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IN THIS ISSUE

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Special Report: Black women and HIV

In this issue of AIDS Alert, *there is a special report about black women and the HIV epidemic in anticipation of new epidemiological and other information that is published annually in conjunction with National Black HIV/AIDS Awareness and Information Day—Feb. 7, 2006.*

Racism, poverty, sexism all play a role in epidemic's spread among black women

New resource guide educates on problem

Black women in the United States had the highest new diagnosis rate of HIV/AIDS of any ethnic/gender group between 2001 and 2004, according to the latest data from the Centers for Disease Control and Prevention (CDC) in Atlanta, GA.[1]

Black women accounted for 68 percent of the new diagnoses among women in that period, while black men accounted for 44 percent of the new diagnoses among men.[1]

While white men and black men each have greater numbers of new infections, black women are not far behind them in total numbers, with 30,483 new diagnoses estimated in 33 states, compared with 38,218 for white men and 49,704 for black men.[1]

Public health officials and others who work to

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COMING IN FUTURE ISSUES

■ **Stress and medication adherence:** Stress, anxiety, negativity contribute to problem.

■ **Anal cancer and HIV:** New study shows link between rise in anal cancer and HAART.

■ **Dual AIDS/HIV diagnoses:** Many people are tested late in the disease—Is this a problem?

■ **Here's the latest on vaccine efforts:** Is funding the chief issue?

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stem the epidemic say there are a variety of reasons why black women have been disproportionately impacted by AIDS.

"Among women the epidemic has always been overwhelmingly in blacks and Hispanics, as opposed to men where in the early days of the epidemic it was well-represented among white men," says Judy Sackoff, PhD, deputy director for HIV surveillance at the New York City Department of Health and Mental Hygiene in New York, NY.

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Editorial Questions

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There are places in New York City where the epidemic's prevalence among blacks is comparable to parts of sub-Saharan Africa.

There's a project in Brooklyn where some buildings don't have a tenant who isn't infected with HIV, says **Diana Williamson**, MD, MPH, a New York City-based volunteer chair of the scientific committee and co-founder of the Black AIDS Institute of Los Angeles, CA.

"What ends up happening is the suspicion of health providers and lack of access to care in the United States makes the epidemic among certain black people, but not all, as bad as it is in parts of Africa," Williamson says. "They may not have access to care or antiretrovirals, and if you give some patients a prescription, they'll sell it because they need the food more than the drugs."

The Black AIDS Institute has produced a new report called, "Getting Real: Black Women Taking Charge in the Fight Against AIDS" as an educational tool for HIV providers and outreach workers. The report is available on-line at www.blackaids.org. (See excerpt from report, p. 16.)

"Anyone can download the report," Williamson says. "I would hope there would be some government agency or someone who would take this report and put it in the hands of every medical student, doctor, psychologist, clinician, and anyone who does treatment of HIV."

One new study has found that African American women drug users were not discussing HIV status with the drug-using and sexual partners.

"One of the big public health messages now is to know your status and discuss this, so the message obviously hasn't reached all parts of the population," says Caroline Korves, SD, postdoctoral research fellow, department of epidemiology, Mailman School of Public Health at Columbia University in New York, NY.

"We asked within the survey whether or not a person thought their partner has HIV and whether they had actually discussed it," Korves says. "Most people had not discussed HIV, so they didn't suspect HIV status among partners."

Investigators interviewed women who used heroin, crack, cocaine, or marijuana daily, and they recruited risk network members, who were either sexual or drug-using partners. All participants were tested for HIV, and 18 percent were HIV positive.[3]

The participants reported knowing that 7 percent of their risk network partners were HIV positive, but actual testing of the risk network members showed that 18 percent were HIV positive.[3]

"The take-home message here is there are a lot of people who still are engaging in high risk behavior just due to the fact they're having sex and doing drugs with people who have HIV," Korves says. "Their partners are infected, and still this message that people need to discuss their serostatus has not reached everyone within the population."

Most black women newly diagnosed with HIV were infected through heterosexual contact, with that accounting for 76 percent of reported transmission and injection drug use accounting for 21 percent.[1]

"Heterosexual HIV in the black community is driven by poverty, sexism, and racism, and unless we address the underlying issues here we won't stem the epidemic," says Peter Leone, MD, associate professor of medicine at the University of North Carolina at Chapel Hill.

