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BLOOD PRODUCTS AND RELATED MATTERS

NOTE OF A JOINT DHSS/SHHD MEETING ON MUTUAL PROBLEMS HELD ON FRIDAY 11 MARCH 1977 AT DHSS, HANNIBAL HOUSE, LONDON.

PRESENT:	Mr A L Parrott	(Chairman) DHSS
	Mr T E Dutton	DHSS
	Dr A D McIntyre	SHHD
	Dr W d'A Maycock	BPL Elstree
	Mr R N Roberts	SHHD
	Mr L Vallet	BPL Elstree
	Dr Sheila L Waiter	DHSS
	Mr J Watt	PFC Edinburgh
	Mr R P Cleasby	DHSS

1. APPOINTMENT OF CHAIRMAN

It was agreed that Mr Parrott should take the chair.

2. PRODUCTION CAPACITY OF THE UK CENTRAL BLOOD PRODUCTS LABORATORIES

2.1 Mr Watt suggested that the UK fractionation needs were of the order shown below:

5000 L	plasma	per	week	for	AHG
1000 L	"	"	"	"	albumin
3000 L	"	"	"	"	PPF
9000 L	"	"	"		

The effective fractionation capacities for the above products of the UK central laboratories were:

Elstree and Oxford : 3000 L for PPF and albumin including 1400 L plasma per week for AHG.

Edinburgh : 1500 L plasma per week (supplies sufficient for Scotland's needs)

= 27 million iu AHG concentrate per annum (46 weeks)

This indicated a UK shortfall in capacity of 4500 L plasma per week.

2.2 PFC Edinburgh's effective capacity was however much lower than its potential capacity, due to the problem in the present phase of Incomes Policy of entering into an agreement with the trade unions on shift working. If a shift system could be introduced, as was originally intended, the capacity could rise to 6000 L plasma per week (3 shifts) or 3000 L per week (2 shifts). The extra cost to achieve 6000 L per week was not expected to be more than about £20,000 in capital and £30,000 a year in revenue. As the Scottish NBTS

does not at present produce more than 1500 L plasma per week, the additional quantities of plasma required to keep Liberton functioning economically would have to come from England, Wales and Northern Ireland or elsewhere. A two-shift system could just be viable on a turnover of 2000 L per week, which suggested that initially England would have to supply an additional 500-600 L per week. English/Welsh RTDs would be consulted about the possibility of this. When the Liberton plant had been planned its capacity was worked out on the assumption that it would receive in the first instance up to 500 litres of time expired plasma a week from E & W when the capacity of BPL had been taken up. It was understood that a contribution to the capital cost of the plant had been made on this basis but this would be checked.

2.3 SHHD said that they had explored all possible approaches to settling the dispute at PFC Edinburgh, but the PTB Whitley Council Management Side were unable to make an acceptable offer because of current pay policy. The Chairman agreed that it was essential to try to break the existing deadlock and to raise the matter again within DHSS, if SHHD would supply full details; the new round of pay policy being drawn up might provide opportunities which the present policy did not provide. It would of course be necessary to ensure that the additional plasma would be available in the event of the dispute being settled.

The fractionation capacity at Elstree and Oxford would probably be reached in mid 1977. On the basis of the present input of fresh, frozen and time-expired plasma it was estimated that the following components would then be produced annually:-

Approximately 15,000,000 iu of AHG concentrate.
130,000 bottles PPF and 12,000 bottles of dried plasma
5-7000 units of 20% albumin
normal immunoglobulins in excess of requirements.
specific " from all available specific plasma

Elstree worked an extended day; there were no plans at present for changing from the batch system of production. It would almost certainly be necessary for Regional Transfusion Centres in England to spend more money if more plasma was to become available. The Elstree plasma at present being stored at Liberton (accumulated during repairs to the cold store at BPL) would be fractionated as soon as the Liberton stockpile had been fractionated.

It was apparent that if the UK requirements of AHG concentrate turned out to be as high as 60,000,000 international units per annum, as some clinicians were now suggesting, it would take up all the existing capacity at Elstree and Oxford and the whole of the output of which Liberton was theoretically capable. In view of the low yield of AHG per litre of plasma, obtained in all 3 fractionation laboratories, it became increasingly necessary to ensure that the active principle was not lost in storage and transport. The time between collection and freezing and the manner of freezing were important factors.

2.4 It was AGREED:

i The Directors of the central laboratories would furnish Mr Dutton with complete figures relating to the production capacities of the laboratories so that these could be reviewed in greater detail.

ii Dr Maycock would ask RTDs in England and Wales to consider how they might set about providing an additional 500-600 litres of time-expired frozen plasma a week for PPF.

iii Armed with the information which SHHD would provide, Mr Parrott would bring to the notice of the Whitley Division concerned the problem which the inability to introduce shift working at Liberton was causing, the regrettable underusage of production capacity and the dire consequences for the NBTS.

