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ADAPs worst-case scenario arrives with a vengeance

Waiting list for drugs now tops 6,700 people

For years HIV experts and advocates have warned that unless federal funding for the AIDS Drug Assistance Program (ADAP) was ramped up significantly then thousands of Americans could be left off the roles and face risks of illness and death without dependable access to antiretroviral therapy (ART).

It looks like 2011 is the time when their worst-case scenario is realized. More than 6,000 HIV patients have lost access to their medications through ADAP, putting pressure on HIV clinics, providers, and AIDS service organizations to help people find their life-saving drugs before the virus rebounds and they become ill. And at least one HIV/AIDS patient has died while waiting for access to ART.

Before the recession, ADAPs appeared to be doing fairly well with more generous formularies and easier access than in the early years. States had increased their own funding, expanded their formularies, lowered eligibility requirements, and there were no waiting lists. But this situation began to reverse in the past 18 months as the recession resulted in strapped state budgets, causing some drastic ADAP cutbacks, particularly in Southern states.

The problem has ballooned in the past year. As of the end of February 2011, there were ADAP waiting lists in 11 states, totaling 6,704. This includes Florida with 3,407 people on the list and Georgia with 1,009 people on the list, according to The ADAP Watch, a weekly report by the National Alliance of State and Territorial AIDS Directors (NASTAD). *(See related story, p. 39.)*

South Carolina, a relatively small state, has 468 people on the list and another 200 clients about to be pushed off ADAP. At least one South Carolinian with HIV has died while waiting to receive antiretroviral drugs, says **William E. Arnold**, director of the CANN-Community Access National Network in Washington, DC.

The ADAP waiting list is record high, but even that doesn't tell the

entire bleak story, Arnold says.

"We have somewhere over 1,000 people who have been dis-enrolled from ADAP," he says. "Some states have reduced the eligibility requirements for the ADAP program, so if someone is making too much money they are not eligible and are not on a waiting list."

These eligibility requirements were made retroactive so that an HIV patient, whose $30,000 annual income qualified him for ADAP drugs last year, now makes too much money, and he's told to find his medications elsewhere.

Federal help unlikely

With states being forced to make draconian budget cuts, the only practical way to change this bleak situation would be to increase federal funding, and that seems unlikely given the current budget crisis, Arnold notes.

"The prospects of getting additional money has gotten worse and worse over the last four to five years, particularly from the federal contribution," he says. "Go back to 2001, and the federal government picked up 70% of ADAP expenditures, and now they're around 49%."

While President Obama's FY2012 budget calls for some HIV/AIDS funding increases, the continuing resolution FY2011 budget proposed by the new Republican-led House of Representatives makes drastic cuts to health care infrastructure for the poor and flat-funds HIV programs, says **Ronald Johnson**, vice president of policy and advocacy for AIDS United of Washington, DC.

Plus the House budget would cut funding for the new Affordable Care Act. If the House budget bill was passed, there would be little hope that access to HIV medications would improve in 2014 as many of the health care reform bill's policies take place.

The House's continuing resolution would cut all funding to Planned Parenthood clinics, cut global funding for reproductive health, and cut funds to community health clinics — all of which are places where the nation's and world's poor and dispossessed, including HIV patients, seek health services, Johnson says.

"That would undermine the public health infrastructure," he says. "With a prohibition on funding, about 500 of 800 Planned Parenthood affiliates would close, and that's critical for HIV because Planned Parenthood does HIV testing."

As the Republic-led House carries forward campaign promises to stop implementation of the Affordable Health Care for America Act of 2010, there is a bigger threat to ART access on the horizon, Arnold notes.

The health care reform bill will provide ART access through Medicaid for many low income,

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Hard times: ADAP cuts widespread

The National Alliance of State and Territorial AIDS Directors (NASTAD) of Washington, DC, provides regular updates on changes in AIDS Drug Assistance Programs (ADAPs) nationwide. The ADAP Watch report, released on Feb. 25, 2011, noted these changes:

ADAPs with waiting lists:

- Arkansas — 36 people
- Florida — 3,407
- Georgia — 1,009
- Idaho — 4
- Louisiana — 718
- Montana — 20
- North Carolina — 130
- Ohio — 438
- South Carolina — 468
- Virginia — 471
- Wyoming — 3

Cost-containing strategies used by ADAPs from April 2009 to February 2011:

