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CENTRAL BLOOD LABORATORIES AUTHORITY

Self-Sufficiency in Blood Products in the New Manufacturing Unit

MEETING THE DEMAND FOR PLASMA

PREAMBLE

1. It has always been recognised that a redeveloped B.P.L. capable of achieving national self-sufficiency would be dependent upon an adequate supply of good quality plasma from the R.T.C.'s.

2. The work of an ad hoc group, formed by Dr. G.H. Tovey in 1980, was consolidated by the formation of a Working Party on Plasma Supplies by the Advisory Committee on N.B.T.S. In its two reports (AC(81)11) and (AC(81)18) the means of adequate plasma procurement and the best information on costs were reviewed. Following acceptance of the reports, the Advisory Committee asked R.H.A.'s to determine how the increases in plasma supply would be managed.

3. In response, the 10 R.H.A.'s who replied accepted the principle of self-sufficiency but, in general, qualified this statement by questioning whether financial resources would be available to achieve this aim within the relatively short time-scale envisaged (AC(82)7).

4. During 1983, the Director of B.P.L. and Dr. H.H. Gunson held meetings with R.T.D.'s to discuss the practicalities of meeting the enhanced plasma supply. The target of 450,000 litres per year by 1987 was established as feasible by the use of optimal additive solutions to maximise the recovery of plasma from whole blood supplemented by a programme of plasmapheresis. R.T.D.'s were asked to put proposals to their R.H.A.'s based on a scaling-up of plasma supply commencing in 1984/5 to be completed in 1987/8.

5. During the latter part of 1983, Dr. H.H. Gunson wrote to R.T.D.'s enquiring of the progress made. His report to the C.B.L.A. (84(1)) detailed only three R.T.D.'s who were confident of obtaining the necessary financing and it concluded by stating that it would be unwise to assume that the necessary quantity of plasma would be available.

6. The Advisory Committee on N.B.T.S. agreed that Regional Administrators would be asked to state the arrangements which were being made to meet targets for plasma supply. In November, 1984, it was reported to the Advisory Committee that, with 12 replies received, only five R.H.A.'s had given assurances that their targets would be met, although six others had given qualified replies on funding and/or timing. One R.H.A. had not taken any decision.

7. At the meeting of the C.B.L.A. in November, 1984, when the facts in para. 6 above were reported, it was agreed that the matter was now so serious that the Director of B.P.L. must review the options available for an assured increase of the plasma supply and this should be audited by Dr. H.H. Gunson. The most acceptable option with costs should be presented to the Policy Division of D.H.S.S. (H.S.2) and would be discussed with the Chairman of C.B.L.A. with a view to its presentation to Ministers early in 1985.

THE MAGNITUDE OF THE PROBLEM OF PLASMA SUPPLY

8. Currently R.T.C.'s are providing approximately 150,000 litres plasma per year to B.P.L., largely derived as a by-product of blood collection, in that it is removed from whole blood donations. Some R.T.C.'s have introduced, and others are committed to do so in 1985, optimal additive solutions which allows the collection of 50 per cent more plasma from each unit of whole blood. It is difficult to assess the increase in plasma that these operations will provide but it should be between 200,000 and 250,000 litres plasma per year by 1986. The latter figure should be regarded as a maximum.

To attain the target of 450,000 litres per annum, therefore, it will be necessary to supplement the plasma derived from whole blood by the acquisition of an additional 200,000-250,000 litres plasma per year.

OPTIONS AVAILABLE FOR MEETING THE PLASMA DEMAND AND THEIR ANALYSIS

9.1 Purchase of the additional quantity of plasma

Plasma, obtained by plasmapheresis from paid donors is available on the world market originating from the U.S.A. The cost will depend on the size of the order, but would average between $50-60 per litre plus shipping costs,the total cost, therefore, for 200,000-250,000 litres would be between $15M - $18M (£13M-£16M). This price should not be used to compare costs of plasma derived from whole blood.

Such a policy, however, would be contrary to the principles of W.H.O. which are supported by H.M. Government. For medical, ethical and political reasons it cannot be considered a viable option.

