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ICAAC highlights new and better drugs

HIV-infected patients who are failing current antiretroviral regimens and their clinicians have new cause for hope as HIV researchers are drawing closer to bringing some potent new drugs to the market. Entry inhibitors, integrase inhibitors, and other new antiretrovirals were highlighted at the 42nd Interscience Conference on Antimicrobial Agents and Chemotherapy in San Diego. HIV experts call the news very encouraging cover

AIDS patients often depressed

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New drugs and drug types boost hope for the future

Report from ICAAC

Some novel antiretroviral treatments that the HIV community has been watching for the past few years are approaching reality, giving clinicians hope for new drugs and new approaches for patients who are close to exhausting existing HIV therapy. Integrase inhibitors, fusion inhibitors, once-daily protease inhibitors, and some other new drugs were in the spotlight at the 42nd Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), held in San Diego in September. ICAAC is organized by the American Society for Microbiology in Washington, DC.

"What I saw at ICAAC was very encouraging," says **Joseph Eron, MD**, an associate professor of medicine in the infectious diseases division of the University of North Carolina at Chapel Hill. "It looks like several drugs are moving to the point where not only will we have them in clinical trials, but we'll be able to give them to patients." Eron spoke about the recent advances in HIV therapy at the National HIV/AIDS Conference held in Atlanta in October. "The biggest news: The new agent that is going to have the most significant impact would be T-20, a fusion inhibitor. The reason I say this is because it's a drug that's in a totally new class of agents, an antiretroviral that works at the step of entry."

Entry inhibitors, including fusion inhibitors, hold hope in defeating HIV in even the most treatment-experienced patients who have drug-resistant virus, he notes. T-20, also named enfuvirtide, is the first fusion inhibitor that targets HIV gp41. In a phase III study in which enfuvirtide was added to an optimized background regimen and compared with an optimized background regimen only, it was found

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that the enfuvirtide group of highly antiretroviral experienced patients had additional viral suppression when compared to the group on an optimized background regimen alone.¹

T-20 has been developed by Trimeris of Durham, NC, and it's administered through subcutaneous injection twice a day, so it may not be for every patient, Eron says. "But in the grand scheme of things, to have an agent that targets a whole new process gives a lot of encouragement to patients and physicians. But we may see this drug by the spring." Trimeris has submitted a new drug application to the Food and Drug Administration

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Editorial Questions

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(FDA), and it has to be reviewed at an FDA meeting before it can be brought to market, Eron says. "The virus will be susceptible to this drug, so there's one active agent we can work with to build a successful therapy for them. Whereas right now, for some of our patients, we have very little to work with."

This latest approach involves the creation of drugs that will stop one of the processes involved in HIV's entry into human cells. The three-stepped entry process involves the gp120 protein that exists on the surface of HIV, explains **Richard W. Krawiec**, PhD, vice president of investor relations and corporate communication for Progenics Pharmaceuticals Inc. of Tarrytown, NY. "For HIV to enter a human cell, gp120 must bind to a CD4 receptor, and the second step is for a small cleft to open up and the gp120 protein binds to another receptor called CCR5," he says. "When that happens, it's really accomplished opening the first two doors, and the third step is the fusion of the membrane of the virus of the cell."

The way this happens is that a portion of gp120 protein called gp41, a coiled-up protein, uncoils and pierces the cell membrane and permits the membrane of the virus and the membrane of the cell to fuse, Krawiec says. "So there's now an opening, and through that opening can come the RNA material of the virus to infect the cell."

T-20 was designed to stop that last step, preventing the fusion between the HIV protein and the human cell. Progenics has been studying a drug called PRO 140 that is designed to block the HIV protein gp120 from attaching to the CCR5 receptor at the second step of the process. Developed by Progenics, PRO 140 is a monoclonal antibody that has been humanized, he says.

PRO 140 was found in an in vitro study to broadly and potently block HIV-1 entry through CCR5 without interfering with the receptor's normal activity.²

Progenics has entry an inhibitor in Phase II clinical studies, called PRO 542. This one is designed to thwart the virus at the first step in the entry by preventing the gp120 protein from binding to the CD4 receptor, Krawiec says. "PRO 542 and 140 block the binding and attachment steps," he explains. "PRO 542 is designed to block binding; and unlike drugs out there now that work on human cells, it's designed to neutralize the virus, so there's a fundamental difference there."

