UKBTS/NIBSC EXECUTIVE COMMITTEE
MINUTES OF THE SEVENTH MEETING OF THE EXECUTIVE COMMITTEE HELD AT THE WEST MIDLAND RTC, BIRMINGHAM ON FRIDAY 28 JUNE 1996

Present: Dr M De Silva, Dr M Ferguson, Dr P Flanagan, Dr V James, Dr M Kavanagh, Dr E Love, Dr D McClelland, Dr P Phillips, Dr A Robinson, Dr W Wagstaff (Chairman), Dr R Warwick.

1. APOLOGIES:

Dr T Barrowcliffe, Professor J Cash, Professor G Schild.

2. MINUTES OF THE 6TH MEETING 26 September 1995:

There were no corrections.

3. MATTERS ARISING:

3.1 (page 2):

Dr Kavanagh had written to Dr Robinson.

5.2 (page 4):

The definition of a closed system will stand for this version of the Red Book Guidelines.

6.1 (page 5):

With reference to the recommendations for plasma for fractionation in relation to Anti-D quantification and other blood group antibodies, Dr Barrowcliffe's suggestions have now been incorporated into the Guidelines.

Dr Wagstaff confirmed that the amendments to the Red Book Guidelines had been made and all that was now required was funding to enable the Guidelines to be published.

ACTION - DR WAGSTAFF

4. STANDING ADVISORY COMMITTEE ON DONOR SELECTION:

4.1 EC19/96
4.2 EC20/96:

From these two sets of minutes Dr James highlighted three main issues:

1) **CJD:**

A letter had been sent to all Donor Healthcare Consultants with recommendations for direct questioning regarding family history of CJD. This will be implemented by 1 August 1996. It had been originally intended to obtain details of relatives where there is a family history of CJD. In the absence of ethical approval for this it was felt not to be acceptable to request such information. This information can be obtained at a later date if permission is obtained for the Look-Back study.

There is to be a national meeting of Donor Healthcare Consultants on 10 July 1996. Dr Warwick pointed out that tissue bank medical staff/co-ordinators should be included for the future as they are not necessarily the same individuals as the Donor Healthcare Consultants.

2) The next version of the A-Z Guidelines will be due in February 1997 and will incorporate all the changes which have occurred during the previous year. It was noted that some Centres are still using subsidiary documents in addition to the A-Z Guidelines and it was hoped that these could be dispensed with as soon as possible.

3) A Working Party chaired by Dr Frank Boulton is to consider the current guidelines for haemoglobin values pre-donation. It will look at all the work which has been done so far in this area. The Working Party is due to report in 6 months' time but Dr James felt that it would need longer to consider whether lower haemoglobins for pre-donation are safe.

Comparison with European Guidelines reveals the same levels as the UK and bleeding at lower levels is at the discretion of a competent healthcare professional. It was noted, however, that many European countries do not necessarily adhere to the Council of Europe guidelines.

Dr James remarked that the concessionary route for changes in the A-Z Guidelines is working and improvements are continuing to be made in the way that information is disseminated.

ACTION - DR JAMES

5. STANDING ADVISORY COMMITTEE ON COMPONENTS:

Dr McClelland reported that no further meetings had been held as the guidelines document is complete. A further meeting is planned in September to consider a broad framework for the next version of the guidelines and these proposals will be brought to the Executive at the next meeting. It may be necessary to reconvene the membership of this SAC.

Dr McClelland felt there may be a need for a technical manual and is keen to set out the specifications in a rather different way by bringing in the design of components and appropriateness for clinical indications. At present three bodies are concerned with component matters. These are the SAC, BCSH and Transfusion Handbook Group and it will be important in the future to establish links between these.

ACTION - DR McCLELLAND

The next Executive Meeting should consider the future organisation in conjunction with the BCSH and Transfusion Medicine Handbook Groups.

ACTION - DR WAGSTAFF

6. STANDING ADVISORY COMMITTEE ON REAGENTS FOR IMMUNO-HAEMATOLOGY AND HLA:

6.1 EC29/96 and EC30/96:

Dr de Silva outlined the main points from the previous meetings of the Reagents SAC as follows:

1) Changes in membership had been proposed to include expertise on automated testing.

2) A replacement reagent is required for 91/608 Anti-D used to test operator efficiency. Dr de Silva has made a request of Dr Sue Knowles that the replacement could be sent out via the NEQAS scheme in order that it may be defined further for the testing of operator efficiency.

3) Dr Phillips had been approached by the WHO to produce standards for developing countries and agreed to produce candidate material in conjunction with Dutch colleagues. This would be compared against UK standards.

