EC 9/98

UK BTS/NIBSC STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTIONS (SACTTI)

CONFIDENTIAL

Minutes of the meeting held at North London Centre, (Training Suite, DBR) on 21 January 1998 at 11.00 am.

Present:

Dr. P. Flanagan (PF) - Chair
Dr. P. Hewitt (PEH) - (Secretary)
Dr. J. Barbara (JB)
Dr. E. Follett (EF)
Professor I. Franklin (IF)
Dr. B. McClelland (BMcL)
Dr. P. Mortimer (PMo)
Dr. P. Minor (PMi)
Dr. A. Robinson (AR)

1. Apologies

Dr. T. Snape (TS), Professor R. S. Tedder (RST), (first half of meeting only)

2. Declaration of interests

IF was asked to provide a written declaration, as laid out in the instruction to SACs. All other members were asked to provide their annual written declaration. Any members requiring the guidance notes should contact PEH's PA (Marina Mobed).

3. Minutes of last meeting

Item 9: virally safer FFP.

4. Matters arising

i. Item 4.1:

PF has written to Dr. Bill Wagstaff who is moving this issue forward. PF will continue to press for satisfactory resolution. AR stated that she has now obtained an agreed form of words which satisfies the JCC (Joint Consultative Committee) and can be used for all members of staff. The DoH need to agree indemnity for non NBA members and for non medical staff. AR will write to Dr. Bill Wagstaff and the other national medical directors.

There still remains an issue for non medical staff, who would be indemnified for any clinical negligence claim, but would have no means of representing themselves professionally in defence of such a claim.

ii. Item 7:

PF has responded to Dr. Herborn.

iii. **Item 8:**

To be considered with agenda item 8.

iv. **Item 12i**

A paper was prepared for the Minister in mid 1997, but it is believed this has not yet been presented to the Minister. AR has pursued this with DoH in view of the recent corneal graft case and the concern over FF femoral head bone (see 6(v)). Some tissues (e.g. bone marrow, stem cells and cord blood) need further consideration.

5. **Minutes of UKBTS/NIBSC Executive meeting (previously distributed)**

Noted.

6. **CJD issues**

i. **(5/98) Position statement by NBA.**

AR spoke to this item. The position statement has been presented to the NBA Board. The implications of the recent plasma recall were far reaching, as 41 countries were in receipt of product containing small amounts of the withdrawn albumin an excipient.

AR informed the meeting that the agenda for the next MSBT meeting includes an item relating to the exclusion from donation of all individuals who have received a blood transfusion or tissue graft. Similar action has been taken in France. AR is accumulating information on the impact of this proposal on the Transfusion Services. This issue was also discussed at EAMA at a meeting last week, where it was agreed that the whole matter should be discussed "at a relevant forum". PF noted that the Amsterdam Treaty establishes that the European Union is responsible for blood. PF emphasised that discussions are taking place in a variety of fora, not all of which are known about to UK Transfusion Services. Continual efforts must be made to ensure that these discussions are known about and can be influenced.

The meeting approved the NBA position statement, subject to regular review and to ethical advice.

Action: This item to be a standing agenda item at each meeting.

ii and iii (21/98 tabled)

The was an extensive discussion on the issues arising from vCJD and the interactions between the National CJD Surveillance Unit

and the UK Blood Transfusion Services. It was agreed that the UK BTS must take the lead and agree the method of notification of the CJD cases by the Surveillance Unit. Such notification should be in writing to the named Medical Director. PEH proposed that the database currently being used for the Transfusion Medicine Epidemiology Review (TMER) could be utilised to collate all information on vCJD notification within the UK. This has already been agreed by Dr. Gail Williams on behalf of the Welsh Transfusion Service; a reply from Dr. Morris McClelland of the Northern Ireland Service is awaited. IF agreed that a copy of the notification could be sent to the NBA database.

Action: PEH to devise a notification form (in liaison with IF) to be used by the CJD Surveillance Unit.

