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# World HIV treatment making progress, but domestic AIDS agenda floundering

*Funding cuts could make everything worse*

The annual HIV/AIDS progress report by the World Health Organization (WHO) shows heartening progress in the worldwide battle against the pandemic.

New HIV infections have been reduced by 17% since 2001, according to the 2009 AIDS Epidemic Update. And the number of new infections in the world's hardest hit region, sub-Saharan Africa, has declined by 15%.[1]

Another study focuses on HIV transmission rates and finds that the global HIV transmission rate dropped by 19.6% between 2001 and 2007, suggesting some success in global HIV prevention efforts.[2]

"Most of our progress is in sub-Saharan Africa where there were 400,000 fewer new infections in 2008 than in 2001," says **Paul De Lay**, MD, deputy executive director of the Joint United Nations Programme on HIV/AIDS (UNAIDS). De Lay spoke at an international media teleconference, held by the World Health Organization (WHO) and UNAIDS, to discuss the 2009 AIDS report.

"This is a sign that our efforts are making a difference," De Lay says.

The 2009 report also highlights the fact that 2.9 million lives have been saved globally because of antiretroviral drugs and greater access to ART worldwide, says **Teguest Guerma**, MD, acting director of the HIV/AIDS department at WHO. Guerma also spoke at the media teleconference on the 2009 AIDS report.

"AIDS-related deaths declined by over 10% in the past five years," Guerma says. "For example, in Kenya, AIDS-related deaths declined by 29%."

These declines are attributed to increased access to ART. The 2009 AIDS Epidemic Update noted that 4 million people in low- and middle-income countries were receiving antiretroviral therapy, a 10-fold increase over five years. Globally, new HIV infections peaked in 1996 when an estimated 3.5 million people were newly infected with the virus. This compares with an estimated 2.7 million new HIV infections

in 2008, representing a 30% decrease.

While noting these positive trends, the latest AIDS report discusses gaps in prevention approaches and cautions against complacency.

"We're strongly advocating we don't let treatment programs diminish in any way," De Lay says. "We want to scale up for people who need it because the numbers are clear that only through prevention can we turn this epidemic around."

AIDS activists have been less diplomatic about what's needed.

On World AIDS Day, Dec. 1, 2009, activists from ACT UP Philadelphia, Health GAP, DC Fights Back, and others groups protested at the White House and the Wilson Building in Washington, DC, against what they called a flawed course in HIV policy by President Barack Obama's administration and the Washington, DC, city government.

According to a recent study, an estimated 3% of adults in Washington, DC, are infected with HIV, a prevalence rate that is comparable to some sub-Saharan African countries.[3]

Global AIDS groups gave Obama a D+ score for his failure to deliver on promises to increase HIV/AIDS funding.

Their chief concerns center around proposed flat-funding for global AIDS initiatives and Washington, D.C.'s epidemic's problems.

Also, the ADAP Advocacy Association called on Obama and the U.S. Congress to stop with "fancy proclamations" and provide an emergency supplement of $268 million to the AIDS Drug Assistance Program (ADAP).

All that has been provided so far by Congress is a token $20 million increase to ADAP, despite a drug waiting list that has increased by more than 800% since January, 2009, says **Bill Arnold**, director of the ADAP Working Group in Washington, DC.

As of World AIDS Day, nine states had lists of people waiting to receive ARTs through ADAP for a total of 342 people living with HIV/AIDS.

"We are starting to advocate right now for additional money, and the impetus for that will have to come from the White House, either through emergency federal funding or stimulus funding or returned TARP funding," Arnold says.

"It's not like we need billions of dollars, but it's clear we need hundreds," Arnold says.

States have cut $167 million from AIDS programs in the past year, and the federal commitment to ADAP also has fallen as a percentage of the total funds, according to a December ADAP report.

For instance, in 2000, federal funds accounted for 72% of ADAP funding, and now the federal share of ADAP funding is only 54%. The difference is made up by states, drug company rebates, private money, and other funds, Arnold says.

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Recent surveillance data from the Centers for Disease Control and Prevention (CDC) of Atlanta, GA, suggest that more than 1.1 million Americans are living with HIV infection, as of 2006, and 21% of these adults and adolescents are undiagnosed.[4]

Even as the number of Americans living with HIV/AIDS increases, as new infections increase, and as increasing numbers of people lose private insurance and need assistance to pay for their antiretroviral drugs, ADAP's funding has remained flat, Arnold says.

