AIDS ALERT®

The most comprehensive source of HIV/AIDS information since 1986

August 2011: Vol. 26, No. 8
Pages 85-96

IN THIS ISSUE

Statement of Financial Disclosure: Editor **Melinda Young** and Executive Editor **Gary Evans** report no relationships with companies related to this field of study. Physician Reviewer **Morris Harper**, MD, reports consulting work with Agouron Pharmaceuticals, Gilead Sciences, Abbott Pharmaceuticals, GlaxoSmithKline, and Bristol-Myers Squibb. Nurse Planner **Kay Ball** is a consultant and stockholder with Steris Corp. and is on the speaker's bureau for the Association of Perioperative Registered Nurses.

AHC Media

AIDS Alert Special Report: HIV physician shortage

Is there a doctor in the house? Shortage threatens HIV gains

'The current HIV medical workforce is in trouble.'

There have been recurrent warnings that the United States is facing an HIV clinician shortage that could lead to a critical setback in the fight against AIDS. In response, the federal government is proposing a two-year study to assess the risk of attrition in the HIV clinician workforce.

The Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) has proposed conducting a 24-month HIV clinician workforce study to provide state and federal agencies with estimates of the number of primary care clinicians

Continued on p. 86

CDC trial: HIV PrEP works for heterosexuals

A 63% reduction in HIV risk

A landmark new CDC study dubbed TDF2 — along with a separate trial released July 13, 2011 — provide the first evidence that a daily oral dose of antiretroviral drugs used to treat HIV infection can reduce HIV acquisition among uninfected individuals exposed to the virus through heterosexual sex, the Centers for Disease Control & Prevention reports.

"Given the severity of the HIV epidemic among heterosexual men and women globally — and the critical need for female-controlled prevention methods — this study provides exciting and welcome news," says **Jonathan Mermin**, MD, director of CDC's Division of HIV/AIDS

See CDC trial, p. 88

providing medical care to people living with HIV or AIDS in the United States.

The HRSA survey will seek clinician demographics, their hours in direct patient care, the size and characteristics of their HIV patient load, their patient management strategies, and their workload changes and retirement plans.[1] The study also will seek projections of the magnitude of the expected shortage through 2015.

HIV physicians in some regions don't need a survey; the provider shortage is a major problem now.

"We have approximately 800 HIV-positive individuals in our practice, and I see most of them myself," says **Sharon Lee**, MD, executive director of Family Health Care in Kansas City, KS. Lee also is the chief executive officer of the American Conference for the Treatment of HIV (ACT HIV) and is a clinical professor at the University of Kansas Medical Center's department of family medicine, also in Kansas City. Lee has practiced HIV medicine since the 1980s.

"I have a younger doctor who is going to be leaving in a month, and I don't have another one until next year," Lee says.

There is one other provider in Kansas City who sees a large number of HIV patients, and another who sees about 130 patients. Together the three providers see 90% of the people identified with HIV, Lee says.

If something were to happen to Lee and her clinic had to close, then it would be highly unlikely her 800 patients could be absorbed into the current network of Kansas City HIV providers, she says.

"The current HIV medical workforce is in trouble," she says. "I'm 60, and at some point as people of my generation are retiring, there are a lot of folks who are having trouble finding replacements for themselves."

The HIV Medicine Association (HIVMA) of Arlington, VA, has addressed this issue for the last few years. In one survey published last year, the HIVMA asked Ryan White Part C programs to discuss their most serious challenges. The two top barriers they cited were reimbursement and a lack of qualified providers.

"We found the majority of programs reported difficulty recruiting and retaining HIV clinicians," says **Andrea Weddle**, executive director of HIVMA.

"Our survey was conducted of programs and not individual clinicians, so we've called for a national HIV medical workforce study to assess and get a good handle on the number of HIV clinicians now and how many we'll need," she adds. "HRSA is going to do that, and we're anxious to see the results."

Nationally, it's difficult to find physicians willing to work as HIV clinicians, says **Kathleen**

AIDS Alert® (ISSN 0887-0292), including AIDS Guide for Health Care Workers®, AIDS Alert International®, and Common Sense About AIDS®, is published monthly by AHC Media, a division of Thompson Media Group LLC, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals Postage Paid at Atlanta, GA 30304 and at additional mailing offices.

POSTMASTER: Send address changes to AIDS Alert®, P.O. Box 105109, Atlanta, GA 30348.

AHC Media is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

This activity has been approved for 15 nursing contact hours using a 60-minute contact hour.

Provider approved by the California Board of Registered Nursing, Provider #14749, for 15 Contact Hours.

AHC Media is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

AHC Media designates this enduring material for a maximum of 18 *AMA PRA Category 1 Credits™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

This enduring material is intended for HIV/AIDS physicians and nurses. It is in effect for 36 months from the date of publication.

This continuing education program does not fulfill State of Florida requirements for AIDS education.

Because of the importance of investigational research relating to HIV/AIDS treatment, AIDS Alert sometimes discusses therapies and treatment modalities that have not been approved by the U.S. Food and Drug Administration.

Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

SUBSCRIBER INFORMATION

Customer Service: (800) 688-2421. Fax: (800) 284-3291. Hours: 8:30 a.m.-6 p.m. M-Th, 8:30 a.m.-4:30 p.m. Friday EST. E-mail: customerservice@ahcmedia.com. Web site: www.ahcmedia.com.

Subscription rates: U.S.A., one year (12 issues), $499. Add $17.95 for shipping & handling. Approximately 15 nursing contact hours or 18 AMA PRA Category 1 Credits™, $549. Outside U.S., add $30 per year, total prepaid in U.S. funds. Discounts are available for group subscriptions, multiple copies, site-licenses or electronic distribution. For pricing information, call Tria Kreutzer at 404-262-5482. Missing issues will be fulfilled by customer service free of charge when contacted within one month of the missing issue date. Back issues, when available, are $83 each. (GST registration number R128870672.)

Editor: **Melinda Young**, (864) 241-4449.
Executive Editor: **Gary Evans**, (706) 310-1727, (gary.evans@ahcmedia.com).
Production Editor: **Kristen Ramsey**.

EDITORIAL QUESTIONS?
Call Gary Evans
at (706) 310-1727.

Squires, MD, professor of medicine, director of the division of infectious diseases, Jefferson Medical College, Thomas Jefferson University of Philadelphia, PA.

Pressure to go into a specialty

There are several reasons behind the trend, including massive student loan debt.

"The average medical school debt is $170,000 for people finishing internal medicine," says **Donna E. Sweet**, MD, AAHIVS, MACP, a professor of internal medicine at the University of Kansas School of Medicine in Wichita, KS. Sweet is the chair of the American College of Physicians (ACP) Foundation initiative's national HIV workforce expansion steering committee.

"It's like having a mortgage without a house," Sweet adds. "So when they get their first job the impetus is to get into a higher-paying specialty."

These medical students with their huge college debts often believe that going into a specialty area of medicine will help them pay back their obligations, Squires says.

"So there is a dearth of people who are interested in doing primary care medicine," Squires says.

Also, even when medical students decide to go into internal medicine, only a small percentage chooses outpatient medicine, Sweet notes.

"They're hospitalists and go into subspecialties," Sweet says. "It's the money, but also the lifestyle."

Hospitalists work 12-hour days and then get seven days off, while physicians in outpatient medicine have to be available around the clock, she explains.

"Our kids are much more aware of their own needs," Sweet says. "People like me carry a beeper and talk to people at night and make arrangements to have people seen so they don't have to go into the emergency department."

Sweet has experienced this problem first-hand as her own internal medicine practice has had to expand to handle an additional 100-plus HIV patients a year, although Ryan White funding has not kept pace.

"In my clinic, I've made a commitment that we'll find a spot for new patients," she says.

But it's increasingly difficult, and her clinic needs at least one more HIV physician, she says.

"I lost the other HIV physician in my clinic a year ago, and we haven't found one who wants to do HIV care," Sweet says. "This is a time of change and uncertainty."

Another reason for the reduced new HIV physician pipeline is that new physicians who might be attracted to HIV care are more interested in treating international populations, Squires notes.

"I've heard from medical students and residents that their interest in HIV is on an international arena rather than here in the United States," Squires says.

There still are altruistic medical students entering the workforce, but their altruistic tendencies are taking them elsewhere, Lee says.

"I think the issue is that those folks who are tending to be in medicine for altruistic reasons are finding sexier areas to go into," Lee adds. "So if they do HIV care, they're much more likely to do that in Africa; we're exporting some of our doctors and have a brain drain going on."

For new physicians in the 1980s, HIV care was a higher calling. Their patients often were young, very sick, and dying.

"I opened a clinic to care for the poor in Kansas City at the exact moment a lot of people with HIV were losing their jobs and losing their insurance and becoming poor while they were afflicted with this terrible disease that no one had any treatments for," Lee recalls. "There was a difficult period of time when we lost 200 patients a year."

U.S. docs: HIV `not a big problem'

Today's new doctors see HIV care differently. It's the era of antiretrovirals and most Americans with the disease are living long enough to have to worry about heart disease.

Clinicians in training in the 2010s do not get as much exposure to patients with HIV as did young clinicians of the 1980s and 1990s, Squires explains.

"Their perception is that HIV is not a big problem in the United States," Squires says. "Also, it's because residency training for internal medicine is on the inpatient side, and you don't see a lot of HIV on the inpatient side now; it's become an ambulatory care specialty."

The HIV clinician shortage is part of a bigger picture in which the U.S. will experience a shortage of more than 90,000 doctors in the next decade, according to the Washington, DC-based Association of American Medical Colleges (AAMC) in a recent report.

"We're very concerned about the physician crisis and shortage we're facing," says Len Marquez, director of government relations for the AAMC.

"In the next three to five years we're looking at a physician shortage of greater than 60,000 physicians," he adds. "And by 2020, it will be more than 90,000."

