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May 2001 • Volume 16, Number 5 • Pages 53-68

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State ADAPs face summer crisis, needing \$50 million extra

The national AIDS Drug Assistance Program (ADAP) is \$50 million short of averting an emergency this summer as states continue to see increases in the number of people applying for HIV medications through the program. A few states already have waiting lists, but many more might experience difficulties beginning in June, ADAP officials say. Meanwhile, congressional efforts to pass a Medicare drug benefit could have a positive effect on ADAPs, which have some clients who would be eligible for Medicare coverage, but this solution is a long way from becoming a reality Cover

Medicare drug bill could have positive impact on ADAPs

Although it's still a long way from becoming a reality, a Medicare prescription drug bill could be one solution to funding problems experienced by AIDS Drugs Assistance Programs (ADAPs), whose client lists are growing faster than their funding. While Medicaid expansions through waiver programs would also be useful, those types of efforts require committed state governments and completion of a lengthy bureaucratic process. And as the recent National ADAP Monitoring Project Report notes, federal-level initiatives to allow states to expand Medicaid coverage to low-income, non-disabled people living with HIV have not succeeded. 56

Important factors in ADAP help: Location, location, location

Uninsured HIV-infected people in New York who earn less than \$44,000 per year, which is more than 500% of the federal poverty level, may choose from six protease inhibitors, three non-nucleosides, 16 opportunistic infection prophylaxis drugs, and 408 other medications from the state AIDS Drug Assistance Program (ADAP), according to the 2001 National ADAP Monitoring Project Report. In other states, however, the selection is much slimmer 57

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More patients seek drugs through ADAPs, creating \$50 million deficit

Changes in Medicare, Medicaid might have impact

The national AIDS Drug Assistance Program (ADAP) continues to experience shortfalls in the amount of federal and state funding necessary to provide antiretroviral medications to everyone who needs treatment, and ADAP officials say there is no remedy in sight.

Meanwhile, Congress and President Bush's administration are trying to find a way to provide drug coverage through Medicare, which theoretically could help relieve some of ADAP's financial strain. On the other end of the spectrum, many states are experiencing budget crises of their own, so it's less likely that they will be able to fill in the budget gap.

ADAP serves about 70,000 people, a 12% increase over 1999, and ADAP's expenditures for HIV medications increased by nearly double that amount in one year's time, according to a new report.

State ADAP programs had a 22% increase in expenditures, filling 209,501 prescriptions, in June 2000 when compared with June 1999 among the 47 jurisdictions that provided complete data for those periods, according to the National ADAP Monitoring Project Report, released in March 2001. (See story on **ADAP Monitoring report highlights, p. 57.**)

Although states are in much better shape for providing HIV medications to those in need than they were a couple of years ago, the recent increases in new ADAP clients and drug expenditures have created the potential for a crisis this summer, says **Bill Arnold**, chair of the ADAP Working Group in Washington, DC.

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HIV patients often overuse emergency rooms

A California study shows that clinicians need to educate HIV-infected patients about when to contact their physicians instead of automatically going to the emergency room when faced with a health crisis. Patients often use the emergency department instead of visiting their regular doctor, even for common symptoms such as tension headaches, concludes the study published in the December 2000 issue of the *Journal of General Internal Medicine* 58

AIDS Alert International

New partnership will try to reduce infections, deaths

While the consciences of industrialized nations are awakening to the AIDS pandemic in sub-Saharan Africa, most people, even in the United States, are unaware that the Caribbean has the world's second-highest prevalence of HIV infection. A new Pan-Caribbean Partnership, formed earlier this year, is designed to bring attention to the Caribbean's HIV epidemic, and it will help Caribbean governments and organizations meet the challenges of treating HIV-infected people and preventing HIV infection 59

AIDS vaccine efforts have followed long and bumpy road

Author Jon Cohen discusses the arduous journey taken by researchers and others working to develop an AIDS vaccine. In his new book, *Shots in the Dark: The Wayward Search for an AIDS Vaccine*, Cohen documents the frustration that many in the HIV community feel regarding the lack of cohesive planning that has gone into the AIDS vaccine search. 64

HIV academy sets qualifications for 'HIV/AIDS specialist'

The new American Academy of HIV Medicine of Washington, DC, has established standards for clinicians who specialize in treating HIV/AIDS patients. To be designated an HIV/AIDS specialist, a clinician first needs to be state-licensed as a physician, nurse practitioner, physician assistant, or doctor of pharmacology 66

COMING IN FUTURE ISSUES

- **What's in store for 2002 funding?** With the current administration's focus on tax cuts, will HIV care be left out?
- **Anti-lipodystrophy drug:** Recent studies suggest HIV regimens containing nevirapine show a lipid profile that might be beneficial to patients over the long term
- **Coaching HIV patients:** Therapy/counseling model of treating patients' emotional needs and behavioral issues is giving way to new 'co-active coaching' approach
- **Update on OIs:** Snapshot look at latest trends, treatments, prevention techniques
- **Latest data on drug resistance testing:** Multiple studies show benefits of individualizing drug therapy according to resistance patterns

"We've already written to President Bush, saying, 'We've got a crisis and need emergency supplemental appropriation in this year of \$50 million,'" Arnold says.

"What's mainly driving the crisis at the national level is that more people continue to come out of the woodwork who need ADAP help," he adds.

About 600 additional people join ADAP rolls nationwide each month. Attrition is not as significant a factor as it once was, thanks to the drugs keeping people alive longer.

"We asked for an additional \$60 million last year, which we did not get," Arnold says. "So we ran figures and said, 'People will cut back in small ways you won't notice much, but we'll still have a \$50 million crunch.'"

Large states will be hit first

Some state ADAPs will begin to experience problems as early as June, Arnold predicts.

"ADAP programs will not be able to add any new drugs, and in some places they'll have to cap their enrollment, which means you'll have to wait for somebody to die before you get a slot, and there will be official or unofficial waiting lists," Arnold says.

Large states with high numbers of HIV-infected people will feel the effects of the shortage first, Arnold predicts. These include California, Florida, and Texas. Some smaller states that historically have had waiting lists for ADAP enrollment also might feel the crunch, including South Carolina, Alabama, and West Virginia.

Alabama has 340 people on a waiting list and a total of 890 people enrolled in the program, says **Jane Cheeks**, MPH, JD, state AIDS director of the Division of HIV/AIDS Prevention and Control in the Alabama Department of Health in Montgomery.

Those on the waiting list are receiving medications from emergency sources, such as HIV/AIDS clinics or pharmaceutical assistance programs, Cheeks says. "We don't know of anybody at this point who wants medication but can't get it through our clinics."

Each month, the Alabama ADAP receives 20 to 30 applications for assistance, but the program can only add a new person when someone else has been taken off the list permanently, either through dying or moving out of state, Cheeks says.

"We've had some people who went back to work, but they are not making enough to pay for

medications, or they are making too much to be eligible for Medicaid,” Cheeks adds. “We’re not seeing much of people getting private insurance.”

South Carolina has a small waiting list of 59 people. These people also receive medications through other sources, says **Joann Lafontaine**, MPH, program manager of Ryan White Title II at the South Carolina Department of Health and Environmental Control in Columbia.

“We have had a waiting list for a very long time,” Lafontaine says.

