JPAC Enc. 02/17

UKBTS/NIBSC STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS
WEST END DONOR CENTRE, LONDON
12 NOVEMBER 2001

SACBC 01.4 1.1 **PRESENT**

Dr L Williamson (Chair) from item 5.4	**LW**
Mr M Bruce (Secretary)	**MB**
Mrs M Ashford	**MA**
Mr N Beckman	**NB**
Dr S Maclennan from item 4.0	**SM**
Mr G Rowe	**GR**

SACBC 01.4 1.2 **APOLOGIES**

Apologies were received from Dr K Forman; Dr C V Prowse; Dr R Stebbings; Dr T Wallington.

SACBC 01.4 1.3 **DECLARATIONS OF INTERESTS**

There were no new interests to declare.

SACBC 01.4 1.4 **MINUTES OF THE 05 JULY 2001 MEETING**

Regarding 2.2 and 2.3.1, it was noted that the agreed acronym for the Joint UKBTS/NIBSC Professional Advisory Committee was the JPAC (not JUNPAC as recorded in the unapproved minutes).

Regarding 2.5.4 ii bullet 4, it was noted that NBTS should read WBTS.

With these minor changes the minutes were approved as a true record. MB to amend and issue. **MB**

SACBC 01.4 2. **MATTERS ARISING NOT ON THE AGENDA**

2.1 Regarding diversion of the initial "30ml" of blood it was noted that:

- NBS Executive have not yet given approval to proceed.
- NIBTS implemented from June 2001
- SNBTS would roll out from April 2002 (with new bag tender)
- WBTS rolling out from 13 November 2001, to be complete end March 2002.

SACBC 01.4 3. **JOINT UKBTS/NIBSC PROFESSIONAL ADVISORY COMMITTEE**

3.1 **MINUTES OF MEETING, 14 JUNE 2001 (L386)**

It was noted that the content of 14.2, item 4.2 was out of context. (The heading was HCVNAT, the context referred anti-HBC testing). LW agreed to report back to JPAC. **LW**

3.2 **LW NOTES OF MEETING, 11 OCTOBER 2001 (L378)**

SACBC noted L378.

3.3 **CURRENT STRUCTURE (L387)**

SACBC noted L387. When LW arrived she advised this version had been

superseded. The SAC on Tissue Banking now had a second sub-committee dealing with Tissue Banking.

3.4 **MEMBERSHIP OF SACS (L388)**

MA advised she is not a member of the SACBC Technical Sub Committee. LW to notify V James. **LW**

3.5 **LETTER FROM V JAMES TO JPAC MEMBERS (L379)**

3.5.1 The SAC discussed this correspondence which seemed to contradict earlier guidance that the Red Book would now be revised biannually.

3.5.2 It was agreed that CVP would be asked to co-ordinate SACBC revisions for a 2002 edition. J Rider/R Cardigan had expressed a wish to revise Chapter 8 (previously Chapter 7); NB had commenced a major revision of the format of Chapter 7 (previously Chapter 6) – to be discussed at this meeting (L384); CVP had previously offered to revise Chapter 6 (previously Chapter 5). **MB to ask CVP**

3.5.3 CVP to be asked to request that draft revisions be circulated to the Technical Sub Committee prior to their meeting on 21 January 2002. This would allow further revision and circulation to SACBC for comment in February 2002. This in turn would permit further revision prior to the March SACBC. **MB to ask CVP**

3.6 **DRAFT TERMS OF REFERENCE FOR SUB-COMMITTEE ON APHERESIS (L381)**

3.6.1 The SAC felt the remit should be redrafted to reflect the role that was envisaged i.e. they are fulfilling an advisory role for the 4 services, not setting policy.

3.6.2 Regarding point 1, the sub committee also needs to be aware of new technology under development.

3.6.3 Regarding point 2, the sub committee does not make recommendations, rather it provides advice and guidance to the UK services on request.

3.6.4 Regarding point 3, this should reflect the fact that the sub committee develops the evaluation protocols and the UK services will decide where, when and if the evaluations are performed.

