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NATIONAL DIRECTORATE OF THE NBTS

National Management Committee

Minutes of the eighteenth meeting of the National Management Committee held on 16th January 1992, Gateway House, Manchester.

PRESENT: Dr. H.H. Gunson (in the Chair)
Dr. C.C. Entwistle
Dr. I.D. Fraser
Dr. J.F. Harrison
Dr. R.J. Moore
Dr. E.A.E. Robinson
Dr. W. Wagstaff

1. Apologies for absence - Dr. S.M. McDougall.

2. Minutes of the seventeenth meeting.

Correction to minute 10.21. This should read as follows:

"Information regarding serious untoward incidents during blood collection, such as arterial punctures, A-V fistulas and how these were dealt with at the RTC, should be disseminated between RTCs".

3. Matters arising

3.1 **Revision of the AID Leaflet**

The comments made by the Divisions were considered.

With respect to those of the Eastern Division concerning the exclusion of homosexuals and bisexuals prior to 1977, Dr. Wagstaff expressed surprise since Dr. Hewitt is a member of the SAC on Medical Selection of Donors and agreed to the omission of 1977 when this matter was considered in March 1991.

Dr. Gunson considered that a leaflet on infectious diseases was unnecessary since a leaflet specifically directed against HIV infection would still be required.

Dr. Gunson tabled Guidelines from the European Commission (111/8379/85 - EN) which are to be used in the implementation of Directive 89/381/EEC on medicinal products derived from human blood and human plasma. These Guidelines come into operation on 01-05-92. In the section on selection of donors it states "The criteria of the Council of Europe and of WHO shall apply to the selection of blood donors and blood donations."

The proposals currently put forward from EAGA are those in the revision of the recommendations of WHO Expert Committee on Biological Standardisation (an update of the Technical Report No. 786, 1989). The WHO report does not include geographical exclusions and EAGA have been advised that at present the major risk activity is heterosexual contact with persons who are living or have lived in Africa (except the Mediterranean countries). However, the wording of this clause should be altered and a two year exclusion period could be used.

With respect to ear piercing, acupuncture, electrolysis etc. the WHO recommendation includes "unless these are performed under sterile conditions". It was agreed that this applied to ear piercing carried out by jewellers and acupuncture in hospitals. Also, the two year exclusion did seem excessive and Dr. Gunson was asked to contact Dr. D. Thomas, the U.K. representative on the WHO Committee, to ask for this to be reconsidered. Tattooing, however, was considered to be a high risk activity.

Dr. Mitchell's Committee would draft a leaflet which would then be tested for intelligibility on donor groups.

Action - Dr. Gunson

3.2 **Working Party on Retention of Records**

Dr. Gunson stated that he had received a draft report from Dr. Lloyd and had made various comments on it. Dr. Lloyd has agreed to submit a final report in two month's time.

3.3 **Bone Banking in RTCs**

The report from the Allograft Bone Bank Committee was now ready to be submitted to EAGA who had requested recommendations. Dr. Entwistle reported that there would be a recommendation that some RTCs should be involved in this activity in a manner similar to that pioneered in Scotland. He has asked, also, that DH send the report to RTDs.

3.4 **AIDS and the Workplace**

The Eastern Division raised various comments on the testing of prospective employees for HBsAg. These samples could be archived with the agreement of the employee but their use must be specifically defined. It is likely that there would be little benefit derived from this procedure.

Some concern was expressed about HBsAg carriers working in components laboratories and on blood collection sessions, although the risk of cross-infection was probably very small. If prospective employees were to be restricted in their work activities then prior to interview they should be informed that appointment was subject to a satisfactory medical examination which would include a test for Hepatitis B.

3.5 Management Training for BTS Medical Staff

The Eastern Division (except S. Thames, who were not represented at the meeting) were not in favour of national management courses. The Western Division and the Northern Division - except the Northern RTC - expressed an interest. Appropriate courses would be investigated.

