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Community MRSA infections rising in people with HIV/AIDS

'It's an alarming trend because these strains are very hardy.'

Community-associated methicillin-resistant *Staphylococcus aureus* (CA-MRSA) infection has become a growing problem in HIV/AIDS patients, clinicians and researchers report.

"This is definitely an emerging phenomenon with community-acquired MRSA," says **Tony Trinh**, MD, an internal medicine resident at the Warren Alpert Medical School of Brown University and Rhode Island Hospital in Providence, RI.

"It's emerging in the general population and in the HIV population," Trinh adds. "It's an alarming trend because these strains are very hardy, and they obviously tend to go in circles and groups of people who are at high risk."

Also, CA-MRSA can be life-threatening if it migrates to the blood stream or causes pneumonia, he says.

Research also has shown a statistical association between HIV and CA-MRSA among an HIV population investigators studied in Chicago, IL, says **Kyle Popovich**, MD, an infectious diseases physician at the Rush University Medical Center in Chicago.

According to published studies, CA-MRSA infections are being observed nationally, in particular with skin and soft tissue infections, in outpatient clinics and emergency rooms, Popovich says.

"So while our study looked at this HIV population, what we saw is going along with what's in the literature for the United States," she says.

A 2007 study found that CA-MRSA rates have increased significantly among HIV-infected population since 2003. The incidence was 40.3 cases/1000 person-years in 2005, an 18-fold higher than general population incidence among the population served at a large HIV clinic in Bethesda, MD.[1]

The same study found that 90% of the CA-MRSA infections were skin and soft-tissue infections, and 21% of patients experienced a recurrent infection.

Other affected populations

CA-MRSA infections have emerged nationally among children, athletes, prisoners, and military personnel, Popovich notes. Close proximity and shared items have been cited as among the likely reasons.

"It's unclear why certain populations are being affected, and now we're seeing community-acquired MRSA even among people who are not part of these populations, so it's spreading," she says.

"The recent growth of CA-MRSA cases has been higher among HIV-positive individuals than among HIV-negative individuals in the population we examined," she adds.

Trinh's research has observed that CA-MRSA patients often present with skin and soft-tissue infections. The key is for HIV clinicians to maintain a high level of suspicion of possible CA-MRSA when their patients have skin infections, he says.

"If you drain an abscess, send it to culture, then you'll know what kind of strain it is, and it's easy to identify from the microbiological standpoint," Trinh says. "From the clinical standpoint, patients show up with these abscesses and are not comfortable because these are painful."

Popovich and co-investigators reviewed cases and found that HIV patients with CA-MRSA and skin and soft-tissue infections were often seen in outpatient clinics and emergency rooms.

"Studies have shown that skin and soft-tissue infections in some ERs are very common," Popovich says.

Among the HIV patients that were hospitalized with CA-MRSA skin and soft-tissue infection, the study population was predominantly African American and male. More than 80% were black, and 72% were men, and the mean age was around 40 years. Other common characteristics included a history of illicit drug use among 61% and men who have sex with men (MSM) among 22%.[2]

"We looked at people who were hospitalized, and we looked at intensive care unit admission," Popovich says. "We focused on skin and soft tissue infections, but didn't look at bloodstream infections."

The MRSA strain is particularly adapted to skin and soft-tissue infections, Trinh notes.

Treatment options

Patients with CA-MRSA skin and soft-tissue infections can be treated on an outpatient basis with trimethoprim-sulfamethoxazole or tetracycline. In Trinh's study, antibiotic susceptibility was high with these two medications at 96.5% for tetracycline and 95.2% for trimethoprim-sulfa-

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methoxazole.[3]

Although CA-MRSA has virtually no resistance to vancomycin and rifampin, these drugs aren't good candidates for first-line treatment because they would need to be administered in an intravenous form that is expensive and would require an inpatient setting, Trinh says.

Treatment also includes incision and drainage, which can be done by surgeons or by physicians in primary care or HIV clinics.

The key is following the principle of having adequate source control and treating abscesses that are larger than three or four centimeters, Trinh says.

In another study there was a high rate of recurrence of CA-MRSA among HIV patients, particularly in a population seen at the Naval Medical Center San Diego between 2000 and 2007. The population was almost entirely male, predominantly Caucasian (58%), followed by Hispanics (23%), and African Americans (16%).[4]

Popovich's study also found a statistical association of having a high CA-MRSA infection rate in communities with high rates of prison exposure, Popovich says.