"What we're really getting caught up in here is the people who need the service are living longer, and the basic population is swelling, and the resources have not kept track," Arnold explains.

A decade ago, ADAPs had fewer people who needed the drugs, and the formularies were more limited. Now people with HIV/AIDS routinely are living into third and fourth decades of being infected, and they'll need ART every day of those longer lifetimes, Arnold says.

Also, HIV drugs are expensive, although ADAPs pay less than most entities, Arnold says.

An antiretroviral drug regimen for HIV typically costs patients $1,000 a month, he adds.

"The other exacerbating factor is that many states that used to be able to chip in some money for ADAPs now are in deep trouble fiscally and can't get their budgets passed," Arnold says.

The list of troubled state ADAPs is growing longer with Tennessee being one of the latest states forced to start an ADAP waiting list, Arnold says.

"California already is embroiled in discussions of cutting their ADAP, and California represents close to 20% of the U.S. AIDS epidemic, so if California's ADAP collapses, it's trouble," he says.

Ohio, Arizona, Indiana, Mississippi, and Washington state also are close to having major problems funding their ADAPs, he adds.

Arnold, like other AIDS advocates, thought the nearly decade-long trend of flat-funding for domestic HIV/AIDS programs would be reversed in 2009 when Democrats led Congress and the White House for the first time in nearly two decades.

"It is past time for those who represent the people who are disproportionately affected by this epidemic to storm the ramparts," Arnold says. "I was surprised a Democratic Congress didn't give ADAPs more money."

It's understandable that the White House is focusing on health care reform and has been reluctant to wade into specific details, including ADAP funding, but the problem of ADAP waiting lists is growing, Arnold notes.

"I think whether or not the economy improves, you can't be sacrificing these people just because bonuses on Wall Street might have to be cut," he adds.

International AIDS prevention and treatment programs also need additional funding, world health officials say.

While the international AIDS report shows a positive trend, international health officials and HIV/AIDS activists warn that all of the progress made could be reversed if the U.S. and other nations reduce their financial support, particularly as the international economic crisis takes its toll.

"We've been analyzing the impact of the economic crisis for the last year," De Lay says.

"Particularly we're looking at how it affects AIDS response, prevention, and treatment," he adds. "And what we've seen is that most of the impact has been in middle-income countries in their domestic budgets."

There's been more of a delay in impact to international funding, but the impact of declining funding assistance is expected to play out in 2010, he says.

For the domestic AIDS epidemic, nearly all of the success is in the treatment arena. While there are many proven prevention methods, and a national strategy of the past eight years of targeting people who are infected with prevention interventions, these appear to have little impact on new infections in the U.S.

"Most people would say, and I would say that the problem is the lack of a highly visible national HIV prevention program for almost a decade," Arnold says. "The hard to reach communities and younger generations coming along year after year, well if they haven't been reached with a prevention message, then guess what? As STD rates go up then HIV rates go up."

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# Fatigue chief complaint? A surprising explanation

Fatigue is such a common complaint among HIV patients that it's often ignored or expected in clinical care.

Now an HIV researcher has found a correlation between fatigue and psychosocial problems, and she's working on an intervention to address this issue.

"I've been working with HIV patients for many years, and their number one complaint was being fatigued," says **Julie Barroso**, PhD, ANP, APRN, BC, FAAN, an associate professor and research development coordinator in the office of research affairs at Duke University School of Nursing in Durham, NC.

Barroso would suggest strategies to help reduce patients' fatigue, but made little progress, so she decided to conduct a series of pilot studies to get a sense of what their fatigue was about and how it impacted their daily lives.

"This work helped me develop an HIV-related fatigue scale so we could better measure fatigue," Barroso says.

The scale measures the intensity of fatigue, the circumstances surrounding fatigue, and the consequences of fatigue.

"There are people who are very fatigued and somehow get through their day," Barroso explains. "And then there are some people who are so fatigued they can't do anything."

For example, one woman told Barroso that she couldn't even stand in front of the dryer to fold clothing, and another man talked about not being able to take his grandchild to the park anymore.

"Fatigue is so much more than being tired," Barroso says. "We're all tired — it's a state of life for all of us these days, but this is profound fatigue, and it impacts the state of their lives."

It's a frustrating symptom from a clinician's perspective because its cause is elusive, and there are no proven effective treatments, she adds.

