MINUTES OF THE 15TH MEETING OF THE UKBTS/NIBSC JOINT EXECUTIVE LIAISON COMMITTEE
held on 5 October 1999
at the National Institute for Biological Standards and Control

ACTION

PRESENT:

Dr Chitra Bharucha	CB
Dr Frank Boulton	FB
Dr Mahes De Silva	MDS
Prof Ian Franklin	IF
Dr Henry Hambley	HH
Dr Virge James (Chair)	VJ
Dr Mike Kavanagh	MK
Dr Liz Love	EL
Dr Brian McClelland	BM
Dr Morris McClelland	MM
Dr Peter Phillips	PP
Dr Angela Robinson	AR
Dr Geoffrey Schild	GS
Dr Ruth Warwick	RW
Dr Lorna Williamson	LW

IN ATTENDANCE:

Mrs Margaret Smith (Minutes)	MS

1. Apologies for absence

Dr Morag Ferguson	MF
Dr Terry Snape	TS

2. Minutes of the 14th meeting - 30 June 1999

The following amendments were noted:

7.2	Heading should read "MAD and A-Z"
9	3rd para, 2nd sentence delete "as the EC does not have suitable expert opinion".
10.1	3rd sentence of the COBE Spectra Platelets para. should read "If the validity of the data is confirmed ..."

It was agreed that the minutes would be amended and re-circulated.

3. Matters Arising

3.1 Distribution of Minutes

It was confirmed that only approved SAC minutes would be distributed with Red Book papers. **ALL**

ACTION

3.2 MAD and A-Z

There was discussion on the possibility of the MAD guidelines and the Scottish A-Z becoming a single document. At the moment there were approximately 16 differences between the two documents which made it difficult for the Scots to use the current version of the browser. FB said that there would be discussion on these issues at the next meeting of the SAC on Care and Selection of Donors. **FB**

RW commented that the same principles would apply to MAD-T.

3.3 SHOT

AR advised that the Chairmanship and constitution of MSBT was currently under review in light of comments being received and the links which needed to be established between the various committees on blood safety and blood supply.

It was noted that the future of the NBS National Blood User Group is under review.

3.4 Recommendation No. R(95)15 "Preparation, Use and Quality Assurance of Blood Components" 6th edition: 1999 version

AR had forwarded comments received to Karl-Friedrich Bopp. The document would now go back to SP-HM in November for rubber-stamping or modification.

It was noted that the paragraph on repeat grouping of donors, added this year was causing concern and CDSP would be asked to reconsider this paragraph. **AR**

3.5 Bleed Times

VJ confirmed that she would take the comments regarding 12 minutes and 15 minutes bleed times to the Council of Europe meeting but she would need supporting documentation. **VJ**

3.6 DNV Report

CB reported that she had written to AR on this issue and clarification on the legal position was being sought. SACTTI had made a decision, endorsed by MSBT and steps should be taken within the transfusion services to prevent recipients of donations from individuals who subsequently develop nvCJD from **CB/AR**

ACTION

entering the donor pool. A definitive reply was being sought from the DoH.

FB suggested informing donors who have had blood transfusions that details of those transfusions may need to be checked.

It was noted that the NBA Chief Executive and Chairman agreed the need for an Ethical Committee for donors where such issues could be considered. Members felt that if an Ethical Committee was established it should be UK-wide.

3.7 Name of the Committee

It was noted that concerns had been expressed at the change of name to Joint Standards Committee and the lack of consultation with SACs. The main point of concern was use of the word "Standards". It was confirmed that there was no intention to change the title of the Red Book and this would remain "Guidelines for the Blood Transfusion Services in the UK".

Following discussion it was agreed that VJ would recirculate the remit of the Committee to members for further consideration. Members were also asked to suggest alternative titles for the group and in the meantime it would revert to the name "UKBTS/NIBSC Joint Executive Liaison Committee". The problem with the current title was that the group had no executive power. **VJ/ALL**

4. Organisation Chart (Paper JSC 01/99)

The latest version of the Red Book organisation chart had been circulated.