"We don't know what that means, and we need to research further to tease that out," she adds.

What makes the skin and soft-tissue CA-MRSA cases different is that traditionally MRSA has emerged in health care facilities as an infection that is acquired in hospital settings, Popovich says.

HIV-infected patients have a high incidence of CA-MRSA skin and soft-tissue infections, according to another U.S. study.[5] A retrospective review of 900 HIV-infected outpatients from January, 2002, to December, 2007, showed that 8% were colonized or infected with MRSA.

The same research concluded that HIV-infected patients at significant risk for MRSA were those who had a CD4 cell count of less than 200 cells and who had antibiotic exposure. Patients who had been on antiretrovirals for the previous year had a significantly reduced risk of MRSA colonization.

Trinh's study concluded that most patients with CA-MRSA did not have immunological/virological markers consistent with severe HIV/AIDS disease. HIV and CA-MRSA have an intriguing relationship, Trinh says.

While Trinh's research did not show a relationship between AIDS-defining illness and CA-MRSA infection, there definitely is an immune deficiency related aspect to why HIV patients are presenting with these soft-tissue infections, Trinh explains.

"It's not wholeheartedly explained by immune deficiencies that come with HIV, but these are alluding to possible processes that are not well-defined yet," he adds.

Another new study found that CA-MRSA is prevalent in wounds of injection drug users (IDUs), which potentially could be a factor in the rising rate of CA-MRSA among an HIV population and in some other groups. The study sampled 218 people from a community-recruited cohort of IDUs at a supervised injection facility and found that 27% had at least one wound and 43% of these wounds were positive for *S. aureus*, of which more than half were MRSA.[6]

The skin and soft-tissue manifestation of CA-MRSA can be treated in outpatient settings, but there are cases where it causes more invasive disease and enters the bloodstream, she adds.

For HIV clinicians the take-home message is to continue good infection disease control practices, such as washing hands with soap and water between each patient, and teaching patients to practice better hygiene at home.

"If an HIV patient has a wound or scrape, he or she should keep it covered," Popovich says. "If they're changing family members' bandages, they should wash hands and avoid contact with wounds or bandages, and avoid sharing personal items."

Diagnosing the infection can be fairly straightforward. Patients may notice a mark on their skin that looks like a spider bite, she says.

"Typically, it's described as an area of the skin that's warm and inflamed," Popovich says.

"In some areas, there is an increased awareness of the CA-MRSA epidemic," she adds. "However, education on proper infection control practices and prevention measures is still needed."

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Federal funding climbs for HIV/AIDS

But is it too little, too late?

The good news is that HIV advocacy groups, clinicians, and others haven't seen so many HIV/AIDS program federal budget increases since the 1990s. The bad news is that it might be too little, too late in a recessionary environment in which state budgets are forcing draconian cuts.

The AIDS Budget and Appropriations Coalition shows in its compiled chart of HIV/AIDS and related program funding for fiscal years 2009, 2010, and proposed for 2011 that most sections have had increases. *(See AIDS Budget and Appropriations Coalition FY2011 appropriations chart, p. 67.)*

These additional federal dollars for HIV/AIDS treatment and prevention funding are a positive change from budgets in the past decade when programs mostly were cut or flat-funded.

"We're overall encouraged with the president's FY2011 proposed budget when there was much talk of domestic funding being frozen," says **Ronald Johnson**, deputy executive director of AIDS Action Council of Washington, DC.

"In the context of a very tight budgetary situation, especially when it comes to discretionary domestic spending, we did see a demonstration of the president's commitment to the HIV/AIDS agenda," Johnson adds. *(See story about good news in federal HIV/AIDS budget, p. 65.)*

But with state funding for HIV/AIDS programs being slashed dramatically, there remain big problems.

For example, the state of South Carolina has rolled back its funding for AIDS Drug Assistance Programs (ADAPs) to the point that 900 HIV-infected patients are being disenrolled from the program, says **William E. Arnold**, director of T11 CANN (Community Access National Network) in Washington, DC.

According to a "Dear Provider" letter the South Carolina Department of Health and Environmental Control (DHEC) sent on April 27, 2010, the state's ADAP waiting list has 57 patients, but an additional 900 active patients will be removed from the program by Sept. 1, 2010, unless the state receives additional funding.

