BPP(73)1.M

JOINT STEERING COMMITTEE ON BLOOD PRODUCTS PRODUCTION

Note of first meeting held in DHSS, Euston Tower, London on 20 June 1973

Present	Dr. W.d'A. Maycock	Chairman
	Dr. J. Darnborough	Regional Transfusion Director, Cambridge
	Mr. L. Vallet	Blood Products Laboratory, Elstree
	Dr. J.A. Holgate)	
	Dr. S.L. Waiter)	DHSS
	Mr. W.A. Walters)	
	Mr. R.L. Fenner)	
	Dr. R.A. Cumming	Regional Transfusion Director, Edinburgh
	Dr. J. Wallace	Regional Transfusion Director, Glasgow
	Mr. J. Watt	Protein Fractionation Centre, Edinburgh
	Miss M.K. Macdonald)	
	Dr. I.S. Macdonald)	SHHD
	Dr. A.E. Bell)	
	Mr. R.N. Roberts, Secretary)	

1. Apologies for absence were received from Dr. R. Biggs and Dr. C.C. Bowley.

2. The Chairman welcomed members to this first meeting of the Joint Steering Committee. It had been originally intended that the chair and secretariat should alternate but it was agreed that both should now rotate annually between England and Scotland.

INTRODUCTION

3. In his introductory remarks the Chairman said that about 10 years ago an outbreak of rubella had revealed a shortage of immunoglobulin and exposed the inadequacy of production capacity. Planning to enlarge the Blood Products Laboratory at Elstree (BPL) was begun in 1962, completed in 1968, and building commenced in October 1969 with a target completion date of 1971 and operation at capacity from April 1972. In fact the new building was taken over in February 1972 and has been operating at full capacity from October 1972. The original buildings at Elstree are now being modernised and this work is expected to be complete by August 1973.

4 Scotland had been invited to make provision in the new Protein Fractionation Centre, Edinburgh (PFC) beyond its own requirements to process the equivalent of 1/3 the planned weekly intake of the BPL ie 500 litres of time-expired plasma on a 46 week year basis. Because of the need for collaboration

and co-ordination several informal meetings between the staffs of the two centres have already taken place.

5 The first meeting of the Steering Committee had been precipitated by the fact that product licences had been granted to two firms to import antihaemophilic globulin concentrate which might entail large sums being spent by NHS authorities on these products. It was foreseen that the Steering Committee might need to meet frequently; in addition the possibility of small groups of medical and scientific members of the Steering Committee being asked to consider specific problems was also proposed.

MEMBERSHIP

6. The Steering Committee is made up of representatives of the two Health Departments, the English and Scottish Regional Transfusion Directors and the Blood Products Laboratory and the Protein Fractionation Centre.

TERMS OF REFERENCE

7. The Chairman explained that the terms of reference (Paper BPP(73)1.2) were framed to cover the whole field of plasma fractionation and were not intended to inhibit discussion in any way and should not restrict co-option of experts as necessary. It was not intended that "co-ordination of research and development" should inhibit work at either the BPL or the PFC.

8. Dr. Holgate from the Medicines Division of DHSS said that he was glad of any point of contact with the production of blood products. The Division's interest was in procurement and quality control. It was agreed that the terms of reference should be extended to include a new item (g) "Matters concerning the application of the Medicines Act 1968".

9. The Steering Committee then adopted the proposed terms of reference with the amendment in para. 8.

DEVELOPMENT OF FACILITIES

10. Mr. Vallet reported that full-scale production at the BPL had now been achieved and was at the stage of final adjustment. He hoped to produce a paper similar to that prepared for PFC.

11. Mr. Watt's Paper BPP(73)1.5 set out the programme and timetable of commissioning for the PFC. The system of production used would be an automatic one and any problems which arose would originate from the scale of the system itself. : No Scale of operation yet.

12. The aim, initially, at Liberton was to produce 6.5 containers of plasma protein fraction (PPF) per 1000 population in Scotland. This figure has been recommended by the Central Consultative Committee on Blood Transfusion. Dr. Cumming thought that it might have to be increased to as much as 10 or 12 units per 1000 population. Production capacity at the PFC would be sufficient to meet these higher figures if this were necessary. In England the estimated capacity was 3.2 units per 1000 population including the production to be undertaken in the PFC for England.

13. Mr. Watt made the point that 6.5 per 1000 population was based on the plasma intake at RTC Edinburgh about 6 months ago; since then demand, from some areas at least, had risen above that figure. Plasma to meet this increasing demand was being collected now. Dr. Wallace said that in the West of Scotland Region PPF was being used almost exclusively as a plasma volume expander and that it was essential to plan to meet the forecast increased demand. The 1975 estimate in Scotland assumes that the plasma from 60% of blood donations would be needed to prepare PPF.

