AIDS ALERT®

The most comprehensive source of HIV/AIDS information since 1986

AHC Media LLC

IN THIS ISSUE

- Details of HIV clinic survey ..3
- AIDS in America sends Obama a request for first 100 days 4
- HIV-infected women often switch doctors because of communication problems 5
- Suggestions for new president.....6
- Teen attitudes and condom use.....7
- **FDA Notifications 8**
  — Final rule issued on condom classification
  — New ART adult guidelines released
  — Maraviroc label changes

Statement of Financial Disclosure:
Editor Melinda Young, Managing Editor Gary Evans, and Associate Publisher Coles McKagen 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.

JANUARY 2009
VOL. 24, NO. 1 • (pages 1-12)

HIV physician shortage may cause increased access problems

A changing of the generational guard

National HIV/AIDS groups predict a shortage of HIV physicians in the coming years as the doctors who became impassioned to work in this field early in the epidemic begin to retire.

"We share the medical provider workforce crisis that we've read about so much in primary care," says **Christine Lubinski**, vice president for global health at the Infectious Diseases Society of America (IDSA), who spoke at a recent teleconference on the first 100 days of President Barack Obama's administration and what Obama could do to help fight the domestic HIV/AIDS epidemic.

"We have a limited number of clinicians, many of whom have been doing this work since the beginning of the epidemic, and many of whom who will be looking for retirement in the next five to 10 years," Lubinski says. "And there's no evidence that there are providers to replace them."

Already, IDSA has received reports of areas that have lost their HIV clinicians and haven't been able to replace them, she adds.

The HIV Medicine Association (HIVMA) of Arlington, VA, conducted a survey of HIV clinics last year in collaboration with the Forum for Collaborative HIV Research at George Washington University in Washington, DC.

The survey's early results indicate that close to 70% of the programs surveyed said it was very difficult to recruit physicians, says Andrea Weddle, executive director of HIVMA.

"We surveyed Ryan White, Part C programs and clinics," Weddle says.

"We picked them for the survey because they provide care for people with HIV, and we were interested in their challenges in recruiting," Weddle explains. "We asked about nurse practitioners, physician assistants, and physicians."

Investigators are continuing to analyze data, but so far it appears that programs across the country were reporting that it is very difficult

to recruit for all three disciplines, although they're having the greatest difficulty finding HIV doctors, Weddle says. **(See survey in a nutshell, p. 3.)**

"We really see our study as a first step," Weddle adds. "We really think we need a federally-funded study that takes a look at the issue nationally and also gets a handle on the differences regionally."

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 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 740059, Atlanta, GA 30374.

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

AHC Media LLC designates this educational activity 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 activity 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.

Subscriber Information

Customer Service: (800) 688-2421. Fax: (800) 284-3291.
Hours of operation: 8:30 a.m-6 p.m. M-Th, 8:30-4:30 F 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.
Associate Publisher: **Coles McKagen**, (404) 262-5420, (coles.mckagen@ahcmedia.com).
Managing Editor: **Gary Evans**, (706) 310-1727, (gary.evans@ahcmedia.com).
Production Editor: **Ami Sutaria.**

Editorial Questions?
Call **Gary Evans** at (706) 310-1727.

One key issue in expanding access to health care for HIV populations is having enough providers, Lubinski says.

"The Centers for Disease Control and Prevention (CDC) is calling for free HIV screening to all adults who don't know their HIV status, who need to be in care, and who need to protect their partners against transmission," Lubinski says. "We need to have care capacity and care for those individuals once they're identified."

The reasons why medical students are drawn to work in the HIV/AIDS field over the past 25 years have changed as the epidemic has evolved.

"When AIDS first appeared in the U.S., it was among a group of gay men who were marginalized and stigmatized in society, and then they had a fatal disease too," says **Kathleen Squires**, MD, a professor of medicine and director of the division of infectious diseases at Jefferson Medical College in Philadelphia, PA.

That marginalized, stigmatized, and rapidly dying population attracted doctors who wanted to help and were cause-driven, Squires notes.

"Now HIV has become a chronic illness, and there's not the perceived urgency anymore," Squires says. "Working with HIV patients was almost a cause for people in my generation because you had this very rapidly fatal disease."

Idealistic medical students continue to be drawn to work with HIV/AIDS patients, but they're attracted to work overseas in resource poor countries, Squires says.

"Part of the excitement with medical students is the global epidemic because that's what's being publicized now through PEPFAR and television commentaries," Squires says.

At a 2008 World AIDS Day program, Squires gave a presentation at a session for medical students, and she used a tool to show how quickly HIV can spread in a population.