South Carolina's ADAP served 2,100 patients per month in 2009, a nearly 15% increase from 2008. Meantime, the state's base funding was cut 3%, and its supplemental funding was cut 21%.

"State funds will likely be cut by over 51%," the SCDHEC provider letter states.

And that number is not yet reflected in the national ADAP waiting list which has grown to 1,001 people in 10 states, as of May, 2010.

Also, ADAP client enrollment has increased at unprecedented numbers in recent years with an average increase of 1,554 new clients per month in FY2008, according to the National ADAP Monitoring Project Annual Report of May, 2010. The report is published by the National Alliance of State and Territorial AIDS Directors (NASTAD) in Washington, DC.

The national ADAP budget was $1.59 billion in FY2009, a 4% increase from FY2008, but the state funding contributions decreased by 34%, the annual report notes.

"This marks the lowest state funding contribution to ADAPs since 2003 and exemplifies the severity of state fiscal crises nationwide," the report says.

President Barack Obama's proposed budget for FY2011 proposes a $20 million increase to ADAP spending. This amount is inadequate to meet the need, but AIDS groups are more alarmed by today's ADAP funding crisis.

"We're all focused on getting emergency supplemental money for fiscal year 2010," Arnold says.

The main issue is that ADAPs depend a great deal on state funding. But the state money well is dry as state legislatures are forcing across-the-board budget cuts in efforts to balance budgets, as is required by law in many states. At the same time tax revenues have plummeted.

So states have cut back on many of the gains they've made in the past decade in funding ADAPs. For instance, Kentucky has pulled out all of its

state ADAP funding, and the result is having 200 people on its waiting list, Arnold says.

North Carolina is coping with state ADAP cuts at a time when the state is seeing increasing numbers of HIV cases and greater ADAP need, he adds.

"The epidemic is expanding in North Carolina more than the current distribution system is making an allowance for," Arnold says.

The result is a North Carolina ADAP waiting list that is the nation's largest at close to 500 people.

Appearance and reality

Plus there are a number of states that choose to avoid the bad local publicity associated with ADAP waiting lists, and instead are making ADAP eligibility and other changes that eliminate funding. Although they effectively are cutting people from their ADAP roles, they avoid the transparency of waiting lists by saying these clients no longer are eligible to receive antiretroviral treatment through ADAPs.

"About two months ago, Louisiana stopped taking any new ADAP clients," Arnold says. "People are filling out ADAP forms, but they're not being accepted into the program, and the state's governor is not allowing Louisiana to maintain a waiting list."

In Utah, state officials made the eligibility criteria more stringent for ADAP, and this cut drugs for an unknown number of people, he adds.

"They say these people are not eligible, so of course they're not on the ADAP waiting list," Arnold says.

HIV/AIDS advocates and treatment groups have sent an emergency request for $126 million in ADAP funding in an April 29, 2010 letter to President Barack Obama, asking for supplemental funding to prevent state ADAPs from collapsing under the weight of increased need, reduced state funding.

"ADAP continues to be a crisis situation in so many states," Johnson says. "It's compounded by the budget crisis that states themselves are experiencing and that minimizes their ability to augment their ADAP budgets."

The HIV/AIDS advocacy letter for emergency ADAP funding says states made $167 million in budget cuts to AIDS programs in 2009. The state cuts have had a bigger impact than they would have a decade ago because the federal government's percentage of ADAP expenditures has dropped from 72% in 2000 to 51% in 2009, the letter states.

"This staggering drop in the federal commitment to ADAP in addition to state budget crises has largely been the catalyst for the most recent spike in HIV wait lists," the letter says.

The letter to the president also makes the point that 74% of the people on an ADAP waiting list are in Southern states and that half of the people served by ADAP have annual incomes of below the federal poverty level.

"The currently proposed $20 million increase in appropriation for FY2011 will only be enough to cover 2,307 people, not enough resources to allow Ryan White to continue to act as a safety net for those already in the program and on wait lists, let alone the steadily growing need," the letter states.

"While we expect implemented health reform to provide significant relief to ADAP we must do everything we can to keep the 1-2 million HIV positive Americans alive, working, and well until health reforms are in place in the coming years," the letter says. ■

HIV/AIDS funding aligns with advocacy goals

Abstinence funding is out; needle exchange is in

The final version of the federal HIV/AIDS program budget for fiscal year 2010 is about as close to what AIDS advocates have wanted as they've seen in nearly a decade.