The HIV infection rate for black women in North Carolina is 14 times higher than it is for white women.[2]

Leone has studied the differences between black women, ages 18 to 40, who are HIV infected versus those of the same age group who are HIV negative to see what factors might play a role in HIV risk.

The case study looked at newly-diagnosed women in the state of North Carolina, who were diagnosed between January, 2003 and August, 2004, and who were infected through sex with a man. When comparing this group with black women of the same age group who were not infected, the chief difference was socioeconomics, Leone says.

"The things that jump out at you is there wasn't much difference in age at first intercourse and previous unprotected vaginal sex and HIV testing, both groups were similar," Leone says. "But the big driving difference was socioeconomics, where those who were positive were 7 to 8 times more likely to be on public assistance than were those who were negative."

The women who were HIV negative were similar in marital status and educational level, but they were less likely to be unemployed or to have received public assistance.[2]

Also, the HIV-positive women were more likely to have herpes, and were less likely to have discussed their sexual and behavioral history with their male sex partners.[2]

"The women we interviewed, both HIV positive and negative, felt very unempowered in their relationships and in their communities," Leone

Here's an excerpt from special report about black women and HIV epidemic

Look for report on-line

The Black AIDS Institute of Los Angeles, CA, has produced a special report, "Getting Real: Black Women Taking Charge in the Fight Against AIDS," which is available for a free download at the institute's Web site at www.blackaids.org.

The report is written in a casual style that speaks directly to black women, but also provides statistics, prevention strategies, and other information that would be useful for providers.

Here's an excerpt from the report:

Looking Out for #1

Because Black women are generally socialized to take care of others, many sistahs become skilled at identifying others' desires, but never consider what they want. "I see so many young women whose conversation is 'How do I keep him?' and 'What does he want?'—as opposed to 'What do I want?'" observes therapist Gary Bell. But you can't get your needs met if you don't put them out there. Practice saying these phrases to put yourself first.

- I want a relationship with a man who is committed to me.
- I expect you to do what you say you'll do.
- I expect a man to support me emotionally.
- I want to further my education.
- I love and respect myself and won't engage in that behavior.
- I always use condoms.
- I won't risk my life for you. We need to use protection.
- I won't settle for less.

says. "They themselves felt they put themselves at risk for HIV based on their own low self-esteem and their need to feel connected in their community."

One complicated issue that it's unique to the black community is the lack of available black male partners, partly because of an increased mortality rate due to cardiovascular and other diseases for African American men, increased death rate due to violence, and a higher incarceration rate, Leone explains.

Among the HIV-positive black women, 81 percent said their sexual partners included men who had been incarcerated, and 59 percent of the HIV-negative black women reported having a sexual partner who had been incarcerated.[2]

"One of the things that is still a fall-out of poverty and racism is the fact we have a very closed society in terms of sexual networks," Leone says. "For black women, the majority of their partners are going to be black, so when the prevalence rate goes up in a community, your likelihood of coming into contact with someone who is HIV positive increases."

In New York City, where an important part of a city-wide health plan includes knowing one's HIV status, there has been an encouraging trend seen in new HIV diagnoses, including those among black women, Sackoff says.

"The good news is that the number of new HIV diagnoses has been declining for years," Sackoff says. "Since we started keeping track in 2000, the number of new diagnoses in New York City has declined about 500 every year, so we're down to 3,653 new HIV diagnoses in total."

Women accounted for 31.5 percent of the new HIV diagnoses in 2004, and blacks accounted for 53.5 percent of new diagnoses that year.[4]

The bad news is that the proportion of concurrent HIV/AIDS diagnoses among black women has climbed from 22.5 percent in 2001 to 28.4 percent in 2004, Sackoff says.

"We know that at the time women are diagnosed with HIV, more than one-fourth also have AIDS," Sackoff says. "I would speculate that it is stigma that keeps people from being tested."

Concordant diagnoses of HIV and AIDS are a disturbing problem on the 10th anniversary of protease inhibitors and highly active antiretroviral therapy (HAART), Leone says.

"A study in our own UNC clinic has shown the CD4 cell count at the time of presentation has declined over the 10-year period," Leone says. "People are presenting with more advanced disease now than they did 10 years ago, so we have HAART and mortality has dropped, yet people are coming in later, and it's more likely to occur in minorities."

