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IN THIS ISSUE

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Special Report: Bridging the gap for inmates

Mean streets: Out of prison, out of HIV med compliance

Prisoner re-entry needs targeted focus

[Editor's note: A new study finds a large care gap that imperils the public health response to HIV prevention and treatment. When prisoners are released into the community, they often do not seek care or access their HIV medications. In this issue of AIDS Alert, *we examine the implications of this problem and how the study reached its conclusions. Also, in the August, 2009, issue of* AIDS Alert, *we'll have a story about a New York prison re-entry program that serves as a vehicle for HIV prevention, as well as a way to reduce prison recidivism.]*

A number of studies have examined HIV testing, counseling, and treatment in U.S. jails and prisons. Still others have looked at the effectiveness of prison HIV prevention programs.

However, one new study has found a glaring hole in HIV care for prisoners, suggesting the need for a major public health response.

Researchers who examined the antiretroviral therapy (ART) experience of every inmate released from prison in one major state from January, 2004, through December, 2007, found that more than two-thirds did not fill their ART prescriptions within two months of their release.[1]

The cohort of 2,115 inmates had received optimal HIV care and treatment while in prison, and they were released with 10 days of ART medication, says **Jacques G. Baillargeon**, PhD, an associate professor of epidemiology in the department of preventive medicine and community health at the University of Texas Medical Branch in Galveston, TX.

However, in this four-year period, only 5% of the newly-released inmates in Texas had obtained HIV medication before exhausting their 10-day supply. Also, 17% had accessed medication within 30 days, and 30% had accessed medication within 60 days.[1] **(See story about how**

the study was conducted, p. 75.)

"We were very surprised by the findings," Baillargeon says. "This is one of the largest correctional institutions in the United States, and it has a large number of HIV-infected inmates among a racially and ethnically-diverse population."

The Texas prison system's experiences probably are mirrored across the United States, which highlights the public health problem inherent in prisoner re-entry to the community, he notes.

"The Texas prison system and other prison systems do a very good job of getting patients on these medications and having them stay adherent while they're incarcerated," Baillargeon says. "Prison acts as an opportunity to screen, treat, and reach people who are outside of the general health population."

Prisoners often are tested for the first time and then are linked immediately to care. So it is essential to get them linked to community care once they are released, he adds.

"Our hope is that as a result of this study there will be some discussion about improving HIV discharge planning in prisons," Baillargeon says.

This is a public health issue, as much as a compassionate issue, he says.

"This is a public health crisis, and it impacts everybody," Baillargeon says. "These inmates are incarcerated for a few years, and then they're out in the community."

If they are infected with HIV and engaging in high-risk behaviors, there is a big public health issue, he adds.

The study's findings compelled state health and HIV/AIDS officials to hold a summit, scheduled for July 10, 2009, in Austin, TX.

Fifty people were invited to attend the one-day meeting. The attendees represent the Texas Department of Criminal Justice, the University of Texas Medical Branch, the Texas Department of State Health Services, and 25 non-profit agencies, says **Dwayne R. Haught**, MSN, RN, manager of the HIV medication program, which is an AIDS Drug Assistance Program (ADAP) and part of the Texas Department of State Health Services in Austin, TX.

"We planned this quickly because we wanted to do something quickly," Haught says. "This is just the beginning of something we hope will be ongoing."

The initial goal is to find a way to link more inmates to HIV care upon their return to the community, he says.

"We're looking to strengthen those post-incarceration linkages," Haught says. "We feel strongly that the care provided while they're in the department of corrections is excellent."

Broken links

But the linkage to community care is unclear.

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"We're not sure who's doing what," Haught explains. "So at this meeting we'll look to strengthen those outside linkages."

For example, it might be possible for the state to shift state funds to an ART bridge program for newly-released inmates. This way, they could be directed to immediate drugs through ADAP rather than having to wait until their formal ADAP application is approved, he suggests.

"About 99% of the 115 inmates released each month are eligible for ADAP, but they have to meet strict federal requirements, and you have to do due diligence to prove they don't have any other medication payers," Haught says. "If I can move some of the general (ADAP) revenue to another line in our program, then we could get those people on their medications immediately as we sort out our payer of last resort issue."

