~~Draft~~. 11.4.83.

PLASMA SUPPLY -

NATIONAL BLOOD TRANSFUSION SERVICE

A meeting of the Regional Transfusion Directors was held at the Blood Products Laboratory on Monday, 28th March 1983, to receive information concerning the future requirements for increased supply of plasma for fractionation. A request was made that the data, with a supporting commentary, should be made available for further consideration. The data are detailed for Transfusion Directors; it does not follow that this data, in the form presented, is appropriate for presentation to Authority officers or DHSS committees - in fact it could be counter-productive. The object of providing the data is to make possible further study of national and regional requirements to increase procurement of plasma on a controlled basis and with assurance about the related cost effectiveness of procedures.

INTRODUCTION

The Blood Products Laboratory is in the process of being recast in a form which can meet NHS requirements for components based on human plasma and at a standard identifiable with best practices in the pharmaceutical industry. Until a new factory is commissioned into manufacture, the intervening period has been described as the Interim Programme within which certain defined needs have been, or are being, resolved:

1. a new factory
2. new management
3. new terms of reference
4. relevant conditions for employment of staff.

The intrinsic function of the Interim Programme is to prepare the existing Blood Products Laboratory for proper expansion into the new enlarged pharmaceutical manufacturing environment. For this purpose, the Interim Programme contains several phases of growth as part of the overall planned redevelopment, including the commissioning of the new factory and manufacture at self-sufficiency levels. In the Interim phased redevelopment, examples of various components include (1) rebuilding - designed to give the existing laboratory a nominal fractionation capacity approximating to 150,000 kg per annum; (2) a basis for increasing staffing in line with total manufacturing needs of the existing and new factories and meeting Good Manufacturing Practice; (3) new inputs from computerisation, engineering, quality control and R & D.

+7/350

1704

An element of high priority in the Interim Programme is a qualitative and quantitative increase in the supply of plasma for fractionation: the reason for itemising other parts of the phased growth is to draw attention to the fact that plasma supply and all other functions of the organisation are inter-related since they collectively influence the growth in total resources. By the same reasoning, activities at the Blood Products Laboratory which influence resources, interact with the planning and redevelopment of the Regional Transfusion Services at most levels. It is apparent at BPL that growth in resources and increase in production are linked to each other and to the budgetary requirements of the organisation: effective growth can only take place at a rate approximating to the slowest changing parameter. Mobilisation of resources to meet the needs of the new Blood Products factory therefore presents a significant challenge, since the date for completion of the new factory is December 1985. If work were to be co-ordinated immediately on all NBTS matters concerned with increased plasma procurement, the rate of required growth would still pose significant problems.

REQUIRED GROWTH IN PLASMA SUPPLY

Estimated fresh frozen plasma input to BPL during the financial year 1982/3 will be 125,000 kg. The maximum capacity of BPL during the remainder of the Interim Period approximates to 150,000 kg FFP per annum; thus, a modest increase in fresh frozen plasma is still required to meet Interim production targets. This increase in supply is expected to take place early in the financial year 1983/84.

Nominal fractionation capacity of the new factory is 450,000 kg FFP + approximately 50,000 kg time-expired plasma and other source materials. In theory, the nominal transition in capacity occurs acutely in January 1986, but it is unrealistic to plan growth to match the profile of the theoretical manufacturing capacity. The sudden jump in requirements will need to be smoothed out by planning a steady growth in plasma supply and related resources between now and April 1988 which will permit routine manufacturing to occur up to December 1985 with planned simultaneous accumulation of excess stored FFP to buffer the sudden increase in demand of the new factory from January 1986 onwards. Figure 1 sets out one programme meeting this stepped demand: the buffer stock of FFP amounts to approximately 90,000 kg, i.e. a quantity comparable with 10 months' current input. The financial implications of developing this buffer stock of plasma are considerable and must be clearly defined for budgetary

47/35i

purposes: data which follow provide a basis for assessment of plasma procurement costs and indicate that any forward estimates will be highly dependent upon systems for plasma collection which are to be employed.

REDEVELOPMENT OF THE BLOOD PRODUCTS LABORATORY

Figure 2 shows in summary a preliminary schedule of the redevelopment. A capital sum of £21.1M has been allocated for the redevelopment and the necessary approvals obtained. It is intended that work commences on site at the beginning of May 1983 and that commissioning of plant and systems occurs during the first half of 1985. Process commissioning is planned to commence in July 1985 and final commissioning and take-over of the facility is due in December 1985.

The method for design, contracting and building allows for rapid progress which is seen as essential to achieve the economic targets for the laboratory on which the basic cost appraisal was made. For budget control purposes, the cash flow for rebuilding has been projected over the next 30 months, the profile being a typical S-curve: the bulk of expenditure occurs during 1984.

The mobilisation of associated resources, e.g. the build-up in plasma procurement, will need to parallel the building curve and not relate, in stepwise manner, to annual production estimates. If the latter were to occur, the main input of resources into plasma collection would not take place until after the new BPL had been commissioned - the result would be a serious manufacturing hiatus due to lack of source material, lasting three or more years.

