EC 31/98

MEETING OF UKBTS/NIBSC
STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS
NEWCASTLE BLOOD CENTRE
12 DECEMBER 1997

MINUTE

			Action
SACBC 97.4	1.1	**Present**	
		Dr L Williamson, Chair	LW
		Mr M Bruce, Secretary	MB
		Mrs M Ashford	MA
		Dr C Dash	CD
		Dr K Forman	KF
		Mr P Garwood	PG
		Dr P Metcalfe	PM
		Dr D Pamphillon	DP
		Dr C V Prowse	CVP
		Mr A Slopecki	AS
SACBC 97.4	1.2	LW introduced CVP and welcomed him to the SAC	
SACBC 97.4	1.3	DECLARATION OF INTERESTS	
SACBC 97.4	1.3.1	It was noted that formal declarations had not been received from all members. MB to circulate the format outlined by the Red Book Executive.	*MB*
SACBC 97.4	1.3.2	LW and CVP advised that they were in receipt of a grant from Baxter for the evaluation of methylene blue treated (MBT) cryoprecipitate production.	
SACBC 97.4	1.4	MINUTE OF THE LAST MEETING	
		It was agreed that the following additions be made.	
SACBC 97.4	1.4.1	re Section 10, "Accredited Donor Status; FFP/Cryo"	
	SACBC 97.3 10.3	LW had received a request from SACTTI enquiring whether the principle of using "accredited" donors for FFP for clinical use could be applied to platelet donations. MA agreed to investigate and report back to the next meeting.	*MA*
	SACBC 97.3 10.4	Correspondence had been received requesting that the SAC explore the possibility of restricting FFP production to plasma from untransfused males to reduce the risk of TRALI. MA to investigate and report back.	*MA*
SACBC 97.4	1.4.2	It was noted that the first para of 6.4 should have been the last para of 6.3.	
SACBC 97.4	1.4.3	A few typos were noted i.e	

page 3, SACBC97.3.4, iii, line 2, not → nor
page 4, SACBC97.3.4.2, vi, 1997 → 1998
page 5, SACBC97.3.4.5, explaining → exploring
page 9, SACBC97.3.7.3, components → component
page 10, SACBC97.3.11.0, proposed → proposal

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

SACBC 97.4 **2. VERBAL UPDATE FROM RED BOOK EXECUTIVE**

SACBC 97.4 2.1 **IDEMNITY OF SAC MEMBERS**

LW summarised the view of the Red Book Executive i.e. BTS medical staff were already covered by medical defence agencie and expected that the National BTS's would confirm they would idemnify non-medical staff; NIBSC had written confirming idemnity for their staff; non NIBSC/UKBTS members had been asked to pursue idemnity from their Trusts but this has proved problematic.

W Wagstaff has asked SAC Chairs to provide details of non-NIBSC/UKBTS staff in order that he can write to their Trust Chie Executives.

SACBC 97.4 2.2 **TERMS OF REFERENCE**

2.2.1 The Executive had approved the proposed remit for SACBC. The SAC noted that, when appropriate, decisions should be elevated to the Executive for approval.

SACBC97.4 2.2.2 In this regard the SAC had concerns that a "fast track" procedure should be available as the Executive meets only twic per year. LW will raise with the Executive. ***LW***

SACBC 97.4 2.3 **GENERIC EVALUATION PROTOCOLS**

LW had submitted the latest drafts of these to the Executive for comment. Comments had only been forthcoming from W Wagstaff. The SAC discussed the various points raised by W Wagstaff. The following action was agreed:

2.3.1 AS will write to WW to explain point 2 iii. ***AS***

2.3.2 AS will redraft the generic component and blood pack evaluatio protocols and submit to LW by 05 January 1998. ***AS***

2.3.3 DP will redraft the red cell component evaluation protocol and submit to LW by 05 January 1998. ***DP***

2.3.4 LW will redraft the FFP/cryo protocol and will reply to W Wagstaff. ***LW***

2.3.5 re blood pack evaluations, LW would write to the BCSH Transfusion Task Force to enquire whether the group drafting guidelines for the administration of blood would identify factors ***LW***

they consider important from the users perspective.