A fusion protein, PRO 542 mimics the structure of CD4 on its tip, so when normally HIV would

target CD4 cells, it would be diverted to the PRO 542 antibody-like molecule, which prevents the virus from completing the first step in infecting the cells, Krawiec says.

Phase II testing of PRO 542 showed that the agent broadly protects primary cells from HIV-1 infection by neutralizing free and dendritic cell-associated virus.³

"PRO 542 and 140 are modifications of human monoclonal antibodies, and they're very clever," Eron notes. PRO 542 looks like an antibody and serves as a decoy for HIV, he says. "The thing about that drug is that it has to be given by IV infusion, but it has been studied in adults and children and appears to have some activity."

PRO 140 is another CCR5 inhibitor that has to be administered by infusion, Eron adds.

Clinical studies have shown that a single intravenous infusion of PRO 542 lowered viral loads for as long as six weeks and that the lowered viral load was statistically significant for a month, Krawiec says.

The drug has had clinical activity in some of the sickest AIDS patients, who have high viral loads and low CD4 counts. It holds promise as a salvage therapy for patients who are failing conventional antiretroviral therapy, he says. "One IV infusion lasts at least a month with these patients, and that's a single dose," he says. "The next step is to learn how to better use the drug."

The company is studying different options for administering the drug, including developing a formulation for subcutaneous injections, Krawiec adds. "We know it reduces viral load, and now it's incumbent upon us to continue to substantiate the favorable safety profile and become more comfortable with that. We have to understand how best to give the drug in the clinic, whether to administer it with more frequency."

PRO 140 has not yet been studied in human subjects, but it will enter clinical trials next year, he says.

Integrase inhibitors attracting interest

Another type of new HIV medications that are worth noting are the integrase inhibitors, Eron says.

"HIV has three enzymes that it uses, makes itself, and takes over human cells and brings along these three enzymes of reverse transcriptase, protease, and integrase," he explains. "We've known about integrase for a long time but never had an inhibitor of integrase before."

Then in the past year, Shionogi USA Inc. of Florham Park, NJ, and Merck Research Laboratories of West Point, PA, have been developing integrase inhibitors that they're about to study in humans. The in vitro and animal studies have looked promising, Eron adds.

S-1360, Shionogi's new HIV-1 integrase inhibitor for oral use, was found in a recent study to not have an effect on fat metabolism, retinoid signaling, and other problems associated with protease inhibitor use.⁴

Merck researchers presented an abstract at ICAAC highlighting the discovery of a series of novel 8-hydroxy-1,6-naphthyridine HIV-1 integrase inhibitors.⁵

Eron notes that S-1360 is synergistic with all three current classes of antiretrovirals, has minimal animal toxicity, and is comparable to some common nucleoside reverse transcriptase inhibitors (NRTIs) in mouse models of HIV. "The other area where I think we'll make progress in the next six months to a year is in making some improvements in our current treatments," he says. "What we're going to have are drugs that are less cumbersome and perhaps less toxic."

One example is Wallingford, CT-based Bristol-Myers Squibb's investigational protease inhibitor atazanavir. Atazanavir proved to have potency comparable to efavirenz in a clinical trial where it was administered in combination with zidovudine and lamivudine to treatment-naïve HIV-infected subjects. The 48-week study demonstrated that a combination containing atazanavir suppressed HIV RNA below 400 copies/mL of blood of 72%, compared with a response rate of 69% for the efavirenz regimen.⁶

"In a very large phase III trial, atazanavir was compared to the most potent of non-NRTIs [NNRTIs], and it had equivalent potency," says **Kathleen Squires**, MD, associate professor of medicine at the Keck School of Medicine at the University of Southern California in Los Angeles. What makes atazanavir unique is that, unlike other protease inhibitors, it can be administered as two pills once a day. This way it can be combined with other once-daily antiretrovirals, she says.

"In terms of side effects, it looks like this drug doesn't really effect serum lipids, such as triglycerides and cholesterol, and that is different from what is described of other [protease inhibitors]," Squires points out.