It is also crucial that released inmates make appointments with HIV medical providers, which is why the summit is necessary, Haught says.

"We tell HIV providers to overbook their clinics and get the inmates in right away," he says. "We may only have one opportunity to get them into the system, and it's a tough system."

A prison re-entry program in New York offers a glimpse into what can be done for newly-released inmates if a community-based organization (CBO) teams with public health agencies and the department of corrections.

The AIDS Council of Northeastern New York in Albany, NY, has a full-time community re-entry specialist who works with newly-released inmates who are at risk for HIV. Besides providing HIV prevention education, the program assists the men and women with finding housing, jobs, and substance use counseling.

"It's considered a prevention readiness intervention," says **Nancy Fisher**, director of prevention services for the AIDS Council. "We have a grant through the Department of Health AIDS Institute and a cooperative agreement between the [New York] Department of Corrections and Department of Health."

The AIDS Council started the re-entry HIV prevention program about four years ago after receiving a federal grant, says David Howard, community re-entry specialist.

The goal was to work with at-risk inmates to slow down their prison recidivism rate, engage them in work and in their communities, and to prevent HIV infection, he says. "We're ahead of our time in the state of New York," Howard says.

"There are no other programs that do what we do," he says. "Nobody else meets someone from the prison gate and walks them out of the gate and tries to help set them up."

The re-entry program is an HIV prevention program in a much broader context, Fisher notes.

"It combines all of those skills-building and positive things in their lives, which we see as prevention tools," she adds.

The New York re-entry program represents a good model of prison discharge planning, but it is unique, Baillargeon notes.

"The vast majority of prison systems in the United States would probably have results comparable to ours," he says. "This is a big public health issue because we have a large concentration of HIV-infected persons who move through the correctional system in the United States."

Since HIV infection is over-represented in this population, correctional settings represent an opportunity to screen and educate this group, he adds.

"This is an opportunity we don't want to squander," Baillargeon says. "The fact that we are able to identify and treat these people in prison is a good thing, and the next step is to present good discharge planning."

Reference

1. Baillargeon J, Giordano TP, Rich JD, et al. Accessing antiretroviral therapy following release from prison. *JAMA*. 2009;301(8):848-857. ■

Most HIV-infected inmates are eligible for ART

Connecting with medication right away [is the] problem

A new study with surprising results about the low percentage of HIV-infected inmates accessing antiretroviral therapy (ART) post-release could be seen as a model for following this population.

"We knew there was a problem where a lot of inmates returned to prison with higher viral loads and t-cell counts than they had when they left, but there was nothing in the literature that showed the actual rates of linkage to care among HIV-infected inmates," says **Jacques G. Baillargeon**, PhD, an associate professor of epidemiology in the department of preventive medicine and community

health at the University of Texas Medical Branch in Galveston, TX.

"We looked at all the [HIV-infected] inmates released over this four-year period," Baillargeon says. "And we know the vast majority of inmates at the time of release don't have access to health insurance, private health insurance." So it was safe for investigators to assume that no one had an alternative source of care within the first couple of months of their release from prison, he adds.

In fact, about 99% of HIV-infected inmates are eligible for ART through the AIDS Drug Assistance Program (ADAP), says **Dwayne R. Haught**, MSN, RN, manager of the HIV medication program, which is an AIDS Drug Assistance Program (ADAP) and part of the Texas Department of State Health Services in Austin, TX.

All of the Texas inmates infected with HIV were released with a 10-day supply of medications, so investigators used ADAP records to see whether they had access to ART within 10 days, when their supply would end, or at 30 days or at 60 days post-release.[1]

The study found that only 30% of HIV-infected inmates received ART within 60 days. It also found that inmates with an undetectable viral load upon release were more likely to fill a prescription within 10, 30, and 60 days.[1]

And inmates who were helped in filling out a Texas ADAP application were more likely to fill a prescription within the same time period. About 55% of the inmates studied received ADAP assistance. Inmates who were in prison for more than a year and those released on parole were more likely to have received the assistance.[1]

Also, older inmates were more likely to have filled an antiretroviral prescription within 60 days than were inmates under age 30.[1]

Texas ADAP workers assisted investigators as they obtained the data and were interested in the results, Baillargeon says.

