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IN THIS ISSUE

- Only considerable lobbying will keep various budgets from being cut cover
- NASTAD's FY2007 Appropriations for Federal HIV/AIDS Programs chart . . . 39
- NASTAD's FY2007 Appropriations for Global HIV/AIDS Programs chart . . . 40
- ADAP funding still fails to meet the growing need 41
- Are there advantages to finding acute HIV infection? Studies say yes 43
- Study: No evidence of HIV-1 strains transmitted between infected sex partners 44
- FDA Notification 45

Insert: AIDS Alert International

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President's budget, FY2006 final appropriations paint dim picture

ADAP waiting list near 1,000

Just when HIV/AIDS groups have adjusted to flat domestic HIV/AIDS funding for the past five years, the latest budget proposals arouse fear of budget cuts that could result in fewer prevention programs and longer waiting lists for antiretroviral drugs.

President Bush's FY2007 budget request would cut all funding (\$99 million) from prevention block grants in the budget of the Centers for Disease Control and Prevention (CDC), and it would continue the funding cut of the CDC's DASH-HIV prevention education. (See **domestic budget charts**, p. 39-40)

But the president's proposal would add nearly \$90 million to the CDC's HIV prevention and surveillance and \$95 million to the Ryan White CARE Act total.

Even the good news is greeted with skepticism by AIDS groups that have been through this process repeatedly in the past five years.

"We were excited to see there would be additional money in place for the CARE act for both testing and medications, however, the missing link is everything in between," says **Diana Bruce**, manager of government affairs for AIDS Alliance for Children, Youth & Families of Washington, DC.

"We represent women and children and young people living with HIV infection, and for our populations they need more than a doctor and pills," Bruce says.

"They need a comprehensive support network that outreaches to them, provides case management, and links them to care and treatment," Bruce explains. "They need comprehensive case management, transportation, and they need childcare."

There's a funding bridge between positive HIV tests and HIV care and education, and that bridge was flat-funded for the third year in a row, Bruce says.

"It's gone from \$75 million in funding to \$71 million in just a few years, while the new infections are still at 40,000," she says. "We were totally disappointed to see that Title IV, of which 88% of the clients are

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people of color, was flat-funded and left without the resources to meet the demand for care.'

The peak funding year was Fiscal Year 2003, but it's been downhill since then, Bruce says.

"There's a lot of confusion about where the new money is going for Ryan White," says **Christine Lubinski**, executive director of the HIV Medicine Association in Alexandria, VA.

"There's discussion about targeting it to places with a clear need," Lubinski says. "But it's unclear how they're going to do it; and while the increase is welcome, how they do it really matters."

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Editor: Melinda Young, (864) 241-4449.

Vice President/Group Publisher: Brenda Mooney, (404) 262-5403, (brenda.mooney@thomson.com).

Editorial Group Head: Lee Landenberger, (404) 262-5483, (lee.landenberger@thomson.com).

Managing Editor: Alison Allen, (404) 262-5431, (alison.allen@thomson.com).

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For example, one HIV Medicine Association board member's HIV clinic will have to take a 5% cut in providing care services because of Ryan White Care Act Title III flat funding, Lubinski says.

"It concerns me that we would fund some sort of new program when current services are in trouble," Lubinski says.

The extra money proposed for the CDC is all for rapid testing and outreach, says **Laura Hanen**, director of government relations for the National Alliance of State & Territorial AIDS Directors (NASTAD) of Washington, DC.

And while this is a positive proposal, the CDC in the meantime is cutting FY2006 prevention funding by proposing a 2.98% cut in state cooperative agreements, Hanen says.

Initially, the CDC proposed a 4.6% cut in the agreements, but reduced it to a 2.98% cut, which still is greater than the average cut across the CDC of 2%, Hanen notes.

"They are making a disproportionate share of budget cuts on HIV and STD prevention," Hanen says.

States will receive letters about FY2006 awards, telling them of the cuts to their final awards, she says.

Another unknown factor in the president's budget is the \$25 million proposal to expand outreach efforts by providing new community action grants to faith-based community organizations, Hanen notes. "I would say the AIDS community and NASTAD will advocate with Congress to get the additional funds for Ryan White because this is a very tight budget year again, and, again, we want them to go through the traditional funding lines."

The biggest problem with the proposed budget and with what Congress is likely to decide about HIV/AIDS spending is providing care and treatment to the growing list of people infected with HIV, AIDS care advocates say. (See story on **ADAP funding**, p. 42.)

Slow going on the Hill

Meantime, the budget work is moving slowly on Capitol Hill.

"All we know at this point [in early March] is the House and Senate is working together in closed door meetings twice a week," says **Greg Smiley**, MPH, public policy director with the American Academy of HIV Medicine in Washington, DC.

FY 2007 Appropriations for Federal HIV/AIDS Programs

(March 2006; Increases or decreases from previous fiscal year are shown in parentheses)