Generally, such side effects will occur quickly after a patient begins taking a protease inhibitor, so if the side effect was not found in atazanavir

during a 48-week study, that is a good sign, she adds. Also, the drug-resistance profile looked good with the most common mutation found among research subjects taking the atazanavir/NRTI combination was a mutation suggesting resistance to lamivudine, Squires says.

Interestingly, test tube studies have shown that when HIV is exposed to atazanavir and then placed with other protease inhibitors, it appears that the virus is more sensitive to the other protease inhibitors, suggesting that it has the opposite effect of drug resistance, she says. "The good point is that it looks like patients will be able to be treated with other [protease inhibitors] without any compromising of activity," Squires adds.

Another notable new drug discussed at ICAAC included TMC 125, a next generation NNRTI that has demonstrated potent activity against HIV in both treatment-naïve and NNRTI-resistant patients.⁷

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Depression is common among AIDS patients

Psych consult often is necessary

A national survey indicates that it's fairly common for HIV physicians to identify depression and similar symptoms in HIV-infected patients.

A telephone survey conducted in October, of 136 United States AIDS physicians, found that 84.3% reported that their HIV-positive patients suffered from depressive symptoms, says **Ewald Horwath**, MD, director of the Washington Heights Community Service Inpatient Unit at the New York State Psychiatric Institute in New York City. He is the author of the study, which appeared in the October issue of *International Association of Physicians in AIDS Care*.

"The physicians were a fairly experienced group," he says. "About 60% of them saw more than 20 HIV-infected patients a week, and a majority of them, about 70%, had more than 10 years experience in the field." About one-third of the physicians were infectious disease doctors, and 40% were internal medicine physicians.

Horwath presented the survey results at the Infectious Disease Society of America conference, held in late October in Chicago. The survey was conducted by telephone, with a follow-up in which the person surveyed completed a paper or web site reply form that was returned to the surveyor, he says.

The survey highlights how commonly HIV/AIDS patients have problems that go beyond their infection, Horwath says. "Oftentimes, a patient with AIDS walks into a doctor's office, and it's almost as if they come in with AIDS written on their forehead — the disease becomes the patient. The important thing to remember is that although the patient has AIDS, which implies immune problems and opportunistic infections, etc., they also are quite likely to suffer from psychological and psychiatric problems, including depression."

Their depression may be in response to their disease or to their history before infection, or to the stress that results from antiretroviral treatment, Horwath notes.

The surveyed physicians also were asked about diagnosing and treating depressive symptoms, and 95% said they routinely screen for symptoms of depression. In most cases, the HIV clinicians had a variety of strategies for treating depression, and these included prescribing antidepressants, referring patients for a psychiatric consultation, and sometimes switching antiretroviral therapy when a particular drug was likely the cause of the symptom, he explains.

"In particular, efavirenz was identified as one of the drugs associated with a large risk of psychiatric and central nervous system side effects," Horwath says. Physicians surveyed also reported that common problems among HIV patients included anxiety, headaches, lethargy, and insomnia. About 87% of the doctors attributed some of these symptoms to one of the antiretroviral agents, he adds.

The causes of the symptoms may vary widely. For example, headaches are very common among medical patients of all types as well as among HIV patients, and they can be caused by a variety of different factors. "It's a common symptom in people who are depressed and among people who have various types of central nervous symptoms," Horwath says. "OIs [opportunistic infections] — like toxoplasmosis and meningitis — can present with headaches, and even HIV itself can cause headaches, especially very early after infection." Since each symptom has a potentially complicated causality, it's important to take a patient's history and investigate the various possibilities, he advises.

While the survey couldn't determine the cause of symptoms, it did show that physicians often are aware of the possibility of mental health problems and they will identify them and either evaluate the patients themselves or refer patients for evaluation.

"One of the tricky things about treating AIDS is that one is often faced with a variety of symptoms that can be either medical or psychiatric, and you don't know the cause because the patient has so many things going on," Horwath notes. "The average HIV patient is taking antiretroviral drugs, has OIs, may have a history of substance abuse and a pre-existing psychiatric disorder."

So when clinicians first see a patient who presents with symptoms of depression, they may not know what causes the symptoms and they'll have to start an evaluation process, he says.

