AMERICAN HEALTH CONSULTANTS®

AIDS ALERT®

The most comprehensive source of HIV/AIDS information since 1986

June 2000 • Volume 15, Number 6 • Pages 61-72

IN THIS ISSUE

Special Report: ADAP Funding

In This Issue **continued on next page**

Many Southeastern states lack adequate ADAP funds to meet Medicaid needs

Officials predict $163 million shortfall for 2001

While rising HIV drug costs, coupled with federal funding shortfalls, created dwindling AIDS Drug Assistance Program (ADAP) budgets last year, an AIDS advocacy group is predicting a $163 million ADAP budget shortfall in fiscal year 2001.

Also, a new report on ADAP shows that some states, particularly in the Southeast, are struggling with inadequate ADAP funding that results in waiting lists and more stringent enrollment criteria.[1]

The ADAP Working Group of Washington, DC, predicts that ADAP will have a $163 million shortfall next year.

"We have some problems, but not a programwide disaster by a long shot," says **Bill Arnold**, chair of the ADAP Working Group. "Across the board, you have to give ADAP a very high mark, especially when you think that back in 1995, this was a dinky program that gave people medicine that made things easier while they were dying, and now there's 10 times that amount of medication activity, six times the number of clients, and eight times the amount of money."

Special Report: **ADAP Funding**

Most states have emerged in good shape from several years of growing pains as ADAP funding increased to cover antiretroviral medications for a growing number of HIV-positive people, Arnold says. For instance, the national ADAP budget ballooned from $207.5 million in fiscal year 1996 to $665.5 million in fiscal year 1999.[1]

In This Issue **continued from page 61**

COMING IN FUTURE ISSUES

■ **A Q&A chat with an HIV treatment pioneer:** Keith Henry, MD, explains why he believes clinicians and health systems treating HIV patients will have to make a paradigm shift in their management practice to prevent the nation's fragile HIV care ecosystem from collapsing

■ **Resistance not high among non-adhering homeless patients:** California study finds that 38% of the homeless population adhered well to medication regimen

■ **Community-based intervention works well:** Project used 'opinion leaders' to help devise HIV prevention strategies

■ **CDC demonstration projects fail to prove 'stages of change' model works:** Condom use increased in both intervention and control groups

■ **Patients with AIDS more likely to have memory problems:** Study will help clinicians identify patients at greater risk of failing to follow their drug regimens

ADAP finally is able to provide a basic range of antiretroviral therapy to low-income, uninsured, or underinsured people, says **Arnold Doyle**, MSW, director of the HIV Treatment Program for the National Alliance of State and Territorial AIDS Directors (NASTAD) in Washington, DC. Doyle is a co-author of "National ADAP Monitoring Project: Annual Report March 2000," funded by The Henry J. Kaiser Family Foundation of Menlo Park, CA, and produced by NASTAD and the AIDS Treatment Data Network in New York City. **(See story on the ADAP report, p. 67.)**

The ADAP Working Group estimates that the average cost of treatment per person on ADAP will be a little more than $10,000 for fiscal year 2001. This includes the costs of treating and preventing opportunistic infections. Based on this estimate, the advocacy coalition, which includes AIDS advocacy groups and pharmaceutical companies, projects that it will cost $895 million to adequately fund ADAP in fiscal year 2001. The projected base budget is $732 million, which is how the group arrives at its $163 million shortfall figure.

Special Report:
ADAP Funding

Doyle says he doesn't necessarily agree that ADAP's remaining problems could be solved by a large increase in federal funding. "Because of the way it's run through the formula and trickled down to smaller states, they don't see huge increases that will make a dent in their budget problems," Doyle says.

"I think the situation is good in terms of the fact that the programs are reaching a lot of people, and they're reaching a lot of racial and ethnic minorities," Doyle says. "But there are persistent limitations in some states, like the Southeast and frontier states."

State funding is key to problem areas

Problems remain in the states that put no or very little state money into the program, such as the Dakotas, which provided no state ADAP funding in 1999, and in Southern states that have less expansive Medicaid programs combined with smaller contributions to ADAP than are needed, Doyle explains.

"ADAPs and Ryan White programs are meant to be gap fillers, to fill in gaps in access to treatment for lower-income people," Doyle says. "If you have a less expansive Medicaid program,

you have more people in that gap, and the gap that ADAP has to cover will be larger."

For example, South Carolina, which is one of the resource-poor states when it comes to Medicaid funding, has an ADAP with a three-month-long waiting list of 150 HIV-positive people. Moreover, South Carolina is one of a handful of states that still require people with HIV to meet a medical requirement of having a low CD4 cell count (less than 500) before they qualify for ADAP coverage.

Compounding South Carolina's problem is a growing AIDS population. The state began to receive additional federal money this year because of its growing number of AIDS cases, says **Joann Lafontaine**, MPH, program manager for Ryan White Title II, South Carolina Department of Health and Environmental Control in Columbia.

While the waiting list is longer than what it has been in the past, it still is a short enough period of time that patients on the list can receive antiretroviral drugs from the state's HIV consortia, which provide regional support medical services to HIV patients. The consortia receive their own Ryan White Title II funds. "What happens when the waiting list gets long is we eat up money in the consortia," Lafontaine says. "This is not good in the long run because it's not the best use of funding."

AIDS rate stays level, but ADAP funding falls

The largely rural southern state has the fifth-highest rate of AIDS cases per 100,000 in the nation, and this is part of the reason the state has a waiting list, Lafontaine adds. "And our HIV rate has stayed fairly level, but you see most everyone else's HIV rate going down."

To make matters worse, infectious disease specialists in the state are reporting many cases in which HIV patients' drug regimens are failing, Lafontaine says.

"We don't know if it's actually a drug failure or a patient who is not able to comply with the drug regimen," she adds.

While the state's federal funding has increased, its contribution to ADAP is lagging behind. South Carolina's contribution to the total ADAP budget is about 8%, down from 13% in 1998, according to the report.

