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Innovative HIV prevention campaigns focus on high-risk youth, minorities

Black ministers step into HIV testing limelight, sending message home

It's taken 12 years, but the watershed moment finally has arrived in HIV prevention, as far as The Balm in Gilead of New York City is concerned. The HIV prevention group's campaign to engage African-American churches and ministers in efforts to fight the epidemic has begun to reap rewards, with prominent black ministers announcing that they are being tested for HIV and increasing numbers of churches participating in community-wide prevention projects.

"We feel this is a real turning point where we're engaging churches to encourage African-Americans to be tested," says **Pernessa Seele**, founder and chief executive officer of The Balm in Gilead. "We're no longer just talking about churches getting involved, but we're now at a place where churches are calling on the community to get tested."

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Some of the new HIV prevention campaigns aimed at minorities include the following:

• Researchers at the University of Illinois in Chicago have begun a unique project that provides prevention information and intervention to Latino women in Chicago communities. **(See story on prevention project for Latino women, p. 89.)**

• Florida has started an advertising campaign directed toward African-Americans and other minorities about HIV testing, condom use, and abstaining from sex. The ads, which feature young

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International AIDS conference coming next month

See the August issue of *AIDS Alert* for special coverage of the XIII International AIDS Conference in Durban, South Africa, which is expected to host nearly 10,000 delegates from around the world. Look for updates on major advances in drug treatment, vaccine development, and prevention efforts that have arisen since the previous World AIDS Conference held in Geneva in 1998.

people talking about AIDS in social situations, will appear on television, radio, billboards, and newspapers during the next year.

• Alameda County in California has an AIDS education campaign that targets African-American and Latino gay men and minority teen-agers. The ads are explicit, showing shirtless men about to engage in sex, and caused a controversy among local officials. So instead of putting them on billboards and bus stop benches, the ads will be displayed on matchbooks and condom packages.

Low-rider car used to reach Latinos

• The California Department of Health Services last spring started a prevention campaign for minorities that features a 1953 Chevy Bel-Air low-rider car. The car, which is expected to draw a large Latino turnout, will be taken on a statewide tour through mid-2001. Local AIDS groups will hand out information and discuss HIV at each stop.

• A Detroit program called Sisters and Daughters of Sheba received a CDC grant earlier this year to provide HIV prevention services to African-American women. The program provides basic HIV information and discusses self-esteem issues with women, teaching them to care about themselves and their own health. It also involves peer mentors who teach teen-age girls about safe sex.

• About 70 ministers of minority churches in Georgia have formed a partnership with the Fulton County health department to educate their congregations about HIV / AIDS, teen pregnancy, cancer, and sexually transmitted diseases. There will be a teen summit and health screenings.

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• Phoenix Body Positive in Arizona has expanded its prevention and AIDS support work to increasing numbers of women, Latinos, and African-Americans by working with churches, physicians, and testing centers to provide HIV counseling and support services, such as day care and respite care.

• The Harlem Directors Group and other organizations in New York City have begun a program called "Test, Link, Care — A Community Partnership" in Harlem. The program has 28 outreach workers who meet with people who do not know their HIV status, sending them to health care facilities and mobile units for testing.

• Washington, DC, has been running a series of print ads that feature the numeral 2000 with colored condoms in the place of zeros. The ads appear in bus shelters, subway stations, and in local newspapers, and they feature a Spanish version. Some of the ads feature a checklist of HIV prevention measures and mention abstinence.

• Community-based prevention programs in Arizona, including La Zona Hispana and TRIBE, try to increase HIV awareness among Hispanics and new Mexican immigrants by distributing pamphlets and condoms at bars and stores.

Hairdressers dispense HIV prevention advice

• Charlotte, NC-area barbers and beauticians hand out condoms and advice on safe sex and HIV prevention as part of a program that targets AIDS prevention in the African-American community.

The drive behind many of the new prevention projects is federal grant money made available specifically for HIV prevention programs for minorities.

"In October 1998, the Clinton administration declared HIV to be a severe health crisis in African-American communities and other communities of color, and with that announcement came $156 million for HIV intervention targeted to African-American communities," says **Peter Velasco**, director of communications for the National Minority AIDS Council in Washington, DC.

That money has taken some time to spread through the pipeline, and now, along with increases in 1999 funding, is finding its way to the community level.

"More resources became available to communities of color, and this enabled the communities to take action," Velasco adds. "We also saw several very prominent community leaders, including the Rev. Jesse Jackson, become tested for HIV and really display their leadership by sending the message that everyone should be tested for HIV."

Increasing numbers of prevention strategies also are being aimed at stopping HIV infection among minority and white youths, using language and visual cues that are relevant to this population, as well.

For example, the Henry J. Kaiser Family Foundation of Menlo Park, CA, has opened an on-line resource for teen-agers who have questions about sex, STDs, HIV, and birth control. The Web site is located at www.itsyoursexlife.com.

"In the United States, it's estimated that one in four people with HIV were infected by age 21," says **Donna Futterman**, MD, director of the Adolescent AIDS Program at Montefiore Medical Center in the Bronx, NY. "So do the math with the numbers of people who have AIDS, and there are maybe 100,000 young people in the U.S. with HIV infection, and the vast majority don't know they're infected," Futterman says.

An estimated 16% of youths infected with HIV are aware of their status, compared with two-thirds of adults who are aware of their HIV status.[1]

This problem is coupled with the fact that studies have shown that adolescents are twice as likely as adults to engage in risky behavior. For instance, a new surveillance study published by the Centers for Disease Control and Prevention in Atlanta indicates that about half of all high school students have had sexual intercourse, and 42% of these students had not used a condom during their last sexual intercourse experience. More than 16% of the students said they had had four or more sexual partners. The youths also had a high prevalence (81%) of having tried alcohol, and more than 47% had tried marijuana. While only 1.8% of youths said they had ever injected illegal drugs, nearly 15% had sniffed glue or used other inhalants, 9.5% had used cocaine, and more than 9% had used methamphetamines.[2]

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"For most young people, their prevention strategy is thinking they can tell if their partner has HIV. They say, 'He looks clean, he looks fine,'" Futterman says. "Three-quarters of the HIV-positive kids didn't know their partner was positive, so I think prevention messages have to be given consistently over time."