3.6.5 Regarding point 6, see 3.6.3 and 3.6.4 above.

3.6.6 "Membership" states the group will not deal with clinical issues but this contradicts point 6.

3.6.7 Regarding proposed membership, NB advised he is not the National QA Manager NBS but the Lead Processing Specialist, Quality Monitoring. Via LW, TW had proposed the sub committee might benefit from the expertise of a stem cell person from the stem cell sub committee.

3.6.8 It was suggested the sub committee should be responsible for co-ordinating a UK index of evaluation reports.

3.6.9 It was also suggested that the Apheresis Sub Committee may find the remit for the SACBC Technical sub committee helpful when redrafting their remit.

3.6.10 LW to forward these comments/suggestions to M Gesinde. **LW**

3.7 **USE OF VIDEO CONFERENCING**

3.7.1 SACBC noted the JPAC comments on the use of videoconferencing. A number of those present had experience of this. The following observations/limitations were noted

- Would need to consolidate the number of sites to 3 or 4 maximum
- Much more difficult to manage the meeting (difficulty increases with number of sites)
- Demands greater concentration from all concerned
- May be more appropriate for meetings where the agenda was short and focused
- Expensive (£300 per hour and costs increase with number of sites).

3.7.2 Despite this, SACBC felt it would be worth trying out this technology. LW to consider. **LW**

SACBC 01.4 4. **MATTERS ARISING**

4.1 **MEDICAL DEVICES DIRECTIVE ON REAGENTS**

The SAC noted the communication GR had exchanged with MDA and the report prepared by MB, both of which had previously been circulated. These were supplemented by the comments provided by A Slopecki which were incorporated in the JPAC minute of 24 June 2001.

4.2 **ISO DRAFT INTERNATIONAL STANDARD ON COLLAPSIBLE CONTAINERS**

4.2.1 **BSi COMMITTEE CH/11**

MB advised that in his new role he was finding it impossible to keep up with the activities of this committee, MB proposed standing down from this group to allow a more effective contribution to be made to the benefit of all concerned. After discussion it was agreed that M Nightingale would be an excellent replacement.

MA to contact MN to establish his willingness to take on this role. MA will then contact MB who will offer his resignation to CH/11 and recommend M Nightingale as a replacement. **MA** **MB**

4.2.2 Regarding the draft correspondence prepared by LW, (L389), some changes to the last paragraph were proposed and accepted. LW also agreed it would be appropriate to remind users that as all blood components were now leucodepleted by the UK Blood Services, there was no need for bedside filtration. **LW**

4.3 **AGENDA FOR JOINT SACBC/SACTI MEETING, 26 NOVEMBER 2001 (L382)**

(LW arrived at this point in the agenda (technical failure on British Rail), a few of the points discussed prior to this point were revisited for input from LW)

4.3.1 The SAC felt the programme of presentations was satisfactory but was concerned that there should be a clearer direction on the outcomes to be achieved.

4.3.2 It was suggested that the outcomes might be delivered with more certainty if the afternoon sessions took the form of workgroups preparing key recommendations and reporting back. LW to discuss with Liz Love. **LW**

4.4 **RED BOOK, 5TH EDITION**

4.4.1- **DISCREPENCIES BETWEEN FINAL DRAFT AND PRINTED VERSION (L383)**

L383 illustrated the fact that the published version contained changes that were not reflected in the final versions agreed and provided by SACBC. LW explained that in an attempt to reduce the burden on SAC, V James's office had proof read the printed versions and LW proposed that, in future, SACBC should retain responsibility for this action. This was agreed – LW to communicate this view to V James and JPAC **LW**

4.4.2 **WEBSITE PROPOSALS**

For information – LW tabled a proposal on this which had been considered by JPAC (JPAC 01/61 for reference).

4.5 **ISBT 128**

4.5.1 MB advised that the joint SACBC/SACTI working group had not met since the SACBC meeting in July 2001 and added that SNBTS were not keen to progress implementation of phase 2 in the foreseeable future – if ever. MA advised there was a similar lack of enthusiasm in England.

