NATIONAL DIRECTORATE OF THE NBTS

National Management Committee

Minutes of the seventh meeting of the National Management Committee held on Thursday 4th January, 1990.

Present: Dr. H.H. Gunson (In the chair)
Dr. F.A. Ala
Dr. M. Contreras
Dr. I.D. Fraser
Dr. J.F. Harrison
Dr. D. Lee
Dr. R.J. Moore
Dr. W. Wagstaff

In Attendance: Mr. P.J. Cosgrove

1. Apologies for absence

No apologies for absence were received.

2. Minutes

The minutes of the meeting held on 2nd November 1989, were approved subject to the following amendments:-

2.1 Minute 3.7 Bone Marrow Panel

Dr. Wagstaff reported that Dr. A. Bloom might take up the Chairmanship rather than Professor Hoffbrand as previously reported.

Dr. Gunson reported that draft guidelines on non-related bone marrow transplantation by RcPath had not been sent to the Department of Health. It was now proposed that a Working Party would be set up to consider all aspects of non-related bone marrow transplants.

2.2 Minute 12 vaccination of staff for Hepatitis B

It was agreed that Minute 12 should be amended to include the following statement:-

"That the risk of infection is minimal providing proper safety precautions are taken to identify staff who may have been put at risk and appropriate action taken."

3. Matters arising

3.1 Guidelines on the use of FFP

Dr. Gunson advised the Committee that he had received

a letter from Dr. Napier suggesting that Dr. Ala be co-opted to the BSH/BCSH Transfusion Task Force which had identified Guidelines on the use of FFP as one of its objectives.

Dr. Ala said he would be happy to do this and, as this would simplify the publication and distribution of the Guidelines, it was agreed that Dr. Ala would contact Dr. Napier on this matter.

Action: Dr. Ala

3.2 Antenatal administration of anti-D IgG

Dr. Lee informed the Committee that questions had been raised as to whether the project in its present form was ethical.

A meeting of the Working Party has been called for Friday 12th January 1990, to decide whether to proceed with the trial as planned; to redesign the trial so that a comparison of the effectiveness of different doses can be made either on a random basis or not; or abandon the trial and make a recommendation to DOH.

Dr. Lee undertook to inform the Committee of the Working Party's decision as soon as possible.

Action: Dr. Lee

3.3 NBTS 110

It was agreed that the wording of the statement to be signed by the donor having read the information on AIDS should not be amended.

With regard to the diseases listed on NBTS 110 it was agreed that Toxoplasmosis should be deleted from the list and Glandular Fever be included.

Action: Dr. Moore

3.4 Use of first donations

Dr. Gunson advised the Committee that he had received a letter from Professor Cash, SNBTS in which, in the light of figures from the USA regarding the calculation of HIV transmission risk in the "window period", he had raised the question of not using products from first time donations.

Approximately 20% of all donations received by the NBTS were first time donations it was not therefore feasible to discard them. Some RTCs did not use first time donations for the preparation of platelets but this situation was increasingly difficult to maintain due to the rise in demand.

It was agreed that Dr. Gunson would contact Mrs. Mortimer to enquire whether sufficient data was available to calculate similar risks for the U.K.

Action: Dr. Gunson

3.5 AIDS leaflet : supplementary list

Dr. Gunson informed the Committee that Dr. Abrams had agreed on behalf of the EAGA that a supplementary list of countries with a high prevalence of HIV infection should be issued to BTS receptionists.

If a potential donor has visited one of these countries the receptionist will refer the donor to the doctor or nurse in charge of the session before a donation is made.

It was agreed that a table showing countries where the prevalence of HIV is high would be circulated and the Committee would draw up the list at its next meeting. The draft leaflet would proceed to printing.

Action: Dr. Gunson

3.6 Medical audit in the BTS

Dr. Wagstaff advised the Committee that the proposed meeting of heads of Divisions has been postponed due to the 'Flu Epidemic'. An observer from the SNBTS would be invited for the rescheduled meeting on Monday 5th February.

4. Provision of donors

Dr. Moore reported that members of the POD Committee had attended a two day workshop on 31st November/ 1st December 1989, with representatives from RBL, the Marketing Consultants.

At the workshop RBL had presented the results of surveys regarding attitudes to the NBTS of the general public; staff at sessions; employers; and donors at sessions.

From the work done so far the POD Committee will pursue two main objectives. Firstly, the development of communications material and, secondly, examine operational matters i.e., session times, procedures, staff attitudes etc.

The next phase of RBL's work will be the submission of a qualitative analysis which will enable a range of poster material to be produced by April, 1990.

A summary of the findings from RBL will be available in February/March, 1990.

5. MIS

Dr. Moore reported that a workshop for Management Information Coordinators (MICs) had been held on 8th November, 1989.

The hardware and basic software for use had been delivered to each Region and an order placed for the data modelling software "EPIC". It was planned that data for October 1989, would be sent to the Directorate by 12th January 1990, and data for November and December, 1989 by 16th February, 1990.

This timetable would enable the full system to begin operation in April 1990.

