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Needle exchanges, syringe access laws improve prevention

Despite continued federal opposition to needle-exchange programs, many states are permitting them to operate, using both public and private funding, and state legislatures have been changing laws to make it easier for injection drug users (IDUs) to obtain syringes legally from pharmacies and clinics. Prevention advocates say these efforts are encouraging, but still are moving too slowly to make as much of an impact on national HIV infection rates among IDUs as they'd like to see. Cover

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Needle-exchange programs are slowly finding greater acceptance

Needle prescriptions are new possibility

Despite continued federal resistance to needle-exchange funding, these programs are growing across the nation, and some states have also moved toward legislation that permits addicts to buy needles over the counter.

Improving access to clean needles still is a long way from solving the problem of HIV transmission among the nation's injection drug users (IDUs), who inject drugs an estimated 920 million to 1.7 billion times per year.¹

The problem is evident: Among AIDS cases reported through June 2001, 25% were among injection drug users, and another 6% were men who have sex with men (MSM) and inject drugs. Among those who reported transmission through heterosexual contact with a person who had a known transmission risk, the vast majority (30,607 total) were women and men who had sex with an IDU, according to data from the Centers for Disease Control and Prevention in Atlanta.²

"Give us the resources, and we'll stop the pandemic among injection drug users," says **Dave Purchase**, director of Point Defiance AIDS Project, which is funded to operate the North American Syringe Exchange Network (NASEN) of Tacoma, WA.

Efforts made by NASEN and others committed to HIV prevention among IDUs are starting to show some positive outcomes.

There were 154 needle-exchange programs in the

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Editorial Questions

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

U.S. in 2000, and now there are about 180 programs, showing that there is a growth rate of about 10% to 15% per year, says **Don Des Jarlais**, PhD, director of research for Baron Edmond de Rothschild Chemical Dependency Institute of Beth Israel Medical Center in New York City.

"About half of them receive either state or local funding, so that even though the federal government has been remiss in supporting HIV prevention, the city and state governments are increasingly involved," Des Jarlais says.

Des Jarlais' research, based on surveys of 127 needle-exchange programs nationwide, estimates that the number of syringes exchanged increased significantly between 1994 and 2000, from close to 10 million to more than 22 million. The mean budget of a needle-exchange program currently is \$100,648.

Also, needle-exchange programs are most common in the West and least common in the South. Most of those that are provided offer HIV counseling and testing in addition to exchanges. Some also provide hepatitis C counseling and testing, screening for sexually transmitted diseases, hepatitis B counseling and testing, hepatitis B vaccine, medical care, and hepatitis A counseling and testing.

On-site social services are provided by some needle-exchange programs, including food, case management, and transportation, and most of these needle-exchange programs provide free drug-related items, such as alcohol pads, cotton, cookers, water bottles, bleach, antibiotic ointment, ties, and hygiene kits. Most programs also provide participants with condoms, lubricant, female condoms, and dental dams.

Des Jarlais has conducted research on the impact of needle-exchange programs on communities and is familiar with the many studies that address the subject.

"There is no evidence of harmful effects in terms of increased drug use, increased drug-related crime, or any other hypothesized ill effects," he concludes.

Studies repeatedly show that needle-exchange programs do not encourage drug use, increase community crime, or result in improperly discarded syringes, at least in communities where needle exchanges are legal and syringe disposal options are available.³⁻⁷

On the contrary, needle-exchange programs appear to do precisely what they are intended to do, which is to reduce the transmission of HIV among injection drug users, and by extension, to

their sexual partners.⁸⁻¹¹

"To stop the transmission of HIV among IDUs and from IDUs to heterosexuals, you need to prevent IDUs from becoming infected," Des Jarlais says. He presented some of his needle-exchange research at the 12th North American Syringe Exchange Convention, held April 24-27 in Albuquerque, NM.

Needle-exchange programs are one of the most effective ways of doing this. Des Jarlais points to New York's strong needle-exchange focus as an example of success.

"Here in New York, where we arguably have the best data, we are actually seeing dramatic reductions in HIV among drug injectors," Des Jarlais says. "Ten years ago, roughly 50% of drug injectors in New York City were infected with HIV, and now that's down to under 20%"

With the HIV epidemic firmly entrenched in the United States, it will never be enough to rely solely on needle-exchange programs, because they are not available everywhere and are not available as often as addicts may need needles, some argue.

Politics govern needle-exchange policy

Plus, needle-exchange policy is subject to the whims of state and local governing officials, and this policy can change with the political tide.

For instance, California has only in recent years permitted syringe exchanges in areas where local governments declare a public health emergency, Des Jarlais says.

"Prior to that, they were doing it on an ambiguous basis," Des Jarlais adds. "Oakland had done it, and the county prosecutor fought them and shut the needle exchange down, and then a new governor and state legislature passed a law that made it fully legal to operate exchanges if the local health department declares a public health emergency."

So there is a second concerted effort among HIV prevention advocates aimed at making syringes and needles easier to purchase from pharmacies, hospitals, and clinics.