Just about all programs from HIV prevention money to HIV/AIDS treatment and research funding have been given millions of dollars extra in federal appropriations.

"We have seen some increases in domestic funding to reverse the dismal trend we have been experiencing in recent years of reduced or flat funding," says **Ronald Johnson**, deputy executive director of AIDS Action Council in Washington, DC.

"The Obama administration is mindful of the neglect of the domestic academic and domestic HIV epidemic and how it still is a very serious one that has impacted communities of color and gay men," Johnson says.

Here are some of the budget highlights:

• **AIDS funding better aligned with evidence-based science:** Despite years of studies showing

that abstinence-only education does not produce positive outcomes, the previous presidential administration and Congresses have approved over $100 million for such efforts and typically gave the programs spending increases, even when many other programs were cut.

Now this has reversed. The president's FY2011 budget proposes no funds for community-based abstinence education, and the FY2010 budget shows no funding, as well. This is a $99 million decrease from FY2009.

Also, the new budget includes a line item for a Teen Pregnancy Prevention Initiative that is under the Labor Health and Human Services, National Institutes of Health, Discretionary Budget Authority. This initiative was begun in FY2010 with $114.5 million in funding, and it's proposed to be increased in FY2011 with $133.7 million.

About $50 million for abstinence-only funding was put in the health care reform bill by a congressman, however, Johnson says.

"We had hoped to get that taken out," he adds.

• **First-time federal funding for needle exchange programs:** "Lifting the ban on federal funding for syringe exchange was a huge victory we achieved in the FY2010 budget," Johnson says.

"We are hopeful we are able to sustain that," he says. "We're remaining vigilant to make sure it's not reinstated."

The ban's removal will open the door for federal prevention efforts to include what studies of needle exchange programs have shown is a very effective way to stem the spread of HIV among injection drug users (IDUs).

• **CDC prevention programs:** In recent years funding for surveillance and prevention under the Centers for Disease Control and Prevention (CDC) has been flat, undermining the CDC's mission to cut new HIV infections.

For instance, in FY2009, there was no new funding for the HIV Prevention and Surveillance budget. But for FY2010 there was an additional $36 million in funding, and the president's budget proposes another $31 million. ■

Women at risk for HIV: What is on the horizon?

In the United States, women and teen girls accounted for more than one-fourth of all new HIV/AIDS diagnoses in 2007 and more than 93,900 cumulative deaths from AIDS. Black women are at heightened risk. The incidence rate of new diagnoses in black women is almost 15 times higher than that of white women, according to statistics compiled by the Centers for Disease Control and Prevention.[1]

Why are black women at increased risk? According to authors of a recent editorial in *The New England Journal of Medicine*, the increase in risk might be due more to vulnerable social and economic situations and sexual networks than women's own risky behaviors.[2]

"Socioeconomic disadvantage and instability of partnerships due to high rates of incarceration among men in their communities may lead women to engage in concurrent relationships or serial monogamy," the editorial states. "In addition, they may be unaware of their partners' HIV status or may be involved in abusive or economically dependent relationships and thus be unable to negotiate safer sex with their partners."

The National Alliance of State and Territorial AIDS Directors (NASTAD) has issued a new issue brief in its ongoing efforts to reduce racial and ethnic health disparities in the HIV/AIDS and viral hepatitis epidemics.[3] The release of the brief is part of the organization's efforts to draw attention to the impact of HIV/AIDS on women and the need to increase support for science-based, effective HIV and STD prevention programs for them. (Download a copy of the brief at the organization's web site, www.nastad.org. Under "Highlights," click on "Black Women and HIV/AIDS: Findings from the Southeast Regional Consumer and Provider Focus Group Interviews.")

NASTAD will continue to advocate for increased awareness and services for women impacted by HIV/AIDS, says **Michelle Batchelor**, MA, senior manager of racial and ethnic health disparities. While strides have been made, the collective response to women's needs have not been met at the level that the crisis deserves, she states.

Put a ring on it

One way to help women protect themselves against HIV/AIDS to boost female-controlled prevention methods. The Female Health Co. (FHC), manufacturers of the FC2 Female Condom, are supporting a new social marketing campaign in Chicago designed to educate women about HIV/AIDS and boost awareness, availability, and access to the FC2 condom.