Florida has no waiting list at present. The state will receive a \$5.8 million increase in federal Title II funding for the fiscal year which began April 1, 2001, but even that increase won’t cover all of the growth the state’s ADAP has experienced in the past year, says **Joseph May**, ADAP manager at the Florida Department of Health in the Bureau of HIV/AIDS in Tallahassee.

Florida’s ADAP budget is about \$70 million, so the \$5.8 million increase is less than 10%. On the other hand, the state ADAP added 1,680 new clients to its ADAP list in 2000, about 13% of its total caseload of 13,000. Some people have come off the ADAP caseload, but the net growth is still high, May says.

“Our concern is that our net growth will more than eat up our funding increase,” May says.

Colorado, which is a state that has had some significant problems with ADAP funding in the past, now has no waiting list and is adequately funded. However, that situation will likely change this year as the state makes its financial eligibility requirement less stringent, says **Karen Ringen**, program administrator for the Ryan White Title II Program in Denver.

Colorado’s previous financial eligibility requirement to qualify for ADAP — income at 185% of the federal poverty level (FPL) — was among the nation’s strictest, according to the ADAP Monitoring Project Report.

The only states with less generous financial restrictions are North Carolina (125% of FPL) and North Dakota (150% of FPL), the report notes. **(See State ADAP chart, inserted in this issue.)**

New York state, while having one of the most generous ADAP formularies and one of the largest HIV populations, has gotten through the past year without having to add restrictions or tolerate a waiting list, says **Lanny Cross**, ADAP director at the New York State Department of Health in Albany.

“Definitely a number of states are right on the edge financially,” Cross says. “I know that states

like California and Illinois are counting every dollar every day to see if they can get through the current year.”

NY’s Medicaid program provides coverage

New York’s ADAP has been helped by the fact that the state’s Medicaid program is comprehensive and provides medical and pharmaceutical coverage to HIV-infected people regardless of whether they have AIDS symptoms. “In other states, you have to be disabled, which puts more of a burden on those who are asymptomatic with HIV,” Cross says.

If the national ADAP program does not receive the \$50 million emergency increase, then New York’s program may have to transfer money from other AIDS programs to make up for the shortfall, but there likely will not be any ADAP cutbacks, Cross says.

Besides hoping for more funding, ADAP directors would like to see Congress pass a Medicare pharmacy benefit, which would take some people off ADAP lists.

“About 8% of ADAP clients were reported to be on Medicare, as well,” says **Arnold Doyle**, MSW, director of the HIV Treatment Program of The National Alliance of State and Territorial AIDS Directors in Washington, DC. **(See story about how Medicare could help ADAPs, p. 56.)**

“So, potentially, if those folks had access to drugs from other places, they would be able to use that benefit before ADAP,” Doyle says. “The same thing would happen with Medicaid expansions.”

Unfortunately, in the case of Medicaid, most states do not consider people who are HIV-positive to be eligible for coverage unless they are poor and disabled, such as having AIDS-defining illnesses, Doyle adds.

Some states have applied for Medicaid waivers that would allow them to provide coverage to HIV-positive individuals, Doyle notes.

“In the cases where the waivers have been approved, including Maine, Massachusetts, and DC, it’s been shown to be budget-neutral,” he adds.

In the meantime, ADAP enrollment continues to grow at a much faster rate than its funding.

South Carolina’s ADAP program continues to add more clients, but there is little chance of receiving additional state funding, Lafontaine says.

“Our state is in the same situation as many states, where we’re seeing huge shortfalls in the

state budget, so we won't get their attention this year or in the near future," Lafontaine says.

Colorado's program is another case in point: While the program now offers eligibility to a greater number of clients and has added treatment for opportunistic infections to its formulary, its new funding that went into effect April 1, 2001, was increased by only \$127,000, just enough money to cover 15 additional clients, Ringen says.

"We don't want to be in a situation where we offer medications to more clients and then in a couple of years have to stop their medications," Ringen adds. ■

Medicare drug bill could lend boost to ADAPs

Both elderly, disabled would benefit

Although it's still a long way from becoming a reality, a Medicare prescription drug bill could be one solution to funding problems experienced by AIDS Drugs Assistance Programs (ADAPs), which have client lists that are growing faster than their funding.

Medicaid expansions through waiver programs would also be useful, but those types of efforts require committed state governments and completion of a lengthy bureaucratic process. As the recent National ADAP Monitoring Project Report notes, federal-level initiatives to allow states to expand Medicaid coverage to low-income, non-disabled people living with HIV have not succeeded.

Further, Medicaid waivers and expansions probably will not be the solution for cash-strapped ADAPs because the Medicaid programs in most states are facing their own budget problems, says **Tanya Ehrmann**, director of public policy for AIDS Action in Washington, DC.

"A lot of states in the last few months have become very concerned about being able to meet the needs of their current Medicaid population over the long term," Ehrmann says. "Some states have caps on prescription drugs and don't provide adequate payment for Medicaid beneficiaries to have access to the best HIV doctors."

The more important change would be for Medicare to start offering drug benefits, which would move some of the most vulnerable members of the HIV-infected population over to

Medicare funding of their drugs, Ehrmann says.

However, President Bush, Congress, and interested parties are a long way from agreeing on how a Medicare drug plan should be designed.

In March, Congressional Budget Office (CBO) Director **Dan Crippen** said President Bush's proposal for Medicare reform and a prescription drug benefit would provide only a "fairly thin" benefit. The CBO estimates that the \$153 billion over 10 years that Bush proposes is a fraction of the \$1.1 trillion needed to provide a full drug benefit, which would have a \$1,000 annual deductible.

"How this Medicare prescription drug program will be designed is critical," Ehrmann says. "There has certainly been a lot of talk about providing prescription drugs only to low-income Medicare beneficiaries, and I haven't heard anything in that discussion about the disabled population that's low-income and that is spending tremendous amounts of money out-of-pocket on prescription drugs."

States face money crunch

Ehrmann and others say the federal government cannot expect states to throw more money at HIV treatment when their budgets are already so tight, and this leaves the bulk of responsibility with ADAPs.

However, a Medicare drug benefit would help both elderly HIV patients and younger patients who receive Medicare because they are disabled by AIDS.

"Medicare drug benefits would relieve pressure on ADAP," says **Lanny Cross**, director of the ADAP Program at the New York State Department of Health in Albany. "Disabled people on Medicare who are earning above the Medicaid income level could receive Medicare drugs if this is passed."

Ironically, there were some Medicare HMOs in Florida that did provide prescription coverage to some HIV patients, but recently there has been a trend of those plans curtailing their pharmacy benefits. This has forced more people to apply for ADAP assistance, says **Joseph May**, ADAP manager with the Bureau of HIV/AIDS in the Florida Department of Health in Tallahassee.

"We've documented needs of over \$1 million from people who have health insurance without adequate pharmacy benefits," May says, adding that a Medicare drug benefit would have a positive effect of taking many of those clients off ADAP rolls.

A Medicare drug benefit would benefit HIV-infected people like **Rae Lewis-Thornton**, a spokeswoman for AIDS Action in Chicago. Lewis-Thornton has lived with HIV infection for 16 years. For the past seven years, she has received federal disability checks, which now amount to \$800 a month. Because she is disabled, Medicare pays for her hospitalization and outpatient medical treatment.

Lewis-Thornton's disability income places her in an income bracket too high to qualify for Medicaid, so she has no insurance coverage for her medications. Until recently, she had received her \$2000-per-month drug regimen at no charge through the Core Center in Chicago. Core Center is a state-of-the-art infectious disease center founded as a collaborative effort between Cook County Hospital and St. Luke Rush Presbyterian Hospital, both of Chicago.