The study highlights some gaps in ADAP that need to be filled, Haught says.

"It's connecting with medication right away that's a problem," Haught notes.

"We have a pre-discharge application," he adds. "But what happens is when people are incarcerated and released the application has an address that they don't necessarily go back to, so we need to verify the information."

Build the bridge

Rather than have discharged inmates wait for days or weeks to receive final approval and their medications, the key is to prescribe ART through a bridge program, Haught suggests.

Everyone in HIV and public health care should be concerned about the ART gap in re-entry of inmates because of the high risk of these infected individuals transmitting HIV to others in the community, Baillargeon says.

"A lot of people have recognized that this initial month or two is a critical time for inmates," Baillargeon says. "Many are likely to be vulnerable to engaging in high-risk behaviors, and when they're not accessing medications they can develop HIV drug resistance and as a result be even more contagious."

The next step in this research is to find out why inmates re-entering the community do not access HIV care, he says.

"What socio-behavioral factors are at work here, and what is the timeline for that?" he says. "What happens during that first week, second week, and third week that might explain why they aren't getting their ADAP application done?"

Further research is needed to inform interventions aimed at this population.

"We want to get in and figure out what's happening," Baillargeon says. "That's the way we'll ultimately be able to develop effective intervention strategies for discharge planning."

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1. Baillargeon J, Giordano TP, Rich JD, et al. Accessing antiretroviral therapy following release from prison. *JAMA*. 2009;301(8):848-857. ■

Clinician's Corner

Researchers weigh continuing benefits of having HIV specialists

Coordinated system of care best option

HIV care in industrialized nations might best be served by a coordinated system of care that includes a general practitioner working with an HIV clinic, research suggests.

A recent study shows that initial HIV treat-

ment once was complex and varied, but now is largely homogenous.[1]

This is good news from a clinical perspective because it suggests that HIV clinicians and specialists could devote more of their time to the complex cases of patients who have received treatment and now are experiencing treatment failures. Or they could focus on patients with complex comorbidities.

The simpler regimens needed by most new patients could be handled by general practitioners, who are working with HIV clinics, a researcher suggests.

There are two major clinical trends in HIV treatment, and the first is the increase in patients needing help from HIV clinics, says **James Alexander McKinnell**, MD, a fellow in infectious diseases at the University of Alabama at Birmingham, AL.

"If you look at currently-funded Ryan White clinics, they're running at capacity, and there's not much room for these clinics to grow and expand," McKinnell says. "They're experiencing a crisis in maintaining an HIV workforce."

The second trend is that HIV clinicians are doing very well with HIV care and treatment, helping patients live longer than once imagined possible.

Antiretroviral therapy (ART) might have reached its state-of-the-art moment.

For many HIV patients, HIV disease is not necessarily their primary concern. Their issues might be blood pressure and cardiovascular disease, McKinnell says.

"Up until 2002, ART regimens were very complicated," McKinnell says. "By comparison, now the guidelines are more simplified, and there's becoming a standard of care."

Although no one has formally said there is a standard of care model, McKinnell and co-investigators have found that this is what HIV clinical practice suggests.

"The purpose of our study was to look at how regimen selection has changed over time," McKinnell says. "What regimens do we use for initial therapy in each calendar year?"

Researchers found that this has changed dramatically in the past decade.

From 2000 to 2006, the number of unique initial regimens ranged from 10 to 16. Then there was a precipitous drop in 2007, and since then the number of unique initial regimens has been two to four. The number of regimens used in initial therapy ranged from 15 to 25 and then dropped to six in 2007.

"In 2003-2004, there were a whole bunch of regimens used, and HIV care was very complicated," McKinnell says. "In 2007, more than 90% of patients were started on one of two regimens."

So over the past few years, providers and patients have developed a preference for what they think is a good initial therapy, McKinnell says.

"I looked at the number of initial regimens used to treat 100 naïve patients, allowing for comparison from year to year," McKinnell says. "If I look from 2000 to roughly 2005, that number ranges from 15 to 25 regimens per 100 patients."

Then in 2007, the number dropped down to six, suggesting that variability has decreased, McKinnell says.