This created some interest among the students, but it would also help if the United States started a national AIDS Agenda, just like the global AIDS agenda, Squires says. **(See story about Obama and a national AIDS agenda, p. XX.)**

Medical students need to be shown how the domestic epidemic also needs their help since there are 40,000 to 65,000 new HIV cases each year, and the epidemic largely impacts poor and minority communities, Squires suggests.

Recruiting new HIV doctors to the Adult HIV Programs at New Jersey Medical School in Newark, NJ, hasn't been a problem so far since the New York City metropolitan area trains and

attracts many medical school graduates, says **Sally L. Hodder**, MD, professor of medicine and director of the Adult HIV Programs.

But at a recent national meeting with AIDS clinicians, Hodder heard many other clinicians say that years of flat-funding for AIDS programs has dried up money available to train new investigators in HIV care.

"When you look around the room you see the same folks who've been in the field for 20 years," Hodder says.

One of the problems is that HIV care now is primary care for HIV patients, and there has been a shortage of students being attracted to primary care in recent years, Hodder notes.

Fewer students are interested in this area of message because of lower reimbursement and less a sense of passion about the cause now that an HIV diagnosis is no longer a death sentence, she adds.

At least one young HIV physician and researcher was drawn to the field through his post-medical school work in New York City, where he quickly learned of the injection drug use (IDU) community's struggles with the epidemic.

"I graduated medical school in 2000," says **Benjamin Linas**, MD, MPH, an instructor in medicine at Massachusetts General Hospital and Harvard University in Boston, MA.

"I started working in HIV while living in New York City," Linas says. "Part of what attracted me to HIV as a social cause was the issue of underserved populations and access of care issues."

Later, Linas moved to Argentina where he was involved in HIV prevention efforts among poor areas of the country.

For most people HIV is a global health issue, but the domestic epidemic also needs attention since there are some areas of the United States where HIV is rampant and people live in third-world conditions, Linas says.

HIVMA has tried to address the HIV physician shortage by providing minority clinical fellowship awards to young doctors, Weddle says.

Started two years ago, the program targets primary care, newly-trained physicians who are interested in working with HIV patients and underserved, minority populations, she explains.

"It offers them a one-year fellowship to concentrate on training in HIV," Weddle adds.

So far, six fellowships have been awarded.

Another possible reason why young physicians are not moving into HIV treatment is because it's both a very demanding and challenging field of medicine, and it's not very well reimbursed, Weddle says.

"In part, there's a broader primary care physician shortage, and for conditions like HIV, it's

HIV clinician survey results in-a-nutshell

A new survey that looked at the workforce challenges experienced by Ryan White Part C programs is expected to be published in 2009. The initial findings of the study, which was conducted by the HIV Medicine Association (HIVMA) of Arlington, VA, and the Forum for Collaborative HIV Research at George Washington University in Washington, DC, are as follows:

- HIVMA vice-chair Mike Saag, MD, sent a 32-question survey by email to 363 Ryan White Part C program directors on June 30, 2008.
- A total of 252 (70%) of the programs responded by the deadline.
- All of the clinics surveyed receive Ryan White Part C funding; they served 134,851 patients in 2007.
- Two-fifths of the respondents are located in the Southern United States, and three-fifths of the respondents are located in metropolitan areas with populations greater than 100,000.
- The clinics had an average new HIV patient caseload of 112 in 2007, and they served an average of 651 HIV patients in 2007.
- For the past three years, 70% of the clinics had an increase in patient caseload, and the average reported increase was 29%; 40% of the clinics in the South and 40% of those in rural areas reported rapid patient caseload growths of greater than 33%.
- The clinics reported that 37% of their new patients began care with an AIDS diagnosis.
- Also, the clinics reported that 37% of their patients had a serious mental illness, 35% had substance abuse disorders, and 23% were co-infected with hepatitis B or C.
- The clinics reported an average wait for newly-diagnosed patients of 1.5 weeks and a waiting time of 2.3 weeks for patients who had returning appointments; waiting time in the South was an average of 1.7 weeks, while it was 1.1 weeks in the Northeast.
- Southern clinics reported greater difficulties in recruiting clinicians and handling increasing caseloads.
- Most of the Ryan White Part C patients were low income with complex cases; most were either uninsured or received Medicaid.

even more challenging because it does require primary care, but you have to stay on top of a field that's constantly changing," Weddle says. "Physicians who have a lot of experience also have better outcomes for their patients, and the care is generally more cost-effective."

HIV medicine is an under-reimbursed specialty, Linas acknowledges.

"It's tough," he says. "Working in Boston, I'm having a hard time."

Linas does inpatient HIV consults at Massachusetts General and he works in HIV outpatient care, but he devotes much of his time to HIV research.

