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# AIDS and privacy groups criticize proposed changes to federal privacy rule

*Changes will not safeguard HIV patients, they charge*

The importance of medical privacy protection was perhaps never made more clear than when the AIDS epidemic emerged and many HIV-positive people discovered that strangers had access to their private medical information.

Fear of HIV status disclosures without consent is often cited as one of the primary reasons at-risk people refuse to be tested unless anonymous testing is available.

Then, with the passage of the 1996 Health Insurance Portability and Accountability Act (HIPAA), a new privacy rule offered hope that all patients, including those infected with HIV, would have greater protection against undesirable medical disclosures.

This hope has been dampened in recent months as the Department of Health and Human Services (HHS) has issued proposed changes to the privacy rule that undermine many of its protections, according to HIV and privacy advocates, as well members of Congress.

HHS under President George W. Bush's administration has proposed relaxing rules about obtaining privacy consent. Under the original privacy rule, health care providers would need to obtain an individual's consent prior to using or disclosing protected health information for treatment, payment, and health care operations. HHS now proposes to eliminate the prior consent requirement and substitute it with a good-faith notification.

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■ What's the latest on CDC's prevention goals? Here's an update on prevention projects, studies, and results

■ Children continue to suffer from epidemic worldwide: International groups highlight HIV's toll on children in developing nations

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**Editorial Questions**

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"President Clinton did what he could, and now the pendulum swings backwards, and President Bush's administration says the privacy regulations are too restrictive," says **Scott Brawley**, MSW, director of public policy for AIDS Action in Washington, DC.

On the other side of the issue, the American Hospital Association (AHA) of Chicago applauds the administration's changes, saying in an April 25, 2002, letter to HHS secretary Tommy Thompson that the switch from written privacy consent to privacy notification would eliminate barriers to care and redundant paperwork.

The AHA says in a prepared question-and-answer memo for hospital patients that patients' rights will still be protected even if they are not required to sign a written consent form for privacy.

"Hospitals are still required to provide you with a written notice of their privacy practices (called a 'privacy notice') that explains how hospitals are permitted to use your medical information," the Q&A memo states.

HIV and privacy advocates say the biggest problem with the proposed regulations and changes is the change in consent requirements, because a privacy notice is not as strong a protection.

"If we're going to give people a right to privacy, then they need to have real control over it," says **Jeffrey Crowley**, MPH, project director for the Institute for Health Care Research and Policy in Washington, DC.

"Some people say there's little difference between notice and consent, but I say there's a huge difference," Crowley says. "Where someone has to be told and has to confirm to consent is different from a notice that anybody can argue they had given to a patient."

In an April 26, 2002, letter to HHS, **Bill Thomas**, chairman of the AHA committee on ways and means, and Rep. **Nancy Johnson**, chairman of the House Ways and Means committee's subcommittee on health, write, "Patient care could have been seriously harmed if providers were required to obtain consent prior to treatment. However, we are concerned that the requirement that providers make a good faith effort to obtain written acknowledgement of a covered entity's notice of privacy practices will be confusing for patients and lacks any meaningful confidentiality protection."

Thomas and Johnson continue to urge HHS not to implement the change and to simply require the notice to be provided without written acknowledgement.

In an April 26, 2002, letter to Thompson, 16 members of Congress say the administration has proposed several steps that would undermine privacy, including the elimination of the patient consent requirement for treatment, payment, and health care operations. **(See story on other proposed changes to the privacy rule, p. 84.)**

Other concerns the congresspeople raise include:

- a marketing definition that would allow disclosure without permission by patients of their patient records for marketing activities;
- "public health" disclosures that would give drug companies new access to patient records without patient permission;
- a loophole that will allow the disclosure of medical information to non-health care components by expanding the category of "covered entities."

Even under the existing privacy consent requirement, health care providers would need to educate patients about their rights, but at least consent would be required, Crowley says.

"Because of ongoing discrimination faced by people with AIDS, these concerns could be more pronounced," Crowley says.

## *Serious breaches already have occurred*

If HIV/AIDS patients have some paranoia about how their health information is being used, it's probably because some very serious breaches of privacy have become public knowledge.

