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IN THIS ISSUE

In This Issue **continued on next page**

ADAP programs fight for survival with less money and more clients

North Carolina's list tops 700 by midyear

To hear AIDS advocates tell it, ever since the late 1990s when the first antiretroviral cocktails were prescribed, there never has been enough money for the AIDS Drug Assistance Program (ADAP) to provide drugs to all of the HIV-infected and uninsured people who need them.

It might have been easy for legislators and the public to think the annual plea for more funds was a case of the little boy crying wolf.

But this year is different, they say. The wolf's finally at the door: In 2004, the waiting lists for ADAP assistance are the longest since the program began, and there is very little hope that the situation will improve before the next fiscal year begins.

Three years of economic trouble, combined with state budget crises and increasing numbers of uninsured and poor people living with HIV/AIDS have resulted in the worst-case scenario that ADAP activists have been warning about for years.

"Eight weeks into the program year, and we already had over 1,500 people on waiting lists — it's the worst year ever," says **Bill Arnold**, director of the ADAP Working Group in Washington, DC.

"It seems to be clear that it's off to a bad start

(Continued on page 87)

In This Issue **continued from cover page**

AIDS Alert International

COMING IN FUTURE ISSUES

- **Long-term HIV survivors:** Experts discuss how those with chronic HIV infection will fare in coming decades
- **Acute HIV infection research:** The technology makes it possible to identify people within days of infection, but what can be done with the information?
- **Highlights from the 2004 international AIDS conference:** Here's a look at latest research, findings
- **The prevention for positives initiative:** Where is the money going, what programs are available, and when might results be seen?
- **Latest treatment success stories:** Here's an update on antiretrovirals and other therapies in the pipeline

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with every indication that it's going to get worse," he says.

Combine the poorly funded ADAP situation with flat-funding and decreases in HIV prevention money, and the result likely will be an uptick in the epidemic and increases in AIDS deaths, Arnold predicts.

"There are some indications the AIDS death rates already are increasing," he says. "HIV infection will continue to spread instead of being cut in half as the [Centers for Disease Control and Prevention (CDC)'s] stated objective, and we'll start to undo what we've accomplished over the last 20 years."

Funds decrease as waiting lists grow

The Bush administration has proposed a $35 million increase in ADAP funding at a time when it would take $121 million in an emergency supplement to prevent the ADAP waiting list from escalating to more than 3,000 people, Arnold explains.

"The White House is trying to do the same thing as last year when we needed about the same amount of money and we ended up with a modest increase of $20 million to $30 million," Arnold says. "So the $175 million we didn't get last year is showing up on some waiting lists, or it has evaporated because this or that state took drugs off a formulary or reduced the eligibility requirements."

While ADAP waiting lists clearly illustrate the HIV drug-funding crisis, there are many hidden signs, as well, he notes.

"From a political point of view, if a governor's state doesn't have a waiting list, there will be institutional resistance to establishing one," Arnold explains. "So you have extended application review processes instead of waiting lists."

States have reduced their drug formularies, established annual expenditure caps, increased cost-sharing, reduced or failed to increase eligibility, and otherwise found ways to reduce their ADAP roles, Arnold says.

The ADAP crisis looms ominously over the South, which accounts for about 80% of the nation's ADAP waiting list.

In North Carolina, the waiting list grew to about 800 people by midyear, and there is faint hope of this situation improving, ADAP officials say.

What has happened in North Carolina is similar to what has happened in Alabama and other rural Southern states, says **Patrick Lee**, JD, project director for Piedmont HIV Integration Community Access System of the Piedmont HIV Health Care Consortium in Durham.

"The ADAP funds aren't following the epidemic on a national level," he says. "The South, as a whole, is receiving far less funding for HIV care." **(See story on Southern ADAPs, p. 89.)**

North Carolina's ADAP funding has been about $8.3 million to $10 million, while the federal contribution is $14 million to $16 million, Lee adds.

While North Carolina's governor had proposed a $4.2 million increase in state ADAP spending, by mid-June, the legislature appeared to be leaning toward a far smaller increase, says **Steve Sherman**, AIDS policy and ADAP coordinator for the North Carolina Department of Health and Human services in Raleigh.

"Without new dollars, we'll have a waiting list for an awfully long time," he says.

Inadequate ADAP funding is only one piece of the public health care pie, and federal and state cuts to domestic spending will impact HIV-infected patients in other ways as well, Arnold points out.

More people will not receive treatment

Cuts in funds for prevention programs, public hospitals and clinics, Medicaid, and other areas all will contribute to a situation in which increasing numbers of HIV-infected people will not receive adequate health care and treatment, Arnold and other AIDS advocates say.

Even Medicare spending, the one area of public health spending that has received a big boost, likely will make things worse for many low-income AIDS patients, says **Bill Vaughan**, director of government affairs for Families USA in Washington, DC.

Due to the new Medicare drug bill, all people who are eligible for both Medicaid and Medicare, including many HIV/AIDS patients who are disabled, will have to receive their antiretroviral drugs through HMOs or free-standing plans, he says.

"They will actually be a little worse off," notes Vaughan. For example, people who are dually eligible for Medicaid and Medicare will be subject to all of the new Medicare drug bill's restrictions at an income of 150% of the federal poverty level, he explains.

For a single person who makes $13,965 a year before taxes, this means he or she will have to

pay a full premium for the drug coverage, including a $250 deductible plus $3,600 in out-of-pocket costs before receiving catastrophic protection, Vaughan says. "What is serious about this is the gaming where some of these for-profit companies can make more money by avoiding very sick people," he adds.

"They can look like they're covering stuff, but by leaving part of the antiretroviral cocktail off, they can discourage really sick people from joining their plan," Vaughan points out.

So in the cases where an HIV-infected person has signed up for such a plan and goes ahead to pay out-of-pocket for drugs that are not on the formulary, then those out-of-pocket expenses do not even count toward the $3,600 deductible, he says.