"People are becoming more homogeneous in what they're using in regimens," he adds. **(See story on how ART prescription patterns have changed, p. 78.)**

"For decades we've been approaching HIV patients with the mindset of 'We're going to try to take care of the patient, and we'll try to do everything for the patient,'" McKinnell says.

"At most HIV clinics, we're really adept at handling psychiatric issues, social issues, and a coordinated comprehensive model of care, and that's how we handle it," he explains. "When you look at other diseases like diabetes you find that the quality of care model [most often employed] is inferior to the HIV one where someone is coordinating everything."

So it's worked well to have a health care team that includes social workers, psychologists, case managers, and others work with HIV patients, who primarily are treated by HIV or infectious diseases specialists.

But for people receiving initial HIV treatment, the specialist's role might be augmented by a general practitioner who could assess the patient's whole health picture at each visit.

The HIV prescribing patterns research would suggest that the HIV treatment model would benefit from the inclusion of general practitioners, McKinnell says.

A general practitioner who works with an HIV or infectious diseases specialist would provide more holistic care.

"We utilize general medical specialists in our system [at the University of Alabama at Birmingham HIV clinic]," McKinnell says. "The primary care is a group process; if I recognize that my patient has diabetes, then a diabetic consultant will come in and get involved."

McKinnell is the one responsible for making sure all of the necessary medical care is provided.

Under Ryan White Care Act funding, the HIV physician needs to be at the center of the care model, he notes.

"This is great because Ryan White allows for all of the needs of the HIV patient, including social work, pharmacy, mental health, and drug abuse counseling," McKinnell says.

"Ryan White allows my clinic to provide coordinated care to these patients, and without that funding, we couldn't afford to do that," he adds. "It encourages a coordinated care system."

Transferring new HIV patients to community physicians probably would be a big mistake, McKinnell says.

"It's easy to say we should have general practitioners choose the initial regimen and go from there," he explains. "But although it's an easy solution, it's not very viable."

If HIV clinics send the overflow of patients to primary care clinics, then the primary care clinics won't have the funding to make decisions on subsequent ART regimens, McKinnell says.

"But we would love their help in managing patients," he says. "If you have a primary care provider and an infectious diseases provider working together on a patient, then you get the best of both worlds: good virological control, good cardiovascular care, and general internal medical care."

This coordinated system of care is the ideal model, McKinnell says.

Reference

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ART prescribing patterns evolve over past decade

Research, experience have winnowed down choices

Research has found that combination antiretroviral therapies and studies showing superior benefits of some drugs over others have led to wide acceptance in recent years for two initial therapy regimens.

Three to 10 years ago, there were more than a dozen initial therapies prescribed by HIV clinicians. Now there are two.[1]

One of the chief factors in the change is the success of combination medications, and especially the success of one particular combination: emtricitabine (Emtriva®)/tenofovir (Viread®), which is called Truvada®, says **James Alexander McKinnell**, MD, a fellow in infectious diseases at the University of Alabama at Birmingham, AL.

For a short period, another drug combining lamivudine and zidovudine, called Combivir® was widely prescribed, he notes.

"Some studies have compared Truvada with Combivir, and patients on Truvada did better," McKinnell explains. "Those results were published in 2004, and if you look at our study's treatment share graph, you will see HIV physicians stopped prescribing Combivir after that."

Combivir had been one of the most popular combination drugs, and in a couple of years it was gone, McKinnell says.

The study's chief limitation is that many of the ART regimens were crafted before resistance testing was widely available, McKinnell says.

"We could not measure the impact of resistance of ART in my study," he says. "But the vast majority of patients do not have much resistance."

McKinnell and co-investigators took their analysis one step further, looking at what happened to HIV patients after they began the initial ART. They looked at how many patients changed regimens and what happened after they changed.

The study found that many patients started on initial therapy soon need to have their ARTs changed, and the medications used in the second-line treatment varied widely.

Patients with stable initial treatment, but many other medical issues, could benefit from care by a general practitioner, in addition to their care at an HIV clinic, he adds.

"We found very quickly that many needed to change therapy because of side effects or virological failure," he says. "We found that the simplification of the first regimen doesn't continue."

