UKBTS/NIBSC EXECUTIVE COMMITTEE
Minutes of the 12th Meeting held at
The West Midlands Centre - 14th December 1998

Present:

Frank Boulton	FB
Ian Franklin	IF
Henry Hamley	HH
Virge James (Chair)	VJ
Mike Kavanagh	MK
Elizabeth Love	EL
Angela Robinson	AR
Terry Snape	TS
Bill Wagstaff	BW
Ruth Warwick	RW
Lorna Williamson	LW

VJ welcomed Henry Hamley as a new member of the Executive Committee and Bill Wagstaff as the past Chairman to the meeting.
and Frank Boulton as the new chairman of SACDCS

1. Apologies:

Chitra Barucha	CB
Mahes de Silva	MS
Morris McClelland	MM
Morag Ferguson	MF

2. Minutes of the 11th Meeting 15.06.98

There are two corrections:-
Page 3 Risk of incompatible transfusion, after "1 in 3.75 million" delete "50% and the following sentence".

Page 7 The implementation date for NAT should be 1st July 1999 not 1998.

3. Matters Arising

3.1 The new chair of the Executive Committee is Virge James who had submitted a discussion paper for later in the meeting.

3.2 The ABO mislabelling letter was issued by AR. AR said that the legal advisor was concerned that the letter be construed as a guarantee of correct labelling. AR explained that this was not the case and that professional guidance should come from the BCSH. In correspondence with Paul Kelsey he had stated that the BCSH was unlikely to make specific comment about the letter. AR will discuss further with Paul Kelsey and then ask advice of Steven **AR**

Janisch.

3.4 **Handbook of Transfusion Medicine**
Action still outstanding **VJ**

3.5 VJ had clarified the position on the 70th birthday and the posters have been withdrawn.

3.6 AR had circulated the Council for Europe document for discussion.

3.7 **Section 4 - Tissue Banking**
This had been circulated, no comments received and it has now been issued.

3.8 LW said that protocols 18/98, 19/98, 20/98 and 23/98 were all ready and needed to be put into common format. **LW**

4. **The Red Book and Europe**
WW explained the relationship between the Council of Europe and the European Commission and the various groups leading into these two bodies. His notes will be circulated to the group by VJ. **VJ**

He mentioned the newly formed (September 1998) European Blood Alliance which is roughly equivalent to the EPFA (European Plasma Fractionators Association) and deals with labile components rather than plasma fractions. Most of the Western European countries are represented and within the UK there is representation from England and Scotland although not from Wales and Northern Ireland. The purpose of this group is to act as a concerted voice within Europe regarding recommendations, guidelines and directives in transfusion medicine. In the past this has been dominated by a rather bureaucratic system without specialist experience.

Hitherto, the Council of Europe and the European Union have generally not agreed on policies but now within DGV (of the EU) there has been a change of personnel. This has resulted in better liaison with the Council of Europe and the WHO on transfusion matters.

WW spoke further on the Council of Europe Guidelines and was

asked the procedure for new proposals. These should be given to AR and this can be done at any time but the next meeting is in Spring 1999.

Although the Council of Europe and European Union may not always agree, for donor selection there must be harmony between the Council of Europe and the European Union documents. The status of these is currently recommendation not directive.

WW discussed a number of documents in preparation.

He alluded to the EU meeting in Adaire 1996 where a number of transfusion issued had been identified which DG5 wished to explore to obtain harmony in Europe. These were:-

- donor issues
- QA/GMP in blood centres
- haemovigilance
- optimal use of blood
- inspection/accreditation
- training of inspectors
- public information

The next directive to be worked on is the QA/GMP and MK mentioned that he had already attended a meeting.

LW said that she had attended a meeting on haemovigilance but the proceedings were confidential.

Another issue which will impact on the Red Book is revision of Annexe 14 of the EU Guide on GMP. A further development is the European Council on Laboratory Medicine (ECLM) which will identify essential criteria for quality systems in medical laboratories.

VJ felt that it would be very useful to have a flow chart of the various meetings which take place in Europe and of the UK attendees. VJ will prepare a document for circulation to the committee. **VJ**

MK then mentioned a further scheme, the Pharmaceutical Inspection Co-operation Scheme (PICS). This comprises

European and some other countries and it has just produced a guide on the inspection of blood centres. The prime movers were the Dutch. MK agreed to provide a copy of this document to VJ. **MK**

5. Current Structure, Remit, Terms of Reference, Proposals for the Future

5.1. Remit

VJ had prepared a discussion document (SACIT) (EC40/98). It was felt that the committee should be renamed and ideas should be sent to VJ. **ALL**

VJ discussed the original remit of the group which was still considered to be valid. One point was the identification of research topics. It was felt that the committee might still have a role in recommending where research could be carried out. Such recommendations would go to medical directors for inclusion or not in their strategic plans. Any resultant research protocols would need to go through the appropriate channels to obtain resources.

