

**MINUTES OF THE MEETING OF UKBTS/NISBSC JOINT STANDARDS
COMMITTEE
held on 30th June 1999 at the British Library**

ACTION

PRESENT:

Dr C Bharucha	CB
Dr F Boulton	FB
Mr M Bruce	MB
Dr M De Silva	MD
Dr M Ferguson	MF
Dr H Hambley	HH
Dr V James	VJ
Dr M Kavanagh	MK
Dr E Love	EL
Dr M McClelland	MM
Dr P Phillips	PP
Dr A Robinson	AR
Dr R Warwick	RW
Dr L Williamson	LW

1. Apologies:

Dr T Snape	TS
Prof. I Franklin	IF

2. Minutes of the 13th meeting - 1st April 1999

The following corrections were noted:-

Page 5, 1st paragraph should read "*BSHI*" not "*BHSI*"

Page 9, 1st paragraph, the action was on MB not CB

3. Matters Arising

3.1 Handbook of Transfusion Medicine

VJ had sought Brian McClelland's views. There was a need to update the handbook but it has no "parentage". Brian McClelland's view is that it should be the remit of the UKBTS/NIBSC Joint Standards Committee and that it would be appropriate to form a specific SAC to deal with the matter. At this point the views of the committee were sought. FB favoured the idea of a specific SAC as long as hospital representation is emphasised. Others expressed the view that the "Red Book" as a basis for the Handbook of Transfusion Medicine would deter non UKBTS "ownership". The question of whether the Handbook could come under the auspices of the BCSH or the BNF was also discussed.

**MINUTES OF THE MEETING OF UKBTS/NISBSC JOINT STANDARDS
COMMITTEE**

held on 30th June 1999 at the British Library

ACTION

The overall view, although not without reservation, is that a new SAC should be set up with Brian McClelland as the Chair recognising the need to establish strong hospital links and links with the BCSH and the Haemophilia Directors in particular.

VJ

3.2 New Name for the Committee

There was further discussion on the new name (See header). MK confirmed that he was happy for the use of the term "Standards" in the title.

3.3 Distribution of the minutes

Currently there is some duplication with minutes being distributed to SAC Chairs by the Secretaries of SAC's and also being sent out with other papers for Red Book Committee meetings. It was agreed that in future it will be necessary to distribute the minutes only with Red Book papers.

ALL/VJ

RW raised the subject of transparency of Red Book minutes and asked whether they could be distributed to members of her SAC as there were frequently pertinent points which required discussion in the SAC. There was concern that premature sharing of minutes could lead to misinterpretation of recommendations, as has happened in the past.

After considerable discussion it was agreed that Red Book minutes could be distributed to all SAC members (some SAC Chairpersons are already doing this) but it should be strictly stipulated that the minutes are not for onward distribution.

It was agreed that SAC minutes should not be distributed more widely to the Consultant body as a whole. SAC updates could serve a wider audience.

Members were reminded that the purpose of the SAC's and Red Book is to make recommendations to advise the National Medical Directors.

4. Red Book 4th Edition - Printing and Distribution

VJ tabled proposals for publishers. The choice lay between the Stationery Office (formerly the HMSO) and the RSM. It was felt that a sum of approximately £15,000 would be required for the first year.

**MINUTES OF THE MEETING OF UKBTS/NISBSC JOINT STANDARDS
COMMITTEE**

held on 30th June 1999 at the British Library

ACTION

After some discussion there was agreement in principle to professional publication which gave several advantages including the fact that the publisher would then host the internet site for the Red Book.

The Stationery Office seemed to be the preferred option with a solid bound annual publication of the Red Book rather than loose leaf bi-annual publication. In future the Red Book would not be issued as a controlled document. Amendments would be published on an annual basis but any urgent amendments could be sent out separately. VJ suggested a small editorial board and FB and EL agreed to assist her with this task. The first draft would be required by November 1999 with a publication date in April, 6 weeks from the final draft. Internet versions would always be the latest and disclaimers may be needed. All Red Book Chairpersons were asked to examine their contents of their contribution and make decisions regarding the relevance of various sections.

ALL

5. Red Book Budget

VJ tabled a paper identifying a budget requirement of approximately £40,000 per annum. AR felt that the UKBTS's should share the costs of this. VJ and AR will refine the paper and present to Steve Morgan prior to presenting to the Medical Directors of the UK Blood Transfusion Services. Generally there would be free distribution to Hospitals. Some copies would be sold but will not cover the cost of publication.

VJ/AR

6. Organisation Chart

6.1 Red Book (EC19/99)

All SAC Chairs were asked to update this document and forward any amendments to VJ as soon as possible.

With respect to questions about the Immunoglobulin Working Party VJ had not received a reply from Stan Urbaniak.