"Since the beginning of the epidemic, 10 states have taken some action to deregulate the sale or possession of some number of syringes, and in the last four years that trend has been accelerated," says **Scott Burris**, JD, professor at Temple University Beasley School of Law in Philadelphia. Burris also is the senior associate of the Johns Hopkins University School of Hygiene and

Public Health and is associate director of the Center for Law & the Public's Health at the CDC Collaborating Center Promoting Public Health Through Law.

It's not that most states had previously prohibited over-the-counter sales of syringes, but many had not addressed the issue directly, and this ambiguity impacted their accessibility, Burris says.

"There are pharmacy regulations that limit what pharmacists can do; there are paraphernalia laws, prescription laws, and, by and large — whatever the rules are — pharmacists usually don't leave syringes sitting out on the counter," Burris says. "A bunch of states have pharmacy regulations that require the pharmacist to make sure the syringe will be used for legitimate legal purposes."

Now some states are trying to clarify their laws to make it easier for addicts to buy syringes. One way they're doing this is by making certain that syringes are excluded from paraphernalia laws, meaning that people in possession of syringes would not automatically be lawbreakers. Without these legislative changes, IDUs could be and have been arrested for possession of syringes, and pharmacists would be reluctant to sell them to addicts.

Wanted: A clean and new needle each time

"From the health perspective, the reality is very simple," Burris says. "You have to make sure that anybody injecting illegal drugs uses a clean and new needle each time, and that prevents disease of all types."

That argument is winning converts within states. At present, only six states require people to have a prescription to purchase a syringe, says **Glenn Backes**, MSW, MPH, director of health policy at the Lindesmith Center Drug Policy Foundation in Sacramento, CA.

"There seems to be greater and greater understanding among Republicans and Democrats to allow individuals to use their own money to protect the health of themselves and others," Backes says.

However, the six states where over-the-counter syringe sales are illegal pose a particular problem because most of these are states with major AIDS problems, Backes says.

These states are California, Illinois, New Jersey, Delaware, Pennsylvania, and Massachusetts. "It's almost stunning that Massachusetts is one of the last remaining states to have this counterintuitive law," Backes says.

Every state should have a comprehensive HIV prevention policy that includes expanding drug treatment and needle exchange, as well as permitting people to walk into a pharmacy to buy syringes that will protect the public's health, Backes adds.

The Lindesmith Center has chosen to lobby for state legislation that will give addicts easier access to clean needles through over-the-counter sales, which is less politically charged than needle-exchange programs, Backes says.

However, the fight for more funding for needle-exchange programs has not been lost, despite opposition among both Republican and Democratic presidencies.

Needle-exchange proponents are optimistic that even New Jersey, the toughest nut among the states, will be cracked now that there is a new governor. Former Gov. Christine Todd Whitman was opposed to even privately funded needle-exchange programs and directed police to arrest needle-exchange volunteers. This was despite the state's growing problem of HIV infection and transmission among IDUs and their sexual partners.

"The highest levels of IDU transmission rates are in New Jersey," Purchase says.

"New Jersey's [anti-needle exchange] laws still are in place, but it looks like the pendulum will swing in our direction," he says. "But the pendulum swings slowly."

On the positive side, there have been no arrests of syringe exchange volunteers since Whitman left office to join President George W. Bush's administration, Purchase says.

While Purchase agrees that easier needle access also is needed, he sees this as a less direct way to reduce HIV transmission among IDUs.

"Over-the-counter sales are still at the discretion of the pharmacy," he explains. "As good as it is, it simply allows for commercial activity for syringes, and that does nothing to provide outreach to the injecting community."

Needle-exchange programs were directly responsible for preventing the HIV epidemic among Australia's IDU population because the country started the programs early enough and has kept them funded, Purchase adds.

Another strategy employed by industrialized nations has been to provide needle exchanges in prisons, where drug use is common and HIV infection can be high, and there is some evidence that these programs are successful.¹²

Spain and Germany, for example, have experimented with prison needle-exchange programs.

But despite the need, this hasn't been attempted in the United States, and it's unlikely to happen any time soon, Purchase says.

"What you have in prison is the worst imaginable shooting gallery, and I don't think there's one of us who if we got the call today wouldn't be there in an hour to do syringe exchange," Purchase says. "But the politics and restrictive legislation make that very hard to do, and there's no such thing anywhere in the United States."

Another little-tried option for making needles more accessible involves encouraging physicians to prescribe needles to their drug-addicted patients, Burris says.

Syringe prescriptions reduce sharing

An HIV and infectious disease physician in Rhode Island started a research project a couple of years ago that involves prescribing syringes to IDUs, and so far the results are promising.

"We recruited 350 very high-risk patients, and the majority had shared syringes at some time," says **Josiah Rich**, MD, MPH, an infectious disease physician at Miriam Hospital in Providence, RI. Rich also is an associate professor of medicine and community health at Brown University Medical School in Providence.