PROGRAM	FY2005	FY2006 Final ¹	FY2007 President's Budget Request	FY2007 HIV/AIDS Community Request
HRSA: Ryan White CARE Act Total	\$2,048.3 m	\$2,037.7 m (-\$10.6 m)	\$2,133 m ² (+\$95 m)	\$2,614.5 m (+\$576.8 m)
Title I	\$610.1 m	\$604 m (-\$6.10)	\$610.1 m (0)	\$725.0 m (+\$114.92 m)
Title II: Care	\$334.3 m	\$331.0 m (-\$3.3)	\$334.3 m (0)	\$384.3 m (+\$50.0 m)
Title II: ADAP	\$787.3 m	\$789.6 (+\$2.3 m)	\$859.6 m ³ (+\$70 m)	\$986.5 m (+\$196.9 m)
Title III	\$195.6 m	\$193.6 m (-\$2 m)	\$193.64 m (0)	\$236.6 m (+\$41.0 m)
Title IV	\$72.5 m	\$71.79 m (-\$0.74m)	\$72.53 m (0)	\$113.3 m (+\$40.72 m)
Part F: AETCs	\$35.1 m	\$34.7 m (-\$0.36)	\$34.7 m (0)	\$50.0 m (+\$15.3 m)
Part F: Dental Reimbursement	\$13.2 m	\$13.2 m (0)	\$13.2 m (0)	\$19.0 m (+\$5.78 m)
(SPNS⁴)	(\$25.0 m)	(\$25.0 m)	(\$25.0 m)	(\$25.0 m)
CDC: HIV, STD, TB Total	\$960.7 m	\$946.6 m (-\$14.1 m)	\$1,033.0 m (+\$86.4 m)	\$1,545.3 m (+\$584.6 m)
HIV Prevention and Surveillance	\$662.3 m	\$651.1 m (-\$11.2 m)	\$739.6 m (+\$88.5 m)	\$1,049.2 m (+\$386.9 m)
STD Prevention	\$159.6 m	\$158.0 m (-\$1.4 m)	\$156.9 m (-\$1.1 m)	\$269.7 m (+\$110.1 m)
TB Prevention	\$138.8 m	\$137.4 m (-\$1.4 m)	\$136.5 m (-\$0.9 m)	\$226.4 m (+\$87.6 m)
CDC: Viral Hepatitis	\$17.36 m	--	--	\$50.0 m (+\$32.6 m)
CDC: National Immunization Program	\$493.6 m	\$519.8 m (+\$26.2 m)	\$507 m (-\$12.8 m)	

1. FY2006 conference figures include a 1% rescission.

2. \$25 million is for outreach efforts through faith and community-based organizations.

3. Budget language indicates that the \$70 million does not have to run through the ADAP earmark, but can be.

4. Special Projects of National Significance (SPNS) is funded through an evaluation tap across all PHS programs, the tap in FY2004 is 2.2% and 2.4% in FY2005, and is not included in the RWCA total

Source: National Alliance of State and Territorial AIDS Directors, Washington, DC

FY 2007 Appropriations for Federal HIV/AIDS Programs

(March 2006; Increases or decreases from previous fiscal year are shown in parentheses)

PROGRAM	FY2005	FY2006 Final	FY2007 President's Budget Request	FY2007 HIV/AIDS Community Request
CDC: DASH - HIV Prevention Education	\$46.64 m	--	--	\$66.6 m (+\$20 m)
CDC: Prevention Block Grant	\$131.8 m	\$99 m (-\$32.8 m)	\$0 (-\$99 m)	\$132 m (+\$0.2 m)
HRSA: Community Health Centers	\$1,733.8 m	\$1,782.3 m (+\$48.5 m)	\$1,963.0 m (+\$180.7 m)	\$2,000 m (+\$266.2 m)
HRSA: Title X	\$285.9 m	\$283.1 m (-\$2.76)	\$283.1 m (0)	\$350 m (+\$64.1 m)
Minority HIV/ AIDS Initiative (across multiple programs)	\$398.7 m ⁵	\$394.7 m (-\$4 m)	\$394.7 m (0)	\$610.0 m (+\$211.3 m)
ACF: Abandoned Infants Assistance	\$12.0 m	\$11.88 m (-\$0.12 m)	\$12.0 m (0)	\$20.0 m (+\$8.0 m)
NIH	\$28.28 b	\$28.3 b (+\$0.34 b)	\$28.6 b (+\$0.3 b)	\$30.0 b (+\$1.72 b)
OAR	\$2,921 m	\$2,895 m (-\$26 m)	\$2,880 m (-\$15 m)	\$3.1 b (+\$200 m)
SAMHSA: Center for Substance Abuse Treatment	\$422.4 m	\$398.9 m (-\$23.5 m)	\$375.4 m (-\$23.5 m)	\$440.3 m (+\$41.4 m)
Substance Abuse Block Grant	\$1,775.6 m	\$1,757.8 m (-\$17.8 m)	\$1,758.6 m (+\$0.8 m)	\$1,851.0 m (+\$93.2 m)
SAMHSA: Center for Substance Abuse Prevention	\$198.7 m	\$193.1 m (-\$5.6 m)	\$180.6 m (-\$12.5 m)	\$214.7 m (+\$15.9 m)
SAMHSA: Center for Mental Health Services (CMHS)	\$901.3 m	\$884.0 m (-\$17.3 m)	\$848.9 m (-\$35.1 m)	\$939.6 m (+\$55.6 m)
Subset of CMHS: Mental Health Block Grant	[\$432.8 m]	[\$428.5 m] [(-\$4.3 m)]	[\$428.5 m] [(0)]	[\$451.2] [(+\$22.7 m)]
HUD: HOPWA	\$281.7 m	\$286.1 m (+\$4.4 m)	\$300 m (+14 m)	\$385 m (+\$103.3 m)

This figure represents NASTAD's best estimate based on the past three years of rescissions.

Source: National Alliance of State and Territorial AIDS Directors, Washington, DC

"We expect those [budget] pots to be the same size if note smaller than last year's pots," Smiley says. "So in essence what that means is Ryan White will unlikely see a lot of increases."

The problem with flat-funding is that it becomes a decrease when across-the-board budget cuts are made, as has happened in recent years. Also, there are decreases in the money available because of the increased costs and

increased numbers of people needing the care and services provided, Smiley says.

"We're really losing ground, and it's not just hundreds of dollars," Smiley says. "We're losing millions of dollars."

Meantime, the Ryan White Reauthorization continues to be postponed, although Sen. Tom Coburn (R-OK) has introduced reauthorization legislation.

Congress appears to want to finish the reauthorization process by spring since there's a limited window available for completing legislation, Hanen says.

Some fundamental issues related to how Ryan White funds are distributed have made the reau-

thorization complicated, Hanen notes. "What is the most appropriate way to fund states and cities to enable them to provide treatment and care and support services?" she says.