PLANNING PLASMA RESOURCES

Supply of fresh frozen plasma needs to increase by nearly four times during four years. There have been numerous papers written about ways to collect 450,000 kg of FFP utilising the normal voluntary donor whole blood resource of NBTS (approximately 2.1M donations per annum) augmented by varying amounts of plasmapheresis by manual and machine methods. It is known that less than half the plasma requirement can be met using Recovered Plasma from normal blood donations unless substantially increased whole blood donation is performed, regardless of wastage considerations and their associated costs. It is therefore opportune that the development of blood collection, coupled to red cell resuspension in SAG-Mannitol or other optimal additive solutions, appears to provide the one feasible economic

method which meets NBTS requirements for plasma from whole blood.

In examining how plasma needs can be met, three systems have been analysed:

1. Routine or Recovered Plasma from whole blood
   (single donation 190 ml per unit)
2. Single donation plasma from blood separated into SAG-M
   (single donation 290 ml per unit)
3. Plasmapheresis donated plasma (Source Plasma-Human)
   (single donation 500 ml per unit).

In estimating distribution, it has been assumed that Routine Recovered Plasma or SAG-M plasma would be the methods of choice, with plasmapheresis making up any deficit.

For calculation purposes, plasma supply is based on provision of 100M international units of factor VIII, obtaining a yield of 225 iu factor VIII per kg plasma. Thus, the arithmetic plasma requirement is 444,000 kg per annum: for most purposes, this is rounded up to 450,000 kg.

A series of simple matrices has been developed as set out in Figures 3, 4 and 5, showing how the requirement can be met by varying plasma inputs from Routine and SAG-M sources, balancing deficits by pheresed plasma.

Figure 3 indicates the results in tonnage, where 1 tonne = 1,000 kg.
Figure 4 shows plasma collection in terms of kg per thousand population.
Figure 5 converts collection as tonnes into donations of plasma per thousand population.

Each figure shows an example which indicates how the matrix can be read.

From Figure 3, it can be seen that procurement of Routine Recovered Plasma from 70% of the total whole blood donations per annum releases only 275,000 kg of plasma, which must therefore be substantially augmented from other plasma sources. Alternatively, 70% procurement of plasma from SAG-M whole blood virtually meets the plasma target of 444,000 kg. Between these extremes can be found all the variable mixes of inputs using the three source plasma types; thus, it is possible to select a system of collection which suits local requirements at Regional Transfusion Centre level.

Two outstanding considerations remain:

1) the variation of total plasma cost across the matrix;

47/353

2) the financial requirement to supply 444,000 kg of FFP which represents a real expansion in Blood Transfusion Service activities above current levels and which therefore affects management and mobilisation of resources.

PLASMA COST CONSIDERATIONS

A recent comparative costing exercise completed in the N.W. Region has indicated two figures for plasma cost which have been used in the costing exercise below:

		Cost per litre
1) Routine Recovered Plasma (190 ml)	=	£38
2) SAG-M plasma (290 ml)	=	£26.90

A paper setting out the basis for determining these costs is attached as an appendix to this document: questions should be addressed to Dr. H.H. Gunson.

The price of plasma obtained by manual and machine pheresis has been set at £50 per kg, but there is a possibility that this could be reduced followin a reduction in soft- and hardware charges of certain machines. Whether plasma of pheresis origin will become cheaper per kg than Routine Recovered Plasma is uncertain and the degree of any price reductions in pheresis equipment is likely to be related to large-scale acceptance of the system providing economies of scale.

Figure 6 shows the outline of plasma costs taken from the matrix in Figure 3. The outline costs demonstrate the extremes, which are sufficient for the current discussion. From the plasma costs provided and the plasma inputs shown in matrix 3, any particular grouping of plasma collection figures can be costed on a comparable basis.

The cost variation across the matrix is from £12.21M to £20.78M to collect 444,000 kg FFP - this is a 41.3% variation. The increase in cost is made up entirely from the increments of plasma collection by Routine and plasmapheresis methods. The high cost of pheresed plasma substantially influences calculations where the low-cost benefits of SAG-M plasma are least observed.

Whilst the cost of plasma collection is considerable at all levels, it must be set against the shelf value of finished products manufactured from this plasma and provided to the NHS.

In Figure 7, the increase in shelf value of NHS plasma products is

47/354

shown against the increase in tonnes of FFP fractionated. It is necessary to integrate the value of manufactured products per unit weight of plasma fractionated with the variable on-cost arising from different systems of plasma procurement. This integration will show not only the extent of cost-effectiveness at the more economic end of operations, but will also indicate a situation where steep rises in on-costs due to more expensive plasma procurement, impinge upon the overall profitability of operations. Information of this type would seem to be essential for Transfusion Directors and other officers when planning budgets to support approved programmes of blood collection and plasma separation during the next quinquennium.

PLASMA COLLECTION SYSTEMS - SPECIAL CONSIDERATIONS

The awareness that plasma collected from SAG-M systems can be a major factor contributing towards NBTS self-sufficiency in blood products, must be associated with a cautious evaluation of its likely feasibility. A management decision to commit resources to expanded plasma collection using SAG-M blood is not a soft option that can be easily modified at a later date. If it is decided to base the main production drive on a high proportion of SAG-M blood, there exist no viable alternatives to this choice which do not introduce the need for a substantial increase to the commitment of planned resources. It is therefore essential that acceptability of SAG-M blood collection within the BTS and within the fractionation organisations is properly based on reliable scientific and market information. At present, an initial survey suggests that much of the required information is not forthcoming: examples being acceptance by users, impact of SAG systems on other BTS product requirements, implications for plasma collection containers and anticoagulants, and associated problems in manufacturing.