Teen HIV prevention programs also need to provide affordable and easily accessible condoms, says **Janet Livingstone**, director of U.S. programs for Population Services International in Washington, DC. The private nonprofit agency has a goal of improving the health status of low-income populations.

"Most of our work has been targeted at teens who are sexually active and at risk of sexually transmitted diseases," Livingstone says. **(See story on youth-oriented prevention campaigns, p. 88.)**

While youth-oriented campaigns try to reach teens in their favorite places to hang out, such as skating rinks, record stores, and video arcades,

the campaigns aimed at African-Americans largely involve ministers of Christian churches, because they have tremendous influence within the black community.

"The most influential persons in our community are the preachers, and the loudest voice we have is the pulpit," Seele says.

Launched in June, The Balm in Gilead's new campaign, called "The Black Church Lights The Way: The Black Church HIV Testing Campaign," involves 10,000 churches nationwide. Seele says that when she started the organization in the late 1980s, there were only 50 Harlem churches involved with HIV prevention. Now the organization receives CDC funding to provide free guidance to black churches and organizations through the Black Church HIV/AIDS National Technical Assistance Center.

Black church traditionally helps with crises

The new campaign draws on the history of black churches traditionally providing support to African-Americans through years of slavery, segregation, poverty, church bombings, and police brutality.

The Balm in Gilead's HIV testing campaign brochure tells people to get tested because one in 50 black men and one in 160 black women are living with HIV, and AIDS is the No. 1 cause of death among black men between the ages of 25 and 44. For more information about HIV testing, call The Balm in Gilead hotline at (800) 864-8607 or visit its Web site at www.balmingilead.org. Black churches that wish to join the campaign can call (888) 225-6243.

One example of a black church taking a leadership role in preventing HIV is Antioch Baptist Church in Cleveland, Seele says.

"They changed the basement of the church into an HIV testing clinic and partnered with the Cleveland Medical Clinic," she explains. "I think it's an extraordinary linkage, because you have nurses and health care providers at a testing place where people can receive spiritual counseling as well as HIV/AIDS counseling."

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Youth programs take pop-culture approach

Two national campaigns showing some success

The typical HIV prevention message often is ignored by teen-agers, who don't relate to the same issues that concern adults. Yet young people need to know more about HIV and prevention because studies show they are far more likely than adults to engage in risky behavior.

"A lot of people think, 'We did this HIV prevention already, so why aren't the kids getting it?'" says **Donna Futterman**, MD, director of the Adolescent AIDS Program at Montefiore Medical Center in the Bronx, NY. "And part of the reason is that until teens see it validated in popular culture, it doesn't seem real to them," Futterman adds.

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So the key is to design prevention messages for youths that reach them in their favorite hangouts and are written in the language of their own popular culture.

And because young people with HIV are much less likely to know their serostatus than are adults with HIV, prevention programs designed for youths focus on HIV testing as much as on HIV prevention.

The Adolescent AIDS Program's multicity project, called "HIV. Live With It. Get Tested," has tried to break through the barriers that discourage youths from becoming tested. For instance, the program includes youth-friendly testing sites that offer confidential or anonymous testing. Youths who test positive are provided HIV care.

"One of the things we've learned is that to reach young people, we have to speak to them in their language, using messages that they understand," Futterman adds. For instance, the HIV "Get Tested" campaign uses the slang terms "get busy" and "hitting it" as euphemisms for having sex.

Youth-oriented campaigns also make use of media and public places that appeal to young people. The Adolescent AIDS Program includes a peer outreach component in which youths speak with other young people and hand out materials at schools, youth clubs, skating rinks, and parks. The program also will expand to the Internet in August, with a Web site at www.hivlivewithit.org.

Montefiore's Adolescent AIDS Program initiated the campaign and drew on the help of advertising agencies in designing it to be replicated in other cities.

So far, the project has built tremendous interest and HIV awareness in each of the cities involved, Futterman says. "Hundreds of kids called local hotlines and came in for testing."

Pulling in community leaders

Another national prevention campaign for teens, called Project ACTION, uses a four-pronged approach that focuses on community mobilization, mass media messages, skills building, and making condoms available, says **Janet Livingstone**, director of U.S. programs for Population Services International (PSI) in Washington, DC.

PSI coordinators meet with local community leaders and health care workers to explain the program's goals and approach to protecting teens' reproductive health. "It means meeting with youth services organizations that provide social support such as shelters and rehab centers for addiction treatment, and meeting with school boards and schools to the extent they are interested in the program," Livingstone says.

Then program directors research the target audience of youths before developing mass media messages. They find out what sort of media are available and will reach teens, including television, print ads, radio, billboards, and Internet Web sites.

The third step is to help youths understand their risk and help them acquire the skills necessary to communicate with their peers about protecting themselves from HIV and pregnancy. "We help them to negotiate condom use, in other words," Livingstone says.

The final step is to make condoms inexpensive and accessible to youths. PSI has placed condom vending machines in local businesses in targeted communities. For example, the organization has installed 125 condom machines in Portland, OR.

"We put these in places where kids are hanging out," Livingstone says. "The machines have a positive mental health message on them, such as 'Protect yourself, use a condom,' or 'Don't think about it without a condom.'"

The machines sell condoms at a subsidized price of 25 to 50 cents, and they are located in recreation centers, pizza shops, record stores, and video arcades.

"There were no objections to the machines, because we had already talked to everyone we could think of beforehand," Livingstone says. "I believe we were able to bring the religious groups in at the beginning and say, 'We know these kids are having sex and pregnancy rates are high, and we want to make it easier for them to protect themselves even if we can't stop them from becoming sexually active.'"

The project was replicated in San Jose, NM, and Seattle, and each city had positive results, Livingstone says.