On top of that, there is the threat that Congress could cap entitlement spending and ax domestic programs as a reaction to the huge deficit that has popped up in the past three years, Vaughan explains.

"There goes Medicare, Medicaid, and ADAP. What we've read and see coming down the pike is unconscionable — you either laugh or you cry," he notes.

A picture of funding from three states

Several state ADAP directors and AIDS advocates offer this picture of how ADAP funding has fared so far this year:

- **Kentucky.**

The state's waiting list, which began in early 2000, topped 120 by midyear.

For eight years, the state has received only $90,000 for ADAP from the state, and the federal funds amount to $4.5 million, says **Lisa Daniel**, MPA, HIV/AIDS branch manager for the Kentucky Department for Public Health in Frankfort.

The state's ADAP eligibility extends to people who earn up to 300% of the federal poverty level, and about 700 clients are on the ADAP caseload, she says.

Each month, the program receives about 20 applications and about five people drop off the ADAP roles, Daniel says.

To make certain ADAP money is spent efficiently, the state verifies that drug prescriptions are filled and will require clients to explain what has happened when they haven't filled their prescriptions in a few months, she notes.

Also, ADAP will pay copays for HIV-infected people who have health insurance through a Ryan White Title II base program, and ADAP will pay health insurance premiums for people who have access to insurance but cannot afford the premiums, Daniel says.

"But as expenditures for drugs increase and our average dollar per client increases, that leaves fewer financial resources for other folks," she continues

- **Idaho.**

Idaho's waiting list of 13 by midyear was about 10% of its 112 active clients.

"We have had quite an influx of eligible applicants applying for ADAP, and it has exceeded what we can afford with our budget, and so we've had to go to a waiting list," says **Linda Tomlinson**, ADAP specialist with the Idaho STD/AIDS program at the Department of Health and Welfare in Boise.

The state also has a restricted formulary compared with many other states, and ADAP eligibility is at 200% of the poverty level, she says.

The waiting list is at its highest level and will only grow since there will be no increase in funding until April, 2005, Tomlinson adds.

- **Colorado.**

More than 300 people were on the state's ADAP waiting list by midyear.

The list has grown steadily since the state capped enrollment in ADAP, May 1, 2003, says **Scott Barnette**, program manager for the Ryan White Title II Program of the Colorado Department of Health in Denver.

The state also took opportunistic infection medications off the formulary list, but has not made a change to its eligibility requirement of 300% of federal poverty level.

"We need some additional funding to get people off the waiting list, and it has to be funding that shows we can sustain them on the program," Barnette says.

About 700 clients are served with $1.3 million in state funding and $4.5 million in federal funding, he notes.

"We're in contact with people on the waiting list, and to the best of our knowledge, they're all receiving medications through some mechanism: patient-assistance care, AIDS service organizations," Barnette adds.

Although there are no expectations for additional state or federal ADAP money, the ADAP office is working on an alternative plan that would find a creative way to accept private or corporate funding to supplement ADAP, he says.

"I've had some inquiries from corporations that have some interest in this," Barnette explains. "It is rather difficult due to the fact that it's hard for a state government to accept money from outside sources beyond the government entities, and we're trying to figure out a mechanism to do that." ■

Southern states receive insufficient ADAP money

North Carolina, Alabama face crises

While the HIV epidemic has shifted toward poor, rural Southern areas, the funding mechanism behind the AIDS Drug Assistance Program (ADAP) favors the populated, urban states where the epidemic first erupted 25 years ago, southern AIDS advocates say.

Even in states where legislatures contribute a large portion of the ADAP budget, waiting lists and eligibility restrictions continue due to a lack of adequate funding. The results are people who need antiretroviral drugs, but who are unable to afford them and cannot qualify for ADAP or Medicaid.

Is U.S. in an inexcusable situation?

This is an inexcusable situation for a wealthy nation, AIDS advocates say.

"I believe people should have equal access to HIV medications," says **Patrick Lee**, JD, project director for the Piedmont HIV Integration Community Access System of the Piedmont HIV Health Care Consortium in Durham, NC.

"We're in a country where that can happen," he says. "We don't have to be a country of haves and have-nots."

The issue is a personal one for Lee: His own mother died from AIDS, and he is an HIV-positive, African American gay man, Lee says.

"My mother died of AIDS in 2000, and I have other family members who are affected by it," he adds.

The AIDS epidemic no longer is simply a medical issue since effective treatment has been created and is available; rather, it's a social justice issue, says **Peter Leone**, MD, an associate professor in the department of medicine at the University of North Carolina in Chapel Hill.

"I have a hard time to think of any communicable disease for which we have effective therapy and where we don't make that therapy available to everyone," he says.

"What complicates it more is this is an issue of transmission, and treatment will lower viral load, and we have reason to believe it will lower transmission rates," Leone notes.

Yet in Leone's own state, there are more than 800 people on the ADAP waiting list and arguably hundreds, if not thousands, more people who need HIV treatment but are not receiving it.

"We have the lowest ADAP eligibility of any state in the Union, and so if anything, the problem is bigger than it appears here," he explains.

North Carolina's ADAP eligibility is the lowest in the country with assistance only going to people who earn no more than 125% of the federal poverty level.

However, the program still has the nation's largest waiting list for ADAP drugs, and there are more than 2,500 people enrolled in ADAP, says **Steve Sherman**, AIDS policy and ADAP coordinator for the Department of Health and Human services in Raleigh.

Reasons for this vary from the traditionally low income and rural nature of much of the state, the hard-hit local economies, possibly more efficient screening for HIV infection due to acute HIV infection research, in which Leone is involved, and other factors, he says.

The state has been moving from a textile, furniture manufacturing, and tobacco economy into a high-tech economy, Sherman notes.

"We've lost a lot of jobs in all of those industries, and a number of high-tech companies in the Research Triangle area have had significant layoffs of high-paying jobs," he says. "They say the economy is recovering, but the job sector doesn't see it quite as readily."

