UKBTS/NIBSC STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS
WEST END DONOR CENTRE, LONDON
20 MARCH 2000 AT 11.00 AM

SACBC 00.1 1.1 **PRESENT**

Dr L Williamson (Chair)		**LW**
Mr M Bruce	(Secretary)	**MB**
Mrs M Ashford		**MA**
Dr K Forman		**KF**
Mr P Garwood	(Not for items 6-8)	**PG**
Dr P Metcalfe		**PM**
Dr D Pamphilon		**DP**
Dr CV Prowse		**CVP**
Mr A Slopecki	(Not for items 6-8)	**AS**

SACBC 00.1 1.2 **APOLOGIES**

Apologies were received from Dr C Dash.

SACBC 00.1 1.3 **DECLARATION OF INTERESTS**

Members had no new interests to declare.

SACBC 00.1 1.4 **MINUTES OF 15 DECEMBER 1999 MEETING**

A few minor corrections were noted, ie:

SACBC 99.5	3.2.4	outlet post should read outlet port
	3.7.3	NIBTS should read NIBSC
	4.4.1	the Clinical Affairs Working Group was an EPFA Group
	4.4.2	Soldana should read Saldahna

With these corrections the minutes were agreed as a true record.

SACBC 00.1 2. **DRAFT MINUTES OF THE JOINT EXECUTIVE LIAISON COMMITTEE**

SACBC 00.1 2.1 SACBC reviewed these draft minutes and noted a number of occasions where NBS had been recorded but UKBTS was intended, eg 2. 3.3; 10. 1; 12.3.

SACBC 00.1 2.2 Re 3.8, it was felt this should be re-worded to make its content explicit.

SACBC 00.1 2.3 Re 7.2, CVP advised he had sourced the Finnish information on bleed time for platelet production from Gunnar Myllyla. This, and correspondence from Myllyla, confirmed 15 minutes was satisfactory.

SACBC 00.1 3. **RED BOOK 4TH EDITION**

SACBC 00.1 3.1 LW reviewed the production plan for the 4th Edition. Proofs would not come back to SACs.

SACBC 00.1 3.2 Minor comments made on the drafts of Chapters 5, 6 and 7 were as follows:

- Chapter 5, p3, 5.3.10.2 says 106 not 10^6;

- Re Chapter 6, the SAC preferred the former approach of starting a new page for each component. As a minimum, the SAC would like to see the headings for all components (including neonatal) emboldened;
- Re Chapter 5, 5.11, delete the reference to annex 5.

LW to ensure these were forwarded to VJ. **LW**

SACBC 00.1 3.3 The SAC were disappointed that all references given were not to be included in the document. CVP proposed that references might be posted on the website. LW will raise this with VJ. **LW**

SACBC 00.1 3.4 DP advised that the experience of Bristol and Leeds had been that apheresis granulocyte harvests certainly do not reach the $>10x10^9$ specification on ≥ 75% of occasions. This to be reviewed for the 2001 edition. **MB**

SACBC 00.1 4. **MATTERS ARISING**

SACBC 00.1 4.1 **BLOOD PACK AND APHERESIS HARNESS WORKING GROUP (BPWG)**

4.1.1 LW had met with R Bedford and RB has drafted the terms of reference for this group. (L289)

4.1.2 LW advised that SACIT are content with this draft remit.

4.1.3 SACBC discussed the draft remit (L289) and the following were agreed/noted:

- the UK BPWG should include apheresis harnesses;
- the BPWG should interact with the Technical Group. This would include cross-membership;
- the outputs from BPWG should go into the Red Book;
- BPWG need to prepare their 5th Edition Red Book entry for December 2000;
- MDA are aware of the formation of the UK BPWG and have no objections;
- various suggestions were made with regard to membership. It was agreed it may be appropriate to have a core group with additional people drafted in for specific projects/work items.
- LW to ensure these points are communicated to RB. **LW**

SACBC 00.1 4.2 BLOOD BAG / GIVING SET INCOMPATIBILITY

4.2.1 MA/AS advised that the NBS BPWG are incorporating outlet port spiking into their evaluation protocol.

4.2.2 Fifteen different administration sets have been identified by NBS. Three or four of these account for 80% of all sets used in England and Wales. The NBS BPWG will evaluate all 15 .

4.2.3 It was agreed that the Technical Subgroup should hold a listing of compatible port/spike combinations. **CVP/AS**

4.2.4 MB had previously advised there were three administration set suppliers on the approved list for the NHS in Scotland. (Baxter, Codan and Braun).

4.2.5 Re BSi/ISO, MB had just received a large bundle of paperwork from BSi and would review this and update as appropriate re standards. **MB**

4.2.6 Giving set/port incompatibility did not seem to be giving rise to fault reports in

England. MB described an incident reporting scheme in use in Inverness which includes wards. This has disclosed a regular occurrence of spiked packs – some 28 in the past year.