The shortage comes at a time when baby boomers are on Medicare, and a third of the physician workforce will be aging and ready to retire, Marquez says.

"You can't just flip a switch and say, 'Let's have more doctors,'" he says. "We need 10 years to educate and train an MD, and we have a concern that if this problem is not addressed now we'll have a real crisis."

While family medicine is facing a bit of a crisis, it's not to the extent of the HIV physician shortage, Lee says.

"The best way to handle the HIV clinician shortage is to take physicians trained as a family doctor and teach them specifics about HIV," Lee suggests. "The problem is our medical schools and residency programs have not geared up quickly enough to respond to this disease as an ambulatory outpatient disease, and this is where we get [in a crunch] right now."

This is why HIVMA is making the provider shortage a priority.

"We're trying to help sort out the workforce issues," says Lee, who is on the HIVMA board.

HIVMA and the American Academy of HIV Medicine jointly made a number of recommendations for addressing the shortage. These included loan forgiveness for some HIV medical providers, increased federal support of clinical training opportunities, and increased Medicaid payment rates for HIV providers. (*See story on potential solutions to crisis, p. 90*).

The current anti-spending climate on Capitol Hill would make federal funding solutions seem improbable, but no less necessary, Marquez notes.

"We have this physician shortage, and it will be a crisis if you just look at the numbers, so we need to do something to address this," he says. "The question becomes, 'How do we pay for this?' And that's the pushback we hear."

REFERENCE

1. Agency information collection activities: proposed collection: comment request. *Fed Reg*. May 27, 2011; 76(103):30949-30950. ■

CDC trial

Continued from cover

Prevention. "The next important step is to fully review the data and assess when and how PrEP should best be used for HIV prevention among heterosexuals."

The CDC TDF2 study, conducted in partnership with the Botswana Ministry of Health, found that a once-daily tablet containing tenofovir disoproxil fumarate and emtricitabine (TDF/FTC, known by the brand name Truvada) reduced the risk of acquiring HIV infection by roughly 63% overall in the study population of uninfected heterosexual men and women. The strategy of providing daily oral antiretroviral drugs to uninfected individuals prior to HIV exposure is called pre-exposure prophylaxis, or PrEP.

In a separate announcement, the University of Washington (UW) released preliminary results of the Partners PrEP study, which also found that daily PrEP reduced HIV transmission among heterosexual couples in Kenya and Uganda. CDC co-managed two of the nine sites for this study. The Partners PrEP study found that two separate antiretroviral regimens — tenofovir (known by the brand name Viread) and TDF/FTC — significantly reduced HIV transmission among serodiscordant couples, in which one partner is infected with HIV and the other is not. The findings were released after the trial's independent data safety monitoring board conducted an interim review of the trial data and recommended that the placebo arm of the study be discontinued early due to strong evidence of effectiveness, so that all participants could be offered PrEP. For more information on this study, visit http://www.uwicrc.org.

The CDC study findings were discussed at the International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention in Rome by the CDC principal investigator Michael C. Thigpen, M.D. A previous study (iPrEx) had already shown PrEP reduced HIV transmission among men who have sex with men (MSM) last fall, but it was not previously known if the strategy could prevent HIV infection among heterosexuals.

The CDC and UW study results follow preliminary findings from another PrEP study earlier this year, the FEM-PrEP trial, which did not demonstrate a protective effect of PrEP among heterosexual women. Researchers from that study are conducting additional analyses, including a close examination of adherence among women in the trial, to better understand the potential reasons for

the interim outcome of that study.

In addition to finding PrEP reduced the risk of HIV infection by roughly 63% in the study population overall, researchers from CDC's TDF2 study also conducted a separate analysis to better understand the level of effectiveness among trial participants believed to be taking study medications. This analysis excludes any HIV infections that occurred more than 30 days after a participant's last reported drug dose, because those individuals could not have been taking study pills at the time of infection. These results indicate that TDF/FTC reduced the risk of HIV infection by 78%.

Overall, a total of 1,219 HIV-uninfected heterosexual male and female participants (aged 18-39) in Botswana were enrolled in the TDF2 trial and randomly assigned to take a daily TDF/FTC pill or a placebo pill. All participants in the study were provided comprehensive HIV prevention services, including male and female condoms, intensive risk-reduction behavioral counseling, and testing and treatment for sexually transmitted infections. Three participants were determined to be HIV-infected at the time of enrollment, and 16 of the participants randomized never began study medication. Those individuals were excluded from these analyses, which include data on the remaining 1,200 participants who were HIV-negative at the time of enrollment and began study medication (54.7 % male, 45.3 % female).

In the primary analysis, among the 601 participants who received TDF/FTC, there were nine who became infected with HIV during the study. Among the 599 individuals who received a placebo, 24 became infected with HIV during the study. This translates into a statistically significant overall reduction in risk of 62.6%.

