

File 1.105  
 2002

NOTE OF MEETING OF SNETS DIRECTORS AND HAEMOPHILIA DIRECTORS  
 HELD IN ST ANDREW'S HOUSE ON 14 NOVEMBER 1975

PRESENT: Dr McCreadie (Chairman)  
 Dr C Cameron  
 Dr J D Cash  
 Dr I A Cook  
 Dr S H Davies  
 Dr A A Dawson  
 Major General H C Jeffrey  
 Dr H B M Lewis  
 Dr G A MacDonald  
 Dr C R M Prentice  
 Dr D Shaw  
 Dr J Wallace  
 Mr J G Watt

IN ATTENDANCE:

Dr A D McIntyre )SHHD  
 Mr G N Munro )

Mr R N Roberts }Secretariat  
 Mr J Docherty }

Dr McCreadie explained that he had taken the chair because Dr Scott, who had chaired previous meetings, had been promoted to DCMO and was now involved in other duties.

APOLOGIES FOR ABSENCE:

1. Apologies for absence were intimated on behalf of Professor Douglas, Professor Girdwood and Doctor Tudhope.

The Chairman welcomed Dr Shaw who was attending in place of Dr Tudhope.

MINUTES OF PREVIOUS MEETING HELD ON 8 MAY 1975:

2. These were accepted as true record subject the substitution of "Dr S H Davies" for "Professor S H Davies" in the list of those present.

MATTERS ARISING:

3. The Chairman explained that all matters arising from the minutes of the meeting on 8 May had been incorporated in the agenda.

REQUIREMENT OF FACTOR VIII

4. In speaking to his paper Major General Jeffrey referred to the need for a more precise method of assessing requirements. While he accepted that this would be difficult he hoped that Directors would co-operate in formulating a new system.

5. Mr Watt referred to paragraph 4 of the paper and told the meeting that the amount of activity per vial was variable but reminded Directors that this was a new product and there had been some problems eg in standardisation. The aim was for an activity of 250 units per vial and while some were outside this figure it had been decided that, rather than waste material, the final assay value should be printed on the vial label; in time the numbers outside the figure would decrease.

The figures for the issue of concentrate Factor VIII for the period 1 September to 14 November 1975 were:

Glasgow	628	doses
Edinburgh	415	"
Dundee	40	"
Aberdeen	85	"
Inverness	168	"

6. Members felt that it would be extremely difficult to achieve a more precise method of calculating requirements: because of the many variations between patients eg body-weight of patients, length of bleeding, etc - but agreed that an attempt should be made. Dr Davies had in fact prepared a first draft of a proforma for issue to haemophiliacs which would be completed by them and which would give some of the information required.

7. Directors agreed to co-operate in the provision of information but pointed out some of the difficulties that would be encountered eg very small children; difficulty in estimating the exact volume of cryoprecipitate, and the problems associated with those patients who were relatively inaccessible eg those living in the Island of Lewis. It was thought essential that the information should include details of relapse rates.

8. Attention was drawn to apparent discrepancies in table IV of the paper in the use of cryoprecipitate arising from the differences in the management of patients between Edinburgh and Glasgow and concern was expressed that if the threshold currently obtaining in Edinburgh spread to Glasgow this would have serious consequences for manufacturers and predictions for the future. It was explained that the Glasgow figures related to a course of treatment possibly lasting 6 days and using this information the differences were not so wide.

9. In Edinburgh haemophiliacs were encouraged to assess their own bleeding and to come to the centre on their own initiative "no questions asked"; it had been found that the patient's assessment of whether or not cryoprecipitate was required was usually very good. In Glasgow the situation was that the hard core of patients were seen frequently but that the balance were rarely seen. To an extent therefore haemophiliacs in Edinburgh were in a similar situation to someone getting home treatment in that they were making the decision as to when treatment was required. The encouragement of home treatment would not necessarily increase demands and it was agreed that this had proved to be the case elsewhere also.

10. The Chairman recognised the difficulty in initiating a scheme to enable more precise estimates of requirements to be made and suggested that Dr Davies' draft proforma could form the basis for consideration by a small Study Group comprising Drs Cash, Davies, Wallace and either Dr Prentice or Dr MacDonald. Major General Jeffrey agreed to convene the group and to arrange a meeting. Centres were to be given an opportunity of commenting on the proforma when it was available in draft.

#### SUPPLIES OF FACTOR VIII

11. At the May meeting of Directors it had been agreed to look again at the possibility of releasing material to Haemophilia Centres before the stock target of 1,000,000 units had been reached and as a result Major General Jeffrey had agreed with Mr Watt that reserves could be held in Blood Transfusion Centres rather than in the Protein Fractionation Centre. There had however been a hold up in receiving labels for the vials and this, together with the reports of adverse reactions, had led to a delay in distribution.