For instance, if a patient was started on a lamivudine/zidovudine combination medication that began to fail, then they were not necessarily switched to the emtricitabine/tenofovir combination pill, McKinnell says.

"There was tremendous variability there, and we looked across a whole spectrum of patients,"

he adds. "Forty-three percent of patients needed a second regimen over the course of the 2000 to 2007 time period of the study."

Reference

1. McKinnell JA, Willig JH, Westfall AO, et al. Contemporary antiretroviral therapy: Is it time for the generalist to return? Poster presented at the 48th Annual ICAAC/IDSA 46th Annual Meeting, held Oct. 25-28, 2008, in Washington, DC. Poster:H-1260. ■

2nd generation female condom OK'd by FDA

Campaign to kick off in 9-city push

Female-controlled HIV prevention options are set to expand with the Food and Drug Administration (FDA) March 2009 approval of the second generation of the female condom manufactured by the Female Health Co. With the introduction of a new proprietary nitrile material and a less labor-intensive manufacturing process, the company will be able to offer the condom, known as the FC2, at a public health sector cost some 30% less than the original FC1 polyurethane condom.

Robert Hatcher, MD, MPH, professor of obstetrics and gynecology at Emory University in Atlanta, points to these key points about the FC2 condom:

It is a source of female-controlled protection. "In Africa, 70% of women who become infected with the HIV virus are infected by their husbands, who in many instances refuse to use male condoms," notes Hatcher.

The FC2 is less noisy than the polyurethane FC1 female condom,[1] which may lead more women to use it.

While the importance of an effective vaccine against AIDS and an effective vaginal microbicide cannot be denied, both are several years from being available.

"Given the deplorable resistance of so many men to male condoms, the new female condom may be the best thing we have to offer women for the prevention of AIDS and other infections for the next 10 years," says Hatcher.

Look for Female Health Co. to make an announcement in early summer 2009 regarding public sector product availability and ordering information, says **Mary Ann Leeper**, PhD, the company's senior strategic adviser. Family planning agencies and health departments will be able to place orders directly with the company, rather than through a distributor, she reports. This move will enhance cost savings for agencies, Leeper explains.

The company will launch a nine-city campaign in early September to promote the public sector availability of the new condom, says Leeper. The campaign will target health departments, nonprofit community-based organizations, and nongovernmental organizations in Washington, DC; Chicago; Philadelphia; Atlanta; Houston; Miami; Baltimore; Los Angeles; and San Francisco, she states.

The campaign will include training based on New York City's successful female condom program. The city Department of Health and Mental Hygiene's female condom distribution program increased its allocation from 2006 to 2007 by 200,000 female condoms due to popularity of the program.[2] In 2008, the department placed a contract to purchase 2 million female condoms to be distributed free of charge through health clinics and organizations across the city as part of its efforts to increase HIV prevention. Local public health officials estimate heterosexual transmission accounts for 92% of new HIV cases among women in the city.[2]

With the FDA approval now in hand, the U.S. Agency for International Development now can procure the second-generation female condom for U.S.-supported HIV/AIDS prevention and family planning programs around the world. To handle increased demand, the Female Health Co. plans to install six more production lines for the FC2 and increase its production capacity from 30 million units to about 75 million to 80 million units.

Health advocates also have launched a global campaign, Prevention Now!, to demand increased access to the female condom in communities heavily affected by HIV/AIDS. While public health programs around the world distribute 11 billion male condoms every year, 26 million female condoms were distributed in 2007, health advocates estimate.[3]

While female condoms may be a powerful tool in preventing transmission of sexually transmitted diseases (STDs), women need education in order to use them effectively. Results from a recent study indicate that skills training can increase female condom use and the overall level of protected sexual acts.[4]

The public sector will serve as the initial U.S. access point for the FC2 condom as the Female Health Co. searches for a retail partner. According to Leeper, the company is in talks with male condom companies, as well as pharmaceutical companies involved in over-the-counter female health products, to find the best fit for increased access for the FC2 condom. The company is searching for a business that is committed to women and will push to make the FC2 available to them, she says.

"Our whole focus is empowerment of women, and we want someone who is committed to do that," states Leeper.

Once a retail partner is found, marketing plans will be developed and distribution lines put in place, she says. She estimates it might be spring 2010 before the FC2 is available on U.S. retail pharmacy shelves.

