SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE

Minutes of Directors' Meeting held in the SNBTS Headquarters Unit on Tuesday, 8 December 1981

Present: Dr J D Cash (in the chair)
Dr E Brookes
Dr I A Cook
Dr D B L McClelland
Dr R Mitchell
Mr J G Watt
Miss M Corrie (Secretary)
Dr A E Bell, SHHD
Mr J H F Finnie, SHHD
Dr H H Gunson, Manchester
Dr W Wagstaff, Sheffield

1. INTRODUCTION AND APOLOGIES FOR ABSENCE

Dr Cash welcomed Dr Gunson to his first meeting and invited Dr Gunson and Dr Wagstaff to contribute to the discussions.

An apology was intimated on behalf of Dr H B M Lewis.

2. MINUTES OF THE PREVIOUS MEETING

The minutes of the meeting held on 22 September 1981 had been circulated. Some proposed amendments had been circulated and one comment and an amendment from Dr Lewis were read.

The following changes to the minutes were agreed:-

Minute 3e.ii

First line, page 4, to be replaced by -
"was 2 million iu/10^6 population in the proportions 10% cryoprecipitate, 10% high purity F VIII concentrate and 80% intermediate concentrate."

It was noted that the target had changed, since the last meeting, to what had been minuted.

Minute 4

First sentence, second paragraph to be replaced by -
"Dr Bell suggested that if (as stated at the meeting referred to in Minute 3(g)) RTCs did not require product licences, there might be flexibility in the application of BP specifications to locally prepared blood products."

Minute 3f

A comment submitted by Dr Lewis was read and noted.

Minute 3(h)

It was agreed that the word "consultants" in line one should remain.

3. MATTERS ARISING FROM THE MINUTES

a. SNBTS Working Group on anti-tetanus IgG (Minute 3bii)

Dr Cash reported that there had been a productive meeting of the Working Group since the last Directors' meeting. A report including recommendations would be prepared in due course. In the meantime, Dr Robert Crawford had been invited to co-ordinate a sub-group on assays and standards and Dr Cook had agreed to re-examine the concept of obtaining supplies of plasma from a small selected group of hyperimmunised donors.

b. Proposed Inspection of RTCs by Medicines Inspector (Minute 3g)

Dr McClelland and Dr Mitchell reported having heard from the Medicines Inspector that he would visit them in February 1982. Dr Brookes and Dr Cook had not heard anything. Mr Watt expected further visits in December 1981 and February 1982. Mr Watt advised his fellow-Directors to nominate a senior member of their staff to accompany the Inspector throughout his visit. Their own (RTDs) participation should (it was agreed) be limited to the Inspector's introductory and summary sessions. The member of staff accompanying the Inspector should prepare a daily report for the information of the Director. This daily report brought the Director fully into the picture in time for the Inspector's summary session (which Dr A T B Moir of SHHD would attend also), on the last day of the visit.

Hopefully within one month of the inspection the Director would receive a draft report which would require checking for accuracy only at that stage. This checking procedure should be done as soon as possible with a view to the Reports return to the Inspector within 14 days. A final report including the Inspector's criticisms and recommendations would follow. A Director had the right to decide who would attend the summary sessions. It was noted that the Inspector had the authority to require the immediate cessation of any practice which he considered to be dangerous. Dr Wagstaff reported that the 'new' Inspectors were making their preliminary, informal, visits to Transfusion Centres in England and Wales.

c. BP 1980 - Addendum 1981 (Minute 4)

Dr Cash reported that he had contacted Mr Haythornthwaite to clarify the status of the BP, particularly in relation to the formulation for concentrated red cells (BP = packed volume of greater than 70%, Scottish practice = aiming for a mean of 70%). Mr Haythornthwaite said that the Scottish practice would not present an unsurmountable problem. It was thought that the Medicines Inspector would be more interested in validation procedures than in the formula itself.

There was some discussion on the cost-effectiveness of quality assurance and Mr Watt thought he detected signs that the regulatory authorities were also questioning the value of some tests which were being undertaken.

At the previous meeting the Directors had agreed to send to Dr Cash data on their products. Only one set of data had been received and Dr Cash said he intended to hold a workshop on the subject in 1982.

d. Testing for hepatitis (Minute 5)

It had been agreed at the previous meeting that Dr Cash should make a formal proposal, through Dr Wagstaff, for the establishment of a Working Party on Post-Transfusion Hepatitis.

Dr Cash and Dr Wagstaff reported that the SNBTS proposal had been made and would be discussed at the January 1982 meeting of the NBTS Transfusion Directors.

4. NATIONAL STOCKS OF BLOOD PRODUCTS

A table had been circulated on which were shown in each case the actual national stock at 18 November 1981 of PFC products and the issues for the year to 31 March 1981 plus in some cases a target national stock. The stock of freeze-dried plasma at W Scotland BTS at 31 October 1981 and the 1980-81 issues were also shown.