Basically, everyone wants to do something to address the problems faced by states that don't

Global HIV/AIDS Programs

PROGRAM	FY2005	FY2006 Final	FY2007 President's Budget Request	FY2007 HIV/AIDS Community Request
CDC: Global HIV/AIDS⁶	\$123.9 m	\$122.6 m (-\$1.3 m)	\$121 m (-\$1.6 m)	\$147.0 m (+\$26.0 m)
CDC: Research	\$11.0 m	\$10.9 m (-\$0.11 m)	--	\$13.0 m (+\$2.0 m)
CDC: TB & Malaria	\$15.9 m	\$15.7 m (-\$0.16 m)	--	\$16.0 m (+\$0.1 m)
NIH: Research	\$332.3 m	\$346.5 m (+\$14.2 m)	--	\$382.0 m (+\$49.70 m)
USAID: Tuberculosis	\$80.0 m	\$79.2 m (-\$0.8 m)	\$89.0 m (+\$9.8 m)	\$300.0 m (+\$220.0 m)
USAID: Malaria	\$90.0 m	\$100.0 m (+\$10.0 m)	\$225.0 m (+\$125.0 m)	\$200.0 m (+\$110.0 m)
USAID: HIV/AIDS	\$347.2 m	\$346.5 m (-\$0.7 m)	\$325.0 m (-\$21.5 m)	\$417.0 m (+\$16.7 m)
State: Global AIDS Coordinator⁷	\$1,373.9 m ⁸	\$1,795 m ⁹ (+\$421.1 m)	\$2,782.0 m (+\$987.0 m)	\$1,970.0 m ¹⁰ (+\$175 m)
Global Fund - Total	\$434.1 m	\$594 m (+\$159.9 m)	\$300 m (-\$135 m)	\$1,500.0 m (+\$1,066 m)
Global Fund - HHS	[\$99.1 m]	[\$100 m]	[\$100 m]	--
Global Fund – USAID	[\$335 m] ¹¹	[\$250 m]	[\$100 m]	--
Global Fund – State		[\$200 m]	[\$100 m]	
Other (DOL, DOD, DOA, FMF, USAID)	\$91.3 m	--	--	--
Total - Global HIV/AIDS, TB and Malaria	\$2,899.6 m		\$3,000 m (+\$100.45 m)	\$4,945.0 m (+\$2,045.5 m)

7. The Global AIDS Initiative is made up of Global AIDS Coordinator and USAID HIV/AIDS funding.

8. This figure includes \$27 million for IAVI, \$27 million for UNAIDS, and \$30 million for microbicide development.

9. This figure includes \$30 million for UNAIDS.

10. This figure includes \$42 million for microbicide development.

11. This figure includes an additional \$87 million in carry-over funds from the previous fiscal year.

Source: National Alliance of State and Territorial AIDS Directors, Washington, DC

receive Title I funding because they lack an eligible metropolitan area (EMA).

The problem is how to make the distribution of funding more fair to these states while not cutting services provided in the states that do have large cities impacted by HIV/AIDS, Hanen says.

"We have a proposal to get supplemental funding to states without EMAs, and it also includes two states that have more than 50% of cases outside of EMAs, Louisiana and Ohio," Hanen says.

Supplemental funding is the best way to approach this because if the funding is redistributed it could destroy infrastructure that has been in place for 16 years, Hanen notes.

Meantime, AIDS groups continue to work on improving funding for Ryan White and other programs directed at the HIV/AIDS epidemic, but all optimism is gone.

This year, even the National Institutes of Health (NIH) is looking at decreased funding, Smiley notes.

"It's not just the Ryan White funding that we're depressed and sort of anxious about, but the CDC under HIV prevention figures from the president took a huge cut, and the NIH, which is the darling of all health programs, is being cut," Smiley says.

Some institutes within NIH are looking at drastic cuts of 15%, so it's not just HIV/AIDS programs being targeted, but all research programs at NIH, he adds.

"That gives you a picture of what we're fighting against, so sometimes we take a flat funding and have a sigh of relief at the status quo," Smiley says.

AIDS groups have become resigned to the ongoing funding crises, he notes. "I think there's a certain sense that you're beating your head against the wall," Smiley says. "The reason why is because different members of Congress push the blame somewhere else: they say you have to talk to the president and get him to ask for higher funding; you go to the appropriations people, and they say, 'Where is it going to come from?'"

The blame could be placed on tax cuts, war, deficits, defense spending, hurricanes, etc., but the bottom line is there really isn't any extra money to work with, Smiley says. "We can lobby as hard as we can, but if other interest groups are making the same case, and in essence every mother thinks her child is the prettiest, then you're arguing to draw from the same pot of money," Smiley says. "And it's very difficult to make the case that will result in those increases." ■

ADAP funding still fails to meet the growing need

Waiting list near 1,000

Nearly 1,000 people were on waiting lists for AIDS Drug Assistance Programs (ADAPs) at the beginning of 2006, and this number is expected to jump at least 10% when the 118 people who receive medication through the President's ADAP Initiative join the ranks since the initiative's funding ran out in March.

Fiscal year 2006 money became available on April 1, but that funding is the same as last year, which was insufficient by more than \$200 million, says **Bill Arnold**, executive director of Title II Community AIDS National Network and director of the National ADAP Working Group, both in Washington, DC.

"Some states have stepped in with meaningful increases," Arnold says. "And the drug manufacturers are throwing back in close to \$100 million a year."

Still, these measures cannot entirely solve ADAP's budgetary shortfall, which is why the waiting lists have grown in 10 states and another seven states and a territory have added new cost-containment measures.

The new Medicare drug benefit is making the problem worse for ADAPs because it has eliminated Medicaid's role in providing medication to many who need HIV antiretroviral drugs, Arnold says. "A lot of people who were on Medicaid before and had no co-pays or deductibles now have co-pays and deductibles under the Medicare drug program, and ADAPs are paying for some of those," Arnold says.

"Some people will be eligible for low-income subsidy, and some will have incomes that are too high for that," he says.

The new Medicare drug prescription program has a catastrophic coverage clause that limits how much of these co-pays and deductibles an individual has to pay, but there is no limit on how much of these are paid by ADAP, Arnold explains.

