AIDS ALERT

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AIDS directors seek help to fight epidemic in the South

Call to action for more money, resources, research

As HIV continues to spread faster in the South than in any other region, health officials from 13 states are sending out a strong message: The South needs help fighting an epidemic that is becoming increasingly rural, female, African-American, and poor.

"The South is in desperate straits now, and the disparity is so great that if we don't act now, it's going to be that much harder to catch up," says **Evelyn Foust**, MPH, director of HIV control for North Carolina in Raleigh.

Foust and AIDS directors from 12 other states have documented the growing problem in a 34-page document titled *Southern States Manifesto; HIV/AIDS & STDs in the South: A Call to Action.* In April, the manifesto will be sent to AIDS directors across the country, as well as to key federal and state public health partners, including the Centers for Disease Control and Prevention (CDC) and the Human Resources and Services Administration.

Endorsed by the National Association of State and Territorial AIDS Directors, the report is unusual in that it advocates special assistance for a region itself rather than for a specific population or risk group.

"When we met in Nashville, [TN] last summer, we were astounded at how much we had in common," Foust said. "There are strength in numbers

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AIDS Alert International

COMING IN FUTURE ISSUES

- HIV testing results: A new protocol for routine HIV testing can increase testing yield in urgent care centers
- Update on the search for an effective vaccine
- ADAPs faltering in some states: Long waiting lists, restrictions, and other problems cited as result of cash-poor state governments, less federal money available

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Editor: **Melinda Young**, (864) 241-4449.
Vice President/Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@ahcpub.com).
Editorial Group Head: **Glen Harris**, (404) 262-5461, (glen.harris@ahcpub.com).
Managing Editor: **Robin Mason**, (404) 262-5517, (robin.mason@ahcpub.com).
Senior Production Editor: **Ann Duncan**.

Editorial Questions

For questions or comments, call **Melinda Young** at (864) 241-4449.

and hopefully this says to our federal partners we are serious about this and more needs to be done."

Poverty is not unique to the South, but as the report points out, the region shares several characteristics that make it prone to the epidemics, particularly as the HIV profile has increasingly become rural, African-American, and female. **(See related story on AIDS in rural South, below.)**

In November, the Kaiser Family Foundation, based in Menlo Park, CA, sponsored a regional summit focusing on the STD / HIV epidemic in the South.

It released a report showing that the South has a greater proportion of people living with AIDS than any other U.S. regions and the proportion been steadily increasing.

High rates of trauma, distrust in rural HIV-positives

Chronic violence and abuse, often stemming from childhood neglect, are pervasive among HIV-positive people living in the rural South, according to two new studies. The findings suggest that clinicians need to address a host of interpersonal issues, ranging from sexual abuse to post-traumatic stress syndrome.

"These are often people who have survived. As one patient puts it, 'HIV is just icing on the cake of a terrible life,'" says **Kathryn Whetten-Goldstein**, PhD, MPH, director of the Health Inequalities Program at Duke University in Durham, NC, and author of *You're the First One I've told: New Faces of HIV in the South.*

Her book chronicles in rich detail the plight of 25 patients, all of whom reported histories of physical or sexual abuse, violence, and stress so chronic that it resembles post-traumatic stress syndrome.

Whetten-Goldstein also is principal investigator of an National Institutes of Health-funded study — Coping with HIV in the Southeast (CHASE) — that has enrolled more than 900 people living with HIV in six Southern states. One goal of the study is to identify unique characteristics of Southern rural life that make it responsible for such high rates of sexually transmitted diseases (STDs), low birth weight, teen pregnancy, and other health indicators. Similar efforts are part of the North Carolina Services Integration Project, which has been collaborating with state medical and social service providers to create a sustainable and replicable model of integrated care for HIV-positive, geographically dispersed residents.[1]

"What we realized in trying to implement the different demonstration projects was that we really needed to go back to ground zero, and that is when we went back to case study methodology," she says.

While other studies have shown high rates of depression, violence, and suicide in the rural poor, Whetten-Goldstein's in-depth interviews showed how childhood histories were powerful predictors of behaviors and attitudes. One-third (33%) of the participants reported a history of substance abuse, while 70% reported symptoms of mental illness.

Collectively, more than 160 incidences of abuse were identified among the 25 patients. Stigma and racism, coupled with the South's strong social hierarchy, has lead to a distrust for the medical profession that still thrives among the rural poor today.

"They don't trust the system and feel on a basic level they need to figure things out for themselves," Whetten-Goldstein says. The clinical implications of these findings are not insignificant. For example, each of the participants had gone off their HIV medications at one time or another. "If their medications are not working, they are not going to call their providers and say they are feeling sick. They are just going to quit," she says.

The CHASE study now has preliminary results from more than 50% of the participants, half of whom live below the poverty level. The results support findings from her book. They include:

- 100% believed information about AIDS was being withheld from them.
- 50% were not sure if the government had created HIV to kill minorities.
- 50% of women had experienced phobias.
- 43% had witnessed someone seriously injured or killed.
- 25% had been attacked with the intent to kill.
- 17% had a family member killed during a crime.
- 10% had been placed in foster care.

Those factors help explain the fatalism and denial that is driving STD and HIV transmission rates in rural areas of the country. Indeed, a new study of rural HIV-infected patients found that more than half had engaged in unprotected sex — one third of whom reported that their partners were HIV-negative.[2]

Such findings have even greater implications for the South, particularly in the Bible Belt, where comprehensive sexual health education has been denied to many students. "It's not just that we have a lot of people in rural areas," Whetten-Goldstein says. "There is something else happening that we need to figure out."

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1. Nguyen TQ, Whetten K. Is anybody out there? Integrating HIV services in rural regions. *Public Health Rep* 2003; 118(1):3-9.

2. Heckman T, Silverthorn M, Waltje A, et al. HIV transmission risk practices in rural persons living with HIV disease. *Sex Transm Dis* 2003; 30:134-136. ■

The estimated number of new AIDS cases in the South increased between 2000 and 2001, while other regions experienced declines or relatively stable levels. Eighteen of the top 25 U.S. communities hardest hit by the HIV / AIDS epidemic are in Southern states, according to Kaiser Family Foundation data. In addition to HIV, the South also has the highest case rates for syphilis, chlamydia, and gonorrhea in the nation.

