



e-Network Forum

CALIFORNIA BLOOD BANK SOCIETY

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Handling of Donor Recalls/Withdrawals for a diagnosis of CJD in a family member

A colleague in Boston wonders how transfusion service medical directors would handle recalls/withdrawals in the following situation: a blood donor's **father died with a positive CJD diagnosis in 2006**. The donor provided **numerous donations dating back 1-10 years prior** to the father's death. Would you recall some or all of the products, contact all or some of the recipients' physicians, and/or contact all or some of the recipients? Please provide details.

The following comments have been received.

1. **According to Dr. Roger Dodd, Vice President, Research and Development of the American Red Cross Holland Laboratory** (attribution used with permission), the FDA has a [guidance document](#) on this topic, dated April 25th, 2002. Basically, the FDA document recommends withdrawal of in-date products in circumstances that are described by the inquiring Boston physician, but does **not recommend tracing and notification of recipients of prior donations**. However, it does indicate that a [Biological Product Deviation Report](#) should be filed. The donor must be permanently deferred unless genetic testing shows that he or she is free of any CJD-associated prion protein allele. Dr. Dodd indicate that his laboratory has **ongoing research studies on donors of this type**, and the Boston physician (or other physicians with similar cases) may wish to contact Larisa Cervenakova MD, PhD for further information (cervenakl@usa.redcross.org).
2. **A transfusion medicine physician with many years of experience in blood donor collection and follow up** reports that the case under discussion appears to be one of classical CJD. His interpretation of the [FDA guidance of January 2002](#) is that it leaves notification and counseling to the **discretion of physicians**. In his opinion, there is sufficient evidence today indicating that **classical CJD**, differently from variant CJD, is **not transmitted by transfusion**. Thus, in this case, he would **not notify hospitals, physicians or recipients** of prior donations. **If this were a case of vCJD, he would notify** because there is documentation of transmission and that is the procedure being followed in the UK.

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3. **A colleague in New York who is affiliated with a large regional blood collection center** reports that she **agrees** with the comments of Dr. Roger Dodd in [posting #1](#). The donor in question did not have CJD, so only indate product retrieval is indicated and the donor must now be deferred. However, she does **NOT agree** with the second respondent's comments in [posting #2](#), that if this discussion was about a donor whose father had vCJD, tracing and notification of recipients of prior donations should be done. In the New Yorker's opinion, such **tracing and notification should only be done if the donor him/herself had a diagnosis of vCJD** (not the donor's father), and that there is no reason to think that a person with vCJD has any impact on their family members.
4. **Edward P. Notari IV, M.P.H Project Leader of the Transmissible Diseases Department at the Jerome H. Holland Laboratory, American Red Cross** (attribution used with permission) reports that "the Jerome Holland Laboratory of the American Red Cross (ARC), in collaboration with the Centers for Disease Control and Prevention (CDC) and with support from blood centers across the country, has been **conducting look-back investigations on blood donors who are diagnosed with classic CJD**. The objective of the study is to assess whether classic CJD can be transmitted through blood transfusion. This study was originally started in 1995 by the American Red Cross and was transferred to the National Blood Data Resource Center, an independent subsidiary of the American Association of Blood Banks, in 1997. As of October 2003, study management returned to the American Red Cross. Our study looks at blood donors who subsequently developed classic CJD and requests information on the recipients from the entire span of the donor's history. **If you are aware of a blood donor who received a positive CJD diagnosis and you are interested in the study**, you can contact Ms. Kerri Dorsey, MPH of the CJD Look-back Study Group at dorseyke@usa.redcross.org to report a donor case or to inquire further about the study. Thank you for your support."

Please submit comments to the [e-Network Forum](#).

[Ira A. Shulman, MD](#)

CBBS e-Network Forum Editor & Moderator



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Addenda: June 22, 2006

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