MINUTES OF THE UKBTS/NIBSC EXECUTIVE COMMITTEE MEETING

HELD ON 21ST NOVEMBER 1997

AT WEST MIDLANDS BLOOD CENTRE - BIRMINGHAM

		ACTION
	Present: Dr M de Silva Dr M Ferguson, NIBSC Dr P Flanagan Prof I Franklin Dr V James Dr E Love Dr M McClelland Dr T Napier Dr A Robinson Dr T Snape Dr W Wagstaff (Chair) Dr R Warwick Dr L Williamson	
1.	**Apologies** Dr M Kavanagh Dr P Phillips Dr G Schild Dr Wagstaff welcomed the following to their first meeting of the Executive Committee: Dr L Williamson Professor I Franklin Dr T Napier Dr M McClelland	
2.	**Minutes of the meeting - 19th June 1997** Dr V James asked for the following to be clarified:- Page 2, item 4, sentence 2 "The" questionnaire should be replaced by "A" questionnaire. Page 4, item 6.2, sentence 3 The term "must be identical" is not quite correct as some aspects are irrelevant and subject to individual country	

decisions. It should be replaced by alternative wording as follows "should conform with".

3. **Matters arising**

3.1 Indemnity

Dr Wagstaff had not received a definitive legal opinion. He had again written to all national competent authorities in the UK asking for confirmation that those involved in Red Book activities will be covered by the normal rules governing the professional activity for which they are contracted. He is awaiting replies from England, Scotland and Northern Ireland. The PHLS and NIBSC have signified agreement.

Dr Wagstaff had requested details of other (hospital) members of SAC's and will write individually to their employers. **WT**

With respect to medical members of SAC's the MDU would not wish to become involved because it regards such activities as part of an individuals professional work, which is therefore indemnified by the employers. It was recommended that this should be explained to all new members before confirming the co-option onto a committee. Dr Wagstaff will prepare a standard letter which he will circulate to SAC Chairman. **WW/SAC Chairmen**

8.3 Malaria Testing

Dr Flanagan confirmed that the Launch test had been approved. There had been problems obtaining "Go/No Go" control sera but one had now been obtained. The test has been introduced in the South East and South West Zones and will be introduced in all Zones by the end of December 1997 (but only into those centres which have PULSE).

10.0 Tissue Banking/Cadaver Samples

The issues involved in biological testing of Cadaver blood samples have been considered by a working party of Tissue Bankers and Virologists from NIBSC and elsewhere. The group was convened by Dr Jeffrey Schild with some imput from Dr Ruth Warwick. The group was chaired by Morag Fergusson and a meeting held at MIBSC. It will examine a library of cadaver samples, devise protocols for testing for both serological and nucleic acid tests. **MF**

Dr Warwick pointed out that as many non NBS tissue banks are involved in cadaver retrieval, particularly for eyes and valves and there is a need for the proposed core liaison group involving all aspects of tissue banking to include representatives from non NBS banks together with NABSC. A core group has been established and a number of working parties from that group will follow.

4.0 **Clarification of roles, responsibilities and authority of individual SAC's**

Dr Robinson expressed concern that there is confusion particularly when SAC's make recommendations which by-pass the Executive for example when it is necessary to "fast track" a particular issue.

The correct route is as follows:-

- SAC's consider an issue and make recommendations.
- The recommendations are presented to the Red Book Executive.
- When the recommendations are ratified they pass to the UK Medical Directors who have the responsibility, together with their respective Boards, whether or not to implement the recommendations. If such a decision is made an implementation strategy should follow as a prelude to actual implementation.

  It is not the responsibility of SAC's to devise implementation strategies nor to implement recommendations. However the relationship is somewhat blurred on occasions e.g. the leucodepletion issue.

  Where it is necessary to "fast track" a recommendation in the NBS for example, Dr Robinson undertook to inform fellow medical directors promptly.

5. **Guidelines for Cord Banking**

Dr Warwick said that numerous guidelines exist and the Council of Europe also makes suggestions from time to time. The EBMT documents are based on American standards (FAHCT) and the BSBMT may decide to work along EBMT guidelines. The question is whether the UK should adapt existing guidelines or compile new ones.

Professor Franklin recommended that the UK needs its own view and aspects of North American Guidelines for example would not be applicable. He suggested a group to examine and synthesise a UK version from existing guidelines.

In summary it was agreed that UK guidelines are needed and that these should be based on what already exists. It is logical for these guidelines to be included as a section in the Red Book. It was agreed that all haemopoietic progenitor cells should be contained within the proposed guidelines. It was recommended that a working party should be set up reporting to the SACTB. Dr Warwick will nominate a chair person. **RW**

6. **Standing Advisory Committee on Donor Selection**

6.1 **Minutes EC16/97**

6.2 **Minutes EC17/97**

No further comments.