For example, the Lambda Legal Defense and Education Fund of New York City is representing a case that is being presented to the U.S. Supreme Court that involves job discrimination against an HIV-positive dental hygienist. While the court case doesn't address the privacy issue, the entire case would never have occurred were it not for the fact that the HIV patient's doctor violated the man's privacy.

"We're representing Spencer Waddell, a dental hygienist who worked for Dental Associates in Atlanta, and he went to his doctor and was given an HIV test and he tested positive," explains **Catherine A. Hanssens**, JD, director of the AIDS Project for Lambda Legal Defense and Education Fund Inc.

"His personal physician took it upon himself to call Spencer's employer without Spencer's knowledge or consent to say that they had an employee who tested HIV-positive," Hanssens says.

"Mr. Waddell was a highly regarded professional until the day he was found to be HIV-positive, and then his employer responded by giving him a choice between becoming a receptionist at half the salary or to get fired," Hanssens adds. "He chose not to work at the front desk, and we lost the case in district court and the court of appeals and now are asking the Supreme Court to look at the case." (*Editor's note:* Shortly before *AIDS Alert* went to press, the Supreme Court declined to review this case.)

While Waddell has a separate action against the physician who violated his trust, any victory he receives there will do little to remedy the situation, Hanssens says.

The fact is that according to guidelines from the Centers for Disease Control and Prevention in Atlanta, the risk of a dental hygienist transmitting HIV to dental patients is so tiny that it's practically a zero risk, Hanssens says.

"You can't put the genie back in the bottle," Hanssens notes. "This man lost his job, and he is now working for a dental clinic that treats only people with HIV, and he figures his options are over, so he's going public to demonstrate the level of discrimination that people with HIV experience."

Unfortunately, Waddell's privacy breach is not an isolated case. There have been other instances of hospital receptionists, pharmacists, and other health care professionals who have gossiped about HIV patients, causing them problems at work and with their families, who may not have known their HIV status.

And the privacy rule with its proposed changes will do little to alleviate fears of these sorts of disclosures, Crowley says.

"Say you're in a small town and you go into the hospital, and you don't want your neighbor who is a nurse there to know you're HIV-positive," Crowley speculates. "The initial privacy rule would allow you to make a request that you give your consent to share information, but you would like to make certain this nurse doesn't see it."

The hospital would either accept or deny your request. But under the proposed consent changes the hospital will merely give you notice of your privacy rights, and you may never have the opportunity to make such a request, Crowley says.

"People who claim the consent requirement is too burdensome are overlooking the fact that right now we go in for health care and have to sign forms," Crowley says. "It can't be too burdensome because we're already doing it." ■

# HHS seeks to 'fix' aspects of privacy rule

*Marketing, loopholes attacked in proposal*

While critics of the proposed changes to the federal health care privacy rule are most concerned about the elimination of a signed consent, they also say some of the other proposals will seriously undermine patients' right to privacy.

The Department of Health and Human Services (HHS) has proposed these changes:

- Allow treatment-related conversations while maintaining the "minimum necessary" rule. The proposed change would make it clear that doctors could discuss a patient's treatment with other professionals involved in the patient's care without fear of violating the privacy rule. Improper disclosures, such as failing to protect against incidental disclosures, would still violate the rule.
- Parental access to their children's records is assured, subject to state laws.

## Permission required for marketing

- Records are prohibited from being used for marketing purposes, but appropriate communication is permitted. Pharmacies, health plans, and other covered entities are required to first obtain an individual's specific authorization before sending them any marketing materials.
- Researchers would not be required to use multiple consent forms and could instead use a single combined informed consent/privacy form.
- Rather than requiring covered entities to have contracts with their business associates to ensure they follow the privacy rule, covered entities would be able to adhere to model business associate contract provisions, which are easier to follow and less costly.
- A single type of authorization form could be used to obtain a patient's permission for a specific use or disclosure that otherwise would not be permitted under the rule.

Sixteen members of Congress, in an April 26, 2002, letter to HHS secretary Tommy Thompson, say they are concerned about the proposed changes in how the privacy rule will affect marketing.

"The Administration's proposed authorization requirement for marketing activities is rendered

virtually meaningless by the proposal's creation of broad exceptions to the 'marketing' definition," the congresspeople write.

