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New studies highlight racial disparity, treatment access among HIV patients

Differences chiefly due to economic disparity

The good news from some of the latest research into the differences between minority and white HIV patients and access to HIV treatment is that there were not huge disparities within HIV programs.

On the other hand? "When you sum it up across states and programs, you get disparities," says **Stephen F. Morin**, PhD, professor of medicine at the University of California-San Francisco (UCSF), AIDS Research Institute.

"So it's a complicated picture, and there's a huge difference in how people receive care through Medicaid and the AIDS Drug Assistance Program (ADAP)," Morin adds.

"African-Americans are far more likely to receive access to antiretrovirals through Medicaid, and people on Medicaid are less likely to be on optimum therapy than people in ADAP," he says.

Research presented at the recent 2002 Ryan White Comprehensive AIDS Resources Emergency conference, sponsored by the Health Resources and Services Administration (HRSA) of Rockville, MD, indicated that differences in household income and disability status led to proportionately more African-Americans in Medicaid programs than are whites and Latinos.

Studies also showed a greater proportion of Latinos in ADAP programs than in Medicaid, a difference that investigators attributed partly to the fact that Medicaid programs require a residency test for enrollees and ADAPs do not.[1]

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FDA Notifications

COMING IN FUTURE ISSUES

- **42nd ICAAC:** Look for special coverage of the ICAAC conference, held Sept. 27-30
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- **HIV and prisoners:** Here's a look at issues affecting minority women and incarcerated men at risk for HIV
- **Counseling via computer:** Researchers develop a practical, inexpensive way for cash-strapped clinics to provide HIV counseling and education

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However, while Medicaid programs in many states tend to provide less optimal medication coverage for the HIV-infected person than ADAPs, that doesn't mean necessarily that ADAPs provide better access to HIV care, notes **T. Anne Richards**, MA, a research specialist with the UCSF Department of Medicine.

"The main issue with ADAP is a lack of comprehensive services or limited comprehensive services," Richards says.

"ADAP does a great job of filling the gap, and everyone at every single clinic we studied said they were so grateful for what ADAP provided," she adds. "But there also were those patients who didn't have a disability or AIDS diagnosis, and so how do they go about dealing with their other medical needs?"

In the Texas HIV clinics that were studied, there were huge system barriers, such as services that were spread out geographically, making it difficult for poor and working-class clients to take advantage of all that was offered. And in some cases, there were no Spanish-speaking providers on hand, so Hispanic patients might have to rely on less reliable translation services, Richards says.

The third system barrier was a $5 copay requirement for prescriptions made through ADAP, which is an enormous financial barrier for the low-income HIV clients who often had to pay that copay on three or four medications, Richards says.

Policies vary by state

Perhaps the biggest problem with the current Medicaid/ADAP safety net for uninsured and poverty-level people infected with HIV is that their access to care is largely dependent upon their state of residence and whether they were tested for HIV soon after becoming infected, the research shows.[2]

Some states have stringent Medicaid requirements in which enrollees must have an AIDS-defining illness or a disability before they qualify for HIV medications and services. And in some states and communities, minorities are less likely to learn their HIV status until after they begin to experience symptoms, Richards says.

"In an African-American clinic in rural Florida, many people didn't want to know their HIV status because there was so much stigma attached to it," Richards recalls.

But in a New York urban clinic, African-Americans were as likely to be tested early as whites because this was an area where the disease had been around for a long time, perhaps lessening the stigma attached to it, Richards adds.

Another reason minorities often begin HIV treatment later than whites is because of a lack of trust in government and a suspicion of HIV drugs, investigators surmise.[2]

This issue of early testing and access first became a public health concern in 2000 during the Ryan White reauthorization, says **Scott Brawley**, MSW, director of public policy for AIDS Action, an advocacy group in Washington, DC.

"The underlying theme over the past 2½ years for all Ryan White Care Act programs has been to bring people into care sooner," Brawley says.

HRSA's interest in the issue of disparity in HIV care initially was prompted by concerns raised by the Congressional Black Caucus after some earlier national statistics indicated that African-Americans were less likely to participate in ADAPs than other racial groups, Morin says.

"The only way you can find out what's going on is to do state-based case studies because the aggregate national data are all confounded by states setting criteria for both Medicaid and ADAP," Morin explains. "So we had to go into state records to find out exactly what is going on."

Investigators in California, New York, and Texas began to study the issue by closely examining the reimbursement claims and AIDS surveillance data and interviewing administrators and others in those three states, as well as in Florida.[1,2,3,4]

Their findings showed that racial disparities exist in the utilization of antiretrovirals, but this was only a small part of the picture.

Researchers also found that many clinicians, clinics, and states were taking positive steps toward reducing these disparities and improving early HIV testing and care among minority groups.[4] **(See article on how states, clinicians are working to reduce disparity, p. 136.)**

For example, New York has an excellent Medicaid system that provides financial incentives to specialty providers, so they are motivated to treat low-income patients with HIV infection, Morin points out. New York's Medicaid program does not require enrollees to have a disability or advanced illness before they may participate, and this means that patients are treated earlier in the course of their infection, he adds.

In New York, there are proportionately more African-Americans enrolled in Medicaid due to a lower socioeconomic status overall, says **Guthrie S. Birkhead**, MD, MPH, director of the New York

State Department of Health, AIDS Institute in Albany.

However, this doesn't mean that African-Americans in that state receive less optimal care, Birkhead says. "Medicaid provides a range of services that include hospital care, intensive case management, and other services," he says. "We have AIDS-designated hospitals and enhanced fees for physicians who sign up to care for AIDS patients, and that has enabled us to develop a clinical infrastructure to provide HIV services."

