DRAFT Minute of Meeting to Discuss the Management of Incidents Involving Blood and Blood Products
Thursday 2nd August, 2.00pm, Royal College of General Practitioners

Attendees:
Chair

Dame Professor Lesley Southgate	Chair, Royal College of General Practitioners

Members

Rev. Professor Michael Banner	Ethicist, Chair of CJD Incidents Panel
Professor Don Jeffries	Virologist, Vice Chair of CJD Incidents Panel
Dr Tim Wyatt	Consultant Microbiologist, Belfast
Dr Roland Salmon	Public Health Laboratory Service
Dr Patricia Hewitt	National Blood Authority
Dr Hester Ward	National CJD Surveillance Unit

Specialist Advisors

Professor Bob Will	National CJD Surveillance Unit
Dr Lincoln Tsang	Medicines Control Agency
Dr Mike Kavanagh	Medicines Control Agency
Dr Nigel Goulding	Medicines Control Agency
Mr Charles Lister	Blood Policy Unit, DH
Dr David Gorst	Advisory Committee on Microbiological Safety of Blood and Tissues

Observers

Dr Martin Donaghy	Scottish Executive Health Directorate
Dr Martin Simmons	National Assembly of Wales
Dr Lorraine Doherty	DHSSPS, Northern Ireland

DH CJD Incidents Panel Secretariat
Dr Philippa Edwards
Dr Nicky Connor
Miss Claire Mills

Welcome and Introductions

1. The Chair welcomed the group and thanked members for attending. It was explained that a number of specialists who were familiar with, and responsible for, current systems involving blood and blood products had been invited to the meeting to inform the discussion and assist in developing the draft framework CJD Incidents document.

Purpose of the meeting

2. It was explained that the Panel had drafted guidance on the management of CJD incidents involving surgical instruments, but had not yet considered the

management of incidents involving blood and blood products. The purpose of the meeting was therefore as follows:

i. To inform the Panel drafting group of the current systems in place for investigation and management of incidents involving potentially infected blood donations and plasma derivatives;

ii. To inform those currently involved in the management of incidents involving blood donations and plasma derivatives of the CJD Incidents Panel's principles, as set out in the draft framework document;

iii. To identify any changes in the current systems for the management of incidents needed to involve the Panel in the process;

iv. To agree a proposal for drafting the relevant sections of the Panel's framework document to set out the system for investigation and management of incidents involving blood donations and plasma derivatives.

Summary of framework risk assessment and management proposals (Paper 4, Paper 5, Paper 14)

3. The Panel was in the final processes of drafting a framework document for the management of CJD incidents. Good progress had been made regarding the risk assessment and management of incidents involving surgical instruments and it was proposed that the document would undergo a consultation exercise.

4. The Panel had identified two basic patient risk groups. The first was a 'contactable group' who would be actively informed that they were considered to have been placed at a significant risk of being exposed to CJD. In order to prevent a further risk to public health these patients should not donate organs, blood or other tissues and would need special precautions taken if they were to undergo further surgical procedures. Members were concerned that the medical care of these patients should not be compromised, and the principles outlined in the draft framework document should be amended to state this.

Action: Secretariat

5. The second was a 'database group', who had been exposed to a low level of risk, and whose details would be entered onto a database to enable the gathering of epidemiological data. These patients would not be actively informed, but the general public would have the option to find out if their details were on the database and remove their name if they so desired. The details of those in the 'contactable' group would also be retained on the database and this group would not have the option to remove their details.

6. The Panel had started to draft guidance on incidents involving blood and blood products and would then consider organ and tissue donation. The risk assessment for blood components was relatively simple and would remain essentially as written in the current draft of the framework document. However, the risk assessment for plasma derivatives was much more complicated, and the Panel's most recent draft framework document had been criticised following its presentation to the Advisory Committee on the Microbiological Safety of Blood and Tissues (MSBT).