- Arizona: reduced formulary
- Arkansas: reduced formulary, lowered financial eligibility to 200% federal poverty level (FPL); dis-enrolled 99 clients
- Colorado: reduced formulary
- Florida: reduced formulary, lowered financial eligibility to 300% FPL, transitioned clients to Welvista
- Georgia: reduced formulary, implemented medical criteria, continued participation in the Alternative Method Demonstration Project
- Idaho: capped enrollment
- Illinois: reduced formulary, instituted monthly expenditure cap
- Kentucky: reduced formulary
- Louisiana: discontinued reimbursement of laboratory assays
- North Carolina: reduced formulary
- North Dakota: capped enrollment, instituted annual expenditure cap, lowered financial eligibility to 300% FPL
- Ohio: reduced formulary, lowered financial eligibility to 300% FPL (dis-enrolled 257 clients)
- Puerto Rico: reduced formulary
- South Carolina: lowered financial eligibility to 300% FPL
- Utah: reduced formulary, lowered financial eligibility to 250% FPL (dis-enrolled 89 clients)
- Virginia: reduced formulary, only distributes 30-day prescription refills
- Washington: instituted client cost sharing, reduced formulary (for uninsured clients only), only pays insurance premiums for clients currently on antiretrovirals
- Wyoming: reduced formulary, instituted client cost-sharing. ■

Editor' note: For the latest update on ADAPs nationwide, visit the NASTAD website at www.NASTAD.org.

currently-uninsured clients when major provisions go into effect in 2014.

"What we're trying to do is preserve access to medications for the 160,000-plus people in ADAP until health care reform comes in and a huge percentage of our ADAP folks go to Medicaid," Arnold says.

But this is assuming the health care act survives in a way that is at all useful, he adds.

"When all of these things happen in the next 30 months, then we'll have some idea what the national picture is," Arnold says. "In theory, there is relief coming in the distance, but how much damage will we do between now and then if ADAP resources are not adequate in-between times?"

President Obama has proposed about $80 million for ADAP, but his budget is unlikely to be approved as it is, Arnold says.

"We need even more funding than the president currently proposes in his FY2012 budget," Johnson says.

"And we won't get the FY2012 money for 18 months from now," Arnold says. "The ADAP budget is six months behind the regular federal budget."

A 'devastating impact'

The federal funding crisis is compounded by state fiscal problems.

"There is no question of the severity of the nationwide crisis at the state level," Johnson says.

Governors and state legislatures are cutting Medicaid services as they struggle to balance state budgets, but this is harming vulnerable populations and will result in someone somewhere paying a great deal more as people increasingly go to emergency rooms for treatment of preventable illnesses, he explains.

"This is having a devastating impact on low income people and people living with HIV/AIDS," Johnson adds. "It also highlights the importance of a provision in the Affordable Health Care

Act called maintenance of effort, which prohibits states from making changes in eligibility that would drastically reduce the Medicaid role."

HIV/AIDS advocates have been calling on governors to be flexible in their budgeting process and not make short-sighted cuts to programs that prevent bigger expenses down the road.

"We're in a period when the public health infrastructure and viability and safety of health care programs are threatened," Johnson says. "AIDS United is working with partners throughout the HIV community to maintain vigilance." ■

Will the safety net hold? New partnerships help

Patient influx 'an administrative nightmare'

With unprecedented numbers of HIV patients pushed onto waiting lists to receive antiretroviral (ART) drugs from AIDS Drug Assistance Programs (ADAPs), the bottom rung safety nets are barely holding, experts say.

In the past year, HIV service organizations and clinics with case managers who work to find ART funding for patients have been flooded with new cases to handle.

"For example, Virginia ran out of money, so they're shifting 650 people as we speak to patient assistance programs (PAPs)," says **William E. Arnold**, director of the CANN-Community Access National Network in Washington, DC.

Fewer than 12 clinics with maybe 15 case workers suddenly have to handle 650 additional clients. And Virginia's ADAP waiting list already topped 470.

"We know from local Virginia providers — because they're a stone's throw from my office — that people are falling through the cracks," he adds. "Having 650 people handed to patient assistance programs on a month's notice is an administrative nightmare."

Until recently this would be the end of the story. But a silver lining has appeared in the dismal domestic picture of HIV care and access during the Great Recession.

Last summer, the Heinz Family Foundation of Washington, DC, began to have a conversation with Abbott Laboratories of Abbott Park, IL, about emerging ART access problems among low income HIV patients, says **Jeffrey Lewis**, president of the Heinz Family Foundation.

"The problem with the ADAPs is that more and more of these people had not been shifted to a patient assistance program, and they should have been," he says.

PAPs are complex and bureaucratic, largely because of legal and regulatory obstacles.

"There is no single form to do a PAP," Lewis says. "There are multiple forms for multiple companies, which is inefficient and inhumane."

