IN CONFIDENCE

SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE

Minutes of Directors' Meeting held in the SNBTS Headquarters Unit on Tuesday 22 September 1981

Present: Dr J D Cash (in the chair)
Dr E Brookes
Dr H B M Lewis
Dr D B L McClelland
Dr R Mitchell
Mr J G Watt - morning only
Dr A E Bell (SHHD)
Mr J H F Finnie (SHHD) morning and part afternoon
Dr W Wagstaff (Sheffield)
Miss M Corrie (Secretary - morning)
Mr D Gilhooly (Secretary - afternoon)

1. INTRODUCTION AND APOLOGIES FOR ABSENCE

Dr Cash welcomed Dr Wagstaff to his first meeting as an observer on behalf of the Regional Transfusion Directors of England and Wales. Apologies for absence were notified from Dr I A Cook and Dr H H Gunson.

2. MINUTES OF THE LAST MEETING

The following amendment was agreed to minute 6 of the meeting held on 23 June 1981:

Second sentence to read "Dr Mitchell, who did not think they had been condemned for use in the plasma drying plant at W Scotland BTS, had succeeded in obtaining a further year's supply."

With this amendment the minutes were agreed to be a true record.

3. MATTERS ARISING FROM THE MINUTES

a. Serum and plasma for quality control (3a)

i. Contribution by W Scotland BTS

Dr Mitchell explained that there had been some doubt as to whether the original minute was correct. Subsequent studies had revealed this was so.

ii. Departure of Dr J Ratcliffe to Manchester Univeristy

Dr Cash reported that Dr Ratcliffe had been appointed to the Chair of Chemical Pathology at the University of Manchester, and that he had conveyed congratulations to Dr Ratcliffe on behalf of BTS Directors.

It was not known to what extent, if any, Dr Ratcliffe would maintain his involvement in the work previously undertaken in conjunction with the SNBTS, although the work undertaken in his Glasgow Laboratory would continue until at least the end of 1981. Dr Mitchell confirmed that sufficient sera had been made available for at least another 12 months.

iii. Dispersal of serum supplied to the Peptide and Hormone Steering Group

Dr Cash reported that as from April 1982 Dr Hunter would provide BTS with a list detailing serum distribution.

b. Anti-tetanus IgG

i. Current plasma procurement

Dr Cash spoke to a table which had been circulated and to one which he tabled. The anti-tetanus plasma received by PFC from the Transfusion Centres since 1976 had been as follows:-

Year to 31 March	Kg.
1976	220
1977	338
1978	236
1979	192
1980	192
1981	350
1982	1500 (based on first 5 months)

It was recognised that the SNBTS had responded to an acute rise in demand for the IgG but supply was now outpacing demand. Dr Mitchell acknowledged that the increase in anti-tetanus plasma was attributable to his Region. He had now reduced the donor recall rate and was using the lower-titre donors to produce source plasma instead. He had met casualty surgeons in W Scotland (where there were considerable differences in usage) and the general effect was a reduction in use of anti-tetanus IgG.

Mr Watt reported his stock position at 16 September as follows:-

Plasma	235.8 kg.
5000 iu doses	15
250 iu doses	1110

ii. SNBTS Working Group

Dr Cash said the first meeting of the Working Group would be held soon.

c. Anti-D IgG

i. Assay

It was noted that Dr Urbaniak had agreed to investigate ways of improving anti-D quantitation and to report periodically to the Transfusion Directors.

ii It was noted also that Dr Urbaniak would undertake the next round of graded Kleihauer proficiency tests. Dr Mitchell agreed to send the record of his experience of conducting the test to Dr Wagstaff. It was noted that a move was probably being made to absorb the test into the national U.K. QC scheme.

d. Fractionation for Northern Ireland

Dr Cash spoke to a paper (which had been circulated). It was noted that the present request for 7,000 kg. per annum could increase to 12,000 kg. Taken together with the "Trends" programme for Scotland, this could mean a combined NBTS/SNBTS requirement for 1,750 kg./working week, i.e. in excess of the existing capacity at PFC operating on a single period of work each day.

Approval was given to the course of action proposed by Dr Cash, namely a working group from CSA, SNBTS and SHHD who would examine the steps necessary to meet the request of the DHHS, Northern Ireland. The terms of reference were agreed and Dr Cash agreed to approach CSA Secretary to establish the Working Group.

It was confirmed that Mr Watt would not be in a position to accept any plasma from Northern Ireland until a formal agreement had been reached as a result of the Working Party's efforts.

e. Visit to Belgium by SNBTS group

i. Miss Corrie reported that the group had made a very worthwhile visit to the Leuven Branch of the Belgian Red Cross Blood Transfusion Service. They had been conducted by the Director on a tour of plasmapheresis centres as well as having lengthy discussions. The Leuven programme produced 38% of the country's FFP from 5% of the population by operating a chain of 8-bed plasmapheresis centres in communities numbering 7000-10000 inhabitants. These were staffed by four people and the plasma was separated and frozen down on site for subsequent fractionation principally to freeze dried cryoprecipitates: 20% of the input went to purified FVIII and was reserved for special needs. The group felt that a good deal of what they had seen could be applied in Scotland.

Dr Cash said he would be inviting the group to present their findings at a workshop to be held in February 1982. Before that, however, there should be a special meeting of the Directors to consider a formal report (to be circulated) by the group.

(Secretary's note: meeting arranged for 26 November).

ii. Relationship of the visit to "Trends"

Dr Cash reminded his colleagues that he was awaiting from them a note of the resources which they expected they would need to meet the targets of fresh frozen plasma which had been noted at previous meetings. He asked for the information by 31 December. Anyone in difficulty should contact him by 31 October, when he would be pleased to help formulate the need.