"I was told yesterday that the clinic is not going to provide medicine anymore, only in special situations, and we all have to apply for ADAP," Lewis-Thornton reports. She says the change concerns her because she has no idea if the state's ADAP formulary would cover all of the medications she needs, or how long it will take for ADAP to approve her application.

Medicare drug benefit would help some

All of this uncertainty could be alleviated if Congress passed a Medicare drug benefit that would cover disabled people with HIV infection, Lewis-Thornton says.

She has told her story to members of Congress, and she emphasizes that a Medicare drug benefit would not only be humane, but also cost-effective in many cases.

For example, several years ago Lewis-Thornton was hospitalized with pneumonia. She is allergic to the standard treatment, and this was her third round with the disease, so her physicians decided she would need to receive a 21-day treatment with an intravenous antibiotic. The treatment could be given to her at home by a home health nurse, which would be approximately 80% cheaper than a hospital stay for those same three weeks. However, her physicians had to change their minds and keep her admitted in the hospital because Medicare would not pay for the \$275 per day medication regimen while she was at home.

"The best HIV treatment has to look at what is more cost-effective," Lewis-Thornton maintains. ■

Location strongest factor in getting ADAP help

Here's a look at good, bad, and ugly

The AIDS Drug Assistance Program (ADAP) benefit formulary in New York reads like a five-star restaurant menu: Uninsured HIV-infected people who earn less than \$44,000 per year, which is more than 500% of the federal poverty level (FPL), may choose from six protease inhibitors (PIs), three non-nucleosides, 16 opportunistic infection (OI) prophylaxis drugs, and 408 other medications, according to the 2001 National ADAP Monitoring Project Report.

Suppose the same HIV-infected person grew tired of cold winters and moved south to North Carolina. The formulary in that state includes five PIs, three non-nucleosides, 11 OI prophylaxis, and 22 other medications. But it's only available to people earning 125% FPL or less, which basically means the average client would have an income lower than the \$10,000-\$15,000 annual cost of an HIV antiretroviral regimen.

Some states give no money to ADAPs

The amount of money that states contribute to ADAPs also varies widely. About 60% of the ADAP budget in New Mexico comes from the state's contribution. By contrast, Rhode Island, Wyoming, Montana, North Dakota, Arkansas, Delaware, Iowa, Indiana, Kansas, Louisiana, and Michigan contributed no money to the total ADAP budget in fiscal year 2000, the ADAP report says. The report is the fifth in a series of annual reports about ADAP and is published by The National Alliance of State and Territorial AIDS Directors of Washington, DC, the AIDS Treatment Data Network, and Henry J. Kaiser Family Foundation of Menlo Park, Calif.

Here are some of the report's major findings:

- The population receiving help from ADAP is 40% white, 30% African-American, and 25% Hispanic.

- ADAP programs with inadequate funding will add restrictions and limitations, including lower financial eligibility criteria, smaller formularies, enrollment caps, and restricted access to antiretroviral medications.

- ADAP formulary coverage varies from states that cover no OI treatments to 16 OI prophylaxis

treatments covered in California, Alaska, Hawaii, New Jersey, New York, and Oregon.

- The number of clients served by ADAPs more than doubled between July 1996 and June 2000. The change reflects a growth in the number of people living with HIV/AIDS, increasing client demand due to the availability of more effective therapies, and increases in funding available to ADAPs.

- Monthly program expenditures increased more than threefold between July 1996 and June 2000. This increase was caused by rising drug costs and the increasing complexity of treatment regimens.

- In June 2000, 46% of ADAP program expenditures paid for nucleoside analogues; 29% paid for protease inhibitors; 12% went to non-nucleoside reverse transcriptase inhibitors; and 13% went for other medications.

- Expenditures for OI medications and other drugs rose overall by 19% between July 1997 and June 2000 among the 32 ADAPs that cover these drugs and provide complete data.

Only 10% of ADAP clients have drug coverage

- Most ADAP clients are uninsured, with only 10% receiving some prescription drug coverage through private insurance in June 2000.

- The fiscal year 2000 budget for ADAP was approximately \$724.5 million, an increase of 9% over the previous fiscal year.

- The federal contribution to ADAP increased in 2000 to 73%, compared with 69% of the national ADAP budget in fiscal year 1999 and 27% in fiscal year 1996.

- Ten states reported having capped enrollment to their ADAPs, and 17 states reported one or more current and/or projected program limitations.

- Six ADAPs increased their financial eligibility levels since the last report, and almost two-thirds of ADAPs now have financial eligibility set at or above 300% of the federal poverty level.

- Eight states offer all 16 category A1 drugs recommended under the Public Health Service/Infectious Disease Society of America guidelines.

- Nine states reported implementing or expanding insurance continuation and insurance purchasing programs using Title II base, ADAP, and state funding. Indiana will move all ADAP clients into the state's high-risk insurance pool and pay for client premiums, deductibles, and pharmacy co-pays. ■

Even with other options, patients overuse ERs

Study highlights findings and explanations

A California study shows that clinicians need to educate HIV-infected patients about when to contact their physicians instead of automatically going to the emergency room when faced with a health crisis.

Patients often will use the emergency department instead of visiting their regular doctor, even for common symptoms such as tension headaches, concludes the study, which was published in the December 2000 issue of the *Journal of General Internal Medicine*.¹

"I thought the findings were moderately surprising," says **Allen L. Gifford, MD**, assistant professor of medicine at the University of California in San Diego. Gifford was the lead investigator of the study, which involved the VA San Diego Healthcare System in San Diego and the University of California San Diego School of Medicine in La Jolla.

Researchers initially wanted to study what HIV patients did when they were experiencing common HIV symptoms, both serious and minor. Their concern was that patients might tend to ignore the symptoms that could worsen and lead to more severe — and costly — problems.

"The good news is, people didn't tend to do that," Gifford says. "If they had important symptoms, they'd go right in and get seen."

However, rather than call their physician and seek an appointment, many patients went to the emergency department, and this may be a problem for both economic and clinical reasons.

"As a primary care physician myself, I am concerned that over and above the cost issue, patients who get a large part of their care in the ER may in some cases get poorer care because the continuity of care is disrupted," Gifford says. "A lot of times, the information about their care doesn't get back to their doctors, and sometimes medications are changed."

There could be a variety of explanations for this type of behavior. One reason might be that patients perceive seeing their primary care physician as being less convenient, even if they visit the ER during daytime hours, Gifford says.

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AIDS ALERT.

INTERNATIONAL

Special Report: Caribbean's HIV epidemic

New partnership will try to reduce infections, deaths

Partnership will bring needed attention to region

(Editor's note: This is the first in an occasional series about the AIDS epidemic in the Caribbean, which is fueled in part through tourism by travelers from the United States and other industrialized nations. Future AIDS Alert International sections will feature more about the Pan-Caribbean partnership and various HIV prevention efforts, as well as profiles of the epidemic in various Caribbean nations and how their governments and private organizations are coping with the challenge.)

While the consciences of industrialized nations are awakening to the AIDS pandemic in sub-Saharan Africa, most people, even in the United States, are unaware that the Caribbean has the world's second-highest prevalence of HIV infection.

A new Pan-Caribbean Partnership, formed earlier this year, is designed to bring attention to the Caribbean's HIV epidemic, and it will help Caribbean governments and organizations meet the challenges of treating HIV-infected people and preventing HIV infection.