"Catastrophic coverage does not kick in because you can't count the ADAP expenditure towards it," he says. "If 10 percent of our people's co-pays could be paid by ADAP and counted toward the catastrophic coverage, then we could open up another ADAP treatment slot to an HIV-positive person on the waiting list."

Two other factors that could greatly increase the ADAP rolls are the CDC's extra push into outreach and testing programs and the new scientific research suggesting that HIV antiretroviral therapy should begin soon after a person becomes infected, Arnold notes.

"Ethically, it's a real problem because you tell me how anyone can say that if someone tests positive they can guarantee them treatment," Arnold says. "We have cases where we know that can't happen."

The president's budget proposal calls for \$70 million to be directed toward providing health care and treatment services to individuals in the greatest need, including those who were newly diagnosed because of increased HIV testing, says **Laura Hanen**, director of government relations at the National Alliance of State & Territorial AIDS Directors of Washington, DC.

"But we don't really know what that means," Hanen says. "We'll be advocating for the \$70 million to go through the ADAP formula to address our ADAP crisis." ■

Acute infection patients have more partners

Higher chance of infection spreading in networks

New research suggests that patients with acute HIV infection have a significantly larger number of partners than what has been reported, historically, by HIV patients with non-acute infection.¹

"The research suggests people with acute infection are more likely to be in sexual networks that are a little more complex or are more likely to have more partnerships at that time than other infected people," says **Christopher D. Pilcher**, MD, an assistant professor in the school of medicine at the University of North Carolina at Chapel Hill.

"That may lead to a higher likelihood of infection spreading in a population," Pilcher says. Pilcher was involved with several studies involving the North Carolina Department of Health and Human Services Screening & Tracing Active Transmission (STAT) program, which were presented at the 13th Conference on Retroviruses and Opportunistic Infections (CROI), held in Denver, Feb. 5-8.

The sexual network finding was part of an investigation that included tracing individuals who were identified as having acute infections, Pilcher says.

All 135 public HIV-testing sites in North Carolina have used a combined HIV antibody and RNA testing algorithm through the State Laboratory of Public Health, as part of the STAT program, which has become well-known for its success in identifying acute HIV infection cases.¹

Since the program began Nov. 1, 2002, through Oct. 31, 2004, there were 227,566 public tests conducted, and of these 1,123 were newly antibody positive, and another 44 were true acute infections. Investigators interviewed 41 of the people with acute infections.¹

"Disease intervention specialists from North Carolina were remarkably successful at reaching these patients very quickly, as well as reaching their partners and counseling exposed partners that they might be at risk for HIV infection," Pilcher says.

The disease intervention specialists followed the partners, providing HIV testing, counseling, and, sometimes, clinical evaluation, for up to two years, Pilcher says.

They found that of 12 partners, who were completely evaluated and had documentation of previous HIV negative status, three were antibody positive initially and another three were RNA positive, indicating an acute infection, Pilcher says.

"So half were newly HIV positive, and at least three of them we're certain were acutely infected as a result of their exposure to their HIV infected partners," he says. "So this is a very real world kind of reinforcement of the value of following up on partners of newly diagnosed HIV patients."

Among the acute infection cases were 16 women, and five of the women were pregnant at the time of their testing, Pilcher says.

During this same time period there were six infants born with HIV infection in North Carolina; and in three of those cases the mothers had been tested and were negative early in their pregnancies, so they had seroconverted during their pregnancy, Pilcher notes. "So we managed to detect and avert five additional acute infections during pregnancy, just through the testing program," Pilcher says.

Researchers concluded that standard antibody tests miss at least 4% of the HIV-infected pregnant women in the state, and so the use of STAT could significantly improve the performance.²

"We should not only repeat HIV testing at the time of labor for women who are tested and negative, but we should also include the use of nucleic acid testing for any HIV testing during pregnancy, because it seems clear that acute infection occurring during pregnancy is responsible for a large proportion of residual mother to child transmission in North Carolina," Pilcher says.

Another study related to the STAT program looked at its cost effectiveness and found that the cost per quality-adjusted life-years (QALY) was \$4,345, which is well below the cost-effectiveness threshold of \$50,000.³

Investigators concluded that screening negative samples for acute HIV infection using the STAT approach should be considered wherever there is a 0.55% positive HIV test rate and where notification and follow-up are possible.³

The study tried to quantify what would be the direct results of detection of acute HIV infections that would otherwise be missed over a one year period of testing, Pilcher explains.

"The study did not account for the downstream impact of transmitting infection to many individuals," Pilcher notes. "It looked at what would happen in 12 months of time if it detected the exact number of cases that we detected and averted exactly the number of cases that we believe we averted."

Since only one-third of babies are infected with HIV naturally from their HIV infected mothers without intervention, the discovery of five acutely infected pregnant women would have saved, conservatively, one or two babies from HIV infection, Pilcher says. "So by plugging in all of the real numbers and knowing exactly what the outcomes were and then estimated from the published literature what the costs of an HIV infection are over an individual's lifetime, the study came up with the cost of the additional testing per quality adjusted life year," Pilcher says.

"For cost effectiveness modeling we used extraordinarily conservative assumptions about what the impact was of telling partners and patients and the impact of risk reduction counseling for acutely infected patients and their partners," he says. "We assumed there would be only a 50% reduction in risk after knowing their status."

This means there would be about ½ to 1 adult case averted each year, Pilcher says.

"We believe in reality it is much higher, but we felt in terms of a cost effectiveness analysis that it was important to use the most conservative model possible," Pilcher says. ■

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No evidence of HIV-1 strain cross transmission

Superinfection is very rare occurrence

Researchers in one recent study have found no evidence of HIV superinfection between chronically-infected sexual partners.

Sixteen HIV-infected men who have sex with men (MSM), recruited from a Seattle cohort for a study about HIV and anal dysplasia, reported having long-term sexual partners, says **Mary Campbell**, MD, a senior fellow in infectious diseases at the University of Washington in Seattle.

"So we had sexual behavioral data, data about the length of their partnerships, and we also had quite a bit of clinical data about any AIDS-defining or HIV symptoms they had prior to the study and in follow-up," Campbell says. "And we had data on antiretroviral treatment and CD4 cell counts and viral load."