There was further discussion on the relationship between the Apheresis Technical Group and the Apheresis Sub Committee. Whilst there is a need to clearly separate guidelines from implementation, there appears to be considerable value in combining the remits for the Apheresis Sub Committee to include technology

**MINUTES OF THE MEETING OF UKBTS/NISBSC JOINT STANDARDS
COMMITTEE**

held on 30th June 1999 at the British Library

	ACTION
and it was also noted that there is a need for the Apheresis Sub Group to link in not only to the SAC on donor care but also to the SAC on blood components. VJ will contact Moji Gesinde to examine the terms of reference of the Technology Group.	VJ
CB requested support for a new sub group of the SACTTI to keep a watching brief on variant CJD. She envisaged a fairly informal short term group which would need to co-opt experts. After some discussion, it was generally felt that such a group would not necessarily be short term and therefore the proposal for a Sub-Committee on TSE's was supported.	CB
6.2 Membership involvement in WHO, Council of Europe and EU Committees	
This table had not been completed and VJ agreed to send it out after the meeting.	VJ
7. Tissues and the Red Book	
7.1 Letters from RW	
a) EC 20/99	
b) EC 21/99	
a) EC20/99	
RW said that the NBS is a major source of tissues in the UK and therefore full recognition of the NBS infrastructure by tissue bankers, as being appropriate to tissues, is needed. This could tie in with regulatory aspects, for example inspection by the MCA or possibly even the CPA. This need has been recognised by the Department of Health. MK informed the meeting that the DOH wants to develop fairly rapidly guidelines and regulatory measures for tissues which will also recognise tissue banking outside the National Blood Service and therefore is likely to involve new standards. The MCA has been asked if it is willing to take on inspection and accreditation. MK has prepared a paper for the MCA board as there are resource implications. It was noted that the British Society for Bone Marrow Transplantation is also setting up its own accreditation scheme. The British Society for Bone Marrow Transplantation has adopted the ISHAGE documents and RW noted that there will be compatibility between these and the Red Book Tissue Guidelines.	
RW also said that the Council of Europe has started to write standards for tissues, organs and haemopoetic progenitor cells and also other	

**MINUTES OF THE MEETING OF UKBTS/NISBSC JOINT STANDARDS
COMMITTEE**
held on 30th June 1999 at the British Library

ACTION

cells (e.g. pancreatic islet cells). It has not yet been decided whether HPCs will continue to be considered with blood. If they are not, the regulation for HPCs is likely to be delayed from 2 years to 5 years.

RW strongly requested that the tissue guidelines remain with the Red Book and said that this view is also applicable to haemopoietic progenitor cells (HPCs).

It was agreed that SACTB guidelines should be included in the Red Book for the present as they are currently ready for publication.

RW

b) EC21/99

RW discussed the matter of confidentiality of donors/recipients data. Currently organ transplant co-ordinators have no overall structure and to increase participation in transplantation schemes, there is a tendency to disclose and indeed encourage the disclosure of recipient information in order to encourage donation. The organ transplant co-ordinators now wish to extend this practice to tissues, where the organisation is entirely different. RW pointed out that it would be extremely difficult, if not impossible, to track such information but furthermore in keeping with the ethos of the Blood Service, the SACTB strongly recommended that confidentiality of recipient information be maintained. Whether or not such a statement should be included in the Red Book was discussed and it was agreed that it would probably not be appropriate to take such action. However, the committee endorsed the recommendation to maintain confidentiality and RW will therefore write to advise all National Medical Directors.

7.2 MAD and A-Z

VJ suggested that there should be a single name for these to be consistent. However, MB indicated that there are small differences and therefore there is a need to retain separate names for the time being.

8. SHOT Report 1997/8

VJ said that the reason for considering this item is to place it in the context of EC27/99 (Item 16). LW said that there was a need for a blood safety committee as currently there are multiple channels for dealing with blood safety issues and therefore a complex system of organisation. The need for a unified body had recently been debated in the SHOT Steering Group. It was not clear where NICE would fit in and LW had identified a need to contact key individuals in the User

**MINUTES OF THE MEETING OF UKBTS/NISBSC JOINT STANDARDS
COMMITTEE
held on 30th June 1999 at the British Library**

	ACTION
Force. EL agreed to copy relevant chapters to Paul Kelsey.	EL
In general wide circulation of the draft Guidelines was not favoured but it was agreed that the Red Book should be circulated more widely in the future.	VJ
10. SAC on Blood Components	
10.1 Minutes of Meeting 11th March 1999 EC22/99	
LW raised three matters:-	
<ul style="list-style-type: none">• Bleed times As a result of the need to standardise within the Northern Zone LW had been asked if the SACBC would consider bleed times of 15 minutes for components other than platelets and 12 mins for platelets in accordance with Council of Europe Guidelines. It was noted that $\frac{2}{3}$rds of England and the SNBTS are using 15 mins for all components. MB said that the SNBTS had written to the AABB who stated that there seemed no real evidence for 12 mins -v- 15 mins. VJ is to challenge the Council of Europe Guidelines but in the meantime centres practising a 15 mins bleed time overall would not change their practice.	VJ
<ul style="list-style-type: none">• COBE Spectra Platelets - Bacterial Data SNBTS data from a thousand procedures supports the view that there is no evidence of increased risk of bacterial contamination. The SNBTS needs to confirm that the Spectra platelets so produced met the specification for leucocyte depletion since they were not thought to be LRS platelets. If the validity of the data is confirmed there will be no need to reassess bacterial contamination for Haemonetics leucodepleted platelets.	
<ul style="list-style-type: none">• FFP<ul style="list-style-type: none">a) In the future each specification will be less prescriptive with emphasis on the end product quality rather than the timing of production. This will allow greater flexibility of practice.(b) Virus inactivation:- In view of the concern about methylene blue FFP in Germany the MSBT has reconfirmed that UK plasma for clinical FFP is satisfactory for use. The MSBT did not express concern about toxicology. AR emphasised that clinicians want guidelines on the use of VI (Viral Inactivated) FFP but the MSBT said that it was	