Leone speculates that socioeconomic pressures make knowing one's HIV status a low priority, and he says he's concerned that some at-risk groups feel disenfranchised from the health care system and so are not convinced they would be

helped even if they did know their HIV status.

"While testing is critical in terms of reducing ongoing transmission of HIV, we have to couple that with broader prevention messages, and the money is not being given to the main chain of prevention programs," Leone says. "And our AIDS Drugs Assistance Program in North Carolina is still the lowest in terms of eligibility in the country."

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Some PIs have greater impact than others on heart disease

Patients on atazanavir had less heart problems

Recent research has highlighted the cardiovascular problems that some HIV patients have had while being treated with protease inhibitors (PIs), but it's been difficult for physicians to determine exactly which drugs are causing the most trouble.

Now a new study, presented at the 45th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), held Dec. 16-19, 2005, in Washington, DC, shows that there is a significant difference in coronary risk depending on which PI a patient takes.

Investigators found that patients receiving atazanavir had a significantly lower risk over a 10-year period of coronary heart disease than did patients receiving nelfinavir, and this lower risk remained statistically significant for patients who had other heart disease risk factors, including smoking, diabetes, and hypertension.[1]

"There are a million people in the United States who have HIV and probably about half of those people are under the age of 25 years of age," says Craig I. Coleman, PharmD, an assistant professor of pharmacy practice at the University of Connecticut School of Pharmacy and director of the pharmacoeconomics and outcomes studies group at Hartford Hospital in Hartford, CT.

"So that means there will be a lot of patients out there, particularly as HIV drugs improve, who will live longer and die from things other than HIV/AIDS," Coleman says.

For some time, clinicians have known that PIs can cause metabolic problems, including hypoglycemia, insulin resistance, hyperlipidemia, and this was generally thought to be an across-the-board problem, Coleman notes.

"Then in mid-2004, atazanavir came out, and it has the benefit of not causing the same abnormalities," he says. "In fact, it may even have a little better cholesterol value—going in the direction you want."

Investigators wanted to find out if the difference was significant, so they analyzed 48 weeks of data from phase II clinical trials by the drug's manufacturer and compared 2 PIs, combined with didanosine and stavudine as part of a highly active antiretroviral treatment (HAART). They pulled data about patients' LDL and HDL values and used those values to model what a patient's 10-year risk of coronary artery disease would be on each of those different therapies, Coleman explains.

"Some of these patients are much younger and will live for those 10 years, so the complications become very important," Coleman says.

Using the Framingham risk equation, they determined the risks of patients having coronary heart disease and found that on the atazanavir regimen patients would have significantly less risk, he says.

"We were able to show that you're relative risk of having a coronary heart disease event like a myocardial infarction [MI] or dying from an MI would be lowered by one-third in patients who were taking atazanavir instead of nelfinavir," Coleman says.

Even for the patients who were diabetics, smokers, and already at higher risk, there was a significantly lower risk of coronary heart disease if they were taking atazanavir, he says.

"If the person was a smoker, a diabetic, and had hypertension, it was a 29 percent risk reduction," Coleman says.

While it would be useful to conduct a randomized control trial to confirm the answer the model suggests, it would be extremely expensive to undertake such research, and it's unlikely pharmaceutical companies would sponsor such investigation, Coleman says.

"You would have to follow patients for a very long period of time, because coronary artery disease doesn't kill immediately," Coleman says. "It takes many years for arteries to clog and cause an event and death, so you can't just give people the drug and do a study and follow-up."

Since such a study would take 10-15 years to complete, the data derived from the study model might be the best available, Coleman says.

"The study point was to demonstrate to clinicians that the choice they make in terms of the PI they use may have repercussions 10 years down the line," Coleman says. "Choosing a PI with less lipid abnormalities and which has the least negative effects may reap benefits down the line."

Of course, there are limitations to the model's predictions. For instance, the model assumes patients would receive the same PI throughout the 10-year period, either nelfinavir or atazanavir, he says.

"And there are all kinds of problems with resistance, so will people be on the same regimen for years?" Coleman says.

"And beyond the lipid impact, these drugs could cause changes in body fat, redistributing it in the chest, losing it other places, and getting big humps on their backs, so there's a lot of concerns with these drugs," Coleman says.

Still, clinicians might consider atazanavir for patients who are at high risk of coronary heart disease, Coleman suggests.

