



Safety Updates

West Nile virus

Testing of North American blood donations for West Nile virus (WNV) began in July and infected donations have been identified in several regions. WNV blood tests produced by Roche and Chiron are both being used for the first time this summer.

Mexico and the United Kingdom have both reported WNV this summer. In Mexico, WNV has been detected in horses and cattle. In the U.K., a study published in the *Journal of General Virology* showed that close to half of birds in the U.K. have antibodies for WNV, suggesting they had been exposed to the virus in the past. Scientists note there is no evidence that humans have been exposed to WNV in the U.K.

WNV is a mosquito-borne virus that can be transmitted in untreated blood products. Last year, WNV killed over 300 people in North America. Up to August 14th, there have been over 470 reported human cases of WNV and 10 deaths; no cases or deaths have been attributed to blood transfusions this summer.

<http://www.cdc.gov/ncidod/dvbid/westnile/>

Creutzfeldt-Jakob disease

No new cases of Bovine Spongiform Encephalopathy (BSE) or “mad cow disease” have been detected in North America since it was found in one cow in May in Alberta, Canada. BSE is a prion disease related to variant Creutzfeldt-Jakob disease (vCJD) in humans. Since May, Canadian beef has been banned from most markets, including its two major customers, the United States and Japan. The U.S. has started to lift its ban on Canadian beef and the two countries have started to introduce strict controls on animal feed since meat and bone meal contaminated with brain and spinal tissue from infected cows is considered a likely cause of mad cow disease.

<http://www.hc-sc.gc.ca/english/diseases/bse/index.html>

Britain's Food Standards Agency has recommended that a ban on the sale of cattle over 30 months old be replaced with testing of older animals. In the U.K., 137 people died from vCJD. The number of cattle infected with BSE

has declined from a peak of 37,000 in 1992 to just 600 last year. <http://www.foodstandards.gov.uk/bse/bsearchive/>

Aventis Behring has announced that it has developed an improved method for detecting human prions in plasma. The technique increases by a hundred times, the sensitivity of testing for prions and was described in the July 2003 *Journal of General Virology*.

<http://vir.sgmjournals.org/>

Severe Acute Respiratory Syndrome

The World Health Organization (WHO) has lifted travel advisories on all SARS-affected areas. As of July 11, 2003, the WHO is reporting 8437 cases of SARS and 813 deaths worldwide. Current evidence suggests that SARS does not pose a risk of transmission through plasma-derived products, such as clotting factor concentrates. SARS is likely caused by a new coronavirus – a lipid-enveloped single-stranded RNA virus. Lipid-enveloped RNA viruses, such as the coronavirus, should be removed or inactivated during manufacturing of plasma derivatives through intentional viral clearance procedures. Some researchers are concerned that SARS will re-emerge during flu season this winter.

Work continues in laboratories around the world on SARS tests and a SARS vaccine. Roche has released an experimental PCR test for SARS. Cerus corporation of California, USA, a Baxter subsidiary, has announced that its “Intercept Blood System” inactivates the SARS virus in platelets and red blood cells. The system is being developed for use with plasma.

<http://www.who.int/csr/sars/en/index.html>

HIV/AIDS developments

Pakistani Drug users more likely to donate blood

A study by Johns Hopkins University has found that 30% of injection drug users in Pakistan sell their blood to collection centers, while knowledge of AIDS and how it is transmitted remains low. The researchers warn that if HIV “seriously penetrates the injection drug user community,” a generalized epidemic could result in Pakistan. The study was published in the June 2003 issue of the *Journal of Urban Health* <http://jurban.oupjournals.org/>

HIV rises among US injection drug users

The CDC is reporting that HIV diagnoses among injection drug users rose in 2000 after several years of decline. The CDC is calling for routine AIDS testing and counseling to counter the trend.

<http://www.cdc.gov/od/oc/media/mmwrnews/n030711.htm#mmwr2>

HIV cases increasing in Russia

The CDC also reported that HIV cases are increasing rapidly in Russia, in both urban and rural settings. The key source of new infections is among young male injection drug users and their partners.

<http://www.cdc.gov/od/oc/media/mmwrnews/n030718.htm#mmwr1>

4.58 million have HIV/AIDS in India

The Indian government has announced that 4.58 million Indians are living with HIV/AIDS. This is a significant increase since the previous year. India's National AIDS Control Organization, <http://naco.nic.in/>

Government and regulatory news**Japan's new blood law comes into force**

A new Japanese blood law, designed to ensure self-sufficiency in blood and blood products for Japan took effect on June 30. The law requires manufacturers to maintain records for 30 years so that patients can be notified if products they used are later found to be infectious. The legislation also calls for Japan to be self-sufficient in blood plasma by 2008. This will require a 75% increase in the number of donors. The commercial fractionators trade group, the Plasma Protein Therapeutics Association (PPTA) has criticized the law, saying it is protectionist and does nothing to enhance safety. The PPTA has threatened to take the case to the World Trade Organization. Paid donation of blood and plasma is banned in Japan. Today, 62% of factor VIII used in Japan is imported. Japanese Ministry of Health, <http://www.mhlw.go.jp/english/index.html>; PPTA, <http://www.pptaglobal.org/index.cfm>

Health Canada folds National Blood Safety Council

The Canadian Government has merged the National Blood Safety Council with the Expert Advisory Committee on Blood Regulation. The Canadian Hemophilia Society expressed disappointment in this move, stressing that the NBSC was an important way to ensure transparency in Canada's blood system and involve stakeholders in maintaining vigilance. The CHS statement can be viewed at <http://www.hemophilia.ca/en/15.php>