LW would also enquire on the extent to which NBS User Group could play an integral role in blood pack evaluations. ***LW***

2.3.6 The redrafted evaluation protocols will be circulated for commen - to be submitted to LW/MB by 27 January 1998. LW/MB will convert to a generic format for end February 1998. ***All*** ***LW/MB***

2.3.7 MB indicated that Professor Franklin had recently contacted him to ask if SNBTS was content with the evaluation protocols. This raised an important point of principle about the extent to which consultation was required. It was recognised there was a need to balance the authority of the SAC to make policy proposals against acceptance of the policy (and any funding consequences) by the 4 National Services. In this respect SACBC was significantly different from SACTTI. LW would rais this issue with the Executive. ***LW***

2.4 **ADDENDA TO 3RD EDITION**

2.4.1 LW advised that the Executive had indicated that the intended date for submitting items to be included in the 1998 addendum to 3rd edition was end of February 1998.

The SAC considered this deadline was unrealistic. LW agreed to write to W Wagstaff requesting:

- the deadline be delayed to end May 1998 ***LW***
  - to allow adequate time to complete revisions
  - to complete the work on evaluation protocols
  - to allow consideration of progress with VIP and leucodepletion
  - to allow for adequate consultation
- the milestones in the process of addendum production
- an assurance that all SACs will work to the same timetable

2.4.2 Re Changes/Additions to Current Edition

1. LW agreed to write to W Wagstaff to request Executive Committee approval to change the "accredited donor" FFP criteria to "donors who have previously given a mandatory screen negative donation in the previous 24 months" - this change already has the approval of SACTTI. ***LW***

2. The SAC to submit comments on the current (3rd edition) Red Book to LW/MB by 05 January 1998. ***All***

3. Neonatal Components Section to be revised to incorporate: ***LW/MB***
   - definition of neonates i.e infants < 1 year
   - leucodepletion as standard
   - platelets for IUT

4. Spec to be established for methylene blue treated (MBT) plasma, cryo and cryodepleted plasma. ***LW/ CVP***

5. LW to write to W Wagstaff and R Warwick to enquire whether stem cells should now be administered by the Tissue Banking SAC. (A new sub group was being established to oversee Cord Banking). ***LW***

SACBC 97.4 **3. PLATELET EVALUATIONS**

Progress on this evaluation protocol had been left in abeyance pending the outcome of the recent platelet consensus conference in Edinburgh.

CVP agreed to take forward the development of this protocol. The SAC to submit comments to CVP by mid January 1998. ***CVP*** ***All***

SACBC 97.4 **4. VIRUS INACTIVATED PLASMA**

SACBC 97.4 4.1 LW updated the SAC on progress since the last meeting, which had seen NBS decide against contract production of SD VIP by Octopharma. NBS now intended to produce a MBT component and have received approval from MSBT to do so in a slightly longer timescale.

SACBC 97.4 4.2 NBS and SNBTS were undertaking a joint evaluation of MBT plasma components.

4.2.1 SNBTS were investigating the use of O.5 CPD for MBT FFP/cryoprecipitate/cryosupernatant but had discontinued the evaluation because of a skin reaction experienced by staff handling the packs. It was hoped to recommence the trial in the New Year. CVP/LW will report on progress at next SAC meeting. ***CVP/ LW***

4.2.2 NBS were undertaking an operational evaluation of the MBT process which was being led by MA and Jim Knipe. This would conclude with the production of 1000 packs of MBT FFP at Newcastle and Colindale. LW suggested that AS and MB should undertake an audit of the MBT process once this stage was reached. This was agreed. ***AS/MB***

4.2.3 MA/PG advised that Baxter were reluctant to undertake modifications to their lightboxes to provide evidence that packs of plasma had been subjected to the MBT process. The SAC viewed this as a very serious matter and asked MA to communicate their concern to Baxter. ***MA***

Note added after meeting: MA and LW had since met with Baxter who had produced proposals answering all important quality concerns. These included light sensitive labels.

4.2.4 As an alternative to "in-house" MBTS production NBS were exploring contract production of MBT plasma by Griffols in Spain. To this end, MA and AS were undertaking a 2 day audit at the Griffols plant. It was noted that the Irish BTS Board had recently contracted Griffols to undertake their MBT process.

SACBC 97.4 **4.3 GUIDANCE NOTE ON VIP**

4.3.1 LW updated the SAC on progress. BCSH Blood Transfusion Task Force had agreed that they would issue this guideline and had already commented on an earlier draft produced by LW. The latest version, planned for publication in March 1998, was circulated as L84. This required some revision i.e.

