DRAFT Minute of Meeting to Discuss Incident Number PI 37 (Incident Involving Blood and Blood Products)
2.00pm, 26 March 2001, 103 Skipton House

Attendees
Professor Don Jeffries – **Chair** – Virologist, St Bartholomew's Hospital
Dr Patricia Hewitt, National Blood Authority
Dr Noel Gill, Communicable Disease Surveillance Centre
Professor Dame Lesley Southgate, Chair Royal College of General Practitioners
Professor John O'Neill, Ethicist, Lancaster University
Dr Mike Simmons, National Assembly of Wales
Dr Paul Darragh, Deputy Chief Medical officer, Northern Ireland
Mr Charles Lister, DH Blood Policy Unit
Dr Philippa Edwards, CJD Incidents Panel Secretariat
Dr Nicky Connor, CJD Incidents Panel Secretariat
Miss Sonia Gooden, **Minutes**, CJD Policy Unit

Apologies
Dr Martin Donaghy, Scottish Executive Health Directorate

Welcome and Introductions
1. The Chair welcomed the group and thanked them for attending. The apologies were announced as above.

Panel Advice on PI 37
2. The incident involved blood products derived from pooled plasma, which included plasma donated in 1996 and 1997 by a person who later developed vCJD. The possible size of the cohort could be up to 40, 000 patients. Other parts of the donor's blood may have been used in labile blood components. However, the NBA was not currently in a position to confirm this as yet.

3. Note added after meeting: Three labile blood components were produced from the donor in question in 1996 and 1997. Two of these have been traced and the names of the recipients are known. The third component was issued to a hospital, but cannot be traced to a recipient at hospital level.

4. The incident was reported in December 2000. The MCA had instructed the product manufacturers, Bio Products Laboratory, to inform hospitals of the implicated batch numbers. No recall was necessary, as all products were beyond their expiry date. In January, the Haemophilia Society and the Primary Immunodeficiency Association had notified their members of the incident and the UK Haemophilia Doctors Organisation had written to Haemophilia Centre Directors advising them on how to handle enquires from patients. Specific guidance in relation to other patients had not been issued on this occasion, although guidance had been issued by the department in 1998. A draft letter from the Deputy Chief Medical Officer was provided for comment and Panel advice was requested regarding what information should be provided to other patients regarding the risk of transmission. Since late 1998, plasma had been sourced from outside the UK.

5. The current NBA policy is that any individual who presents to donate blood, and who is not accepted as a donor, should be given a full explanation of the reason for exclusion. It is considered ethically unacceptable to take a donation knowing that it will be discarded. At present, pending guidance from the Panel, the NBA has a list of names of individuals who have been identified as recipients of blood components originating from donors who have later develop0ed vCJD. These individuals have not been informed of the situation, but it was considered wise to ensure that, if any of these individuals presented as donors, their donation would not be issued for use. It would be practically unacceptable to refuse their donation at the donor clinic. On first presentation, therefore, a donation would be taken, but not used. At that point, the NBA would have a duty towards the individual as a blood donor and would take steps to inform him/ her of the situation. The NBA was uncomfortable with this interim solution, which was introduced two years ago and required resolution.

6. Some concern was expressed that actively informing patients would compromise patient care, as at least one haemophiliac who had received the implicated batches had already had surgery postponed. It was agreed that this was unacceptable, and that any advice the Panel may give should not compromise patient care/ safety.

7. It was agreed that there should be a facility for patients to determine if they had received implicated blood/ blood products, if they so wished, even if they were not considered to be at a significant risk of infection Those considered to be at significant risk would need to be informed, as certain actions would be necessary, for example in future surgery or in terms of organ or tissue donation. Flagging patient notes was not a practical option as records are only stored for a limited time period. It was also possible that such identification could be interpreted in a way that prejudices patient care. There was a need to have a long-term record of patients who may be at risk, in order to gather epidemiological evidence.

8. It was noted that a database for haemophiliacs already existed. Therefore there would be no need to include haemophiliacs on a new database set up by the Panel.

9. It was explained that the suppliers had informed hospitals of the implicated batches, but had not made a distinction between the various types of plasma products. It was suggested that the Panel should contact the MCA and suggest that they request manufacturers to change the wording of the document issued to Trusts informing of implicated plasma products.

Conclusions to be taken into the draft guidance

10. It was explained that, based on epidemiological evidence, fractionated blood (i.e. plasma products) would have only a low risk/ level of infectivity. It could also be hard to identify all recipients of fractionated blood, as tracking was not necessarily in place for this product.

11. Whole blood and blood components were not considered to be of a low level of risk.

12. There was a need to reinforce the message of a need for traceability and to be clear regarding which blood product is being addressed throughout the document, as different products would contain different risks.

13. The Panel had agreed at the meeting in February 2001 that those who were considered to have been placed at a significant risk of infection would need to be actively informed. However, there was still a need to define what comprised a 'significantly high risk'.

14. It was agreed that there was a general lack of clear knowledge/ evidence basis for the levels of infectivity in blood and blood products. The Secretariat agreed to perform a literature search on blood and blood products and TSEs. This would be provided to the Chairman and a paper prepared to be put to the Panel for consideration. There was also a need for a risk assessment for surgery on haemophiliacs. A further meeting could be held once the literature search had been conducted.

Comments on the draft letter from the Deputy Chief Medical Officer

15. It was agreed that there was a need to develop a more generic guidance, which could be used in the event of any future similar incident. Therefore Anti-D would need to be addressed.

16. It was important to stress that there was no risk of person to person spread of the disease via normal social contact.

17. The following phrases referred to in the document should be amended:
    i. 'theoretical risk' should be amended to 'unknown risk' or 'unquantifiable risk';
    ii. 'classical CJD' should be amended to 'sporadic CJD';
    iii. 'counselling' should be amended to 'support and advice or information';
    iv. 'fear' referred to in the first paragraph in the section 'purpose' should be amended to 'wish to know'

18. The following paragraphs should be removed/ amended:
    i. The final paragraph of the section 'Purpose' should be made clearer;
    ii. Section (iv) of 'Handling enquiries from patients' should be made more general
    iii. The final paragraph of 'Handling enquiries from patients' should be removed
    iv. The final sentence of the first paragraph in the section 'Patient records' should be removed

Summary of Action Points:

- Secretariat to provide DNV Report and perform literature search regarding blood and blood products in relation to TSEs;
- Charles Lister to re-draft letter from Dr Pat Troop;
- Secretariat to contact the MCA;
- Secretariat to consider a risk assessment for surgery on haemophiliacs;
- Secretariat to prepare a paper, n consultation with the Chairman, on the risks from blood and blood products.

- Secretariat to arrange a further meeting to discuss blood and blood products.