UKBTS/NIBSC EXECUTIVE COMMITTEE MINUTES OF THE SIXTH MEETING OF THE EXECUTIVE COMMITTEE HELD AT THE WEST MIDLAND RTC, BIRMINGHAM ON TUESDAY 26 SEPTEMBER 1995

Present:	Dr T Barrowcliffe	Professor J Cash	Dr M de Silva
	Dr P Flanagan	Dr V James	Dr M Kavanagh
	Dr E Love	Dr P Phillips	Dr A Robinson
	Mr N Tandy	Dr W Wagstaff (Chairman)	

In attendance:

Dr Imelik

Dr Wagstaff welcomed Dr P Imelik visiting from Estonia.

1. APOLOGIES:

Dr F Ala, Dr B McClelland (represented by Mr N Tandy) and Dr G Schild.

2. MINUTES OF THE 5TH MEETING (EC32/95) 20 June 1995:

There were no corrections.

3. MATTERS ARISING:

3.1 Legal Status of Guidelines:

Dr Wagstaff discussed the contents of a letter from Messrs LeBrasseur & Tickle, Solicitors. This emphasised that although the guidelines have no legal status they have been constituted as good practice by a reasonable body of persons and would be relevant in a Court of Law. Dr Kavanagh's view was that although not legally binding the guidelines represent a sensible view and he would wish to see them followed.

Professor Cash indicated that the Scottish view is that where a body of people have agreed best practice there would be great difficulty in accepting a different view even if it was supported by other individuals. Professor Cash emphasised the need for the employing Authority to clarify the status of the guidelines especially with respect to donors who should be regarded as suppliers of the raw materials and not patients.

Dr Robinson had been questioned about the remit of the Specials Licence and sought clarification from Dr Kavanagh who confirmed that the Specials Licence covers single donor components as well as plasma for fractionation. Dr Kavanagh will write to Dr Robinson to confirm this.

ACTION - DR KAVANAGH

4. STANDING ADVISORY COMMITTEE ON DONOR SELECTION:

4.1 EC33/95 - Minutes of meeting held on 14 June 1995:

There had been a further meeting on 19 September 1995 and subsequently Chapter 1 has been completed and was tabled (EC46/95).

Following the last meeting there had been no further significant changes. With the removal of donor selection information to form the A-Z guidelines there was concern that the overall value of Chapter 1 of the Red Book for other countries/bodies who may wish to purchase the guidelines would be diminished. However Dr James emphasised that the A-Z which has proven popular outside the UK is covered by the same HMSO copyright as the Red Book guidelines and should be easily accessible. The A-Z has already been translated into French, Italian and German.

It was suggested that a paragraph be inserted to the effect that those who wish to obtain a copy of the A-Z should write to either of the Medical Directors.

ACTION - DR JAMES

Other changes to Chapter 1 had involved a greater referral to national documents and a move away from specific examples.

Changes to the protocol for reinstatement have been incorporated as agreed previously with the SACTTI.

Professor Cash voiced his concern that further "honing" of Chapter 1 may increase the differences between the Scottish and English guidelines and it was agreed that the principles should remain as in the new version of Chapter 1.

4.2 EC34/95 Revision to guidelines for Apheresis volunteer donors:

Major changes were highlighted as follows:-

1) The guidelines refer to machine apheresis only and Professor Cash recommended that this be indicated in the title.

2) The previous age restriction had been removed to be replaced with age criteria as for whole blood donors. As this represents a major departure from previous guidelines Dr Duguid will be asked to confirm that the recommendations are in accordance with Europe and the AABB.

3) Since the new guideline indicates the requirement for only one previous whole blood donation Dr Duguid will be asked to consider whether the interval since the first donation should be specified.

4) **Point 3.2.2.2:** - Dr Duguid will be asked to check this statement against any specifications set by the plasma fractionation facility (BPL). Dr James was also asked to check the A-Z guidelines for any reference to apheresis donors.

5) **Point 3.3.3 - Complex procedures**: - Dr Pamphilon had voiced concern about possible citrate toxicity in procedures continuing beyond 90 minutes. Dr Duguid will be asked to incorporate a statement drawing attention to this possibility.

6) **Point 3.4.4:** - This should be reinstated according to Council of Europe guidelines.

ACTION - DR LOVE to convey the above comments to Dr Duguid.

Dr James to follow up Point 4 in relation to A-Z guidelines.

Amendments should be made as soon as possible and returned to Dr James.

5. STANDING ADVISORY COMMITTEE ON COMPONENTS:

5.1 EC35/95 Revision to Chapter 5:
Item 5.4.3 Prevention of microbial contamination:

There was lengthy discussion about the definition of closed systems particularly in relation to apheresis harnesses. Dr Tandy was asked to take this back to the Components Group for re-consideration.