Plus, HIV patients each have multiple drugs that are manufactured by multiple pharmaceutical companies, and the same cumbersome application process has to be completed separately for each prescription.

"The paperwork alone is exhausting," Lewis says.

"If there was a single patient assistance program form that could be used across companies then it would make for easy administration," he adds. "We will go forth with pharma to create that, but it's not without legal pain: how do you make it operational, and how do you do it without an antitrust issue?"

A more immediate problem

And there is the more immediate problem of people infected with a deadly disease who suddenly are losing access to their life-saving medications.

The foundation's goal was to see if pharmaceutical companies, working with nonprofit organizations, could provide antiretroviral drugs for free to HIV patients who had lost their medications through ADAP and now were on waiting lists.

"We recognized that if we could move the private sector to come together to solve a national crisis then we could do it without interference," Lewis says. "Abbott immediately agreed to join the effort."

With Abbott on board, the Heinz Family Foundation spoke with Merck of Whitehouse Station, NJ, and then another company until all of the major ART manufacturers agreed to a new safety net program. They would provide free ARTs to all patients on ADAP waiting lists. In addition, the pharmaceutical companies, along with the Heinz Family Foundation, would provide funding to a pharmacy to handle the administrative cost of distributing the drugs where they were needed.

The foundation needed a pharmacy partner and found Welvista of Columbia, SC. A nonprofit pharmacy that was founded 18 years ago to provide free

drugs to indigent South Carolinians with chronic diseases, Welvista had the infrastructure necessary to expand into the world of HIV medication. The pharmacy serves close to 20,000 clients who are at less than 200% of the federal poverty level. And the pharmacy already had experience working with pharmaceutical companies who donate medications for indigent chronic disease clients.

Since beginning this new partnership last summer, Welvista has expanded to sending medications to HIV patients on ADAP waiting lists in nearly all of the states with such lists, says Ken Trogdon, chief executive officer.

"We had a long-standing relationship with Abbott and Merck, so it was an easy push to get their products on formulary," he adds.The fourth piece to the puzzle was to convince ADAP coordinators to work with Welvista.

"If there's a state with an ADAP waiting list, their local ADAP coordinator faxes to us a prescription that we developed for patients on the waiting list," Trogdon says. "We fill the prescription and send it to the patient's home or clinic."

HIV clinics, providers, and case managers do not have to be involved. No one has to fill out paperwork, and patients do not have to wait longer than a few days for their medications. It keeps patients from having gaps in their treatment, Trogdon adds.

Welvista has been certified to provide the ART medications in nine of the 11 states, with still some work to go in Virginia and Louisiana, Trogdon says.

"They're more challenging, and we're still in the process of getting licensed in those states," he adds.

Obstacles remain

There are a few drawbacks to this approach, including the fact that most HIV/AIDS patients need multiple medications in addition to antiretroviral drugs. Many ADAP formularies include prescriptions for non-ART drugs, such as drugs to treat opportunistic infections and chronic diseases. But the Welvista program is limited to ARTs. HIV patients who are dropped from the ADAP role still will need to apply for patient assistance programs to receive their other medications.

Another issue is that states have been cutting their ADAP roles so quickly and through such a variety of tactics, including reducing eligibility requirements and other criterion that many HIV patients who were receiving ADAP drugs are not even eligible for being on the ADAP waiting list now. There is no easy answer for what will happen to these people since the Welvista program is restricted to providing medications to those who are on the ADAP waiting lists.

Also, it's uncertain what will happen to the program should the ADAP waiting lists decline as they have in the past.

"We're trying to have a conversation with companies about where this is going in the long term," Trogdon says. "I think folks on the waiting lists have been scrambling to find solutions, and this offers a seamless solution, but we don't know the impact it's going to have on a much larger level."

Pharmaceutical companies are committed to making certain that no HIV/AIDS patient uses an emergency room when it can be prevented, Lewis says.

"If we can adapt an ADAP solution, we can keep thousands of people from being forced to go to the hospital emergency department because they can't get the medications they need," he adds. ■

Certain cancers increase in pts on long-term ART

Focus should be on screening

HIV clinicians are seeing increasing numbers of patients who are developing cancers associated with infectious agents, particularly in the areas of the oropharynx and genitals, researchers say.

A chief culprit is the human papillomavirus (HPV). Squamous cell carcinomas (SCC) are associated with HPV at specific sites.[1]

"We've found HPV in tissues of young African American men who have sex with men (MSM)," says **Minh Nguyen**, MD, an assistant professor of medicine at Emory University in Atlanta, GA.

"We have found that the incidence of SCC is higher among people with HIV in our clinic than among the general population in the metro-Atlanta area in Georgia," Nguyen says.