The next step is for the New York Medicaid program to move toward a managed care model for HIV patients, creating an environment in which patient care is coordinated, Birkhead adds.

While New York's program might be a model for Medicaid, the reality is that in many states the poor people who qualify for Medicaid economically must be very sick before they are eligible for antiretroviral drugs, Brawley says.

"Medicaid has categorical eligibility requirements of single mothers, poverty level, and children on Medicaid. HIV in some states is a categorical option, but not a required option," he says.

This is why AIDS Action and other national HIV advocacy groups have been pushing for national legislation that would remove barriers to early treatment for HIV-infected people through Medicaid. U.S. Rep. Nancy Pelosi (D-CA) and others in Congress have sponsored a bill called the Early Treatment for HIV Act of 2001, which would enable more HIV-infected poor people to receive antiretrovirals and HIV treatment before their disease progressed to illness, Brawley says.

However, the bill has been stalled in the House subcommittee on health shortly after it was introduced in June 2001. Also, 2002 has not been a good year for a bill that would cost states more money, he notes. "Now states are facing such extreme shortfalls," Brawley says. "Some states [such as] North Carolina and Tennessee say they can't bring more people into Medicaid programs."

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Progress reported on curbing disparities

One type of program doesn't fit all

As researchers examined the issue of racial disparity in HIV care and treatment, they found that some clinics and states have made progress in reducing disparity through a variety of programs and measures.

Through studying various HIV programs in four states, researchers have found that the chief obstacles and solutions vary by region and minority culture, so there probably will never be one model for care that would work for all states and programs.

However, they have collected an assortment of strategies that work for some areas and could be used in areas where disparity is a major problem.

"The most promising strategy is to contract with minority community-based organizations (CBOs) to do treatment education and outreach," says **Stephen F. Morin**, PhD, professor of medicine at the University of California-San Francisco (UCSF) and the AIDS Research Institute in San Francisco. "This has been done for years in New York and has emerged as a major strategy in California," Morin says.

Another strategy is to create a position of regional minority coordinator whose job is to provide treatment education and outreach efforts. This method has been employed by Florida, he explains.

In Florida, there also has been an outreach program that has used black universities and colleges and their football games to spread the word about HIV treatment and information, Morin says.

Providers also have been involved with HIV awareness outreach through minority media outlets in California, New York, Texas, and Florida, he points out. The only drawback is that none of these outreach efforts have been studied with regard to outcomes, and researchers have recommended that the Health Resources and Services Administration (HRSA) in Rockville, MD, begin to study these programs to evaluate outcomes, Morin adds.

New York state's approach to providing Medicaid services for HIV enrollees is another example of a government's strategy for reducing disparity.

While some states have Medicaid programs that limit enrollment to people who meet both income and disability requirements, meaning that many HIV-infected people would not qualify until they acquired AIDS-defining illnesses, New York's program is more liberal with no barriers for HIV-infected people who meet the income eligibility, says **Guthrie S. Birkhead**, MD, MPH, director of the New York State Department of Health AIDS Institute in Albany.

New York's Medicaid program also provides early, quality care for HIV patients, so even if minorities are disproportionately receiving their HIV treatment through Medicaid, they still are receiving services comparable to those offered to HIV patients with private insurance.

Another way New York has reduced racial disparity is through assembling advisory groups and engaging community organizations and local leaders in efforts to design prevention and treatment programs for minorities.

"We make an effort to work with the Centers for Disease Control and Prevention with their directly-funded programs for minorities," Birkhead says. "The community-developed initiative funds organizations in the African-American and Hispanic communities to assess what the needs are and work with us to meet those needs."

In comparing eight clinics that either target Hispanic or African-American populations, investigators found that in some cases, the clinic and clinicians themselves were the ones coming up with ways to reduce disparity in treatment.

For example, one HIV physician made certain she was readily available to HIV patients by giving them her beeper number, says **T. Anne Richards**, MA, research specialist with UCSF.

"That was pretty amazing to me — she was really engaged," she says.

Also, a clinic in San Francisco offered HIV patients an array of services that covered more than clinical needs, Richards says. "They looked at a person's total situation and made a determination on an individual basis of what needed to happen in that person's life to facilitate HIV care, and then they'd meet weekly to do a case review. So it was an interdisciplinary approach."

The clinic's methods included collaborating with patients to make them active participants in their HIV clinical decisions. There also was a heavy emphasis on educating patients before they started on antiretroviral medications, she says. "If the patient's basic life needs weren't covered, then HIV falls in priority, so the clinic would help them make arrangements for housing and check in with them to make sure the housing situation was conducive to their taking medications."

Since the clinic's staff were well aware of issues pertaining to their Latino population, they also came up with strategies for helping clients stay on their medications when they left the United States for long periods of time, an issue that might never occur to clinicians who work with a primarily white population.

The San Francisco model also had an effective method for keeping newly diagnosed clients from falling through the cracks. Once a client received a positive HIV serostatus notice, the clinic's staff would walk the patient to the clinic to make a medical appointment, Richards says.

"That moment of receiving notice of serostatus is one with a lot of fear and anxiety, and it's a critical time where people will disappear from the system and not show up again until they're symptomatic," Richards says. "They realized this was a critical time to bridge the gap from testing to treatment."