"I'm finding it difficult to pay my bills through HIV medicine," Linas says.

The new Obama administration could have an impact on increasing the pool of HIV clinicians if he were to create a targeted loan forgiveness program for physicians who practice HIV medicine in underserved areas, Weddle says.

"The one idea I've heard is to designate Ryan White, part C clinics as an eligible site for physicians who go through the National Health Service Corp (NHSC) to do their work," Weddle says.

"We'd be very supportive of having HIV included as a national service," Lubinski says. "For people to work in community-based organizations, there is all kinds of work to be done, and, in regards to clinicians, we'd like to see a loan forgiveness program."

Medical students graduate with an average student loan debt of $200,000, Lubinski notes.

"It's very difficult to convince them to go into a medical field that's not very lucrative," she adds. "So we'd like to see incentives for them to go into this field."

A loan forgiveness program for physicians and other HIV clinicians would definitely help attract more talent to the field, Linas says.

"No matter how well-intentioned people are, the finances have an impact," he adds. ■

Advocates push national HIV agenda for 1st 100 days

A surge of optimism

The demand for attention to the domestic HIV crisis has been pent-up for so long that within two days of the presidential election, a group of dozens of HIV/AIDS organizations sent the Obama-Biden transition team a letter requesting major changes to the how the domestic epidemic is handled.

Calling themselves "AIDS in America," the group called for renewed leadership and a comprehensive and adequately-funded response to the domestic epidemic, according to the Nov. 6, 2008, letter sent to John Podesta, Valerie Jarrett, and Peter Rouse, co-chairs of the Obama-Biden Transition Project.

Among the group's request for the first 100 days of Barack Obama's presidential term was a call for the development of a National AIDS Strategy for the U.S. Its goals would be to lower HIV incidence, increase access to HIV care, and reduce racial disparities in the epidemic, and integrate HIV with other programs at the local level, including programs targeting tuberculosis, sexually-transmitted diseases, and viral hepatitis. **(See chart with some goals from AIDS in America, p. 6.)**

"It's pretty clear to us that the United States over 25 years into this epidemic has never set an accountable agenda for epidemic with a specific time table for getting results," says **Rebecca Haag**, executive director of AIDS Action Council in Washington, DC. Haag was as co-signer of the Nov. 6 letter and spoke at a December, 2008, teleconference on the impact of the Obama administration.

AIDS in America is asking Obama to appoint a panel that would deliver in his first year as president a national AIDS plan, Haag says.

The group is calling for a PEPFAR-like program that would have a plan with measurable outcomes and strategies to fix the problems, Haag adds.

"It's shameful for all of us to realize that in Washington, DC, the HIV infection rates are worse than in many sub-Saharan countries," Haag says.

AIDS groups are optimistic, says **Carl Schmid**, director of federal affairs for The AIDS Institute in Washington, DC. Schmid also spoke at the teleconference.

"While Obama ran for president, he said he's focus on the domestic AIDS epidemic and initiate a national AIDS strategy and have programs based on evidence and increased funding for HIV prevention and care and treatment," Schmid says.

"We are optimistic that we will see progress in the epidemic with Obama and his administra-

tion," Schmid says.

Another reason for the optimism is because of Obama's emphasis on national health care reform.

"In the early 1980s, there were many who argued that the health care response to the AIDS epidemic was a lens through which you could see all the fragmentation of our health care system," says **Christine Lubinski,** vice president for global health at the Infectious Diseases Society of America (IDSA).

"So obviously, we're very excited about the potential for health care reform," Lubinski says. "We represent a community that is very poor with multiple health care needs, so if a health care plan works for people with HIV/AIDS, it will work for all of us."

While no one expects national health care reform to occur overnight, there is some short-term action that could help stem the epidemic.

For example, the Obama administration could heed the overwhelming scientific evidence that needle exchange is a good prevention approach and lift the ban on federal funding for needle exchange programs, Haag suggests.

Also, since the Obama administration will focus on evidenced-based interventions, then it might mean an end to abstinence-only programs that result in people engaging in riskier sex because they're unaware of safer alternatives, Haag adds.

"We want the Centers for Disease Control and Prevention (CDC) to look at new prevention models that work in the most-affected communities, particularly looking at gay men of color and new prevention for African American women," Haag says.

The Bush administration did not apply a lot of the evidence-based methodology to HIV prevention strategies by promoting abstinence-only and banning funding for needle exchanges, Haag notes.

At a congressional hearing in September, it was announced that 2,000 organizations were waiting to be educated on the CDC's DEBI list of approved HIV prevention interventions, and they're not receiving the training because of a lack of funding, Schmid says.

