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HIV/HCV coinfection cases require special attention

Experts discuss current treatments, concerns

Until recently, an HIV and hepatitis C (HCV) coinfected patient who was managing well with HIV antiretrovirals might die from liver disease due to HCV infection. Now treatment has advanced, and the health prospects for coinfected patients are brighter than ever.

However, problems and challenges still remain, experts caution.

"Many HIV patients have a history of drug abuse, and in that group, there are a lot of people infected with hepatitis C, hepatitis B, and some with tuberculosis," says **Morris Harper**, MD, an HIV physician in Waynesberg, PA.

Since the mid-1990s and the widespread use of antiretroviral therapy in the United States, a significant number of patients with HIV/HCV coinfection no longer die from AIDS, but die from HCV, Harper adds.

"Patients who are HIV-positive are good candidates for treatment of hepatitis C and hepatitis B," Harper says.

Saint Michael's Medical Center in Newark, NJ, has a clinic that specializes in treating HIV/HCV coinfected patients because the care of these patients is time-consuming and requires additional expertise, says **Jihad Slim**, MD, an assistant professor at Seton Hall University in West Orange, NJ. Slim and colleagues at Saint Michael's have studied HCV and the immune response.

"Having a clinic for coinfected patients is helpful because you can train nurses and provide specialized treatment," he says.

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Hepatitis C is common among HIV patients, but it requires more time spent in clinical care than for HIV disease alone, Slim adds.

"You may have to see the patient every week in the beginning if the person is coinfected and receiving treatment," he explains. "For clinicians who have an interest in doing this, the treatment is doable if they have the time; but unfortunately, not everyone has the time."

Also, small HIV centers may not find it financially feasible to treat a handful of HIV/HCV coinfected patients a year, Slim notes. "You really get the experience and treat patients much more easily once you have treated a dozen coinfected patients."

There are a number of important clinical issues to consider in the treatment of HIV/HCV coinfected patients, including the following:

- **HIV/HCV coinfection causes more complications for each disease.**

"In a nutshell, hepatitis C is not a good thing to have when you have HIV," Slim says. "It may not be the worst thing you can have, but it's not a good comorbid infection with HIV." In addition to increased risk of liver disease, coinfection may cause skin rashes, vasculitis, and other health problems, he explains.

Coinfection also may increase mortality and morbidity, although the research is inconclusive. One recent study showed that AIDS-associated deaths had increased among women who were coinfected with hepatitis C.[1]

Women coinfected with HIV and hepatitis C were significantly more likely to develop AIDS, explains **Andrea Kovacs**, MD, director of Maternal, Child and Adolescent Center for Infectious Diseases and Virology at the Los Angeles County, University of Southern California Medical Center. Kovacs also is an associate professor of pediatrics and pathology.

In the population studied, 20% had HCV viral clearance, meaning no HCV replication in the blood, she says.

"They were infected because the antibody was positive, but the virus had not replicated, so they had cleared the virus when they were infected," Kovacs explains. "Then they got HIV after the hepatitis C, and that's generally what we think happened because we don't have a date of when they got infected with each virus."

Investigators divided HIV-infected subjects into groups of those who were not HCV viremic; those who were RNA-positive, meaning they were HCV viremic; and those who were HCV-negative. They found that those who were HCV-negative had a rate probability of developing AIDS at three years of 25.9%; those who were HCV-positive but RNA-negative had a rate probability of 20.2%; and those who were HCV viremic had a rate probability of 35%, Kovacs says.

"There was an increased rate of progression among those who were viremic vs. those who were not," she points out. "Our theory was that those who cleared the virus probably have better immunity, but we haven't studied that group yet."

Although the study started before the era of combination HIV therapy, the study's predictions included antiretroviral therapy into the adjusted model; and it predicted that hepatitis C independent of HIV therapy was predictive of developing AIDS, Kovacs adds.

Liver problems also appear to be compounded with coinfection, Harper notes.

"Most studies tend to show that untreated HIV tends to worsen the hepatitis C, and that's why hepatitis C patients who don't have HIV may take 20 to 35 years to get to that end-stage liver problem, while the patients who are coinfected may get there eight to 10 years sooner," he says.

