

0006

MINUTES OF THE MEETING OF THE HAEMOPHILIA AND BLOOD TRANSFUSION WORKING GROUP  
WHICH WAS HELD ON 14 NOVEMBER 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  
Dr R J Perry

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

CHAIRMAN'S REMARKS

The Chairman welcomed members, in particular Dr Foster and Dr Perry who were attending in place of Mr Watt.

APPROVAL OF MINUTES

The minutes of the meeting held on 22 March were approved.

Heat-treated Factor VIII Concentrate

The Chairman invited Dr Ludlam and Dr Forbes to report on their clinical evaluation of a trial batch of the new heat treated product which had been prepared at the PFC.

Dr Ludlam said that he had received a supply of concentrate which had been used to treat one haemophiliac patient on 3 occasions spaced over a period of 1-3 weeks. The results compared favourably with other products used previously with 8½-13 hours half life and a recovery of about 80%. However the patient experienced minor adverse reactions on each occasion and had become anxious. It was not clear whether or not the product was the only cause of his upset.

Dr Forbes had just received a supply of material, from a different batch, and was about to put it to trial.

Dr Foster informed members that 4 batches of the heat treated material had been prepared and that full scale production was on target. The batch which Dr Ludlam had received had been heated at 60° for 10 hours which at that time was considered to be appropriate. However a virology study had since been undertaken and completed, and it was now believed that a greater viral kill could be achieved with more severe heating conditions. Further small batches would be prepared heating up to 70°C, taking heat treatment as far as possible without major loss of factor VIII activity.

Dr Cash reminded members about the collection of data on liver function tests of "virgin haemophiliacs", and raised the question of the number of virgin patients available in Scotland. Dr Forbes said that there were not enough virgin patients. He was however writing up his experience of hepatitis in 12 mild cases treated with PFC VIII. This data he would submit to Dr Cash. It was agreed to wait until Dr Forbes' data was available before considering the use of English patients. When there was a sufficient amount of the new product available Dr Ludlam would be prepared to try it out.

Anti-CMV in haemophiliacs

The Chairman asked members if they were able to add any information on the presence of anti-CMV in haemophilia patients.

Dr Forbes said that nothing had shown up in the study which he had undertaken. Dr Mitchell had examined a random selection of blood donors and selected haemophilia patients, and had found no evidence of a greater incidence of antibody in the haemophiliacs. Dr Mitchell's findings are set out in his letter and tables provided subsequent to the meeting and appended to the minutes.

#### AIDS

Members were asked for their views on the effectiveness of the leaflet which had been prepared by the SNBTS and DHSS. The leaflet asked potential donors who were members of the specified high risk categories not to give blood. It was felt generally that the leaflet had not been particularly useful although it had been put out freely at donor sessions and had been made widely available at other locations including VD clinics. A few donors had responded by declaring that they were homosexual but the problem of how to screen out those who might present as donors in spite of the leaflet, remains.

Dr Cash was of the view that a reprint of the leaflet should include changes and that different ways of bringing it to the attention of donors be sought, though the method of distribution should be left to the Regional Transfusion Directors. It was agreed that meantime vigilance in donor assessment should be emphasised.

#### Factor IX Concentrate for haemophilia B and non B

It had been established that there was a demand for a small amount of factor IX and Dr Cash was satisfied that very little was used for other than Christmas disease.

Dr Ludlam had been asked to test Supernine, those tests had been satisfactory and he would recommend the PFC go into routine production.

Dr Cash said that the licensing authority were reluctant to grant an additional licence and wanted a licence for Supernine to be at the expense of DEFIX. It was desirable to retain DEFIX since it was an interim solution for some patients and had a higher production yield than Supernine. Dr Perry said that while it would be simpler to substitute one for the other and it was costly to submit applications to the licensing authority, it was necessary to provide the product which was needed, and to know which product to heat treat.

#### Adverse Reactions

The Chairman commented that finding a reliable method of reporting adverse reactions to blood products was an ongoing exercise. Dr Perry had been having discussions with the West of Scotland and good progress was being made. It was agreed to keep the matter in view.

#### Haemophilia Register

Dr Ludlam said that the 1982 information should be available in November/December and could hopefully be presented at the meeting of the full group in February.

#### LFTs in Mild Haemophiliacs

This item was considered under item 1 on the agenda.

#### Any Other Business

##### a. Compensation for Clinical Trials

Dr Ludlam said that he would like to bring to the Group's attention his concern about the lack of formal arrangements for compensation for patients

who willingly participate in the clinical evaluation of products and may be disadvantaged as a result. Dr Bell outlined the insurance position of government departments in general and the particular arrangements for blood donors. Dr Cash agreed to raise the matter with the CSA who could take legal advice and liaise with SHHD. Dr Ludlam also drew attention to the report of the Stuart-Harris Committee relating to staff volunteers. The Chairman agreed to keep the matter in view.

b. Members agreed that the minutes of the last two meetings of the Working Group could now be made available to the members of the full Group.

Date of Next Meeting

The next meeting of the Working Group was arranged for Monday, 12 March 1984 at 2.15 pm.

SHHD