SACBC 00.1 4.3 SACBC TECHNICAL SUBGROUP

4.3.1 The SAC discussed L290. CVP advised that Alison Kruse would be taking up a new position with Baxter and therefore, will be replaced. CVP will action. **CVP**

4.3.2 The work list in L290 was reviewed and the following items were added:

- the definition of 'discard limits' for out of specification components detected when performing quality monitoring tests;
- shelf life of FFP, cryo, cryosupernatant: 1 year versus 2 years;
- outlet port: spike compatibility list;
- bleed time limit for FFP/platelet production.

4.3.3 CVP had received a request from Willie Murphy (National Medical Director, Irish BTSB) to have observer status on the Technical Subgroup. SACBC supported this request. LW to seek the views of the Joint Executive Liaison Committee. (JELC) **LW**

SACBC 00.1 4.4 EUROPEAN COMMISSION SCIENTIFIC COMMITTEE ON MEDICINAL PRODUCTS AND MEDICAL DEVICES: OPINION ON QUALITY AND SAFETY OF BLOOD

4.4.1 LW explained the background to this document (L291) for which comments were needed in a very short timeframe (received 02 March, needed 03 March). LW's comments were provided as L292.

4.4.2 SACBC noted these documents and considered that L291 was generally satisfactory but did not provide comments as the deadline had passed.

4.4.3 SACBC felt it would be useful to know the membership of these EC groups and wished to express concern that many important documents were being received for comment with an unreasonably short deadline. LW to raise these points with the JELC. **LW**

4.4.4 L293 and L294 were noted as was the information that Austria are now also excluding UK residents and visitors from blood donation.

SACBC 00.1 4.5 COUNCIL OF EUROPE SP-R-GS MEETING

4.5.1 SACBC noted L295. A significant number of the SAC's comments had been incorporated into the draft new edition.

4.5.2 Re the final comment on page 2 of L295, SACBC considered that the adoption, by SP-R-GS, of the generic evaluation principles produced for the Red Book would satisfy their requirements.

4.5.3 SACBC noted that SP-R-GS would be releasing the updated draft for comment and asked LW to request that this be made available to SACBC in a timely manner. **LW**

SACBC 00.1 **5. FFP, vCJD AND VIRUS INACTIVATION**

SACBC 00.1 5.1 LW reviewed the position (set out in L297) and advised that at a meeting the previous week, MSBT had agreed that the best way forward was to propose a formal risk assessment, similar to that performed previously by DNV.

SACBC 00.1 5.2 M McGovern (DoH and MSBT member) will be working this up into a UK proposal.

SACBC 00.1 5.3 It was noted that MSBT had asked UK Transfusion Services to develop an option appraisal on the provision of virus 'safe' plasma components to include the use of non-UK plasma.

SACBC 00.1 5.4 PG was leading this for NBS and CVP had already produced an initial draft document, including the introduction of fibrinogen concentrate for SNBTS.

SACBC 00.1 5.5 The NBS project team would be meeting on Friday 25 March and CVP passed a copy of his draft document, with MB's comments appended, to PG. MB passed PG an extract of an unconfirmed minute of the SNBTS Medical and Scientific Committee Meeting of 02 March 2000, which covered aspects of this topic.

SACBC 00.1 5.6 CVP/PG will produce a joint document. CVP to liaise with NIBTS; PG to liaise with Welsh BTS. **CVP/PG**

SACBC 00.1 5.7 LW to contact Octopharma and Grifols to establish whether their VIP product could be used to produce cryoprecipitate. **LW**

PG felt that via the Red Book Structures, UK BTS should take a more proactive role in reducing the use of UK plasma. SACBC agreed an option appraisal should be prepared for measures such as mandating the use of platelet additive solutions and considering (perhaps even supporting the development) of platelet substitutes. **LW**

SACBC 00.1 5.8 MACOPHARMA MBT

5.8.1 CVP summarised L302 (tabled) and indicated that Macopharma MBT FFP seemed to give marginally higher factor VIII and fibrinogen values than had been obtained with the Baxter Pathinact system.

5.8.2 Although data on cryo production from Macopharma MBT FFP were provided, SNBTS were still investigating these results.

5.8.3 SNBTS have not yet evaluated MB removal filters. Macopharma are discussing the provision of such filters with various companies. The filters remove around 95% of MB (approximately equivalent to the limit of MB detection).

5.8.4 Springe are planning to submit their MB removal step to PEI and are awaiting PEI guidance on whether they will need to repeat the toxicology studies, having made this change to their process.

SACBC 00.1 **6. ISBT 128 AND BLOOD COMPONENT CODES/LABELS**

SACBC 00.1 6.1 PA/MC gave a PowerPoint presentation on mapping of UK Codabar Blood Component Codes to ISBT Code 128 and tabled:

- a handout of the presentation;
- a glossary of terms used in this mapping exercise;
- details of the actual mapping.

SACBC 00.1 6.2 SACBC confirmed that 'expiry date' should be replaced with 'do not use after'.

