EC 06/97

MINUTES OF UK STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTIONS

4TH NOVEMBER 1996 NORTH LONDON BLOOD CENTRE

Present: Dr P Flanagan (Chair)
Dr L Williamson (Secretary)
Dr P Minor
Dr J Barbara
Dr P Hewitt
Dr P Mortimer
Dr E Follett
Dr T Snape
Dr J Gillon
Dr B McClelland
Dr A Robinson

1. Apologies: Prof R Tedder

2. Declaration of interests: PF reminded the meeting that not all members had sent returns to the secretary (a proforma is attched to these minutes).

Action:all

3. Minutes of last meeting 1st July 1996: Accepted

4. Matters arising:
(i): see item 2 above

(ii): EPFA residual risk analysis: it was agreed that the best way to generate meaningful data was to use rigorous epidemiological techniques, and that the approach taken by Kate Soldan was ideal.
Although BPL and PFC were each members in their own right, it was proposed that TS, on behalf of SACTTI, should work with EPFA to ensure a consistent UK approach.
Action: TS to contact Theo Evers

(iii) Malarial antibody testing: evaluation of the scaled up kit was ongoing, and so far had achieved 100% concordance with the prototype version.
Action: JB to produce a formal report for the next SACTTI meeting, to include answers to the questions raised at the last meeting.

(iv) Letter to diagnostic laboratories regarding cases of HIV, HBV or HCV notified to CDSC, in whom transfusion was mentioned as a risk factor, but where Transfusion Services had no knowledge of the case. The question was whether the diagnostic laboratory could ethically release details of the case to a Transfusion Centre.
There were issues both of confidentiality and duty of care to consider. The workload was not likely to be excessive but returns may be low.
It was felt that this question raised wider issues which needed more formal discussion with CDSC.
Action: PH to discuss with Kate Soldan and Mary Ramsay at CDSC
JG to discuss with Scottish PHL

5. Report from UKBTS/NIBSC Executive - meeting 9th October 1996

PF reported from this meeting. The main points were:

(I) The 3rd edition of the Red Book would be issued during this financial year with Transfusion Service funding. Distribution to hospitals would be via Transfusion Centres.

(ii) All SAC's were instructed to ensure that a system for declaring interests was in place. It was agreed that a common system should be used by all SACs and this issue will be progressed at the next meeeting.(iii) It had been emphasised to Chairs that SAC's were UK bodies, and that discussions should not overemphasise any one Transfusion Service.

(iv) The SAC on plasma fractionation was to be revived, as there were critical issues of donor selection and testing which impacted on plasma for fractionation.

(v) Dr W Wagstaff was looking at the statutory position of the guidelines particularly as European Guidelines would come under the umbrella of the European Parliament rather than the Council of Europe. A special meeting of the Red Book Executive was to be arranged to discuss this specific issue.

6. CMV antibody testing (papers 43/96-46/96 refer).

Replies had been received from several experts regarding the use of combined IgG and IgM kits to detect donors earlier in the window period. The theoretical benefit of an IgM component to the assay was recognised, but in the absence of suitable systems for sensitivity determination it was recognised that confirmation of this theoretical role could not be easily demonstrated. The current edition of the red book did not identify specific requirements for assays used for designating components to be "CMV safe", and neither the NBS or SNBTS kit evaluation had currently addressed this issue.There did not seem to be the resources to do an evaluation at present, particularly as there was no library of samples of seroconverting donors.

It was however recognised that combined IgM/IgG assays were available and that the track record of safety of CMV antibody negative components was largely based on the use of such assays.

PF asked if IgG only assays were currently being used for the screening of blood donations. This was considered not to be the case but JAB was requested to review the position within NBS centres.

Agreed - The use of IgG only CMV antibody detection systems should only be considered if suitable mechanisms, ideally incorporating a panel of samples relating to acute infections, was in place to demonstrate that the performance of such assays was of equal sensitivity to the "total" antibody assays currently used for this purpose.

Action: JAB to review use of CMV tests within NBS

7. HTLV screening (papers 47/96 and 48/96 refer).

This will be reviewed by MSBT on 18th November. Graham Taylor was providing further data on clinical effects of HTLV. The background work on assays had been useful, but it was now clear that even if a decision to implement were taken on 18th November, this would not be possible by 1st April 1997.