But there now are some answers, and there might be an intervention available once Barroso concludes her research.

"We've gotten a five-year grant through the National Institutes of Health (NIH) Institute of Nursing Research to look at a large number of variables to see what predicts fatigue," Barroso says.

Investigators followed patients to the Duke General Clinical Research Center (GCRC) and collected data about their fatigue and variables that could impact it.

"They were able to come here every six months for three years," Barroso says. "We finished data collection last April, and we're currently analyzing data."

An early look at the first year's results has some surprises, she notes.

HIV patients' CD4 cell counts, viral loads, and even whether or not they are taking antiretroviral therapy (ART) have not predicted fatigue, Barroso says.

"Fatigue is listed as a prominent side effect for nearly every ART," Barroso says. "You may think they're fatigued because they're on the drugs, and there are people who believe the medications are making them sick."

But investigators found no relationship between being on ART and experiencing fatigue. Both patients who are on ART and those who are not taking HIV medications experience fatigue at the same rate, Barroso says.

"We looked at all kinds of demographics, including employment rate, education level, who they lived with, HIV-related variables, any illnesses, and a huge number of physiological variables," she says. "With physiological, we looked at hepatic function, thyroid function, anemia, testosterone, everything."

Investigators also looked at psychosocial indicators, including depression, anxiety, social support, adult and childhood trauma, life stress events, and both daytime sleeping and nighttime sleep quality.

"The only things that predict HIV fatigue are the psychosocial variables," Barroso says. "None of the physiological variables predicted it."

Even the researchers were surprised by the findings.

"When we had a first year of data, I said, 'Let's look at physiological first,' and our statistician said there was nothing there," Barroso recalls. "I said, 'Run the data again,' because for there to be nothing at all was really striking."

But the findings held up for the first two years of data, and the third year is still being analyzed,

she adds.

Investigators analyzed the fatigue scores. The higher a person's fatigue score, from a zero to 10 scale, the more intensely they're experiencing fatigue. They compared these scores with the other measurements to determine correlations.

"So if you have a high score on the anxiety scale and the fatigue scale, then that's a strong correlation," Barroso says.

### *Complementary maladies*

The HIV patients who had the highest fatigue scores specifically scored high on depression, anxiety, and stressful life events, she says.

"In our sample there was as an extraordinarily high amount of childhood trauma and adult trauma, as well," Barroso says. "We do a very intense stress of life interview, and they fill out a questionnaire before the visit, and our research coordinator interviews them about these answers."

Of all of the variables, the main predictor of increased fatigue was a person having had a stressful life event in the previous six months, and this also led to people being depressed and anxious, Barroso explains.

Investigators even looked at the use of antidepressants and found that fatigue scores were the same whether or not their depression was treated, she adds.

"You might get some reduction in the depressive symptoms, but you don't necessarily get a reduction in the fatigue, as well," Barroso says.

Starting in January, 2010, investigators will implement a cognitive behavioral stress management intervention that is directed at stress management and teaching HIV patients better coping skills.

"We hope that since stress is the primary predictor we can reduce fatigue with this intervention," Barroso says. "These people have such trauma in their lives they need counseling and not just an antidepressant."

The fatigue research suggests that clinicians should consider psychosocial issues, especially stressful live events, as causes of fatigue once they've ruled out physiological factors, Barroso says.

"You should check for anemia and low testosterone in men, which are the two most common causes of fatigue that are physiologically based," she says. "But if you don't see anything beyond those two, then you don't need to go on a search."

Also, Barroso suggests that clinicians avoid giving patients platitudes about how their CD4 cell counts are up, their viral loads are down, and so they should feel fine or, even worse, that they should just take a nap.

Instead, clinicians should ask patients about their fatigue and to try to determine when they feel better and when the fatigue is worse, Barroso says.

"Some people will feel better in the morning, but hit a wall in the afternoon," she says. "The other thing we know from looking at our data is the most fatigued 20% stayed the most fatigued with no variability, while the middle group bumped around a little."

This means a patient with severe fatigue won't spontaneously get better, and the literature suggests fatigue likely will impact their adherence to treatment, Barroso says.

HIV clinics that have social workers and other psychosocial support should make sure severely fatigued patients receive these services, particularly when patients report having had traumatic life events, including sexual abuse, she adds.

