EC. 18/95

UKBTS/NIBSC EXECUTIVE COMMITTEE

Minutes of the fourth meeting held at West Midlands RTC

On 15 February 1995

Present

Dr F Ala
Dr M Kavanagh
Dr M Ferguson
Dr V James
Dr D B L McClelland
Dr P Phillips
Dr E Angela Robinson
Dr M de Silva
Dr W Wagstaff (Chairman)

1 **Apologies for absence were received from**

Dr T Barrowcliffe, Professor J D Cash, Dr G Schild (represented by Dr Morag Ferguson and Dr P Phillips).

Dr M Kavanagh of the Medicines Control Agency was welcomed to his first meeting of the Executive Committee.

2. **Minutes of the Meeting of the Executive Committee held on 5 September 1994.**

The minutes of this meeting were accepted as a true record of discussions held, with the following amendments:

In item 5, Dr J Stivala should read Mr J Stivala.
In item 5.2, progenitis should read progenitor
In item 7, Dr Ruth Cuthbertson should read Dr Bruce Cuthbertson

3. **Matters Arising**

3.1 Adoption of Guidelines by National Authorities.

It was agreed that it be confirmed with the Chief Executives of the NBA and of SNBTS that the two National Medical Directors represented their authorities on this Executive Committee. It would also be confirmed that the MCA were now represented in the person of Dr M Kavanagh.

Members were still in favour of the current balance of the Executive Committee, and hoped that Chief Executives would now be happy that there was sufficient "all round" representation.

The question of consultation on amendments to the Red Book having been raised in the past, members agreed that experts outside the Service would be consulted as necessary by the various Standing Advisory Committees, before reaching consensus on the final amendments. It was felt that in this way the practicalities would have been covered and that there was no need for further delay in outside consultation. It was agreed that formal documentation of outside expert opinion by the SAC's was an imperative.

The implementation date of amendments was to be taken as the date of printing, but it was agreed that final drafts could be circulated (marked accordingly) to give advanced warning to users who might have to take action on the amendments.

It was agreed that Department of Health be approached with regard to the mechanism of printing and proof reading, for both amendments and new editions of the Red Book. Ideally, this should be in the hands of the Red Book Organisation, perhaps processed through the financial departments of one of the two National Authorities. Apart from relieving the DoH of an extra burden, this would facilitate the production of a textual database for the next edition, which would in turn help with the editing of amendments and indexing, etc.

3.2 RTC Charges for Raw Materials

The letters from Brentwood and Colindale RTC's were noted.
It was agreed that no charge is usually made for source plasma to be used for the production of virology standards, charges have occasionally been made for material which would otherwise be sent to BPL or used clinically. Since most cases in this latter category occur in the NBS, it was agreed that Dr Robinson would take the matter back to the NBA Executive. The general feeling of the meeting was that it would be better to have a free exchange of plasma for standards, the sums involved are not large and Transfusion Centres inevitably have a different accounting system to NIBSC.

4. Standing Advisory Committee on Donor Selection

4.1 The minutes of meetings held since the last meeting of the Executive Committee were accepted. Dr James wished for certain items to be highlighted.

4.1.1 The A - Z Guidelines have now replaced the appropriate Red Book chapter. Dr H H Gunson had kindly agreed to act as Editor for the Medical Assessment of Donor Guidelines, which would be ready for implementation by April 1995. The WHO 1994 Guidelines on Malarial areas are now used, colour maps will be distributed with the Guidelines.

4.1.2 It was agreed that, however rare a condition might be, it should be included in the A - Z list if notified to the SAC, to avoid complications from pressure groups and geographical variation in interpretation.

4.1.3 The philosophy on donor selection is now to get away from blanket permanent deferral. More flexible policies based on advice from appropriate experts in each condition will be employed.

4.1.4 The new 'Aids' leaflet will be generic in approach, not just covering HIV. The draft has already been through the SAC on Transfusion Transmitted Infections, and through the SNBTS advisory system, and is due to go to the MSBT meeting to be held on I4 March 1995. The final draft should then go to EAGA on 28 April 1995. The new leaflet should simplify exclusion rules and times, but may not be out until the autumn of 1995, therefore a reprint of the old leaflet may be necessary. MSBT and EAGA have agreed that a draft may be circulated to this Executive Committee in an effort to save time.

4.I.5 In future, the A - Z list of conditions will be handled by Read coding, to enable it to instantly fit in with the new national IT system.

5. Standing Advisory Committee on Components

5.1 The minutes of the meeting held on 21 January 1995 were tabled. Dr McClelland drew several points to the attention of the meeting, from these minutes and from the previous meeting of the SAC held on the 24 January 1995.

5.1.1 Frozen/thawed/washed red cells - there is no recommendation at the present for a change in the guidelines, but the SAC feel that a proper survey of the use of this component is required.