Problems relating to a suitable plasma container to accommodate the increased plasma volume are in hand associated with a study aimed at optimising the primary pack anticoagulant to minimise anticoagulant water put into fractionation. Data should be available by the end of June 1983. Requirements to educate users, possibly through publication of BTS policies and scientific views should be seriously entertained as a forerunner to the major introduction of red cells separated in SAG-M.

Transportation requirements for the new bulk plasma supplies and resultant products will need to be properly resolved on an economic basis.

It is not the primary objective of this document, however, to deal with

47/355

the specific elements which will determine whether SAG-M blood and associated plasma becomes a reliable, economic and acceptable system for the BTS and the NHS. The data are provided as a basis for the next stages in planning which will fall broadly into two areas:

1. An approach from CBLA members and from BPL to Ministers and to Regional Health Authority treasurers to establish the need for the growth in NBTS resources to meet self-sufficiency targets within the allotted time schedule.

2. A collective survey of growth requirements in NBTS resources and their impact on established policies, based on individual regional assessments of their needs.

The cumulative assessment of regional needs is probably the most important single factor influencing the management of the remainder of the Interim Programme and phased redevelopment of BPL if secure decisions on use of resources are to be made.

BUDGETARY CONSIDERATIONS BASED ON PLASMA REQUIREMENT

Figure 1 shows the relationship between budget forecast dates and the plasma production curve. By September 1983 at the latest, the budgetary commitment to increased plasma supply in 1984/5 needs to be defined, taking into consideration that Pro Rata return of products will be based on 150,000 kg FFP and that the FFP excess (essential to manufacturing after January 1986) will be placed in stock. Using the schedules below, and the data in Figure 1, the minimum excess FFP will need to be 20,000 kg.

Equally, by September 1983, outline budget forecasts for 1985/6 will need to be available in substantial detail for treasury purposes.

1985/6 will be a complex year in that the new BPL is scheduled to commence manufacture in January 1986. The minimum total plasma requirement will be 265,000 kg FFP, of which 235,000 kg is required for manufacture during the financial year.

A series of Manufacturing Projections is shown in Table 1. Here, the use of plasma in 1985/6 is shown: Interim manufacture (April - December 1985) accounts for 112,000 kg and a further 10,000 kg FFP is set aside to commission the new plant (this 10,000 kg will not be considered for return of product and will not appear in Pro Rata). In addition, between April and December 1985, 70,000 kg FFP is the minimum amount to be placed in the buffer plasma stock.

47/356

The plasma production forecasts for 1985/6 can therefore be summarised:

April - December 1985	$\frac{3}{4}$ x 150,000	=	112,500
April - December 1985	plasma stock	=	70,000
August - December 1985	Commissioning	=	10,000
*January - April 1986	$\frac{1}{4}$ x 290,000	=	72,500
	Total	=	265,000 kg

* The plasma output figure of 290,000 kg for this first quarter in 1986 is obtained from the plasma curve in Figure 1.

Table 1 shows the plasma balance for 1985/6 to be +30,000 kg but the figures obscure the fact that between October and December 1985 (before plasma supply goes into negative balance) the minimum stock of FFP requiring -40°C storage at BPL will be 90,000 kg. The extent of negative plasma balance on stocks after January 1986 is shown by the closing stock figure of 30,000 kg FFP at April 1st 1986 - 60,000 kg of the reserve stock will enter manufacture in the last quarter of 1985/6.

The minimum plasma collection schedule is summarised in Table 2. This plasma input will allow the new BPL to function at full capacity but with no stock provision for FFP after March 1987. This situation has serious implications in terms of quality control and reliability of manufacture.

EXAMPLES OF PLASMA PROCUREMENT PLANS

1983/4 poses no particular issues since it is assumed that budget allocations are now made and that NBTS joint output of plasma will increase to the Interim target of 150,000 kg FFP mainly from Routine Recovered source plasma.

Table 3 examines plasma procurement at 30% and 40% levels of off-take from whole blood. The effect of plasma collection from SAG-M blood is included for comparison.

Using Routine Recovered plasma at 40% off-take, the current Interim plasma collection target can be met, but there is a deficit on the strategic target which should place 20,000 kg FFP in stock during 1984/5.

The impact of SAG-M plasma is significant. At 30% off-take, all the plasma requirements for 1984/5 are met - in fact, there is an excess of 13,000 kg FFP on the strategic plasma target. At 40% off-take of SAG-M plasma, the excess over the strategic target rises to 74,000 kg - the

47/357

calculated total plasma output being 244,000 kg FFP per annum. From Table 2, it is seen that 40% off-take of SAG-M plasma nearly reaches the requirement of 265,000 kg FFP per annum for 1985/6.

A combined approach of 30% off-take of SAG-M plasma in 1984/5 and 40% off-take of SAG-M plasma in 1985/6 would provide 183,000 + 244,000 = 427,000 kg FFP against a combined projected target for the two years of 170,000 + 265,000 = 435,000. The difference is unimportant to the example being made.

Clearly, uniform introduction of SAG-M plasma at reasonable levels of off-take from whole blood can meet the strategic requirements for supply during the remainder of the Interim Period and through the commissioning period of the new BPL.

Equally clear is the fact that Routine Recovered Plasma is incapable of meeting more than the current Pro Rata manufacturing needs up to December 1985: there would be no buffer FFP stock and the new BPL would commence work at approximately 40% capacity.