"It's certainly one factor to keep in mind when you're prescribing," Coleman says. "Whether patients are treatment-naïve or treatment-experienced, what other risks and resistance they have, and there are a number of issues that go into choosing an agent, so this is one they can consider."

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Clinical reminder might assist physicians in deciding when to offer HIV testing

Created through collaborative effort at VA hospital

Investigators have developed a clinical reminder that provides clinicians with a simple guide to when it's important to offer HIV testing to patients.

"This has been a collaborative effort that has come out of the Veteran Administration's strategic health care group in Washington," says Matthew B. Goetz, MD, chief of infectious diseases at the VA Greater Los Angeles Healthcare System in Los Angeles, CA. Goetz also is a professor of clinical medicine at the David Geffen School of Medicine at the University of California Los Angeles.

"The method takes advantage of the electronic record and uses electronic reminders to prompt clinicians to apply appropriate care to at-risk patients," Goetz explains.

The electronic record provides electronic access to lab records and patient risk factors, and it is used to screen for a variety of diseases, including recent adaptations for HIV, sexually-transmitted diseases (STDs), substance abuse, and hepatitis C infection, Goetz says.

"It's not an entirely perfect screening method because there are some risk factors and behaviors that are not captured by an electronic record, in part because patients don't always acknowledge their behaviors," Goetz says. "But clinicians in the day-to-day practice are sufficiently busy that they don't have the ability to screen patients themselves for risk factors."

The system works this way: clinicians enter progress notes on the computer and look to see if there are any clinical reminders that need to be addressed for that particular patient, Goetz says.

"They have reminders for diabetes care, hypertension care, screening for cancer, amongst many other items," Goetz says.

"We adapted it for HIV care and the reminder software goes into the patient's database, saying the patient is known to be infected with hepatitis C, for example," Goetz

explains. "When the clinician clicks on the reminder box, it says, 'This patient has a risk factor for HIV infection.'"

Then the clinician can click on the link to see what the risk factor is, Goetz adds.

"The reminder instructs the provider how to counsel and test the person for HIV, and it's all consistent with the VA and federal regulations regarding voluntary nature of HIV testing," Goetz says.

Typically the entire screening process takes 2 to 3 minutes, although if patients ask a lot of questions it could take longer, Goetz says.

"And there are providers who have to give everything a lengthy explanation," Goetz says.

"The template gives the provider an algorithm to follow to appropriately counsel the person and get informed consent for testing, and it gives the provider an opportunity to see if the patient has been tested outside the VA and then to enter the results into the system," Goetz says.

Pilot testing of the system took place in Los Angeles and San Diego, using a network personal computer system in which a computer is in every exam room, so physicians can look at it while examining patients, Goetz says.

"The computer is like our right hand," Goetz says. "And I believe the VA has the most advanced medical records system in the country, if not internationally."

The software includes hyperlinks to instructions, including hospital policy and details, and it provides various scenarios for every suggestion, he says.

For instance, when the screen window says the patient has a risk factor, it also provides 4 different responses as to how to satisfy the request for HIV testing, Goetz says.

"If the patient indicates he wishes to undergo HIV testing, then the instructions say how to fill out the HIV consent form, and the form goes through detail on the meaning of the HIV test, confidentiality and care for patients who have HIV," Goetz explains.

There are technical instructions regarding the test, and the physician can order the test electronically and then have the blood drawn, he says.

"There's another project going on where we're looking at patients' acceptance of rapid HIV testing, and we're looking at procedural matters so it could be implemented in an effective way," Goetz says. "Interim data is favorable, and we anticipate implementing rapid testing in our facility."

Research about the use of the electronic screening method has shown that it is cost effective down to a prevalence rate of about 0.5 percent, and it is effective even to a prevalence rate of 0.1 percent if you consider the impact of HIV testing and HIV therapy on subsequent HIV transmission, Goetz says.

"Across the VA as a whole, we believe our HIV prevalence is 1 percent," Goetz says.

"We don't recommend that all veterans are screened because we don't have enough evidence that it's cost effective," Goetz notes. "We're trying to demonstrate in this population that this is a process that can be incorporated into standard clinical practice."

Since the screening method has sufficiently small impact on physician work flow and it has a high yield in terms of new diagnoses of HIV, investigators are hopeful that if it's successful they'll move to the next step of using the screening system routinely, Goetz says.