Among participants known to have a supply of study drugs (the separate analysis described above), protection was even greater, with a statistically significant risk reduction of 77.9%. Additional analyses of the level of effectiveness based on the level of adherence to the study regimen, as well as an examination of the level of protection provided by detectable drugs in the blood, are under way but are not yet complete.

Consistent with other PrEP studies, preliminary analyses did not identify any significant safety concerns associated with daily use of TDF/FTC. Participants assigned to receive the study drug were more likely than those assigned to the placebo arm to report nausea, vomiting, and dizziness.

All participants infected during the study were immediately referred to medical care. All uninfected participants will be offered the study drug for a year as part of a CDC follow-up study.

CDC officials note that the trial would not have been possible without the dedication of the more than 1,200 participants and the strong collaboration between the Botswana Ministry of Health and CDC. Additional study funding was also provided by the National Institutes of Health, and Gilead Sciences, based in Foster City, Calif., donated the study drug.

TDF/FTC is FDA-approved and marketed for use in the United States under the name Truvada, for use in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older. It is not FDA-approved for PrEP. In the wake of the findings, CDC will fully review the data from all of the heterosexual trials and will begin working with a range of stakeholders and with established guidelines development working groups. The goal is to develop guidance specific to the use of PrEP among heterosexual men and women in the United States.

CDC urges heterosexual men and women and their health care providers in the United States to await that guidance before considering PrEP. However, if providers have patients for whom they believe the initiation of PrEP is urgent, CDC recommends following the cautions and procedures previously published for PrEP use in MSM (http://1.usa.gov/pXNSHI). The Partners PrEP finding that TDF alone was as effective as TDF/FTC in studies for prevention of heterosexual transmission suggests that providers may consider daily doses of either regimen in this population. However, for MSM, the interim guidance remains that only TDF/FTC should be prescribed, because there are no data on effectiveness for TDF alone to prevent HIV acquisition by MSM.

It will also be critical for providers to consider factors unique to heterosexuals, including concerns related to the use of PrEP among women who may become pregnant.

Points to ponder

Importantly, anyone considering using PrEP should know:

- PrEP should only be used among individuals who have been confirmed to be HIV-negative. Initial and regular HIV testing is critical for anyone considering using PrEP. All individuals considering PrEP must also be evaluated for other

health conditions that may impact PrEP use.

• PrEP should never be seen as the first line of defense against HIV. It was only shown to be effective in clinical trials when provided in combination with regular HIV testing, condoms, and other proven prevention methods.

• Taking PrEP daily is critical. No other dosing regimen was evaluated in these studies.

• PrEP must be obtained and used in close collaboration with health care providers to ensure regular HIV testing, risk reduction and adherence counseling, and careful safety monitoring. Anyone considering using PrEP should speak with his or her doctor.

• PrEP has only been shown in clinical trials to reduce HIV infection among heterosexual men and women and among men who have sex with men. At this time, there are no data on its benefits or risks among injection drug users.

• Because pregnant and breastfeeding women were excluded from participation in PrEP trials, further evaluation of available data will be needed before any recommendations can be made regarding the use of PrEP for women during conception, pregnancy, or breastfeeding.

For more information on efforts to evaluate and plan for PrEP implementation in the United States, visit www.cdc.gov/hiv/prep. ■

Special Report: HIV physician shortage

National groups look to increase HIV doctors

Increased federal support is top need

Medical schools, HIV organizations, foundations, and the federal government will need to work together to avert a crisis as the supply of HIV-trained physicians dwindles, experts say.

Fortunately, all three groups have begun efforts to solve the problem.

"This is a challenging time," says **Andrea Weddle**, executive director of the HIV Medicine Association (HIVMA) of Arlington, VA.

"There are opportunities to hopefully make some headway, but we have to be creative to make those happen," Weddle says.

The Association of American Medical Colleges (AAMC) of Washington, DC, has urged its members to increase the number of students by nearly a third to address the national physician shortage, says **Len Marquez**, director of government relations for the AAMC.

AAMC's data show that there will be an additional 7,000 medical school graduates every year over the next decade. But there might be no substantial increase in the number of residency training positions supported with federal funding, and this is the bigger issue, Marquez says.

"The problem is if you increase the number of graduates, but they don't have residency slots to match the increased numbers then you face a problem where you have more graduates than residency slots, and you end up losing physicians," Marquez says.

Any residency program can increase its number of residents being trained, but it has to be approved, he adds.

"There's a cap on the number of slots that have a portion of the costs reimbursed by Medicare," he says.

The U.S. Congress can lift the freeze on Medicare-supported residency positions, which has been in place since 1997. With a 15% increase in these positions, teaching hospitals could prepare an additional 4,000 physicians a year.

Networking, mentoring

There are other changes the federal government and others can make to increase our supply of HIV physicians. Even current HIV clinicians can attract new doctors to their field through networking and mentoring altruistic-minded health care practitioners before they enter medical school. (*See related story p. 91.*)

For example, the HIVMA and the American Academy of HIV Medicine jointly have recommended that the United States take these actions to address the HIV clinician shortage:

• **Increase the National Health Service Corps loan forgiveness program to target HIV medical providers that work at Ryan White Part C-funded sites:** The Health Resources and Services Administration (HRSA) under the U.S. Department of Health and Human Services (HHS) has been charged with creating a negotiated role-making committee to look at criteria used in the loan forgiveness program, Weddle says.

