

**TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES
ADVISORY COMMITTEE MEETING**

February 12 and 13, 2004

Silver Spring, MD

Issue Summary Topic #1.

**Presumptive transfusion transmission of variant Creutzfeldt-Jakob Disease (vCJD):
Possible implications for FDA policies**

ISSUE

On December 17, 2003, authorities in the U.K. announced that a recipient of blood components from a donor who later developed variant Creutzfeldt-Jakob disease (vCJD) had developed that disease¹—one of 15 known recipients of such components followed by the U.K. Transfusion Medicine Epidemiology Review². Because the likelihood of coincidental occurrence of vCJD in the two cases appears to be very small, and recognizing the accumulating evidence that, in a number of transmissible spongiform encephalopathies (TSEs) of animals, infectivity can be present in blood, the CDC³ has concluded that this is a probable transfusion-transmitted case. (The FDA terms it a “presumptive” transfusion-transmitted case, because, while probable, the role of transfusion cannot be proven—or disproved; but prudence dictates that the case be accepted as transfusion-transmitted for purposes of public health policy.) FDA has previously advised blood programs to take steps to reduce the theoretical risk of transmitting CJD and vCJD by blood and blood products⁴. We must now consider whether the recognition of a probable transfusion-transmitted case of vCJD has implications for current FDA blood policies that are in place to reduce the potential risk of such transmission by U.S. blood products.

Background

In March 1996, a clinically healthy young blood donor donated Whole Blood to the U.K. National Blood Service. Packed red blood cells—not leukoreduced—were transfused into an older surgical patient. The donor developed vCJD about three years later and died. The diagnosis of vCJD was confirmed at autopsy. The recipient of the blood developed vCJD about six and a half years after the transfusion and died in autumn 2003; the diagnosis of vCJD was confirmed at autopsy. The recipient was one of 15 identified recipients in the U.K. of blood components from donors who later died with definite vCJD. (None other 14 recipients has had a diagnosis suggesting vCJD during periods as long as 10 years after transfusion.) The route of infection of the recipient cannot be known with absolute certainty, and it is not impossible that both donor and recipient were infected independently with the BSE agent by consumption of contaminated meat or meat products. However, prudence dictates that—considering the low overall incidence of vCJD in the U.K., especially in the age group of the recipient—the recipient’s case must

be considered as a presumptive transmission of vCJD by transfusion. Based on a similar conclusion, discussions of potential implications for public health in general and blood safety policies in particular have begun in the U.K.⁵

Studies in animals with TSEs—reviewed at previous meetings of TSEAC—have long suggested that small amounts of infectivity might be expected to be present in human blood, both during asymptomatic incubation period and clinical illness with TSEs. Largely based on results of animal studies, FDA has recommended a number of precautionary deferrals of blood donors (and some donors of Source Plasma) who may be at increased risk for CJD or vCJD. FDA recommended reducing the theoretical risk of transmitting vCJD, by deferring certain donors who had spent time in countries where there was a substantial possibility of exposure to the agent of BSE (the presumed source of vCJD), donors who might have consumed U.K. beef while on U.S. military bases in Europe, donors who injected bovine insulin sourced from the U.K. since 1980, and donors who received blood transfusions in the U.K. since 1980⁴. In light of the recent report from the U.K., FDA believes that the measures it has recommended to reduce the risk of transmitting CJD and vCJD remain prudent. FDA welcomes further discussions of its current policies in the context of scientific issues that may be raised by the presumptive transfusion-transmitted case of vCJD. As in previous discussions, the possible effects that any proposed changes in blood and plasma donor suitability policies or product manufacturing may have on reducing the risk of transmitting CJD and vCJD must be balanced against any negative effects that those changes might have on the quality or supply of blood and plasma.

References

1. U.K. Department of Health. Blood transfusion incident involving vCJD. Dec 17, 2003.
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2. vCJD: Blood transfusion incident. Statement to the U.K. House of Lords, citing previous statement by U.K. Secretary of State for Health, Dec 17, 2003. Column 1170 et seq.
3. CDC. National Center for Infectious Diseases. Fact sheet: New variant Creutzfeldt-Jakob disease. Reviewed by CDC Dec 29, 2004
www.cdc.gov/ncidod/diseases/cjd/cjd_fact_sheet.htm, accessed on Jan 27, 2004
4. DHHS. FDA. Guidance to Industry “Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products ” at <http://www.fda.gov/cber/gdlns/cjdvcjd.htm>, January 2002
5. Bird SM. Recipients of blood or blood products “at vCJD risk.” *BMJ* 2004;228:118-119

Attachments

Department of Health. Blood transfusion incident involving vCJD. Dec 17, 2003

CDC. National Center for Infectious Diseases. Fact sheet: New variant Creutzfeldt-Jakob disease (vCJD). Reviewed by CDC Dec 29, 2004

Bird SM., Recipients of blood or blood products “at vCJD risk.” *BMJ* 2004;228:118-119