"Mainly through quantitative research among the target audience, we were able to show that these kids during and right after the project were using condoms at a much higher rate," she explains. "For example, in Portland, condom use with new or casual partners increased from 72% before the project to 90%."

Even with businesses donating space for the machines and with thousands of minutes of free public service ad time, the project was expensive, costing $500,000 in Portland over the two-year period, Livingstone says.

PSI has begun a fourth Project ACTION campaign in the Santa Cruz, CA, area, targeting rural Latino communities.

"We're developing bilingual materials and a culturally appropriate version of the Project ACTION model," she says.

[Editor's note: For more information about the "Get Tested" campaign, call Montefiore's Adolescent AIDS Program at (718) 882-0232.] ■

Growing problem in Latino community sparks interest

Chicago research concentrates on women

HIV infection continues to rise among Latinos in the United States, particularly among Latino women. While Hispanic women accounted for 18% of the cumulative AIDS cases among Hispanics in 1998, they accounted for 21% of the newly reported AIDS cases that year, according to data collected by the Centers for Disease Control and Prevention in Atlanta.

Among Hispanics in the United States, heterosexual transmission of HIV accounts for 12% of

cases, while injection drug use accounts for 28% of cases. CDC researchers say transmission related to substance abuse is a significant problem among Hispanics, especially among those of Puerto Rican descent.

The problem has been that few prevention programs are directed specifically to the Latino community and even fewer to women within that community. This is why a Chicago researcher has targeted this population for a new prevention campaign.

"I started this project because the incidence of HIV among Latino women has been increasing," says **Nilda Peragallo**, DrPH, RN, FAAN, associate professor at the College of Nursing in the University of Illinois at Chicago.

"Here in Chicago, HIV among women has increased, especially heterosexual transmission among women of color, both African-American and Latino," Peragallo says. "So whatever we're doing in prevention work is not getting through to that particular population."

With funding from the Washington, DC-based National Institutes of Health and the National Institute of Nursing Research, Peragallo has begun a three-year study to test a culturally tailored intervention that she has designed.

The study will include more than 750 women in Chicago's Latino communities. Their age range will be 18 to 44 years, and they'll be of Mexican or Puerto Rican descent. Another criterion is that they have been sexually active within the last three months.

Focus groups helped with model design

"Initially, we had some focus groups in the community, looking at what the issues were in their communities and whether HIV was an issue," Peragallo says.

Focus group participants addressed these questions:

- What are the problems in getting the message out about HIV prevention?
- What areas of prevention are they interested in?
- What do women want from an HIV intervention?
- Where would women want an intervention to be held?
- What sort of program would be more culturally relevant and acceptable to them?

The focus group suggestions were incorporated into the prevention program's design and were part of a pilot intervention project that has been under way for more than one year.

Here's how the interventions were designed:

1. Set up intervention sessions.

Two-hour intervention sessions are held once a week for six weeks. The sessions are provided to groups of eight to 12 women, and they have a facilitator nurse who is bilingual and Latino.

"It's important for the facilitator to understand the context of the culture and to value it," Peragallo says.

Here is a summary of each session:

- **First session:** This one is about women knowing their bodies. It provides a discussion of anatomy and physiology of both the male and female bodies and the reproductive system. "The women get a chance to ask questions that they have never had the chance to ask before, and that makes them feel very comfortable," Peragallo says.
- **Second session:** The facilitator talks about HIV and sexually transmitted diseases (STDs) in the participants' community, bringing the epidemic home to them. "We give participants some very accurate statistics, but provide them in an understandable manner so it makes sense," Peragallo says.
- **Third session:** This session deals with condoms and teaches participants how to use both male and female condoms.

"We talk about how to properly use them and discuss what has been their experience in using them and why they haven't used them in the past," Peragallo says. "And we talk about all of the attitudes that are prevalent in our community and what the pros and cons are with using condoms and what our choices are."

- **Fourth session:** The facilitator teaches the women better communication and negotiation skills, using role-playing techniques. The class is interactive, involving participants in finding solutions to potential communication problems that arise with their partners, their families, and their children.

Women learn to 'downscale' conflict

"We teach them how to downscale conflict and not make it bigger," Peragallo says. "We have an exercise in which we say, 'Tell him what you never dared to tell him,' and they pick another person in the group to be their partner, and they tell that person whatever it is they have wanted to tell their partner but never had the courage to do so."

For example, one woman in the pilot intervention told the role-playing partner, "I hate to cut your toenails, and I've always wanted to tell you that." This exercise gave the women an opportunity to release some of the tension and resentment that had been building up in their relationships, and it provided them with better skills for speaking their minds to their family members.

• **Fifth session:** This session dealt with how to prevent violence. While this is not a typical HIV prevention intervention, it is an important part of the overall prevention picture, Peragallo says.

"The reason is because we find, and it's not just in this Latino community, that violence inhibits the communication process or negotiation," she adds. "How can you negotiate with someone about using a condom when you're not equally in power in the relationship?"

The session includes discussions about gender roles and what these mean. For instance, there's a discussion about what it means to be "macho" and the positive and negative aspects of this. There's also a discussion about how the family is valued.

Discussing the effects of violence

"When we talk about violence, we talk about how to prevent it and what the effect of violence is on the family: the women, the perpetrator, and also the children, because a lot of women are not aware of how this affects their children," she says. "With the discussion, they begin to realize how their children's grades are going down and they're not doing well at school."

• **Sixth session:** This session provides a review of all of the previous sessions. Each woman participant is encouraged to present a review of her favorite part. Some women may speak about communication, clarifying certain issues. Their presentations are decided the week before. Also, the last session involves a party with refreshments and cake.

"Then we give them a diploma for their completion, and they come to the session all dressed up," Peragallo says.

After each session, the women do "homework," such as practicing using a female condom or using their new communication skills with a member of their family.

"We always emphasize that the choice is theirs," Peragallo says. "We try to let them know that we value their opinions and their ways of thinking and their experiences, so they know best how to apply these things."