About 2% of the Caribbean population is infected with HIV, and nine of the 12 countries with the highest HIV prevalence in the Americas are in the Caribbean.¹

In Haiti, the epidemic reaches sub-Saharan Africa proportions, as an estimated 12% of the urban population and 5% of the rural population are living with HIV/AIDS.¹ It's estimated that 100 people in Haiti die of AIDS each day.¹ The Dominican Republic's prevalence rate is estimated to be just under 2%, although some surveys have shown that the prevalence rate among pregnant women in one town is 8%.¹

The partnership was formed out of the Regional Caribbean Task Force on HIV/AIDS, and it will be coordinated by the Caribbean

Community (CARICOM), which comprises all of the independent states and dependencies of the Caribbean, with the exception of Cuba.

"A decision was made in December in Barbados to expand the task force to become a partnership with participation by donors and lenders in the Caribbean, including UNAIDS," says **Ruben F. del Prado**, MD, MPH, acting team leader for the Caribbean and UNAIDS InterCountry Programme Advisor & Technical Network Development for the Caribbean in Trinidad and Tobago, West Indies.

"The partnership is nothing more than an extended forum to generate the needs and the resources into the same room," del Prado says.

One of the partnership's challenges will be to encourage political commitment and assist in designing actions when the countries participating have such diverse cultures and governments. For instance, unlike South and Central America, the Caribbean does not have one predominant language or religious influence, so any action involving religious leaders would have to accommodate multiple religions and beliefs, including Islamic, Protestant Christian, Rastafarian, and Catholic.

"We need a more active religious leadership," del Prado says. "They have to stop the hypocrisy and acknowledge there is HIV/AIDS. Although we have multiple religious cultures, we have to make one faith when it comes to HIV/AIDS."

Religion not only influences the people of the Caribbean nations and their beliefs, but it is a main influence on political decisions.

"What is important to note here is that socioeconomic, political, and religious influences are decisive in the course of all epidemics in the pan-Caribbean," del Prado says. "Every country and territory is different in that aspect, hence the diversity."

Del Prado says it's sheer hypocrisy for political leaders, religious leaders, and parents to say their children should abstain from sexual activity.

Children as young as 11 and 12 are having sex and are getting pregnant, and everyone knows this.

“Abstinence is UNAIDS’ message, but when people are not abstaining and are having sex, then you have to offer them protection,” del Prado says. “These are human rights, and children have rights too.”

Caribbean children and youth are at greater risk for HIV infection because they are more likely to be exposed to sexual abuse and sexual exploitation. Surveys show that as many as 21% of boys and 18% of girls may have been sexually abused before age 16.² Another survey of adolescent youth in four English-speaking Caribbean countries showed that more than 40% of youth said their sexual debut had occurred before the age of 10.² Sex tourism involving minors also is on the rise in Belize, Haiti, and the Dominican Republic. With one-third of the Caribbean population under the age of 15, these statistics signal dire consequences with regard to HIV risk.

However, the main factor driving the epidemic is poverty, which is pervasive in the Caribbean. Poverty has given a boost to the Caribbean’s sex industry, which is linked to tourism in the islands. Young girls and boys, as well as married and single women and men, trade sex for school fees, food, and money. There also is a growing trend of male prostitution in the form of “beach boys” across the Caribbean.² **(See story on factors driving the epidemic, at right.)**

Political leadership addressing HIV prevention must begin at the top, del Prado says.

“Having administrators hidden somewhere, pushing documents and printing out posters and leaflets with education about HIV and AIDS, is not how you run a national program,” del Prado says. “You need a strong unit under a vice prime minister or prime minister, which will have the broad-based coordination that is necessary.”

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2. The Caribbean regional strategic plan of action for HIV/AIDS. Prepared by the Caribbean Task Force on HIV/AIDS. September 2000.

3. CAREC strategic plan for the prevention and control of the HIV epidemic in the Caribbean, 2001-2005. Final version. Produced by the Caribbean Epidemiology Centre, the Pan American Health Organization, and the World Health Organization. December 2000. ■

Factors driving the HIV epidemic in the Caribbean

CAREC develops regional five-year plan

The Caribbean Epidemiology Centre (CAREC), which serves 21 member countries of the Caribbean, developed a strategic HIV prevention and control plan in December 2000 that clarifies the root of the epidemic and offers possible solutions. The “CAREC Strategic Plan for the Prevention and Control of the HIV Epidemic in the Caribbean 2001-2005” summarizes the factors driving the epidemic in this way:

1. Economic

- Poverty and grossly inequitable income distribution
- Unemployment
- Urbanization creating “ghettos”
- Globalization creating internal economic pressures
- Migration and tourism removing social control and providing incentives for risky behavior

2. Social and cultural

- Globalization with cultural penetration distorting value systems, including the fostering of materialism
- Dysfunctional gender relations, including male insecurity, resulting in antisocial behavior
- Lack of general education, and, specifically, sex education
- Marginalization of young people
- Cultural and religious sexual taboos, contrasting with social norms that promote sex
- Discrimination and stigmatization of people living with HIV/AIDS, men who have sex with men, and other vulnerable groups
- Reluctance to provide information and sex negotiation skills to young people

3. Behavioral

- Multiple sexual partners
- Low condom usage and reluctance to promote condom usage
- Low tolerance for men who have sex with men, causing hiding and mixing of partners
- Sex work of various types: full-time (career), part-time (ranging from school girls through employed women to married women)
- Substance abuse leading to risky behaviors

4. Biomedical and access to care

- Presence of other sexually transmitted diseases (STDs)

- Lack of access to health care for certain populations
- Lack of standards of care, treatment, and support procedures for STDs and HIV
- Attitude of health care workers towards people with HIV: judgmental, fear, reluctance to treat

5. Legal

- Illegal status of vulnerable groups, e.g., mobile population, sex workers and men who have sex with men, driving them underground
- Lack of protection for people living with HIV/AIDS, especially in the workplace
- Lack of legislation addressing issues surrounding people with HIV/AIDS
- Lack of legislation to ensure minimum standards of care ■

Race for vaccine stirs hope in developing areas

IAVI sets moral compass for vaccine development

With HIV devastating parts of the developing world and continuing to gain hold in countries that once had a negligible HIV rate, researchers and governments around the world continue to hold out hope for a successful HIV vaccine that will signal the beginning of the end of the two-decade-old epidemic.

However, the vaccine answer to AIDS has been as elusive as the Holy Grail, despite years of investigation and work that has taken many different approaches.

The good news is that there are 25 promising vaccine candidates that could enter Phase I human trials within the next six years, says **Kay Marshall**, director of communications for the International AIDS Vaccine Initiative (IAVI), a global, nonprofit organization founded in 1996 to bring leadership to the search for an AIDS vaccine.

“We believe it is possible to have an AIDS vaccine of at least limited efficacy sometime in the next decade, if the world accelerates its vaccine development effort,” Marshall says.

IAVI’s cornerstone program is its Vaccine Development Partnerships (VDPs), which are designed to move promising experimental vaccines into clinical trials as quickly as possible, Marshall says.

“VDPs link researchers from academia or biotechnology companies with vaccine manufacturers and with clinical researchers in developing

countries,” Marshall says. “For each partnership, the candidate vaccine is tailored to match the predominant HIV strain in the VDPs’ developing country.”

