Min 6

2/38

SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE

Minutes of Directors' meeting held at Protein Fractionation Centre, Edinburgh at 11.00 on Tuesday, 26 October 1976.

Present: Dr. J. Wallace (in the chair)
Dr. C. Cameron
Dr. J. Cash
Dr. I. Cook
Dr. H.B.M. Lewis
Mr. J.G. Watt
Dr. A.D. McIntyre, SHHD
Mr. E.D. Roberts, SHHD
Dr. Sheila Walter, DHSS
Miss M. Corrie (Secretary)
Dr. A.T.B. Moir (item 6)

1. INTRODUCTION

Dr. Wallace welcomed Dr. Walter to the meeting and notified apologies from General Jeffrey and Dr. Haycock.

2. MINUTES OF THE LAST MEETING

It was agreed that in minute 3b the expressions "progress projects" should be replaced by "proposed projects".

There was discussion on comments made by Mr. Watt, which had been circulated, concerning minute 5b. The following amendments were agreed.

a. deletion of "and Edinburgh" from line 1.

b. sub-paragraph (i) should read "recall of the batches from users to BTS Centres which should notify PFC of the recall and await instructions."

With the above amendments the minutes were agreed to be a true record.

3. MATTERS ARISING FROM THE MINUTES

Supply of factor VIII concentrates (3a)

Dr. Wallace, Dr. Cash and Mr. Watt had attended a meeting of English Transfusion Directors and Haemophilia Reference Centre Directors at the Sheffield Blood Transfusion Centre on 22 October. They had concluded that, although Scotland's problem was smaller than in England and Wales, there was still a long way to go towards setting ultimate targets for the production and use of factor VIII products. It was agreed that a firm attempt should be made at the meeting of Haemophilia Directors planned for 24 January 1977 to set interim Scottish targets. Meanwhile more factor VIII produced from cryosupernatant (known as CS VIII) had been issued and it was hoped to report results at the meeting on 24 January.

4. HUMAN SPECIFIC IMMUNOGLOBULINS

a. anti-D.

Dr. Cook, Scottish representative on the newly-formed working party on anti-D gave a report of the first meeting. Current production in England and Wales appeared to be double the usage and the countries held two years' stock in powder whereas Scotland was managing only to produce its day-to-day needs. Directors discussed likely reasons for the difference, one of which was the possibility that the product was being administered

to a higher proportion of potential recipients in Scotland than in England and Wales. Mention was made of the Joint Working Party on Haemolytic Disease of the Newborn whose latest report would shortly be issued to general and hospital practitioners in England and Wales. This might result in higher usage of anti-D. It was agreed not to request a supply of powder from NBTS but instead to continue with the Scottish programme which included 12 male volunteers in Edinburgh and further donations expected from Inverness early in 1977. Dr. Cook reported that consideration had been given in the Working Group to the possibility of high titres of saline anti-D in the starting plasma being responsible for some of the failures to prevent immunisation. Dr. Gunson and Mr. Maycock were studying the matter and would report back to the Working Group. Concerning anti-D quantitation Dr. Wallace tabled the results of the latest proficiency testing exercise. The consistency in respect of the two identical samples PT6 and PT8 was pleasing. There was, however, considerable variation from Centre to Centre in the determined levels of anti-D and it was suggested that the reason for this was a difference in the standard used. Dr. Wallace agreed to issue a sample of the low standard with the unknown specimens at the time of the next exercise. Participating Centres would then determine the level in each unknown sample against their own standard and also the low standard.

b. <u>anti-hepatitis</u>

It was explained that concern had been expressed at a recent meeting of RTDs in England and Wales about the diminution in supply of plasma containing anti-hepatitis IgG. As a result it was recommended that Centres should resume the total screening of donations for the presence of anti-HBs. The intake of plasma was diminishing in Scotland also and it was agreed that the Scottish service should continue its existing efforts to collect the plasma.

Concerning the proposal made at the meeting on 1 July to offer to the government of Iran FFC's existing stock which was due to expire within a year Mr. Watt explained that he had intended an exchange for fresh plasma containing anti-hepatitis IgG. The matter was discussed further and it was decided <u>not</u> to pursue the possibility of exchange principally because of some Directors' doubts about the quality of the Iranian plasma. It was however agreed that the concept of exchange should be borne in mind for other occasions. It was pointed out that an exchange system already existed under the auspices of the Council of Europe.

c. <u>Human normal IgG for measles prophylaxis</u>

It had been stated at the meeting on 1 July that SHHD was awaiting advice from one of its expert groups as to whether there would be a need for 1% mg. doses of normal human IgG for vaccination of debilitated children as part of a national campaign on active immunisation against measles. Dr. McIntyre confirmed that there was no further news to report. Meanwhile FFC had very large stocks based on current usage.

5. PLASMA DRYING:

Dr. Wallace reminded Directors of his report to the meeting on 1 July that the plasma drying plant at his Centre required expenditure of between £15,000 and £20,000 if it was to continue to function and that it had been remitted to the Co-ordinating Group to consider funding the repair. Time had not permitted discussion at the Co-ordinating Group meeting on 18 August and in the interim the cost of repair had been confirmed as £20,000.

In discussion the following main points arose:

a. Existing usage of SPFS plus dried plasma was 6.2 bottles per per 1,000 population p.a. The maximum number of bottles of SPFS which PFC could produce from its existing intake of plasma was 4.7 bottles per 1000.

b. Whatever the supply of SPFS there would continue to be a need for dried plasma, probably at the rate of 5,000 bottles a year (1975/6 usage 20,175). Research appeared for instance to show that SPFS was less effective than dried plasma in restoring blood volume in patients in burns units.

c. PFC could not dry small-pool plasma on the scale required at present without increases in staff and equipment.