2. Provide follow-up "booster" session.

After three months, the women meet again for a booster session.

"Basically, what we want to do is ask them how they're doing and what are some things that have been problematic for them," Peragallo explains.

Women give feedback at booster session

The women write a few paragraphs about how they feel, and they talk about the areas that have given them the most difficulty. For example, they might not have liked using the female condom, or maybe they couldn't get their partners to use the male condom, she adds.

"Then we interview the women because this is a randomized study with a control group," she adds.

3. Analyze the results.

Participants are given HIV pre-tests and post-tests in either Spanish or English. They're asked demographic questions and questions about their culture identification, such as how long they have lived in this country. Researchers investigate whether the women suffer from depression or self-esteem problems. They also look at partner characteristics and behaviors, because many women's risk for HIV is more related to their partner's behaviors than to their own actions, Peragallo says.

"Then we ask them about self-efficacy and their knowledge of HIV and their own behaviors, including the use of condoms and whether they've had STDs within the past three months," she adds. "We ask about their drug use and the HIV status of their partner and if they knew or ever asked about that status."

The interview process takes about an hour, and all interviewers are bilingual.

Results from the pilot project have not yet been published. However, analysis from the baseline interviews shows that the women who report a history of violence in their relationships are more likely to be depressed, have low self-esteem, and be at high risk for HIV infection.

"That's based on 347 baseline interviews, the preliminary results," Peragallo says. "I think that's important because of the implication that we have to address the topic of violence in designing an intervention for women." ■

Protease inhibitors cause diabetes in some patients

Data could help in developing better PIs

New research shows how protease inhibitor drugs cause some patients to develop insulin resistance and can even lead to type 2 diabetes.

"A small number of patients at this point have developed full-blown diabetes after being placed on protease inhibitor [PI] therapy," says **Michael M. Mueckler**, PhD, professor of cell biology and physiology at the Washington University School of Medicine in St. Louis.

More than 80% of the people on protease inhibitor therapy in one study developed lipodystrophy, and a smaller fraction developed diabetes, all within an 18-month time period. This shows the potential growth of the problem as people stay on PI therapy for years and even decades.

"Diabetes is a disease that takes a long time to develop, and it's quite possible that a good fraction of people who continue to be on PI therapy will develop type 2 diabetes, especially if they have predisposing factors like obesity and a family history," Mueckler adds. "So this is not at all trivial."

PIs are also associated with the metabolic abnormalities of peripheral fat wasting, central adiposity, hypertriglyceridemia, and hypercholesterolemia. The Cardiovascular Disease Focus Group established by the U.S. AIDS Clinical Trials Group has released guidelines for managing lipid abnormalities in HIV patients on antiretroviral therapy. **(See summary of guidelines for managing dyslipidemia, p. 93.)**

PIs inhibit glucose transportation

Mueckler and other investigators studied the mechanism in PIs that causes insulin resistance. Aided by research on mice, investigators discovered a Glut4 glucose transporter that is necessary for full-body glucose disposal. In patients on PI therapy, the Glut4 glucose transporter is not working properly or responding adequately to insulin that's released with increased activity.

"What this Glut4 protein does is to take up glucose from the blood into muscle tissue and fat tissue," Mueckler explains. "So we tested the hypothesis that HIV protease inhibitors were inhibiting the function of the Glut4 gene, and we found that was indeed the case," he adds.

Researchers further theorized that PIs were binding directly to the Glut4 protein and somehow altering and inhibiting its activity. Lab tests using oocytes confirmed that PIs were blocking activity of the Glut4 transporter, but not the Glut1 transporter that is responsible for transporting glucose to the brain.

"If PIs inhibited all glucose transporters, including Glut1, it would probably kill people," Mueckler says. "And obviously, PIs are not killing people and are not affecting brain function as far as we know, either."

The next step is to determine how PIs are inhibiting the Glut4 transporter.

"Once we know that, it hopefully will assist in the design of a new generation of protease inhibitors that hopefully will inhibit HIV protease but not inhibit the glucose Glut4 transporter," Mueckler says. "And we think that's the most important ramification of this work."

Pharmaceutical companies could use a simple assay that measures Glut4 activity to determine whether new protease inhibitors have the propensity for causing the metabolic syndrome, he adds.

Until new PI drugs that do not cause glucose/insulin imbalances become available, clinicians should treat patients on PI therapy as if they could develop diabetes, Mueckler suggests.

Regularly monitor patients' blood sugar

HIV clinicians need to be aware of the insidious nature of diabetes, which can cause heart disease, kidney failure, and blindness.

"The important thing is to have patients' blood sugar monitored on a regular basis, especially if they have the two major predisposing factors of obesity and a family history of type 2 diabetes," Mueckler says.

Because PIs work so well in controlling HIV infection, putting patients on an alternative therapy is a less viable option that should be decided on a case-by-case basis, he adds.

On the positive side, the insulin problems caused by PIs are probably reversible.

"The effect we saw in PIs on the glucose transporter occurred very rapidly, within minutes, and also was rapidly reversible," Mueckler says. "We feel it will restore insulin sensitivity if they stop the drugs."

The study will be published in the *Journal of Biological Chemistry*. An unedited version of the article is available on the journal's Web site at www.jbc.org/cgi/reprint/C000228200v1. ■

Guide for managing HIV patients with dyslipidemia

Focus group plans to issue periodic updates

The U.S. AIDS Clinical Trial Group (ACTG) Cardiovascular Disease Focus Group's new guidelines for evaluating and managing dyslipidemia in HIV-infected adults acknowledge that the condition is prevalent among patients receiving antiretroviral therapy.

The guidelines were released in a preliminary version on the Internet, prior to a summer publication in the *Clinical Infectious Diseases* journal.

One study has shown that 47% of people on protease inhibitor therapy had lipid abnormalities.[1] While researchers have yet to determine whether these higher triglycerides and cholesterol levels put HIV patients at a greater risk for heart disease, the ACTG has decided the potential risk is grave enough to warrant treatment guidelines. Plus, it's more difficult to treat HIV patients with dyslipidemia because of potential drug interactions with their antiretroviral treatment.