The San Francisco clinic also encouraged HIV patients to bring their family members and friends into the clinic where they could be involved in decision making and providing the patient support, she says. "This is a real community model of what defines the neighborhood of services. This is not rocket science; it's simple, practical things." ■

Special Report: Club Drugs & HIV

Drug treatment best hope for meth-using MSMs

Researchers want to get word out about problem

(Editor's note: This is the second in a two-part series about the increase in methamphetamine and stimulant use among gay and bisexual men across the country and how this is tied to increased HIV risk and incidence in various communities.)

New unpublished and published research show that gay and bisexual men who use methamphetamine have a greater prevalence of HIV infection than men who have sex with men

(MSM) who do not use the drug.

This finding has led some researchers to speculate that methamphetamine use could result in a resurgence of the virus among MSM. And it highlights the need for targeted substance abuse programs directed toward MSM who use methamphetamine.

"I see HIV in my community, and it's in drug users and drug-using gay men," says **Steve Shoptaw**, PhD, principal investigator with the Friends Research Institute in Los Angeles. Shoptaw also is an associate research psychologist at the University of California-Los Angeles.

"If 62% of the guys are infected by the time they show up for [substance abuse] treatment, then that tells me there's a high concentration of the virus where these guys interact," he says.

Drug treatment significantly reduces HIV-related sexual risk behaviors immediately, and those reductions are observed at a one-year follow-up, according to Shoptaw's most recent research.

"We see, on average, men coming in and reporting three or four instances of unprotected anal receptive intercourse with someone other than their primary partner at baseline in 30 days prior to their first visit," he says. "After treatment, at one-year follow-up, it's [less than] one instance."

Methamphetamine use also has dropped after the treatment intervention, Shoptaw notes. "At baseline, there were nine to 10 average days out of 30 of meth use, and at a 52-week follow-up, there were three to 3.5 days."

Taking drug use out of the picture

These findings make it starkly clear that for certain MSM populations, one of the first HIV prevention strategies may be to encourage men to enter substance abuse treatment.

"When you pull the drug out of the picture, the men make different decisions about their sexual behavior," Shoptaw says.

Shoptaw and colleagues have observed methamphetamine-abusing MSM since 1996, listening carefully as the men sometimes outline their own HIV-prevention and drug-management strategies.

"And all of those men have fallen and become dependent or needed intervention, and so at this point, I no longer say you should be doing harm reduction or encourage lower amounts of use because there's not a lot of benefit to that. We should be coming out strong, emphasizing the value of abstinence," Shoptaw says.

To that purpose, the Friends Health Center has developed a treatment manual and behavioral intervention program for methamphetamine-abusing MSM. The program provides detailed interventions directed to this particular substance abusing population. **(See article on behavioral intervention program, p. 143.)**

Crystal meth addiction is hard to beat: The drug creates a strong dependence because a person with low self-esteem may feel like the king of the world, says **Perry N. Halkitis**, PhD, assistant professor of psychology at New York University and co-director of the Center for HIV Educational Studies & Training in New York City.

"My personal opinion is harm reduction is not going to work, and it needs to be a clean-cut break," he says. "People can realize they have a problem and go to a meeting, but eventually dependence is not going to be eliminated with a harm reduction approach."

Halkitis recommends substance abuse treatment in the form of cognitive-based therapy programs that use motivational interviewing that gets people to think about their behavior and motivates them to change.

"The other thing we're working on here is to treat the addiction through medications because we know what the substances do to release pleasure neurotransmitters in the brain," he says. "And when you're stressed, your brain fires other receptors that cause pain, which you counter by doing drugs."

But the pharmaceutical approach always raises the question of whether it's prudent to treat drug addiction with other drugs, Halkitis adds.

Clinicians need to start probing and find out more about methamphetamine use in their areas because substance abuse and mental health services do not collect data on meth use in New York City and other areas, he says.

"Clinicians need to be aware of symptoms of substance abuse," Halkitis says.

And clinicians working with MSM patients need to catch the substance abuse early as methamphetamine typically begins as weekend party behavior, but eventually spreads to everyday use and addiction, he adds.

While not every expert on methamphetamine use among MSM would agree that total drug abstinence is the only solution, there is some agreement that some substance abuse treatment is necessary as part of an HIV prevention strategy.

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Debt cancellation tops agenda of international groups

Issue receives increasing political clout

International AIDS activists have begun to succeed in bringing the issue of debt relief/cancellation to the attention of political leaders, as well as to the general public, in the past year, and they express optimism that some major changes have begun.

"I absolutely think there's reason to hope, and awareness of issues is growing," says **Mara Vanderslice**, an outreach coordinator for Jubilee USA Network of Washington, DC.

Jubilee is an advocacy group for debt cancellation and has been teaming with AIDS activists to pressure the World Bank to increase debt relief. To goal is to use the money saved in debt interest payments to fund AIDS prevention and treatment programs.

"The debt relief that has been provided so far wouldn't have happened without ordinary people raising their voice to Congress and the media," Vanderslice says. "Health experts could be powerful advocates for the community and Congress."

The Office of the United Nations High Commissioner for Human Rights and the Joint United Nations Programme on HIV/AIDS of Geneva have recently revised the "HIV/AIDS and Human Rights International Guidelines."

Quick debt relief is recommended

This includes a recommendation that creditor countries and international funding institutions implement debt relief for developing countries more quickly and extensively.

The recommendation further notes that states should dedicate a proportion of debt relief resources to HIV/AIDS prevention, treatment, care, and support. **(See story on revised human rights guidelines, p. 141.)**

Another example of the changing political tide is the April 2002 introduction of the Debt Relief Enhancement Act of 2002 in the U.S. Senate and the Debt Cancellation for the New Millennium Act in the U.S. House of Representatives. The bills have been stalled in subcommittees since May.

