

0002

MINUTES OF THE MEETING OF THE DIRECTORS OF THE SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE AND HAEMOPHILIA DIRECTORS HELD IN ST ANDREW'S HOUSE ON WEDNESDAY 5 MARCH 1986

Present:-
 Dr J M Forrester (Chairman)
 Dr B Bennett
 Dr D B L McClelland
 Dr E Brookes
 Dr R Mitchell
 Dr M McClelland
 Dr J D Cash
 Dr R J Perry
 Dr P Foster
 Dr T Taylor
 Dr I Hann
 Professor R H Girdwood
 Dr G A McDonald
 Dr E Mayne
 Dr C D Forbes
 Dr S Urbaniak
 Dr F Boulton

PROTEIN TRANSFUSION SERVICE	
Received:	21 MAR '86
File No:	AE4 - SNBTS/Haem Dir mty
DR. R. J. PERRY	

In Attendance:-
 Dr A D McIntyre
 Mr A I M Morrison, Secretary

INTRODUCTIONS

Dr McDonald welcomed Dr Forrester (who had replaced Dr A E Bell) to his first meeting of the SNBTS/Haemophilia Directors and introduced him to the members of the Committee.

CHAIRMAN'S REMARKS

Dr Forrester thanked Dr McDonald for his warm welcome. He then informed those present that Dr G R Tudhope, Director of the Dundee Haemophilia Centre plans to retire this year and has made arrangements to hand over the Directorship to Dr Andrew Happleston, Consultant Haematologist at Ninewells Hospital, Dundee.

1. Apologies for Absence

Apologies for absence were received from Dr Wilson, Dr Dawson and Dr Ludlam.

2. Minutes of Meeting held on 7 March 1985

Dr Cash pointed out that the figure of 100,000 iu on page 2 (6(i)) should read 150,000 iu. The minutes have been amended accordingly.

3. Minutes of Meeting of Working Group held on 15 May 1985

The minutes of the meeting were approved.

4. Matters Arising from the above Minutes

Dr Cash introduced the paper which he had prepared to facilitate discussion with regard to future SNBTS planning for the production of blood products required for the management of patients with haemostatic or thrombotic disorders within the Scottish Health Service. He thanked SNBTS Directors and Dr Perry for their assistance.

(i) Current target for FVIII production and data on usage of FVIII

Dr Cash reminded members that both sets of Directors have repeatedly agreed that the target for FVIII production should be set at 2.75 m.i.u./m.pop./year. He said that current clinical uptake of FVIII is in the region of 1.7-1.8 million international units per million population per year, and that it is becoming clear that heat treatment reduces yield to the extent that the current plasma supply is all committed. Accordingly the SNBTS Directors do not anticipate being able to respond to increase in demand without increasing the fresh plasma supply. However the Directors intend to seek additional central funds, to enable them to aim at a production of 2.75 m.i.u./m.pop./year over the next 3/4 years. He asked both sets of Directors to consider whether the target of 2.75 m.i.u./m.pop./year should remain.

Dr McDonald congratulated SNBTS Directors on the upward trend of fresh plasma procurement from 28,474 kg in 1981 to 52,480 kg in 1985. The figure of 2.75 had been derived after considerable debate and took into account data from the UK as a whole and also Europe. He referred to Appendix IV of Dr Cash's paper which indicated that over the last 2 years only one RTC in Scotland has used commercial FVIII rather than the SNBTS products.

A lengthy discussion then ensued in which the following points emerged:-

- a) Total "use" of FVIII concentrates was highest at the Edinburgh centre, at 2.3 m.i.u. per million population.
- b) Northern Ireland drew 1.75 m.i.u. per million population at present, and could perform more surgery than is now possible if, say, 2.0 m.i.u. were available; but demand might rise little further.
- c) Dr Hann found that enough was available now for the needs of children.
- d) Demand may rise beyond its current level when apprehension about AIDS diminishes.
- e) The current target south of the Border is 2 m.i.u.

It was agreed on balance to adhere to the present target of 2.75. But the Chairman stated that if the figure was challenged, Haemophilia Directors would be invited to provide data on numbers of patients etc. to support the figure. Dr Cash said that he could obtain information from abroad if necessary.

(ii) Batch Dedication

It was agreed that the batch dedication system, which was established to enable Directors to treat individual patients with a particular batch of FVIII within its shelf life, was operating effectively and should be retained for a further 12 months.

(iii) Retrospective Checking

In response to a question, Dr Cash explained that in individual cases it was possible to trace previous blood donations over approximately 1½ past years, and test them for HTLV III antibodies.

