Isle of Man Blood Transfusion Service

Urgent to Charles Lister
Copy Dr Troop
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Dr McGovern -

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* Ask Dr Troop to handle as well
* Please keep in B/F and prepare draft.

Our ref: JKW/SAC

9 February 2001

Professor Liam Donaldson MSc, MD, FRCS(Ed), FRCP, FFPHM
Chief Medical Officer
The Department of Health
Richmond House
79 Whitehall
London SW1A 2NL

Dear Professor Donaldson

Albumin manufactured from a plasma pool
which included a donation from a donor now diagnosed with vCJD

On 19 December 2000, the Isle of Man Blood Transfusion Service was notified by the UK National Blood Service that plasma-derived products from the Bio-Products Laboratory (BPL), supplied to the Isle of Man, have been manufactured from pooled plasma, including plasma from a UK donor who subsequently was diagnosed with variant Creutzfeldt-Jakob Disease (vCJD). The Isle of Man Blood Transfusion Service was informed, by the enclosed fax, that it had been sent 40 bottles of human albumin (Zenalb 4.5%) from the pool containing that donor's plasma.

The fax quoted advice, originating from your Department, contained in a letter by Graham Winyard to NHS Trust Medical Directors on 6 February 1998. That advice stated that the Department of Health considered that there was no need to inform patients who had received blood components or products collected from donors who subsequently developed vCJD, because:

1. It is thought unlikely that vCJD will be transmitted in this way;
2. There is no diagnostic test for vCJD;
3. Even if a test were available, there is no preventative treatment that could be offered.

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The advice went on to state that patients would not benefit from the knowledge and that it could create an uncertainty, and unjustified worry, which would permanently blight their lives. I met with Mr John Wilson, Head of Administration, Isle of Man Department of Health and Social Security, to discuss the situation. It was decided that patients on the Isle of Man would not be told that they had received albumin from the above mentioned batch. This decision was based on the quoted advice from the UK Department of Health.

Recent media coverage of this occurrence has revealed that haemophiliacs who received Factor VIII Concentrate from the same batch of plasma are being, or have been, told of the situation. In view of this, I should be grateful if you would inform me whether your Department has changed the advice given in 1998 and quoted by the National Blood Service.

In addition, I have been advised by my medical defence society, the Medical Protection Society, that, under the Good Medical Practice Guidelines issued by the General Medical Council in July 1998, I have a duty to explain fully to the patient any situation occurring within an area under my responsibility which may have caused them harm for any reason (paragraph 17 "If things go wrong"). I consider that, if one group receiving products from this batch are told about the illness of one of the donors, all those who have received blood products manufactured from this plasma pool should be informed. I have also been advised by that, in the current atmosphere surrounding past withholding of medical information, it would be difficult to defend not informing the recipients of the albumin.

For the above reasons, I should welcome a written statement, giving a risk assessment and guidance on disclosure, from the UK Department of Health, upon which the Isle of Man DHSS can base its own response to the situation. I am also writing to Dr Angela Robinson, Director of the UK National Blood Authority, which, as supplier of the product, has a responsibility to those patients who have received it.

Yours sincerely

GRO-C

DR J K WARDLE
Consultant Pathologist
Director, Isle of Man Blood Transfusion Service

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