- **Anemia is bigger problem with coinfection.**

Both HIV and HCV can lead to problems with anemia, and the problems could be compounded by some HIV and HCV medications, Harper adds. "AZT in some patients will cause anemia and drop the blood count." Likewise, HCV treatment might lead to anemia, so physicians need to monitor patients for anemia, he advises.

The most recent treatment for hepatitis C is pegylated-interferon alfa-2a (Pegasys) plus ribavirin (Copegus) which is the most effective HCV therapy to date, but that often causes anemia, particularly within the two- to five-week window of treatment, says **David Henry**, MD, a clinical associate professor of medicine and hematologist/oncologist at the Joan Karnell Cancer Center of Pennsylvania Hospital in Philadelphia.

"HIV patients can be anemic; hepatitis C patients are sometimes anemic; and so coinfected patients are anemic," he says. "Then along came Pegasys and ribavirin; and if patients weren't anemic before this, medication will certainly make them anemic within two to six weeks."

Henry and co-investigators have studied anemia in coinfected patients being treated for HCV and have found that their anemia could be improved if they were prescribed epoetin alfa (Procrit) to replace the serum erythropoietin their bodies are missing.[2]

"We found the patients' ability to make enough EPO when getting Pegasys-ribavirin is about half of normal, and Procrit replaces what they're missing," Henry explains. Moreover, epoetin alfa is well tolerated and causes no side effects or drug interactions with the HIV and HCV treatments, he says. While HIV clinicians often ignore signs of anemia, paying more attention to other HIV/HCV problems, they'd be remiss in not screening for anemia and treating patients who have hemoglobin values of 10 g/dL or less, Henry notes.

Anemia's effect on the quality of life

Anemia affects a patient's quality of life and also may result in a patient missing clinic appointments due to feeling ill and tired. Plus the solution to this problem is easy and well tolerated, he adds. "The most significant time frame for taking Procrit is from two to six weeks after initiating HCV treatment. Since the drug doesn't work instantly, you might need up to eight weeks of treatment; but the patient won't need it forever."

- **Depression, neurocognitive problems also can be an issue.**

"Depressive symptoms are more common in people coinfected with HIV and HCV, compared with people infected only with HIV," says **Howard Libman**, MD, director of the HIV program in Healthcare Associates, Beth Israel Deaconess Medical Center in Boston.

Libman and co-investigators studied depressive symptoms, using the Center for Epidemiologic Studies Depression (CES-D) scale among 379 HIV-infected patients who had a history of alcohol problems.[3]

"What we found were depressive symptoms were significantly more severe in coinfected rather than in just HIV-infected patients," Libman says.

"However, then we tried to adjust for factors that might also affect the likelihood of depressive symptoms like alcohol consumption, gender, age, race, CD4 cell counts, homelessness, injection drug use, and the general status of medical comorbidity that might affect depressive symptoms," he notes. "And when that kind of analysis was done, the difference between HCV-positive and HCV-negative groups diminished significantly."

While HCV coinfection seemed to have some effect on depressive symptoms, it was no longer significantly greater than HIV monoinfection, Libman adds. Research studying the neurocognitive impact on patients who are coinfected have had mixed results, with some smaller studies showing an increase in problems but without identifying a mechanism for how HCV might have direct neurocognitive effects, he says.

Other studies find no difference among coinfected and monoinfected groups. For example, one recent study of 20 HIV/HCV coinfected subjects and 20 HCV monoinfected subjects showed no evidence of greater cognitive impairments between the coinfected and monoinfected groups.[4]

Depression is fairly common among HIV patients, including coinfected patients, and researchers hypothesize that HIV has a direct impact on brain function and depressive functions, Libman explains.

"I think there will be more abstracts and articles addressing this whole issue of neurocognitive dysfunction and depressive symptoms with HCV/HIV coinfection," he says. "You'll see more of it in the dual cohort because if HCV does something bad to the brain, you're more likely to see it first in HIV/HCV coinfected patients."

In addition, depression is common among people with alcohol problems and with patients being treated for HCV with interferon, Libman points out. "Hepatologists are getting more aggressive about treating patients with a history of depression and even those with mild depressive symptoms with a mild antidepressant before starting interferon and ribavirin treatment," he says. "There are enough antidepressants out there that we can usually find an antidepressant drug that can be used in the context of treatment of HIV and HCV."