**MINUTES OF THE MEETING OF UKBTS/NISBSC JOINT STANDARDS
COMMITTEE**

held on 30th June 1999 at the British Library

ACTION

not its place to produce guidance. TS agreed to provide some risk assessment figures but it was not clear what should be done with these. Possibly they should be incorporated into BCSH Guidelines.

AR made reference to the "expert" group, a small group of haematologists which met earlier in the year to make recommendations on virally inactivated FFP. A statement was issued from the group but AR pointed out that in fact the experts concerned did not wholeheartedly sign up for this. AR/LW to raise the problem of the need for a virally inactivated product once more.

AR/LW

- **Specification for Leucocyte depleted components**

LW stated that this should be 5×10^6 in 99% of components within 95% of statistical confidence. VJ will raise this with the Council of Europe Group.

VJ

11. Standing Advisory Committee on Care and Selection of Donors

11.1 Minutes of the Meeting held on 22nd April 1999 (EC23/99)

FB raised one point and that is that the Safety of Blood leaflet needs to be re-drafted. It is currently carrying a rather negative image with undue emphasis on the safety of the test. FB's group is to work on the text.

FB

11.2 MAD and A-Z

A-Z Version 007 was due out in August and currently training documents are circulating for comment. T Cruzii recommendations have not been included as they have not yet been fully endorsed because further consultation with a parasitologist was recommended. CB argued that the issue involved making questioning safer and the interpretation of primitive living conditions. Any recommendations will be incorporated into version 008, or earlier as a concession if necessary.

Changes involving the history of jaundice will be included in 007.

11.3 Haemochromatosis and Sickle Cell donors

FB to supply a statement

**MINUTES OF THE MEETING OF UKBTS/NISBSC JOINT STANDARDS
COMMITTEE**

held on 30th June 1999 at the British Library

ACTION

12. Standing Advisory Committee on Information Technology

12.1 Minutes of Meeting held on 13th May 1999 EC24/99

EL said that the main focus of attention of the SACIT continued to be ISBT 128. The ISBT 128 Task Force is in the process of compiling the UK working document for ISBT 128 and will also draw up guidelines for implementation. In the meantime a questionnaire had been sent to UK hospitals to ascertain their state of readiness for Phase I of the change in April 2000. Results will be reported at the next SACIT.

13. Standing Advisory Committee on Reagents for Immunohaematology

No recent minutes are available. MS updated the meeting on the changes within the SAC to incorporate a new structure with two additional subcommittees. Mike Murphy had been asked to nominate experts for the Platelets/Granulocytes Sub Committee and VJ will nominate automation experts.

MS commented that many changes would be needed for the relevant Red Book chapter and these would be unlikely to be completed in time for the next edition. Each new Sub Committee would elect a Chair and inform MS who will then inform VJ.

MD

14. SAC on Tissue Banking

14.1 Minutes of Meeting - 8th December 1998 (EC25/99)

No specific comments

14.2 RW informed the members that a special SACTB/SACTTI meeting would be held at committee level to discuss mutual issues.

RW/CB

15. SAC on Transfusion Transmitted Infection

15.1 Minutes of Meeting - 15th may 1999 (EC26/99)

CB raised the following items:-

- **Malaria antibody testing**

This has been suspended from the 5th July because of supply problems with approved test kits.

**MINUTES OF THE MEETING OF UKBTS/NISBSC JOINT STANDARDS
COMMITTEE**

held on 30th June 1999 at the British Library

	ACTION
<ul style="list-style-type: none">• HTLV Testing CB said that the SAC had previously examined the evidence and recommended the introduction of HTLV screening and that the SACTTI believes that the situation with regard to HTLV screening recommendations has not changed. A small group has been set up to review the European prevalence data and consideration of protocols for further UK prevalence studies.• DNV report There is a need to clarify the position on recipients (of blood products manufactured from a pool which includes plasma from a donor subsequently identified as suffering from nvCJD) who may become donors and there was a letter from Patricia Hewitt to that effect appended to the minutes. DOH's advice is being sought.	 CD CB
17. Items raised by NIBSC No items	
18. Any other business	
18.1 SAC's - Issues for decisions VJ said that it would be helpful if these could be listed at the end of the minutes as action points for VJ.	 VJ
18.2 Yersinia Case - Nottingham 21.06.99 This is currently being investigated and VJ mentioned concerns about the anonymity of the donor in view of the fatal outcome which had been reported in the press.	
19. Date of future meetings Next meeting: - Tuesday 5th October 1999 at NIBSC.	