Investigators screened HIV envelop sequences derived from mononuclear cells at the initial and final study visits, and they analyzed those sequences biogenetically to determine the relatedness between individuals and their partners, Campbell explains.

Researchers used phylogenetic methods to analyze HIV sequences.¹ Most of the men were followed for three to five years, and at each study visit they completed detailed questionnaires about sexual behavior, she says.

Researchers had access to information about eight pairs of chronically HIV-infected male partners, whose partnerships were of three to 15 years duration, Campbell notes.

"The main findings were that for three of the couples it appeared that either one partner had

transmitted the virus to the other partner prior to enrollment in the study, or they had a third partner in common who had transmitted to them both because the viral sequences were very similar and unable to be separated biogenetically," Campbell says.

"For the remaining pairs there was no evidence of epidemiologic linkage between viral strains at either time point, which suggested no transmission," she adds.

The data are consistent with the hypothesis investigators have had for several years about how superinfection is a very special case and not a frequent event, says **James I. Mullins**, PhD, a professor of microbiology at the University of Washington. Mullins was a co-investigator in the study.

When infection with multiple HIV strains has occurred, in almost all instances it has been reported early after acquisition of the first strain or during a drug holiday after a period of suppression, Mullins says.

"The situation that is found in the naïve or newly-infected host or the host that has been on antiretroviral suppression for a long time is the high abundance of susceptible target cells," Mullins explains. "So someone who has been chronically infected for some time will have a low level of uninfected susceptible cells."

Typically, when a cell becomes infected it is less susceptible to being re-infected, Mullins adds. "Superinfection is certainly less common in chronically infected individuals," Campbell says.

When superinfection has been detected in a person with established infection it has been a very unique circumstance of the person having gone off their antiretroviral drugs for weeks or days and then encountering a new strain, Mullins says.

Since the small study did not find evidence of superinfection, its findings are consistent with the idea that superinfection requires a large number of target cells to be susceptible and available for infection by a new strain, Mullins says.

This might reassure clinicians that under normal circumstances their patients won't become re-infected, although they might be concerned when there's a possibility of therapy interruption, Mullins notes.

"We are not trying to say this study is definitive or that superinfection does not occur following the establishment of initial infection, but we're building up a data set to give us an idea of what are the windows of opportunity for

superinfection," Mullins says. "And so far, the windows are very early after acquisition of first infection and during drug holidays, and we have no evidence of it occurring at other times." ■

Reference

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FDA discusses studies to support OTC HIV test kits

Below is contextual information regarding the design of proposed studies to support marketing approval of Over-the-Counter (OTC) home-use HIV test kits which includes an historical overview of rapid HIV test kit approval in the United States, and key issues for consideration by the FDA Blood Products Advisory Committee. Once posted, transcripts of the March 10, 2006 advisory committee meeting will be available on the FDA website at <http://www.fda.gov/ohrms/dockets/ac/cber06.html#BloodProducts>

The FDA seeks the advice of the Committee on proposed studies that would be needed to validate a home-use HIV test kit with regard to test accuracy, test interpretation, and medical follow-up based on the provision of informational material in place of a trained test operator and counselor.

Background on rapid HIV tests:

Over the past four years, THE FDA has approved a number of rapid HIV tests of low complexity, which are simple to use, require no special storage conditions and provide a highly accurate test result within 20 minutes for the detection of antibodies to HIV. Two of these tests were found to be simple enough to perform that

they received a CLIA waiver, expanding the availability of testing. The FDA has required, as a condition of approval, that the lower 95% confidence bound for estimated test sensitivity and specificity should be 98% or greater.

Whereas most HIV tests require the use of a blood specimen, THE FDA also approved the OraQuick ADVANCE Rapid HIV-1/2 Antibody Test in March 2004 to detect antibodies to HIV-1 and HIV-2 in oral fluid specimens. The labeled sensitivity of the test is 99.3% (95% CI = 98.4%-99.7%) and the specificity is 99.8% (95% CI= 99.6%-99.9%), which is within the acceptance performance set by the FDA (1). A CLIA waiver for this indication was granted in June 2004. [Note that reports of reduced specificity of the test (to a level as low as 99.1%) in some locations are under investigation at this time.]

Testing using oral fluid involves swabbing the device against the upper and lower gums once, inserting the device into a buffer vial, and reading the test result after 20 minutes. The test result is read visually. A single control line (controls for adequate specimen collection and proper functioning of the device) is a non-reactive result that is interpreted as negative for antibodies to HIV-1 or HIV-2.

The presence of both a control line and a test line (consisting of HIV-1 and HIV-2 peptides) is a reactive test result that is interpreted as "preliminary positive" for HIV-1 and/or HIV-2 antibodies and reported to the test subject. Reactive test results should be confirmed using an additional, more specific test. However, this requires an independent action that may not always occur. Those with confirmed positive test results should be counseled appropriately and be referred for medical follow-up.

Since 2002, all rapid HIV tests were approved as restricted devices, with the following sales and use restrictions in place:

1. Sale is restricted to clinical laboratories that have an adequate quality assurance program, including planned systematic activities to provide adequate confidence that requirements for quality will be met, and where there is assurance that operators will receive and use the instructional materials.

2. The test is approved for use only by an agent of a clinical laboratory.

3. Test subjects must receive a "Subject Information" pamphlet and pre-test counseling prior to specimen collection and appropriate counseling when test results are provided.

4. The test is not approved for use to screen blood, cell, plasma, or tissue donors.

Purchasers of the test receive a customer letter stating that by purchasing the test they agree to abide by these restrictions.

Home use tests

Home-use tests are used at home by untrained persons without the help of a health care professional. Most home-use tests, such as tests for blood glucose, cholesterol, and pregnancy, are available OTC without a prescription.

There are two types of home-use tests: test kits and collection kits. With a test kit, you take your own sample, test the sample, and read your own result. There are currently no home-use test kits approved for the detection of any infectious agent.