Potential impact of FFP collection from SAG-M blood is taken further in Table 4 where the quinquennium is reviewed.

The profile represents a possible average NBTS response to the projected FFP requirements in Table 2. The approach uses mixed systems of collection starting with Routine Recovered Plasma (190 ml) and moving towards SAG-M plasma.

The example moves plasma procurement into levels of off-take not currently established, but it can be seen that 50% off-take from SAG-M blood provides a positive plasma balance until April 1987 after which time, the balance goes seriously into deficit.

The feasibility of proposed combinations of systems has got to be firmly established and it is necessary to repeat that the data needed for this purpose are not adequate. It seems inevitable that whatever collective approach is adopted nationally, it will be largely experimental and will need close control, efficient co-ordination and procedures for regular management communication.

The Interim and long-term impact of automated plasmapheresis remains to be properly assessed. Financial implications are highly significant

47/358

yet, taking the data presented in this paper into consideration, it remains evident that 100-150,000 kg FFP p.a. will be collected by pheresis unless SAG-M off-take of plasma can rise to 70%. In this unlikely event, plasmapheresis and cell separation may have essential supporting roles in collection of platelets and plasma for infusion.

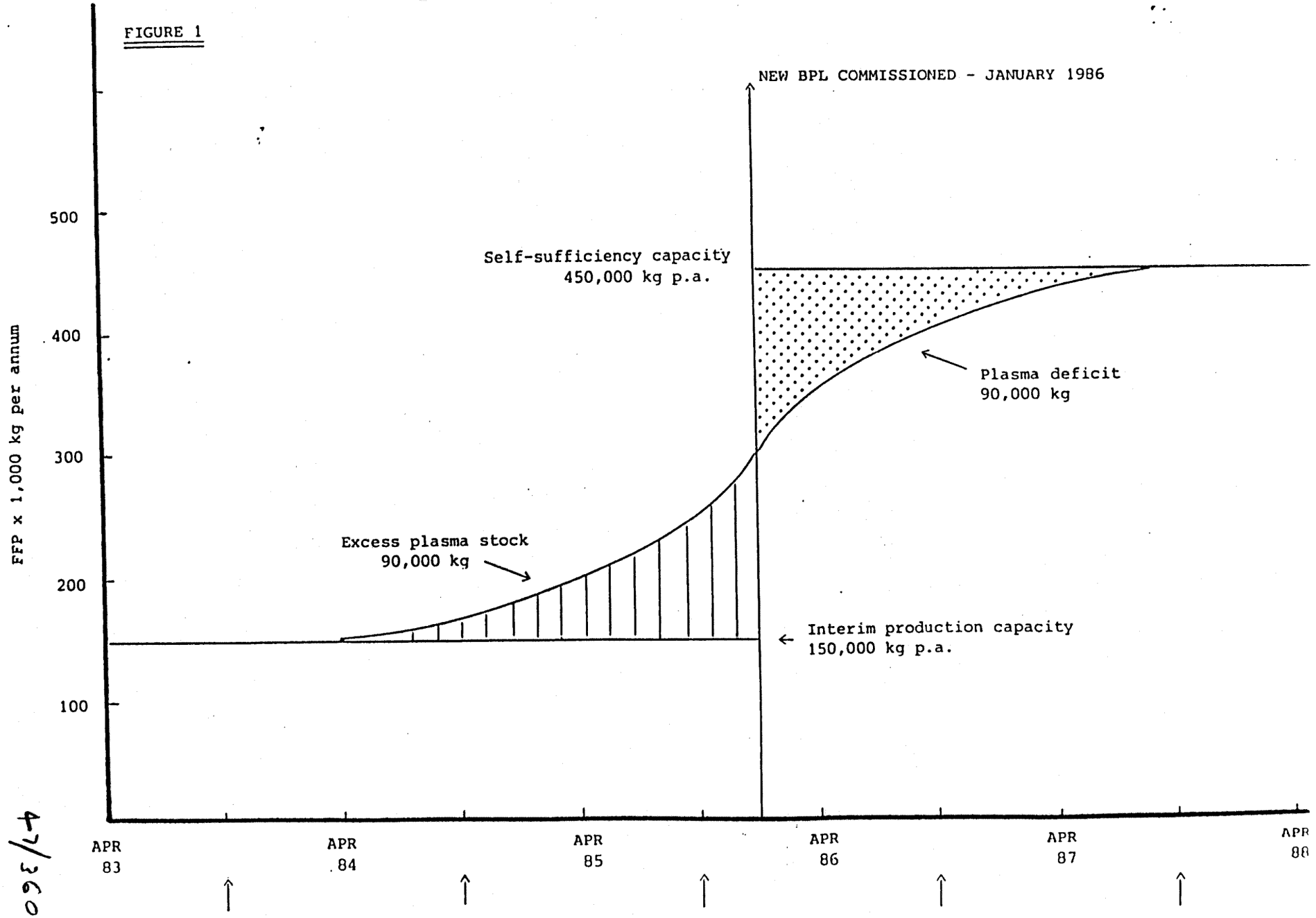
CONCLUSION

To develop the national projections further, a document is in preparation which asks RTDs to draw up a five-year plan aimed at supplying regional BTS needs and the projected plasma supplies. Attention is drawn to detailing serious resource deficiencies and pinpointing their likely effect within a management control plan.