"The CDC has 49 approved interventions in its compendium, and that compendium was not updated for the first seven years," he adds. "So hopefully with the Obama administration we will see more interventions and more research."

The new president also will have an opportunity to send a strong message about his commitment to fighting the domestic epidemic by increasing funding for HIV prevention and care programs in his first budget.

"Obama will have to propose a budget for fiscal year 2010, and it will come out in early February," Schmid says. "I think this will be a good signal of the Obama administration's commitment to the epidemic if he calls for increases in funding for prevention, the CDC, and for Ryan White Care Act programs."

Last year the Ryan White program was cut by $3.5 million, and this year the Congress is calling for a zero increase, despite large numbers of people infected by HIV/AIDS in our own country, Schmid says.

"People are living longer, so they need their health care and drugs much longer," Schmid says. "In addition, we have people being infected at a much higher rate, and they need treatment and medical costs and drug costs are increasing." ■

Communications breakdown: HIV+ women and providers

Nearly half of black women change clinicians

A new study finds that many HIV-infected women have had less than ideal interactions with their medical providers.

"The take-home message was there is room for improvement in terms of interactions between HIV-infected women and their health care providers," says **Kathleen Squires**, MD, a professor of medicine and director of the division of infectious diseases at Jefferson Medical College at Thomas Jefferson University in Philadelphia, PA.

The study surveyed 700 women who were recruited from a U.S. national network of AIDS counseling centers. It found that 60% of the women had changed health care providers while receiving HIV treatment.[1]

Hispanic and African American women, who accounted for over 70% of those who were surveyed, were more likely than Caucasian women to change health care providers because of communication issues.[1]

Nearly half of African American women changed providers because of communication

AIDS in America's goals for Obama

These could be done in first 100 days

AIDS in America, an umbrella HIV/AIDS advocacy group has written the Obama-Biden transition team, requesting that greater attention be paid to the domestic HIV/AIDS epidemic within the first 100 days of Obama's presidency. Here are some of their suggestions to the new president:

- Increase funding for HIV prevention and surveillance by at least $200 million in fiscal year 2009 and $877 million in fiscal year 2010 for a total of at least $1.569 billion.
- Increase overall funding for the Ryan White Program by $100 million for FY2009 and $614.49 million for FY 2010 for a total of at least $2.78 billion.
- Increase funding for the AIDS Drug Assistance Program (ADAP) by $28.3 million in FY2009 and by $134.6 million in FY2010 for a total of at least $943.5 million.
- Increase funding for Ryan White, Part C, by $6.2 million in FY2009 and by $100.5 million in FY2010 for a total of at least $299 million.
- Increase funding for the AIDS Education and Training Centers by $600,000 in FY2009 and by $15.9 million in FY2010.
- Increase overall funding for the National Institutes of Health by $1.65 billion in FY2009 and by $4.38 billion in FY2010 and include an increase of $450 million for HIV/AIDS research.
- Support lifting the federal ban contained in appropriations bills on all syringe exchange programs to allow for the broader implementation and scale up of evidence-based, proven HIV prevention programs for injection drug users (IDUs).
- Support evidenced-based sexuality education by discontinuing funding for abstinence-only until marriage programs, including those funded through the Community-Based Abstinence Education.

problems, and 37% of Hispanic women cited communication as the reason for their switching providers.[1]

"Over half of the women said they and their physicians had never really talked about whether there were gender-based differences in treatment issues," Squires says.

These would include differences in reactions to drugs, different side effects, and the complications of pregnancy.

"All of us were surprised at the magnitude of some of the communication gaps," says **Sally L. Hodder**, MD, a professor of medicine and director of the Adult HIV Programs at New Jersey Medical School in Newark, NJ.

Women of color especially expressed concern about communication with their providers, Hodder says.

"In the United States, women of color constitute almost 80% of HIV cases among women," Hodder says. "This suggests we really need to have effective cultural competency and communication strategies with patients, whomever they are."

Also, a large percentage of women, who had been pregnant or were considering becoming pregnant, had never been asked by their health care provider of what they thought about becoming pregnant and what they might do to change their antiretroviral regimen if they were to become pregnant, Squires says.

These women perceived being stigmatized by society if they wanted to have children, Hodder says.

"I was really surprised by the enormous perceived stigma that HIV-infected women expressed," Hodder says. "If folks feel that society urges them not to have children, then why would they want to communicate with a provider about that?"

This means it's important for HIV clinicians to be proactive and ask women of childbearing years about their thoughts on having children, Hodder says.

"A lot goes into preconception counseling, including talking about smoking and drinking," she adds.

Three-quarters of the women said that having HIV impacted their activities of daily living, Squires says.

