Health Protection Agency

CJD Section
Communicable Disease Surveillance Centre
61 Colindale Avenue
London NW9 5EQ

10th September 2004

To Medical Directors of Trusts

Variant Creutzfeldt-Jakob Disease (vCJD) and Plasma Products

Dear Doctor,

I write to inform you that the Bio Products Laboratory (BPL) and Protein Fractionation Centre, Scotland (PFC) will shortly be releasing details of plasma product batches that present a possible risk of transmission of vCJD. These batches were manufactured from plasma start pools containing a donation from an individual who subsequently developed vCJD.

The purpose of this letter is to provide you with background information and to describe the actions expected to be undertaken locally.

Previous notifications of UK donors who later developed vCJD, in 1997, 1999 and 2000, resulted in some recipients of implicated plasma products being traced but not put in an 'at-risk' group for vCJD. Following these notifications, the CJD Incidents Panel, on behalf of the UK Chief Medical Officers, has made a detailed assessment of vCJD risk from implicated plasma products. As a result, the Panel now recommends that certain special public health precautions need to be taken for some recipients of UK-sourced plasma products who may have been exposed to potential vCJD infectivity. This is in order to reduce any possible risk of onward transmission of vCJD. The Clinical Information document (attached) gives background information on the assessment of risk, special public health precautions, and infection control issues for staff caring for affected patients. This is supplemented by 'Information for Patients' (attached). The Recommendations of the CJD Incidents Panel are also enclosed.

The Health Protection Agency's Communicable Disease Surveillance Centre (Colindale) is handling the patient notification in England, Wales and Northern Ireland. The Scottish Centre for Infection and Environmental Health is handling this notification in Scotland.

The notification of exposure to potential vCJD infectivity will involve three groups of patients:

1) patients with bleeding disorders (including congenital and acquired haemophilia (haemophilia A and haemophilia B), Von Willebrand Disease, other congenital bleeding disorders) and congenital antithrombin III deficiency,

2) patients with primary immunodeficiency, and

3) some patients with other conditions whose treatment may have involved sufficient quantities of implicated plasma products for them to be considered 'at-risk' of vCJD for public health purposes. It is not possible to give an exhaustive list but examples include:

   - conditions requiring several infusions of intravenous immunoglobulin G (incuding secondary immunodeficiencies; certain neurological conditions and autoimmune illnesses such as idiopathic thrombocytopaenic purpura),

   - conditions requiring large volumes of albumin 4.5% (including plasma exchange recipients and patients with severe burns), and

   - patients with certain other conditions requiring critical care (including acquired antithrombin deficiency or patients requiring rapid warfarin reversal).

Patient Notification and Management

Arrangements are underway with both the UK Haemophilia Centre Doctors' Organisation and the UK Primary Immunodeficiency Network to contact their members directly with details of how to manage their patients. The Trusts with haemophilia centres or clinicians who are part of the UK Primary Immunodeficiency Network may need to review whether the support available is likely to be adequate for the work that will be required.

You are being asked to implement arrangements for managing the other groups of patients that could have been exposed to sufficient quantities of particular implicated plasma products for them to be considered 'at-risk' of vCJD for public health purposes.

This will require:

- a trace-back of implicated plasma products to patients treated in your Trust so that an assessment can be undertaken of the individuals' risk (a flow chart summarising the actions to be taken is attached), and

- where appropriate, ensuring that suitable arrangements are made to inform the few patients for whom special public health precautions are warranted.

Managing any patients 'at-risk' of vCJD for public health purposes will involve:

- ensuring that extra infection control precautions are taken should these patients require further invasive medical procedures (see ACDP TSE Working Group guidance, 2003 http://www.advisorybodies.doh.gov.uk/acdp/tseguidance/Index.htm).

- ensuring that any relevant past surgical procedures are reported to the CJD Incidents Panel (details are given in the Clinical Information document),

- liaising with the general practitioners of any patients who are 'at-risk' of vCJD for public health purposes so they may:

  - know that their patient is being informed about their 'at risk' status,
  - record the patient's vCJD 'at risk' status and the special precautions required in their primary care records,
  - include this information in any referral letters should the patient require surgery or other invasive medical procedures, and
  - provide information on the patient's recent surgical history at other hospitals.

The clinical care of the patients identified as 'at-risk' for public health purposes should not be compromised in any way.

Batch details

Details of the batch numbers of **ALL** known plasma products manufactured using donations from people who subsequently developed vCJD, including batches previously notified, are listed in the Tables attached (see vCJD Implicated Batch Numbers Tables 1 to 3), stratified according to their potential level of risk, and identifying the batches that were notified previously.

These batches refer to plasma products sourced from UK donors until 1998. None of the implicated batches are within shelf life.

A list of the specific **subset** of implicated plasma products known to have been supplied to your institution will also be forwarded from the plasma product suppliers (BPL), via the manufacturer's consignees. These are likely to be sent to your Principal Pharmacist, the Manager of your Blood Transfusion Laboratory or Hospital Blood Bank, and your Haemophilia Centre. However in some cases this information may not be available for a number of weeks or may be incomplete, because other distributors may be involved in the supply chain and need to hand search paper archives.

