EC 32/95

UKBTS/NIBSC EXECUTIVE COMMITTEE

MINUTES OF THE FIFTH MEETING, HELD AT
WEST MIDLANDS RTC ON TUESDAY, 20TH JUNE 1995

Present:

Dr. F. A. Ala
Dr. T. Barrowcliffe
Dr. V. James
Dr. B. McClelland
Dr. P. Phillips
Dr. A. Robinson
Dr. G. Schild
Dr. W. Wagstaff (Chair)

1. APOLOGIES had been received from:

Professor J. Cash; Dr. M. de Silva, Dr. M. Kavanagh

2. MINUTES OF THE MEETING OF THE EXECUTIVE COMMITTEE HELD ON 15TH FEBRUARY 1995

The Minutes were accepted as a true record of discussions, with the following amendment:

Item 8.13: "Professor John-Pierre Allen" should read "Jean-Pierre Allain".

3. MATTERS ARISING:

3.1 "Notified Bodies". Draft Directive on in-vitro Diagnostic Devices (EC 19/95)

The "In-Vitro Diagnostic, Medical Device Directive" (IVDMD) is due to come into effect two years after signature - probably in mid-1997. The Directive applies to all reagents, such as virology assay kits, blood-grouping anti-sera, cell panels, and "accessories" to reagents like LISS, utilised outside the environment of the "parent" legal entity. Indeed, it is relevant to "reagent systems", comprising blood grouping and other automated equipment, as well as the computer software driving it, rather than merely to in-vitro reagents alone. Dr. Peter Phillips emphasised that a two-year lead-time is extremely brief in preparing for full compliance.

The British Standards Institute is already designated as a Notified Body. The National Institute for Biological Standards and Control would like to be nominated. It may be that the two agencies can collaborate. NIBSC has the expertise to complement BSI in this context, bringing to bear their expertise in examining or validating dossiers and auditing manufacture.

Dr. Phillips has kept all relevant individuals within the Blood Service appraised of current regulations, and the revised section from the SAC Group on Reagents has been brought up-to-date, in line with impending European standards, requirements for labelling, instructions for use, etc.

Some discussion ensued regarding the function of Notified Bodies in relation to virology assay kits. Once a CE Marque is awarded to manufacturers by a Notified Body, free movement of the product within the Community becomes mandatory. The potential customer does, however, retain the right to evaluate the product critically in order to determine its "fitness for the intended purpose", without breaching the regulations. The Technical Sub-Group of SACTTI and NBA are urgently studying the possibility of providing a "rapid response" mechanism for allocating funds to PHL for the evaluation and validation of new viral assay kits. Manufacturers would serve as the source of funding, although this would not involve a commitment to purchase.

4. STANDING ADVISORY COMMITTEE ON DONOR SELECTION (EC 20/95)

4.1 Dr. James only wished to touch upon two salient issues:

4.1.1. There are two routes for the introduction of amendments to the A-Z Guidelines, and resolving any conflicts between these and the appropriate section of the "Red Book". Given an annual implementation date early in January for less urgent entries, bringing together decisions taken and circulated for comment throughout the course of the preceding year, A-Z amendments would be produced in the autumn and sanctioned by the Executive Committee in September, allowing some two months for staff training before they come into force.

A second, rapid, concessionary pathway also exists for the resolution of urgent issues, which by-passes this conventional route, such as the exclusion of sexual partners of anti-HCV seropositive donors, or measures which will prevent the needless waste of potentially usable donations. Such proposals would be urgently circulated to relevant staff before approval and implementation.

4.1.2. A-Z Changes for Autumn 1995

Dr. James sought and obtained the agreement of Committee Members for applying the rapid, concessionary approval to Acupuncture and Electrolysis. Donors who have undergone these procedures will be accepted in the future.

The "AIDS Leaflet" (which is now generic, with an eye to overall blood safety, rather than the threat of AIDS alone), is currently being field-tested.

The Hepatitis section is being re-written.

The validation of malaria antibody testing by Dr. Chiodini's trial, will alter selection of donors who have been at risk. Implementation awaits the accolade of peer review and acceptance for publication by Vox Sanguinis.

5. STANDING ADVISORY COMMITTEE ON COMPONENTS

5.1. The Committee had met 10-12 days previously, to review the relevant section of the Red Guide, which still remains to be completed and edited. The final draft is to be sent to all Centres for comment, with a mid-July deadline. Once these comments have been inserted, the completed manuscript will be forwarded to Dr. Wagstaff by mid-August, in time for approval at the next Executive Meeting, on 26th September 1995.