"Some of these patients have had horrible life situations, and many did not have the parenting they needed to teach them how to cope with stress," Barroso says. ■

## ADHERENCE STRATEGIES

# Social support research provides clues to possible adherence strategies

*Study looks at its impact*

HIV clinicians often work with patients who have such an overwhelming number of barriers to optimal treatment adherence that it's difficult to know where an adherence intervention should begin.

There are issues of homelessness, substance use, mental illness, stigma, drug side effects, etc. Primary care physicians will see the chief problem as being one particular barrier, while special-

ists and case managers might think a different problem should be targeted.

Now at least one researcher who approaches treatment adherence from the perspective of a nurse believes the best possible intervention will incorporate a variety of disciplines and approaches in one package.

"I remember having a few conversations with the medical director, saying, 'What you need in a program like this is a theoretical approach that different disciplines can agree on and to approach care from this perspective,'" says **Donald Gardenier**, DNP, FNP-BC, a nurse practitioner, assistant professor, and clinical program director in the division of general internal medicine at Mount Sinai School of Medicine in New York, NY.

"That's not an unusual approach for a nurse, but the medical director being a physician was intrigued and unfamiliar with this," Gardenier recalls. "So I dove into this a little bit further and came up with a social support theory as a way to contextualize care in this setting."

Gardenier's work has led to research into an adherence intervention approach for HIV-infected patients who qualify for enhanced services based on one or more threats to optimal adherence or health outcomes in terms of their HIV disease.

"These can be multiple medical problems, decreased social support based on family systems, homelessness, incarceration, and almost all of them have at least one psychiatric diagnoses and substance use issues — either currently or in the past," Gardenier says.

The patients attend an AIDS day health care (ADHC) program to which they are referred by providers based on their need for psychiatric services.

"The services are based on the statistical or evidence-driven needs of people with HIV, including housing services and nutrition services," Gardenier says. "These are in addition to being basically a psychiatric day treatment program with onsite primary care."

Gardenier first studied the ADHC's population, comparing patients' participation and reported adherence and measured social support.[1]

"I used the Social Provisions Scale (Cutrona & Russell, 1987), which was uniquely suited to this population," Gardenier says. "So it seemed to me in looking at it as a nurse that different disciplines could look at different aspects of social support and design different interventions around them."

It's not as useful to ask clients if they have social support because clients might list having a spouse, although their mate is not socially supportive or they might not think to mention the social support they receive from peers in the day program, he explains.

"Some studies say it doesn't matter where you get social support so long as you're getting it," Gardenier adds.

In the Social Provisions Scale, social support is measured with 24 items, divided between six subscales, including these: reliable alliance, attachment, guidance, nurturance, social integration, and reassurance of worth.

Reliable alliance and guidance are the types of support an HIV patient might receive from the medical professionals who help him or her, Gardenier says.

The more emotional support provisions involve attachment, nurturance, social integration, and reassurance of worth, he adds.

"Attachment is the closeness and intimacy that fosters a sense of security," Gardenier says. "Social integration is a sense of belonging to a group with similar interests and concerns."

HIV patients who experience reassurance of worth are given recognition of their abilities and competence, and nurturance is the feeling that one is needed by others, he adds.

When Gardenier measured social support among the ADHC population, he found that the highest social support scores were among the instrumental provisions of reliable alliance and guidance.

"This was not a surprise because people are in this intensive program, receiving guidance," he says. "And among the emotional provisions, the highest scores were in social integration, which is belonging in a group and also was not a surprise."

The HIV clients reported the lowest social support in the area of nurturance, suggesting they did not feel needed, he says.

"If you think about how someone experiences life during and after substance use, I think it's fairly common in the pathology of substance use to find that people who otherwise rely on you learn not to," Gardenier says. "So even when you go through a recovery period, you lack this social support."

HIV patients struggle with the feelings that they're unneeded, but this also is a social support that a comprehensive HIV/AIDS program can foster, he notes.

"We had one man in the program that really had his life together, and he came to the day program every day for years, participating in all the groups," Gardenier recalls. "He had a key spot in social integration in the place, and you had to ask what he was doing there because he had his life together."

The answer was that the man showed up each day because he felt needed, and so his attendance fostered the experience of nurturance, he adds.

"Once I saw the limitations of what I could do in correlating social support and adherence in using this instrument, there was more than enough material to use and apply toward the design of an intervention," Gardenier says.

There's considerable potential for such an adherence intervention, he notes.

