REGIONAL TRANSFUSION DIRECTORS MEETING

Minutes of the 208th Regional Transfusion Directors Meeting
held in Room 67, DHSS Hannibal House, on Wednesday
29th June, 1988 at 11.00 a.m.

Present: Dr. W. Wagstaff (Chairman)
Dr. F. A. Ala
Dr. D. J. Anstee
Dr. A. K. Collins
Dr. M. Contreras
Mr. B. Crowley
Dr. I. D. Fraser
Dr. T. B. Gibson
Dr. H. H. Gunson
Dr. J. F. Harrison
Dr. U. Jayaswal
Dr. R. S. Lane
Dr. D. Lee
Dr. W. M. McClelland
Dr. R. J. Moore
Dr. J. A. F. Napier
Dr. H. Pickles (DHSS)
Dr. K. Ll Rogers
Dr. A. J. N. Shepherd
Lt. Col. M. J. G. Thomas
Dr. L. A. D. Tovey
Dr. W. Whitrow

1. Apologies

Apologies for absence were received from Professor J. D. Cash, Dr. D. J. Darnborough, Dr. C. C. Entwistle and Dr. D. S. Smith.

2. Minutes of the 207th Meeting

The Minutes of the 207th Meeting were accepted subject to an amendment to Item 4; Dr. Gunson pointed out that the ten subjects found by CNTS (Para 3) were not blood donors but had been found by screening samples from STD Clinics.

3. MATTERS ARISING

NBTS Management Study

Directors were disappointed when Dr. Moore told the meeting that the report of the study was with Ministers and that he was unable to say when it would be released though he hoped that this would be within weeks rather than months. Concern was expressed by Dr. Fraser about the deteriorating position in Bristol where he had ten vacancies for trained MLSO's which he could not fill. Dr. Rogers indicated that he had not yet been able to agree his capital or revenue Budgets and believed that the RHA were deferring decisions pending the publishing of the report. Dr. Tovey reported that Mr. Giles Shaw MP had visited the Leeds Centre in response to an invitation from the Scientific staff and had written to the Minister highlighting problems.

Dr. Moore assured Directors that there had been a lot of progress since the last RTD Meeting and hoped that the report would be released before the end of July.

Charging for Anti-D Immunoglobulin

Dr. Moore told the meeting that the DHSS view was that a charge should be levied for Anti-D Immunoglobulin issued to the private sector. He saw no reason why Anti-D should not come into line with other products. He believed that the charge would be only a small part of the total bill for a termination of pregnancy and would therefore not be a factor in preventing eligible patients from receiving it. Dr. Tovey mentioned that the Anti-D Working Party had hoped that a charge could be levied on overseas patients but Dr. Moore believed that it would be unworkable to distinguish between these and UK nationals. Dr. Wagstaff asked if charging for Anti-D could be regarded as a Contract to supply it even if another National shortage occurred. Dr. Moore indicated that as Anti-D was not a licenced product, it should therefore be treated similarly to whole blood, i.e. that issues to the private sector were subject to availability for all patients. Dr. Tovey referred to special problems of supply in Brighton; Dr. Rogers believed that these were due to difficulties in transferring the product between regions. After further discussion it was clear that opinion was divided and a vote was taken with ten for and three against instituting charges.

Blood Pack Purchases

The Chairman referred to the long held concern that a monopoly situation might not be in our long term interests. Dr. Moore reported his discussions with the Procurement Directorate who had indicated that keeping a second supplier in the market would not necessarily be more expensive, and that the supplies division wished to explore again the possibility of a National Contract. The Chairman asked if it was envisaged that a Central Contract could be placed for less than 100% of the packs purchased. Discussion turned to the current position with tear-down technology; the letter from Dr. Perry suggested that technology was not as advanced as had been thought. Dr. Lane commented that the Scots were evaluating a Tuta design and that the machine designed by Haemonetics would be used to assess packs at BPL from several manufacturers but that he was not yet in a position to do this.

BPL Up-Date

Dr. Lane referred to the serious international shortage of Factor VIII which had prompted BPL to concentrate on the provision of Factor VIII from the new building. Output was currently 15,000 vials/month which he hoped would be 20,000/month by September, equivalent to 50 million i.u./annum. Over the summer it was hoped to increase fractionation from two pools to three pools/week. He recognised that there would be problems with Factor VIII supply in the next few months. He referred to a recent circular from the Directors of Haemophilia reference centres indicating that 8Y and 9A are the products of choice for new patients.

Both Anti-D and normal Human Immunoglobulin production were satisfactory.