Hospital in New Zealand breaks its budget buying clotting factor concentrates

Christchurch Hospital in the New Zealand capital spent NZ\$ 4.9 million (US\$2.9 million) treating 50 people with hemophilia last year, although government funding only covered NZ\$3.2 million (US\$1.9 million) of that expense. The problem is partly caused by people from outside the hospital's region seeking treatment there. The New Zealand Haemophilia Foundation has called for the government to find a way to fund hemophilia care on a national basis. <http://www.haemophilia.org.nz/index.htm>

Lawsuit over UK age policy

A British man with hemophilia, who contracted HIV and HCV from tainted clotting factor concentrates, is suing to be treated with recombinant clotting factor. In 1998, the government provided funding for all people with hemophilia under the age of 16 to be provided with recombinant clotting factor. The U.K. Haemophilia Society has been campaigning since 1996 for recombinant products for all patients with hemophilia. Scotland and Wales have already moved all patients to recombinant products and Northern Ireland is in the process of doing so. However, in England, only those up to 21 years of age receive recombinants.

Guidance for industry

The US Food and Drug Administration has released two guidance documents related to blood and blood products:

Revisions to Labeling and Storage requirements for Blood and Blood Components, Including Source Plasma, <http://www.fda.gov/cber/rules/labelstorbld.pdf>

Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires, <http://www.fda.gov/cber/gdlns/donorsaq.pdf>

Supply news**FDA approves first plasma and albumin free clotting factor**

Baxter announced on July 25 that the FDA approved its new factor VIII product Advate, the first made with no human or animal plasma proteins. The product is based on Baxter's Recombinate and will be priced higher than that recombinant product. Advate is being reviewed in Europe and Canada and Baxter expects it will be available in those regions later this year. http://www.baxter.com/utilities/news/releases/2003/07-25-03-fda_advate.html

Baxter to close plasma collection centers

Baxter has announced that it will reduce its annual plasma production from 4.6 million liters to 4 million liters by cutting 2500 jobs and closing 26 plasma collection centers and its fractionation facility in Michigan.

<http://www.baxter.com/utilities/news/releases/2003/07-02-03-restructuring.html>

Grifols gets QSEAL certification

The Plasma Protein Therapeutics Association (PPTA) announced in July that Instituto Grifols has successfully met the criteria for certification under its Quality Standards of Excellence, Assurance, and Leadership (QSEAL) program. Grifols, based in Spain, is the sixth company to be certified.

US Federal Trade Commission ends investigation of Wyeth

Wyeth has announced that an investigation by the FTC into licensing agreements for its hemophilia treatments has been closed. The government was investigating agreements between Wyeth and other pharmaceutical companies relating to the research, manufacture, and sale of recombinant factor VIII.

Expiration date change for Baxter's Recombinate

Baxter has announced that it has begun manufacturing its own sterile water for injection supplied with Recombinate. There is a possibility that the expiration date on the vial of water will not match the expiration date on the vial of factor. Baxter notes that the clotting factor concentrate is good up until the expiration date marked on its vial. Consumers with vials of water that have expired should contact their provider for replacements. See the National Hemophilia Foundation's medical advisory on this at <http://www.hemophilia.org/News/advisories/ma398.htm>

Tainted blood updates

New Zealand destroys clotting factor

Health officials in New Zealand report destroying US\$2.7 million worth of clotting factor because of fears it was contaminated with HIV. The New Zealand Blood Service said it destroyed a two-month supply of clotting factor after a donor tested positive for HIV. The donor had given blood previously and it had been sent to Australia for processing. New Zealand authorities say that no contaminated products were used. Until stocks

are rebuilt, elective surgeries have been put on hold and a supply of Australian clotting factor will be used in case of emergencies.

Charges laid against donors of tainted blood

Five people in Indiana, USA have been charged with selling HIV-positive blood to plasma collection centers in that state. The charges could lead to prison sentences up to eight years. Those charged all knew of their HIV-positive status at least a year before the contaminated donations were made.

French court dismisses tainted blood charges

France's highest court threw out charges against 30 doctors that had prescribed contaminated blood products in the early 1980s. The court ruled the doctors could not have known the products, made by the state-run blood center, were dangerous in the years before 1985. More than 4000 people, most of them with hemophilia, were infected with HIV. Several French officials have served time in jail for their roles in the scandal.

Lawyers for Irish people with hemophilia have fees cut

The lawyers who represented the Irish Haemophilia Society (IHS) in the Lindsay tribunal investigation into tainted blood have had their fees cut by 20%. The IHS has said it objects to the reduction. The Lindsay tribunal sat from 1999 to 2001 and produced its final report in 2002. The IHS was given full representation in the inquiry. The government pays lawyers' fees in inquiries such as Lindsay.

Canadian Hemophilia Society calls for HCV compensation fund review

Less than a third of the CDN\$ 1.17 billion dollar fund to compensate people infected with hepatitis C by blood products between 1986 and 1990 has been paid out. The fund was set up in 1998 with strict rules on who would qualify for compensation. Although the government said 22,000 claimants were expected, only 7,878 have been approved. The Canadian Hemophilia Society has called for a review of the fund.

Gene therapy news

Phenotype correction of Hemophilia A in mice

Researchers in the U.S have used spliceosome-mediated RNA trans-splicing to repair mutant factor VIII mRNA. This produced sufficient functional factor VIII to correct the Hemophilia A phenotype in mice.

<http://www.nature.com/nm/>

Upcoming events

PPTA Technology Workshop

5 September 2003, Tokyo, Japan

3rd WFH Global Forum on the Safety and Supply of Hemophilia Treatment Products

22-23 September 2003, Budapest, Hungary

PDA/EMEA European Virus Safety Forum

29 September 2003, Langen, Germany (PEI)

EBA-EPFA International Blood and Plasma Conference

9-10 October 2003, Vienna, Austria

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