"About 70% of the doctors said they rely on psychiatric consultation," Horwath adds. "So a consultative relationship between the psychiatrist

and infectious disease specialist or internist is something we believe is an important element of treating patients with HIV." Horwath says he hopes HIV clinicians will realize from the survey's findings that they need to screen patients for mental health problems and then possibly refer patients to a psychiatrist, psychologist, or another mental health professional for evaluation.

"They need to think of possible medical causes for the symptoms, and these could include opportunistic infections, medication side effects, and potential psychological issues, like stresses from the illness and other problems the patients experience," he adds.

The New York State Psychiatric Institute has been involved with the Columbia University HIV Mental Health Training Project, which began its work in 1998 as a collaborative effort to work with mental health providers and mental health agencies that are interested in learning more about HIV and mental health issues.

"So we have a group of people, including myself and other psychiatrists and psychologists, who are experienced in the area and go out and train other professionals about it," Horwath says.

The training includes lectures, interactive workshops, and discussions of risk behaviors and how to get patients to talk about HIV and some of the things they've done to put themselves at risk for infection, he adds. "We talk about what we refer to as triply-diagnosed patients, which are those with HIV infection, substance abuse problems, and psychiatric disorders. We talk about how to manage patients with that complicated combination, which is quite common actually." ■

New trend by states is to integrate HIV programs

Collaboration saves some resources

Until recently, a typical state model for providing HIV services has been to delegate prevention and testing programs to one group of experts, serving on a separate board from the experts who are overseeing HIV treatment and care programs.

While many states still adhere to this model, there's a new trend in which state health departments are encouraging the two groups to collaborate and even merge boards. The goal is to increase

efficiencies, save board members' time, and improve communication between the two camps.

"When the epidemic first happened in the early 1980s, prevention and care grew separately," says **Chris Aldridge**, MSW, HIV prevention and care program specialist with the National Alliance of State and Territorial AIDS Directors (NASTAD) in Washington, DC.

"But with highly active antiretroviral therapy (HAART), people are living longer and have a better quality of life, and what has happened is that prevention and care have grown closer together. Some of their goals are more in common now." So it makes more sense for the people involved in prevention planning and care planning to collaborate, he adds.

One good example of this collaboration can be found in Michigan, where prevention and care processes recently have been merged, Aldridge notes. "At the end of this year, Michigan will have one single statewide group that works on prevention and care planning." Other states that have moved toward collaboration of prevention and care include Nebraska and Utah, he says.

Here's a brief look at what these three states have done to change their prevention and care planning:

- **Michigan.** The state has a regional configuration for HIV care and prevention that has been in place for several years, says **Liisa Randall**, PhD, prevention consultant for Southeastern Michigan Health Association in Okemos.

In 1994 when the Centers for Disease Control and Prevention (CDC) first released guidance on community planning, state officials met with community health agencies, AIDS service organizations, and other nongovernmental organizations (NGOs) to discuss HIV services, she says.

"We asked them, 'What is the best way to safely enact guidelines, and how do we address Ryan White requirements?'" Randall says. "They said, 'Get this as local as possible, but don't go nuts and make it an administrative nightmare.'"

Since Michigan has 83 counties, it seemed to be a good idea to avoid having a planning group in each county, so the state began taking a regional approach to providing HIV care and prevention. At first the state had parallel processes for prevention and care with groups representing each aspect. State bodies, representing each, brought together the regional groups, she says. "About 18 months into the planning process, there were a number of community folks who said, 'This is a little bit crazy.'"

Most of Michigan is rural, and many of the group members from rural areas already were serving dual purposes by sitting on boards for both prevention and care services. Plus an AIDS Policy Commission formed through legislation advised the state to look into consolidating planning processes. "We convened the Too-Many-Meetings meeting," Randall says. In less than three days in 1997, representatives from prevention and care regional groups, state officials, and others met and came to an agreement that separating prevention and care planning required too many meetings and wasted human and other resources.

So HIV state officials met with prevention and care partners to discuss collaboration and how the two processes could be brought together.

Through this process, state officials discovered that the two factions had different definitions for some words, such as the word "outreach." To prevention people, outreach had to do with field-based, community-based education programs. To people working in HIV care, the word outreach referred to early intervention services for HIV-positive patients.