IF mentioned the issue of consent. At a meeting with Dr. Bob Will before Christmas, it was mentioned that relatives of cases will be asked to sign a consent form, agreeing to release of information to the UK Blood Transfusion Services. Dr. Will has indicated that he will not notify cases to the Transfusion Services if consent is withheld. All present expressed their grave concern.

Action: AR to write to Dr. Jeremy Metters.

Currently, vCJD cases are only notified to the country of residence. Within the Scottish NBTS it is possible to check for a donor record throughout the country. In England, the details are only checked with the local centre, although any cases occurring post final Pulse implementation (the last Centre will be live in April) will make a national check possible. It was agreed that, for the sake of consistency, all names notified to the NBA should be check with all English Centres. Currently, there is no facility for exchange of information between the 4 countries, and Dr. Will has insisted that he will only notify the relevant Medical Director, based on residence of the case. Concern was expressed that cases may have donated blood outside their locality, for instance on holiday. It would be sensible for all cases to be checked throughout the UK.

Action: PEH to ensure that all names notified in England are checked with all English Centres. AR to write to Dr. Jeremy Metters.

Investigation of transfusion history in confirmed CJD cases (and controls)

The "reverse arm" of the Transfusion Medicine Epidemiology Review consisted of identifying transfusions given to CJD cases (and controls). A discussion on the practicalities are proceeding with the proposal followed. The actual number of cases likely to be traceable at hospitals is small. The total number likely to be

traceable is less than 50 for the whole of the UK. It was agreed that this was not an unreasonable workload. Although hospitals may be able to trace patient names through laboratory records, there would be little sense in asking for this to be carried out unless the Transfusion Centre would have equivalent donor records from the same time frame. The investigation will proceed, but all Centres will be asked to send information to hospitals, only if transfusion centre records would be available for the same time frame.

It was also noted that a small number of vCJD cases have a possible history of blood transfusion. It has been agreed that these should be followed up with the hospitals concerned. PEH has already supplied the data to the relevant Centres.

Action: PEH to proceed, emphasising the need to check transfusion centre data before contacting hospitals.

iv) Update on risk assessment

This is progressing, using a commercial agency experienced in BSE issues. This is a wide review, looking at processes within blood services and the possibilities of reduction of risk in these processes. An interim report is to be presented at DoH on 5/2/98, with a final report due end of February.

A second group is carrying out work on modelling of vCJD, assuming that if food as a source was excluded in 1989, and if blood transmission occurs, what would be the extent of the epidemic.

The leucodepletion project is also to be presented at the DoH.

AR informed the meeting about an initiative within the NBA looking at recent developments (monoclonal antibodies, column removal etc). A Research and Development CJD Strategy Group is chaired by PF, secretary David Anstee. Members of the Group include representatives from NIBSC, SNBTS, DoH. Individual members will take responsibility for specific tasks and co-opt appropriate expertise. The first priority is to secure funding for research projects, awaiting the outcome of the 5th February meeting.

RST joined the meeting at this point.

v) Fresh frozen femoral head bone and vCJD

The correspondence from Drs. Warwick and Kearney was noted. PF has asked AR to take up this issue with MSBT. AR has already written to Dr. Jeremy Metters. RST pointed out that the processes

involved in washing and freeze drying might in themselves increase risk through cross-contamination of pooled material. It is important to review cleaning protocols of the equipment used in this process.

AR reminded the meeting that the UK Standing Advisory Committees were advisory bodies set up to advise the UK BTS and the four Medical Directors, who could then consult with their relevant health departments. The correct channels of communication must be followed and individual chairs of SACs should not act unilaterally outside these channels.

7. i and ii. CPMP/BWP/390/97

An UK BTS response, signed by the four Medical Directors, was prepared for the deadline of the 22nd January. This has suggested a phasing of full implementation, mirroring the concerns over the timing required to full implementation. This item led to a wide ranging discussion. Concern was expressed that, although other European Transfusion Services may find themselves in a similar situation, no other country had an appropriate forum through which this could be addressed. The UK response would be more likely to meet with consideration, if similar responses were received from other European countries. While it is known that, for example, France, Italy, and Greece etc. would have significant problems in the time-scales suggested, it is unlikely that a unified response from the Transfusion

Services will be forthcoming. Responses have also been sent by both the SNBTS and NBS to EPFA.

iii.

