

February 19, 2009

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

**1. PURPOSE:** This Veterans Health Administration (VHA) Directive provides policy for tracking patients identified in the Creutzfeldt-Jakob Disease (CJD) initiative, established in January 1995, as part of the lookback notification to 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 withdrawals in November, 1994 of certain lots of blood component products based on discussions with the Food and Drug Administration (FDA). The precautions were taken because a frequent 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. VHA patients were among those across the Nation who received these products. Subsequent to this withdrawal, VHA was notified three more times between 1996 and 1998 of potentially CJD-contaminated plasma products that may have been administered to patients.

b. Iatrogenic transmission of CJD from blood components or plasma derivatives has not been reported. *NOTE: This is in contrast to recent reports of human transfusion transmission of variant CJD, the agent associated with bovine spongiform encephalopathy.* The Centers for Disease Control and Prevention (CDC) characterized the risk of CJD transmission from blood derivative products as “small and immeasurable” and “theoretical.” 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 care. In January 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 of products to these 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. 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 to determine if there is an increase in CJD cases over time.

**THIS VHA DIRECTIVE EXPIRES FEBRUARY 28, 2014**

#### **4. ACTION**

a. **VHA Central Office Infectious Diseases Program Director.** The National Infectious Diseases Program Director is the steward for the CJD lookback database.

b. **VHA Central Office Infectious Diseases Program Office (IDPO).** The IDPO is the repository for the CJD lookback database and is responsible for updating the status of patients in the CJD lookback database every 2 years (odd years) using the following mechanisms:

(a) The IDPO sends to Veterans Integrated Service Network (VISN) Chief Medical Officers (in those VISNs that had previously identified patients through the CJD lookback notification initiative) a list of the facilities within their VISN that had made the original patient identifications. After a point of contact (POC) is identified at each facility, the IDPO sends a listing of reported patients for whom updated data are required using VA Form 10-0401, CJD Lookback Notification Report Form. This listing of patients includes sensitive data, and therefore is transferred securely to facilities using a VA-approved encryption mechanism (e.g., Public Key Infrastructure (PKI) certificate, Rights Management Server (RMS)) in accordance with current VA policy. Prior to transferring the listing of patients, the appropriate facilities are provided with a document from the IDPO stating:

1. The need to maintain patient confidentiality;

2. The method of secure data transfer to be used to implement this Directive, and

3. The Facility Information Security Officer (FISO) is to be consulted, if necessary, for guidance on compliance with VA requirements for secure transmission of sensitive data.

(b) In some situations, the IDPO collects data to update the CJD lookback database using VHA electronic patient records and other available sources.

(c) Providing summary reports to the VHA Chief Patient Care Services Officer after each biennial CJD lookback tracking activity is completed.

c. **VISN Chief Medical Officer.** On receipt of the document from the IDPO listing the facilities in the VISN with patients in the CJD lookback, the VISN Chief Medical Officer informs the appropriate facility Chiefs of Staff that a facility POC is to be selected to correspond with the IDPO for the transfer of patient information.

d. **Facility Chief of Staff.** The facility Chief of Staff is responsible for:

(1) Ensuring that a POC at the facility is selected for correspondence with the IDPO and for secure transfer of patient information. This POC needs to have the capability to exchange data using the VA-approved encryption mechanism that is used to implement this Directive.

(2) Determining within their facility the most appropriate mechanism for obtaining the patient information requested in VA Form 10-0401 (e.g., status of alive, deceased, or unknown; any CJD diagnosis; date and cause of death) while complying with VA security requirements for protection of sensitive data and maintaining patient confidentiality. *NOTE: The facility POC for secure data transfer does not necessarily need to be the person who completes the form.*

e. **Facility POC.** The facility POC is responsible for:

(1) Contacting the IDPO to receive the list of patients in VA Form 10-0401 for whom updated status information is required. *NOTE: Since the patients had been previously notified through the CJD lookback initiative, additional patient notification is not warranted, and*

(2) Transferring the completed status report for patients listed in VA Form 10-0401 and any supporting documents (e.g., autopsy reports) to the IDPO using the secure mechanism selected for implementation of the Directive.

**5. REFERENCE:** 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 are referred to the Infectious Diseases Program Office at (513) 475-6398.

**7. RECISSION:** VHA Directive 2003-019 is rescinded. This VHA Directive expires February 28, 2014.

Michael J. Kussman, MD, MS, MACP  
Under Secretary for Health

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