AIDS BUDGET AND APPROPRIATIONS COALITION
FY 2011 Appropriations for Federal HIV/AIDS Programs

March 29, 2010

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

PROGRAM		FY 2009 Final	FY 2010 Final	FY 2011 President's Budget Request	FY 2011 Coalition Request
CDC	Total - HIV, Hep, STD, TB line	$1,006.4 m (+$4.2 m)	$1,045.4 m (+$39 m)	$1,083.3 m (+$37.9 m)	$2,175.5 m (+$1,130.1 m)
	HIV Prevention & Surveillance	$692 m (+$0 m)	$728 m (+ $36 m)	$759 m (+$31 m)	$1,606 m (+$878 m)
	Viral Hepatitis	$18.3 m (+$0.7 m)	$19.3 m (+$1.0 m)	$21.1 m (+$1.8 m)	$50 m (+$30.7 m)
	STD Prevention	$152.3 m (+$0 m)	$153.9 m (+$1.6 m)	$160.6 m (+$6.7 m)	$367.4 m (+$213.5 m)
	TB Prevention	$143.9 m (+$3.5 m)	$144.3 m (+$0.4 m)	$143.1 m (-$1.2 m)	$220.5 m (+$76.3 m)
	DASH - HIV Prevention Education	$40.2 m (+$0)	$40.2 m (+$0)	$40.2 m (+$0)	$60.2 m (+$20 m)
HRSA	Ryan White Programs Total	$2,238.4 m (+$71.6 m)	$2,290.9 m (+$52.7 m)	$2,330.4 m (+$39.5 m)	$3,101.5 (+$810.8 m)
	Part A	$663.1 m (+$35.9 m)	$679.1 m (+$16 m)	$679.1 m (+$0 m)	$905 m (+$225.9 m)
	Part B: Care	$408.8 m (+$7.9 m)	$418.8 m (+ $10.0 m)	$428.8 m (+$10.0 m)	$474.7 m (+$55.9 m)
	Part B: ADAP	$815 m (+$20.6 m)	$835 m (+ $20.0 m)	$855 m (+ $20.0 m)	$1,205.1 m (+$370.1 m)
	Part C	$201.9 m (+$3.1 m)	$206.9 m (+$5.0 m)	$211.9 m (+$5.0 m)	$337.9 m (+$131 m)
	Part D	$76.9 m (+$3.2 m)	$77.8 m (+ $.94 m)	$77.8 m (+ $0 m)	$84.8 m (+$7.0 m)
	Part F: AETCs	$34.4 m (+$0.3 m)	$34.8 m (+ $.42 m)	$37.4 m (+$2.6 m)	$50 m (+$15.2m)
	Part F: Dental	$13.4 m (+$0.6 m)	$13.6 m (+$.17 m)	$15.4 m (+$1.8 m)	$19 m (+$5.4 m)
	Part F: SPNS	$25 m	$25 m	$25 m	$25 m