Here are the ACTG's recommendations, as released in preliminary guidelines:

• Evaluate serum lipids, including total cholesterol, HDL cholesterol, and triglycerides, after eight to 12 hours of fasting.

• If fasting triglyceride levels exceed 400 mg/dL, then the LDL calculation may be unreliable. Intervention decisions can be based on other measurements.

• Screen patients for other risk factors, including family history, smoking, hypertension, menopausal status, physical inactivity, obesity, diabetes, excessive alcohol use, hypothyroidism, renal disease, liver disease, and hypogonadism.

• Prescribe diet and exercise to any HIV patient with fasting triglycerides of greater than 200 mg/dL. Patients with isolated hypertriglyceridemia of greater than 1000 mg/dL are candidates for drug therapy.

• For hypercholesterolemia, first institute non-drug therapies, giving these a thorough trial before beginning drug treatment. In some HIV patients, it is more important to address problems with wasting before suggesting they change their diet due to dyslipidemia.

• Lovastatin and simvastatin have potential toxicity when combined with protease inhibitors. Fluvastatin likely interacts with nelfinavir. Few drug interaction data are available on cerivastatin.

The guidelines are offered in an abbreviated version on the Internet at: http://aactg.s-3.com/pub/docs/lipid_guidelines.htm.

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New class of HIV drugs good tools in the battle

Recent advances fuel hope for future drugs

[Editor's note: Constance Benson, MD, professor of medicine at the University of Colorado Health Sciences Center Division of Infectious Diseases in Denver, has led clinical trials on the new HIV antiretroviral drug ABT-378. Abbott Laboratories of Abbott Park, IL, has recently submitted a new drug application with the U.S. Food and Drug Administration to market ABT-378/r (lopinavir/ritonavir) and to receive accelerated approval. Benson also is the vice chair of the Adult AIDS Clinical Trials Group, the principal investigator of the Mountain Plains AIDS Education and Training Center, and an expert on treatments for HIV-infected patients and opportunistic complications of HIV-1 infection. AIDS Alert *asked Benson a few questions about new antiretroviral regimens and what these might mean in the long-term treatment of HIV disease.]*

AIDS Alert: How do new drugs like ABT-378 compare in tolerability, dosing requirements, and potency to the older generation of antiretroviral drugs?

Benson: ABT-378 is co-formulated with low-dose ritonavir, which enhances the pharmacokinetic profile of ABT-378, resulting in concentrations of drug approximately 30-fold greater than the 50% inhibitory concentration (IC50) for wild-type HIV-1, and prolonging the duration that the concentration of drug is maintained above the IC50. These

result in a drug with enhanced potency that can be administered in a twice-daily regimen.

Clinical trials with ABT-378/r have shown that the drug is well-tolerated, with few patients discontinuing drug due to an adverse effect. In my own clinical experience, mild gastrointestinal upset and/or mild diarrhea have been the principal side effects, and these have occurred in only a small number of patients, making this a very well-tolerated drug.

In terms of how this agent compares to other antiretroviral drugs, no studies directly comparing their tolerability and potency have been completed to date. However, based on in vitro data, the ratio of peak concentration to IC50 for wild-type HIV-1 is substantially greater for ABT-378/r than for other currently available protease inhibitors when the latter are used as single agents, suggesting that ABT-378/r may be more potent than first-generation protease inhibitors as single agents.

In general, rates of side effects associated with ritonavir, indinavir, and nelfinavir are reported to be higher than with ABT-378/r, and this has been my clinical experience as well. Ritonavir, alone or when combined with saquinavir, and nelfinavir can be dosed twice daily, similar to ABT-378/r. Dosing requirements are primarily a problem with indinavir when it is used as a single agent, due to its dosing schedule of every eight hours, the need to administer the drug on an empty stomach, and the hydration requirements to prevent nephrolithiasis. However, the combination of indinavir with low doses of ritonavir alters the pharmacokinetic profile of indinavir in a similar fashion to that of ABT-378/r, allowing the combination to be used twice daily and with less regard to timing of administration with food.

AIDS Alert: When you began your research work, did you have a clear idea of what a perfect HIV drug might be?

Benson: The attributes of a "perfect HIV drug" are theoretical. In my opinion, a "perfect" drug would be one that is potent and effective, can be taken once or at the most twice daily without regard to food or hydration, has minimal to no side effects, and can be safely taken long-term. These attributes can be applied to any drug used for treatment of a chronic illness, and my opinion has not changed with research work in HIV. I have, however, developed a more realistic view of the difficulties that have been and continue to be encountered in the development of new drugs that meet these characteristics, and realize the development process is a long, difficult one in which incremental progress is more likely to be observed than a single blockbuster finding.

AIDS Alert: How have the long-term priorities of HIV treatment changed since protease inhibitors were first widely used about four or five years ago? How has this shifted research?

Benson: The long-term priorities for HIV treatment have evolved in an interesting fashion. The optimism experienced with the initial availability of protease inhibitor regimens and the attendant reductions in mortality and opportunistic infections continues as the beneficial effects of more potent regimens continue. However, this optimism has been tempered by the recognition that many of the newer drugs and regimens are associated with substantive toxicities, some of which are treatment-limiting. In addition, the difficulties with dosing schedules, adherence, and toxicities — and the accompanying emergence of drug resistance — have led to a re-evaluation of critical issues such as when to start therapy, how to best individualize therapy and preserve future treatment options, and how to use new technology such as ultrasensitive plasma HIV-1 RNA assays and genotypic and phenotypic resistance testing to optimize treatment. As patients will require treatment, in most instances, for life, research is now focused on strategies that will provide the most effective and durable therapies associated with the least toxicity over the long term and that preserves the broadest variety of future treatment options.

AIDS Alert: In your opinion, what are some of the most promising possibilities that are occurring as a result of the recent advances in HIV treatment?