4.5.2 It was agreed that a UK consensus view on this matter be progressed either via JPAC to UK Forum or directly to the UK Forum by individual services thence to JPAC. LW/MA would discuss with P Garwood on Wednesday 14 November 2001. **LW/MA**

SACBC 01.4 5. **RED BOOK – DRAFT REVISION CHAPTER 7 (L384)**

5.1 It was acknowledged that L384 did much to reduce avoidable duplication in the current format. Equally, it was accepted that this change meant important information on specific components was dispersed throughout the chapter and some may be overlooked.

5.2 On balance, SAC BC felt it was important to refine the approach embodied in L384 before passing judgement on which format was most helpful.

5.3 NB agreed to continue to develop L384 and would take the following comments into account when so doing.

- The incorporation of discard limits into specification tables
- The inclusion of Maximum platelet concentration and number, acknowledging that these are specified by platelet storage pack suppliers
- The need for a system to allow concessionary release when outwith specification e.g. release of an R_2R_2; Fy(a-); Jk(a-); SS unit with a Hb content of 34g.
- The possibility of partitioning the section into red cells, platelets then plasma components.
- The possibility of removing the descriptors to a glossary of terms.
- The potential for tabulating technical information e.g. for neonatal components.
- The need to advise CVP of aspects that might be more appropriately located in Chapter 6.
- The replacement of Hct with Hb content, with 75% of red cell components intended for use in adults having an Hb value of > or = 40g per unit.

SACBC 01.4 6. **COUNCIL OF EUROPE RECOMMENDATIONS 8TH EDITION FEEDBACK ON UK COMMENTS**

6.1 LW advised that, as agreed, V James had provided feedback on the extent to which comments provided by SACBC had been accepted/rejected.

6.2 SACBC agreed that receiving feedback was a very positive step forward. However, there was concern that the feedback was to be briefed verbally.
LW agreed to circulate the feedback provided. **LW**

6.3 SACBC were satisfied that a significant number of comments made had been taken on board. However, there was concern that on a number of issues where the UK would be unable to meet the minimum Council of Europe specification, it seemed that our views were being ignored e.g. the persistence with a lower limit for platelet pH of 6.8 versus an international perspective of 6.4; the adherence to a 28 day shelf life for red cells when 35 days was perfectly acceptable.

6.4 SACBC felt very strongly that applying such specifications run counter to the notion of achieving a realistic minimum standard for blood components across Council of Europe members. To this end, LW agreed to review V James' comments on the SACBC submission with a view to highlighting those areas where the UKBTS do not meet the minimum council of Europe specification and will forward this information to V James (and the UK Forum). **LW**

SACBC 01.4 7. **NON UK PLASMA**

7.1 LW advised that in NBS for England, this was being managed by a Project Board chaired by MA. This NBS group had, in the face of failure to stimulate DoH approval to proceed with universal replacement, produced an implementation plan that addressed a phased approach to implementation i.e. neonates and children born since the offal feed ban (1996) first. It was anticipated this would be approved in discussions with ministers that would also address anti-HTLV minipool screening.

7.2 MB advised that SNBTS had been asked by SEHD, probably against the background of the NBS approach to DoH, to review the options for procurement and further processing of FFP for neonates; for patients under 16; for use in TTP and for congenital deficiencies of specific coagulation factors.

7.3 MA advised that if given at all, NBS approval to implement, will follow a stepwise process and indicated the NBS costs for importation and secondary processing of FFP for neonatal use alone will be <£1 million.

7.4 MB advised that although SNBTS had some reassuring data regarding FVIII levels in US plasma for fractionation, he was anxious to have an assurance that the process of thawing, methylene blue treatment, removal and freezing will deliver a clinically efficacious product. MB would wish to base such an assertion on an appropriate number of components derived from an actual (i.e. not pilot) production process.

7.5 This view was supported and prompted renewed discussion on the suitability of factor VIII as a marker for the efficacy of FFP.
It was agreed there would be merit in estimating prothrombin time with a view to considering whether this would be a more appropriate marker.

