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ADAP fund officials predict shortfall that threatens lives of HIV patients

Congress can fix funding shortage with a $90 million infusion

The latest antiretroviral treatments have been so successful that the demand for such drugs may exceed what can be funded under the present Ryan White funding programs.

Unless Congress infuses about $90 million in the nation's AIDS Drug Assistance Programs (ADAP), funded through Ryan White Title II, then some states may have to start cutting off new enrollment for HIV drugs and others may have to restrict drug access to those already receiving ADAP-funded drugs, charges **Bill Arnold**, co-chairman of the ADAP Working Group, a Washington, DC-based ADAP advocacy coalition that consists of AIDS advocacy organizations and pharmaceutical companies.

It's not that Congress has ignored ADAP funding, which actually increased substantially from $285.5 million in FY 1998 to $461 million in FY 1999.

"Congress has been relatively generous with the ADAP program because of the positive impact of HIV treatment," says **Arnold Doyle**, MSW, research associate with The National Alliance of State and Territorial AIDS Directors in Washington, DC.

"Congress sees ADAP as a worthwhile fund for improving health care, lessening deaths, and decreasing mortality, while keeping people productive longer," he says.

Funding can't keep up with growing numbers of patients

But the problem is that funding increases have had trouble keeping up with the rising numbers of HIV patients — numbering 40,000-plus new infections a year — and with the increasing costs of antiretroviral drugs.

While antiretroviral therapies have become more effective in recent years, they also cost more. When ADAP was founded in 1987, the first approved anti-HIV drug, zidovudine (AZT), cost about $10,000 per year. Now drug therapies that include protease inhibitors can cost $12,000 to $15,000 per year.

"What we're saying is, there will be a $90.2 million shortfall if the trends continue the way we see them, and the pharmacological model

we use has been extraordinarily accurate," Arnold says.

Plus, HIV patients are living longer and therefore staying on the medications longer, which also pushes up ADAP's expenses, Arnold says. "Add all those things up, and in the course of a year, you come up with a number essentially in the millions."

States struggle to fund costly treatments

Tens of thousands of HIV-infected people have relied on federal and state funds to help pay for the costly antiretroviral drug treatments in recent years. While Medicaid is the largest provider of health care funds for HIV patients, covering 90% of all HIV-positive children and 50% of all people with HIV, state ADAPs have filled the gap of paying for drug therapies for people who earn too much money to qualify for Medicaid.

ADAPs set income eligibility in terms of the federal poverty level. Some states fund up to 100% of the poverty level, which is $7,890 per year for one person; a few states fund up to 400% of the poverty level.

Given enough money, ADAPs also would fund medication adherence programs and drugs to treat opportunistic infections, in addition to giving clients access to the newest and most effective drug therapies, Doyle says.

"In the last several years, the programs have certainly improved in terms of providing a wider array of antiretroviral drugs," Doyle says. "But there are some shortcomings, depending on the resources in a state."

Since protease inhibitors hit the market, some states have shut down ADAP funding to new enrollees and restricted access only to a small percentage of the working poor. Last year, 26 states cut ADAP services or faced budget shortages, according to the *1999 National ADAP Monitoring Report*, which is a joint project of the National Alliance of State and Territorial AIDS Directors and the AIDS Treatment Data Network.

State ADAPs served 53,765 clients in June 1998, a 23% increase over the 43,494 people served in July 1997, according to the report. And 40 states had increases in the numbers of ADAP clients between July 1997 and June 1998. States that reported increases of 50% or more included Alaska, Delaware, Iowa, Kansas, Missouri, Ohio, Oregon, South Carolina, and West Virginia. The District of Columbia also reported increases of 50% or more.

At the same time, ADAP drug expenses have grown even faster, with 18 states reporting increases of 50% or greater. Nationally, per-client ADAP expenditures rose by 12% between July 1997 and June 1998, the report says.

States took drastic measures in 1998

Faced with increasing numbers of clients and rising drug costs, many states had to take drastic emergency measures last year, including the following:

- Eleven states capped program enrollments and maintained waiting lists for new ADAP clients.
- Six states had waiting lists for access to protease inhibitors or other antiretroviral drugs.
- Arkansas and South Dakota did not cover any protease inhibitor treatment because of budget constraints.

Ironically, the ADAP Working Group's call for more federal Ryan White Title II money comes at a time when most state ADAP programs finally have received enough funds from both state and federal sources to get rid of their drug waiting lists and reopen enrollment to new patients.

In Florida, for example, the state legislature injected an additional $8 million into the state's ADAP program, bringing its total funding to more than $60 million in FY 1999. **(See ADAP funding chart, p. 99.)** In 1997 and 1998, the Florida program had an HIV drug waiting list of about 2,000 people, says **Joseph May**, manager for the Florida ADAP program in Tallahassee.

