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REGIONAL TRANSFUSION DIRECTORS MEETING

Minutes of the 199th Regional Transfusion Directors Meeting held at the Regional Transfusion Centre, Plymouth Grove, Manchester, on Wednesday and Thursday 24th and 25th April, 1986.

Present: (Chairman)
(24.4.86 only)
(24.4.86 only) (CBLA)

(24.4.86 only)

(DHSS)

(DHSS)

(SNBTS)

1. Apologies

Apologies for absence were received from and

was welcomed on his first attendance at an R.T.D. Meeting representing the Scottish Directors. The Chairman also welcomed who was taking over as the Director of the B.G.R.L. until the 6th November 1986.

2. Minutes of the last Meeting

Amendments

It was noted that was with the M.O.D. and not the D.H.S.S. pointed out that paragraph 19 recorded her difficulties with meeting Platelet demands, but not the commitment from other R.T.D's to assist her with this. On Page 4 "B.P.L. Control Sera" should read "PHLS Control Sera".

Matters Arising

(a) Notes on Transfusion

The Chairman reported that Notes on Transfusion would be re-written and that had agreed to be the Editor. He will approach

(Cardiff) and (Manchester) to assist and may co-opt others.

(b) CMV Hyperimmune Plasma

was asked to clarify how CMV plasma would be handled and distributed. He said that all CMV plasma should be sent to the B.P.L., who would dispatch it to the P.F.C., Libberton. The finished material will be returned to B.P.L. excluding any material specifically set aside for trials. The B.P.L. will maintain an audit of CMV use and particular plasma collections could be collected for particular trials. Small amounts of CMV immunoglobulin are available from Elstree for general use on request. CMV immunoglobulin for trials would be supplied from P.F.C., Libberton. noted that some plasma which he had sent to P.F.C. had been discarded and asked if the B.P.L. criteria would be the same. This was affirmed by drew attention to an article in the New England Journal of Medicine reporting that CMV immunoglobulin was ineffective.

(c) Axon Health Care

reported that after the last meeting he had written to expressing concern about advertisements in the Cambridge Press for donors. The issue had remained quiet until the 23rd April when had again been in touch to ask if the BTS were going to co-operate with the provision of buffy coat samples. reported that a letter had been sent from the D.H.S.S. to discouraging his activities following the last N.B.T.S. Advisory Committee Meeting. stressed the need for tight controls before parting with Buffy Coats or cell lines and pointed out the the SNBTS had developed a very tight protocol to ensure that the Service shares in any benefits.

AGENDA

4. AIDS and AIDS Testing

reported that had asked for a standard format for referring HTLV3 positive samples to the PHLS for confirmation and a draft form had been circulated for our comments. It was noted that the name or reference number would suffice. reported that pads of forms would be printed and circulated.

reported an approach from seeking the Directors agreement to the publication in the C.D.S.C. bulletin of the results of HTLV3 testing in the N.B.T.S. asked if the number of positives found in each region should still be regarded as confidential. indicated that the DHSS attitude was slightly less rigid in this regard and that the DHSS had been approached for donor results. It was agreed that the figures could be published on a national basis at quarterly intervals. It was also felt that regional figures should be available to Directors, even if they were not published. drew attention to the high figure for HTLV3 positives in March and asked if there had been any change by Wellcome in its Quality Control or test format which might explain this. He was concerned that the incidence in the U.K. appeared to be much less than in the rest of Europe. did not share this concern, but suggested the need to run both an antiglobulin and a competitive assay

in parallel. reported that 11,600 samples had been tested by Glasgow B.T.S. using the Abbott and Wellcome tests. 44 samples positive by Abbott had been negative by Wellcome and none of these had been confirmed when tested independently.

reported that wanted to look in detail at non repeatable positive sera with antiglobulin technique. We were being asked to send to a separate 2-5ml sample sample, using Bronidox and not Azide as a preservative (in addition to that going to the P.H.L.S.) when a positive was referred for confirmation. said that the P.H.L.S. result would be definitive in the event of a discrepancy between their result and those of had indicated that he would like to have the name and date with each sample in case the same donor gives in more than one region. This was agreed. proposed that samples should go go initially for a period of six months, followed by a review. asked if would seek the co-operation of Scottish colleagues in this project. also asked to seek the agreement of Scottish Directors to the inclusion of their HTLV3 results in quarterly statements in the C.D.S.C. bulletin.