When Hurricane Floyd struck North Carolina last fall, causing disastrous flooding and other storm damage, the state diverted more than $4 million of state ADAP funding to flood relief efforts. North Carolina still will have enough money to handle all eligible HIV cases in fiscal year 2000, says **Arthur Okrent**, manager of the AIDS Care Unit ADAP of the North Carolina Department of Health and Human Services in Raleigh.

In November 1998, the North Carolina legislature approved giving $8 million to ADAP, making it one of the few states to provide more than 50% of the total ADAP budget.

The state had only begun to explore expanding its ADAP financial eligibility from among the lowest in the nation at 125% of poverty level to 250% of poverty level when the hurricane struck. The report on expanding eligibility still needs to be reviewed by the state legislature. Meanwhile, there were not as many people added to the ADAP rolls as anticipated, so the program can survive without the state money that was diverted to flood relief, Okrent says.

Special Report: ADAP Funding

"We're cautiously optimistic and have no waiting list," Okrent adds. "We're accepting all comers who qualify for the program."

Georgia, Florida eliminate waiting lists

Georgia has headed off ADAP funding problems by changing the way the program is administered and by doing budget forecasting, Doyle says.

"Georgia had a persistent waiting list for years, and recently was able to pull everyone off the waiting list and put them on the program," he adds. "Georgia also has expanded its formulary to cover opportunistic infections treatment, which it hadn't covered in the past."

Florida also has improved its program's access with these changes:

- eliminating its waiting list two years ago;
- improving access by making drugs available to people earning up to 300% of the poverty level;
- adding 20 drugs to the formulary list.

"We have a pretty good chance of getting additional state funds," says **Joseph May**, AIDS Drug Assistance Program Manager for Florida ADAP in Tallahassee.

The only hitch is that Florida Gov. Jeb Bush has proposed a billion-dollar cut in Medicaid expenses. If Medicaid is squeezed, there could be an indirect effect on ADAP, which picks up HIV

(Continued on page 66)

State-by-State ADAP Profile

State	Financial Eligibility as % of FPL	Medical Eligibility (CD4=CD4 Cell Count, vl=Viral Load)	Protease Inhibitors Covered (5 Drugs Approved)	Non-nucleosides Covered (3 Drugs Approved)	OI Prophylaxis Covered (16 Drugs Recommended)	Other Medications Covered	Total FY 1999 Est. Budget (Federal/State Sources)	State $ Contribution as % of Total Budget	ADAP Clients Served In June 1999	Emergency Cost-Containment Measures In Place as of September 1999
Alabama	250%		5 *(4)*	3 *(2)*	5	2	$5,805,609	3%	627	Capped enrollment/waiting list
Alaska	300%		5 *(4)*	3 *(2)*	0	0	$385,071	0%	29	
Arizona	200%		5 *(4)*	3	5	6 *(3)*	$5,057,517	20% *(30%)*	608	
Arkansas	300% *(100%)*	***	5 *(0)*	3 *(1)*	9	18 *(19)*	$2,354,032	0%	276	Capped enrollment/waiting list
California	400%		5 *(4)*	3 *(2)*	12	90 *(85)*	$123,499,119	34% *(42%)*	11,097	
Colorado	185%		5 *(4)*	3 *(2)*	0	0	$5,918,178	20% *(16%)*	650	
Connecticut	300%		5 *(4)*	3 *(2)*	11	44 *(42)*	$8,656,890	7% *(9%)*	753	
Delaware	230%		4	3 (2)	10 (8)	30 *(27)*	$1,672,761	0%	146	
D.C.	300%		5 *(4)*	3 *(2)*	12	25 *(24)*	$11,909,410	3% *(7%)*	678	
Florida	300% *(200%)*		5 *(4)*	3 (1)	8	10 *(9)*	$61,517,886	13% *(9%)*	8,748	
Georgia	125%	***	5 *(4)*	3	0	0	$18,668,288	10% *(9%)*	1,233	Capped enrollment/waiting list
Hawaii	400%		5 *(4)*	3	11	15 *(14)*	$1,905,197	21% *(22%)*	107	
Idaho	200%	CD4 <500	4	3 *(2)*	1	2	$641,834	31% *(40%)*	57	Capped enrollment/waiting list
Illinois	400%		5 *(4)*	3 *(2)*	16	35 *(34)*	$21,684,730	33% *(31%)*	2,031	Monthly/yearly per capita expenditure caps
Indiana	300%		5 *(4)*	3 *(2)*	8 *(6)*	47 *(5)*	$3,907,398	0% *(36%)*	338	Waiting list
Iowa	200%		5 *(4)*	3 *(0)*	6	9 *(6)*	$863,345	0%	99	
Kansas	300%		5 *(4)*	3	8	18 *(17)*	$1,700,000	0% *(15%)*	177	
Kentucky	300%		5 *(4)*	3 *(2)*	5	9 *(7)*	$2,967,407	3% *(8%)*	323	Capped enrollment/waiting list, transferred funds from other accounts
Louisiana	200%		5 *(4)*	3 (0)	0	0	$8,451,555	0%	1,209	
Maine	200%	CD4 <400 or vl >20k	5 *(4)*	3 *(0)*	6 *(4)*	4 *(2)*	$589,748	10% *(13%)*	62	Capped/restricted access to PIs/antiretrovirals, transferred funds from other accounts
Maryland	400% *($8,750 - $29,400)*		5 *(4)*	3 *(2)*	16 *(13)*	30 *(13)*	$14,833,000	4% *(5%)*	949	
Massachusetts	<$27,000 p.a.		5 *(4)*	3 *(2)*	10 *(11)*	19 *(9)*	$11,891,611	23% *(41%)*	938	
Michigan	362%		5 *(4)*	3 *(2)*	6	7 *(6)*	$6,712,489	0%	423	
Minnesota	300%		5 *(4)*	3 *(2)*	10	26 *(25)*	$2,174,469	7% *(10%)*	269	
Mississippi	400% *(200%)*		5 *(4)*	2 *(1)*	9 *(6)*	5 *(2)*	$5,499,774	14% *(17%)*	356	
Missouri	300% *(185%)*		5 *(4)*	3 *(2)*	13 *(11)*	47 *(48)*	$7,264,955	29% *(26%)*	599	Monthly/yearly per capita expenditure caps
Montana	Need-based		5 (4)	3 *(2)*	0	1	$371,286	0%	39	Capped enrollment/waiting list
Nebraska	200%		4	3 *(2)*	0	0	$808,381	19% *(0%)*	108	
Nevada	400% *(200%)*		4	3	4 *(5)*	1 *(0)*	$4,380,240	30% *(39%)*	508	Capped enrollment/waiting list, capped/restricted access to PIs/antiretrovirals

