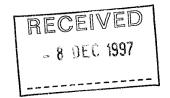


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5 December 1997

Dr Angela Robinson Medical Director The National Blood Authority Oak House Reeds Crescent Watford, Herts WD1 1QH



Dear Angela

Recipients of donations from individuals later identified with CJD

I am concerned about the recent press reports of the recipients of corneal and scleral tissue donated by a donor subsequently identified with CJD. From what I can gather, the three recipients in this case have all been informed that the donated tissue was taken from a donor with CJD. This has possible implications for blood transfusion recipients, who are not currently being informed in similar circumstances.

When we first set up the joint study with the CJD Surveillance Unit, we took ethical advice over notification of recipients who had received transfusions originating from donors who subsequently were identified with CJD. I took ethical advice from Professor Ian Kennedy and a submission was reviewed by the Lothian LERC. The advice at that time was that recipients should not be informed for the following reasons:

- 1. There is no evidence that CJD has been transmitted by blood transfusion.
- 2. There are no screening tests which can be applied to detect evidence of infection with CJD.
- The only diagnostic test is a brain biopsy.
- 4. There is no therapeutic intervention which can be offered to those who have been infected.

North London Centre Colindale Avenue London NW9 5BG

Tel: 0181 258 2700 Fax: 0181 258 2970

Part of the National Blood Authority

The ethical advice was qualified and recommended that the Blood Transfusion Services should retain information on all identified recipients so that, if any of the above circumstances changed, there would be the ability to contact and notify the recipients and their medical attendants. We took note of this advice in developing the transfusion medicine epidemiological review. In order to aid the conduct of the review, it was agreed to include a control group of donors, the information about patient and control donors being blinded to the Transfusion Services.

When the requirement to identify plasma from donors who developed variant CJD was notified, the blinding with respect to these donors was removed. The donors are positively identified and the recipients of the cellular components are known. We sought fresh ethical advice as to whether there should be any change in the policy for notification of recipients in these cases. The ethical advice remained the same. We therefore have a number of donors, known to the Transfusion Services as variant CJD cases, for whom recipients have been identified. The recipients of the corneal and scleral transplants have, however, being treated differently.

As different policies have been implemented with respect to these two groups of recipients, I think it is important to understand the reason for these differences. As MSBT was involved in the initial considerations relating to blood transfusion recipients, could MSBT be asked to review the current policy. I am uncomfortable that two different decisions have been taken, and would appreciate an acknowledgement and an explanation of the different approaches.

Yours sincerely

GRO-C

Patricia E Hewitt

Lead Consultant in Transfusion Microbiology

Direct Tel: GRO-C Fax: GRO-C

Copy: Dr R Will
Dr J Gillon

With best wishes.