"The HIV / AIDS epidemic remains a critical health concern for the U.S. as a whole, but is especially troubling for the Southern region," says **Drew E. Altman**, PhD, president and CEO of the Kaiser Family Foundation.

In North Carolina, more than 1,200 new HIV / AIDS cases were reported from 2000 to 2002, with nearly half diagnosed only after developing AIDS, Foust notes. More than 70% of the new infections are in African-Americans.

Indeed, some North Carolina counties report HIV infection rates of 3% in African-American males. "This is a percentage we consider a tipping point, where looking internationally, you see the disease is probably going to take off and be worse in coming years," says **Kathryn Whetten-Goldstein**, PhD, assistant professor of public policy at Duke University in Durham, NC.

The persistently high rate of other STDs in the South is a major factor in the growing spread of HIV. Foust notes that genital ulcer diseases, such as herpes and syphilis, can pose a three- to five-fold increased risk of HIV transmission.

In 2001, the South continued to have a higher rate of syphilis than any other region of the country, accounting for 56% of reported cases. North Carolina ranks seventh in syphilis rates, and Robeson County now has the highest rate in the country. As with HIV, more than 70% of syphilis cases are in African-Americans, Foust says.

Another factor is the high rate of poverty (eight of the top 10 states having the highest population living below the poverty level are in the South). With poverty come its attendant problems, such as high uninsurance rates, less access to quality care, and lack of education about health issues.

Medicaid eligibility requirements also tend to be less advantageous in the South, the result being that many poor Southerners have no means to afford treatment and care, says Foust. Even if they did, the health care infrastructure is spread so thinly throughout large rural areas that access is a huge barrier. In Albany, GA, for example, one HIV clinic services 14 counties, forcing some patients to drive three hours one way.

"I consider it a terrible public health failure that we cannot guarantee that everyone infected with HIV gets access to medication," Foust says.

The unique history of the South, coupled with the history of the AIDS epidemic, has almost assured that infections would increase. For the first years of the epidemic, the South largely was

Facts: HIV/AIDS in the South

A background report prepared by the Kaiser Family Foundation for its recent Southern States Summit on HIV/AIDS and STDs, includes these facts:

- ✔ At of the end of 2001, the South had the greatest number of people estimated to be living with AIDS (AIDS prevalence) in the United States. While due in part to the fact that the South has the largest population size of all regions in the U.S., AIDS has had a disproportionate impact in the South. While the South represents a little more than one-third of the U.S. population (36%), it accounts for 46% of the estimated number of new AIDS cases.
- ✔ The impact of AIDS in the South may be increasing. The South represents a growing share of people estimated to be living with AIDS in the nation, rising from 35% in 1993 to 40% in 2001. By comparison, AIDS prevalence as a proportion of overall prevalence in the Northeast, West, and Midwest regions of the country either decreased over this same period or remained constant.
- ✔ While the estimated number of new AIDS cases in the U.S remained relatively stable between 2000 and 2001 (increasing by 1%), estimated AIDS incidence in the South increased by 9%. Incidence decreased in the Northeast (-8%) and West (-4%) and increased slightly in the Midwest (2%) between 2000 and 2001.
- ✔ The South has the second-highest AIDS case rate per 100,000 in the nation (18.2 in 2001). The Northeast has the highest AIDS case rate (23.5). Seven of the states with the 10 highest AIDS case rates in the nation are in the South.
- ✔ The South has the greatest number of people estimated to be living with AIDS in the nation (when compared to the Northeast, West, and Midwest).

(Editor's note: More highlights of the Kaiser Family Foundation's Summit can be found found at: www.kaisernetwork.org/healthcast/kff/14nov02.)

Source: Kaiser Family Foundation. Southern Summit report. Menlo Park, CA; November 2002.

AIDS Cases by Region and Population Area, 2001

Region	MSA 500,000	MSA <500,000	Nonmetro
Northeast	11,444	680	298
Midwest	3,004	520	361
South	13,610	2,616	2,104
West	5,834	447	222

Source: Centers for Disease Control and Prevention, Atlanta; 2002.

ignored as funds and resources were focused in big cities on the East and West coasts.

Also, there has been little advocacy for poor, disenfranchised African-Americans to call attention to their needs. Consequently, HIV-infected patients in the South receive nearly $500 less in Ryan White funding than for the rest of the country, according to the report.

"Some of what all this means is that new dollars are needed for the South," Foust says.

It also means that the time has come for researchers and public health officials to devote more effort to determine what is driving the epidemics in the South and to develop interventions that are specific to its population.

"I don't want the South to get lost in one of the topics discussed at a national conference," Foust says. "I want a discussion with the highest leadership at the CDC to say, 'Lets see what we can do to solve this problem.'" ■

New testing strategy to help track HIV

Detuned testing initiated at 24 sentinel sites

The Centers for Disease Control and Prevention (CDC) is moving quickly to monitor HIV incidence across the country using its "detuned" testing technology, with nearly $6 million this year committed to 24 sentinel cities.

And while the CDC's test doesn't meet Food and Drug Administration (FDA) criteria for use as a clinical test, the private sector is showing increased interest in the potential market for a commercial test, particularly in developing countries.

"This initiative is the single most important new direction for the CDC," says **Ward Cates**, MD, MPH, president of Family Health International in Research Triangle Park, NC, and a CDC advisor. "We have to know where the incidence is going and the sooner we can drive resources from measuring old infections to new infections, the better off we will be."

With the advent of highly active antiretroviral therapy, CDC surveillance has lost its edge in following the HIV epidemic as the time gap between HIV infection and progression to AIDS has grown increasingly wide. While HIV reporting is required in most states, some of the most populous states still report only AIDS cases, giving the CDC an incomplete picture of trends in new infections.

To solve that problem, the CDC created the Serological Testing Algorithm for Recent HIV Seroconversion or STARHS. The algorithm is based on the simple idea that antibodies to HIV rise through the period of infection. The "detuned" test allows researchers to identify newly infected people — within four to six months — with a fairly high degree of sensitivity.

