with his work in the HIV community, "will provide a solid foundation to his work in developing a national HIV/AIDS strategy that bolsters prevention efforts, helps HIV treaters provide the high quality care, and enables all people living with HIV/'AIDS in the United States to access the life-saving care that they need—particularly those within our most vulnerable populations."

"Comprehensive health reform is a key issue," he said. "A number of those issues will be addressed as we consider health care reform."

Regarding the Ryan White AIDS Program, which received \$2.1 billion in both FY 2007 and 2008, Crowley indicated changes are coming.

"We really need to think about how Ryan White interacts with health care reform," he said. "No matter what happens, there will be a role for Ryan White, but it may change. I can't prejudge how that will change or what will happen." In fact, the Administration's budget included a \$54 million increase for Ryan White and \$53 million in additional funding for HIV prevention.

Crowley said a number of other proposals contained in the Obama DHHS budget for next year would prove beneficial to those who treat HIV/AIDS patients, including:

- · Acceleration of health information technology and utilization of electronic health records.
- Expanded research comparing the effectiveness of medical treatments to give patients and physicians better information on what works best.
- An investment of over \$6 billion for cancer research at the National Friedman pointed out that AAHIVM previously collaborated with institutes of Health as part of the Administration's multi-year commit-

ve Initiative to Reduce HIV

Crowley "to ensure greater access to HIV care through Medicaid, and we ment to double cancer research funding. look forward to continuing our working relationship to develop strong, sound HIV policy that helps HIV treaters provide the most accessible, best possible care for Americans living with HIV/AIDS."

While he had been on the job less than two months when our interview took place, Crowley said he had begun to "reach out to stakeholders inside and outside of government to get input — not to prejudge what the strategy will be, but how we need to go about it while being transparent in what we are doing."

Crowley said he intends to continue that outreach and "in the near future, we hope to report to the public our plan." He said his office is committed to a process that is "open and inclusive, transparent, and based on a strong partnership."

Jeffrey S. Crowley, MPH

• Investment of \$330 million to increase the number of doctors, nurses, and dentists practicing in areas of the country experiencing a shortage of health professionals.

> The American Recovery and Reinvestment Act of 2009 also provided \$1.1 billion for Office of Aids Research initiatives (See "Research: A Ray of Hope"). It included incentive payments for Medicare physicians beginning in 2011 for using a certified electronic health record (EHR), followed by financial penalties starting in 2015 for failure to comply. It provides incentive payments to Medicaid providers, including physicians, to help purchase, implement, and use certified EHR technology.

> The stimulus provisions are now law, but the issues involving the pending budget and health reform must negotiate Congress at a time of national financial

While the outcome is uncertain, clearly Crowley's appointment signals a new commitment and direction to the nation's attack on HIV/AIDS.

When President Obama appointed Crowley, he said:

"Jeffrey Crowley brings the experience and expertise that will help our nation address the ongoing HIV/AIDS crisis and help my administration develop policies that will serve Americans with disabilities. In both of these key areas, we continue to face serious challenges, and we must take bold steps to meet them." HIV

Federal Initiatives

The summary for the Department of Health and Human Services (DHSS) budget released in February said the plan "increases resources to detect, prevent, and treat HIV/AIDS domestically, especially in underserved populations."

Crowley said he understands, as does President Obama, that "times are tough and Americans are hurting," and there have been serious economic implications for those who treat HIV/AIDS patients, as well as the patients themselves.

ESPITE THE NATION'S ECONOMIC CRISIS, a new transfusion of federal funding is on its way to help finance AIDS research at the National Institutes of Health (NIH), where the Office of AIDS Research (OAR) has made prevention of HIV infection, including development of a new HIV vaccine, its highest priority.

at NIH contained in the FY 2009 budget signed by President Obama in March, the \$800 billion Economic Stimulus Act of 2009 included another \$10 billion for NIH, about \$1.1 billion targeted for OAR initiatives.

"HIV/AIDS research activities will

benefit greatly from the stimulus bill," Anthony S. Fauci, M.D., director of the National Institute of Allergy and Infectious

In addition to the 2.9 percent increase in HIV/AIDS research funding

of drugs" has been developed to control HIV infection, there are 2.5 million new infections worldwide each year and for every person placed in therapy, there are two or even three who become newly infected.

"Although there's great successes with therapy, numerically you're losing the game if you continue to have so many additional people getting infected," he said. "So prevention looms large as a real major challenge, and the scientific aspect of that is developing a vaccine, and vaccine has been very elusive over the last many years for a number of reasons."

In September 2007, two clinical trials of a promising HIV vaccine candidate were halted after it failed to show efficacy. Since then, NIH and HIV vaccine researchers "have held intensive consultations" to decide on future strategies.