4.3.2 There was no mention of CJD.

4.3.3 Dr B Gibson (Chair BSH Paediatric Haematology Forum) had written to request more information regarding the toxicity of MBT FFP in neonates. CD offered to ask a contact in Springe to provide data collected by them for their submission on MBT plasma to P.E.I. ***CD***

LW would pursue similar information from.Octopharma and respond to BG's concerns. ***LW***

Note added after meeting: to answer BCSH queries, publication will now be delayed until June.

SACBC 97.4 **5. ADMINISTRATION OF GROWTH FACTORS TO DONORS**

SACBC 97.4 5.1 LW had followed up this item as requested at the last SAC meeting and it had been discussed at the last Executive meeting. The Executive recognised the need for a formal UK position not only for GCSF but also for TPO which was now being used widely within the US to stimulate platelet numbers in volunteers prior to plateletpheresis.

SACBC 97.4 5.2 DP was asked to lead a group to develop guidelines and agreed to do so. LW advised that Professor Franklin wished to be involved in this group and DP said he would be contacting Dr V James to enlist a recruit from the SAC on Donor Care and Selection. ***DP***

Existing draft guidelines in this subject area, produced by BBMT and ABMT, were available and would be a useful starting point.

SACBC 97.4 5.3 CD will contact Amgen for information on their GCSF product and will make this available to DP. ***CD***

SACBC 97.4 **6. SELECTION OF DONORS FOR FFP AND PLATELET PRODUCTION**

SACBC 97.4 6.1 FFP

Following an enquiry, MA had been asked by the SAC to determine whether it would be possible to produce FFP exclusively from untransfused male donors (to minimise the risk of TRALI). MA reported that the logistics of such a requirement would be extremely difficult to implement.

In the absence of evidence of the scale of the problem (TRALI) or the extent to which it would be alleviated by using

untransfused male donors, the SAC considered that this proposal should not be progressed at this time. This decision will be reviewed at a future meeting once the first annual report of the SHOT system has been released. LW will reply *LW*

SACBC 97.4 6.2 **PLATELETS**

6.2.1 MA had investigated the potential impact of producing platelets from donors with previous negative microbiology results only. Whilst this was routine practice in the London and South East Zone it was accepted that this policy could not be implemented on a national basis without considerable operational change and would pose a significant risk to platelet availability.

6.2.2 LW advised that a key concern of SACTTI re new donors was the increased risk of retrieving the wrong donation for retesting and subsequently releasing a Microbiology positive donation to stock.

The SAC felt this was an extremely unlikely circumstance. (Previously, the frequency of such lab errors had been estimated to be around 750,000, McClelland et al Transfus Med 1996; 6: 1-10).

PG agreed to meet with the London & SE Zone microgroup to map out the potential for errors attributable to computer/equipment/staff failures occurring that might lead to the wrongful release of a micro positive donation. The objective would be to produce some estimate of relative risk to help inform any further discussion on this matter. *PG*

6.2.3 LW will write to P Flanagan to advise him of the outcome i.e 6.2.1 and 6.2.2. *LW*

SACBC 97.4 **7. LEUCOCYTE DEPLETION TO REMOVE THE THEORETICAL RISK OF CJD**

LW provided an update of progress to date. Key issues were :

SACBC 97.4 7.1 A risk assessment of 100% leucodepletion of blood components was being undertaken by DoH. This will report end February 1998. T Snape, B McClelland, B Perry and P Flanagan were invited by DoH to represent UKBTS interests.

SACBC 97.4 7.2 UK Blood Transfusion Services are working on the operational requirements and costs to implement this policy and are working jointly on the medical and scientific aspects of implementation.

SACBC 97.4 7.3 LW had circulated a briefing paper on the medical and scientific evaluation and invited the SAC to send comments. *All*

(re Point 6 CVP noted that Dr R Green (Glasgow) was involved in a study of leucodepletion in cardiac surgery).

SACBC 97.4 7.4 LW offered to circulate the briefing paper which had been produced for MSBT/SEAC on leucocyte depletion and other *LW*

measures of avoiding allogeneic exposure.

