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HAEMOPHILIA & THROMBOSIS CENTRE
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84 Castle Street
Glasgow G4 0SF
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NHS
Greater Glasgow

20th September 2004

GRO-B

GLASGOW

GRO-B

Dear GRO-B

Haemophilia Treatments and Variant Jacob-Creutzfeld Disease (vCJD) - IMPORTANT INFORMATION

As Haemophilia Directors in the United Kingdom, we have been asked by the UK Departments of Health to send the enclosed letter and information to all patients born with bleeding disorders (haemophilia, or von Willebrand's disease) who are currently registered at our Centre.

According to our current records, we believe that you received clotting factor concentrates (factor VIII, factor IX, factor XI or von Willebrand factor concentrates) from UK blood donors between 1980 and 2001.

Please read the enclosed information carefully. As a public health measure (to protect people from the very small risk of developing vCJD through blood or organ donations, or through re-using contaminated surgical or medical instruments during certain procedures), you are being asked -

- Not to donate blood, organs, semen/eggs
- To inform all healthcare professionals who treat you (doctors, nurses, dentists) about the possible need to use disposable instruments. We have already copied this information to your general medical practitioner (GP).

As Haemophilia Directors in Scotland, we are aware of only one blood donor who contributed to Scottish National Blood Transfusion Service (SNBTS) batches of clotting factor concentrate (which were used between 1987 and 1989) who has since developed vCJD. We wrote two years ago to all our patients who, according to our records, received ANY SNBTS clotting factor concentrates AT THAT TIME, asking them whether or not they wished to know if they had received such batches: it is possible that you received that letter. We are aware that some of you previously indicated that you did not wish to receive any further details about vCJD but, as stated above, we have been directed to give you this information.

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POSITIVE ABOUT DISABLED PEOPLE

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As you will see from the enclosed, we are offering to see any of our patients (or their parents) who wish to discuss their own situation, including whether or not they received any such batches - a reply form and envelope are enclosed.

Please do not hesitate to contact our Centre if, having read the enclosed information, you wish to arrange an appointment to discuss. The enclosed information also gives other sources of advice and support.

Yours sincerely

GRO-C

Prof G D O Lowe **Prof I D Walker** **Dr R C Tait**
Haemophilia Centre Co-Directors

It is important for everyone to read the rest of this letter and the enclosed 'Information for Patients' that has been prepared to help you understand this changing situation.

What has happened?

You may be aware of product recalls in 1997, 1999 and 2000 when donors who provided plasma used to make clotting factors or antithrombin were subsequently found to have vCJD. These previous notifications involved products made by the Bio Products Laboratory in England and the Scottish National Blood Transfusion Service. You may have been informed at the time.

We are writing to you now to give you further information about these and about further batches of clotting factors or antithrombin that have been made using plasma from donors who later developed vCJD; what action is being taken; and to offer you the opportunity to discuss this with us. None of these batches are now in use.

Who is looking into this?

The CJD Incidents Panel (the Panel) is an expert committee set up by the UK Chief Medical Officers to advise on incidents of possible transmission of CJD through medical procedures. These include treatment with blood or plasma products. When people are diagnosed with vCJD, any blood donations they have given are traced. The Panel has reviewed in detail all batches of plasma products known to date to have been made using plasma from donors who later developed vCJD. We refer to these below as 'implicated' products and batches.

What is the risk from these implicated products?

The Panel has used scientific evidence and expert opinion, together with information from the plasma product manufacturers, to examine the possible risks to health from having received implicated plasma products. This risk is on top of the general risk from eating beef and beef products that may have been contaminated by the agent causing Bovine Spongiform Encephalopathy (BSE or 'mad-cow disease').

The potential additional risk to health depends on the type of plasma product and how each batch was manufactured.

For most batches of implicated products the potential additional risk is so low as to be considered negligible. For example some batches of factor VIII, where only the albumin (which is used to stabilise factor VIII in the vial) has been sourced from a donor with vCJD, are extremely low risk. However, batches of factor VIII where the clotting factor (and not the albumin) has been sourced from a donor with vCJD, and other implicated products, which include factor IX and antithrombin, carry a higher risk.

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To all West of Scotland Adult Haemophilia Centre Patients
Registered at Glasgow Royal Infirmary

20th September 2004

IMPORTANT INFORMATION

Dear Patient

Variant Creutzfeldt-Jakob Disease (vCJD) and Plasma Products

This letter is being sent out to all patients and the parents of children with haemophilia, other bleeding disorders and congenital antithrombin III deficiency. It gives new information about certain plasma products available between 1980 and 2001, the possible risk of vCJD and the need for precautionary health care measures following certain medical procedures and surgical operations.

This information does NOT affect ALL patients.

- **PATIENTS AFFECTED** by this information are those with haemophilia, other bleeding disorders or congenital antithrombin III deficiency who received treatment between 1980 and 2001 with clotting factors or antithrombin manufactured by the UK Bio Products Laboratory (BPL) or the Protein Fractionation Centre (PFC) of the Scottish National Blood Transfusion Service (SNBTS) using plasma pools sourced from the UK. These include concentrates of factor VIII, factor IX, factor VII, factor XI, factor XIII and prothrombin complexes as well as antithrombin.

- **PATIENTS NOT AFFECTED** by this information are those who have only ever received recombinant products, DDAVP (desmopressin), clotting factors or antithrombin made with non-UK sourced plasma, or who have never been treated.

