

0003

Scotland and Northern Ireland Factor VIII Working Party1st Report April 1989

Remit "To recommend methods and strategies for the validation and testing of existing and new factor VIII products supplied by PFC."

Membership

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The first meeting of the Working Party was held on 23rd June 1988 and to date there have been 8 meetings.

The following topics are currently under consideration.

1. Factor VIII use by Haemophilia Centres

- a) 1983 - 1988 These have been collected and one appended. (Appendix A).
- b) Monthly statistics A scheme has been devised for the collection of blood product use at Haemophilia Centres on a monthly basis. This is co-ordinated by Dr. Stewart, who collects and collates the data. A summary of use is issued at the middle of the following month.

2. Factor VIII issues from PFC 1988/89 - 1989/90

Details of issues of SNBTS factor VIII to Haemophilia Centres during the financial year 1988/89 are given in Appendix B. Also listed are the original allocations by SNBTS which were based on use during 1987/88. The reallocation was achieved by a cumbersome system of "cross charging" and "exchange" between Health Boards.

The Haemophilia Directors proposals for factor VIII distribution for 1989/90 are also listed. It will only be possible to achieve such a distribution if Scotland

and Northern Ireland are considered together and there is a unified financing arrangement for the purchase of commercial product. This is needed because the amount of commercial product used is not related to patient numbers at any one Haemophilia Centre but to the pattern of previous use of non-NHS products.

3. Factor VIII output from PFC

During the year 1988/89 it is anticipated that approximately 10.8 M units of factor VIII will have been manufactured. Issues to Haemophilia Centres were 8.8 M units and 2 M units were set aside to recreate the National Reserve. During 1989/90 it is anticipated that total manufacture for issue will be at least 11.0 M units.

4. Demographic statistics of individuals with Haemophilia and von Willebrand's Disease

In order to evaluate the requirements for blood products at Haemophilia Centres patient statistics are being gathered. This will include diagnosis, age, severity and number of individuals with anti-factor VIII inhibitors. Although such data is available from the Oxford Register it is hoped that by collecting it locally it may be more accurate.

5. Development of new factor VIII product

The present factor VIII manufactured by PFC (28) is not an optimal product and a new higher purity concentrate is under development. This has progressed more slowly than originally anticipated. The project is strongly supported by the Working Party.

It is anticipated that the first infusions will occur in June and a formal Phase I study (i.e. recovery/half life) will take place at Drug Development (Scotland) Ltd. in September.

Thereafter a Phase II study will follow to demonstrate clinical efficiency.

Prior to any product evaluation in vivo a CTX will be obtained by PFC and a letter giving ABP1 Guidelines cover will be issued to each clinical investigator.

6. Viral safety of SNBTS factor VIII

There is no evidence to suggest that the present product

heated at 80 C for 72 hours will transmit HIV or non A non B hepatitis. Although there is substantial evidence to demonstrate HIV safety (no seroconversions are known since 1985 when heat treatment was introduced) there is very little data to demonstrate non A non B hepatitis safety. To date the second 8Y study in England and Wales has not recorded any episodes of non A non B hepatitis. One meeting of the Working Party was given over solely to consider methods for viral inactivation. The opinion of the group was that at present only heat treatment was preferable to a solvent detergent technique.

CONFIDENTIALDRAFT FACTOR VIII USAGE STATISTICS (CALENDAR YEARS)

	<u>1987</u>		<u>1988</u>		<u>Estimate</u> <u>1989</u>	
	<u>NHS</u>	<u>COMM.</u>	<u>NHS</u>	<u>COMM.</u>	<u>NHS</u>	<u>COMM.</u>
EDINBURGH	2.50		2.61	0.32	2. ⁸ 7 0	0. ⁴ 3 0
ABERDEEN	0.55		0.37	0.03	0. ⁷ 3 0	0.07
DUNDEE	0.56		0.56		0. ⁶ 3 0	
INVERNESS	0.37		0.43		0.40	
GLASGOW	4.50		4.75	0.56	^{4.6} 5.00	0.50 ⁹
BELFAST	<u>1.80</u>	<u>1.10</u>	<u>1.21</u>	<u>1.26</u>	^{1.8} 0.50	<u>1.31</u>
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<u>TOTALS</u>	10.28	1.10	9.93	2.17	9. ¹ 0	2.30
<u>ANNUAL TOTALS</u>	11.38		12.10		11.9	

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1983	2.3			0.36		0.32
1984	2.4	2.4		0.34		0.34
1985	1.7	2.1		0.35		0.36
1986	2.0	2.7	0.60	0.44		0.30
1987	2.7	3.6	0.92	0.56	0.55	0.37