This year, the list is gone; the state now provides drugs for about 8,300 people; and the program has expanded to include people who have incomes at 300% of the federal poverty level. Previously, Florida had a 200% poverty level cut-off.

"The bottom line is, we're in a much better position financially than we were a year and a half ago, but we're not ready to say we're adequately funded," May says. "If we lost some federal funding, that would be a serious reversal and could make an immediate crisis for us."

ADAP money pays for drugs for people who have a medical diagnosis of HIV and who are low-income as defined by their states. Participants' incomes can range from about $8,000 to more than $30,000 for a single person. About 60% of people with HIV / AIDS receive treatment through

(Continued on page 100)

ADAP Funding Information, FY 1999

Grantee	Title II Base	Title II Earmark	Title I	State Funds	Other Funds
Alabama	$1,665,027	$3,980,313	$0	$153,000	$0
Alaska	$0	$323,829	$0	$0	$24,000
Arizona	$0	$4,057,517	$0	$1,300,000	$0
Arkansas	$0	$1,807,868	$0	$0	$0
California	$12,873,984	$65,267,693	$0	$47,466,000	$0
Colorado	$136,000	$3,787,302	$600,000	$1,171,671	$0
Connecticut	$0	$7,793,350	$259,500	$618,000	$0
Delaware	$0	$1,672,761	$0	$0	$0
Washington, DC	$0	$7,690,410	$1,179,006	$800,000	$0
Florida	$5,012,114	$48,505,772	$0	$8,000,000	$0
Georgia	$2,000,000	$13,815,288	$1,000,000	$1,124,450	$0
Guam	$0	$10,723	$0	$0	$0
Hawaii	$143,000	$1,323,197	$0	$340,000	$0
Idaho	$124,438	$317,396	$0	$200,000	$0
Illinois	$0	$14,548,730	$0	$7,136,000	$0
Indiana	$0	$3,907,398	$0	$0	$0
Iowa	$62,000	$791,345	$0	$0	$0
Kansas	$273,674	$1,426,136	$0	$0	$0
Kentucky	$155,574	$2,223,914	$0	$95,000	$0
Louisiana	$414,613	$8,061,420	$0	$0	$0
Maine	$0	$529,708	$0	$60,040	$0
Maryland	$0	$14,175,575	$301,583	$600,000	$0
Massachusetts	$0	$8,413,129	$0	$2,000,000	$0
Michigan	$0	$6,712,489	$0	$0	$0
Minnesota	$976,008	$2,024,469	$0	$150,000	$0
Mississippi	$2,269,803	$2,725,742	$0	$750,000	$0
Missouri	$0	$5,127,655	$0	$2,200,000	$0
Montana	$250,000	$227,324	$0	$0	$0
Nebraska	$0	$658,381	$0	$0	$0
Nevada	$0	$3,079,595	$0	$1,200,000	$0
New Hampshire	$0	$553,298	$168,388	$40,000	$0
New Jersey	$0	$25,275,844	$0	$700,000	$3,000,000
New Mexico	$0	$1,351,076	$0	$1,473,000	$0
New York	$9,214,235	$85,949,879	$17,414,701	$8,300,000	$0
North Carolina	$0	$6,371,503	$0	$8,770,000	$0
North Dakota	$0	$75,060	$0	$0	$0
Ohio	$513,066	$6,914,078	$0	$4,397,117	$0
Oklahoma	$71,884	$2,129,553	$0	$686,000	$0
Oregon	$50,000	$2,790,079	$0	$0	$0
Pennsylvania	$0	$15,041,980	$0	$9,004,000	$979,200
Puerto Rico	$3,437,230	$15,505,206	$0	$4,000,000	$0
Rhode Island	$100,483	$1,284,594	$0	$0	$0
South Carolina	$0	$5,966,180	$0	$500,000	$50,000
South Dakota	$22,486	$105,084	$0	$0	$0
Tennessee	$0	$5,357,124	$0	$0	$0
Texas	$4,861,802	$32,998,423	$0	$2,700,000	$0
Utah	$0	$1,136,619	$0	$114,800	$0
Vermont	$274,000	$238,047	$0	$200,000	$0
Virgin Islands	$0	$340,986	$0	$0	$0
Virginia	$2,707,360	$8,252,286	$0	$1,037,000	$0
Washington	$0	$5,400,015	$0	$2,200,000	$0
West Virginia	$181,002	$797,778	$0	$74,833	$0
Wisconsin	$280,362	$2,082,373	$0	$588,300	$0
Wyoming	$500	$96,506	$0	$0	$0
TOTAL	$48,070,645	$461,000,000	$20,923,178	$120,149,211	$4,053,200

* Dollar amounts are based on projections reported in FY 1999 Title II applications and may not all be final dollars funded.

Source: Ryan White Title II Community AIDS National Network, Washington, DC.