"I can see how a case manager would look at this and see how to teach services to clients, who could then provide services for each other," Gardenier explains. "For example, a peer could lead an HIV group, and then you'd re-measure adherence and see how that has changed with the peer."

### *Reference*

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# Detecting highly transmissible acute HIV

*CDC: NY success may lead to national effort*

Screening STD clinic patients — especially men who have sex with men (MSM) — for signs of an acute, highly transmissable stage of HIV infection could heighten detection and prevention efforts, the Centers for Disease Control and Prevention. "Surveillance for acute human immunodeficiency virus (AHI) is feasible and can identify circumstances in which HIV prevention efforts should be intensified," the CDC emphasized in a recently published report.1 CDC is considering a national AHI case definition for use in national HIV surveillance to identify areas or populations in which HIV infection is spreading, and for assessing new methods for AHI screening.

(AHI) is a highly infectious phase of disease that lasts approximately two months and is characterized by nonspecific clinical symptoms. AHI contributes disproportionately to HIV transmission because it is associated with a high level of viremia, despite negative or indeterminate antibody (Ab) tests. Diagnosis of AHI with individual or pooled nucleic acid amplification tests (p-NAAT) can enable infected persons to adopt behaviors that reduce HIV transmission, facilitate partner referral for counseling and testing, and identify social networks of persons with elevated rates of HIV transmission. Unfortunately, the national HIV surveillance case definition does not distinguish AHI from other stages of HIV infection, and the frequency of AHI among reported HIV cases is unknown.

In 2008, to increase detection of AHI and demonstrate the feasibility of AHI surveillance, the New York City Department of Health and Mental Hygiene (NYC DOHMH) initiated p-NAAT screening at four sexually transmitted disease (STD) clinics and enhanced citywide HIV surveillance (using a standard case definition) to differentiate AHI among newly reported cases. Seventy cases of AHI (representing 1.9% of all 3,635 HIV diagnoses reported in New York City) were identified: 53 cases from enhanced surveillance and 17 cases from p-NAAT screening (representing 9% of 198 HIV diagnoses at the four clinics). Men who have sex with men (MSM) constituted 81% of AHI cases.

"The findings in this report confirm that p-NAAT can increase AHI diagnoses among high-risk STD clinic patients, and indicate that AHI diagnoses can be made apart from p-NAAT screening programs," the CDC concluded.

The 70 AHI cases identified by NYC DOHMH represent a fraction of the 4,762 new infections previously estimated to occur annually in New York City, highlighting the need to improve awareness and detection of AHI. Notably, 81% of AHI cases identified in New York City were among MSM, reflecting the high HIV incidence in MSM and demonstrating the risk for missed diagnoses when HIV-Ab testing alone is used in a high-risk, high-incidence population. Without p-NAAT screening, 9% of the HIV infections documented by the four STD clinics during the screening period would have been missed. However, because HIV RNA is not detectable for approximately 10 days after infection), even NAAT will not identify all infected persons. The

CDC recommends that persons with very recent high-risk exposures be encouraged to retest after 4 to 6 weeks, even if p-NAAT is negative. Based on the results, NYC DOHMH has expanded p-NAAT screening to all nine New York City STD clinics and improved ascertainment of AHI in routine surveillance.

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# Condom wrap-up, new options for prevention

Good news for prevention of HIV and other STDs as a new year dawns. The second-generation FC2 Female Condom is available for purchase in the United States, which gives American women a nonlatex, female-controlled option in disease protection. Men also have new choices when it comes to nonlatex condoms; two options now are available in the United States.

The Food and Drug Administration gave approval in March 2009 for U.S. sale of the second generation of the female condom manufactured by the Female Health Company (FHC). With the introduction of a new proprietary nitrile material and a less labor-intensive manufacturing process, the company can offer the condom, known as the FC2, at a public health sector cost that is about 30% less than the original FC1 polyurethane condom. The FC2 offers another option to the male condom and is a suitable choice for those with latex sensitivity. Some women have found FC2 quieter than the first-generation FC Female Condom.

The company announced the U.S. product rollout at company at an October 2009 meeting of the Southeastern Urban Initiative for Reproductive Health, a coalition of reproductive health advocates from Southern states that is seeking increased federal funding for HIV prevention. Reception of the second generation condom by conference participants was "exciting," says **Mary Ann Leeper**, PhD, FHC senior strategic adviser.