"This suggests that it's really important to emphasize screening for that cancer," says **Kira Harvey**, MPH candidate and research assistant in global epidemiology at Emory University.

For female HIV patients, a cervical pap smear twice a year when they first are seen at a clinic is common practice, Nguyen says.

"If there are any abnormal cells then they get a more detailed examination of the cervix," Nguyen

says.

MSM also need to be screened for HPV infection in the mouth or rectal-anal areas.

"Rates for cervical cancer are lower than for rectal-anal cancer, and cervical cancer screening is emphasized a lot," Harvey says. "Also, it's important to look at seeing whether an HPV vaccine could in the future lower these rates."

Some studies have shown that it's acceptable to use the HPV vaccine on HIV-positive individuals, Harvey notes.

A three-pronged approach to preventing squamous cell carcinomas in an HIV population involves encouraging HIV patients to be vaccinated against HPV, educating them about practicing safe sex with condoms and dental dams, and doing more screenings and diagnoses, Nguyen says.

However, rectal-anal screening for HPV in men remains a controversial issue, Nguyen notes.

"The cervix doesn't connect to the bowels so you can keep on burning it and destroy normal tissue without affecting other tissue," he explains. "But with the rectum if you burn it a person can become incontinent, so the approach is different than how you would approach the cervix in women."

The New York Department of Health does not recommend screening that would remove tissue for testing in the rectal area because it's more subject to scarring than the cervical area, he says.

"So the New York Department of Health is recommending providers do a digital rectal exam once a year, feeling for any kind of mass," Nguyen says.

Other experts have recommended an anal pap smear, but high resolution endoscopy would be a better screening approach, he adds.

"We're now recommending high resolution endoscopy," Nguyen says.

Annual dental exam a must

Each year, HIV patients should be given a dental exam in which the clinician looks for bumps under the neck area, tongue area, and inside the mouth. These could be a marker for HPV infection in the mouth, Nguyen says.

HIV clinicians also should encourage their patients to get the HPV vaccine and practice safe sex with condoms and dental dams, he adds. *(See related story p. 43.)*

"In our clinic we recommend safe sex for everybody," he says.

Harvey, Nguyen, and co-investigators became interested in learning more about the types of cancers impacting patients of an urban AIDS clinic in the era of successful antiretroviral therapy (ART).

"We compared cancers between 2000 and 2007 with the general population and with the metro-Atlanta population," Harvey says.

"We looked at age distribution and risks, and what we found was that for almost all of the squamous cell carcinoma there was a significantly higher incidence in clinic patients than in the general population," she says. "We looked at patients enrolled in the clinic and studied cancers in the head, neck, rectal, lungs, and genital areas."

For the bronchial and lungs areas, there were not any conclusive or significant findings, Harvey says.

For cervical cancer there was a significantly lower one-year survival time among HIV patients. Also, for cervical, head and neck, and anal-rectal cancers, there was a significantly lower survival time for the clinic population, she adds.

"We could not find results for the bronchial area because nobody survives for five years with that cancer," Harvey says. "Basically, for most of these cancers, people who have them in the clinic survived less."

Investigators tried to control for smoking, but were unable to do so because of a lack of accurate data, she notes.

"Some studies have found a link between lung cancer and HIV beyond increased smoking, but this study looked at one kind of lung cancer and not at lung cancer in general," Harvey says.

They did find that the majority of cancers occurred among clinic patients who were in the 30 years to 50 years age group, while most of the cancers among the general population occurred in people over age 50, she adds.

"But that also reflects the demographics of this clinic which has a younger population," Harvey says.

"In the future we want to look at other risk factors and whether people are on treatment when they're diagnosed, but we didn't have the medical records to do that for this study," she adds.

REFERENCE

1. Harvey K, Sumbry A, Reddy D, et al. Increased rates of

squamous cell carcinoma in an urban AIDS clinic. Poster 1088. Presented at the 48th Infectious Diseases Society of America's Annual Meeting, Oct. 21-24, 2010, Vancouver, Canada. ■

Time to boost uptake of HPV vaccine in men

Many think it is only for women

While the human papillomavirus (HPV) vaccine has been approved for use in men, how many are open to receiving it? New research indicates men might be more willing to receive vaccination when they learn the vaccine can prevent cancer.[1]

The Food and Drug Administration (FDA) in December 2010 approved Gardasil, the Merck & Co. quadrivalent vaccine, for prevention of anal cancer and associated precancerous lesions (anal intraepithelial neoplasia grades 1, 2, and 3, related to HPV types 6, 11, 16, and 18 in males and females ages 9-26. The vaccine also is approved for the prevention of genital warts caused by types 6 and 11 in males and females.

