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To: NHS Trust Medical Directors

cc: NHS Trust Chief Executives
Health Authority Chief Executives
Directors of Public Health

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Dear Colleague

VARIANT CJD: PATIENTS WHO HAVE RECEIVED IMPLICATED BLOOD PRODUCTS – INTERIM GUIDANCE

Introduction

Last year, the Government established the CJD Clinical Incident Panel to develop a framework for managing all clinical incidents involving potential transmission of CJD and vCJD The Panel's remit encompasses surgical instruments, blood and blood products and tissues. Their proposals for managing incidents will be subject to consultation later this year and, in the case of blood and blood products, will supersede the guidance issued by the Department on 6 February 1998 (PL(CO)(98)1).

This work has been overtaken, to some extent, by an incident involving blood products made from plasma donated in 1996 and 1997 by a person who subsequently developed vCJD. The products involved were Factor 8, Factor 9, Antithrombin 3, Intravenous Immunoglobulin and Albumin. In December 2000, the Bio Products Laboratory wrote to hospitals and clinicians who received the affected batches. No recall was involved as all batches were beyond their expiry date and should, in any case, have been returned to BPL as part of the recovery and replacement exercise in 1999 when BPL switched to using US plasma in the manufacture of all their blood products.

As this incident has generated considerable media and patient interest, hospitals may find it helpful to have interim guidance on managing requests for information from patients who fear that they or their children may have been given these products, pending completion of the Incident Panel's more detailed framework,

General Principles

The main change from the guidance in PL(CO)(98)1 is that ethical thinking has now moved towards giving patients the opportunity to decide for themselves whether to be told that they, or their children, have received vCJD-implicated products. This leads us naturally to the following general principles:

- the public should be informed when such incidents occur and be given enough information to decide whether the incident might apply to them or not. We are waiting on the CJD Clinical Incidents Panel's advice on how this should be done;

- patients who think they may have been affected should be able to discuss their concerns with a suitably qualified individual and, on the basis of that discussion, have the right to choose whether to know if they have received an implicated product;

- people who discover that they have received a vCJD-implicated product should have access to counselling if needed;

- hospitals should ensure that they have prescribing systems in place that allow patients who have received implicated batches of blood products to be traced and notified if this is what they decide.

Haemophilia doctors are already in the process of writing to their patients about the recent incident and the implicated batches of clotting factors. Enquiries to hospitals are therefore more likely to come from patients worried that they may have received vCJD-implicated immunoglobulin, albumin or antithrombin. Pending advice from the CJD Clinical Incident Panel, we are not proposing that hospitals contact patients pro-actively about these products. However, we recommend that hospitals follow this guidance in handling enquiries from patients.

Handling Enquiries from Patients

In handling enquiries from patients who want to know if they, or their children, have received vCJD-implicated blood products, hospitals should ensure that:

(i) patients fully understand the facts about vCJD, so far as they are known, and are clear about the implications of being given this information should they have received one of the affected batches. It is particularly important that patients understand that there is no way of assessing the degree of risk to which they may have been exposed (as the risk of vCJD transmission via blood or blood products remains theoretical and unquantifiable); that there is no diagnostic test available and no specific treatment for those who develop the disease.

Those advising patients may wish to make the following points:

- classical CJD occurs in roughly one in a million people worldwide. Variant CJD is a newly recognised condition with cases mainly in the UK and a small number in France and the Republic of Ireland;

- it is presumed that vCJD has been transmitted to humans by eating beef from cows with BSE. If this is so, anyone who has eaten contaminated beef may be at risk of developing vCJD;

- there are no reported cases of classical CJD or vCJD transmitted by blood or blood products. The risk at this time is therefore theoretical;

- all plasma products now made by the Bio Products Laboratory are made with plasma from US donors where there have been no reported cases of BSE or vCJD;

- there is no test for vCJD that can be used to test blood donors or to identify people with vCJD before they become unwell. There is also no specific treatment for the disease.

- there may be further notifications in future if other patients with vCJD have been blood donors.

(ii) after this initial counselling, patients who wish to know should be told if they have received one of the implicated batches.

(iii) Counselling should be made available, if needed, for patients who have received one or more of the implicated batches The information should also be recorded in their hospital notes.

(iv) In many cases, the batch numbers of blood products (in particular albumin) received by patients may not be recorded in their hospital notes. Hospitals may therefore not be able to tell patients whether or not they received the implicated batches, and counselling services should anticipate the distress this may cause to some patients.

Wider Public Health Implications

The CJD Clinical Incidents Panel are addressing the wider public health implications for patients who may have been exposed to vCJD through surgical instruments, blood & blood products and tissues. Issues under consideration include whether exposed patients should be permitted to donate blood, organs or tissues in future and whether there are implications for patients who need surgery. If patients ask about these issues, you may wish to say that the guidance from the Panel will cover these questions and that, in the meantime, current National Blood Service and UK Transplant exclusion criteria for blood, organ and tissue donors remain valid.

Patient Records

Hospitals should ensure that they have prescribing systems in place to trace patients who have received implicated batches of blood products when these are notified, ideally through a central database. These should have the capability of facilitating wider look back studies capable of informing public health policy. Haemophilia Centre systems already allow such traceability.

Further Information

Further information on this guidance is available from Charles Lister [details} or Mike McGovern [details].

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