However, the fact that North Carolina and other Southern states receive less federal money than their epidemics possibly warrant is another factor cited by AIDS advocates.

The Southern State AIDS/STD Directors Work Group, representing 15 southern states and areas, from the District of Columbia to Texas, has been lobbying for improvements in ADAP funding and in how ADAP money is distributed.

"We're working with the federal government to get a larger appropriation for the South," Lee says.

Many Southern states receive less federal ADAP money when compared with their own

state ADAP funding than do northern and western states.

For instance, North Carolina puts in more than one-third of its total ADAP funding, and Alabama puts in one-fourth of its ADAP funding, while California's state share for ADAP is in the single digits, according to Lee and **Kathie Hiers**, chief executive officer of AIDS Alabama in Birmingham.

Waiting list in Alabama continues to grow

Partially due to this inequity, Alabama has an ADAP waiting list with more than 400 names, despite the fact that the state's formulary only funds 31 drugs and the eligibility is at 250% of the federal poverty level, Hiers explains.

To make matters worse, Alabama is facing potential state cuts in ADAP funding that could result in hundreds more names added to the ADAP waiting list, she says.

"The way the funding distribution is set up is unfair — it's unacceptable," Hiers points out. "We've been pushing hard on this issue because basically any state that doesn't have a Title I city under the Ryan White Act doesn't get their fair share."

The way the system was established, it distributes funding in a formula that considers the numbers of AIDS cases 10 years previously, and this formula doesn't consider how rapidly the epidemic has shifted from an urban, gay, white male disease to a rural, poor, cultural, and ethnic minority disease, she says.

For instance, the formula considers all of Alabama rural state, needing less ADAP resources than states with Title I city environments, and this is despite the fact that Birmingham, is a metropolitan statistical area with more than 1 million people, Hiers adds.

"We have 46% of new infections, 40% of people living with HIV in the state, and we get 15% to 20% of the funding, and so there's something dreadfully wrong with this picture," she continues. "And it's no wonder why states like North Carolina and Alabama struggle the way they do."

Centers for Disease Control and Prevention (CDC) of Atlanta statistics show greater AIDS case rates in the South than elsewhere. The South also has a greater percentage of people living in poverty and a greater problem with HIV among rural, poor, and minority individuals, according to *Southern States Manifesto*, published March 2, 2003, by the Southern States group.

But the ADAP funding troubles in North Carolina, Alabama, and elsewhere in the South due to inequitable funding formulas shouldn't overshadow the major issue that ADAP nationwide is underfunded, and there are people everywhere who need treatment but are unable to receive it because of a lack of private and public health care funding, Leone says.

"So we're fighting over the scraps and argue about one state giving up resources from another state," he says.

However, the major issue that crosses state lines is that the HIV epidemic mainly affects people with whom society finds some discomfort, including people who acquired the disease through sexual activity and injection drug use, and so there is less sympathy for providing treatment to these groups, Leone notes.

"The only reason they don't have access to care is because they're poor, and that's why I think it boils down to a social justice issue," he says.

Yet there's another aspect of HIV treatment and care that transcends state lines, and that's the public health issue, Leone adds.

Even if the public is unable to muster compassion for people living with HIV/AIDS, as they might for the child whose family solicits donations for an organ transplant, the public should be concerned about the epidemic spreading further into society at a great public cost, he says.

"Treatment is a prevention strategy," Leone says. "Access to care should lead to more HIV-positive people identified and treated, and it will reduce transmission substantially." ■

AIDS advocates returning to their activism roots

Protesters welcome arrests and publicity

AIDS advocates now say they look back at the late 1990s as a time when they never had it so good: New antiretroviral regimens turned HIV infection into a chronic rather than fatal disease; AIDS funding increased each year; and most states improved their funding for the AIDS Drugs Assistance Program (ADAP).

Sure, everyone had complaints each year when the budget was passed with a little less money than most in the AIDS community would have liked, but it was a far cry from the 1980s when

AIDS activists routinely were forced to take to the streets to capture attention from the media, public, and politicians.

Now, AIDS advocates say, we're back to the stark future of decreased funding, increasing need, and the reliance on protests, rallies, and civil disobedience to gain attention from the Bush administration and state governments.

Arrested development for advocates

During the first half of 2004, AIDS activists gathered at rallies in Washington, DC; California; and elsewhere to protest inadequate funding of ADAP. At the Washington, DC, rally, about 100 people among the 1,000 Protesters were arrested as part of a calculated civil disobedience, says **Bill Arnold**, director of the ADAP Working Group in Washington, DC.

Arnold, who was among the group arrested, says the event included marching by the Democratic National Committee and Republican National Committee headquarters and was organized civil disobedience in the best tradition.

"I'm too old for this," Arnold emphasizes. "But we made almost a half-page in the *Washington Post*, and we made CNN and Fox News and probably a few other places."

However, the rally had another impact that may have greater repercussions in the long term, he says.

"The word went through the advocacy community all over the country that the time for demonstrations is back," Arnold continues.

"I remember in the late 1980s and the early 1990s, you could get several thousand people in Times Square for a demonstration if you needed to. Sometimes, that's what it takes to get back on the political radar," he notes.

Other activists agree.

"Yes, people are going to have to be prepared to scream and holler, and ADAP clients, particularly, are going to have to be visible and remind people how important these medications are to their long-term survival," says **Dana Van Gorder**, director of state and local affairs for the San Francisco AIDS Foundation.

AIDS advocates sent members of Congress empty pill bottles in January 2004, as part of their efforts to draw attention to ADAP's underfunding. "We're back to doing what we did at a time when the federal government wasn't paying attention to our needs, and we again think the federal government, and in many cases the state governments, aren't paying attention to our needs," says **Ryan Clary**, policy advocate for Project Inform in San Francisco.