"The pending bills in Congress would deepen relief, but so far the Bush administration has rejected those," explains **David Bryden**, communications director of Global AIDS Alliance in Washington, DC.

However, this issue will not go away because the AIDS epidemic highlights its importance, Bryden says.

Many countries saddled with huge debt

"The burden of debt on countries affected by the AIDS epidemic is important," Bryden says. "Payments that countries have to make on a backlog of old debt and on new debt could be better spent and should be better spent on fighting pressing crises like AIDS."

International debt amounts to nearly $300 billion for African countries, and half of this is owed by 34 countries included in the World Bank and International Money Fund's (IMF's) Heavily Indebted Poor Country (HIPC) debt-relief initiative.[1]

However, current debt-relief programs do not go far enough to relieve the financial pressure on the world's poorest nations, which now are being crushed under the burden of the AIDS pandemic, AIDS activists say.

With 70% of the world's 40 million HIV-infected people living in sub-Saharan Africa, where the debt burden is extraordinary, there clearly has to be an elimination of debts so that these governments can shift every possible resource to AIDS prevention and treatment,

according to **Asia Russell**, an activist with Health Global Access Project of New York City.

"Debt relief used for mitigating AIDS in the third world is on the top of the agenda of a coalition of groups because the AIDS crisis is the clearest example of how policies of the U.S. Treasury, IMF, and World Bank have failed people in developing countries," Russell says.

ACT UP in Philadelphia also has become involved in this issue, marching with protesters opposing IMF and World Bank policies. "These two organizations are largely responsible for an obstruction to health care access for impoverished countries," says **Kris Hermes**, an ACT UP member.

Examining the history of third-world debt

A look at the history of third-world debt may offer an explanation why AIDS activists and others are convinced that international debt cancellation is necessary and humane.

"A lot of private banks in the 1970s, with no accountability, lent to countries," Vanderslice says. "There was a lot of stolen wealth for military conflicts or development projects that were never finished."

For example, in the Philippines, there was an international loan made for a nuclear power plant that was located, at the advice of Western donors and experts, on an earthquake fault line, Vanderslice says.

"That plant never went on line, and the Philippines now is paying $170,000 a day until the year 2018, which is more than 5% of that country's debt, on that loan," she points out.

Vanderslice compares the 1970s' loan accesses to developing nations to the loan accesses in the 1980s made by U.S. savings and loan (S&L) companies to developers.

However, the big difference is that the U.S. government bailed out the S&Ls, and the defaulted loans were not repaid by the bankrupt developers. With nations, there are imposing obstacles to defaulting on international loans, even when these were taken out by corrupt dictatorships that have since been replaced by more responsible governments, she says.

"The poorest countries don't have the power and leverage to say, 'We're declaring bankruptcy, and we're not going to pay,'" Vanderslice says. "Their need for new loans is used for leverage to require these countries to implement policies favorable to the wealthiest countries."

While critics may say that canceling debt in third-world nations will just lead to more inappropriate borrowing and increased expenditures toward military campaigns, Jubilee's studies have shown that this has not been the case in nations where debt relief has already taken place, she points out.

"We've seen a lot of emerging democracies in Africa and Latin America that are more accountable than past governments," Vanderslice says. "And we don't have private banks lending so much anymore, so it's very controlled."

However, these same governments are being hindered in their efforts to improve and become more self-sufficient because of debt accumulated from past decades, she notes.

"Some countries are selling off anything they can to get revenue to pay debt," Vanderslice says. "They have to repay the debt in the currency of the creditor, and they can only get that currency through export sales, so they're shifting from domestic agriculture to export crops, which is a long process of impoverishment."

Debt cancellation restrictions could prevent the money from being diverted to buy additional arms, but even without oversight of these stipulations, the trend has been that countries receiving debt relief are shifting more money toward necessary domestic programs, she says.

"There's a great track record," Vanderslice says. "Our report shows that 10 countries receiving debt relief all had increased spending in health and education and no change in military spending."[1]

Current initiatives don't go far enough

The problem with current debt relief initiatives is that they do not go far or fast enough to rescue developing nations from the burden of the AIDS epidemic, AIDS activists say.

"There has been very limited debt relief in the last couple of years," Russell says. "The debt burden so far has been too conditional and irrational in structure."

Critics of the World Bank's and IMF's debt relief efforts point out that some of the requirements for this debt relief are counterproductive with regard to helping poor nations improve their health care systems.

The restrictions are meant to ensure the countries implement austerity policies, but these often go too far, Vanderslice says.

For example, nations receiving debt relief are

required to privatize their water systems, which means that private companies taking over the public water supplies will charge water fees that are too expensive for the vast majority of residents, she says.

The same has happened with health care services, where these countries are required to charge people a user fee prior to receiving hospitalization or health care services, Vanderslice adds.

"It's quite deadly, and we have stories of people coming to the hospital with a child who is dying, and they can't get in because of the 60-cent fee," she says. "Those are some examples of IMF policies that are trade liberalization, and these all have huge impacts on the economy and stability of the community."

For instance, when these nations are forced to use international industries for local services and products, it results in the local companies being unable to compete and local people losing jobs, Vanderslice adds.

Jubilee and other groups propose more radical debt cancellation that does not include stipulations that lead to worse social and health care climates in developing nations, she says.

The U.S. House of Representatives' debt cancellation bill would be a very good start, Vanderslice adds.

