Rcd em MB 4-11-02

UKBTS/NIBSC STANDING ADVISORY COMMITTEE ON BLOOD COMPONENTS
SNBTS PROTEIN FRACTIONATION CENTRE, ELLENS GLEN ROAD, EDINBURGH
12 SEPTEMBER 2002

SACBC 02.3 1.1 **PRESENT**

Dr L Williamson (Chair)	**LW**
Mr M Bruce (Secretary)	**MB**
Mrs M Ashford	**MA**
Mr N Beckman	**NB**
Dr C V Prowse	**CVP**
Mr G Rowe	**GR**
Dr S Maclennan (11:45)	**SM**
Dr R Strebbings	**RS**

SACBC 02.3 1.2 **APOLOGIES**

Apologies were received from Dr K Forman and Dr T Wallington.
LW to clarify whether Dr W Murphy (Dublin) is to attend SACBC as an observer. **LW** ✓ email 10/11

SACBC 02.3 1.3 **DECLARATIONS OF INTERESTS**

GR advised he had been involved in a trial of Gambro Trima double red cell apheresis and an evaluation for Pall. GR to send written details to MB. **GR**

SACBC 02.3 1.4 **MINUTES OF THE 13 MARCH 2002 MEETING**

The minutes were agreed as a true record. MB to issue. **MB**

SACBC 02.3 2. **CHAIR AND SECRETARY**

2.1 LW advised that having completed 6 years as SACBC Chair she had tendered her resignation. On 11 September 2002 SM had been invited to take over as SACBC Chair and had accepted. LW/SM will meet soon to hand over relevant paper work. SM will attend JPAC in October.

2.2 After 12 years as SACBC Secretary, MB had also tendered his resignation.

2.3 These changes create 2 spaces on the Committee and LW asked members to make suggestions regarding replacements to SM (CVP proposed GR for secretary). **ALL**

SACBC 02.3 3.0 **MATTERS ARISING**

3.1 **APHERESIS SUB COMMITTEE** (taken after SM arrived).

SM advised that M Gesinde had now redrafted the remit for their subcommittee in line with SACBC comments. A copy was tabled, (L427 for reference). SACBC to forward comments to SM for incorporation in next revision. **ALL**

3.2 **DRAFT SPECIFICATION FOR DIVERT POUCHES**

MA advised that the NBS group had concerns that some systems (esp apheresis) could compromise component sterility. It was agreed that MA would document the various concerns on this issue and forward them to CVP. CVP will ask the technical sub group to consider. **MA** **CVP**

3.3 **RECOMMENDATION RE: BACTERIAL CASE MONITORING**

3.3.1 GR tabled a draft 'ticklist' to be used to record data items following a transfusion transmitted bacterial infection. This was discussed and a number of changes were proposed (arm prep method; Bactalert testing; Pathogen Reduction; extended platelet shelf life; additional processes e.g. washed) and it was recognised that Services should have mechanisms in place to log the implementation date of relevant changes.

3.3.2 It was agreed that GR/NB would revise and recirculate the draft for initial comment by SACBC. GR/NB to redraft and send final draft to the 4 Territory QA Managers and K Soldan * who will be asked to consult and feed back comments. **GR/ NB**
(it was noted that K Soldan is shortly to leave PHLS)*

3.3.3 LW to link this document into the SHOT process and to ensure KS's replacement revises the SHOT report form to include the donation number identifier. **LW** find document.

3.4 **ISBT CODE 128**

3.4.1 It was noted in the JPAC minutes (L411, 11.3) that SACIT were preparing a full ISBT Code 128 implementation plan (i.e. all blood pack barcodes) and that a paper had been submitted to the UK Forum.

3.4.2 LW/MA will raise this issue with issue with M Gorham/P Garwood and MB/CVP will raise with A MacMillan Douglas. **LW/ MA MB/ CP** ✓ email 10/11

3.4.3 It was thought this matter would be discussed at the EBA meeting in Edinburgh on 04 October 2002.

3.5 **JOINT SACBC/SATTI MEETING, 26 NOVEMBER 2001**

3.5.1 SACBC were concerned that the SACTTI Working Group/s proposed at the above workshop had not yet met. LW will raise again with L Love. **LW** ✓ email 10/11

3.5.2 LW advised that the NBS were planning a blood component bacteriology test workshop at the West End Donor Centre on Friday 25 October 2002. LW proposed that she would ask C MacDonald/R Elgin to change the context of the meeting to make it UKBTS wide. At the same time she would explore whether a larger venue would be more appropriate. **LW** ✓

3.5.3 CVP advised that W Murphy was organising an EBA meeting on prevention of bacterial TTI/pathogen reduction. The meeting would take place in Dublin on 6-7 March 2003.

SACBC 02.3 4.0 **MEETING OF JPAC, 13 JUNE 2002**

4.1 Re minute (L411), item 5.1

4.1.1 LW referred to this request from the UK Forum and indicated that she and B McClelland had met and would produce a framework document based on the WHO Blood Safety Intervention Framework. This would not include toxicology which LW/BMcC considered was outwith their sphere of expertise. The document would be sent to JPAC then to the UK Forum. **LW** ✓ handed on to Sheila.