"We're back on the streets and getting arrested and are back to doing things we didn't think we had to do anymore," says Clary, who also was arrested at the Washington, DC, protest.

"I definitely feel we are entering into very different times now," says **Jeff Graham**, executive director of the AIDS Survival Project in Atlanta. "We've gotten far too complacent."

Funding cuts to AIDS programs are coming from federal, state, local, and even philanthropic sources, he adds.

"Funding is starting to diminish, and this system is bursting at the seam with people falling through the cracks," Graham says. "People are getting sick; mortality rates, we fear, are going up. ADAP waiting lists and restrictions are more common, and agencies are cutting staff or even closing down."

Successful campaigns

AIDS activists cite several examples of how rallies and demonstrations, as well as traditional lobbying, have been successful, both in attracting public attention and in improved funding.

For instance, in Alabama, where there is a 400-plus waiting list for ADAP funding, a group called AIDS Alabama has lobbied state legislators since the mid-1990s.

This has resulted in an increase in state ADAP funding from zero dollars to $2.76 million last year, says **Kathie Hiers**, chief executive officer of AIDS Alabama in Birmingham.

Each year, AIDS Alabama holds a big rally day in the spring, scheduled to coincide with the state legislature's budget decision time, she says.

"We encourage HIV consumers and other advocates to meet for a training session, and we give out materials and then go to the Hill and inundate the legislature with our materials and visits," Hiers explains.

"We go to the appropriations room wearing our red ribbons, and then we have a reception at noon and invite all legislators for heavy hors d'oeuvres, and we hold a press conference," she adds.

The group has considered protest rallies and had considered sending 100 coffins to the state capitol, but opted not to take a more confrontational approach at the suggestion of their legislative champions, Hiers says.

Also, they'd had a bad experience during their first year of activism.

"Our first year, we were pretty naïve and held a statewide training session with our HIV-positive consumers and we taught them how to go to the capitol and educate legislators," Hiers notes. "We got them together and trained them and unleashed them on Montgomery and had a [bad] reaction from legislators."

One legislator spit on an activist; another announced to the crowd that a woman, who happened to be a mother with five children, was HIV-positive, she recalls.

In California, where the state legislature already is sympathetic to the issue, taking-it-to-the-streets activism was very successful earlier this year.

AIDS groups held rallies in Los Angeles; in San Francisco, drawing 300 people; and in Sacramento, drawing 800 people, Van Gorder says.

At stake was California governor **Arnold Schwarzenegger's** January budget proposal, which would have capped ADAP enrollment and created a waiting list, Clary explains.

"We estimated it would have put 800 people on the waiting list in the first six months," he says. "We did a lot of media work and put public pressure on the government, and advocates met with his staff in Sacramento."

A two-pronged approach

California AIDS advocates took a two-pronged approach: At the same time, they held large public rallies in support of ADAP funding, they met with the governor's staff to show him how state spending on ADAP results in rebates from pharmaceutical companies, Clary adds.

"AIDS advocates want to make sure the rebate money goes back into the ADAP program because that's one way of keeping the program solvent," he says.

The Schwarzenegger administration was responsive to the public demonstrations and to the media coverage that featured HIV-infected people who were at risk of losing their drugs, Van Gorder notes.

"We also were backed up by pharmaceutical companies who were saying, 'We're providing these rebates to make certain the program is whole, and please don't take them away,'" she adds.

As a result, Schwarzenegger revised his budget request to include additional ADAP funding, Van Gorder says. "We had been requesting an additional $25 million in the program, and he put in $27 million," she says.

Activist efforts in Georgia have kept that state's ADAP in the enviable position of having a solvent program that provides antiretroviral therapy to people who are at 300% of the poverty level.

Its drug formulary provides about 60 medications in all classes of antiretrovirals, and the state's funding has increased from $300,000 in the mid-1990s to $11.3 million this past year, Graham points out.

"It's a program that now has widespread bipartisan support in the state legislature," he says. "We've done a tremendous amount of education about how HIV is no longer just a problem for metro Atlanta; it's a big concern for people living in all health districts and counties in the state of Georgia."

Georgia AIDS activists focus on targeted legislative advocacy, working with the state health department to identify unmet need for the program on an annual basis, Graham explains.

People who are living with HIV and AIDS tell the media and legislators their own stories, and that has helped considerably with influencing legislative action, he adds.

However, AIDS advocates launched their lobbying efforts in 1996 with a large World AIDS Day rally on the steps of the state capitol, he says.

"We saw the AIDS drugs that were on the horizon, and we really used the events from the World AIDS conference to launch this campaign," recalls Graham.

A life-or-death issue

Now, although Georgia's ADAP situation continues to look good, the times call for a return to that type of activism, he adds.

"I feel that in desperate situations, you need to use every possible means of getting the word out," Graham says. "I was part of the group that was arrested in Washington, DC, where we went because we can see that Georgia is fine today, but Georgia might not be fine in six months or 12 months from now."

Activists wanted to send a message to policymakers and the public that people's lives are in jeopardy, he adds.

"It's a life-or-death issue throughout the country, and I think life-or-death issues require an appropriate response even if it is confrontational," Graham says.

"If we're not able to find a way to stop the backtracking and backsliding on AIDS funding, then we could be faced with a whole new epidemic on our hands," he adds. "It would be shameful for that to happen here, and it presents a challenge to all of us." ■

Acute HIV infections are discovered in Charlotte

Program that uncovered outbreak to lose funding

North Carolina investigators found evidence earlier this year of an HIV outbreak among white men who have sex with men (MSM) in the Charlotte area.

The cluster of cases in Mecklenberg County were associated with MSM who used crystal methamphetamine and found sexual partners via the Internet, says **Peter Leone**, MD, an associate professor in the department of medicine at the University of North Carolina in Chapel Hill.

Investigators began an outbreak investigation in June after finding 16 cases of acute HIV infection since the beginning of 2004, he says.

