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# AIDS ALERT

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# CDC's 5-year prevention plan: Ambitious but feasible

*Plan calls for new SAFE action*

*(Editor's note: This is the second part of a two-part series on the CDC's launch of new prevention efforts tied to the 20th anniversary of the discovery of AIDS. The July issue of* AIDS Alert *reported the CDC's findings that HIV risk has increased among young black gay and bisexual men.)*

AIDS groups applaud the five-year prevention strategy plan developed by the Centers for Disease Control and Prevention in Atlanta, saying the plan's goals are ambitious and might even be achieved, provided domestic HIV funding continues to increase.

"The CDC goal is admirable, and I think it can be achieved," says **Scott Brawley**, MSW, policy and program analyst for AIDS Action of Washington, DC. "But you can't have prevention efforts as one of your goals and not fund it adequately."

Brawley refers to the Bush administration's flat funding of domestic HIV care and prevention services in the proposed FY 2002 budget. As of the end of June, Congress had taken no action to increase HIV funding in the proposed budget for next year.

The CDC's five-year prevention goals are as follows:

- **Increase voluntary counseling and testing from the current 70% of HIV-infected people to 95%.**
- **Increase the proportion of HIV-infected people who are receiving treatment and care from the current 50% to 80%.**
- **Decrease the number of people at risk for acquiring HIV infection by 50%.**

To achieve these goals, the CDC has targeted programs for those populations at greatest risk of

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## COMING IN FUTURE ISSUES

- **HIV ads annoy strait-laced communities:** As prevention work increasingly narrows its focus and becomes hip to its audience, what can be done about community protests?
- **Heterosexual HIV support:** Program targets HIV-positive heterosexuals with services from acupuncture to dating ads
- **HIV's battle plan in body:** Investigators detail how HIV causes cellular damage
- **Devastation in Eastern Europe:** HIV cases are increasing faster there than anywhere else
- **International AIDS conference:** Here's what is being said and done

becoming infected. These include minority men and women and young gay men, especially those of color.

"We really have dramatically expanded our efforts in working with communities at greatest risk, and we will provide $400 million to state prevention programs targeting high-risk individuals, among which gay men are among the highest-priority category," says **Helene D. Gayle**, MD, MPH, director of the CDC's National Center for HIV, STD, and TB Prevention. Gayle spoke at a special teleconference in June 2001 about the CDC's prevention plan.

"We owe it to the people who have been part of the HIV epidemic for the last 20 years to really invest ourselves and make the impact that we know we can and that we have to make to meet the epidemic in this country and further reduce the spread of HIV to all," Gayle adds.

The most important part of the CDC's prevention goals is to reduce new HIV infections, and the nation is well on its way to achieving that goal, says **Nancy Palmer**, PhD, director of education and prevention for AIDS Action Committee of Massachusetts in Boston.

"In terms of prevention, we're at a point where we're offering pretty intensive, enhanced prevention interventions which are reaching those at highest risk of acquiring or transmitting the virus," Palmer says.

Recent CDC reports about the rising rates of HIV infection and sexually transmitted disease (STD) infection among young gay and bisexual men, particularly those who are African-American or Hispanic, have served as a call to action that has jolted the public out of its complacency about the disease. These reports also underline the importance of targeting prevention and testing/counseling campaigns to those populations at greatest risk of infection.

"I think this is going to call for states to focus more on this population and look for ways to target resources to the [minority men who have sex with men] population," says **Leo Rennie**, associate director of prevention programs for the National Alliance of State and Territorial AIDS Directors in Washington, DC.

"We're hoping to work closely with the CDC at the national HIV prevention conference in August, and we're looking toward identifying gaps in behavioral research and developing effective interventions for men who have sex with men," Rennie adds.

One of the successful changes made by the

CDC and others focusing on prevention campaigns has been the increased emphasis on targeting HIV-positive people. The CDC plan calls for a new prevention program that does just this. The program, called Serostatus Approach to Fighting the HIV Epidemic (SAFE), will attempt to significantly increase voluntary testing to identify HIV-positive individuals and link these people with prevention services, treatment, and care.

The SAFE program has these goals:

• **Make anonymous and confidential HIV testing widely available in all public and private health care settings, including emergency rooms, STD clinics, and community health centers.**

• **Evaluate and adopt rapid testing technologies to be used in street outreach programs and other nontraditional sites.**

• **Work with national, state, and local partners to develop additional educational, testing, and partner referral programs.**

Some states and AIDS service organizations have followed the CDC's recent example and also have instituted prevention messages that target those who are already infected.

"For instance, in New England we had our first ever positive prevention conference this year," Palmer says. "That's an important shift, and it will enable us to realize the goals of the CDC plan."

While it seems logical to target HIV-positive people in prevention campaigns, this was considered less necessary a decade ago when the life expectancy of HIV-positive people was lower. Services directed toward HIV-positive people tended to focus on preparing for illness and death.

"People are living longer now, so they have a longer period of time in which to keep negotiating their sexual decisions and choices," Palmer explains.

Prevention messages that target at-risk populations also need a higher level of sophistication, because some cultural issues make traditional appeals ineffective, Brawley says.

For example, it won't work to simply send urban African-American women the message they should always have their partners use a condom, because in some African-American communities a woman may demonstrate her love and trust for a man by allowing him not to use a condom, he says.

"So you need to show women how to protect themselves and still express their love," he adds. "Using a condom for a man is a simple decision of you either use or you don't, but for a woman there are emotional aspects, such as if you ask a partner to use a condom do you risk being struck or being subject to physical abuse."

The CDC's other strategic goals will need some careful consideration in order to be achieved, Brawley says.

The goal to increase HIV testing and counseling to reach 95% of those who are infected is certainly possible, but it may not occur as long as youths under age 25, who account for about half of all new infections, fear parental notification, partner notification, or name-based reporting, he notes.

Also, there should be a greater emphasis on mobile vans to provide rapid HIV tests, he adds. Mobile vans are useful because a person can sit in the van for 20 minutes reviewing HIV educational material while waiting for test results.

