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REGIONAL TRANSFUSION DIRECTORS MEETING

Minutes of the 202nd Regional Transfusion Directors Meeting held at D.H.S.S. Hannibal House on Wednesday, 21st January, 1987 at 11.00am.

Present:
Dr. I. D. Fraser (Chairman)
Dr. F. Ala
Dr. G. W. G. Bird
Dr. J. D. Cash
Dr. A. Collins
Dr. M. Contreras
Dr. J. Darnborough
Dr. C. C. Entwistle
Dr. H. H. Gunson
Dr. J. F. Harrison
Dr. D. Lee
Dr. M. McClelland
Dr. R. J. Moore (DHSS)
Dr. J. A. F. Napier
Col. D. Robson
Dr. A. Shepherd
Dr. D. S. Smith
Dr. A. Smithies
Dr. L.A.D. Tovey
Dr. W. Whitrow
Dr. W. Wagstaff
Dr. T. Wood
Dr. P. Mortimer)
Dr. R. Tedder) Item 1 only
Prof. R. Weiss)
Mr. E. Walsh Item 7 only
Mr. N. Pettitt Item 5 only

1. Apologies

Apologies were received from Dr. R. S. Lane and Mr. W. P. N. Armour.

2. HIV Update

Dr. Mortimer introduced the topic of HTLV1 with a brief summary of current knowledge about the virus. He drew attention to its prevalence in parts of Japan and also in Africa and the Caribbean and possibly in Southern Italy. A serological survey in the U.K. two years ago had identified the virus in a small number of intravenous drug abusers and a small number of HIV infected patients with PGL and in one haemophiliac who was Japanese. There were sporadic reports of leukaemia and neurological disease associated with HTLV1 infection in the U.K. restricted almost entirely to the West Indian population. The virus did not appear to produce an acute illness but was associated with tropical spastic paraparesis and with leukaemia, though in only one to five per cent of sero positive individuals with a lag of between 15 and 60 years between infection and symptoms. Many infections appeared to be transmitted vertically within families. Dr. Mortimer felt that in spite of the low prevalence and the development of sequelae for only a minority of those infected, that the BTS should act to screen both random donors and also donors whose ethnic origins were associated with a higher risk of carrying the virus. Professor Weiss supported the need to examine the problem and reported a study undertaken in London and Birmingham in which four per cent of West Indians were found HTLV1 positive with strong family clustering especially amongst children from HTLV1 positive mothers.

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available if a member of staff has a cut or abrasion. The Eastern Division concurred, pointing out that gloves do not protect against needlestick injuries. Dr. Smithies undertook to reply to Mr. Thompson. Dr. Entwistle tabled a proposal to abandoned existing donor haemoglobin tests. The Chairman asked Directors to consider these proposals which would be included on the Agenda for the next meeting.

Autologous Transfusion

Several Directors reported approaches from interested parties in their Regions. The recent Leading Article in the BMJ was discussed and although it was felt to be misleading on some points, it was agreed that the practise of autologous transfusion would grow. The Northern Division's proposal to convene a Working Group with three BTS Consultants, three Haematologists and Clinical users, e.g. Anaesthetists, Surgeons, was accepted and Dr. Lee was asked to convene the group.

QC of HIV Tests

The Chairman raised for discussion the question of more active monitoring of results of the PHLS HP and LP sera. Dr. Gunson commented that the results with HP and LP were distributed to all Centres and he assumed that this provided a basis for critial assessment of the performance by each Director. He pointed out that scrutiny of these results had enabled the identification of three poor batches of Wellcome plates. It was noted that one or two Centres were making use of HIV antigen testing for special purposes, e.g. screening of immunising and boosting cells.

3. Minutes of the Last Meeting

The Minutes of the 201st Meeting were confirmed.

4. Matters Arising

Election of Chairman

Dr. Gunson emphasised the importance of continuity of Chairmanship in view of the DHSS Management Study. He proposed that Dr. Fraser be invited to continue as Chairman for a further year. Dr. Fraser agreed to carry on for a period of a year or less until the Management Study finished. He asked that a Chairman elect be nominated at the April or July Meeting.

Anti-HBc and ALT Screening

Dr. Gunson reported that the Working Party on Transfusion Associated Hepatitis was due to meet on the following day to finalise a proposal to the DHSS to fund a limited study of 12,000 donors, looking for anti-HBc and abnormal ALT with follow-up of selected donors and possibly recipients. He said that the significance of raised ALT was uncertain, with up to 60% of raised values being due to obesity or alcohol. However, as the most recent information in the USA was seven or eight years old, another study was needed. Dr. Napier asked if consideration had been given to a study beginning with transfused patients. He was unhappy about the poor association between the markers in question and transmission of the virus. Dr. Gunson reported that this had been discussed, but was felt to be costly, difficult and not practical. The proposed approach would give information

Japanese experience suggested a two out of three chance of transmitting the virus by transfusion of HTLV1 positive blood. The Japanese recognised 21,000 new infections each year, of which 50 per cent were due to blood transfusion. In discussion, it was recognised that in some regions there were very few blood donors from the ethnic groups at risk, though in others donors of Caribbean origin were positively identified so that their red cells could be used selectively. Dr. Collins drew attention to Japanese workers in the car industry in the North East. Dr. Gunson reminded the meeting that he had 12,000 samples collected during the assessment of HTLV3 tests which could be made available. Attention was also drawn to the proposed survey of anti-HBc and ALT which would look at 12,000 samples from three centres in England and Wales and one in Scotland as another source of material for a survey. Asked about DHSS support for the survey, Dr. Smithies felt that the decision to undertake testing or screening was a clinical one for the centres who may be at risk. The DHSS would not have any objection to the studies which were being proposed. The Chairman summarised the intention to make available for testing 12,000 retrospective and 12,000 prospective samples. The three London Centres (assuming Dr. Rogers was agreeable) and Birmingham would provide samples from donors whose ethnic origin could be identified.

HIV2

Dr. Tedder summarised developments which pointed to the emergence of a second virus associated with immune deficiency, with a growing prevalence in West Africa on the "bulge" from Southern Morrocco almost to Nigeria where the incidence had risen from a very low level in 1982 to approximately 5% in STD Clinics recently. The names HTLV4 and LAV2 had both been used to describe the new virus/viruses and it remained unclear how similar these were. Professor Weiss offered additional evidence about the behaviour of the new virus and of its appearance in Europe. Professor Weiss suggested that the picture was similar to early 1970 in Zaire and that there was a need to act to minimise another epidemic. Samples from any donors who have visited West Africa would be of value, though it became clear in the ensuing discussion that to take samples on the session from donors who had been rejected because of their social behaviour during a visit to Africa would present problems in some regions. It was agreed that Sessional Medical Officers questioning donors about social activity during African visits should advise those who had had sex to seek counselling and possibly testing.

Additional FDA Recommendations

It was agreed that, as proposed in Dr. Esber's letter, that those who had engaged in prostitution should be added to the list of risk groups on the next AIDS leaflet. It was also agreed that the cut off date should conform and be changed to 1977. Dr. Smithies envisaged another reprint of the AIDS leaflet within four months. The Chairman asked if RTD's could see and comment on the final draft of the next AIDS leaflet. This was agreed though Dr. Smithies pointed out that final wording could be influenced by the publicity section at DHSS.

Wearing of Gloves

Dr. Tovey reported that the Northern Division had expressed the view that the wearing of gloves should not be obligatory but that gloves should be

about the effect of anti-HBc and ALT screening on donor panels and blood collection.

Management Services Study

The most recent Meeting to discuss the study had highlighted a number of problems in the NBTS including duplication of effort, poor purchasing policy, uncoordinated research and development and uncoordinated computerisation. Concern had been expressed about relationships between Transfusion Centres and Hospital Blood Banks. The Chairman reported that the Study Group felt that coordination between Centres needed to be strengthened but the steps which might be considered to achieve this would be expensive. Some consideration was being given to a suggestion of re-organising the service based on fewer Centres serving larger populations. The role of the CBLA in relation to the NBTS was also being studied. Nine Centres had been visited so far and the preliminary report from the Study Group was expected in April.

AIDS Donor Leaflet

The Chairman reported the initiation of a Scottish study of the effectiveness and acceptability of donor literature.

HIV Antibody/Elisa Conversion

The Chairman reported that this topic would be discussed by the EAG at their next meeting.

Volunteer Bone Marrow Transplant Panel

The Chairman reported that the Steering Group had met and that two working groups had been formed, one under the Chairmanship of Dr. Bradley to examine DNA technology and the other under the Chairmanship of Dr. Gillon to study literature for prospective marrow donors and their subsequent documentation. He hoped that the two groups would convene together at the end of February to report progress.

NIBSC/NBST Interface

The Chairman reported that he and Dr. Cash had met Dr. Geoffrey Schild a few days previously who had welcomed involvement of NIBSC to look at the products and reagents from Transfusion Centres as well as fractionation products. He believed there was a need to set up a core group for the U.K. with representatives from the NBTS and NIBSC to include Duncan Thomas and Peter Philips and the Directors of the two Fractionation Laboratories. The Group would be known as the NIBSC/UKBTS Liaison Services Group on Guidelines for the Manufacture of Biological Products used in Transfusion Medicine. It was suggested that this Group would write specifications for blood products and that, where appropriate, NIBSC would provide biological standards. The Chairman said that he would be approaching Chairmen of Divisions for nominations for the core group. From the core group it was proposed to form three working parties to look at therapeutic products prepared by Regional Transfusion Centres; at therapeutic products produced by fractionation centres; and at diagnostic reagents for immuno-haematology. It was hoped that a Transfusion Director would chair the core group with an ongoing committment over two or three years. The Chairman remarked on the need for

funding for some aspects of this work. Dr. Smithies acknowledged a major interest by the Medicines Division and undertook to sort out if funding would be available from there or from central DHSS funds.

5. BLOOD PRODUCTS

Albumin

The Chairman expressed concern that large amounts of HAS had been distributed at very short notice by BPL apparently to satisfy BPL policy that all products issued after December 1986 would have been prepared from HIV tested plasma. This action by BPL had raised doubts about the status and safety of the product. Should Clinicians be advised accordingly? Mr. Pettit explained that the BPL deadline had arisen because of their interpretation of a Parliamentary answer during 1986 and that Dr. Lane, in correspondence and discussion with the Committee of Safety of Medicines had confirmed his position since December. Mr. Pettit did acknowledge, however, that Factor XIII and Factor VII were to be made exceptions and that the December deadline might be open to retrospective revision. Dr. Moore indicated that the December deadline referred to in the Parliamentary answer had been intended to relate to Factor VIII and Factor IX and indeed the statement could still be interpreted in this way. He gave a positive assurance that the Human Albumin Solution which had been issued recently and prepared from untested plasma was entirely safe.

Anti-D

Dr. Tovey reported on the Meeting of the Anti-D Working Party which had examined the input of raw plasma from Centres, the anticipated increases in input and had prepared a provisional pro-rata table. Mr. Pettit provided detailed information about the production position with both 500iu and 250iu ampoules of Anti-D. A high intake of raw plasma in October had not been sustained and intake had fallen back to levels which only just sufficed to balance current issues. He anticipated that at the end of March virtually all stocks of 500iu doses would be issued just before the next batch of anti-D was released. Asked about the choice of Cutter to provide anti-D recently, he indicated that this was the only Company able to provide the amount needed in the time available. During the discussion, Dr. Cash offered to consider how S.N.B.T.S. might be able to assist with another shortfall. Dr. Gunson drew attention to the fact that Anti-D was also affected by the December 1986 deadline for the issue of products prepared from untested plasma. He believed that there were significant stocks of 2,500iu doses of Anti-D Immunoglobulin and that if these could not be released, the present difficulties with Anti-D would be exacerbated. It was agreed that the relevant part of the Minutes should be prepared and sent to Dr. Lane at the earliest opportunity.

6. Central Committee for Research and Development

Dr. Gunson reminded the Meeting that the M.R.C's Committee for research in blood transfusion had been wound up in 1982. The Central Committee on

Research and Development had been set up under the wing of the CBLA and included one Scottish member who was there in a personal capacity. Dr. Moore had been examining the function of the committee and had made the proposals for restructuring it which had been circulated. Dr. Gunson pointed out that the committee, both in its present form and in its restructured form, had no funding and could therefore act only in an advisory capacity. Dr. Cash felt that the effectiveness of the committee would be seriously hampered by the absence of funds at its disposal. Dr. Moore emphasised the coordinating role of the Committee. After further discussion, the meeting gave general support to the new proposals.

7. Blood Bags - Central Purchasing Policy

The Chairman introduced Mr. E. Welsh, the Regional Supplies Officer for N.E. Thames R.H.A., who spoke to his proposals which had been circulated. He indicated that in response to an undertaking to buy bags from Travenol for the next three years, that these would be available at a price which was better than that being offered to any individual Centre at present. Travenol would wish to work with Directors to ensure that we did not fall behind with new developments and technology. He reminded Directors that Travenol were the only manufacturers of bags in the U.K. and that they were under pressure from their U.S. managers to improve their present marketing position. In response to concern about the opportunity given to competitors to tender, Mr. Welsh replied that he was obliged to advertise within Europe but he believed that no other Company was in a position to supply. Dr. Tovey pointed out that the pattern of purchasing over many years had kept at least two suppliers in the market and he doubted if the 20% which Travenol would not have in a contract was sufficient to retain the interestof other suppliers. Mr. Welsh replied that the pattern of purchasing at the present time was infact very similar to what was proposed in the contract. Dr. Wagstaff expressed concern about the position if blood collection were to fall by 20% during the next three years. He also asked about the ability of the N.B.T.S. to change pack format during the contract. Mr. Welsh replied that Travenol already recognised an obligation to meet necessary change and he pointed out that the contract could be terminated if Travenol did not meet our requirements. Dr. Cash expressed strong reservations about the proposal and indicated that Scottish policy was to have a major involvement from more than one manufacturer. It was pointed out, however, that this option was not available in England and Wales because there was only one manufacturer making the I.P.P. The view was also expressed that a contract of this type might be more appropriate in a years time when tear-down packs should be available. Information regarding progress on this should be soon forthcoming from the single pack committee. After further discussion the Chairman advised Mr. Welsh that the feeling of the Meeting was that a widely drawn advertisement should be placed and that this should include pack requirements for Wales. He asked if tenders would be available by July and who would adjudicate on the merits of the tenders. Mr. Welsh indicated that tenders would probably be available by July, that he would adjudicate, but that he would welcome assistance.

8. Private Blood Bank in Gloucester

The Chairman reported that a private blood bank called the Lister Arthur Medical Centre had been established in Gloucester. This was a private business concern who have obtained medical advice from Dr. J. Sharp who is a private haematologist working in London. The aim of this private blood bank is to collect units of blood from individuals and store it for them until

such a time they may require a blood transfusion. The proposal is to charge £465 to lay down four units of blood and then charge £165 per annum for keeping it. Dr. Fraser said that he had reported the development to the DHSS and that Dr. Sharp had given him the impression that he had DHSS approval. Dr. Sharp had also said he intended to visit all Transfusion Directors to seek support for this scheme. The project was for patients in the private sector and donations would be accepted from all parts of the U.K. Asked about the role of the Medicines Inspectorate, Dr. Moore said that the DHSS were in the process of clarifying this.

Private Sector Charges

The Chairman asked for D.H.S.S. guidance on whether or not a charge should be made for blood which had been issued to the private sector and was returned before its expiry date. From the discussion it emerged that at least three Regions are charging or are about to charge for all blood issued to the private sector irrespective of whether or not it is returned. It was noted that the existing agreement made no provision for charging for blood which was returned in date and Dr. Tovey reminded Directors that this was based on their collective decision several years ago. Dr. Moore said that a meeting was being arranged in the near future with the private sector to review charges.

9. NEQAS and Blood Group Serology

The Chairman advised Directors that they would receive a letter from himself, Peter Philips and Colin Whitton to the effect that NEQAS Exercises in Blood Group Serology between now and April had been cancelled. This was because Colin Whitton had been moved to BPL Diagnostics and was no longer available and he expressed concern that the exercises had been cancelled without any consultation with himself as organiser of the exercises, with Dr. Philips or with Professor Jenkins who is the Chairman of the Steering Panel. He indicated that it was most unlikely that NIBSC would be ready to start issuing NEQAS Exercises until September at the earliest. Dr. Moore however expressed a hope that an exercise would be circulated in April and that the gap would only be for January, February and March.

The Chairman sought the agreement of the meeting to defer remaining items to a subsequent meeting, possibly in conjunction with a meeting which Dr. Lane was planning at BPL during February.

10. Representation of Blood Transfusion on NEQAS Haematology Panel

Professor Water's letter was discussed and the Chairman undertook to reply indicating that Directors were unanimous in their view that the B.B.T.S. should be asked to nominate someone to represent Transfusion on the NEQAS Haematology Panel.

21. Date and Venue of Next Meeting

Wednesday, 15th April, 1987 in London. The other Meetings for 1987 were fixed for Wednesday, 15th July and Wednesday 7th October.

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