Medicaid. But not all state Medicaid programs fund the entire antiretroviral regimen for HIV patients.

The Florida ADAP might even expand further, if the money remains available, May says.

"We focus on HIV-fighting drugs, but if someone has HIV or AIDS, they could have a variety of medical needs, and that goes beyond direct HIV treatment. What we'd like to do is look toward expanding our drug formulary," May explains. "We're also very concerned that there could be pockets of people out there in Florida who are not aware of our program."

NC injects $8 million into ADAP

North Carolina is another example of a state that has turned around its funding problems after a troubling period from September 1997 to November 1998 when the ADAP program had to close to new enrollees because of a lack of money.

"We had to scrounge for money to provide services to people who were already enrolled in the program," recalls **Arthur Okrent**, manager of the AIDS Care Unit ADAP, which is part of the North Carolina Department of Health and Human Services in Raleigh.

Then, the state passed a budget in November 1998 that sent more than $8 million to ADAP. The state received more federal money, as well. According to ADAP figures, North Carolina is one of the few states that actually provides more money for ADAP than it receives from Ryan White Title II funds.

The additional money has enabled the program to pay for drugs for about 1,500 people. If the program is permitted to raise its criterion of a net 125% of poverty level, which equals a $10,500 income after taxes, then there's enough money to pay for drugs for about 2,200 people, Okrent says.

For now, North Carolina will study its HIV problem to see how the money can be used most effectively.

"We're in the process of beginning to study a number of issues relating to disease progression from HIV to AIDS, and we're looking at issues about adherence to treatment and if there's any way to increase that," Okrent says.

Other states also have struggled to provide medications and other services through ADAP in recent years. Here's a thumbnail sketch of what several states have experienced:

• **Mississippi:** Mississippi's ADAP came out of a financial crisis in recent years, but only after the state contributed $750,000 to the program. The crisis resulted in a 200-plus waiting list for HIV medications, and a few people lost services. Like with other states, the financial problems were caused by the advent of protease inhibitors and multidrug regimens.

"When the National Institute of Health's recommendations came out urging wide use of the three-drug cocktail, including protease inhibitors, ADAP officials approached the state legislature seriously for the first time for funding for AIDS drugs," says **Robert Hotchkiss**, MD, director of the state office of community health services in Jackson.

Mississippi ADAP officials also took a closer look at the state's ADAP enrollment, looking for people who would qualify for Medicaid drugs. They found that a number of people had not picked up their HIV medications in more than six months. When they asked these people to renew their enrollment, a large percentage of them dropped out of the program, which freed up money for new enrollees, Hotchkiss says.

More available funds — now no waiting list

The state funded up to 200% of the poverty level at that time. Now the state funds up to 400% of the poverty level and has 500 enrollees. There no longer is a waiting list.

However, the state still has one problem, which is proving chronic: There are too few providers qualified to treat HIV patients, Hotchkiss says.

"With protease inhibitors, it requires someone with infectious disease qualifications or someone who has had special training in managing these very different and complex regimens," he says. "So that's where we're placing our efforts right now — to try to identify those individuals who are qualified but are not seeing AIDS patients, and we're trying to work with others to try to obtain the training necessary to see AIDS patients."

• **Colorado:** Colorado's ADAP had been running low on funds for three straight years, even though the program received more money from both Ryan White Title II and from the state legislature, says **Karen Ringen**, executive director of the Governor's AIDS Council in Denver.

"But each year that we got more money, our need went up even more than the money we got," Ringen explains. "Our clients increased; the

drugs each client needed increased; we weren't able to keep up with the demand."

Colorado's ADAP offers antiretroviral treatment to more than 800 people who meet the criteria of having incomes up to 185% of the poverty level, which is $14,000 for one person.

Despite the program's financial difficulties, the state has never had a waiting list, largely because pharmaceutical companies helped provide free drugs when the program had a shortfall.

"We ran into deficits in the past," Ringen says. "We felt this therapy was so important that we couldn't have a waiting list and say to someone, 'We can't help you.'"

The program is solvent, at least for now, thanks to the state's infusion of about $1.2 million.

If there is a change in federal funding, the state could run into trouble again, Ringen says.

"The money we have will get us through March, and then we'll have to evaluate what the client population is at that point," she adds. "In the past, the pharmaceutical companies have been very generous, and we would hope they would continue that help if there is another crisis."

• **Illinois:** The Illinois ADAP ran into trouble in 1996 but never instituted a waiting list, says **Nancy Abraham**, ADAP administrator for the Illinois Department of Public Health in Springfield.

"Illinois was one of the first states to run into funding problems, and then the state gave us an additional $5 million," Abraham says.

Illinois now has sufficient funding to serve the 1,600-1,700 people it helps each month with up to four HIV drugs. The state funds up to 400% of the poverty level, which is an income of $32,960 per year for one person.