Testifying before the House Committee on Oversight and Government Reform last September, Dr. Fauci said NIH has launched a new initiative to "spur fundamental research that will contribute directly to the development of an HIV vaccine as well as to encourage the participation of in-

> vestigators from an array of life sciences disciplines in this endeavor."

> The ultimate goal, he explained, is to prevent infection. "However, we must also recognize that even a vaccine that does not prevent infection, but significantly alters the course of disease or the infectivity of the individual could have a positive impact on both individuals and the community," he said. "I remain cautiously optimistic that, despite recent setbacks, we will

Diseases (NIAID) told HIV Specialist in an interview.

All of this is welcome news since the total NIH AIDS research budget over the past five years has been flat-lined, slashing actual buying power and reversing the doubling of the budget that occurred between 1998 and 2003.

"It is important to note that these budgetary constraints have occurred during a time of significant public health need and scientific opportunity," said

for 2010. "Increased demand and urgency for government funding is further necessitated by concurrent significant reductions in pharmaceutical and biotechnology company investment in basic and clinical AIDS biomedical research."

OAR requested \$3.35 billion for FY 2010, an increase of 15 percent over 2009. "That was our wish list," Dr. Fauci said, acknowledging that he does not expect that full amount to be approved – especially given the current economic climate.

"We're hoping to get enough money to fund the grants worthy of being funded," Dr. Fauci said.

"What about vaccine research?" he was asked.

"We will have enough to do vaccine research," he replied.

In Search of a Vaccine

Dr. Fauci, who received the Presidential Medal of Freedom last June for contributions in HIV/AIDS research, said that while a "whole menu

a document prepared by OAR to inform Congress as to funding needs eventually have a vaccine that will be an effective tool in controlling the

FEDERAL FUNDING FOR HIV/AIDS RESEARCH T

HIV pandemic."

OAR asked Congress for \$616 million, up \$56 million or 10 percent over 2009, to support basic research studies in vaccine development. The agency said the earlier disappointing vaccine initiatives "underscore the critical need to reinvest in basic research on the virus and host immune responses that can inform the development of new and innovative vaccine concepts, as well as the development of improved animal models to conduct preclinical evaluations of vaccine candidates."

If Congress failed to meet its funding request, OAR said it would be unable to fund additional basic research on HIV and host immune responses. "Findings from this important research could provide new information for the design and development of new vaccine concepts and the preclinical/clinical development of vaccine candidates in the pipeline. These funds are critically needed to support these changing priorities in HIV/AIDS vaccine research," OAR told lawmakers.

However, less clear are the complex interactions of behavioral and cellular events, and the potential differential of susceptibility between individuals of different racial and ethnic backgrounds, the agency said, adding that the use of alcohol or drugs of abuse also may have both behavioral and health consequences related to susceptibility to infection.

"There is a continuing need to better understand how HIV is transmitted in the course of human relationships, occurring in social contexts that vary by location and culture," OAR explained. "Interventions to reach and change the behaviors of large numbers of at-risk individuals are urgently needed, particularly interventions that target MSM, as well as men and women from racial and ethnic populations."

In addition, OAR said its funding request gives highest priority to research that will:

• Develop and evaluate new agents and drug regimens to prevent and treat comorbidities and comortalities (malignancies, cardiovascular



diseases, metabolic disorders, and other complications) associated with long-term HIV disease and antiretroviral treatment.

- Develop and evaluate new strategies to prevent and treat HIV coinfections, including multi-drug resistant and extensively drug resistant TB, hepatitis C, and malaria.
- **Identify** genetic determinants of disease progression and treat-

- \$849 million, a 19.7 percent increase, for research focused on gaining a better understanding of how HIV infection is established and maintained, and what causes the associated profound immune deficiency and severe clinical complications. OAR said these studies are crucial to answering essential questions about HIV pathogenesis and disease progression and the development of new and better treatments and prevention strategies.
- \$201 million, an 18.9 percent increase, for training of domestic and international biomedical and behavioral AIDS researchers, as well as the equipment for the conduct of AIDS-related research and clinical studies.

• \$51 million, an 18.6 percent increase, for information dissemination efforts, which the agency said are "integral to HIV prevention

and treatment efforts and critical in light of the continuing advent of new and complex antiretroviral treatment regimens, issues related to adherence to prescribed treatments, and the need to translate behavioral and social prevention approaches into practice."

Dr. Fauci cautioned that no single prevention strategy or intervention method would be 100 percent effective in preventing HIV infection.

"We must confront this disease," he said, "with multiple effective interventions, assem-



ment response and develop methods to optimize therapeutic regimens bling a comprehenbased on an individual's genomic sequence.

• Identify and evaluate the viral and host factors associated with toolkit that may inantiretroviral therapy failure.