8. CJD (papers 49/96 and 50/96 refer).
(I) Proposals for lookback - these were with relevant Ethics Committees and would then go to MSBT. JG and PH would provide liaison for the whole of the UK. Results could be expected within 1 year.
(ii) Experimental research - it was agreed that, following minor modifications, the paper produced by P Minor and LW should be forwarded to Professor Pattison for SEAC, and to Drs Robinson and McClelland for MSBT.
Action: P Minor
PF to send revised paper to Professor Pattison
EAR to submit revised paper to MSBT

9. Designated laboratories for reference work (paper 51/96 refers).
The revised paper by EF was welcomed by members. The importance of such testing was emphasised by the possible effects of the results on plasma pools, so the value of MCA inspection and CPA accreditation was emphasised. Additional roles for such a centre could include epidemiology, evaluation of novel technologies and as a source of advice to fractionators. The criteria for such a laboratory could be met by a current diagnostic laboratory, but possibly also by a solely Transfusion Service facility if the throughput were high enough.
The importance of the laboratory head having previous experience in a diagnostic laboratory was emphasised. Ongoing involvement could be provided by shared appointments.
Some further minor amendments to the paper were suggested. The recommendations may be incorporated into the 4th Edition of the Red Book.

Action: EF to send a final revised version to PF, and to AR and BMcC.

10. Storage of archive samples (papers 52/96 and 53/96 refer).
The work done by Phil Nuttall and Steve Ramskill was gratefully acknowledged. The 10 recommendations suggested were broadly accepted, the main points being that a minimum volume of 500 ul, with a positive sample ID record, should be maintained at -20oC or below for a minimum of 3 years. Access would be through a local designated consultant for investigation of individual cases, but access for research purposes would require approval from national Medical Directors. The points which required further clarification/discussion related to temperature control and maximum duration of storage, which need not be defined. Archived samples were recognised not to be necessarily suitable for genomic testing. Access for investigation of non-microbiological major events eg TRALI was also appropriate via a designated consultant. Once finalised, the recommendations will be promulgated via the 4 National Medical Directors. They will eventually appear in the 4th Edition of the Red Book and thus be subject to MCA inspection.

Action: PF to discuss with P Nuttall and S Ramskill and provide revised recommendations consistent with decisions at meeting.

11. Letters from Dr P Hewitt re eligibility of donors with a history of hepatitis B (papers 34/96 and 54/96 refer).
(I) donors with a past history of hepatitis B. There is currently no mandated system for the investigation of donors who give a specific history of hepatitis B, even although regular donors who seroconvert have to show clearance of HBsAg within 6 months, and have immune levels of anti-HBs before they can be reinstated.

Agreed: **all donors with a specific history of hepatitis B should have anti-HBc and anti-HBs performed, and only donors with immune (>100 iu/L) anti-HBs will be able to donate.**

It was considered unnecessary to introduce this policy for all donors with a history of unspecified hepatitis, as most would turn out to be hepatitis A. To ensure rapid implementation, the above recommendations will be incorporated into the MAD Guidelines.

(ii) sexual partners of HBsAg carriers. While a policy was made to exclude sexual patrners of HCV positive individuals, the situation with HBV was more complicated, because of the possibility of immunity, either naturally acquired or via vaccination.

Agreed: **such donors are acceptable provided the anti-HBs level is >100 iu/L, irrespective of the e antigen status of the donor.**

ACTION: **PH to take recommendations to SAC on donors for inclusion in next revision of MAD guidelines**

12. 'Virally safer' FFP (paper 55/96 refers).
PF reported on discussions held recently within the UK Transfusion Services. The immediate actions which had been agreed on that occasion were:-
- UKTS's to produce guidelines for Octaplas, to be available should it become licensed
- standard FFP would continue to be produced, unless DoH mandated otherwise
- future options would be discussed with relevant manufacturers, with BPL opening discussions with Octapharma regarding SD treatment of UK plasma, and PFC pursuing a collaborative development programme into Methylene Blue.

AR and BMcC had produced a paper which had gone to MSBT, and a Public Health opinion was being sought. Should 2 products become available, wide consultation with users would be required as to the best use of each, given that any method of viral inactivation would have major cost implications.

Actions: **TS to convene a group to write a guide for users on untreated FFP, and to report back to AR/BMcC.**
TS to begin discussions with Octapharma regarding SD treatment of UK plasma. BMcC to pursue MB option via PFC.
EAR to submit proposals to MSBT, in particular aimed at determining whether a requirement for the use of "virally safer " FFP would be mandated within the UK.

13. Serious Hazards of Transfusion (paper 56/96 refers).
LW reported that the 'non-infectious' arm of SHOT would be going live mid-November, with an editorial in the BMJ. There would be no change in the current arrangements for reporting infectious hazards via Transfusion Centres to Kate Soldan.

Date of next meeting: PF to provide options to LW for circulation with the minutes.