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PROGRAM		FY 2009 Final	FY 2010 Final	FY 2011 President's Budget Request	FY 2011 Coalition Request
	Community Health Centers	$2,146 m (+$125 m)	$2,146 m (+$0)	$2,436 m[1] (+ $290 m)	$2,553 m (+$363 m)
Office of	Title X[2]	$307.5 m (+$7.5 m)	$317.5 m (+$10 m)	$327.4 m (+$9.9 m)	$394 m (+$76.5 m)
NIH	NIH[3]	$30.32 b (+$630 m)	$31.0 b (+$692 m)	$32.09 b (+ $1.09 b)	$35.0 b (+$4 b)
	[Transfer to Global AIDS][4]	[-$300 m]	[-$300 m]	[-$300 m]	[$0 m]
	AIDS Research	$3.02 b (+$82 m)	$3.09 b (+$ 90 m)	$3.18 b (+$ 98.7 m)	$3.5 b
ACF	Community-Based Abstinence Education	$99 m (-$14 m)	$0 m (-$99 m)	$0 m (+$0 m)	$0 m (+$0 m)
Office of Adolescent Health	Teen Pregnancy Prevention Initiative[5]	N/A	$114.5 m (+$114.5 m)	$133.7 m (+$19.2 m)	$114.5 m (+$0 m)
SAMHSA	Center for Substance Abuse Treatment	$412 m (+$12 m)	$452.6 m (+$40.6 m)	$486.7 m (+$34.1 m)	$529.6 m (+$77.0 m)
	Substance Abuse Block Grant	$1,779 m (+$20 m)	$1,799 m (+$20 m)	$1,799 m (+$0 m)	$2,009 m (+$210 m)
	Center for Substance Abuse Prevention	$201 m (+$7 m)	$202 m (+$1 m)	$223 m (+$21 m)	$277.2 m (+$75.2 m)
	Center for Mental Health Services (CMHS)	$969 m (+$59 m)	$1,005 m (+$36 m)	$1,028 m (+$23 m)	$1152.8m (+$147.8 m)
	Subset of CMHS: Mental Health Block Grant	[$421 m] [(+$0 m)]	[$421 m] [(0 m)]	[$421 m] [(0 m)]	[$482.7m] [(+$61.7 m)]
MAIHU	Minority HIV/ AIDS Initiative (within multiple programs)	[$402.9 m] [(+$.3 m)]	[$402.9 m] [(+$0 m)]	[TBD]	[$610 m] [(+$207.1 m)]
HUD	HOPWA	$310 m (+$9.9 m)	$335 m (+$25 m)	$340 m (+$5 m)	$410 m (+$75 m)
White House	Office of National AIDS Policy	$1.4 m (+$1.4 m)	$1.4 m (+$0 m)	N/A	$1.4 m (+$0 m)

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1 Includes $25 million to enhance the availability and quality of substance abuse treatment at community health centers by integrating qualified behavioral health and addiction specialists into this primary care setting.

2 The coalition requests that funding for Title X be increased to $700 million over five years beginning with an increase of $76.5 million in FY11.

3 Labor HHS NIH Discretionary Budget Authority

4 The LHHS appropriation for the Global Fund to Fight AIDS, TB and Malaria comes out of NIH's budget through a pass-through, presenting an inaccurate total amount to the NIH for research. The coalition supports the Global Fund appropriation to come out of Foreign Operations appropriations.

5 ABAC supports the expansion of the Teen Pregnancy Prevention Initiative to be a comprehensive education initiative that includes STD and HIV prevention.

The Chicago Female Condom Campaign includes a coalition of 20 HIV/AIDS, reproductive justice, and women's and men's health organizations that are mobilizing outreach to women and men living at risk of HIV in Chicago. The campaign was launched on March 10, the 2010 observance of National Women and Girls HIV/AIDS Awareness Day.

The campaign is conducting a multifaceted communications and marketing effort to promote the female condom as an acceptable and affordable HIV prevention option for women and men. With funding and technical support provided by FHC and other partners, it is sponsoring in-person trainings to equip Chicago-area service organizations with the skills to promote female condoms. Those skills include knowledge of correct use and strategies for negotiating female condom use with partners. Many of the community-based partners serve African American and Latino women, who are disproportionately impacted by the city's HIV/AIDS epidemic. The campaign is launching a mixture of social media channels to spread awareness including a female condom web site (www.ringonit.org), a Facebook fan page, and a Twitter account (twitter.com/ChiFemaleCondom).

Women might have another option when it comes to HIV prevention if a current large-scale clinical trial proves successful. The Vaginal and Oral Interventions to Control the Epidemic (VOICE) study is examining whether antiretroviral medications normally used to treat HIV infection also can prevent HIV infection in women when applied as a vaginal gel or taken as once-daily oral tablets.

The study, launched in 2009, looks to enroll some 5,000 HIV-uninfected women at risk for HIV infection in multiple sites in Africa. Scientists are enrolling participants at sites in Zimbabwe, Uganda, and South Africa, with additional sites in South Africa expected to come on board soon, says **Jeanne Marrazzo**, MD, MPH, VOICE Study co-chair and associate professor of medicine in the Division of Allergy and Infectious Diseases at the University of Washington in Seattle. The study is expected to run about three and one-half years.

The trial will test the safety and efficacy of two HIV prevention strategies: an investigational microbicide gel containing the antiretroviral drug tenofovir, and oral tablets containing tenofovir or a combination of tenofovir and emtricitabine. The tablets are taken prior to exposure in an approach known as pre-exposure prophylaxis, or PrEP. Testing a microbicide and PrEP in the same trial will enable scientists to directly compare the two strategies' safety and acceptability.