Specific requests included:

- \$133 million, a 12.7 percent increase over 2009, for research to develop a microbicide that would provide women a means to protect themselves from HIV.
- \$490 million, a 19.2 percent increase, for behavioral studies and social science research to provide greater understanding of how to change the behaviors that lead to HIV acquisition, transmission, and disease progression, including preventing their initiation, and how to maintain protective behaviors once they are adopted.
- \$751 million, a 10.8 percent increase, for a comprehensive therapeutics research program to design, develop, and test drugs and drug regimens to prevent and treat HIV infection and its associated coinfections and comorbidities.

sive prevention clude vaccines, topical microbicides, circumcision, and behavioral in-BY BOB GATTY, EDITOR, HIV SPECIALIST terventions, such as abstinence, fidelity, and

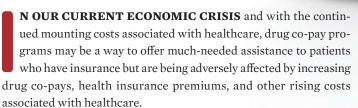
condom use, depending on the target population. Only then will we

be successful in effectively controlling the HIV pandemic both domestically and globally."

Dr. Fauci said his office is doing everything possible to make its case for increased resources for HIV research.

"We've set forth the concepts and identified what we are trying to do. I'm hopeful," he said. HI





Most, if not all, HIV pharmaceutical companies already provide some level of patient assistance to individuals who are unable to afford their HIV medications. These are typically for uninsured patients only and those who qualify financially. Providers should contact the manufacturer directly to see if a patient is eligible for a specific patient assistance program (PAP).

Several companies have also recently instituted co-pay assistance programs. Co-pay programs may cover all or part of the drug co-pay for many privately-insured patients, up to a specified amount, and for a pre-determined period of time (for example, up to one year). Certain restrictions and eligibility requirements apply (for example, ADAP, Medicare, and Medicaid are not accepted), and eligibility requirements may vary from program to program. Patients usually get their co-pay cards directly from their provider, or in some cases from the manufacturer's website or by calling a toll-free number. Once eligible the patient can bring the co-pay card to their pharmacy when filling a prescription and the pharmacy is then reimbursed for the amount covered.

These co-pay programs are the direct result of several years of intense work and negotiations between the Fair Pricing Coalition (FPC) and representatives of the pharmaceutical industry. The FPC, founded by the late Martin Delaney, works on HIV drug pricing issues and to help control costs, helping to ensure access to life-saving medications for recipients of state AIDS Drug Assistance Programs (ADAPs),

Medicare, and Medicaid, as well as for those who are privately insured, underinsured and uninsured.

Nowadays many health insurers contract with Prescription Benefits Managers (PBMs) to reduce healthcare costs through the use of mail order pharmacies. Unfortunately many of the most widely-used mail order pharmacies in the U.S. do not honor co-pay cards, simply because their systems are not setup to handle them or they don't have the software to process this type of reimbursement. This is an important issue as more and more patients are required by their company's healthcare plan to acquire their medications through a mail-order pharmacy, and one that the Fair Pricing Coalition is currently working to address.

There may be medications in addition to HIV drugs that patients must take, such as those needed to control other conditions including high cholesterol or diabetes. To find patient assistance or drug co-pay programs for these and other types of drugs, visit www.needymeds.com.

Together Rx is a prescription savings program for uninsured individuals sponsored by many of the nation's leading pharmaceutical companies. For more information call toll-free 1-800-966-0407, or patients can enroll online at www.TogetherRxAccess.com.

Below is a brief description of currently available HIV co-pay programs. For more information, patients can also call the Project Inform Hotline at 1-800-822-7422, or visit www.positivelyaware.com and www.aidsmeds.com.

Abbott: Positive Partnership PLUS Card—This program includes

E E Drug Co Day Drogger

Drug Co-Pay Programs Offer Financial Help for Those with Drug Coverage But High Co-Pays

BY JEFF BERRY

12 months of co-pay savings and covers Kaletra plus up to two other

ARVs, no income or co-pay eligibility criteria. Patients can save up to \$50 toward their Kaletra co-pay, plus up to \$100 of the cost of other HIV medications (up to \$50 for each additional ARV with a limit of \$100 total—must be part of a Kaletra regimen.) Patients must get their card from their provider. Visit www.kaletra.com for more information. Norvir is currently not part of this program.

Bristol-Myers Squibb: Reyataz and Sustiva Co-pay Benefit Program—covers Reyataz and Sustiva; for high co-pays only. Patient responsible for first \$50 plus any amount over \$250. If healthcare provider does not have card, patients can call 1-888-281-8981 or visit www.bristol-myers.com/static/patient_assistance/data/programs.html.