Government bureaucracy also hinders counseling and testing services through complicated policies and funding mechanisms, Palmer says.

However, increasing HIV patient referrals to care and services is quite feasible once HIV testing becomes routine for at-risk populations, Palmer says.

"In the past 20 years, we've really been able to be strong in getting folks who are positive linked right into care and services," Palmer adds. "I think we can just continue that process, and that's something we can do real well." ■

# How some HIV clinics handle substance abuse

*Service integration is key element*

*(Editor's note: This article is the second part of a series on HIV and substance use. The first article in the series appeared in the July issue of* AIDS Alert.*)*

HIV providers routinely deal with substance use issues that sometimes affect patients' ability to adhere to antiretroviral therapy.

For this reason, some HIV clinics and AIDS service organizations in major cities have started their own substance use programs, ranging from inpatient care to day treatment and counseling. Here's a quick look at what is being offered:

• Whitman-Walker Clinic, Washington, DC.

This large HIV health care facility provides extensive substance use services for HIV patients, including an inpatient unit called the Lambda Center that provides psychiatric and addiction services for gay, lesbian, bisexual, and transgendered patients.

A step down in service intensity from the Lambda Center is a partial-hospitalization program that is much more intensive than typical day treatment, says **Anne Clements**, LICSW, director of mental health, addiction, and day treatment services for the Whitman-Walker Clinic.

"That service has patients in a hospital setting, but they don't spend the night," Clements explains.

The clinic also has a six-month residential treatment program for people who are diagnosed with HIV, substance abuse, and mental illness. Patients will stay in an eight-bed house within the community, Clements says.

"For the first 30 days, they are on restrictions and are getting more complete detoxification care," she adds.

Because these patients are mentally ill, they often are incapable of following the typical 12-step substance use program. So the residential treatment program has a cognitive-behavioral approach that challenges patients' faulty thought processes and teaches them alternatives to drinking or using drugs, Clements explains.

"Therapists use behavioral contracts with patients, and they can go back to the contract if the patient strays," Clements says.

Patients in the residential treatment program include people diagnosed with mood disorders, adjustment disorders, and depression.

The clinic also has a new program called Women's Healthy Connection. The program is funded through a grant that targets services toward African-American mothers who have HIV and an addiction.

"Women who have kids just naturally prioritize the needs of their children first, and when you've got an addiction and HIV, you can't do that and ignore yourself, or you can't expect to live very long," Clements says. "So this is a program that accommodates children."

The program helps women find respite child care, whether through Head Start, a day care center, or temporary child care provided by the program, which has four child care workers.

"A major component of the program is to heal the attachment between the mom and the kid," Clements says, adding that addiction often interferes with that attachment.

"We model healthy ways to interact with children," she says.

Mothers attend the program between 8 a.m. and 3 p.m. in two shifts over a nine-month period. The program is divided into three phases.

Another substance use program that was started by the clinic years ago as a special service for gays and lesbians is a three-month outpatient program that recently has received funding to include HIV-positive patients.

"It's just a step down from the intensive outpatient program or the residential program," Clements says. "It's for building a support network that will help you keep on your recovery, and it's very Alcoholics Anonymous-oriented." That program meets three nights a week.

## *Accepting the patient's substance use*

• **Lower Eastside Harm Reduction Center, New York City.**

The center provides services for people who are actively using substances. "We start with the assumption that someone is using, and we don't add stigma to that," says **Mark Gerse**, deputy executive director. "We talk about other issues, such as housing, how to manage HIV treatment, and legal problems."

The center provides a mental health assessment because of the high rate of depression among people who use substances.

Unlike detox and treatment centers, the center does not make it a goal to help a person stop all substance use. The harm reduction approach takes the philosophy that a counselor will accept the patient and the substance use and does not expect the patient to stay completely sober despite treatment for the substance use, Gerse explains.

"Nobody's perfect, and any improvement in the person's well-being or living situation is a success," he adds.

Gerse is a strong advocate of providing antiretrovirals to HIV patients who inject drugs or abuse alcohol, despite potential problems with adherence.

"We all use substances of one order or another, so they're really talking about people who demonstrate signs of poverty," Gerse says. "If someone goes to a doctor and has some resources, the doctor is going to assume that person can take care of

himself, and so the doctor will prescribe drugs."

• **Gay Men's Health Crisis, New York City.**

GMHC provides harm reduction services through trained counselors and has a substance abuse program that includes alternative health approaches, such as acupuncture, says **Sheila H. Mabry**, CSW, assistant director of HIV Prevention.

The AIDS service organization also may hold a harm reduction conference in the near future, Mabry says. Conference participants could share the work they're doing in helping HIV patients with substance use problems, providing a network of referrals and new ideas for treatment and counseling.

AIDS providers who have harm reduction or substance use programs need more information about how various substances may affect HIV treatment because the problem is growing, Mabry notes. "It's important to have that information and share with clients how something is going to be impacting them." ■

# HIV adherence strategies take a high-tech route

*Electronic gadget gives verbal messages*

An investigational HIV-adherence device has demonstrated that it can keep patients on track with their antiretroviral therapy more effectively than a monthly educational session, according to a recent study.

The pocket-sized electronic device, called the Disease Management Assistance System (DMAS), tells patients when to take various medications and what side effects to monitor.

"One of the main reasons patients say they do not take their medication is because they simply forget it," says **Adriana Andrade**, MD, MPH, senior clinical pharmacology fellow at Johns Hopkins University School of Medicine in Baltimore. Andrade was a chief investigator in a study involving the device. Results of the ongoing study were presented at the 8th Conference on Retroviruses and Opportunistic Infections, held Feb. 4-8, 2001, in Chicago.

The DMAS emits a beeping sound when patients are supposed to take their medication. The beeping prompts patients to press a "play" button on the DMAS. Then the device will play a verbal medication reminder. Once patients take their medication and press a "yes" button, the device will record the dosing time. The recorded data can be uploaded to generate an adherence report for clinicians to review, Andrade explains.