Four of the five VDPs are in Africa, and one is in India, although more are planned, including a VDP for China, Marshall adds.

Two IAVI-sponsored vaccines based on the common HIV strain in East Africa, subtype A, have entered Phase I human safety trials, Marshall says.

One of the first subtype A vaccines was tested on volunteers in Kenya and the United Kingdom.

IAVI makes financial contributions to each VDP and provides technical and management support. The organization also funds infrastructure improvements in developing countries, such as contributing to the University of Nairobi’s state-of-the-art laboratory for vaccine trials in Kenya, Marshall says.

In exchange, IAVI secures unique intellectual property agreements from all parties. This way, if the vaccines prove effective, they will be made available to developing countries at a reasonable price, Marshall explains.

“Meanwhile, developers are free to sell the vaccines sold in industrialized nations at the market price,” Marshall adds.

The IAVI has filled a vacuum left by big pharmaceutical firms that, until this year, have largely stayed away from AIDS vaccine research, says **Jon Cohen**, correspondent with *Science* magazine and author of the new book *Shots in the Dark: The Wayward Search for an AIDS Vaccine*. (See **Cohen’s discussion of the HIV vaccine search, p. 64.**)

“There are indications that a few big pharmaceutical companies are very serious about making an AIDS vaccine,” Cohen says. “But a lot of time has been wasted, and I think that scientists and companies both have ducked behind the argument that the science was too complicated and that industry only gets involved once they know enough to do something.”

Cohen calls the early AIDS vaccine efforts a market failure because IAVI and governments in North America and Europe have had to form consortiums and create industry rather than the usual scenario of industry creating a product to fill a need. The opposite occurred with HIV antiretroviral drug development, in which industry leaped to the rescue and created a wide variety of treatment options. Activists helped push the drugs to market more quickly by lobbying government and industry, Cohen says.

No such collaboration was seen between industry, government, activists, and researchers in the early years of HIV vaccine search, he explains.

"It's been a real cultural wake-up call to the scientific community about the limits of governments only funding basic research when industry doesn't have the incentive to bring that fruit to market," Cohen says.

One of the more positive HIV vaccine announcements in recent months was the pledge of \$100 million made by the Melinda and Bill Gates Foundation of Seattle to IAVI for vaccine research over the next five years.

Philanthropic money has fewer constraints and therefore can be used for bolder research initiatives than government money, which is why the Gates Foundation donation is particularly helpful, Cohen says.

Meanwhile, some important ethical considerations still need to be fully addressed by the scientific community, industry, governments, and the public, Cohen says.

"I think that ethical dilemmas are going to complicate vaccine trials, and they are complicating them right now," Cohen says. "One of the issues is risk vs. benefit."

In communities where people have a higher risk of becoming infected, such as areas of South Africa, uninfected people have a greater incentive to try an experimental vaccine because they have more to gain from a successful vaccine. So they may be more willing to try vaccines that have both a greater risk of harm and a greater potential for protection than a person from an industrialized country, he points out.

Does this mean investigators should offer riskier vaccines to people in these high-HIV-risk populations?

"Right now, I don't think there is much thinking going on about the amount of risk the hardest-hit communities are willing to take," Cohen says. "It's a tough, very tough question."

The other ethical issue involves whether HIV antiretroviral drugs should be offered to vaccine trial participants in developing nations, where such drugs are cost-prohibitive to most people.

"There's been a raging debate about whether people who sponsor vaccine trials should offer drugs to anyone who becomes infected during the trial, not because the vaccine infected them, but because the vaccine didn't protect them," Cohen says. "That's a real thorny issue if you want to evaluate whether a vaccine prevents or

delays disease, because people who take the drugs are going to cloud the question."

Also, if a vaccine trial offered free HIV drugs to anyone who becomes infected, would that constitute undue influence on the individual participant's decision of whether to volunteer for the trial? These are the kinds of issues an international group representing all interested parties needs to address, Cohen says.

IAVI's position is that these difficult decisions are up to the countries themselves, Marshall says.

"It must be up to the country in which a trial is conducted to decide whether it is ethical," Marshall says. "It must be up to the country to determine if, when, and to what extent those who become naturally infected during a trial are offered antiretroviral therapy."

The broader ethical consideration is how long can the world wait for an effective vaccine when there are 15,000 new HIV infections each day, Marshall adds.

"The world cannot afford to wait until candidate vaccines are far along in development before key questions of safety and efficacy are identified and agreed on internationally," Marshall says. "As vaccine candidates proceed along the development continuum, companies will need to devise studies that are calculated to answer all relevant questions."

It's important to remember that the best vaccine goal is not necessarily to find the most effective and safest vaccine before making it available to the public. The first polio vaccine was only 60% effective and it was used by 70% of the population, but it brought down the polio infection rate by 96% between 1955 and 1961, Cohen says.

"There was a calculation done with HIV that said if you had a 60% effective vaccine today, then 10 years from now you would have prevented more infection than if you had a 90% effective vaccine introduced five years later," Cohen says.

IAVI is funding multiple vaccine efforts in hopes that one of these will prove efficacious within the next 10 years. While the first vaccine to make it to market probably won't provide 100% protection, it could save lives while other vaccines are being prepared, Marshall says.

"And multiple vaccines may be needed for worldwide coverage, both because of different HIV strains and regional variation in immune systems," Marshall adds. "So while the first vaccine is within a decade's reach, sadly the end of the epidemic is not." ■

“Maybe the physician would make them wait longer, or it’d be more complex to wait there, and this is a big factor for people with kids or who work,” Gifford explains. “Even if they recognize that they could be seen by their primary care physician, they’d have to take off work to do so, and the ER is open at night.”

Another explanation could be that patients did not believe their HIV physician was experienced in handling their more serious HIV symptoms, such as pneumonia, but factors relating to access probably were the main cause for excessive ER use, Gifford says.

“HIV providers need to see if they can open up for more hours, particularly as HIV disease tends to become more of a continuous chronic illness with lots of people in the workplace,” Gifford says. “This is an issue in health care for women with children and for all kinds of people in the work force.”

The study found no differences by gender, but investigators did find consistent differences with regard to socioeconomic factors, such as income level.

Also, investigators found that African-Americans had a higher propensity to seek their care in the ER than whites or people of other races, Gifford says.

“We need to find out what’s going on here,” Gifford says. “One of the major speculations raised in editorials is whether this is a bit of a cultural phenomenon in the sense that in some African-American communities, perhaps due to years of interacting with health care systems, the habits and culture of how to interact with health care providers have led to a tendency to use the ER in this way.”

The behavior continues even when educational and economic factors are accounted for, he adds.

Other factors contributing to a patient’s overuse of the emergency room were poverty and higher levels of depression and stress.

Basically, the study highlights the need for HIV physicians to be aware that this could be a problem. They might educate patients about what steps to take in the event that they experience various HIV symptoms, Gifford says.

The education needs to be specific to that provider’s circumstances and include detailed information, and it should be presented in clear language with reading-level appropriate sentences if it is written down, he adds.

“Secondly, we need to look at how primary care practices are set up for patients, as well as the structural factors, including the hours of providing care,” Gifford says.

If an HIV doctor does not see patients after 5 p.m., then it might be appropriate to provide on-call contact numbers or a nurse line to the patient and educate patients on how to use those services.

Urgent care centers could be answer

Another potential solution is for HIV physicians to direct patients to use urgent care centers, which ideally would be associated in some way with the HIV clinic instead of the hospital emergency department, Gifford says.