"The criteria now used to designate clinician shortages were developed in the 1970s and have not been updated," she says. "So HRSA looked at those criteria and made recommendations to update them."

HIVMA advocates for the criteria to include areas with high rates of HIV disparity and underservice, she adds.

"We'd like to increase opportunities for loan forgiveness in HIV clinics funded by Ryan White," Weddle explains.

One solution would be for the loan forgiveness program to include a mechanism for HIV clinics to qualify for the program if they are serving special populations, where the patients are low income and underserved, Weddle says.

The HRSA negotiated role-making committee is expected to come up with a proposal by October, she adds.

• **Provide more federal support for clinical training opportunities in HIV medicine:** HIVMA began

AIDS Alert Special Report: HIV physician shortage

Physician "grew her own" HIV doc for practice

Volunteer returns as doc with a calling

At least one HIV physician is not waiting for a federal or foundation-based solution to her personal HIV doctor shortage problem. Instead she has tackled the problem by "growing" her own HIV clinician.

Sharon Lee, MD, a long-time HIV clinician, provides care to indigent patients at Southwest Boulevard Family Health Care in Kansas City, KS. Lee and an HIV doctor colleague have provided care for 800 patients at the practice which Lee opened decades earlier when her patients mostly needed palliative care and much of the care took place in inpatient settings.

But the unthinkable happened when her colleague of the past five years announced he had to move because of his wife's job in another state.

"So he's looking for a job in New Mexico in HIV care," Lee says. "It's not so bad that we're losing an HIV treater in the nation; I'm just losing an HIV treater in my practice."

Luckily, Lee has a replacement in the wings: "I have a fellow finishing his residency in family medicine, and he'll be joining me next summer," she says.

The new HIV physician was a volunteer in Lee's clinic when he was a high school student. He became dedicated to the cause of treating HIV/AIDS patients and attended medical school with that ambition in mind.

"I'm really excited," Lee says. "We have our home-grown fellow coming back."

Training this young family medicine doctor comes naturally to Lee who also began her career in family medicine, opening a clinic for the poor at the same time doctors nationwide began to see the strange symptoms that later were identified as characteristic of AIDS.

"The first time I saw somebody in my office with AIDS, I called one of my infectious disease buddies and said, 'I think I'm seeing this thing we've heard about – AIDS, and I don't know what to do,'" Lee recalls. "He said, 'If he doesn't have insurance, don't send him to me because you can handle it since there's not much we can do for them; the treatment is mostly to die with dignity.'"

Lee took his advice, received a certification in palliative care as soon as this was available, and soon became one of the largest HIV care clinics in the area.

HIV clinicians might not have any control over national training of HIV doctors or the number of available, federally-supported residency spots. But they can mentor students and others interested in becoming HIV physicians, growing their own replacements as their retirement years approach, Lee suggests.

"It will be part of the job of doctors who are doing the work to attract these new doctors into the fold," she says.

The new doctor who will be joining Lee's clinic received financial help with his medical education, and that's another important factor. HIV doctors could help interested individuals find grants and loan-forgiveness programs that would make medical school fiscally feasible.

"When people choose to work at our clinic they are making a very significant financial sacrifice," Lee says. "In our situation, that's particularly true, but that's also the case for most primary care doctors."

People who choose to go into primary care, which is the least lucrative of the medical professions, do so because they're interested in helping others, she adds.

"We can help them be more interested by mentoring them," Lee says. ■

the HIV Minority Clinical Fellowship Program four years ago. The small, but successful initiative targets fellowship grants to African American and Latino physicians who wish to pursue a year of HIV-dedicated training, Weddle explains.

"Physicians who are willing to serve underserved populations can use this as a pathway to enter HIV medicine, and we've trained 10 physicians as of June 30, 2011," she says. "The feedback we've gotten has all been positive, and all of the physicians are staying in the HIV field, most continuing to work with underserved populations, and most say it would not have been possible without this year of training."

This is a good model that should be expanded with federal support, Weddle says.

"Right now there's not a specific training pathway for physicians, nurse practitioners, or physician assistants who are interested in focusing on HIV medicine in their career," she says.

• **Raise Medicaid payment rates for HIV providers:** Currently, 40% of HIV patients depend on Medicaid for health coverage, and that percentage is expected to grow as health reform is implemented: "This is the solution that's more complicated and the one we're most concerned about," Weddle says. "The Affordable Care Act does increase payments for primary care physicians up to Medicare levels for some services, but it's narrowly defined."

The increase basically covers internists and family medicine and pediatricians who primarily provide primary care services, she adds.

"We're concerned HIV clinicians will be left out of this," Weddle says.

Ideally, states would have flexibility to create coordinated programs similar to the level of care under Ryan White for chronic and HIV care delivery, she says.