Bristol-Myers Squibb and Gilead Sciences: Atripla Co-pay Assistance Program—covers Atripla; for high co-pays only. Patient responsible for first \$50 plus any amount over \$250. If healthcare provider does not have card, patients can call toll-free 1-866-784-3431 and one will be mailed to them.

Gilead Sciences: Truvada Co-pay Assistance Program—Covers Truvada, Emtriva, and Viread. For high co-pays only; kicks in above \$50 and up to \$200/month. If healthcare provider does not have the card, patients can call toll-free 1-888-358-0398 and one will be mailed to them.

GlaxoSmithKline: MySupportCard—This is the easiest program to qualify for and to access, with no income criteria. Card is valid for the amount of patient's actual out-of-pocket cost up to a maximum of \$100 for each prescription. All GSK HIV drugs (Combivir, Epivir, Epzicom, Lexiva, Retrovir, Trizivir, and Ziagen) are covered. Patients can get the card from their provider or print out the card online at www.mysupportcard.com.

Tibotec: Tibotec Therapeutics Patient Savings Program—Covers Prezista and Intelence. Saves up to 80% of the amount of your actual out-of-pocket cost up to \$100 per drug, per month. Patients can visit www.prezista.com/prezista/patient_assistance.html or call toll-free 1-866-961-7169.

Merck does not have a specific insurance co-pay assistance program, however they do have a patient assistance program for Isentress and Crixivan called "Support." Those needing co-pay assistance for Crixivan or Isentress should use the "Support" program. Call 1-800-850-3430, or visit www.isentress.com, click on the site map, and then click "Support." Merck is planning to launch a co-pay program later this year.

Pfizer does not offer co-pay assistance for HIV medications; however, they do provide reimbursement assistance, appeals assistance, and patient assistance for Selzentry, Viracept and Rescriptor, and also offer information on obtaining assistance with tropism testing. Call the Pfizer RSVP program at 1-888-327-RSVP (7787) M–F, 9:00 am – 8:00 pm Eastern Time; fax 1-888-773-0121, or write to Pfizer RSVP, PO Box 220574, Charlotte, NC. 28222-0574. For assistance with all other Pfizer medicines, call Pfizer Helpful Answers (PHA) at 1-866-706-2400, or visit www.pfizerhelpful answers.com. HIV



Jeff Berry is Director of Publications for Test Positive Aware Network and editor of *Positively Aware* magazine, co-chair of the AIDS Treatment Activists Coalition (ATAC) Drug Development Committee (DDC), and a member of the Fair Pricing Coalition. Adapted

with permission from the 13th Annual Positively Aware HIV Drug Guide, March/April 2009.



FOREFRONT

When is the Best Time to Start HIV Treatment? PART II

NTHE FIRST ISSUE OF HIV SPECIALIST, we discussed data presented at ICAAC/IAS by Dr Mari Kitahata for the North American AIDS Cohort Collaboration on Research and Design (NA-ACCORD). This cohort includes patients from 22 centers in Canada and the U.S. in active care from 1996 through 2006.

Initial analysis surprisingly found that patients who had CD4 counts between 351 and 500 cells/mm3 and deferred therapy had a 74% greater relative risk of death compared to those who started ARV treatment.

At this year's 16th Conference on Retroviruses and Opportunistic Infections (CROI), Dr. Kitahata and colleagues looked at the same cohort of patients (n=9,174), and again used all-cause mortality as the primary clinical endpoint.

They identified 2620 (29%) patients who initiated ARV therapy with a CD4 count greater than 500 cells/mm3 and 6553 (71%) who deferred therapy. Median CD4 count of those starting therapy was 674; for the deferred treatment group, 390 cells/mm3.

The authors controlled for established risk factors for mortality in HIV disease that affect decisions to defer treatment including age, IVDU, and HCV co-infection. There were 196 deaths in the immediate treatment group compared to 410 in the deferred group, or a 1.6 relative hazard of death (or 60% higher risk of all-cause mortality) for those who deferred therapy during the 10 years of follow up in the study. Older age also was associated with a significant increase in mortality.

Baseline CD4 count within a range of >500 and baseline viral load were not independent predictors or mortality, however increasing age was (p<0.001). Dr. Kitahata said these data support initiation of HAART at a CD4 count above 500 cells/mm3 to improve survival. She believes the size and characteristics of the NA-ACCORD participants make these findings generalizable to similar populations where ARV treatment is available.