One of the reasons such a screening tool is needed is because physicians tend to believe HIV testing is special and that they aren't qualified to screen for HIV unless they are trained experts, Goetz says.

"We're trying to change the paradigm for doing this and show HIV testing as a normative behavior, just as testing for hepatitis C and testing for syphilis and hepatitis B," he says. "One does not need to stigmatize the patient or stereotype the interaction."

So in addition to providing an electronic tool, it's important to educate clinicians about HIV testing and how to have a dialogue with patients in which HIV risk and HIV testing are discussed, Goetz says.

"We have our study staff go down to the clinic and talk with doctors," Goetz says. "We don't have a fully-developed process at this time, but we're trying to determine what educational materials providers need and how to customize those materials to different levels."

Eventually, there might be enough societal acceptance of HIV infection that it will become normalized, and the screening process will become routine and very brief, Goetz says.

"We've talked with other VA facilities that are interested in adopting our model," Goetz says. "No one outside the VA has contacted me, but there are lessons that would be of interest to other integrated health care management groups and others with electronic medical records because the overall model is streamlining HIV testing to make it part of the standard of care of patients."

COMPLIANCE CORNER

Research helps identify those at risk for non-adherence

Identify those at risk using 3 elements

Behavioral compliance interventions typically are time-consuming and costly, but it might work more efficiently if clinicians quickly could identify the patients most in need of such assistance.

New research suggests a 3-part strategy for identifying HIV patients who are at risk for poor adherence and who might benefit from a behavioral intervention.

"For those of us working with HIV patients, we've seen tremendous gains in the use of highly active antiretroviral treatment [HAART]," says David Ramstad, PsyD, MBA, director of training at the Carl T. Hayden VAMC in Phoenix, AZ.

"But a subset of people are failing, and most of the research seems to be focused on people who are compliant, and those are not the people we're having problems with," Ramstad says. "The biggest number of those who are not doing well are those who have poor adherence."

HIV patients most at risk for poor medication adherence are those who are abusing substances and those who are depressed, Ramstad notes.

"One of the things we also know is when people come into the clinic, they don't say, 'I'm not taking my medicine,'" he says.

So Ramstad and co-investigator Lagen Biles, a former intern at the VAMC, investigated the use of a quick procedure for identifying patients who need adherence assistance.

"We reviewed the guidelines that are available, and they didn't seem realistic in terms of the amount of time a physician has when seeing patients in a clinic," Ramstad says. "So we came up with quick measures that could be implemented in almost any setting and implemented by anyone—the receptionist could do one part, and the nurse could do a part."

The 3 elements used to identify those at risk for poor adherence and the study's recommended assessment method are as follows:

- Substance use: collect urine drug screens;
- Depression: administer the Beck Depression Inventory (BDI);
- Continued transmission risk: provider inquiry of risk exposures and adherence to treatment recommendations.[1]

The last category was selected because investigators were interested in identifying people who might be re-exposed through additional exposures, whether through sex or needles, Ramstad says.

The BDI is an 18-item measure that gives a score for a person's level of depression, and it could be administered while a patient is waiting for the doctor's visit to begin.[1]

The urine screening, which could be administered along with other laboratory draws, will easily tell if someone is using substances, he explains.

Investigators created a 3-question survey for assessing transmission risk, and the questions can be asked by the nurse or physician when the patient is brought back into the office, Ramstad says. The questions are as follows:

- Have you shared any needles with someone else?
- Have you engaged in any sexual activity that might have re-exposed you to HIV?
- Are you taking an active stance to try to prevent transmission to HIV?

"What we're finding in our clinic, which is probably true in most clinics with established patients, is our patients are very straightforward and honest with us," Ramstad says. "This may not be true when someone is going to a clinic where they don't have an established relationship with providers."

Patients may minimize their risk factors if they are afraid of a lecture or of being treated badly, Ramstad says.

Investigation into the use of the screening methods continues, Ramstad says.

"We're trying to establish in a more psychometric fashion the degrees to which these approaches will help us predict which people have better adherence for HAART," Ramstad says.

"We're still in the process of data collection, but essentially, we're finding the data does support our hypothesis that depression is an indicator for poor compliance," Ramstad says. "We're finding that at mild-to-moderate levels of depression it does not impact adherence, so it's only for more severe cases of depression."

This finding confirms previous research showing that when people have more severe depression the illness itself impacts a people's functional level and their ability to manage their lives, Ramstad notes.