VJ explained that a link had been created from the Apheresis Technical Working Group into the Sub-Committee on Apheresis and if the ATWG produced, for example, a novel procedure, this would be reported to the Sub-Committee on Apheresis, and then on to the SAC. There was some concern, however, that there may be some blurring of issues between the ATWG and the Sub-Committee on Apheresis.

It was noted that the Working Party on Immunoglobulin had met as and when required to update Section 1 Chapter 4 and Annex 4 and 4a. There was some discussion about the need to include these sections as UK plasma was currently not collected. IF asked what criteria BPL and PFC considered when selecting suppliers of hyperimmune plasma and decisions about inclusion of these sections would depend on the answers. **VJ/TS**

ACTION

5. Red Book 4th Edition

VJ confirmed that the proposed budget for the Red Book had been agreed and funding would be divided along the same lines as the SHOT allocation.

The fourth edition was due to be published in early April and, to meet this deadline, updated chapters would need to be ready and approved by mid-January. The content of the fourth edition would be the same as the current edition with appropriate amendments. If additional pages were to be included, this would affect costs. **ALL**

Following a query from Peter Phillips, it was confirmed that SAC secretaries could obtain an electronic copy of the Red Book from MS.

6. Draft Proposal for EU Directive

AR advised that she and IF would be attending a one-day meeting in Luxembourg on 25 October to discuss the proposed EU directive and therefore comments were needed urgently. The main points raised during the discussion were:

- haematopoietic progenitor cells should be included with tissues and stem cells and not be included with blood
- all reference to blood precursor should therefore transfer to tissues
- the definitions on page 16 needed to be amended
- the criteria listed on page 17 for blood pressure, pulse, haemoglobin, were felt to be too restrictive and non-evidence based
- the testing requirements in Annex 2 were inconsistent and there appeared to be a lot of unnecessary testing

AR felt that there were three options:

1. To obtain Ministerial approval that the Directive would be unacceptable for the UK Transfusion Services. (This was considered to be unlikely.)
2. To seek the support of other countries, via the EBA, for more time so the Directive could be rewritten and agreed by an appropriate group of experts.
3. To identify those key parts which were unacceptable and should be amended.

AR requested that a list of comments be sent to herself and IF by Friday 8 October. **ALL**

ACTION

GS stressed the importance of going through the document in great detail to avoid future problems.

7. SAC on Blood Components (Paper JSC 03/99)

7.1 Proposal for a Working Party on Blood Packs

LW advised that it was proposed to set up a Working Party to look at blood packs, giving sets, labelling etc. and Richard Bedford had been approached to chair the group. It was agreed that this should go ahead and Terms of Reference would be produced. **LW**

7.2 Granulocyte Transfusion

Reference was made to a section of the Red Book containing a specification for granulocytes collected by apheresis without G-CSF mobilisation. Trials of G-CSF mobilised granulocytes were currently taking place and some helpful guidelines had been produced. LW agreed to forward these guidelines to the SAC on Care and Selection of Donors. **LW**

At this point RW explained the current status of the pilot study for G-CSF mobilised stem cells from unrelated PBSC/Bone Marrow donors. At the moment only 3 donors had undergone PBSC donation according to the protocol and pressure was already mounting to speed up the pilot study by extending the indications. She was concerned that G-CSF use would be approved before completion of the pilot study. There was support from the Committee that the pilot study should be completed before extensive use of G-CSF in unrelated donors. She would keep the Committee informed of developments. **RW**

7.3 Leucocyte Depleted Frozen Components

LW referred to the implementation of the manufacture of leucodepleted components with effect from 1 November 1999. At that time there would still be frozen components in stock which may not be leucodepleted. It would not be possible for a common date for universal availability of frozen leucodepleted components for the 4 UK transfusion services. This situation was noted.

8. Standing Advisory Committee on Clinical Transfusion Medicine

8.1 Handbook of Transfusion Medicine

BM circulated a paper which detailed suggested links with various established bodies and the organisations which should be represented on the new SAC.

ACTION

BM said there could be a need to establish a Cochrane review group for transfusion medicine.