Changes from the 1999 report are in bold. Data in *italics* are from 6/98. Shaded areas indicate restrictions lifted since the March 99 report. * These ADAPs have medical criteria for access to ARV drugs.**

Source: Doyle A, Jefferys R. "National ADAP Monitoring Report: Annual Report March 2000." The Henry J. Kaiser Family Foundation, the National Association of State and Territorial AIDS Directors, and the AIDS Treatment Data Network. Web site: http://www.kff.org/content/2000/1582/.

State-by-State ADAP Profile

State	Financial Eligibility as % of FPL	Medical Eligibility (CD4=CD4 Cell Count, vl=Viral Load)	Protease Inhibitors Covered (5 Drugs Approved)	Non-nucleosides Covered (3 Drugs Approved)	OI Prophylaxis Covered (16 Drugs Recommended)	Other Medications Covered	Total FY 1999 Est. Budget (Federal/State Sources)	State $ Contribution as % of Total Budget	ADAP Clients Served in June 1999	Emergency Cost-Containment Measures In Place as of September 1999
New Hampshire	300%		**5** *(4)*	3	**12** *(10)*	**16** *(17)*	**$721,686**	**0%** *(8%)*	**73**	Transferred funds from other accounts
New Jersey	**500%** *(<$30,000)*		**5** *(4)*	**3** (2)	**16** *(11)*	**43** *(19)*	**$25,975,844**	**3%** *(1%)*	**2,217**	
New Mexico	300%		**5** *(4)*	3	**12** *(9)*	**24** *(20)*	**$3,588,076**	**62%** *(75%)*	**286**	
New York	<$44,000 p.a.		**5** *(4)*	**3** *(2)*	**16** (14)	**371** *(192)*	**$120,060,815**	**5%** *(10%)*	**9,959**	
North Carolina	125%		**5** *(4)*	**3** *(2)*	10	**10** *(9)*	**$14,141,503**	**55%** *(13%)*	**518**	
North Dakota	150%		**5** *(4)*	**3** *(2)*	**10** *(13)*	**37** (28)	**$75,060**	**0%** *(5%)*	**13**	
Ohio	281%		**5** *(4)*	3	**6** *(7)*	**8** *(6)*	**$12,919,001**	**41%** *(42%)*	**1,085**	**Monthly/yearly per capita expenditure caps**
Oklahoma	150%		**5** *(4)*	**3** *(2)*	**6** *(7)*	**3** *(2)*	**$3,422,553**	22%	**357**	Capped/restricted access to PIs/antiretrovirals, monthly/yearly per capita expenditure caps, **capped enrollment/waiting list, transferred funds from other accounts**
Oregon	325%		**5** *(4)*	**3** *(2)*	**16** *(13)*	**175** *(167)*	**$2,840,079**	**2%** *(0%)*	**278**	
Pennsylvania	<$30,000 p.a.		**5** *(4)*	**3** *(2)*	**14** *(13)*	**37** *(38)*	**$24,114,878**	**38%** *(43%)*	**1,760**	
Puerto Rico	certified as indigent	CD4 <500 or vl >10k	**5** *(4)*	**3** *(0)*	**15** *(13)*	**79** *(80)*	**$24,566,311**	**23%** *(24%)*	**2,664**	
Rhode Island	400%		**5** *(4)*	**3** *(2)*	11	**9** *(8)*	**$1,385,078**	0%	**173**	
South Carolina	300%	CD4 <500	**5** *(4)*	**3** *(2)*	**7** *(8)*	**11** *(10)*	**$6,516,408**	**8%** *(13%)*	**649**	Capped enrollment/waiting list
South Dakota	300%		0	**2** (1)	**7** *(8)*	**21** *(19)*	**$127,570**	0%	**28**	**Capped enrollment/waiting list,** monthly/yearly per capita expenditure caps
Tennessee	300%		**5** *(4)*	**3** *(2)*	**9** *(7)*	**12** *(4)*	**$5,357,124**	0%	**159**	
Texas	200%		**5** *(4)*	**3** *(2)*	**7** *(8)*	**4** *(3)*	**$53,128,319**	**26%** *(11%)*	**4,925**	**Transferred funds from other accounts**
Utah	sliding scale		**5** *(4)*	**3** *(2)*	0	**1**	**$1,251,419**	**9%** *(12%)*	**156**	
Vermont	200%		**5** *(4)*	3	12	**18** *(13)*	**$470,000**	43%	**45**	
Virginia	200%		**5** *(2)*	**3** *(2)*	9	**6** *(3)*	**$11,996,846**	**9%** *(12%)*	**1,152**	Transferred funds from other accounts
Washington	370%		**5** *(4)*	**3** *(1)*	**11** *(10)*	**48** *(45)*	**$6,831,604**	**2%** *(38%)*	**725**	
West Virginia	250%		**5** *(4)*	3	**1** *(2)*	**6** *(5)*	**$1,053,613**	**7%** *(12%)*	**100**	
Wisconsin	200%		**5** *(4)*	**3** *(2)*	**5** *(6)*	**5** *(3)*	**$2,698,135**	**12%** *(24%)*	**288**	
Wyoming	300%		**5** *(4)*	**3** *(2)*	13	**42 (38)**	**$196,506**	0%	63	**Monthly/yearly per capita expenditure caps**

Changes from the 1999 report are in bold. Data in *italics* are from 6/98. Shaded areas indicate restrictions lifted since the March 99 report. * These ADAPs have medical criteria for access to ARV drugs.**

Source: Doyle A, Jefferys R. "National ADAP Monitoring Report: Annual Report March 2000." The Henry J. Kaiser Family Foundation, the National Association of State and Territorial AIDS Directors, and the AIDS Treatment Data Network. Web site: http://www.kff.org/content/2000/1582/.