4.1.2 CVP will copy the Best Framework Document to SACBC, BMcC and L Love. **CVP**

4.2 Re Minute (L411), item 10.1

RS to discuss the implications of this item with T Barrowcliffe/SJ Urbaniak. **RS**

SACBC 02.3 5. **MINUTES OF SPECIAL MEETING ON GRANULOCYTES WITH RECOMMENDATIONS**

5.1 Re Minutes (L412) a few minor amendments were noted (F Wilson = K Wilson), page numbers needed. LW to progress and issue. **LW** Done

5.2 LW advised that K Wilson; Mike Murphy; D Pamphilon; S Devereux will be meeting soon to develop a trial protocol. → SM Nov 02

5.3 Re recommendation 2i. JPAC thought this was too cumbersome to work in practice. LW had subsequently clarified with D Pamphilon what was intended i.e. a group of experts would develop guideline indications for granulocytes to be followed by hospital clinicians. In those instances where the intended patient's condition was not included in the 'indications' the patient's clinician would refer the matter to the group of experts for guidance.

5.4 There was some discussion about whether this group would report to the SAC on Clinical Transfusion Medicine or to the BCSH Blood Transfusion Task Force. SM to discuss with B McClelland and J Duguid. **SM**

5.5 Re recommendation 2ii, it was proposed that the expert group referred to in 5.3 would maintain the register of patients treated with granulocytes. SM to take forward. **SM**

5.6 Re recommendation 2iv, it was agreed that there was a need to consider functional assessment of granulocytes. CVP advised the Technical Subgroup has this in hand. MA advised G Nicholson is doing some work using starch to prepare granulocytes from buffy coats.

5.7 **RE 'LYMPHOCYTES'**

5.7.1 MA reported on an incident within NBS which highlighted the need for a Red Book Specification on lymphocytes. (Lymphocytes had been harvest from a sibling donor, labelled as 'Granulocytes, apheresis' and subsequently irradiated in error). SACBC agreed there was a need to develop a specification for this component which should include on the label 'LYMPHOCYTES, DO NOT IRRADIATE'.

5.7.2 It was agreed that SM would ask the Apheresis Subgroup to develop a generic 'lymphocytes' specification, cc Dr G Galea as chair of SAC on Tissues to ensure he agrees the Apheresis Subgroup is the most appropriate group to develop the document. **SM**

SACBC 02.3 6. **CHAPTERS 6 & 7 AMENDMENTS**

6.1 NB has received a draft document from the printers via V James. Chapter 6 contains a few minor typos. A few 'leucocyte depleted' in component names to be removed. NB to highlight these changes and emphasise to V James the position regarding 'Leucocyte Depleted'. **NB**

6.2 SACBC recorded their thanks to GR and especially NB for the considerable efforts they made in delivering the revised chapters.

6.3 SM to ask JPAC for clarification/guidance on the timing/intentions for the next revision. **SM**

6.4 As outgoing chair, LW will write to V James indicating that SACBC is not confident it could resource a new edition for next year. The preference would be to confine any revision to new components e.g. Platelets in Additive Solution.

LW email 10/11

SACBC 02.3 7. **COUNCIL OF EUROPE GUIDELINES, DRAFT 9TH EDITION**

7.1 Collated SACBC comments had been sent to V James, cc SACBC, on time. (L415 was the 'wrong' document).

7.2 Regarding clarification of the Council of Europe position on FFP, LW tabled (L428 for reference), an e-mail from V James to C Lister at DOH. This clarified the COE position/intention regarding pathogen reduction of FFP – the clarification will appear in the 9th edition of the Council of Europe Guidelines.

7.3 V James had advised that she felt that the drafting group were beginning to listen to SACBC concerns about the pH of platelet components (they continue to recommend >pH 6.8 at expiry). CVP to work up paper previously prepared with MB, to include Quality Monitoring data, and forward to V James. **CVP**

7.4 CVP raised a proposal from the BEST Group to replace paired crossover radiolabelled platelet studies for new platelet components. CVP to copy and table, L429 for reference. **CVP**

SACBC 02.3 8. **NON UK PLASMA**

8.1 **SPECIFICATIONS**

8.1.1 Noted HTLV needed to be added to the testing criteria.

8.1.2 LW to check with P Hewitt whether HBsAg standard should now be 0.2IU/ml.

LW email 10/11 do Path/Reagt L2L

8.1.3 MB advised L418 (SNBTS Spec) is now out of date and agreed to forward the current version. **MB**

8.1.4 SNBTS were further down the line with regard to contracting with a US Supplier for FFP. Specification issues which have arisen to date include:

- Do not test for high litre anti-A/B
- Do not test for factor VIII
- Do not test for residual platelets
- Do not test for residual wbc
- Reluctant to provide only from previously tested donors
- Unable to provide from male donors only

8.2 **INSTRUCTION TO PROCEED/IMPLEMENTATION**

8.2.1 NBS had not received a formal instruction from DoH authorising them to proceed. NBS have advised implementation will take 15 months from the date of this authorisation.