3. PROCESSING AND LABELLING OF PLASMA FRACTIONATED ON BEHALF OF BPL ELSTREE

3.1 Mr Dutton had raised with SHHD the question of the wording on the labels of plasma which PFC Edinburgh were to process on behalf of DHSS.

3.2 Dr Maycock thought that it was necessary for Scottish and English fractions to be comparable; it would however be desirable for products to be labelled showing the laboratory responsible for preparation. He mentioned that it had been agreed in the past that plasma from English RTCs would reach Scotland only via BPL Elstree, and to this extent PFC would be processing on behalf of the England/Wales service.

3.3 Mr Watt was concerned about the amount of information that was required on each vial already and had reservations about adding to it. He preferred a direct relationship with the centres supplying plasma to be processed at PFC and he did not wish to see any scheme which suggested that PFC occupied a position subordinate to BPL.

3.4 The meeting established that there was no question of a master-subordinate relationship between BPL and PFC. It was agreed that the Directors of the plasma fractionation units would meet to design suitable labels incorporating the information that the product had been prepared at PFC Edinburgh on behalf of the English and Welsh services.

4. POLICY ON THE DISPOSAL OF SURPLUS BLOOD COMPONENTS

4.1 SHHD had last year sought DHSS views on possible uses for blood components surplus to Scottish needs. It was estimated that up to 100,000 doses of normal immunoglobulin could be produced annually from the surplus plasma. The desirability of a common DHSS/SHHD policy on its sale or disposal otherwise to foreign countries was noted.

4.2 The meeting considered the acceptability of charging on a commercial basis for blood products supplied overseas. It was thought unacceptable to levy a charge in respect of blood itself; but charges to cover processing service costs could be justified. The possibility of fixing the service charge so as to obtain a profit - to be used for the benefit of the blood transfusion services - was referred to and it was agreed that a discreet

survey by RTDs and RDOs to assess donor reaction to charging should be undertaken before further discussions took place.

5. CONTROL AND DISTRIBUTION OF COMMERCIAL BLOOD PRODUCT SUPPLIES

The meeting noted the differing practices in the 2 services. In some areas of Scotland all blood products, both commercially and NBTS-produced, were issued through Regional Transfusion Centres; in England and Wales, however, the absence of a central authority for the NBTS and the relationships between DHSS and health authorities prevented such an arrangement being imposed in all Regions. (In one English Region, commercial products were issued through the RTC). It was agreed that the cooperation of clinicians in devising suitable arrangements for England and Wales was necessary, and Dr Waiter agreed to discuss the matter informally with Haemophilia Reference Centre Directors.

6. INSURANCE POLICIES : COVER FOR DONORS

The Departments had recently corresponded about the need to approach the Life Offices Association to ascertain the effect on the life assurance policies held by people who volunteered to (a) be immunised for the production of anti-A and anti-B sera for diagnostic (ie non-therapeutic) purposes and (b) donate by means of a cell separator. Mr Dutton questioned the advisability of approaching the Association without adequate knowledge of the risks involved because of the uncertainty which would ensue if they were not prepared to cooperate but the general view of the meeting was that Departmental policies on the use of volunteers would have been formulated differently if it had been thought that the volunteers would be placed at a disadvantage. It was accordingly agreed in principle to approach the Association, and the Departments would consider the exact form of approach.

7. FUTURE MEETINGS

After discussion it was agreed:-

i that the meeting had been extremely valuable and that similar meetings should be held periodically;

ii such a joint working party could usefully assume the functions of the former Joint Steering Committee on Blood Products Production;

iii the membership of the working party should be smaller than that of the former JSC, corresponding roughly to that of the present meeting;

iv the Directors of the plasma fractionation units should meet as and when required to discuss scientific matters and other subjects not appropriate for consideration by the full working party. For the benefit of the Directors and their successors minutes of these meetings would be prepared;

v the frequency of meetings would be twice-yearly.

8. DATE OF NEXT MEETING

22 August 1977 in Edinburgh

DHSS
H1/B15/02

cc those present

File

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 of 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, 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 the planned full-scale production at the BPL had now been achieved and was at the stage of final adjustment. A paper on the capacity actual and potential of the laboratory for various products would be prepared.

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 most problems which arose would originate from the scale of the system itself.

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.

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. DHSS undertook to let SHHD know when such a visit could be made.

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 250,000 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 in volume 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 ¼ 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 products 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 3000G was ideal. Immediately after separation plasma should be frozen and stored at or below minus 30°C.

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) DHSS should re-examine the estimates for PPF as it appeared that these were low. DHSS 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, in Conference Room D.