THE Central Sheffield University Hospitals

SHEFFIELD HAEMOPHILIA AND THROMBOSIS CENTRE

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MM/JHP

16 January 2001

Mr D G Ferguson
Medical Director, CSUH
Director of Emergency Services
8 Beech Hill Road

Dear Mr Ferguson

Re: New variant CJD and patients who have received implicated blood products

Yesterday I attended the UK Haemophilia Centre Directors' Organisation meeting and, as promised, I am writing to let you know what was discussed regarding the above issue. As you can imagine, this is a problem in every Haemophilia Centre in the country, and everybody is facing the same issues. Two things became clear during the meeting:

a) There will be no rapid response from the Department of Health because the next meeting of the Advisory Committee that decides these things is not until the end of February. Until then, the current advice is that stated in a letter from Graham Winyard dated 6 February 1998. Although I, and most Centre Directors, were aware of part of this letter, many of us have never seen it before. It is actually possible in Sheffield that this letter could have been sent to Eric Preston who was the Director at the time.

b) The Haemophilia Society has produced a letter that is going to go to all its members, probably at the end of this week. They were going to have sent it already, but they were asked to wait until after the meeting yesterday. I do not have a copy of that letter, but the Chairman read it out and the information it contains makes it clear that we have to decide our response by the end of the week.

Three possible options for a response were discussed.

a) Do nothing, as advised by the Department of Health in the letter dated 6 February 1998, which I enclose. None of those present was in favour of taking this route. Since the relevant government bodies chose to disseminate the information as to which batches were involved down to the individual Centres, it was felt we should not sit on this information and do nothing.

b) We should inform all patients who received these batches by letter, explaining the issues and offering them all an early appointment to come up to the Haemophilia Centre to discuss this further and explain the uncertainties involved. Two large Centres in the UK have chosen to follow this route and have already informed their patients.

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c) An alternative option that was considered was to send all patients who received blood products (irrespective of whether they were implicated or not) a letter informing them of the issues and asking them if they would like to know, either now or in the future, if they have received an implicated batch. A reply slip will be included in each letter. Those who answer in the affirmative will then be sent the information as to whether they received the implicated batch or not. Anybody who receives the letter informing them that they actually received an implicated batch will be offered an early appointment for counselling. The Chairman of the UKHCDO is drafting a letter that will be used by the Centres taking this approach. The letter will not come from the Organisation itself but from the individual Centres, but it was felt it would be useful to have a uniform approach in the UK. This letter will be sent by e-mail to everybody that was present at the meeting. I am hoping that this will be done either later today or tomorrow. Once I receive this letter I would like to meet with you and discuss our approach.

Intravenous immunoglobulin and new variant CJD

When I met you last week you informed me about the three batches of intravenous immunoglobulin that were used in the Trust which are now amongst the implicated batches. I spoke to Ian Cawthorne and the following is the situation. The Bio Products Laboratory have indicated that they have sent three different batches of implicated intravenous immunoglobulin to the Royal Hallamshire Hospital (batches VGC047, VGC048 and VGD050). According to the Pharmacy records, we purchased 150 bottles of the first batch, 200 bottles of the second batch, and the Pharmacy can find no trace of us having bought the third batch. I was rather surprised to find that we cannot trace any of the recipients of these batches because the Pharmacy computer system only keeps data for 400 days and any computer data more than 400 days old is permanently deleted and is not archived. According to Ian Cawthorne there is no way of us being able to identify which patients received these implicated batches. The Pharmacy have now extended the time their computers store the information to 800 days, but I believe this is clearly a temporary measure that buys us some time before a better system is in place. The Trust's Clinical Risk Management Group will have to urgently consider how the Trust keeps a permanent record of all batches of blood products which will need to include intravenous immunoglobulin and albumin, as well as the more specialised clotting factors that we use.

Kind regards

GRO-C

M MAKRIS
Senior Lecturer/Honorary Consultant in Haematology

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