Although the study was a survey and not a randomized clinical trial, it was the largest survey of its type, and the results are revealing, she notes.

"The results say that in terms of health care there is room for improvement," Squires says. "For health care providers, it's useful to see the results of this study to help them understand."

Hodder speculates that the communication problems are partly due to time constraints in HIV care.

"In the current health care system you have a return appointment in most clinics lasting 20 minutes," Hodder says. "Clinicians have a lot of

pressure to see the patient, examine the patient, sign a note, write a prescription, and they don't think they have time to adequately address with open-ended questions what's going on in the patient's life."

Since HIV infection often occurs in the context of poverty, substance abuse, homelessness, and other social issues that impact the patient's medical condition, the 20 minutes is not enough time to address all of these issues, Hodder explains.

"One of the things I think is very important in an HIV clinic is to have not just one person caring for a case, but having multiple people with expertise in multiple areas," she adds. "We'll see if Ryan White funding will continue to support those HIV clinics at a financial level that will permit multidisciplinary clinics."

Reference

1. Hodder S, Aberg J, Feinberg J, et al. Perceptions of care by HIV-infected women in the United States. Abstract presented at the 48th Annual ICAAC/IDSA 46th Annual Meeting, held Oct. 25-28, 2008, in Washington, DC. Abstract: H-443. ■

Condoms: Teens fear partner disapproval

HIV high risk behavior linked to teen attitudes

A survey of more than 1,400 adolescents and young adults indicate that teens who don't use condoms were significantly more likely to believe that condoms reduce sexual pleasure and also were more concerned that their partner would not approve of condom use.[1]

In addition, a separate study found that adolescents might not be getting the information they need when it comes to condom use and negotiation skills. Commonly used abstinence-only curricula don't provide complete, current, or accurate medical knowledge about the effectiveness of condoms, states a 2008 review of current programs.[2]

The three programs assessed were *Me, My World, My Future* (published by Teen-Aid for use by middle school students), *Sexuality, Commitment & Family* (published by Teen-Aid for use by high school students), and *Why kNOw* (published by AAA Women's Services for sixth grade through high school). They often provide inaccurate medical information to adolescents, and this information including false or misleading statements about the effectiveness and safety of condoms, the review says. The programs inflate the actual failure rate of condoms, which suggests that using condoms is somewhat like playing "Russian roulette" with HIV, the report notes.

To understand teens' use of condoms, investigators from the Bradley Hasbro Children's Research Center in Providence, RI, and three other institutions surveyed more than 1,400 adolescents and young adults between the ages of 15 and 21 who had unprotected sex in the previous 90 days.[1]

Study participants in Atlanta, Miami, and Providence completed an audio computer-assisted interview to gather information about sexual risk behaviors including condom use. Questions included attitudes and perceptions about condom use, and communication and negotiation with partners about condom use. The study group included 797 females and 613 males. About half were African American. Almost one-fourth (24%) were Hispanic, and 19% were white.

Researchers found that two-thirds of adolescents did not use a condom the last time they had sex. Participants also reported an average of two partners and about 15 incidents of unprotected sexual activity within the 90-day period. In addition to concerns about reduced sexual pleasure and partner disapproval, teens who did not use condoms also were less likely to discuss condom use with their partners. Those findings held true across racial/ethnic groups, gender, and geographic locations, researchers report.

"It's clear that we have to address these attitudes, fears, and concerns that many teens have regarding condom use, if we want to reduce their risk for contracting a sexually transmitted infection," says **Larry Brown**, MD, professor in the Department of Psychiatry and Human Behavior in the Alpert School of Medicine at Brown University. "The good news is that these attitudes may be easily influenced and changed through clinical and community-based interventions."

What influences condom use?

What are some of the most common attitudes and concerns influencing condom use in adolescents? Consider these possibilities, says Brown, who served as lead author for the current research:

- Teens might have negative feelings about

personal factors about condoms. They might see donning a condom as a hassle, something that will ruin the mood of sex, and make sex less pleasurable.

• Teens worry that their partners won't want to use condoms, says Brown. They might be suspicious about the reason for using a condom, or they might want to not use one as a sign of commitment.

• Teens might not use condoms when they have difficulty talking with their partners about condom use in the role of safer sex. Adolescents might not feel that they are able to refuse or delay sex until it is safer, says Brown.

"Two other reasons teenagers and older couples don't use condoms is that they think condoms don't work; one reason why they think that they don't work is because they frequently break," says **Robert Hatcher**, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta. "When used, condoms are effective in preventing both infection and pregnancy, and when used correctly, condoms break only 1% to 2% of the time."