Information from fourteen regions will be assembled into a national framework which will be suitable for costing and development of forecast cash limits.

47/359

FIGURE 1



47/360

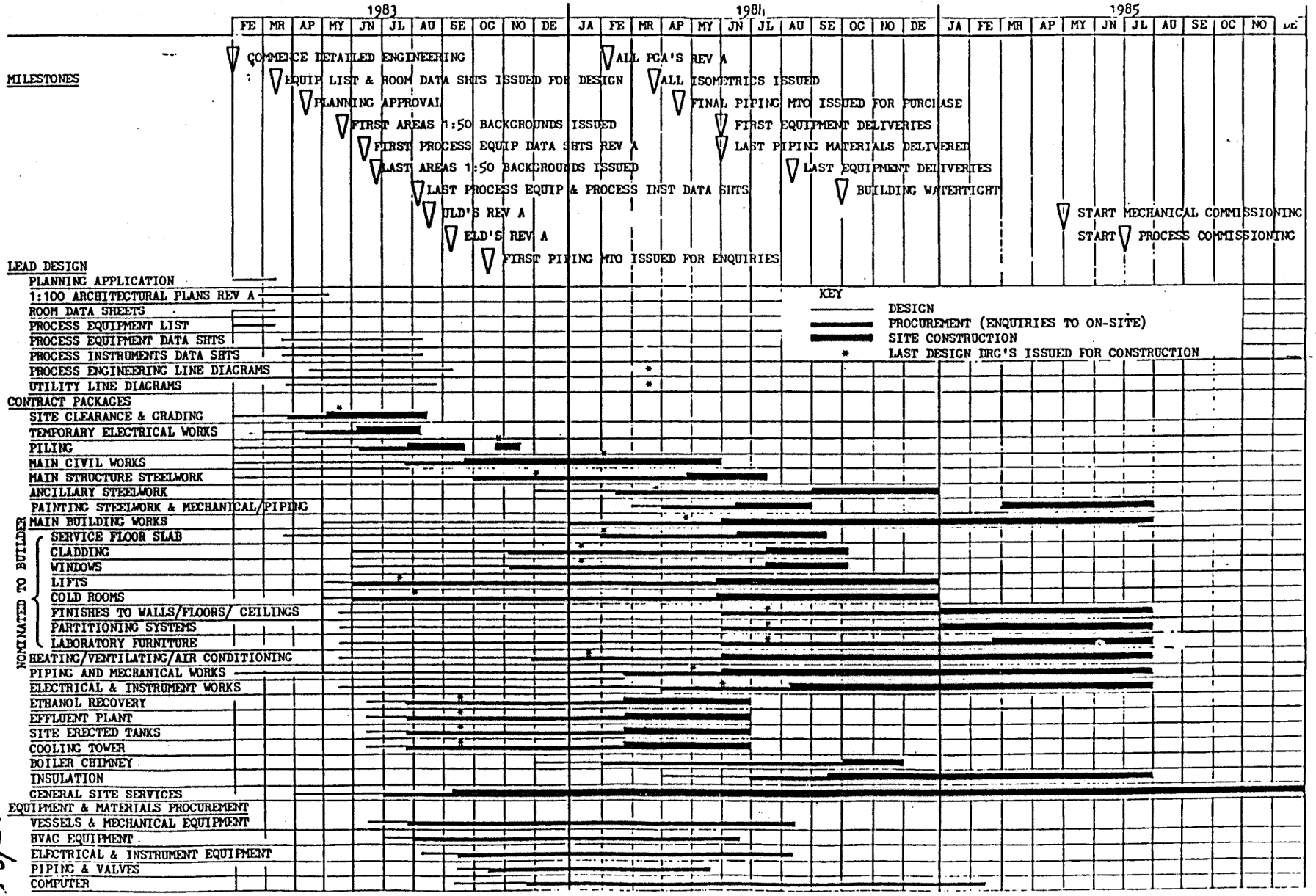
CBLA0001778_0011

MATTHEW HALL NORCAIN ENGINEERING LTD.

REDEVELOPMENT OF BLOOD PRODUCTS LABORATORY - ELSTREE

TARGET DESIGN PROCUREMENT & CONSTRUCTION PROGRAMME SUMMARY

FIGURE 2



PROGRAMME ESCO 2615 00 22 11 437 REV 0. ISSUED FOR CLIENT COMMENTS 18-3-83

47/3/61

Figure 3

100 ues = 22.5 M iu F.VIII

Tonnes (max input 444 tonnes)
(-all column totals made 444 tonn

	Routine %	0	10	20	30	40	50	60	70
SAG.M %	SAG.M				-	-	-	-	-
	Routine				118	157	196	235	275
0	Total				118	157	196	235	275
	P/P				326	287	248	209	169
				60	60	60	60	60	60
10				78	118	157	196	235	275
				138	178	217	256	295	335
				306	266	227	188	149	109
		120	120	120	120	120	120	120	120
20		-	40	78	118	157	196	235	275
		120	160	198	238	277	316	355	395
		324	284	246	206	167	128	89	49
		180	180	180	180	180	180	180	180
30		-	40	78	118	157	196	235	275
		180	220	258	298	337	376	415	455
		264	224	186	146	107	68	29	-
		240	240	240	240	240	240	240	
40		-	40	78	118	157	196	235	
		240	280	318	358	397	436	475	
		204	164	126	86	47	8	-	
		300	300	300	300	300			
50		-	40	78	118	157			
		300	340	378	418	457			
		144	104	66	26	-			
		360	360	360	360				
60		-	40	78	118				
		360	400	438	478				
		84	44	6	-				
		420	420	420					
70		-	40	78					
		420	460	498					
		24		-					

eg. @ 50% routine takeoff
No. of routine dons
= 50% x 2065428
= 1032714 dons
@ 0.19 kg/don
= 196 tonnes