6.4 **Implications of Current Policies on Donation Interval and the proposed changes in threshold Haemoglobin concentration EC18/97**

Dr James said that there must be a balance between the donation interval and the haemoglobin cut off and that the current levels for male and females are probably satisfactory at present and it would not be particularly productive to change this.

The executive approved the following:

- Retain copper sulphate testing.
- Venous samples by hemocue on copper sulphate failures.
- Accept donor if venous sample is 13.0 g/dl or above for men, 12.0 g/dl or above for women.
- Donation intervals should not normally be less than 16 weeks.
- Occasionally it is permissible to collect a donation at an interval of 3 months so long as there are no more than 3 donations per annum.

The Red Book will need some revision in the next edition. **VJ**

The implications for double red cell collections need to be clarified but probably in the apheresis guidelines. No decision was taken on this. **VJ at a later date**

6.5 **Donor Age Summary Document EC19/97**

Dr Robinson said that the Dept. of Health would need formal notification of the intention to reduce donor acceptance to the age of 17 years and she will write to DOH. **AR**

For the upper age limit (65 - 70 years) this is simplifying what is already happening in different ways in the NBS. The current questionnaire should be able to resolve any medical issues.

The recommendations are compliant with the Council of Europe.

With regard to 17 year olds the phrase "of sound mind" was not considered desirable and should be changed. **VJ**

6.6 **Final Donor Tick Box Questionnaire**

Two questionnaires had been piloted within the NBS and the general consensus was that they had been well received by donors.

Subsequently the two questionnaires have been amalgamated and trialed by Craig, Ross and Dawson to investigate donors' understanding. On the whole the questionnaires were acceptable and understood. The final questionnaire, a distillation of the foregoing was tabled, **EC34/97.** Some corrections are needed. **VJ**

For the question on brain surgery Dr James said that in the light of available data it had not been possible to specify this question further. (Post meeting note: Dr James received further information from Prof. Pickard, Cambridge, requesting the question to read: "Before August 1992, did you have any brain surgery or an operation for a tumour or cyst on the spine?")

The question about receipt of pituitary gonadotrophin for treatment of infertility was superfluous in the UK as it is believed that every person who had received potentially infected material had been traced. **VJ**
Recommendations: the question will stand.
There was some discussion on the donor declaration and the position should a donor be found to have lied. It is unlikely that a donor would be held liable under these circumstances. The question of whether to delete the sentence "I have completed the questionnaire truthfully" or to trial this for donor attitude, was not resolved. **VJ**

6.7 **Changes to A - Z 1998**

These are as follows:-

- Age of Donors (1st April 1998)
- Babesiosis
- Brain Surgery (1st January 1998)
- Re-write Hepatitis section
- Re-write Malaria section
- Post donation illness

The question about brain surgery will be introduced via the fast track, Concessionary route, to take effect as from January 1998
Dr Snape mentioned that the MCA does not have a copy of the A-Z. Mike Kavanagh could receive the guidelines as a controlled document. **VJ**

6.8 **The Red Book and the Internet**

Dr James suggested that notification of the existence of the Red Book could be placed on the internet. The question of whether or not to publish fully would need further thought as this is a controlled document. It was suggested that the NIBSC web site would be a more suitable site than that of the NBS. **VJ**

7. **Standing Advisory Committee on Information Technology**

7.1 **Minutes EC20/97**

7.2 **Feedback from Meeting 3.11.1997**

(Minutes not yet available)

Dr Love summarised the main points of the last two meetings:-

- **ISBT 128 matters.**
  These have occupied much discussion time in the past two years. The SACIT has recommended that ISBT 128 should be adopted but cannot progress further in the absence of a central decision. The NBS business case is with the DOH but no-one on SACIT has yet seen this. It is understood a copy is on its way to EL.
  Many hospitals perceive that the introduction of ISBT 128 is more beneficial to the NBS than themselves but a link with EDI would help to "sell" the concept. The greatest problem for hospitals is perceived to be the long number strings which need to be recorded particularly on the Wards - there are ways of alleviating this but any further developments should await a decision.

- **EUROCODE**
  Controversy continues to rage. This is not a European code but is being promoted by Germany which is itself divided on the subject.
  Efforts continue to be made by several authorities to try to ensure that ISBT 128, as an international standard, is accepted in Europe.

- **Barcode Labelling Guidelines**
  The working party has completed its task of revising the Guidelines which are now ready for printing and will be issued as a controlled document with further copies for sale to commercial interests.
  The barcode working party which reports to the SACIT has now "stood down" and will reconvene as needed on a project basis. Mike Moores continues to be the keeper of codes and Mike Clarke controls the document.

- **EDI Initiatives**
  A small project group (three individuals) has been set up by the SACIT to review National and international developments in this field with a remit to make a final report in 6 months and an interim report in three months to the SACIT.