Developed several years ago, the detuned assay has been used in small cohort studies, most notably the Young Men's Survey, which found high rates of new infections, particularly in African-American males who have sex with males. Since 2001, the CDC has been working to make STARHS its strategy for monitoring HIV incidence across the country.

After numerous consultations, the CDC funded five demonstration sites to develop protocols and explore methodologies for integrating the detuned technology into HIV surveillance activities. The technical issues are complex and involve not only testing specimens but collecting data on testing histories. To enable statisticians to estimate HIV incidence in the general population, information is needed on how often people are tested for HIV.

"We need a statistical system based on how frequently people are tested in order to come up with viable estimates," says **Matthew McKenna**, MD, director of the CDC's HIV Incidence and Case Surveillance Branch.

The 24 sites were selected based on having HIV reporting in place prior to January 2001 and having greater than 300 AIDS cases per year. Setting up STARHS in all 50 states would be too expensive, McKenna adds.

From input gathered from the sites, it has become clear that flexibility is important, as "different places will want to do this in different ways," he says.

The CDC test, which is sensitive only to HIV-1

subtype B, could be a useful tool for U.S. clinicians. However, diagnostic companies don't see a large enough market in this country. "We don't know of any manufacturer who is going to step up to the plate and do all the necessary studies and paperwork to satisfy FDA approval for clinical use," McKenna says.

However, several tests are being developed that capture other subtypes and would have broader applications. One test looks at specific antibody isotopes instead of just antibodies alone. "The interest has become so intense, not so much in the United States but globally, that we are optimistic some manufacturers may be interested in it," he adds.

Several consent issues surrounding STARHS must be worked out. One of the more sticky ones is whether results from detuned testing can be given back to patients.

The testing program is considered a non-research activity. While knowing when a patient was infected could have clinical value, especially for treatment considerations, providing that information would put the program into the "research" category.

"Right now the FDA is adamant that giving back test results constitutes research, and that would mean setting up IRBs [institutional review boards] and getting consent," McKenna explained.

The IRB process ensures the protection of human subjects in CDC research.

The CDC officially defines research as "a systematic investigation, including research development, testing, and evaluation, designed to contribute to generalizable knowledge." ■

Syphilis role in HIV being studied in California

STD and HIV surveillance working together

For the past three years, syphilis outbreaks in men who have sex with men (MSM) have worried health officials because of what they indicate about a resurgence in high-risk behaviors. But are these syphilis outbreaks facilitating HIV transmission or is syphilis contained mostly to MSM who are already HIV-positive?

California's sexually transmitted disease (STD) and HIV health officials hope to answer that question with assistance from the Centers for Disease Control and Prevention (CDC) and its new detuned testing technology.

"We need to get some better information quickly, and so we are combining our HIV and STD efforts to find the answer," says **Gail Bolan**, MD, the state's director of STD control.

In March, the state requested the Centers for Disease Control and Prevention (CDC) to conduct an Epidemic Intelligence Service (EIS) investigation, also known as an Epi Aid, which can quickly mobilize resources for a health problem that needs immediate attention. The CDC will be providing two EIS officers, while the state's existing EIS officer will help coordinate the effort.

Just how much STDs contribute biologically to facilitating HIV transmission is an ongoing debate. Three years after large studies in Africa attempted to quantify the impact, the results have been inconclusive. Most recently, an analysis of a study in Uganda concluded that STD control has a minimal impact in an already mature HIV epidemic. While it's clear the United State's syphilis epidemic is starting a new cycle, the HIV epidemic is harder to qualify, Bolan says.

In the United States, CDC behavioral surveillance suggests so far that the syphilis outbreaks haven't facilitated HIV transmission in MSM because many men appear to be engaging in "sexual positioning" (HIV-positive men having sex with other positive men).

But information from syphilis partner notification interviews suggests differently, Bolan says. "Our data really don't support that. We talk to a lot of men who claim they are having a lot of sex with partners of unknown status. So we really need to know what is going on here."

Until now, this kind of research hasn't been easy. First, controlling for behaviors is notoriously difficult. Second, it's hard to always know which infection came first: syphilis or HIV. With detuned testing of specimens, however, the time of HIV infection can be pinpointed more precisely.

The easiest way to measure the syphilis impact on HIV transmission is to conduct HIV testing in a cohort of MSM recently infected with primary syphilis, Bolan says.

"That would tell you if the infection was more likely related to an ulcer," she explains. "You could then compare the results with people who are not infected with primary syphilis but who have similar behaviors."

California's collaborative effort could be a model for other areas of the country where

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U.S. AIDS funding is smoke and mirrors, critics charge

Distribution could take more than a year

When President George W. Bush announced at his January State of the Union address that he would provide a five-year, $15 billion Emergency Plan for AIDS Relief worldwide, his efforts were lauded internationally.

However, when the fiscal year 2004 budget proposal was released later, AIDS activists called the Bush plan a funding shell game that shifts money from domestic areas to international programs.

"When the president spoke and released his proposal this was bombastic news — an enormous amount of funds dedicated for the pandemic," says **Ana Oliveira**, executive director of the Gay Men's Health Crisis (GMHC) in New York City. "We were all very happy and surprised," she says.

But the good news didn't last long. Several problems quickly emerged, including how the money will be distributed — over a five-year period — and how long it will take people suffering from the epidemic to benefit from the funding, Oliveira says.

The $15 billion is a five-year initiative that will help the most afflicted countries in Africa and the Caribbean, according to the Office of National AIDS Policy in Washington, DC.

Countries that will be the focus of the initiative include Botswana, Cote d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, and Zambia.

The United States proposes working with private groups within these countries to create a comprehensive system for diagnosing, preventing, and treating AIDS.

The Office of National AIDS Policy issued a statement, which said the money will help improve health care infrastructures, including laboratories, specialized doctors and nurses, and satellite clinics; and it will provide antiretroviral drugs and education on prevention of the disease.

"By truck and motorcycle, nurses and local healers will reach the farthest villages and farms to test for the disease and to deliver lifesaving drugs," said the statement issued by the Office of National AIDS Policy.

Also, the initiative's goals are to prevent 7 million new infections, provide antiretroviral drugs to 2 million HIV-infected people, and help care for 10 million HIV-infected individuals and AIDS orphans. The first $2 billion in funding would be distributed in fiscal year 2004.