With a collection kit, you take your own sample, mail it to a laboratory, and get your result over the phone or in the mail. There is currently one FDA approved home-use collection kit on the market for HIV testing.

There are a number of potential benefits to home-use HIV test kits, including:

- Of the approximately one million HIV-infected individuals in the US, approximately 25% are not aware of their HIV status. Anonymous testing could potentially lead to more of these people knowing their HIV status.

- Home-use test kits empower consumers in their health care decisions.

- Home-use HIV test kits may lead to earlier diagnosis of HIV infection and therefore earlier intervention, translating into better clinical outcomes with currently available therapies.

There are a number of potential risks associated with home-use HIV test kits, including the following:

- Inappropriate use of the test or test result, including misinterpretation (e.g., relying on the test to provide an accurate result after a very recent exposure), may lead to a false sense of security. Continued high risk behavior may result in additional HIV infections.

- Home-use tests kits rely on informational material for pre-test and post-test counseling. Without live counseling there is a potential for adverse outcomes following obtaining a positive test result.

- Individuals may not be able to be reached for follow-up and for partner notification (though partners may be informed by the self-tested individual).

Additional issues include:

- Obtaining a test result without a supplemental test
- The cost and availability of a home-use HIV test kit for those who need the test the most
- Potential conflict with state and/or federal public health reporting requirements.

The test kit manufacturer must demonstrate to the FDA that the test is safe and effective.

History of FDA consideration of HIV OTC tests

The FDA has discussed HIV home-use test kits and home-use collection kits over the past 10 years in various forums. This included communications with manufacturers of home collection systems in 1988-89, the BPAC in June 1994, and in Federal Register notices in 1989, 1990, 1995, and, most recently, in 2005.¹⁻⁴

In the course of discussions held prior to 2005, appropriate regulatory criteria were identified for home-use specimen collection kits for HIV testing, but not for home-use HIV test kits. With improved test kit technology (ease of use, freedom from biohazards, and excellent performance characteristics), we believe it may be feasible to identify regulatory criteria for home-use HIV test kit.

On Nov. 3, 2005, the FDA brought the issue of approaches to the validation of over-the-counter (OTC) home-use HIV test kits to BPAC for discussion in response to renewed interest. At that meeting, the committee heard presentations from OraSure Technologies on its currently approved OraQuick ADVANCE Rapid HIV-1/2 Antibody Test when used with oral fluid specimens; from CDC on changes in HIV testing practices and counseling recommendations, including the role of rapid HIV tests in the HHS Advancing HIV Prevention initiative and the results of post-marketing surveillance for rapid HIV tests and home sample collection HIV tests; from CDC on quality system considerations for home-use HIV test kits; from an expert on psychological and social issues associated with HIV testing, including the finding that, although death from suicide is common among people with advanced HIV infection, notification of a positive HIV test does not appear to lead to a sudden and substantial rise in

suicide death; and from CDRH on its review practice for OTC IVDs.

Discussion

What test characteristics favor possible approval of an OTC home-use HIV test?

- The risk of an incorrect test result is extremely low in the hands of trained operators. This would be supported by a demonstration of analytical and clinical sensitivity and specificity, as well as demonstration that the test is not affected by conditions of operational stress.
- The test is simple to use compared to other types of HIV tests and earlier versions of rapid HIV tests, suggesting that untrained persons will be able to perform the test properly.
- The test does not require special storage conditions.
- The test provides highly accurate results for the detection of antibody to HIV within 20 minutes.
- The use of a non-infectious oral fluid specimen eliminates concerns about biohazardous conditions (no blood and no sharps).
- Informational materials supplied with the test are sufficient to provide adequate information to potential users on performing the test and to substitute for live counseling. ■

This article is from the FDA website: www.fda.gov/oashi/aids/listserve/listserve2006.html

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COMING IN FUTURE MONTHS

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CE/CME objectives

The CE/CME objectives for *AIDS Alert*, are to help physicians and nurses 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.

Physicians and nurses participate in this medical education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue.

Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any question answered incorrectly, please consult the source material.

After competing this activity at the end of each semester, you must complete the evaluation form provided and return it in the reply envelope provided to receive a credit letter. When your evaluation is received, a certificate will be mailed to you.

CE/CME questions

13. A study of the Screening & Tracing Active Transmission (STAT) program's cost effectiveness found that its cost per quality-adjusted life-years was how much?
 - A. \$1,323
 - B. \$4,345
 - C. \$9.652
 - D. \$52,988
14. In a recent study of 16 men who have sex with men who are infected with HIV and who are involved in long-term relationships, researchers found that what number of men had evidence of superinfection?
 - A. 0
 - B. 2
 - C. 4
 - D. 5
15. As of the beginning of 2006, how many people were on the waiting list of people who need antiretroviral drugs through the AIDS Drug Assistance Program (ADAP)?
 - A. 123
 - B. 388
 - C. 724
 - D. About 1,000
16. Each day, about how many children, under age 15, are newly infected with HIV worldwide?
 - A. 850
 - B. 1,200
 - C. 1,550
 - D. 1,800

Answers: 13. B; 14. A; 15. D; 16. D

AIDS ALERT® INTERNATIONAL



Tijuana's HIV prevalence rate has had an alarming increase in recent years

Border town's epidemic could be new trend

Anew study has found a rising HIV prevalence rate in the border town of Tijuana, Mexico, and researchers say this could be the start of a disturbing trend.

Overall, the prevalence rate ranged from 0.3% to 0.8% in the general adult population, ages 15-49, in Tijuana, says **Kimberly Brouwer**, PhD, an assistant professor at the School of Medicine at the University of California, San Diego. UCSD investigators collaborated with researchers from the Centro Nacional para la Prevencion y Control del VIH/SIDA of Mexico City, Mexico, on the study.