"They're overwhelmed and don't have the energy and resources to manage it," he says. "That was consistent with what anecdotally we expected to find."

With substance use, even mild abuse of alcohol and drugs significantly impacts adherence, Ramstad says.

"Anecdotally, it makes sense," he says. "If someone was out partying all night and sleeps in, then he misses his morning dose."

The data reveal mixed results on the transmission risk factors, Ramstad says.

"But we do know, not from our data, but from other's, that people who are using substances are more likely to engage in risk behaviors because their judgment is impaired," he says. "They're out and having a good time and meet someone, and maybe if they were sober they wouldn't engage in risky behavior, but that's from other people's data."

A chief advantage to using this type of screening for poor adherence is it will give clinicians a faster indication of problems than if they were relying on viral load and t-cell data, Ramstad says.

The study indicates that a proven adherence strategy is motivational interviewing in which clinicians use the stages of change model.[1]

Broken into its 5 essential elements, the provider using motivational interviewing can do the following, according to the study:

- Express empathy: show understanding of ambivalence toward change;[1]
- Develop a discrepancy: point out discrepancy between behavior and desire to change;[1]
- Avoid arguing: avoid confrontation—it strengthens maladaptive behavior;[1]
- Roll with resistance: revisit the discrepancy of goals and behavior;[1]
- Self-efficacy: support personal responsibility and support their successes.[1]

The next phase of research is to conduct an outcomes study with motivational interviewing to see if the behavioral intervention works with the patients who are found at risk through the 3-part screening process, Ramstad says.

"We hypothesize this is the approach that will work with them," Ramstad says. "It's consistent because it comes out of the old, client-centered approach, which is nonjudgmental and allows people to gain on inner strengths."

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HIV patients taking antiretrovirals should avoid garlic, St. John's wort

Other health products were fine

Many people infected with HIV look to natural health products to supplement their conventional medical care, and clinicians, understandably, are concerned about drug interactions.

Most of the time, there's little risk of problems, but patients and clinicians should be aware of potential risk when HIV patients ingest St. John's wort and supplemental garlic, a researcher says.

"We looked at all natural health products, and the important interactions we found may exist with St. John's wort, garlic, and possibly vitamin C," says Ed Mills, DPH, MSc, a fellow at McMaster University in Hamilton, Ontario, Canada, and a lecturer at Oxford University in Oxford, United Kingdom. Mills also is the director of the division of clinical epidemiology at the Canadian College of Naturopathic Medicine in Toronto, Canada.

Since conducting the first study, investigators have ruled out vitamin C, Mills adds.

"Since that time we have redone the vitamin C [part of study], and we found it did not have the potential to interact in our clinical study," Mills says. "Garlic and St. John's wort are a valid concern."

Mills and co-investigators looked at clinical studies that examined drug interactions and assessed their methodological quality, he says.

Investigators found there was an important interaction between garlic and protease inhibitors and an important interaction between St. John's wort and indinavir.[1]

"The use of natural health products is in line with the belief system of many people living with HIV, and they use the products to improve their quality of life," Mills notes.

So when the clinical community reacts by suggesting HIV patients should not take any natural health products because of the potential for interac-

tions, the patients' response is that they are being forced into increased medicalization, he says.

The research is limited in addressing this issue, he says.

"A lot of studies on the topic have inferences drawn from it that are weak," Mills says.

"There have been studies like that in the past about St. John's wort, but the concern is there are side effects of St. John's wort in the long term," Mills says. "It uses enzyme systems that metabolize antiretroviral drugs, so it can reduce the level of antiretroviral drugs in the body."

Mills says the research suggests HIV patients should avoid St. John's wort, although it's an important herb because many people with HIV do have depression, which is what it is used to treat by some people.

The studies involving garlic used large doses of garlic, and these also competed for the same pathway as antiretroviral drugs, Mills says.

"We don't think people should be concerned about the amount of garlic in their food," Mills says. "Garlic has some evidence of a [positive] effect on heart conditions, so it's disappointing that it would compete for the same pathway, but we don't recommend people take garlic supplements."

Vitamin C and milk thistle, which is used for liver conditions, were found to have no interactions with antiretroviral drugs, so they likely are safe to take, Mills says.