To perform the study, women are randomly assigned to one of five regimens, each performed once daily: applying tenofovir gel vaginally, applying a placebo gel vaginally, taking a tenofovir pill and a placebo pill, taking a tenofovir/emtricitabine pill and a placebo pill, or taking two placebo pills.

Why are researchers hopeful that this particular approach will be effective in women? Marrazzo points to two possible reasons. "First, the strategies we are using — vaginal and oral products — use antiretroviral drugs [ARVs] that we know work very well to treat HIV," she notes. "Second, use of ARVs has been successful in preventing mother-to-child transmission of HIV, so that provides a great real-world model of its potential."

However, until the trial is complete, scientists won't know for sure whether the ARV-based gel or the pill will be safe and effective, and whether one will be more acceptable than the other for women to use on a daily basis, states Marrazzo.

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Antiretroviral initiation during or following treatment of TB

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: In this study, 642 patients coinfected with HIV and TB were studied in an open-label, randomized, controlled trial in which patients were assigned to initiating antiretroviral therapy (HAART) early, later during the course of TB treatment, or after the completion of TB treatment. Initiation of antiretroviral therapy during TB treatment improved survival.

Source: Abdool Karim SS, et al. Timing of initiation of antiretroviral drugs during tuberculosis therapy. *N Engl J Med*. 2010; 362:697-706.

An open-label, randomized, controlled trial of early vs. delayed initiation of HAART was conducted in 642 patients with active TB and HIV infection in Durban, South Africa. Patients were randomized 1:1:1 to one of three study groups. In the "early integrated therapy" group, ARV therapy (consisting of ddI, 3TC, and efavirenz) was initiated within four weeks after starting TB treatment. In the "late integrated therapy" group, HAART was initiated within four weeks after the completion of the intensive phase of TB treatment (initial two months of INH, rifampin, PZA, and EMB in patients with first episode TB and three months of RIPE plus SM for two months in patients with recurrent TB). In the "sequential therapy" group, HAART was initiated within four weeks after completion of the 6-8 month entire course of TB treatment.

The primary endpoint of the study was death. There were 25 deaths in the integrated therapy group (rate 5.4 per 100 person-years) vs. 27 deaths in the sequential therapy group (rate 12.1 per 100 person-years).

Although not quite reaching statistical significance, the combined integrated therapy groups were more likely to be cured, or to successfully complete TB therapy, and were less likely to require interruption of TB treatment. Integrated therapy patients were significantly more likely to achieve HIV RNA < 400 copies/mL at 12 months following randomization than were sequential therapy patients (90% vs. 78%), and to have a better CD4+ lymphocyte count incremental increase (207 vs. 84 cells/uL).

Commentary

This is an important study which is likely to alter clinical practice in both the developed and developing worlds. Current practice of many TB clinics is to defer antiretroviral therapy in patients with HIV/TB coinfection unless CD4+ count is < 200 cells/uL.

This study provides strong clinical support for not delaying HAART while treating TB. However, one of the limitations of this study is that the somewhat unusual HAART regimen studied (ddI, 3TC, and EFV) does not result in significant drug interactions with the TB medications used. From a practical standpoint, it is most problematic to use ritonavir-boosted protease inhibitor (PI) regimens in patients receiving rifampin. Rifampin is a potent inducer of the cytochrome P450 CyP 3A/4 isoforms, and results in marked reduction of PI serum levels, even in the presence of ritonavir boosting. Rifabutin in significantly reduced doses can be substituted for rifampin but, in combination with ritonavir, it may cause ocular toxicity. Also, concern has recently been raised about frequent subtherapeutic levels of rifabutin seen when used in combination with ARVs.

The bottom line from this study, from my perspective, is that EFV-containing HAART regimens can and should be started early during TB treatment in patients whose baseline HIV genotypes do not show primary NNRTI resistance. However, additional studies should be done to better define optimal dosing of TB regimens and timing of initiation of HAART, with respect to TB treatment in patients who require ritonavir-boosted PI regimens. Although I am not aware of published data to support this practice, another attractive treatment option in patients on TB treatment that require non-EFV-containing HAART regimens would be a combination of NRTIs -- plus the integrase inhibitor raltegravir (due to the paucity of drug interactions associated with raltegravir, which it is not metabolized by the cytochrome P450 system.) ■

FDA NOTIFICATIONS

FDA approves new dosing for Kaletra

On April 27, 2010, FDA approved a new dosing regimen for lopinavir/ritonavir (Kaletra®) tablets and oral solution.