7. It was noted that there was a lack of relevant data on blood infectivity. The group endorsed the Panel's suggestion that an expert group be convened to draft a risk

assessment for plasma derivatives. In the meantime, the Panel needed to determine the current systems in place for the investigations of incidents involving plasma derivatives, and how these could assist in the Panel's management of such incidents. The Panel would adopt a precautionary approach when advising on these incidents, until a more robust evaluation of the potential infectivity in plasma derivatives was available.

National CJD Surveillance Unit (NCJDSU)/ UK Blood Services (UKBS) Transfusion Medicine Epidemiology Review

8. It was explained that the NCJDSU had been conducting a study in collaboration with the UKBS over the last five years to investigate whether there is any epidemiological evidence that CJD or vCJD may have been transmitted via the blood supply. Cases of vCJD were notified to the UKBS by the NCJDSU and a search established whether any had acted as donors. Donation records are then checked and all components traced through hospital records. Details of recipients are then forwarded to the NCJDSU for subsequent checking. In the reverse procedure, patients with vCJD reported to have received blood transfusions are identified by the NCJDSU and notified to UKBS. Details are traced through hospital records and relevant donors identified and notified to the NCJDSU for subsequent checking.

9. The study had been given local ethical approval on the basis that any individuals identified would not be informed. The study had previously been suspended due to concerns regarding this clause and had been re-started 18 months ago. However, the Scottish Blood Transfusion service had recently not provided information relating to the reverse TMER procedure to the NCJDSU due to concerns regarding donor/patient confidentiality, although this may have been due to a misunderstanding.

10. The NCJDSU were concerned that they provide information to the NBS, who may then pass this information to the Panel, who in turn may inform the recipient, as this may compromise the study. The group agreed that any systems established to inform patients who may have been exposed to risk via blood donations should not in any way compromise this study.

Outline of existing system for follow-up for plasma derivatives (Paper 6)

11. The NCJDSU notifies the relevant UK Blood Service (UKBS), who determine if any of the donation went for fractionation and inform fractionators, who in turn trace the implicated batches and notify the Medicines Control Agency (MCA). The MCA inform the fractionators of action needing to be taken, such as withdrawing products. The fractionators then inform the consignees in the UK and any overseas distributors. The fractionator provides no guidance as to further action. Haemophilia centres are generally able to trace recipients, and have done so. In many Trusts, central records of fate of batches of products (other than Factor 8) are not kept. Although for some products, in certain Trusts, it was relatively easy to trace batch numbers, in many cases it would be necessary to trawl through patient records to identify recipients.

12. It was explained that when the UKBS informs the fractionator of products, who in turn informs the manufacturer, they use a donation number, which is linked in the blood service records to the donor. The system was therefore not totally anonymous, but it should not be possible for anyone outside the NBS to identify the donor.

13. To date there had been three incidents involving pooled plasma products. The first two incidents occurred in 1997 and any products still in use were withdrawn. The third incident occurred in December 2000. No withdrawal was necessary, as the products were beyond their 'use by' dates.

14. It was noted that since 1998 plasma has been sourced from outside the UK and therefore all incidents would be retrospective.

Discussion of how this might be modified to input Panel advice (Paper 7)

15. It was anticipated that all of the blood component recipients would fall into the 'contactable' risk group. However, if a donation was used to make a plasma product, the Panel would need to determine the pool size and which products were made and the traceability before it could provide satisfactory advice. Members suggested that the Panel could be informed of an incident and be provided with the details by the fractionators, at the same time as it informs the MCA. The Panel would then have sufficient information on which to provide advice.

16. The group was informed that there was some difficulty in linking batches distributed from hospital pharmacies to recipients. This made the follow-up for incidents more complicated, and there was a need for traceability in this area. It was suggested that this responsibility rested more with the MSBT than the Panel and the Panel should request that the system be improved to aid decision-making.

