

0002

MINUTES OF THE MEETING OF DIRECTORS OF THE SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE AND HAEMOPHILIA DIRECTORS HELD IN ST ANDREW'S HOUSE ON THURSDAY 2 FEBRUARY 1984

PRESENT: Dr A E Bell (Chairman)
Dr B Bennett
Dr Ewa Brookes
Dr J D Cash
Dr P Foster
Dr I Hann
Dr C A Ludlam
Dr R Mitchell
Dr D B L McClelland
Dr M McClelland
Dr G A McDonald
Dr R J Perry —
Dr G R Tudhope
Dr T G Taylor
Dr S Urbaniak

IN ATTENDANCE: Dr A D McIntyre SHHD
Mrs M J Learmonth Secretariat

CHAIRMAN'S REMARKS

The Chairman welcomed members, particularly Dr M McClelland from the Northern Ireland Transfusion Service, Dr Hann from the Royal Hospital for Sick Children, Glasgow and Dr Perry, acting Director of the Protein Fractionation Centre, who had newly joined the group.

1. APOLOGIES FOR ABSENCE

Apologies for absence were received from Dr Dawson, Dr Forbes, Professor Girdwood, Dr Mayne and Dr Wilson.

2. APPROVAL OF MINUTES

The minutes of the meeting which was held on 21 January 1983 were approved.

3. MATTERS ARISING

The matters arising from the minutes would be dealt with in items 4 and 6 of the agenda.

4. REPORT FROM THE WORKING GROUP

Dr Bell explained for the benefit of those attending for the first time that the Working Group had been set up so that matters of continuing interest could be discussed in greater detail and progress monitored during the year. Dr Bell invited Dr McDonald to report on the Working Group discussions (paper 84/1). Dr McDonald drew members attention to the minutes of the meeting held on 22 March which had been circulated and reported on the main items discussed. The Group had also met on 14 November 1983 and had discussed the progress which was being made in the development of heat treated factor VIII concentrate. Other items dealt with included:-

- (i) Anti- CMV in haemophiliacs
- (ii) Factor IX concentrate for haemophilia B and non B
- (iii) AIDS

- (iv) The reporting of adverse reactions this being an ongoing exercise would be discussed in detail later in the agenda.

The minutes of the November meeting would be made available to the full Group when they had been cleared by the Working Group at its next meeting.

5. REVIEW PAPER FROM SNBTS (Paper 84/2)

Dr Cash introduced the paper which he had prepared to facilitate discussion of SNBTS planning for the production of the products required for the management of patients in the coming year.

(i) Details of the amount of fresh plasma processed for factor VIII concentrates and the issues of concentrates indicated that the production level was about right. However trends over the last 5 years indicated that the SNBTS production of factor VIII concentrates may be exceeding clinical demand in that current stocks at RTCs appear to be increasing.

Members were agreed that it was desirable to stick to the target production figure of 2.75 million iu per annum/million total population, and that the existing stocks required to be held for sudden demands which could be made in the service, and to bridge the period when the PFC would be converting to a heat treated product. If a surplus of factor VIII became a reality other parts of the UK could be asked if they wished to make use of the product in preference to purchasing from other sources. No wastage was envisaged at present.

(ii) Members discussed the suggestion that the production of cryoprecipitate could now be reduced. Dr Ludlam said that cryoprecipitate was preferred in the treatment of children at present, because of the new danger of AIDS. Dr Hann concurred. A policy seemed to be emerging however to use less cryo for haemophilia A patients. It was agreed that a certain minimal amount of cryo was required and Dr Cash pointed out that TDs could produce it in emergencies.

(iii) Dr Cash asked for views about the phasing in of heat treated factor VIII for routine clinical use and how this could be achieved and quantified.

Dr Foster said that 2 batches had been released for study. Dr Ludlam expressed some concern about higher sorbitol levels in the product and reported that there had been some adverse reaction in 1 patient. Dr McDonald reported that, in Dr Forbes' trial using a second batch with reduced sorbitol, 3 patients had been monitored and following treatment were haemostatically secure. Dr Ludlam agreed to take part in further trials with a different batch of material and the Working Group would monitor progress. Dr Ludlam also agreed to ascertain whether this type of product was efficacious in the management of appropriate patients with Von Willebrand's Syndrome.