"Half of these patients were homeless and had been doing drugs for a long time," Rich adds. "With the program, we had a dramatic decrease in syringe sharing and syringe reuse, and it seems quite promising from that standpoint alone."

Rich became interested in the idea of prescribing syringes because, until recently, half of Rhode Island's HIV population were IDUs. The problem was that the state made syringe possession a felony punishable by five years in prison until September 1998, when it was changed to a misdemeanor charge. Then, again with lobbying by the HIV prevention community, the state finally legalized syringe possession and permitted needles to be sold over the counter at pharmacies, Rich says.

Since fellow New England states Delaware and Massachusetts still haven't permitted syringes to be sold over the counter, those would be ideal places for HIV clinics and physicians to prescribe syringes to addicts, Rich says.

"In reality, most physicians are not going to be interested in doing this, but you don't need a lot of them to prescribe syringes to make a big change," Rich adds. "And from a physician's

standpoint, I find it very satisfying because it provides much better patient-physician interaction and relationships."

Lawyers who have examined the issue have found that there's little legal risk to physicians who do so, although the fear of repercussions prevents them from being proactive in this way, Burris says.

"The problem that physicians worry about is that they may somehow be charged with a crime and have their license revoked, which is their death penalty, even if the charge is a misdemeanor," Burris explains. "So it's not an insubstantial thing to worry about."

However, most state laws clearly permit physicians to prescribe needles legally to drug-using populations. Even in New Jersey, this can be done, and it wouldn't take very many physicians writing the prescriptions to have a big impact on reducing HIV transmission among IDUs, Burris says.

"What you need are physicians committed to the population and who are willing to do it in an area where there are no other means of getting syringes, and New Jersey certainly is that place," he says.

Doubt about the legality of prescribing needles to IDUs could be resolved by medical advisory boards or state legislation that clarifies the issue.

Program might get started in hospital

There is some talk now about starting a needle-exchange program in a hospital in New Jersey, which is a way to make needle exchange less threatening, at least to the not-in-my-backyard folks, Burris says.

"Doing it in hospitals is a problem for everyone involved, and it's not going to be popular, but it's a first step," Burris adds. "Even under Whitman, I was a proponent of the idea that some brave hospital should set up a hospital exchange program as the most legally defensible way of improving needle access under New Jersey law."

While there remains strong opposition from some corners to needle-exchange programs, the fact remains that there is no scientific evidence to suggest that needle-exchange programs create any problems, Purchase says.

"So what that tells you is the opponents, no matter how they talk, are not talking about the science of preventing deaths," Purchase says. "They have other reasons to resist."

Advocates for the prevention of HIV transmission among IDUs will continue to push for changes to state laws and expansion of needle-exchange programs for as long as it's necessary, Burris says.

"We're having a victory of a thousand cuts; we're winning, but winning slowly," he says. "More and more states each year are getting with the program and seeing the light, but it's taking too long, and literally thousands of people are becoming infected every year because the law makes it impossible for them not to, given that they're going to use drugs, and that's shameful."

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ADAP report offers sobering view of programs

10 states/territories have restrictions in place

AIDS Drug Assistance Programs (ADAPs) are facing growth problems that have resulted in restricted access to drugs and capped enrollment in at least 10 U.S. states and territories, according to the April 2002 annual ADAP report of the National ADAP Monitoring Project, prepared by the Henry J. Kaiser Family Foundation of Menlo Park, CA.

States and territories that had restrictions as of February 2002 included Alabama, Georgia, Idaho, Kentucky, Maine, North Carolina, South Dakota, Texas, Wyoming, and Guam.

Among these states, Maine, Texas, and Guam reported capped or restricted access to antiretroviral drugs. Others had expenditure caps and capped enrollment.

In Texas, funding problems have resulted in an expected \$7 million ADAP deficit in 2003, a \$12 million ADAP budget shortfall in 2004, and a \$16 million budget need in 2005, according to an April 22, 2002, letter signed by **I. Celine Hanson**, MD, chief of the Texas Bureau of HIV and STD Prevention of the Texas Department of Health in Austin.

As a result, Hanson writes, the bureau may have to modify its current drug formulary, limit the cost per client of medications provided, or close the program to new clients.

Problems for states like Texas have surfaced even as the national ADAP budget grew by 12% to \$810 million in fiscal year 2001, according to the report. This is a fourfold increase since FY 1996.

State funding to ADAPs also increased by an average of 12% to \$149.6 million in FY 2001, although 16 states provided no state funding and relied solely on federal funds, the report says.

The latest ADAP report makes it clear that even double-digit funding increases are not keeping pace with the need. Among the ADAPs with complete client information, the overall growth rate between 1996 and 2001 was 144%.

"Despite the overall growth in the national ADAP budget, access to ADAPs continues to vary greatly depending upon where one lives, as indicated by wide variations in income eligibility criteria and formulary coverage across states, and

the continued use of waiting lists and other access restrictions by some jurisdictions," the report says.