- **Coinfection and immune function need to be more clearly understood.**

Some research has suggested that HCV/HIV coinfection can lead to poor immune response, but this is another area where studies have had mixed results. One recent study did support the theory that HCV could delay immune response to antiretroviral medication in coinfected patients, but liver problems did not appear to play a role.[5]

"Our main goal was to see if there was a difference in immune change," explains **James Fallon**, director of infectious disease clinical trials at Saint Michael's Medical Center. "We were hoping to see that the worse the liver fibrosis, the fewer CD4 cells you would have; but over a year, there was no change."

Investigators based the study on retrospective data that did not differentiate between naïve and memory cells, so their ongoing work is a prospective study that will focus on naïve cells to see if there is an increase of these cells, Fallon adds.

"You want new naïve cells to have a greater

increase to show true immune reconstitution," he says. "The thought is if we could eradicate hepatitis C, patients will have a more significant increase in CD4 cell count."

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One size doesn't fit all in Hispanic population

Funding changes may cut off some programs

Organizations successfully targeting Latino populations for HIV services and prevention have developed strategies specific to very different groups, including young men who have sex with men (MSM); rural, low-income Hispanics, and Latino migrants or Mexican border town residents.

The problem with finding a one-size-fits-all approach to Latino prevention and care is Hispanics are not homogenous, experts say.

"Previous studies have compared Hispanics to African Americans, and my concern has been that Hispanics are a very heterogeneous group," says **Leo S. Morales**, MD, PhD, assistant professor of medicine at the University of California, Los Angeles (UCLA) School of Medicine. Morales studies sociodemographic differences among Hispanic patients in the United States.

"One Hispanic is not the same as another, and there's a lot of evidence and historical reasons for a large variation among Hispanics," he explains. "One message is that Hispanics should not be looked at as a monolithic group."

Morales and co-investigators analyzed data collected on HIV-positive patients to see if there were differences in access to care among various Hispanic subgroups, focusing on whether language or culture played a difference in treatment access. The study did not find large variations in access to care.[1]

"In a sense, that is a negative finding; but on the other hand, it suggests that people are doing a good job of providing care — or at least the people in care are getting good care whether or not they are acculturated or whether they are citizens or whether their primary language is English or Spanish," Morales says. The study also showed Hispanic females tend to have better access to care than Hispanic males, contrary to most research of general populations, he notes.

"We thought it might be something to do with the fact that among Hispanic women, there's a large amount of childbearing, and because of that, they may be accessing care for other reasons already," Morales says. "As a result, when they discover they are infected with HIV, they are already plugged into the health care system."

Generally, the HIV prevention interventions available for Latinos are revamped from strategies already used in other populations, and while this is an efficient way to provide HIV education, it may not be as effective as interventions designed specifically for a certain Latino population, say experts.

"It's almost like when you're in college and you take 101 courses before you move onto advanced courses," says **Ronald Gonzalez**, technical assistance specialist with Rural Opportunities Inc. in Rochester, NY. "All of these organizations that take on HIV prevention work with migrants need sensitivity training before they do prevention work because they don't have the capacity."

Rural Opportunities is one of four capacity-building assistance providers, funded by the Centers for Disease Control and Prevention (CDC). The organization serves migrant farm workers and has received additional funding to target young MSM, including Latinos, Gonzalez adds.

The organization developed an intervention called Impacto Positivo, which focuses exclusively on young Latino MSM. The prevention intervention speaks to the culture of young Latino MSM and their issues with sexual identity within migrant farm labor camps, he says.

Counselors trained specifically for this population soon learn that it's difficult to obtain access to the migrant camps and that selecting bars to target for prevention work can be complicated, Gonzalez explains.

"A colleague and I went to a Northern California county and went to a bar, which you would consider to be a heterosexual bar, but it had performances by drag queens or transvestites, and the men would socialize and mix with transgender folks," he explains.

Impacto Positivo worked with AIDS service organizations to provide outreach workers with sensitivity training and strategies for targeting the specific subgroup of young MSM who are Latino and probably migrant workers, Gonzalez says.

