

Dr. Reyman Mr. Reyman Miss Towner Mr. M. Skinner

PRIVATE & CONFIDENTIAL Telephone 0171 210 5591

Dr R G Will Consultant Neurologist Department of Clinical Neuroscience Western General Hospital Crewe Road EDINBURGH EH4 2XU



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Dear Dr Will

CJD AND BLOOD TRANSFUSION

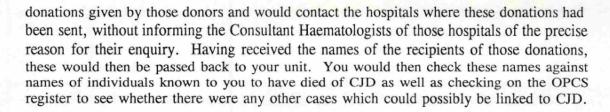
Thank you very much for your letter of 29 April. Its arrival could not have been better timed, as there was a meeting of the Committee on Microbiological Safety of Blood and Tissues for Transplantation (MBST) 48 hours after your letter arrived. CJD and blood transfusion was already on the Committee's agenda, not for the first time. The Committee had considered a look-back on CJD last year. At that time, it was thought inappropriate.

I, colleagues here and Dr Angela Robinson, the Medical Director of the National Blood Authority, had also reached the conclusion that given the ability to trace particular units of blood, the UK is very well placed to carry out a study to determine if blood donated by someone who subsequently developed CJD, had resulted in the occurrence of CJD in a recipient.

The Committee, which incidently covers the whole of the UK, agreed that this research now needs to be done but without any contact being made with recipients of blood from donors who subsequently developed CJD. The MSBT agreed that this study would be helpful in giving more information on whether it is possible that CJD is transmitted by blood transfusion. There is obviously an important ethical question here, and the research protocol will need clearance by a Research Ethics Committee.

Obviously a jointly developed research study between the CJD Surveillance Unit and the National Blood Authority in England and Transfusion Services in Scotland, Wales and Northern Ireland will be the best way to proceed. Your existing data base of 50 cases of CJD who have previously acted as blood donors is a robust starting point.

The Committee recommended that the CJD Surveillance Unit should discuss this proposal with the Blood Transfusion Services and prepare a proposal for this work. My understanding is that you are willing to pass on in strict confidence to named individuals at the Transfusion Centres names of the 50 individuals who have died from CJD and who have been identified as blood donors. The Transfusion Centres would then check in their records for the



It was suggested that once your proposal has been agreed with the BTS, you and BTS may wish to pass it to the Department of Health and other Health Departments for their comments. As to the rest of the study design, I believe that would be best worked out between your Unit and the Transfusion Service Authorities. I have taken the liberty of suggesting that Dr Angela Robinson should write directly to you to take the practical arrangements and design of the study forward.

In your penultimate paragraph you raise the question of donor exclusion criteria for relatives of patients who developed CJD. You drew my attention to the fact that no case of hereditary CJD has ever been identified anywhere in the world that does not have a mutation of the PrP gene. The Council of Europe guidelines which are followed by the UKBTS and by the EU and European Pharmacopoeia in respect of blood products simply state that individuals who have a family history of CJD are debarred from donation. This is a subject MSBT may need to return to, although I suspect that, for public reassurance, any exclusion criteria relating to CJD will have to be applied uniformly and not restricted to relatives of those who have a mutation of the PrP gene. This does not mean that in a given case where a donor is excluded the BTS is accepting that there is a family connection in respect of CJD. It is simply not practical to arrange for PrP gene analysis in each case.

Thank you for writing and for the excellent timing of your letter. I hope we will have a chance to discuss this question face to face before very long.

Yours sincerely

GRO-C

J S METTERS Deputy Chief Medical Officer

(Dictated by Dr Metters and signed in his absence.)

Copies to: Dr A Keel

SHHD Dr J Ludlow WO Dr G Mock DHSS NI

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