Dr. Wagstaff observed that a number of our blood component labels are at odds with the European Pharmacopoeia and contravene EC regulations.

A letter from Dr. Napier, Chairman of the BCSH Task Force was cited, concerning the need for drawing attention to establishing security systems for blood components by hospitals, in the Guidelines, without being over-prescriptive or zealous, however.

6. STANDING ADVISORY COMMITTEE ON REAGENTS FOR IMMUNO-HAEMATOLOGY AND HLA (EC 21,22,23/95)

6.1 In the absence of Dr. Mahes de Silva, Dr. Phillips summarised the activities of the Committee.

Section 3 of the Guidelines has been completely revised, to incorporate latter-day concepts regarding reagents. These are now part of a reagent system, or are plate-based, rather than merely bottles of material defined by titre and potency. Unequivocal results are now the measure.

Minimum standards for HLA typing in the context of bone marrow transplantation and platelet-matching have been defined; the complement-testing section has been re-written. The difficult issue of employing historical serologic data to avoid confirming phenotypes of successive donations was discussed once again. Whilst it must be conceded that current reagents are much more precise than in the past, no change in the recommendations is foreseen at the moment. The introduction of a new, reliable information technology system in the future may help to improve the validity of historical data. As examples of areas of uncertainty, Dr. Phillips cited pre-loaded microplates delivered in a plastic pouch. The label identifying the plate is applied to the outer wrap, so that when it is removed, there is no label at all. Even though this arrangement is in accord with European regulations, the lack of safety inherent in this practice has been pointed out to the manufacturers, with a request for rectification. Further, rapid changes in tissue typing and the introduction of DNA technology are causing similarly rapid change in nomenclature. Also DNA probes are being synthesised in individual laboratories, for direct use, without any form of validation. New entries in Section 3 of the Guidelines will reflect the need for adequate evaluation and verification of probe specificity.

Finally, the acceptable allo-antibody content of blood components is being defined.

In the general discussion that followed, a number of important issues were touched upon:

i) It was recognised that it is essential to establish a document control facility to identify amendments, and an archiving mechanism for administering and keeping track of all documentation, editorial changes, comments, literature references and scientific evidence which form the whole background and audit trail, culminating in the current Guideline Standards. This onerous task calls for the appointment of a librarian who would construct a data-base and codify all this data. Dr. Schild will investigate the possibility that NIBSC may be able to help. Dr. Schild also undertook to explore the possibility that funding for printing and proof-reading of future Guideline editions might be devolved from the DOH, so that their production comes under the control of the Executive.

ii) Even though both Authorities (SNBTS and NBS) are well represented at meetings of the Executive Committee, it is not clear who is formally responsible for the Guideline document. It was felt that legal representatives of SNBTS and NBS should be consulted regarding the official standing of the "Red Book" and that a preamble to future editions should outline the manner in which Guidelines are drafted, produced and controlled through a process of wide consultation and comment.

7. STANDING ADVISORY COMMITTEE ON PLASMA FOR FRACTIONATION (EC 31/95)

7.1 One meeting of the SAC has been held, in September 1994, where some of the salient issues discussed were:

i) Virus validation (Paul Ehrlich Institute meeting, 10th November 1994) and relevant British, European and international standards.

ii) Factor VIII testing in plasma - methodology used and numbers of samples to be tested. Consideration was given to organising an autumn workshop to raise standards of testing within the Blood Service.

iii) The development of descriptive "Product Characteristics" similar to a Scottish Compendium of Product Information". It was suggested that data sheets regarding plasma fractions and componenets might be included in a separate chapter of the British National Formulary, for the benefit of hospital medical staff.

iv) The inevitability of start pool plasma testing by PCR techniques. The US currently required HCV RNA testing of plasma pools destined for intra-muscular or i.v. immune globulin. Dr. Schild informed members that NIBSC has created an international technical/scientific group for exchange of information and materials in relation to the standardisation of gene amplification methods. Membership is widely representative, and includes delegates from Japan, European countries, the US FDA, as well as UK experts such as Simmonds, Yap, Tedder, Follett, etc. Dr. Schild offered to make Minutes of the meetings available to the Committee, and include appropriate members of the Executive among its participants. WHO is apparently anxious to provide sponsorship of these meetings.