Johns Hopkins investigators studied the device, putting 50 patients randomly in one of two groups. The intervention group received the DMAS plus monthly antiretroviral education and counseling, and the control group only received the education and counseling. All participants were given eDEM Caps, a special medication cap with a microcomputer chip that noted the times and dates when patients opened the bottle to take medications, Andrade explains. The eDEM Caps were used to validate the data obtained from the DMAS. Subjects were followed for six months.

Patients' viral loads and spinal fluid were tested at baseline, prior to antiretroviral initiation, and at three months and six months after starting treatment. Memory testing was performed at baseline and at the end of the study to check the impact of HIV-mediated memory deficits on medication adherence.

The study examined patients who were starting highly active antiretroviral therapy for the first time or who had failed it once or twice in the past.

"We wanted a representation of naive and experienced patients to see whether this device would affect medication adherence the same way in the two groups," Andrade says.

The study's target is 86 subjects, and 52 were enrolled through June 2001. A preliminary data analysis of the first 19 patients who completed the study showed that the overall mean adherence score for the intervention group was 92%, as compared to 83% for the control group, Andrade says.

Data analysis also showed that memory-impaired subjects assigned to the DMAS group reached mean adherence scores of 90%, compared to 80% in the control arm.

"So it seems, as we suspected, that neurocognitive deficits do affect adherence to antiretroviral therapy," Andrade says. "Also, it seems the device does make a difference, even in a setting of mild or moderate neurocognitive impairment."

Patients' viral loads in both plasma and spinal fluid showed a 1.5 log decrease for patients who used the device, whereas there was only a 0.5 log

decrease among the control group, Andrade says. "This change was statistically significant.

"When we looked at the CD4 cell count, the DMAS users over six months had increased their count by a mean increase of 50 CD4 cells, and the control group had an increase of 10 CD4 cells," Andrade adds.

The study, which is ongoing, shows that the DMAS device holds promise for clinicians who are dealing with HIV patients who have memory deficits. The device also may improve adherence among other HIV patients who might be at higher risk of forgetting to take their medications. The device currently is available only through investigational trials.

"We are trying desperately to come up with novel ways to address the adherence issue and improve that," Andrade says. "Electronic devices might be another way to improve compliance to antiretroviral therapies." ■

# Study shows HAART reduced inpatient costs

*Women, minorities, poor still have high costs*

A nationwide study presents a clear picture of how highly active antiretroviral therapy (HAART) has reduced inpatient hospital costs for HIV patients. But the benefits of antiretroviral therapy are less pronounced among women, minorities, and poor people infected with HIV.[1]

"We see a pattern very clearly where people who don't have excellent access don't experience that shift in costs [from the hospital to medications]," says **Samuel A. Bozzette**, MD, PhD, senior scientist with RAND Health in Santa Monica, CA, and a professor of medicine at the University of California, San Diego. Bozzette also is the director of Health Services Research Unit at the Veterans Administration Hospital in San Diego.

"Traditionally underserved groups — women, poor, minorities — display the old pattern where hospital costs still remain the largest component of costs," Bozzette explains. "So the second point is that we know the drugs didn't diffuse through the population equally."

The HIV Cost and Services Utilization Study, sponsored by the federal Agency for Healthcare Research and Quality (AHRQ) of Rockville, MD, was conducted by a consortium led by RAND Health. The study, published this year in the *New England Journal of Medicine,* determined the mean expenditure per patient per month from 1996 to 1998. Its chief conclusion was that the total cost of care for HIV-infected adults has declined since the advent of HAART, even though the cost of medications has risen.

Another important finding of the research is that the care provided by more experienced clinicians was less expensive, Bozzette notes.

The study found that physicians who saw the most HIV / AIDS patients per month had a lower monthly cost of care, and this was unrelated to disease severity.

This study differs from earlier cost studies of HIV treatment in that it studies a nationwide population and thus is more representative.

"The study is a nationally selected random study, and these are the closest we have to unbiased estimates," Bozzette says.

"There have been a number of studies looking at costs in selected populations," he adds. "Some find declines in overall costs and some slight increases, but all find a decline in hospital use and increases in drug use."

## Cost ratios shift over the years

The year 1996 represented the period of change in HIV treatment from pre-protease inhibitors to post-protease inhibitors, says **Fred Hellinger**, PhD, a senior economist with AHRQ.

"What we found in the early 1990s to the late 1990s was a dramatic decrease in hospital costs and a subsequent increase in drug costs," Hellinger says. "Drug costs in the early 1990s were 10% of total costs, but now drugs are above 40% because the antiretroviral drug cocktail costs $10,000 to $15,000 per year."

Future cost studies will tell a very different story because people on HAART are living very long with the disease, Hellinger says.

"People are living longer with HIV disease, and rates of infection aren't changing," Hellinger explains. "That is going to have a dramatic impact on the total cost of the disease as we continue."

Early hopes that HAART would reduce HIV to a level where it couldn't replicate were dashed, so it appears that HIV patients will have to stay

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# Wealthy nations called on to boost support efforts

*Five-year plan estimated to cost $9.2 billion*

Using the 20-year mark in the history of AIDS as a catalyst, the United Nations and other international organizations have called on the world's wealthier nations to increase attention, support, and funding to HIV / AIDS prevention and treatment efforts. This call to action included a series of meetings with business and political leaders and culminated in the first United Nations General Assembly Special Session on HIV / AIDS (UNGASS), held in June.

"Only through a truly global alliance will AIDS be defeated," said United Nations Secretary-General **Kofi Annan** in remarks addressed to the United States Chamber of Commerce on June 1 at a meeting in Washington, DC.

"And in our shrinking world, all of us need to be involved in the solution because, one way or the other, sooner or later, all of us will be involved in the problem," Annan added.

Annan went on to ask the U.S. chamber for its support in the campaign against HIV / AIDS, explaining that American businesses need to start becoming involved in the campaign because the pandemic affects business through expanded costs and shrinking markets as 42% of U.S. exports go to markets in the developing world.