FC2 may be purchased from the company's two public sector distributors: Total Access Group (www.totalaccessgroup.com) and Global Protection Corp., (www.globalprotection.com/store). In addition, FHC has launched a web site, www.fc2femalecondom.com, which includes tiered pricing information for ordering a minimum quantity of 25,000 units directly from the company. Price per unit will decline based on the volume purchased, state company officials. The maximum price to purchase FC2 from the company's distributors is $0.82/unit regardless of quantity, which represents approximately a 30% decrease from the unit price paid for FC1.

The new condom will be available in certain retail outlets. FHC is seeking a partner with appropriate experience to promote FC2 directly to consumers in the United States, says Leeper. Retail outlets are being identified, and the company is negotiating retail sale agreements, she adds.

The company is developing a seeding program to provide free allotments of FC2 Female Condoms to reproductive health service organizations as part of an introductory awareness and education program. The program will include training for health care providers on how to integrate female condom education into reproductive health counseling. Organizations may obtain further information on program enrollment by visiting www.fc2.us.com. The site also offers free resources, such as a training manual, "Safer Is Sexy," a counseling tips handout, and a fact sheet on negotiating condom use.

### Consider polyisoprene

Men now have two more options when it comes to nonlatex condoms: Durex Avanti Bare and LifeStyles Skyn. Both condoms are made of polyisoprene. LifeStyles introduced its Skyn condom in July 2008, and the Durex Avanti Bare arrived on market shelves in August 2009.

Both condoms are available in all outlets where condoms are routinely sold. Most drugstores retail Avanti Bare 12 counts for $13.99, says Stephen Mare, senior brand manager for Durex Consumer Products.

How do polyisoprene condoms compare with polyurethane condoms? According to Mare, polyisoprene is much softer and more elastic than polyurethane. They are easier to don and provide a supple, natural feel for the user. The result is a very pleasant-feeling condom that most users prefer to polyurethane, Mare says. Polyisoprene condoms react similarly to latex condoms in the presence of oil, so providers

should instruct users to use only water-based or silicone lubricants with them.

Are such condoms safe for use in people with latex allergies? While 1%-6% of the U.S. population are believed to be allergic to latex, the prevalence of latex sensitivity is believed to be much higher among health care workers who have repeated exposure to latex-containing medical devices, such as surgical and examination gloves.[1] Ask patients whether they experience itching, rash, or wheezing after wearing latex gloves or inflating a balloon. If you suspect a patient has latex sensitivity, consider recommending synthetic condoms, and refer the patient for allergy skin testing. While latex condom use is contraindicated in patients with general latex sensitivity, synthetic and natural membrane condoms can be recommended for prevention of pregnancy. Only synthetic condoms should be recommended for prevention of sexually transmitted infections, including HIV.[1]

"Dermatological testing shows that Durex Avanti Bare condoms have minimal potential for induced delayed hypersensitivity, also called 'Type IV allergy' and 'allergic contact dermatitis,'" states Mare. "Some people who are sensitive to natural rubber latex may also have a sensitivity to these condoms. Consumers who experience any allergic reaction should stop using them and see a doctor."

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## Journal Review

# Fatal H1N1 infection in an HIV positive woman

*Negative flu tests, HIV infection delay treatment*

The authors describe a fatal case of H1N1 pandemic influenza A associated with pneumonia, which resulted in respiratory and renal failure in a 39-year-old HIV-positive woman. She had type 1 diabetes and a diagnosis of AIDS 7 years ago and had received highly active antiretroviral therapy. She also had an ill child at home with an influenza-like illness.

Her medical history included pleuropericardial Nocardia spp. infection, recurrent pleural effusions requiring thoracentesis, and hepatomegaly of unknown cause. Her most recent CD4 cell count was 166 cells/μL with undetectable viral load 1 month before admission. Medications prescribed included combivir, efavirenz, and rimethoprim/sulfamethoxazole but she was noncompliant. She had received the 2008–09 seasonal influenza vaccine and pneumococcal vaccine.

The patient was admitted to Winthrop-University Hospital in Mineola, NY on June 5, 2009, for community-acquired pneumonia. She received empiric moxifloxacin and atovaquone. Because of concern for persistent *Nocardia* spp. infection, she was also treated with doxycycline. The result of a rapid influenza test was negative for a nasal swab specimen on day 1 of hospitalization. Over the next 48 hours, her clinical status deteriorated, and she experienced worsening hypotension and respiratory distress.

