UKBTS/NIBSC EXECUTIVE COMMITTEE

Minutes of the second meeting, held at West Midlands RTC

on Wednesday 2 February 1994

Present

Dr W Wagstaff (Chairman)	-	Trent Regional Transfusion Centre
Dr F Ala	-	West Midlands Regional Transfusion Centre
Dr T Barrowcliffe	-	National Institute for Biological Standards and Control
Prof J D Cash	-	Scottish National Blood Transfusion Service
Dr M de Silva	-	North London Blood Transfusion Centre
Dr H H Gunson		
Dr V James	-	Trent Regional Transfusion Centre
Dr E A Robinson	-	National Blood Authority
Dr G Schild	-	National Institute for Biological Standards and Control

1. **Apologies for Absence**

Apologies were received from Dr D B L McClelland, in coming chairman of the Standing Committee on Blood Components.

1.1 A welcome was extended to new members of the committee, Dr F Ala (new chairman of the Standing Committee on Transfusion Transmitted Infections), Dr V James (new chairman of the Standing Committee on Donor Selection) and Dr E A Robinson (new chairman of the Standing Committee on Information Technology).

2. **Minutes of the Meeting of the Executive Committee Held on 12 July 1993**

The minutes of the meeting of the Executive Committee meeting held on 12 July 1993 were accepted as a true record of discussions held.

3. **Matters Arising**

3.1. Standards

A progress report on the British Working Standard (BWS) for HBsAg (EC8/94) was tabled, together with a progress report on the development of working standards for anti-HIV1 and anti-HCV (EC9/94). It was noted that the BWS for HBsAg was now in routine use at all Blood Transfusion Centres in the UK.

Variations in responses had been noted:

(a) with same standard being used at the same centre against the same assay kit, where the workload was high.

(b) with the same standard tested against different assay kits.

These variations are being investigated further to determine whether the level of automation used at a centre affects reproducibility, and whether new standards would be required to cater for different kit technology.

The proposed standards for anti-HIV1 and anti-HIV2 were approaching completion of work up, and were due to go out for trial in the near future.

3.2. Guidelines Disclaimer

The document on clinical guidelines produced by the Royal College of Physicians of Edinburgh was noted. The documents main thrust, that any documented guidelines produced should be regularly revised and that competent authorities should perhaps take basic guidelines for the building of protocols, was accepted by the Executive Committee. It was also emphasized that there should be a record made of any consultation involved in the production and publication of guidelines, since in spite of their name, adoption and application would be the expected norm.

With regard to the printing of the disclaimer within published guidelines, it was not thought by the committee that the Red Book need go beyond the type of disclaimer introduced into the second edition, on the advice of the Legal Advisor of Trent RHA.

3.3. Adoption of Guidelines by National Authorities

Responses from the Health Authorities in Wales and Northern Ireland indicated that they were prepared to accept the Guidelines unconditionally.

The response from Scotland indicated that the Chief Executive of SNBTS would prefer to wait until the Guidelines had been adopted by the NBA before taking similar action in Scotland. It was pointed out during discussion that the professional organisation in Scotland had advised immediate acceptance and adoption of the Guidelines as they stand.

With regard to acceptance by the NBA, it was stated that the only delay was due to the new authority not taking up responsibility for the transfusion service as a whole until 1 April 1994. Dr Gunson thought that there would be no problem following this date, and further agreed that the NBA would not take over writing of the Guidelines but recognised that these documents are results of professional input.

It was however agreed that some guidelines may need a managerial stamp e.g. for validation of kits. It was the opinion of the Standing Committee on TTI that this committee should organise trials of kits for microbiological testing, but that validation should be through the recently developed NBA/SNBTS link. The Chief Executive of the NBA is understood to be of the opinion that he should meet with his oppositive number in Scotland to confirm the integration of the Guidelines into operational

management by adoption of the common quality standards set out within them.

3.4. Revised UKBTS/NIBSC Liaison Organisation

The new family tree was circulated in advance of the meeting, showing new chairmanship of the standing committees, and the integration of the newly formed Standing Committee on Information Technology. It was agreed that this family tree could be circulated through the BBTS newsletter, the SNBTS blood letter, the NBA newsletter, and through the offices of Q.A. managers and regional directors.

