

0006

NOTE OF MEETING OF HAEMOPHILIA AND BLOOD TRANSFUSION WORKING GROUP ON
WEDNESDAY 4 MARCH 1981

Present:

Dr G A McDonald (Chairman)
Dr J D Cash
Dr P Foster (Vice Mr J G Watt)
Dr C A Ludlam
Dr R Mitchell

In attendance:

Dr A D McIntyre (SHHD)
Dr A E Bell (SHHD)
J H F Pinnie (SHHD)
Mrs M Learmonth (Secretary)

1. Apologies for absence were intimated on behalf of Dr Forbes and Mr Watt.
2. The Chairman welcomed members to this first meeting of the Working Group established by the Haemophilia/Blood Transfusion Directors to consider the specific proposals in Dr Cash's paper and certain other issues. The aim was to meet when necessary and report back to the main group in approximately one year's time. The Chairman suggested that this first meeting be devoted to delineation of the issues, consideration of the options and allocation of specific tasks to members.

3. Production Target

Proposal: that a target of 2.75×10^6 iu of VIII/10⁶ pop/year be considered as the one to which the SNBTS should aim for the next 5 years with an increment thereafter of 100,000 iu pa.

The Chairman invited members to consider this proposal in the Scottish context, without reference to the position in England and Wales. Target figures should also reflect the availability of financial and human resources.

4. Dr Cash presented further information showing target figures in Denmark and Belgium, together with a recent study in the USA which portrayed the type of care likely to emerge in this country, whereby patients were managed in Comprehensive Care Clinics in which some form of prophylactic home therapy programme was practised. Improved life expectancy for haemophiliacs would increase the demand for factor VIII, as would the higher incidence of surgical procedures in elderly patients.

5. It was suggested that some additional finance input might be necessary, particularly in the West of Scotland where more plasma was required for factor VIII,

but members agreed that the target had to be related to what could be afforded. Changes in attitude and practice in the treatment of haemophiliacs could make a difference to the amount of FFP required, as could improved yields of factor VIII from PFC which while improving considerably would not show immediately obvious benefits.

6. Concern was expressed at the level of commercial material being purchased and it was agreed that the aim must be for the NHS in Scotland to be self sufficient. This could be achieved with good planning, and steps had been taken to improve the input of plasma. Dr Cash suggested that self sufficiency included the provision of a reserve stock capable of meeting unexpected demands such as a temporary failure at PFC. The Chairman thanked Dr Cash for the wealth of material he had produced which gave the best possible information on the present state of knowledge and practice. After discussing the many issues involved it was agreed that 2.75×10^6 iu/ 10^6 pop/pa be accepted as a reasonable target figure.

7. Production of Freeze Dried Cryoprecipitate

The Chairman invited Dr Cash to comment on the proposal that freeze dried cryoprecipitate be produced with a view to studying, on a multicentre basis, its role in home therapy, with specific emphasis on side effects, efficacy, practicability and cost.

8. Dr Cash indicated that there were two factors in favour of cryoprecipitate (a) the increased yield and (b) the increased pool size, although there was a school of thought in the UK that the larger pool size may increase the risk of hepatitis. He urged members to think carefully before embarking on a full scale programme and to bear in mind the allergic reactions and side effects which could arise. The majority of home therapy patients had no problems when using cryoprecipitate and in Belgium it was used extensively.

9. The Chairman suggested that this could be a research and development project but Dr Foster said that PFC did not have resources for this at present. There was however a study being undertaken under a clinical licence for the Medicines Inspectorate in the West of Scotland which was being extended to include children with the help of Dr Willoughby. Dr Ludlam expressed his interest in the treatment of children, particularly the need to protect them from the problems of liver disease and hepatitis.

10. It was not felt practicable to include an Edinburgh team in the study being undertaken in the West of Scotland, but the Chairman and Dr Mitchell undertook to report results as quickly as possible from the West of Scotland trial. It was agreed to await the data from this pilot evaluation and discuss the findings at the next meeting.