She was transferred to the intensive care unit and required intubation, pressor support, and continuous venovenous hemofiltration for fluid removal. Empiric oseltamivir (150 mg 2×/d) was started on hospital day 3; moxifloxicin was discontinued, and meropenem was given for pneumonia. Thoracentesis showed transudative fluid negative for acid-fast bacilli, bacteria, and fungi. Results of blood cultures and urine analysis for Legionella spp. antigen were negative. Repeat chest radiography showed a right-sided pneumothorax and worsening bilateral airspace disease. A chest tube was inserted in the right lung, and bronchoscopy was performed on hospital day 5. Results of bronchoalveolar lavage (BAL) were negative for *Pneumocystis jiroveci*, virus inclusions, fungi, acid-fast bacilli, bacteria, and mycobacteria. However, clusters of filamentous organisms were seen. On hospital day 5, results of a second rapid influenza test, respiratory fluorescent antibody test, and nasopharyngeal virus culture were negative. Diagnosis was based on a positive result for pandemic H1N1 influenza A by real-time reverse transcription–PCR (RT-PCR) for a nasopharyngeal swab specimen. Despite empiric treatment with oseltamivir, the patient died on June 15, 2009 (day 11 of hospitalization).

Symptoms of pandemic (H1N1) 2009 in HIV-

infected persons are not known, the authors note. However, they have a higher risk for complications. In previous seasonal influenza outbreaks, HIV-infected persons had more severe infections and increased hospitalization and mortality rates.

"Although a diagnosis of pandemic (H1N1) 2009 was first considered for our patient because of her ill child, she was not initially treated with oseltamivir because of the negative influenza test result and concern for opportunistic infections," the authors report. "Only the result of an RT-PCR for pandemic (H1N1) 2009 was positive. No other pathogens were detected in her blood, urine, sputum, BAL, or thoracenthesis fluid."

Empiric treatment in patients with pandemic (H1N1) 2009 should be considered in those seeking treatment for influenza-like symptoms, especially in the setting of sick contacts with respiratory illnesses. Rapid influenza tests, respiratory fluorescent antibody tests, and viral cultures may not provide a diagnosis. An RT-PCR for pandemic (H1N1) 2009 may be needed to provide a diagnosis, the conclude.

### *Reference*

1. Klein NC, Chak A, Chengot M, et al. Fatal case of pneumonia associated with pandemic (H1N1) 2009 in HIV-positive patient [letter]. *Emerg Infect Dis.* 2010 Jan; [Epub ahead of print] ■

# *FDA Notifications*

## Combination lamivudine and tenofovir tablet approved

On Nov. 5, 2009, using expedited review procedures developed to support the President's Emergency Program For AIDS Relief (PEPFAR), the Food and Drug Administration (FDA), granted tentative approval for lamivudine and tenofovir disoproxil fumarate fixed dose combination tablets, 300mg/300mg.

The fixed dose combination product, indicated for use in combination with other antiretrovirals for the treatment of HIV-1 infection, is manufactured by Hetero Drugs Limited of Hyberdad, India.

The FDA's tentative approval of this product means that while FDA cannot fully approve the product for sale in the United States because of existing patent protections, it has been shown to meet all of FDA's safety, efficacy and manufacturing quality standards. Tentative approval qualifies the product for purchase using PEPFAR funds.

Fixed dose combination products like this one can help ease pill burden and simplify therapy, and may help increase adherence to therapeutic regimens, potentially reducing development of resistance to the separate drugs. Fixed dose combination products can help also help reduce costs associated with treatment for HIV infection.

Lamivudine and tenofovir are Nucleoside Reverse Transcriptase Inhibitors (NRTIs). ■

## Pediatric dosing recommendations revised

On Nov. 6, 2009, the Food and Drug Administration (FDA) approved revised pediatric dosing recommendations that expand dosing to include children starting treatment at four weeks of age.

The revised label contains the following recommendation:

• The recommended dosage in pediatric patients 4 weeks of age and older and weighing ≥4 kg is provided in Table 1. Zidovudine (Retrovir®) Syrup should be used to provide accurate dosage when whole tablets or capsules are not appropriate.

• Table 1: Recommended Pediatric Dosage of zidovudine: Body Weight (kg) Total Daily Dose Dosage Regimen and Dose b.i.d. t.i.d 4 to < 9 24 mg/kg/day 12 mg/kg 8 mg/kg ≥ 9 to < 30 18 mg/kg/day 9 mg/kg 6 mg/kg ≥ 30 600 mg/day 300 mg 200 m. ■

## ART guidelines for adults & adolescents are revised

On Dec. 1, 2009, the Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents were revised to reflect

the following changes. You can find the complete, revised guidelines on the AIDSinfo web site.