“That’s good only if you have good communication between the primary care doctors and the urgent care center,” he adds.

Here are a few details about the study:

- Investigators interviewed more than 2,800 HIV-infected patients between January 1996 and April 1997 about how they would seek care for key HIV-associated symptom complexes.
- Most patients (78%-87%) with advanced HIV disease who were experiencing symptoms said they would seek care immediately from an emergency department or from a primary care provider.
- Symptom scenario questions included: “Suppose you began to have difficulty breathing and had a cough with fever. What would you do?” and “Suppose you had a headache with pressure behind the eyes and nose. What would you do?”
- Investigators determined a patient’s propensity to use the emergency department by summing the number of “go to the emergency room” responses across the three symptom scenarios, using categories of low if they would not go to the ER for any of the clinical scenarios, medium if they would go to the ER for one scenario, and high if they would go to the ER for two or three scenarios.
- Percentages of early HIV disease patients who said they would first go to the ER according to various symptoms were as follows: 42% would go to the ER if experiencing respiratory symptoms with fever; 18% would go the ER if they had a headache behind the nose and eyes; and 14% would go to the ER if they had oral white patches.
- Percentages of advanced HIV disease patients who said they would first go to the ER according

to various symptoms were as follows: 45% if they had respiratory symptoms with fever; 25% if they had a headache with stiff neck; 29% if they had a loss of vision.

Reference

1. Gifford AL, et al. Propensity of HIV patients to seek urgent and emergent care. *Journal of General Internal Medicine* 2000; 15:833-840. ■

AIDS vaccine efforts have followed long, bumpy road

Writer covering the journey says there is still hope

(Editor's note: Author Jon Cohen's new book, Shots in the Dark, is an account of the long struggle to develop a successful AIDS vaccine. AIDS Alert asked Cohen to speak about the vaccine efforts and discuss the potential of various vaccine initiatives now under way. Cohen, a correspondent with Science and a writer for The Atlantic, Discover, and The New Yorker magazines, has followed the AIDS vaccine efforts since the early years of the epidemic. Here are Cohen's answers to some of AIDS Alert's questions about the vaccine:)

AIDS Alert: First, could you tell us a little about how close the various vaccine efforts are to developing a product that could be used in at-risk populations, either here or in developing nations?

Cohen: About three dozen vaccines have entered human trials. Human testing requires three phases that moves from small groups to larger and larger groups of people. Only one vaccine has made it to Phase III testing. That vaccine has not impressed most AIDS researchers, and the National Institutes of Health [NIH] decided in 1994 to not even fund the Phase III trials, but that trial is now nearing its end. As early as this coming fall, we could have results from that trial. It was privately funded. A company was started just to run efficacy trials, which I think was unprecedented. I can't think of another example of that. The company making the vaccine spun off a new company just to stage these efficacy trials. That company is called VaxGEN in the San Francisco Bay area. I think it's great that this test is happening, and I also think the NIH made a

mistake for not funding the test. It's not because I think the vaccine looks promising, because I don't. But I think the field could learn a lot from its failure if indeed it does fail, and if it succeeds, obviously that would be a great thing.

AIDS Alert: Would that be a vaccine for HIV-1 or HIV-2 or others?

Cohen: For HIV-1. There is no active development of an HIV-2 vaccine that I know of. That should be a simple matter if any HIV-1 vaccine works, because it should also work.

AIDS Alert: Where are they conducting the VaxGEN tests?

Cohen: There are two big trials going on. One is in the United States, Canada, and the Netherlands. That involves about 5,000 people, mostly gay men. The other trial is in Thailand, and it involves 2,500 people who are injecting drug users. The first trial is a little further along, but they are both Phase III efficacy trials.

AIDS Alert: Please tell me why scientists are skeptical that this particular vaccine will prove to be the one.

Cohen: In the earlier stages — the Phase II studies, which involved hundreds of people — researchers took antibodies from those people's bodies and mixed HIV in test tubes with the antibodies, and the antibodies could not stop the virus. So researchers basically concluded that the vaccine wasn't strong enough; it wasn't leading the immune system to produce the right kind of antibodies.

There also has been a huge shift in thinking about what a vaccine must do to stop HIV. In the early days of the AIDS vaccine search, most everyone focused on antibodies. But there is another arm of the immune system, called cell-mediated immunity, or cellular immunity, and now most of the leading vaccines focus on that, with some attention paid toward antibodies. Antibodies are now taking a back seat.

The difference between these two arms of the immune system is simple to explain: Antibodies stop things from getting inside of cells; cellular immunity does a mop-up job, cleaning up already-infected cells and eliminating them. So you can see how the two can go hand-in-hand, or it could be you only need one. Who knows? That's still a giant mystery that makes development of an effective AIDS vaccine so difficult, because we don't know — no one knows — what are called the correlates of protection. No one knows exactly which immune response a vaccine must elicit to work.

AIDS Alert: You've detailed in your book a great deal about the problems with primate AIDS vaccine research. Was all that pretty much pointless in the end, or did primate research tell us anything?

Cohen: I don't think it was pointless. You can do tests in primates that you could never do with humans. Specifically, primates are given an AIDS vaccine and then are injected with live versions of the AIDS virus, which in the case of primates, is HIV's cousin, SIV. You can never ethically do such a test like that in humans. It's ethically complicated in monkeys, for that matter, but you couldn't do this in humans. But you can get strong information from these monkey studies about whether your vaccine has promise.

What most people have done with monkey studies is use them to perfect their own vaccine ideas. What no one has yet done is a major comparative study that allows you to put different vaccines side by side and determine which ones looked like they worked the best in monkeys. So that's what is so maddening to me, is you can't compare the results from one lab to another lab. They use different species of monkeys; they use different strains of SIV; they use different reagents; they use different testing protocols; and at the end of the day I'm dizzy, and so is everyone else.

I'm not calling for anything radical. The things I'm pointing out are suggestions and recommendations made by AIDS researchers in official documents. They've called for this comparative trial, but it just hasn't happened. So people only partially gamble on the monkey model. You can always say that monkeys are not human and it's a model, but that's always going to be true. Of course SIV is not HIV. But people are kind of playing footsy with the model.

There's a tremendous amount of AIDS vaccine primate research still under way, and the research that is going on does lead to insights about which immune responses protect monkeys and how to rejigger your vaccine to make it stronger. But again, the real question I think the world has to ask is more ambitious still: Given all the good ideas out there, which ones look best? Certainly, you can answer that question in human trials, but there's a clock ticking. We have an imperative to

move as quickly as we can, and that's why I'm arguing that a comparative monkey study of every good idea might shave years off the time that it takes to find a working vaccine. I'm not arguing, mind you, to stop anyone from what they're doing. If what they're doing is ethical and scientifically sound, then I think that's fine. I'm saying that in addition to everything that's going on, there is an entirely different way to approach this whole problem that is not being applied right now.

AIDS Alert: You discuss at length in your book Jonas Salk's early polio research. If a similar scientist had as few bureaucratic and liability constraints today, do you think we would already have an HIV vaccine?

Cohen: No. I don't think there is any guaran-

tee we will ever have an AIDS vaccine. And I also think that if HIV were as simple a virus to defeat as polio, we'd have a vaccine today. The biggest obstacle is the virus. But once you accept that, then the question becomes, "Are there ways to improve the way the enterprise moves, to streamline and organize?" And that's where the March of Dimes model is relevant, because the answer is resoundingly "yes," there are many things we could do that are not being done that could streamline the search.