The Chairman referred to letter about the analysis and presentation of HTLV3 results on the Apple computer. noted that a similar programme from Sanguine could be used with an Apricot Computer.

6. HTLV3 Antibody Testing on Staff - providing samples for reagents

drew attention to a document from the D.H.S.S. concerning HTLV3/LAV in diagnostic reagents, which would be effective from 1.5.86, which appeared to have been distributed to hospital laboratories but not to RTC's. The main problem concerned staff who give samples for reagents and cell panels. Should consent be sought for HTLV3 testing and if so, how often? It was noted that this circular's proposals were prospective and need not be applied retrospectively to reagents in stock. pointed out that the draft document indicated that if a positive result were found that the General Practitioner concerned should be informed and that this needed to be changed. pointed out that hospital laboratories collecting pools from patients for quality control purposes might now seek similar material from the B.T.S. knowing that it would be HTLV3 tested. indicated that the third draft of this document was now in preparation and that these observations would be included.

7. NEQAS for Microbiology

The Chairman raised this issue since it appeared that not all Centres were aware of a NEQAS Exercise for HTLV3/LAV serology and that in some Centres the relevant correspondence was not being sent to the Director. After discussion it was agreed that the Chairman should write to indicating that all Centres in England and Wales wished to take part and asking that the character of the panel be modified to include weak positive results such as might be found in routine testing and asking that correspondence and results in future be sent to the RTD.

8. Blood Group Reference Laboratory

summarised a number of decisions which have been taken by the CBLA. He began by thanking for taking on the post of Director

until November 1986. He indicated that future policy would be to exploit monoclonal antibodies, since it was the view of the Directors that immunisation of volunteers could not be sustained ethically where a monoclonal alternative was available. He indicated that the production side of the B.G.R.L. would move to the B.P.L. when space was available, with the appointment of a Deputy Director responsible for diagnostics and there would be a further senior post responsible for quality control. Another appointment would be that of Director of Research and Development for the B.G.R.L. He also indicated the willingness of the C.B.L.A. to continue to host NEQAS in Blood Group Serology, but with independent control. indicated that the Quality Control of Diagnostic Reagents would be embraced by the wider quality control and quality assurance at B.P.L. He indicated that he would also like to see an external quality control on the lines of the American Food and Drugs Administration. He believed that B.P.L. cannot compete adequately as a manufacturer until we have a similar independent authority, which he felt should be linked to the National Institute for Biological Standards. It was noted that the Deputy Director for Diagnostics and Quality Assessment would have direct access to the Chairman of the C.B.L.A. The Chairman told the Meeting that the R and D Part of B.G.R.L. would move to Bristol B.T.S. as it was hoped that Dr. Anstee would direct this aspect of the work. commented on the need for proximity to an academic Centre while maintaining links with the C.B.L.A.

indicated that the new arrangements were intended to allow the B.G.R.L. to provide the best reagents and to compete with commercial enterprises. believed that there was a need for a portfolio of monoclonals from the N.B.T.S., and hopefully the U.K. as a whole, for use within the U.K. The N.B.T.S. should indicate what they needed and he would endeavour to meet this demand as cheaply as possible. He hoped that the N.B.T.S. would recognise this and continue to support reagent production at B.P.L. In response to , indicated that a new Chairman was being sought for the NEQAS Steering Committee and had probably been found, though she was not yet able to name him today. It was clear, both to the British Society for Haematology and the D.H.S.S. that NEQAS should not be associated with reagent production and needed to be separated from the B.G.R.L. The Department were therefore concerned to identify an independent organiser and venue for the exercise. commented that it was not always clear that NEQAS was separate from the B.G.R.L. and stemmed from the D.H.S.S. The responsibility for the exercise was vested in and the exercise had been housed at the B.G.R.L. for convenience. Material for the NEQAS exercises had always been selected by several centres. There was a plea from the meeting that the new organiser of NEQAS should be a serologist with a detailed experience of blood group serology. said that he would much prefer that the B.G.R.L. dealt directly with hospitals about supply of reagents and cross-charging in view of the extra work involved. indicated that he would deal with different regions in whichever way was found to be most appropriate for recharging.