4) The cost of NIBSC standards would be as follows:

Primary standards £35 each
Working standards £35 per set of 5

All standards used in connection with UKBTS work will be moved into the working category from 1 July 1996.

There followed discussion on the possible overlap of the MDA and the NBA Kit Evaluation group. Dr Flanagan reminded the committee that the remit of the NBA Kit Evaluation group is to assess tests for plasma fractionation. However, in the case of PRISM it was not possible to isolate the kit evaluation from equipment evaluation and so this group had considered the equipment in addition. Normally, as far is equipment is concerned, it is for Centres to ensure that an acceptable kit works satisfactorily on that Centre's equipment.

It was pointed out that other countries may have an interest in what is approved in the UK. It is most important that this information is not distributed in such a way that it may be deemed to be recommending or approving certain products.

7. STANDING ADVISORY COMMITTEE ON PLASMA FRACTIONATION:

7.1 EC31/96:

This paper containing the final revision for the specification for plasma intended for fractionation was tabled at the meeting.

8. STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTION:

8.1 Dr Flanagan commented that a formal system for the declaration of committee members' interests was now in place. Dr Wagstaff reminded members that this is required of all SAC'S.

ACTION - ALL

8.2 EC22/96 - HIV sub-type 0:

Most manufacturers have modified their kits to detect this and therefore there is now a need for some type of assessment for sub-type O. It is essential to ensure that there is no overall decrease in sensitivity. In the absence of suitable samples for testing, performance must be assessed on the basis of manufacturers' information at present. Dr Philip Mortimer has obtained some suitable samples and is intending to undertake mini-evaluations of kits which are successful in tender exercises.

8.3 EC23/96 - CJD:

Following a meeting held in April, several actions have been identified as follows:

a) Direct questioning of donors - to be implemented from 1 August 1996.

b) MSBT have in principle endorsed look-back and surveillance and it was recommended that CJD and variant CJD should be regarded as separate entities. Look-back proposals are to be discussed at SACTTI and MSBT next week. There is also to be a meeting on Monday, 15 July at Colindale with Professor Paterson (SEAC) to up-date on experimental data concerning CJD. Executive members are invited to attend if available.

ACTION - DR FLANAGAN

8.4 EC24/96 - HTLV-1:

Following a meeting held on 14 May at Leeds with SACTTI, Red Book Executive Members and other individuals, it had been recommended that in the light of currently available data the UK position regarding HTLV-1 should be reviewed and specific steps taken to reduce the risk of transmission. The only practical means of doing this at present is by screening and the desirability of first-pass testing could be assessed following the introduction of routine screening. The minutes of this meeting have been sent to all MSBT members.

Dr Flanagan was congratulated on the excellent organisation of the meeting which was felt to have been most successful.

Additional items highlighted by Dr Flanagan were as follows:

a) **VIFFP:**

The possible imminent licensing of the Octapharma product is of concern. Dr Kate Soldan is collating data regarding residual risk of virus transmission from UK FFP and a position statement will be circulated shortly.

b) **SACTTI Update:**

The second up-date has just been circulated. Dr Flanagan favoured wide distribution to ensure awareness of all individual consultants. There had been excellent feedback so far. Circulation is to all Consultants in England, Wales, Scotland and Northern Ireland and requests have also come from the

Irish Republic. Some Centre Operations Managers have also requested copies of the up-date.

9. EC25/96 - STANDING ADVISORY COMMITTEE ON INFORMATION TECHNOLOGY:

Dr Love remarked that the main topic of conversation in recent meetings had concerned two main issues:

a) The introduction of dual bar code labels with PULSE implementation.

b) UK introduction of ISBT Code 128.

Dual Bar Code Labels:

The dual bar code issue has been resolved for the time being and a suitable label has been chosen for PULSE version 1.0. This, however, is a change from the original version recommended by the UK Bar Code Working Party. The Working Party had not been consulted on the change of label and was now a little confused as to its future role.

ISBT Code 128:

There had been considerable confusion and somewhat contradictory statements over the intention to introduce ISBT Code 128. There is an international commitment for this to happen by mid-1998.

The picture is becoming a little clearer. Dr Robinson has informed the DOH but stated that it is unlikely that there will be a directive from the DOH and this is not an MSBT issue. The NBA is committed to its introduction. Scotland will initially use Codabar with its new computer system and will recommend a planned transition to ISBT Code 128, probably later than June 1998. Dr McClelland stressed the importance of a sound administrative system to support ISBT Code 128, separate funding and contracts specifically in relation to quality issues. It is not clear who will undertake administrative responsibilities in the UK. A European Technical Advisory group (supported by the Council of Europe and yet to be set up) would be likely to be the repository of some of the functional work. It would be important to have a UK representative on the European TAG.