1 x SAG.M don = 0.29 kg / 1 x routine don = 0.19 kg / 1 x Plasmapheresis don = 0.5 kg (P/P)

Total NBTS collection 1981 = 2065428 donations

47/362

Figure 4

Input as kgs/1000 population

Total NBTS Collection = 2065428 dons
Population assumed at 50 million (England & Wales) Total 8.9 kg/1000

SAG.M %	Routine %	0	10	20	30	40	50	60	70
	SAG.M				-	-	-	-	-
	Routine				2.4	3.1	3.9	4.7	5.5
0	Total				2.4	3.1	3.9	4.7	5.5
	P/P				6.5	5.8	5.0	4.2	3.4
				1.2	1.2	1.2	1.2	1.2	1.2
10				1.6	2.6	3.1	3.9	4.7	5.5
				2.8	3.6	4.3	5.1	5.9	6.7
				6.1	5.3	4.6	3.8	3.0	2.2
		2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4
20		-	.8	1.6	2.4	3.1	3.9	4.7	5.5
		2.4	3.2	4.0	4.8	5.5	6.3	7.1	7.9
		6.5	5.7	4.9	4.1	3.4	2.6	1.8	1.1
		3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6
30		-	.8	1.6	2.4	3.1	3.9	4.7	5.5
		3.6	4.4	5.2	6.0	6.7	7.5	8.3	9.1
		5.3	4.5	3.7	2.9	2.2	1.4	0.6	
		4.8	4.8	4.8	4.8	4.8	4.8	4.8	
40		-	.8	1.6	2.4	3.1	3.9	4.7	
		4.8	5.6	6.4	7.2	7.9	8.7	9.5	
		4.1	3.3	2.5	1.7	1.0	0.2	-	
		6.0	6.0	6.0	6.0	6.0			
50		-	.8	1.6	2.4	3.1			
		6.0	6.8	7.6	8.4	9.1			
		2.9	2.1	1.3	0.5	-			
		7.2	7.2	7.2	7.2				
60		-	.8	1.6	2.4				
		7.2	8.0	8.8	9.6				
		1.7	0.9	0.1	-				
		8.4	8.4	8.4					
70		-	.8	1.6					
		8.4	9.2	10.0					
		0.5	-	-					

eg. @ 50% routine from Table 1
input = 196 tonnes routine
then input/1000 population
$= \frac{196.000 \text{ kg}}{50.000}$
= 3.9 kgs/1000 population

1 x SAG.M don = 0.29 kg / 1 x routine don = 0.19 kg / 1 x plasmaphoresis don = 0.5 kg P/P

4-7/363

Figure 5

Conversion of tonnes in to donations/1000 population

SAG.M % @ 0.29 kg/don	Routine % @0.19 kg / SAG.M Routine Total P/P @0.5 kg don	0	10	20	30	40	50	60	70
	SAG.M				-	-	-	-	-
	Routine				12.4	16.5	20.6	24.7	28.9
	Total				12.4	16.5	20.6	24.7	28.9
	P/P				13.0	11.5	9.9	8.4	6.8
10				4.1	4.1	4.1	4.1	4.1	4.1
				8.2	12.4	16.5	20.6	24.7	28.9
				12.3	16.5	20.6	24.7	28.8	33.0
				12.2	10.6	9.1	7.5	6.0	4.4
20		8.3	8.3	8.3	8.3	8.3	8.3	8.3	8.3
			4.2	8.2	12.4	16.5	20.6	24.7	28.9
		8.3	12.5	16.5	20.7	24.8	28.9	33.0	37.2
		13.0	11.4	9.8	8.2	6.7	5.1	3.6	2.0
30		12.4	12.4	12.4	12.4	12.4	12.4	12.4	12.4
			4.2	8.2	12.4	16.5	20.6	24.7	28.9
		12.4	16.6	20.6	24.8	28.9	33.0	37.1	41.3
		10.6	8.9	7.4	5.8	4.3	2.7	1.2	-
40		16.6	16.6	16.6	16.6	16.6	16.6	16.6	
			4.2	8.2	12.4	16.5	20.6	24.7	
		16.6	20.9	24.8	29.0	33.1	37.2	41.3	
		8.2	6.6	5.0	3.4	1.9	0.3	-	
50		20.7	20.7	20.7	20.7	20.7			
			4.2	8.2	12.4	16.5			
		20.7	24.9	28.9	33.1	37.2			
		5.8	4.2	2.6	1.0	-			
60		24.8	24.8	24.8	24.8				
			4.2	8.2	12.4				
		24.8	29.0	33.0	37.0				
		3.4	1.8	0.2	-				
70		29.0	29.0	29.0					
			4.2	8.2					
		29.0	33.2	37.2					
		1.0	0.2	-					

Conversion of Table 1 to dons/1000 population
eg. @50% routine takeoff
= 50% x 2065428
= 1032714 dons
then 1032714/50.000
= 20.6 donations per 1000 population