There are no guarantees, but there never are in wars, and it's a war of us against the virus. I think that if we better organized our troops, we'd stand more of a chance of winning. But I'm not certain — and nobody can guarantee — there will be an AIDS vaccine. There are lots of hopeful reasons to think there will be. There are a lot of signs that we can defeat HIV with a vaccine, and we know from history that vaccines are one of the most powerful medical tools ever devised. Smallpox virus now only exists in laboratory freezers because of a vaccine. It's not in the population anymore. That is a tremendous accomplishment. Polio doesn't exist in the United States any longer, or in Europe or most of the world for that matter, because of vaccines. We have freed generations from fear because of vaccines.

AIDS Alert: You mention in the book some efforts by pharmaceutical companies to get Congress to pass a law offering them special liability protection. Has there been anything passed?

'It's a war of us against the virus. I think that if we better organized our troops, we'd stand more of a chance of winning. But I'm not certain — and nobody can guarantee — there will be an AIDS vaccine.'

Cohen: No, there has been nothing passed. And I think the California State Supreme Court made an enlightened ruling in 1988 that the federal government should consider. Basically, if you make a vaccine according to FDA standards right now and you do everything right, but it harms someone, you can still be sued under what is called “strict liability.” In California, the State Supreme Court said that drugs — and presumably vaccines — are different because they’re for a social good. If you make it according to specifications and you inform the consumer about the risks, then you cannot be held liable if that person gets hurt because they are “unavoidably dangerous” products. I think that’s a very sane way to approach liability. If you have unavoidably dangerous products that are good for the public and you inform people about the risks, then I don’t see why you should be held liable.

‘One in five adults are infected in South Africa. If we had one in five adults infected in the United States, I suggest that every solution I float in my book would have happened long ago.’

AIDS Alert: If you were speaking to a group of high-risk individuals in the United States, would you tell them they shouldn’t hold out hope for a vaccine any time soon?

Cohen: I think people need hope. I think it’s human nature to want hope, but I do speak with groups of high-risk people, and I do tell them that right now there is no working vaccine and that even if there were a working vaccine, they would still be at risk if their behavior was something the virus liked. The virus likes certain behaviors: it likes people to have lots of partners; it likes to get directly into blood; it likes sores; it likes needles.

AIDS Alert: Is there any other point you’d like to get across?

Cohen: The lessons from what has happened so far in the AIDS vaccine research similarly apply to many other infectious diseases: Malaria, TB, hepatitis C all have faced problems because of a lack of interest in vaccines from industry, and it questions the scientific culture to its core. And it’s a critical question because, in each case, time matters. There are now at least 36 million HIV-infected people in the world. One in five adults

are infected in South Africa. If we had one in five adults infected in the United States, I suggest that every solution I float in my book would have happened long ago. That doesn’t mean we would have a vaccine today, but that does mean we’d be closer, and the same holds true for these other diseases. So at what point do we learn from our mistakes? And we’ve made plenty of mistakes. ■

HIV academy sets criteria for ‘HIV/AIDS specialist’

Designation available to four disciplines

The new American Academy of HIV Medicine (AAHIVM) of Washington, DC, has established standards for clinicians who specialize in treating HIV/AIDS patients. To begin with, to be designated an HIV/AIDS specialist, a clinician needs to be state-licensed as a physician, nurse practitioner, physician assistant, or doctor of pharmacology.

The academy’s standards include the following:

1. The HIV/AIDS specialist must have clinically managed at least 20 HIV patients in the past two years.
2. The specialist must demonstrate continuous professional development in one of three ways:
 - Physicians must have successfully completed the infectious disease board certification or maintenance of certification examination for the current year.
 - Specialists must have completed annually at least 30 hours of HIV-related CME category 1 credits.
 - Specialists must have completed annually at least 15 hours of HIV-related CME category 1 credits plus participated annually in an HIV Medicine Competency Maintenance Examination, as soon as it is available.

The AAHIVM’s qualifications statement says HIV/AIDS specialists who adhere to these guidelines can function as cost-effective primary HIV care providers in any health care delivery model, and they can recognize, diagnose, treat, and manage the medical complications of AIDS.

As of March 2001, the AAHIVM has 1,000 members who care for more than 225,000 HIV patients. About 10% of the membership includes nurse practitioners and physician assistants. ■



New warnings and alerts in HIV care

Source: Gangar M, et al. The frequency of rash during initial use and rechallenge with nevirapine and delavirdine. *Ann Pharmacother* 2000; 34:839-842.

Severe, life-threatening hepatitis has been reported in two health care workers who received nevirapine (NVP) for postexposure prophylaxis (PEP) for occupational exposure. The first case was that of a 43-year-old female health care worker who received AZT, 3TC, and NVP following a needlestick injury, and developed such fulminant hepatitis and hepatic failure that she required liver transplantation. The second case was of a 38-year-old male physician who received the identical regimen following a mucous membrane exposure, with resulting severe fulminant hepatitis. Both cases occurred last fall.

Comment by **Carol A. Kemper, MD, FACP**

No single antiretroviral regimen has been recommended for use as PEP after sexual exposures and needlestick injuries in health care workers, and clinicians and health care facilities variously use combinations of two or three antiretroviral agents. Some experts advocate the use of protease inhibitors, and others favor the convenience of the non-nucleoside reverse transcriptase inhibitor (NNRTI) NVP (Viramune, Boehringer Ingelheim/Roxane Laboratories). While NVP has not been formally recommended for use in PEP, many clinicians and institutions have included it as part of a combination PEP regimen because of its high level of activity against HIV-1, its known effectiveness as a single dose in the prevention of neonatal transmission, and because it is generally well-tolerated and convenient to administer.

The most common side effect observed with NVP is rash, which reportedly occurs in anywhere from 16% to 48% of patients, usually within the first two to six weeks of use. However, in our experience, while cutaneous reactions occurred more commonly after delavirdine administration,

those due to NVP were more frequently severe and more frequently resulted in hospitalization. Nearly 40% of cutaneous reactions to NVP in our patient population were moderate to severe in nature (14.6% of the cohort), and fully 7.2% of patients receiving NVP required hospitalization for severe or life-threatening reactions, including angioedema, Steven's Johnson syndrome, and toxic epidermal necrolysis. As a result, the drug was temporarily or permanently discontinued in 28% of our patients receiving NVP. Of course, most PEP regimens are taken for short periods of

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.

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time, varying from one to four weeks, which decreases the risk of adverse events.

Another common potential side effect of the NNRTIs is elevation of hepatic transaminases, which are generally mild and asymptomatic in nature. Serious elevations in liver function tests have been reported, and may be more frequent in patients with underlying hepatitis B or C infection. Because of concerns of increased hepatotoxicity, physicians have been warned to avoid using NVP in combination with interleukin-2.

Following the occurrence of these two cases in health care workers, the Centers for Disease Control and Prevention and the Food and Drug Administration surveyed the incidence of serious adverse events due to NVP taken for PEP during the last three years using the MedWatch reporting system. Twelve cases of severe hepatotoxicity were identified, four of whom also had severe skin reactions. One patient developed severe liver failure requiring liver transplantation; seven had clinical hepatitis with fever, abdominal pain, jaundice, and/or hepatomegaly; and four were reported to have elevations in hepatic transaminases. Abnormal liver function tests were obtained a median of 21 days after initiation of NVP for PEP (range, 13-36 days), although symptoms of abdominal pain, fever, malaise, and rash generally occurred sooner. Information on whether NVP was appropriately dose-escalated in these patients was not available, but all of the patients received 200 mg either once or twice daily.