Redundant structure

But critics charge that the United States has created a large cumbersome vehicle for distributing international AIDS funds, when a much faster and more efficient vehicle already exists: the Global Fund to Fight AIDS, Tuberculosis and Malaria, based in Geneva.

The whole idea of the Global Fund was to create a vehicle for quickly distributing AIDS money. The Bush proposal, alternatively, will require congressional approval and then another 18 months minimum to work its way through federal bureaucracies, Oliveira says.

"The distribution of these funds over five years is a method that connects the funding for AIDS with governments that the U.S. is friendly with and supports," she says. "The government that the U.S. does not have direct contact or a relationship or is friendly with is not getting this aid."

Distributing a large sum of money in this fashion could destabilize certain regions, Oliveira contends.

"Take sub-Saharan Africa, for example," she says. "Small resources would go to one country, let's say, and the country surrounding it wouldn't necessarily get those resources."

For instance, Zimbabwe is not on the Bush administration's list, although that nation is surrounded on three sides by countries that are on the list, and its own AIDS epidemic affects one in three adults, with more than 2.3 million children and adults living with HIV / AIDS. The epidemic has caused more than 200,000 deaths and has resulted in nearly 800,000 orphans, according to the most recent UNAIDS data.

Zimbabwe is saddled with an internationally unpopular leader, President Robert Mugabe, who caused an exodus of white farmers in the past few years and rigged the 2002 presidential election, according to the *2002 Central Intelligence Agency (CIA) World Factbook*.

Other sub-Saharan nations could be excluded from receiving U.S. funds as well, including Zambia, Angola, Somalia, Malawi, and the Republic of Congo.

Threatening explosion

The proposed $15 billion also would not help nations with struggling economies in Eastern Europe, where the HIV epidemic is exploding, or in India and China where potential for a pandemic exists without powerful prevention efforts.

More than 100 physicians and other health care professionals in the United States wrote Bush on Jan. 22, 2003, urging a sensible approach to funding HIV / AIDS programs internationally. The letter stated, "When you took office, experts grossly underestimated how quickly the pandemic would spread. Now we know that the disease threatens to explode in the world's most populous nations: 50 to 75 million people could be infected by 2010 in China, India, Russia, Nigeria, and Ethiopia; and it continues to reach record levels in Southern Africa."

An unequal distribution of AIDS money could result in problems in immigration, networks, and destabilization, Oliveira says.

Had the same money been placed in the Global Fund, it would have been distributed to those in need who applied through grants, and it would have been free of bureaucratic red tape and political favoritism obstacles, she explains.

"The Bush administration is not being a team player with other nations to collectively resolve this enormous plague," Oliveira says. "It's a plague that requires global humanity response."

Other AIDS groups also criticize the administration for not putting the $15 billion in the global AIDS fund, where it could be used quickly and fairly to ease suffering and increase prevention efforts.

"The president's budget included almost nothing for the Global Fund to Fight AIDS, TB, and Malaria," says **Paul Davis**, director of U.S. governmental relations for Health GAP Coalition in Philadelphia.

"He pledges $200 million a year for the next five years, and the fund needs $1.8 billion by 2004, or else it will be bankrupt and not able to fund a new round of grants coming later this year," he says. "The president is putting chump change for the Global Fund, but giving money to a bilateral initiative."

AIDS activists want the United States to donate an additional $10 billion to the Global Fund, but that is an unrealistic expectation, Davis says. Meantime, the Global Fund is struggling to fund the grants already approved, he adds.

Richard Feachem, MD, executive director of the Global Fund, told the fund's board on Jan. 29 in Geneva, that while the Global Fund was fully funded through a second round of grant applications, it had no funding for the third round.

Since the fund's policy was to cover grant agreements by cash and this pertains to the first two years of each five-year program, then the fund will run out of money, Feachem told the board.

"The Global Fund needs $6.4 billion in 2003 and 2004; so far, we have $1.2 billion pledged," he said in his speech. "Eighty percent of our fundraising is ahead of us."

The world's wealthiest nations must step forward to support the fund, Feachem said. "In this context, we are pleased to hear President Bush's commitment . . . to the fight against HIV / AIDS and to the undertaking to provide additional funds to the tune of $1 billion to the Global Fund beginning in 2004."

Gag rules, etc.

The Bush administration appears to be intent on keeping control over how most of the international AIDS money is spent and to whom it is distributed, Davis and Oliveira say.

For example, there are policy attachments to the international funding, such as gag rules prohibiting the money from going to organizations or clinics that include a mention of abortion in reproduction counseling, even if the U.S. money doesn't fund that specific educational activity. The Bush administration also seeks to promote

abstinence education when that is a poor HIV prevention strategy, Oliveira says.

"The money is attached to many policies detrimental to HIV prevention," she says.

"So on the global scene, the money is not that much money; it's spread over a significant period of time, and it's encumbered with restrictions," Oliveira says. "The money is strategically connected to alliances of the United States, and it will create instabilities."

President Bush's proposal for increased funding for international AIDS initiatives may give the appearance of an administration that is friendly to AIDS causes, but this view is belied by the FY 2004 budget numbers, says **Scott Brawley**, director of public policy at AIDS Action in Washington, DC.

Funding offsets

While there is a $50 million increase in proposed spending for global HIV / AIDS programs in the FY 2004 budget, that increase partially is offset by a proposed $858,000 decrease in HIV money targeted for the Centers of Disease Control and Prevention in Atlanta, and cuts in programs targeting sexually transmitted diseases, and tuberculosis.

"We certainly recognize that the United States has to be part of a global response to HIV / AIDS; however, we're concerned that domestic programs are being cut for HIV prevention, especially in a time when we have seen rising infections and rising STD infections," Brawley points out.

The Bush administration previously set a goal of a 50% reduction in new HIV infections in the United States by 2006.

"If you are taking away money to do prevention activities or not adding new money, then you're shooting in the dark on this plan," Brawley says.

"And so the message is that the federal government is saying, 'We have this very lofty goal, but we're not funding it,'" he adds.

Another problem with the FY 2004 budget's immediate increase in international HIV funding is that there is no way to know how it will be spent and where it will be sent, he says.