NB. 1032714 dons
@0.19 kg = 196 tonnes

@0.29 kg = 300 tonnes

47/364

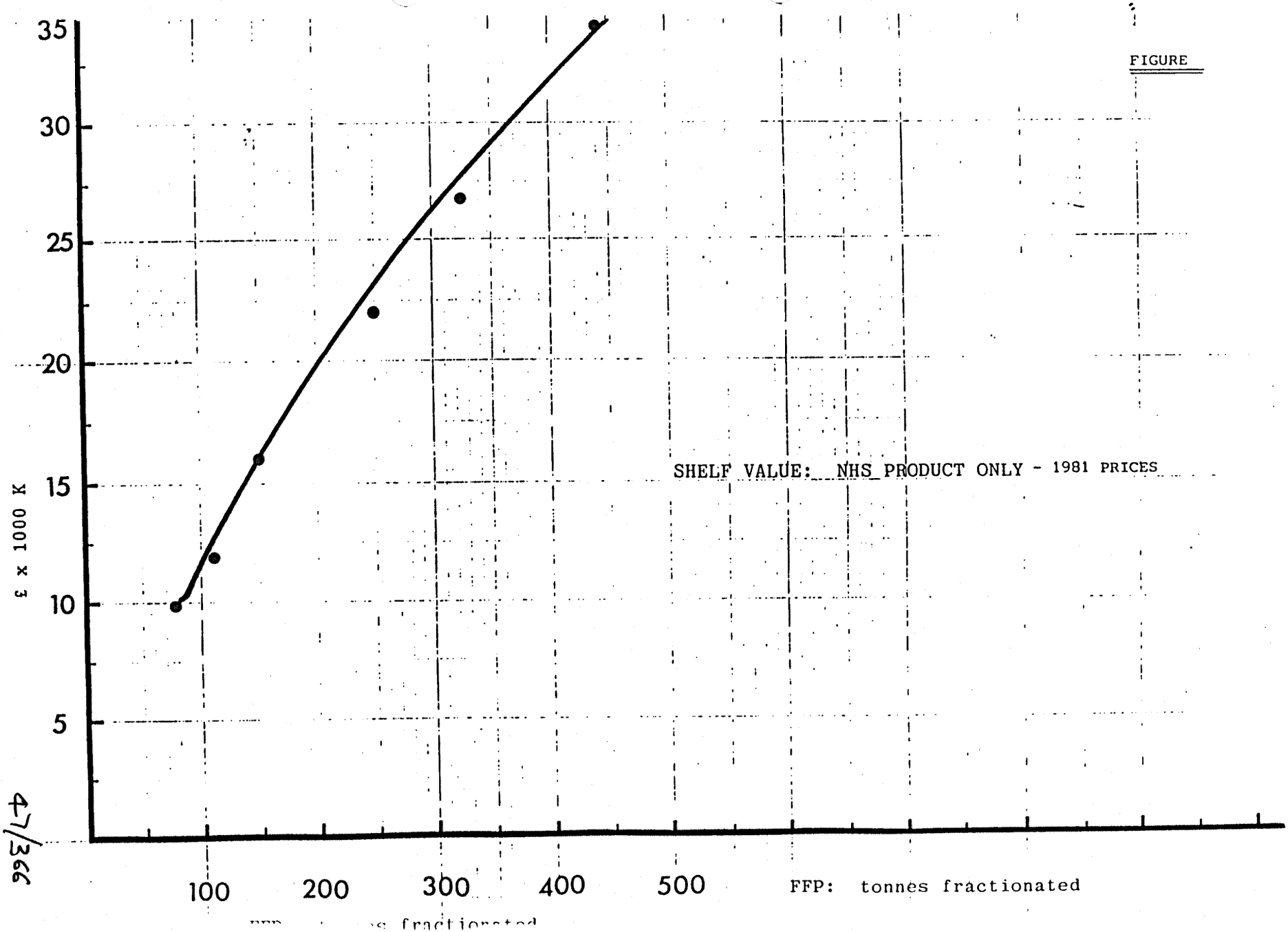
FIGURE 6

Routine% → / £K →	0	10	20	30	40	50	60	70
	-	1520	2964	4484	5966	7448	8930	104
SAG.M %								
0	-			20784				189
10	1614		19878					175
20	3228	19428						161
30	4842	18042					15222	
40	6456	16656				14304		
50	8070	15270		13854				
60	9684	13884	12948					
70	11298	12498	[12210]					

41.3% matrix variation

47/365

FIGURE



47/366

TABLE 1

MANUFACTURING PROJECTION 1984-5	kg FFP
Opening plasma stock, April 1984	0
Nominal manufacturing target	150,000
Mean projected annual plasma collection	170,000
Plasma balance	20,000
Closing plasma stock, March 1985	20,000

MANUFACTURING PROJECTION 1985-6	
Opening plasma stock, April 1985	20,000
Nominal manufacturing target *	235,000
Mean projected annual plasma collection	265,000
Plasma balance	30,000
Closing plasma stock, March 1986	50,000

*[Interim Apr.-Dec. 1985: $\frac{3}{4}$ x 150,000 = 112,500
FFP for commissioning new BPL 10,000
New BPL Jan.-Mar. 1986: $\frac{1}{4}$ x 450,000 = 112,500
235,500]

MANUFACTURING PROJECTION 1986-7	
Opening plasma stock, April 1986	50,000
Nominal manufacturing target	450,000
Mean projected annual plasma collection	405,000
Plasma balance	-50,000
Closing plasma stock, March 1987	0

MANUFACTURING PROJECTION 1987-8

Full manufacturing at 450,000 met by BTS plasma collection.