The finances required depended on the numbers of copies made freely available. AR would get a unified view from the Clinical Policies Group of how many are required and what is the best method for distribution. She advised that an audit of use of the Handbook had been done in the SW by Nicky Anderson and agreed to send a copy to BM. **AR**

Discussion followed on the handbook, how often it should be updated and what the distribution should be. It was noted that a revised version could be available for August 2000. **BM**

9. SAC on Care and Selection of Donors

9.1 Minutes of Meeting held on 28 June 1999 (Paper JSC 04/99)

FB advised that a further meeting had taken place since the meeting on 28 June when discussion on sickle trait donors had taken place. Consideration was being given to ways of allowing these donors to give blood.

It was agreed that this would be further discussed at the next meeting when the minutes would be available.

10. SAC on Information Technology

10.1 Minutes of Meeting held on 22 July 1999 (Paper JSC 05/99)

Issues which had been discussed at the meeting included:

- ISBT 128 - a request had been made for the implementation date and removal of dual labels to be put back to December 2000.
- EDI/CEN - EL would be writing to Mike McGovern regarding links with the NHS and CEN. **EL**

11. SAC on Immunohaematology

11.1 Minutes of HLA Sub-Committee meeting on 6 July 1999 (Paper JSC 06/99)
11.2 Granulocyte Immunology - proposed contents for Red Book (Paper JSC 07/99)
11.3 Minutes of Red Cell Immunohaematology/Automation Sub-Committee (Paper JSC 09/99)

ACTION

MDS advised that there were now two Sub-Committees, one for HLA, Platelets and Granulocytes and one for Red Cell/Automation. Their main tasks would be the revision of the relevant chapters/sections of the Red Book. The proposed contents for granulocyte immunology should be ready in time for the fourth edition, space permitting. Any changes due to the pending IVD EC legislation would go into the 2001 edition.

There was discussion on whether there should be guidelines for patient testing for automation or whether this should be just used for donors. MDS would prepare a paper to clarify this although any guidelines would probably not be ready for the next edition. **MDS**

12. SAC on Tissue Banking

12.1 It was agreed that the new chapter on haemopoietic stem cells will be incorporated in the next version of the Red Book as a new section.

12.2 Regulation of Tissue Banking

It was noted that the MCA Board had agreed in principle to expansion to include regulations for tissue banks and hospital blood banks which stored bone and PBSC. Discussions were taking place with the DoH to take this forward.

12.3 RW has been asked by the Council of Europe to act as a consultant and has been charged with drafting the 30,000 word guidance document for organs, tissues and stem cells. She will incorporate as much of the existing UK guidance as the group will permit. This will improve the UK's ability to easily comply with the guidance when it is produced.

12.4 Meeting of SACTTI and SACTB

RW reported that a joint meeting had taken place on the implementation of NAT testing and testing of cadaver donors. SACTB and SACTTI will be producing joint minutes of the meeting of the two SACs.

13. SAC on Transfusion Transmitted Infection

13.1 Notes of Special Meeting "Screening for 'other' Transmissible Infections" held on 6 July 1999 (Paper JSC 08/99)

CB referred to the summary notes of the special meeting which had been circulated and these would be further discussed at the next SACTTI meeting. **CB**

ACTION

A sub-group was to be set up to look at HTLV and to discuss protocols for accumulating further prevalence data. Validation of T. Cruzi tests was currently being performed and would be reviewed later in the year.

14. Items raised by NIBSC

14.1 WHO Expert Committee on Biological Standards

This group would be meeting later in the month to consider proposals to create new international standards.

14.2 GS stated that a TSE/nvCJD project was being set up.

14.3 GS reported that NIBSC had been given funding to build a new laboratory which would enable more and better standards to be made.

14.4 On 17 November NIBSC would be hosting a ½ day workshop on leucocyte counting. Further details can be obtained from Pamela Lane at NIBSC.

15. Any Other Business

15.1 Leaflet on Blood Safety

This was now being redrafted and would be going to the next MSBT meeting.

15.2 SHOT

IF referred to correspondence regarding SHOT and potential links with NICE. LW gave some background information on this and referred to other confidential enquiries which came under the umbrella of NICE.

16. Date of Next Meeting

The next meeting will be on Thursday 10 February 2000 - venue to be confirmed.

The previously circulated further dates may need to be amended in the light of participants with regular commitments on Thursday. This will be done as soon as possible.