A second study by Dr. Jonathan Stern from the University of Bristol, UK and When to Start Consortium, presented data which included 21,247 ARV-naïve patients from 15 cohorts in Europe. These were patients who started ARV therapy after 1997 with a CD4 count of <550 cells/mm3.

| HIGHER CD4 RANGE | LOWER CD4 RANGE | HAZARD RATIO (95%CI) |
|------------------|-----------------|----------------------|
| 451 to 550 | 351 to 450 | 0.99 (0.76 to 1.29) |
| 426 to 525 | 326 to 425 | 1.12 (0.87 to 1.43) |
| 401 to 500 | 301 to 400 | 1.09 (0.85 to 1.38) |
| 376 to 475 | 276 to 375 | 1.19 (0.96 to 1.47) |
| 351 to 450 | 251 to 350 | 1.28 (1.04 to 1.57) |
| 326 to 425 | 226 to 325 | 1.21 (1.01 to 1.46) |
| 301 to 400 | 201 to 300 | 1.34 (1.12 to 1.61) |
| 276 to 375 | 176 to 275 | 1.59 (1.30 to 1.95) |
| 251 to 350 | 151 to 250 | 1.71 (1.43 to 2.04) |
| 226 to 325 | 126 to 225 | 2.01 (1.73 to 2.35) |
| 201 to 300 | 101 to 200 | 2.21 (1.91 to 2.56) |
| 176 to 275 | 76 to 175 | 2.61 (2.27 to 3.00) |
| 151 to 250 | 51 to 150 | 2.59 (2.29 to 2.92) |
| 126 to 225 | 26 to 125 | 2.88 (2.56 to 3.25) |
| 101 to 200 | 0 to 100 | 3.35 (2.99 to 3.75) |

The study compared the effect of immediate versus deferred initiation of ARV therapy on the rates of AIDS and death, and death alone in adjacent CD4 ranges. Deferring antiviral therapy until a patient was at a CD4 range of 251-350 cells/mm3 was associated with a higher rate of AIDS and death. However, the hazard ratios were not significantly different in the patients who started therapy above a CD4 count of 350 cells/mm3.

Whether either study will lead to a change in the Department of Health & Human Services guidelines remains to be seen. Both studies are observational by design and subject to selection bias and other residual confounders. However I suspect a trend to initiate treatment earlier, especially if requested by patients, will be a growing practice in developed countries with access to ART. A randomized controlled trial, a "START" trial, designed to answer the "when to start" question is only beginning to enroll patients and will not be completed for several years. HIV

References:

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Sterne, J. When should IV-1-infected persons initiate ART? Collaborative analysis of HIV cohort studies. 16th CROI, Montreal. Abstract # 72LB



About the Author: Dr. Jeffrey Kirchner is Medical Director–Comprehensive Care Center for HIV at Lancaster (PA) General Hospital. He is on AAHIVM's Board of Directors and is chair of *HIV Specialist*'s Editorial Advisory Group.

SECOND IN A SERIES EMR & the HIV Practice

Converting from a Paper to an Electronic System: A Checklist

electronic medical record (EMR) system must be carefully considered as it will require a major commitment of both time and money. Many colleagues have plunged ahead and invested without sufficient planning. and have only partially implemented the systems or abandoned them, returning to their previous paper systems. Here are some steps to consider.

COMMIT

It is imperative to be absolutely certain your practice will benefit from, and will convert to, an EMR. Discuss the pros and cons with your partners and staff and stress the potential obstacles and speed bumps that will lie ahead.

The change is a process, not a simple turn of a switch. Buy-in is essential for success; lack of support from fellow physicians and staff will likely lead to failure. In addition to having a physician "champion," it is helpful to have a proponent from the nonclinical staff. The advocates can then serve as mentors to help the rest of the staff, who may be less technologically savvy and more skeptical about the change.

PLAN

EMR vendors will help your practice choose the necessary system components, but it is best to do your own homework first.

How much is the practice able to spend? While this is an expensive undertaking, there are affordable systems that will suit your practice's needs. Much, if not all, of the cost will be recouped with such efficiences as elimination of transcription costs and a file-clerk's salary, enhanced coding and thus improved reimbursement, improved pay-forperformance bonus documentation, etc.

Do you already have an effective medical management and/or billing system? If so, the EMR system should interface with it. Or do you want a fully integrated EMR and practice management and billing system? Must the EMR be certified by the Certification Commission for Healthcare Information Technology (CCHIT)? For many practices, this

HE DECISION TO PURCHASE and implement an is preferable because it will be current with all governmental requirements and, thus, optimize potential financial recoveries. However, there are many small companies that have not paid the fee to become CCHIT-certified and so are a less costly option that may be appropriate for some.

> It is important to buy a system with full capabilities so it can link to laboratories (for electronic test resulting and reviewing) and pharmacies (for e-prescribing), the potential for a patient portal, etc..

> Implementation should be in phases for higher success. Some practices may consider using an Application Service Provider (ASP), an internet-based system through which software is rented rather than purchased. The server and, thus, the data will be off-site at the ASP. While this is less costly initially, it often will prove more expensive long-term.