"It's not easy for the HIV population to make decisions, and further research is needed on this issue," Mills says. "But this information has to be balanced, and I don't think people should be overly concerned about drug interactions with natural health products—even the studies on St. John's wort were inconsistent."

Clinicians should discuss natural health use in an open and nonjudgmental manner, realizing that use of complementary medicine is in line with many of their patients' beliefs, Mills suggests.

"The problem is that data are so limited at the moment that it's difficult to say with certainty that anything is safe," Mills says. "But clinicians should provide a balanced view, saying researchers have looked at all drug interaction trials and at the moment the only thing patients should be concerned about are St. John's wort and garlic."

As antiretroviral drug use spreads to sub-Saharan Africa and other parts of the world, more research on interactions of antiretrovirals and natural health products should be a research priority, Mills says.

"Further research is required to look at the safety of traditional medicines for use in that population," Mills says. "The current minister of health in South Africa is recommending the use of traditional plants in South Africa, and there is in vitro evidence that this traditional plant, an African potato, does interact with antiretroviral drugs so research is needed quite quickly."

Reference

1. Mills E, et al. Natural Health Product—HIV Drug Interactions: A Systematic Review. *Int J of STD AIDS*. 2005;16:181-186.

Study of efavirenz over 96 weeks shows durability, efficacious regimen

Results from 48-96 weeks essentially same

Recent results from the Daily Antiretroviral Therapy (DART 1) trial show promising results for antiretroviral-naïve patients.

The 96-week study results from 65 patients who were treated with the combination of once-daily efavirenz (600 mg), lamivudine (300 mg), and didanosine (400 mg) showed that the rates of patients achieving HIV-1 RNA viral loads of less than 400 copies were essentially the same as the previous 48-week results.[1]

"For the 96-week study, the HIV RNA of less than 400 copies in an intent-to-treat analysis was 74 percent, and in the treated analysis, which only included patients who were able to remain on the study, it was 100 percent," says Edwin DeJesus, MD, medical director of the Orlando Immunology Center in Orlando, FL, lead author of the study.

"When we looked at an analysis of less than 50 copies, the intent to treat group had 68 percent, and the treated analysis group was at 92 percent," DeJesus says.

The intent to treat group included responses from patients who had discontinued the study for various reasons, DeJesus explains.

"Once a patient took a dose of medication, the patient was counted," he says.

The once-daily regimen was a simple one of 3 pills, chosen for its convenience and safety, DeJesus says.

"We want to be able to provide future patients with options that are less toxic and lead to less chronic adverse events," DeJesus explains. "This regimen provides a good alternative for that."

The phase IV, open-label, single arm study followed patients prospectively for nearly 2 years, looking at both efficacy and safety in patients who were new to antiretroviral treatment.

"It's important to study the durability of these regimens," DeJesus says.

The patients had baseline viral loads of greater than 1000 copies, and their baseline CD4 cell counts were equal to or greater than 100, he says.

"These patients couldn't have an AIDS diagnosis, but they could have had it in the past, as long as they were antiretroviral naïve," DeJesus says.

"The beauty of these results were when you compare the week 48 to week 96, the results were essentially the same," DeJesus says. "All of the patients who continued the study continued from week 48 to 96, so there was no virologic breakthrough from week 48 to 96."

This means that once patients took the once-daily medication regimen they continued to respond, and they had no virologic breakthroughs of having a HIV viral load of less than 400 copies on 2 consecutive occasions.[1]

"The main take-home message of this study is that there was no discontinuation on the second year of follow-up due to virologic failure, breakthrough virus, or lack of efficacy," DeJesus says. "The importance of this study is it gives us another simple option with 3 pills, once a day."

Reference

1. DeJesus E, et al. Efficacy and Safety of a Once-Daily Efavirenz-Based Regimen for Treatment Naive HIV Subjects: 96-Week Results from the DART I Trial. Presented at the 10th European AIDS Conference/The European AIDS Clinical Society, Nov. 17-20, 2005, in Dublin, Ireland. Poster: PE7.3/3.