ACTION - DR WAGSTAFF

It is not clear which body should drive the introduction of ISBT Code 128 but there is an obvious need for assessing the impact of its introduction (costs etc) and considerable preparation and education. Dr Flanagan thought that costing information would be available from the NBA IT Group (Neil Hogg).

ACTION - DR LOVE

Dr Ruth Warwick cautioned that a commercial company is due to hold a meeting on ISBT Code 128 to which hospitals have been invited and she will obtain further details.

ACTION - DR WARWICK

The following points were summarised:

1) The introduction of ISBT Code 128 is inevitable.

2) It is likely to be introduced on or around June 1998.

3) It will be necessary to contact hospitals regarding this introduction in good time.

4) The UKBTS/NIBSC Executive recommends that a European TAG should be set up without delay.

ACTION - DR WAGSTAFF

5) The possibility of a parallel session at the forthcoming BBTS (September 1996) will be explored.

ACTION DR FLANAGAN/DR LOVE

Note added after the meeting: A parallel session will be held on 8 September 1996 at the BBTS Annual Scientific Meeting. Provisional speakers: Dr Johan Van Der Does and Mr Ian Harris (Telepath Users' Group). Chair: Dr Contreras.

Dr Love also raised the matter of voting membership on the ISBT Code 128 Working Party. Dr Fisher has been the voting member until now but is due to resign. Dr Love and Mr Mike Moores will attend future Working Group meetings and will decide who is to be the voting member on behalf of UK interests.

ACTION - DR LOVE

10. STANDING ADVISORY COMMITTEE ON TISSUE BANKING:

10.1 EC26/96 - Structure:

Dr Warwick outlined the structure of this SAC and its various Working Parties. The aim is to have a chapter ready for the next Red Book Guidelines in 3 years.

After some discussion it was considered preferable to prepare the guidelines as a separate document which can be inserted into the current Red Book Guidelines and to subsequently work on integrating the guidelines into the next version to follow in 3 years.

There will be a special meeting of SACTTI to consider Tissue Banking matters in 1997.

ACTION - DR FLANAGAN/DR WARWICK

10.2 EC27/96 - Guidelines and Accreditation of Tissue Banks:

Currently tissue banking is an unregulated activity. Many small banks are operating to sub-optimal standards. The BATB has recommended voluntary registration of tissue banks which may ultimately lead to audit against standards.

The DOH is undertaking a review of tissue banking and Dr Warwick expressed concern over the appointment of a regulatory body. The MCA has indicated that it does not have the staff to deal with this. Tissues are not regarded as medicinal products.

It appears that no formal decision has yet been made and clarification will be requested at the MSBT meeting next week.

ACTION - DR ROBINSON/DR McCLELLAND

11. SECOND BRITISH WORKING STANDARD FOR HBsAg AND HIV:

11.1 EC28/96:

This paper was circulated with the minutes.

With respect to HB_SAg, Dr Flanagan commented that PRISM HB_SAg testing had detected a significant number of "core only" HBV transmitters and therefore appeared to be much more sensitive than current detection methods.

The Committee recommended Dr Wagstaff to write to Professor Schild accepting the standards and congratulating Dr Morag Ferguson for the excellent work done on these.

12. ANY OTHER BUSINESS:

12.1 Chairman of the Immunoglobulin Working Party:

A new chairman has not yet been selected. With respect to guidelines for the use of anti-D immunoglobulin, Dr de Silva commented that there was no intention for the HDN SIG to produce guidelines on its own. The SIG will be playing a very active role in the consensus conference to take place in Edinburgh next year. Formal guidelines should be under the remit of the BBTS/BCSH.

12.2 There was some discussion over the composition of the Standing Advisory Committees and whether or not they need to be reconvened. Dr Wagstaff reminded the Chairmen that they have discretion over membership.

12.3 **Peripheral Blood Stem Cells:**

Dr James chairs a Working Party on voluntary unrelated stem cell donors and Dr Ruth Warwick is a member of this Working Party. A number of NBS donors have so far been used and follow-up details will be sought. It is also hoped to include some Anthony Nolan Panel donors.

ACTION - DR JAMES

13. DATE OF NEXT MEETING:

Wednesday, 9 October 1996 - 11.00 a.m. - West Midlands Blood Centre.