"AIDS is uniquely disruptive to economies, because it kills people in the prime of their lives," Annan noted. "More than four out of five people dying of AIDS are in their 20s, 30s, or 40s."

Annan's recent speeches and the Joint UN Programme on HIV / AIDS (UNAIDS) have followed a strategy of urging private-sector businesses to join in partnerships with governments in fighting the spread of HIV infection. UNAIDS estimates that AIDS prevention and care costs will need to rise by $7 billion to $10 billion a year in low- and middle-income countries. Current spending totals $1.8 billion, and projected costs through 2005 amount to $9.2 billion if enough money is spent to reverse the spread of the disease, according to UNAIDS estimates.

"We are in the middle of development, creation of a global fund, which will only be one of several mechanisms to make sure necessary money will be there," says **Peter Piot**, executive director of UNAIDS.

"There is no way that the epidemic can be stopped and that people can have access to treatment without additional resources," Piot adds. "If we do this right, this fund should be more efficient to provide the money to where it matters on the community level."

The appeal appeared to be working in late June as some companies announced donations to the U.N. Global AIDS and Health Fund.

The $9.2 billion figure includes the money that nations such as Brazil are themselves spending on providing antiretroviral drugs to their HIV-infected citizens, says **Bernhard Schwartlander** MD, chief epidemiologist for UNAIDS.

However, in the nations of sub-Saharan Africa, about 80% of the funding for antiretroviral treatment must be raised by the international community, and that means billions of dollars, Piot says.

"The $200 million from the United States is like a down payment, a start-up for this year for this fund," Piot says.

While Annan and UNAIDS have publicly applauded the United States' recent pledge to the international AIDS cause, not everyone is pleased with the $200 million commitment. The international medical aid organization Doctors Without Borders (Medecins Sans Frontieres) recently held a teleconference in which physician advisors and coordinators criticized the lack of support from wealthier nations.

For example, the U.S. pledge of $200 million is a fraction of what is needed and nowhere near the sort of contribution the United States typically

## The pandemic: By the numbers

The HIV pandemic's impact on Africa and other areas is dramatic by both human and economic standards, according to the latest UNAIDS numbers. Here's what has happened:

• The estimated annual per capita growth in the gross national product in half of the countries of sub-Saharan Africa is falling by 0.5%-1.2% as a direct result of AIDS. By 2010, per capita gross domestic product may have declined by 8%, and per capita consumption will have fallen even farther.

• The number of people living in poverty has increased by 5% in some countries, at least partially due to AIDS.

• Governments and private sector companies are losing skilled employees to the epidemic, and they are facing higher costs in training, insurance, benefits, absenteeism, and illness, as well as in health care costs, which are expected to increase 10-fold within a few years.

• In the hardest-hit countries, productivity growth may be cut by as much as 50%.

• Lower food production is being reported in some areas due to households having to switch to less labor-intensive and less nourishing crops and due to families having to sell land and other assets to cover the costs of AIDS care and funerals. ■

makes to international crises, says **Daniel Berman**, coordinator of the MSF Access to Essential Medicines Campaign.

The United States had an opportunity to lead the rest of the world in turning this global AIDS fund into the powerhouse it needs to be, and instead one of the richest nations in the world gave the fund a drop in the bucket, says **Paul Davis**, a member of the Health GAP Coalition and ACT UP Philadelphia.

Davis, who was among the protesters at UNGASS, says the United States' contribution should be closer to $2 billion than $200 million.

Secretary of State Colin Powell criticized contributions to the fund made by the European Union, saying the $582 million raised early on was little more than a good start.

However, Powell's criticism of his neighbors is ironic, because England, France, and Canada were only following the United States' lead, Davis says.

"When President Bush announced the $200 million contribution, he derailed momentum on the fund," Davis says. "He appeared to be a leader, but he set the rung so low that other contributors accepted this, and it decreased expected contributions from wealthy donors."

By the end of UNGASS, Powell had announced that the United States would provide more money to the global fund and said the $200 million was only seed money.

Berman also criticized some governments for causing delays in implementing antiretroviral treatment in developing nations.

"Let's be honest, the policy of the South African government is unacceptable," Berman says. "A lot more is possible, and if they are not willing to talk about that policy and to say that they can begin treating patients now on a national basis, at least starting pilots, then there's something wrong there."

Doctors Without Borders officials also addressed the need for lower costs and greater access to antiretroviral treatment in Africa and other places where very few people have access to the life-prolonging drugs. The organization launched a campaign to coincide with UNGASS in which the word "decimation" was printed inside the outline of a pill capsule with a trademark symbol representing a patented prescription drug. The image is printed on a black background on t-shirts, postcards, and posters. Above the image are printed the words: "8000 people died today from AIDS because treating them is not 'cost effective.'"

Despite poor health system infrastructures throughout much of the developing world, these countries should be able to offer antiretroviral treatment to many of the people infected with HIV, says **Anne-Valerie Kaninda**, MD, medical advisor to MSF's Access to Essential Medicines Campaign.

"Today in almost all of the capital and urban cities in sub-Saharan Africa, you could at least start some pilot programs and start treating people," Kaninda says. "I think that in South Africa, for instance, at least 52% of the people infected with the virus live in urban areas, and that means they can have access to clinics and medical centers."

Also, so long as antiretroviral treatment is unaffordable or simply not offered to the vast majority of sub-Saharan Africans, then they have no incentive to be tested for the virus, and this in turn hampers prevention efforts, says **Chris Ouma**, MD, of Action Aid Kenya. Ouma treats AIDS patients in the slums of Nairobi and is an outspoken critic of international trade agreements that have kept antiretrovirals out of the reach of many people in Kenya and other developing countries.

HIV prevention remains the most effective strategy in fighting the epidemic, but it won't work well without treatment, and what has happened in Africa is an example of this fact, Ouma adds. "The number of people coming in for testing is quite low because nothing will come of knowing their status."