Previous information suggested the prevalence rate was 0.09% among pregnant women in Tijuana, who are a sentinel group for HIV surveillance, Brouwer says. Then a recent study of 1,064 women in labor in Tijuana found an HIV prevalence rate of 1.1%, with the HIV prevalence at less than 1% among non-drug using women and 6% for those who use drugs or had partners who used drugs.^{1,2}

"With the magnitude of the rise in HIV prevalence among pregnant women, we thought it was important to look at other risk groups," Brouwer says. "What we did was collect available data from community-based studies, from published reports, from the National Center for the Prevention and Control of HIV/AIDS in Mexico, and they were collaborators on this work," Brouwer explains. "We combined those sources and were able to get an estimate of HIV prevalence and also the size of that population."

When investigators combined this information with Mexican census and other data, they estimated a high risk and low risk scenario of HIV prevalence, she adds.

The prevalence among men who have sex with men (MSM) had increased from 11% in the early 1990s to about 19%, and for injection drug users (IDUs), the prevalence increased from less than 2% in the early 1990s to a current range of 2.3% to 6.5%, Brouwer says.

"It's not the current magnitude of HIV prevalence, because an infection rate of 0.3% to 0.8% overall means Tijuana now rivals a lot of major U.S. cities, such as San Diego where an estimated one person in every 126 persons is HIV positive," Brouwer says. "What really concerns us is the rapid rate of increase in HIV prevalence in Tijuana, and given that trajectory, it shows a real need for interventions to occur."

Tijuana, located in Baja California, the northernmost state of Mexico, is a rapidly growing city with a growth rate of 6% a year, Brouwer notes. "Tijuana is just south of San Diego, California, just a 20 minute drive between the two cities, and this border crossing is the busiest land border crossing in the world. Over half of the northbound crossings in the United States happen at the junction of the two cities."

The migration goes in both directions, because a lot of Americans will travel to Tijuana for tourism and business, she says. "And you get a huge number of Tijuana residents commuting on a daily basis to work in San Diego or to meet with family. There are a lot of illegal crossings, as well."

Tijuana's role as a border town hosting people migrating both north and south makes the city at greater risk for the HIV epidemic, she notes. "You're getting interaction between populations on both sides of the border. And migrants tend to be an at-risk group in and of themselves."

Migrants typically are detached from a support system and they usually don't have social ties with the communities they are from, so there's social and cultural alienation, as well as a fear of deportation and violence that affects their decisions, Brouwer says.

"All of these factors have been found in other migrating populations when researchers investigate HIV risks," Brouwer says. "Migrants tend to be at an increased risk for HIV infection."

Sexual tourism possibly another factor

Another factor that might explain Tijuana's increase in HIV prevalence is sexual tourism, where there is a quasi-legal system of commercial sex work, Brouwer explains.

Tijuana health officials test registered commercial sex workers for sexually-transmitted diseases (STDs), but there are a great number of unregistered sex workers, as well, she says.

"They test for chlamydia and gonorrhea, but not necessarily HIV," Brouwer says. "That's one concern, and we're working with authorities in Tijuana to make sure they have increased access to HIV testing."

Commercial sex work is tolerated in Tijuana, and there is a section of town used for MSM sex trade, although the female sex worker population is much larger than the male sex worker population, Brouwer adds.

Tijuana's increasing HIV prevalence also might be impacted by the city's role as a major drug trafficking route, Brouwer says.

"Mexico has a much lower rate of the use of drugs and a lower prevalence of injection drug use, but Tijuana has one of the highest rates of drug use in all of Mexico," Brouwer says. "As we saw in our model, injection drug users were the second-largest group of HIV positive persons, and that's another reason why this border is at increased risk."

Investigators theorize that the HIV prevalence is high among MSM in Tijuana because this is the group in which HIV traditionally has taken hold and because there is a lot of overlap between IDUs and MSM, Brouwer says.

"I believe you're seeing a lot of high-risk people who may be involved in more than one activity," she says. "We see the same thing between commercial sex workers and drug users because a lot of commercial sex workers are taking methamphetamine and cocaine to be able to stay awake and work in the manner they do."

Researchers have encouraged Tijuana officials to improve prevention and care among HIV positive populations.

Since the study about a high HIV prevalence among pregnant women was publicized, the Tijuana General Hospital decided to offer HIV testing to all pregnant women entering the hospital, and so far 95% have agreed to be tested, Brouwer says. "So that's a bright spot in the situation in Tijuana," she says. "There also are some non-governmental organizations that are involved in HIV prevention."

For example, the University of California, San Diego School of Medicine donated a recreational vehicle to a non-governmental organization (NGO) called Cirad in Tijuana. The NGO takes the RV to at-risk neighborhoods in the Tijuana community and distributes condoms and literature on HIV/AIDS, Brouwer says.

"The nice thing about this effort of having a mobile prevention vehicle is that if you are going out to people instead of having them come into the clinic, it reduces the stigma people feel when they walk into a specific HIV testing clinic," Brouwer says. "And the RV goes around with this big logo on its side about HIV prevention, and so it's hopefully increasing HIV awareness in the community as a whole."

The authors of the study about estimated HIV infections in Tijuana also are trying to lobby for increased HIV prevention funding at the U.S./Mexico border, Brouwer says.

"We're still waiting to hear if that will happen, but hopefully, we'll see an increase in funding in this area," she says.

San Diego County spends more than \$2 million a year on HIV prevention, and part of that money covers concerns about cross-border transmission, she notes.

"Health officials both at local and national levels have been tremendously cooperative," Brouwer says. "Our only concern is having cooperation with those who control the budgets in Mexico."

Since Mexico has had a comparatively low HIV prevalence rate in the past, HIV/AIDS was never treated as an epidemic with great urgency and concern, she says. "Hopefully, studies like ours will start to change this perspective, especially along the U.S.-Mexico border."

