



REGIONAL TRANSFUSION DIRECTORS MEETING

Minutes of the 209th Regional Transfusion Directors Meeting held in the Wharfedale Suite of the Hotel St George, Harrogate on Tuesday, 4th October, 1988 at 11.00 am.

Present: Dr. W. Wagstaff (Chairman)
Dr. F. Ala
Dr. D. J. Anstee
Dr. A. K. Collins
Dr. M. Contreras
Dr. J. Darnborough
Dr. C. C. Entwistle
Dr. I. D. Fraser
Dr. H. H. Gunson
Dr. J. F. Harrison
Dr. R. S. Lane
Dr. D. Lee
Dr. V. J. Martlew
Dr. R. J. Moore (DOH)
Dr. J. A. F. Napier
Dr. H. Pickles (DOH)
Dr. K. L. L. Rogers
Dr. D. S. Smith
Lt-Col. M. J. G. Thomas
Dr. L. A. D. Tovey
Dr. W. Whitrow

1. Apologies

Apologies of absence were received from Professor J. D. Cash and from Dr. W. M. McClelland.

Dr. Wagstaff welcomed Dr. Martlew who was attending her first RTD meeting.

2. Minutes of the 208th Meeting

The minutes were accepted.

3. Matters Arising

(a) NBTS Management Study

The Chairman offered his congratulations to Dr Gunson on his appointment as National Director of the Service. He invited Dr Gunson to brief the meeting about how the new National Directorate would function. Dr Gunson's remarks were summarized in a paper which he tabled and which is included as Appendix 1 of these minutes.

Referring to Section 1 of his paper, Dr Gunson told the meeting that the Deputy Director (Administration) would be Dr. R. J. Moore and that his personal assistant would be Mrs. L. Bond. The other appointments will be made as soon as possible. Referring to Paragraph 3, he said that members of the NBTS Coordinating Committee would be:

RHA Chairman: Mr Colin Walker (Cambridge)
Regional Medical Officer: Dr Michael O'Brian (Cambridge)
Regional General Manager: Mr Bob Nichols (Oxford)
Regional Treasurer: Mr Arthur Wilson (South Western)
Chairman CBLA: Mr Smart

Responding to comments, Dr Gunson confirmed that the RDOs Committee would report to the Management Committee (Para 6.4) and that the Advisory Committee (NBTS) would no longer exist. Dr Darnborough asked if the anomalous position of Lewisham could be corrected and Dr Gunson indicated that he, Dr Rogers and Dr Kemp had already met to discuss the issue. Referring to Paragraph 6.8, Dr Gunson indicated that the DHSS Plasma Supply Group had a temporary role to deal with an urgent problem but that the NBTS/CBLA Liaison Committee would be a permanent standing committee dealing with the plasma supply. Dr Rogers questioned the need for continued meetings of the RTD Committee in addition to the NBTS Management Committee (Para 6.2). Dr Gunson referred to the importance of the divisional structure and felt that the RTD's should continue to meet while recognising that the character of the meetings might change, eg, to deal with one or two particular topics rather than a long agenda. Responding to another question, Dr Gunson indicated that the Research Committee for the NBTS would have a brief for England and Wales but that he would welcome cross-representation and liaison with its counterpart in Scotland. Asked about wider liaison with Scotland, Dr Gunson indicated that the Management Committee would be constituted with representatives of England and Wales only. He indicated that the document which he had tabled was not confidential and that information about the structure and function of the new National Directorate could be disseminated. Dr Wagstaff asked if, in the light of several imminent retirements, examination of the management arrangements in Transfusion Centres could be a priority. Dr Gunson indicated that his intention in visiting Centres in the near future was to tackle this matter.

Dr Gunson's proposals were agreed by the meeting.

(b) Publicity Budget

The Chairman invited Dr Moore to comment on the papers which had been circulated. Dr Moore indicated that a budget of £400,000 was available for the year and indicated the intention to spend about £50,000 on publicity over the Christmas period. Money had been set aside as a contingency during the postal strike and would not now be needed.

The chairman asked what representation, in the light of the new structure of the Publicity Committee, would be required from the RTD's. It was agreed that a representative from each of the Divisions would be appropriate who could be drawn from any of the Consultant Staff. Dr Contreras proposed Dr Harrison to represent the Eastern Division and the Chairman asked for the other two nominations as soon as possible.

Dr Contreras wished to place on record, her view that £400,000 was an insufficient publicity budget in the current climate, eg the cost of television advertising; the Chairman believed that this debate would be more appropriately conducted by the Publicity Committee.

(c) Bone Marrow and Platelet Donor Panel

Dr Pickles reported that a decision on the availability of funding would not be available for several weeks. It was noted that the amount involved was £35,000 (not £25,000 as in the Minutes of the last meeting).