Problems with Albumin continued. Supplies had only been maintained by using facilities in the old building to finish fraction V from the new building. Two problems were responsible for the delay; the system for sterilising the

containers and the pasteurisation ovens. Dr. Lane indicated that he believed that these problems had now been resolved and that bottling of Albumin would begin in the new building on 4th July, and that this product would be available for issue eight to ten weeks later, i.e. in September. He indicated that the May issue had been made and that the June issue would be halved. He indicated that there would be no further issue of Albumin until September. He will be asking NIBSC to expedite the approval processes and asked for Departmental support for this. 20% Albumin, manufactured in the old building, was in normal supply. Dr. Fraser asked if the CBLA would write to Regional General Managers to provide them with first-hand information about the problems. He suggested that the letter should come from the Chief Executive. Mr. Crowley agreed as a one off but indicated that Gaynor Fryers was normally responsible for circulating this sort of information. Dr. Tovey anticipated that the Albumin shortfall would result in his being £1 million pounds overspent in the current financial year. Dr. Lane reminded Directors that he had predicted a stock-out situation at some point during the commissioning of the new building and that he had wanted to buy Fraction V at a competitive price from the USA a year ago to try to avoid this, but had been advised not to do so. Dr. Tovey asked about intravenous immunoglobulin and Dr. Lane reported that the IVIg line had not yet been commissioned to GMP standards. His current priorities were Factor VIII and Albumin. He reminded Directors that he had asked for volunteers to assist with evaluating the new product. So far only Dr. Wallington had offered. Dr. Lane indicated that Haematologists as well as Immunologists would be welcome. Dr. Napier asked if the supplies of 20% Albumin could be increased but Dr. Lane indicated that he did not have the manpower to do this.

Disclosure of Information for Criminal Investigative Purposes

The Chairman referred to a letter which Dr. Moore had recently written indicating the DHSS view.

Package Inserts

Dr. Moore indicated that he had the information to respond and suggested that this would be most helpful if it were circulated which he undertook to do.

4. HIV Update

Dr. Gunson reported that the letter which he had written to all RTD's following the last meeting had been severely criticised by Scots colleagues who had questioned the authority for the letter and had asked if the contents had ministerial approval. Dr. Gunson reminded the meeting of the background to his letter. The overall policy relating to HIV had been established by the AIDS Working Party of the RTD's on which the Scots were represented. In May 1987 it was agreed that testing for HIV2 should be undertaken where appropriate and four of the regions represented on the Working Party had agreed to send samples. This had resulted in too many irrelevant samples and Dr. Mortimer had produced a list of fifteen relevant African countries following which some regions had responded and others had not. HIV2 testing had retained a low profile until there were reports of HIV2 infection in several European Countries including the UK. This had prompted a Meeting between Dr. Mortimer, Dr. Smithies, Dr. Tedder and Dr. Gunson who were agreed that additional surveillance was needed and that

Regions should be asked to send appropriate samples for screening. At this point the Sunday Times became interested asking what the BTS was doing about HIV2 infection and in particular what was being done with products during the wait for test results. At the Meeting of EAGA in April a paper had been discussed from the DHSS about HIV2 infection. Dr. Gunson had advised at that meeting that blood products should be quarantined until test results were available. He had presented the same view to the RTD Meeting at Birmingham the next day and this had been agreed by all present; hence Dr. Gunson's letter a few days later. Dr. Gunson said that it was the imperative language in the letter to which the Scots had taken exception and that Dr. McClelland had taken the letter to the EAGA for further discussion. Dr. Gunson indicated that he still believed that screening for HIV2 was important. He said that the laboratory at Manchester had had an opportunity to test the serum of the UK case which had given an equivocal result with first generation DuPont, a negative result with Wellcome Monoclonal and a positive result with second generation DuPont. Dr. Wagstaff commented that Sheffield took part in an informal annual QA exercise from CNTS and that this year's panel had included four examples of HIV2. Detection had been very patchy with current tests. Dr. Whitrow pointed out that part of the Scots' concern was about the effect of testing on stocks of plasma awaiting fractionation - would this become another mountain of untested plasma which would need to be discarded? He was also concerned about the speed of return of results. The Chairman indicated that he believed that if Dr. Mortimer received more samples that he would be able to provide a more rapid response. He asked if there was support, pending further considerations by the EAGA, for a policy of quarantine of products and this was agreed. Dr. Whitrow believed that the Scots would probably comply on a voluntary basis in spite of reservations about the plasma supply. Dr. Gunson indicated that Dr. Pickles had had a letter from the Foreign Office amending the list of fifteen countries. Dr. Pickles commented that anonymous ante-natal testing had revealed another HIV2 infection.