It was finally agreed that Scotland should retain plasma drying facilities in two locations, particularly since it was known that BPL Elstree could not undertake drying on behalf of SNBTS. There was therefore no option but to repair the plant at the West of Scotland Centre and Dr. Wallace agreed to fund it in the first instance from his current year's allocation for medical equipment.

6. MEDICINES ACT 1968

Dr. Wallace welcomed to the meeting Dr. A.T.B. Moir of SHHD who had offered to explain to Directors the implications of the Medicines Act following discussion at the previous meeting on a communication on suspected drug toxicity which Mr. Watt had received from the Committee on Safety of Medicines.

Dr. Moir outlined the history of the legislation leading to the Medicines Act (1968) and explained how the latter applied to the Transfusion Service. The Licensing Authority for all UK ministries was the Medicines Division of DHSS, through which the manufacturer's licences held by BTS Centres in Scotland "as of right" had been issued. Licence holders "as of right" would be inspected before long by members of the Medicines Inspectorate. Dr. Moir said he intended to be present at the inspections and that he hoped to be accompanied by Dr. D.P. Fletcher of the Biological Substances Sub-Committee of the Committee on the Safety of Medicines. Directors asked that Dr. McIntyre should also be present.

Dr. Moir explained that requests to submit applications for product licences were likely to be received within the next six months and that applications would have to be submitted within three months of the request. The method of application had not yet been made known so that the period available for producing licence documents could be short. He anticipated difficulties arising over the assessment of applications for product licences by the Inspectorate because the legislation had been drafted to cover a very wide range of preparations vastly different from blood products. Since there was no alternative source of whole blood or plasma it was unlikely that the Inspectorate would ask for any process to be stopped; time would be granted to phase in alternative methods of production. It was also possible that application of the Act to <u>whole blood</u> might be waived under Section 47 of the Act.

Directors expressed disquiet at the amount of work involved in preparing licence applications and at the possibility of their having to take precedence over production to the detriment of the service. Dr. Moir thought that licence applications would not need to be detailed.

Dr. Moir said that he hoped, by attending the inspections of BTS Centres, to identify problems early in the proceedings, his role being that of interpreter between the Committee on the Safety of Medicines and BTS. The Inspectors' reports would be in two parts:-

a. Factual description of the premises and processes. This would be sent to the Centre to be checked for accuracy.

b. Recommendations, which would not be made available to the Centre before submission to the Committee.

Directors welcomed the referal under a. above and thought it was essential that they should also have access to document b. Dr. Moir explained this would be impossible.

Dr. Moir stressed that his role was to help BTS and that he would be pleased to meet Directors again if they so wished. Dr. Wallace thanked him on behalf of the meeting for a most informative talk.

7. TRAINING OF CONSULTANTS IN BLOOD TRANSFUSION

Dr. Wallace reminded the meeting that the task on which Directors had embarked following the meeting on 1 July was consideration of medical staffing and training needs against the background of SNBTS organisation. It had been hoped to present simultaneously one paper on medical staffing and another on management of SNBTS. In the event it seemed advisable to submit urgently to Dr. McIntyre a paper on the management question and this had been done. It was agreed that further consideration should be given to medical staffing at a special meeting to be held on Friday 12 November at 11.00 at PFC.

8. RED CELL GROUPING REAGENTS

a. Centralised production

Discussion centred on a paper produced by General Jeffrey (based on answers to a questionnaire issued in March 1975) which had been circulated. This recommended in the short term a special effort to remove the need to purchase commercial supplies and in the long term the establishment of a centralised production unit as part of the proposed microbiology laboratory at PFC. The latter proposal was not favoured but Directors expressed the need for a Scottish Blood Group Reference Laboratory. The existing BGRL was known to be under review following the withdrawal of the MRC interest. It was agreed to continue the discussion at a future meeting. It was agreed also that the Blood Transfusion Advisory Group should be asked to consider the use in the NHS of commercially produced reagents.

b. Anti-A and Anti-B

Dr. Cash introduced this item which concerned the giving of booster injections to donors to raise the titre of naturally occurring antibodies and asked whether volunteers participating in production of diagnostic reagents enjoyed the same legal cover as those helping to produce therapeutic agents such as anti-D. Dr. Cash explained also that his Centre was evaluating the injection of antigens prepared from saliva into volunteer members of staff.

Dr. McIntyre agreed to consult Scottish Office solicitors on both matters.

9. ANTIBODY TO HUMAN ROTA VIRUS

Mr. Watt reported having received a request from Ruchill Hospital, Glasgow, for the production of immunoglobulin from plasma containing a high titre of anti-rota virus. The proposal was that the IgG fraction should be given orally to patients suffering from gastroenteritis associated with rota virus. Further discussions are to be held between Mr. Watt and colleagues at Ruchill Hospital, but Mr. Watt expressed reservations about an IgG preparation given orally reaching the intestine. It was agreed to discuss the matter at the next meeting.

10. ANTI-CMV

Mr. Watt asked for information about plasma containing a high titre of anti-CMV. Dr. Wallace indicated that he would ask Dr. Sommerville to prepare a paper on the results of screening random donations for viral antibodies. This would be presented at the next meeting for discussion.

11. DATE OF THE NEXT MEETING

a. Special meeting on medical staffing Friday 12 November.
b. Date of next regular meeting to be fixed by correspondence.