"We have heard that the $50 million primarily will be sent to programs unilaterally, directly to programs or governments," Brawley notes. "So the administration is trying to hand-select the places where they want this money to go to." ■

High-income countries see increase in epidemic

Italy sees increase in sexual transmission

The HIV / AIDS epidemic has grown to include about 1.6 million people who live in high-income countries, including the estimated 76,000 people who became infected with the virus in 2002.

Unlike the majority of the 42 million people infected worldwide, this small subset of people infected with HIV has access to the antiretroviral treatment.

However, this advantage has not stopped the epidemic from spreading to populations within high-income countries that largely were unaffected by the epidemic 20 years ago.

Italy's HIV / AIDS epidemic's shift from an injection-drug-using population to transmission through heterosexual intercourse is one good example of this trend.

UNAIDS of Geneva reports that complacency among people at risk and lackluster prevention efforts have led to increases in HIV transmission among heterosexuals. Between 1997 and 2001, the proportion of new HIV diagnoses occurring through heterosexual intercourse increased by 57%, according to UNAIDS.

In the United Kingdom, the number of new HIV infections resulting from heterosexual transmission increased from 33% in 1998 to more than 50% in 2001, UNAIDS states.

Frightening data

The data showing HIV increasing among heterosexuals and women are frightening, says **Ingrid Kloet**, a board member of the Global Network of People Living with HIV / AIDS (GNP+) in Amsterdam, The Netherlands.

In the United States between July 2000 and June 2001, for instance, the bulk of new HIV infections among youths (ages 13-39) were among females, according to data from 34 cities and regions reported to the Centers for Disease Control and Prevention of Atlanta.

Sexual transmission, especially among heterosexuals, has accounted for a much greater proportion of new HIV infections in Italy in recent years, says **Giovanni Rezza**, MD, director of AIDS and STD Unit, Lab of Epidemiology,

Insituto Superiore di Sanita in Rome.

"Let's say, 10 years ago, about 80% of cases were among drug users and less than 10% among heterosexuals," he says. "Now it's the opposite: less than 20% are injection drug users, and more than 80% are due to sexual contact."

Male-to-male sexual contact probably amounts to about 15% of that total, Rezza adds.

The first phase of the epidemic in Italy was sustained by transmission among injection-drug users, he says.

"It was the same pattern as in Spain of a big epidemic among drug users and low [transmission] among homosexual men," Rezza explains. "Now the situation is changing as most injection drug users are heroin users, and the epidemic of heroin use is going down."

Most transmissions are sexual

Plus, there are fewer heroin users among Italy's youth, who use other drugs, such as ecstasy, he adds. So now most of Italy's new HIV cases are attributable to sexual transmission, both man to man and heterosexual, Rezza says.

"We have had a recent phenomenon of increased cases of syphilis, both primary and secondary syphilis. These increases have been reported especially among homosexual men, and there is a high proportion of cases diagnosed among HIV-infected people who are under highly aggressive antiretroviral treatment," he says.

Since the epidemic has shifted from the injection drug population to a heterosexual population, there also has been a shift in the median age of those infected. Unlike the trend reported in other high-income countries of the epidemic increasing among youths, in Italy the opposite has occurred, Rezza says.

"The median age of people affected by AIDS is increasing. And the median age of people who are being diagnosed with new infection is increasing," he adds. The explanation for this phenomenon is that the epidemic largely affected youths in the late 1980's and early 1990's when it was spread primarily through injection drug users, who mainly were in the 20- to 30-year-old range, he continues.

"Now the epidemic is through sexual transmission, and it affects all of the sexually active age classes, so it's not only the young generation," Rezza says.

When the epidemic was limited primarily to one population it was easier to target prevention, testing, and treatment. However, Italy's health officials now have to cope with several new obstacles to reducing new infection rates.

Despite the nation's national health system which provides free access to HIV testing and treatment, there has been a surprising increase in the proportion of people diagnosed with AIDS who did not know they were infected with HIV before developing AIDS symptoms, Rezza says.

Most of the people who arrive late for treatment are those who were infected through sexual transmission, he adds. "I'm not surprised by heterosexual cases because they have a low perception of risk because they are not homosexuals or injection-drug users. But it's surprising that a large proportion of cases diagnosed with AIDS among homosexual men did not get treatment before their diagnosis."

Change in perception

Early in the epidemic's history in Italy, homosexual men were active in HIV testing and in finding out their diagnosis, and drug users typically were identified early as well, Rezza says.

So among the populations at risk for HIV, there apparently is a change in perception about HIV infection, and this means the Italian government has some work to do with regard to HIV education and intervention, he says.

"We are thinking we need to give information again [to at risk groups] or at least try to raise the risk perception among the general population who are at risk for sexual transmission of HIV," Rezza says.

"I think the information-level is not bad, but the problem is it seems these people have not seen their friends die from AIDS, and so are removed from the risk of HIV," he explains.

To better address this perception problem, Italy has launched a new information campaign targeting the general population, in conjunction with smaller campaigns aimed at special groups, including youths and foreigners, he explains. "Special attention is given to particular media used by young people, like MTV, for example."

Also, Italy's minister of education has begun to distribute a leaflet with AIDS information directed toward youths.

While some critics of the educational campaign say it doesn't provide direct information about condom use, the government's plan is to assess the success of this particular campaign and then make changes if needed, Rezza says. ■

(Continued from page 58)

syphilis and HIV coexist. "We hope the model we use in California can be a model the South can use to prove to the CDC that syphilis has really contributed to HIV," Bolan notes. "They want hard data, and this can help get some information fairly quickly."

So far, traditional syphilis control efforts have not been able to quell the outbreaks, which continue to spread into other communities.

"Unless there is a collective approach between HIV and STD prevention, it's going to be hard for STD control to do it alone," she says. "We can use our control, but we really need some new innovative strategies," she says. The state could have preliminary results by this summer, Bolan adds. ■

CDC ramps up HIV behavioral surveillance

Data collection begins this summer in 15 cities

Ask public health officials what behaviors are driving the recent syphilis epidemics, and their answers are limited at best. That may change in the next year as the Centers for Disease Control and Prevention (CDC) implements behavioral surveillance systems in 15 cities across the country.