"Folks had some fears, and some of those fears were difficult to get past," Randall says. "One of the biggest fears was that when prevention and care merged, one of them would get all of the money." However, this fear was unfounded because the money dispersed to each remains separate, she notes.

After several years of answering concerns and working toward collaboration, the care and prevention planners began to trust each other, Randall says. Now the collaboration is producing positive outcomes in terms of joint activities and events, and the two groups have a much better understanding of how the other one works, she adds.

"The most important thing is that our planning partners have embraced the notion of primary prevention for HIV-infected individuals, and they want us to understand how to do that," Randall says. "By the same token, clinicians are now beginning to understand how to integrate prevention into clinical services."

For instance, now clinicians realize that if they are seeing patients on a long-term basis it makes sense to do prevention services, and clinicians are educated about community resources to which they can refer patients.

"We are also holding one-and-two-hour workshops with a little skills building for physicians and medical students," she says. "These are little

things, but penetrating the provider community in that way is a challenge because of issues with time, resources, and interest."

Through these educational efforts, state health officials have learned that physicians are uncomfortable discussing gay sexuality. So a medical provider education project, SCRUBS, was launched for doctors, physician assistants, and others: Gay and lesbian speakers discuss AIDS, health care, and sexuality, Randall says. "Providers who went through the SCRUBS program say they are much more comfortable and much more confident discussing gay sex."

In 2000, the merger was complete with the two state bodies becoming one group that deals with both prevention and care. A next step will be to facilitate local links between prevention and care services, Randall says. "Those serving HIV-infected individuals will spend two days in the spring working with case managers, disease intervention specialists, and partner counseling and referral folks to talk about how to better move individuals to prevention and care and other supportive services," she explains. "They'll discuss how we help them and identify their needs and help them get to a place that's appropriate for their needs."

The consortium approach

- **Nebraska.** Since the state has a low incidence of HIV infection, but is a large state geographically, there long has been a trend of HIV planners doubling up, says **Sandra Klocke**, BSN, MS, administrator of the HIV Prevention & Ryan White Title II program in Lincoln. "When we had regional collaboration for planning and treatment, the same people were doing both. The rural areas elected to merge prevention and treatment in 1999."

At the same time, there were six regional groups but no statewide group, and as state officials tried to build capacity and skills in the six regional groups, the task proved frustrating, Klocke recalls.

"We decided we needed to merge them together into one group, and now there are six regional advisory groups. When we merged the six groups into one, it made sense to merge care and prevention," she adds. Thus, the new Nebraska HIV Care and Prevention Consortium was born.

"One of the challenges this year is how to develop a comprehensive care that includes care and prevention," Klocke adds. At focus groups that included people living with HIV/AIDS, planners asked what kinds of services were

needed and whether they needed more representation, she says.

This information, added to surveys and paid research, provides state officials with an idea of how to make HIV services as meaningful as possible and which services are needed in the state.

The merged consortium is becoming very cohesive and is advocating for the state's HIV funding needs. "They are learning to look at both sides of a question of what is prevention and what is care," Klocke says. "If we're doing prevention services, counseling, and testing, we want to ensure that every new HIV-infected person has good resources as a step-up to care."

By combining prevention and care planning, the state is able to link those two areas more effectively. In fact in the state office, prevention and care staff work together, which makes communication between the two much easier, she explains.

"So it's yelling over the cubicle sometimes," Klocke adds. "We also have good service with data people about HIV trends and a good link with primary AIDS organizations and a good relationship with the University of Nebraska Medical Center in Omaha, which is our ADAP [AIDS Drug Assistance Program] partner."

At the front line of HIV care and prevention, providers and others working with the HIV population see better coordination of services. Everyone knows who to contact in care and prevention, and they respect each other, she says.

"People understand that good care provides a direct avenue to some good prevention, as well," Klocke says. "If you have people in care who are taking medications, that's a frontline prevention piece because their viral load is going to go down, and they will be living better lives."

Some of the efficiencies that have resulted from the collaboration include a shared staff person who is involved with both community planning and case management and care and Ryan White funding and prevention, Klocke says. "We share staff, broken up by payment source and the rest of the staff participates in activities as a team," she adds.

