

MINUTES OF THE MEETING OF THE DIRECTORS OF THE SCOTTISH NATIONAL BLOOD
TRANSFUSION SERVICE AND HAEMOPHILIA DIRECTORS HELD IN ST ANDREW'S HOUSE
ON THURSDAY 7 MARCH 1985

PRESENT: Dr A E Bell (Chairman)
Dr B Bennett
Dr D B L McClelland
Dr R Mitchell
Dr M McClelland
Dr E Brookes
Dr J D Cash
Dr P Foster
Dr R J Perry
Dr T Taylor
Dr C A Ludlam
Dr I Hann
Professor R H Girdwood
Dr R Sharp
Dr G A McDonald

IN ATTENDANCE: DR A D McIntyre, SHHD
Mr A I M Morrison, Secretary

Chairman's Remarks

The Chairman welcomed members and apologised for the change of the date of the meeting. He introduced Dr Sharp from Dundee, who was attending in place of Dr T Tudhope, and congratulated Dr Perry on his recent appointment as Scientific Director of the Protein Fractionation Centre.

1. Apologies for Absence

Apologies for absence were received from Dr Mayne, Dr Urbaniak, Dr Dawson and Dr Forbes.

2. Minutes of Meeting held on 2 February 1984

The minutes of the meeting were approved.

3. Minutes of Meeting of the Working Group held on 14 November 1983

The Chairman explained that the minutes had not yet been approved because the Working Group had not met since November 1983. The minutes were then approved.

4. Note of Special Meeting held on 29 November 1984

The note of the meeting was approved.

5. Matters Arising not otherwise on the Agenda

There were none.

6. Review Paper from SNBTS

Dr Cash introduced the paper which he had prepared to facilitate discussion about future SNBTS planning for the production of blood products required for the management of patients with haemostatic or thrombotic disorders. He thanked SNBTS Directors and Dr Perry for the information they had provided.

(i) Factor VIII Concentrate - Production Targets


Dr Cash invited members to consider whether the SNBTS should continue to plan for an annual total Factor VIII concentrate use of 2.75 miu, quoting for example data received from West Germany which if applicable to Scotland would indicate a considerable escalation in demand (200,000 iu required for severe haemophiliacs).

After a general discussion in which it was considered that a severe adult haemophiliac in Scotland would need about 100,000 iu, using a genetically engineered safe heat treated product, it was agreed to stick to the figure of 2.75 miu. It was also agreed that Haemophilia Directors would provide the SNBTS with data on the actual usage of Factor VIII in Scotland and N. Ireland which would supplement the Oxford figures.

(ii) AIDS, including Heat Treatment

Dr Perry informed members that a new intermediate Factor VIII concentrate, dry heat treated at 69° for 24 hours, was ready for clinical evaluation.

Dr B McClelland reported on plans for the new screening tests for HTLV III antibodies to be evaluated on a UK basis. There was deep concern about reports indicating a high proportion of false positive tests in the trials carried out in the United States.



(iii) Cryoprecipitate

Referring to the trend shown in Appendix II of the review paper, Dr Cash invited clinical colleagues to comment on the present level of usage of cryo.

Haemophilia Directors confirmed the general reduction in the use of cryo, though it was still considered to be valuable in the treatment of some cases of Von Willebrand's Disease. However there appeared to be an increase in the use of cryo for non-haemophiliacs, believed to be attributed to cardiac cases. One family in Glasgow severely affected by VWD.

(iv) Batch Dedication

Dr Cash reviewed the current position as presented in Appendix VI of his paper, and said that although there were substantial national supplies there was still a need to build up further stocks at the PFC. Pilot schemes in Edinburgh and Glasgow indicated that batch dedication was feasible, though not without problems. It was likely that only a limited system of batch dedication could be applied to N. Ireland and to the smaller Scottish centres. National stocks of Factor VIII would be decentralised, there was greater risk of waste, related to shelf life, and less choice of vial size. However it was thought that with close co-operation of clinical staff individual patients could be treated with a particular batch inside the shelf life.