5.1.2 It was felt that no written specification for quarantined FFP for clinical use is possible until there is proper classification of:

a) definitions, eg of donors to be accredited, type of plasma, etc.

b) a procedure capable of being validated throughout and

c) a definition of required microbiological safety.

It was noted that a special meeting of SACTTI would be held on 3 March 1995 to discuss this topic, the understanding being that MSBT has accepted a concept in principle.

The SAC on components was also requested to consider and make recommendations on the presence of red cell antibodies in plasma containing components.

5.1.3 The survey on components for neo-natal use has not yet been completed. It is anticipated that recommendations will be made to the meeting by September 1995.

5.1.4 Irradiation of Components - the Red Book covers components, whereas BCSH Guidelines straddle producers/middle-men/users. Amendments to the Red Book to be completed by September 1995 will hopefully clarify and solve this overlap.

5.1.5 Leucocyte Depleted Components are receiving ongoing consideration. The SAC were proposing to ask for specific labels to be made available for such halfway components as 'Cobe Spectra' platelets. After discussion, the Executive agreed, once more, that the brief is to define achievable standards, but not to go into techniques of reaching them. Neither should the Red Book guide give details of the measuring of compliance, eg counting of residual leucocytes in cellular components.

5.1.6 The SAC has almost finished a preliminary specification for peripheral blood stem cells, which will be communicated to the label group for allocation of a label. The SAC had coincidentally received advice that users may need some form of supplementary information to expand what is already available on component labels. They will produce a workable draft for consideration at the next Executive Committee meeting.

5.1.7 It was noted that the new NBS IT system will need immediate identification and Read coding of all components, however unique, currently issued from English Transfusion Centres. This list is being assembled by Dr Marlene Fisher and Dr McClelland will obtain a copy for consideration by his SAC. Otherwise, the proposal for allocation of new component labels set out in paper EC 6/95 was accepted by the meeting.

5.1.8 The SAC will keep a watchful eye on the achievability of specifications of all components contained in the Red Book Guidelines.

5.1.9 It was agreed that the SAC on reagents would advise the component SAC on acceptable levels of antibody in donor plasma and on the effect of therapeutic use of donor red cells which have a positive direct AHG test.

6. Standing Advisory Committee on Reagents for Immunohaematology and HLA

6.1 Dr de Silva reported that the final draft of suggested amendments for the Red Book has gone round to reagent SAC members, these amendments being made necessary by the arrival of newer techniques, test kits and European standards.

The SAC had once more raised the question of abstraction of technical details from the Guidelines, which would be of use to users rather than manufacturers. It was agreed that there could well be a place for a user technical manual, but once more stressed by members that the current Red Book Organisation was not the place for the development of such a manual.

The question of the use in the next edition of the Red Book of EU standards for ABO and Rhesus typing was raised, though these standards have not yet been finalised. It was considered essential that drafts of the standards for reagents (prepared by CEN on behalf of EU) be seen and taken into account. The appropriate European Directive will be fully implemented in 1997, and it is assumed that it will cover cellular as well as non cellular grouping reagents. Under this directive, the competent authority, ie DoH will designate the "notified bodies" who will ensure that manufacturers meet standards. No decision has yet been made on these notified bodies, it may even be that appropriate notified bodies may be outside the UK.

Dr Peter Phillips agreed to circulate abstracts of the draft directive to members of the Executive Committee.

6.2 A survey of extended phenotyping on successive donations, carried out by Dr de Silva, showed a O.5% error rate due to:

a) the use of old and inadequate reagents on the first testing, and

b) errors in data transfer

At this survey, four Transfusion Centres were not complying with current recommendations after the testing of two successive donations. The SAC felt sure that the problem would disappear with secure data processing, but cannot yet recommend that the current guidelines of retesting each donation be rescinded.

6.3 The HLA sub committee of the SAC have noted that British Reference Reagents 90/694 and 92/556 are now established. The sub committee is developing guidelines on DNA and PCR techniques for the Red Book. It was noted that UKTTS are soon to abandon distribution of liquid reagents for Class 1 typing, and appropriate antisera may soon be in short supply. It was also noted that some laboratories will continue to have a need for screening sera until they can change to DNA technology.

The sub committee is also producing guidelines for the minimal HLA requirements for the placing of a volunteer on a Bone Marrow Panel of donors.

7. Standing Advisory Committee on Plasma for Fractionation

7.1 The minutes of the meeting held on the 17 September 1994 were noted. It was agreed that the Red Book Guidelines should deal only with the supply of plasma from Transfusion Centres to fractionators. It was not felt appropriate to continue with a section on product characteristics, nor to develop a section on process design. The Chairman agreed to communicate the feeling of the meeting on this point to Dr Barrowcliffe.

8. Standing Advisory Committee on Transfusion Transmitted Infection

Minutes of meetings of this committee and of the sub committee on laboratory aspects had been previously circulated (EC 12/95, 13/95 and 14/95).

Dr Ala brought several points forward for consideration by the Executive Committee.