The project eventually fell victim to CDC budget cuts and the shift to science-based interventions. The program had never been fully studied for outcomes, and so it is not one of the grocer's dozen of interventions that the CDC is requiring organizations to use, he adds.

"There isn't anything like this . . . ," Gonzalez notes. "Probably, the closest thing is the SISTA program, which calls for ethnic and gender pride." The trouble is that SISTA was developed for young black women, who mostly are college-bound or upwardly mobile.

"The CDC says you can take that and adapt it and tailor it, and that's the conundrum that community-based organizations (CBOs) are faced with: How do you adapt it and keep the key elements and make it work for a young Latino MSM population?" he adds.

PROCEED Inc. of Elizabeth, NJ, is another organization that has received CDC funding to develop interventions for Latinos, specifically focused on HIV-positive Latinos, says **Deanna McPherson**, MPH, CHES, a capacity building coordinator for PROCEED.

The organization interviewed Latinos and New Jersey program directors and eventually formed the Prevention with Positives National Resource Network, she says.

PROCEED then formed a focus group, held in Spanish with HIV-positive Latino men and women. The group met for about two hours to discuss their issues of concern, and included on that list these items: housing, transportation, treatment, adherence, sexuality, disclosure, and stigma, McPherson explains.

Then the organization held a conference, attended mostly by Latinos, to discuss HIV and AIDS issues and to provide workshops on the issues of most concern, she adds.

"Our goal was to develop an intervention, and all along we were collecting this information, which came from the key interviews, the focus group, and the conference," McPherson explains.

With the help of a psychiatrist researcher, the organization developed an intervention that incorporated the elements HIV-positive Latinos and others identified as important to this population, she adds. "There was a small amount of people bringing individual expertise to this team, and they created modules that they'd bring back to a work group for improvement and suggestions, starting in January 2003."

Using the theoretical model of motivational interviewing, the intervention that was developed from these efforts has four sessions, including one individual session. (**See Latino prevention for positives intervention, p. 115.)**

Although the intervention's outcomes have not yet been published, PROCEED would like it to be included in the CDC's list of effective interventions, McPherson says. "We saw behavior change at the end of sessions, and that's one of the things we're looking at now with data analysis. In January, we were turned down from that request because their interventions were proved with scientific rigor, and they didn't want to use the ones that the four of us had created, although they had funded it. All of the organizations have mailed me their pre- and post-tests from the intervention, and we sent out an implementation questionnaire that people are filling out about how they felt about the project as a whole."

She plans to write a final report and resubmit the intervention to the CDC.

Although HIV treatment programs tend to be similar for all populations, there are important advantages to having a clinic that treats a specific population, such as border-town Latinos, says **John Wiebe**, PhD, assistant professor of psychology at the University of Texas at El Paso.

The Centro de Salud Familiar La Fe CARE Center in El Paso serves HIV-positive Latinos who may live in Mexico or the United States, but who also frequently move back and forth between the two countries, he says.

"It's imperative to have prevention here for so many reasons, but partly because the resources are so poor in Mexico, and the border is extremely fluid," Wiebe notes.

Wiebe was a co-author on a study about how a nurse-based HIV disease state management model at the border provides a feasible method of disease state management for a resource-poor community.[2] "The HIV problem that occurs on the Mexican side of the border due to lack of resources and treatment and screening abilities affects folks on both sides," he explains.

The border population treatment model was developed over the past five years to answer the problem of a shortage of HIV specialists in the area, Wiebe says. The town has no medical school, and there is a shortage of general practitioners, as well, he notes.

"At the time we started the program, we had 300 patients, and we had the part-time services of one infectious disease doctor who had a full-time job at an academic institution," he says. "We also have a nursing school here, and when we started the model, we had a fair number of fluently bilingual nurses in the area, so we chose to hire nurses and train them extensively in HIV service."

Nurses, who are tested in HIV treatment, became the point people for care teams that included social workers and HIV-positive peer advocates, Wiebe says.

The nurses provide the wellness care, and the peer advocates provide support, while the social workers assist patients with resource issues and coordinating care, he explains. "The nurses triage to physicians as needed, and we have a nurse practitioner who works full time at the clinic."