SACBC 97.4 7.5 It was agreed that SACBC should organise a specific meeting on this theme to which SACTTI and other relevant personnel will be invited. ***LW/MB***

SACBC 97.4 **8. REVIEW OF QUALITY MONITORING**

SACBC 97.4 8.1 MA and MB had reviewed and produced sampling and Q.M data for discussion by the SAC. AS had discussed the issues around specifications and statistics with the NBS QA Managers and tabled some proposals.

SACBC 97.4 8.2 Constraints of time prevented prolonged discussion. However, the following points were agreed:

8.2.1 That standardisation of sampling techniques (including anticogulants used) and counting methods was a prerequisite for meaningful progress. MA will take this forward, probably co-opting I Wilcox; J Seghatchia plus an individual with experience in cell counting. ***MA***

8.2.2 That the principles outlined in AS's proposals were sound and should be developed further. In this regard, AS would work with NIBSC statisticians. ***AS***

8.2.3 Since the proposed way forward could be seen as being at variance with Council of Europe Guidelines (and, possibly, MCA) LW agreed to write to W Wagstaff to outline the approach being planned and to solicit his view on the extent to which this would be acceptable to Council of Europe. ***LW***

8.2.4 It was agreed that this topic would have a special SACBC meeting in 1998. AS/MA/MB to progress. ***AS/MA/ MB***

SACBC 97.4 **9. REVIEW OF COBE COMPONENTS**

SACBC 97.4 9.1 **BACTERIAL VALIDATIONS OF COBE LRS PLATELETS**

(L86 refers). LW advised that the NBS validation of the above had not progressed as planned and, as a result, only 200 of the planned 1000 donations had been cultured. The SAC considered that insufficient evidence had been generated to allow it to "sign off" this exercise. LW to write to I Wilcox advising him of this decision. ***LW***

SACBC 97.4 9.2 **PLATELETS FOR IUT**

(L87 refers). the SAC discussed the draft provided by DP and suggested a few changes. DP to modify and resubmit. LW/MB to incorporate in addenda to current Red Book. ***DP LW/MB***

SACBC 97.4 9.3 **COBE SPECTRA LRS TURBO**

Unfortunately the information supplied (L88) provides no information on volumes or pH. The SAC considered that

provided the component can be split to standard platelet concentrations that this need not necessarily be a problem - LW to contact M Gesinde to obtain relevant information. ***LW***

SACBC 97.4 **9.4** **COBE TRIMA**

LW advised that it was planned to evaluate this instrument in Oxford under the supervision of Dr M Murphy. Platelet and plasma data seemed to meet current specifications but data on plasma would need to be submitted to fractionators for approval. The SAC approved Dr Murphy's proposals set out in L89.

DP commented that experience with an early version of this equipment produced poor quality red cells.

SACBC 97.4 **10.** **COMMENTS ON COUNCIL OF EUROPE GUIDELINES**

It was noted that a new draft of the above, incorporating the comments submitted, will be circulated in due course.

SACBC 97.4 **11.** **NEWSLETTER**

LW advised she would be producing a Newsletter for distribution. ***LW***

SACBC 97.4 **12.** **HAEMOLYSIS IN SALVAGED RED CELLS**

Deferred until next meeting ***MB***

SACBC 97.4 **13.** **FUTURE MEETINGS**

13.1 The SAC agreed there was a need to increase the frequency of meetings in 1998. Three special meetings and three routine meetings were proposed.

Special meeting topics were:

- leucodepletion (with SACTTI and others)
- bacterial contamination of blood components (with SACTTI and after SHOT report has been published).
- quality monitoring of blood components.

LW/MB would compare notes on availability and sent out a proposed calendar for 1998. It was noted that Tuesdays should be avoided. ***LW/MB***

13.2 DATE, TIME, VENUE AND CONTENT OF MEETINGS FOR

1998

25 Feb 98	Colindale	Addenda to 3rd ed Red Book
22 Apr 98	Colindale	General Meeting
17 Jun 98	Edinburgh	SACTTI/Leucodepletion
10 Sept 98	Colindale	General Meeting
04 Nov 98	Newcastle	Quality
17 Dec 98	Colindale	General Meeting

Please note change of tel/ fax details for MB:

Tel	Main Switchboard	0131 536 5700
	MB Office	0131 536 5747
	MB Office (with answering machine)	0131 536 5748
Fax	HQ General Office fax	0131 536 5701
	MB Office fax	0131 536 5749

E -mail please note, we have been experiencing coding/decoding problems with our e-mail system. I'll advise once these have been resolved.

Martin