• **Connecticut:** Connecticut is another state that has never had a waiting list for ADAP drugs. Currently, the funding cutoff is set at 300% of the poverty level, which amounts to a $24,720 annual income for a single person. The state has about 960 people receiving HIV drugs through ADAP.

"We have been given a permissive legislative mandate of increasing [the income criteria], and it's in the discussion phase now of when and how we'll be able to implement that," says **Bette Smith**, AIDS Program Coordinator with the Connecticut Department of Social Services in Hartford.

The state also is exploring the possibility of using ADAP money to fund insurance that would pay for medications, which is an option that has been pursued by some other states. ■

CD38 assay may be better predictor of progression

Marker shows how well immune system works

Clinicians who would like a more complete picture of how well their patients' immune systems are holding up under antiretroviral therapies now can order a test that measures CD38 molecules.

"We need markers more than viral load and CD4 counts to help us figure out how patients are doing," says **Joseph C. Gathe Jr.**, MD, FACP, a Houston internal medicine specialist who treats more than 2,000 HIV patients.

A CD38 test shows whether a patient's immune system is active. If it's active, that means viral replication is taking place. "This looks to me as a clinician like one of the most important markers," Gathe says.

He points to research conducted by a Los Angeles cellular immunologist as evidence that the CD38 marker would be a good tool in helping physicians decide when to start antiretroviral drugs.

That research suggests that a CD38 assay is a better tool in predicting risk of HIV progression to AIDS than the tests measuring CD4 cell count and viral load, says **Janis V. Giorgi**, PhD, professor of medicine in the division of hematology-oncology and director of the University of California-Los Angeles School of Medicine.

Clinicians who use CD38 tests in combination with CD4 cell counts and viral load tests will get a very clear picture of how close a patient is to the brink of AIDS-defining illnesses, Giorgi says.

"If you look at CD4 cells, you know how much immune deficiency a person has, but if you look at CD38, you'll see how fast they're using up their reserves, so between the two of them you have the whole immune picture," Giorgi says.

Giorgi compares HIV infection to a perpetual war in which the patient's immune cells are soldiers that at first are young and healthy, but begin to age, tire more easily, and eventually die as the war progresses over the years.

"The virus can't be gotten rid of, and it can't be eradicated, so all that can be done is to help the immune system fight it," she explains. "So the more intensely the fight has to be carried out at the beginning of infection, the faster the soldiers get killed off."

The CD38 marker might be compared to the soldiers' armor. When the soldiers are at war, they wear their uniforms. When they're at peace, they wear civilian clothing. So if a test shows a high number of CD38 molecules, that means the soldiers are at war. The higher the number of CD38 molecules, the harder they're fighting and the less likely that they'll be able to keep up that pace for long.

"The fact is that the CD38 test is even more important than viral load because even though the viral load is the cause of the CD38 count being high, the CD38 is a better reflection of the immune system's response to the virus," Giorgi says.

Therefore, if a patient on antiretroviral therapy has a high viral load and a high CD38 marker, then a clinician will need to be concerned that the patient's immune system is activated and may be wearing itself out — even if the person's CD4 cell count remains high.

"If a person with a high viral load has more CD38 activation, then it's a worse situation than if a person has the same viral load but not as much CD38 activation," Giorgi explains.

A healthy person who is not infected with HIV probably has about 1,000 CD38 molecules / CD8 cell.

In a study published in the *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology*, Giorgi and fellow investigators suggested that CD38 measurements be categorized in this way:

- low = fewer than 2,500 molecules / CD8 cell;
- medium = 2,500-3,999 molecules / CD8 cell;
- high = 4,000-7,000 molecules / CD8 cell;
- very high = more than 7,000 molecules / CD8 cell.[1]

Giorgi says research has determined that a relative risk of developing AIDS according to the CD38 marker is as follows:

- low CD38 count = 4% of people developed AIDS in three years;
- medium CD38 count = 18% of people developed AIDS in three years;
- high CD38 count = 40% of people developed AIDS in three years;
- very high CD38 count = 73% of people developed AIDS in three years.

CD38 research also has generated these findings:

- CD38, a flow cytometric marker of T-cell activation of CD8 T cells, can predict HIV disease progression independently of plasma viral burden and CD4 T-cell number. So measuring CD38 antigen expression on CD8 T cells of HIV patients may help clinicians assess the impact of therapeutic interventions.[2]
- T-cell immune activation is important in determining how long a patient will survive with advanced HIV-1 infection. Shorter survival rates are associated with elevated cell surface expression of CD38 activation antigen on CD4 and CD8 T cells. However, the advanced patient's survival duration was not associated with plasma virus burden and viral chemokine co-receptor usage.[3]

CD38 assay now available for clinical use

The CD38 test actually has been available for a few years, but so far it has mostly been used by researchers. "The assay is done on the same kind of instrument that the CD4 cell count is done on, so any lab doing CD4 counts using a flow cytometer can do the CD38 assay," she says.