Kaninda and Ouma also point out that there is no reason why the short-course regimens to prevent mother-to-child transmission of HIV cannot be offered routinely in all developing nations. In 2000, when some pharmaceutical companies announced they would offer these short-course drugs at little or no cost to some of the poorest nations, there still were more than 540,000 infants who acquired HIV from their mothers.

### *Prevention efforts face 'an obstacle of fear'*

In Eastern Europe, which in terms of medical infrastructure more closely resembles the developing world than Western Europe, there is a lesson to be learned about the limits of HIV prevention messages, notes **Konstantin Lezhentsev**, MD, who works with MSF's HIV treatment program for mothers and children in Ukraine.

"There have been huge prevention activities, and during the past 10 years the main prevention message of changing behavior has been met with an obstacle of fear," Lezhentsev says.

Since Eastern Europeans who are infected have very little or no access to antiretrovirals, they equate HIV infection with death and therefore are afraid of being tested or even of facing the possibility that they could become infected through their own actions, he adds.

"By providing HIV treatment, you reduce the fear of the death penalty," Lezhentsev says. "And that's the main goal and how the prevention message could be effective."

Besides the problem of limited access to antiretroviral drugs, sub-Saharan African and Eastern European nations also have problems with obtaining prophylaxis medications and other drugs to prevent or treat opportunistic infections, the MSF physicians say.

These drugs have generic versions, but there is so little competition in selling these to the developing world that the prices remain too high, Lezhentsev says.

In Kenya and East Africa, there is adequate access to drugs for respiratory tract infections, but there is a limited supply of medications for the more serious infections, Ouma notes.

Also, even if prophylaxis drugs were readily available, they would not be used by enough HIV-infected people because so many of those who are infected do not know they are at risk since they haven't been tested, Ouma adds. ■

## Christian group attacks UN health fund push

*Calls new fund unrealistic*

The new Global Health Fund proposed by the United Nations and G8 nations is beginning to attract substantial pledges, apparently responding to calls made by Kofi Annan, UN secretary-general, and other UN agencies for financial support. The Bill and Melinda Gates Foundation has announced a $100 million commitment to the Global AIDS and Health Fund, which it said should be used "for innovative HIV / AIDS prevention efforts."

But UK-based Christian Aid has attacked the proposed fund, maintaining that the AIDS pandemic in Africa and Southeast Asia cannot be tackled by drugs alone. It says the problems of poverty and poor health care systems need to be improved before the spread of the disease can be tackled successfully. The charity is one of the first to openly oppose the fund.

"Christian Aid believes the international community needs to direct its energy toward massive increases in aid through existing channels," said **Mark Curtis**, head of policy at the charity. "It also needs to focus on reforming those existing channels rather than being distracted by discussions of a new fund."

He also warned that the fund risks becoming a subsidy for the pharmaceutical companies, with little benefit to AIDS sufferers.

The UN's Annan has said the proposed fund needs $7 billion to $10 billion initially. The pledges trickling in so far are quite small — the United States has promised just $200 million, and Britain is proposing to offer $100 million over three years, in addition to the Gates Foundation's $100 million pledge — so it seems unlikely that more than $1 billion will be raised this year.

AIDS treatment with antiretroviral drugs, even at the special reduced prices now being offered by suppliers, will cost up to $1,100 per patient per year. Almost 3 million sub-Saharan Africans died of AIDS last year. Some European and American government officials are irritated with Annan for raising unrealistic expectations. ■

# CDC report provides hard statistics on AIDS' toll

*Latest news is grim*

As the leading cause of death in Africa and the fourth-leading cause of death worldwide, the HIV / AIDS pandemic poses one of the greatest challenges to global public health, according to a special report published in the Atlanta-based Centers for Disease Control and Prevention's June 1, 2001, issue of *Morbidity and Mortality Weekly Report*.

The report notes that AIDS also has caused tuberculosis rates to escalate over the past decade in sub-Saharan Africa and South-East Africa, in some places increasing fourfold and reaching peaks of more than 400 cases per 100,000 population.[1]

More than 36 million people are infected worldwide, 20 million have died of AIDS, and between seven and eight people become newly infected with HIV each minute in Africa.

Here is a summary of the CDC's report on the state of the pandemic worldwide:

• **Sub-Saharan Africa:** An estimated 25.3 million people were infected with HIV in this region of the world in 2000, and the average prevalence of HIV infection among people ages 15-49 was greater than one in 11 people.[1]

In Eastern Africa, about one in five people are infected; in Botswana, which has the highest HIV prevalence, 36% of the adult population is infected.[1]

Prevention strategies have succeeded in slowing transmission in several countries, including Uganda, where the overall adult HIV prevalence declined from 14% to 8% from 1990 to 2000.[1]

Senegal, in West Africa, has held steady with a 2% prevalence due to prevention efforts aimed at regulating commercial sex, condom promotion, community mobilization, and treatment of sexually transmitted diseases (STDs).[1]

• **Asia:** High-risk populations continue to spread the disease at rapid rates. For example, Chinese injection drug users have an HIV rate of 82%. Another alarming factor is that there has been an increase in reported STDs among Asian men and women between 1989 and 1998.1

The estimated HIV prevalence in India for the 15-49 age group is 0.7%, which, while low, still means that more than three million people are infected.[1]

Thailand, where there is a 100% condom use campaign for commercial sex, has had a decline in STD and HIV prevalence in military recruits and women attending prenatal clinics.[1]

• **Eastern Europe and Central Asia:** Injection drug use has fueled a recent growth spurt in HIV infection rates as reflected in the rise of reported HIV cases in the Russian Federation from 10,000 in Jan. 1999 to 70,000 in Dec. 2000. In Ukraine, newly reported infections increased from 47 cases per year in the early 1990s to about 15,000 cases reported in 1997.[1]

• **United States and Western Europe:** Deaths have dropped substantially since the mid-1990s when multidrug antiretroviral therapies were introduced, but STD rates have risen in recent years and CDC officials are concerned that there might be a similar increase in HIV infection rates.[1]

• **Latin America and the Caribbean:** The adult prevalence rate is 2.1% in the Caribbean, and it's about 1% in Barbados, Belize, Dominican Republic, Guyana, Haiti, and Suriname. Brazil leads the region in providing treatment to HIV / AIDS patients, with free and universal access to antiretroviral therapies. As a result, Brazil has reported a decline in HIV-related deaths from 25 per 100,000 in 1995 to 15 per 100,000 in 1999.[1]

## Reference

1. The Global HIV and AIDS Epidemic, 2001. *MMWR* 2001; 50:434-439. ■

(Continued from page 98)

on antiretroviral drugs indefinitely, which will increase costs, Hellinger adds.

