To: NHS Trust Medical Directors

cc: NHS Trust Chief Executives
Health Authority Chief Executives
Directors of Public Health
Primary Care Trusts

[ ] May 2001 pharmacy nursing

Dear Colleague

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

Introduction

1. Last year the Department of Health established a CJD Incidents Panel to develop a framework for managing clinical incidents involving possible transmission to patients of CJD and variant CJD. The Panel's remit encompasses surgical instruments, blood, blood products and human tissues. The Panel is developing a framework for managing incidents which 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).

2. In the meantime, it has been discovered that blood products were 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 NHS Bio Products Laboratory (BPL) wrote to hospitals and clinicians who had 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.

Purpose

3. This interim guidance provides advice to hospitals on how to respond to patients who wish to know whether they or their children may have been given variant CJD-implicated blood products, pending completion of the CJD Incidents Panel's more detailed framework. This advice should serve for any other blood product incidents that arise between now and the publication of the framework.

4. The Panel is also considering the arrangements that should be put in place for managing recipients of red cells and other blood components donated by individuals who subsequently developed variant CJD. This does not form part of this guidance.

Current Advice

5. Members of the public have a general right to know about specific incidents involving variant CJD and, if they wish, the right to know whether they might or might not have been exposed to a potential risk. An individual's right not to know that they have been exposed should also be respected. The Panel is still in the process of developing guidelines on the best mechanisms for achieving these objectives.

6. Pending that advice, the Department of Health proposes that hospitals do not contact patients pro-actively about these products. However, we recommend that hospitals follow this guidance in handling enquiries from patients.

Handling Enquiries from Patients

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

- fully understand the facts about variant CJD, so far as they are known;

- are clear about the implications of being given this information should they have received blood products from one of the implicated batches.

8. It is particularly important that patients understand that the risk of variant CJD transmission via blood or blood products remains unknown; that there is no diagnostic test available and no specific treatment for those who may develop the disease.

9. Clinicians advising patients may wish to make the following points:

- sporadic CJD occurs in roughly one in a million people worldwide. Variant CJD is a condition first recognised in 1996 with cases mainly in the UK and a small number in France and the Republic of Ireland. The most likely explanation for the variant CJD cases to date is exposure to the BSE agent;

- there have been no reported cases to date of sporadic CJD or vCJD transmitted by blood or blood products. Epidemiological evidence suggests that sporadic CJD is not spread by blood or blood products. Research into the risk of transmitting variant CJD is underway but there is no clear evidence to date that it can be transmitted by this route. The risk from variant CJD therefore remains unknown;

- CJD cannot be transmitted between people through normal social contact. Anyone potentially exposed should be assured that they will not be putting their friends or family at risk;

- since 1998, plasma from UK donors has not been used in the manufacture of blood products. Blood products made by the NHS Bio Products Laboratory are made with plasma from donors in the United States where there have been no reported cases of BSE or variant CJD;

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

- it may not always be possible to establish with certainty whether a given patient has received variant CJD implicated blood products as the batch numbers may not be recorded in their hospital notes.

10. After this initial advice patients who wish to know should be told whether they have received product from one of the implicated batches, assuming this information is available from their hospital notes.

11. Information and support should be made available, if needed, for patients who are informed that they have received product from one or more of the implicated batches. Support may also be needed in cases where it cannot be established whether the patient received implicated products.

Further Advice to Patients

12. The CJD Incidents Panel is considering whether patients who may have been exposed to variant CJD through surgical instruments, blood components, blood products and tissues should be permitted to donate blood organs and tissues and whether there are implications for patients should they require surgery or dental treatment. If patients ask about these issues they should be advised that, pending guidance from the Panel, current exclusion criteria for blood, organ and tissue donors remain valid. Guidance on the eligibility of organ and tissue donors is set out in *Guidance on the Microbiological Safety of Human Organs, Tissues and Cells used in Transplantation*, published by the Department of Health and available at the Department's website at www.doh.uk/msbt. Patients can obtain information on exclusion criteria for blood donation from their local blood donor centre or by calling the Blood Service's free helpline on 0845 7711 711

Patient Records

13. As a matter of good practice, hospitals should ensure that they have prescribing systems in place that record the batch numbers of blood products given to patients. Haemophilia Centre systems already have such systems.

14. 13. Although any future variant CJD incidents involving products produced by the Bio Products Laboratory will pre-date 1998 when BPL began using US-donor plasma, the possibility of future incidents remains should variant CJD emerge in countries which export plasma or blood products to the UK. Traceability is also desirable in case of any new or emerging diseases associated with plasma-derived products. Hospitals should ensure that their prescribing systems provide this.

Further Information

15. Further information on this guidance is available from Charles Lister in the Department's Health Services Directorate. He can be contacted on GRO-C (charles.lister@ GRO-C)

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