Benson: Recent advances that I think provide promise for the future are the ongoing development of potent drugs in several classes of compounds that have the potential to be active against drug-resistant strains of HIV-1, such as ABT-378/r, BMS-232632, second-generation non-nucleoside reverse transcriptase inhibitors, and tenofovir, among others; the development of entirely new classes of drugs that do not have cross-resistance with currently available agents, such as integrase inhibitors, CCR5 inhibitors, and fusion inhibitors; the availability of genotypic and phenotypic resistance assays that can

be employed in a number of settings to optimize treatment; and the development of potent, less complex, and/or better-tolerated regimens (once daily or twice daily without regard to food) that may improve/enhance adherence, and as a consequence, reduce the risk of emergence of drug resistance. All of these are on the horizon and will continue to improve our ability to treat HIV-1-infected patients. Additional work with immunomodulators or immunotherapeutic interventions may show promise, although results are not yet available to discern whether the latter approaches will add to or supplant antiretroviral therapies.

AIDS Alert: What advice do you have for clinicians designing HIV antiretroviral regimens for patients? What are the factors they need to consider, and how should they go about making these choices?

Benson: Treatment of HIV-1-infected individuals should be undertaken by health care providers experienced in their care and who have had and continue to have appropriate training and continuing medical education to acquire and maintain their expertise. Antiretroviral therapy should be individualized based on a number of factors, including — in no order of priority — CD4+ T-cell count; plasma HIV-1 RNA level; prior treatment history; presence or absence of drug susceptibility; tolerability and complexity of the regimen; ability of the patient to understand, accept, and adhere to the therapy; social support; fiscal resources; and other underlying conditions or use of concomitant medications with which antiretroviral therapies may interact.

There are a number of approaches to the initial therapy of antiretroviral-naive patients recommended in the U.S. Department of Health and Human Services and/or IAS-USA guidelines for treatment of HIV-1 infection, both of which are published and can be used as resources for clinicians. Perhaps the most important factor in making the best treatment choices for patients is the development of a trusting, caring, and collaborative relationship between the patient and the provider. Spending the time necessary to educate the patient about their choices, the risks and benefits of treatment, the appropriate manner in which the prescribed drugs should be taken, and assuring appropriate monitoring and follow-up to deal with subsequent issues are part of the trusting, caring, and collaborative therapeutic relationship. ■

Efavirenz available for children and teens with HIV

Oral liquid formulation is more convenient

With more than 10,000 HIV-infected children in the United States, clinicians continue to look for new and improved antiretroviral treatments that will help this population.

Now physicians have another option in HIV treatment of youths. The drug efavirenz (Sustiva) is available to children and adolescents through age 16 as part of an expanded access program.

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A recent study has shown that children who take efavirenz along with one or two other antiretrovirals have an excellent antiviral response over a 48-week period, says **Stuart Starr**, MD, professor of pediatrics at the University of Pennsylvania School of Medicine in Philadelphia. Starr also is the chief of immunologic and infectious diseases at the Children's Hospital of Philadelphia.

Because the children enrolled in the study had to be able to take capsules, many younger children were excluded. However, now efavirenz is available in an oral liquid formulation that is being studied under the expanded access program as an open-label, multicenter study of children and adolescents who are unable to swallow capsules. The liquid formula is clear and has a strawberry / mint flavor. The package contains an oral dosing device with detailed instructions for parents. Dosing depends on the child's body weight. The drug has not been studied in children weighing less than 10 kg or younger than 3 years of age, so these children are excluded from receiving the drug.

The protocol is open to antiretroviral-experienced and treatment-naive children ages 3 to 16.

The *Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection*, released by the Working Group on Antiretroviral Therapy and Medical Management of HIV-Infected Children, recommend the use of efavirenz as a first-line therapy for HIV-infected children in combination with two nucleoside reverse transcriptase inhibitors.[1]

In the pediatric trial that used efavirenz capsules, the types of adverse events observed were similar to those commonly observed in adult patients, except there was a higher incidence of rash among children. Rash occurred in 40% of the children, as opposed to 26% of adults taking the drug. Other adverse events were diarrhea / loose stools in 39% of children, fever in 26%, cough in 25%, nausea / vomiting in 16%, and nervous system symptoms in 9%.

For more information on prescribing efavirenz, contact Wilmington, DE-based DuPont Pharmaceuticals Co. at the company's Web site: www.sustiva.com or by calling (800) 4PHARMA (800-474-2762).

Reference

1. Working Group on Antiretroviral Therapy and Medical Management of HIV-Infected Children. *Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection*. Convened by the National Pediatric and Family HIV Resource Center, the Health Resources and Services Administration, and the National Institutes of Health. January 2000. ■

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. ■

AIDS ALERT®
INTERNATIONAL

AIDS epidemic in Africa threatens security worldwide

President Clinton's recent announcement shows depth of catastrophe

It's no coincidence that an increasing number of media reports on AIDS this year have focused on the epidemic's effects in Africa. The spread of HIV among southern African nations has reached such gigantic proportions that it's impossible to ignore, HIV experts say.

The World Health Organization (WHO) in Geneva, Switzerland, announced in June that the average life span in southern Africa has been reduced by 15 to 20 years because of AIDS.

"What you have happening in a lot of these countries is between 10% and 40% of your population of reproductive age is infected with HIV, and it will take a devastating health toll," says **Eve Lackritz**, MD, assistant chief for science in the international activities branch of the Division of HIV / AIDS Prevention for the Centers for Disease Control and Prevention in Atlanta.

Threat to development imperils security

"This erodes the entire infrastructure, obliterates it, and affects every component of your society, so that would include education, government, health, and development — and it's that threat to development that makes this a security threat," Lackritz says.

In some African nations, as much as 70% of military personnel are infected with HIV. Also, as many as 90% of those infected with HIV may not know they are infected and therefore are continually spreading the virus, says **Jacob Gayle**, PhD, senior technical advisor and The Joint United Nations Programme on HIV / AIDS (UNAIDS) secretary in Washington, DC.