With regard to groups forming under the umbrellas of the two authorities, it was agreed that the Data Standards Group of the NBA has a task which is management focused, but should be interactive with the SC on IT. Dr Robinson agreed to liaise with this Data Standards Group to watch out for duplications/contradiction of work in the definitions and standards set out in the Guidelines organisation.

4. Standing Committee on Donor Selection

4.1. The minutes of the meeting of this SC on 7 December 1993 were received and accepted. Dr James summarised the proposed changes in acceptability criteria for donors, these were accepted by the Executive Committee. It was also agreed that, for future editions of the Red Book, section 1.5. in the chapter on Donor Selection should be replaced by a simple statement referring the user to "NBA/SNBTS A to Z Guidelines". It was agreed that the SC on Donor Selection should undertake the task of combining the two national A to Z Guidelines, in such a way as to keep both documents up to date and non-contradictory.

It was also noted that revision of the Aids leaflet would be undertaken by the SC, this proposal having been accepted by NHSME. The input of EAGA and MSBT to this revision was briefly discussed, though it was acknowledged that resolution of this problem was not within the remit of the Executive Committee, but should be left to the good offices of the two National Directors. The Chairman agreed to write on behalf of the Executive Committee to Dr Metters, asking that direct contact should be made possible between the SC on Donor Selection and MSBT, especially with regard to the revision of the Aids leaflet.

4.2. The suggestion made by Professor Cash, that all matters relating to selection of donors are the automatic responsibility of the appropriate SC, but that there should be contact between this group and the SC on TTI, was agreed by all members of the committee. It was pointed out that collaboration between the two groups was already catered for by the presence of double joint representation (Dr P Flanagan and Dr P Miner).

5. Standing Committee on Components

No meeting of this SC had taken place since the last meeting of the Executive Committee. It was pointed out that this SC currently had no representation from NIBSC, and it was proposed that Dr Paul Metcalf, in view of his knowledge of platelets, would be a good

recruit. The Chairman undertook to write to Dr McClelland suggesting that Dr Metcalf be taken into the membership of the SC.

The current problems with regard to shelf life of irradiatored components, and minor discrepancies between the section in the Guidelines on Components for Neonatal Use and the new BCSG Guidelines on Neonatal Transfusion were acknowledged as being priorities for resolution by the SC on components.

6. **Standing Committee on Reagents for Immunohaematology and HLA (Minutes of the 10th meeting held on 27 October 1993 previously circulated and numbered EC12/94)**

Dr de Silva spoke to the three recommended amendments to the current Guidelines embodied in the circulated minutes. The correction to the reference to the use of Pantone as a colouring agent was accepted as was the two replacement paragraphs dealing with contaminating antibodies in antibody reagents. The committee felt unable to accept the proposed paragraph on the relationship between foetal calf serum and bovine spongiform encephalopathy, and referred this back to the Standing Committee for further discussion.

Opinion was divided on the whether the Guidelines should be sent free of charge to commercial reagent manufacturers. There was majority decision that this should not be done, but that the attention of potential reagent suppliers should be drawn to the Guidelines and the recommendations on reagents set out within them.

It was also recommended that a reagent defect reporting system be set up, but that this responsibility lay outside the remit of the UKBTS/NIBSC Liaison. The Chairman undertook to write to the competent national authorities to this effect.

Dr Schild reported that NIBSC are anticipating expansion into the realm of tissue typing, and may have access to extra funds for this purpose. The need for liaison with the Histocompatibility Working Party of the SC on Reagents was stressed, if NIBSC appoint a new scientist to deal with histocompatibility and immunogenetics, it is possible that he or she could be immediately co-opted to the Working Party.

7. **Standing Committee on Plasma for Fractionation**

The minutes of the meeting of this SC held on 9 September 1993 were accepted, there being no recommendations put forward for revision to the current Guideline text. Three items are, however, under active consideration by the SC, these being product characteristics, hepatitis A antibody content of plasma fractionation, and endotoxin content of the plasma.