"If physicians want the test, they can demand it because the technology is here now," Giorgi adds.

Most laboratories use the FACScan or the newer FACSCalibur flow cytometers, and they can easily adapt the instruments to measure CD38 molecules, says **Todd Christian**, product manager of Becton Dickinson Immunocytometry Systems in San Jose, CA. Becton Dickinson manufactures the flow cytometry equipment that was used in the CD38 research. The company also has the CD38 antibody that's needed for the assay.

Giorgi has published on the Internet the procedure for calibrating the instrument. It's available free to any laboratory or clinician visiting the Web site at http://cyto.mednet.ucla.edu. Once on the Web page, click on "protocols," and then click on the link to "CD38 Fluorescence Intensity Quantitation."

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NYC study of gay men offers outreach, education

HIV rate is low, and safer sex is status quo

A recent study in New York City of the sexual behavior of gay and bisexual men shows that communities can successfully combine data-collecting efforts with outreach services and education to target a specific population for HIV prevention.

The survey was administered on New York City streets by a large group of volunteers with the Gay Men's Health Crisis (GMHC), a New York City-based AIDS advocacy group. Called the GMHC HIV Prevention Department 1998 Gay and Bisexual Men Sexual Health Survey, it included self-reports of sexual behavior by 7,065 men.

This type of grass-roots survey could be modified for use among minorities, teen-agers, injecting drug users, and other at-risk populations for which more data are needed before communities launch new prevention campaigns.

The GMHC survey results brought good news to the HIV / AIDS community: 89% of the men surveyed said they had taken an HIV test, and only 13% of the men surveyed said they had tested positive for HIV.

While it was the first large-scale study of its kind in New York City, previous surveys conducted in cities like San Francisco in the 1980s have placed the percentage of HIV-positivity among gay men at 50%.

Also, the survey showed that 78% of men reported using a condom during their first anal intercourse, which is more than double the 34% who reported the same practice in 1985.

While newspaper reports of the survey focused on the fact that 39% of the men said they had engaged in unprotected anal intercourse within the past year, researchers say this doesn't tell the whole story with regard to safe-sex practices.

Only 11% of the men surveyed reported having unprotected anal intercourse with a person whose HIV status was different from their own or whose HIV status was unknown, says **Tracy Mayne**, PhD, director of epidemiology and surveillance for the New York City HIV / AIDS Prevention Planning Group. Mayne was a principal investigator for the survey.

"What's really important is even if we look at the 39%, we find that these men are more likely to be having unprotected intercourse with a single partner," Mayne says. "So if two men get together and form a monogamous relationship, and they're both sero-negative, should we call that risky if they're having unprotected intercourse?" Mayne compares that type of behavior to married couples who don't use condoms during sexual intercourse.

Gay men report having fewer partners

And the New York gay men reported having fewer sexual partners than gay men have reported in previous studies. About 60% of white gay men reported having five or fewer partners in the past year, while 80% of black men reported having five or fewer partners, and 75% of Latinos reported the same. Gay men reporting having zero or only one partner in the past year were 30% for whites, 36% for blacks, and 37% for Latinos, Mayne says. **(See story on the survey's results, p. 104.)**

The survey even compared the prevalence of HIV-positive men choosing to be receptive partners during unprotected anal intercourse, and found that even when practicing unprotected anal intercourse, men are choosing positions that are less likely to transmit HIV, Mayne says.

"There are definitely cultural norms about safer sex that exist now, and those norms certainly have changed [since AIDS]," Mayne says. "We have better success in getting people to use safer sex practices than we do to get people to floss their teeth."

The GMHC survey served dual purposes, both collecting data that could be used to track trends and direct HIV prevention efforts and providing outreach and education to gay men. Nearly 93% of the men who turned in a survey had filled it out entirely and correctly.

"The fact that we had over 7,000 men fill out that survey is remarkable, and, in itself, groundbreaking," says **Bob Bergeron**, CSW, director of HIV prevention for GMHC.

"Research done in New York for gay men has not always been helpful for us in HIV prevention because of limitations of research size and difficulties getting to diverse populations," Bergeron says. "We reached what researchers have labeled difficult-to-reach populations, and we have a diverse scope in the survey by race and age, with our youngest person surveyed age 12 and the oldest 88."

Minority gay men have higher rates of HIV

Prevention efforts should target blacks, Hispanics

A New York City survey of men who have sex with men (MSMs) found that black and Latino men had the highest HIV rates and were less likely to adhere to safe-sex practices.

"In New York, young black and Latino men who have sex with men are definitely at risk, and we need to increase resources there," says **Tracy Mayne**, PhD, director of epidemiology and surveillance for the New York City HIV / AIDS Prevention Planning Group. Mayne was the principal investigator for the Gay Men's Health Crisis HIV Prevention Department 1998 Gay and Bisexual Men Sexual Health Survey.