47/367

TABLE 2

MINIMUM PLASMA COLLECTION SCHEDULE

	kg FFP
1983-4	150,000
1984-5	170,000
1985-6	265,000
1986-7	405,000
1987-8	450,000

47/368

TABLE 3 PROJECTIONS FOR 1984/5

	At 30% plasma capture from whole blood		At 40% capture from whole blood	
	Total	Increment per million population	Total	Increment per million population
1. Interim Manufacturing plasma target (kg FFP)	150,000	3,000	150,000	3,000
2. Strategic plasma target (kg FFP)	170,000	3,400	170,000	3,400
3. Units FFP collected (190 ml)	630,000	12,600	840,000	16,800
4. Quantity as Routine Recovered Plasma (kg)	120,000	2,400	160,000	3,200
5. Plasma price at £38 per litre (£)	4,560K	91,200	6,080K	121,600
6. DEFICIT on interim manufacturing target (kg)	30,000	600	0	0
7. DEFICIT on strategic plasma target (kg)	50,000	1,000	10,000	200
8. Quantity of plasma (kg) from SAG-M blood (290 ml)	183,000	3,650	244,000	4,870
9. Plasma price at £26.90 per litre (£)	4,923K	98,450	6,564K	131,300
10. EXCESS on interim manufacturing target (kg)	33,000	660	94,000	1,880
11. EXCESS on strategic plasma target (kg)	13,000	260	74,000	1,480
12. Budget increase: SAG-M over Routine Plasma collection		7.4%	-	7.4%
13. Increased plasma supply SAG-M over Routine Plasma collection		34.4%	-	34.4%

695/47

TABLE 4

POTENTIAL IMPACT OF SAG-M BLOOD COLLECTION

YEAR	COLLECTION SYSTEM	INPUT kg FFP	TARGET kg FFP	CUMULATIVE PLASMA BALANCE kg
1983/4	~40% routine Plasma	~150,000	150,000	-
1984/5	20% Routine plasma 30% SAG-M plasma	260,000	170,000	+110,000
1985/6	10% Routine plasma 40% SAG-M plasma	285,000	265,000	+160,000
1986/7	50% SAG-M plasma	310,000	405,000	+ 20,000
1987/8	[50% SAG-M plasma [10% Routine plasma	345,000	450,000	- 85,000
	OR			
	60% SAG-M plasma	370,000	450,000	- 60,000

Projected deficit -60,000 kg FFP met by 120,000 plasmapheresis donations or 70% procurement from SAG-M blood.

47/370

COMPARATIVE COSTS OF PLASMA FROM S.P.P. AND SAG(M) SYSTEMS

Factors to be considered:-

(1) COSTS OF SAG(M) AND S.P.P. PACKS

COST OF SAG(M) PACK SYSTEM £5.00

COST OF S.P.P. DOUBLE PACK £2.98

COST ATTRIBUTABLE TO PLASMA COLLECTION

SAG(M) £2.02

S.P.P. £1.60

(2) ESTIMATION OF ADDITIONAL TIME REQUIRED TO SEPARATE 275 ml PLASMA (SAG(M) COMPARED WITH 180 ml (S.P.P.)

Difference = 95 ml, i.e. 1.5 x separation time for SAG(M) compared with S.P.P.

Cost of separation will not equate with this because:-

(i) Supervision will be the same for both.

(ii) Documentation will be the same for both.

In Manchester RTC it was estimated that labour costs to separate 87,315 blood components with equal weighting was £60,435 p.a. To arrive at a conclusion one must make certain assumptions, thus:-

(i) Chief MLSO as supervisor will be the same for both SAG(M) and S.P.P. plasma separation.

(ii) 15 per cent of the time of other staff is spent on documentation.

The total cost of these is £16,806 p.a.
Therefore, the residual cost is £43,629 or £0.50 for the separation of one S.P.P. unit.

Thus the cost of separating one SAG(M) unit is £0.75

(3) INDIRECT COSTS

If the separation rate is similar for both systems the indirect costs will be the same. This was estimated as £4.50 for each unit at N.W.R.T.C.

(4) COST OF SEPARATING PLASMA FROM ONE PACK OF SAG(M) AND S.P.P. SYSTEMS

(i) SAG(M)	Cost of pack		£2.02
	Labour cost	(a) separation	£0.75
		(b) supervision, documentation	£0.20
	Indirect costs		£4.50
		TOTAL	£7.47

47/371

Contd./over

(ii) S.P.P.	Cost of pack		£1.60
	Labour costs	(a) separation	£0.50
		(b) supervision, documentation	£0.20
	Indirect costs		£4.50
		TOTAL	£6.8

(5) COST PER LITRE OF PLASMA SEPARATED FROM SAG(M) AND S.P.P. SYSTEMS

No. donations per litre in SAG(M) system = 3.6

No. donations per litre in S.P.P. system = 5.6

Therefore, cost per litre:-

(i) SAG(M) system = 3.6 x £7.47 = £26.9

(ii) S.P.P. system = 5.6 x £6.8 = £38.0

47/372