The Program for Appropriate Technology in Health (PATH) is continuing its research of a female condom. The agency began research in 1996 to develop a woman's condom tailored to the needs of the women in the developing world, with support from the U.S. Agency for International Development, the Bill & Melinda Gates Foundation, and other donors. More than 50 prototypes were examined, with field testing performed in Mexico, South Africa, and Thailand. PATH entered a collaborative agreement in July 2008 with Chinese manufacturer Shanghai Dahua Medical Apparatus Co. to manufacture the condom.

The Woman's Condom (WC) is a 9-inch thin, pliable plastic pouch that conforms to the shape of the vagina. It has a flexible soft outer ring designed to protect the external genitalia, with four oblong foam pieces on the outside of the pouch that are engineered to cling lightly to vaginal walls, which ensures device stability. The distal end of the pouch and foam pieces are packaged into a capsule that serves as an insertion aid; it dissolves quickly when inserted into the vagina.[5]

In a randomized crossover study designed to evaluate the functional performance, safety, and acceptability of the FC1 and the WC, 75 couples were assigned to one of two condom use sequences (WC/FC1 or FC1/WC) at centers at the University of Pennsylvania Medical Center, University of Pittsburgh/Magee Womens Research Institute, and Advances in Health. Four condoms of the first type were used by couples during sex over a two- to four-week period. After a follow-up visit, these procedures were repeated with the second assigned condom type. In a substudy of 25 participants, a colposcopy was performed prior and subsequent to the first condom use of each of the two condom types.

Researchers evaluated condom performance by calculating measures of function from questionnaires completed by the couple after each condom use. Safety was evaluated by reported urogenital symptoms with a given condom during or immediately following condom use and colposcopic signs of genital irritation in the substudy.

Total condom failure (slippage, breakage, etc., divided by the number of female condoms opened) was 31% for the WC and 42% for the FC1; total clinical failure (slippage, breakage, etc., divided by the number of female condoms used) was 17% for the WC and 24% for the FC1. The proportion of condom failures was 10.9% points less, and the proportion of clinical failure 6.7% points less, when couples used the WC compared to the FC1 (90% confidence interval: -18.5 to -3.3 and -12.6 to -0.8, respectively).

Findings indicate that fewer women reported symptoms or signs of urogenital irritation when using the WC. Among participants with a preference, the WC was preferred over the FC1 by twice as many males and by 2.6 times as many females.5 The WC is ready for a combined Phase 2/3 clinical trial, say PATH officials.

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ABSTRACT & COMMENTARY

Guidelines: Opportunistic infections and HIV patients

By **Dean L. Winslow**, MD, FACP, FIDSA, Chief, Division of AIDS Medicine, Santa Clara Valley Medical Center; Clinical Professor, Stanford University, School of Medicine

Synopsis: The U.S. Department of Health and Human Services (HHS) has updated their guidelines for the prevention and treatment of opportunistic infections (OIs) in HIV-infected adults and adolescents, effective March 24, 2009.

Source: http://www.cdc.gov/mmwr/pdf/rr/rr58e324.pdf

These guidelines were last updated for adults in 2002 and for adolescents in 2004. The document (available in pdf format through the link above) is a 209-page file containing 1,391 references which update current recommendations for the prophylaxis and treatment of HIV-related OIs. As with most guidelines published in recent years by professional societies, a well-qualified expert panel has thoroughly reviewed both new and old data and has developed a relatively comprehensive document which will be of use to physicians who treat complicated HIV patients. An attempt has been made to qualify recommendations with both the strength and quality of evidence supporting each recommendation. Obviously, it is not possible to summarize the entire document, but six major changes from previous iterations of the OI guidelines stand out in the March 24, 2009 guidelines:

Emphasis is placed on the importance of antiretrovirals for the prevention and treatment of OIs, especially for those diseases in which specific antimicrobial treatment is minimally effective.[1]

Guidance on the diagnosis and management of immune reconstitution/inflammatory syndrome (IRIS) complicating specific OIs is given.