(Continued from page 63)

patients who are ineligible for Medicaid, Arnold says.

May says the governor's proposed Medicaid cuts, particularly any pharmaceutical reductions, are a big concern.

"It's really odd in this booming economy that we have such talk of massive cutbacks in social services," May says.

Still, the Florida legislature gave ADAP an additional $8 million for fiscal year 1999, and there still is the possibility that state officials could raise that to $12 million this year, May adds. "We could lose some federal funds if we don't receive that additional matching money," he says.

But, the state with the most dire prospects this spring is Tennessee, which may be forced to close its statewide TennCare program. TennCare, the state's managed health care program for low-income families, needs $200 million more in state money or it might close, says **William L. Moore Jr.**, MD, state epidemiologist and acting director of Ryan White AIDS Support Services in Nashville.

Special Report:
ADAP Funding

"The problem with TennCare is that it's been underfunded according to managed care organizations and providers," Moore says.

TennCare, which received a 1115b waiver from the Health Care Financing Administration in 1993 to cover Medicaid-eligible people and Medicaid-ineligible underinsured and uninsured, enrolled 1.2 million people. Nine managed care companies contracted with TennCare to provide all health care needs for TennCare enrollees. But as of June 30, contracts expire for the biggest insurers, including Blue Cross/Blue Shield. And the insurers have said they will not renew unless the state puts $200 million more into the program, Moore says.

"Unfortunately, the governor's budget projects a $380 million shortfall next year, and that's not including the $200 million," he adds.

If TennCare closes, ADAP could encounter major problems because TennCare provides coverage for many HIV patients' drugs and medical care. Currently, ADAP is used to cover drugs for HIV patients for 120 days or less, depending on how quickly they can become enrolled in TennCare, Moore explains. For this reason, Tennessee has not had to provide any state funding to the ADAP program. But if TennCare closes, the $5.4 million ADAP budget likely will be strained to cover everyone eligible.

For example, South Carolina and Tennessee receive a similar amount of federal ADAP funding,

Clinton: AIDS crisis threatens U.S. security

The Clinton administration declared in May that the global AIDS crisis threatens U.S. national security because of its devastating effect on African military forces and other infrastructure.

"Look at southern Africa . . . at the progress they've made as far as economic and democratic reform," White House Press Secretary **Joe Lockhart** said at a press briefing. "And then you look at the infrastructure . . . you've got projections in some places where 50% of the military will contract HIV/AIDS in the not-too-distant future."

Lockhart said there has been no official designation, but the president and the National Security Council (NSC) consider AIDS a major threat.

"We have an interest in Africa, as far as our own national security, and we need to look at this problem as the NSC has done — very much so this year, but going back over the last couple of years — as a national security issue," Lockhart said.

The United States is contributing $250 million toward preventing HIV infection in African nations, which is only a beginning as far as what is needed, Lockhart added.

"We have to do more as far as working with Congress to get resources," he said. "We have to do more as far as mobilizing the international community and getting other countries [involved]. This is not a U.S. problem alone. There are other countries in the world with an interest in making sure that this problem is effectively dealt with."

(*Editor's note:* AIDS Alert *will provide more information about how the global AIDS crisis threatens national security in the next installment of* AIDS Alert International, *which will be published in August 2000.)* ■

but while South Carolina served about 650 HIV-infected clients in 1999 through ADAP, Tennessee served about 160 people. Tennessee's ADAP expenses were one-fourth those of South Carolina in 1998.

Still, problems like those in Tennessee can be solved with more state funding and an increase in federal ADAP money, Arnold says.

"States that don't throw in state money to help out and are just using federal money, run into the problem of having too few drugs on the formulary, or they set eligibility criteria very low, or they end up with a waiting list," Arnold says.

Reference

1. Doyle A, Jefferys R. "National ADAP Monitoring Report: Annual Report March 2000." The Henry J. Kaiser Family Foundation, the National Association of State and Territorial AIDS Directors, and the AIDS Treatment Data Network. Web site: http://www.kff.org/content/2000/1582/. ■

Report details good news, bad news of ADAP funding

States are doing better, but not out of woods yet

The AIDS Drug Assistance Program's (ADAP) simple mission, when founded in 1987 to help states purchase AZT, has become a $700 million-plus force in providing a variety of antiretroviral drugs and treatments to HIV patients in all states and territories.

Serving 61,000 people in 1999, ADAP contributed to improving the AIDS survival rate of the past few years, says **Bill Arnold**, chair of the ADAP Working Group in Washington, DC. The advocacy coalition consists of pharmaceutical companies and AIDS organizations.

"It's quite clear that one of the reasons we're not losing 40,000 people a year to AIDS and instead are dropping down to 16,000 deaths is because we are providing the medications through ADAP," Arnold says.

A new report on ADAP highlights how the program has expanded considerably in the past few years, as antiretroviral regimens became the treatment standard.

Along with the growth, a number of states experienced problems, as many had long waiting lists for people who needed the drugs and others limited drug coverage or eligibility, according to the "National ADAP Monitoring Project: Annual Report March 2000," which is a joint effort of the National Alliance of State and Territorial AIDS Directors (NASTAD) of Washington, DC, the AIDS Treatment Data Network of New York City, and The Henry J. Kaiser Family Foundation of Menlo Park, CA.

