Medical News

Edited by Gina Pugliese, RN, MS

FDA Approves Combination TB Drug

The U.S. Food and Drug Administration (FDA) recently approved the drug Rifater, a product that combines three existing tuberculosis (TB) drugs into a single tablet-isoniazid, rifampin, and pyrazinamide. The drug is designed to decrease the number of patients who do not comply with the standard long-term, multidrug regimen for treating TB. In addition, the use of Rifater will prevent inadvertent under- or overdosing.

Rifater, manufactured by Marion Merrell Dow, has been used in Europe, Africa, and Hong Kong since the mid-1980s. The use of combination products for treating TB has been recommended by numerous organizations, including the World Health Organization, and the Centers for Disease Control and Prevention (CDC).

FROM: *FDA Talk Paper* Rockville, MD: U.S. Food and Drug Administration Press Office; June 2, 1994.

CDC Releases Guidelines for Preventing HIV Transmission Through Organs

Exclusion of donors based on risk behaviors and screening of prospective donors of blood, organs and tissues for human immunodeficiency virus (HIV) has markedly reduced the risk of HIV transmission through transplantation, However, a 1991 case of HIV transmission from a screened, antibody-negative donor to several recipients raised questions about the need for additional federal oversight of transplantation of organs and tissues.

A working group formed by the Public Health Service (PHS) in 1991 to address these issued concluded that further recommendations should be made to reduce the already low risk of HIV transmission by transplantation of organs and tissues. In revising these recommendations, the PHS sought assistance from public and private health professionals and representatives of transplant, public health, and other organizations.

The revised guidelines address issues such as donor screening, testing, and exclusionary criteria; quarantine of tissue from living donors; inactivation or elimination of infectious organisms in organs and tissues before transplantation; timely detection, reporting, and tracking of potentially infected tissues, organs and recipients; and recall of stored tissues from donors found after donation to be infected. Factors considered in the development of these guidelines included differences between the screening of living and cadaveric donors; time constraints due to organ/tissue viability that may preclude performing certain screening procedures; differences in the risk of HIV transmission from various organs and tissues; differences between procuring and distributing organs and tissues; the effect of screening on the limited availability of organs and some tissues; and the benefit to the recipient.

FROM: Guidelines for preventing transmission of HIV through transplantation of human tissues and organs. *MMWR* May 20, 1994;43(RR-8):1-17.

Canada Announces Campaign to Inform Former Transfusion Recipients of HIV Risks

The Ontario Hospital Association (OHA) has announced Canada's first comprehensive campaign to inform patients who received blood between 1978 and 1985 that they may have been exposed to HIV OHA officials have explained that, although people may be aware of the risk of infection through transfusion, many people don't remember or were never told that they had a transfusion as part of their medical treatment. The OHA public awareness campaign is using ads in French- and English-language newspapers, posters, flyers, public service announcements, and an information video to get the message out to the widest possible audience.

The OHA's provincewide campaign complements the efforts of local hospitals, which have launched their own community-based initiatives. The OHA campaign has been shared with the Canadian Hospital

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Association for consideration as a model of other interested provinces.

CDC Releases Simplified Patient Vaccine Information

As required by the National Childhood Vaccine Injury Act of 1986, the U.S. Department of Health and Human Services issued extensive vaccine information materials in October 1991 for distribution by healthcare providers to the legal representatives of any child receiving particular vaccines. These included diphtheria, tetanus, pertussis, measles, mumps, rubella, and polio vaccines. Since April 15, 1992, any healthcare provider who intends to administer one of the covered vaccines is required to provide copies of vaccine information materials prior to administration of these vaccines.

Because of concerns expressed by providers about the length and readability of the vaccine information materials (each of the three existing pamphlets is 10 pages long) and the lengthy development and revision process required by the rule making, the U.S. Congress revised the law. The revisions include simplification of the information provided and the process for develop ment. In addition, Congress clarified that the materials also must be provided to any adult who receives the vaccine.

The CDC has finalized the vaccine information materials and published them in the June 20, 1994, *Federal Register.* For further information, call the CDC's National Immunization Program at (404) 6398200.

FROM: Centers for Disease Control and Prevention. New vaccine information materials. *Federal Register* 1994;50(117):31888-31892.

Drug-Resistant TB Outbreak in California High School

Following the diagnosis of three high school students with active TB in a high school in Westminster, California, public health officials conducted an investigation to identify the source case and any additional cases. The *Mycobacterium tuberculosis* isolate from all three students was resistant to isoniazid, streptomycin, and ethionamide (ISE).

To find additional cases, in the fall of 1993 all current students, 1993 graduates, and staff were screened with a TB skin test. The source case patient was a Southeast Asian immigrant student in the class of 1994, who developed a cough in January 1991; her doctors did not diagnose TB until 13 months later and did not report her case to the health department. She was sputum acid-fast bacillus smear positive and not adherent to therapy until July 1993; no contact investigation ever was performed.

Additional cases of active TB were found in 9 of 1,402 current students, 3 of 352 1993 graduates, and none of the staff. Of the 16 total cases, five had susceptibility patterns different from the source patient with the ISE-resistant strain. The remaining 11 cases were epidemiologically linked, and eight were culture positive with ISE resistance; seven available isolates had identical DNA fingerprints. Of the 1,402 current students, 1,266 (90%) had tuberculin skin tests (TST). Preliminary data showed that 292 out of 1402 students (23%) had TST conversion (>10 mm). The TST conversion rates for the class of 1994, the class of the index case, was 34%.

This outbreak of drug-resistant TB transmitted in a school may have been prevented with prompt recognition, treatment, and bacteriologic monitoring of the source case patient. Secondary cases may have been prevented if classroom contacts had been screened early for tuberculous infection and given preventive therapy.

FROM: *New York Times* July 17, 1993:A1. Also from: Ridzon R, Kent J, Shefer A, et al. Outbreak of drug-resistant tuberculosis at a high school, California, 1993. Presented at the 43rd Annual Epidemic Intelligence Service Conference; April 1821, 1994; Atlanta, Georgia.