6. Commercial utilisation of time expired red cells

The Committee were advised of a confidential enquiry from an American company concerning time expired red cells. It was felt that even if the purchase price on offer was substantially increased the work involved would not generate any real income. Also, the risk of alienating donors was considered to be preclusive. The proposal was rejected.

7. Guidelines on sponsorship arrangements

The Committee received a paper putting forward guidelines on sponsorship agreements and income generation. They welcomed and endorsed its contents and it was agreed that this paper should be sent to Divisions.

8. Pilot trial on anti-HCV testing

Dr. Gunson tabled a report which summarised the findings of the pilot studies on anti-HCV tests in the N.E. Thames, Trent and W. Midlands Region's and which included comments on the test from N.E. Thames and Trent.

Both N.E. Thames and Trent highlighted the shortcomings of the washer, which has an inadequate reservoir; and the lack of flexibility of the software provided.

In N.E. Thames approximately 0.5% of tests developed a visible colour reaction but below the manufacturer's cut off point and Trent reported that 1% of donor samples gave ODs higher than the negative mean, but below the manufacturers cut off point.

It was noted that plasma samples had consistently lower ODs than serum samples in the Trent trial, plasma from four out of the seven repeatedly positive serum samples were below the cut off point though the OD was raised.

The distribution of the seropositives appeared to be sporadic though Dr. Harrison commented that they were examining the data in more detail to determine whether there was clustering in certain parts of the Region.

Dr. Gunson undertook to prepare a more comprehensive report for distribution to all RTCs and to the ACVSB.

Action: Dr. Gunson

Dr. Gunson advised that the ACVSB was to complete a cost benefit exercise on the introduction of anti-HCV testing.

Dr. Gunson reported that the Abbott test was available for evaluation but it had recently come to light that the Ortho test has prescribed ordering dates, the first two being 5th January, 8th March, 1990. Tests ordered on these dates would be delivered 90 days thereafter.

Dr. Gunson agreed to bring this to the attention of the ACVSB.

Action: Dr. Gunson

With regard to the absence of a confirmatory test Dr. Gunson advised the Committee that the ACVSB did not see this necessarily as a barrier to the introduction of routine screening but the ACVSB would insist that any test for routine use must have been licensed by the FDA. Some progress had been made toward a confirmatory test using the same antigen in blot form and this may be available at the end of January.

The question was raised as to what appropriate action should be taken in respect of those donors in the trial whose sera was repeatedly positive.

It was agreed that such donors should be asked to give again and tested on at least one more occasion.

Contact had been made with hepatologists in Trent and N.W. Thames and their response was positive and encouraging.

Dr. Contreras said that about 1% of those tested in the N.W. Thames region had been found to be repeatedly positive, but that not all of these were found to be infectious and it appeared that not all of those who had received blood donated by such people had developed HCV.

The prevalence of HCV in England and Wales appeared to be similar to that experienced in some states in the USA, but lower than the estimated prevalence in Denmark, Italy, Spain and about the same as in Finland.

9. <u>Research co-ordinating committee</u>

Dr. Gunson introduced this item by reminding the Committee that there had previously been a MRC Research Co-ordinating Committee which had been wound up in 1982.

Despite the fact that funds were still not available for distribution by a Research Committee, recent experience indicated that a Research Co-ordinating Committee could still have an important role to play.

It was agreed Dr. Gunson should proceed with the setting-up of such a Committee, which he would chair, with the following terms of reference:-

> To review and propose areas of research in blood transfusion medicine and make recommendations to the Management Committee of the NBTS.

Dr. Gunson received the names of several nominees whom he will contact in the near future.

Action: Dr. Gunson

10. <u>Accountability review</u>

The Committee considered the first draft of the report of the National Directorate of the NBTS for the accountability review to be held on 24th January 1990.

The following suggestions were made:-

1. That attention should be drawn to:-

   a) The need for Senior Registrars in training posts.

   b) The need for specialists in non-training posts, e.g. as Managers of apheresis centres.

   c) The need to recruit more scientific staff.

2. That there is a need to stress that the BTS is not merely a collecting and issuing service but one which has a considerable input to clinical medicine e.g. in bone marrow transplant referral work; providing advice on and solving haematological problems; and the ongoing work in establishing Hospital Transfusion Committees fostering good practices and reducing morbidity.

The following amendments and corrections were also put forward:-

1. That the Immunoglobulin Working Party be added to the list of Committees.

2. That the text in the Executive Summary, Appendix III be reworded.

Concerning the future of the NBTS it was agreed that this would be discussed more fully later in the year.

11. Meetings of other committees

11.1 NBTS/CBLA Liaison Committee

11.11 Concerning a uniform price per i.u. of anti-D for all plasmas, it was agreed to accept as a minimum baseline £60/kg, with an additional 3.75p per unit thereafter.

Action: Dr. Gunson

11.12 Regarding "pigtails" it was reported that extreme problems would occur if these were in with the pack, it was necessary, therefore, that these should be kept separate.