Special Report: ADAP Funding

"Since combination therapy was introduced in late 1995 as the standard of care, ADAPs have experienced a tremendous growth in monthly expenditures and a large influx of new clients," the report says.

The report notes a trend of annual increases in the monthly ADAP expenditures and the number of new clients, says **Arnold Doyle**, MSW, director of the HIV Treatment Program for NASTAD and a co-author of the report.

"We're still seeing increases, but not as great as when they peaked in 1996 when combination therapy came on the scene," Doyle says. "Also what is happening is new medications, new diagnostics, and new monitoring tests are available, and the program will start to deal with how to pay for viral resistance testing, for example."

The report's key findings are as follows:

• People with HIV receive differing levels of care, depending on where they live. In North Carolina, for example, they must have an income below 125% of the federal poverty level to be eligible for ADAP medications, while in New York state they are eligible at 500% of the poverty level. **(See state-by-state ADAP profile chart, pp. 64-65.)**

• The amount and types of drugs covered by ADAP also vary from state to state. Some states, such as Alaska, Nebraska, and Colorado, cover fewer than 20 drugs. But in California, New York, Oregon, and Puerto Rico, more than 100 drugs are available through ADAP.

ADAP clients doubled in 3 years

• The number of people served by ADAPs doubled between 1996 and 1999 to about 60,000, and the monthly costs tripled to $43 million in June 1999. These increases largely have affected the states hit hardest by the AIDS epidemic, including New York, California, Florida, and Texas.

• Antiretroviral drugs, which account for about 90% of all expenditures, represent the largest cost increases.

• Southeastern and frontier states are both increasingly affected by AIDS and continue to have the worst ADAP funding problems, resulting in capped enrollment, restricted access to protease inhibitors, and budget shortfalls.

• Those receiving ADAP assistance primarily are very poor, with an average income below 200% of the poverty level. Nearly half of ADAP beneficiaries have an income below 100% of the poverty level.

• People receiving ADAP help rarely have other insurance coverage. Only 7% received Medicaid, and another 7% had private insurance that included some prescription drug coverage.

• About 31% of ADAP clients are African-American, 40% are white, 25% are Hispanic, and Asians and Native Americans account for 1%. The race of 3% is unknown.

• Five states continue to use medical eligibility requirements, in addition to documented HIV infection, to determine ADAP coverage (down from 12 states in 1997). These eligibility requirements typically are based on CD4 cell counts and/or viral-load measurements. The five states are South Carolina, Idaho, Maine, Arkansas, and Georgia (Puerto Rico also has such a requirement).

• A total of 23 states cover 10 or more of the 16 drugs recommended by the Guidelines for the Prevention of Opportunistic Infections for Persons Infected with HIV.

The report also details outreach programs 10 states have implemented in efforts to expand their ADAP coverage of minority HIV patients. Here's a brief synopsis of what the states are doing:

• **Alabama:** The state's Department of Public Health is conducting a needs assessment that will be used to develop a comprehensive statewide HIV/AIDS plan that focuses on providing better access to care and prevention activities to minority populations.

• **California:** The state has tripled the number of ADAP-participating pharmacies to more than 2,600, and much of the expansion serves geographic areas of minority concentration.

• **Florida:** The state Department of Health will conduct a statewide ADAP needs assessment that will be used in targeting outreach efforts.

• **Indiana:** The state Department of Health has joined forces with the statewide Comprehensive HIV Services Planning and Advisory Council to increase the participation of minorities in HIV care planning. The council also will conduct a needs assessment to look at potential disparities in access to HIV care.

• **Louisiana:** To assess potential disparities in access, the state has reviewed the demographics of people served by Ryan White Title II funding. Regions that had a disparity of 10% or greater will be explored in depth, including a look at prescribing patterns of individual physicians and chart reviews to determine why clients may not be on combination therapies.

• **Maryland:** The Maryland ADAP Transitional Assistance Program works with HIV/AIDS case managers and discharge planners in the state's prison system to verify whether inmates being discharged meet ADAP eligibility requirements.

• **Mississippi:** The state redirected a portion of Ryan White funds to correct problems minorities experience in obtaining access to care and to expand treatment services at the University of Mississippi Medical Center, where many ADAP clients receive care.

• **New York:** The state routinely compares ADAP demographics with those of reported AIDS cases to identify any disparities. The state health department also commissioned a study to identify barriers to ADAP access. ADAP outreach programs focus on developing a referral network of agencies that serve minorities, gays/lesbians, criminal justice offenders, prostitutes, immigrants, substance abusers, the homeless, the mentally ill, and the hearing-impaired. A bilingual outreach staff targets Hispanic populations, and the state has culturally appropriate models for poster campaigns, as well as ads in Hispanic and African-American-oriented newspapers and radios.

• **Virginia:** Virginia is part of a multi-state and federal pilot program that provides clinical consultations to prison medical officials and offers pre-release ADAP assistance to provide a continuity of care.

• **Washington:** The state Department of Health is assessing treatment disparity issues, providers' knowledge of ADAP and other HIV services, minority HIV patients' knowledge of ADAP and HIV services, and client satisfaction with ADAP services. Also, the health department contracts with the state department of corrections and the state's alcohol and substance abuse agency to encourage appropriate medical care for HIV-positive people. ■

Gene research could be key to HIV treatment advances

Procedure could block HIV replication in cells

It's a long way from being used in a clinical setting, but Philadelphia researchers have had some success in testing a process that could actually render HIV harmless.

"We tested a concept that it might be possible to block replication of HIV in cells that are already infected," says **Stuart Starr**, MD, professor of pediatrics at the University of Pennsylvania Medical School and chief of immunologic and infectious diseases at The Children's Hospital of Philadelphia.