7.6 MB proposed that US plasma for fractionation (at PFC and BPL) would be a good starting point and this was agreed. MB and NB to take forward in SNBTS/NBS. **MB/NB**

7.7 LW will discuss with R Cardigan the possibility of incorporating PT estimations in the evaluation of frozen/thawed MBT FFP. **LW**

7.8 NB will estimate PT in a number of current FFP to provide a baseline and also in FFP prepared after overnight storage at 4^0C and room temperature. **NB**

7.9 MA advised that the estimated time frame for S59 Pathogen Inactivation of plasma was the 3rd quarter of 2003.

7.10 LW advised that the NBS group had asked EOR to quantify the relative vCJD risks in importing plasma from Europe versus America and had been advised there was no discernible difference.

7.11 LW advised that the NBS group had asked EOR to re-examine the health economics of the case for importing plasma for adults as the cost per litre was, at present > 50% higher than when the position was originally considered (currently around $190-200 per litre).

SACBC 01.4 8. **PROCUREMENT OF NON UK RED CELLS AND PLATELETS FOR NEONATES**

8.1 MB updated the SAC on the status of this work within SNBTS, i.e. MB had, with the approval of DoH and the Scottish Executive Health Department (SEHD) contacted a number of Blood Services to establish the feasibility of this approach.

8.2 Replies had been received which, on the basis of numbers of components alone, indicated it might be possible to meet UK needs for cellular neonatal components.

8.3 MB had prepared a summary report for the SEHD which was presently being scrutinised by a number of senior SNBTS personnel.

8.4 The document summarises the facts and seeks approval to proceed to the next stage which involves detailed consideration of a range of complicating factors such as epidemiology and logistics. SACBC agreed that this stage should take place on a UK wide basis.

8.5 LW will contact M Gorham and request he in turn contacts A McMillan Douglas to ask if the SNBTS document on cellular imports and the documents provided in confidence to LW by CVP could be made available to UKBTS colleagues. **LW**

SACBC 01.4 9. **USE OF ECONOMIC AND OPERATIONAL RESEARCH (EOR) BY NBS (L385)**

LW advised the SAC of the background to L385. NBS had funded a Principal Analyst and a more junior analyst to work within EOR with a focus on blood safety. These individuals will be based at Skipton House and take up post in January 2002. LW has drafted a workplan (L385) and has been advised that Charles Lister and Vicky King (who replaces Mike McGovern) at DoH have also been asked to produce a workplan.
LW to send L385 to DoH. **LW**

SACBC 01.4 10. **REPORT FROM THE TECHNICAL SUBCOMMITTEE**

As the Technical Subcommittee had not met since the July 2001 SACBC and, in CVP's absence, this item was not taken. However, it was noted that the work of the subcommittee has continued over the summer and a workplan is being developed.

SACBC 01.4 11. **SACBC WORKPLAN FOR 2002**

The following were agreed

- Granulocyte meeting, 17 May 2002, London tc develop/refine guidance and specifications.
- Review of quality monitoring aspects e.g. exploring whether PT should replace FVIII estimation for FFP.
- Data gathering in support of specifications for new components e.g. FFP MBT, MB removed, S59 treated platelets, platelet additive solutions.
- Revision of blood component chapters of the Red Book.
- Developing the principle of "discard limits" for components which when QC tested fall outside specified values.
- Continuing to develop guidance and specifications in support of vCJD precautionary measures e.g. UK specification for imported FFP and for imported cellular components.
- Develop an evidence base to allow limits to be set for holding/handling components prior to preparation and storage.
- Options for TRALI prevention.

SACBC 01.4 12. **DRAFT AGENDA FOR SPECIAL SACBC MEETING ON GRANULOCYTES**

LW tabled a draft agenda for the above which is scheduled for 17 May in London. (L386 for reference). A few suggestions were made which LW agreed to incorporate. **LW**

SACBC 01.4 13. **FUTURE MEETINGS**

13 or 14 March 2002, Newcastle Blood Centre
17 May 2002, London (venue TBA)
12 September 2002, Edinburgh (venue TBA)
16 December 2002, London (venue TBA).