

FDA Recalls Blood Products After Donor Diagnosed with Creutzfeldt-Jakob Disease

The FDA recently reported a voluntary market withdrawal of certain blood and plasma products by the American Red Cross, in cooperation with Baxter Healthcare Corporation and Miles Inc. The market withdrawal was initiated because a frequent Red Cross blood donor was diagnosed with Creutzfeldt-Jakob Disease (CJD).

Although there never has been a reported case of transmission of CJD by blood or plasma products, it is not known whether CJD can be transmitted by blood. However, FDA agreed with the Red Cross and Miles Inc. that it was prudent to withdraw the products to ensure the continued safety of the blood supply.

CJD is a fatal degenerative disease of the central nervous system thought to be caused by a virus-like agent. The annual incidence of CJD in the United States is less than one case per one million people. Patients harbor the agent for many years before developing symptoms. CJD has been transmitted to individuals who received certain human tissue transplant material, including corneas and brain-associated membrane, as well as patients treated with human pituitary-derived growth hormone. Blood from patients with CJD has been reported to transmit infection to animals if inoculated directly into the animal's brain.

FDA has consulted with the Centers for Disease Control and Prevention and the National Institute of Health to gather more information on the potential for transmission of CJD through transfusion and to assess the public health risk from various blood products when there is a CJD donor. The FDA will report the measures taken to its Blood Products Advisory Committee, a group of outside experts, for the purpose of reevaluating the current approach to product withdrawal.

FROM: FDA Talk Paper; November 17, 1994:T94-55.

Elimination of Gowning in Neonatal Intensive Care Does Not Affect Infection Rates or Hand-Washing Patterns-Saves \$120,000 Annually

The effect of gowning on colonization, infection, and hand-washing patterns in a neonatal intensive care unit (NICU) recently was studied by Susan Pelke and her colleagues at the Kapiolani Medical Center in Honolulu. Alternate Z-month gowning and no-gowning cycles were established in a 24-bed, level-III NICU for 8 months, with respiratory site, umbilical, and stool surveillance cultures performed weekly. Throughout the 8-month study period, an initial Z-minute hand scrub was recommended for staff and visitors, with a minimum of a 15-second hand wash between handling infants. Without the knowledge of the staff, a neonatal research nurse observed hand-washing patterns.

During the gowning period, nursing staff, ward clerks,

and residents changed into hospital-laundered scrub dresses or suits when they reported on duty. Long-sleeved cloth gowns were worn over the scrubs when they left the NICU. Other physicians, hospital staff, and visitors wore gowns over street clothes for entry into the NICU.

During the no-gowning period, nursing staff wore hospital-issued pant suits, washed at home through ordinary methods and worn from home. No gowns, jackets, or laboratory coats were worn outside the NICU. Ward clerks, physicians, hospital staff, families, and visitors wore street clothes without gowns. Only residents continued to wear hospital-laundered scrubs.

The results indicated that there was no significant difference between the gowning and no-gowning periods in the rate of any type of infection, including respiratory syncytial virus and necrotizing enterocolitis. There also was no difference in rates of bacterial colonization or any effect on hand-washing compliance.

A number of other studies in the NICU that have similar results have compared infection rates during periods of gowning as usual with periods of gowning only when infants are handled (modified gowning). This study is the largest of only two studies in the NICU in which gowning was compared to a period of no-gowning. Elimination of gowns saved this hospital more than \$120,000 on laundry and linen costs in one year.

FROM: Pelke S, Ching D, Easa D, Melish E. Gowning does not affect colonization or infection rates in a neonatal intensive care unit. *Arch Pediatr Adolesc Med* 1994;148:1016-1020.

Formula Supplemented with Bifidobacterium bifidum and Streptococcus thermophilus Prevents Diarrhea and Shedding of Rotavirus in Infants

Acute diarrhea is a serious cause of infant morbidity and mortality. Bifidobacteria (which constitute the predominant intestinal flora of breast-fed infants), as well as other lactic acid-producing organisms, such as *Streptococcus thermophilus*, are thought to have a protective effect against acute diarrheal disease. However, their efficacy has not been assessed in controlled trials.

Dr. Jose Saavedra and colleagues from Johns Hopkins University School of Medicine and Mount Washington Pediatric Hospital in Baltimore recently reported the results of a study that found formula supplemented with *B bifidum* and *S thermophilus* reduced episodes of diarrhea and the shedding of rotavirus in infants.