The cost study points to the need for clinicians to make certain that all HIV patients receive necessary treatment, and they should be especially attentive to people who traditionally have less access to health care services.

"It seems the major issue is not what happens to people once they get into a clinic," Bozzette says. "The major issue is getting people to see experienced and knowledgeable AIDS providers so patients don't present for care when they are sick enough to be hospitalized."

### Reference

1. Bozzette SA, Joyce G, McCaffrey DF, et al. Expenditures for the care of HIV-infected patients in the era of highly active antiretroviral therapy. *N Engl J Med* 2001; 344:817-823. ■

# Experts discuss findings on drug resistance

*Resistance testing linked with better outcomes*

*[Editor's note:* AIDS Alert *asked* ***John Mellors****, MD, professor of medicine and chief of infectious diseases at the University of Pittsburgh, and* ***Sharon Kemp****, director of HIV Research for Virco UK in Cambridge, United Kingdom, to discuss a study presented in June at the 5th International Workshop on HIV Resistance and Treatment Strategies in Scottsdale, AZ. The study found that a change at position 318 in the genetic code of HIV can make the virus highly resistant to treatment with non-nucleoside reverse transcriptase inhibitors (NNRTIs).[1] Mellors also is on the organizing committee of the annual International Workshop on HIV Drug Resistance. Mellors' and Kemp's discussion of the study is presented here in a question-and-answer format.]*

***AIDS Alert:*** Please explain the significance of the recent findings that a change in position 318 in the genetic code of HIV can make the virus highly resistant to treatment with NNRTIs. For example, how prevalent might this mutation be?

**Kemp:** Although this mutation is relatively uncommon, our analyses suggest that it is more than seven times more common than the "signature" delavirdine mutation 236L. Furthermore, it occurs at a similar frequency as some of the other well-established mutations known to cause NNRTI resistance. This mutation can render HIV-1 highly resistant to delavirdine on its own and can combine with other mutations to make the virus highly resistant to efavirenz. Its effect on nevirapine resistance is not clear, although it does not appear to confer nevirapine resistance by itself.

***AIDS Alert:*** How is the Tibotec-Virco drug resistance test able to detect this mutation when other resistance tests do not?

**Kemp:** The Virco resistance tests are designed to capture and analyze a longer and more complete portion of the HIV genetic code than other tests, covering the whole of the protease gene and reverse transcriptase out to position [codon] 400. Most other assays stop between positions 200 and 300, and some miss out certain sections. The reason they stop here is that technically this is easier, and other providers do not necessarily appreciate the significance of capturing sequence information beyond codon 300.

***AIDS Alert:*** As increasing numbers of studies are being published about HIV mutations and drug resistance, what do we now know about the disease that we didn't know several years ago?

**Mellors:** In general terms, we know that HIV drug resistance is increasingly common and is being transmitted in more and more cases. Recent studies suggest 15% to 20% of new infections in the United States and Europe may involve transmission of resistance virus. Even if the viral load is very low or even below the limit of detection, viral replication may continue at a low rate and resistance can develop.

The genetic basis of resistance is extremely complex. There are approximately 250 different mutations involved. These combine in complex ways. For example, neural network analyses suggest that 28 mutations may be involved in lopinavir resistance and at least 26 to d4T. A mutation at 184 causes resistance to 3TC but counteracts the effect of AZT mutations. A mutation at codon 333, which also can only be detected if RT is sequenced to this codon, counteracts the effect of the 184V mutation and can enable the development of resistance to both 3TC and AZT.

Because of these facts, genotypic resistance testing requires sophisticated analysis, and the

## Recommendations for Resistance Testing from the IAS and EuroGuidelines

| Clinical Characteristics | IAS Recommendations | EuroGuidelines Recommendations |
|---|---|---|
| Treatment-Naive Patients Primary Infection | Consider testing | Recommend testing |
| Established HIV Infection | Consider testing | Consider testing |
| Treatment Failure | Recommend testing | Recommend testing |
| Pregnancy | Recommend testing | Recommend testing |
| Postexposure Prophylaxis | Clinical characteristic not included in recommendations | Recommend testing |
| Pediatrics | Clinical characteristic not included in recommendations | Recommend testing in children born to mothers with detectable viremia while on treatment |

*Source:* International AIDS Society, San Francisco; the EuroGuidelines Group.

rules-based interpretation methods can differ significantly in their analysis of the same genetic sequences.

Data have accumulated demonstrating the clinical utility of resistance testing in managing antiretroviral therapy in HIV-infected patients. Treatment decisions made using the results of resistance testing yield virologic responses superior to those obtained when decisions are made without the benefit of resistance testing.

***AIDS Alert:*** At which points in HIV treatment should a clinician recommend resistance testing, and how can this additional cost be justified?

**Mellors:** This is a matter for the clinician and patient to decide. It is generally accepted that resistance testing should be considered whenever treatment is started or changed. ***(Editor's note: For a table summarizing the recent joint recommendations of the International AIDS Society panel of HIV drug resistance testing and the EuroGuidelines Group, see chart, above.)***

***AIDS Alert:*** How can investigators continue to improve and update resistance tests to keep up with the virus's evolution?