14 The Chairman felt that some control over the use of donations of human blood might be necessary if human blood or its derivatives were used in place of entirely acceptable materials of non-human origin which gave equivalent clinical results. Point was not made we use of plasma derived from pools in late fifties and substituted with cryoblurb. Reasonable to foresee replacement of cryoblurb by plasma based solution of better quality.

15. It was pointed out that one way of increasing the amount of plasma available was to encourage the use of concentrated red cells. Dr. Wallace reported that in his region 40 per cent of blood issued is in the form of concentrated red cells. The use of plastic packs was essential in this connection.

16. It was urgent for PFC to know what volume of plasma they would be asked to fractionate for England.

17. SHHD invited a group composed of medical and scientific experts to visit PFC to see the new process and it was proposed that this would be possible before the Joint Steering Committee next met in Edinburgh in October. DHHS undertook to let SHHD know when such a visit could be made.

Please advise

REASSESSMENT OF MATERIALS NEEDED TO TREAT HAEMOPHILIA - PAPERS BPP(73)1.3 and 1.4

18. The following additional papers were tabled:-

a. BPP(73)1.6 - Letter from Dr. Biggs about supply of high potency human factor VIII concentrate.

b. BPP(73)1.7 - Details of donations used in England to prepare fresh frozen plasma and cryoprecipitate.

c. BPP(73)1.8 - Notes on a scheme to increase the preparation of Factor VIII concentrate from 200 to 1000 litres of plasma per week at BPL Elstree.

d. BPP(73)1.9 - Summary by Chairman of aims and consequences.

19. The question of the treatment of haemophilia had been discussed at an ad hoc meeting on 20 March at which Dr. Biggs paper BPP(73)1.4 had been considered. A note of the meeting had been circulated as paper BPP(73)1.3.

The main points that emerged from the discussion were:-

a. It was decided in principle to treat the UK as a whole and that the first target should be Dr. Bigg's lower estimate of the plasma from 400,000 donations with 700,000 donations as the ultimate target.

b. The initial aim should be to provide anti-haemophilic globulin concentrate from 250,00 donations by 1975.

c. The UK should opt initially to meet most of the requirement with an "intermediate potency product" but about 10% of the total output should be a "high potency product".

d. DHSS was considering making "call-off contracts" for two commercially produced anti-haemophilic globulin concentrates which would be available through Haemophilia Centres. It was agreed that it would be of considerable interest to the Joint Steering Committee to have details of the rate of purchase by the Centres.

e. The UK should aim to be self-sufficient by 1975.

20 Experience at BPL had been that small volume production gave higher yields. New methods under trial were yielding concentrates comparable with high potency products.

21. The PFC experience was that intermediate potency material had a potency of 10 units/ml final product; no difficulty was foreseen in increasing this to 20 units/ml final product.

22 Dr. Holgate said that minor variations, for example in temperature or pH, might affect the product. For this and also other reasons it was necessary for licence requirements to be kept flexible. He cited vaccine licences as an example.

23. In the South-Eastern region of Scotland, population approximately 1 1/4 million,there was no restriction in use; Factor VIII from the equivalent of about 12,000 donations per year was already being used. Scotland was already well on the way to using plasma from 50,000 donations per year to prepare Factor VIII concentrate. This latter figure contrasted with the earlier figure of 34,000 donations given in paragraph 1 of paper BPP(73)1.9 as the number of donations used in Scotland for the treatment of haemophilia. The intake of plasma for Factor VIII productions was already within the range suggested by the Haemophilia Directors.

24. The Joint Steering Committee then discussed how to collect the additional donations. Plasmapheresis was a possible method but carried additional risks for the donor. Most of the plasma would have to be frozen. In Scotland 95% of plasma was separated within 6 hours of collection but acceptable if frozen within 18 hours of donation. The quality of separation was important and it was suggested that centrifuging for 1 hour at minus 30°C at 3000G was ideal.

25 Summing up, the Chairman said

(i) Scotland had apparently nearly reached and might exceed their proportion of the target for donations for the treatment of haemophilia suggested by Dr. Biggs.

(ii) DHHS should re-examine the estimates for PPF as it appeared that

these were low. DHHS might decide that SHHD should be asked to arrange for PFC to fractionate more time-expired plasma on their behalf than had been arranged in 1968.

(iii) SHHD asked to be informed as soon as possible if the estimate was revised, so that modifications to PFC, if necessary, could be made while the contractor was on site.

DATE OF NEXT MEETING

26. The next meeting was arranged for 10.30 on Tuesday 9th October 1973 in St. Andrew's House, Edinburgh.