A year ago, the same investigators had discovered an outbreak of HIV infection among male students at African American colleges across the state. This outbreak led to an investigation by the Centers for Disease Control and Prevention (CDC) and resulted in enhanced HIV screening and prevention efforts by the state and colleges.

The latest outbreak involves some continuing HIV transmission among the college students, but also results from a new cluster of cases among white MSM in their 30s and older, Leone explains.

"We have had meetings with the community and are doing case investigation and are planning an intervention," he adds.

As of mid-June, the CDC was not involved in investigating the outbreak, although CDC officials likely would be called to join the investigation, Leone says.

"I think we're seeing a very large increase in new cases," he explains. "We don't know the extent of it yet because our [HIV testing] pickups are at voluntary testing and counseling sites, and there may be acute cases in the community that we've missed."

Half of the 16 cases were discovered through routine surveillance, and the others were found through referrals from clinicians who saw patients presenting with symptoms of acute HIV infection, Leone adds.

North Carolina's HIV screening program, the Screening Tracing Active Transmission (STAT), is unique in that it can detect HIV infection among people who were infected very recently and who test negative on the antibody test.

This ability to identify acute infections almost immediately is the result of an HIV pooling process developed by Leone and other investigators.

Basically, the process takes the samples of blood, collected for HIV testing at public clinics, and uses multistage pooling of the negative samples to retest with the HIV RNA or qualitative nucleic acid test that can detect new infections.

When the RNA test comes up positive, that particular pool of samples is divided and tested again until the one or more samples that represent an acute case of HIV are singled out. Then the sample is identified back to its source and that person is notified of the results.

Through this relatively inexpensive process, health officials are able to find HIV transmission trends and clusters almost as soon as they begin to occur, Leone notes.

"The real benefit is we can identify people during their most infectious period, and by notifying them, we can at least remove them from behavior that causes more transmissions," he says. "Even a short-term prevention intervention can make a tremendous difference on HIV transmission in the community."

Without the pooling program, the same HIV outbreak might not be discovered for years, Leone explains.

Plus, people who engage in high-risk behavior and then go into a center for testing might see a negative HIV test as positive reinforcement for their risky activity.

Meanwhile, if the same people actually are in the acute phase of HIV infection, they likely are even more contagious and likely to transmit the virus than someone whose blood tests positive for HIV antibodies, he notes.

"So it's critical to identify folks, and we showed how it can be done relatively cheaply," Leone says. "If you have people coming into care to be tested, it makes sense to do everything you can, and the technology is there to do the acute testing — so it's a question of will and money."

Ironically, at the very time the North Carolina program is yet again identifying an outbreak of HIV and at the same time that the CDC has

begun a new push for early HIV testing and prevention for positives, the pooling program may go belly-up from lack of funding, he says.

The CDC has issued a Request For Applications (RFA) for nucleic acid testing to research whether it is an effective testing therapy, says **Robert Janssen**, MD, director of the CDC's Division of HIV/AIDS Prevention.

"This is in line with one of our goals of advancing HIV prevention and to implement new models for diagnosing HIV infections," he says.

The request states this would be a $2 million, two-year grant.

Leone says it's a positive sign that the CDC will invest in the process, but North Carolina would not qualify for the grant proposal and still has a funding problem.

According to the request, applicants for part 1 must demonstrate their ability to provide samples from 50,000 seronegative individuals and most demonstrate a seropositivity rate of HIV tests of at least 1.5%. North Carolina would not meet this qualification, he adds.

For the second part of the grant, the applicant must be able to return pooled nucleic acid testing results within seven days of specimen receipt and must be able to process 8,000-10,000 specimens per month, the RFA states.

It's doubtful the North Carolina lab could handle that volume, Leone adds.

"Right now, our program will not have additional funding after October of this year, and it seems ironic to me that there is an RFA to replicate our program, and we may not have additional funding," he says.

"We're not eligible for the RFA because we don't have a high enough incidence to qualify," Leone points out.

Thus far, the pooling program has received a patchwork of funds from private, state, and other sources, but all of it will expire this year.

"It's going to cost $300,000 to maintain the lab on an annual basis for screening, and the money isn't there — so we're up against the wall on this," Leone says.

Logically, it would make sense for the CDC to fund the North Carolina project so it could continue to serve as a model for future use of the pooling program and investigators who have already invested considerable intellectual time and effort into developing the process could continue to build on their work, using their experiences with the program in the state, he explains.

When asked via email about North Carolina's request for funding, Janssen referred to the RFA as an example of the CDC providing funding for this type of research. ■

Treating mental problems also helps HIV treatment

Therapy along with medical treatment works best

Mental illnesses have had a great impact on the AIDS epidemic, and new research shows that providing psychiatric treatment to HIV-infected patients who have a psychiatric comorbidity will produce better treatment outcomes, a researcher says.

"A lot of data show that antiretrovirals are less likely to be taken by patients who have mental illness, and patients with comorbid mental illness are less likely to have antiretrovirals," says **Glenn J. Treisman**, MD, PhD, an associate professor of internal medicine and an associate professor of psychiatry and behavioral sciences at Johns Hopkins University School of Medicine in Baltimore.

HIV clinicians at Johns Hopkins discovered early in the AIDS epidemic that a high percentage of people presenting for HIV care also had psychiatric problems, including depression, personality problems, addictions, bipolar disorder, and schizophrenia, he says.

Psychiatric illness can lead to greater risk behaviors for HIV infection, and data show once someone is infected, a psychiatric comorbidity is likely to exacerbate HIV disease, Treisman notes.

"We already have data to show psychiatric disorders have a bad impact on compliance with highly active antiretroviral treatment (HAART)," he says. "And there are good data to show that HIV infection increases the likelihood and severity of depression."

The good news is that HIV-infected patients who receive psychiatric treatment have better outcomes, Treisman adds.