"For example, in contrast to the final rule, under the Administration's proposal, communications to an individual regarding medical products or services are not considered 'marketing' even if (1) the communications are made by a party other than the individual's health care provider or health plan, and (2) the individual's health care provider disclosed the individual's medical records to the party for the purpose of the communications and received remuneration for this disclosure," the letter states.

## Drug companies could get private info

This change could pose critical disclosure problems for patients, particularly those with HIV, says **Scott Brawley**, MSW, director of public policy for AIDS Action in Washington, DC.

"If an HIV patient sees a doctor and receives a prescription, then maybe the company that makes the drug will contact the pharmacist to have the patient reminded to have the prescription filled," Brawley says.

Under the final privacy rule, the pharmacist would have to let patients know that the pharmacy is being paid by the drug company to give patients this notice, and if a person doesn't wish to receive these notifications, then the person can call and be taken off the mailing list, Brawley says.

That's not going to be possible under the proposed changes, because communication related to health or treatment may not be considered marketing, he adds.

Then there are non-health related marketing practices that many people might find offensive, such as companies that send AIDS patients notices that they can sell their life insurance policies in exchange for cash advances, Brawley says.

Under the final privacy rule, a patient would need to give informed consent before any health care provider could supply these sort of companies with private information. It's unclear with the changes proposed whether patients still are protected from these non-health-care marketing tactics, Brawley says.

With the proposed changes to the marketing aspect of the rule, it's possible that patients could be inundated with health care material they do not wish to receive, says **Jeffrey Crowley**, MPH, project director of the Institute for Health Care Research and Policy at Georgetown University in Washington, DC.

"It could be a nuisance or it could be harmful," Crowley says. "Like, what happens if a mother sees that her son is receiving mailings about AIDS drugs, and she didn't know he was infected?"

The disclosures HIV patients probably will have to worry about the most are those that they have no idea are occurring, says **Catherine A. Hanssens**, JD, director of the AIDS Project for Lambda Legal Defense and Education Fund in New York City.

"I think a lot of times people with HIV will not know that disclosures are happening without their knowledge," Hanssens says. "I learned from a physician of mine that a drug manufacturer sent him a complete print-out of all of my prescribing history, when I had taken a certain drug, and what other products the physician might want to recommend or prescribe."

If Hanssens' doctor had not told her about this, she would never have known that her private medical information was being used by a drug manufacturer in an effort to increase business.

"This means the manufacturer of my drug pays the pharmacy chain for personal information about my prescribing history, and it's not in the hands of people who are devoted to my medical care," Hanssens says.

## Minors would lose some privacy rights

The congresspeople also expressed concerns about changes to the rules governing minors' privacy rights. In some states, this would mean providers could disclose private health information to parents without the minor's knowledge or permission, even in cases where the minor is legally permitted to obtain health care without parental consent.

Another proposed change that the congresspeople oppose involves the proposal to eliminate the right of an individual to receive an accounting of disclosures of the individual's medical records by an entity pursuant to the individual's authorization, the letter to Thompson says.

"The Administration's proposal to take away this right would effectively leave no check on what an entity does with an individual's health information once the individuals have signed an authorization," the congresspeople write. "We urge you to abandon this proposal." ■

# Minority patients ignored in HIV drug trials

*Both doctors and patients might be at fault*

Using a snapshot representing all HIV patients in the United States, researchers found that African-Americans and Latinos had substantially less access to clinical trials than whites.

"This was true even when they had comparable health insurance, socioeconomic status, and education to whites," says **Allen L. Gifford**, MD, assistant professor of medicine at the Center for Research on Patient-Oriented Care, the VA San Diego Healthcare System and the University of California - San Diego Department of Medicine in San Diego.

The analysis was conducted as part of the RAND-led HIV Cost and Services Utilization Study Consortium, which is sponsored by the Agency for Healthcare Research and Quality in Rockville, MD.

Its chief findings were that race or ethnic group and type of health insurance influence HIV patients' participation in research trials and access to experimental treatment.[1]

"We were specifically interested in the issue of experimental trials and medication," Gifford says. "This is a piece of an overarching and emerging area of research that describes different ways in which people from minority groups often tend to be underserved with access to treatment, particularly with diseases such as HIV where treatments develop very rapidly."

