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Pro Files

COMMUNICABLE DISEASE PROFILES

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A bi-monthly newsletter for Ontario public health units

Hepatitis B Immunization Tender Award

The 2002-2003 Grade 7 Hepatitis B Immunization tender has once again been awarded to Merck Frosst Canada & Company for a 2-dose program. The vaccine will be Recombivax HB® available in 3 dose, 3 ml vials. The vaccine and syringes will be distributed by *Ontario Government Pharmaceutical & Medical Supply Service (OGPMSS)* based on the number of eligible students and distribution patterns from previous programs. Various promotional materials such as posters, pamphlets and dosage cards are available from Merck Frosst Canada & Company. Order forms for vaccines and supplies, and a request for coverage data for the 2001-2002 school year were sent to health units in July 2002. Most health units have already returned these forms to the Public Health Branch. We appreciate the extra work required in completing these documents. Keep up the good work and good luck in the 2002-2003 campaign.

Source: Disease Control Service, Public Health Branch

Important Drug Safety Update on FSME-IMMUN® (tick-borne encephalitis vaccine)

Health Canada (HC) has recently released information sounding caution about a potential theoretical risk that may be associated with the administration of a vaccine, FSME-IMMUN®. This vaccine is used to protect against the tick-borne encephalitis (TBE) virus where the disease is widespread (specifically areas of Russia and other countries of the former Soviet Union as well as parts of Europe), during April through August. The vaccine is not approved for marketing in Canada, but is available under HC's Special Access Program (SAP) through an arrangement with the manufacturer, Baxter Corporation.

The human serum albumin (HSA) used as a stabilizer in this vaccine, was prepared from plasma collected from European donors. Due to the prevalence of Bovine Spongiform Encephalopathy (BSE) in European countries, there is a theoretical possibility that donors living in these countries may be silent carriers of prion agents through their exposure to BSE infected beef products. Traditionally, HC requires that all plasma-derived products approved to be marketed in Canada, whether administered directly or as constituents of other products such

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as vaccines, be prepared from plasma collected from Canadian or U.S. donors.

Against this background, HC is advising that persons who have received or will receive this vaccine must be informed about this remote and theoretical but potential risk. The decision to start or continue a course of immunization with FSME-IMMUN® should be based on the evaluation of all potential risks for the individual. Disclosure of all the facts can help patients understand the theoretical nature of this risk. Health Canada is not requiring persons who have received this vaccine to forego future blood donations.

The Chief Medical Officer of Health, Dr. Colin D'Cunha, has communicated details of this HC safety update to all Medical Officers of Health.

Source: Biologics and Genetic Therapies Directorate, Health Canada, July 4, 2002

First Canadian Case of Variant Creutzfeldt-Jakob Disease (vCJD)

In April 2002, a suspected case of variant CJD was reported to Health Canada's CJD Surveillance System. Because of the clinical presentation, age of the patient and past multiple stays in the United Kingdom (UK), this was classified as a possible vCJD case. However, the diagnosis of classical CJD was also considered.

The patient, a male under the age of 50 from Saskatchewan, had multiple stays in the UK during the outbreak of Bovine Spongiform Ecephalopathy (BSE), commonly know as "mad-cow disease." While staying in the UK, the patient ate processed meat products. Processed meat products made from cows infected with BSE carried a high risk of transmission of BSE. After coming to Canada in the early 1990s, the patient ate very little beef and had not eaten venison from deer or elk. The patient has not donated blood in Canada. The patient underwent a medical procedure (endoscopy) in Canada.

Upon learning of the patient's procedure, Health Canada immediately advised the hospital to remove from service the medical devices used during the procedure, until such time as a diagnosis be confirmed. The hospital immediately complied with Health Canada's recommendation. Following the death of the patient at St. Paul's Hospital in Saskatoon, an autopsy was performed and vCJD was confirmed by Canadian experts. However, because this was the first case of vCJD diagnosed in Canada, final confirmation was sought from an expert on vCJD in the UK. This expert confirmed vCJD. The attending physician was notified and spoke to the family of the patient.

The hospital, together with provincial authorities and Health Canada, has identified 71 individuals who were exposed to the medical devices before the diagnosis of vCJD was suspected in that patient. As a precautionary measure, the hospital has a plan of action in place to advise those individuals not to donate blood, organs, or tissues. However, if any of these individuals have donated blood since their procedure, their blood components that have not been pooled will be retrieved and destroyed. If any blood components donated by those individuals have been pooled, the theoretical and remote risk of vCJD transmission does not merit further action.

Although the risk of acquiring variant CJD from the medical devices used on the patient with the disease is considered to be extremely low, Health Canada recommended the medical devices be permanently removed from service now that the diagnosis has been confirmed. This situation does not represent a threat to those who have been in contact with this person, since vCJD is not contagious through personal contact. For example, there is no evidence that vCJD can be spread through touching or kissing a person with the disease. Similarly, health care workers who have provided usual care to a patient with vCJD do not have an increased risk of acquiring the disease from that patient.

Because the disease has a long incubation period, it was expected that a case of vCJD would be diagnosed in Canada several years after a person acquired the disease while staying in the UK.

Source: Press Release, Health Canada, August 8, 2002 and Press Release, Government of Saskatchewan, August 8, 2002 (edited)