ACTION - DR TANDY:

5.2 EC36/95 Revision to Chapter 6:

Dr Tandy outlined and explained the main changes and comments were received as follows:-

1) In several places there is conflict with BCSH guidelines on neonatal transfusion and irradiation of blood components. It was emphasised that these should be consulted in order to achieve professional uniformity.

Dr de Silva voiced the concerns of Clinicians with regard to the reduced volume of red cells following leucodepletion which may be of significance when given to transfusion dependent patients such as thalassaemics. The need for locally specified volume ranges was emphasised.

With reference to the status of platelet additive solutions there is currently insufficient data to set guidelines but Centres who are using this component have been asked to supply data. In the meantime issue of such components is on a named patient basis locally.

2) **Item 6.19:** - Cryopreserved red cells should not be excluded from requirements for irradiation.

3) **Item 6.3.4 & 6.5.4** - Dr de Silva asked for clarification in relation to requirements for filtration and subsequent storage.

4) **Item 6.19.4.4** - With reference to radio-sensitive labels Council of Europe guidelines should be acknowledged and the discrepancy with BCSH guidelines rectified.

5) **Item 6.20.1** - Reference to possible use of growth factors in volunteers could be misleading although it was presumed that this relates to related volunteers only. This point requires clarification.

6) **Item 6.20.5 - Testing:** Professor Cash asked for clarification of "sterile".

Dr Robinson requested some recommendations regarding reference ranges for cell yields.

Again it was recommended that the BCSH guidelines on collection and storage of peripheral blood progenitor cells be consulted.

7) **Item 6.21 - Other Components:**

In relation to new components issuing should be on a named patient basis only and Professor Cash recommended that the development of new components be logged with the SAC Components Chairman.

ACTION - DR TANDY to take the above comments back to SAC Components for consideration.
Dr Wagstaff to write to SAC Chairmen reminding them of the need to take account of existing BCSH and other relevant guidelines.

6. STANDING ADVISORY COMMITTEE ON REAGENTS FOR IMMUNOHAEMATOLOGY AND HLA:

6.1 EC37/95 - Revision to Section 3:

Dr de Silva summarised by saying that this chapter had been completely re-written to incorporate modern concepts of reagents. More specific information was given about product inserts and more attention paid to the immediate container and labelling requirements. With reference to fully typed donors it was felt that historical data could not be relied upon at present because of deficiencies in the current IT systems.

Annexe 3 to Section 1 - Mandatory Testing of Blood Donations (EC47/95) was discussed and comments made as follows:-

Item 5.4 Dr Barrowcliffe will liaise with Dr de Silva over the recommendations for plasma for fractionation in relation to anti-D quantitation and other blood group antibodies

ACTION - DR BARROWCLIFFE and Dr de SILVA

Item 6.1 The need to alert users to the possibility of haemolysis from incompatible large volume single donor plasma was recognised but the recommendations for testing were not agreed and it was acknowledged that the practical problem needs to be resolved at some point.

It may be of value to consult with those who have begun to make a study of this problem and it was thought that the Northern Zone Designate Functional Group on testing had considered the matter. Dr Wagstaff will write to Dr McClelland highlighting this concern which has resulted from a change in clinical practice.

ACTION - DR WAGSTAFF

6.2 PROPOSED NEW APPENDICES:

6.2.1 - EC38/95 - GUIDELINES FOR THE USE OF DNA/PCR TECHNIQUES:

It was recommended that this new annexe be included in Chapter 2, General Guidelines for Serological Tests.

6.2.2 - EC39.95 - MINIMUM STANDARDS FOR HLA TYPING AND MARROW DONORS:

It was recommended that where this paper highlights types as "serological specificity not defined" this should be changed to "molecular techniques required".

It was agreed that this new annexe be incorporated in the components section and it has already been sent to Dr McClelland for consideration.

At this point Dr Wagstaff wished to ensure that revision of other annexes should be covered by appropriate SAC committees and these are as follows:-

1. Donor selection - SAC donor selection
2. Premises - SAC donor selection
3. i) General specifications for laboratory tests - SAC Reagents.
   ii) Mandatory tests already covered.
   iii) Additional testing

3.2-3.4 SAC Reagents

3.5-3.6 SAC TTI

4. Accredited donors of red cells for RHD immunisation

4 & 4a Revisions have already been suggested by the Immunogloblin Working Party and Dr de Silva will consult with Dr Lee

ACTION - SAC Chairmen - as above

7. STANDING ADVISORY COMMITTEE ON PLASMA FOR FRACTIONATION:

7.1 Revision to Section 2.

The final paper had not been received due to the need to take account of the most recent European Pharmacopoeia Monograph which has not yet been published but which has been sent out for consultation through the usual channels. Mr Barrowcliffe will circulate amendments to Section 2 as soon as possible.

8. STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTIONS:

8.1 EC40/95 - Minutes of meeting held on 12 June 1995:

With reference to the relationship between SACTTI and MSBT Dr Robinson clarified Dr Jeremy Metters' view that there should not be a formal relationship.

However although the SACTTI is not formally represented on the MSBT three members of the SACTTI sit on the MSBT. Although minutes cannot be shared directly pertinent matters may be brought to the attention of SACTTI through these members.

8.2 EC41/95 - Minutes of SACTTI Special Interest Meeting on 11 June 1995:

Recommendations for the standardisation of counselling for HCV infected donors and archive sample storage were noted.

8.3 EC42/95 - Financial Interests of Members:

The letter from Professor Cash was noted and discussion ensued on concern about possible conflict of interests of Red Book Committee members.

It was recommended that a Code of Practice be developed and that there should be better mechanisms for declaration of ongoing interests of members. Professor Cash clarified that he was not asking members with interests to be excluded from contributing but merely to declare their interests. Dr Wagstaff emphasised the need for UK Red Book Committee members to be seen to be above criticism and this view was echoed by Dr Kavanagh who indicated that it is standard practice for members to declare interests at every meeting of the CSM for example.

Dr Flanagan agreed to take these recommendations back to Dr Ala but it was emphasised that any recommendations should apply to every Committee not just the SACTTI.
ACTION - DR FLANAGAN and ALL SAC CHAIRMEN AND WORKING PARTY CHAIRMEN (via SAC CHAIRMEN)

9. STANDING ADVISORY COMMITTEE ON INFORMATION TECHNOLOGY:

There was no report as this newly re-formed group has not yet met. A meeting has been called for 3 October 1995.

10. WORKING PARTY ON TISSUE BANKING:

10.1 EC43/95 - Minutes of meeting held on 23 May 1995:

Dr Wagstaff outlined the difficulties which this group had encountered not least because of the very rapid development of other advisory groups in this field.

It would be important for this group to build on what has been already achieved by the previous group and the importance of liaison with the BATB was emphasised. Dr Robinson proposed that Dr Ruth Warwick be asked to Chair the new group.

ACTION - DR WAGSTAFF

11. EC44/95 - CONTROLLED CHANGE TO GUIDELINES

The letter from Mr McDougall and Dr Wagstaff's reply were discussed. Dr Wagstaff emphasised that changes were subject to consultation within the SAC and any other external consultation as deemed necessary. All changes to existing guidelines must be validated, justified and recorded by respective SAC Chairman.

The concessionary route for changes in the A-Z guidelines was fully supported and it appears that the problem may lie with Centres who may not yet have in place suitable control mechanisms for the management of the concessionary route.

Dr Wagstaff will write again to Mr McDougall indicating that the matter has been discussed and that the Liaison Committee are in agreement with previous recommendations.

ACTION - DR WAGSTAFF

12. STATUS OF RED BOOK vis-a-vis EUROPEAN GUIDELINES

12.1 EC45/95 - Correspondence from Professor J D Cash and Dr G Galea:

Professor Cash voiced his concern about the need to keep abreast of developments outside the UK particularly USA and Europe and he felt that feedback from Europe was not comprehensive.

The difficulties of gaining access to important information from elsewhere was discussed as currently representation in Europe is at DOH level although Dr Robinson is occasionally asked to attend as an expert.

Dr James asked Dr Wagstaff to remind each SAC to consider routinely AABB and European developments.

In addition Dr Wagstaff will write to the Chairman of the NBA Board to express his grave concern at lack of communication from DOH.

ACTION - DR WAGSTAFF

13. ANY OTHER BUSINESS:

13.1 SAC on Plasma for Fractionation: Replacement of TC Medical Representative (previously Dr Forman)

It was recommended that Dr Vanessa Martlew be invited on to that Committee.

ACTION - DR BARROWCLIFFE

13.2 EC48/95 - Chapter 2 Guidelines for Quality Systems:

It was recognised that BS45001 renders BS9001 superfluous but there had been insufficient time to re-draft the document. Mr Slopecki had recommended that a re-draft be conducted to meet the next guidelines revision. Dr Phillips had recommended acceptance of these proposals.

Mr Slopecki will be asked to update terminology with reference to RTCs, RTDs etc.

ACTION - DR ROBINSON

13.3 Proposals for UKBTS/NIBSC Secretariat:

Further information will be forthcoming at a subsequent meeting.

13.4 The title of the new Red Book guidelines will be as before.

13.5 Suggestions about options for printing had not been taken any further as they are dependent on DOH funding.

13.6 Deadlines:

Dr Wagstaff emphasised that the whole document should be on final disc by the end of December with the aim to publish before April 1996. It was considered that this could be accomplished by correspondence rather than further meetings.

14. DATE OF NEXT MEETING:

Tuesday 6 February - 11.00 a.m. West Midlands Blood Centre - Dr Wagstaff to confirm.

ACTION - DR WAGSTAFF