"We don't have a good surveillance system in place to know what have been the trends in common over time," says **Matthew McKenna**, MD, director of the CDC's HIV Incidence and Case Surveillance Branch. "Nor do we have a good system that allows us to tie together whether persons are being influenced by prevention programs."

Although the CDC has supported various data collection efforts on behavior, including surveys at HIV testing sites, the scope was limited and didn't provide ongoing data. This new initiative, which received $5.8 million in federal funds this year, will focus on setting up sustainable systems with standardized methods of sampling. The strategy includes developing formative research with community groups, identifying community members who can develop sampling frames, such as venue-based and "snowball" sampling, and developing standardized questionnaires.

"We plan to be in these areas for years to come," McKenna says.

Six of the 15 sites have been conducting the Serological Testing Algorithm for Recent HIV Seroconversion research, as well, and those studies have found high rates of new HIV infections among young men who have sex with men (MSM). The CDC plans to repeat the methodology of those studies and try to better identify the behaviors responsible for infections.

The first year of the project will focus on injection drug users and MSM, and then expand to high-risk heterosexual populations.

Better behavioral surveillance is critical to making best use of prevention resources, he says. Data from the sites, for example, would help public health officials get a handle on which behaviors are responsible for syphilis outbreaks and whether they are also responsible for increasing rates of HIV transmission.

Public health officials welcome the added investment in behavioral surveillance but question whether more can't be done with existing HIV prevention programs. One public health advisor suggested that HIV programs could sample HIV cases and collect behavioral data in face-to-face interviews similar to what is done with syphilis programs. ■

Coalition seeks funds for HCV/HIV co-infection

Integrating services makes economic, medical sense

After years of neglect, efforts are building to form a coalition that will draw more attention to the treatment and care needs of patients co-infected with HIV and hepatitis C virus (HCV). And while federal and state funding for HCV has remained flat or is being cut, health experts say integrating services is not as demanding as is often assumed.

The National AIDS Treatment Advocacy Project (NATAP) in New York City is in the initial stages of organizing a national coalition to promote awareness of HCV/HIV co-infection, which began with a legislative briefing in late March that touched on lack of funding for national programs, the disproportionate co-infection rates among minorities, and barriers to treatment and care.

"We are tying to bring the issues onto the table that co-infected patients deal with, because a lot of the public is not aware of the problems," says **Nadia Cohen**, NATAP spokeswoman.

An estimated 4 million Americans are infected

with HCV. Among HIV-infected persons, studies indicate that up to 40% also are infected with HCV, increasing to 60% to 90% among injection drug users. Moreover, liver diseases associated with HCV have become the leading cause of death in HIV-positive patients.

Hepatitis B virus (HBV) also has re-emerged as a growing problem in HIV-positive people. A prevalence study presented at the 10th Conference on Retroviruses and Opportunistic Infections in Boston, found that 65% of 240 patients enrolled in the AIDS drug treatment study either had past or active infection with HBV. [1]

Despite the medical and financial burden of co-infection, NATAP faces an uphill battle in its efforts to increase funding. HCV funding for the National Institutes of Health has remained fairly flat, with $95 million earmarked in 2002, $104 million projected for 2003, and $108 million for 2004. The Centers for Disease Control and Prevention (CDC) budgeted only $21 million for HCV last year.

Short of the resource question, there are few arguments for not integrating viral hepatitis services into HIV clinics, say public health officials. Yet for various reasons, including uncertainty of demand and the need to retrain staff, integrating viral hepatitis services is a public health goal that most clinics haven't embraced, public health officials tell *AIDS Alert*.

"A one-stop shop for putting services together for viral hepatitis and HIV is good public health and the way things ought to be," says **Steve Jones**, MD, associate director of science for the CDC's Division of HIV/AIDS Prevention. "I'd even say it's bad public health not to do it."

Texas program integrates testing

While most states lack hepatitis plans, some have become models for how HCV screening can be incorporating into existing HIV prevention programs. Benefiting from a strong advocacy response at the grass-roots level, coupled with background information provided by the state health department, Texas has been offering HCV screening at its HIV counseling and testing sites for the past three years. In 2000, the state legislature approved nearly $3 million to conduct seroprevalence studies, establish education programs, and integrate hepatitis screening into its 72 HIV counseling and testing sites, which test about 140,000 people each year. The appropriation came despite flat funding for other public health programs.

The Texas Department of Health's push for HCV screening followed a federal retrospective HCV study of blood donors in the early 1990s. That effort identified the need for a more broad-based, practical approach to hepatitis prevention. The health department published a white paper on HCV and helped establish a working group of public health agencies and community-based organizations.

Educating key legislators and promoting strong community advocacy were crucial to getting the bill passed, state health officials say.

"The overall lesson has been that it makes a lot of sense — not just fiscal but programmatic — to offer both HCV and HIV screening simultaneously," says **Felip Rocha**, MSW, acting AIDS director for the Texas Department of Health in Austin. "You have the person in front of you, so you might as well serve them as comprehensively as possible."

The funding has been a good first step but hardly adequate for offering HCV services at all the state's HIV counseling and testing sites. This year, $750,000 was earmarked for testing, which allowed only 21 sites — those with a high population of injection drug users — to offer testing, he says.

One of the biggest challenges has been allocating resources to get through each year, especially for testing costs. (The RIBA, recombinant immunoblot assay, test costs $150 in Texas.) Another concern has been screening for HCV yet not having resources for treatment. Now with the state's budget crisis, the very existence of the program looks doubtful.

"It's highly likely the program won't be renewed, and that is unfortunate," Rocha adds.

With limited funds, the state health department had to train staff as efficiently as possible. The department decided early on not to create a new model but rather modify existing prevention counseling guidelines.

For example, the department's four-day training course for sexually transmitted disease (STD) and HIV prevention counseling was modified to include all aspects of viral hepatitis. Through the CDC's STD Prevention Training Center in Dallas, two clinical updates were provided each year, giving up to 150 counselors a two-day overview of HCV, including video showing examples of HCV client-based counseling.

The main goal was to reinforce the fact that skills required for good HCV counseling are the same for HIV. In addition, the department had to modify its data collection forms submitted by the clinics so HCV data could be reported.

"The counselors have been able to make the adjustment remarkably well," Rocha tells *AIDS Alert*.

