

To note - follows on from Lindsey Davies submission to you. **IMPORTANT**  
Submission on gone to PS(PH) & SofS - recommends  
written ministerial statement [PS(PH) is very keen on  
a statement]

**RESTRICTED - POLICY**

GRO-C

To: 1 PS(PH)  
2 SofS

From: Ailsa Wight

Date: 12 July 2004

Spoke to end 18/7.  
Noted proposed way forward

Copies: see email cover

GRO-C

**vCJD update: New MSBT recommendations for blood donor exclusions**

**Issue:**

In the oral statement to the House, 16<sup>th</sup> March 04, "Developments in vCJD", SofS indicated that he had asked the Committee on the Microbiological Safety of Blood and Tissue for Transplantation (MSBT) to consider whether further measures were needed to ensure protection of the blood supply. **At a meeting on 29<sup>th</sup> June 04, MSBT recommended tightening the exclusion criteria for two groups:**

1. **Previously transfused apheresis donors- see below**
2. **Donors who were unsure if they had previously had a blood transfusion.**

This note advises you on the new exclusion criteria proposed by MSBT and sets out handling recommendations.

**Timing:**

Urgent – it would be helpful to publicise the MSBT advice as soon as possible in line with previous commitments.

**Recommendation:**

To accept the advice of the Chief Medical Officer to introduce the new exclusion criteria as recommended by MSBT. And to update the House by way of a Written Ministerial Statement later this week- **see handling section below.**

**Background:**

When the original exclusion decision was taken, it was decided **not** to exclude the following groups of donors:

1. **Previously transfused Apheresis donors-** This involves a small pool of committed donors who make frequent attendance's to donate. Apheresis is a method of obtaining one or more blood components by machine processing of whole blood in which the residual components of the blood are returned to the donor during or at the end of the process.
2. **Unsure Blood Transfusion donors-** donors who were unsure whether they had previously had a blood transfusion.

Both these groups were exempt from exclusion until the implications for reduced blood supplies could be assessed and managed. Apheresis donors are used to collect a pool of platelets in one go – this provides about 50% of the total platelet requirement. At the time of the original exclusion the number who had been transfused was unknown, and could have seriously affected the supply of platelets. An early estimate was that up to 3% of the donor base could have been affected. For the 'unsure' group, to have excluded them originally had been estimated to result in around 6.5% loss of donations – this would have a profound affect on blood supplies.

In the light of experience since the exclusions came into effect, the number of donors who have indicated that they did not know whether they had had a transfusion has been under 2000, which is a lot lower than anticipated, and the number of apheresis donors that have had a transfusion is only around 80, again well below expectations. MSBT think it will now be practical to exclude these groups without adverse impact on the blood supply.

The new advice from MSBT is therefore to extend the exclusion criteria to these two groups of donors and that this should take effect from **2<sup>nd</sup> August 2004**.

#### **Handling:**

In the previous oral statement SofS stated "I have asked the advisory committee to consider whether any further action is required as part of the general review of the measures, and to report back to me".

Whilst SofS did not explicitly say that he would update the House once he received this advice, in light of the new exclusion criteria and given his previous desire to be open on this issue, it is recommended that a Written Ministerial Statement is made to update the House.

The statement would indicate that these further exclusions are an extension of the positive moves by DH to protect public health, and would remain under continuous review.

As the new exclusions will have a minimal impact on the blood supply, a written statement rather than an oral statement would seem more proportionate. A written statement would be supported by a press release.

#### **2<sup>nd</sup> possible vCJD transmission by blood transfusion (Scotland) - separate but related issue:**

You have previously been alerted to the second possible transmission of vCJD by blood transfusion following the post mortem of a patient in Glasgow - see previous submission of 14<sup>th</sup> June 04.

Both SEAC and MSBT have considered this latest finding and do not recommend any changes in policy as a result of this case. The new exclusions set out above are **not** linked to this second case.

Following a recommendation from SEAC, this case will be made public via publication of an article in *The Lancet*. Their next editorial group meeting is on Tuesday 13 July, and we will update this submission once publication date has been confirmed. Following discussion with colleagues in Comms it was proposed to respond reactively to this case.

However, in light of the recommendation to make a Written Ministerial Statement on new exclusions, you may want to consider using this statement as a vehicle for updating the House on this issue as well.

If you want to do this, then it will be important to make sure that it is clear that the new exclusions are not being introduced as a result of this second case- with careful drafting this should be possible.

**Conclusion:**

You are asked to:

1. Agree to introduce the new exclusion criteria for apheresis donors and unsure blood donors as set above.
2. Agree to updating the House on the new exclusions by way of a Written Ministerial Statement.
3. Advise on whether you wish to use this statement to update the House on the 2<sup>nd</sup> Case of possible vCJD transmission through blood transfusion.

A statement on the new exclusions could be made this week. If you wish to update the House on the 2<sup>nd</sup> case of possible transmission in this statement then it would make sense to make the statement on the same day as the article goes in the Lancet.