Ten states carry the bulk of the ADAP burden, serving 77% of all clients, according to June 2001 data, and the top five of these states serve 61% of all clients. Nearly the same 10 states had the biggest ADAP expenditures as of June 2001, although there were some notable differences.

For example, by far the top two states in drug expenditures for June 2001 were California with \$13,959,151 and New York with \$13,530,163. However, Florida, which is No. 3 in expenditures with \$4,837,867 for the month, actually served more clients than did New York.

The difference in spending might be partially explained by the very different formularies in the two states. Florida's financial eligibility is 350% of the federal poverty level (FPL), which for a household of one amounts to a little more than \$30,000. New York's cap is \$44,000 in income. Both states cover all nine nucleoside reverse transcriptase inhibitors (NRTIs) approved at the time, six protease inhibitors (PIs), and three non-nucleosides, but New York provides coverage for 16 opportunistic infection (OI) prophylaxis drugs, whereas Florida provides coverage for eight OI prophylaxis drugs. New York also covers 437 other medications, and Florida covers 27. (See state-by-state summary ADAP profile, inserted in this issue.)

Florida does contribute a greater amount to its ADAP budget as a percentage of the total budget, but the total FY 2001 estimated budget from both federal and state sources is considerably higher in New York, where it amounts to more than \$140 million, nearly double Florida's total budget of \$73.1 million.

Here are some other key findings from the ADAP report:

- ADAP clients as of June 2001 were primarily people of color, with 34% African Americans, 24% Hispanic, and 38% white non-Hispanics.
- Eighty percent of ADAP clients were men.
- Nearly 80% of clients served by ADAPs reported incomes at or below 200% of the FPL, which means incomes of less than \$17,200 per year. Those reporting incomes of less than the FPL of \$8,590 per year accounted for 44% of ADAP clients.
- Most ADAP clients are uninsured, with 6% receiving Medicaid, 10% receiving Medicare, and 11% having some sort of private insurance coverage.

- States reporting capped enrollment and waiting lists included Alabama, Georgia, Kentucky, North Carolina, and South Dakota.

- States reporting restricted access to PIs/antiretrovirals include Texas, Maine, and the territory of Guam.

- Idaho has a monthly per capita expenditure cap, and Wyoming has a yearly per capita expenditure cap.

- ADAP drug expenditures by dollar amount in June 2001 were distributed as follows: 46% for NRTIs; 29% for PIs; 12% for non-nucleoside reverse transcriptase inhibitors; 8% for OIs/others; and 5% for the 16 drugs recommended for OI prophylaxis.

- ADAP formularies ranged from 18 drugs covered in Louisiana and Utah to New York's coverage of 471 drugs. Massachusetts and New Jersey changed to an open formulary since last year's report.

- Nineteen states provide coverage for resistance testing, and 15 of these provide coverage for both genotypic and phenotypic testing. ■

Multistage pooling finds acute and early infection

Study catches infections that are often missed

Typical HIV screening with enzyme immunoassay (EIA) testing often fails to identify people who have recently become infected, creating missed opportunities to educate and prevent further transmission.

North Carolina researchers have studied a cost-effective way to identify the early infections, and they've convinced state officials to implement the program on a trial basis.

When investigators assessed the feasibility of universal screening for acute HIV infection among patients who volunteered to be tested, they discovered a significant number of false negatives. Potentially, there could have been a 23% increase in total HIV diagnoses in North Carolina, and it's possible that 19% of HIV-infected people who show up for routine testing could have acute HIV infection that is undiagnosed.¹

The problem traditionally has been that it's too expensive for communities or states to screen

populations for HIV using the RNA polymerase chain reaction test.

However, a new program is using a testing model that greatly reduces the cost, and North Carolina will be the first state to launch a demonstration project using the program, says **Christopher D. Pilcher**, MD, assistant professor of medicine at the University of North Carolina - Chapel Hill.

"The state of North Carolina has adopted acute infection screening, using this method as state policy, and is going along with a year-long demonstration project to show that we can identify people with acute infection," Pilcher says.

"This is something that governments or even the Centers for Disease Control and Prevention thought was feasible, to make large-scale acute infection screening a goal," Pilcher says. "But we think we may have figured out a way to do that and make it feasible."

The EIA antibody test typically doesn't work when someone is newly infected. P24 antigen tests will identify HIV infection early on, but may only be an effective tool for one to three weeks after the onset of acute infection symptoms, Pilcher explains.

The RNA or qualitative nucleic acid tests will identify an HIV-positive specimen a week before the P24 antigen test normally would identify it, and it will continue to be effective until the time an antibody test would show the patient to be positive.

The cost of testing all negative antibody samples with the RNA or P24 antigen tests is high, which is why it's not routinely done, Pilcher says.

One way to circumvent the cost vs. benefit issue is to use a model that pools all of the negative samples and to look cross-sectionally at antibody tests to see how many had RNA in them, Pilcher explains.