What are some specific ways that health care providers can address those attitudes and concerns? Screen teens' sexual behavior, says Brown. Discuss whether they are having sex and whether condoms are used at all and with all partners. If consistent condom use is not in play, discuss what barriers impede such use.

Teach teens how to bring up discussions of sex and condoms in a mutually caring, respectful, and tactful manner, says Brown. Counsel that most partners won't refuse with this approach, he notes.

Reduce teens' discomfort with condoms by encouraging them to continue to try condoms and finding a brand that provides optimal fit, comfort, and sensation. Condom makers now are making condom use more pleasurable with freshening wipes, lubricants, ribbings, and even vibrating rings, reports **Anita Nelson**, MD, professor in the Obstetrics and Gynecology Department at the David Geffen School of Medicine at the University of California in Los Angeles.

Refer teens to small group interventions with other teens, such as those offered at community-based organizations, that address those issues, offers Brown.

Continue to provide comprehensive sexuality education to adolescent patients, especially if your state accepts abstinence-only sexuality education funds. As of August 2008, the following states had opted out of Title V abstinence-only federal funding: Alaska, Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Idaho, Iowa, Maine, Massachusetts, Minnesota, New Jersey, New Mexico, New York, Ohio, Pennsylvania, Rhode Island, Tennessee, Vermont, Virginia, Washington, Wisconsin, and Wyoming.[4]

States that have rejected federal abstinence-only funds generally cite concerns about the efficacy and accuracy of abstinence-only curricula.Those states also tend to have progressive governments and strong advocates for comprehensive sexuality education, notes an overview of state trends.

References

1. Brown LK, DiClemente R, Crosby R, et al. Condom use among high-risk adolescents: Anticipation of partner disapproval and less pleasure associated with not using condoms. *Public Health Rep* 2008; 123:601-607.

2. Lin AJ, Santelli JS. The accuracy of condom information in three selected abstinence-only education curricula. *Sex Res Social Policy* 2008; 5:56-70.

3. Kirby D. The impact of abstinence and comprehensive sex and STD/HIV education programs on adolescent sexual behavior. *Sex Res Social Policy* 2008; 5:18-27.

4. Raymond M, Bogdanovich L, Brahmi D, et al. State refusal of federal funding for abstinence-only programs. *Sex Res Social Policy* 2008; 5:44-55. ■

FDA Notifications

Final rule issued on condom classification

The Food and Drug Administration (FDA) published a final rule on Nov. 10, 2008 amending the classification regulation for male condoms made of natural rubber latex (latex condoms) and latex condoms with spermicidal lubricant containing nonoxynol-9 (N-9), designating a guidance document containing labeling recommendations as a special control for latex condoms.

The final rule will become effective January 9, 2009.

The FDA is establishing the labeling guidance as a special control because it ensures that manufacturers will address the issues identified in the guidance. Regular guidance imposes no requirements. However, where a guidance document has been designated as a special control by a rule, manufacturers must address the issues identified in the guidance, either by following the recommendations in the guidance, or by some other means that provides equivalent assurances of safety and effectiveness.

Establishing a guidance document as a special control affords greater flexibility than a rule mandating specific labeling language, and can facilitate updating of the labeling as new scientific information becomes available because the special control permits manufacturers to use any labeling that affords equivalent assurances of safety and effectiveness for latex condoms.

In developing the rule and guidance, FDA evaluated a variety of scientific evidence and information about condoms and STIs. to assess the overall effectiveness of latex condoms in preventing transmission of STIs,

Based on review of scientific information and of existing latex condom labeling, FDA concluded that existing latex condom labeling was medically accurate in presenting the conclusion that, overall, condoms are effective in reducing the risk of sexually transmitted infections (STIs).

However, to help consumers make appropriate choices for their particular needs, and therefore to ensure the safe and effective use of condoms, FDA is establishing the labeling special control to address some additional, more nuanced information about condoms and STIs, as well as to provide information about contraception, and about appropriate directions and precautions for use of latex condoms.

The regulatory changes are intended to help ensure that latex condoms are used safely and effectively by providing labeling that conveys a concise, accurate message that neither exaggerates the degree of protection provided by latex condoms, nor undervalues overall STI-risk reduction provided by latex condom use.

The Nov. 10, 2008 Federal Register Notice of Final Rulemaking, which contains detailed information about the rule, and FDA's findings regarding effectiveness of latex condoms for a variety of STIs, is available on the FDA web site at http://www.fda.gov.

Background information is also available about the earlier Proposed Guidance for Condom Labeling. ■

New ART adult guidelines released

On Nov. 3, 2008, the Department of Health and Human Services' Panel on Antiretroviral Guidelines for Adults and Adolescents released a revised version of the Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents.