Investigators plan to compare the Tijuana epidemic to other parts of Mexico as the next phase of research, Brouwer notes. "We picked Tijuana because of its proximity, but also because this city

is at a confluence of risk factors that makes it unique compared with other parts of Mexico," she says. "We had a suspicion that this was an area of concern, but it would be good to know if this increase has been seen along the Mexico/U.S. border and penetrated into Mexico." ■

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Global Partners Forum advocates for children

18 million AIDS orphans by 2010

One in six global AIDS deaths and one in seven new HIV infections worldwide are among children under age 15. Also, an estimated 15 million children are orphans because of AIDS, and in sub-Saharan Africa, this number is expected to rise to 18 million orphans by 2010.1

The Global Partners Forum met in London, United Kingdom, in February to bring together representatives from 90 international organizations and governments to discuss strategies for improving the lives of children impacted by the AIDS pandemic.

UNICEF, a sponsor of the forum, has pointed out that less than 10 percent of the children who are impacted by the AIDS epidemic have received public support or services. (**See chart about children and AIDS, this page.**)

"The major challenge is that in Southern Africa, in particular, where the majority of children affected by HIV and AIDS live, these types of services are generally not provided by the government," says **Gerrit Beger**, HIV/AIDS section, programme division of the United Nations Children's Fund (UNICEF) of New York, NY.

"However, it is encouraging to see that during the last 2 years an increasing number of countries in sub-Saharan Africa have started conducting assessments, analysis and planning of actions to support children affected by HIV and AIDS," Beger says. "With increasing funds becoming

UNICEF statistics about children and AIDS

A 2005 UNICEF report titled "A Call to Action; Children, The Missing Face of AIDS," provides these statistics about how the HIV epidemic has impacted children worldwide:

- Nearly 1,800 children under age 15 become newly infected with HIV each day, and most of these infections occur because of mother-to-child (MTC) transmission.
- Every day, more than 6,000 young people, ages 15 to 24, are infected with HIV.
- Despite ample research showing how efficiently antiretroviral drugs given during pregnancy and birth can prevent MTC transmission, less than 10% of pregnant women are offered MTC prevention services.
- More than two-thirds of young women, ages 15-24, in sub-Saharan Africa understand how to avoid being infected with HIV.
- Children in sub-Saharan Africa account for more than 85% of all children under age 15 living with HIV infection.
- In South and East Asia, children under age 15 are the largest group of children living with AIDS and dying from the disease outside of sub-Saharan Africa.
- Every minute of each day, a child under age 15 dies of an AIDS-related illness.
- Of the 24 countries with the world's highest levels of HIV prevalence, sub-Saharan Africa is home to 24 of them.
- More than 12 million children in sub-Saharan Africa have been orphaned because of the AIDS epidemic, and less than 10 percent of them are receiving public support and services.
- About 35% of children born to HIV-positive women will contract HIV if there are no prevention measures taken.
- An estimated 300,000 children under the age of five die each year from AIDS-related illness.

available from national governments, donors, and funds like the Global Fund, it is expected that in the coming few years we will see a significant scaling up of service provision to children affected by HIV/AIDS."

Many non-governmental organizations (NGOs) do not provide comprehensive services to children affected by HIV, Beger notes.

"The major challenge for many NGOs is that they often work in a relatively small geographically area and only reach a small proportion of all children affected by HIV and AIDS in the country," he says.

At the recently held Global Partners Forum on children affected by HIV and AIDS, strategies were discussed for strengthening the capacity of families to protect and care for orphans impacted by the epidemic, Beger says.

"Some of the areas where urgent scaling up is required include universal access to health care, including prevention of mother to child transmission of HIV; access to treatment for HIV-infected mothers and children; universal access to education; strategies to reduce poverty including social welfare and cash transfer, and access to birth registration to enable legal protection and provision of services," Beger explains.

In many sub-Saharan countries there have been increasing numbers of local and international NGOs providing services to people impacted by HIV/AIDS, Beger says.

"NGOs have done a tremendous job in advocating for AIDS, and initiating and piloting of interventions to support children affected by HIV and AIDS," he adds. "However, because of limited resources and scope of work, NGOs are normally not able to scale up their intervention to a large geographical area not to mention a national level."

What's needed is close collaboration between NGOs, governments, and others to ensure they all work together towards one nationally agreed plan of support for children affected by HIV/AIDS, Beger suggests.

"There should be one coordination mechanism for all implementing partners to maximize the limited resources available and to prevent duplication and waste," he says. "And there should be one monitoring and evaluation system that allows monitoring progress and through which all partners can learn from each other about what strategies work and which can be scaled up."

The HIV resources pie has not provided well for children impacted by HIV/AIDS.

"It is not just the matter of the pie being too small," Beger says. "Part of the problem is that the available pie might not be suitable for children and that the fork needed to feed the pie is not commonly available."

For example, antiretroviral drugs for adults are commonly not suitable for children as they are not in the right dosage and are often in pill form when a syrup version would be more suitable for young children, Beger explains. Some antiretroviral dosages don't exist as drug companies have too small of a market for these in industrialized countries, he says.

"Where they do exist they are often much more expensive than adult dosages," Beger says. "It is encouraging to see that the pharmaceutical industry is increasingly responding to pleas by UNICEF and other partners to develop dosages suitable for children and reducing the prices."

The other challenge is that when policy makers think about treatment, they normally think about treatment for adults only, so it's important to advocate to policy makers to include treatment for children when they're developing treatment policies and guidelines and allocating resources, Beger adds.

The Global Partners Forum lists education as a major area of focus because in the worst-affected countries, HIV/AIDS disrupts the demand for education, resources available for schools, and the supply of teachers.

"The most important thing is to remove financial barriers to education," Beger says. "In many countries parents and guardians pay school fees and many other costs like books, and uniforms."

Taking away the financial barriers will be a key strategy in increasing access for the most vulnerable children, including children who are affected by HIV and AIDS, Beger says.

The impact of the epidemic has such far reach that even teachers who are not themselves infected with HIV often may miss work because they are caring for sick relatives, and their absences impact morale and working conditions, he says.

The poorest households often cannot afford school fees, the cost of uniforms and educational materials, and as the epidemic spreads, children are missing out on the knowledge and confidence they'll need to protect themselves and achieve productive lives.¹

The 2005 World Summit addressed this issue by resolving to urgently implement a number of quick-impact initiatives, including the elimination of user fees for primary education.¹

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