Researchers at the University of North Carolina at Chapel Hill (UNC-CH) Gillings School of Global Public Health and the Lineberger Comprehensive Cancer Center have found that men are more open to getting the HPV vaccine when it is described as also preventing HPV-related cancers, including anal cancer, as opposed to preventing genital warts alone.

What led the research team to look at this issue? The researchers were seeking how to get more boys and men to get their recommended doses of HPV vaccine, says **Annie-Laurie McRee**, a UNC-CH doctoral student and lead author of the study. "In a previous study, we found that how you 'frame' HPV vaccination messages can make the vaccine more acceptable to women,"[2] says McRee. "So we wanted to explore how the added benefit of preventing cancer in men would affect men's interest in HPV vaccine."

Researchers surveyed a national sample of more than 600 men ages 18-59 and asked about their willingness to get vaccinated. Sixty percent wanted the cancer-preventing vaccine, compared to 42% when the vaccine was depicted as only protecting against warts. The effect of outcome framing was the same for heterosexual and gay/bisexual men and for the cancer types examined.

Why is it so important that men be reached with the correct message about HPV vaccination? The very low use of HPV vaccine by men and boys indicates clinicians are missing an important public health opportunity, says **Noel Brewer**, PhD, senior investigator on the study, UNC-CH Lineberger member and associate professor of health behavior and health education in the public health school. It is estimated that fewer than 1% of boys ages 11 to 17 have been immunized against HPV; on college campuses, the share of vaccinated men might be closer to 15%.[3]

"Some men mistakenly believe that the vaccine is just for women; now they can know that it is for men, too," Brewer says. "Our findings show that it is critical for men to get the message that HPV vaccine can prevent cancer in men in addition to genital warts, because that increases their willingness to get vaccinated."

Data upholds efficacy

In talking about the Gardasil HPV vaccine, be sure to include results from a just-published study which shows it prevents 90% of genital warts in men when it is offered before exposure to the four HPV strains covered by the vaccine.[4] The study also found a nearly 66% effectiveness in the general population of young men regardless of prior exposure to these strains.

The four-year international clinical trial study, led by researchers at the H. Lee Moffitt Cancer Center in Tampa, FL, and the University of California San Francisco (UCSF) provides the first reported results of using the HPV vaccine as a prophylactic in men. Initial data from the study was reviewed by the FDA in its initial approval for use of the vaccine in men to prevent warts, while results from a substudy led the agency last year to expand approval to prevent anal cancer.

The double-blind study included 4,065 healthy men ages 16-26, enrolled at 71 sites in 18 countries. Of those patients, 85% reported having exclusively female sexual partners, with the remainder self-identified as having sex with men.

The men were tested at the onset of the trial for previous exposure to HPV strains 6, 11, 16, and 18, and were randomly selected to receive a placebo or a vaccine that targeted the four strains. Men with a history of anal or genital warts or lesions were excluded from the study. Participants

received six follow-up examinations over the following three years to assess the vaccine's effectiveness. Researchers report that in addition to preventing warts, the vaccine also effectively prevented HPV-persistent infection in 86% of the participants without previous exposure.

The study results represent an "exciting development" in the world of sexually transmitted diseases, said **Joel Palefsky**, MD, a UCSF professor of medicine who co-led the research along with epidemiologist Anna Giuliano, PhD, from the H. Lee Moffitt Cancer Center and Research Institute. "It shows that if we vaccinate males early enough, we should be able to prevent most cases of external genital warts in this population," said Palefsky in a release accompanying the study's publication.

REFERENCES

1. McRee AL, Reiter PL, Chantala K, et al. Does framing human papillomavirus vaccine as preventing cancer in men increase vaccine acceptability? *Cancer Epidemiol Biomarkers Prev* 2010;19:1937-1944.
2. Sperber NR, Brewer NT, Smith JS. Influence of parent characteristics and disease outcome framing on HPV vaccine acceptability among rural, Southern women. *Cancer Causes Control* 2008;19:115-118.
3. Harris G. US panel debates value of HPV vaccine for boys. *New York Times*, October 28, 2010. Accessed at http://www.nytimes.com/2010/10/29/us/29vaccine.html.
4. Giuliano AR, Palefsky JM, Goldstone S, et al. Efficacy of quadrivalent HPV vaccine against HPV infection and disease in males. *N Engl J Med* 2011;364:401-411. ■

Interim guidance for PrEP In MSM

CDC: Do not expand to other risk groups yet

The Centers for Disease Control and Prevention is developing formal guidelines on preexposure prophylaxis (PrEP) to prevent HIV in men who have sex with men (MSM). In the interim, the CDC has issued the following recommendations to guide clinical practice.[1]

Before initiating PrEP determine eligibility

- Document negative HIV antibody test(s) immediately before starting PrEP medication.
- Test for acute HIV infection if patient has symptoms consistent with acute HIV infection.
- Confirm that patient is at substantial, ongoing, high risk for acquiring HIV infection.
- Confirm that calculated creatinine clearance is ≥ 60 mL per minute (via Cockcroft-Gault formula).

