

PAPER 24/1
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Minutes of the Meeting of the Haemophilia and Blood Transfusion Working Group which was held on Tuesday 22 March 1983 in St Andrew's House.

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

In attendance: Dr A E Bell
Dr A D McIntyre
Mrs M J Learmonth (Minute Secretary)

Apologies for absence:

There were none.

Chairman's Remarks

Dr McDonald welcomed members of the Working Group and introduced the Agenda which was made up mainly of items raised at the meeting of the full Group on 21 January 1983.

1. Heat-Treated Factor VIII Concentrate - (Minute 4e)

It had been agreed that the Working Group would keep in view the development of the new heat-treated Factor VIII product at the PFC, and Mr Watt was asked to report on progress. Mr Watt explained that they were not trying to heat-treat the present product, and that Dr Foster in cooperation with colleagues in the USA was working on a completely new Factor VIII product of higher quality with low fibrinogen content. Although it was not yet possible to go ahead with routine production, a trial batch of plasma had been used to provide small amounts of this new product in two forms - a Factor VIII concentrate (not heated) and one heat-treated at 60°C for 10 hours. These were now available in small quantities for clinical trials in comparison with the routinely used intermediate concentrate. There were approximately 55 vials, and although it would take some time to reach full production (approx 1 year) Mr Watt indicated that 4 more lots could be made available.

In response to Dr Bell, Mr Watt said that the changes in production method associated with the new products could easily be accommodated at the PFC and that the new processes had been patented. However some changes in equipment design would be required since the heating process required the container to be in a closed system and a separate container was needed for each fraction.

Mr Watt indicated that the new product was not the same as the heat-treated VIII currently being marketed commercially, and in response to enquiries about the purity of the product said that the heating process of 10 hours at 60° was generally expected to be capable of reducing infectivity, the results being encouraging.

It was suggested that the new products should now be given to a small number of patients for clinical evaluation. Dr Forbes and Dr Ludlam expressed willingness to take part in trials and, with assurances from Mr Watt that sufficient material would be available, it was agreed that 5 patients be involved, 3 from the West and 2 from East Scotland. It was left to Dr Cash to coordinate the necessary arrangements.

2. Anti-CMV in Haemophiliacs

Dr Cash drew members' attention to a discussion paper indicating the possibility that patients were being exposed to CMV and suggested that it would be useful to establish an information base of anti-CMV in haemophiliacs. It was agreed that a screening programme could be valuable and Dr McDonald reported that where the adult population in the West had been screened no problem had been recorded. It was agreed to keep the matter on the agenda and that Dr Forbes and Dr Ludlam would provide an up-date as more information becomes available.

3. AIDS (Minute 6a)

Members were reminded of the recent articles both at home and abroad about AIDS. Dr Ludlam reported that in the UK a letter and questionnaire had been sent out to haemophilia directors. AIDS was an emotive issue in the USA and Canada, and was causing a move away from factor VIII concentrate to the use of cryoprecipitate, with resultant supply problems. There was concern that AIDS might appear in the UK, and the Haemophilia Society was attempting to reassure its members and put fears of infection from blood products into perspective.

The Transfusion Directors were loathe to ask questions to which exception could be taken by potential donors but it was hoped that homosexuals and others at risk might be discouraged from being blood donors. In the meantime the Transfusion Directors were considering how best to ensure the safety of the plasma supply, and Dr Forbes was conducting a sample study of the immunological status of haemophilia patients.

The Chairman agreed to keep the matter in view and bring it up for discussion at the next meeting.

4. Packaging of PFC Products (Minute 6b)

The Chairman reminded members that at the meeting of the full group in January the packaging of the PFC materials had been thought to be too bulky. Dr Boulton had gathered some information and Mr Watt was consulted. Mr Watt informed members that it was difficult without going to a lot of expense to change the size of the packaging - however a new pack had been designed which consisted of a moulded plastic sleeve which held together the two components of the product. Among the advantages of the new design were that although the package could be given to the patient as a unit the water could be separated for suitable domestic storage; storage in centres is easier, there being 70% less bulk; and the new design is estimated to save approximately £5,000 per year on packaging.

Members welcomed this development and the Chairman thanked Mr Watt for his efforts. Mr Watt asked members if it would be possible for them to take up some of the stocks held at the PFC. The forthcoming renovation work at the PFC would make storage difficult. Members agreed to try to accommodate additional stocks.

5. Factor VII Concentrate (Minute 4g)

The Chairman invited Dr Cash to bring members up to date with the progress made on the clinical evaluation of the factor VII concentrate which he and Dr John Davidson had agreed to undertake - after it had been animal tested. Dr Cash said that although some progress had been made it was necessary to be satisfied that the product was not thrombogenic. Mr Watt said that there had been production problems and that this question was accorded a lower priority.

It was agreed to leave this meantime.

6. Factor IX Concentrate for haemophilia B and non B (Minute 5a)

The Chairman reminded members that the main Group had asked the Working Group to try to establish the demand for factor IX concentrate. It was agreed that the number of patients who use this product is small. Some centres would be able to supply the information, eg from the register of products issued, while others would require to obtain the information by investigation. Members agreed to look into ways of obtaining this information.

7. Adverse Reactions (Minute 5b)

The Chairman reminded members of the Group's commitment to finding a more effective method of reporting adverse reactions to blood products. The investigation by Dr Crawford and his report were informative but required more discussion. It was pointed out that the Medicines' Inspectorate was insisting on documentary evidence of a reporting system and that some sort of form would have to be prepared. The Chairman felt that it was important to impress upon clinical colleagues the necessity for speedy reporting of adverse reactions and that until such time as suitable forms could be prepared a telephone call with the batch numbers would be sufficient. It was agreed that the Transfusion Centres would be required to assume the task of establishing a reliable reporting system.

8. Haemophilia Register (Minute 5c)

The Chairman invited Dr Ludlam to report on the examination of the Oxford data. Dr Ludlam said that there was little to add to the discussion which had taken place at the meeting of the full Group. He felt that the returns were useful and, in response to Dr Bell, said that the information was capable of being used to assess the need for products. Dr Bell indicated that the Department was content if Dr Cash was able to use the information for planning purposes.

It was unfortunate that the Scottish data was not sub-divided into Regions but members agreed that the missing information could be made available from the Transfusion Directors. The returns would be received annually. The Chairman thanked Dr Ludlam and it was agreed to keep the matter in view.

9. Reporting to the Full Directors Group

Dr Bell asked members to consider giving the members of the full Group access to the discussions of the Working Group, in view of the fact that a year elapsed between the meetings of the full Group. Members agreed that the easiest way to do this was to send copies of the Working Group minutes to all members after clearance by the members of the Working Group.

10. Any other business

Dr Cash asked members to consider the possibility of a study of liver function tests in mild haemophiliacs and referred to a study undertaken in Birmingham. Dr Forbes and Dr Ludlam would consider this.

11. Date of next meeting

Dr McDonald thanked members for their attendance and it was agreed the next meeting be arranged for Monday 14 November 1983 at 2.15 pm in St Andrew's House.