"We're hoping states will provide these for HIV beneficiaries," she adds. "We hope to document the value of investing in payment upfront in terms of cost effectiveness and patient outcomes."

Another model for addressing the HIV workforce shortage is one that combines physician organizations with private industry and foundation funds. For instance, the American College of Physicians (ACP) Foundation, with a Bristol-Myers Squibb Awards Grant, has an HIV workforce capacity building initiative that will address the U.S. medical provider shortage.

Called Positive Charge, the $2.93 million, three-year grant will support skills transfer programs that benefit HIV patients in areas of high unmet needs. For instance, there will be a mentoring program that pairs HIV experts with primary care clinicians in areas of high HIV prevalence.

"Increasingly, we have a young, minority, disenfranchised population that often has no health insurance, and Ryan White is maxed out," says **Donna E. Sweet**, MD, AAHIVS, MACP, a professor of internal medicine at the University of Kansas School of Medicine in Wichita, KS. Sweet is the chair of the American College of Physicians (ACP) Foundation initiative's national HIV workforce expansion steering committee.

There are federally-funded community health centers (CHC) that could care for this population. CHCs are receiving increased funding through the Affordable Care Act, but these primary care sites have clinicians who typically are untrained in HIV care, Sweet explains.

"My group is trying to mentor people at CHCs," she adds. "We're trying to expand the workforce."

The plan is to expand HIV care to CHCs and other primary care settings because HIV disease now is a chronic illness, so CHCs could be a medical home for many patients with HIV infection, Sweet says.

CHCs provide access to care for everyone, regardless of their ability to pay, she notes.

The HIV new infection rate continues at a steady pace, and those already infected with the virus are living longer, which means there are rising numbers of people in need of HIV care.

This trend will continue as predictions suggest that half of the people with HIV/AIDS by 2015 will be over the age of 50 and in need of colonoscopies, heart disease treatment, and other preventive measures for older populations, Sweet says.

The concept of medical homes for HIV patients is not new, as Ryan White pioneered the model of providing care for all of the medical needs HIV patients have, she notes.

What's new is the idea of building the medical home for HIV patients in hundreds of primary care settings where physicians are not infectious disease specialists, she adds.

Primary care physicians in private community practices also could be trained to handle HIV patients.

"Primary care is becoming the major model of care because we've been so successful at controlling direct replication of HIV," says **Kathleen Squires**, MD, professor of medicine, director of the division of infectious diseases, Jefferson Medical College, Thomas Jefferson University of Philadelphia, PA. ■

IAS 2011: AIDS at a watershed moment

'Remember that history will judge us.'

The global AIDS response is at "a scientific watershed" that includes both dramatic recent advances against HIV and the formidable challenge of extending the benefits to impoverished nations. That was the common theme recently in Rome at the opening of the 6th IAS Conference on HIV Pathogenesis, Treatment and Prevention (IAS 2011), where some 5,000 researchers, scientists, clinicians, community leaders and policy experts gathered.

"The excitement around these advances in research — whether they be the CAPRISA 004 vaginal gel, the HPTN 052 study on treatment as prevention, talk around the path towards a cure, or the encouraging signs on PrEP and vaccines — is very much driving the debates and discussions," said **Elly Katabira**, IAS 2011 International Chair and International AIDS Society President.

Translating this momentum to reduced infections and better courses of treatment for high-risk populations was a common subtext at the conference.

"IAS 2011 delegates, like many professionals working in the international response to HIV, are understandably excited about recent scientific breakthroughs," said IAS 2011 Local Co-Chair **Stefano Vella**, Research Director at the Istituto Superiore di Sanità (ISS). "However, we need to ensure that the advances we are making in research such as the now proven concept of antiretroviral treatment as a means of HIV prevention — is translated into action for people in developing countries.

In an opening session keynote speech, UNAIDS Executive Director **Michel Sidibé** said that gaps in access to HIV treatment within and between countries and key populations were an affront to humanity that can and must be closed by innovations in developing, pricing and delivering treatments and commodities for HIV, TB, malaria, reproductive health and other health issues.

"We have to remember that history will judge us not by our scientific breakthroughs, but how we apply them," said Sidibé.

The IAS Conference series focuses on the translation of research into practice, particularly in low- and middle-income countries. The conference revealed promising new data across several key scientific tracks — particularly in the areas of HIV treatment as prevention, HIV cure efforts, new drugs and new antiretroviral combinations, and the scale up of effective prevention and treatment interventions in resource-limited settings. From a scientific perspective, there was an air of optimism that hasn't been seen since the mid-1990s, when the promise of combination antiretroviral therapy (ART) began to be realized. ■

IAS: `Game changers' must be widely adopted

'The old dichotomies no longer exist'

Researchers and clinicians are achieving game-changing results that are revolutionizing HIV prevention, care and treatment, **Michel Sidibé**, Executive Director of the Joint United Nations Programme on HIV/AIDS (UNAIDS) said recently in Rome at the IAS 2011 conference.