Psychiatric treatment should include both medications and psychotherapy to be most effective, he says.

"Without therapy, they don't take the medications and respond as well," Treisman explains. "We think it's important to be on antidepressants and psychotherapy at the same time."

Johns Hopkins has a psychiatric treatment model for HIV-infected patients that includes substance abuse treatment for those with addictions, group therapy, and individual therapy, he says.

The psychiatric service is comprehensive, intensive, and expensive except when the cost of not providing the treatment is taken into consideration, Treisman notes.

"Mental illnesses are driving the HIV epidemic, and if we don't treat them, they are a vector into the epidemic and an impediment to treatment," he says. "Treatment allows HAART to have the best chance to work and ultimately saves money."

For example, last year, Treisman treated a patient, who had been congenitally infected with HIV, who had been in and out of hospitals for months. Each hospital episode resulted in costs of $10,000 to $30,000. Finally, the patient was referred to the psychiatry department where the patient was treated for three months as an inpatient, he recalls.

While the three-month cost was $90,000, it has already produced a savings in health care resources because the patient has not been hospitalized in the six months since being discharged, Treisman points out.

The patient now is functioning normally and is back in school, he adds.

"It's much cheaper in the long run to treat a patient like that for three months and have the patient then take HAART, maintain an undetectable viral load, and practice safer sex," Treisman says.

The two main obstacles to HIV clinicians referring mentally ill patients to psychiatric services are the prevalent attitude that certain personality disorders and psychiatric illnesses cannot be treated, and the short-term public health strategy

CE/CME *directions*

To complete the post-test for *AIDS Alert*, study the questions and determine the appropriate answers. After you have completed the exam, check the answers **on p. 96**. If any of your answers are incorrect, re-read the article to verify the correct answer. At the end of each six-month semester, you will receive an evaluation form to complete and return to receive your credits.

CE/CME *questions*

5. North Carolina investigators developed a process for identifying acute HIV infections at a feasible cost. How does the process work?
   A. The process takes samples of blood, collected for HIV testing at public clinics, and retests each of the negative samples with the HIV RNA or qualitative nucleic acid test.
   B. The process takes samples of blood, collected for HIV testing at public clinics, and uses multistage pooling of the negative samples to retest with the HIV RNA or qualitative nucleic acid test that can detect new infections. When the RNA test comes up positive, that particular pool of samples is redivided and retested until the one or more samples that represent an acute case of HIV are singled out. The sample is identified back to its source, and that person is notified.
   C. Clinicians are trained to identify signs of acute infection and then refer those clients to the program for HIV RNA testing.
   D. none of the above

6. AIDS advocates from Southern states say the way the AIDS Drugs Assistance Program (ADAP) money is distributed is unfair to poor, rural states where the HIV epidemic recently has spread, and they cite which of the following as a reason?
   A. ADAP funding distribution is based on 10-year-old data of AIDS cases and is weighted more heavily in favor of large urban areas where the epidemic originally surfaced.
   B. Northeastern and Western states receive a greater portion of the ADAP money because of successful maneuvers by their senators and representatives.
   C. Southern states have fewer HIV testing sites and, therefore, identify fewer of their infected population.
   D. all of the above

7. MTCT-Plus is a mother-to-child-transmission program in Africa that provides what service to HIV-infected pregnant women?
   A. HIV treatment to prevent transmission to their babies and follow-up psychosocial care
   B. HIV treatment to the women, their HIV-infected children, partners, family, or household members for the long-term
   C. adherence support, tuberculosis management, and family planning
   D. all of the above

(Continued)

CE/CME *questions*

8. Which of the following is **NOT** something that research has shown about patients who are infected with HIV and who also have a comorbidity of psychiatric illness?
   A. Data show once someone is infected, a psychiatric comorbidity is likely to exacerbate HIV disease.
   B. Data show antiretrovirals are less likely to be taken by patients who have mental illness.
   C. Data show that people with HIV and a psychiatric comorbidity are more likely to be violent.
   D. Data show that a psychiatric comorbidity is likely to exacerbate HIV disease.

of limiting funds for treatments that prevent health care problems rather than react to them, he says.

"The public has taken the view that these are untreatable disorders, but that's not true," adds Treisman. "It's not like giving someone penicillin, but it is like treating someone after a stroke: The person can be rehabilitated and can dramatically improve, but may never be 100%."

Likewise, it's a mistake to believe that people who abuse substances always will return to the substances after substance use treatment, because at least one-third of these patients will stay off drugs or alcohol if they receive long-term treatment, he says.

To the other issue of short-sighted health care resources, Treisman says this is an irrational approach in a nation as wealthy as the United States.

Treisman has co-authored a book, published this summer, about psychiatric disorders and AIDS. *The Psychiatry of AIDS: A Guide to Diagnosis and Treatment*, published by the Johns Hopkins University Press, offers a model for psychiatric care of HIV-infected patients. ■

CE/CME *answers*

Here are the correct answers to this month's CME/CE questions.

5. B **6. A** **7. D** **8. C**

CE objectives

After reading this issue of *AIDS Alert*, CE participants should be able to:

- identify the particular clinical, legal, or scientific issues related to AIDS patient care;
- describe how those issues affect nurses, physicians, hospitals, clinics, or the health care industry in general;
- cite practical solutions to the problems associated with those issues, based on overall expert guidelines from the Centers for Disease Control and Prevention or other authorities and/or based on independent recommendations from specific clinicians at individual institutions. ■

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South Africa begins implementing ambitious HIV program

Government-funded initiative faces great challenges on several fronts

With the waning of the publicity hoopla over international support for providing antiretrovirals to sub-Saharan Africa and other developing regions, the actual work of bringing antiretroviral medications to millions of people has begun, and experts say it shows both great promise and great challenges.

While the United States' program is not yet available, American researchers and government officials in South Africa have begun to implement that nation's ambitious roll-out of antiretrovirals for millions of HIV-infected citizens.