**Mellors:** Firstly by studying the resistance profiles of new drugs as an early part of the drug development process; secondly by applying sophisticated techniques such as neural networks, an AI technique, and recursive partitioning to unravel the genetic causation of drug resistance, thereby adding to our understanding of the relationships between complex genotypes and phenotype. Such understanding will help to improve a critical part of a genotypic resistance test, i.e., its interpretation.

***AIDS Alert:*** What is being done to convince state AIDS Drug Assistance Programs [ADAPs] and other payers to add drug resistance testing to their formularies, and how commonly is this test being reimbursed by state ADAPs, Medicaid, and other payers?

**Kemp:** Virco Lab, our U.S. subsidiary, is actively working to achieve an adequate level of reimbursement and utilization guidelines for resistance testing by state Medicaid programs and state and local Ryan White programs.

This effort is under the direction of the Virco Professional Affairs Group, which brings together the assistance of national and local medical HIV opinion leaders and advocacy groups. The effort concentrates on providing the latest developments in resistance testing technology, clinical application, and medical economic outcome information.

Over the past 18 months or so, American Medical Association CPT codes have been issued for genotype, phenotype, and virtual phenotype. Reimbursement and the necessary procedures for reimbursement have been established and are in place or are in the process of approval in the majority of states for genotype, phenotype, and virtual phenotype. This progress is due, at least in part, to the efforts of the Virco Lab Professional Affairs Group.

### Reference

1. Kemp SD, Salim M, Stammers DK, et al. A mutation in HIV-1 RT at codon 318 (Y--F) confers high level NNRTI resistance in clinical samples. Abstract presented at the 5th International Workshop on HIV Resistance and Treatment Strategies. Scottsdale, AZ; June 6, 2001. ■

# 'Co-active coaching' could help HIV patients

*New type of counseling involves goal-setting*

A counseling technique that takes an action-oriented approach to helping people make major life changes, much used by business executives and other professionals in recent years, now appears to offer some value to HIV patients. Co-active coaching could be a solution to mild depression and inertia for some HIV-infected patients who have difficulty making decisions about how to spend a lifetime living with the disease.

"I think it has tremendous potential for people with HIV," says **Miriam Garfinkel**, MA, LMFT, a psychotherapist who provides organizational consultation and training in independent practice in San Francisco.

"Business coaching and executive coaching have gotten trendy, but co-active coaching is more about looking at one's values in life, one's sense of balance, and addressing all aspects of life," Garfinkel says. "It's really very holistic in that it looks at what makes any of us happy in our lives as a whole."

Garfinkel has worked with HIV-infected people for many years, but has more recently integrated co-active coaching theory into her sessions. The change occurred as a result of the advent of protease inhibitors and antiretroviral combinations that have made HIV infection more of a chronic disease. Suddenly, people with HIV have had to consider the possibility of living years longer than they thought they would, and their decisions about how to spend their time naturally have begun to change, she says.

The stakes grew even higher when these same people found they could no longer take their antiretroviral regimens for granted as the virus became resistant to drugs, again making a long-term prognosis uncertain, Garfinkel adds.

While some HIV patients find traditional psychotherapy helpful, others want a more action-oriented approach. "They're stuck and don't know what else to do with their lives," Garfinkel explains. "So they want an approach that helps them clarify their values, look at their lives to see where it's balanced and unbalanced, and have someone look with them, like a personal trainer for your life."

Co-active coaching is not so much a type of therapy as it is a professional relationship in which one person (the coach) assists another person in making major life decisions and setting and meeting goals that would lead to desired changes.

"The coach functions by asking powerful and illuminating questions to excite curiosity in the client and to encourage the client to identify and do what would bring the most fulfillment and success, however the client defines that," explains **Eileen Blumenthal**, JD, EdM, principal of Rocket Science Coaching and Consulting in San Francisco. Blumenthal provides co-active coaching services to HIV-infected people and others.

"I've worked with a lot of people who have HIV, and there are several very valuable and rich possibilities with treatment involving communication, setting limits, re-defining their lives, purpose, and passion," Blumenthal says. "It's a very powerful relationship."

Blumenthal gives the example of a client of hers, an HIV-positive man with a high-powered job who was very successful in his career at the time he began to experience symptoms of AIDS. The man became very ill and at one point was given only six months to live. However, thanks to new medications, he recovered and regained his energy and health.

"So his death sentence became a life sentence," Blumenthal says. "His doctor advised him that his prognosis was very favorable, and the man realized he had his future back, but he didn't have a clue about what to do."

With Blumenthal's coaching help, the man learned how to be optimistic about the future. Some of the questions he answered with her guidance included:

- What are your personal values?
- What will bring you satisfaction and fulfillment?
- What are you committed to?
- What would really make life worth living given a second chance?
- What do you want your future to be like?

While the man could have answered these questions on his own or with the support of family or friends, Blumenthal as his coach added an additional layer to the relationship: She held him accountable for his actions.

"I asked him probing questions and challenged him, and then I championed him and held his feet to the fire," Blumenthal explains. "I counted on him to do what he said he would do."

The coaching sessions were action-oriented and did not focus on therapeutic issues. After six months of co-active coaching, the man applied for and was offered a job in a new field.

"It was very different from the work he had done before, but it made his heart sing," Blumenthal says. "And, he had a perspective on work that he hadn't had before."

The man now understood that if one's life could be thought of as a pie, then work is only one slice. Other pieces include such aspects of life as spirituality, community, fitness and recreation, and personal relationships.

"I think he was very pleased with the results of the coaching in terms of securing that job and because he was happy with this regained sense of hopefulness and control," Blumenthal says.

Co-active coaches do not necessarily have to have degrees in social work, psychology, or psychotherapy. While nurses and people with therapy training could easily provide co-active coaching, other professionals with training in the technique could do so as well, Garfinkel says.

"It's not standardized or regulated at this point," Garfinkel says. "The coach could be anyone who will listen to clients and understand the idea of working with the client's agenda as opposed to their own."

Coaching is essentially client-centered counseling that uses visualization and other tools to help clients clarify their values and establish goals.