"About 10% of the total number were HIV-positive and had negative antibody tests, but were positive for RNA," Pilcher says.

This is how it works: Using a pool of 1,000 HIV negative samples, take a tiny amount of serum from each of those samples that was negative and then combine these into pools of 10 specimens. Each of the 10 pools is clearly connected to the original individual samples.

Each of these 10 pools is tested using an ultra-sensitive RNA test. The pool that shows a positive RNA for HIV infection is then subdivided into smaller pools and, again, each of these is tested with the RNA test.

This process is repeated until the samples can be narrowed down to the individual samples that have evidence of acute HIV infection. The number of RNA tests required would be far smaller than if all 1,000 samples were tested.

"If your HIV prevalence in a population was 50%, then this would make no sense, but we suspect it would be relatively low, on an order of one in 1,000," Pilcher says.

"The additional effect is that the likelihood of false positives is greatly reduced because we're only testing the final ten specimens for each one true positive," he adds.

"It's a fact that if you were to test each specimen individually in the thousand, you would expect to get 10 false positives per 1,000 samples," Pilcher explains. "Actually, what we found in the end is an overall specificity of 0.9999, which means there was less than one in 10,000 likelihood of a false positive in our scheme," he adds.

The multistage pooling protocol is a much more efficient and effective way for public health officials to identify people who have recently become infected with HIV, because it doesn't rely on clinical exams or a patient's own intuition.

Clinicians who are presented with patients who have mono-type symptoms or who suspect they may have recently been exposed to HIV infection can always order an RNA test or a P24 antigen test as a precaution, Pilcher notes.

The benefit of the multistage pooling protocol is that clinicians don't know exactly whom to weed out for RNA testing, especially if the person isn't in a high-risk category, doesn't have acute symptoms, or has symptoms that easily can be attributed to other causes, Pilcher adds.

North Carolina will do the RNA pooling protocol for about a year to try to identify HIV-positive people within two weeks of their HIV test, so they can be notified along with their partners. Then the program will prospectively screen their partners, because people who are in the acute phase of HIV infection are highly infectious, Pilcher says.

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Vaccine trial participants may show false positives

Patients could face discrimination, other problems

There are a variety of HIV vaccine studies under way, including some that have reached the clinical stage, and they have the potential to produce HIV antibodies that could be seen as false positives on HIV tests, according to a recent study.

"Vaccine constructs are designed to produce an immune response, and these also produce antibodies that are parts of HIV virus and that are the same antibodies that current screening tests are designed to detect," says **Marta-Louise Ackers**, MD, MPH, a medical epidemiologist for the Division of HIV and AIDS Prevention of the Centers for Disease Control and Prevention in Atlanta.

"We decided to test selected serum samples from vaccine trial participants in the United States with a variety of different screening tests," Ackers says. "Essentially we looked at 490 serum specimens from 461 vaccine recipients, and basically we found that 100 or 20% reacted on at least one serologic screening test."

When investigators followed up those 100 specimens using a Western Blot confirmatory test, they found that 65 of these specimens tested positive, 31 were indeterminate, and four were negative.¹

"Then we just reported that among vaccine trial participants, potentially 65 could have been misidentified as HIV-infected," Ackers says.

Because vaccine participants undergo extensive testing, including PCR testing and RNA testing, the vaccine investigators monitor their true HIV status.

Insurance screening for HIV poses risk

However, there is always the possibility that these vaccine participants could be tested for HIV during the course of a life or health insurance screening or for some other reason, and they would be at risk for social harms because of their false positive results, Ackers says.

For example, a false-positive vaccine participant could be denied health or life insurance coverage or be rejected from blood donation centers. They could even be denied entry to countries in which they would like to travel, Ackers says.

"We need to determine what future solutions are available to us to continue accurate HIV testing when there are a lot of different trials using different constructs going on," Ackers says. "Do we modify the current HIV testing algorithm, or do we create new screening tests?"

Clinicians who treat vaccine participants could help prevent these problems by having the patients notify any companies that intend to screen them for HIV infection that they were involved in an HIV vaccine trial and could have a false positive test result.

There have been instances in the past when vaccine participants were turned down from donating blood because of the HIV antibody, and now participants are told by vaccine trial investigators that they won't be able to donate blood, Ackers says.

"People think the antibody will wane and they won't be positive anymore, and in some cases that's true," Ackers adds. "But some remain positive for six to 12 months after vaccination, and there's not any data on whether they could remain positive for years."

Reference

1. Ackers M-L, Parekh B, Evans TG, et al. HIV seropositivity among uninfected HIV vaccine recipients. Presented at the 9th Conference on Retroviruses and Opportunistic Infections. Seattle; Feb. 25-28, 2002. Poster 294-W. ■

Drug-resistant virus tracked through 3 men

Transmission chain runs from 1994 to 1998

Clinicians and researchers in Birmingham, UK, have found evidence that AZT-resistant HIV-1 was sequentially transmitted through three individuals over a four-year period.