12. By the end of the September, however, 1,115,000 units had been issued. There was no week in which no AHF was being made.

13. The Edinburgh Centre would like to increase the number of haemophiliacs on home treatment but were inhibited from doing this until they felt that the supply position was more secure. There could be repercussions if because of a reduction or interruption in supplies patients had to be taken off home treatment.

14. The meeting was, however, assured that supplies would be secured if the present average level of plasma intake at the PFC continued. The weekly intake level of plasma until recently had been increasing slowly and 40 to 50,000 international units per week could be anticipated.

15. Dr Wallace did, however, sound a warning on the plasma supply position. There had been an enormous increase in the West in the demand for cryoprecipitate and this had meant that little fresh frozen plasma was going to the PFC. 30,000 donations of fresh blood per year were being processed in the West for this purpose and this was unlikely to change until the demand was reduced.

16. In Edinburgh the contribution to the PFC had been increased by 90% to 2,000 litres but with contributions from elsewhere going down the net total input had remained static and was very recently beginning to show a slight decrease.

17. The contribution from the South East was approaching the maximum under the present arrangements and might be adversely affected if there were large demands for fresh plasma for use in other therapeutic regimes including cell separator.

18. The meeting was reminded that it had been forecast about two years ago that stocks of Factor VIII would be low during the PFC commissioning period and that it had been suggested that authority should be given for the purchase of commercial products as a "tidying over" exercise. No such authority had been given as it was against Departmental policy; this policy was still operative but would be kept under review. The real problem now was the limited quantities of fresh plasma available rather than the production potential of the PFC.

19. The point was made that without commercial purchase the transfer from the use of cryoprecipitate to the use of concentrate could take up to 15 years. The production of Factor VIII including quality control took up to 6 months and the commercial concentrate could theoretically at least, be used to fill temporarily the gap created by diversion of plasma from cryoprecipitate to the PFC. General Jeffrey, however expressed himself as against the purchase of commercial material unless for a particular patient; he was against its use as a routine treatment. He thought that the present difficulty might last for about 6 months to a year.

20. While it was accepted that it could be unethical to use commercial products from commercial donor blood it was felt that pressure from patients could increase to the extent where such purchase would have to be made.

21. The position was to be kept under review.

#### PATIENT REACTIONS ASSOCIATED WITH TREATMENT WITH PFC FACTOR VIII:

22. Dr McIntyre reported to the Committee on reports he had received, on adverse reactions in patients after receiving treatment with two different batches of Factor VIII produced at the PFC. He had written to Regional Transfusion Directors explaining the situation and recommending that the use of PFC Factor VIII for home treatment be temporarily discontinued.

23. Major General Jeffrey reported that his paper, copies of which had been previously circulated, was an appreciation of the situation in which he had tried to be specific about various types of reactions. The paper had been discussed with Dr Maycock (DHSS) and Professor Girdwood (a member of the Committee on Safety in Medicine) who were in agreement with the conclusions reached.

24. The crux of the matter was the conclusion, on Page 5 of the paper, that any biological preparation could potentially produce allergic reactions and the Committee on Safety in Medicine had been asked about any reported reactions to commercial products. There was no formal procedure for notifying reactions and non-reactions and there was no information available. The fraction had passed all quality control tests except the Pyrogen Test and it was difficult to relate the rabbit test to humans. Dr Davies and Mr Watt had agreed however to collaborate in a trial of material where the pyrogen test result was more than a total of 3 in three rabbits.

25. It was agreed that more precise information was required about reactions and Directors indicated their willingness to document all reactions; these would then be added to the Transfusion Directors quarterly report. Major General Jeffrey agreed to consider how the information might be presented.

26. The Glasgow Directors were prepared to start using PFC Factor VIII again but not meantime for home treatment.

#### ACTIVATED FACTOR IX CONCENTRATE

27. Dr Cash reported that the MRC were undertaking a national exercise on activated Factor IX concentrates for the management of Haemophiliac A patients with inhibitors..

#### ANY OTHER BUSINESS:

28. Mr Munro explained that circular NHS No 1975 (Gen) 86 about arrangements for the care of persons suffering from Haemophilia and related diseases had been prepared in consultation with Health Boards and DHSS, but as Directors were able to point out errors he agreed to confirm some of the detail. There was no information in the circular about hospitals which specifically treated children and this should be rectified.

#### DATE OF NEXT MEETING

29. It was agreed that the next meeting be held on Friday, 19 March at 2.30 pm in St Andrew's House.