

0002

MINUTES OF MEETING OF HAEMOPHILIA AND BLOOD TRANSFUSION WORKING GROUP  
HELD ON WEDNESDAY, 15 MAY 1985

Present: Dr G A McDonald (Chairman)  
Dr J D Cash  
Dr C D Forbes  
Dr R J Perry  
Dr P Foster  
Dr C Ludlam  
Dr R Mitchell  
Dr I Hann  
Dr F E Boulton  
Dr B Bennett

In Attendance: Dr A E Bell  
Dr A D McIntyre  
Mr A I M Morrison (Secretary)

Chairman's Remarks

The Chairman welcomed members, particularly Dr F E Boulton and Dr B Bennett who had been invited to join the Working Group.

1. Apologies for Absence

There were none.

2. Minutes of Meeting of Directors held on 7 March 1985

The minutes had been previously circulated for information.

3. Batch Dedication of Factor VIII (Paper - Appendix VI, February 1985)

Dr Perry reported that the PFC had 15 lines of Factor VIII throughout Scotland. He expected the 68°C (dry heat) for 2 hours material would be exhausted in July/August and it would be replaced by the 68°C (dry heat) for 24 hours material which is thought to be a superior product and may also reduce the transmission of Non A/Non B hepatitis. He explained that the PFC issues would be in complete batches (1 batch - 1 centre). It was agreed that PFC would not issue the 68°C for 24 hours material until stocks of the 2 hours material had been exhausted. In response to a question, Dr Foster informed members that the decrease in yield of Factor VIII using a 24 hours dry heated method would be between 15 and 20%.

It was agreed that the batch dedication system was operating well at the various RTCs and would continue to be monitored.

#### 4. Adverse Reactions

Dr Cash reported that the SNBTS Directors had made little progress because of other high priority tasks. They are considering compiling a form covering all general adverse reactions and Dr Cash is to have further discussions on the subject with the Medicines Inspectorate.

He hopes to report further progress at the next meeting of the Working Group.

#### 5. Factor VIII Vial Content

At the Haemophilia/BTS Directors annual meeting, Dr Ludlam requested that the Factor VIII vial content should be increased from 200 to 250 units and it was decided to refer the matter to the Working Group.

Dr Boulton said that Edinburgh would prefer vial sizes of 250 and 500 units because an adult haemophiliac having a joint bleed at home would require 2 or 3 vials of 220 units and this was wasteful.

After a general discussion, it was decided that this was not an appropriate time to change the vial content, but the Working Group could consider introducing a range of vial sizes when new products become available and the supply position was stabilised.

It was agreed that the Working Group would review in 12 months' time.

#### 6. Heat Treated Factor IX

Dr Perry informed members that the heat treatment of Factor IX was a high priority project and that dog tests were underway at Cambridge. PFC expected initial clinical evaluation studies to begin in 2/3 months' time. Dr Cash was pleased to inform members that the first results received from Cambridge looked promising and tests had shown no trace of DIC in the heat treated product.

He reported that progress would remain somewhat slow due to splitting the technical resources with BPL.

#### 7. SNBTS Heat Treated Factor VIII: Evaluation Studies

Dr Perry reported that the PFC had continued to manufacture Factor VIII at 68°C (dry heat) for 24 hours plus 2% sorbitol. Preliminary clinical evaluation studies performed at Edinburgh, Cardiff and Belfast had been encouraging and the PFC can now proceed to heat unheated stocks.

##### (i) Bioacceptability Studies

Dr Boulton reported that he was coordinating bioacceptability studies being undertaken by Drs Ludlam, Bloom and Forbes and the results received to date were satisfactory - (Dr Ludlam's 3 patients had 100% recoveries of reconstituted Factor VIII 24 hours after the infusions and half lives of 8, 12, and 16 hours).

Dr Perry indicated that the licensing authority might only require a statement of the heat treatment conditions, but he believed the clinical studies were vital. He said that the PFC now had sufficient data to start production.

It was agreed that the PFC should commence production in August before the next Working Group meeting. It was agreed efforts should be made to study at least 2 VWD patients as soon as possible.

Dr Perry outlined the position regarding the validation of HTLV - III virus kill. It was noted that studies would be carried out by Dr R Weiss' (London) and Professor Montagneir (Paris).

##### (ii) Residual Infectivity

Dr Cash said that virgin patients were required for this type of study.

It was agreed that preoccupation with other major tasks meant that consideration of this item should be deferred until the autumn.

(iii) Strategy

Dr Cash explained that the SNBTS would like to see a library of plasma samples established to enable studies to be done in the light of newly emerging techniques. The SNBTS are giving consideration to a central storage facility which would be available to Centres which do not have sufficient storage space.

It was agreed that the Working Group could consider this matter further after the Scottish Haemophilia Directors discussed it at their meeting in the summer.

8. Compensation and Clinical Trials

Dr McIntyre reported that the BPL are faced with similar problems. He had discussed the matter with the Chief Pharmacist (SEHD) whose view was that blood products, whether used in clinical trials or ordinary therapy, were covered by the crown indemnity provisions. He said that Solicitor's Office were presently considering the Department's position.

A general discussion then ensued covering a wide range of topics including protection of staff rights and insurance claims and it was agreed that the Working Group should review progress from time to time.

The Chairman thanked Dr McIntyre for his efforts.

9. Any Other Business

The Chairman expressed his sincere appreciation to Dr Bell, who is leaving the Civil Service to take up a post in Fife Health Board, for his excellent service to the SNBTS. He said that it was largely due to Dr Bell's initiative that Haemophilia and BTS Directors had met to discuss medical matters. The Chairman acknowledged Dr Bell's considerable help and efficiency to all aspects of the Scottish Health Service but particularly to the SNBTS. On behalf of the members of the Working Group, the Chairman wished Dr Bell every success in his new post and hoped that he would keep in touch.

Dr Bell thanked the Chairman for his kind remarks.

10. Date of Next Meeting

The date of the next meeting has still to be arranged.

SHHD

May 1985