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COAGULATION FACTOR WORKING PARTY

1 MAY 1992

HAEMOPHILIA CENTRE

ROYAL INFIRMARY, EDINBURGH

Present: Dr C A Ludlam (Chairman)
Dr R R C Stewart (Secretary)
Dr B E S Gibson
Dr I Walker
Dr R J Perry
Dr C V Prowse

In attendance Mr D McIntosh
Dr A Keel

1 Apologies and Introduction ACTION

Apologies were received from Professor Cash, Dr Mayne and Dr Lowe.

Dr Ludlam welcomed the group and in particular Dr Keel in her role as SOHHD representative.

Dr Ludlam informed the group that he had been asked whether Dr W Murphy could join the Working Party in his role as senior lecturer in Transfusion Medicine. While wishing to avoid the Working Party becoming too large, it was agreed that Dr Murphy's presence would be valuable.

2 Minutes of Last Meeting

(i) The minutes of the meeting of 20 January 1992 were accepted as a true record of the meeting.

(ii) There were no matters arising which are not included elsewhere on the agenda.

3 Distribution/Usage of Coagulation Factors

Dr Stewart reviewed the position, and supplied copies of the graph of usage. It was noted that this was on target (copies attached).

Dr Stewart agreed to perform a check of PFC issues to RTC against the Coagulation Factor Usage Survey results. RS

ACTION

Dr Perry tabled a report on PFC stocks of Factor VIII (copy attached).

It was noted that no Z8 had been manufactured from HCV-tested plasma and accordingly could not be issued by the SNBTS after 31 December 1992 unless current CPMP proposals were altered. Dr Perry stated that the plan was to allow Z8 to become 'de-licensed' at this time.

It was agreed that the Haemophilia Directors would discuss this and report back to the SNBTS. HD's

Drs Perry and Prowse reported that plans were being prepared for the development of a fibrinogen concentrate by the SNBTS, and that this may be available for trial purposes in 1992. The product will be dry-heat treated.

Dr Gibson pointed out that defining an appropriate trial group may be difficult. She felt that much cryoprecipitate is used for neonatal DIC.

4 Update on HPVIII

It was noted that, particularly due to the delay in starting the efficacy study for HPVIII, there would be insufficient clinical experience data with the product to permit a licence application in late 1992. Dr Stewart suggested that this would be first quarter 1993. Dr Ludlam did not think that this would cause a problem, and colleagues agreed.

Dr Stewart reported that he had received no forms for the trial of semi-tartan HPVIII and that he would be visiting haemophilia centres in the next month to do so.

There was discussion on whether fortnightly liver function tests were still required for a PUP study. It was noted that the ICTH are to discuss this in July. It was agreed that the Haemophilia Directors would discuss whether it was acceptable to aim for monthly LFTs in addition to anti-HCV results. HD's

The resourcing of the HPVIII trials was discussed, and Dr Ludlam thanked Mr McIntosh for his efforts (and success) in finding money to support them. There had been some delays in appointing staff, but matters are now progressing.

Haemophilia Directors should liaise direct with Mrs Enid Soutar at SNBTS HQ.

ACTION

5 Experience with HPVIII - Pharmacokinetic study

Dr Stewart presented an interim report, which was discussed.

Dr Ludlam wished to minute the appreciation of the group for the efforts Dr Stewart had put in to ensure that the trial went smoothly.

It was discussed whether the group should recommend that HPVIII be more widely used. It was agreed that this was a decision for the manufacturer and their medical adviser.

6 Possible Specification for von Willebrand Factor

Dr Prowse tabled a paper comparing Haemate, 8Y, VHP-vWF (copy attached)

He reviewed the options for the SNBTS in developing a product for vWD. He suggested that the most straightforward was to modify the current HPVIII process to optimise its vWF content.

This was agreed and Dr Prowse agreed to bring back a more detailed specification. CVP

7 PUP Study

Dr Ludlam distributed a modified version of the PUP Study report. He asked colleagues to comment within 7 days. They agreed to do so.

Dr Stewart stated he was reminding members that they had agreed to check the PUPs for Factor VIII inhibitors. HD's

8 Adverse Reactions

Dr Ludlam reported one patient who previously reacted to Factor VIII and cryoprecipitate and who reacted to Lille HPVIII and semi-tartan HPVIII. He was now on PFC HPVIII and had not reacted yet. His reactions tend to be episodic.

Dr Walker reported a patient who had been taken off Lille HPVIII because of very vague symptoms and was now back on Z8 without any problem.

Dr Gibson reported that she had treated a baby with pyloric stenosis with high doses of Lille HPIX and had encountered no problems.

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9 Annual Meeting with SHHD — ACTION

Dr Ludlam's draft report was discussed. It was agreed that Dr Stewart's report on demand and usage should form an appendix of Dr Ludlam's report. It was agreed that Dr Stewart should remove the usage of Factor VIII per million population on a Regional basis from his document, as this supplies little valuable information. Dr Stewart also agreed to draft a short report on the Coagulation Factor Usage Survey. — RS — RS

10 Any Other Business

(i) Dr Mayne wished the recent letter from Armour stating that the data on high purity Factor VIII concentrates and immune function related only to monoclonally purified products brought to the attention of the group. It was suggested that a trial take place comparing HPVIII and Monoclate in anti-HIV positive patients. Mr McIntosh indicated that he would be prepared to support such a study. The Haemophilia Directors agreed to discuss and report back. — HD's

(ii) Mr McIntosh asked the members to further consider a name for HPVIII, as they were the people who would need to use it each day. Members agreed to do so but generally agreed that HPVIII was adequate.

(iii) Mr McIntosh asked the group for opinions on developments on HPVIII, eg. should it be heat treated in addition to solvent/detergent.

It was agreed that this and consideration of the impact of discontinuation of use of cryoprecipitate should be added to the next agenda.

11 Date of Next Meeting

The next meeting will be at 11.00 am on 9 October 1992 in the Board Room, Department of Medicine, Royal Infirmary, Glasgow.