(iv) High Purity Product

Dr Cash informed members that even material dry heated at 68°C for 24 hours may not be non-infective with regard to HTLV III and Non A/Non B hepatitis. Dr Perry explained that the PFC had recalled all residual stock of material heated at 68°C for 2 hours for testing, although no seroconversions have resulted from its use. He said that difficulties have arisen in relation to the heat treatment of the new high purity product and it has been decided to introduce an intermediate stage: a product which is only 2-3 times purer than the existing intermediate FVIII but can be dry heated at 80°C for 72 hours. It is hoped that this intermediate product will be available for clinical evaluation in April and for routine clinical issue within 3 months. He emphasised that there would be a substantial overlap when the high purity product is issued in the summer. He also reported that there was no further loss of fractionation yield using the high purity product.

Dr Cash pointed out that current information indicates that the HTLV III virus is killed when dry heated at 80°C for 72 hours. It was suggested that this information should be released to the media because of the recent adverse publicity claiming that dry heat failed to kill the virus. However, although publicity was desirable, it was decided that a media release would be premature.

It was also agreed that the new products could be slotted into the batch dedication system.

(v) FIX Concentrates

Dr Cash informed members that this product has not been introduced into the batch dedication system. It was agreed that its use should not be encouraged till further toxicity studies (currently underway) are completed.

(vi) Anti Thrombin III Concentrate

Dr Perry reported that AT III is now included in the formulation of heat treated DEFIX. Dr Ludlam had written to the Chairman to express doubt whether both PFC and CBLA need manufacture Anti Thrombin III, since demand is very small. Drs Perry and Cash believed that CBLA could not at present manufacture it and pointed out that the technology has manifold applications.

(vii) Von Willebrand Factor

Dr Perry informed members that the technology used for the manufacture of FVIII in high yield, of high purity and non-infective, is equally applicable to the isolation of VWF as a pure fraction. He invited Directors to comment on the potential demand if such a product were to be made available.

Dr Boulton pointed out that demand varies enormously from patient to patient: eg one patient in Edinburgh has received 40,000 units, while 8 others have received modest doses of FVIII concentrate. Dr Cash noted that there are approximately 40 cases of von Willebrand Disease per million population in Britain and on average each consumes 8,000 units per year. Dr Forbes reported that some of his VWD patients are HTLV III positive and that in the UK VWD cases were comparable in numbers to Haemophiliacs. It was agreed that the PFC should press ahead with this development project.

(viii) Study and Reporting of Patients - Seroconversions and Neo-antigens

It was proposed that a small Working Group to consist of Haemophilia/SNBTS Directors should be formed to consider the system for the study and reporting of patients, looking for seroconversion and evidence of antibody formation to neo-antigens. Since the remit and intended membership were not yet clear, Dr Cash offered to give the matter further thought, make approaches and inform the Chairman.

(ix) Danazol

Dr Cash referred to published papers suggesting that Danazol (an attenuated androgenic steroid) can increase FVIII and IX levels in haemophilia A and B patients, respectively, or increase FVIII and IX bypassing activity. But members (including Dr Ludlam, who had so informed the Chairman) saw no use for Danazol in relation to haemophilia.

(x) Anti-HTLV III Seroconversions in Patients with Haemophilia in Scotland

The meeting discussed Dr Ludlam's paper concerning the above which gave details for Scotland. Dr Mayne provided data for Northern Ireland (see copy attached). Dr Forbes stated that the average time to seroconversion is 84 days but that it has been reported as early as 2 weeks and as late as 11 months. Dr D B L McClelland stated that the late seroconversion had all been from one batch of SNBTS FVIII and that there is no evidence of infectivity in any other batches. Dr Perry informed members that the SNBTS are presently holding discussions with Professor Weiss regarding inactivation studies.

(xi) Compensation for Volunteers in Clinical Trials

Dr Forrester said that the question of compensation for clinical trials is a UK issue which the Department is pursuing with DHSS colleagues. He stressed that HM Treasury is not prepared to give any firm undertaking to provide compensation, but compensation for mishaps in relation to anti-D or hepatitis B immunisation or to apheresis can already be referred for advice to a small panel, and this system might be extended.

Dr Cash drew attention to the EC Directive on Product Liability which will be effective from July 1988. Dr D B L McClelland was alarmed at the extraordinary responsibility put on the shoulders of manufacturers of products by the Directive. Professor Girdwood said that it was important to establish whether an individual was to be sued under English or Scottish Law.

5. Future Organisation of Parent Group and Working Group

Dr Forrester proposed that the Parent Group and previous Working Group would work better if they were consolidated into a single Directors Group, to meet at least once a year, and intermediately if necessary.

This proposal was agreed by those present.

6. Any Other Business

There was none.

7. Date of Next Meeting

The date of the next meeting has still to be arranged.