The following changes have been made to the Jan. 29, 2008 version of the guidelines. Key new updates are highlighted throughout the posted document (see below).

Format Changes: This revision is developed under a new format, whereby the relevant tables and references for each section are incorporated into the body of the document. Some larger tables are placed in an appendix at the end of the document. A separate PDF file with all the tables can be found at the AIDSinfo Web site.

Rating Changes: A new rating scheme is used in this guideline to be more consistent with other guidelines in infectious diseases.

The changes are outlined below:

• Strength of Recommendations - The D (should usually not be offered) and E (should never be offered) ratings have been removed. The A, B, and C ratings rate the strength of the statement. For example, an A rating for "not to initiate nevirapine in women with pre-treatment CD4 cell count >250 cells/mm3" indicates a strong recommendation to not initiate nevirapine in these patients.

• Quality of Evidence - Previously, only randomized trials with clinical endpoints were given a I ranking. In this new rating scheme, a I ranking includes randomized trials with either clinical or validated laboratory outcomes (e.g., viral load). A II rating includes non-randomized trials or well-designed observational cohort studies with long term clinical outcomes. A III rating remains a recommendation based on expert opinion.

• Content Changes - The key changes to the different sections of the guidelines are outlined below:

• Laboratory Monitoring - A new table (Table 3) provides recommendations for laboratory tests

to obtain at baseline and while receiving antiretroviral therapy to monitor for safety and treatment responses.

• The Panel recommends that resistance testing be considered in patients with viral loads of 500–1,000 copies/mL but recognizes that it may not always be reliable at those levels (BII).

What to Start in Antiretroviral-Naïve Patients:

• Protease Inhibitor–Based Regimens: Ritonavir-boosted darunavir has been added as a preferred PI component (AI). Once-daily ritonavir-boosted lopinavir has been moved from alternative to preferred PI component (except for pregnant women) (AI).

• Dual-NRTI Options: Abacavir + lamivudine has been moved from a preferred to an alternative dual-NRTI component because of concerns regarding an increased risk of myocardial infarction in patients with high cardiac risk factors, as suggested by large observational cohort studies, and concerns regarding virologic potency in patients with baseline viral loads >100,000 copies/mL (BI).

• Combinations Not to Use or to Use with Caution: A combination of unboosted atazanavir + didanosine + emtricitabine (or lamivudine) is not recommended because of efficacy concerns (BI). A combination of nevirapine + tenofovir + emtricitabine (or lamivudine) should be used with caution and with close monitoring of virologic responses because of reports of early virologic failure in several small studies (CII).

• Management of Treatment-Experienced Patients:

• Regimen Simplification: A new section on Regimen Simplification for virologically suppressed patients has been added to the discussion of Management of the Treatment-Experienced Patient.

• Additional Updates: The following sections and their relevant tables have been updated:

- Introduction
- CD4+ T-cell count
- Viral Load Testing
- Coreceptor Tropism Assay
- What Not to Use
- Exposure Response and Therapeutic Drug Monitoring (and table for recommended antiretroviral drug concentrations)
- HIV-Infected Adolescents
- HIV-Infected Illicit Drug Users
- HIV-Infected Women
- Adherence to Antiretroviral Therapy (with a new table)
- Antiretroviral-Associated Adverse Effects (and table for detection and management of adverse effects)
- Antretroviral Drug Interactions (with a new format for interactions between antiretroviral and other drugs)
- Tables describing the characteristics of antiretroviral drugs.

The complete Nov. 3, 2008 version of the adult treatment guidelines is available on the AIDSinfo web site at http://aidsinfo.nih.gov. ■

Maraviroc approved for use in treatment-experienced CCR5-tropic HIV-1

On Nov. 25, 2008, the FDA granted full, traditional approval for the use of maraviroc in treatment-experienced patients infected with CCR5-tropic HIV-1. The change from accelerated to traditional approval was based on 48-week data from two double-blind, randomized, placebo-controlled,multicenter studies in subjects infected with CCR5-tropic HIV-1(A4001027 and A4001028).

Subjects were required to have an HIV-1 RNA of greater than 5,000 copies/mL despite at least 6 months of prior therapy with at least one agent from three of the four antiretroviral drug classes or documented resistance or intolerance to at least one member of each class. All subjects received an optimized background therapy (OBT) consisting of 3 to 6 antiretroviral agents (excluding low-dose ritonavir) selected on the basis of the subject's prior treatment history and baseline genotypic and phenotypic viral resistance measurements. In addition to the OBT, subjects were then randomized in a 2:2:1 ratio to maraviroc 300 mg once daily, maraviroc 300 mg twice daily, or placebo.