Funds for public education have been minimal, however, resulting in wide variability in the quality of information. Health officials had initial fears, which proved unwarranted, that the wrong messages could set off a "run" on testing sites. One public service message, for example, urged testing for anyone with a history of military experience, dental work, or immunization.

Before considering integration, HIV programs should consider whether demands for HCV testing, particularly those serving high-risk populations, could divert existing resources from HIV services. Specifically, partner services for infected clients could be a big drain on limited staff.

"It's a real challenge to describe what your priorities are and how you're going to allocate resources," says **Casey Blass**, the state's former AIDS director, who helped start the program. "If you look at the prevalence, it would be easy for hepatitis C to overwhelm many sites, so we had to set up a system to preserve the infrastructure we had in place."

Reference

1. Sherman K. Shire N, Rouster S, et al. Prevalence of occult hepatitis B infection in HIV-infected patients: Analysis of a geographically distributed ACTG cohort. Presented at 10th Conference on Retroviruses and Opportunistic Infections. Boston; 2003. Abstract # 820. ■

States going at slow pace developing hepatitis plans

Lack of funding and resources, combined with competing demands, help explain why only a handful of states have hepatitis prevention plans in place, according to a recently completed survey.

"It's pretty disheartening," says **Scott Connor**, a researcher at the Atlanta-based Council of State and Territorial Epidemiologists (CSTE), which developed the survey.

As a result of the findings, CSTE awarded $20,000 in competitive grants last year to six states in efforts to help develop plans.

As the survey showed, states have a long way to go before they adequately address the needs for hepatitis control and prevention. Although half of the 40 states and territories that responded to the survey have begun writing plans, only eight have completed them.

The states listed several barriers to completion, the most common being lack of personnel resources (62%), lack of funding (57%), and competing demands (42%).

Other findings from the survey include:

- Only 19% of states had funds dedicated to hepatitis prevention plans, and one-third had no hepatitis planning support.
- Most states had fewer than two full-time employees dedicated to hepatitis prevention planning. There are only about 30 hepatitis C coordinators in the country.
- Only about 15% had a line item in the state budget for hepatitis A, B, or C. Only 20% had total hepatitis plan budgets of more than $200,000.
- More than one-third (37%) had less than $50,000 set aside for adult hepatitis B vaccination.
- Only 42% provided partner notification as part of their hepatitis outreach activities.
- Nearly half (47%) offered no hepatitis C counseling and testing at publicly funded sites.
- Only 35% had a mechanism for referring clients with chronic hepatitis B or C for medical evaluation and possible treatment.
- Only 30% had completed hepatitis C prevalence estimates statewide. ■

Resources for integrating HCV and HIV services

The National Association of State and Territorial AIDS Directors (NASTAD) in Washington, DC, has a Viral Hepatitis Program that provides guidance and information for HIV/AIDS programs. The materials help staff develop training on viral hepatitis and assess how to incorporate viral hepatitis issues into their existing program.

Current materials on viral hepatitis and HIV include:

- The HIV-Viral Hepatitis Connection: A Select Annotated Bibliography of the Public Health and Biomedical Literature.
- NASTAD's own module "Starting Up: First Steps Toward the Integration of Viral Hepatitis into HIV/AIDS/STD Programs."
- *Viral Hepatitis and HIV: A Primer for Community Planning Groups (CPGs).* Designed to increase CPGs' understanding of viral hepatitis, the primer provides general information on viral hepatitis and offers a rationale for including

viral hepatitis in the HIV community planning process.

- *Viral Hepatitis in the Correctional Setting: The Role of State, Territorial, and Local HIV/AIDS Programs.* The guide provides an overview of the correctional system and of the issues that HIV / AIDS programs may encounter when working with Departments of Corrections.
- *Integrating Viral Hepatitis Services into HIV and STD Clinics.* This is an issue brief that describes six HIV and STD clinics that have successfully integrated viral hepatitis services into their existing clinic services.
- *Viral Hepatitis Education: Instructor's Guide.*
- The National Commission on Correctional Health Care has created a curriculum geared for correctional officers, developed with support from the CDC's Division of Viral Hepatitis.

This "off-the-shelf" curriculum, which contains print and CDC versions, enables health professionals to provide comprehensive and manageable information on hepatitis A, hepatitis B, and hepatitis C. It includes: instructor guide with pointers on the characteristics of adult learners; pre- and post-tests to gauge the presentation's effectiveness; lecture notes; handouts and resources for the students; and overhead transparencies.

To order the free curriculum (one copy of each version per customer; shipping charges do apply), contact: National Commission on Correctional Health Care, 1300 W. Belmont Ave., Chicago, IL 60657. Telephone: (773) 880-1460. E-mail: ncchc@ncchc.org. ■

Computer tool helps plan cost-effective strategies

Most important variable is HIV incidence

With hundreds of HIV interventions available, community planning groups often are at a loss for deciding which ones to use. Now a new tool will allow health departments to enter local data and determine which programs are most cost-effective.

"It's proving to be a nice little tool," says **Thomas Farley**, MD, a researcher at the Tulane University School of Public Health. "It helps you to see how some interventions that have been pretty popular are 100 times less cost-effective than other interventions you never thought of."

The tool, Maximizing the Benefit: A Practical Tool for Community Planning Groups and Health Departments, was funded by the Centers for Disease Control and Prevention (CDC), and developed by Farley and the Rand Corporation. The tool will be offered to community planning groups around the country when completed sometime this spring.

In addition to measuring cost effectiveness, Maximizing the Benefit also contains a tool to help planning groups prioritize interventions based on other factors as well, such as feasibility and acceptability. The tool uses mathematical modeling that analyzes local data and weighing the score using five criteria. For example, a score is affected by the strength of evidence supporting the effectiveness of an intervention. Other factors include HIV prevalence, duration of the intervention, and program cost.

"What drives cost effectiveness more than anything is prevalence, so if you are dealing with teenagers, probably no strategy will turn out to be cost-effective," Farley says. "On the other hand, almost anything targeting gay men will prove cost-effective." For example, one strategy that is shown to be cost-effective is limiting post-test HIV counseling only to those who test positive. "Post-testing counseling on negatives just isn't cost-effective," Farley says.