Bilingual services are essential to the clinic, since about 60% of the patients speak only Spanish, Wiebe explains. Also the use of peer advocates builds trust and rapport with patients, and the coordinated team approach is another feature that works well with this particular population, he says. "The more traditional, physician-based model isn't practical in our area."

Since the program was formed, the clinic has seen improvements in patient's care, including increases in adherence and no decline on average in CD4 cell counts, he points out.

"We've seen a very slight increase in mental health across the group as a whole, although not all patients are receiving mental health services," Wiebe says. "We've seen a substantial increase in appointment attendance, which is a nice thing to see with this model."

The model easily could be adapted to other resource poor areas, although one obstacle would be the recent national nursing shortage, he adds.

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Motivational interviewing seeks specific solutions

Interventions shift responsibility to the clients

The key to a four-session HIV prevention for positives program targeting Latinos, called Positively Latino, is the adaptation of the theoretical model of motivational interviewing, which is a different approach than the traditional case management model.

"Motivational interviewing allows the client to make a decision based on his or her own motivations," says **Deanna McPherson**, MPH, CHES, capacity building coordinator for PROCEED Inc. in Elizabeth, NJ. "It's the interviewer's responsibility to try to find ways to motivate the client to try to make a change in risk behaviors."

This approach works particularly well with HIV-positive clients because it shifts the responsibility for preventing HIV transmission to them without shifting blame for the epidemic, she says.

McPherson explains how the Positively Latino program, which mostly is conducted in Spanish, works:

✔ **First session:** This includes a pre-test and obtaining the client's consent for videotaping the session, she says. It lasts 90 minutes.

The counselor or case manager, who has been trained in motivational interviewing will discuss the concept with the client. The counselor also will talk with the client about HIV prevention methods and the person's own responsibility, McPherson says.

The counselor discusses the client's motivation for change and emphasizes that the counselor is not there to try to change him or her because that is up to the client, she adds.

"Then they'll spend time looking at the client's point of view of the problem," McPherson says. "The counselor, using skills of motivational interviewing, asks open-ended questions with affirmations. For example, the client might say, 'I don't use condoms all the time, but I use them with my main partner.'

"Then the counselor will reply, 'It's good that you're using them with your main partner and perhaps using condoms with your other sexual partners is something that you can think about working on or that you might like to work on,'" she continues.

The client will fill out a questionnaire that asks

how many sexual partners the client has had and whether the client knew his or her partners' HIV status. The questionnaire also asks about alcohol and substance use and how that might impact sexual risk. There also are questions about depression and whether a client feels threatened by a partner, McPherson says.

The form also inquires about whether clients feel responsibility for protecting partners or themselves from sexually transmitted diseases (STDs), she adds.

"Then after they fill out the feedback forms, the counselor spends some time with them on commitment to change, and the counselor would see whether the client is ready to make a change, and what the roadblocks are to thinking about making a change," McPherson says.

✔ **Second session:** This is held a week later. The counselor asks what has changed in the person's life and then re-emphasizes what was discussed in the first session, she says. Then the counselor returns to the idea of a change plan and discusses developing it or reviewing a change plan if one had already been made, McPherson explains.

A change plan worksheet is available as a template, and it includes open-ended statements, such as the following:

- "The changes I want to make are . . ."
- "The most important reasons I want to make these changes are . . ."
- "The main goals for myself for making these changes are . . ."
- "I plan to do this to reach my goals . . ."

Then the client may list a plan of action, a target date, and steps that he or she may take to make a change and what might interfere with that change, McPherson notes.

It's also important that the client identify other people in his or her life who can assist with the change and the specific ways those people can help.

Clients and counselors then discuss the goal of positive results and how the client will know whether the plan is working, she says.

"What we found and some preliminary results found was that often clients were using condoms when they were having sex, but their main problem was depression and dealing with being positive and disclosing their HIV status to friends and relatives, McPherson recalls. "Their social network was small, and the stigma of being a Latino who was HIV-positive was difficult."