Lopinavir/ritonavir can be administered once daily (800/200 mg) in patients with less than

three lopinavir resistance associated substitutions. Once daily administration of lopinavir/ritonavir is not recommended for adult patients with three or more of the following lopinavir resistance-associated substitutions: L10F/I/R/V, K20M/N/R, L24I, L33F, M36I, I47V, G48V, I54L/T/V, V82A/C/F/S/T, and I84V. Of note, once daily administration of Kaletra is not recommended in pediatric patients.

The complete revised label will be posted soon at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory1. ■

PIs have new drug-drug interaction language

The approved protease inhibitors for the treatment of HIV-1 infection now all include the following drug-drug interaction information, according to the U.S. Food and Drug Administration:

• Sildenafil (Revatio®) as a contraindicated medication when prescribed for the treatment of pulmonary arterial hypertension.

• alfuzosin (Uroxatral®) as a contraindicated medication.

• Recommendation that salmeterol (brand names are Advair® and Serevent®) should not be coadministered.

• New dosing recommendation for bosentan (Tracleer®) and tadalafil (Adcirca®) when prescribed for the treatment of pulmonary arterial hypertension. Note, coadministration of bosentan and atazanavir (Reyataz®) without ritonavir is not recommended.

• New dosing recommendations for colchicine when prescribed for the treatment of familial Mediterranean fever or gout.

• New dosing recommendations for colchicine when prescribed for the prophylaxis of gout;

• Recommendation that colchicine should not be coadministered with protease inhibitors in patients with hepatic or renal impairment.

Below is an example of the new dosing recommendations for protease inhibitors and the following concomitant medications:

Colchicine:

Treatment of gout flares: 0.6 mg (1 tablet) x 1 dose, followed by 0.3 mg (half tablet) 1 hour later. Dose to be repeated no earlier than 3 days.

CNE/CME QUESTIONS

16. Recent studies have shown that community-associated methicillin-resistant *Staphylococcus aureus* (CA-MRSA) rates have decreased significantly among HIV-infected populations in the last three years as more effective antibiotics became available.
    A. True
    B. False

17. For treating HIV patients with CA-MRSA skin and soft-tissue infections on an outpatient basis, which of the following would be good first-line treatments?
    A. Vancomycin or rifampin
    B. Trimethoprim-sulfamethoxazole or tetracycline
    C. Erythromycin
    D. Penicillin

18. The latest federal appropriations for HIV/AIDS programs will impact AIDS Drug Assistance Programs (ADAPs) in which way?
    A. Cut funding by 2% for FY2010
    B. Increase funding by $20 million
    C. Inadequately fund ADAP needs, resulting in more than 1,000 people on the ADAP waiting list
    D. Both B and C

Answers: 16. B; 17. B; 18. D.

COMING IN FUTURE MONTHS

■ Risk reduction intervention for teens has some success

■ New TB vaccine could be boon for HIV populations

■ Experts study best ways to assess adherence

■ Study details ART's impact on deaths among HIV/AIDS populations

Note: Fosamprenavir (Lexiva®) without ritonavir: 1.2 mg (2 tablets) x 1 dose. Dose to be repeated no earlier than 3 days.

Prophylaxis of gout-flares: If the original colchicine regimen was 0.6 mg twice a day, the regimen should be adjusted to 0.3 mg once a day. If the original colchicine regimen was 0.6 mg once a day, the regimen should be adjusted to 0.3 mg once every other day.

Note: Lexiva without ritonavir: if the original regimen was 0.6 mg twice a day, the regimen should be adjusted to 0.3 mg twice a day or 0.6 mg once a day. If the original regimen was 0.6 mg once a day, the regimen should be adjusted to 0.3 mg once a day.

Treatment of familial Mediterranean fever (FMF): Maximum daily dose of 0.6 mg (may be given as 0.3 mg twice a day).

Note: Lexiva without ritonavir: maximum daily dose of 1.2 mg (may be given as 0.6 mg twice a day). ■

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.