5.2. Organisation

- Working parties should have defined remits and time scales and chairs of SAC's were asked to notify VJ of current working parties with a note of any previous ones. **Chairs of SACs**

VJ explained that the Automation Users Group had not met for some time. It previously came under the Red Book "umbrella". She felt that there was a need for such a group and that it should be reconvened and feed into the SAC on Reagents. Committee members were asked to consider this proposal. **ALL**

5.3 VJ said that there needed to be a reference to Quality Systems cross referenced to the European groups and AS will be asked to review this on an annual basis in the future. **VJ**

5.4 Terms of Office

It was proposed that the chair of the Executive be for 5 years with 3 years further renewable term of office.

The role of DoH observers was discussed and it was felt that

currently the committee is a professional one is no role for DUH observers.

As far as SAC membership is concerned, it was agreed that 3 plus 3 year term for the chair and 3 plus 3 year term for members would be acceptable. There needs to be flexibility in the system to allow the chairs of SACs to vary the terms of office under particular circumstances for example a shortage of expertise. It was agreed that new members would be chosen by the chair in consultation with the membership of the SAC and these should be notified to VJ for approval. This did not need to await a full meeting of the executive.

Chairs of SACs

RW expressed the view that all members of SACs should be given specific responsibility and questioned whether there should be a quality presence on each SAC. It is felt that there is extensive quality input into the Executive and therefore this is not necessary on all SAC's but would certainly be essential on some.

It was felt that each SAC needs a critical mass to enable learning and "new blood" but this does not need to be the same for each SAC.

It was agreed that chairs of SACs should be nominated by the Executive.

The question of cross membership between SACs was raised by LW and there is a need to formalise this for particular SACs but not for every one. It was agreed that chairs would discuss with the members of the SACs the essential representation which should be included in that particular SAC.

It was agreed that in certain circumstances some sub-committees may need to be more or less permanent e.g. the sub committee on Apheresis Donors which comes under the Care and Selection of Donors.

5.5 Output

5.5.1 Red Book

VJ said that an electronic version would be welcomed by hospitals. Expert internet legal advice would be needed. There was discussion on the cost of this with lack of agreement as to whether use of the website would cost less than circulation of

hard copies of the Red Book. For the time being there would probably still be a requirement for hard copy and ideally an attempt should be made to charge for every copy. Some members expressed the view that hospitals may be reluctant to pay a charge.

5.5.2 **Updates**

After some discussion it was concluded that these should remain individual for SACs. VJ asked for circulation lists for updates so that these could be held centrally. **Chairs of SACs**

5.5.3 **Joint Meetings of SAC's**

There have been a number of these, particularly between the SACBC and the SACTTI. These are more appropriately termed special meetings of SAC's. It was agreed that there was probably no need for these to come under the "umbrella" of the Executive. The meetings always arise from necessity to consider special circumstances and there was felt to be no need for change in the way that they are organised. It was agreed however, that all chairs of SACs should be informed of any future meetings.

5.5.4 It was agreed that minutes of the Executive could be copied to SAC members if relevant.

There was some discussion as to whether minutes of other SACs should be circulated at SAC meetings. There was concern that this could lead to premature implementation of what are in fact only recommendations and VJ will clarify the mechanism to ensure that recommendations are not misinterpreted as matters for implementation. **VJ**

5.5.5 **Finances**

It was agreed that there is a need for a budget for a part time secretary, to pay for venues if necessary and cost of publications if this cost cannot be recouped by charging.

Funding for special speakers should continue to be ad hoc and has so far been funded from AR's travel budget.

Travel/subsistence for chairs of SAC/members could be provided where these are not otherwise available through the employing authority. This could be particularly important for ***non*** UKBTS

members of SAC's.

A "first pass" budget of approximately £35,000 has been identified by VJ and she will re-evaluate this in the light of discussions at the meeting. If the size of the budget can be agreed, AR felt that it would be reasonable for the UK blood services to fund the Red Book activities in a similar manner to the way that they fund the SHOT scheme. **VJ**

6. **Amendments/changes to the 3rd edition of the Red Book**
It is planned to distribute these early in 1999 with a complete re-write for the end of 1999 for publication in the year 2000.

It was felt that IT chapters, if ready, could go as new annexes for 1999 with a complete new section for 2000. Any documents for inclusion for 1999 must be sent to VJ within the next month. **Chairs of SACs**

7. **Fractionation**
EC42/98
TS discussed this paper.