(iv) Dr Cash drew attention to the situation where, following some reported adverse reactions, it had been noted that individual patients were often exposed to a large number of batches in any one year. It was suggested that, in view of the current reserves of SNBTS intermediate factor VIII, efforts could be made to reduce the number of batch exposures per patient per year. It was recognised that this would not be easy but could be achieved with close co-operation with clinical colleagues.

(v) Dr Cash asked members to consider whether, given the present SNBTS production level of factor VIII concentrates, it was necessary to purchase commercially unless exceptionally a superior product was available.

Dr McDonald said that the adult centre in the West was totally satisfied with the NHS product and it was no longer necessary to purchase commercially. Dr Hann however found himself in the position of having inherited 30,000 iu of commercial factor VIII which was rapidly going out of date and which he was prepared to dispose of.

Dr Ludlam said that he required to have a small stock of high purity commercial material for a very few patients.

Dr Bell emphasised that the aim of the SNBTS and of national policy was for Scotland to be self sufficient, and although the Department would not wish to intervene in what clinicians prescribed, it was not sensible to purchase imported material when suitable NHS product was available.

It was also pointed out that an accurate assessment of future need could only be made if commercial purchases were fully identified and taken into account.

6. (i) FACTOR IX CONCENTRATES

Dr Cash referred to the paragraphs on page 7 of his paper about the supply trends for Defix and PPSB. Some Defix was still required and its availability would be retained, but subject to the provision of data which satisfies the Licensing Authority it was hoped to introduce Supernine for routine use throughout the SHS in 1984/85. These arrangements were seen as an interim development pending the development of a heat treated product, details of which were set out in the paper.

(ii) FACTOR VII CONCENTRATE

Page 9 of Dr Cash's paper. There were no comments.

(iii) ANTITHROMBIN III CONCENTRATE

It was reported that the PFC intend to continue the development of a heat treated product. In the meantime an excellent heat treated product was available from BPU (Oxford).

(iv) FACTOR XIII CONCENTRATE

Members were asked to consider the need for this product. It emerged that the number of deficient patients was small and it was thought that it would be appropriate to think in UK terms. It was agreed to consider a survey of say 50 patients. Dr Ludlam would make enquiries.

(v) AIDS

Members discussed the reports from abroad which suggested that recipients of blood could also be at risk. The effectiveness of the leaflet addressed to blood donors was discussed. It was felt that some modifications might be made and stressed that the leaflet must in the absence of a test to screen out donors be given to all prospective donors.

(vi) ANTI-CMV IN HAEMOPHILIACS

Dr Mitchell and Dr Forbes were undertaking studies into the incidence of anti-CMV in haemophiliacs. Dr Mitchell presented updated figures.

(viii) HAEMOPHILIA REGISTER

Dr Ludlam informed the members that the annual returns from Oxford had been distributed. The information was considered to be useful and thanks were expressed to the Oxford organisation.

(ix) REPORTING OF HEPATITIS

It was agreed that reporting of incidence was good. Dr Ludlam was collecting data on patients who go completely yellow. It was agreed to leave meantime.

(x) COMPENSATION AND CLINICAL TRIALS (Paper 84/3)

Dr Ludlam expressed his concern about an apparent lack of guidance on compensation arrangements for patients who take part in clinical trials and as a result might suffer damage.

Dr Bell thanked Dr Ludlam for the articles which had been circulated but was not in a position to give directly relevant advice at present, though he mentioned the arrangements which existed for blood donors throughout the UK.

It was agreed that Dr McClelland (Edinburgh) would prepare a paper on this subject for submission in the first instance to the BTS Sub Committee of the CSA.

7. Any other business.

There was none.

8. Date of Next Meeting

It was agreed that the next meeting of the Group would be held on 7 February 1985.