The bill, as introduced, would require:

- Debt relief provided by IMF and the World Bank under the Enhanced HIPC Initiative to be sufficient to cancel 100% of the HIPCs' debt.
- Debt relief would have no provision to be conditioned on any country's implementing a structural adjustment or stabilization program of the Poverty Reduction and Growth Facility of the IMF.
- All HIPCs that are working to develop and implement their Poverty Reduction Strategy Papers would not be required to make service payments on their debts, ensuring that the savings from the debt relief would be invested in HIV/AIDS treatment and prevention, health care, education, and poverty reduction programs.

Reference

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UNAIDS guidelines update includes expanded agenda

Changes occur with sixth guideline

Recent changes made to the "HIV/AIDS and Human Rights International Guidelines" include recommendations that hold governments accountable for developing policies that will improve HIV treatment and care.

Among the new recommendations, made by the Office of High Commissioner for Human Rights and the Joint United Nations Programme on HIV/AIDS are some of the more controversial issues facing the international AIDS community.

For example, one change to guideline six recommends that states enact laws to enable HIV/AIDS information to be spread through the mass media and to ensure this information is not subject to censorship.

Another item recommends that states ensure that intellectual property agreements do not impede access to HIV/AIDS prevention and treatment.

Providing governments a framework

The guidelines also instruct creditor countries and international funding institutions to implement debt relief for developing countries and that developing nations use a proportion of the resources freed up by debt relief to provide HIV/AIDS prevention and treatment services.

"The purpose of the guidelines is to give practical guidance, as well as to provide a framework to governments to redesign their policies and programs within HIV/AIDS human rights," says **Miriam Maluwa**, LLB, LLM, law and human rights advisor in the Office of the Director of the Department of Social Mobilisation and Information for UNAIDS in Geneva.

The entire guideline six is new because a lot has changed worldwide in the six years since the initial guidelines were developed, Maluwa notes.

"There has been quite a noticeable strengthening on international human rights law relating to HIV/AIDS," Maluwa says.

"A number of key human rights mechanisms have made pronouncements or given legal interpretative value on how the right to health can be realized in the context of HIV," she adds.

Before the recent revision, guideline six

focused largely on the regulation of goods, services, and information. Now there's a greater focus on defining what states' obligations are under guideline six, Maluwa explains.

Many countries already have policies and regulations that follow the points made under the revised guidelines, especially those pertaining to the recommendation that states ensure their laws and policies do not exclude, stigmatize, or discriminate against people living with HIV/AIDS with regard to access to health care services, she says.

Some progress is seen

There also has been some progress made in ensuring that legislation provides prompt and effective remedies in cases in which a person living with HIV/AIDS is denied access to health care treatment, Maluwa says.

"We've seen HIV/AIDS related litigation of people discriminated against," she says. "The judicial structure, courts, and tribunals have led to regress granted to those who have a complaint."

For example, HIV/AIDS litigation has been under way in South Africa, India, Venezuela, and Costa Rica, Maluwa says.

Also, some countries, including Uganda, Thailand, and the Philippines, have strong community engagement policies as part of their HIV prevention and treatment programs, as is recommended in the revised guideline, she adds.

However, there are a number of areas that most nations have not addressed. Maluwa offers these observations on several of the more controversial recommendations:

- **Debt relief**

"Generally, we, as an institution, have been advancing debt relief as an approach to ensure that resources allocated to HIV/AIDS are increased," Maluwa says.

"And we're doing it in the context of ensuring that countries that are benefiting from debt-relief programs," she says.

UNAIDS has been trying to make certain that elements of the poverty reduction plans of debt-relief initiatives include components of HIV/AIDS, she adds.

- **Intellectual property laws**

"Issues of intellectual property laws and HIV treatment and the dynamism of how they work varies a lot from country to country," Maluwa says.

For example, Brazil has been able to guarantee universal and free access to antiretroviral medications since 1996 through a number of strategies that include ensuring the production of generic drugs within the country, Maluwa says.

"Brazil has struck the balance between increasing access of antiretrovirals without intellectual property law being an impediment to that, and they have produced quite good results between 1996 and 2000," she adds.

"Brazil's hospital admissions have dropped by 80%, and AIDS mortality rates have fallen by 50% because of this guaranteeing of free access to HIV medications."

Some other countries, including Venezuela, Costa Rica, and Kenya are currently developing agreements to increase access to HIV medications, Maluwa says.

"They are looking at what legal framework would best advance that on a national level," she points out.

Censorship issues

- **HIV information censorship**

"I can't cite countries as examples of this censorship, but certainly the relationship between censorship of information and the failure to advance HIV programs, particularly prevention, is quite obvious," Maluwa says.

"Any kind of censorship on issues related to sexuality or sexual terminology makes it very difficult to implement prevention programs because you can't talk about how to prevent without talking about how it is sexually transmitted and how to put a condom on the penis," she says. "So one can see quite easily a correlation between censorship and failure to advance prevention."

- **Providing universal access to HIV treatment**

The first point of guideline six, which is about how states should develop and implement a national plan to progressively realize universal access to comprehensive treatment, care, and support for HIV patients, is a new component of the guidelines. It remains to be seen how well that is implemented around the world, Maluwa says.

"That would be quite a move if we see that guideline effective in a number of countries," she says.

"Very few countries have provided international access, so if we saw a system where 50% of the countries in the world have national plans on treatment that would be a massive contribution to ensuring equitable HIV-related care." ■

(Continued from page 138)

"Some treatment and harm reduction need to be offered," says **Michael C. Clatts**, PhD, medical anthropologist and an associate professor of public health in the Department of Sociomedical Science at Columbia University in New York City. Clatts also is the director of the Institute for International Research on Youth At Risk at the National Development Research Institutes in New York City.