He highlighted the diminishing value of the section on plasma products of the Red Book and the section on plasma fractionation is also redundant. Plasma products are very well specified by manufacturing and regulatory constraints and therefore the Red Book is unnecessary from that point of view. He felt that the SAC in its present form had served its purpose and should be wound up and that the current chapters could possibly be replaced with a resource list which could be compiled by a corresponding group rather than a specific SAC (TS/Bruce Cuthbertson/Trevor Barrowcliffe). This could be managed by the Regulatory Affairs Dept at BPL.

FB took the view that we should retain official expertise in plasma products in the hope that the UK plasma may be reinstated and also as an opportunity to remain up to date. A chapter in the Red Book should be maintained as an independent view.

There was much discussion on the purpose of a chapter on plasma products and was felt that something needed to be included on regulatory affairs. TS agreed to discuss the future of the SAC

with his group and also what should be included for the Red Book. MK will also have input. **TS/MK**

8. Standing Advisory Committee on Blood Components

8.1-8.5 Minutes of Meetings EC31/98 EC32/98, EC33/98, EC34/98, EC35/98

LW summarised the activities of the SACBC:-

- The section on components for neonates has been re-written and expanded to include infants and platelets for RUT.

- A section on component evaluation has been produced as an annexe. This comprises several documents including the general approach, evaluation of blood bags, novel red cells, platelets and FFP. These have been used in the approach to leucodepletion implementation and their value is being assessed.

- Specification for methylene blue FFP had not been approved. MK said that methylene blue FFP now has a CE mark and could be used (i.e. It is a device). LW asked for a letter to this effect clarifying the position. It is planned to wait for a further year and then review the situation. There is still some concern about the Factor 8 yield and the total efficacy of the process. In England, at least every option for producing methylene blue FFP seems to be thwarted in some way.

9. **Leucodepletion** matters have taken up a great deal of discussion time in the SACBC. A whole day meeting is planned for the 17th December 1998 which will particularly focus on quality issues.

10. Standing Advisory Committee on Care and Selection of Donors

FB said that the last meeting has been in June 1998. This had been a general meeting for donor care doctors in October 1998 and also a meeting again in that month to consider the Safety of Blood leaflet.

There were two new members of the group:- Liz Caffrey and David Hutton.

Minutes of meetings in 1998 will be submitted by FB

11. Standing Advisory Committee on Information Technology

11.1-11.3 EC36/98, EC37/98, EC41/98

EL focused on the latest minutes of the meeting held on the 17th September 1998 (EC41/98). She explained the approach which was being recommended for ISBT 128 implementation.

12. Standing Advisory Committee on Reagents for Immuno haematology and HLA sub committee

VJ said that there was a need to clarify the position of plasma only donors with low level antibodies and she has asked MS to consider this. **VJ**

It was noted that Mike Murphy wants to set up a Platelet Immuno haematology Group and it was agreed that this should be part of the remit of the SAC on Reagents for Immuno haematology and should be UK wide not specifically orientated to the NBS. **VJ**
VJ will reply to Mike Murphy.

It was considered that the remit and title of this SAC should be reviewed. VJ to discuss with MS. **VJ**

13. Standing Advisory Committee on Tissue Banking

13.1 MADT Guidelines

These have been published and were inadvertently distributed to Donor Care Consultants who in many cases are not the same as the Tissue Banking Consultants. The remainder of the copies are with Quality Managers for distribution.

13.2 RW said that the Council of Europe is preparing documentation for tissue donors similar to that for blood donors.

13.3 RW said that there had been a review of the UKTSSA and any decisions made may have an impact on the SACTB. There needs to be more interaction in the future with other tissue groups. There may even be a need for a different Red Book for tissues. However, it was agreed that the SACTB wish to remain an integral part of the Red Book Executive.

14. Standing Advisory Committee on Transfusion Transmitted Infection

EL asked for clarification of page 8, item 13, referring to testing for anti Hepatitis B core. VJ said that it had been practice for tissue donors to have samples taken for anti Hepatitis B core if there had been a history of Hepatitis. This had resulted in increasing workload for the

laboratory. VJ had also submitted results from the ongoing pilot study from Trent for consideration. This whole issue should be discussed with Philip Mortimer and Richard Tedder and the question was asked:- Should testing be taking place? **VJ**

15. Items raised by NIBSC

Unfortunately Morag Ferguson was not present.

LW mentioned that the NIBSC have been approached regarding a possible role in monitoring for leucocyte depletion. A reply had not yet been received. However, in the meantime it had become known that NEQAS are well advanced in producing material for this purpose and have been working with Trent Blood Centre. This will be followed up further by the Leucodepletion Project Implementation Board. **LW**

16. Any Other Business

16.1 PS asked how routine issues of NAT testing will be handled in the future? Will this be done by the SACTTI? It was agreed to defer this item for discussion at the next meeting. **VJ**

17. Dates of future meetings

It was agreed that there would normally be 3 meetings per annum and VJ will circulate some alternative dates. **VJ**