• **Utah.** An advisory council consisting of both prevention and care planners helped the state develop a plan that would combine certain meetings and put both planning processes on the same schedule, says **Lynn M. Meinor**, manager of HIV Prevention Program in Salt Lake City.

"What we've done is combine orientation for all committee members and give them an overview of

community planning and an overview of treatment and care," she says. Since recently beginning the collaboration process, there has been a noticeable effort toward partnership between service providers and prevention providers, Meinor says.

"They now have more of an understanding from the orientation process and getting to know each member on that committee," she says.

"We've realized that we won't be able to combine every meeting because our processes are so different, but there is more of a collaborative partnership that is strengthened." State HIV officials have discussed sharing staff between prevention and care, but that hasn't been done yet, Meinor adds. "One other benefit is that we have committee members on treatment and care and also on community planning committee."

The state has formed a combined subcommittee about prevention for positives which includes members from both care and prevention groups, Meinor says. These members who serve on both committees are able to offer a different perspective about unmet treatment or prevention needs. ■

Computer education may bridge affordability gap

Electronic 'counseling' is easy and accessible

While there are a multitude of well-proven HIV prevention programs and models that resulted from studies funded by the Centers for Disease Control and Prevention (CDC) and other agencies, there are few options for the cash-strapped HIV clinic or doctor's office.

Keeping this obstacle in mind, researchers from three universities and the CDC are collaborating with a Seattle computer consulting business to create a computer-assisted, client-centered, prevention and education CD-ROM product that will encourage risk-reduction behaviors and increase testing for HIV and other sexually transmitted diseases (STDs). Participants in the program include the University of Washington in Seattle; California State University in Long Beach; Indiana University School of Medicine in Indianapolis; and Resources Online, a Seattle computer business.

"We've been trying to figure out more efficient ways to get more people tested for HIV and STDs, and also to be counseled to reduce their risks," says **Ann Kurth**, CNM, PhD, a certified

nurse midwife and STD fellow at the Center for AIDS and STDs at the University of Washington.

Studies have shown that brief sessions of counseling both before and after an HIV test is administered can result in significant risk reduction and behavior change, says **Freya Spielberg**, MD, MPH, assistant professor of the family medicine department at the Center for AIDS Research of the University of Washington.

"There are many venues, [such as] emergency rooms and STD clinics, where they don't have the time or skilled counselors to provide this service, and we're hoping we can create something that is similar to what is known to be effective prevention counseling," Spielberg says. "This is a client-centered approach for places that don't have it, so they'll be able to offer an effective replacement for pre-test counseling."

The theory behind the computerized counseling program is that most HIV/STD care is done in private practices where providers don't have the time, money, or staff to do risk-reduction counseling, Kurth points out.

"So our goal is to deliver this proven counseling technique through the computer to multiple sites," she explains. "Interactive computer counseling has been used for genetic counseling, smoking cessation; but as far as we know, this is the first time it's been used for HIV and STD, client-centered counseling."

It's not enough to provide educational materials because studies show these alone are not as effective as client-centered counseling, Spielberg says. "We're going to try to come as close as we can to creating client-centered counseling, using an interactive computer program."

While this approach won't put a patient face to face with a counselor, it's a cost-effective alternative that could be made available to many different HIV health care settings, Kurth says.

Client-centered counseling is an approach that has been recommended by the CDC and has been proven to be effective in reducing risk behaviors. Unlike the typical didactic counseling method, in which a physician asks questions, assesses risk, and then lectures the patient, client-centered counseling takes into consideration what the client needs and is capable of learning at that particular point in time. And the counselor helps them decide on a risk reduction plan that is attainable for them.

"First you begin with a nonjudgmental attitude, which is critical to effective counseling," Spielberg says. "With this approach, the client

does most of the talking."

Clients will describe their understanding of their risk for HIV, and the counselor heightens their awareness of risk by giving feedback, when necessary, she says.

"You explore with them what happened during their most recent risk and what they have tried in the past to reduce their risk," Spielberg explains. "And then you help the client come up with a specific risk-reduction plan that the client feels can be accomplished."

Rather than asking clients to agree to never again have unprotected sex, which may be unrealistic for many clients, counselors ask clients to commit to carrying a condom with them the next time they go out. Or they may be asked to consider talking to their next partner about HIV before they have sex, she adds.