> Assess your practice needs in advance. How many locations, how many users and what is the anticipated growth? Try to look ahead from three to five years, but anything further into the future is unpredictable. It can be economically advantageous to purchase the required hardware and user licenses up front instead of adding them later, although the latter approach can certainly be taken. The size of the practice and number of locations will also influence which product is ultimately purchased.

REASSESS

The final step before writing the check should be one last reevaluation to be certain this is the path your practice should travel. Everyone should be in agreement and willing to make short-term sacrifices for long-term rewards.

Once the physicians and office staff are on the same page you can begin the next task of talking to vendors to find the best EMR for your practice. HIV



About the Author: Dr. Richard Prokesch is in private practice in Riverdale, GA. He is chair of AAHIVM's Atlanta, GA chapter, and is on AAHIVM's Board of Directors.

As an AAHIVM member, you are part of a dedicated group of physicians, physician assistants, nurse practitioners and other health care professionals committed to promoting excellence in HIV/AIDS care through advocacy, education, and its professional credentialing program. For more information or to join, visit www.aahivm.org, email membership@aahivm.org, or call 202-659-0699, ext. 11.

Raising The Bar

VERY SPRING, hundreds of HIV-treating physicians, physician assistants, nurse practitioners and pharmacists go through the rigorous process to become certified HIV Specialists™ or HIV Experts through the credentialing program developed in 2001 by the American Academy of HIV Medicine (AAHIVM).

The program is unique, bold and ambitious as it establishes a standard for the delivery of quality HIV care for HIV medical providers on the care continuum. This includes HIV-specializing ID, internal medicine, family practice and general practice physicians (both MDs and DOs), as well as physician assistants (PAs), nurse practitioners (NPs) and pharmacists.

Since its inception, more than 2,000 providers have achieved and/or are maintaining their HIV Specialist™ or HIVExpert credentials. The designation must be renewed every two years.

WHY THEY CREDENTIAL

Why do thousands of providers choose to go through this process every two years, when medical board recertifications are often every six or seven years? Some say it is to inspire confidence in their patients.. Many also require or encourage their clinical staff to be credentialed with AAHIVM.

"Even though I'm board certified in Infectious Diseases," said Michael Ing, MD, AAHIVS, chief of the Infectious Diseases (ID) Section at the JL Pettis Memorial Veterans Administration Medical Center in Loma Linda, CA, "I find being credentialed by AAHIVM is another way to assure my patients and colleagues that I continue to stay current in the rapidly changing field of HIV medicine. I recertify every two years. I encourage my ID Clinic Staff (another ID physician, an ID Nurse Practitioner, and an ID Pharmacist) to also credential and recertify."

David Cennimo, MD, FAAP, AAHIVS, an Infectious Diseases Fellow at the University of Medicine & Dentistry Hospital, Newark, NJ, concurs. "I think AAHIVM credentialing sends a message to patients that we are committed to the absolute pinnacle of HIV care. It also serves as an advertisement to patients who are searching for a physician."

"I wanted to get credentialed to show patients I was dedicated to HIV care and to encourage my colleagues to do the same," said Dr. Andrew Petrol, MD, MS, AAHIVS, assistant

professor of medicine in the Division of Infectious Diseases at the Medical College of Wisconsin. "Continuing to renew my credential is part of staying current in the rapidly changing field of HIV medicine."

[Credentialing is] "a good way to demonstrate current your knowledge base," said Sanjiv Shah, MD, AAHIVS. "All physicians who provide HIV primary care in our practice are certified by AAHIVM. Some insurance companies and the New York State Department of Health also accept my AAHIVS [HIV Specialist"] certification as proof of my capability as a competent HIV provider for their requirements."

HISTORY

In the late 1990's, Los Angeles, CA physician Scott R. Hitt, MD, Chair of President Clinton's Advisory Council on HIV/AIDS was dismayed by the lack of standardization or professional recognition for skilled medical providers in HIV primary care. There was no board certification, no certificate of added qualification (CAQ), and no other properly developed training or measurement mechanism that truly related to expert HIV primary care.

As HIV became more of a chronic, manageable disease, it was clear that ID board certification did not equate to a high level of competency in the long-term primary care management of HIV, simply because many ID providers were not experienced in all of the other aspects of routine primary care.

"Clinical management of HIV infection requires both infectious disease expertise and strong, and broad family practice or internal medicine skills," said Dr. Caperna.

Dr. Hitt and others then helped establish a valid and defensible HIV provider credentialing program leading to the development of the American Academy of HIV Medicine's (AAHIVM's) HIV Specialist™ and HIV Expert exam programs.

In its seventh year, this respected program has been carefully constructed and maintained using expert guidance from the testing and certification industry, yielding a highly defensible measurement mechanism. Inclusion of non-ID physicians, physician assistants (PAs), nurse practitioners (NPs) and HIV specialized pharmacists reflects the reality of the continuum of care that patients receive from diverse provider types.