"I think this is the first time that the secondary sexual transmission of drug-resistant HIV has been proven," says **Stephen Taylor**, MD, a doctor and clinical research fellow who treats HIV patients at Birmingham Heartland Hospital in the United Kingdom.

"Sequential transmission has always been theoretically possible, and this case confirms the theory," Taylor says. "What we're showing here is that resistance can not only be transmitted from one person to another, but that the second person

can subsequently transmit the same resistant virus to others.”

The transmission chain was discovered while a patient Taylor calls Patient B was being treated at the clinic. During this time, Patient B’s partner, Patient C, was discovered to have seroconverted, Taylor says.

“Because I knew Patient C’s partner had been on medications, we did resistance testing, and that’s how we picked up that he had unusual mutations,” Taylor explains. “Then we found that Patient B had identical mutations.”

Sexual history proves crucial

When investigators checked Patient B’s blood samples from 1994, when Patient B first tested positive, they discovered that his very first blood sample already had five AZT mutations, which suggested that he had been infected with a resistant virus, because he hadn’t yet been on any antiretroviral medications at that point, Taylor says.

“Then we tested blood samples from 1997 and 1998, and found that the same resistant virus persisted for a four-year period despite several changes in therapy,” Taylor says.

The blood samples from Patient C, taken in 1998, showed that he had seroconverted with four of the original five AZT mutations.

The next step was to find the original source of the drug-resistant mutations. Through obtaining a sexual history, investigators learned that another patient, called Patient A, had been a monogamous sexual partner of Patient B’s until Patient A’s death in 1995. Patient A had tested HIV-positive in 1991 and had been treated with AZT monotherapy. Blood samples from Patient A demonstrated five drug-resistant mutations, Taylor says.

After Patient A died, Patient B had become sexual partners with Patient C, who had seroconverted in 1998. Patient B, while receiving highly active antiretroviral therapy in recent years, had not been treated with drugs prior to 1997, and he never received AZT, Taylor says.

“He received stavudine and lamivudine in 1997, but the blood sample that was checked for mutations was from 1994,” Taylor adds.

Investigators analyzed the mutations and found that evidence of sequential transmission was supported by both epidemiological and phylogenetic evidence. The specific reverse transcriptase drug-resistance-associated mutations found

in the three different men were M41L, E44D, L210W, and T215D.¹

Through the phylogenetic analyses, investigators proved that the viruses were truly related and likely came from a single source, Taylor says.

“What brought our attention to Patient C is that he had a mutation called T215D, and that is what we call a reversion mutation,” Taylor explains. “This mutation is sometimes seen in people infected with AZT-resistant virus.”

Another implication from the transmission study is that resistant virus can persist through generations and is more virologically “fit” than previously theorized, Taylor says.

The study’s evidence that four out of the original five mutations were transmitted intact from Patient A to Patient B to Patient C over four years suggests that despite their possible impaired fitness, these resistant viruses are certainly fit enough to be sexually transmitted and subsequently cause disease, he adds.

“We also looked at virus in blood and semen of Patient B, and found that the transmitted virus was more closely related to the virus found in the genital tract than the virus found in the blood, which makes sense,” Taylor says. “This is a proof of the principle that drug-resistant viruses can persist and be transmitted from one person to the next and go through multiple generations, which is of concern for newly infected individuals.”

Reference

1. Taylor S, Cane P, Xu L, et al. Identification of a transmission chain of HIV-1 containing drug resistance-associated mutations. Presented at the 9th Conference on Retroviruses and Opportunistic Infections. Seattle; Feb. 25-28, 2002. Poster 374. ■

New rapid HIV tests fare well in study

CDC researchers evaluate available tests

The good news is that there are at least a few rapid HIV tests that can accurately detect HIV seroconversion as soon or sooner than the standard enzyme immunoassay (EIA) test. However, these tests still need to be approved before clinics and prevention programs can reap the full benefit of their technology.

"None of these are approved yet, and the manufacturers have to do their own studies," says **Bernard Branson**, MD, chief of the HIV diagnostics and surveillance methods section of the Division of HIV Prevention at the Centers for Disease Control and Prevention in Atlanta.

"The CDC feels it's crucial for several reasons to get a rapid test on the market, and one big factor is because a lot of people don't come back to get their HIV test results," Branson says. "And up to 30% of people who test HIV-positive don't ever receive their results."

When rapid tests are available, a testing site could give a person the results within 10 to 20 minutes, making it possible to take a sample of blood and then give the person preventive counseling while waiting for the results, Branson notes.

All rapid tests outperformed SUDS

To this end, CDC investigators have studied the specificity and sensitivity of a variety of new rapid tests, including Determine, MedMira, Multispot, OraQuick, OraQuick oral, Quix, HemaStrip, and Unigold, compared with the only approved rapid test, SUDS, which was first available in 1992.