Two biological interventions shown to be effective are HIV treatment and circumcision.

"The use of these three biologic interventions are currently widespread. However, they are rarely used for the expressed purpose of preventing HIV transmission," the authors note. "The evidence that they reduce the spread of HIV infection is at least as strong as that for educational and psychological interventions, so they should be considered in the range of options when planning HIV prevention strategies."

Cost effectiveness, which the tool analyzes as both per client cost and per community cost, cannot be the only factor in making a decision for one strategy vs. the other. Yet when dollars are being cut, the tool could be the deciding factor.

"Because the cost-effectiveness estimates are imperfect, we do not advocate that these be the sole criteria for prioritizing interventions," the authors note. "Other factors, such as feasibility, scalability, replicability, and acceptability, and others that may be important in your community, should also be considered when finalizing how resources are to be allocated." ■

FDA News

Price criticized for new anti-HIV drug

The FDA's accelerated approval of Fuzeon (enfuvirtide) for use in combination with other anti-HIV medications has drawn mixed reactions: excitement that a new class of drugs is now on the market and disappointment that its manufacturer, Trimeris, has priced the drug so high.

Fuzeon is the first product in a new class of medications, called fusion inhibitors, to receive marketing approval. Drugs in this class interfere with the entry of HIV-1 into cells by inhibiting the fusion of viral and cellular membranes. This inhibition blocks the virus' ability to infect certain components of the immune system. It will be used mainly as salvage therapy in patients who have failed other drugs because of resistance.

"Fuzeon adds an important dimension to our armamentarium of anti-HIV treatments. By affecting viral spread in a different way from existing medications, it helps reduce viral loads, which has been shown to slow HIV progression in patients who have developed resistance to currently available medications," said Commissioner of Food and Drugs **Mark B. McClellan**, MD, PhD.

Michael Saag, MD, director of the AIDS Outpatient Clinic at the University of Alabama, notes that patients are becoming resistant to the best therapies and need new options. "This drug attacks the virus in a new way, so it can work for patients whose virus is resistant to other therapies," he says.

The FDA based its accelerated approval of Fuzeon on an analysis of six months of data from two ongoing clinical studies of Fuzeon involving approximately 1,000 patients. The data showed that the addition of Fuzeon to a combination of other anti-HIV medications reduced HIV viral load in the blood more than the use of the combination of anti-HIV medications alone. The long-term effects of Fuzeon are not known at this time, but are being evaluated by the ongoing clinical studies.

Because of the FDA's approval, the study, T-20 vs. Optimized Regimen Only Study 1 (TORO 1), was published early in an on-line version of the *New England Journal of Medicine*.[1] It concluded that adding Fuzeon to an existing "optimized" antiretroviral regimen "provided significant

CE/CME *questions*

17. Which of the following is true about HIV/AIDS in the South?
    A. Cases in all groups have leveled off in recent years.
    B. It has a growing share of Americans living with AIDS, rising from 35% in 1993 to 40% in 2001.
    C. The region has a disproportionate number of injection-drug users.
    D. The number of African-American females with AIDS has grown at the same proportion it has in white females.

18. What proportion of HIV-positive patients in the United States are believed to be co-infected with hepatitis C virus?
    A. 12%
    B. 40%
    C. 60%
    D. 73%

19. What condition has become the leading cause of death in HIV-positive patients?
    A. liver disease
    B. lung cancer
    C. pneumonia
    D. heart attack

20. What is the main therapeutic benefit of the newly FDA-approved drug, Fuzeon?
    A. It is less expensive than other drugs in its class.
    B. The side-effect profile is better than other drugs.
    C. As a new class of drug, it is effective as salvage therapy in patients who have failed other drugs because of resistance.
    D. none of the above

Answer Key: 17. B; 18. B; 19. A; 20. C

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 answer key above. 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.

antiretroviral and immunologic benefit through 24 weeks" in participants who had previously received multiple antiretroviral drugs and who had multidrug-resistant HIV.

Trimeris, the biotech company that developed Fuzeon, and Roche, the Swiss pharmaceutical company producing and marketing the drug, expect to begin shipping Fuzeon by early April. But already, activists are protesting the high cost of the drug, set at $20,500 per year. ACT-UP New York, for example, has staged a demonstration at Roche's headquarters in New Jersey.

"There's no guarantee, perhaps not even a likelihood, that most of the people who truly need this drug will be in a position to get it," says **Martin Delaney**, founding director of Project Inform. "The AIDS Drug Assistance Program [ADAP] is facing a financial crisis without even considering the addition of Fuzeon, and the cost of the drug will be a hard blow to already strapped Medicaid budgets."

Despite assurances from Trimeris that new rebates for the drug will be given to ADAPs, the drug will likely remain out of reach. **Ryan Clary**, senior policy advocate for Project Inform, says "For many state ADAP programs, the only option may be to take other drugs off the formulary or make other major changes to the program if they really hope to add Fuzeon. This would pit one set of patient needs against another's."

It is estimated that half of the $60 million in additional federal ADAP money for anti-HIV medications in FY2002 was spent to cover price increases alone. Trimeris and Roche have both defended the pricing, noting that the drug has cost more than other FDA-approved anti-HIV drugs and that manufacturing is extremely complex.

With extensive data in the past year showing dramatic rises of HIV drug resistance, Fuzeon could be in great demand. Yet because of the lengthy manufacturing process, Roche anticipates that currently it will only be able to fill prescriptions for about 3,000 patients.

"We are fully in line with our manufacturing schedule despite the extraordinary challenges that Fuzeon production has posed," says **William M. Burns**, president of Roche Pharmaceuticals.

Reference

1. Lalezari JP, Henry K, O'Hearn M, et al. Enfuvirtide, an HIV-1 fusion inhibitor, for drug-resistant HIV infection in North and South America. *N Engl J Med* 2003; Mar 13 (e-pub ahead of print). ■

CE/CME objectives

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

- Understand the risks and cofactors that put rural Southerners at high risk for HIV infection.
- Identify unique characteristics of the HIV epidemic in the South.
- Know the benefits and challenges of integrating hepatitis C virus screening with HIV testing and counseling services.
- Become familiar with a new tool that can evaluate the cost effectiveness of HIV prevention interventions. ■