11. The clinical role of intermediate and high purity Factor VIII

Dr Cash intimated that the proposed study to delineate the clinical role of intermediate factor VIII and a higher purity VIII was part of a research and development exercise being undertaken at the PFC, as were the studies to improve further the yield of intermediate VIII and develop a product of higher potency (per mg total protein) than intermediate VIII. No action by the Group was required for the present. Dr Foster explained that the solution to some of the points mentioned was technical. He indicated however that information from clinical colleagues would be helpful in determining what degree of purity was required as this would enable PFC to present data on yields viz a viz purity.

It was agreed that Dr Cash and Dr Foster would monitor the studies and report back.

12. Clinical studies of Supernine leading to product licence

Members discussed the setting up of clinical studies of Supernine which would lead to the issue of a product licence. At present the West and South East Regions have access to a limited amount of supernine. A licence had been given for clinical trials. There was a limited use for the product but the main aim was to obtain a product licence.

13. Clinical Studies for Factor VII Concentrate

Dr Cash reported that a factor VII product would only be available when the PFC were satisfied that they had a suitable product. The trials would be limited in that only a few patients would be involved and it could take up to 5 years to obtain a licence for a product which would have limited use.

14. Determination of Quantities of Factor IX Concentrate for Haemophilia B and Non-B patients

Members were invited to discuss ways of determining quantities of factor IX concentrates used in haemophilia B and non-B patients on an annual basis. Dr Cash said that he was concerned about the inadequate tracing of patients and the lack of data available.

15. It was agreed that there should be an effective method of monitoring blood products, recording what product is given to a patient and how the products are used. Members thought that the point of issue was the place where data could be gathered and several suggestions were considered eg a questionnaire or a one day symposium to discuss the problem.

It was agreed that Dr Cash would consult the RTD's and seek help in selecting a suitable hospital where good feed-back could be obtained.

16. Reporting of Adverse Reactions

Dr Foster drew attention to the importance of reporting adverse reactions to PFC products which was necessary to meet the requirements of the product licence, as well as giving PFC the opportunity to withdraw other material of the same batch pending investigation. While agreeing generally with Dr Foster's views attention was drawn in discussion to the difficulties in devising a reporting system which would command the attention and co-operation of users, who in many cases would be clinicians who were not BTS staff. One of the major difficulties was the lack of cohesive information associating products with patients and it was pointed out that product liability made it necessary for the BTS to have this type of information. This could only be effective by co-operation from users and it was agreed that an approach be made to the Scottish Consultant Haematologists Group seeking their co-operation in the reporting of adverse reactions to haemostatic products. Dr Cash would liaise with the BTS directors in the production of a suitable reporting form.

17. National Register of Haemophiliacs

Following the suggestion at the meeting of the parent committee, members were invited to consider further the setting up of a register of haemophiliacs in Scotland, having regard to the information which was available from the national register in Oxford. It was agreed that the proposed Scottish register should contain the following data:-

1. The number of haemophilic patients registered with each centre.
2. Classification of each patient -- degree of severity.
3. The amount of therapeutic agent required per patient.

Members agreed that this information would be of great value as accurate information would make trends clearer and enable the PFC to plan production on a sound basis. It was agreed that a register in the form suggested be compiled, and that Dr Cash and Dr Ludlam would prepare a form for the use of Haemophilia Directors. The suggested form would be considered at the next meeting. Dr Ludlam expressed concern about the confidentiality of the data which would be collected and it was agreed that the data and any subsequent report be classified Confidential and would be the property of the Working Group.

ANY OTHER BUSINESS

18. It was decided not to issue the minutes of the Working Group meetings to the main group since the BTS and Haemophilia Directors each meet regularly and can receive informal reports from their colleagues. Should the Working Group complete its discussions in less than one year, the full membership would be called together. An interim bulletin could be issued if necessary.

DATE OF NEXT MEETING

19. It was agreed that the next meeting would be held in early September, on a date to be decided by the Chairman and the Secretariat.