9.2 Continuation of discussions with R.H.A.'s

Further direct approaches by D.H.S.S. could be made to those R.H.A.'s who at present will not give a commitment either in finance or in time.

Several factors remain against the success of this approach.

9.2.1 Most R.H.A.'s are now finalising their programmes for 1985/6 and if plasma supply is not among their immediate priorities it may be difficult to persuade them to include it at this stage.

9.2.2 Current targets for plasma supply are based on population, whereas demands on regional transfusion services for fractionated blood products and other components, e.g. platelets do not necessarily depend on population, and in regions where such demands are heavy, there may be considerable difficulty in achieving regional self-sufficiency. To compensate for this factor, certain regions will need to produce more plasma than required by purely regional health care demand. If regions fail to produce plasma in line with nationally determined targets, a shortage will result or the onus on other regions will be increased.

9.2.3 R.H.A.'s are not likely to approve finance for more than regional self-sufficiency, even if inter-regional charging could be offered (and this is unlikely in the short-term) since staffing targets have to be met, and increases of staffat R.T.C.'s require savings elsewhere.

Whilst this option might be considered favourably in line with D.H.S.S. current policy for devolved health service management, doubt must be cast on its feasibility due to the relatively poor response during the past three years and time does not now permit protracted negotiations.

9.3 Independent Collection of plasma by C.B.L.A.

A system could be envisaged whereby plasma to supplement that which can be reasonably obtained from R.T.C.'s could be collected independently by the C.B.L.A.

However, this would involve the C.B.L.A. in a major expansion of activities to include donor recruitment, acquisition of premises, blood collection staff who would require training and the majority of whom would be operating at a considerable distance from their base; there would be competition for donors with R.T.C.'s and conflict would be inevitable. Moreover, it is unlikely that this option could be achieved in the time available and with the need to create a large infrastructure it is likely that costs would be greater than those for obtaining plasma from R.T.C.'s.

9.4 Establishment of central co-ordination of plasma supply

This chould be achieved in two ways:

9.4.1 The cost of the entire plasma collection could be funded centrally, each R.T.C. producing plasma to an agreed target.

Whilst this option holds some advantages, notably placing the plasma supply, both quantitatively and qualitatively on a contractural basis, it poses problems e.g. fixing a plasma price between regions. Without national agreement on organisation and financial management of R.T.C.'s it is difficult to assess the actual cost of plasma separation from whole blood, tied up as it is inevitably with the processing of other labile components often performed concurrently by the same group of staff.

9.4.2 Plasma collection by automated plasmapheresis could be funded centrally.

The disadvantages referred to in 9.4.1, above, would not apply to plasma collection by plasmapheresis since this can be identified as a discrete operation. Even when the collection of plasma is combined with platelet collection, costs can be easily apportioned.

Thus:

(i) A renewed approach could be made to R.H.A.'s to finance plasma collection from whole blood to the level of 250,000 litres per year. Not only has it been agreed that this quantity of plasma is within the competence of R.T.C.'s but also, it would not involve any R.H.A. having to exceed the quantity of plasma required for regional self-sufficiency.

(ii) The plasmapheresis programme would be designed to produce 200,000 litres plasma per year. This could be funded either by specific grants to regions or through the C.B.L.A.

10. THE PREFERRED OPTION FOR MEETING THE PLASMA SUPPLY

10.1 Careful consideration of the facts presented has led to the conclusion that the preferred option would be the collection of plasma from whole blood by R.T.C.'s, funded regionally, together with a centrally co-ordinated and funded plasmapheresis programme (paragraph 9.4.2. (ii)).

10.2 Financing of the plasmapheresis programme through the C.B.L.A. would be preferable. By this means significant logistical and qualitative benefits affecting the specification of the plasma can be built into a form of contract between the R.H.A.'s and the C.B.L.A. for which funding was provided.

10.3 In practical terms, the R.T.C.'s will act on an agency basis for B.P.L. to produce an agreed volume of plasma annually.