8.1 HCV Lookback had been discussed at the meeting of 19 October 1994 but events have overtaken this discussion and the Lookback has now been instituted. It was noted that MSBT have not yet committed themselves with regard to the need for automatic Lookback programmes to be instituted as part of the introduction of any future viral screen.

8.2 It was noted that Dr Terry Snape and Dr Patricia Hewitt have now joined the SAC. The meeting also welcomed the institution of a new joint NBS/CPHL job, to help with the epidemological studies of Transfusion Transmitted Infection. The first postholder would be Dr Kate Soldan.

8.3 It was noted that NIH have decided to discontinue the recommendation for ALT testing, and have accepted anti HBc as a test in its own right with regard to picking up residual HBV carriers. UK data are being assessed with Dr Soldan's help with a view to going back to MSBT on the question of anti HBc Testing.

8.4 A technical group has been set up to find a formal and rapid way of approving changes in microbiological screening kits. Current BPL product licences have to list the kits used, and changes are subject to Variation Orders. It is hoped that these licences will be changed to read "approved kits", provided a mechanism for approval of kits can be set up and agreed with the MCA.

8.5 It was noted that a new group had been set up to produce a reporting system for adverse reactions to transfusion, including bacterial transmission. Some form of card reporting system will be tried, with the Royal College of Pathologists acting as the collection/ collating point. During its discussion on bacteriological transmission by transfusion, the sub committee on laboratory aspects also considered syphilis testing of donations, but was unable to come to any firm conclusion other than that it must continue as a European requirement.

8.6 With regard to HTLV1 screening, it was noted that Afro-Caribbean selective screening is proceeding in South Thames, and that another study is underway in the West Midlands. At this time, no firm recommendation can be made to take up routine screening of all donations.

8.7 A special meeting will be held on HCV epidemiology, with particular reference to sero conversion in established donors and HCV transmission in sexual partners. The SAC on donor selection was awaiting advice from SACTTI on this point, but after full discussion, the Executive Committee advised Dr James to go ahead and implement exclusion of sexual partners of HCV positive people, with immediate effect.

8.8 The question of prisons and donation was once more discussed. So far as members of the Executive Committee were aware, blood donor sessions were no longer held in prisons in the UK, and it was once more reaffirmed that ex prisoners should be picked up by the usual behaviour screen. It was felt inappropriate to ask all donors if they had served a prison sentence in the past.

8.9 It was reported that the project in North London for the assessment and validation of a Malarial antibody screen was ongoing, results and recommendations being awaited.

8.10 The apparently convincing evidence for the existence of HVF as a potential transfusion hazard was noted.

8.11 It was also noted, with interest, that Murex are developing a system for mixed screening reactions in the same well, ie a combined screen test for antibody and antigen.

8.12 Advice on in-house confirmatory testing was summed up in Minute 2.II of the minutes of SACTTI from its meeting held on the 19 October I994, ie "Overall, it was felt that while in-house reference work was permissible provided that this work was totally independent of the screening functions in terms of documentation and compartmentalisation, the increasing levels of sophistication made external reference work very desirable. It becomes essential when donor re-admission is involved". This advice was accepted by the Executive, and asked that Dr John Barbara produce a protocol for the minimum requirements for in-house confirmatory testing.

8.13 The Executive Committee noted the advice of SACTTI that Professor John Pierre Allen should be reinstated as a member of the SAC as soon as thought appropriate. This advice was accepted by all present.

9. Standing Advisory Committee on Information Technology

This Committee had not met since the last meeting of the Executive, the post of Chairman to replace Dr Robinson not yet being confirmed.

It was noted that Mike Moores had taken over as Chairman of the UK Barcode Working Party in place of Dr Marlene Fisher.

10. Working Party on Tissue Banking

A final report from this Working Party is expected (and requested) by April 1995, for consideration at the next meeting of the Executive Committee. At this time, the Executive would decide on whether to wind-up this Working Party, to continue it in some other form, or to pull it into the Red Book Organisation under the umbrella of one of the other Standing Advisory Committees.

11. Any Other Business

11.1 In response to the request from Professor Cash with regard to "lay" representation on the Executive, the meeting considered that NIBSC and MCA presence gave us a sufficient extra - UK BTS perspective. However, Professor Cash could certainly be asked to elaborate, if he so wished, at the next meeting.

11.2 Dr McClelland mentioned that Dr Willie Murphy has been asked to review time limits for storage and use of components in hospitals. Time and temperature limits for transport are also felt to be increasingly relevant and important, and will be considered by the appropriate SAC, though it may be difficult to be more precise than the present wording in the Red Book Guidelines.

12 Date and Place of Next Meeting

20 June 1995, at West Midlands Transfusion Centre, the meeting to begin at 11am.

A further meeting was fixed for the 26 September 1995, at which final drafts for amendments to the current version and suggested new chapters would be considered.

WW/KP