UKHCDO

United Kingdom Haemophilia Centre Doctors' Organisation

Our ref: FGHH/PAM 19 January 2001

Dear Colleague,

You will have received information from BPL about products that contained plasma from a donor who has developed vCJD. At the Advisory Committee meeting we discussed the approach that should be adopted.

Some Centre Directors have written to the patients who received the identified batches. Others had been waiting to discuss the matter further at the Advisory Committee.

An alternative way of approaching the issue is to write to your patients, or parents in the case of children, informing them of the information and establishing whether they wish to know if the information applies specifically to them or not. Some individuals may wish to discuss things further and then choose not to know whether or not they have had an implicated batch. Others will choose to have full information. A letter that can be personalised and sent out from the Centre is enclosed, if you wish to adopt this approach. A reply sheet and a fact sheet on vCJD are also enclosed. Can you please collate the responses to the questions on the reply sheet so that we can gain information about patients' wishes in terms of being informed about specific information.

Whichever approach (these or your own) you decided to use to inform your patients, it is important that the information is recorded in the notes of patients who have received the implicated batches, in case this is of relevance to future clinical events.

By the time you receive this letter, the Haemophilia Society will have informed their members about the BPL notification. You will receive a copy of their letter for information.

The draft letters and fact sheet that were sent to the Advisory Committee for comment have been seen by Mike McGovern and discussed at the D.O.H. The feedback from the D.O.H. is that this is a suitable way of approaching the patients and allowing them to be informed of events but choosing whether they want specific information.

Yours sincerely,

Dr. F.G.H. Hill - (Dictated but not signed)
Chairman – UKHCDO

Enc: 3.

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DRAFT LETTER TO PATIENTS OR PARENT(S)

Dear

Haemophilia Centre Directors have recently been informed by the Bio-Products Laboratory (BPL) about factor concentrates produced in 1996 and 1997 and used before 1998. Since 1998 all BPL plasma products have been made with plasma from USA donors because of the theoretical risk that variant CJD (vCJD) may be transmissible by blood and blood products.

A blood donor has recently been found to have vCJD and plasma donated in 1996 and 1997 was used to make clotting factor concentrates. The plasma from this donor will have been a small volume in a large pool of plasma from other donors. The products made were Replenate, BPL 8Y, Replenine-VF and ATIII.

As yet there have been no reports of any case of vCJD in haemophiliacs or in other patients receiving blood transfusions or blood products.

Action in the UK to minimise the albeit theoretical risk of transmission of vCJD in blood products has been that since 1998 all children with haemophilia are treated with recombinant products and BPL products have been made from American plasma. All blood for transfusion is processed to remove the white cells.

As we have been provided with the batch numbers of these products, individual patients who have received treatment with these have been identified.

This letter is being sent to all patients, irrespective of whether they have received the currently implicated batches, so that you are aware of this occurrence and as there is the possibility of further notifications in the future.

Some may wish to know whether they/their child have received one of these batches, while others may choose not to know this information at this time, as the risk is theoretical and there is no test available at the moment to confirm if vCJD can be transmitted in these circumstances. You are asked to think which approach you would prefer to adopt. Please complete and return the attached reply sheet so that we are aware of your wishes both about the current and similar (if any) future issues.

For patients who have received one of these batches, the information will be recorded in their hospital notes in case it may be important for their care in the future.

Yours sincerely,

Haemophilia Centre Director

Encs: 1. Reply sheet/envelope for return.
2. Fact sheet on vCJD.

REPLY SHEET

To be completed by patient or parent(s) of child and returned to your Haemophilia Centre Director in the enclosed addressed envelope marked **PRIVATE & CONFIDENTIAL**.

(1) I/we have been informed of the notification of donations of plasma from a patient with vCJD being used to make factor concentrates by BPL in 1996 and 1997.

(2) I/we wish to discuss this matter further: YES/NO*

(3) I/we wish to be told if I/our child has received any of the notified batches: YES/NO*

(4) If answering YES to (3):-

I wish to be informed by letter: YES/NO*

I wish to be informed in person: YES/NO*

(5) If similar events occur in the future you will be informed that they have occurred, but please indicate your wishes:-

I/we wish to be told if I/our child has received the identified batch: YES/NO*

Signature(s).....

Name(s).....

Date.....

*Please cross out the wrong information (ie. if you wish to reply YES, cross out NO).

Some Facts about vCJD

1. vCJD is a newly recognised condition with cases mainly in the UK and a small number in France.

2. vCJD is considered to be the human form of BSE, a condition caused in cattle by a prion

3. 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.

4. There is no reported cases of vCJD transmitted by blood or blood products – the risk therefore at this time remains theoretical.

5. There is no test for vCJD that can be used to test blood donors or to identify people with vCJD before they become unwell.

6. All plasma products now made by BPL are made with plasma from USA donors, as there have been no cases of vCJD or BSE in cattle in the USA.

7. There may be further notifications in the future if other patients with vCJD have been blood donors.

8. Some plasma products are made with American and non-UK European plasma. The Protein Fractionation Centre (PFC) in Scotland uses plasma sourced from the USA and Germany. The use of European plasma may be reconsidered in the future as BSE is being identified in an increasing number of European countries.