

April 10, 2003

**TRACKING SYSTEM FOR PATIENTS IDENTIFIED IN THE  
CREUTZFELDT JAKOB DISEASE (CJD) LOOKBACK NOTIFICATION INITIATIVE**

**1. PURPOSE:** This Veterans Health Administration (VHA) Directive establishes policy for tracking patients identified in the Creutzfeldt Jakob Disease (CJD) initiative, established in January 1995, as part of the lookback notification of all Department of Veterans Affairs (VA) patients who may have received certain lots of blood derivatives or blood components produced from donors with CJD.

**2. BACKGROUND**

a. The American Red Cross (ARC), Baxter Pharmaceutical Company, and Miles Pharmaceutical Company initiated voluntary withdrawal in November 1994 of certain lots of plasma derivatives based on discussions with the Food and Drug Administration (FDA). ARC initiated a recall of certain blood components. The precautions were taken because a ten-gallon ARC volunteer blood donor died of CJD, a rare neurological disorder. Plasma from this donor had been made into nearly 200 lots of derivative blood products. CJD has not been shown to be transmitted by the transfusion of blood components or through plasma derivatives. The Centers for Disease Control and Prevention characterized the risk of transmission from blood derivative products as “small and immeasurable” and “theoretical.”

b. Notwithstanding the theoretical nature of the transmission risk, VA believed it had an ethical obligation to inform patients of the exposure to potentially contaminated blood components or plasma derivative products while under VA’s care. On January 6, 1995, VHA initiated a voluntary lookback notification of all VA patients who may have received certain lots of blood derivatives or blood component products produced from donors with CJD.

c. For the CJD lookback notification, Pharmacy Service in VA Central Office identified VA medical centers known to have received shipments of the potentially contaminated products and sent the list to the field facilities. The VA medical centers then identified patients who may have received those blood components or plasma derivatives and notified the patients of the exposure and the risks related to the exposure. If a patient identified through the lookback notification initiative died, the medical center sent a report to the VHA’s Office of Environment Epidemiology Service. The VHA established a tracking system for individuals who received these products to determine if there was an increase in CJD cases.

**3. POLICY:** It is VHA policy to track individuals who were identified through the VA CJD lookback notification initiative (January 4, 1995) to determine if there is an increase in the cases of CJD over time.

**4. ACTION**

a. **VHA Central Office Infectious Diseases Program Office.** The Infectious Diseases Program Office is the repository for the CJD lookback database. It is responsible for updating

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the CJD lookback database using the status reports from the field and is responsible for providing summary reports to the VHA Chief Patient Care Services Officer.

(1) Every 2 years (odd years), the Infectious Diseases Program Office requests from field facilities through the appropriate Network Office an update (using Att. A) on the status of patients who had previously been identified through the VA CJD lookback notification initiative.

(2) Using mail requiring a signature for receipt, the Infectious Diseases Program Office sends to Veterans Integrated Service Network (VISN) Clinical Managers (in those VISNs that had previously identified patients through the CJD lookback notification initiative) a listing (Att. A) of reported patients and the VA facility within their VISN that had made the original patient identifications. A cover memo must be included that states the need to maintain patient confidentiality.

b. **Infectious Diseases Program Director.** The Infectious Diseases Program Director is the steward for the CJD lookback database.

c. **Clinical Managers**

(1) The Clinical Managers must determine within their Network the most appropriate mechanism for obtaining the requested information while maintaining patient confidentiality. *NOTE: Since the patients had been previously notified through the CJD lookback initiative, additional patient notification is not warranted.*

(2) Upon completion of the status reports (Att. A), the Clinical Managers must ensure that the reports are mailed (using a mailing system requiring signature of receipt) to the Program Director for Infectious Diseases VA Central Office at the following address: (111), Cincinnati VA Medical Center, 3200 Vine Street, Cincinnati, OH 45220.

**5. REFERENCES:** VA teletype dated January 4, 1995. Voluntary Lookback Notification of patients in Creutzfeldt Jakob Disease Component/Derivative Recall Process.

**6. FOLLOW-UP RESPONSIBILITY:** The Chief Patient Care Services Officer (11) is responsible for the contents of this Directive. Questions relating to the Directive should be referred to the Office of the Program Director for Infectious Diseases at (513) 475-6398.

**7. RESCISSION:** None. This VHA Directive expires April 30, 2008.

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Under Secretary for Health

Attachment

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