"Current [substance abuse] treatment models don't have good efficacy and come at a big expense at a clinical level," he says. "They break people down and try to rebuild them."

For this reason, Clatts says he'd recommend putting a public health emphasis on harm reduction education. ■

Behavioral intervention for meth-using MSM

Researchers want to spread word

While there is no shortage of substance abuse treatment programs, it's rare that such interventions focus on the particular problems involving methamphetamine abuse. However, researchers at the Friends Health Center in Los Angeles have developed a program that targets the meth-abusing men who have sex with men (MSM) specifically, and the center is willing to share its intervention program with HIV clinicians and facilities.

The first step is to identify methamphetamine-abusing patients, and this isn't always evident, says **Steve Shoptaw**, PhD, a principal investigator with the Friends Research Institute.

The key is to look for elevated liver enzymes and other physical indicators that indicate a patient is abusing stimulants, Shoptaw says.

Then the clinician can talk with the patient about these results and use this opportunity to open a discussion. If the patient admits to using methamphetamine, the clinician could talk about how it affects the liver and the body's ability to move drugs, including HIV drugs, through the body, he suggests.

A next step would be to discuss substance-abuse treatment and to make a referral to a treatment program when the patient is willing.

The only drawback is that a typical substance-abuse treatment program may not specifically address methamphetamine use, which is why Shoptaw's team developed, with a grant from the National Institute on Drug Abuse, a program called "Behavioral Interventions for Methamphetamine Abusing Gay and Bisexual Men: A Treatment Manual Combining Relapse Prevention and HIV Risk-Reduction Interventions."

Here's an outline of how the program works:

• **Acknowledging a lack of control over crystal meth.** Divided into 48 sessions, the interventions begin by asking people with drug dependence to document their last "crystal runs" in a calendar by putting dots on days in which they did not use drugs and writing in the name of the drug on the days when they did use.

They also are asked to think about certain events and activities that triggered their drug use and to record which days they had sex.

The intervention acknowledges the powerful hold methamphetamine has on gay and bisexual men's lives through the use of a "Talking Wall," which was created in San Francisco for the purpose of giving men a place where they could write answers to the question: "Why do we love crystal so much?" This wall can be recreated on a smaller scale in an intervention session by having men write answers to this and other questions about crystal meth on paper panels.

A sexual behavior questionnaire is distributed in the third session, and a discussion is begun about sex after participants engage in an exercise that examines men's sexual tastes.

A fourth session asks men to think about what it means to be a gay or bisexual man and what part crystal meth plays in their lives.

• **Thinking about drug and alcohol abstinence.** Alcohol and marijuana use also are examined through questions about men's usage of these intoxicants. Session six asks participants to think about and list by hour their daily routines and discuss how these would change or become more boring if they were to abstain from using drugs. The seventh session examines drug abstinence and relapse and offers participants some basic principles to follow if they find they cannot totally abstain from drug use.

Participants are asked to write a letter to a fictional Aunt Tina, telling her about their crystal meth addiction and how it has affected their sexual lives and work and relationships. Participants' social webs are examined from the perspective of their drug use.

• **Talking about recovery.** Through anecdotal examples of men for whom crystal meth has

caused major social and work-related problems, sessions 10-16 discuss recovery, triggers for relapse, and reconstructing an individual's gay identify without crystal meth and party drugs.

These sessions ask participants to honestly discuss their drug use and its impact on others, and they cover the various stages of recovery, beginning with withdrawal and ending with resolution. Participants fill out a chart about how honest they can be with support members, and they complete checklists on what triggers crystal meth use.

• **Staying with recovery.** Sessions 17-22 offer participants some behavioral modification methods for handling thoughts about drugs and cravings. For example, one technique is to wear a rubber band around the wrist and snap it each time a drug thought occurs, countering the thought with a silent "No."

The connection between the stimulants and sex is further explored, and men are given exercises to help them think about developing a sexual life without drugs. Also, they are offered strategies for dealing with boredom and depression and unexpressed feelings that can trigger drug use.

• **Learning new social strategies and coping skills.** Since crystal meth use is so closely tied to social reinforcement, several sessions deal with life without that powerful reinforcer. Participants are given visual "social meters" to record how well they do socially without drugs, and they are asked to rate their progress in their career, friends, family, sexual behaviors, and other areas.

Sessions 25 and 27-30 discuss relapse justification, analysis, and offer coping strategies for preventing relapses. Session 26 offers a mental exercise on unloading the baggage of crystal meth.

• **Building new relationships and handling long-term recovery.** Sessions 31-48 provide exercises and discussions about building new and drug-free relationships and how to stay on the path of drug-addiction recovery.

For example, one chart on "Social Checkup" asks participants to think about the different things they'd like to do with friends during their recovery, including having dinner out, exercising, going on a date, etc.

Another exercise asks men to anticipate what their lives will be like in a year, including what their thoughts on drug use will be and how their sex life will be.

Session 34 provides strategies for coping with drug recovery one day at a time, and session 35 addresses how people in recovery often have powerful feelings that can become overwhelming due to losses in their lives.

Several sessions discuss positive thinking and how this can help to prevent relapse. An exercise includes having participants rate their level of confidence in their ability to accomplish treatment-related goals, and there are exercises on problem solving and goal-setting.

Session 38 discusses the red flag reminders that indicate something is not quite right, such as when a recovering person begins to isolate himself and sinks into negative thoughts. Strategies for continuing survival with recovery are offered, and participants are asked to listen to their self-talk about sex and recovery. For example, one question they are asked is: "When you think of having sex without drugs and alcohol, what messages come to you from your physical, emotional, and spiritual experiences? What feels safe, and what feels scary?"