Garfinkel notes that co-active coaching may not be the answer for clients who have other mental health issues, such as clinical depression, because the goal-setting and achieving process could be yet another way for the client to fail and feel worse about him- or herself.

Typically, coaches will initially meet in person with clients and then continue to monitor clients' progress toward goals through telephone calls, e-mail messages, and/or face-to-face meetings.

Since the meetings are not for therapeutic purposes, they could take place in many different settings, and Blumenthal has sometimes met with clients in cafes or even on the beach.

"My preference is to meet in person, at the most for four times a month and about one-half hour at a time," Blumenthal says. "I co-design the sessions with the client." Clients may take notes during the sessions and write down ideas and assignments.

One of the first tasks is for the coach to help the client clarify his or her values in life, such as whether the client places value on community involvement or personal relationship, work or family, etc. The coach will help the client rank various aspects of life according to their importance, including such items as intimacy, autonomy, free time, and living environment.

"We help them look at how they live their lives according to those values, so now they can have a sense of whether they are living according to what they think is important," Garfinkel says.

Coaches assist clients in visualizing themselves in 20 years' time, according to how they might look, where they would live, what their sensibility is, and what they'll be doing with their time. Clients might be asked to imagine what kind of advice the person they are 20 years in the future would give to the person they are today.

## *Coaching focuses on goals*

Co-active coaching is very outcome and future-oriented and less focused on history, Blumenthal notes. Coaches spend a great deal of time helping clients develop concrete and meaningful goals. These goals might involve a career change, a desire to enter into a more intimate relationship with a loved one, a move to a new city, success in sticking to an antiretroviral drug regimen, involvement with a church or community group, or success with a physical, artistic, spiritual, or personal task.

One of Garfinkel's clients was a 40-something lawyer who had avoided HIV infection during its epidemic early years and then became infected much later.

"He hadn't thought it would happen to him," Garfinkel says. "As much as he had lived through years of many people dying and getting ill, he had a lot of reactions about his own infection that he didn't think he would have."

As his coach, Garfinkel validated his reactions, helped him deal with his grief about his future, and then worked with him to re-evaluate his life and goals.

The man suddenly was uncertain about continuing to be a lawyer, so they spent a lot of time talking about his goals and values and what made him happiest in his life. Because the man had some emotional issues regarding his HIV status, he felt it was important to connect with other HIV-positive people, so they set up a goal of having him join a support group.

Although the client first procrastinated about making the calls, Garfinkel gently nudged him toward his stated goal, and eventually he enrolled

in a support program for people who are newly diagnosed.

"It was really great, and he came back talking about all of the helpful questions they asked him, and then he ended up going to support groups," Garfinkel recalls. "He ended up realizing this was the first thing he needed to do, and he didn't really need to change his career right now or move or anything like that."

Probably the single most important thing a coach does is to encourage, remind, push, and even goad a client to take the steps necessary to achieve a desired outcome. This element of co-active coaching differs from traditional therapy.

For example, one of Blumenthal's clients is a business professional who wants to become a professional photographer. One of his assignments is to take at least five photographs a week that he will e-mail to Blumenthal on a deadline.

"It happens consistently that the e-mail arrives 30 minutes before our session, and it's clear to me that a large part of his motivation in taking those pictures is to keep his word," Blumenthal says. "As he's trying to develop some discipline and habit, he's accountable to me."

Occasionally, as a client is pursuing a particular goal, the client may have an insight about some other goal that he or she would rather achieve, so the client and coach can adjust the goals accordingly, Blumenthal adds.

"Pursuit of the goal often is as illuminating and satisfying as making the goal, and sometimes clients fail because coaching is not any guarantee or insurance that they will succeed," she says.

In addition to providing clients with accountability, coaches help them keep a bigger picture in mind. For example, an HIV-infected woman may decide that one goal is to take medications on time each day, but her vision for this goal may encompass improving her health and achieving the best viral suppression she can.

"You say you'll take these pills, and you do, but why are you doing this, and how does this fit in with the bigger picture of maintaining your health and vitality?" Blumenthal explains.

Co-active coaching could be another service offered by an AIDS service organization or a health clinic that treats HIV patients, Garfinkel says.

An ideal situation would be to establish a co-active coaching clinic within a broader mental health program of a multiservice clinic, she explains. This way, clients would have the option

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of co-active coaching in addition to all of the health care services they might need.

"People living with HIV are very complicated, so what presents as a coaching issue could be more of a mental health issue, and this would need to be addressed," Garfinkel says. "I'd like to see co-active coaching as an option for care for people with the potential for referral as appropriate."

*[Editor's note: For more information about various forms of coaching-type counseling, there are two organizations that hold conferences, provide training, and have web sites:*

***Coach U.** Contact information: Sandy Vilas, president, P.O. Box 25117, Colorado Springs, CO 80936-5117. Telephone: (800) 482-6224 or (941) 387-8440. Fax: (800) 329-5655. Web site: www.coachu.com.*

***The International Coach Federation.** Contact information: 1444 I St. NW, Suite 700, Washington, DC 20005. Telephone: (888) 423-3131 or (202) 712-9039. Fax: (202) 216-9646. Web site: www.coachfederation.com. The federation will hold its 6th Annual International Coach Federation Conference Aug. 15-18 in Chicago.]* ■

# Company says it has new diagnostic test

A manufacturer of medical diagnostic test kits says it has completed the development of a new diagnostic test kit to identify individuals who have an antibody that appears to neutralize the HIV virus and prevents HIV infection from progressing into full-blown AIDS.

The company, Hemagen Diagnostics of Columbia, MD, says the test will detect the antibody to an epitope, called R7V, the marker believed to distinguish progressors from non-progressors.

The test is being developed in conjunction with URRMA Biopharma, a Canadian-based biotech company. URRMA has obtained an exclusive global license for the use of a specific antibody (anti-R7V) in a diagnostic test and for the eventual use of the antibody as a therapeutic and preventative treatment for AIDS. Hemagen has an agreement with URRMA to produce this diagnostic kit exclusively for URRMA. ■



# 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. ■