From the Chief Medical Officer
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Department of
Health, Social Services and Public Safety
An Roinn
Sláinte, Seirbhísí Sóisialta agus Sábháilteachta Poiblí
www.dhsspsni.gov.uk

HSS(MD)29-2004

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Medical Directors, HSS Trusts *(for dissemination to Consultant Haematologists)*
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Our Ref: HSS(MD)29-2004
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Dear Colleague

VARIANT CREUTZFELDT-JAKOB DISEASE (vCJD) AND PLASMA PRODUCTS

I am writing to inform you that an exercise is being undertaken by the Health Protection Agency (HPA) Communicable Disease Surveillance Centre to identify and inform certain patients who have received batches of plasma products prepared from plasma donated by people who subsequently developed vCJD. The donated plasma has been used to manufacture clotting factors (including factor VIII and factor IX), antithrombin, intravenous immunoglobulin G, albumin, intramuscular human normal immunoglobulin and anti-D.

You do not need to take any action yourself as a consequence of this letter although this will change if any of your patients are identified as 'at-risk' for public health purposes.

The CJD Incidents Panel (an expert advisory committee set up on behalf of the UK Chief Medical Officers to advise on the risk to patients of acquiring CJD through medical procedures, including blood and plasma treatments) 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 (i.e. for patients who are considered 'at-risk' of vCJD for public health purposes). This is in order to reduce any possible risk of onward transmission of vCJD.

One or more of your patients **MAY** be considered 'at-risk' for public health purposes. Should this be the case the most likely scenario is that you will be contacted by the clinical centre or acute trust that cares (or cared for) your patient. However, it is possible that a concerned patient may present to you in the first instance. The following summary is a guide to what action would need to be taken in this event.

1. **Patients who have received intramuscular human normal immunoglobulin and anti-D**

   Intramuscular human normal immunoglobulin and anti-D are very unlikely to place patients 'at-risk'. The CJD Incidents Panel advises that implicated batches do not need to be traced, and patients who received these products do **NOT** need to be informed.

   Anyone in this category who presents to primary care may be reassured that the risk to health from treatment with these products is considered negligible and so they do not need to take any special precautions.

2. **Patients who have received clotting factors or antithrombin made from UK-sourced pooled plasma (including Factor VIII, Factor IX, Factor VII, Factor XI, Factor XIII, and prothrombin complexes as well as antithrombin)**

   Patients who have received clotting factors or antithrombin made from UK-sourced pooled plasma may be considered 'at-risk'. The UK Haemophilia Centres Doctors' Organisation (UKHCDO) and the Health Protection Agency are contacting local haemophilia centre doctors directly with information on patient identification and management, for patients with bleeding disorders and congenital antithrombin III deficiency.

   Anyone in this category who presents to primary care should be advised to contact their local haemophilia centre who will be able to assess their status and provide appropriate advice.

   Some patients with other conditions requiring critical care may also have received implicated clotting factors or antithrombin made from UK-sourced pooled plasma and be considered 'at-risk'. Please see section 5 below.

3. **Patients who have received intravenous immunoglobulin G**

   Some patients who have received intravenous immunoglobulin G prepared from implicated plasma batches may be considered 'at-risk'. The UK Primary Immunodeficiency Network and the Health Protection Agency are contacting lead immunologists directly with information on risk assessment for patients with primary immunodeficiency.

   Anyone in this category who presents to primary care should be advised to contact the consultant immunologist who normally deals with their primary immunodeficiency as they will be able to assess the patient's status and provide appropriate advice.

   Some patients with other conditions who have received several infusions of intravenous immunoglobulin G may also be considered 'at-risk'. Please see section 5 below.

4. **Patients who have received albumin**

   Some patients who have received large volumes of albumin prepared from implicated plasma batches may be considered 'at-risk'. Please see section 5 below.

5. Identifying patients who have received specific implicated clotting factors or antithrombin, intravenous immunoglobulin G or albumin

The Panel advises that where it is reasonably possible (e.g. where there are computerised records) acute trusts should trace patients who have received implicated batches of some clotting factors, antithrombin, intravenous immunoglobulin G or albumin.

In addition to bleeding disorders, congenital antithrombin III deficiency and primary immunodeficiency there are a range of other conditions, the treatment of which might result in some patients being considered 'at-risk'. It is not possible to give an exhaustive list but examples include:

- conditions requiring several infusions of intravenous immunoglobulin G (including 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).

If a patient who might be in these categories presents to primary care then enquiries should be made of the hospital where the treatment took place. The HPA will be working with acute trusts to assess individual patient's risks in this category.

In case of difficulty please contact your local Consultant in Communicable Disease Control at your local health board.

Patients identified as 'at-risk' for public health purposes

Once a patient has been identified as being 'at risk' for public health purposes they will be asked:

- not to donate blood, tissues or organs,
- to inform people providing their medical, surgical or dental treatment so any special procedures recommended for the instruments used in their care can be arranged, and to consider informing their families in case emergency surgery is needed in the future

They will also be informed that they do not need to take any special precautions in normal life.

You will be informed by the responsible hospital clinician if any of your patients are considered 'at-risk'. For patients treated with single unit blood components (red blood cells, platelets, cryoprecipitate or fresh frozen plasma) donated by people who subsequently developed vCJD these steps are already in place. Patients treated with vCJD implicated single unit blood components are identified by the UK national blood services and the National CJD Surveillance Unit, Edinburgh. Local health teams are then advised to contact these patients so they can take special public health precautions.

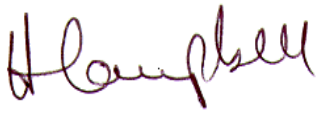
Sources for further information

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.

Information about vCJD with useful links is available from the HPA website http://www.hpa.org.uk/infections/topics_az/cjd/menu.htm. Information for concerned members of the public is available from NHS Direct Online (http://www.nhsdirect.nhs.uk). NHS Direct and its national colleagues are also operating a 'vCJD and Plasma Products' advice line for general enquiries (telephone: 0845 850 9850). In Northern Ireland the helpline number will be 028 90765725.

I hope this information is of value to you. If you need further assistance please contact your Consultant in Communicable Disease Control at your local health board.

Yours sincerely



Dr Henrietta Campbell
Chief Medical Officer

cc Chief Executives of Trusts