9. Supplies of Anti-D and Anti-Tetanus Immunoglobulin

reported that the anti-D immunoglobulin situation was slightly better than figures given to the Anti-D Working Party. Anti-D production was just in balance. He was receiving requests for material for ante-natal prophylaxis and was agreeing to these as he was anxious that clinicians should not seek anti-D from another source. The

uptake of anti-D prophylaxis seemed to be slow and he hope that we could match the increase needed.

Anti-Tetanus Immunoglobulin was a cause for concern as this will run out by the end of 1986. He had had a number of enquiries about the safety of intramuscular immunoglobulin and from these realised that many clinicians were discovering for the first time that the NHS manufactures tetanus immunoglobulin. He felt that the P.H.L.S. could do more to promote this product and was concerned that if the commercial sector reduced its interest in this product as self-sufficiency approached (c.f. albumin) there would be an acute shortage. He pointed out that not all regions provide anti-tetanus immunoglobulin and asked if Directors wanted pro-rata returns for hyperimmune immunoglobulin. Concern was expressed about the enormous variation in the use of anti-tetanus immunoglobulin by certain hospitals.
drew attention to an article in the Prescribers' Journal three years ago which gave clear guidance on the indications for use. It was not clear that pro-rata distribution would help the situation and pointed out, with respect to anti-D immunoglobulin, that a number of Centres had been discourage from embarking on programmes of anti-D immunoglobulin production in the past and that these would now be seriously disadvantaged by a pro-rata arrangement which would exclude them from distribution.
indicated that contributions to hyperimmune immunoglobulins should not significantly interfere with Factor VIII production as the total for specific plasmas amounted to about 15 tonnes per annum. draft letter arising from discussion at the Immunoglobulin Working Party was tabled and it was agreed that this should be addressed to , with an indication of which option from the letter the R.T.D's would prefer.

drew attention to an epidemiological survey of HTLV3/LAV virus by the Blood Transfusion Service. The aims of this were summarised in a letter from which was circulated. He anticipated that would be in touch with all Directors within the next three weeks and would be sending them a substantial portfolio of documents and pro-formas in connection with the study.

10. Letter from , C.D.S.C., regarding the receipt of Immunoglobulin

pointed out that the purpose of this study was to assist with confirming that intramuscular immunoglobulin is an entirely safe product. The consensus of the meeting was against the project as it felt that it would raise unwarranted anxieties about a product about which there was no real cause for concern. It was also pointed out that if it were deemed to be necessary, the same information could be got from women receiving anti-D immunoglobulin more easily. pointed out that another pronouncement from the W.H.O. was imminent regarding the safety of intramuscular immunoglobulin, including studies with 'spiked' material. This pronouncement would almost certainly declare that Cohn fraction 2 immunoglobulin is unequivocally safe.

11. Autologus Blood Transfusion

reminded the Directors that the N.B.T.S. Advisory Committee had asked for a Working Party on Autologus Blood Transfusion. A small group had met on the 21st January and drafted the document which had been circulated. had discussed this with Scots colleagues who were in general

agreement but had reservations about liquid storage of blood. It was felt that a mention of the possibility rather than an active recommendation to pursue would suffice. expressed concern amongst Scottish Directors about the security of documentation and labelling of donations collected in peripheral hospitals which would then be passed to the B.T.S. for storage and subsequent issue. speaking on behalf of the Eastern Division, expressed a similar reservation about liquid storage. The Western Division also expressed misgivings and concern that the stimulus to this discussion was the threat from the private sector rather than any medical indication. The Western Division had also commented that the additional cost of autologus transfusion, in the absence of a medical indication, should be borne by the patient and not the N.H.S. which might prove to be a useful deterrent. reported that the D.H.S.S. had been approached by with a view to setting up a frozen blood bank in the U.K. as he had done in San Fransisco and Sydney. The Chairman undertook to redraft the document with colleagues from Scotland for submission to the N.B.T.S. Advisory Committee.