Other recommended actions

- Screen for hepatitis B infection; vaccinate against hepatitis B if susceptible, or treat if active infection exists, regardless of decision about prescribing PrEP.
- Screen and treat as needed for STIs.

Beginning PrEP medication regimen

- Prescribe 1 tablet of Truvada (TDF [tenofovir disoproxil fumarate] [300 mg] plus FTC [emtricitabine] [200 mg]) daily.*
- In general, prescribe no more than a 90-day supply, renewable only after HIV testing confirms that patient remains HIV-uninfected.
- If active hepatitis B infection is diagnosed, consider using TDF/FTC for both treatment of active hepatitis B infection and HIV prevention.
- Provide risk-reduction and PrEP medication adherence counseling and condoms. Follow-up while PrEP medication is being taken.
- Every 2–3 months, perform an HIV antibody test; document negative result.
- Evaluate and support PrEP medication adherence at each follow-up visit, more often if inconsistent adherence is identified.
- Every 2–3 months, assess risk behaviors and provide risk-reduction counseling and condoms. Assess STI (sexually transmitted infection) symptoms and, if present, test and treat for STI as needed.
- Every 6 months, test for STI even if patient is asymptomatic, and treat as needed.
- Three months after initiation, then yearly while on PrEP medication, check blood urea nitrogen and serum creatinine.

On discontinuing PrEP (at patient request, for safety concerns, or if HIV infection is acquired)

- Perform HIV test(s) to confirm whether HIV infection has occurred.
- If HIV positive, order and document results of resistance testing and establish linkage to HIV care.
- If HIV negative, establish linkage to risk-reduction support services as indicated.
- If active hepatitis B is diagnosed at initiation of PrEP, consider appropriate medication for con-

tinued treatment of hepatitis B.

• These recommendations do not reflect current Food and Drug Administration-approved labeling for TDF/FTC.

REFERENCE

1. Centers for Disease Control and Prevention. Interim Guidance: Pre-exposure prophylaxis for the prevention of HIV infection in men who have sex with men. *MMWR* 2011;60:65-68. ■

HIV transmission to HCWs virtually eliminated

But vigilance must be maintained

The once rare but very real risk of occupational HIV transmission continues to fade in the face of a host of prevention measures that include needle safety devices and post-exposure prophylaxis. Vigilance remains the word, but occupational HIV transmission has nearly been virtually eliminated, according to surveillance data by the Centers for Disease Control and Prevention.

Through December 2001, there were 57 documented cases of occupational HIV transmission to health care workers in the United States. However, only one reported case has been confirmed since 2001, the CDC reports in recently posted fact sheet. (http://1.usa.gov/eHqBnV) Occupational transmission of HIV is reported in the transmission category that includes hemophilia, blood transfusion, perinatal exposure, and risk factor not reported or not identified.

To continue preventing transmission of HIV to health care workers in the workplace, the CDC reiterates the following recommendations.

Prevention Strategies

Health care workers should assume that the blood and other body fluids from all patients are potentially infectious. They should therefore follow infection control precautions at all times. These precautions include:

• routinely using barriers (such as gloves and/ or goggles) when anticipating contact with blood or body fluids,

• immediately washing hands and other skin surfaces after contact with blood or body fluids, and

• carefully handling and disposing of sharp instruments during and after use.

Safety devices have been developed to help prevent needle-stick injuries. If used properly, these types of devices may reduce the risk of exposure to HIV. Many percutaneous injuries, such as needlesticks and cuts, are related to sharps disposal. Strategies for safer disposal, including safer design of disposal containers and placement of containers, are being developed.

Although the most important strategy for reducing the risk of occupational HIV transmission is to prevent occupational exposures, plans for post-exposure management of health care personnel should be in place.

CDC guidelines outline a number of considerations in determining whether health care workers should receive PEP and in choosing the type of PEP regimen. For most HIV exposures that warrant PEP, a basic 4-week, two-drug (there are several options) regimen is recommended. For HIV exposures that pose an increased risk of transmission (based on the infection status of the source and the type of exposure), a three-drug regimen may be recommended. Special circumstances, such as a delayed exposure report, unknown source person, pregnancy in the exposed person, resistance of the source virus to antiviral agents, and toxicity of PEP regimens, are also discussed in the guidelines. Occupational exposures should be considered urgent medical concerns.