Action - Dr. Moore

3.6 Co-operation with Wellcome on Q.A. matters

Dr. Gunson reported that Professor Allain had agreed to convene a small group to meet representatives from Wellcome.

3.7 Dr. Harrison volunteered to collate reports on serious incidents occurring during blood collection. This was accepted.

Action - Dr. Harrison

4. Minutes of the QUIN Committee (5th December 1991)

4.1 Plasma Specification

Dr. Moore commented that a major matter unresolved was the minimum quantity of plasma to be allowed in a pack. It had been decided to investigate the size of the problem since BPL would prefer there to be a minimum of packs which had to be opened manually. The Northern Division suggests 150 ml, but Dr. Robinson commented that this problem may worsen with the increasing number of plateletpheresis procedures.

Dr. Moore replied that Mr. Donald was conducting a prospective study.

4.2 Dr. Entwistle reported that Birmingham RTC can now provide retrospective data for verification of plasma donations.

4.3 Members gave full backing to the plan to identify and provide training for Q.A. Managers in computer system auditing.

5. **Minutes of the U.K. TTD Committee (6th December 1991)**

5.1 Dr. Gunson drew particular attention to the survey on bacteriological contamination of blood and that guidelines on handling these when reports were received would be produced. It was agreed that incidents were under reported and that hospitals should be asked to report all suspicious infections after transfusion of blood and blood products.

The guidelines would be included in the next edition of the "Red Book".

5.2 **Preliminary report on the Sept/Oct Trial of anti-HCV tests**

Members welcomed the report and Dr. Gunson asked if ALT tests could be performed on those results at each RTC when the samples tested were ELISA positive and RIBA indeterminate. Chairpersons of Divisions agreed to pass on this request to RTCs in their Division. If a list of donation numbers was required, Dr. Gunson would arrange for this to be sent. Results giving donation number and ALT result (with normal range) should be sent to Dr. Gunson.

It was agreed:

(i) that the further investigations required to complete this study should be done as quickly as possible

(ii) the commercial firms should receive this report when it had been accepted for publication in a scientific journal but not before

Action - Chairmen of Divisions/ Dr. Gunson

6. **Minutes of NBTS/CBLA Liaison meeting (12th December 1991)**

6.1 Dr. Gunson commented that it might be difficult to achieve the plasma target for 1991/92.

6.2 Dr. Entwistle stated that he was being visited by BPL staff to discuss contracts. He agreed to report back to the National Directorate.

Action - Dr. Entwistle

6.3 Dr. Gunson reported that ALT had not been included as an essential test on plasma for fractionation in the EEC Guidelines supporting Directive 89/381/EEC.

7. **Minutes of POD Committee (18th December 1991)**

7.1 Dr. Moore reported that the new TV filler had been widely used and included insertion at peak times (the Jonathan Ross show). The showing of the filler was equivalent to £640,000 of TV advertising.

7.2 It was stressed that following the Patients Charter, serious consideration should be given to the preparation of a "donors charter" and responses from Divisions were awaited.

7.3 Dr. Harrison agreed to report on the results of her study on donor membership cards.

Action - Dr. Harrison

8. **Minutes of the Automation Users Group**

These were received.

9. **Minutes of Divisions**

9.1 **Northern (9th January 1992)**

(i) <u>Lack of plateletpheresis sets in Moscow</u>

Dr. Moore reported that ODA had received a number of requests for medical supplies etc. and were contacting appropriate manufacturers. Dr. Robinson asked that if there were any Haemonetic sets which were surplus to requirements, but were still in date, could Tom Ford of Haemonetics be contacted.

(ii) It was agreed that it was inappropriate to respond to Dr. Habibi's letter.

9.2 **Eastern (9th January 1992)**

(i) In answer to a question from Dr. Harrison, Dr. Wagstaff explained that the practical content in the Part I MRC Path was to be very basic, e.g. grouping, cross-matching and sample identification of antibodies. More detailed examination of the candidate would take place during the viva in Part II. There had been no change to the 6 months blood transfusion training.