"It's a national plan, but it's in the hands of the provinces to make it happen," says **Gerald Friedland**, MD, director of the AIDS program at Yale New Haven (CT) Hospital and a professor of medicine and epidemiology and public health at the Yale School of Medicine.

Slow process to set up infrastructure

Friedland is involved in research that integrates antiretroviral therapy into existing tuberculosis programs in South Africa, and he visited the country in May 2004.

"It's moving very, very slowly, and it will take a long time for antiretrovirals to get to most if not all of those who will need them," he says.

"They're trying to put together the appropriate infrastructure to do this, and there still isn't a secure supply of drugs," Friedland explains.

Integration of treatment and prevention services will be one of the major challenges of the new program, says **Salim Abdool Karim**, MD, PhD, a professor at the University of Natal in South Africa.

"We have strong support to scale up treatment and prevention and are doing both," he says. "Treatment tends to be provided to individual patients attending government hospitals or private health care services, while prevention is at the nongovernmental level."

The key will be to get both groups to integrate strategies, Karim points out.

While the South African government decided to start the program less than a year ago, it began with the ambitious goal of putting a large number of people on antiretroviral therapy this year, he adds.

"It's proven more difficult than originally planned," Karim notes. "We have complex government processes to procure drugs."

Entirely government-funded

The drugs will be commercial products, and there are details to work out about who will supply them, whether or not they are generic drugs, and this has led to a bottleneck with a lot of bureaucratic frustrations over what will happen, Friedland says.

The program is funded entirely by the government of South Africa with a little support from different organizations, he says.

"All potential sites for administration have been inspected to see if they meet certain standards for administering antiretrovirals, including expertise, pharmacy, monitoring for toxicity, etc.," Friedland explains.

"Four sites have been selected for the first sites for rollout, and those sites now are beginning to put on antiretrovirals," he says.

Patients who will receive drugs include those who have AIDS, as well as those who are asymptomatic but have CD4 cell counts of 200 or less, according to Friedland.

They'll be given a first regimen of efavirenz, D4t, and 3TC, except for women of childbearing age, who will receive nevirapine, D4t, and 3TC, he says.

"They made a decision, which I think is the appropriate one, and picked the best regimen and made sure that will be available across the board," Friedland says. "This is provided through the government, and the government will provide the drugs for free."

All patients will attend several sessions on adherence to medication before they begin the antiretroviral therapy because public health officials recognize the need for education to improve patients' treatment literacy, he adds.

"We didn't do anything like that in the United States, so at least there's attention to the issue of how to successfully take the medications," says Friedland.

Some South African patients already receive free antiretroviral treatment through grant-funded projects, including some of Friedland's studies.

"Through these projects, some patients have received antiretrovirals for a couple of years," he says. "Now that the government's rollout is happening, you actually can feel a change in attitude on the part of health care workers."

Hope begins to replace despair

For instance, the despair that many health care workers had been experiencing as part of their work in treating AIDS patients is slowly being replaced with a positive attitude and hope, Friedland explains.

"We hope the availability of treatment will reduce some stigma and discrimination, too," he says. "But it's too early to know that."

International researchers, including Friedland, have paved the way through research studies in identifying the most efficient ways to administer antiretroviral therapy.

Friedland's research involves integrating antiretroviral therapy into existing tuberculosis programs that use direct observational therapy (DOT).

Patients who are coinfected, and an estimated two-thirds are, receive their TB drugs along with a once-daily antiretroviral regimen under observation by clinic staff, he explains.

"We are looking for an entry point to start antiretrovirals, and this is a very good entry point," Friedland notes. "There already is an infrastructure, and it's better to strengthen it than to start from scratch."

For six months, TB/HIV coinfected patients will take drugs for both diseases, with the TB drugs given five days a week and the antiretrovirals being self-administered on Saturdays and Sundays, he says.

"When TB treatment is finished or as it's approaching being completed, you transition patients to self-administration of antiretrovirals," he adds.

"You have a boost of experience in a structured environment that will extend beyond that, and demonstration projects have shown it is feasible to do that," Friedland explains.

The next step is for research to move this strategy to setting where more patients will be treated, he says.

"I'm hoping this will become one of the strategies used for South Africa's rollout," Friedland says.

While challenges remain, the fact that South Africa has taken this big step is very positive, he notes.

"There's an African proverb that says the best time to plant a tree is 20 years ago; the second best time is now," Friedland says. "It will take a while for this to be up and running, and there's tremendous stress and strain in implementing it in a careful and expert way, and the expertise is not there yet — but it's a major step forward." ■

MTCT-Plus initiative now in eight African nations

Women enter program in pregnancy and continue

The Mother-to-Child-Transmission (MTCT)-Plus initiative was developed in response to the expansion of programs for preventing HIV transmission between mothers and children with the added feature of providing ongoing antiretroviral treatment to mothers.

International HIV advocates have long said the success of the inexpensive treatment that prevents women from transmitting HIV to their newborns is far from a long-term solution since those same infants likely will grow up as orphans if their mothers remain untreated after the pregnancy. Already, there are an estimated 10 million orphans in sub-Saharan Africa.

Now, the MTCT-Plus program is working to keep the mothers alive and healthy for the long term. It's been expanded to 12 programs in eight African countries, and enrollment began in

March 2003. Now more than 3,500 people have been enrolled, says **Wafaa El-Sadr**, MD, MPH, chief of the division of infectious diseases at Harlem Hospital and professor of clinical medicine and epidemiology at Columbia University in New York City.

"The [typical MTCT] programs do not offer the women treatment for their own disease or treatment for their HIV-infected children or partners or household members," she says.

"MTCT-Plus aims to recruit women identified as HIV-infected during pregnancy and offers them a comprehensive package of HIV care including antiretroviral treatment," El-Sadr says. "Women can enroll their partners, household members, and children who are HIV-infected."