With HIV disease, those patients who are not receiving the latest medications, as might be offered in clinical trials, are put at a disadvantage clinically because conventional treatment offers limited options, particularly as their drug regimens begin to fail.

"So I think it's a significant issue that people have as many options as possible when they're in the most severely ill state," Gifford says. "These options include access to and participation in clinical trials as a component of therapy, and so we thought it was a significant issue that African-Americans and Latinos were less likely to have access to these trials."

Overall, 14% of adults receiving HIV care participated in a medication trial or study and 24% had received experimental medications, according to the study, which was published in the *New England Journal of Medicine* on May 2, 2002.

Investigators also found that non-Hispanic blacks and Hispanics were about half as likely to participate in trials as non-Hispanic whites.

Some of the reasons why minorities may have less access to and participation in clinical trials include factors that concern perceptions on their part, as well as on the part of their clinicians, Gifford says.

"If African-Americans and Latinos are less likely to access these therapies and trials, then it could be because the individuals themselves are suspicious, or confused by or less motivated to participate in clinical trials or to elect to use experimental therapies," Gifford says. "That's certainly a possibility, and there are hints in the literature that that does indeed happen."

But there are alternative explanations, as well. For instance, it might be the physicians and people enrolling volunteers in clinical trials who carry biases or erect barriers to enrolling minority patients, Gifford says.

"They may feel these patients are less likely to be good study subjects, such as coming back to appointments," Gifford explains. "Trials are expensive, and there's a lot of money invested in each candidate who participates, and there are some who say — rightly or wrongly — that they believe certain types of patients are less likely to be reliable."

## Patient selection slanted toward whites

So it's possible that some clinicians carry unconscious bias against African-American and Latino HIV patients with regard to clinical trial participation.

"We found evidence that both explanations are taking place," Gifford says. "We found that African-Americans and Latinos were less likely than whites to ever try to access experimental meds and get into a trial, suggesting they might be less motivated, less interested."

Researchers also found that when they limited their analysis to the people who were trying to obtain experimental treatments, they found a significant bias against African-Americans and Latinos to get the medications, Gifford adds.

"The system's selection of patients was slanted toward whites rather than minority subjects," he says.

This means HIV clinicians and researchers need to work harder at expanding options for minority patients, Gifford says.

"Those who participate in clinical trials are more likely to be on appropriate antiretroviral therapy, are more likely to be plugged into primary care visits, and are more likely to receive treatment for opportunistic infections," Gifford says. "So especially for those lower on the socioeconomic scale, participation in these clinical trials may be a way to access clinical services."

In an editorial published in the same issue as the study on participation in research, the *New England Journal of Medicine* states that physicians need to be aware of their own prejudicial attitudes toward minority groups and how these might influence their decisions about treatment.[2]

Patients, sensing these biases, may respond to the physician with mistrust and reluctance to adhere to treatment protocols, the editorial notes.

One strategy is for clinicians to build trust with their minority HIV patients, so that when the physician suggests a clinical trial, the patient will feel comfortable enough to ask questions and raise concerns.

"I can't think of a clinical decision that requires more patient education and consideration by doctor and patient than to participate in a clinical trial," Gifford says. "If nothing else, the best summary of the data we have is that trust is absolutely necessary between the person entering the trial and the investigator they are participating with."

It would also help to increase minority trial involvement if clinical trial centers were located in minority communities, Gifford says.

"We found that people who are very close physically to a clinical trial center that does recruiting and is in the community are more likely to access clinical care and experimental medications," Gifford says. "This is one way to access minority communities, because it works: Place trials in minority communities or rent additional space in these communities where it can be more accessible physically to people."

Another change that would help remedy the situation is for HIV clinics and the HIV/AIDS community to do a better job of educating minority patients about clinical research and the ethical rules that clinical trials must follow, helping patients to better understand the risks and benefits of participation. This education should address some of the past research tragedies, such as the Tuskegee syphilis study, and explain how review boards and other safeguards now protect against such tragedies.

Clinicians also need to consider that there is a public health benefit to enrolling more minorities in clinical trials because it's possible that certain populations may respond to drugs differently than others. If all research is done on whites, it's only theoretical whether the effects would be the same for African-Americans or Latinos, Gifford says.