In data presented at the retroviruses conference, the studies found that most of the rapid tests had very high rates of sensitivity and specificity when tested on stored serum, whole blood, and plasma, and all performed better than SUDS with stored serum and whole blood.¹

Five of the rapid tests — Determine, HemaStrip, OraQuick, MultiSpot, and Unigold — identified an HIV positive sooner than did the Abbott and EIAs.²

"When we looked at the SUDS test, it showed somewhat more false positives than some of the newer rapid HIV tests," Branson says.

Also, the SUDS test has a slower processing time than the newer tests because the serum or plasma tested by SUDS has to be spun and then tested.

"In one study where they did the SUDS test in an emergency room, they'd draw specimens, and there was an average of 150 minutes before the results came back to the patient," Branson says. "With OraQuick and Determine, you can use a finger-stick sample, so it's a different process."

The SUDS test also takes longer to pick up on early HIV infection. For all of these reasons, rapid tests like OraQuick and Determine would

be better choices to use in outreach HIV testing settings, Branson says.

The CDC currently is studying the OraQuick test under a special Food and Drug Administration (FDA) classification, called Treatment Investigational Device Exemption, at 12 sites in five cities. It's being used to screen pregnant women in labor who come into the hospital and don't know their HIV status, Branson says.

"The study is the Mother-Infant Rapid Intervention at Delivery, and it's just gotten started," Branson explains. "So far we have identified two women who came into labor with unknown HIV status and who turned out to be positive."

Once they were identified as HIV-positive, it was possible for clinicians to treat them and their infants with antiretroviral medications in order to prevent their transmitting the virus to their babies.

Also, the CDC is continuing to study rapid HIV tests and is starting the process of assessing about 70 rapid tests that are used outside of the United States, Branson says.

Rapid tests well-suited for outreach settings

Once the most efficient and accurate rapid HIV tests are FDA-approved, then public health officials and HIV clinicians might be able to increase the number of HIV-positive people who receive their HIV test results, Branson says.

"A lot of these rapid tests could be used in outreach settings where the return rates are very low, so overall I think it would have a big impact on people to know their status," Branson says.

Furthermore, the people who are given a positive result from a rapid test are highly motivated to return for the results of a Western Blot test, which would still be used to confirm results, he adds. "It stands to reason when you give a person a preliminary positive test result that they have the motivation to come back."

References

1. Branson B, Uniyal A, Fridlund C, et al. Performance of newer rapid tests for HIV antibody with whole blood and plasma. Presented at the 9th Conference on Retroviruses and Opportunistic Infections. Seattle; Feb. 25-28, 2002. Poster 599-T.

2. Branson B, Meredith N, Mei J, Hannon H. How well do rapid HIV tests detect seroconverters? Presented at the 9th Conference on Retroviruses and Opportunistic Infections. Seattle; Feb. 25-28, 2002. Poster 361-M. ■

CE/CME

20. Research over the past decade has shown that which of the following is true about community-based needle-exchange programs?
- A. Crime rises in areas where needle-exchange programs are conducted.
 - B. The public is placed at risk of being stuck with “dirty needles” in places where needle-exchange programs are conducted.
 - C. Community needle-exchange programs result in a reduction of HIV transmission among injection drug users and do not increase crime or public risk of dirty needles, nor do they encourage drug use.
 - D. Teen-age entry into injection drug using behavior increases in areas where there are needle-exchange programs.
21. The state of North Carolina has approved a demonstration project that will provide universal acute HIV infection screening for people who test negative on the standard antibody HIV test. How will this project work in a cost-effective and efficient manner?
- A. Each negative test will be further tested with an antigen P24 test.
 - B. All negative samples will be pooled and then subdivided and tested with an ultrasensitive RNA test. The pool that indicates a positive response will be further subdivided and retested until it can be determined which individual sample had a true positive.
 - C. Each negative test will be further tested with an RNA test.
 - D. Clinicians are being educated about identifying the signs and symptoms of acute HIV infection.
22. British researchers and clinicians have discovered a sequential sexual transmission chain of drug-resistant HIV.
- A. True
 - B. False
23. AIDS Drug Assistance Programs primarily serve poor and uninsured HIV patients. A recent report says 80% of ADAP patients have incomes at or below 200% of the federal poverty level, which means an annual income that is at or less than which amount for one person?
- A. \$17,200 a year
 - B. \$23,500 a year
 - C. \$26,700 a year
 - D. \$31,100 a year

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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. ■

Source: ADAP Monitoring Project Report, March 2001.

Source: ADAP Monitoring Project Report, March 2001.

AIDS GUIDE

For **Health Care Workers***

Work with treatment centers to help injection drug users

*Collaboration more important
now than ever*

The HIV epidemic has changed greatly in the past decade, increasingly affecting injection drug users (IDUs), minorities, the disadvantaged, and people with multiple physical and mental health problems.

As a result, the HIV/AIDS population often needs substance abuse treatment, mental health services, primary health care services, and hepatitis treatment, in addition to treatment for their HIV, according to the Centers for Disease Control and Prevention in Atlanta.