✔ **Third session:** During this session, clients complete a second questionnaire that is more specific to the drug and alcohol abuse. It asks how long the person has known his or her HIV status, whether the client is taking HIV antiretroviral drugs, and what the last viral load count was, McPherson says.

The client is asked whether in the last six months he or she used alcohol, poppers, crystal methamphetamines, downers, party drugs, marijuana, or other substances, she notes.

The third session also reviews the two previous sessions, and counselors spend time talking about the client's progress and barriers to change, she adds. "Counselors attempt to ask for a commitment or reevaluate the plan if one has been made.

"The session ends with a summary of what was transpiring in session two and provides a summary of change plans for risky sex or other problems identified in that session," McPherson says.

✔ **Fourth session:** A introduction and review of the previous three sessions are held, and the counselors return to the theme of change plans, she says.

"The counselor and client review the change plan to see what the barriers or challenges are," McPherson explains. "What happened with many counseling sessions is clients went into a whole realm of family issues and drug and alcohol issues, and it took some time to get back to the reason for their being in that session."

Counselors then will discuss sexual behaviors and whether the client has used condoms in recent days, she adds.

"The fourth session evaluates the work done and looks at future work and then assesses the client's commitment to change," McPherson says. "Then the counselor will make referrals." ■

Program finds success reaching crack addicts

Improvements seen on all fronts

A new study reports success in reducing risk and improving women's housing and employment status after enrollment in a woman-focused HIV intervention program.

Researchers began designing an HIV prevention intervention for African American women

who use crack in hopes of affecting deep behavioral change, beginning with reduced risk activity and reduced drug use, but also improving their life situation. At six months follow-up, the intervention appears to achieve its goals.

The woman-focused intervention was designed to be personalized with focus on each woman's learning skills for taking care of herself, as well as reducing HIV risk behaviors and reducing drug and alcohol use, says **Wendee M. Wechsberg**, PhD, senior program director at RTI International in Research Triangle Park, NC.

Investigators studied the following groups:

1. three-month and six-month outcomes of the woman-focused HIV intervention;
2. a revised intervention modeled on the National Institute on Drug Abuse (NIDA) standard HIV prevention intervention;
3. delayed-treatment control group.[1]

Researchers see changes in behaviors

Women were randomized to the three groups, and all showed striking decreases in daily crack use.

Women in all the groups reported significant decreases in reported unprotected sex and in trading sex for money and drugs.[1] However, only the woman-focused intervention showed significant reduction in homelessness and a marked improvement in full-time employment, Wechsberg says.

"The woman-focused group did better in the areas that we wanted to emphasize, which were employment and not being homeless," she explains. "These are really important when you think about independence and self-sufficiency."

The NIDA standard HIV prevention intervention, which focuses on teaching women how to use female and male condoms, reducing sexual and drug risk, and going to drug treatment, succeeded in achieving significant reductions in crack use at six months relative to controls.[1]

However, even the control group changed behaviors, Wechsberg notes. "When we asked women in the control group why they changed their behaviors, they said it was because it was important to be in the study and we had asked them questions about it."

It will be interesting to see how the woman-focused intervention continues to affect risk behaviors and lifestyle changes over time, she says.

"The good news about this study is we have another five years of this work. What about the sustainability and durability of interventions because women can't leave these drug-using communities?" Wechsberg asks.

More than 5% of the women who participated in the study were HIV-positive. The woman-focused intervention is a good prevention for HIV-positive women because it focuses on what a woman can do to take care of herself and stay healthy, she points out.

The study was conducted in intervention field sites, which provided a comfortable and safe environment for women to be questioned about their HIV risk behaviors. Women could leave their children with a baby sitter on site, get something to eat, pick up donated clothing and toiletries, and treat the place like a drop-in center, Wechsberg says.

"The study used the same staff and outreach workers and data collectors and interventionists for all three groups. The control group came in, did the data collection and received risk reduction kits and an incentive for their time, but they did not have the benefit of an intervention until the study was over."

The women participating in the NIDA standard intervention were taught about the risks of drug use, AIDS, sharing needles, and the benefits of drug treatment, she notes.

They also were taught about HIV testing and received training on how to properly use the male and female condoms. "The woman-focused intervention and the standard were equal doses of time," Wechsberg adds.