ELIGIBILITY/DEFINITION OF AN HIV SPECIALIST™/HIV EXPERT:

AAHIVM has established the definition of a credentialed HIV Specialist™ using three industry-standard criteria for knowledge measurement:

- **1. Experience:** Maintain current MD, DO, PA, NP or pharmacist state licensure (or international equivalent), and provide direct, continuous, ongoing care for at least 20 HIV patients over the past two years. There is a supervised certification option for providers who see fewer than 20 HIV patients through which they can be "paired" with a highly experienced provider in his or her region. The expert provider serves as an ongoing clinical consultant to the lower-volume provider, ensuring a wide availability of expert care for patients, even in low incidence areas.
- **2. Education:** Completion of at least 30 credits of HIV-related continuing medical education (CME/CE), or of a documented training fellowship or residency in HIV-related medicine, both within the past two years. Other documented educational activities (such as lecturing or other non-accredited relevant learning activity) can be submitted in lieu of CME/CE credits.
- **3. External Validation:** Successful completion of the AA-HIVM HIV Specialist™ or HIV Expert Credentialing Examination, specific to the year of application.

These three elements must be demonstrated and documented every two years to establish and/or maintain the designation. The "AAHIVS" (HIV Specialist™) or "AAHIVE" (HIV Expert) designations are effective for two years starting January 1 of the year following successful completion of the requirements. The examinee group is established each year by application.

EXAM DEVELOPMENT

The AAHIVM testing instruments are based on appropriate "Role Delineations" (RD), a detailed description of the frontline HIV care provider's job. The HIV Specialist™ RD contains four domains. Within each domain are "tasks," and within each task are "behaviors." Each "behavior" is numbered and weighted, and a classification system is derived. Exam items are written, reviewed and edited, by teams of known subject matter experts (SME's) in HIV care, and are used to create and maintain the content item bank. The draft exam is then assembled each year from the updated content item bank using the classification template. The classification template accounts for a weighted relative importance given to each "behavior," respectful to the typical daily administration of care.

In the words of one... WHY CREDENTIAL WITH AAHIVM?

have been credentialed since 2001. Since 1987, I have provided care to HIV infected people. I participated in the roll out of AZT in the Netherlands where I was an internist in Amsterdam.

I have always felt that there should be a way to be recognized for HIV care without being an ID-trained physician, and the Academy's credentialing program provides a forum for this recognition. Unfortunately, there are plenty of patients who need the care we all are able to provide.

All our clinical staff members are AAHIVM-credentialed HIV Specialists. We have three nurse practitioners, three Internal Medicine physicians and two Infectious Disease physicians.

This exam is very real-treatment oriented. It is written by providers in the field and the questions are relevant and timely. Since HIV practice changes quickly from year to year and guidelines are updated on the Web every year, it is important to have a test that also changes from year to year.

I decided to participate in the exam development because I feel that a general internist brings a different expertise to the table in writing test questions. I feel that my area is unique in that I have been struggling with patients with metabolic problems and cholesterol and diabetes and heart disease long before the HIV community became interested in treating these disorders. I also wanted to give something back to AAHIVM and I thought that participating in the content development of the exam would be a great place to start."

Mary G. Van den Berg-Wolf, MD, FACP, AAHIVS Assoc. Professor, Temple University School of Medicine Dept. of General Internal Medicine

Every year, a peer panel of AAHIVM-credentialed HIV care providers meets to review the bank of content, clear it of irrelevant or outdated content, and update it with items related to new or evolving areas of clinical medicine.

"I was quite honored to receive an invitation to participate in content development," said Dr. Cerrimo. The two days that we spent working on the content earlier this year were very academically stimulating. It was a joy to see so many people committed to keeping this program great."

Dr. Caperna agreed, saying he enjoyed seeing the diversity of HIV care styles coming together to create a comprehensive and balanced exam. "The workshop to review, develop and assemble examination questions involves interaction with fellow HIV clinicians from different regions with surprisingly similar common levels of clinical HIV knowledge," he said. "But we also have different styles of HIV care to share and collaborate on."

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Some providers see participating in the content review and development as the best way to continue improving both the content and the process.

Dr. Petrol said, "The credentialing program raises the standard of care for HIV-positive patients. Constructing an examination is an enormous undertaking. [I am] glad to give my time to help in this important cause."

Draft exams are reviewed by additional teams of expert providers, and undergo final review by the Academy's Credentialing Committee, comprised of thought leaders in the field. Items on the fielded exam also gather statistical data every year, and, over many years of exposure, gain increasing measurement validity for their continued use on future exams.