10.4 At a later date this means of financing could be a basis for recharging R.H.A.'s for finished products.

11. ESTIMATED COSTS OF A CENTRALLY CO-ORDINATED PLASMAPHERESIS PROGRAMME

11.1 Details of the estimated costs are set out in Appendices I and II. These are based upon a plasma yield of 1000 litres per machine per year, which requires the recruitment nationally of 60,000 donors. Also, it is assumed that the minimum size of a unit will comprise 10 machines to minimise the number of supervisory, organising and clerical staff per machine. No allowance has been made for blood grouping the donors since this should be a minor commitment; the cost of anti-HTLV3 testing will have to be added when this is known.

In the exceptional circumstances, units of less than 10 machines may be considered, e.g. when an existing unit is to be extended. In these instances the cost-effectiveness will require careful assessment.

11.2 The cost of transporting the plasma to B.P.L., which will have regional variation, is not included in the Appendices; vehicle and staff costs are estimated to be approximately 0.37p per mile when an overnight stay is required to comply with the Transport Act and correspondingly less otherwise. For a 10-machine unit it is estimated that deliveries to B.P.L. will have to be made weekly, i.e. lots of 200 litres. This cost may be modified following B.P.L.'s analysis of plasma transportation.

11.3 It can be seen that the total revenue costs for the collection of 200,000 litres plasma per year is £7,774,800. If one adds to this one-seventh of equipping costs based on a replacement programme between 5 and 10 years, the cost of the plasma is £40.90 per litre, plus the cost of transport.

The cost of plasma currently received at B.P.L. is £6M per annum based upon an estimated cost of £40 per litre of plasma collected from all sources. It can be seen that the cost of plasmapheresis derived plasma now approximates to that of other plasma and it can be estimated that the total cost of 450,000 litres will be approximately £18.2M (This cost can be compared with £21.33M currently used in the investment appraisal of B.P.L.).

11.4 It may be possible to achieve a reduction in both the equipping and revenue costs stated above by negotiating the cheapest rates for machine purchase and for the central purchase and distribution of the necessary disposables.

11.5 Alternatively, instead of the outright initial purchase of machines, it would be possible to implement a hire agreement on a five year contract. A model for such an agreement is given in Appendix II. It will be noted that this will add £2.00 to each litre of plasma produced.

After five years, the machines will become the property of the N.H.S.

Such a proposal effects an initial saving of £2.2M but the total cost will be greater over 5 years due to interest payments.

Note: The costs detailed in Appendices I-III with respect to machines and collection sets have been obtained from Haemonetics Ltd.

12 RECOMMENDATIONS

There are two problems which must be solved by any recommendations:

(i) Sufficient finance must be made available in order to collect the required quantity of plasma.

(ii) A management programme must be evolved which will allow the effective spending of money in the time available; this period, for logistical reasons, will have to encompass two financial years but must be completed by the end of 1986/7.

12.1 In order to effect the annual target of 450,000 litres plasma per year it will be necessary to increase the quantity of source plasma from the existing whole blood programme and organise a plasmapheresis programme.

12.2 That R.H.A.'s be urged to finance the maximum degree of plasma separation from whole blood to reach a level of 250,000 litres per year by 1986/7.

12.3 A centrally co-ordinated plasmapheresis programme consisting of 20-25 units within the fourteen regions, financed through the C.B.L.A., be established in order to collect the balance of 200,000 litres plasma per year.

12.4 Ministers should be approached with a view to the provision of finance for this purpose being made available as soon as feasible.

12.5 A Working Party be established under the aegis of the C.B.L.A., chaired by one of its members, to include representatives of the parties involved. The Working Party will urgently consider detailed proposals for agreement and early implementation.