Sessions 42 and 43 help participants look at what works in their new drug-free lives and how they can stay anchored in their recovery. And the final sessions discuss how addiction is a brain disease, the stages of recovery, and how participants can reinforce their own success through a checkup chart of how satisfied they are with various aspects of their lives and through a discussion of how much they have accomplished and what their confidence level is in continued success.

For example, participants are asked: "How supported do you feel in achieving your recovery goals? Are there any people who you still socialize with who try to pull you back to your old behaviors? Where can you meet people who will support you in your recovery?" ■

Pharmacy project assists with meds adherence

Structured PharmD involvement crucial

An adherence intervention created at the University of Buffalo (NY), School of Pharmacy and Pharmaceutical Sciences provides individualized care that appears to be a better way to keep HIV-infected patients on track with their medication regimens.

In one study that followed 25 patients who

received the adherence intervention, investigators found that this group, when compared with 38 patients who didn't go through the program, had significantly better viral outcomes, says **Lori Esch**, PharmD, clinical assistant professor at the University of Buffalo.

Both groups were similar at baseline, but the intervention group's 48-week data from the 16-week study showed viral loads that were undetectable in 84% of the participants. The comparison group had undetectable viral loads in 37% of patients, she says.

"So obviously there was a huge difference in the patients and how well they did once they were in the program," Esch says.

"A couple of reasons for the big differences, however, might have been that the standard care group included patients who didn't want their medications, but were put on medications anyway," she adds. "But if the intervention patients didn't want medications, they weren't put on the medications, and so that's one reason our numbers were better."

Also, the initial antiretroviral regimens were not standardized between the intervention and comparison groups, and that also may have given the intervention group an advantage, Esch explains.

"A couple of things that make our program so unique are that patients aren't automatically started on medications if they don't feel they are ready, and if they are ready, they're questioned about which medications they'd like to take," she says. "Those are two factors that make our outcomes better."

Esch describes how the program works:

- **Specially trained pharmacists meet with patients to discuss their disease.**

The first step in the program is patient education, and no patients are put on a drug regimen until they receive one-on-one education, she says. "Often, they come into the clinic after being newly diagnosed or referred, and they see the nurse for the first time to have their blood drawn. Then are they given their first referral to the pharmacy program to receive education."

Pharmacists, pharmacy residents, and nurse educators collaborate with physicians in treating HIV-infected patients, and pharmacists will educate patients about their disease before they have been prescribed antiretroviral medications, Esch says.

Physicians encourage patients to discuss medication questions with pharmacists.

Educators assess each patient's level of commitment and interest in his or her health. They help patients understand HIV terminology and the basic issues involved in being treated with antiretroviral medications, she explains.

Through this patient-provider dialogue, pharmacists learn more about the patient's lifestyle, concerns, and potential adherence barriers, such as issues with confidentiality, pill burden, pill time commitments, etc., Esch says.

"Maybe the patient only wants to take pills once a day and that's all he can handle, or maybe he can handle any side effect except diarrhea," she says. "So we figure out what medications the patient would be willing to commit to and how these medications would fit into the patient's life."

- **Patients make repeated visits until they're ready to begin with a medication program.**

A patient's second visit might occur the next day, in a week, or in a month, depending on whether the patient is ready to make a commitment to medications, Esch says.

The second visit might last 30 minutes after the patient has seen the physician, who has made the assessment that the patient probably would benefit from starting an antiretroviral regimen, based on the clinical picture.

When patients decide they are ready to start medications, the team works with them on selecting a time to start the drugs, because some patients might want to put off their drug regimen until after a vacation or a job change or some other life event, she says.

- **The team of providers comes up with a plan for the patient's treatment regimen.**

"This is somewhat a unique step where we're individualizing care rather than suggesting that all patients go on the same medications," Esch says. "We believe a high level of commitment is required to make these work and to not encourage the development of resistance through low drug levels."

Patients are included in the planning, and pharmacists work with physicians to select an optimal antiretroviral regimen for each patient. Physicians have been very open to the pharmacists' suggestions on which HIV medications might be best for a particular patient, she notes.

"Then we bring patients back to the clinic and go over the actual medications with them, showing them what the pills look like, how they should be stored, and what each side effect could be," Esch says.

Pharmacists also discuss how patients should handle side effects and give patients tools, such as beepers, charts with stickers, and alarm watches, to help them remember to take their medications and to fit the regimen into their daily activities, she says. "We talk about what medications to avoid when taking these drugs, and we talk about medication interactions with alcohol, drugs, and herbal remedies, and side effects," Esch says. "We tell them what would be unusual or severe and should be reported immediately, and we make it very clear to them that they can make that differentiation very clearly on their own at home."

- **Ongoing support is provided by the team.**

Generally, within three days of the patients' last visit with the pharmacist, the pharmacist will call the patients to see how they're doing with the regimen. "Usually that's when the patient has the most trouble remembering to take the pills and has difficulty getting the medication regimen into a daily routine," she notes. "We see if the patient has missed any doses or is experiencing any acute side effects."

Then patients are brought back in for a visit with the pharmacist two weeks into the new drug regimen. "We just go through the medications and make sure they're taking the ones they are supposed to be taking and talk with them about adherence, and make sure they can handle any problems," Esch says. "We provide intensive support over the first couple of weeks."

Patients typically will see the physician again four weeks after starting the drug regimen.

As part of the ongoing support, patients are given emergency telephone numbers to call whenever they need help. Also, nurse educators may visit patients, and social workers will be involved in assisting patients with any potential barriers, such as substance abuse issues, domestic violence problems, child care concerns, financial issues, and others, she says.