The Agence France du Sange has responded to CPMP arguing that the time-scale cannot be met. Similarly, the blood banks in the Netherlands are now expressing concern over the time-scales, but it is not known whether a formal response has been sent. **AR asked that PF be congratulated on his efforts in producing a UK wide response, agreed by the DoH. There was unanimous agreement.**

8. i and ii.

PF referred to Dr. Lorna Williamson's reply to his letter re the relative safety of platelets prepared from the first time and repeat donors. Following discussions, it was agreed that JAB should prepare a short paper on the relative risk of the two groups of donors. This will be supplied to SACC, which will then have the information necessary to decide whether platelets should be produced from first time donors. Although concern has been expressed over the operational difficulties of such an action, platelets are not routinely produced from first time donors in some Centres. Secondly, it is not acceptable to have different decisions for platelets and FFP. PF reminded the Group that the SACC had made the decision on FFP.

Action: JAB to prepare a short paper on relative risks on first time and repeat donors.

9. i. GBV-C

JAB emphasised the need for collaboration with clinicians in order to attempt to establish the pathogenicity of this virus. BMcL noted that the issues relating to GBVC, HTLV etc demanded that techniques utilising psoralens and uv light would be usefully included in discussions, as further expense might be better incurred by changing processes, rather than adding further tests.

PCR screening for GBVC would not be a feasible option until PCR testing for mini-pools is fully implemented.

It was agreed that this item deserved wider discussion.

Action: item to be included in a SACTTI special meeting during the current year with a view to formulating a position statement.

10. i. Noted

ii. For information only.

11. i.

AR wrote to Dr. Jeremy Metters on the 7th November 1997, as previously agreed. It is thought that a ministerial decision is awaited.

It was noted that Ireland has commenced HTLV screening and has detected its first HTLV-1 positive donor (a drug user).

Many of those present requested a view of the abstracts provided by Dr. Graham Taylor. These will be circulated with the minutes of the meeting. The data from the South Thames study is not published, but should be available to the Group. The Group was reminded that the data was included in the papers prepared for the SACTTI special meeting on HTLV in 1996. The confirmed positivity rate in the South Thames selected donors was 6 per 1000.

It was the general view of the meeting that the data provided by Dr. Graham Taylor reinforced the previously held view that there was a greater load of disease due to HTLV than was previously recognised. There was no reason for SACTTI to change its view that HTLV screening should be introduced. As pointed out by the NBA legal advisors, SACTTI should continue to press for an understanding of why the advice given 2 years ago has not yet been acted upon, and to keep itself abreast of the current

views on HTLV and pathogenicity. The United States REDS study data reinforces the view. This data could be usefully included in the argument.

Action: (I think someone was to pursue this data ? BMcL)

12. i. and ii.

This item was noted. Members did not wish to reverse their previous decision

13. Any other business

None

14. Date of next meeting

Thursday 12th March 98 (routine meeting).
Tuesday 19th May 98 (NAT Special Meeting)

Distribution:

All members:

Dr. P Flanagan (Chair)	Dr. P. Hewitt (Secretary)	Dr. J. Barbara
Dr. P. Minor	Dr. P. Mortimer	Dr. A. Robinson
Dr. E. Follett	Professor I. Franklin	Professor R. S. Tedder
Dr. B. McClelland	Dr. T. Snape	

All Chairs: SACs

Dr V James (Sheffield Centre)	Donor Selection
Dr M de Silva (North London)	Immunohaematology
Dr R Warwick (North London)	Tissue Banking
Dr L Williamson (Brentwood Centre)	Components
Dr E Love (Manchester Centre)	IT
Dr T Snape (BPL)	Plasma

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