If you have ever received a blood transfusion or immunoglobulin this is treated differently and is not covered in this letter.

We realise this information creates uncertainty and may cause you concern.

What does this mean?

The potential additional risk of actually developing vCJD from receiving any implicated plasma product, on top of the general risk from eating beef, is unknown, but the chances of it happening are likely to be very low.

Some patients who have received certain implicated products do, however, have a greater chance of passing the agent that causes vCJD to others through surgical operations and some other medical procedures. For public health purposes steps need to be taken to prevent spread this way.

Unfortunately, it is likely that further cases of vCJD will occur in people who previously donated blood. This means that more batches of UK-sourced plasma products may be implicated in the future.

Who is affected?

It is likely that special public health precautions will need to be taken for many patients with bleeding disorders or congenital antithrombin III deficiency, because they will have received clotting factors or antithrombin that either are currently implicated (which include particular batches of factor VIII, factor IX and antithrombin) or that may be implicated at a later date. Therefore, **ALL patients with bleeding disorders or congenital antithrombin III deficiency[1] who have received clotting factors or antithrombin derived from UK-sourced plasma[2] between 1980 and 2001 are considered 'at-risk' of vCJD for public health purposes.**

This time period of 1980 to 2001 has been chosen as the most cautious: it runs from when BSE is thought to have entered the human food chain to the last possible expiry date of any product manufactured in the UK that was sourced from UK donors until 1998. Since 1998, plasma for manufacturing plasma products has been imported from the United States.

Am I 'at-risk' of vCJD for public health purposes?

If you have received any UK-sourced plasma derived clotting factors or antithrombin between 1980 and 2001, even if you have not received a currently implicated batch, you are 'at-risk' of vCJD for public health purposes.

If you are not sure whether you have received UK-sourced plasma derived clotting factors or antithrombin between 1980 and 2001, and therefore whether you are 'at-risk' of vCJD for public health purposes, please contact your Haemophilia Centre. You can do this using the reply form at the end of this letter.

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[1] congenital and acquired haemophilia (Haemophilia A and Haemophilia B), Von Willebrand Disease, other congenital bleeding disorders and congenital antithrombin III deficiency.
[2] factor VIII, factor IX, factor VII, factor XI, factor XIII and prothrombin complexes, as well as antithrombin.

What special precautions should I take?

If you are 'at-risk' of vCJD for public health purposes:

- you should not donate blood,
- you should not donate organs or tissues,
- you should tell whoever is treating you before you undergo medical, surgical or dental treatment, so that they arrange any special procedures for the instruments used in your care.
- It would be best if you tell your family about this in case you might need emergency surgery in the future.

If you are 'at-risk' of vCJD for public health purposes then a note of this will be made in your hospital medical records and will be recorded on the National Haemophilia Database. We will also tell your GP of your 'at-risk' status who will record this in your GP medical notes.

Does this affect my care?

If you are 'at-risk' of vCJD for public health purposes, your clinical care should not be compromised in any way. Healthcare professionals need to know you are 'at-risk' so that if any surgical instruments are used in your care they can be treated differently.

How does this affect my family?

If you are 'at-risk' of vCJD for public health purposes you do not need to take any special precautions in normal life. There is **NO** evidence that vCJD can be passed on between people by:

- living in the same house,
- sharing utensils,
- kissing,
- sexual contact,
- from mother to baby through childbirth or breastfeeding.

Can I find out if I have been treated with an implicated batch?

We are currently checking our patients' records to determine who was treated with UK-sourced clotting factors or antithrombin between 1980 and 2001, which of them have received implicated batches and the extent of their exposure. We will record this in patients' hospital medical notes.

If you would like to find out whether you have received any of the implicated batches, or you wish to discuss this further with us, please indicate this on the reply sheet. We expect the process of identifying who has received those batches to take some time, as it may involve hand-searching records from many years ago, and liaising with other Centres. We are sorry for this

unavoidable delay. We will arrange an appointment for you once we have the information.

If you do not wish to find out whether you have received one of the implicated batches, please be aware that this information needs to be recorded in the hospital notes. Despite our best intentions, it is possible that this information may become apparent to you inadvertently, when, for example, looking at your medical records.

Whether or not you have received any of the implicated batches or choose to discuss this with us should **NOT** affect your care, as the same special precautions will be taken for **ALL** patients with bleeding disorders or congenital antithrombin III deficiency who received UK-sourced clotting factors or antithrombin between 1980 and 2001.

How can I decide whether to find out if I have received implicated products?

At present there is no known case of a patient with haemophilia developing vCJD through treatment with blood products. There is no diagnostic blood test for vCJD and there is no treatment or cure for this condition. In addition, the same special precautions will be taken for **ALL** patients who have received UK-sourced plasma derived clotting factors or antithrombin between 1980 and 2001, whether or not they have received an implicated batch.

In the light of the above, you may wish to consider carefully whether or not you wish to know if you have received any of the implicated batches.

How can I find out more?

I enclose an information sheet about vCJD developed by the Health Protection Agency alongside the Scottish Centre for Infection and Environmental Health, clinicians' representatives and patients' groups, which I hope will go some way to answering your first questions.

I do appreciate that this information creates uncertainty that may worry and concern you. Do contact the Haemophilia Centre on **0141 211 5127** if you wish to talk about this.

Yours sincerely

GRO-C

Prof G D O Lowe **Prof I D Walker** **Dr R C Tait**
Haemophilia Centre Co-Directors