Action and timing

The specific actions required by your Trust are detailed as follows and summarised in the flow chart entitled 'Action to be initiated by medical directors of acute trusts with regards the patient notification exercise':

- **An evaluation of the ease with which implicated plasma products are likely to be traceable to individual patients.** This will probably be best undertaken by the Head of your Trust's Pharmacy together with the Manager of your Blood Transfusion Laboratory or Hospital Blood Bank.

- **A trace-back of the implicated batches of plasma products to individual patients and an assessment of each patients' risk.** The CJDIP advises that the individual exposure assessment should be considered only where records are readily accessible and patients can be easily identified as having received implicated batches. Only in such circumstances is the traceback effort likely to be proportionate to any possible public health benefit.

  Your Trust Pharmacy and Blood Transfusion Laboratory may advise you after they have made enquiries, that recipients of implicated batches cannot be reliably identified in your Trust, or that details of the doses the patients received are not readily accessible. Included with the details of the affected batches is a short questionnaire to record the absence of local traceability and an estimate of the potential number of patients who might have been considered 'at-risk' of vCJD for public health purposes. This questionnaire will also provide a means for you to let us know whether or not your Trust actually received any of the implicated plasma products.

- **Completion of each individual exposure assessment.** If patients are identified as having received implicated batches, the hospital clinician responsible for their care should compile the details of the extent of each patient's exposure. A Patient vCJD Exposure Assessment Form is enclosed for this purpose.

The Traceability Questionnaire and any Patient vCJD Exposure Assessment Forms should be returned in confidence to the Consultant Head of the CJD Section, HPA-CDSC (address on form) where a risk assessment will be undertaken. This will involve combining the total amount of implicated material received with the relevant batch specific estimate of infectivity. The data forwarded will be managed in accordance with Caldicott guidance, the requirements of the Data Protection (1998), and the Health and Social Care (section 60, 2001) Acts.

- The HPA-CDSC will report back promptly and directly to each clinician whether the patient should be considered 'at-risk' of vCJD for public health purposes and the further action that may need to be taken.

- **Informing and providing advice and support to those patients considered 'at risk' of vCJD for public health purposes.** The hospital clinician responsible for the care of that patient will be asked to liaise with the patient's GP to agree the best way to inform each patient, advise them of the special public health precautions required, and arrange for on-going support. The HPA will distribute relevant clinician and patient literature when they report the result of each individual risk assessment. The clinician will also need to liaise with your local infection control team and local Health Protection team to ensure that certain special public health precautions are followed.

Patients' individual risk assessments should be based on the batches of implicated product that a patient is known to have received. Where there is doubt, e.g. because of gaps in a patient's treatment record, then the patient should **NOT** be included in the 'at-risk' group.

Patients who have died within the last year should also be assessed and if identified as 'at-risk' have their clinical history reviewed in order to identify and manage any recent surgical incident that may pose an infection control risk. Patients whose care has been transferred elsewhere should be followed up if they are assessed to be 'at-risk' of vCJD for public health purposes.

Because their patients are likely to be most affected, Haemophilia Centre Doctors and Primary Immunodeficiency Network clinicians will be posting letters to all their patients directly on **Monday 20th September** to appraise them of the situation, and inform patients for whom special public health precautions are warranted. A national announcement by the Department of Health about the notification exercise is planned for shortly after this date.

Coordinating the communication exercise in this way will help to ensure that the different patient groups who need to be contacted receive their information as far as possible at the same time. A summary of the patient notification exercise is attached.

Handling enquiries from former and current patients

The level of public interest in this notification is difficult to anticipate. Former and current patients may approach your institution to enquire if they have received implicated batches or are at increased risk of vCJD.

Background information about vCJD with useful links is available from the HPA website http://www.hpa.org.uk/infections/topics_az/cjd/menu.htm. It is planned that from 21st September 2004 information regarding vCJD and plasma products will also be available here. NHS Direct and its national colleagues will also be operating a 'vCJD and Plasma Products' advice line (telephone 0845 850 9850) for general public enquiries from this date.

We suggest that appropriate staff in your Trust are made aware that from 21st September, enquiries from patients may arise. These patients should be advised that they will be contacted in due course if an exposure that warrants further action is traced back to them. If they require further information they should be advised to contact NHS Direct. Staff in your Trust may have similar concerns.

All media enquiries should be referred to the relevant Government Press Office (see Media Handling Protocol attached).

If you, your Head of Pharmacy, your Blood Transfusion Laboratory Manager, or other health professionals in your Trust, have any questions regarding the content of this communication, underlying rationale and action to be taken, enquiries should be directed as follows:

- E-mail enquiries should be addressed to cjd@hpa.org.uk and will be answered as soon as possible.

- Health professionals needing to speak with someone directly should contact the CJD Section at the Health Protection Agency's Communicable Disease Surveillance Centre (Colindale) on 020 8200 6868 extension 7771.

Yours sincerely

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Dr Nicky Connor
Consultant Epidemiologist,
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Enclosed documents

a) Recommendations of the CJD Incidents Panel
b) Tables of vCJD implicated batch numbers (with text insert)
c) Clinical information
d) Information for Patients
e) Patient vCJD Exposure Assessment Form
f) Traceability questionnaire
g) Summary of patient notification exercise
h) Actions to be initiated by Medical Directors of Trusts
j) Media Handling Protocol