"When this approach has been taken in STD clinic settings instead of didactic messages, studies have shown that clients contracted 30% fewer STD infections within the first six months of follow-up," Spielberg notes.

Cost is a big drawback

Client-centered counseling's chief drawback has been the staffing cost and time needed to make it work, and this has kept it from being used in many private practices, clinics, emergency rooms, migrant health centers, and teen health clinics, Kurth says.

Also, there are sites such as emergency rooms where HIV testing is not routinely offered because they are unable to provide the necessary counseling, Spielberg says.

"Some people at high risk may not seek health care outside of the emergency settings, thus an important opportunity is missed for early detection of HIV infection, she adds. "It is our hope that our interactive HIV computer counseling tool will make it possible for more venues to provide HIV testing so that access to HIV testing will be improved for people at risk."

The counseling tool's researchers are building the computer program so that it is appropriate for various at-risk populations, for people of different ages, and eventually for provision in a variety of languages.

"The structure is being set up so we will be able to expand it to allow a more tailored program for people of different ages and from different risk groups, as well as for people from different cultures," Spielberg says.

The development is funded by the CDC, which has requested a CD-ROM product as a starting point, Kurth says.

"We're looking at the possibility of adapting it down the road for web-based access," she adds. "But the reality is that there isn't always web access for personal computers available for patients at many clinics, so that's why the CDC decided on the CD-ROM version."

The program will have a user-friendly interface that asks patients risk assessment questions, followed by individualized counseling messages and negotiation of a realistic prevention plan, Kurth explains. "We're basing it on well-validated elements that are programmed into the computer, incorporating common scenarios and counseling probes that are used by a good counselor."

Depending on how a person responds, there are different options, which is what will make this client-centered, Spielberg adds.

"The program will go through different scenarios of education and counseling, enhancing clients' perceptions of their own risk for HIV and STDs, or how to use condoms if that has been a problem for them in the past," she says. "What they receive will depend on how they respond to the risk assessment and what they identify as their most important concerns."

This way, each patient selects his/her own risk reduction plan based on what they find realistic and what they think they can do.

The patient who has not yet started using condoms regularly may be routed to a short video showing realistic dialogue between a couple who are negotiating sexual safety. Someone who has used condoms that have broken may be routed to an animated clip on how to properly wear them, Kurth says. Since this computerized counseling program mainly will be geared toward youths, it is already designed for an audience that is used to digital communications and high-tech graphics, she explains.

For instance, the product will have a guide to take patients through the program, and the guide may reflect the patient's own ethnicity. "There may be an African-American man or a Latino woman, or a physician in a white coat, and so they'll pick the guide that they are most comfortable with at the beginning of the program," Kurth says.

The program also will be designed to run on a wide variety of computers to reflect the reality of what kind of hardware clinics have available. Likewise, the early versions of the program will

be in English, but more options may be available for later versions in other languages, she says.

Once the program is fully developed, the team's intent is to distribute it widely to make it accessible in many different venues. Users also would be able to customize the program by adding in phone numbers for local resources, for example, or by adding language modules when those become available.

It could be distributed at low or no cost to health clinics and sold on a sliding income scale with the goal of making it accessible in many different venues where counselors are not available, Spielberg says.

"Our goal is for people to use this CD-ROM when there are no human counselors available, or to use it for an initial interview with follow-up by counseling staff," Kurth says. "If this is done in conjunction with HIV testing, then the goal would be to test more people."

Funding for the program's development began in October 2002 with a plan to begin pilot testing and to design a randomized trial of the intervention in 2003.

(Editor's note: For more information about the computerized, client-centered counseling program, go to jim@ronline.com.) ■

'Sexual scripts' help MSM discuss safer sex

Intervention study conducted at 13 sites

Project Community Intervention Trial for Youth (CITY), funded by the Centers for Disease Control and Prevention (CDC), is studying a prevention project that teaches young men who have sex with men (MSM) how to discuss and negotiate safer sex.