The study of 7,065 MSMs in New York City during the summer and fall of 1998 identified these groups in need of targeted safe-sex messages and HIV prevention campaigns:

• **White, drug-using men.** The survey found that white men were more likely to use drugs during sex than minority men. About 27% of white men reported using cocaine, Ecstasy, crystal, K, or crack during sex within the past year, as compared with 12% of black men, 18% of Latino men, and 20% of Asian / Pacific Islander men.

• **Black men.** The survey found that black men have the highest HIV rates, at 17%. Also, while 89% of black men surveyed said they do not have unprotected anal intercourse with someone whose HIV status is unknown or different, a minority of this group is at great risk of getting infected or infecting someone else, the study says.

For example, of all the HIV-infected men who reported having unprotected anal sex with someone who is HIV-negative or whose HIV status is unknown, 28% were black and 20% were Latino. Black men accounted for 24% of all the men surveyed.

• **Latino men who are unsure of their HIV status.** Latino men also had a high HIV infection rate, at 15%. Latino men who reported having unprotected anal intercourse were less likely to know their own HIV status than white, black, or Asian / Pacific Islander men.

One surprising issue was that black and Latino MSMs were less likely than white MSMs to identify themselves as "gay." Fully 20% of black men said they were bisexual, compared with 4% of white men. About 12% of Latino and 8% of Asian / Pacific Islander men called themselves bisexual.

Unprotected sex with women also is problem

The survey asked men about sex with women, and 10% of black men reported having unprotected vaginal or anal intercourse with women in the past year, compared with only 3% of white men. About 8% of Latino and 4% of Asian / Pacific Islander men reported having unprotected anal or vaginal intercourse with women.

The survey also raised questions about whether HIV testing and counseling programs are successfully reaching minority MSMs. Black and Latino men are twice as likely as white men to have been tested for HIV in a hospital. Of all men tested in hospitals, 19% were HIV-positive, compared with 13% of men tested at anonymous sites or 11% tested in clinics. Further research could look into whether these men were tested in hospitals after already having HIV-related health problems.

As a result of the survey, GMHC has created an HIV-testing campaign, called Soul Food, that targets black gay and bisexual men, says **Bob Bergeron**, CSW, director of HIV prevention for GMHC.

"We already have an on-site program for black gay and bisexual men, and on June 15, we created a testing campaign with signs on 1,500 subway cars that encourage black gay men to test for HIV," Bergeron says.

The campaign features interviews with Soul Food volunteers who confide that telling their mothers they were positive was a disincentive to HIV testing. One poster shows a mother, saying, "I know my son messes around with men. We never talk about it, but I want to support him." Then the poster urges men to take a free HIV test at GMHC. ■

The survey demonstrates that AIDS prevention efforts targeted at gay men have been successful in the United States, says **Ron Stall**, PhD, an associate professor at the University of California-San Francisco and a researcher at the Center for AIDS Prevention Studies in San Francisco.

"When you compare the disease trajectory among gay men in New York or San Francisco to that of the heterosexual populations in Asia, Africa, or India, the difference is striking," Stall says. "In those other countries, the HIV prevalence rates over the past 15 years have doubled and doubled, while the prevalence rates among gay men [in the United States] have gone down."

Another important aspect of the GMHC study is that because of its size, it will be very useful for researchers who want to conduct analyses of very specific groups of gay men, such as minority populations, Stall says.

"The usual sample size is, if you're lucky, 500 to 1,000 gay men, and it's impossible to do subanalyses of Asian / Pacific Islanders or other groups," he explains.

The survey included 225 Asian / Pacific Islander men, a larger sample size than most studies have found when specifically targeting this group.

A volunteer effort

Here's how GMHC conducted the survey and provided outreach and education to the target population:

GMHC enlisted more than 2,000 volunteers to distribute the survey in neighborhoods, at bath houses, parties, clubs, and other places frequented by gay men between June 1, 1998, and Nov. 1, 1998. They also attended Gay Pride parades and festivals held in each of New York City's boroughs. Volunteers included HIV-positive and negative gay men, and GMHC tried to match volunteers' ethnicity to their target population, sending black and Hispanic volunteers to neighborhoods populated by their ethnic groups. About 5% of the surveys were written in Spanish.

Volunteers worked in teams of three, with one person carrying a box in which surveys could be placed. They wore T-shirts identifying themselves as part of the GMHC "Beyond 2000 Sexual Health Survey" initiative. When volunteers passed out the one-page, one-sided, 8-inch by 14-inch anonymous survey, they asked men to "take three minutes to answer 20 questions."

Volunteers handed survey respondents pencils and cardboard to write on so they could continue to stand. The pencils had GMHC's phone number, and the men were asked to keep the pencil. Also, volunteers carried a tool belt of HIV prevention items including condom packs.