One of the keys to treating these patients is for HIV clinicians to collaborate with substance abuse clinicians and facilities. In a report titled "Substance Abuse Treatment and Public Health: Working Together to Benefit Injection Drug Users," the CDC offers these suggestions for how this collaboration might best work:

- Staff from public health or substance abuse treatment

centers may not know what questions to ask a patient or how to assess the patient's risk for HIV infection. HIV clinicians could help by providing them with HIV brochures and other information to hand out to their injection-drug-using clients.

- Federal confidentiality protections prohibit substance abuse treatment staff from revealing anything about patients, even to state and local public health staff. This is why it's important that substance abuse treatment staff are given information about HIV testing that they can give to patients to encourage them to seek testing and counseling services. Another strategy is for collaborative agencies to develop Qualified Service Organization Agreements, which are interagency agreements that allow substance abuse treatment and public health provider agencies to share information about patients within the constraints of federal confidentiality protections.

- HIV staff should learn about the structure, funding,

philosophy, and policies of substance abuse agencies and other organizations that work with injection drug users.

- HIV health care workers also should enhance their knowledge about substance abuse, as well as about tuberculosis, viral hepatitis, and other infections that affect HIV patients who inject drugs.

- Health care workers should be willing to make personal connections across agency disciplines, cultures, and bureaucracies. These connections may bridge the divisions by promoting mutual respect and a common vocabulary. They also foster willingness to hear other points of view and motivate staff to develop regular communications and collaborative working relationships with other agencies and organizations.

- HIV staff could be cross-trained to deal with the mental health and substance abuse issues confronting their patients. Successful cross-training initiatives will focus on these areas:

— **Reflect the diversity of the epidemic:** Training should cover prevention, treatment, and care issues for various substance abuse and infectious disease topics, and should include participants from a range of disciplines that work with affected individuals.

— **Obtain high-level participation and endorsement:** High-level administrators should be involved in the planning and execution of the workshops because their involvement can help break down the barriers between disciplines and reinforce the training.

— **Tailor to the community:** Cross-training planners should analyze the community to ensure that topics and skills-building exercises reflect the needs, cultures, and languages of the community, and this needs to be done before the workshops are developed.

Likewise, participants and trainers should reflect the community's cultures and languages.

— **Recognize the value of the cultures and perspectives of each discipline involved in training:** Participants need to be sensitive to other agencies and organizations involved and try to work through differences in priorities, missions, and perspectives that often pose the greatest challenge for collaboration.

— **Work to develop QSOAs before beginning a cross-training program:** Qualified Service Organization Agreements should be in place before cross-training occurs, because this will allow participants to immediately build on relations forged during the training.

— **Follow-up and referrals:** Someone should be in charge of following up on the training

and QSOA to track changes and provide assistance to participants, nurturing the seeds of collaboration that may emerge during a cross-training session. Also, there will be a need for additional cross-training workshops to reinforce the training and to train new staff.

Health care workers dealing with HIV/AIDS patients also need to be aware of some of the strategies, outlined by the CDC, that are key to successful substance abuse treatment:

- Individuals need to be engaged in treatment for an adequate length of time. For example, participation in outpatient or residential programs for less than 90 days is of limited or no effectiveness. Patients should receive a minimum of 12 months of methadone maintenance treatment.

- Addiction often occurs simultaneously with other physical or mental health problems. The treatment plan must take those into consideration.

- All clinicians and health care staff working with patients who have substance abuse problems should learn some of the nuances of "recovery language." These include the following:

— It's unrealistic to use the term "eliminate drug use"; It's realistic to say, "reduce or stop drug use."

— Avoid the word "recovered," and use the term "in recovery."

— Don't say "cured"; say "treated and controlled."

— It's unrealistic to say "forever," but it's more realistic to say, "one day at a time."

— Change patients' views that what they're doing is "on my own" to a view that they are doing it "with help."

— Don't think of substance abuse treatment as a "one-shot treatment," but rather as an "ongoing process."

— And it's unrealistic to expect that a "relapse is unacceptable," but it's more realistic to think, "relapse happens."

For more information about substance abuse treatment and drug users, here are some resources:

- The CDC's web site has information at the address: www.cdc.gov/idu/facts/ or www.cdc.gov/idu. Or obtain IDU-related technical assistance, which is available to health departments funded by CDC to conduct HIV prevention and to HIV prevention community planning groups, by calling (404) 639-5230, or call the Academy for Educational Development at (202) 884-8952.

- The Academy for Educational Development has information on its web site at www.healthstrategies.org/pubs/publications.htm.

- To learn more about the topic of "Substance Abuse and Infectious Disease: Cross-Training for Collaborative Systems of Prevention, Treatment and Care Initiative," visit www.treatment.org/Topics/infectious.html, and the Cross-Training Connections web site at www.hsrnet.com/crosstraining. ■

AIDS Guide for Health Care Workers is written especially for the person working in the health care setting. It explains important issues concerning AIDS in a thorough, yet easy-to-understand style.

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