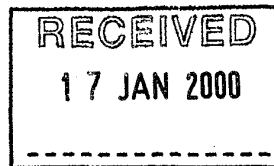


12 January 2000



Executive

Headquarters

Department of
Health

Wellington House
133-155 Waterloo
Road

London SE1 8UG

Tel 020 7972 2000

Dr E A Robinson
Medical Director
National Blood Authority
Oak House
Reeds Crescent
Watford
Herts WD1 2QH

Dear Angela, ¹¹

Management of potential donors known to have received blood from people subsequently shown to have developed variant CJD.

MSBT discussed the management of donors known to have received blood from people who subsequently developed variant CJD at the last meeting on 28th October 1999. This letter outlines that discussion and advice to the National Blood Authority in view of the legal, ethical and public health implications of flagging such potential blood donors to prevent their donations entering the blood supply. It also provides a full reply to your letter of 22 December.

As part of the Transfusion Medicine Epidemiology Review (TMER) study, the four UK national blood services are asked for information about the blood donation histories of all those who die from both classical and variant CJD by the CJD Surveillance Unit. This in turn leads the blood services to trace the donations from these patients with a view to removing any remaining blood components or products from stock. The exercise inevitably reveals information about patients who have received implicated blood components or products. The question is whether these people's blood, should they present as donors in the future, be prevented from entering the blood supply and if so how the situation should be managed.

As you will remember we discussed the issues in detail earlier in the year at a meeting attended by Departmental and NBA lawyers. In addition Dr Sheila Adam and Dr Pat Troop had a further discussion with our lawyers to help clarify the position on flagging donor databases, informing those flagged in this way and what if anything they should be told. The view of the lawyers was that the flagging procedure described by the NBA is not out of line with current requirements of the Data Protection Act (DPA) 1984 or the new 1998 Act. It was also considered that there was probably no requirement under either the old or the new DPA on national blood services to inform people who have received implicated blood components that they were being or had been flagged to avoid their blood getting into national

From Dr Mike McGovern, Senior Medical Officer, Health Services Directorate 1
Office 0171 972 4857, Mobile **GRO-C** e-mail mike.mcgovern@ **GRO-C**

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supplies. Given that these people could present as donors in any of the UK countries we agreed that the 'flagging' information should be shared by all four national blood services to ensure a co-ordinated inclusive approach.

In the event of a 'flagged' person giving blood, it was agreed that the donation identified through the flagging process should not be allowed to enter the supply. It was also agreed that in the spirit of openness and 'contracts' with donors, the blood services would need to consider telling, or offering to tell, the donor why their blood could not be accepted. As, however, there is still little scientific knowledge to inform discussion with the donor, we agreed that the appropriate Health Department should be contacted in the first instance and every such incident discussed and managed on a case by case basis. The NBA agreed to develop a protocol for dealing with these cases in discussion with the Department of Health and the proposed 'Expert Group on the Management of CJD Incidents'. The protocol could of course be adopted by all four national blood services.

As we discussed, this 'Expert Group on the Management of CJD Incidents' will provide a mechanism for the development of a consistent approach to the handling of situations where patients may have been exposed to the potential risk of secondary vCJD infection. It will include consideration of cases where patients were operated on using instruments found to have been used on patients who subsequently developed vCJD, as well patients who have received implicated blood or blood products. The Group is due to have its first meeting on 25 January, under the Chairmanship of Professor Don Jeffries.

It was clear from all the discussions that the decision to flag such potential donors was purely precautionary, not based on any new scientific information, and taken in the face of profound uncertainty. The most recent scientific opinion is that while 'blood may contain low levels of the infectious agent of CJD, blood components have never been identified as a cause of CJD in humans'. The information on vCJD however is in evolution and the position still is that there is no test for the agent, even if there were the implications of a positive test would be difficult to ascertain, and there are no known treatments for the disease. In addition it is not known whether the agent can be transmitted by blood and cause disease in recipients. Because of this our current policy remains that people who may have been exposed to the vCJD agent through blood or blood products should not be informed as set out in Executive Letter PL(CO) (98) 1, issued 6 February 1998. However the policy will be kept under review in the light of developing science and lawyers will be seeking a Counsel's opinion on the extent of our obligations towards those who may have been affected by implicated products. This letter has been copied to colleagues in all four UK countries who will need to consider obtaining their own legal advice and to inform the Chief Executives of their blood services about the position.

GRO-C

Dr Mike McGovern
Health Services Directorate

From Dr Mike McGovern, Senior Medical Officer, Health Services Directorate 1
Office 0171 972 4857, Mobile

GRO-C

e-mail mike.mcGovern@

GRO-C