Most of the latest genetic research into HIV treatments has focused on protecting uninfected cells from becoming infected with HIV. Starr's group instead focused on infected cells and whether a genetic approach might be helpful, along with other therapies.

"So this study is a proof of the concept that a genetic approach might also be considered for infected cells," Starr says.

The researchers already knew that the HIV tat gene is essential for the virus to replicate in the infected cells. So, they designed an anti-tat gene that blocks the HIV tat gene's function. Then they inserted the anti-tat gene into a mouse retrovirus that can enter cells that are sites for HIV replication. Researchers took blood immune cells taken from patients infected with HIV and inserted the beneficial gene into those cells. This effectively blocked the AIDS virus from replicating in those cells and prevented the virus from activating.

The research done so far is only a first step, Starr says.

"In order to test this concept further, we need to move into an animal model and see whether we can achieve similar results," he explains. "There are formidable obstacles to getting this to work in a whole animal, as well as in the test tube, and at the moment I would say this approach is going to require a lot of work to bring it into the clinic."

If the process continues to work on animal models and then in humans, it could offer HIV patients and their physicians an alternative to antiretroviral therapy, or at least a longer latency period in which patients are free of symptoms before antiretroviral drugs are necessary, Starr says.

"One reason for developing this approach is that the other approaches have given outstanding results in terms of short-term clinical improvement and outlook for quality of life, but unfortunately, the drugs don't help everyone," Starr says. "And they have side effects and they are very expensive, so while they've been a tremendous improvement, they may not be the total answer."

Starr estimates the research still is three to five years away from being developed for clinical use.

"Even though we're a long way away from having a genetic approach that has a reasonable chance of working in humans, we thought it was important to take the first step, because this approach eventually may be an important complement to other treatments," Starr adds. ■

New testosterone treatment product easier to manage

Topical gel is applied once a day

Studies have shown that HIV patients who also have low testosterone will benefit from some sort of testosterone treatment, which will decrease their depression, improve their sex drive, and increase lean body mass. But administering yet another treatment to men who already are taking many medications is problematic at best.

UNIMED Pharmaceuticals of Buffalo Grove, IL, recently received U.S. Food and Drug Administration approval for a possible solution to that problem. The company is marketing a testosterone gel called AndroGel, which is the first testosterone treatment approved for use in a gel form.

"Testosterone administration is a difficult problem technically," says **Adrian Dobs**, MD, MHS, associate professor of medicine at Johns Hopkins School of Medicine in Baltimore. Dobs is one of the investigators for the testosterone gel product.

Testosterone given in injections every two weeks has two drawbacks, she explains. "It hurts a little bit, and the levels get very high after the injections and then get low every two weeks," she says. "People call it a roller-coaster effect."

Testosterone also can be delivered by a skin patch. The patches sometimes cause skin irritation, or they might not result in sufficiently high

testosterone levels, Dobs adds. Testosterone pills often don't deliver enough testosterone because they are broken down by the liver so quickly.

The new testosterone gel consistently raises the hormone to high levels and is well-tolerated, Dobs says.

"We've been working with the gel for two years in drug development, and we've had good experiences with it," she notes. "There's no irritation, and the serum levels are quite good."

For example, the normal range of testosterone is 300-800 ng/dL. AndroGel was found to raise levels to 700 ng/dL and keep the levels in this range.

The gel is available in daily application packets that a man rubs on his shoulders, upper arms, and/or abdomen each morning. The product dries within a few minutes. As the skin absorbs the testosterone, it is gradually released into the blood, where it restores normal testosterone levels within one to four hours.

Studies have looked at the gel's use with men who had hypogonadism due to conditions like Klinefelter's syndrome or because of their age. While the product has not been tested on men who have HIV, it would appear to be a solution to low testosterone for them as well, Dobs says.

"We've done studies looking at the end effects of testosterone, and it turns out this has been very efficacious in increasing lean body mass and improving sexual function, and these things are all very relevant to an HIV population," she explains.

Studies showed that the product is very safe, Dobs says. "We did have one man who dropped out of the study because he said it was a little messy."

Clinicians prescribing the gel will need to monitor patients' hematocrit levels every three months for at least a year, Dobs advises.

Other precautions are that the testosterone could be transferred from one person to another through vigorous skin-to-skin contact at the application site. So patients should be cautioned to wash hands immediately with soap and water and cover the application sites with clothing after the gel has dried.

Also, the product is not recommended for men with prostate cancer, breast cancer, or heart, kidney, or liver disease. Also, geriatric patients may be at an increased risk for the development of prostatic hyperplasia and prostatic carcinoma.

The price of the gel had not been determined by the time *AIDS Alert* went to press. ■

HIV patients increasingly at risk for domestic violence

Study shows HIV patients can be victims

Clinicians seeing HIV patients need to be aware of yet another problem their patients might experience during the course of their chronic illness: domestic violence.

Asking patients whether they've experienced any abuse is not a routine part of HIV management, but perhaps it should be, says **Sally Zierler**, DrPh, professor of medical science in the Department of Community Health at the Brown University School of Medicine in Providence, RI.

Zierler was the lead author of a report about domestic violence among HIV patients. The report bases its information on results from the HIV Cost and Services Utilization Study. The report found that nearly 13% of HIV patients surveyed had experienced physical harm since their diagnosis of HIV infection, and their injury came from someone close to them. More than 20% of the women reported violence victimization, and gay men reported more harm than straight men, with 11.5% of homosexual and bisexual men reporting violence vs. 7.5% of heterosexual men.

The study collected data on the number of people who reported physical assaults since their HIV diagnosis and on those who reported some type of physical harm within a loving relationship or relationships that were important to them.

Clinicians working with HIV patients are in a position to identify victims and offer information and resources that could help patients who are experiencing domestic abuse, Zierler says.

"Patients are more satisfied with their care when a provider asks them about safety in their personal relationships," Zierler says. "It is a quick question, and patients for the most part really are grateful to be asked."

