To: NHS Trust Medical Directors

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

[ ] May 2001

Dear Colleague

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

Introduction

1. Last year the Government established the 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 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).

2. In the meantime, there has been 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 (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 products' incidents that arise between now and the completion of the Panel's framework.

4. The Panel is also considering the arrangements that should be put in place for informing 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. The Panel considers that members of the public have the right to know about specific incidents involving variant CJD and, if they wish, the right to know whether they 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 advice from the Incidents Panel, we are proposing 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, and are clear about the implications of being given this information should they have received one of the implicated batches. It is particularly important that patients understand that the risk of variant CJD 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.

8. Those 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;

- 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. For variant CJD, it is probably too soon to detect any transmission by this route. The risk from variant CJD therefore remains theoretical;

- CJD cannot be transmitted from person to person. 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 Bio Products Laboratory are made with plasma from donors in the United States 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;

- it may not always be possible to establish with certainty whether they, or their children, have received v-CJD implicated blood products.

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

10. Information and support should be made available, if needed, for patients who are informed that they have received 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

11. 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 who need surgery or dental treatment. If patients ask about these issues they should be advised that, pending guidance from the Panel, current National Blood Service and UK Transplant exclusion criteria for blood, organ and tissue donors remain valid.

Patient Records

12. 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 allow such traceability.

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 if variant CJD emerges in countries exporting plasma or products to the UK. Traceability is also desirable in case of any new or emerging diseases associated with plasma-derived products.

Further Information

14. 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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