Continued diligence

Continued diligence in the following areas is needed to help reduce the risk of occupational HIV transmission to health care workers.

Administrative efforts. All health care organizations should train health care workers in infection control procedures and on the importance of reporting occupational exposures. They should develop a system to monitor reporting and management of occupational exposures.

Development and promotion of safety devices. Effective and competitively priced devices engineered to prevent sharps injuries should continue to be developed for health care workers who frequently come into contact with potentially HIV-infected blood and other body fluids. Proper and consistent use of such safety devices should be continuously evaluated.

Monitoring the effects of PEP. Data on the safety and acceptability of different regimens of

PEP, particularly those regimens that include new antiretroviral agents, should be continuously monitored and evaluated. Furthermore, improved communication about possible side effects before starting treatment and close follow-up of health care workers receiving treatment are needed to increase compliance with the PEP. ■

Higher risk of perinatal HIV transmission in TB mothers

By **Dean L. Winslow**, MD, FACP, FIDSA, Chief, Division of AIDS Medicine, Santa Clara Valley Medical Center; Clinical Professor, Stanford University School of Medicine. Dr. Winslow is a speaker for Cubist Pharmaceuticals and GSK, and is a consultant for Siemens Diagnostic.

Synopsis: In this study, 783 HIV-infected mother-infant pairs were evaluated as part of a randomized, controlled trial of nevirapine (NVP) given for 6 weeks vs. single-dose NVP to reduce mother-to-child transmission (MTCT) of HIV. Thirty percent of mothers with TB vs. 12% of mothers without TB transmitted HIV to their infants.

Source: Gupta A, et al. Maternal tuberculosis: a risk factor for mother-to-child transmission of human immunodeficiency virus. *J Infect Dis* 2011; 203:358-363.

In this study, 783 HIV-infected Indian mother-infant pairs participated in a randomized clinical trial comparing NVP given for 6 weeks vs. single-dose NVP to prevent MTCT of HIV among breast-fed infants. As a secondary study endpoint, multivariate logistic regression analysis was used to assess the impact of maternal TB occurring during pregnancy through 12 months post-partum. Of the 783 mothers, three had prevalent TB and 30 had incident TB by 12 months post-partum. Of the 33 mothers with TB, 10 (30%) transmitted HIV to their infants vs. 87 of 750 (12%) mothers without TB who transmitted HIV to their infants. In multivariate analysis, maternal TB was associated with 2.51-fold increased odds of HIV transmission, adjusting for maternal factors (HIV RNA, CD4+ count, and antiretroviral therapy) and infant factors (breast-feeding duration, infant NVP administration, gestational age, and birth weight).

Commentary

This is an interesting study done in an area of the world with a high prevalence of TB, and emphasizes the inter-relatedness of TB and HIV in the developing world. While there were no differences at the time of enrollment into the trial in plasma HIV RNA between mothers diagnosed with TB vs. those without TB, the most likely explanation for the increased risk of HIV transmission in mothers with TB would be immune activation and, likely, increased mean HIV RNA levels in the TB-infected mothers, resulting in both increased transplacental, intrapartum, and post-partum transmission. Unfortunately, the design of the study precluded confirming this hypothesis, since post-enrollment maternal HIV RNA levels were not systematically collected. Other potential mechanisms (including maternal immune activation increasing levels of HIV RNA in breast milk and immune activation in the infants leading to increased susceptibility to MTCT) were postulated by the authors, but the design of the study precluded being able to examine these hypotheses.

TB in HIV-infected mothers has been shown to be associated with higher maternal and infant mortality.[1,2] Clearly, it is critical that efforts continue to focus on control of both of these scourges to human health, with particular emphasis on prevention and prompt treatment of maternal TB in HIV-infected women.