"Has clinical research been handled irresponsibly in the past? Yes it has," Gifford says. "But we have evidence that there have been very good and positive, responsible systems put into place to see that it doesn't happen again, and I think we do a good job in general."

### References

1. Gifford AL, Cunningham WE, Heslin KC, et al. Participation in research and access to experimental treatments by HIV-infected patients. *N Engl J Med* 2002; 346: 1373-1382.

2. Editorial. Racial disparities in clinical trials. *N Engl J Med* 2002; 346:1400-1402. ■

# Acute HIV infection transmits greater risk

*Study finds more HIV shedding in semen*

It's long been hypothesized that semen viral load is the explanation for why there appears to be greater HIV transmission associated with acute infection. Now a study confirms this perception.

People who have sex with a partner during an acute HIV infection phase may be at a 20-fold greater risk per exposure than are partners of individuals who are at a virologic set point, according to a recent study.[1]

"Confirming what the natural history of semen HIV viral burden has been a difficult challenge because patients who are acutely infected don't often consent to donate semen, and moreover, they're being treated," notes **Christopher D. Pilcher**, MD, assistant professor of medicine at the University of North Carolina - Chapel Hill.

"So our approach was to collaborate with other investigators who had collected HIV semen levels," Pilcher says.

UNC researchers worked with investigators from the University Hospital in St. Gallen, Switzerland, and Emory University in Atlanta. Together they obtained matched blood and

semen concentrations from 30 patients who had acute infection, Pilcher explains.

"We timed each data point for each individual from the time of their estimated infection, and what we found was that just as has been described in blood, semen HIV burden appears to be much higher in patients around the time of the onset of symptoms," Pilcher says. "And it decreases over time, as is apparent in blood."

The changes observed in semen over time are parallel to those that have been described in blood over time, he adds.

"The decrease is gradual over four months to the virologic set point," Pilcher says.

After running a statistical analysis with their findings and plugging these into a previously published model, investigators were able to estimate the transmission rate per coital act probability for patients with different semen concentrations.

"The partners of patients with acute infection would be at approximately 20-fold increased risk with each sexual act around the time of acute infection, compared with four months later," Pilcher says.

### Reference

1. Pilcher C, Tien H, Stewart P, et al. Estimating transmission probabilities over time in acute HIV infection from biological data. Presented at the 9th Conference on Retroviruses and Opportunistic Infections. Seattle; Feb. 24-28, 2002. Poster 366-M. ■

## Separate lineages of HIV super-fast progressors

*Investigators find patients by accident*

Researchers at the University of Washington in Seattle made an interesting discovery during their routine study of a cohort of HIV-infected patients: Two men in the cohort were discovered to have two divergent subtype B sequences, indicating they had two independent viruses from independent people.[1]

"We sampled at six months post seroconversion and found only one of the lineages, and six months later the other lineage occurred," says **David Nickle**, MS, a research scientist in the department of microbiology.

"That's not to say the second lineage wasn't there in the first time point, because it might have been there at a low frequency," Nickle explains.

The discovery included different lineages within HIV subtype B, meaning the lineages were independent strains and genetically distinct, Nickle says.

Subtype B is the most common HIV subtype in the United States.

"This is atypical," Nickle says. "You don't expect this sort of pattern."

After making the discovery, investigators applied for a grant to study the phenomenon and to study their hypothesis that dual infection leads to fast progression, since both dually infected patients were found to have progressed to AIDS within three to four years, Nickle says.

Both patients died before the advent of highly active antiretroviral therapy, Nickle notes.

Dually infected patients typically aren't discovered because most HIV tests are not designed to pursue this detail, he adds.

"You have to be in a special cohort where people are sampling your blood to detect such a thing," Nickle says.

Investigators found that both subtype B clades co-existed and fluctuated in representation throughout the disease course, and that the two groups evolved at significantly different rates.

"We did one experiment where you sample any independent virus in the database and see how far apart they are from each other, and these two lineages are as far apart from each other as any given random pair in the database, under subtype B," Nickle says.

"What is very interesting is that these two different and separate lineages were maintained through time," Nickle says.

It's common to expect that after many generations, one of the lineages will be lost through genetic drift, but that did not occur in the cases of the two patients, probably because the different HIV clades were using different resources within the patients, Nickle says.