Patients receive clinical and psychosocial services through a multidisciplinary team of providers, she explains.

Each site selects its own primary and secondary antiretroviral regimens, based on national guidelines, El-Sadr says.

"We encourage them to enroll women as early as possible during their pregnancies, so they can be engaged in the program," she notes.

"We use the time of pregnancy to enroll them in the program so they can receive psychosocial support, adherence support, and all of that very early in the pregnancy."

Overcoming stigmas

The programs also help staff support patients in terms of stigma and finding ways to disclose their HIV status to their families, El-Sadr says.

"It's a testament to the programs that they could enroll this many patients even in settings where we know stigma exists," she continues.

"We provide support group training on exposure and have a peer program where people with HIV, who feel comfortable in disclosing, are able to provide support to other patients as well."

Such programs have shown signs of reducing community stigma and discrimination by opening up communication about HIV, rather than denying the disease exists, El-Sadr notes.

Included in the menu of services provided are tuberculosis management, family planning, supportive interventions, and outreach. However, the chief cost is the antiretroviral drugs, she points out.

"A major cost remains the antiretroviral drugs themselves, even though the cost has come down," El-Sadr explains. "We're hoping that as antiretroviral prices come down, they can enroll more women into the program."

Funding comes from eight different foundations and USAID, she says.

"These programs are the first of their kind," El-Sadr adds. "For countries with high HIV seroprevalence, these programs are an important site to identify women with HIV and to engage them in an HIV care program early in the course of their disease." ■

Will better HIV treatment mean higher STD rates?

Acute infection studies offer prevention window

Antiretroviral treatment soon will be available to millions more people in sub-Saharan Africa and other developing nations, and international HIV experts fear they'll see increased risk behaviors when the drugs become commonplace.

In anticipation of this, the Global HIV Prevention Working Group issued a report in June 2004, calling for an expansion of prevention programs and greater integration with existing treatment programs.

The *HIV Prevention in the Era of Expanded Treatment Access* report claims this is a unique opportunity to build a comprehensive approach to treatment and prevention in nations that have struggled with both facets of HIV intervention.

"We want to highlight that there is concern that risk behavior could increase, and we could see an increase in sexually transmitted diseases (STDs) and HIV as we've seen in some Western, developed nations where treatment access has existed for longer periods of time," says **Helene Gayle**, MD, MPH, of the Bill & Melinda Gates Foundation.

She adds that it's hard to say that has happened elsewhere due to a complacency or from a shift in resources.

"But it's clear if we look at the experience of the United States and United Kingdom and others, we're seeing disturbing trends in risk behaviors and increases in HIV and STDs," Gayle notes

For example, in Australia, the rate of new HIV infection has increased 22% over the last five to eight years since the full access to treatment has been available, she says.

Meantime, U.S. investigators and others are

studying ways to identify people who recently were infected with HIV and still are in the acute infection stage.

"We think it's of great public health benefit to identify acute infections," says **Myron Cohen**, MD, a J. Herbert Bates Distinguished Professor of medicine, microbiology, and immunology and director of the division of infectious diseases and the director of the Center for Infectious Diseases at the University of North Carolina at Chapel Hill.

Cost-effective method

Cohen and other researchers have developed a cost-effective way to identify acute HIV infection through a pooling process that tests the blood of individuals who tested negative for HIV on the antibody test. This process, using the HIV RNA, identifies those individuals who are acutely infected.

For example, in one sub-Saharan African clinic, researchers tested 1,300 blood samples and found that 2% of patients had acute HIV infection, says Cohen.

"If two out of 100 people have an acute infection then they're many times more infectious than others," he notes. "So finding those two people is very important."

Researchers have no doubt that the magnitude of viral burden in the first weeks of HIV infection present a major transmission risk, he says. "In addition, many of these people have untreated sexually transmitted diseases (STDs) at the same time."

So a future prevention strategy will be to identify people who are acutely infected with HIV, provide them with prevention information, and ultimately, treat them with a therapeutic intervention designed for acutely infected individuals, Cohen says. "We're in the infancy of developing strategies."

Meantime, there are plenty of prevention strategies that could easily be adapted to work with HIV treatment programs, the global HIV experts say.

For instance, Brazil has had success with integrating prevention and treatment services, says **Paulo Teixeira**, MD, MPH, former director of Brazil's national AIDS program and currently with the World Health Organization in Geneva.

"If you have a comprehensive approach, it's easier to mobilize and involve people and their friends," he says.

"People will feel we are offering something that offers hope to infected people, and this is fundamental to having these people as a partner of the health structure and of our project," Teixeira says.

A national survey of homosexuals and observed behavior in Brazil in 2002 showed that rates of condom use and adoption of safer sex behaviors did not decrease as a consequence of greater access to treatment, he points outs.

So this indicates that when prevention and treatment are integrated, it is possible to prevent the problems Australia, the United States, and the United Kingdom are having with increases in risk behavior and HIV infection, he adds.

"Secondly, the promotion of treatment will have a very important role in prevention, particularly, because you will promote more complete HIV testing," Teixeira says.

The challenge will be for governments to continue and improve prevention funding at the same time additional resources are going toward treatment, Gayle notes.

"The case for treatment is always obvious and more compelling than the case for prevention," she says. "The ability to see people get sick and become better is more tangible and obvious; we spend much more resources on treatment than we do for prevention."

The other issue is that when a government scales up treatment, there's a tendency to make a financial trade-off when it comes to prevention resources, Gayle explains.

"In 2002, there was $2 billion spent on prevention, and by 2005, we need $5.7 billion, so that means there's a gap of $3.8 billion," she says.

However, with the HIV epidemic, any funding cuts in prevention programs eventually will cost more in treatment, Gayle points out.

"We need to remember that people who are HIV-infected also need prevention services," she says. "Prevention services need to be geared to keep people from acquiring it and to keep people who have the potential to continue transmitting HIV to remember prevention as well as their treatment needs." ■