He also commented that Post-Graduate Deans held budgets for post-graduate medical training.

(ii) Dr. Harrison reported that the finalised COSHH data sheets would be available soon.

(iii) Dr. Harrison advised that since NEQAS funding had been devolved to RHA's, RTCs should follow Eastern Division and apply to their RHA's for reimbursement.

(iv) The Blood Transport Working Party has produced a final draft report with recommendations. It has been circulated by Mr. Booth to all RTDs for comment. The report and comments will then be discussed by the appropriate Guidelines Committees.

9.3 **Western (14th January 1992)**

(i) It was agreed that unconfirmed anti-HCV positive donations, when this occurred on more than one donation, should be withdrawn but need not be referred for clinical investigation. Those donors where RIBA indeterminate results were obtained should have their records flagged for the present until a policy for RIBA referral could be defined.

(ii) Some doubt was expressed about the use of historical data on red cell groups other than Rh even if such data was validated by an approved Q.A. system. Dr. Entwistle will take up this matter with Dr. Contreras.

Action - Dr. Entwistle

10. **Involvement of Commercial Firms in the monthly HIV/HCV reports**

The Management Committee were unanimously of the opinion that commercial firms should not have a "manufacturer's comments section".

Opinions were divided in the Divisions, but the majority of RTCs were against the proposal of circulating Miss. Rawlinson's letters to the commercial companies. There was a suggestion from SNBTS that some RTCs may refuse to send data if this were to take place.

It was agreed that these reports should remain confidential to RTCs and "CONFIDENTIAL" would be printed on each page of the report. Unauthorised leakage of the reports should be discouraged.

It was suggested that Prof. Allain's group might hold discussion on Q.A. matters with other manufacturers. Dr. Gunson will investigate.

Action - Dr. Gunson

11. **Haemonetics National Agreement**

The proposal was approved and the bulk discount structure welcomed.

12. **Readmittance of Apheresis Donors who are HBsAg and anti-HIV positive to the Panels**

South Thames RTC had carried out a study involving the quarantining of plasma whilst allowing the donor to continue to donate. They have concluded that there was a danger of issuing potentially infected material and there was a possible hazard to staff.

Dr. Robinson concluded that because of the small numbers involved it probably was more cost-effective to continue to apherese these donors and discard the plasma as appropriate instead of arranging for counselling.

Other members considered that it was preferable to retire these donors, although HBsAg donors could be readmitted (see minutes of U.K. TTD Committee, 6th December 1991) and HIV donors can be admitted according to the current programme agreed by EAGA. All ELISA positive donations should be discarded.

13. **British Bone Marrow and Platelet Donor Panel Minutes of meeting held on 5th December 1991**

These have been circulated to RTDs by Dr. Fraser.

13.1 It was agreed that whenever feasible RTCs should be responsible for collecting the autologous blood for the marrow donor and sending this to the RTC of the region where the donor (either related or non-related) donates the marrow. Some RTCs may find difficulties in supplying this service, Dr. Harrison, in particular, expressed doubts.

13.2 It was agreed that with the new leaflet, publicity for bone marrow donors at NBTS sessions was adequate and the posters drafted by the British Bone Marrow Donor Appeal were not required. In particular, the one asking blood donors for donations of money was unacceptable.

14. **Virally inactivated FFP - S/D Treated**

Dr. Gunson mentioned that he had discussed this with a representative of Octapharma. Investigations into the

possibility of obtaining some of this material for a clinical trial were agreed. Financing of the trial would be an important matter for consideration. Production would need to be co-ordinated through BPL.

15. **Advisory Committee on Science and Technology (ACOST)**

Dr. Gunson explained that he had been asked to submit a report to a Task Force of ACOST which reports to 10 Downing Street on the possibility of RTCs involvement in the development work to establish gene therapy. There was a positive response to this suggestion.

16. Date, place and time of next meeting

Thursday 2nd April, National Directorate, Gateway House, at 11.00 a.m.