"Any epidemic like this that predominantly hits the prime work force and prime reproductive force has some serious consequences," Gayle says.

Also, organizers of the XIII International AIDS Conference chose Durban, South Africa, to host the nearly 10,000 delegates who were expected to attend this year's conference in July. Organizers saw the Durban conference as an opportunity to focus attention where the effects of the epidemic are being felt the most.

In May, the White House announced that the Clinton administration was viewing Africa's AIDS epidemic as a threat to the national security of the United States. Unstable nations that are experiencing the sort of economic insecurity that AIDS is creating in parts of Africa are vulnerable to political strife, coups d'etat, and economic upheavals, the administration said.

Impact of disease far-reaching

President Clinton has continued to emphasize the importance of focusing on the African AIDS problem. For instance, in a May 30 speech at the Pavilion of Knowledge Science Center in Lisbon, Portugal, Clinton said: "In Africa, Asia, and many parts of the world, diseases like AIDS, malaria, and tuberculosis are killing not only people, but hope for progress. In Africa, where 70% of all the world's AIDS cases exist in sub-Saharan Africa, some countries are hiring two employees for every job on the assumption that one of them will die of AIDS."

Clinton also remarked to the scientific community in Lisbon: "In other African countries, 30% of the soldiers have the virus. Millions suffer from strains of malaria that are increasingly resistant to any drug. And a third of the world has actually been exposed to tuberculosis. These diseases can ruin economies and threaten the very survival of societies."

Despite criticism from Senate Majority Leader **Trent Lott** (R-MS) that Clinton was pandering to special interest groups by focusing on the African AIDS problem, many international organizations

and experts agree that the epidemic's impact on sub-Saharan Africa has become an international crisis. And as a senior administration official points out, the Clinton administration has been concerned about the AIDS epidemic in Africa for years. Focusing on it as a national security threat doesn't mean the U.S. will ignore other security threats, such as terrorist activity, rogue states, and other international problems, but it will mean that in the 21st century, the United States is expanding its view of what constitutes a national security threat, the official said.

The WHO and UNAIDS have promoted a greater focus on the epidemic, calling it Africa's top human security issue. UNAIDS says the disease kills 10 times more people in Africa than does war. About half of Africa's HIV infections occur in people below the age of 25, killing many before they are 35 years old.

"AIDS doesn't just affect the health sector; it affects every sector because of the impact on the working populace," Lackritz says.

Statistics on AIDS in Africa

HIV-infected: More than 24 million

Rwanda: 500,000 infected (more than 6% of population)

Nigeria: 5.4% of nation's 120 million people have HIV

South Africa: 4.2 million infected with HIV

Died from AIDS in 1998: 2.2 million

Died from war in 1998: 200,000

Total AIDS deaths through 1999: Nearly 14 million

Children orphaned due to AIDS by 2002 (estimated): 13 million

South African employees lost to AIDS over next decade (estimated): 40%-50% of current work force

Teachers dying from AIDS in Cote d'Ivoire: 7 out of every 10 teacher deaths are caused by AIDS; 5 teachers died from AIDS each week from 1996 to 1998

Number of teachers dying of AIDS in Zambia in 10 months during 1998: 1,300

Percentage of adults infected with HIV in seven sub-Saharan African nations: 20%

HIV prevalence rate in all of sub-Saharan Africa: 8%

TB resurgence caused by AIDS: TB has increased by 500% in some areas

Sources: World Health Organization/UNAIDS, Geneva; international news organizations.

While the problem is as obvious as a plane wing sticking out of a building's roof, solutions are elusive. United States AIDS activists may believe all it will take is cheaper antiretroviral drugs, but those who have worked in Africa or visited African hospitals say cheaper AIDS drugs will not stop the epidemic by themselves.

Experts focus on prophylaxis

"The problem is not only to have the drugs in the country, but mainly to use these drugs properly," says **Badara Samb**, MD, PhD, UNAIDS care advisor in Geneva.

Rather than focusing on affordable antiretrovirals, a better approach is to focus on building the developing nations' health care infrastructure and providing prophylactic medications for opportunistic infections (OIs), Samb and Lackritz say.

"Prophylactics would reduce the mortality of HIV / AIDS and improve the quality of life, and they're very cheap, with the price for one year of prophylactics being maybe as low as $8," Samb says.

"In Africa, there are many bacterial diseases, and those are the main killers of people with HIV," he adds.

Lackritz says the poorer African nations are missing too much infrastructure capacity to be able to deal with antiretroviral distribution.

"The wards are overcrowded with patients with wasting disease, TB, and diarrhea, and the mortality rates are very high," Lackritz says. "Getting hospitalized in that setting is a very poor prognosticator and tends to be a terminal event for many patients."

The first priority should be to help these nations boost their health care infrastructure to ensure accountability and procurement of central drugs and to make an impact in treatment of sexually transmitted diseases, experts say. Then there should be a focus on providing basic prophylactics, such as trimethoprim-sulfamethoxazole (co-trimoxazole). This inexpensive antibiotic is effective against some of the most common OIs, including pneumonias, non-typhoid salmonella, and enteric pathogens.

"Co-trimoxazole should be readily available and very cheap, but the health care delivery system has to be put into place," Lackritz says.

Then, there needs to be increased education of health care providers on what AIDS-defining illnesses are and which drugs are used for treatment

and prevention. And finally, there will need to be a strengthening of lab capacity to diagnose opportunistic infections, including increasing the capacity to do X-rays and simple culturing of blood, stools, and sputum, she adds.

"So it's a three-tiered approach, and we can't deliver antiretrovirals without a drug delivery system, and that just doesn't exist in a lot of places," Lackritz says.

Lackritz was involved with a trimethoprim-sulfamethoxazole prophylaxis study that found that administration of the drug in HIV-1-infected patients with tuberculosis significantly decreased mortality and hospital admission rates. The study also found significantly fewer admissions for septicemia and enteritis in the co-trimoxazole group.[1] Co-trimoxazole also can be used to treat salmonellosis, isopsoriasis, cerebral toxoplasmosis, and bacterial pneumonia.