17. Some members of the group expressed concern that the draft framework document was too definitive, and that it would be wise to separate advice on blood and blood products (where data was poor) from surgical instruments (which had a good level of knowledge). Linking these suggested a greater certainty for the advice on blood products than was the case.

18. It was also noted that there was a peripheral issue of the international distribution of implicated batches that may need examining in the future. Currently there was no mechanism to gather epidemiological data on these recipients.

Outline of existing systems for management of plasma derivatives (Paper 8)

19. Unlike blood components, plasma derivatives are legally classified as medicinal products. The manufacturer/ fractionator is obliged under Directive 91/ 356 EEC, Article 13, to inform the MCA of a defect in one of its products. If the products are not traceable, the MCA will issue a 'Drug Alert' to health professionals in the UK, to ensure that all implicated batches are recalled. The MCA also issues a 'Rapid Alert' to other EC member states affected by the recall and to third countries via the World Health Organisation (WHO). If the products have expired, it is currently for the manufacturer to decide whether or not to inform consignees and other regulatory authorities who may have received implicated batches.

Any changes required to existing systems for management of plasma derivatives? (Paper 9)

20. It was suggested that the Panel could be informed of an incident at the same time as the MCA, so that Panel advice could be issued together with the MCA alerts. It was noted that it may take some time for the Panel to finalise its advice, and the MCA would not wish to delay issuing an alert. However, it was unlikely that there would be a need to recall any future batches, as they should have all passed their expiry date. This would alleviate the need for urgent follow-up action.

21. Members agreed that the Panel would need to be alerted, even if no recall was necessary, so that it can determine if any recipients had been placed at any risk, any potential contactable group identified and information placed on the database. There was some concern that the Panel might not be informed if recall was not, as the MCA would not be alerted. The Panel should always be alerted of an incident by the NBS at the same time as the fractionator.

Outline of existing systems for follow-up of blood component recipients (Paper 10)

22. The NCJDSU informs the relevant UK Blood Service (UKBS), (depending on where the patient resided) of all cases of possible and probable vCJD, unless the patient is less than 17/18 years old (as these patients would not have been eligible to donate). The Blood Services search their computer and manual databases to determine if the patient ever donated blood. The UKBS then notify the fractionators and the Trust that received the blood components. Trusts provide the UKBS with the name and date of birth of recipients of blood components. This information is then passed to the NCJDSU. Each service registers recipients who are in the age range eligible to donate blood on a database and would discard the blood should these patients ever present to donate. The patient/donor would then be contacted by letter and invited to an interview to explain why they could not continue as a donor.

The information gathered by each UKBS was not shared with the other services on ethical grounds in order to provide only the minimum number of people with the minimum amount of information required to ensure the safety of the blood supply. Knowledge of this system was not in the public domain, but had been presented to several professional groups, including the International Society of Blood Transfusion meeting in Paris, July 2001.

24. It was noted that the NCJDSU had applied to the Office of National Statistics to flag the records of recipients of implicated products, but as yet had not received a response to the application.

Discussion of how this might be modified to input Panel advice

25. It was suggested that the NBS create a link to the Panel to inform it of potentially contaminated donations so the Panel could advise on any steps necessary to protect public health. This would be a separate activity to informing the NCJDSU for research purposes, but could be done at the same time. The group again expressed their concern that establishment of a system to involve the Panel does not de-stabilise the NCJDSU/ NBS study.

Next steps

26. The actions arising from the meeting were summarised as follows:

- The risk assessment for blood components and plasma derivatives should be developed further.
- Until this risk assessment was available, the Panel would need to make pragmatic decisions regarding the current incidents awaiting advice, adopting a precautionary approach.
- The draft framework document should be amended to include areas where the Panel was particularly concerned, highlighting that some of the concerns were due to the lack of relevant data.
- The secretariat would arrange a further meeting (a subgroup of the current attendees) to further discuss the management of incidents involving blood and blood products, paying particular attention to contacting/ identifying recipients.