

Mike McGovern

17/08/99 19:54

Sent by: Mike McGovern/HSD1

To: Alison Pitts-Bland/COMMS/DOH/GB@GRO-C
cc: Mark Ferrero/PR-OFF/DOH/GB@GRO-C
Hester McLain/DRS/DOH/GB@GRO-C
Jeremy Metters/DRS/DOH/GB@GRO-C
Sammy Foster/DRS/DOH/GB@GRO-C
Rachel Dickson/PR-OFF/DOH/GB@GRO-C
Jeremy Metters/DRS/DOH/GB@GRO-C
Sheila Adam/HSD/DOH/GB@GRO-C
David Hewlett/HSD1/DOH/GB@GRO-C
Ailsa Wight/PH1/DOH/GB@GRO-C
Peter Jones/PH1/DOH/GB@GRO-C
Tony Kingham/IID-IB/DOH/GB@GRO-C
Charles Lister/HSD1/DOH/GB@GRO-C
Deirdre Feehan/IID-IB/DOH/GB@GRO-C
Gwen Skinner/HSD1/DOH/GB@GRO-C
Aileen.keel@GRO-C
david.salter@GRO-C
Adrian.Mairs@GRO-C

Subject: FDA and Canadian ban on Blood and Plasma Donors resident in UK

Please see line to take and Q&A.

Mike McGovern



Q&A FDA aug 99

The US and Canadian deferral of potential blood and plasma donors visiting or resident in the UK.

Line to Take

There is no new safety issue with British blood products. There is no evidence that CJD or vCJD can be transmitted by blood transfusion or blood products, and the FDA have made that clear in their statement.

Last year we asked SEAC, the world-leading experts on CJD, to advise us on precautionary measures to protect patients against this theoretical risk. They gave us their advice in July 1998 and we acted on it immediately, following their advice to the letter. The steps taken are:

- all major blood products are now made from imported plasma, from countries where there is no evidence of vCJD
- all NHS blood will be leucodepleted – white blood cells removed – by the end of October 1999 as planned.”

General Q&A

In view of the USA and Canadian bans on donations from people who had lived in the UK is the Government planning to source blood for transfusion from outside the UK?

The Committee on Safety of Medicines recommended in principle in February 1998 that all blood products should be sourced from non-UK plasma. Action to implement this recommendation was taken immediately. The Committee confirmed their advice in May 1998 and all blood products are now being sourced from non UK plasma. SEAC recommended in November 1997 the leucodepletion (removal of white cells) of blood. Planning started immediately and SEAC confirmed their advice in July 1998 following completion of a risk assessment. All NHS blood will be leucodepleted by the end of October 1999. We do not believe that it would be practicable to replace the 2.5 million units of blood used every year by high quality sources from abroad.

What exactly are the US and Canada planning to do?

The regulatory authorities in the US and Canada have decided that all potential blood donors who visited the UK from 1980 to 1996 (1 January 1980 to 31 December 1996) for a period of 6 months or more (cumulatively) should not donate blood. Potential plasma donors will also be deferred.

Will this action make the US and Canadian blood supplies safer?

The US and Canadian regulatory authorities consider that this action will reduce the unquantifiable and theoretical risk of transmitting vCJD through blood and blood products. There is no evidence world wide that CJD or vCJD have ever been transmitted through blood or blood products. The US and Canada have considered the balance between the real risks to patients from restricting the blood supply and the theoretical and unquantifiable risk of transmission of vCJD through blood and blood products.

Why isn't the UK taking the same measures or importing blood from abroad?

This is not an option. It would not be possible to replace the 2.5 million units of blood used every year by high quality sources from abroad for the UK. There is no ready market for blood components like there is for plasma. This is because the red cells and platelets have short use by dates and cannot be frozen on a large scale (like plasma.) Any reduction in the current UK blood supply would compromise the care of patients especially those suffering severe accidents, patients with cancer and leukaemia, and those needing surgery.