SACBC 00.1 6.3 Component names were discussed. It was agreed that SACBC would check and 'sign off' the final versions. There was discussion on the space problems associated with naming components for use in neonates and infants under 1 year on CT labels. SACBC agreed this should be shortened to 'infants'. This to be noted for future Red Book revisions. **MB**

SACBC 00.1 6.4 SACBC confirmed that 'Leucocyte Depleted' would not be required on ISBT Code 128 component labels.

SACBC 00.1 6.5 SACBC agreed that the BPWG should check label content and mapping for accuracy. PA/MC asked if this could be done in the next 2 months and agreed to send LW the label text and other relevant documentation. **LW PA/MC**

It was agreed that this was a complex and important task and that it would be appropriate to ask the Blood Pack Working Group to undertake this in the first instance. LW to discuss with Richard Bedford. **LW**

SACBC 00.1 6.6 MB noted that the document setting out the actual code mappings included what appeared to be a number of in-process labels, eg leucocytes, apheresis and leucocytes, apheresis, irradiated.

This component must be irradiated and the provision of a label without this information is potentially dangerous. This issue was not resolved at the meeting.

SACBC 00.1 6.7 There was a lengthy discussion on those instances where PA/MC had identified that multiple Codabar CT label codes mapped to a single ISBT 128 Code. This was essentially a problem for red cells for IUT; exchange and neonatal use.

SACBC 00.1 6.8 PA/MC reasoned that these components were no different from standard components in respect of physical attributes or shelf life (but did/might differ in respect of testing requirements).

Their proposal was that such components:

- could be identified by an attribute, specifically haematocrit, where various haematocrit ranges would tie in with the component specifications, ie Hct > 0.70 ≡ red cells for IUT;
- might have a 'dual' identity with 'standard' and 'suitable for specific' uses being described and individual expiry dates assigned and printed on pack labels for each option.

SACBC 00.1 6.9 SACBC agreed that Red Cells for use in Infants (ie top ups etc) tended to be dedicated for that purpose, those for exchange could be held as suitable for that purpose (for up to 5 days) but were also suitable for general use.

In respect of this latter category, it was agreed that it would be useful to establish the extent to which this practice (ie of conversion from suitable for specific use to available for general use) takes place. MA has some data which she will make available. **LW/MB MA**

SACBC 00.1 6.10 MB expressed concern that the proposed approach may be unhelpful for end users and may not be compatible with all blood component manufacturing software used in the UK. As the proposals had major implications for production, MB suggested that PA/MC should develop a model of the actual proposal and present this to component producers/QA teams. This was agreed. **PA/MC**

SACBC 00.1 6.11 MB asked how other Blood Transfusion Services had dealt or planned to deal with this issue. PA/MC to establish and report back. **PA/MC**

SACBC 00.1 6.12 It was agreed that once SACBC/SACIT had agreed a workable solution to this issue, there should be wide consultation with, eg: **LW**

- BCSH Blood Transfusion Task Force;
- UK BTS User Groups;
- UK BTS Medical and Scientific Policy Groups, ie:
  NBS Clinical Policies Group
  SNBTS (& NIBTS) Medical and Scientific Committee.

SACBC 00.1 6.13 PA/MC had prepared a draft label for autologous components. This was broadly acceptable to SACBC and LW/MB agreed to take this to the BCSH Task Force for comments. **LW/MB**

SACBC 00.1 6.14 Regarding the allocation of new codes, PA/MC had some proposals. These did not match with current Red Book guidelines on generic evaluation protocols. To be discussed next agenda. **LW**

Final allocation of the new codes would not be required for some time. The Blood Pack Working Group should be asked to take this on.

SACBC 00.1 7. **ITEMS FOR NEXT MEETING**

SACBC 00.1 7.1 PLATELETS

- Review of 7 day platelets (CVP)
- Revisit new donor/regular donor for platelet production
- Visual inspection of platelets
- Platelet substitutes
- Bleed time

SACBC 00.1 7.2 OTHERS

- Allocation of component codes (see SACBC 00.1, 6.14)

SACBC 00.1 8. **AOB**

SACBC 00.1 8.1 MEMBERSHIP OF THE SAC

With the revision for the 4th Edition all but complete, LW reminded the SAC about the terms of office for members.

SACBC 00.1 8.2 After discussion, it was agreed that the SAC should write to LW and offer their resignation after the May 2000 meeting. Those who wished to continue should state this in their correspondence. Any thoughts on the 'person specification' for prospective members should be included. **ALL**

SACBC 00.1 8.3 It was agreed that this approach served the purpose of providing an opportunity for selecting a new team and for allowing members to stand down.

SACBC 00.1 8.4 LW asked that the commitment and effort of the current SAC members be recorded in the minute.

SACBC 00.1 9. **FUTURE MEETINGS**

Thursday 25 May 2000, Edinburgh

Monday 11 September 2000 - at Nottingham (after BBTS)

Wednesday 22 November 2000 - joint meeting with SACTTI, West End Donor Centre, London