The survey's questions concerning sexual activity used graphic street vernacular. According to volunteers, the surveys themselves often sparked discussions about safe sex and HIV, Bergeron says. "We provided consciousness-raising about their behaviors through the survey."

The survey included validity questions asking for the same information in different ways to ensure consistency. The survey also included questions about drug use, race, education, condom use at first intercourse, and other topics.

One of the survey's chief limitations is that it targeted areas and gay events where men were likely to identify themselves as gay, so it didn't include a large representation of men who have sex with men but don't call themselves "gay" or "bisexual." Also, more than one-third of the surveys were completed in locations where an admission was charged or where it's expensive to visit, such as the community of Fire Island, so the survey also is likely to underrepresent lower socioeconomic classes.

"We tried to go to a wide range of events that allowed us to reach a large representation of gay men," Bergeron says. "That was a priority to us, to reach a diverse group of gay men."

GMHC will continue the survey, which will give researchers a comparison study. And the 1999 survey will ask even more detailed questions regarding safe-sex practices. For example, one new question will be a follow-up to the question about the HIV status of the gay man's partners.

"We're asking them, "How do you know? Did you ask them their HIV status? Did you have a test together, or did you see the test report?" Mayne says. ■

Bone marrow transplant drug helps suppress HIV

Research to be presented at ICAAC conference

A drug used in bone marrow and stem cell transplantation has shown promising results in blocking HIV when it's used in conjunction with other antiretroviral medications.

Sargramostim or GM-CSF (Leukine), manufactured by Immunex in Seattle, has been approved by the U.S. Food and Drug Administration (FDA) for use in bone marrow transplant treatment and for treatment of chemotherapy-induced neutropenia in older adults with acute myelogenous

leukemia. The FDA has not yet approved sargramostim for use in treating HIV / AIDS.

However, recent studies have demonstrated that sargramostim, administered through injections three times per week, helps block HIV entry into immune system cells. It also reduces the development of HIV resistance to AZT, and it stimulates immune system cells necessary to fight infections.

Drug helps maintain HIV suppression

"Once you've achieved suppression with drugs, it helps to maintain that," says **Jonathan Angel**, MD, a lead investigator in the sargramostim and HIV studies and an assistant professor of medicine at the University of Ottawa in Canada. Angel, who also is an infectious disease specialist at Ottawa General Hospital in Ontario, will be presenting research about sargramostim and HIV at the Interscience Conference on Antimicrobial Agents and Chemotherapy, to be held Sept. 26-29 in San Francisco.

"It's an adjunct therapy to good antiretroviral therapy," Angel adds. "Since antiretroviral therapy fails in many patients, whatever you can add to enhance its ability or prolong its activity or increase its durability is helpful."

The 309-patient phase III sargramostim trial was double-blinded, randomized, and placebo-controlled. The study evaluated the drug's impact on the incidence of opportunistic infections, the rate of survival, and changes in viral load and CD4 cell counts. The trial divided patients in two groups: those with viral loads below 30,000 copies / mL, and those with viral loads above that level. The study found that of the 115 patients with viral loads lower than 30,000 copies / mL, 81% of the patients receiving sargramostim were able to remain on the same antiretroviral regimen and maintain their baseline level of viral suppression throughout the six-month study. This compared with 62% of the patients receiving placebo maintaining a baseline level of viral suppression.

The same research, however, did not show evidence that sargramostim reduced the incidence of opportunistic infections, bacterial pneumonia, or death. But it did reduce the incidence of all infections, Angel says.

"The study started around the time protease inhibitors were being used, and because of protease inhibitors, there were fewer opportunistic infections anticipated, and that's one reason we didn't see fewer opportunistic infections," he explains.

"But if we looked at all infections, including sinusitis, skin infections, and IV-line related infections, there was a decrease in the number, and the infections were less severe, and there was greater delay before the development of infections," he adds.

Trial reveals CD4 increase

A phase I trial, conducted on 20 HIV patients with CD4 cell counts of 10 to 590 and who were on therapies that included ritonavir or indinavir, gave patients either sargramostim or a placebo for eight weeks. During the study, which included four weeks of follow-up, eight of 10 patients receiving sargramostim had an increase of 30% or more in CD4 cell counts, as compared to three of 10 patients receiving a placebo.

A double-blinded, randomized study of 105 patients in Brazil compared the effects of sargramostim in combination with AZT or AZT plus another nucleoside analog to that of a placebo with the additional drugs. All patients had CD4 cell counts of less than 300. At the end of six months, sargramostim reduced mean viral load by -.74 $\log_{10}$ or 69% as compared to -0.11 $\log_{10}$ or 2% in the placebo group. Sargramostim also increased CD4 cell counts by more than 30% in 80% of the patients, while 58% of those in the placebo group experienced a 30% increase. Further, a genotypic analysis showed that sargramostim retarded the development of resistance to AZT.