What's New in the Adults and Adolescent Guidelines Document?

The following key changes were made to update the Nov. 3, 2008, version of the guidelines:

• New Section: Based on interests and requests from HIV practitioners, a new section entitled "Considerations in Managing Patients with HIV-2 Infection" has been added to the guidelines. This new section briefly reviews the current knowledge on the epidemiology and diagnosis of HIV-2 infection and the role of antiretroviral therapy in the management of patients with HIV-2 mono-infection and HIV-1/HIV-2 coinfection.

• Key Updates: Drug Resistance Testing - In this revision, the panel provides more specific recommendations on when to use genotypic versus phenotypic testing to guide therapy in treatment-experienced patients with viremia while on treatment.

Genotypic testing is recommended as the preferred resistance testing to guide therapy in patients with suboptimal virologic responses or virologic failure while on first or second regimens (AIII).

The addition of phenotypic testing to genotypic testing is generally preferred for persons with known or suspected complex drug resistance mutation patterns, particularly to protease inhibitors (BIII).

• Initiation of Antiretroviral Therapy: In this updated version of the guidelines, the panel recommends earlier initiation of antiretroviral therapy with the following specific recommendations:

- Antiretroviral therapy should be initiated in all patients with a history of an AIDS-defining illness or with CD4 count < 350 cells/mm3 (AI);

- Antiretroviral therapy should also be initiated, regardless of CD4 count, in patients with the following conditions: pregnancy (AI), HIV-associated nephropathy (AII), and hepatitis B virus (HBV) coinfection when treatment of HBV is indicated (AIII);

## CNE/CME *questions*

1. How has the rate of new infections globally changed since 2001, according to the most recent data?
   A. The number of new infections has increased by 13.2%
   B. The number of new infections has declined by 10.3%
   C. The number of new infections has been reduced by 17%
   D. The number of new infections has been reduced by nearly 20%

2. In a new study on HIV fatigue, which factor predicted severe fatigue among HIV patients?
   A. Low testosterone or poor thyroid function
   B. Recent life stress or trauma
   C. ART use
   D. Low CD4 cell count

3. A Social Provisions Scale, which is used in recent research to study social support among HIV patients, includes which of the following subscales?
   A. Reliable alliance and attachment
   B. Guidance and nurturance
   C. Social integration and reassurance of worth
   D. All of the above

**Answers: 1. C; 2. B; 3. D.**

## *COMING IN FUTURE MONTHS*

- New scale tests symptom management self-efficacy in HIV patients
- Prevention efforts focusing on African American community offer new strategies
- HIV/TB coinfection predicts higher rate of death, research finds
- New study shows that women are more likely to discontinue ART

- Antiretroviral therapy is recommended for patients with CD4 counts between 350 and 500 cells/mm3. The Panel was divided on the strength of this recommendation: 55% of Panel members for strong recommendation (A) and 45% for moderate recommendation (B) (A/B-II);

- For patients with CD4 counts >500 cells/mm3, 50% of Panel members favor starting antiretroviral therapy (B); the other 50% of members view treatment as optional (C) in this setting (B/C-III);

- Patients initiating antiretroviral therapy should be willing and able to commit to lifelong treatment and should understand the benefits and risks of therapy and the importance of adherence (AIII). Patients may choose to postpone therapy, and providers may elect to defer therapy, based on clinical and/or psychosocial factors on a case-by-case basis.

• What to Start in Antiretroviral-Naïve Patients: Increasing clinical trial data in the past few years have allowed for better distinction between the virological efficacy and safety of different combination regimens. Instead of providing recommendations for individual antiretroviral components to use to make up a combination, the Panel now defines what regimens are recommended in treatment naive patients. ■





## CNE/CME objectives

The CE/CME objectives for *AIDS Alert*, are to help physicians and nurses be able to:
• Identify the clinical, legal or scientific issues particular to the care of patients with AIDS;
• Describe the impact of the clinical, legal or scientific issues particular to the care of patients with AIDS on nurses, physicians, hospitals and clinics;
• Cite practical solutions to the problems associated with the clinical, legal or scientific issues particular to the care of patients with AIDS.

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.

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