Recommendations on the use of interferon gamma release assays (IGRAs) for the diagnosis of latent tuberculosis infection (LTBI) are made.[2] (At this point IGRAs are considered to be more specific than tuberculin skin testing for the diagnosis of LTBI, especially in HIV patients who may have received BCG or have been exposed to other mycobacteria. However, they are no more sensitive than tuberculin skin testing, especially in HIV patients with more severe immunosuppression.)

More specific recommendations are made concerning drug/drug interactions, particularly surrounding the use of rifamycins concomitantly with antiretroviral therapy.

Detailed recommendations are made regarding the treatment of hepatitis B virus/HIV co-infected patients, including the recommendation to avoid HBV antiviral monotherapy with agents such as entecavir due to the risk of selecting M184V HIV reverse transcriptase substitutions.[3]

A section on the bi-directional effects of malaria and HIV co-infection has been added, which is of great significance in the developing world where both of these infections are endemic.

Lastly, it was interesting to note that these latest guidelines contain a well-reasoned discussion regarding the controversies surrounding routine screening for HPV-related anal intraepithelial neoplasia in men who have sex with men.[4,5]

This latest update to the OI guidelines is an important document which will be of value to all physicians who treat HIV-infected patients.

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4. CDC. Workowski KA, Berman SM: Sexually transmitted diseases treatment guidelines. *MMWR*. 2006;55:(No. RR-11).

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FDA Notifications

Generic lamivudine/ zidovudine approved

On May 29, 2009, the Food and Drug Administration (FDA) granted tentative approval for generic lamivudine/zidovudine tablets 150 mg/300 mg indicated for treatment for Human Immunodeficiency Virus (HIV) in patients with or without Acquired Immunodeficiency Syndrome (AIDS).

Tentative approval means that FDA has concluded that a drug product has met all of the required quality, safety and efficacy standards, but that it cannot be marketed in the U.S. due to existing patents rights. However, tentative approval makes the product eligible to be considered for purchase under the President's Emergency Plan for AIDS Relief (PEPFAR) program. Existing patent information is available in the FDA Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations.

The FDA conducts an on-site inspection of each manufacturing facility and of the facilities performing the bioequivalence studies prior to granting approval or tentative approval of these applications to evaluate the ability of the manufacturer to produce a quality product and to assess the quality of the bioequivalence data supporting the application.

A list of all Approved and Tentatively Approved Antiretrovirals in Association with the President's Emergency Plan can be found on the FDA website.

The lamivudine/zidovudine fixed dose combination tablets are a version of the FDA approved Combivir tablets manufactured by GlaxoSmithKline. ■

Testosterone gel must include warning for kids

The Food and Drug Administration is requiring manufacturers of two prescription topical testosterone gel products, AndroGel® 1% and Testim® 1%, to include a boxed warning on the products' labels after receiving reports of adverse effects in children who were inadvertently exposed to testosterone through contact with a person being treated with these products (secondary exposure).

The gels are approved for use in men who either no longer produce testosterone or produce it in very low amounts, and are often used by men living with HIV who have below normal testosterone levels.

Although the Precautions in the current labels instruct users to wash their hands after using the product and to cover the treated skin with clothing, FDA has received reports of secondary exposure to testosterone in children ranging in age from nine months to five years. In most of the cases, users of these products failed to follow appropriate use instructions, resulting in direct contact between treated skin and the child.

Adverse events reported in these children included inappropriate enlargement of the genitalia (penis or clitoris), premature development of pubic hair, advanced bone age, increased libido, and aggressive behavior. In most cases, the signs and symptoms regressed when the child no longer was exposed to the product. In some cases, however, enlarged genitalia did not fully return to age-appropriate size and bone age remained modestly greater than the child's chronological age. In some cases, invasive diagnostic procedures were required.

Signs of inappropriate virilization (development of male secondary sexual characteristics) in children and the possibility of secondary testosterone exposure should be brought to a health care provider's attention.