Although the University of Buffalo program is comprehensive and provider intensive, it can be duplicated in other settings, Esch says. "It's not an all or nothing approach," she says. "Every amount of education and individualization and support that's given to a patient is going to be useful."

While it's important to have a pharmacist involved, the pharmacy involvement could be on a consulting basis, and nurses could be used for the medication education component, and social workers could be more involved with adherence support, she says. "So I think any clinic can use their own resources to at least incorporate parts of this program, and even if they can't do 30-minute visits, they could at least get patients to make a commitment and provide ongoing support," Esch says.

(Editor's note: For more information about the adherence program, visit the university's web site at: www.hiv.buffalo.edu.*)* ■

FDA Notifications

FDA studies private sector patient information

The FDA has announced the findings from a 2001 study designed to assess the extent and usefulness of private sector prescription information patients receive when filling their prescriptions. Study results show approximately 89% of patients received written information about the drugs prescribed for them. The FDA commissioned the study to evaluate the adequacy of private sector prescription drug information given to patients. A federal goal is for 75% of patients obtaining new prescriptions by the year 2000 receive useful written information. The study, conducted by the National Association of Boards of Pharmacy to assess the receipt and usefulness of patient information, reveals that 89% of patients received written information. Although the 89% figure surpasses the goal of 75%, the overall usefulness of information provided, as measured by eight objective consensus-based criteria, was about 50%. The scores for individual criteria varied, with the highest scores (greater than 90%) showing that the information distributed was scientifically accurate, up to date, and nonpromotional. ▼

New treatment approved for chronic hepatitis B

The FDA has approved Hepsera (adefovir dipivoxil) tablets for the treatment of chronic hepatitis B in adults with evidence of active viral replication and either elevations in serum alanine aminotransferase (ALT) or aspartate aminotransferase (AST), or histologically active disease.

Chronic hepatitis B is a serious disease caused by a virus that attacks the liver. The virus, which is called hepatitis B virus (HBV), can cause lifelong infection, cirrhosis (scarring) of the liver, liver cancer, liver failure, and death. According to the Centers for Disease Control and Prevention, approximately 1.25 million Americans are chronically HBV-infected.

Hepsera slows the progression of chronic hepatitis B by interfering with viral replication and causing DNA chain termination after its incorporation into viral DNA.

The FDA said it based its approval of Hepsera on the results of two randomized, double-blind, placebo-controlled studies.

At week 48 of the studies, 53% of patients receiving Hepsera in one study and 64% of patients in the other study showed significant improvement in the liver inflammation caused by HBV compared to 25% and 35% of patients receiving placebo.

A statistically significant improvement in the degree of liver fibrosis (scarring) was observed in the patients who received Hepsera. Moreover, Hepsera has been shown to be effective in treating patients with clinical evidence of HBV that is resistant to another approved antiviral therapy called lamivudine.

The major adverse events associated with the use of Hepsera include severe, acute exacerbation of hepatitis B after discontinuation of Hepsera and kidney toxicity.

Patients who have discontinued other approved products for the treatment of chronic hepatitis B also have experienced severe, acute exacerbation of hepatitis.

This adverse event occurred in up to 25% of clinical trial participants after discontinuation of Hepsera. The labeling for Hepsera states that patients who discontinue Hepsera should be monitored at repeated intervals over a period of time for hepatic function.

Kidney toxicity was reported in patients at risk of or having underlying kidney dysfunction.

In addition, there is a theoretical concern associated with Hepsera that HIV resistance could emerge in chronic hepatitis B patients with unrecognized or untreated HIV infection.

Prior to initiating Hepsera therapy, HIV antibody testing should be offered to all patients. Hepsera (adefovir 10 mg) has not been shown to suppress HIV RNA in patients.

Gilead Sciences Inc., of Foster City, CA, is the sponsor of Hepsera. ■

CE/CME *questions*

17. Which explains why racial disparity exists for HIV treatment and care, according to research?
    A. Since Medicaid programs have a legal residency requirement, in some areas, Hispanics are enrolled in AIDS Drug Assistance Programs (ADAPs) in greater proportion than in Medicaid programs, even if they qualify for Medicaid and may not always receive the clinical services available to those on Medicaid.
    B. African-Americans are more likely to receive HIV care through Medicaid programs, which often limit access to antiretroviral drugs to those who have a disability or AIDS-defining illness, while low-income whites are more likely to receive their antiretroviral drugs through ADAPs upon an HIV diagnosis.
    C. At-risk African-Americans in some areas are suspicious of government programs and may be unwilling to be tested for HIV until they begin to have some AIDS symptoms.
    D. all of the above

18. Of the four states with large HIV-infected populations (CA, FL, NY, TX), which has a "model program" for increasing equal access to HIV services and treatment for all?
    A. California
    B. Florida
    C. New York
    D. Texas

19. New research involving HIV-infected men who have sex with men (MSM), who also abuse methamphetamine, has shown that one of the most important HIV prevention strategies is to target at-risk MSM who use club drugs with what?
    A. focused HIV prevention and condom education
    B. specialized methamphetamine drug treatment and recovery programs
    C. behavioral modification interventions aimed at increasing their safe sex practices
    D. none of the above

20. A study of an HIV medication adherence program intervention developed by University of Buffalo (NY) researchers has found that an effective adherence program should include having clients meet one on one with which clinical discipline?
    A. pharmacist
    B. nurse practitioner
    C. social worker
    D. case manager

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CE objectives

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

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