Dr Fraser told Directors that the meeting held during the Wembley Congress had shown a keen interest in international cooperation, though the drawback of being too well organised was that others might merely use the panel rather than establishing their own. The Chairman again expressed concern that this important scheme might fail because of the lack of a small sum of money. Dr Fraser reminded Dr Pickles that she had recognised the value of the platelet panel which could be used to reinforce her case.

(d) Scientific Staffing Group

Dr Moore reported that an apology was forthcoming from H.A.P. Division about the earlier handling of this document. They had asked several questions: What is the basis of the proposals? Does the National Directorate support the proposals? What is the DHSS view from Dr Moore?

Concern was expressed by several Directors about the need to restructure and to improve prospects for scientific staff in Transfusion Centres to cope with high turnover and poor recruitment. The Chairman indicated that it might be necessary to reorganise in two steps; firstly, as per the Whitley proposals and then secondly, to take account of the particular problems of the NBTS. He emphasized to Dr Moore the need to keep our document alive.

(e) Associate Specialist Appointments

Dr Pickles reported that she had discussed the matter with the Medical Manpower Division and it was not yet in a position to respond formally. It was suggested, however, that the new "staff grade" posts (Achieving a Balance) might be more appropriate. Dr Ala reminded Directors that his application for the Associate Specialist had been turned down and he hoped that the National Directorate would support the continued need for the grade in the Transfusion Service.

(f) Clinical Grading Structure

Dr Harrison tabled correspondence about the contradictory advice she had received from the DHSS as to whether or not the 10% responsibility allowance would continue to be paid to Team Leaders. Dr Moore indicated that the most recent letter from Mr N. B. J. Gurney endorsing the report of Dr Harrison's group was the definitive view. The Chairman expressed disappointment that the working party paper had not been circulated and discussed before it was sent to the DHSS and asked what scope there was for local agreements. After discussion it became clear that the need for an improved career structure for donor attendants was widely accepted. It was noted that the letter from Mr Gurney referred to the fact that "further advice should be welcome" and

it was agreed that the Chairman should write to ensure that even if an interim settlement were all that could be achieved immediately, further talks were essential.

4. BPL Update

Dr Lane began by referring to a shortage of Varicella Zoster Immune Plasma. He anticipated receiving approximately 100 kg this year but needed nearer 500 kg per annum to satisfy requirements. He referred to screening by John Barbara at Edgeware who had found 17 suitable plasmas in 1,000 blood donors. He asked if some other Centres could look at the feasibility of similar screening.

Turning to Factor VIII, he reported that the issue of 15,000 vials of 8Y per month during July, August and September would increase to 17,000 from October (equivalent to 50 million i.u. per annum) rising to 20,000 per month from January. The current yield of Factor VIII was 145 i.u. per Kilogram. Issues of Albumin were imminent with 20,000 bottles in October and 25,000 monthly from November. Production of 500 ml bottles of 4.5% Albumin would begin in November and would be issued from January at a rate of 5,700 per month. Dr Lane referred to factors which continued to influence output. Firstly, BPL had still not taken over the new building because essential utilities were not yet adequate to be termed "fully commissioned". Secondly, there were growing difficulties with staff with the highest ever turnover. Indeed staff could become the rate limiting factor in output. It was disappointing that even the special Terms and Conditions of Service introduced 3 years ago could no longer attract and hold staff in an employment market which had changed dramatically. New proposals were in hand.

Looking ahead, Dr Lane remained optimistic that improvements in Factor VIII yield would be achieved even though this year's target of 165 i.u./kg had not been met. The target for the new building was 90 million i.u. per annum. Dr Lane indicated that recent calculations taking account of differences between gross and net tares for plasma receipts and wastage due to underfilled distorted packs had indicated that the plasma stock was being eroded faster than had been estimated and that expansion in the plasma harvesting programme planned for the next 3 years would need to be achieved in 2. Responding to the Chairman, Dr Lane indicated that the attainment of self-sufficiency in Factor VIII remained problematical and was made more difficult by the independent line taken by Haemophilia Directors. He was concerned that guidelines prepared as recently as 6 months ago nominating 8Y as the product of choice were to be revised to include at least 2 other products as having equal merit. He anticipated that this would lead to the Haemophilia Service using all the factor VIII produced by BPL and continuing to purchase significant additional amounts. The Chairman pointed out the importance of making RHA's aware of what measure would be needed to achieve 550 tonnes per annum particularly as this would be required sooner than expected.