The woman-focused and NIDA standard interventions included two 30- to 40-minute sessions of individual counseling/education and two small group sessions, lasting 60 to 90 minutes.[1]

The woman-focused intervention went beyond the sexual and drug risk behaviors to encourage women to focus on other issues that affect African American women, including racism, domestic violence, education, work, etc., Wechsberg says.

For instance, the intervention taught the women that their addictions keep them in bondage, and it helped them to answer the question of what they could do as an African American woman to get out of that bondage, she explains.

Intervention facilitators told participants that HIV is affecting more black women than white women and encouraged them to ask themselves what it is about their lives and their struggles that leads to HIV infection, Wechsberg says. "How do they reframe how hard life is and empower them to make it better? We say, 'We're not going to do it for you, but we'll talk about your skills and you

need to move forward and not be stuck in this bondage and with a sugar daddy, and so forth.'"

For many of the women participants, the experience of creating emotional bonds with fellow women was a new one, and they were excited about gaining some control in their lives, says Wechsberg.

Participants were asked to imagine their own life plan and think about the biggest change that will enable them to own their lives because the more they give it away, the more they drink and use drugs, she adds.

An outline of both the woman-focused and standard interventions are available in the article, published in July 2004 in the *American Journal of Public Health*.

Reference

1. Wechsberg WM, Lam WKK, Zule WA, et al. Efficacy of a woman-focused intervention to reduce HIV risk and increase self-sufficiency among African American crack abusers. *Am J Pub Health* 2004; 94(7):1,165-1,173. ■

Physicians counsel new patients more effectively

CDC-funded survey highlights problem areas

The Centers for Disease Control and Prevention (CDC) is focusing on the role of physicians in its prevention for positives initiative, but according to one survey funded by the agency, the available prevention counseling is less than optimal.

"What our findings show is that providers are doing prevention counseling more with new patients than with established patients," says **Lisa Metsch**, PhD, associate professor of epidemiology and public health at the University of Miami School of Medicine. "But the prevention counseling is less than optimal for both."

The study found 60% of physicians reported providing prevention counseling to at least 90% of their HIV patients at the first visit, but only 14% of physicians provided prevention counseling to established patients.[1]

Also, HIV physicians were less likely to provide prevention counseling to male patients than to female patients, who tend to communicate better with their doctors.[1]

"Physicians who spent an average of more than 30 minutes with patients were more likely to provide counseling, and those who served more male patients were less likely to counsel," Metsch says. "This is consistent with other literature that has shown that sometimes female patients communicate better with their doctors and they tend to ask more questions than male patients, and women are more comfortable discussing issues of a sexual matter.

"One surprising finding is that infectious disease physicians when compared with other doctors were less likely to provide prevention counseling," she adds. "The reason is all of their other demands and other things that they're focusing on in the clinic visits.

"This study represents, to our knowledge, the only comprehensive physician study done in four cities," Metsch says. "We looked at different factors and found that those who had more time to spend with patients were more likely to be doing prevention counseling."

Specifically, the study concluded that interventions need to be developed with physicians in mind, and these should include strategies for overcoming barriers to doctors providing counseling to HIV-infected patients.[1]

"The CDC has recognized that the physician has been an underutilized resource," she notes. "New guidelines released in July of 2003 emphasize the importance of providers being a partner in providing prevention and counseling to their patients, so intervention strategies with physicians should be developed to improve counseling."

The survey acknowledges a variety of obstacles to optimal physician counseling for HIV patients. These include the following:

- Managing an HIV patient's medical care is time-consuming and requires considerable scientific expertise and time.[1]
- Antiretroviral therapy requires near 100% adherence so providers spend a great deal of time counseling patients about the need to take their medications.[1]
- Physicians sometimes believe patients have psychosocial problems that create a barrier to effective prevention counseling messages, and doctors with larger patient populations may have less time to address these issues.[1]
- Infectious disease specialists tend to have less time to focus on primary prevention, and they may believe counseling is better handled by other health professionals.[1]

Metsch also is involved in a CDC-funded study that is looking at developing an intervention for the HIV medical setting. The multicomponent

intervention will involve a computerized risk message that physicians will give to patients, and it will be followed up with a visit by a peer counselor, she says.