There was some discussion on the relative merits of forewarning CSA now through the BTS sub-committee or of waiting until plans had been prepared and costed. It was agreed to take the latter course of action. It was recognised that SHHD would not hear officially until CSA had been informed.

The targets were confirmed as 2.75 million i.u. of Factor VIII per 10^6 population and that all calculations were currently directed toward intermediate VIII. It was noted that the figure for England and Wales

was 2 million i.u./10^6 population, in the proportions of 5% cryoprecipitate, 95% intermediate FVIII.

f. Replacement of DHSS Glass Container

Dr Mitchell explained that he had succeeded in buying one year's supply of MRC bottles. He understood that the United Glass Company were to continue producing the bottle at a cost little higher than at present. The DIN bottle was incompatible with the plasma drying plant at W Scotland BTS.

Mr Watt explained that DHSS Supplies Division were having difficulty with their first deliveries of DIN bottles. CSA Supplies Division held the total UK stock of MRC bottles (30,280, some 20,000 short of PFC's need for the remainder of 1980-81). He would therefore have to buy bottles in class 2 glass commercially while awaiting his first delivery of class 1 bottles.

It was agreed to keep the position under review.

g. Proposed inspection of RTCs by Medicines Inspector (7)

Dr Mitchell reported on a meeting with the Medicines Inspectors which he had attended with Dr Cash. The meeting had allowed an exchange of views to take place between the Medicines Inspectors and representatives of DHHS, SHHD and the BTS. The Medicines Inspectors had explained their role, and had indicated that there may be a relaxation of the environmental control standards which had originally been suggested, and seemed prepared to consider BTS working practices which had operated satisfactorily for a number of years, because it would be wrong to ignore the cost factor of major changes.

It had been confirmed at the meeting that the United Kingdom had been divided between Medicines Inspectors, and that Dr Haythornthwaite was responsible for Scotland.

Dr Cash said that the Medicines Inspectorate were unlikely to be too rigid during the next five years, and that the introduction of Standard Operating Procedures (SOPs) was probably one of the most important aspects to be considered by the BTS and he intended to include SOPs on the agenda of a future Co-ordinating Group meeting. Dr Mitchell reported that Dr Urbaniak had already written to Directors suggesting that Centres undertake and write specific SOPs, and Dr Cash expressed the view that this could lead to SNBTS Standard Operating Procedures co-ordinated by a national committee.

h. AHG Serum (8)

Dr McClelland and Dr Mitchell reported that the consultants who had studied the production of AHG serum in SE and W Scotland had amended their report, and as a result it had emerged that there was no significant difference in production costs between the two Centres. The meeting was also reminded that it had been previously discovered that the serum produced by both Centres was of the same high quality.

It was agreed that Dr McClelland and Dr Mitchell should prepare a full report for consideration by Directors and, ultimately, the BTS sub-committee which would contain a recommendation of which Centre should make the reagent and the reasons for this.

On the basis of the information contained in the report, Directors would decide on the future production of AHG serum. To save time the report would be discussed at a future meeting of the Co-ordinating Group or circulated to Directors by Dr Cash.

It was agreed that the report should give consideration to whether SAPU should be distribution agents.

4. B.P. 1980 - ADDENDUM 1981

Dr Cash referred to the B.P. 1980 - Addendum 1981 (which had been previously circulated) which had been the subject of correspondence between Mr Watt and Dr Mitchell, and advised that in due course the Medicines Inspectorate would be likely to discuss the specifications of blood products made by Centres. Directors noted that the Addendum contained titles and specification of blood products, and these differed from similar products produced by the SNBTS.

Dr Bell explained that the B.P. was a guideline only, and that he was of the opinion that if product licences had been granted then products could be produced and distributed in accordance with the terms of the licence. It was agreed that Dr Cash would write to Dr Haythornthwaite to seek clarification on this point, and Directors agreed to send Dr Cash data on products produced by Centres.

5. TESTING FOR HEPATITIS

Dr Cash introduced the Third Report of the Advisory Group on Testing for the Presence of Hepatitis B Surface Antigen and its Antibody (which had been previously circulated), and a discussion then followed.

Dr Bell advised that the document was not intended to provide a legal safety net but to provide guidelines on the best procedures to be adopted, and that Directors' clinical judgement and adherence to the recommendations, within the finance available, was all that could be expected of them.

It was agreed that Directors required to be assured that staff were properly trained and also that each Centre participated in a quality control scheme. Dr Cash suggested that Directors should consider whether quality control within the SNBTS was satisfactory, and whether a national training programme should be introduced to supplement regional training. It was noted that the NBTS had various groups examining different topics but that hepatitis testing was not one of them, and it was agreed that Dr Cash should write to Dr Wagstaff with a proposal that a Post Transfusion Hepatitis Working Group be established.

6. SPPS FOR MRC CLINICAL TRIALS

Dr Cash reported that he was Chairman of an MRC Working Party, which was in the early stages of examining the feasibility of setting up clinical trials of crystalloid versus human albumin solutions in the resuscitation of hypovolaemic patients. It was estimated that approximately 9000 bottles of SPPS would be needed for the clinical trials over a two year period, and following a letter from Dr Cash, Mr Watt had indicated that the PFC would be in a position to supply this quantity. A similar enquiry had been made of Dr Lane at B.P.L. Elstree for PFF and a response was awaited.

Dr Cash explained that the MRC trials might not materialise, and if they did the MRC might prefer to use PPF from Elstree or a combination of SPPS and PPF. However, it was necessary to obtain the prior approval of Directors for the possible use of SPPS for this purpose.

Dr Cash advised that the SPPS could be taken from the national reserve and Directors gave their approval to the request.

7. DATE OF THE NEXT MEETING

Tuesday 8 December 1981