The required label changes will provide additional information about the risk of secondary exposure and the steps that should be taken to reduce this risk. The FDA also is requiring that the manufacturers of these products develop a Medication Guide as part of a Risk Evaluation and Mitigation Strategy to ensure that the benefits of these products continue to outweigh their potential risks. The FDA recommends the following precautions be taken to minimize the potential for secondary exposure:

- Adults who use testosterone gels should wash their hands with soap and warm water after every application;
- Adults should cover the application site with clothing once the gel has dried;
- Adults should wash the application site thoroughly with soap and warm water prior to any situation where skin-to-skin contact with another person is anticipated;

• Children and women should avoid contact with testosterone application sites on the skin of men who use these products; and

• Adults should note that use of any similar, but unapproved, products from the marketplace –including the Internet– that can result in the same serious adverse effects should be avoided.

Health care professionals and consumers may report serious adverse events (side effects) or product quality problems with the use of these gels to the FDA's MedWatch Adverse Event Reporting program: Online: www.fda.gov/

MedWatch/report.htm or by fax at (800) FDA-0178 or telephone at (800) FDA-1088 or by regular mail: use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm and mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787.AndroGel 1% is manufactured by Marietta, Ga.-based Solvay Pharmaceuticals. Testim 1% is made by Auxilium Pharmaceuticals, Malvern, PA. ■

Lamivudine/zidovudine tab tentatively approved

On May 7, 2009, using expedited review procedures developed to support the President's Emergency Program For AIDS Relief (PEPFAR), FDA granted tentative approval for lamivudine/zidovudine fixed dose combination tablets, 150 mg/300 mg, co-packaged with nevirapine tablets, 200 mg. The product, indicated for use alone as a complete regimen, or in combination with other antiretroviral agents for the treatment of HIV-1 infection, is manufactured by Hetero Drugs Limited of Hyberdad, India. Both lamivudine and zidovudine are members of the Nucleoside Reverse Transcriptase Inhibitor (NRTI) class of antivirals. Nevirapine is a Nonnucleoside Reverse Transcriptase Inhibitor (NNRTI).

Fixed dose combination and co-packaged products such as this can help ease pill burden and simplify therapy, and may help increase adherence to

CNE/CME *questions*

1. A new study of Texas inmates with HIV found that 60 days after they re-entered the community what% had obtained prescriptions for the antiretroviral drugs they had been taking while in prison?
   A. 5%
   B. 17%
   C. 30%
   D. 62%

2. AIDS Drug Assistance Program (ADAP) officials in Texas estimate what percentage of inmates re-entering the community are eligible for ADAP medication?
   A. 41%
   B. 65%
   C. 78%
   D. 99%

3. A new study shows how initial antiretroviral therapy (ART) has changed over time. From 2000 to 2006 there were more than 10 initial therapies prescribed by HIV clinicians. How many initial therapies were prescribed by 2007?
   A. 2
   B. 5
   C. 8
   D. 9

4. What is one of the chief reasons why initial antiretroviral therapies have become more homogenous?
   A. There are fewer efficacious ARTs on the market now
   B. The combination drug lamivudine and zidovudine called Combivir has taken over the initial ART market
   C. Patients responding to marketing messages request the same types of initial therapies
   D. Emtricitabine and tenofovir combination drug called Truvada has been very successful and popular with patients and physicians and is the medication of choice for initial HIV treatment

Answers: 1. C; 2. D; 3. A; 4. D.

COMING IN FUTURE MONTHS

- ■ Study shows increased HIV risk with HPV
- ■ ART adherence at risk with pot smoking
- ■ New poll highlights HIV stigma in 2009
- ■ Meeting ex-inmates basic needs helps with prevention work

therapeutic regimens, potentially reducing development of resistance to the separate drugs. ■

Many young, black MSM unaware of HIV positivity

More likely to become infected at younger age

The alarming number of young HIV-infected men who have sex with (MSM) who do not know they are infected is driving transmission in this disproportionately emerging population in the AIDS epidemic, the Centers for Disease Control and Prevention reports. In one recent study, 77% of young, urban MSM aged 15–29 who tested HIV-positive as part of the study mistakenly believed they were not infected, the CDC reports in a recently posted fact sheet on young MSM. The percentage was even higher for young black HIV-infected MSM, 90% of whom did not know their infection status. Obviously, people who do not know they are infected might be less likely to take measures to keep from spreading the virus to others.

As a result, the burden of HIV infection falls disproportionately on certain groups of young people, including young men who have sex with men (YMSM) and youth of color. ■

CNE/CME objectives

The CNE/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.