



THE MEDICAL & DENTAL DEFENCE UNION OF SCOTLAND

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Please quote our reference on

ALL correspondence:

A/8/244 17385 RN/VM

Your Ref:

06 February 2001

Dr Julia A M Anderson
Department of Haematology
Royal Victoria Hospital
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BT12 6BA

Dear Dr Anderson

Thank you for your letter of the 30th January 2001. I note you have previously Dr Jim Rodger at the MDDUS to discuss the problem detailed in your letter. This letter has been passed to me to deal with as in a previous existence I was a Consultant Haematologist and Haemophilia Centre Director of the North Hampshire Hospitals Comprehensive Care Centre. The matter is therefore of considerable interest to myself.

I note the problem that you have had in relation to the provision of factor produced from plasma produced by a patient who has suffered nvCJD. It appears that the plasma used from this patient was used to produce Replinate and Replinine as well as antithrombin concentrate. It appears that some of your patients with Christmas Disease have received factor IX concentrates that have been derived from this donor. The UKHCDO have stated that infected patients had to be informed of their exposure, and in the case of one patient with Christmas Disease you have done this.

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However, in light of Department of Health Guidance, it appears that the policy is not to inform patients of their exposure and this is the situation you are left in in relation to your patients that received antithrombin. From your letter it appears that 6 of them have records at your centre and the other two received antithrombin even though they were not "haematology" patients. I also note the fact that two of the patients have major psychiatric past histories.

The ethical principle here is one of information disclosure and what legal position pertains in relation to this. If you chose not to inform your patients that the concentrate they had received was derived from a patient with nvCJD and the patient subsequently found out that this was the case and you knew about it but did not pass this information on, you could have difficulty justifying your position. The comment I would make in relation to this is that as opposed to haemophiliacs who are very well aware of where their blood products are ultimately derived, this will not be the case with patients who have received antithrombin concentrate. I feel it highly unlikely they will know that it had been derived from blood donations. You would therefore be in the situation of having to explain to these patients not only that the product they had received had been derived from blood donors, but that the donation may or may not (depending on the science involved) be affected with nvCJD. In addition, in the case of the two patients with psychiatric problems it would have to be judged whether disclosure of information of this type would lead to further serious mental harm. I presume that some patients that have received antithrombin are not antithrombin deficient and have received it for acquired ATIII deficiency at the time of some major particular thrombotic event and would not normally be considered haematology patients. There is therefore, in addition, the problem of having to inform the initial clinicians who were responsible for ~~their~~ care of this problem.

On balance and in view of the concerns surrounding nvCJD and blood donations in general, I feel it would be appropriate to inform the affected patients that part of their treatment was derived from a patient who has now been diagnosed as suffering from nvCJD. I do not feel it is either appropriate or fair, as pointed out in your letter, for you as a Haemophilia Centre Director, to be put in the position of telling one group of patients that they have this potential problem whereas another group has to be kept in the dark.

Before informing that patients however it would be appropriate to speak to the individual clinicians who are involved in their care, if not yourself, about this problem, and also seek the view of the psychiatrists who looked after the patients with mental problems as to whether or not this information would be harmful to them

It may be worthwhile contacting BPL directly and seeking clarification on what their position is as regards disclosure. I honestly feel that it is in the best interests of everybody to be as open and honest as possible about this at the present time. As mentioned above, if it was shown that you, for the best possible reasons, did not inform the patients involved that they had been exposed to a potential risk, then there could be problems. In terms of the legal position the only remedy a patient would have would be to sue for negligence, but it is far from clear what the grounds for this would be as it would be very difficult to demonstrate any loss. The problem is therefore at present a moral and ethical one rather than legal.

I hope the above information is of some use to you. Please feel free to contact me directly to discuss it if necessary as this is a very complex area, and one particularly fraught with difficulty. You would be in a much easier position were more known about the transmissibility of nvCJD, but at present this is far from certain. Hopefully in the near future science will catch up with the ethical dilemma that is faced at present.

Kind regards,

Yours sincerely

GRO-C

RODERICK NEILSON
Medical Adviser