8. STANDING ADVISORY COMMITTEE ON TRANSFUSION-TRANSMITTED INFECTION (EC 24,25,26, 32/95)

8.1. A few items from the Minutes of the SACTTI, held on 12th June 1995, were highlighted:

8.1.1 The Committee regretted that communications between MSBT and SACTTI were virtually non-existent, and strongly felt that formal channels of communication between these two Committees should be fostered.

8.1.2. It is still hoped that the DOH will support a policy for "one-pass" anti-HBc testing of established donors, confining screening to new donors thereafter.

8.1.3 Although a source of funding for a prospective study of bacterial contamination of donor blood and platelets aimed at demonstrating that the "overnight hold" of blood at 20°C is no less safe than conventional 4°C refrigeration, had not been identified, the current interest of BPL in exploring the potential advantages of this policy, and collaboration with the NBA Platelet Study Group, may enhance the probability of initiating such a study.

8.1.4 A special SACTTI meeting on HCV Epidemiology was due to take place on 21st June. Minutes would be circulated to members as soon as they were available.

8.1.5 VIRALLY SAFER PLASMA. SACTTI members noted with some relief that final recommendations from Dr. Robinson, in this context, proposed a watching brief, rather than adoption of the "Quarantine Policy".

9. STANDING ADVISORY COMMITTEE ON INFORMATION TECHNOLOGY

9.1 The recent appointment of Dr. Elizabeth Love to the Chair of this Committee was welcomed, in her absence.

10. WORKING PARTY ON TISSUE BANKING

10.1 Members of the Executive Committee endorsed a plea from Professor Cash that Tissue Banking (leaving aside organs for transplantation) is an issue which should be under the aegis of this Committee, and that it deserved on-going, blood transfusion-specific consideration by an advisory committee. BATB Guidelines are insufficiently quality-oriented, and the Blood Service must ensure that guidelines regulating this activity are transparently ethical: oriented towards customer care and psychology, as well as quality. It was also considered that the handling of Cord Blood Progenitor Cells should be included by a Tissue Banking SAC. The initial enthusiasm of the Working Party had declined in subsequent meetings, due - in part - to the inhibitory influence of the BATB, organ transplanters, and Centres anxious to retain their widely divergent policies.

It was concluded that Dr. Hassan Atrah's report should be awaited before any decisions regarding the future were taken. In the intervening period, it would be advantageous to establish the practice of mutual audit between BTS Tissue Banks and the Wakefield and Leicester Centres, as Scotland has done.

11. BRITISH WORKING STANDARD FOR ANTI-HCV

This material is to be adopted as a working standard throughout the UK. The BBTS Microbiology Special Interest Group have welcomed and sanctioned introduction of this standard. An HIV Working Standard will also become available before long.

Dr. Schild noted that NIBSC had borne the costs of developing and providing such materials hitherto, but it may not be able to do so in the future, and this is an issue which requires early clarification.

Dr. Robinson is taking up the problem with the NBA and will report the outcome of negotiations.

Members agreed that the adoption of a system of funding at source would be preferable to charging for the materials.

12. BRITISH REFERENCE REAGENT FOR HLA CLASS II SEROLOGY; RABBIT COMPLEMENT

The British Reference Reagent for Rabbit Complement designated for use in HLA Class I serology, has been confirmed to be suitable, at different dilution, for Class II serology as well, and is non-cytotoxic to lymphocytes.

13. HANDBOOK OF TRANSFUSION MEDICINE

Dr. Napier is assisting in contacting transfusion centres, in order to determine the number of copies required. The Handbook is now completed, and has to be checked once more before going to the printers within about one month.

14. ANY OTHER BUSINESS

14.1 Dr. Virge James chairs the Automation Users' Group, which used to report to the RTC Committee in the past. At present, this group - which does serve useful purposes in keeping maintenance charges at an equivalent level, promoting bulk purchases, and keeping the Service informed about the types of equipment in use - is orphaned.

It was agreed that the Group would continue to operate under the aegis of the SAC on Reagents, although it was recognised that it must also interact with the SAC on Information Technology.

14.2 Members were issued with a copy of Chapter 2, Red Book Guidelines - General Considerations, re-drafted by Alan Slopecki, and circulated for consultation. Comments will be incorporated, and a final draft will be available by July.

15. DATE OF NEXT MEETING

The next meeting will take place in Birmingham, on 26th September 1995.

FAA/MP
6.7.95