FDA Notifications

FDA grants tentative approval to generic Nevirapine

The Food and Drug Administration (FDA), on Dec. 27, 2005, granted tentative approval, through an expedited procedure, to generic Nevirapine Oral Suspension, 50 mg/5 mL, manufactured by Aurobindo Pharma LTD., of Hyderabad,

CE/CME *questions*

5. Among all women in the United States, what percentage of new HIV diagnoses are among black women, according to 2001-2004 data from the Centers for Disease Control and Prevention, using data from 33 states?
   A. 47 percent
   B. 55 percent
   C. 63 percent
   D. 68 percent

6. In a recent study, patients taking which protease inhibitor were found to have a significantly lower risk over a 10-year period of coronary heart disease than did patients taking nelfinavir?
   A. Amprenavir
   B. Atazanavir
   C. Lopinavir
   D. Saquinavir

7. Which of the following is not one of the three elements used to identify those at risk for poor antiretroviral adherence, according to a new study about an electronic screening tool?
   A. Substance use: collect urine drug screens;
   B. Risk behavior: 20-question survey about sexual and drug-using risk behaviors
   C. Depression: administer the Beck Depression Inventory (BDI);
   D. Continued transmission risk: provider inquiry of risk exposures and adherence to treatment recommendations.

8. A recent study found that which natural health products had an important and negative interaction with some antiretroviral drugs?
   A. Garlic
   B. St. John's wort
   C. Vitamin C
   D. Both A and B

CE/CME *directions*

To complete the post-test for *AIDS Alert*, study the questions and determine the appropriate answers. After you have completed the exam, check the answers **on p. 24**. If any of your answers are incorrect, re-read the article to verify the correct answer. At the end of each six-month semester, you will receive an evaluation form to complete and return to receive your credits.

India. This product is a generic version of the approved product, Viramune Oral Suspension, 50 mg/5 mL, manufactured by Boehringer Ingelheim Pharmaceuticals. It is indicated for use in pediatric patients with HIV.

Nevirapine is active against the human immunodeficiency virus (HIV) that causes AIDS. It is in the class of drugs called nonnucleoside reverse transcriptase inhibitors (NNRTIs), which helps keep the AIDS virus from reproducing. It is used in combination with other antiretroviral agents for the treatment of HIV-1 infection.

FDA tentative approval means that although existing patents and/or exclusivity prevent marketing of this product in the U.S., it meets all of FDA's manufacturing quality and clinical safety and efficacy standards required for marketing in the United States. As with all generic application assessments, FDA conducts an on-site inspection of each manufacturing facility and of the facilities performing the bioequivalence studies prior to granting approval or tentative approval to these applications to assess the ability of the manufacturer to produce a quality product and to assess the quality of the bioequivalence data supporting the application.

Tentative approval by FDA means that this product will now be available for consideration for purchase under the President's Emergency Plan for AIDS Relief (PEPFAR).

FDA grants tentative approval to generic stavudine

The Food and Drug Administration (FDA) granted, on Dec. 21, 2005, tentative approval to generic stavudine for Oral Solution, 1 mg/mL manufactured by Aurobindo Pharma LTD., of Hyderabad, India. This product is the first generic version of the approved product, Zerit for oral solution, manufactured by Bristol-Myers Squibb. This child-friendly product is indicated for use in pediatric patients with HIV from birth through adolescence.

Stavudine (d4T) is active against the human immunodeficiency virus (HIV) that causes AIDS. It is in the class of drugs called nucleoside reverse transcriptase inhibitors (NRTIs), which helps keep the AIDS virus from reproducing, and is used in combination with other antiretroviral agents for the treatment of HIV-1 infection.

FDA tentative approval means that although existing patents and/or exclusivity prevent marketing of this product in the United States, it meets all of FDA's manufacturing quality and clinical safety and efficacy standards required for marketing in the United States. As with all generic application assessments, FDA conducts an on-site inspection of each manufacturing facility and of the facilities performing the bioequivalence studies prior to granting approval or tentative approval to these applications to assess the ability of the manufacturer to produce a quality product and to assess the quality of the bioequivalence data supporting the application. ■

Tentative approval by FDA means that this

CE/CME objectives

After reading this issue of *AIDS Alert*, CE participants should be able to:

- **identify** the particular clinical, legal, or scientific issues related to AIDS patient care;
- **describe** how those issues affect nurses, physicians, hospitals, clinics, or the health care industry in general;
- **cite** practical solutions to the problems associated with those issues, based on overall expert guidelines from the Centers for Disease Control and Prevention or other authorities and/or based on independent recommendations from specific clinicians at individual institutions. ■

CE/CME *answers*

Here are the correct answers to this month's CME/CE questions.

5. D **6. B** **7. B** **8. D**

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