Dr Gunson drew attention to several problems for RTC's. Firstly, there was the need to accelerate the achievement of 550 tonnes of plasma per annum. Secondly, the recently identified losses of 7 or 8% (due to the inability of equipment at BPL to handle certain packs) needed to be replaced; there was therefore an urgent need during the current year to increase the input to BPL from 27 tonnes per month to 30 tonnes per month during the current year.

Next year's increase to 450 tonnes per annum, would require additional funding but he was aware that RHA's were sceptical about additional funding in plasma harvesting while they continued to pay for Factor VIII and Albumin. He indicated that the plasma supply group would convene after the RTD Meeting.

Dr Harrison asked about the feasibility of BPL buying regional plasma from 1.04.89 to assist with funding for additional plasma harvesting. Dr Moore confirmed that this was the date and that RHA's would be informed within the next month. Dr Rogers appealed for free distribution of the products represented by the present plasma mountain for which no revenue from BPL had been received by RTC's. Asked about differential payments based on the quality of plasma, Dr Lane indicated that industry distinguishes between recovered plasma and pheresis plasma, the latter being better. The Chairman summarized the discussion.

1. The need to increase plasma between now and the end of March 1989 by 10%.
2. In 1989/90, the need to increase from 350 tonnes to 450 tonnes per annum.
3. The question of yield is being actively pursued with an immediate target of improving from 145 iu/kg to 165 i.u./kg.
4. Fractionation at 550 tonnes per annum would not achieve self-sufficiency for Factor VIII unless treatment policy was reviewed by the Haemophilia Directorate.
5. There is a need to provide information to the Department of Health both for Ministers and for RHA's about obstacles to these targets.
6. The Department of Health would circulate a document informing regions of pricing policies.

Dr Fraser expressed serious concern that any of those present could really achieve the increase in plasma supply which was being discussed because of problems not only with funding, and with staff but also falling donor panels.

Dr Lane asked for the assistance of Directors in identifying any monoclonal anti-D products being sold in the UK by Ortho or by Biotest. BPL had licenced 2 monoclonal anti-D lines for use by these companies provided that the final products were not offered for sale in Britain. He believed that this stipulation was being ignored and legal steps were in hand. Specific information would be welcomed.

5. HIV Update

Dr Gunson confirmed that the arrangements for HIV 2 testing were working satisfactorily.

Dr Wagstaff asked Dr Gunson to comment on a recent statement by Dr Mortimer that, bearing in mind the efficacy of current screening tests, confirmation by Western Blot was of no value. Dr Gunson said that the value of Western Blot had always been controversial. It remained important that a screen positive result should be assessed and confirmed by a range of tests before

the donor is approached. Dr Gunson referred to recent studies on a recipient of blood which was Dupont screen positive (confirmatory test negative apart from an isolated P24 band in the Western Blot) who had developed changes post-transfusion, showing an identical and reproducible pattern by the Western Blot to that seen in the donor.

6. NBTS Ethical Committee

The Chairman indicated that he had received a letter from Dr Contreras in which she asked that the role of an NBTS Ethical Committee be discussed. This had been prompted by the fact that local ethical committees were more accustomed to looking at the projects involving patients and did not readily appreciate the different considerations which apply to healthy blood donors. It was agreed after discussion that Local Ethical Committees could not be bypassed but prior consideration and approval from a BTS Ethical Group would help considerably in dealing with local colleagues. Dr Gunson agreed to the suggestion that all major projects should go to the Research Committee of the National Directorate for peer review which would include looking at the ethics of the proposal.

7. Working Parties

(a) NIBSC/UKBTS Liaison Group

Draft papers from all Working Groups covering most topics had been circulated or were tabled. Extensive discussion revolved around whether the final documents should be "proposed requirements" or "guidelines". Good pharmaceutical manufacturing practice will be defined in an imminent EEC document which will largely supersede the obsolescent UK 'orange guide'. It was also noted that European market changes in 1992 may well impose specific statutory requirements. The consensus view of the meeting was that the specifications currently being formulated should be seen as guidelines internal to the UK transfusion and fractionation professions, guidelines which are a first attempt at National all-embracing standardisation in this field. It was agreed they will need regular revision to more, or even less, strict limits in the light of what is reasonably achievable in practice before they should be adopted as "requirements" with all their legal connotations. There should also be improved UK input to co-ordination of the separate interests of transfusion centres, fractionators and licencing bodies both inside and outside the UK.

Reports from individual Working Group Chairman focussed mainly on contentious issues, including the following:

Virus inactivation: 10^{10} particle reduction is wanted but a 10^5 reduction is recognised as the limit of practical validation in any single stage. Additional procedures may improve on 10^5 but not in a simple mathematical way.

A.L.T. testing: results of an impending UK multicentre trial (possibly including Chiron testing) will not be available till late Spring 1989. Definition of "normal" values is also unclear. The A.L.T. issue may be omitted from first guidelines as unresolved.

