CLINICAL CAPSULES

Drug Interaction Warning

Rifampin should not be given along with ritonavir-boosted saquinavir as part of combination antiretroviral therapy for HIV infection, according to the Food and Drug Administration and the drug's maker, Roche Laboratories Inc.

Drug-induced hepatocellular toxicity occurred in 11 of 28 healthy volunteers in a randomized, open-label, phase I trial of rifampin 600 mg once daily given with ritonavir 100 mg/saquinavir 1,000 mg twice daily. Transaminase elevations more than 20 times the upper limit of normal were noted. The study was terminated, and after drug discontinuation, liver function tests in all affected subjects returned to normal. Roche is working with the FDA to make appropriate changes to the package inserts.

Anthrax Vaccine Authorization

Under an FDA Emergency Use Authorization (EUA), adults aged 18-65 years who are at increased risk of exposure to inhalational anthrax due to anthrax attack—as determined by the Department of Defense (DOD)—are now eligible to receive Anthrax Vaccine Adsorbed (AVA) for prevention of the disease.

The FDA issued the EAU as requested by the DOD, which determined that there is significant potential for a military emergency involving a heightened risk to military forces associated with an anthrax attack. This is the first time the EAU authority is being used, and it is required for the use of AVA, because the use of the vaccine for prevention of inhalation anthrax is currently considered unapproved.

In response to a lawsuit in 2003 protesting the DOD's Anthrax Vaccine Immunization Program, the U.S. District Court for the District of Columbia issued a preliminary injunction barring AVA inoculations except in the case of informed consent or a presidential waiver of the informed consent requirement.

Although the injunction was lifted in January 2004, the court remanded the FDA's final rule and final order allowing the injunction to be lifted—effectively reinstating the injunction—to allow for reconsideration following an appropriate notice and comment period. That 90-day comment period began on Dec. 29.

Black Women and HIV

Black women account for the majority of new cases of HIV and AIDS in U.S. women, and this is particularly true in North Carolina, according to the Centers for Disease Control and Prevention.

In 2003, the HIV infection rate in that state was 14 times higher in black than in white women (MMWR 2005;54:89-94).

An epidemiologic investigation of 31 of the 208 black women aged 18-40 years in North Carolina who were diagnosed with HIV between January 2003 and August 2004 and 101 controls recruited from HIV testing sites showed that most women in both groups engaged in HIV sexual risk behaviors. Those receiving public assistance were more likely to be HIV positive (adjusted odds ratio 7.3), as were those with a history of genital herpes (adjusted OR 10.6). Women who discussed sexual behaviors and history with their male partners were less likely to be HIV-positive (adjusted OR 0.6).

The most common reasons given for engaging in risky sexual behaviors were financial dependence on male partners, feeling invincible, low self-esteem coupled with a need to feel loved by a male, and alcohol/drug use.

The findings underscore the need for a multifaceted approach to reducing HIV infection among black women, including programs that encourage delayed sexual activity, condom use, monogamy, and communication, according to the CDC.

MRSA Clone Tackles Athletes

An outbreak of skin abscesses among football players on the St. Louis Rams team was caused by an emerging, community-associated clone of methicillin-resistant *Staphylococcus aureus*, Sophia V. Kazakova, M.D., of the CDC in Atlanta, and her colleagues reported.

During the 2003 football season, eight MRSA infections leading to large abscesses that required surgical intervention occurred in 5 of the 58 team members. All of the infections occurred at turf-abrasion sites, and they were significantly associated with playing lineman or linebacker positions, suggesting that person-to-person contact plays a role in transmission (N. Engl. J. Med. 2005;352:468-75).

The pulsed-field gel electrophoresis patterns of MRSA from competing teams and community-associated cases were indistinguishable from those of the Rams' MRSA, the investigators said, noting that the clone may be widely distributed in the community.

The CDC has begun population-based surveillance in several parts of the United States to help characterize emergence of MRSA in the community and guide public health interventions, they noted.

—Sharon Worcester