If an HIV patient is being abused by a loved one, there is a good possibility that the person will be less compliant with HIV medications and treatments, Zierler theorizes.

"We know from studies with women and health care utilization patterns that women are less likely to access certain services if they're in abusive relationships," she explains. "They're more likely to show up later for prenatal care and are less likely to stay on medications they need."

One aspect of domestic abuse is a control factor, in which the abusive partner may withhold medication or prevent the victim partner from leaving the house for medical treatment, she adds.

Zierler suggests clinicians approach patients on the issue of domestic violence by beginning casually, and saying, "Everybody fights in their home. When you and your partner fight, or when you are with someone you love and you fight, do you ever feel afraid that you are really going to be hurt? Have you ever been hurt? If so, here is a pile of numbers you can call."

However, Zierler acknowledges that if the patient is a man, there may be fewer community resources available to help. "Most of the services have been built around women's needs," she says. "And one of the issues we want to be sure comes out in this paper is that gay and bisexual men really need attention in the area of domestic violence."

Still, some AIDS or gay organizations might be able to help. In Zierler's state of Rhode Island, there is an AIDS volunteer agency that provides counseling for men who are victims of gay male battering, and these types of services probably are available in most larger metropolitan areas.

"Particularly, since we noted that there were high reports of violence among Hispanic gay and bisexual men, it speaks to a particular need for support to groups that are more susceptible to isolation," Zierler adds.

The study found that Hispanic gay men reported the highest prevalence of violence against them, with a rate of 13.6%. Also, the study showed that gay and bisexual men under the age of 40 are three times more likely to be a victim of violence.

While the study did not seek causes for domestic abuse, there was one question relating to this. Participants were asked if they thought their physical harm resulted from or was related to their HIV infection. Close to half of the respondents said "Yes."

Although it's possible HIV infection is a trigger for domestic violence, this study doesn't prove that hypothesis. "This doesn't mean that HIV caused the harm, because we don't know if they didn't have HIV whether the same thing would have happened," Zierler says. "People who are at risk for HIV infection have a lot of violence in their lives, as well."

Zierler says the factors related to risk of partner / relationship violence were a history of drug dependence, homelessness, and unemployment. Racism, homophobia, sexism, and poverty also play a role in raising the risk of violence, she adds.

"The point is that the conditions that set people up for HIV are very similar to those that put them at risk for violence," Zierler says. "These are populations of people who are essentially living lives that have been dehumanized and are finding strategies of resistance to the social forces that are beating down on them day to day."

Clinicians also can look for certain risk factors among their patients. For instance, there is a greater risk of domestic abuse among women who live in the Midwest and among women who have symptoms of vaginal infection. ■

AIDS Alert® (ISSN 0887-0292), including **AIDS Guide for Health Care Workers**®, **AIDS Alert International®,** and **Common Sense About AIDS**®, is published monthly by American Health Consultants®, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodical postage paid at Atlanta, GA 30304. POSTMASTER: Send address changes to **AIDS Alert**®, P.O. Box 740059, Atlanta, GA 30374.

Subscriber Information

Customer Service: (800) 688-2421. Fax: (800) 284-3291. Hours of operation: 8:30 a.m-6:00 p.m. M-Th, 8:30-4:30 F EST. E-mail: customerservice@ahcpub.com. Web site: www.ahcpub.com.

Subscription rates: U.S.A., one year (12 issues), $399. Approximately 18 nursing contact hours or Category 1 CME credits, $449. Outside U.S., add $30 per year, total prepaid in U.S. funds. One to nine additional copies, $319 per year; 10 to 20 additional copies, $239 per year. For more than 20 additional copies, call customer service for special handling. Missing issues will be fulfilled by customer service free of charge when contacted within 1 month of the missing issue date. **Back issues**, when available, are $67 each. (GST registration number R128870672.)

This continuing education offering is sponsored by American Health Consultants®, which is accredited as a provider of continuing education in nursing by the American Nurses Credentialing Center's Commission on Accreditation. Provider approved by the California Board of Registered Nursing, provider number CEP 10864. This continuing education program does not fulfill State of Florida requirements for AIDS education. American Health Consultants® designates this continuing medical education activity for up to 18 hours in category 1 credit towards the AMA Physicians' Recognition Award. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

American Health Consultants® (AHC) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. This CME activity was planned and produced in accordance with the ACCME Essentials.

Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

Editor: **Melinda Young**, (828) 859-2066.
Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@medec.com).
Editorial Group Head: **Coles McKagen**, (404) 262-5420, (coles.mckagen@medec.com).
Associate Managing Editor: **Kim Coghill**, (404) 262-5537, (kimberly.coghill@medec.com).
Senior Production Editor: **Brent Winter**, (404) 262-5401.

Editorial Questions

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

Viral-load self-test kits in future for HIV patients

Kits similar to glucose meters used by diabetics

Michigan researchers are designing a new test kit that will let HIV patients check while at home whether their viral load is remaining stable or increasing.

The home test will use a new technology that operates differently from the current laboratory polymerase chain reaction viral-load test. "It will be a fluorescent-based type of sensor that will look at cell receptors that combine to the HIV virus," explains **Sheila Grant**, PhD, an assistant professor at Michigan Technological University in Houghton, MI. Grant is the chief researcher on the project.

The procedure will join dyes to two different synthetic proteins. Since HIV opens up the cell receptor doors in order to infect a cell, when the receptors are altered with dyes and combined with the virus, it will cause the dyes to elicit a fluorescence that can be monitored. A patent is pending on the process.

With $40,000 in grant seed money, the project is under way and will probably produce a prototype test kit by 2002, Grant says.

The test kit will be designed to handle tiny pin-pricks of a patient's blood. Patients put their blood on a test strip and wait for the digital device to give them a "yes" or "no," depending on whether their viral load has exceeded a predetermined limit. If the viral load is below the limit, then they will know their therapy is continuing to work effectively. If the viral load has risen above the limit, then they will know that it's time to see a physician about making some changes to their regimen.