8. **Standing Advisory Committee on Transfusion Transmitted Infection**

8.1 **Minutes EC21/97**

8.2 **Minutes EC22/97**

No further comments.

8.4 **CJD EC23/97**

Dr Flanagan explained that a risk assessment would proceed in parallel with planning for implementation. Both processes had been requested by the DOH.

Dr Robinson reported that the Haemophilia Directors met on the 20th November 1997 and the outcome of the meeting is awaited.

Professor Franklin enquired about the status of a diagnostic test. This could take several years to develop as a diagnostic screening test. He pointed out that the skills exist within the service to take things further.

8.5 **CPMP Consultation on Implementation of NAT**

Testing of Plasma Start Pools **EC24/97.**

Dr Flanagan asked whether a professional recommendation could be made to CPSM that the implementation date for small pool testing be delayed. He is due to attend a meeting in Paris on 24th November 1997 where a report should be made. This meeting has been convened by the Agence Francaise du Sang. The meeting will focus on the consequences for transfusion centres as the complications of introducing testing are beginning to be appreciated.

Dr Flanagan said that the timescales for implementation are extremely tight and that England cannot with confidence meet the 1st January 1999 deadline.

It was considered that a recommendation by the UK that testing should not be introduced at all would be unlikely to succeed given the commercial pressures which apply.

The second argument that implementation could be delayed or commenced as a pilot study could be further developed.

The SNBTS favours a unified approach with the NBS.

There are many unanswered questions and little factual evidence to support decisions.

The favoured view is that a delay should be sought and that pilot studies would be essential to understand all the implications.

Dr Flanagan with Prof. Franklin will prepare a paper for the CPMP which will be submitted via the DOH, the MCA and Francis Rotblat (Biotech Working Party of CPMP). **PF/IF**

9. **Standing Advisory Committee on Tissue Banking**

9.1 **Minutes EC25/97**

No further comments.

9.2 **Section 4 "Guidelines for Tissue Banking" EC26/97**

It was suggested that amendments for the 1998 Red Book should be accelerated (by the end of February 1998) so that Section 4 can be rapidly incorporated. **SAC Chair-men**

The Tissue Banking A-Z will need some further work but will be distributed as a stand alone document.
Dr Warwick said the DOH is looking at the regulation of tissue banks and will be inviting comment from the Royal Colleges so that it is important to let the Royal Colleges know that the UK Guidelines exist. She will let the Royal Colleges and Dr Peter Bourdillon (DOH) have copies and invite comments by the third week in February 1998. **RW**

10. **Standing Advisory Committee on Blood Components**

10.1 **Minutes EC27/97**

Dr Williamson said that two other meetings had been held and the minutes would be circulated.
Dr Williamson gave an update on virally inactivated plasma. Only 35% of hospitals actually replied to the questionnaire on SDFFP. Following the decision to use methylene blue FFP instead, the working group set up to consider SDFFP will discuss the implementation of methylene blue. A common timetable is desirable. It is expected that operational trials will commence after Christmas at Newcastle and Colindale. There will be a trial of methylene blue cryoprecipitate in the South East Zone and Edinburgh to see if the process is suitable for the production of cryoprecipitate. This will lead to the development of specifications as the current specifications may not be met by methylene blue FFP.

Hospitals have indicated that they wish to be told what to do and the BCSH task force will produce an addendum to the FFP Guidelines hopefully for the March edition of Transfusion Medicine.

Leucocytes for transfusion - the use of GCSF would require ethical committee approval. Is there sufficient evidence for a plausible case? It was suggested that a sub-group be set up to consider this question consisting of members of the apheresis, blood components and donor SAC's but no decision was made.

10.2	**Terms of Reference for EC28/97** These were accepted.	
10.3	**Evaluation of Blood Components EC29/97**	
10.4	**Blood Pack Trial Protocol EC30/97**	
10.5	**Evaluation of New Red Cell Products for Transfusion EC31/97**	
10.6	**General Protocol for evaluation of Novel FFP/ Cryoprecipitate EC32/97** All members were asked to comment by 5th December 1997. It was suggested that these items could be included as Red Book appendices in the future.	**ALL**
10.7	**Donor Selection Criteria FFP/Cryoprecipitate** The Red Book criteria are difficult to implement. A change to acceptance of donors who have donated within the previous 2 years has been recommended and appears acceptable. Dr Robinson did not think it was necessary to take this through the MSBT. It can therefore be implemented.	**LW**
	Can the same criteria apply to platelet donors? Michelle Ashford is collating centre data to try to answer this question.	
11.	**Any other business**	
11.1	Dr Wagstaff indicated that he would be retiring at the end of March 1998 and that the National Directors would need to select a new Chairperson.	**AN/IF/ AR/MMc**
12.	**Date of the Next Meeting** In May/June 1997 - Dr Wagstaff to arrange.	**WW**