

0007

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

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

In Attendance: Dr A D McIntyre
Dr A E Bell
Mr J H F Finnie
Mr K McBryde

There was no formal agenda and topics were discussed in relation to the note of the previous meeting of the Working Group held on 4 March 1981. Parenthetic references to minutes relate to that meeting.

Freeze Dried Cryoprecipitate (FDC) (Minute 7-10)

1.1 It had been agreed at the last meeting of the Working Group that the outcome of a pilot study of the use of FDP in the West of Scotland would be discussed when the results were available.

1.2 It was reported that 14 patients had been treated with FDC prior to dental surgery, using a total of 19 doses of 800 iu. There had been no adverse effects but variability of activity and, compared with factor VIII concentrate, the greater bulk per dose on reconstitution, was considered to have disadvantages. The latter was of particular significance in home therapy. Advantages lay in the high yield and the low cost technology, but it was pointed out that the full costs of quality control, which could be substantial, had not yet been calculated.

1.3 Following discussion touching on UK trends in the demand for cryoprecipitate (wet), the comparative quality of FDC and intermediate concentrate, relative prospective yields and financial considerations, it was agreed that in respect of the transfusion service Dr Cash should review the implications of producing FDP, taking into account the standards required by the Medicines Inspectorate, and report back to the Working Group.

Intermediate and High Purity Factor VIII (Minute 11)

2.1 Mr Watt explained the factors which the PFC had to take into account in developing products with optimum characteristics, and how problems were being tackled and yields improved.

2.2 Dr Prentice reported that the PFC factor VIII was now very satisfactory in terms of acceptability to patients, and congratulated the PFC on their achievements.

Factor IX (Minute 14-15)

3.1 Dr Cash reported that he had intended to take up this matter with the Consultant Haematologists Group, but had not had a suitable opportunity to do so.

Adverse Reactions (Minute 16)

4.1 Concern was expressed by the Blood Transfusion representatives that all adverse reactions were not being reported, particularly less serious reactions that might not greatly alarm the clinician but could be of significance to those responsible for quality assurance and the maintenance of manufacturing standards. (Appreciative comments were however made about the efforts in both Glasgow and Edinburgh Royal Infirmaries in this respect). It was pointed out that the Committee on Safety of Medicines and the Medicines Inspectorate also had an interest.

4.2 Dr Cash said that the Blood Transfusion Service was not yet ready to come forward with a draft reporting form as proposed at the last meeting.

4.3 It was agreed to continue discussion of this matter after consultation with the Scottish Consultant Haematologists Group.

National Register of Haemophiliacs (Minute 17)

5.1 It was reported that, following the proposals agreed at the last meeting of the Group, Dr Cash and Dr Ludl~~y~~ had given the matter further consideration. They had concluded that it would be unwise at the present time to adopt a system requiring major resource commitment at haemophilia centres.

5.2 It was decided that Dr Rizza should be asked if the Oxford computer could extract the Scottish data, and in what form, and that the parent Haemophilia/BTS Group should consider whether our needs could be met in this way.

Clinical Studies of Supernine (Minute 12)

6.1 Mr Watt reported a verbal opinion that it would not be necessary to obtain a separate product licence for Supernine, and that a variation of the DEFIX licence would suffice.

6.2 With regard to mounting a clinical trial, Dr Ludlam and Dr Boulton had been approached, but there were very few patients severely deficient in factor IX and therefore a trial would take some time.

Clinical Studies of Factor VII Concentrate (Minute 13)

7.1 Mr Watt reported that the PFC had prepared a small quantity of factor VII product, but he was unwilling to produce a batch on the scale required for clinical use until the need for it had been demonstrated.

7.2 Considerations relating to likely clinical demand were discussed at some length, including the possibility of combining factor VII with DEFIX or Supernine. It was agreed that there was only a small demand for factor VII and that it was questionable if more than one source of production in the UK could be justified. The possibility of obtaining supplies from Oxford was considered but it was pointed out that only very small quantities were available on a named patient basis. Mr Watt mentioned that over 1,000 doses of PPSB were being issued in Scotland and this gave rise to speculation as to how it was being used.

7.3 It was agreed that Dr Cash should write to Dr Lane about the possibility of BPL Elstree supplying PFC, but it was noted that the clinical policy in England was to restrict the use of Factor VII to congenitally deficient patients.

Production Target for Factor VIII (Minute 3-6)

8.1 It had been agreed at the last meeting that 2.75×10^6 iu/ 10^6 population per annum would be a reasonable target figure. With a view to reaching a firm recommendation there was further extensive discussion, including amongst other considerations the lower targets that were being recommended by interested bodies in England. It was noted that the past record of forecasting trends and matching the availability of blood products to needs was much better in Scotland than in England, and that despite some criticisms of the SNBTS in the past, supplies of NHS Factor VIII were beginning to approximate to demand.

8.2 The most conservative view expressed was that 2.00 - 2.75 would suffice, but most of those present advocated 2.75. Dr Bell interpreted the Department's position that it was the duty of the Group, as experts, to give their professional advice, and that the Department then had to consider the resource implications. If for example the collection of increasing amounts of plasma, essentially only for factor VIII, led to rising marginal costs, this would have to be taken into account. While a target of 2.75 would probably be recognised as realistic, there might need to be flexibility in the timetable for achieving it. Dr Cash pointed out that changing practices and scientific advances would also come into play. Dr McIntyre stressed the value of a reliable register of therapy to haemophiliacs in monitoring trends in the demand for factor VIII.

8.3 It was agreed that a target of 2.75×10^6 iu/ 10^6 population per annum of factor VIII should be the Working Group's firm recommendation.

SHHD

November 1982