"The intervention is designed to fit in with the physician's time slot, and we only ask them to spend five to 10 minutes on this, making it as easy as possible," Metsch explains.

"The patient does a risk assessment on the computer, and with the patient's permission, the physician receives a very specific and tailored prevention message based on the theories of change and the IMB — information, motivation, and behavioral skills models," she explains.

That intervention research should be completed within the next year or two, Metsch points out. ■

FDA Notifications

FDA approves treatment for facial fat loss

The FDA has approved injectable poly-L-lactic acid, an injectable filler to correct facial fat loss in HIV patients.

Injectable poly-L-lactic acid (Sculptra) is the first such treatment approved for a condition known as lipoatrophy, or facial wasting, a sinking of the cheek, eye, and temple areas of the face caused by the loss of fat tissue under the skin, which can affect HIV patients. The FDA expedited review of the product because of its importance in treating people living with AIDS.

The substance is a biodegradable, biocompatible synthetic polymer from the alphahydroxy-acid family that has been widely used for many years in dissolvable stitches, bone screws, and facial implants.

The FDA approval was based on data from four studies, totaling 277 HIV-positive patients with severe facial lipoatrophy. The patients, who were all being treated with antiretroviral drugs, were primarily white males, mostly ages 41 to 45. Patients were given three to six injections at two-week intervals and were followed for two years.

Skin thickness measurements and serial

CE/CME *questions*

13. Recent research has shown HIV patients who are coinfected with hepatitis C may have more difficulty with which type of medical problem?
    A. anemia
    B. faster progression of AIDS
    C. both A and B
    D. none of the above

14. A recent study has shown that HIV-infected women of which ethnic background tend to have better access to care than HIV-infected men of that same ethnic background. Which ethnic group is this?
    A. African American
    B. Hispanic
    C. Asian
    D. Native American/Pacific Islander

15. An HIV prevention program that targets African American women who use crack found that a woman-focused intervention was the only intervention of three studied that reported significant improvements in which areas?
    A. crack use
    B. unprotected sex
    C. trading sex for money or drugs
    D. homelessness and full-time employment

16. A CDC-funded study of physicians and HIV prevention counseling for HIV-positive patients found 60% of physicians reported providing prevention counseling to at least 90% of their HIV patients at the first visit. What percentage of physicians provided prevention counseling to established patients?
    A. 75%
    B. 51%
    C. 39%
    D. 14%

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. 120**. 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.

photographs from clinical studies were assessed, as well as other data submitted by the manufacturer, Dermik Laboratories.

Analysis indicated that the product significantly improved facial appearance, and was safe for restoration and/or correction of shape and contour deficiencies resulting from facial fat loss in patients with HIV/AIDS. The substance was shown to produce significant increases in dermal thickness (up to two to three times baseline values), adding volume to facial tissue and restoring shape to areas of the face with fat loss.

After an initial treatment series, repeat treatments may be needed to maintain the correction.

Most adverse events were related to the injection itself and included nodules, redness, swelling, and bruising in the injection area.

The studies also demonstrated significant improvement in quality of life and measures of anxiety and depression, conditions which can be associated with lipoatrophy. ■

New web page launched for HIV drug deliberations

The FDA has developed a web page to consolidate records of advisory committee meetings related to HIV/AIDS and associated conditions, making them easier to access.

The new page, which lists HIV/AIDS-related advisory committee meetings held since 1996, indexed by topic and by year, can be found at: www.fda.gov/oashi/aids/advisorycom.html.

The page is linked from the main HIV/AIDS page at www.fda.gov/oashi/aids/hiv.html.

The page contains records of meeting held by advisory committees related to drugs, biologics, and medical devices, and will be updated to reflect availability of records of future meetings. Most records contain a variety of documents, such as the meeting announcement, committee rosters, briefing materials, which often contain background materials and slides, and transcripts of the meetings.

Topics include consideration of new drug applications, regulatory policy issues, and trial design topics.

The page also contains a link to the main FDA Advisory Committee page for other resources and topics related to FDA advisory committee meetings. ■

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. ■

CE/CME *answers*

13. C	**14. B**	**15. D**	**16. D.**