"So both are found in the blood, but they are not overlapping in resource use," Nickle explains.

### Reference

1. Li F, Shankarappa X, He H, et al. HIV-1 evolutionary dynamics in a dually infected HIV-1 patient. Presented at the 9th Conference on Retroviruses and Opportunistic Infections. Seattle; Feb. 24-28, 2002. Poster 356-M. ■

# Future spread of HIV will be drug-resistant strains

*Model based on frequency of transmissions*

In a collaboration that includes researchers from California and the United Kingdom, a recent study predicts that people who are newly infected with drug-resistant virus will be the major source of new resistant infections.[1]

"We wished to explore the underlying causes of drug resistance, and made use of retrospective clinical data," says **Andrew Leigh Brown**, PhD, a visiting professor at the University of California - San Diego and a chief author of the study. Brown also is a professor at the University of Edinburgh in Scotland.

Investigators observed drug resistance among a cohort of HIV patients in San Diego. They found that drug resistance existed in a little more than 20% of newly infected individuals between 1998 and 2000, Leigh Brown says.

As part of their investigation into discovering new transmission routes of drug resistance, the researchers compared those who were infected with a drug-resistant virus to those who were not, Leigh Brown says.

"We are developing and refining a model to make a more accurate projection of where and how this epidemic will develop," he says.

The investigators found that patients with acquired resistance harbor both wild-type and resistant strains, and either may be transmitted, whereas people harboring a transmitted resistance strain can transmit only resistant strains until a revertant arises.

This finding led them to surmise that transmitted drug resistance will continue to increase, which means interventions to prevent transmission are more important than ever before.

"It happens very infrequently that people are dually infected with different strains," Leigh Brown says."We know this has to be the case, because worldwide there's a very large recombinance between subtypes, and these could only arise if an individual is dually infected with two subtypes."

No one knows how frequently this occurs, because dually infected individuals are difficult to identify.

"We had a single case where we observed an individual who was infected with two different strains, and our interpretation was that he was dually infected at roughly the same time," Leigh Brown says. "Our interest in that case was because one strain was multidrug-resistant, and the other was not."

Researchers hypothesized that the patient was infected initially with the drug-resistant strain and later acquired the drug-sensitive strain, which was the same subtype but a different strain, Leigh Brown says.

Eventually, investigators expect to develop a clinically relevant model that will be available for use with observations and data on frequency of transmissions and prevalence of drug resistance. This information may aid clinicians in deciding the best course of treatment for a particular patient, Leigh Brown says.

"Previously published models of drug-resistant HIV epidemics have been primarily fundamentally theoretical models that identified possible outcomes," Leigh Brown explains. "We're trying to develop a clinically based model that will allow us to project the likely outcome."

### Reference

1. Leigh Brown AJ, Frost SDW, Mathews WC, et al. Will transmission of drug resistant HIV be driven by individuals infected with drug resistant strains? Presented at the 9th Conference on Retroviruses and Opportunistic Infections. Seattle; Feb. 24-28, 2002. Poster 367-M. ■

# New HIV guidelines offer adverse effects data

*New guidelines available on-line or in booklet*

The "Guidelines for Using Antiretroviral Agents Among HIV-Infected Adults and Adolescents" have been updated with additional information linking the use of antiretroviral therapy to chronic diseases and adverse events.

The guidelines, which are recommendations of the Panel on Clinical Practices for Treatment of HIV, were prepared by the National Center for HIV, STD, and TB Prevention and the Division of HIV/AIDS Prevention - Surveillance and Epidemiology, Centers for Disease Control and Prevention of Atlanta. Representatives from the National Institutes of Health in Bethesda, MD, and Johns Hopkins University in Baltimore also were involved in updating the guidelines.