How at-risk MSM communicate with partners about sex is an important part of an intervention strategy because some preliminary findings indicate that young MSM do not consistently include safer-sex negotiations and behavior in their sexual script, a term that researchers use to indicate patterns of behavior that lead to sex.¹

"When interviewing young MSM about their needs and safer-sex behavior, we asked if they had ever had anal sex with or without condoms and oral sex with condoms," says **David Seal**,

PhD, associate professor at the Center for AIDS Inter-vention Research at the Medical College of Wisconsin in Milwaukee.

"If they said, 'Yes,' we had them tell us about the last time they did that behavior. We were trying to understand the context of how these interactions unfolded for the young people," he explains.

So investigators asked the men these types of questions:

- Who were your partners?
- What were your motivations?
- How were you aroused?
- Was safer sex discussed?
- Did you know your partner's serostatus?
- What were your motivations in these interactions?
- Were you seeking intimacy or driven by passion?
- Was the sex coercive?

Interestingly, researchers found that when the man was motivated by emotional intimacy and feelings of love, trust, and feeling close to a partner, he was more likely to engage in anal sex without a condom, Seal says.

Alternatively, when men reported being motivated by passion and were engaged in casual sexual encounters with partners they didn't know well, they were more likely to engage in oral sex with a condom, he adds.

"The findings that were most troubling for us were that 5% of the narratives involved anal sex in what we would consider rape or highly coercive," Seal says.

Through this preliminary research, investigators began to understand what needed to be addressed in an intervention. Prevention strategies were created to address different scenarios with the goal of helping at-risk men make decisions that will make their sex safer, he says.

The CITY project, conducted at 13 sites nationwide, includes comparison groups at half of the sites.

Sites using the intervention model have five components:

1. Community health advocate training.

Participants are trained to be community health advocates through political or safe-sex education work. Training helped to build their HIV-prevention knowledge and skills, manage risk triggers, and find strategies for talking about HIV risk reduction with peers.²

2. Marketing campaigns.

Marketing campaigns include fliers of safer-sex practices to distribute at bars and coffee shops.

3. HIV social events.

Dances and other events are sponsored with safer sex incorporated into the social program.

4. Group workshops.

Small group workshops involving peer networks are held in a traditional fashion.

5. Community capacity development.

This involves working with youth organizations that have not previously worked with MSM youth. "We worked with an African-American provider to develop a training institute on MSM of color," Seal says. "We planned and hosted a conference of 100 people devoted to MSM of color and had national speakers come in, as well as local presentations."

None of these interventions are new, Seal notes. "But we hope for a synergistic effect."

Some of the capacity building already under way has resulted in training workshops and new services directed toward gay or lesbian populations. One project involved a drag queen show in which the performance was followed by safer sex education.

"You're reaching people for HIV prevention information in a relaxed, non-HIV way," Seal says.

"There's also a youth group called Project Q that is totally youth-driven, and we hold joint events, [such as] dances with a safer-sex theme, with them," he says. Through each of these programs and interventions, the objective is to encourage at-risk youth to change their current sex script for a sex script that naturally leads to safer sexual behavior.

The project's goal is to obtain measurable improvements in risk reduction among young MSM in the communities where the intervention project is employed, Seal says.

"Big studies in the last couple of years show that HIV seroprevalence rates are rapidly rising among young MSM, particularly in communities of color, and for all of us who work with the population that certainly is a cause of concern," Seal says. "We're hoping to see a reduction in risk behavior in the project's surveys."

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CE/CME

questions

21. Entry inhibitors prevent HIV from entering cells in at least one of which three entry processes?
- binding to CD4 receptor; fusing to CXCR-4, and fusing HIV to cell membrane
 - entering CD4 receptor; entering CCR5 receptor; setting up reproduction within human cell
 - binding to CD4 receptor; binding on a CCR5 cell receptor and fusing membrane of virus to membrane of cell
 - none of the above
22. A telephone survey of HIV physicians, conducted in October 2002, found that what percentage of the doctors found that their HIV patients had depressive symptoms?
- 55%
 - 67%
 - 84%
 - 92%
23. Michigan, Utah, and Nebraska are among the first states involved in a new trend to merge HIV planning for prevention and care services.
- true
 - false
24. Washington state researchers currently are developing an affordable and accessible client-centered counseling model that uses which mode of communication with at-risk patients?
- telephone interviews
 - video conferencing
 - interactive computer program
 - face-to-face meetings

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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. ■

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