Is UK blood safe? Almost every medical treatment including blood transfusion is associated with some risk. For this reason doctors need to consider the need for any blood transfusion very carefully with their patients. Two recent major studies from SHOT (Serious Hazards of Transfusion) have demonstrated that blood transfusion in the UK is very safe, that it is becoming even safer with improving technology, and that infection due to blood transfusion is now very rare. There is no evidence world wide that CJD or vCJD have ever been transmitted through blood or blood products.

But what about the risk of CJD from UK blood?

There is no evidence world wide that CJD or vCJD have ever been transmitted through blood or blood products. We need to consider the balance between the real risks to patients of restricting the blood supply and the theoretical and unquantifiable risk of transmission of vCJD through blood and blood products.

What have you done about reducing the risk from vCJD from UK blood?

As the experts have advised we have 1) ensured that our blood services now make all their blood products only from plasma imported from countries with no evidence of vCJD and 2) instituted a plan for universal leucodepletion (removing the white blood cells) of blood (and platelets) for transfusion which we will complete by 31 October 1999 as planned

What reassurance can you give patients who need a blood transfusion?

There is no evidence world wide that CJD or vCJD have ever been transmitted through blood or blood products. We need to consider the balance between the real risks to patients from restricting the blood supply and the theoretical and unquantifiable risk of transmission of vCJD through blood and blood products. We are doing every thing the experts have recommended -importing plasma from which all our blood products are now made and leucodepleting (removing the white blood cells) the blood -to reduce any possible risk.

Do donors continue to need to give blood?

The NHS needs blood donors more than ever before to support the rising demand for blood associated with the increasing number of operations and treatments we carry out in our hospitals.

ADDITIONAL Q&A

Q Where are we up to on making blood safer?

A All the major blood products are being made from non-UK plasma on the advice of the Committee on Safety of Medicines, and there is excellent progress on leucodepletion – removing the white cells from blood destined for transfusion, which is being done on the recommendation of the Spongiform Encephalopathy Advisory Committee. All blood collected after 31 October 1999 will be leucodepleted.

Q **How many people who have died from vCJD have been blood donors?**

A The blood service and the CJD Surveillance unit are collaborating on a study of blood donation history. I understand that 5 of the 43 people who have died from vCJD were blood donors.

Q **How many people have received implicated transfusions?**

A The study which the blood service and the CJD surveillance unit are carrying out has indicated that 10 people had received implicated transfusions.

Q **Are people told if they have received a transfusion of vCJD implicated blood?**

A The measures we have taken are precautionary and this reflects the theoretical and unquantifiable risk of transmitting vCJD through blood and blood products. Where people have received implicated products or transfusions, the general view is that they will not benefit from the knowledge. The uncertainty caused by informing them could have the contrary effect, causing unjustified worry and creating a permanent blight on their lives, in relation, for example, to obtaining life insurance. In deciding whether or not to inform a particular person, clinicians have to consider the balance between benefit and harm for the person's individual situation.

LEUCODEPLETION

Q **Couldn't leucodepletion have been introduced more quickly?**

A In November 1997, on the advice of SEAC we instructed the National Blood Authority to prepare a strategy for leucodepletion. They did this, and we instructed them to implement the strategy in July 1998, again on the advice of the experts. It is a complex process but the blood service is on schedule to complete leucodepletion by 31 October.

Q **What is the cost of leucodepletion ?**

A In a full year the cost of leucodepleting blood in England is in the order of £70 million.

IMPORTATION OF NON UK PLASMA

It is very important that you have a transfusion if it is clinically necessary. Transfusions save lives. We have taken active steps to encourage the better use of blood. If anyone has worries they should ask their clinician. The measures we are taking are precautionary, against the theoretical and unquantifiable risk of the transmission of vCJD through blood.

ADVICE TO BLOOD DONORS

There is no risk of vCJD in giving blood. Blood donors are needed more than ever and their gift is invaluable.