R.S. LANE
H.H. GUNSON

17th January, 1985

APPENDIX I

CENTRALLY CO-ORDINATED PLASMAPHERESIS PROGRAMME

Estimate of the number of machines required:

Staff working time	= 7.5 hours per day
Effective working time	= 6.5 hours per day
Time taken for each procedure	= 45 mins. (0.75 hour)
No donors per machine	= 8.7 per day
Allow for 80% bed occupancy	= 7 donors per machine per day
At 250 working days per year	= 1750 donors per machine per year
Assuming 0.6 litre plasma per procedure	= 1050 litres per machine per year
	SAY 1000 litres per machine per year

To collect 200,000 litres plasma, 200 machines are required.

Estimate of the number of donors required:

Assuming each donor attends 7 times per year;

No. donors per machine per year	= 250
Add 15 per cent for rejections	= 268 donors per machine per year
Add 20 per cent for failure to respond	= 300 donors per machine per year

For 200 machines, 60,000 donors are required

Estimate of staffing costs:

Assuming a unit of 10 machines, the following staff will be required per machine.

	£	
Medical Officer (Clinical Assistant, 1 session/week)	1,792	
Ward Sister II, 0.1 wte	785	
Staff Nurses, 0.5 wte	3,104	
Donor attendants, 0.5 wte	2,210	
Assistant Donor Organiser (Scale 1, A&C), 0.1 wte	693	
Higher Clerical Officer, 0.1 wte	573	
Catering Assistant, 0.1 wte	455	9612

(November 1984 pay and prices, minimum of the scale, empolyers costs included).

Estimate of non-pay costs per machine per year:
(Assuming a unit of 10 machines)

	£	
Collection sets, 1750 at £12.65 each	22,137	
Service contracts, £1100 per machine (after 1st year)	1,100	
Donor publicity	300	
Disposables, £2.50 per procedure	4,375	
Printing, stationery, postage, telephones	100	
Staff uniforms	200	
Services	200	
Hepatitis B testing	850	29,262
Total		38,874

SUMMARY:

Assuming machines are grouped in units of 10:

Staffing costs for 200 machines	1,922,400
Non-pay costs for 200 machines	5,892,400
Total	7,774,800

November 1984 Pay and Prices, inclusive of V.A.T.

APPENDIX II

CENTRALLY CO-ORDINATED PLASMAPHERESIS PROGRAMME

EQUIPMENT COSTS

Assuming 10 bedded unit the following general equipment is required per machine:

	£	
1 blood collection couch	860	
1 i.v pole	60	
1 instrument trolley	100	
Resuscitation trolley (1 per 10 machines)	400	
ECG machine (1 per 10 machines)	50	
Laryngoscope and E.T. tubes (1 per 10 machines)	8	
Suction apparatus (1 per 10 machines)	25	
2 pillows and 2 blankets	30	
Scissors and artery forceps	20	
Bed screens	40	
Sphygmomanoters	35	
Hand sealers	45	
Cooker (1 per 10 machines)	20	
Refrigerator (1 per 10 machines)	15	
Coffee tables (5 per 10 machines)	20	
Crockery and snack trays	23	
Staff lockers (112 per 10 machines)	40	
Easy chairs	100	
Desk and chairs (3 per 10 machines)	40	
Filing cabinets	18	
Drug cupboard (1 per 10 machines)	15	
Typewriter and trolley (1 per 10 machines)	50	
Microprocessing equipment	400	
Fan assisted freezer and formers (1 per 10 machines)	800	3214
Plasmapheresis machine		11,000
Total		14,214

TOTAL COST FOR EQUIPPING 200 MACHINES **£2,842,800**

CAPITAL COSTS FOR CONVERSION OF PREMISES CANNOT BE ESTIMATED

(All costs inclusive of V.A.T.).

APPENDIX III

MODEL FOR HIRE AGREEMENT FOR MACHINE PURCHASE BASED ON A FIVE YEAR CONTRACT

	£
Cost of machine	10,000
*Service for 4 years	4,000
Interest over 5 years	5,000
	19,000
Cost per year, per machine	3,800
With 1750 procedures per year (Appendix I), cost per procedure	2.17 + VAT
i.e.	2.50
With 0.6 litres collected per procedure, additional cost per litre	2.00

Therefore, cost per litre will rise from £40.90 to £42.90

* The first year in the life of the machine is free from service charge.