It was agreed that the concept of self-sufficiency implied uninterrupted supply and that, generally, the national stock should consist of 12 months' usage of products, labelled and ready for issue. It was agreed that the evaluation, in February 1982, of the scheme for the pro rata distribution of PFC products would be an appropriate time to consider in detail the establishment of national stocks of products.

5. SUPPLY OF BLOOD FOR, AND CHARGING TO, THE PRIVATE SECTOR

Dr Cash drew attention to two problems which were emerging in Scotland.

a. The supply of blood to the private sector of medicine was being opposed in certain quarters. Dr Mitchell, for instance, had received from a Trades Council in W Scotland a letter requesting an assurance to trades union members who were blood donors that their blood would not go to the private sector. The letter had been sent by Dr Cash to the CSA and to SHHD. There had also been press comment. Dr. McClelland had been concerned about reactions in his Region to the proposed opening, in East Lothian, of a private hospital owned by, and for the treatment of, non-British nationals. He had written to the SHHD on the subject.

b. Handling charges to the private sector

It was noted that there had been a Ministerial Statement in England to the effect that consideration was being given to this subject with a view to introducing handling charges by 1 April 1982. The NBTS Directors understood that a charge per item of service was the most likely outcome. It was noted that the idea of a handling charge had been initiated by a previous government and that the SNBTS Directors and the SNBTA had expressed their opposition.

It was agreed that the problem was more complex than it had been on the previous occasion, because of the recent rapid growth in the private sector including complications such as the hospital in East Lothian, mentioned in a. above. There was a strong possibility that hospitals catering especially for non-British nationals would wish to import their blood and blood products. One difficulty inherent in imposing handling charges would be how to explain to donors or the general public that the blood was not

being 'sold'; the distinction would never be understood.

It was understood that the Scottish Health Minister was aware of all the difficulties, but it was virtually impossible for Scotland to be spared the introduction of handling charges once they had been agreed for England and Wales.

After a full discussion it was agreed to record the Scottish Directors' view that the prospect of introducing charges, as well as the supply of blood to the private sector at all, was causing difficulty to those BTS staff who faced the public and there was an urgent need for a resolution of both issues. The Directors also wished to record their continued strong opposition to the introduction of handling charges.

6. CODE OF PRACTICE FOR AUTOMATED PLASMAPHERESIS OF VOLUNTEER DONORS: COMMENTS

a. Comments by the executive sub-committee of the NMCC

The code of practice (which had been discussed at the Directors' meeting of 23 June 1981) had been considered by the executive sub-committee of the NMCC who had commented thus:-

i. Medical examination of donors
It was considered by the NMCC that the medical examination should always be carried out by a doctor who was entirely independent of the BTS and that this should be stated in the code.

After a full discussion (including explanation of the practice in some Scottish Regions) it was agreed to recommend that the present wording of the code should stand.

ii. Frequency of donation
The executive sub-committee thought that fortnightly plasmapheresis would be too frequent and that 15 litres per annum would be excessive. It was agreed that Dr Cash should prepare for the SHHD a paper giving a review of the published data on the effects of plasmapheresis.

iii. The code should be reviewed at agreed intervals
The Directors agreed with the executive sub-committee that the code should be reviewed at agreed intervals of time which should be quoted in the code.

It was explained that the advice of the SNBTS and the NMCC would be considered within SHHD.

b. Insurance cover for donors

The Directors agreed with the view expressed to Dr Diana Walford, DHSS, by Dr Wagstaff in a letter (which had been circulated) that it should be the DHSS which approached the Life Offices Association on behalf of donors of plasma by plasmapheresis. It should not be left to individual donors to check with their own life insurance companies.

7. HAEMOPHILIA/BTS DIRECTORS

A recent meeting of the Working Group of Scottish Haemophilia and Transfusion Directors was reported. There had been a short report of a successful clinical trial in W Scotland of freeze-dried cryoprecipitate. There had

been no untoward clinical problems. Dr Cash would seek the Medicines Inspector's views on freeze-dried cryoprecipitate as a product. The cost comparison with intermediate factor VIII would be difficult but it could be made, with specialist accountancy help. The future of the product was partly linked to the freeze-drying plant at BTS Law, which depended on several matters which were being researched, including the needs of the Armed Forces.

There had also been discussion on the current target of 2.75 million i.u. Factor VIII/million population per annum, in view of the fact that the current NBTS target was 2.0 million i.u./million population per annum. It had been decided to retain the target of 2.75.

8. COMMERCIAL BLOOD PRODUCTS PURCHASED IN THE YEAR TO 31 MARCH 1981

A table showing the known commercial blood products purchased for NHS use in Scotland in the year to 31 March 1981 had been circulated. The Directors were congratulated on their success in obtaining the information.

It was noted that anti-D IgG had apparently been purchased in W Scotland and Dr Mitchell agreed to investigate this since the Directors were not aware of any commercial anti-D with a UK licence. He agreed also to try to find out who purchased factor IX and why, since there should be no need unless it was in the form of an activated preparation.

9. DATE OF THE NEXT MEETING

16 March 1982.