REFERENCES

1. Gupta A, et al. Postpartum tuberculosis incidence and mortality among HIV-infected women and their infants in Pune, India, 2002-2005. *Clin Infect Dis* 2007;45:241-249.
2. Pillay T, et al. Perinatal tuberculosis and HIV-1: Consideration for resource-limited settings. *Lancet Infect Dis* 2004;4:155-165. ■

FDA Notifications

Genentech issues letter about Fuzeon® co-product

Genentech has issued the following Dear Healthcare Professional letter for users of Fuzeon and certain other injection products:

"IMPORTANT DRUG WARNING
IMPORTANT SAFETY INFORMATION REGARDING ALCOHOL PREP PADS
MANUFACTURED BY TRIAD
CO-PACKAGED WITH GENENTECH PRODUCTS

(Fuzeon® (enfuvirtide); Boniva® Injection (ibandronate sodium); Pegasys® (pegylated interferon alfa-2a); TNKase® (tenecteplase); Nutropin AQ® (somatropin (rDNA origin)) Pen 10 Kit; Nutropin AQ® (somatropin (rDNA origin)) Pen 20 Kit)

"Dear Healthcare Professional:

Recall of Triad Group Alcohol Prep Products Due to Potential Microbial Contamination

Genentech, Inc., a member of the Roche Group, has learned of a voluntary product recall in the United States involving all lots of alcohol prep pads, alcohol swabs and alcohol swab sticks manufactured by the Triad Group and marketed under various brand names. The Triad Group alcohol prep pads are co-packaged with the following Genentech products: Fuzeon®; Boniva® Injection; Pegasys®; TNKase®; Nutropin AQ® Pen 10 Kit; and Nutropin AQ® Pen 20 Kit. The Genentech medicines have not been affected in any way. In the interest of patient safety, Genentech wants to ensure that you and your patients are aware of this recall of only the alcohol prep products by the Triad Group.

This recall by the Triad Group has been initiated due to concerns about potential bacterial contamination of the alcohol prep products with *Bacillus cereus*. This recall involves alcohol prep products marked as sterile, as well as non-sterile products. As indicated on the FDA website in regard to this recall: "Use of contaminated alcohol prep pads, alcohol swabs and alcohol swab sticks could lead to life-threatening infections, especially in at-risk populations, including

CNE/CME QUESTIONS

10. As of February, 2011, the waiting list for antiretroviral medications through the AIDS Drug Assistance Program (ADAP) had increased to how many people?
    A. 3,331
    B. 4,781
    C. 5,002
    D. 6,704

11. Recent research has found that squamous cell carcinomas have increased in HIV patients at certain sites due to which type of infection?
    A. Hepatitis C
    B. Human papillomavirus
    C. Epstein-Barr virus
    D. Helicobacter pylori

12. There are several strategies for preventing squamous cell carcinomas in an HIV population. Which of the following is *not* one of these strategies?
    A. Vaccination
    B. Education about safe sex and condom use
    C. Prescribing prophylactic antibiotics to at-risk patients
    D. Doing more screenings

Answers: 10. D; 11. B; 12. C

COMING IN FUTURE MONTHS

- Lubricants can increase HIV activity, study finds
- Study demonstrates a decrease in HIV disparities among HAART users
- Children with HIV infection often have psychiatric problems, study finds
- Latest in HIV research from CROI

immune suppressed and surgical patients."

It is important to note that the packaged Genentech products and components (with the exception of the alcohol prep pads) have not been contaminated and may continue to be used in accordance with the package insert.

Genentech recommends that you immediately discontinue use of the alcohol prep pads packaged with these medicines. Inform your patients of this recall and request that they immediately discontinue using the co-packaged alcohol prep pads. The prep pads should be disposed of in the trash. When administering an injection of any of these Genentech products, healthcare providers and patients should use an alternative alcohol prep product that is not involved with this recall or alternatively use a sterile gauze pad in conjunction with isopropyl alcohol for disinfecting the injection site prior to administration.

Genentech is in discussion with the FDA and is currently assessing alternatives to address the situation.

Additional information on this recall by the Triad Group can be found on the FDA's website: http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm239319.htm.

If you or your patients have any further questions or require additional information, please contact the Genentech Resource Center at 1-877-GENENTECH.

You are encouraged to report side effects associated with the use of these products to Genentech and the FDA's MedWatch Safety Information and Adverse Event Reporting Program, which can be found at www.fda.gov/medwatch or call 1-800-FDA-1088.

For the Fuzeon indication, full prescribing information, and important safety information, please visit www.fuzeon.com.

For the Boniva indication, full prescribing information, and important safety information, please visit www.boniva.com.

For the Pegasys indication, full prescribing information, and important safety information including Boxed WARNING and Medication Guide, please visit www.pegasys.com.

For the TNKase indication, full prescribing information, and important safety information, please visit www.tnkase.com.

For the Nutropin AQ indication, full prescribing information, and important safety information, please visit www.nutropin.com.

CNE/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, and clinics;
- Cite practical solutions to the problems associated with those issues.

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 letter of credit. When your evaluation is received, a letter of credit will be mailed to you.

Sincerely,

Hal Barron, MD Executive Vice President Head, Global Development Chief Medical Officer, Genentech, Inc." ■