UNAIDS promotes prophylaxis in Africa

Both the CDC and UNAIDS are working on programs to help boost the African health care infrastructure.

"UNAIDS promoted the use of prophylaxis, as well as access to antiretrovirals, even though the prices still are too high," Samb says.

The CDC will receive some $35 million this year for AIDS programs in Africa and India. President Clinton is asking Congress for $325 million to fight international AIDS, which more than doubles the nation's previous two-year commitment. The administration also has committed more than $70 million for TB prevention, control, and research and more than $100 million to combat the spread of malaria. **(See story on the U.S. - European Union agreement to fight HIV, p. 4.)**

UNAIDS announced in May that the organization had begun to work with five major pharmaceutical companies on ways to accelerate and improve the provision of HIV / AIDS care and treatment in developing countries. These companies are Boehringer Ingelheim, Bristol-Myers Squibb, Glaxo Wellcome, Merck & Co., and F. Hoffmann-La Roche.

Reference

1. Wiktor SZ, Sassan-Morokro M, Grant AD, et al. Efficacy of trimethoprim-sulfamethoxazole prophylaxis to decrease morbidity and mortality in HIV-1-infected patients with tuberculosis in Abidjan, Cote d'Ivoire: A randomised controlled trial. *Lancet* 1999; 353:1,469-1,475. ■

Orphan problem likely to escalate as AIDS spreads

Communities provide care to abandoned children

In Luwero, Uganda, guardians who have taken over the care of AIDS orphans have come up with some interesting ways to make ends meet. One person who supports five orphans, for instance, has begun to rear pigs. Another person plans to start a coffee trade enterprise. Yet another man, who has five children and two AIDS orphans, has a bull and a cow with which he hopes to build a business.

These small enterprises, which have received assistance from Association Francois-Xavier Bagnoud (AFXB), a Boston-based foundation dedicated to international humanitarian action, especially regarding HIV and children, typify much of the care that is going to children left orphaned by the AIDS epidemic. The children are being cared for in a variety of community, family, and governmental homes. And as the number of orphans escalates from the more than 11 million currently to an estimated 40 million within the next decade, these individual and small solutions will continue to multiply as well, although possibly not as quickly as the demand.

Resources lacking to support orphans

"The orphan problem is increasing exponentially," says **Sandra Anderson**, intercountry team care advisor for UNAIDS in Eastern and Southern Africa. She is based in Pretoria, South Africa.

"While there has been a good response from governmental organizations and religious communities, it's nothing in proportion to the magnitude of the problem," Anderson says.

Although the estimate of some 40 million African orphans in future years may seem dramatic, it's not at all unrealistic, notes **Jacob Gayle**, PhD, senior technical advisor and UNAIDS secretary in Washington, DC.

"It's time for the world to strategize on how to deal with the orphans, because these are the next generation of leaders," Gayle says. "These are the future work force and reproductive force, and so there needs to be regional, local, and global strategizing on how to deal with this issue."

Many of the African governments coping with increases in orphans do not have the resources

U.S., European Union join fight against HIV in Africa

Agreement also extends to malaria, TB

The United States and the European Union announced May 31, 2000, that they will respond to the most serious global infectious disease threats with a variety of initiatives, including the following:

- Seek increased government and private-sector resources to combat HIV / AIDS, tuberculosis, and malaria.
- Support an increase in World Bank and regional development bank resources for improving health care system development.
- Encourage poor countries with high debts to use funds under the Cologne Debt Relief Initiative to build health systems, combat AIDS, and fight other diseases.
- Develop new financial investment incentives and public-private partnerships to make drugs and vaccines more affordable and more available, and propose a tax incentive for companies that develop new vaccines for AIDS, malaria, and TB.
- Accelerate education campaigns and disease information in cooperation with African political leaders.
- Increase diplomatic engagement with national leaders to encourage attention to the battle against these diseases.
- Encourage the G-8 nations to address these issues as a top priority.

Specifically, President Clinton has proposed that the United States provide $50 million to the Global Alliance for Vaccines and Immunization to purchase existing state-of-the-art vaccines for developing nations, an increase in research spending, and a $1 billion tax credit for sales of vaccines for the three diseases. ■

for expanding orphanages and foster programs. Orphans therefore run a greater risk of malnutrition, HIV infection, stunted growth, and deprivation of basic education and health care.

Relying on communities, not orphanages

Orphanages won't be the ultimate solution because of a lack of funding and infrastructure. "I don't think people are really turning to orphanages as the solution, except perhaps in South Africa, which has more resources to begin with and there was already a history of homes for children run by the Salvation Army and other groups," Anderson says. "In most other communities, they look toward the community for solutions."

The result is a variety of new family types evolving. These include child-headed households, mothers running community-level orphanages, fostering programs that are called family hospitality, and other forms.

While Westerners might imagine massive international adoption efforts, as there were in Vietnam after the Vietnam War, Anderson says that is unlikely to happen and probably shouldn't be the solution.

"It's important to strengthen the local infrastructure to help families cope," she says. "It would be very sad if [international adoption efforts] happen." Also, some African nations make it very difficult to adopt children internationally, and it's often culturally unacceptable.

Rather, Anderson says, the solution will lie in Western nations sending money and resources to help African communities support their own orphans through community group homes or individual foster care.

Some of the international assistance that already has helped includes donations of food, blankets, assistance with school fees, and other efforts. One such group that has been providing this sort of help is the Family AIDS Caring Trust (FACT) of Mutare, Zimbabwe. AFXB is another organization that has worked on the local level to ease the orphan crisis.

"They really need to mobilize the churches in the communities and decentralize this process and get church members to look after people in their own congregations and in their own geographical areas," Anderson says. "So some organizations have created a whole program of volunteers through the churches, and I think that's the kind of creative response that's sustainable. It uses local resources, keeps children in their homes and their own culture, and has the possibility of helping children over a long period of time." ■