Outlining an ambitious agenda of "Zero new HIV Infections, Zero discrimination, and Zero AIDS-related deaths," Sidibé said such lofty goals are very much on the table.

"These tools are not so far from our reach," he said. "The old dichotomies between prevention and treatment no longer exist, as the science to support each is increasingly converging. We can expect further decreases in HIV stigma and discrimination as passionate advocates and activists, and in particular, people living with HIV, raise their voices and take charge of their health."

The scientific community has provided true breakthroughs this past year, he noted.

"Results from clinical trials have vastly widened our prevention tool-box, including oral pre-exposure prophylaxis and vaginal microbicides that reduce the risk of HIV transmission," he said. "Most recently, the extraordinary results of HPTN052, in which antiretrovirals used by people living with HIV dramatically reduced the risk of HIV transmission to their HIV-negative partners, give us further hope that we will continue to see reductions in the number of new HIV infections."

The Joint United Nations Programme on HIV/AIDS (UNAIDS) is working closely with scientific and community partners to understand how the results from this groundbreaking study can most effectively be implemented, and to advocate for

this implementation, while at the same time ensuring that the rights of people living with HIV are protected, Sidibé said.

Already last year, UNAIDS, WHO and other global and local partners began exploring ways of effectively expanding access to antiretroviral treatment and launched the Treatment 2.0 initiative. Treatment 2.0 is a "radically simplified treatment platform" that will also produce benefits in preventing HIV transmission, he said. The five pillars of Treatment 2.0 are optimized drug regimens, point of care and other simplified lab technologies, cost reductions, service delivery modifications and community mobilization.

At a recent United Nations high level meeting on AIDS, countries set forth bold new targets in a new and robust Political Declaration on HIV. Unanimously adopted at the meeting, the declaration calls on UN Member States to redouble efforts to achieve universal access by 2015.

The declaration is also commendable for recognizing key populations at higher risk of HIV infection, including men who have sex with men, people who inject drugs and sex workers. This is the first time a United Nations declaration has recognized these key populations and will be instrumental in reaching groups most at risk of exposure to HIV with services and new technological and scientific advances, he said.

"In these extraordinary times it is incumbent upon us to continue to advocate for the resources that we need to implement these game-changers, while at the same time ensuring that funding for the next generation of game-changing science is maintained," Sidibé said. "With commitment, perseverance and vision, every day brings us one step closer to achieving our collective goals and lead us to a world without HIV." ■

FDA NOTIFICATIONS

HCV virus protease inhibitor is approved

On May 23, 2011, the Food and Drug Administration approved telaprevir (Incivek®), an hepatitis C virus (HCV) protease inhibitor. Telaprevir is the second direct acting antiviral drug against the hepatitis C virus to be approved.

Telaprevir, in combination with peginterferon alfa and ribavirin, is indicated for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease, including cirrhosis, who are treatment-naïve (patients who have not received interferon-based drug therapy for their infection) or who have previously been treated with interferon-based treatment and not responded adequately, including prior null responders, partial responders, and relapsers.

The current standard of care for patients with hepatitis C infection is peginterferon alfa and ribavirin taken for 48 weeks. Less than 50 percent of patients respond to this therapy.

The following points should be considered when initiating treatment with telaprevir:

• Telaprevir must not be administered as monotherapy and must only be prescribed with both peginterferon alfa and ribavirin.

• A high proportion of previous null responders (particularly those with cirrhosis) did not achieve a Sustained Virologic Response (SVR) and had telaprevir resistance-associated substitutions emerge on treatment with telaprevir combination treatment.

• Telaprevir efficacy has not been established for patients who have previously failed therapy with a treatment regimen that includes telaprevir or other HCV NS3/4A protease inhibitors.

DOSAGE AND ADMINISTRATION:

Telaprevir/Peginterferon Alfa/Ribavirin Combination Treatment:

The recommended dose of telaprevir tablets is 750 mg (two 375-mg tablets) taken orally 3 times a day (7-9 hours apart) with food (not low fat).

For specific dosage instructions for peginterferon alfa and ribavirin, refer to their respective prescribing information.

Duration of Treatment:

The recommended duration of treatment with telaprevir is 12 weeks in combination with peginterferon alfa and ribavirin. HCV-RNA levels should be monitored at weeks 4 and 12 to determine combination treatment duration and assess for treatment futility.

CONTRAINDICATIONS :

Telaprevir combination treatment is contraindicated in:

• Pregnant women and men whose female partners are pregnant because of the risks for birth defects and fetal death associated with ribavirin.

• Telaprevir is contraindicated when combined with drugs that are highly dependent on CYP3A for clearance and for which elevated plasma concentrations are associated with serious and/or life-

threatening events (narrow therapeutic index).

• Telaprevir is contraindicated when combined with drugs that strongly induce CYP3A and thus may lead to lower exposure and loss of efficacy of telaprevir.