12. U.K.T.S. Bone Marrow Panel

The Chairman reminded the Meeting that the panel was set up about three years ago following a request from to assist with finding compatible donors for his patients. The panel now consists of 10,000 donors, 6,500 from the South West Region. Contributions from elsewhere are slow, though has visited all Centres to encourage recruitment. About 140 requests for a search of the panel have been procesed and the enquirers have expressed satisfaction. One problem to which had drawn attention, was that the panel was being made available outside the U.K.; a donor from his region had been found compatible with a recipient in Jerusalem. was also concerned to find that donors were being contacted directly by U.K.T.S. and not through RTD's. He informed the meeting that although the panel was apparently part of U.K.T.S. that the funding for the staff concerned came partly from BTS Bristol (one associate specialist) and partly from the Leukaemia Research Fund (one secretary). He had discussed the Bone Marrow Panel with Scottish colleagues in March and had subsequently had a letter from indicating that Scottish Directors would be willing to promote the recruitment of potential bone marrow donors from within the NBTS and that in the interests of the patients that efforts in Scotland should be integrated with those in England and Wales under the general control of the NBTS. He invited comment from Directors as to whether the future of the bone marrow panel should be drawn more into the control of the NBTS, possibly with Directors meeting to discuss changes. Directors expressed concern that bone marrow donors should not be asked to travel abroad to give marrow. Donors needed to understand fully what they were offering to do when they offered to be bone marrow donors. The Chairman returned to his concern as to how the panel would be funded in the future and questioned the need for both U.K.T.S. panel and the Anthony Nolan Panel. He undertook to ask not to commit donors to going abroad in response to requests for a marrow donation and to ask him to include an update in the annual report of donors recruited, requests and successful matches.

13. Guidelines for the Use of Cell Separators

The Chairman reported that it had been suggested that an addendum concerning the clinical use of cell separators should be appended to our Guidelines but expressed concern that this would delay the document further. said that after discussion with the Directors and the British Society for Haematology, that it seemed more appropriate that the Clinical Task Force of the B.C.S.H. should undertake this rather than a group set up by the D.H.S.S. A distinction between the clinical use of Cell Separators and the use of Cell Separators in hospital to harvest blood products from donors would be useful and the latter could be tackled quickly without delaying the progress of the Guidelines to the standing Medical Advisory Committee for approval. indicated that the B.B.T.S. had proposed and to join the task force for this purpose.

14. Single Pack Committee

The Chairman pointed out the need to consider again the format and function of plasma packs as wanted a dedicated pack, but a number of Centres had expressed an interest in the pack which could also be used for transfusion purposes. The need to re-convene the Single Pack Committee was discussed, but deferred so that the matter could be referred to divisions for further information as to how often flexibility in the use of a plasma pack would be needed and if it would justify the inevitable extra cost of a multipurpose pack with a transfusion port.

15. Biochemistry Control Serum

hoped that Transfusion Centres would be able to continue sypplying serum. Stocks of sera collected prior to October 1985 would not have been HTLV III tested and may have to be discarded.

16. Should the N.B.T.S. carry out a study on NANB Hepatitis

The Chairman reported that this had been discussed by the Scottish Directors and that he had agreed to raise it with RTD's. reminded Directors of two previous attempts, one by the MRC and one by the Transfusion Associated Hepatitis Working Party, to study this problem. After discussion it was agreed that this should not be pursued because of lack of time and resources.

17. Carcinoma of the Cervix and Blood Donation

survey was discussed and it was agreed that in future, donors with a history of Carcinoma of the Cervix which was cured could be accepted.

18. Transfusion in Neonates

Following his survey of this topic, proposed the use of a small blood collection pack with three transfer packs to collect 250ml of blood, possibly making use of underweight donors. suggested that the use of a sterile docking device with a harness and multiple satellites would be another solution.

19. Dental Treatment and Blood donation

Correspondence between South West Thames R.T.C. and the D.H.S.S. was noted.

20. Growth Hormone

reported that following the last meeting he had written to suggesting that through the Growth Hormone Committee, patients who had received Growth Hormones should be advised that they should not be blood donors. had replied that he would take the matter to the Committee and inform us of the outcome.

21. Reports from Divisions

reported that following an enquiry from a 'Herpes orientated' group, had written to in Leeds for expert advice. expressed the view that viraemia was extremely unlikely in herpes and that deferment of donors because of recent herpes was unnecessary. The Division, however, remained unconvinced and the advise in Care and Selection of Donors should stand.

asked, on behalf of the Western Division, if the Minutes of the N.B.T.S. Advisory Committee could be circulated to all Directors. It was agreed the Chairman of Divisions would circulate these.
asked if the Meetings of Divisional Minutes could also be exchanged.