No cases of serious hepatotoxicity were identified in the HIV PEP registry at the CDC, which has accumulated 492 cases of PEP for occupational exposures since October 1995. Only 11 health care workers identified in this database received NVP for PEP, one of whom developed a severe cutaneous reaction.

These data suggest that the risk of adverse reactions to NVP administered for occupational PEP far outweighs the potential benefit of this agent for this purpose, especially when one considers that most exposures are associated with a low risk of HIV infection. This is especially the case for mucous membrane exposures. Any one of multiple alternate agents can be used for occupational PEP in lieu of NVP. NVP continues to be recommended for the treatment of HIV infection, although it may be best to avoid the concomitant administration of other agents with potential hepatotoxicity, and clinicians may wish to monitor patients more closely, especially those with underlying hepatitis, at least for the first four to six weeks of use. ■

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CE objectives

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

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

Common Sense About

AIDS.

AIDS risk is high among young people

Do you have all the facts about HIV?

Americans between the ages of 13 and 24 are becoming infected with HIV at the rate of two people per hour. Youths under age 25 represent about half of all new HIV infections.

The risk is high among young people because they are often more sexually active than older adults. This is why doctors, public health agencies, and others urge youths to use condoms during every sexual encounter. Condoms will protect youths against HIV and many other sexually transmitted diseases (STDs).

Knowledge is power, and knowledge about safe sexual behavior can save lives. So if you are young or sexually active, here are some facts you need to know, presented by the Office of National AIDS Policy at the White House:

- **AIDS is not over.** Scientists believe that there have been 40,000 new HIV infections in the United States every year for the last several years, and that half of those being infected are young people between the ages of 13 and 24.

- **You won't know until you are tested.** Most young people

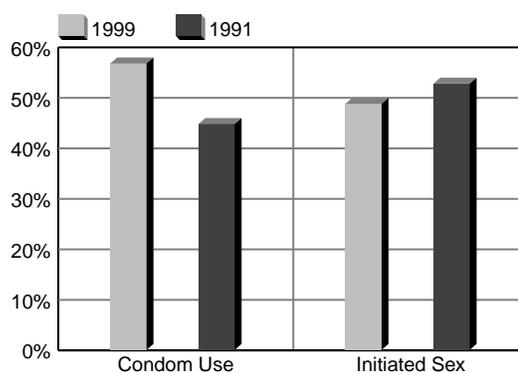
who are already HIV-infected don't know it, and the vast majority of HIV-infected youth do not receive adequate medical care.

- **Medicine can help.** For many young people infected with HIV, new medical treatments could lead to long, productive lives. To make this a reality, they need youth-friendly access to HIV counseling and testing, medical care (including mental health care), and other support services.

- **Young people are at high risk of AIDS.** More than 123,000 young adults in the United States have developed AIDS in their twenties, according to surveillance data from the Centers for Disease Control and Prevention in Atlanta.

- **Teens have sex.** By 12th grade, 65% of American youth are sexually active, and one in five has had four or more sexual partners.

Percentages of U.S. high school students who reported having sex and using condoms, 1991 and 1999 Youth Risk Behavior Surveillance

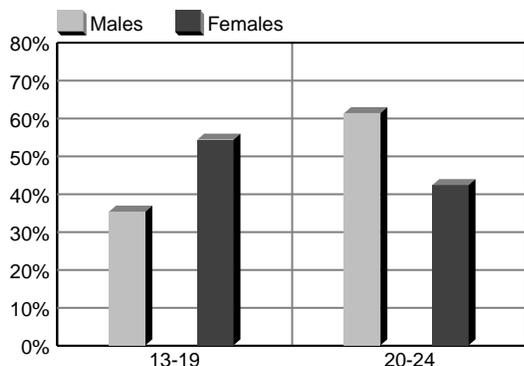


Source: Office of National AIDS Policy, Washington, DC.

- **STDs are common among teens.** Each year, three million adolescents contract sexually transmitted diseases. That's about one in four sexually experienced teens. Of the 12 million Americans with STDs, about two-thirds are young people under age 25. These statistics indicate that many adolescents are engaging in unprotected sex — behavior that places them at risk for HIV infection.

- **Drugs and alcohol play a role.** About 25% of U.S. high school students who have had sex said they were under the

Percentages of HIV cases reported in 1999 among males and females in the 13-19 and 20-24 year old age groups*



* HIV data are reported by 33 states (not including California and New York) and the U.S. Virgin Islands.

Source: Office of National AIDS Policy, Washington, DC.

influence of alcohol or drugs (including marijuana and other illegal drugs, prescription drugs, and low-cost inhalants like gasoline, spray paint, and glue) the last time they had sex. Also, an estimated 1.5 million Americans use cocaine, and about half of them are age 25 or younger. The use of crack has more than doubled among those 12-17 years old since 1991.

• **Binge drinking is a problem.** Binge drinking was reported recently by 31% of high school students. Among young people contacted at home, 38% of those 18-25 years old and almost 46% of those 21 years old reported binge drinking. The definition of binge drinking is having at least five drinks on the same occasion within the last month.

• **Girls are at greater risk now.** More females than males are now being diagnosed with HIV in the 13-19 age group. In this group, 63% of the 828 HIV infections reported last year were among females. In the next oldest group, 20-24-year-olds, women represent about

South and Northeast had the highest HIV infection rates. Prevalences of up to one per 100 were found, with the highest rates in the District of Columbia, Florida, Louisiana, Maryland, South Carolina, Virginia, and Connecticut.

• **Gay and bisexual youths also at high risk.** At least half of the HIV infections reported in 1999 among young men ages 13-24 resulted from exposure to the virus through sex with other men. Young, urban men who have sex with men show alarming rates of HIV infection — just over 7% — with higher rates among African-Americans, Latinos, and those of mixed race than among whites.

• **Blacks and Hispanics are at greatest risk.** African-Americans and Hispanics each make up about 15% of U.S. teenagers. However, African-Americans account for 49% of the 3,725 AIDS cases ever reported among those ages 13-19 and 67% of the 4,796 HIV infections reported to date in this age group. Hispanics represent 20% of AIDS cases among teens.

44% of the 2,386 HIV infections reported in 1999.

• **Women from the South and the Northeast have high risk.** In disadvantaged youth entering the Job Corps, young women from the

• **STD treatment helps prevent HIV.** When you are treated for an STD, you reduce the risk of HIV infection, because the open sores and lesions caused by the STD will be healed.

These sores make it more likely that if you have sexual intercourse with a person who has HIV, you will contract the virus from that person.

• **Parental consent is not required for testing.** Your parent does not need to know that you are being tested for HIV, and these tests are kept strictly confidential. No one but you and your doctor or nurse will know the results.

• **If positive, medical treatment is essential.** New HIV treatments have produced dramatic reductions in the number of deaths from AIDS. Among those 15-24 years of age, the number of deaths in 1998 was 53% less than in 1996.

• **If you have questions, call a free hotline.** The National AIDS Hotline at 1-800-342-2437 is a free source of answers to all of your basic health questions. The hotline can refer you to services and to organizations that will have more in-depth information. ■

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.

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Source: National ADAP Monitoring Project Annual Report, March 2001.

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