8.2.2 SNBTS has been instructed to proceed by SEHD (however funding arrangements have not been agreed) and has indicated it would have finished components ready for issue by 01 April 2003.

8.2.3 It was noted that NBS are currently providing male, apheresis FFP, MBT and MB removed as the sole FFP component for children born since 31 December 1995.

8.2.4 It was noted that NBS/SNBTS would be joining each other's Project Boards to ensure effective information sharing.

8.3 **LABELLING**

SACBC agreed there was a need for 2 new labels/barcodes for imported, MBT, MB removed FFP – one for neonates (splits) and one for paediatric. LW to reply to M Clarke. LW email 1d4/02

8.4 **SHELF LIFE EXTENSION**

LW will confirm with R Cardigan the NBS position concerning the extension of FFP shelf life. It was agreed the National Services should work jointly on this project. **LW**

8.5 **SDFFP SPECIFICATION**

It was agreed to defer this item for now.

8.6 **OVERNIGH HOLD REPORT FROM REBECCA CARDIGAN (L422)**

8.6.1 MA/LW set out the rationale behind the study reported in L422. It was reasoned that as we accept a factor VIII level of 0.5iu/ml in MBT FFP i.e. considerably less than in untreated FFP, then we should be able to promote the acceptance of 'untreated' FFP with <0.7iu/ml factor VIII if there was an associated safety benefit.
The case in point was that overnight hold of whole blood at 4°C before processing would allow FFP to be produced exclusively from male donors. The trade off for this reduction in TRALI risk would be a reduction in factor VIII.

8.6.2 LW agreed to seek guidance from clinical colleagues regarding the acceptability of FFP with a lower factor VIII level. **LW**

8.6.3 There was general discussion about what action would be required to progress a reduction in the specified factor VIII level in FFP (Red Book and Council of Europe).

8.6.4 Discussion also took place on the advisability of re-opening discussions on the 20°C overnight hold debate as things had moved on from the early 1990's when this subject was last addressed.

8.6.5 It was agreed that MA would establish a small group to progress these matters (i.e. 4°C and 20°C overnight hold). **MA**

SACBC 02.3 9. **PATHOGEN INACTIVATION/BACTERIAL TESTING**

9.1 SM had attended the FDA Workshop summarised in L423 and was reporting back. Some key issues included:

- Emphasis that the capacity of these processes to kill viruses is finite i.e. the process is pathogen reduction;
- FDA representatives had expressed concern at the lack of progress with which blood component producers were introducing these processes;
- No agreed actions from the meeting although there was strong support for the view that pathogen reduction (PR) should be introduced and clinicians could chose whether to transfuse PR or untreated components.

SM had copies of the presentations shown at the FDA Workshop. These were copied and tabled at the SACBC Meeting (L431 for reference).

9.2 It was noted that the UK Forum had posed more or less the same question as FDA were asking about Pathogen Inactivation, item 4.1 of this minute refers.

9.3 CVP offered to circulate work in this area being developed by Hans Gullikson on behalf of the BEST Group. **CVP**

SACBC 02.3 **10. TRALI**

10.1 SM introduced her paper on this subject (L425). Discussions on 'overnight hold' (item 8.6 this minute) were also of relevance.

10.2 MB advised that SNBTS has been carefully examining the feasibility of using male donors only for FFP production and had concluded that current constraints (but see 8.6) ruled this out. MB to provide details. MB also enquired whether there was an evidence base that demonstrated whether particular components carried an inherently greater TRALI risk. (i.e. was FFP the best component to target). **MB**

10.3 SM agreed to check out male, untransfused donors for evidence of HLA antibodies (n=50) and will obtain details of the work previously performed in this area by A Lubenko. **SM**

10.4 LW will review the diagnoses and implicated component types for TRALI cases reported to SHOT. **LW** ✓ TK.

10.5 It was agreed that any proposals in this area also needed to take account of the constraints of scale i.e. what might work in a large organisation might not work in a small one. **SM**

SACBC 02.3 **11 VCJD**

11.1 The paper by Hunter et al (L426) and the case of vCJD in Canada referred to in L423 were noted.

11.2 LW advised that the Canadian Blood Service have introduced a permanent deferral for persons who have undergone endoscopy with the same endoscope as the vCJD case as a vCJD risk reduction measure.

11.3 JPAC/UKBTS Position Statement on vCJD.
LW referred to the above (L430 for reference) and asked for comments to be submitted by the end of the week. **ALL**

SACBC 02.3 **12 AOB**

12.1 CVP advised he will circulate minutes of the Technical Subgroup Meeting of May 2002 **CVP**

SACBC 02.3 **13.0 FUTURE MEETINGS**

Next meeting; Monday 16 December 2002, WEDC, London