11.13 Concerning independent assessment on random sampling, it was understood that Dr. Owehand knew of a document stating that pools of plasma should have a titre of less than 1/64. Dr. Contreras undertook to fax a copy of the Central Blood Laboratory Netherlands regulation to Dr. Gunson.

Action: Dr. Contreras

11.14 Regarding anti-CMV immunoglobulin, Dr. Lee reported that Dr. Gooi is preparing a paper on the prophylactic use of anti-CMV Ig.

11.15 It was reported that the contents of vials of Factor VIII received from BPL still exceeded the 240/250ml range.

11.16 The supply of vials containing 500 i.u. of Factor VIII is expected to commence in March/ April, 1990.

11.17 It was reported that BPL would in future undertake the testing for anti-VZ.

11.18 The National Directorate and the CBLA had agreed to prepare a joint paper for Regional General Managers and Regional Treasurers on cross-accounting, reviewing the options for appropriate budget holders and the preferred supply channels for BPL products to maximise their uptake in the NHS.

The CBLA chose to ignore the advice of the National Directorate and proceeded to issue a letter to RGMs and Treasurers without agreeing its contents with the Directorate.

The Directorate has, therefore, disassociated itself entirely from this document and finds this level of 'co-operation' increasingly difficult.

11.2 UK Transfusion Transmitted Diseases Committee

11.21 Dr. Gunson reported than an evaluation of the Behring HIV 1/2 test completed by Trent was available and would be circulated with these minutes.

11.22 Concern was expressed regarding the Wellcome HIV 1/2 test the introduction of which had been delayed again. Members were aware that in earlier tests at the PHLS the sensitivity had been questioned.

11.23 Dr. Contreras reported that the N.W. Thames Region had recently purchased 20,000 Elavia kits at 75p each, and was proceeding with an evaluation of this test.

11.24 Concerning the proposed UK BTS study on anti-HTLV I/II, a meeting between Dr. Mitchell and Dr. Contreras to discuss details of the study has been arranged and Dr. Contreras will advise Dr. Gunson on the results of these discussions.

Action: Dr. Contreras

11.3 Supply of blood and blood products to the Brompton/ National Heart Hospital

The Committee received a report on the arrangements for the supply of blood and blood products to the Brompton/ National Heart Hospital from 1st January, 1990.

With regard to the interim arrangements, Dr. Contreras advised the Committee that she was confident that National Heart Hospital patients could be identified and their requirements other than platelets could be met.

11.4 Minutes of the meeting of the Northern Division held on 14th December, 1989

11.41 With regard to minute 3 (d) if ALT plasma is produced in February then it is expected that BPL production of IvIg will commence in May.

11.42 With regard to production targets BPL expects to receive between 60 to 80 tonnes of apheresed plasma which would lead to a maximum of 120,000 IvIg grammes per year.

11.5 Minutes of the meeting of the Eastern Division held on 7th December, 1989

11.51 Regarding minute 4 (a) it was agreed that the National Directorate should set a standard price for red cells.

Action: Dr. Moore

11.52 Regarding minute 5 (4) Dr. Contreras asked if clearer guidelines could be written for the withdrawal of plasma from pools for fractionation.

Dr. Gunson agreed to take this matter up at the next meeting of the Transfusion Transmitted Diseases Committee.

Action: Dr. Gunson

11.53 With regard to minute 4 (5), Dr. Gunson pointed out that Haemonetics, like any other manufacturer, was liable for the technical quality of its machines despite their national 'free' supply.

11.54 Regarding minute 6, the recommendations of the Apheresis Working Party were not subject to DH approval and there would not, therefore, be a delay of two years.

11.6 Minutes of the meeting of the Western Division held on 4th December, 1989

The Committee received the minutes of the Western Division.

12. Any other business

12.1 Meeting of the Bone Marrow Council

Dr. Fraser reported that the Council was awaiting a response on the request for funds to support a programmer who would be responsible for the bone marrow transplant information held on the BTS computer and be responsible to the BTS Head of Computing rather than the UKBTS.

12.2 Colloquium in recruitment of voluntary donors, Hanover

Dr. Gunson advised the Committee that two representatives from the NBTS had been invited to the Colloquium. It was believed that some RDOs may also have received such invitations; Directors were asked to check and if they had the funds available they could nominate someone for the remaining place.

Dr. Harrison requested information on the Colloquium

Action: Dr. Gunson

12.3 Alt tested plasma for production of i.v.Ig

With regard to ALT testing for production of i.v.Ig the price for ALT tested plasma for both R & D and production purposes will be £62.50 per kg.

12.4 With regard to the starting point for shipments of ALT tested plasma, it was considered doubtful if all regions could meet the original start date, partly due to technical difficulties and partly due to the need to ensure that the additional testing was properly integrated into region's operating procedures. It was agreed therefore that shipments to BPL should be scheduled to commence from 31st March, 1990.

Dr. Gunson undertook to discuss this matter with BPL and enquire whether it was feasible for those RTCs who could commence testing in January to do so.

Action: Dr. Gunson

Revision of dates of meetings for 1990

The following dates were agreed:-

1st March, 1990
30th April, 1990
5th July, 1990
25th October, 1990
10th January, 1991