22. Reports from Working Parties

The deliberations of the Anti-D Working Party have been incorporated in item 9.

23. N.B.T.S. Advisory Committee

reminded Directors that the M.R.C. Blood Transfusion Research Committee had been wound up in 1982. The D.H.S.S., anxious to have advice about R. and D. in Blood Transfusion had set up a U.K. Transfusion Research Committee which is serviced by the C.B.L.A. Although this Committee had a representative of S.H.H.D. and included in a personal capacity, further moves would be needed to fully integrate the Scottish Directors. The Committee was currently concerned with exploiting the in-vivo production of Factor IX.

The N.B.T.S. Management Board has agreed to an investigation into B.T.S. organisation. The terms of reference have been drawn up and circulated to Regional General Managers who may modify but not veto the proposals. This should happen in May to allow the study to begin in June, extending over a period of approximately six months.

reported a discussion on product liability arising from an E.E.C. document being studied by several Government Departments. We would be kept informed of developments. It had already been established that donors are not producers but that Transfusion Centres may have to accept a liability for blood which they issue. Whole blood is not a 'product'.
expressed concern on behalf of the Scots Directors that if some aspects of the document were accepted at their face value, e.g. clinical trials on a named patient basis, would be difficult or impossible.

reported a discussion on the Extended Role of the Nurse to take

charge of blood donor sessions. It had been agreed that immediate implementation would be premature and that the trial should continue for another six months. remarked that he had been approached by his R.H.A. and asked for a paper examining the possibility of nurses in charge of his sessions.

24. Any other Business

Plasma Targets

advised the Directors that because of uncertainty as to when the B.P.L. would be ready for full production, plasma targets should be modified so that although eventual targets remained unchanged, the achievement of these could be delayed. It was hoped that substantial production would be achieved by the end of 1987. Serious concern was expressed about the budgetory and staffing implications of this delay as well as the effect on the recruitment of donors and the additional cost of the purchase of commercial Factor VIII to meet the shortfall. was asked to write to Regions with this information so that budgetory and staffing cuts would not take place.

Dictionary of Product Barcodes

The Chairman summarised a letter from , pointing out that the Bar Code Working Party wanted to up-date the booklet 'Guidelines for the Specification of Machine Readable Labels' and had had an offer of joint sponsorship from of Compu-Inc and of Barcode Services. It was agreed that this offer of sponsorship should be accepted. informed Directors that the I.S.B.T. Dictionary of Product Barcodes was being printed at Sheffield R.T.C. and would be circulated to I.S:B.T. members. There may be some spare copies if others are interested.

Acupuncture and Electrolysis

The Chairman tabled two letters from relating to the rejection of donors on the grounds of acupuncture and electrolosis. It was agreed that there should be no exceptions to the practice advised in the Care and Selection of Donors. would reply to the letter.

ELISA for HBsAg

The Chairman indicated that a number of Centres were exploring the use of ELISA for HBsAg testing and that , B.P.L., had confirmed that ELISA tested plasma would be satisfactory. commented that the B.P.L. were looking into the development of an ELISA HBsAg test for the N.B.T.S.

British Standards Committee

reported that provision of BS2463, blood transfusion equipment, was being prepared and had been circulated for comment. International standards were also being prepared and had been asked to gather comments and advice from Directors about problems in the design of giving sets.

Anticoagulant for Haemonetics

reported that at P.F.C. needs an estimate of the total demand for 46.7% citrate which is used for granulocyte collection with Haemonetics Machines.

Freezer Trailers

reported that five tenders had been received for the manufacture of Freezer Trailers for Plasma Transport. There was a move at B.P.L. to accept the tender from Coolfreeze who had made the prototype trailer used by Oxford and Cardiff. This had been unsatisfactory in use and the firm had been less than assiduous in attending to problems. Another prototype, possibly from DeRoma, should be examined before a contract was placed.

reported that following the recent Administrators Meeting, each Administrator had undertaken to consult his Director and Head Scientist for comments on the transport document. expressed concern about temperature hold on long journey and it was noted that Birmingham B.T.S. had decided against the use of Freezer Trailers. The Chairman proposed that further discussion be postponed until Directors had had an opportunity to see the document.

25. Date and Time of next Meeting

Wednesday, 9th July, 1986 at 11.00am