Dr. Gunson referred to a letter from Dr. Margaret Supran asking for full donations from donors found to be screen positive and also for donations from some donors who were negative in the HIV screening tests.

5. Bone Marrow and Platelet Donor Panel

Dr. Fraser told the meeting that he had not yet had a response to the request from the Executive for funding for three Clerical Officers and an Associate Specialist. He indicated that this was now a matter of urgency as the South West Region and the charity concerned could only provide support for a further limited period. He said that he had had a response to his recent letter from all but four centres. Four centres had indicated that they could increase the number of volunteers handled (three of these were supported by BBMDA); nine out of twelve centres had indicated that they had a specialist supervising HLA. Some regions, e.g. Edgware and Manchester issue a lot of HLA type platelets; eight centres had indicated that they would find a platelet Registry useful, though four would not use it often. Eight out of twelve centres had indicated that they would use the publicity material and Dr. Fraser indicated that 50,000 copies were to be printed in Scotland. He re-iterated the urgent need for resources to support this project and emphasised that unless it was funded properly that the scheme would fold. He reminded the DHSS of their enthusiasm two years ago and pointed out that the amount which he was seeking, around £25,000, was modest. Dr. Pickles accepted that there appeared to have been some delay in the

Department's response. She had been asked to look through the relevant files and correspondence to establish what committment the DHSS had made and this was in hand. Dr. Fraser said that the ISBT Conference would include a session to discuss unrelated BMT which was receiving enthusiastic support in several countries.

6. Publicity Budget

Dr. Moore sought to shed light on confusion about the sums involved. The sum of £250,000 had been budgeted for the current year but this had been increased to £400,000 by an additional sum of £150,000. He had hoped that a further £50,000 would be available. The Chairman referred to the minutes of the Publicity Sub-committee and confirmed that £400,000 was the amount which had been sought. A brief discussion of how that publicity money could best be spent followed. Dr. Whitrow commented that the Scots had recently undertaken a survey which showed that the most fruitful target for publicity was lapsed donors and the next most useful spot TV advertising. Dr. Moore said that COI had commissioned a survey to look at the effectiveness of publicity and that the report on this was with RDO's. The Chairman asked that the summary of this report and the minutes of the Publicity Sub-committee Meeting should be circulated to allow further discussion at the next Meeting.

7. BPAS and Anti-D Donors

Dr. Tovey reported that the topic had been discussed by the Anti-D Working Party and that it had been agreed that this offer of help should be accepted. It was recognised that the numbers would be small.

8. Donors Receiving Treatment for Acne

Dr. Tovey reported that he had approached Professor Cunliffe, an authority on the treatment of acne, who had recommended an interval before blood donation of at least six weeks following Roacutane and at least two years following Tigason. Dr. Pickles suggested that this information should be available to the Patient Information Group for inclusion in their information leaflets about drugs and undertook to follow this up.

9. History of Transfusion in Africa

The Chairman indicated that he would have assumed that donors with a history of transfusion in Africa were automatically in a risk group but recognised that it was not included on the AIDS leaflet. Should it be included in the re-write? Dr. Pickles indicated that the Foreign Office would need to be consulted. The matter was discussed recognising the 'catch 22 situation' of on the one hand, drawing attention to the links between transfusion and AIDS and on the other hand, taking every possible step to exclude donors in this risk category. It was agreed that this would be best dealt with by asking all donors about a history of transfusion and asking sessional MO's to pursue the when and where with donors who had been transfused in Africa.

10. HIV Information on Donors Joining Private Health Care Organisations

Dr. Shepherd had raised this item after discussion with Dr. Gunson who felt it was important that all regions should respond in the same way to such requests. It was agreed that the situation was similar to that which had

already been discussed in relation to releasing HIV information to Insurance Companies which would only be done with the consent of the individual donor.

11. Working Parties

Anti-D Working Party

Dr. Tovey summarised the deliberations of the recent Meeting.

1. There had been an improvement in the supply of Anti-D Plasma in the past three months. There was a need to create a buffer stock at BPL before this additional material would be fully reflected in issues.

2. Pro-rata distribution appeared to be working fairly saisfactorily. It had been agreed that any surplus should go towards the buffer stock.

3. Arrangements for the small dose ante-natal trial (2x250i.u.) were progressing with Professor Whitfield.

4. The specification for Anti-D Source Plasma had been discussed. It had been agreed that a lower limit of 30i.u./ml was appropriate with BPL continuing to specify the proportion of donations of less than 50i.u./ml which would be acceptable.

6. It had been agreed that the DHSS recommendations (1977) and Appendix (1982) on the use of Anti-D Immunoglobulin, needed to be revised and re-published.

7. Loss of Source Plasma because of damage to packs in transit was discussed again. It was noted that in most cases, the practice in Scotland is to include the contents of damaged packs in fractionation pools.

8. Dr. Contreras had undertaken to circulate details of the accreditation of donors of immunising cells used by each centre.

Scientific Staffing Group

Dr. Fraser reported that following the last Meeting he had written to the HAP Division drawing attention to the particular problems in the NBTS. A reply had been received that the matter was already being examined in conjunction with MAS and that Dr. Fraser's submission was not required. Dr. Gunson commented that the HAP/MAS discussions related to hospital staffing and believed that this reply had unfortunately overlooked the particular problems of the NBTS. He asked if Dr. Moore could pursue the matter.

Committee for the Production and Distribution of Plasma Products

Dr. Gunson drew attention to the need for more plasma for fractionation indicating that by 91/92 540 tonnes/annum would be needed. The principle factor behind this increase was poorer yields of Factor VIII. Dr. Gunson said that he would circulate a paper discussing ways of increasing the plasma harvest. Dr. Ala commented on the dramatic increase of the use of Factor VIII in West Midlands which had risen from eight million i.u. to thirteen million i.u.

UKBTS/NIBSC Liaison

It was reported that the recommendations for procedures were taking shape. The next Meeting for the 'core group' was scheduled for September and by then the Working Groups should have met and produced a final draft of their contributions.

Bar Code Working Party

Dr. Gunson paid tribute to the useful work done by this group. The Chairman commented that the nomenclature in the BCWP documents would need to be reconciled with those soon to be issued by NIBSC.

Automated Grouping User Group

The Chairman had been approached about the need to reconvene this group. Dr. Robinson had acted as Chairman briefly but found that her commitments would no longer allow her to do so. Dr. Lee had been asked and had agreed to act.

12. Reports from Divisions

Northern

Dr. Tovey asked if Dr. Napier could disseminate some information about the computer consortium involving Cardiff and other centres. Dr. Napier indicated his intention to produce and circulate a fact sheet.

Dr. Tovey reported that Dr. Lee had been nominated as the Chairman of the Northern Division.

Dr. Gunson drew attention to a new EEC Directive relating to the definitions of plasma products. This would affect mainly the fractionation laboratories, applying to existing products by the end of 1991 and to new products from 1992. It would also relate to Transfusion Centres providing source plasma. Dr. Gunson indicated that he was endeavouring to ensure that the Transfusion Services in the UK would be fully consulted.

Western

Dr. Ala reported that the Division had discussed the criteria for the selection of bone marrow donors. Dr. Fraser confirmed that his group would be providing advice on this topic.

The Western Division felt the need for concerted and unanimous action on the new clinical grading structure for nurses.

Dr. Ala asked for advice on dealing with problems relating to an Associate Specialist appointment in his Region to be in charge of apheresis. Permission for this had been refused by the DHSS. Dr. Wagstaff asked Dr. Pickles to make enquiries and recalled that the BTS had previously been recognised as a 'special case' for Associate Specialist appointments.

Eastern

No Meeting.

13. ANY OTHER BUSINESS

Clinical Grading Structure

During discussion it emerged that although there was general agreement that a uniform policy would be advantageous, suggestions were made for flexible interpretation of the guidelines and for taking the opportunity to improve the career structure for BTS nurses. It was agreed that a small working group to include Dr. Harrison, Mr. Peter Hynes, Miss Pat Mosely, and the Regional Personnel Nursing Manager from North West Thames should convene as a matter of urgency. It was agreed that each region would send information to Dr. Harrison about their current nursing and DA structure together with thoughts on re-grading.

Haemolytic Transfusion Reactions

Dr. Contreras offered to collect and collate reports of haemolytic transfusion reactions with the help of Dr. de Silva. This was agreed.

CMV Immunoglobulin

Dr. Contreras asked if information was available from the trials of this product. The Chairman agreed to ask formally for results of these trials.

NEQAS Blood Group Serology

Dr. Napier drew attention to recommendations with the results of a recent Exercise for modifications of serological techniques which appeared to be at odds with other current advice, e.g. guidelines for compatibility testing. Dr. Fraser indicating that the comments were his and were intended to help the vast majority of hospital haematologists, who, he felt, needed some sort of comment or advice with the NEQAS results.

14. Date and Venue for the Next Meeting

The next meeting will be held on Tuesday 4th October at Hotel St. George, Ripon Road, Harrogate.