In a double-blind placebo-controlled trial, infants aged 5 to 24 months who were admitted to a chronic medical care hospital were randomized to receive a standard infant formula or the same formula supplemented with *B bifidum* and *S thermophilus*. Eight (26%) of the 26 patients who received the control formula and 2 (7%) of the 29 patients who received the supplemented formula developed diarrhea

during the study. Ten (38%) of the subjects who received the control formula and 3 (10%) of those who received the supplemented formula shed rotavirus at some time during the study. The researchers concluded that a decrease in rotavirus shedding may lead to less environmental exposure, which may contribute to a reduced risk of nosocomial infection in infants at risk of gastroenteritis.

FROM: Saavedra JM, Bauman NA, Oung I, et al. Feeding of *Bifidobacterium bifidum* and *Streptococcus thermophilus* to infants in hospital for prevention of diarrhea and shedding of rotavirus. *Lancet* October 15, 1994;344:1046-1049.

New Research Suggests Herpes Virus May Cause Kaposi's Sarcoma

Dr. Patrick Moore and colleagues from Columbia University recently presented research findings that suggest herpes virus may be the cause of Kaposi's sarcoma (KS). These findings were presented during a symposium at the Second National Conference on Human Retroviruses held on January 31, 1995, in Washington, DC. The virus has been tentatively named Kaposi Sarcoma-Associated Herpes Virus (KSHS).

The virus is being grown in tissue culture in the laboratory and mapping of the virus's basic genetic structure has identified it as the largest human herpes virus. Dr. Moore found evidence of the KSHS in 20 out of 21 tissue samples from individuals with KS, compared to only 1 of 21 samples of individuals without KS.

Dr. Steven Miles, from the University of California, Los Angeles Medical School, and co-chair of the session, said that Dr. Moore's findings represent a "major breakthrough in KS and will change the scope of research."

In the same session, Dr. David Cooper, from the University of New South Wales, Australia, presented the results of a clinical trial to treat patients with KS using an experimental drug made by Abbott Laboratories, ABT 538, a protease inhibitor, which resulted in complete or partial regression of disease.

FROM: Roundtable Symposium: Controversies in AIDS Malignancies. Presented at the Second National Conference on Human Retroviruses and Related Infections. January 29 February 1, 1995; Washington DC.

FDA Approves Oral HIV Test

The US Food and Drug Administration (FDA) has approved the first US HIV test system using oral fluid samples instead of blood. FDA has approved the product for collecting specimens of oral fluid and as an ELISA antibody screening test specifically licensed for testing oral fluid samples. The collection device, called OraSure, includes a specially treated cotton pad on a stick and a preservative solution in a plastic container in which to store the specimen until the sample is tested by a qualified laboratory using the Oral Fluid Vironostika HIV-1 Microelisa System.

The FDA has approved this HIV test system with a number of restrictions, including distribution only through physicians, collection done only by properly trained individuals, and restriction from home use. There is also a requirement for providing a subject information sheet to individuals being tested that includes information on the reduced accuracy of testing oral fluids compared with testing blood, the lack of a confirmatory test for use with oral fluid samples, and, if the test is positive, the need to have blood samples drawn and tested to verify HIV status.

The OraSure HIV-1 specimen collection device is manufactured by Epitope Corporation of Beaver-ton, Oregon, and the Oral Fluid Vironostika HIV-1 Microelisa System approved to test the specimens is manufactured by Organon Teknika Corporation of Durham, North Carolina.

HIV-Infected Women Have Increased Risk of Death, Not Disease Progression

HIV-infected women are one third more likely to die without an AIDS-defining condition than are HIV-infected men, according to a study from the National Institute of Allergy and Infectious Disease (NIAID). The investigators could not identify why women had a greater risk of relatively early death but suggest that important factors may involve poorer access to or use of healthcare resources among HIV-infected women as compared to men, domestic violence, and lack of social supports for women.

A total of 768 women and 3,779 men were followed for 15 months in this study, the largest prospective analysis comparing survival and disease progression between HIV infected women and men, while controlling for predictors of disease. Among the surviving HIV-infected people in the study, no gender differences occurred in the risk of subsequently developing an AIDS-associated condition. For both men and women, the most commonly occurring AIDS associated condition was *Pneumocystis carinii* pneumonia.

AIDS among women in the United States now represents nearly 13% of all cases, a more than 20-fold increase since 1981. According to the CDC, the disease is the leading cause of death for women in New York City age 25-44 and among the top five leading causes of death for US women of these same ages.

FROM: Melnick SL, Sherer R, Louis TA, et. al. Survival and disease progression according to gender of patients with HIV Infection *JAMA* 1995;272 (24):1915-1921.

Additional news items in this issue: OSHA Expands Focused Inspections in Face of Limited Resources (page 159), Difference in Antibody Response Rate Between Engerix-B and Recombivax-HB Has No Public Health Significance (page 165).