Here are some of the new aspects of the updated guidelines:

• New studies offer additional information about when clinicians should initiate antiretroviral therapy among asymptomatic patients. One such collaborative analysis of data from 13 cohort studies conducted in North America and Europe showed that there is a 15.8% 3-year probability of progression to AIDS or death among drug-naive patients who do not have AIDS-defining illness, whose viral load is less than 100,000 copies/mL, and for whom therapy was initiated when their CD4+ T-cell counts were 0-49 cells/mm$^3$. This rate dropped to 9.3% for those whose CD4+ T-cell counts were 100-199, to 4.7% among those whose CD4+ T-cell counts were 200-349, and to 3.4% among those with CD4+ T-cell counts of 350 or higher. **(See chart on therapy initiation, at right.)**

• A protease inhibitor (PI)-sparing regimen of abacavir plus two nucleoside reverse transcriptase inhibitors (NRTIs) has been shown to produce a similar viral load suppression and CD4+ T-cell response as PI-containing regimens and the other PI-sparing regimen of efavirenz plus two NRTIs. The guidelines caution that whether these PI-sparing regimens will provide comparable efficacy with regard to clinical outcomes still is unknown.

• Evidence continues to mount that NRTIs can lead to chronic compensated hyperlactatemia. Also, severe lactic acidosis with or without pancreatitis have been reported during the later stages of pregnancy or among postpartum women who were on an antiretroviral therapy of stavudine and didanosine plus other agents during the later stages of pregnancy. There were three reported deaths from this adverse effect.

• The guidelines carry further information about the connections between HIV treatment and hepatitis. Among the non-nucleoside reverse transcriptase inhibitors (NNRTIs), nevirapine has the greatest potential for causing clinical hepatitis. Reports show a 12.5% incidence of hepatotoxicity among patients initiating nevirapine, with clinical hepatitis diagnosed for 1.1% of these patients. Clinicians may watch for signs of unexplained onset and persistence of abdominal distention, nausea, abdominal pain, vomiting, diarrhea, anorexia, dyspnea, generalized weakness, ascending neuromuscular weakness, myalgias, paresthesias, weight loss, and hepatomegaly.

• The guidelines also discuss the potential for hyperglycemia resulting from peripheral and hepatic insulin resistance, relative insulin deficiency, an impaired ability of the liver to extract insulin, and a longer exposure to antiretroviral medications. Reports have put the incidence of hyperglycemia with or without diabetes at 3% to 17% of patients in multiple retrospective studies. The reports found that the symptoms of hyperglycemia were reported at a median of 60 days after initiation of PI therapy. Some of those who discontinued therapy found that their hyperglycemia was resolved, and other patients continued with PI therapy and began treatment with oral hypoglycemic agents or insulin. According

### Risks and benefits of delayed vs. early therapy initiation for the asymptomatic HIV-infected patient

**Benefits of delayed therapy initiation**
- Avoid negative effects on quality of life (i.e., inconvenience)
- Avoid drug-related adverse events
- Delay in experiencing drug resistance
- Preserve maximum number of available and future drug options when HIV disease risk is highest

**Risks of delayed therapy initiation**
- Possible risk for irreversible immune system depletion
- Possible increased difficulty in suppressing viral replication
- Possible increased risk for HIV transmission

**Benefits of early therapy initiation**
- Control of viral replication easier to achieve and maintain
- Delay or prevention of immune system compromise
- Lower risk for resistance with complete viral suppression
- Possible decreased risk for HIV transmission*

**Risks of early therapy initiation**
- Drug-related reduction in quality of life
- Greater cumulative drug-related adverse events
- Earlier development of drug resistance, if viral suppression is suboptimal
- Limitation of future antiretroviral treatment options

*The risk for viral transmission still exists; antiretroviral therapy cannot substitute for primary HIV prevention measures (e.g., use of condoms and safer sex practices).

Source: "Guidelines for Using Antiretroviral Agents Among HIV-Infected Adults and Adolescents," updated 2002.

to the guidelines, "Clinicians are advised to monitor closely their HIV-infected patients with pre-existing diabetes when PIs are prescribed and to be aware of the risk for drug-related, new-onset diabetes among patients without a history of diabetes."

Warning signs should be monitored, such as polydipsia, polyphagia, and polyuria. The guidelines say some clinicians recommend routine fasting blood glucose measurements at quarterly intervals during the first year of PI therapy for those without a previous history of diabetes, and there should be closer monitoring of pregnant women receiving PI-containing regimens. Lacking data, the guidelines make no recommendations on whether a clinician should continue or discontinue drug therapy among patients with new-onset or worsening diabetes. However, the guidelines note that most experienced clinicians recommend continuation of antiretroviral therapy in the absence of severe diabetes.