Grant says clinicians could ask patients to monitor their viral loads at regular intervals, such as once a week.

The home test kit would be less expensive than laboratory reports, and it would be more convenient for patients. They could take it with them when they are traveling, for instance.

Plus, a home test kit might reinforce patients' adherence to their drug therapy and provide them with a psychological benefit from knowing they have some control over maintaining their disease, Grant says. ■

CE objectives

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

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

Common Sense About AIDS®

What you should know about HIV vaccine trials

AIDSVAX enters Phase III

Researchers the world over are currently trying to develop safe and effective HIV vaccines. One vaccine, named AIDSVAX, is undergoing major clinical trials in the United States and Bangkok, Thailand. The Centers for Disease Control and Prevention (CDC) in Atlanta is providing answers to common questions about AIDSVAX on the CDC Web site at www.cdc.gov. Here is some of the CDC's AIDSVAX information:

Why is the AIDSVAX Phase III vaccine trial in Thailand being conducted?

The development of an effective HIV vaccine is a public health priority throughout the world. Because no one knows for sure which vaccine or type of vaccine will be most effective, multiple vaccines are being explored simultaneously.

The AIDSVAX Phase III trial is part of that plan. VaxGen, Inc., a biomedical research company based in San Francisco, developed AIDSVAX, the candidate vaccine to be evaluated. The company will fund most aspects of the study.

Who is conducting the AIDSVAX Phase III trial?

The Bangkok Metropolitan Administration (BMA) is leading the three-year collaborative research trial. BMA is conducting the trial in conjunction with VaxGen, the Mahidol University Faculty of Tropical Medicine in Bangkok, and the HIV / AIDS Collaboration (a longstanding research collaborative between the Thai Ministry of Public Health and the CDC).

What is the trial designed to do?

The trial is designed to determine if AIDSVAX is effective in protecting against HIV infection and disease. While Phase I and II trials have already demonstrated that the vaccine is safe for use and is capable of inducing antibodies against HIV infection, it is not known if the level and type of antibodies produced will prevent HIV infection. This trial will answer that question. Large-scale human testing (called a Phase III trial) is the last and most important step in the evaluation process before a vaccine is considered for licensing.

How is the trial designed?

The trial is being conducted among uninfected injection drug users (IDUs) attending 17 drug treatment clinics in Bangkok. The design is a randomized, double-blind, placebo-controlled trial in which half of the 2,500 volunteers receive the AIDSVAX vaccine being evaluated and the other half receive placebo injections that do not include the vaccine. Neither the researchers nor the participants know which participants are in each half of the trial. To ensure that none of the participants relax their preventive behaviors, all volunteers receive extensive counseling on how to protect themselves against HIV infection, as well as explicit warnings that it is unknown whether or not this vaccine will protect them from infection.

Why is this particular vaccine being evaluated?

Thai officials chose to work with VaxGen to evaluate this vaccine because it has proven safe and effective in stimulating an immune response against HIV subtypes E and B, the subtypes most common in Thailand. If AIDSVAX proves to have a protective effect, it

would therefore be effective against the subtypes causing the local Thai epidemic. AIDSVAX is also the first vaccine to receive approval for Phase III trials.

Why do only some of the participants receive the vaccine? Do the other participants get any benefit from the trial?

A placebo-controlled design (where some of the participants receive the vaccine being tested and some receive no vaccine) is currently the only scientifically sound way to determine if a vaccine works. In order to determine how effective the vaccine is, researchers will compare the rate of HIV infection in participants who receive the vaccine to the rate among those who receive the placebo injection. If people in the vaccine group have lower rates of infection than people with similar risk behaviors in the group that receives the placebo injection, then researchers will know the vaccine works. If the rates of infection are the same in both groups, researchers will know the vaccine does not work.

How do you expect to determine if the vaccine prevents infection if you are counseling everyone to protect themselves from exposure?

Health officials have an obligation to ensure that all participants benefit from proven prevention methods as we search for new ones. And while risk-reduction counseling has proven effective in reducing IDUs' risk for HIV infection, it has not proven effective in totally eliminating HIV risk. If behavior change programs were 100% effective, we would not need an HIV vaccine. Regardless of the best efforts at HIV prevention counseling, some individuals will continue to take risks. By comparing the rates of infection among those at risk in both groups, researchers will be able to determine if the vaccine helps protect these individuals from infection.

Do the participants know that some do not receive any vaccine?

Yes. Because of possible language and educational barriers, Thai health officials have worked with CDC, local clinic staff, and IDUs themselves to design an extensive process to ensure that volunteers understand what their participation in the trial means, exactly what they receive and do not receive as part of the trial, and that trial participation does not protect them from infection. Potentially eligible volunteers participate in an education session on the nature of the study (which includes a video) and then are given the opportunity to ask questions.

If participants become infected during the course of the trial, are they provided medical care?

Yes, the BMA has committed to providing medical care to any participants who become infected according to the Bangkok Metropolitan Administration Guidelines for Clinical Care of HIV-Infected Patients (27 May 1998).

Why has there been skepticism about the potential effectiveness of AIDSVAX?

The AIDSVAX vaccine was developed over a period of 10 years. The first version of the vaccine was based on only one strain of HIV. Because of the increasing genetic diversity of HIV across the globe, many believed it was important to add additional strains. VaxGen has since improved the vaccine by basing different versions of it on different strains of HIV. For use in Thailand, for example, it was necessary to add an HIV strain from the subtype E virus, which is predominant in Thailand. The vaccine used in Thailand is composed of both subtype B (MN strain) and subtype E (A244 strain) antigens. For other areas of the world where the HIV subtypes may differ, the vaccine would have to be manipulated based on the strains common in those particular areas. ■

To the health care worker: *Common Sense About AIDS* is written especially for your patients and other laymen. It explains important issues concerning AIDS in a thorough, yet easy-to-understand style.