Attention was drawn to the activities of the EC Committee for Proprietary Medicinal Products (CPMP) in publishing product characteristics which in their requirements go beyond European Pharmacopoeial Standards e.g. specific immunoglobulin preparations for anti-D, varicella and tetanus. There was lively (!) discussion on the apparently lack of interaction with the EC with regard to the transfusion matters. Representations on this point have already been made by the two National Directors and by the Director of NIBSC. It was noted that the new European Medicines Assessment Agency will be based in London, and this body may have

an impact on this problem. Dr Schild reported that he is soon to have a top level meeting with MCA with regard to European policy and will keep us informed of progress.

8. **Standing Committee on Transfusion Transmitted Infections**

The minutes of the meeting of this SC held on 11 October 1993 were tabled (numbered EC10/94), those of the more recent meeting on 18 January 1994 not yet being available.

Two items were noted in particular:

(a) that the donor reinstatement algorhithm is now in use within the UK.

(b) the DoH decision not to institute anti-HB core screening.

There were no proposed amendments to the Guidelines for consideration by the Executive Committee.

9. **Standing Committee on Information Technology (Minutes of the first meeting of the SC being circulated just before this meeting, and numbered EC11/94)**

Speaking to the minutes, Dr Robinson emphasized that the possible/probably introduction of code 128 instead of a codebar was forming a major discussion item for the new SC on IT. It was recognised that the definitive decision to introduce code 128 outside America may well be taken at the ISBT Working Party which meets at the time of the International Congress in Amsterdam, in July 1994. The America experience suggests that an introduction programme may be a prolonged affair, up to four years in the USA, and that the cost to hospitals of this change in electronic coding of components is potentially enormous (the estimated figure of £10,000,000.00 in the UK has already been put forward). The decision of the ISBT Working Party will be available for the next meeting of this Executive Committee.

In the mean time, Mr Alan Slopecki and Mr Martin Bruce will check the current Guidelines for emergent discrepancies between its contents and the recommendations of the ISBT Working Party, and report back to the Chairman of the SC on IT before the next UKBTS/NIBSC Executive meeting.

10. **Tissue Banking**

It was noted that MSBT now cover this topic, and the question raised as to whether our own Guidelines should do likewise. Since the British Association of Tissue Banks (BATB) has been established as a "Learned Society", it is not clear as to whether it can or even should take responsibility for safety guidelines etc.

Dr Schild reported that UKTSA have approached NIBSC with regard to guidelines for microbiological testing of transplantation samples. Recommendations on this point are currently with MSBT.

It was agreed that the UKBTS/NIBSC Liaison should not be immediately expanded by the establishment of a new standing committee on tissue banking, but there was a need for an active group to draw up, or monitor the drawing up, of guidelines covering those aspects of tissue banking which mirror our current activities in the transfusion field.

At the suggestion of the committee membership, the Chairman agreed to write to Dr H Atrah at West Midlands BTS, asking him to set up a multi-disciplinary group to draft guidelines for tissue banking, with the emphasis on bone, to cover incipient regulatory affairs such as microbiological testing storage parameters etc. It was stressed that this group should be truly multi-disciplinary, with a strong suggestion that Dr John Kearney of Pinderfield Hospital in Wakefield should be involved.

11. **Any Other Business**

11.1. Dr Gunson informed the meeting that DoH statutory instruments on the implementation of EC89/381 are all now in force. He undertook to copy these to members of the committee.

11.2. A letter from Dr Ala to Dr Gunson regarding products potentially out of specification was discussed. The committee agreed that it would agree to the issuing of such products if all other guidelines were met and there was no reason to believe that any danger to the patient existed in the use of such components.

11.3. Dr Schild reported that funding for the production of standards was still proving problematic. He still has a preference for central funding for this work, but accepts that this will probably not be possible. The DoH view is that the users should pay, but Dr Schild stated that he would first make sure that all possible avenues for central funding had been explored. He also record that a blood virology unit has been officially set up at NIBSC headed by Dr Morag Ferguson.

12. **Date, Place and Time of Next Meeting**

Monday 5 September 1994, West Midlands RTC at 11.00 am.

The meeting closed with a unanimous request from all committee members that the minutes should record grateful thanks to Dr Gunson for all the work he has done over the years in pursuing excellence within the field of transfusion medicine in the UK, and particularly for his invaluable contribution to the formulation and publication of the UK Guidelines. It was agreed by all present that they would probably never have happened but for his input.