• Evidence from recent research suggests that dyslipidemias, which have been associated primarily with PIs, may be a drug-specific rather than class-specific toxicity. The guidelines say dyslipidemia frequently is severe enough to consider therapeutic interventions, and it's possible that lipid elevations may be associated with accelerated atherosclerosis and cardiovascular complications among HIV-infected patients.

• The NNRTI class of drugs is the class most commonly associated with skin rashes within the first weeks of therapy. These tend to be mild to moderate, and some clinicians recommend managing the rash with antihistamine for symptomatic relief without drug discontinuation. Recent research shows that female patients may have a seven-fold higher risk for developing grade 3 or 4 skin rashes than male patients. Based on recent data, the guidelines do not recommend using systemic corticosteroid or antihistamine therapy at the time of the initiation of nevirapine to prevent the skin rash, because this has not proven effective and may even result in a higher incidence of skin rash.

To obtain the entire guidelines, references, and tables, contact the HIV/AIDS Treatment Information Service (ATIS). Telephone: (800) 448-0440. Fax: (301) 519-6616. Web site: www.hivatis.org.

The information also is available at these web sites: www.cdcnpin.org, http://hiv-web.lanl.gov, or www.cdc.gov/mmwr/preview/mmwrhtml/rr5107a1.htm. ■


1. Which is a controversial change proposed in March 2002 to the privacy requirements of the 1996 Health Insurance Portability and Accountability Act?
   A. Health care providers and other covered entities would be required to obtain signed privacy consent from patients before they receive treatment.
   B. Providers would be required to notify patients about their privacy rights and practices before they receive treatment, but a signed informed consent requirement would be eliminated.
   C. Providers would need to both notify and obtain informed privacy consent from patients before providing treatment.
   D. None of the above

2. Which of the following is not a proposed change to the privacy requirements of the 1996 Health Insurance Portability and Accountability Act?
   A. Parental access to their children's records are assured, subject to state laws.
   B. Records are prohibited from being used for marketing purposes, but appropriate communication is permitted. Pharmacies, health plans, and other covered entities are required first to obtain an individual's specific authorization before sending him or her any marketing materials.
   C. Researchers would not be required to use multiple consent forms and could instead use a single combined informed consent/privacy form.
   D. All of the above are proposed changes.

3. Which class of drugs is most commonly associated with skin rashes within the first weeks of therapy, according to the 2002 "Guidelines for Using Antiretroviral Agents Among HIV-Infected Adults and Adolescents"?
   A. Protease inhibitors
   B. Nucleoside reverse transcriptase inhibitors
   C. Non-nucleoside reverse transcriptase inhibitors
   D. Integrase inhibitors

*(Continued on page 92)*

CE/CME

4. According to a study recently published in the *New England Journal of Medicine*, which group(s) of HIV patients have the lowest rate of accessing clinical drug trials and experimental drugs?
   A. Women
   B. African-Americans and Hispanics
   C. Asians and Pacific Islanders
   D. People with incomes below $10,000 per year

# FDA Notification

## Shortage of test kits for detecting HIV-1 antibodies

The Public Health Service has become aware of a potential shortage of supplemental test kits used for confirmatory testing of HIV antibodies in specimens obtained from either patients or blood and plasma donors.

On April 17, 2002, Calypte Biomedical Corp. in Alameda, CA, announced the company might stop manufacturing the Cambridge Biotech HIV-1 Western blot kit. The distributor, bioMérieux of Durham, NC, immediately notified customers that it no longer would be able to distribute the Cambridge kit, which is one of two HIV-1 Western blot kits licensed by the U.S. Food and Drug Administration (FDA) for supplemental testing of serum, plasma, and dried whole-blood spot specimens.

The period during which kits might be in short supply is uncertain. The Centers for Disease Control and Prevention and the FDA have contacted manufacturers about increasing production to ensure that sufficient quantities of supplemental test kits will be available for patient and donor screening. CDC is collaborating with FDA and other private and public health partners about the evaluation of alternative strategies for HIV diagnostic testing in case shortages of supplemental test kits continue. Laboratories experiencing difficulty obtaining manufactured kits for supplemental testing can contact CDC at (404) 639-4581. ■



# CE 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. ■