• The contraindicated medications include the following:

— Alfuzosin
— Rifampin
— Dihydroergotamine
— Ergonovine, ergotamine, methylergonovine
— Cisapride
— St John's Wort (Hypericum perforatum)
— Atorvastatin, lovastatin, simvastatin
— Pimozide
— Sildenafil (Revatio®) or tadalafil (Adcirca®) [for treatment of pulmonary arterial hypertension].

WARNINGS AND PRECAUTIONS:

The Warnings and Precautions for telaprevir include drug interactions and the following:

• Pregnancy (Use with Ribavirin and Peginterferon Alfa): Ribavirin may cause birth defects and fetal death; avoid pregnancy in female patients and female partners of male patients. Patients must have a negative pregnancy test prior to therapy and have monthly pregnancy test and for six months after treatment ends. Hormonal contraceptives may not be reliable during telaprevir dosing and for up to two weeks following cessation of telaprevir. During this time, female patients of childbearing potential should use 2 non-hormonal methods of effective birth control. Examples of non-hormonal methods of contraception include a male condom with spermicidal jelly or female condom with spermicidal jelly (a combination of a male condom and a female condom is not suitable), a diaphragm with spermicidal jelly, a cervical cap with spermicidal jelly, or an intrauterine device (IUD).

• Serious Skin Reactions: Serious skin reactions, including Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) and Stevens-Johnson Syndrome (SJS) were reported in less than 1% of subjects who received telaprevir combination treatment compared to none who received peginterferon alfa and ribavirin alone. These serious skin reactions required hospitalization, and all patients recovered. The presenting signs of DRESS may include rash, fever, facial edema, and evidence of internal organ involvement (e.g., hepatitis, nephritis). Eosinophilia may or may not be present. The presenting signs of SJS may include fever, target lesions, and mucosal erosions or ulcerations (e.g., conjunctivae, lips).

If a serious skin reaction occurs, all components of telaprevir combination treatment must be discontinued immediately and the patient should be promptly referred for urgent medical care.

• Rash: Rash developed in 56% of subjects who received telaprevir combination treatment.

COMING IN FUTURE MONTHS

- Microbicide research extends to prevention for pregnant women
- ADAP rolls skyrocket through summer with funding uncertainty
- Experts discuss best strategies in HIV/hepatitis C coinfection care
- More from AIDS/HIV conference in Rome

CNE/CME QUESTIONS

1. The Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) has proposed conducting a 24-month HIV clinician workforce study that will seek which of the following information?
   A. Clinician demographics
   B. Clinician's hours in direct patient care
   C. The size and characteristics of clinicians' HIV patient load
   D. All of the above

2. According to the Washington, DC-based Association of American Medical Colleges, the United States will have a physician shortage by 2020 of how many doctors?
   A. 35,000
   B. 61,000
   C. 84,000
   D. 90,000

3. Which of the following is *not* a recommendation made by the HIV Medicine Association and the American Academy of HIV Medicine for actions the United States should take to address the HIV clinician shortage?
   A. Increase the National Health Service Corps loan forgiveness program to target HIV medical providers that work at Ryan White Part C-funded sites
   B. Have the federal government invest in medical schools, creating tuition-free slots for 25% of students on HIV medical tracks.
   C. Provide more federal support for clinical training opportunities in HIV medicine
   D. Raise Medicaid payment rates for HIV providers

Severe rash (e.g., a generalized rash or rash with vesicles or bullae or ulcerations other than SJS) was reported in 4% of subjects who received telaprevir combination treatment compared to less than 1% who received peginterferon alfa and ribavirin alone. The severe rash may have a prominent eczematous component.

Patients with mild to moderate rashes should be followed for progression of rash or development of systemic symptoms. If rash progresses and becomes severe or if systemic symptoms develop, telaprevir should be discontinued. Peginterferon alfa and ribavirin may be continued. If improvement is not observed within 7 days of telaprevir discontinuation, sequential or simultaneous interruption or discontinuation of ribavirin and/or peginterferon alfa should be considered. If medically indicated, earlier interruption or discontinuation of ribavirin and peginterferon alfa should be considered. Patients should be monitored until the rash has resolved. Telaprevir must not be reduced or restarted if discontinued due to rash. Treatment of rash with oral antihistamines and/or topical corticosteroids may provide symptomatic relief but effectiveness of these measures has not been established. Treatment of rash with systemic corticosteroids is not recommended. ■

CNE/CME OBJECTIVES & INSTRUCTIONS

The CNE/CME objectives for AIDS Alert, are to help physicians and nurses be able to:

- Identify the particular clinical, legal, or scientific issues related to AIDS patient care;
- Describe how those issues affect nurses, physicians, hospitals, and clinics;
- Cite practical solutions to the problems associated with those issues.

To earn credit for this activity, please follow these instructions.

1. Read and study the activity, using the provided references for further research.
2. Log on to www.cmecity.com to take a post-test; tests can be taken after each issue or collectively at the end of the semester. First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice or renewal notice.
3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.
4. After successfully completing the last test of the semester, your browser will be automatically directed to the activity evaluation form, which you will submit online.
5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly.