PI ✓ Item 3 of 21.1.87

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REGIONAL TRANSFUSION DIRECTORS MEETING

Minutes of the 201st Regional ~~Transfusion Directors~~ Meeting held at D.H.S.S. Hannibal House on Wednesday 8th October, 1986 at 11.30am.

Present: Dr. I. D. ~~Fraser (Chairman)~~
Dr. F. Ala
Mr. W. P. N. Armour
Dr. G. W. G. Bird
Dr. J. D. Cash
Dr. A. Collins
Dr. M. Contreras
Dr. J. Darnborough
Dr. C. C. Entwistle
Dr. J. F. Harrison
Dr. D. Lee
Dr. R. Moore (DHSS)
Dr. J. A. F. Napier
Dr. K. Ll. Rogers
Dr. A. Shepherd
Dr. D. S. Smith
Dr. R. J. Sokol
Dr. L. A. D. Tovey
Dr. W. Whitrow
Dr. B. A. Bradley (Item 16 only)

1. Apologies

Apologies for absence were received from Dr. H. H. Gunson, Dr. M. McClelland, Col. D. Robson, Dr. A. Smithies and Dr. W. Wagstaff.

2. Minutes of the last Meeting

The Minutes of the 200th Meeting were accepted.

3. Matters Arising

(a) HIV Update

The Chairman reported that Dr. Wallington had completed the papers for the epidemiological study of patients receiving HIV infected blood. He had sought advice from the Chairman of the B.M.A's Ethical Committee, who had recognised the importance of the study and advised that the proposal should be put to seven ethical committees selected randomly from England and Wales starting with the Ethical Committee at Southmead Hospital. Unfortunately the reaction from this body had been unfavourable, two Physicians on the panel arguing that in no circumstances would their patients be approached to take part in such a study. Dr. Wallington proposed to approach six other ethical committees in due course. Arising from this there was some discussion as to what action should be taken about informing recipients of HIV infected blood. It was agreed that as a first step the Physician or Surgeon in charge of the case should be approached. Opinion was divided as to how to proceed if the Clinician concerned was unwilling to take further action. It was felt that, particularly with younger patients, other steps

should be considered if this was felt to be in the patients interest. A point was made that when tracing the recipients of earlier donations of donors found HIV Positive, that the fact that the recipient was dead was not necessarily the end of the story since the organs for some recipients would be used for transplantation and could transmit the infection to the organ recipient.

(b) The Chairman reported that the AIDS leaflet had been printed and distributed and would be discussed under Item 5.

(c) Monoclonal Anti-A and Anti-B

The Chairman reported that Dr. Lane and Mr. Armour had visited Bristol Polytechnic to discuss bottling of monoclonal Anti-A and Anti-B and it was hoped that by December material should be available for distribution to R.T.C's for evaluation.

(d) Buffy Coats

It was reported that a Meeting had taken place, attended by Dr. Gunson, Dr. Tovey, Dr. Darnborough, Dr. Fraser, Dr. Smithies, Dr. Moore and D.H.S.S. Lawyers, to discuss the handling of Buffy Coats for the preparation of monoclonal sera and that a document was in preparation. Dr. Tovey reported that he and Dr. Smithies were arranging a Meeting for those interested in aspects of Rh prevention to include consideration of trials of new immunoglobulin preparations for the prevention of Rh Haemolytic Disease.

4. HIV Update

This was made on Dr. Gunson's behalf by the Chairman. Dr. Gunson expressed thanks to Directors for the returns on HIV testing in R.T.C's which were proving very useful for epidemiological studies.

Dr. Gunson reported that he had received replies to the majority of the questionnaires which had been sent out asking about the availability of information on the composition of donor panels. He asked that those who had not yet made returns would do so.

Dr. Gunson had written recently to R.T.D's with further details of studies to monitor the accuracy of blood donor screening. Dr. Richard Tedder had indicated that he was getting samples from some but not all regions and appealed for complete participation. Dr. Gunson also asked in this letter for data on the HP and LP controls, which he hoped could be provided without undue difficulty.

Dr. Gunson proposed to write a paper with Miss Rawlinson's assistance, on behalf of R.T.D's, presenting the results of the first year of HIV testing. He asked for information about the age, sex and risk group status of donors who had been found positive. A draft of this paper will be circulated before submission for publication.

5. AIDS Donor Leaflet

The Chairman reported that the new leaflet had been printed and distributed to R.T.C's. Some concern was expressed about the fourth risk group but Dr. Moore emphasised the importance of the heterosexual context in Africa. Dr.

Moore agreed to provide a list of countries to which visits did not constitute a risk and suggested that this could be incorporated in an update of the appropriate section of Care and Selection of Donors. Dr. Moore indicated that the new leaflet should be distributed with donor call-ups. Dr. Cash expressed concern that the leaflet dated the risk factors from 1978 and not 1977 in line with WHO and North America. Dr. Cash also expressed concern that the AIDS leaflet was not being taken seriously and supported this with evidence of his own experience as a donor recently. He said that Directors in Scotland were considering sending a health check letter with every call-up which would incorporate the details in the AIDS leaflet. Dr. Rogers was unhappy about the reference to heat treated blood products in the leaflet since this had been shown to be ineffective with at least one product and argued that the leaflet should not be distributed. Dr. Cash appealed for cross border co-operation in the preparation of future literature and asked the Chairman to approach the DHSS regarding his proposals for a study into the effectiveness of the literature in self-excluding donors in high risk groups. One proposal was that closer attention to the exclusion of donors from malarious areas would assist with excluding those who had visited countries where HIV was endemic.

6. HIV Antibody/ELISA Conversion

Dr. Cashs' letter was discussed. It was noted that where a donor was repeatedly positive in the screening tests, but where positivity was not confirmed by the reference laboratory, it had been agreed that such donors should be withdrawn from the panel on the basis that their results were not fully understood. However, the observation to which Dr. Cash was referring was made where a considerable number of samples had been tested from donors giving false positives and some of these did indeed become negative. Opinion appeared to favour the reinstatement of such donors and Dr. Cash reported that opinion in America was moving similarly but that FDA approval had not yet been given. The Chairman proposed that he would write to the expert advisory group on AIDS for further advice.

7. CMV Plasma

Dr. Lane reminded Directors that CMV Plasma is not at present fractionated at Elstree but at P.F.L. Libberton. The first call on the final product is for the Bone Marrow Transplant Trials and any remaining material is returned to Elstree where the basis of issue is that priority is given to Regions supplying raw plasma. He said that several letters had passed between Dr. Apperley and himself in which he had tried to clarify the position to her. It was not clear whether part of her requirements lay outside the BMT Trial or if the amount of material used had increased. Concern was expressed from some present that the issue of CMV Immunoglobulin from B.P.L. was less than straightforward. Dr. Lane suggested that this may have been due on some occasions to the fact that stocks were extremely low or because some scrutiny of enquirers who might be unfamiliar with the correct use of the product was undertaken. The Chairman pointed out that the Leukaemia Research Fund was running a Bone Marrow Transplant Day at the Royal College of Physicians in November and suggested that this would provide an excellent opportunity to get all those interested together to discuss CMV Immunoglobulin. He undertook to identify the co-ordinators of the prophylactic and therapeutic trials. Dr. Cash reminded Directors that fractionation capacity for intravenous immunoglobulin is not unlimited; Dr.

Lane indicated that the new plant would provide additional capacity from next year.

9. Letter from Blood Transfusion Nursing Forum

The Chairman began by outlining the background which was that Dr. Harrison had approached him earlier this year to say that Miss Banks wished to circulate a questionnaire to B.T.S. Head Nurses. The Chairman agreed with Dr. Harrison that the questionnaire should be sent directly to Head Nurses with a simultaneous letter to Directors for information. The Chairman indicated that he had seen the document and understood it to be looking for information from R.C.N. members on a personal basis about Community Nursing and future nurse training. Dr. Harrison confirmed that this was her understanding of the document and indicated that it was intended that the analysis of the response should include both the wider views of the nursing profession and the views of special interests. It was recalled that at the Northern Divisional Meeting Dr. Wagstaff's concern was that in reply to the questionnaire, Head Nurses should be seen to express personal views and not to speak for the N.B.T.S. as a whole. There was general agreement that this was how the document was seen by other Directors.

10. Transfusion Medicine: Council of Europe Proposals

Dr. Cash introduced the topic by telling Directors that the Council of Europe had undertaken an examination of transfusion practise in the member countries and that a report had been prepared for member Governments. The report highlighted the lack of uniformity between Transfusion Services; for example in the U.K. Blood Transfusion was a sub-specialty of Haematology, in Sweden a sub-specialty of Clinical Chemistry and in Austria a sub-specialty of Anaesthetics. The Council proposed a new and clearly defined specialty of Blood Transfusion and went on to indicate the topics which training should cover and the type of examination which would be used to test those who completed the training. The new specialty and the training would be in centres of excellence which would be Regional Transfusion Centres and the new proposals were concerned only with those who were full-time in blood transfusion practise. He indicated that Scottish colleagues had welcomed the proposals both for the specialty and the examination and hoped that similar support would be forthcoming from the R.T.D's in England and Wales. The proposals were strongly supported by Dr. Bird, who believed that Blood Transfusion needed to be recognised as a multi-disciplinary specialty. Dr. Bird indicated that support was also forthcoming from the B.B.T.S. During the discussion concern was expressed that, particularly in hospital transfusion practise, Blood Transfusion could not be divorced from Haematology. It was also pointed out that the proposed specialty could mean a committment to blood transfusion earlier in ones career than at present and that this could be detrimental to recruitment. There was also some anxiety that the number of Consultants in the N.B.T.S. with only two or three replacements per annum might be too small to support a training programme. Dr. Cash emphasised that the proposals which he had outlined were concerned with coming generations of R.T.D's and Consultant in R.T.C's and were not intended to disturb or interfere with hospital transfusion practise. Dr. Cash indicated that he hoped to be able to approach the J.C.H.M.T. in the near future; the Chairman proposed that this should wait until after further discussion had taken place in the at the Working Party's Meeting at Sheffield in November.

16. Volunteer Bone Marrow Transplant Panel

The Chairman introduced Dr. B. A. Bradley who had circulated his proposals for a Bone Marrow Panel within U.K.T.S. Dr. Bradley summarised his proposals for a panel which would include the following features. The panel would be a special development, part of the transplant programme funded by the D.H.S.S. Donors would be volunteers, screened for transmissible disease with the altruistic motivation of blood donors. Access to the panel for searches and matching tests would be free of charge. Dr. Bradley emphasised the confidentiality necessary in the registration of volunteers and the need for potential donors to be protected both from recipients and their medical attendants. The organisation of the panel would include facilities for updating regularly the administrative details of volunteers. Volunteers would have the opportunity to have an explanation according, to a standard procedure, of the risks and drawbacks of bone marrow donation and of informed consent. It was envisaged that the new arrangements would allow a more rapid response by holding a genetic bank from all registrants for use with DNA probes. Searches would be selective because some tissue types are so rare as to be not worth looking for. The proposed panel could form a basis for the development of research projects for all recipients receiving marrow from unrelated donors. Dr. Bradley reminded Directors that a grant from the Leukaemia Research Fund had been made to set up a registry within the B.T.S. to examine the problems which would be encountered. At the present time, the registry consisted of approximately 10,000 volunteers increasing at approximately 3,000 per annum. There had been 165 searches this year and the rate was doubling annually. Although some searches were undertaken for potential recipients abroad, the prime aim was to provide donors for the U.K. The pilot study had identified two particular areas of concern, the cost of HLA typing and the length of the request/select interval which is at the order of three to four months. Dr. Bradley circulated a table showing how many matches could be expected from donor panels of various sizes, drawing attention to the fact that a panel of 100,000 donors would be expected to provide 10 HLA identical donors for a potential recipient. The figure 10 was important as approximately 1 in 10 HLA-A,B and DR compatible random individuals have a negative MLR. To increase the size of the registry to the necessary numbers it would be necessary both to type more donors in the U.K. and to network registries with other European Countries. He emphasised the importance of the application of new technology, both to the automation of tissue typing and in the use of DNA technology for DR typing where there was the possibility that this could partly or completely replace MLR.

The Chairman voiced the concern of many Directors when he asked for information about the results of unrelated compatible bone marrow transplants. Dr. Bradley replied that information was scant, that in some series unrelated transplants had been reported as being as good as family transplants with one HLA mismatch. There were very few reported cases of fully matched nonfamily donors, but success was of the order of 40% two year survival. Dr. Bradley agreed with the Chairman's earlier proposals that a Steering Group was needed with participants from the B.T.S., the B.M.T. field and the D.H.S.S. to look more deeply into recruitment, informed consent, requests for marrow, ethical issues, etc. He also asked that the D.H.S.S. examined the question of funding the exercise as a special development. The role of the Anthony Nolan Panel in this development was discussed widely and it was generally agreed that the development should be discussed within the steering group which had been proposed, particularly as

the developments which Dr. Bradley had outlined represented the application of new technology to the problem as well as a new framework for considering the ethical and other issues.

8. Anti-D Immunoglobulin; Anti-Tetanus Immunoglobulin

Dr. Tovey opened the discussion by reminding Directors that the supply of anti-D Immunoglobulin had been a matter of concern for some time and that following the last meeting of the Anti-D Working Party, he had written to Dr. Smithies asking her to explore the possiblity of the purchase of commercial anti-D to bridge the acute difficulties while long term strategies were resolved. Dr. Lane reported that he had written to all producers (who are not licensed in the U.K. but are in Europe) and had identified a number of problems involved in attempting to purchase anti-D. He reminded Directors that he had been drawing attention to impending difficulties in anti-D supply for over two years. He asked Directors to identify for how long a buffer supply would be required. In discussion, it emerged that some Centres have taken steps to boost donors and increase the frequency of donation. One Centre had instituted a new programme of immunisation and boosting of new volunteers. The value of pro-rata distribution of anti-D was discussed and on this opinion was divided but it was clear that it could not be implemented immediately. Dr. Rogers expressed concern about the safety of immunising and boosting at the present time because of the risk of transmitting infection to volunteers and indicated that he was unwilling to undertake this. He also drew attention to the large number of 500 iu doses used to cover late terminations of pregnancy in Private Clinics in his region, adding that many of these patients had come from abroad. Dr. Contreras suggested that if all Abortion Clinics offering facilities to patients from overseas bought commercial anti-D and used it on a named patient basis that the shortage of anti-D could be resolved. Dr. Lane suggested that the scheme, whereby the B.P.L. would buy raw immunoglobulin plasma from Regions with Regions buying back the finished material which they needed, should be explored. Dr. Whitrow pointed that the S.N.B.T.S. Directors have targets for their raw plasma which they should collect but that they can barter between regions to provide an equitable distribution of work provided that these exchanges are registered centrally. The Chairman summarised with the following proposals:

(a) that Obstetricians should be discouraged from using anti-D for ante-natal prophylaxis

(b) that anti-D immunoglobulin be given only to Rhesus Negative women having Rh D Positive infants

(c) that a six month buffer stock be acquired - Dr. Lane to explore further

(d) that all Directors write to Dr. Tovey with plans for anti-D and other immunoglobulins

(e) that pro-rata distribution of immunoglobulins would be difficult but that regions supplying less than they use need to act

Dr. Lane rounded off the topic with the result of a calculation of the cost of a six month buffer stock which he estimated to be of the order of £1 million.

11. N.B.T.S./N.I.B.S.C. Interface with U.K. Transfusion Services

Dr. Cash drew attention to the likelihood of new legislation, possibly 1988, to bring the U.K. into line with a E.E.C. directive on product liability. The change could mean for example that recipients of blood who developed non-A non-B hepatitis could sue successfully even if there were no negligence. To have 'done our best' or to plead insufficient funding would be an inadequate defence. He emphasised the need for standard specifications and standard operating procedures and quality assurance for products. He believed that product licencing was inevitable. Links with N.I.B.S.C. would therefore be valuable. It was agreed that an approach to N.I.B.S.C. from the two Transfusion Services should be made. Dr. Lane supported this co-operation with N.I.B.S.C. but emphasised what he saw as a separate issue, i.e. the need for a statutory independent authority to pass judgement on the diagnostic products which would be issued by the B.P.L.

12. Management Services Study of the N.B.T.S.

The Chairman reported briefly on the first meeting of the Steering Group. The visits to the first two centres had provided the opportunity for an extensive discussion of the way in which centres worked both in the London Region and in the Provinces, with considerable evidence accumulating in support of the need for a co-ordinated N.B.T.S., though as Dr. Moore pointed out all the options still remain open. The Chairman indicated that by the time all centres had been visted and a draft report prepared, this could not be expected before May/June 1986 at the earliest.

13. Single Pack Committee

The Chairman reported that the Single Pack Group had met on the previous day and had recognised Dr. Lane's requirement for a specification for a plasma pack which would meet with F.D.A. approval. It had been agreed that such a pack could have an additional port. The Eastern and Western Divisions preferred a pack not designated to plasma; the Northern Division believed that 90% of blood collected for plasma would find its way to Elstree and that flexibility was only required for the remaining 10%. Dr. Lane outlined his discussions with a number of companies over several years, in particular with Biotest. He summarised the problems of a high through-put of plasma extrusion at a temperature of less than -30°C. He agreed with the Chairman that there was still not an alternative pack for plasma. He offered that Directors would have a chance to see the Biotest 'tear-down' system as soon as it was at the stage for field trials. Efforts to promote the use of the same teardown pack by more than one company had been unsuccessful.

14. Anti-HBc and/or ALT Testing

The Chairman reminded Directors that the possibility of screening for anti-HBc had been discussed previously, and that studies of the incidence of anti-HBc in the donor population had been undertaken at Edgware, Bristol and Manchester about three years ago. Developments in America meant that this topic must be considered again as anti-HBc/ALT screening were soon to be essential for the accreditation of Blood Banks in the U.S.A. The Chairman proposed that the R.T.D's should approach the DHSS to fund a prospective study of 10,000 donations to see if the incidence of anti-HBc had changed since this was last examined. He added that Haemophilia Directors were

pressing for plasma for fractionation to be tested both for anti-HBc and for abnormal ALT levels. It was agreed that a further trial should be undertaken at Edgware, Bristol and possibly Manchester and that an approach be made to Dr. Smithies and Dr. Moore for assistance with this. It was recognised however that even if the incidence had reduced significantly since the last trial, because of self exclusion or for other reasons, the introduction of anti-HBc/ALT screening seemed very likely.

15. Election Procedure for Chairman of R.T.D. Committee commencing April 1987

The Chairman reminded Directors that continuity in the Chair was important and proposed that Directors give consideration to the election of their new Chairman before or during the January Meeting so that the Chairman elect will have the opportunity to make useful preparation for the April Meeting. He proposed that nominations be sent to him so that a ballot could be arranged for which Dr. Lee would act as scrutineer.

17. Reports from Divisions

Topics discussed at the Northern Divisional Meeting had been covered by items on the Agenda.

Dr. Darnborough drew attention to the relative cost of several products in the recently circulated pricing document which appeared to be discrepant. These prices were identified in discussion to have been derived from the costing exercise undertaken by Wessex and North Western Centres in conjunction with a firm of Accountants. Dr. Darnborough complained that the results appeared to be no more than a vehicle for recharging the Private Sector whereas the original intention was that they would provide a management tool. Dr. Smith undertook to discuss the exercise with Dr. Gunson and to report to the next meeting.

The Western Division did not meet.

18. Reports from Working Parties

Dr. Napier reported that the Quality Assurance Working Party had met on two occasions and that there had been meetings of subgroups with encouraging progress.

The Chairman reported that a small Working Party had been set up to work with Dr. Lane looking at the packaging of diagnostic laboratory reagents for hospital use consisting of Dr. Gunson, Dr. R. W. Doughty, Miss Eleanor Lloyd, Dr. D. Anstee and Dr. N. Hughes-Jones.

21. Date and Venue of Next Meeting

Wednesday, 21st January, 1987 in London.