It was agreed that the Working Group should review progress.

(v) Plasma Pool Selection

Dr Cash said that the LFT studies performed by BPL in their pilot scheme had shown some improvement. He felt that this would be a major task for the SNBTS and would be both operationally difficult and very expensive.

(vi) Commercial Purchases

Dr Bell reported on the review carried out by the Chief Pharmacist (SHED). 3 responses from HBs were still awaited.

(vii) Oxford Returns

Dr Ludlam reported that the system continued to work well and the information provided by Miss Spooner was invaluable. It was agreed that it was desirable that the figures for Northern Ireland should be shown separately and Dr M McClelland said he would discuss this with colleagues.

(viii) Filter Needles

Dr Perry indicated that there had been slightly longer solubility times for Factor VIII as a result of heat treatment. Dr Ludlam and Dr E McClelland agreed but said that this was no real problem. Difficulties were more probably due to technical factors concerning the filter needle and the rubber bung.

(ix) Factor VIII Vial Content

Dr Ludlam proposed that the Factor VIII vial content should be increased from 200 units to 250 units, because on some occasions the present dosage of 200 units had proved insufficient. Dr Perry said the PFC would consider this, but it could not be given high priority at this time when so many other changes were taking place.

It was decided to review the situation at next year's meeting and that the Working Group should keep the proposal before them.

(x) Clinical Evaluation Studies

Dr Cash introduced Appendix X of his paper, outlining proposals for preliminary clinical evaluation studies, and emphasised the urgent need for evaluation of the new 68⁰/24 hour Factor VIII product.

After a general discussion covering a wide range of topics connected with the evaluations, it was remitted to the Working Group to consider the matter in greater detail and to facilitate clinical evaluations in Scottish centres. It was also proposed that the Working Group should look into the question of involving hospital Ethical Committees in evaluation protocols, and Professor Girwood reminded members of the need to inform the Committee on Safety of Medicines about adverse reactions

(xi) Factor IX

Dr Perry said that there had been a substantial increase in the use of DEFIX and the PFC currently had only 2/3 months supply, which was insufficient for a programme of batch dedication. The target was a 12 months supply.

Dr Ludlam enquired about the prospects of SNBTS heat treated factor IX and whether it might be advisable to buy commercial concentrate for certain patients. Dr Perry explained that the PFC's plans for factor IX did not include a crash programme of heat treatment but aimed for a high purity product. Dr Cash commented that the lack of animal facilities had been a handicap and it was only very recently that arrangements had been made for animal thrombogenicity testing at Cambridge. However it was hoped that clinical evaluations for heat treated factor IX would soon be completed, and noted that the BPL programme was no further ahead.

(xii) Factor VII and AT III

Dr Cash paid tribute to Dr J K Smith (BPU), Oxford for his assistance in the supply of BPU Factor VII and AT III and also for the data he had provided.

7. Factor XIII Concentrate

Haemophilia directors were collating data in respect of coagulation defects on a UK basis and in addition, Dr Ludlam is preparing a register of patients with platelet disorders. It was agreed to await the national returns.

8. Compensation and Clinical Trials

It was generally agreed that the current situation was unsatisfactory and Dr Cash explained the difficulties that the SNBTS had perceived in attempting to resolve the problems through the CSA. Dr Ludlam requested that some action should be taken urgently.

It was agreed that the SNBTS would submit a paper to the CSA with a view to discussion at the next BPC Sub Committee meeting, and Dr McIntyre undertook to raise the matter within the Department.

9. Any Other Business

The Chairman asked Dr McDonald if he was willing to continue to chair the Working Group and Dr McDonald's agreement to do so was welcomed by members.

✓ 10. Date of Next Meeting

It was agreed that the provisional date of the next meeting would be Thursday 6 March 1986.

SHHD

25 April 1985

8 Now 5 March