Serological standards: NIBSC will be involved in production of standards but insist the guidelines refer only to standards "where they exist".

Donor arm cleansing: is of course essential, but suffers from a dearth of hard scientific data to validate either procedures of security of products.

Transfusion acquired infection: similarly lacks hard data, and also a formal reporting system.

Further General Points

It was agreed that the guidelines should be published in toto, rather than piecemeal according to availability of the various sections. It is intended that the final documents will be put out for consultation with RTC's Haemophilia centres and Department of Health in the New Year, and the first edition will be released by 1st April 1989. Thereafter wider consultation with industry, European and World Health bodies etc, would lead to modifications in subsequent editions.

Long term follow-up will need a small secretariat which could perhaps most appropriately be located at NIBSC.

(b) Bone Marrow Transplant and Platelet Working Party

Already dealt with earlier in the agenda.

(c) Anti-D Working Party

Dr Tovey reported that the Anti-D supply appeared satisfactory. Plans for the Antenatal Trial using 2 x 250 i.u. of anti-D were progressing.

8. Reports from Divisions

(a) Eastern Division

The meeting had not taken place. The election of a new chairman by postal ballot was in hand.

(b) Northern Division

Items not already discussed during the meeting included the topic of CMV Immunoglobulin; Dr Gooi had circulated a paper discussing the indications for use. Dr Shepherd had proposed that the possibility of using BPL as a clearing house for non-urgent postal communication between Transfusion Centres be explored. Such an arrangement would have been of particular value during the recent postal strike. This suggestion was discussed briefly and was discouraged by Dr Lane. The question of accepting donors having acupuncture outside medical supervision was raised again following an approach from the secretary of the Acupuncturists' professional body. After brief discussion, Directors expressed reluctance to change earlier decisions on this matter, ie that medical supervision of acupuncture was essential for those wishing to be blood donors subsequently.

(c) Western Division

The only point not already covered by the agenda was a discussion of cross-charging, prompted by steps taken by the West Midlands RHA to introduce the system of cross-charging for BTS services.

9. Any Other Business

(a) BBTS Books

Dr Lee told the meeting that approximately 300 each of the Educational Book and the Book of Abstracts produced for the Wembley Conference were still available. It had been proposed at the BBTS Council Meeting, the preceding day, that these might find a useful role as institutional copies in Transfusion Departments in District General Hospitals. He asked if Directors would be willing to distribute these books to appropriate hospitals in their Regions and, as there were insufficient for every hospital in the country, to place them where they would be most useful. This was agreed. Dr Whitrow asked that Scotland be included in the distribution.

(b) HIV Conversion

Dr Lane drew attention to 2 reports of HIV Conversion following treatment with 8Y and emphasized that both of these had no foundation. One had arisen from a transcription error resulting from confusion of "seroconversion" with "Factor VIII Inhibitor". The other report alleged sero conversion 8 weeks after receiving 8Y in a previously untreated patient. Further investigations showed that this patient had, in fact, received 15 bottles from 3 batches of untreated Armour product prepared from untested plasma. He asked for assistance in dispelling these rumours.

(c) BPL RIA for HBs Ag

Dr Lane noted that fewer Centres were using the BPL RIA test for HBsAg. He was concerned that four positive plasma donations had been received recently at BPL, one of which was included in a batch of Factor VIII resulting in the loss of 2,200 bottles. These four positives were notified to BPL when confirmatory results from PHLS were received by the Centres concerned. He appealed for attention to detail in documentation and despatch so that no plasma which was screen positive for HBs Ag was sent to BPL.

(d) Health Circulars

Dr Contreras asked if health circulars relating to the Transfusion Service could be circulated by the new National Directorate.

(e) ABSD

Colonel Thomas made three brief points. Firstly, operation Wintex (an international exercise involving NATO cooperation) was approaching. On the

day, he would telephone all Centres to establish what blood could be available. Secondly, he indicated that the classification of war plans had been downgraded from "secret" to "restricted". Thirdly, next year will mark the 50th Anniversary of Blood Transfusion in the Army and an event to mark this will be held on 3.09.89 to which all would be invited.

(f) Retirements of Dr Tovey and Dr Smith

The Chairman observed that this would be Dr Tovey's last attendance at an RTD meeting and expressed the appreciation of those present for his long membership of the RTD Committee. Dr Wagstaff also referred to Dr Smith's imminent retirement and hoped to offer similar good wishes to him when the date was known.

(g) Future Meetings

Dates for future meetings were agreed as follows:

18 January 1989 (Hannibal House)
12 April 1989
28 June 1989
4 October 1989
24 January 1990