Sal, a person living with HIV in Washington, DC, was asked his opinion about his own provider's HIV Specialist[™] status. "It makes me feel much more confident in my doctor. I like having the comfort of knowing my doctor can guide me. Now that I know about this program, I know that I would always choose a provider who has voluntarily achieved this certification."

SCORING AND RESULTS

After each exam group has finished testing, a "cut score establishment" process occurs, in compliance with testing industry standards. Yet another independent subject matter expert (SME) panel of known leaders in the field is assembled and establishes a defensible exam cut score range. This occurs in part via a carefully prescribed process of "weighting" the relative perceived difficulty of every item on the exam — process controlled by the AAHIVM testing vendor to avoid bias. The pass point is then set by the AAHIVM Credentialing Committee within the range established through the cut score process.

DEFENSIBILITY AND VALIDITY

The Role Delineation (RD), classification system, classification weighting, cut-score difficulty ratings and item bank have all been created and reviewed by teams of active SME providers working in the field. They represent all geographical regions, all provider types eligible for the exam and a wide variety of clinical practice settings. The exam development work is supervised by expert academicians and doctoral level psychometricians from the AAHIVM testing vendor. The program is operated and managed by testing professionals on the Academy staff and is not supported by funds from any entity related to content on the exam.

ROOM TO GROW

Though the AAHIVM Credentialing program has become a well-respected professional certification activity that uniquely establishes a standard of HIV care knowledge, there is still room for the program to grow and evolve.

"I am still not sure that such frequent recertification examinations are practical, said Dr. Ing. "The ability to construct a pertinent, updated, yet comprehensive examination requires a very large bank of questions which continually need updating. If the examinations every two years contain a significant amount of questions (sometimes up to 20-30%+) on which the examinee already was tested just two years previously, then maybe the question bank would need to be enlarged or the recertification examination would need to be given less frequently."

Amy Sitapati, MD, AAHIVS, associate director of the University of California San Diego Owen Clinic, said, "Last year, regarding test content—I thought some of it was a bit obscure." "I think the test should not be asking specific outcomes when those outcomes might be uncertain"

It is important to note that these challenging opinions are exactly what the Academy cultivates each year in its content development and review meetings. This healthy argument and analysis helps ensure that each exam item has been seen by as many providers as possible in the development process.

STILL THE ONE

While still evolving, the AAHIVM credentialing program is the most widely known and defensible program of its kind, and has a growing role within the HIV medical community.

"The AAHIVM credentialing program is the only program I know of that offers a standardized, reproducible examination in the comprehensive clinical management of HIV infection," said Dr. Caperna. "There is no other organization in the world that offers credentialing in HIV like AAHIVM does."

"The AAHIVM credentialing program is unique in both its breadth and frequency of certification," Dr. Cennimo noted. "It represents a collaborative, multidisciplinary approach to HIV care engaging physicians as well as other health providers. The curriculum is state of the art and strives to incorporate the latest information and issues. I have yet to find a better resource for studying HIV." HIV

 $\textbf{For more information} \text{ on the HIV Specialist}^{^{\sim}} \text{ or HIV Expert credentialing program visit www.} AAHIVM.org, or email credentialing@aahivm.org$

YOUR COMMENTS ARE WELCOME!

Rob Banaszak, Director of Communications

robert@aahivm.org

PH: 202-659-0699, ext. 17

FX: 202-659-0976

Bob Gatty, Editor

bob@gattyedits.com 301-908-1918 240-437-0278

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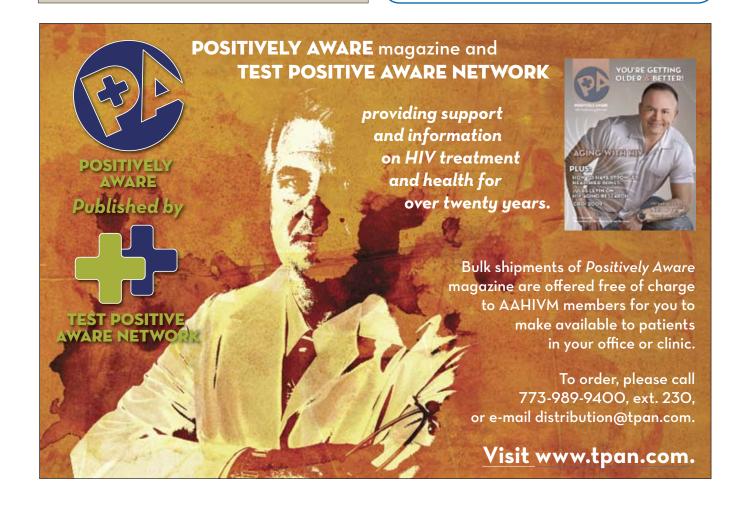
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