COMING IN FUTURE MONTHS

- Black leaders, others look for ways to reduce HIV among minorities
- HIV drug pricing controversy continues
- Neurological problems still plague AIDS/HIV patients
- Program targets teens for reducing risk behavior, sticking with treatment
- More long-term support services for HIV patients are needed

Sargramostim is well-tolerated by patients, Angel says. The most significant side effects were mild injection site reactions (requiring no treatment) and mild weight loss.

"From our study, there are not any significant risks associated with the drug other than its cost and inconvenience of patients having to take injections," Angel says.

The main drawback to physicians prescribing sargramostim is that, at present, it would be an off-label drug for HIV patients in the United States, and thus would not be reimbursed by payers. The drug is not available in Canada because there are no distributors for it. ■

Working with HIV patients does not increase TB risk

Normal precautions provide sufficient protection

Health care workers need not fear contracting tuberculosis while working with a population of HIV-positive patients because their risk is no greater than when they work with a non-HIV patient population, according to a Veterans Affairs (VA) Medical Center researcher in Washington, DC.

"Basically, we found there was no obvious correlation between taking care of people who were HIV-positive and subsequent converting of TB," says **Karen Zahnow**, RN, MEd, research nurse for the VA Medical Center.

"It seems that providing direct medical or nursing care to HIV patients did not increase an individual's risk of acquiring TB infection," Zahnow adds. "There was a slight trend toward a conversion rate of health care workers who cared for people with new tuberculosis, which makes sense."

However, even this trend was not the result of whether the person with TB also had HIV infection, she says.

The study's results mean that health care workers who treat HIV patients need only use the same TB protection guidelines they would use if they were working with a non-HIV population. **(See TB guidelines for health care workers, inserted in this issue.)**

"If we're suspicious of TB infection, then we look for it and rule it out, and the appropriate infection and control measures work," Zahnow says. "It was a relief to my co-workers to know that so long as we're paying attention and don't let our guard down when the appropriate safety measures are in place, then we're OK."

Some facilities, however, will want to take additional steps to discover whether or not HIV patients have TB, because HIV patients are more susceptible to TB infection. Zahnow says her hospital's policy is that anyone who is HIV-positive and has a chest infection automatically will be tested for TB.

The study, which began in 1992, resulted from a grant from the National Institutes of Health and its network of 17 hospitals, clinics, and private physicians who treat HIV-infected people. The network is called the Terry Beirn Community

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Editor: **Melinda Young**, (828) 859-2066.
Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@medec.com).
Executive Editor: **Susan Hasty**, (404) 262-5456, (susan.hasty@medec.com).
Managing Editor: **Coles McKagen**, (404) 262-5420, (coles.mckagen@medec.com).
Senior Production Editor: **Brent Winter**, (404) 262-5401.

Editorial Questions

For questions or comments, call **Melinda Young** at (828) 859-2066.

Programs for Clinical Research on AIDS.

Staff and volunteers at 16 of the Terry Beirn sites participated in the observational study, submitting information about the number of patients seen with HIV or TB. A total of 1,014 health care workers were enrolled. About half of those enrolled averaged 10 or more hours per week of direct hands-on care of patients, including physical examinations. They completed a questionnaire, which could be submitted anonymously, and identified themselves as HIV-positive or -negative, unaware of HIV status, or unwilling to answer the question.[1]

One in five health care workers had TB

About 21% (209) of the health care workers had a history of TB or a positive tuberculin skin test. Of 201 workers who had a positive tuberculin skin test, 157 had information about when they became positive, when they entered the health care field, and the amount of time they worked with HIV patients.

Of the 157, 25% tested positive before working in health care; 25% tested positive after entering health care
but before working with HIV-infected patients; and the remaining 50% had become infected after working with HIV patients.

The 805 workers who had no history of TB or a positive skin test received a baseline purified protein derivative (PPD) tuberculin skin test. This resulted in 39 workers testing positive and 766 workers testing negative.

• During the course of the study, 22 of the 766 workers followed with skin-testing each six months converted their PPD or received TB prophylaxis. This produced a rate of 1.8 per 100 person-years of follow-up.

• The study concluded that there was no apparent relation between caring for HIV-infected people and the rate of PPD conversion among the health care worker cohort. However, those who performed cough-inducing procedures had tendencies toward higher conversion rates than those who didn't, but without correlation to the HIV status of the patients.

Reference

1. Zahnow K, Matts JP, Hillman D, et al. Rates of tuberculosis infection in healthcare workers providing services to HIV-infected populations. *Infect Control Hosp Epidemiol* 1998; 19:829-835. ■

CE objectives

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

• identify the particular clinical, legal, or scientific issues relates 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. ■