After 48 weeks of therapy, the proportion of subjects with HIV-1 RNA <400 copies/mL receiving maraviroc compared to placebo was 56% and 22%, respectively. The mean changes in plasma HIV-1 RNA from baseline to week 48 were –1.84 log10 copies/mL for subjects receiving maraviroc + OBT compared to –0.78 log10 copies/mL for subjects receiving OBT only. The mean increase in CD4+ counts was higher on maraviroc twice daily + OBT (124 cells/mm3) than on placebo +

OBT (60 cells/mm3).

Some of the major labeling changes associated with the approval are shown below:

• Under the "Indications and Usage" section of the label the first bullet now reads "Tropism testing is required for the appropriate use of SELZENTRY."

• Under the "Warnings and Precautions" section of the label the second sentence under subsection 5.2 Cardiovascular Events now reads "Eleven subjects (1.3%) who received SELZENTRY had cardiovascular events including myocardial ischemia and/or infarction during the Phase 3 studies [total exposure 609 patient-years, (300 on once daily + 309 on twice daily SELZENTRY)], while no subjects who received placebo had such events (total exposure 111 patient-years)."

• Under the "Use in Specific Population" section of the label, subsection 8.7 Hepatic Impairment, now reads "Maraviroc is principally metabolized by the liver; therefore, caution should be exercised when administering this drug to patients with hepatic impairment, because maraviroc concentrations may be increased. Maraviroc has not been studied in subjects with severe hepatic impairment. [see Warnings and Precautions (5.1) and Clinical Pharmacology (12.3)]."

• Under the "Clinical Pharmacology" section of the label, Hepatic Impairment section was added following the Excretion section and reads, "Maraviroc is primarily metabolized and eliminated by the liver. A study compared the pharmacokinetics of a single 300 mg dose of SELZENTRY in patients with mild (Child-Pugh Class A, n=8), and moderate (Child-Pugh class B, n=8) hepatic impairment to pharmacokinetics in healthy subjects (n=8). The mean Cmax and AUC were 11% and 25% higher, respectively, for subjects with mild hepatic impairment, and 32% and 46% higher, respectively, for subjects with moderate hepatic impairment compared to subjects with normal hepatic function. These changes do not warrant a dose adjustment. Maraviroc concentrations are higher when SELZENTRY 150 mg is

CE/CME *questions*

1. A recent survey of Ryan White, Part C clinics has found which of the following?
   A. 37 percent of new patients began care with an AIDS diagnosis
   B. 37 percent of patients had a serious mental illness
   C. 23 percent of patients were co-infected with hepatitis B or C
   D. All of the above

2. An advocacy group called AIDS in America asks the Obama-Biden transition team to make which of the following immediate changes in Obama's presidency?
   A. Increase HIV funding for PEPFAR by $4.9 billion
   B. Lift the federal ban on syringe exchange programs and discontinue funding for abstinence-only until marriage programs
   C. Start a national HIV prevention campaign, including billboards and television commercials
   D. All of the above

3. A new study of HIV-infected women found that many change their providers because of perceived communication problems. Which group reported changing doctors for this reason more frequently than others?
   A. African American women
   B. Caucasian women
   C. Hispanic women
   D. Asian women

Answers: 1. D; 2. B; 3. A.

COMING IN FUTURE MONTHS

- ADAP could improve outcomes by prioritizing clients differently, study shows
- Prior authorization places big burden on providers
- Evidence mounts for opt-out HIV testing
- HIV testing in jails can help bring people into care

administered with a strong CYP3A inhibitor compared to following administration of 300 mg without a CYP3A inhibitor, so patients with moderate hepatic impairment who receive SELZENTRY 150 mg with a strong CYP3A inhibitor should be monitored closely for maraviroc associated adverse events. The pharmacokinetics of maraviroc have not been studied in subjects with severe hepatic impairment. [see Warnings and Precautions (5.1)]"

• Under the "Clinical Pharmacology" section of the label, subsection Effects of Maraviroc on the Pharmacokinetics of Concomitant Drugs, the following was added after the first paragraph: "Maraviroc does not induce CYP1A2 in vitro. In vitro results indicate that maraviroc could inhibit P-glycoprotein in the gut and may thus affect bioavailability of certain drugs."

Selzentry is distributed by Pfizer Labs. ■

CE/CME objectives

The CE/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.

Physicians and nurses participate in this medical education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any question answered incorrectly, please consult the source material. After competing this activity at the end of each semester, you must complete the evaluation form provided and return it in the reply envelope provided to receive a letter of credit. When your evaluation is received, a letter of credit will be mailed to you.