1983 Trewent Symposium for NBTS.

VALUE OF SAG-M SYSTEMS IN THE PROVISION OF PLASMA PRODUCTS

In simple terms, collection of whole blood for separation into SAG-M suspended red cells and fresh frozen plasma increases single-unit mean plasma volume of recovered plasma from 190 ml to 290 ml - an increment of 35.5%.

Since the quantity of plasma needed to obtain self-sufficient provision of blood products in the NHS is approximately 450,000 kg per annum, this could be obtained from current whole blood donations, without recourse to other measures, if 72% of the current blood-take were directed into SAG-M systems and the fresh plasma dedicated to fractionation.

However, the output analysis is impracticable and this presentation deals with four problem areas - there are others.

(1) MANUFACTURING
(2) ANTICOAGULANT
(3) PACKS
(4) PLASMAPHERESIS.

(1) MANUFACTURING

The NBTS Blood Products factory is being rebuilt to a capacity of 450,000 kg per annum fresh frozen plasma. Current projections for fresh plasma fractionated annually between 1983 and 1985 are about 150,000 kg, thus an acute threefold capacity rise will occur in the last quarter of 1985, when the new plant comes on line.

How this increase in plasma source material will be made is under discussion, but basic logistic considerations show that the rate of incremental gain in plasma will not parallel the nominal fractionation capacity. A theoretical plasma growth curve has been drawn, as shown in Figure 1, which allows plasma collection to grow evenly over a 5-year period, in a manner where initial plasma-stock gains over manufacturing capacity will offset later net deficiencies in source material, occurring over an estimated period of 24 months after the new factory is working.

Mean annual plasma collection rates are set down in Table 1 and, for reasons which are discussed below, the critical year is 1986-87. The annual plasma collection increments are intensely dependent upon the blood collection systems which will be used, thus programming use of these systems will be a disciplined matter for managers.

Figure 2 demonstrates the systems-dependence in a two-dimensional matrix involving the outcome of blood collection into CPD-A systems (with a Routine Recovered Plasma volume of 190 ml), and into SAG-M systems (with a recovered plasma volume of 290 ml). The matrix examines offtake of plasma from whole blood at levels between 0 and 70% of total donations and analyses the balance between plasma capture at each level with the theoretical maximum fractionation requirement of 444,000 kg plasma per annum. Deficits of plasma are recalculated as the necessary plasmapheresis component to augment whole blood-derived source plasma.

It is immediately evident that Routine Recovered Plasma in 190 ml volumes cannot meet NBTS requirements and, on its own, would require substantial augmentation by plasmapheresis. This observation, per se, carries no untoward implications.

Collection of blood into SAG-M systems is capable of a significant improvement in any forward projections. However, with only marginal levels of valid market research on clinical acceptance of SAG-M red cells at more than conservative levels of presentation, it would be unwise to assume a higher offtake of plasma from SAG-M blood than, say, 50% of total donations - when programming future plasma collection schedules. Indeed, 50% may prove to be far too high as a mean national target. As with other components, Regional acceptance of SAG-M suspended red cells is likely to show marked heterogeneity unless a national policy structure in this area is forced onto clinicians.

Two potential plasma collection programmes are set out in Tables 2 and 3.

Table 2 examines the potential impact of SAG-M blood collection and relates outputs to current targets as defined by the plasma curve in Figure 1. SAG-M plasma makes a significant contribution up to 1986-87 but cannot sustain manufacturing thereafter unless plasma offtake exceeds 50% of total blood donations.

Table 3 sets out a specimen plasma collection schedule in a form which allows comparison with the theoretical targets shown in Table 1. The comparison shows a critical shortfall developing in 1986-87.

Taking the information from existing Tables and making a graphic analysis as shown in Figure 3, the combined role of blood collection in CPD-A and SAG-M systems is related to the need for plasmapheresis.

The CPD/SAG-M composite plasma curve is taken from Table 3 and stripping this curve from the theoretical plasma curve gives the curve for plasmapheresis input and growth. The curve assumes that plasmapheresis units so defined are fully functional at the times shown, thus their introduction should go one year in advance.

Having considered the logistic potential from SAG-M systems, other important manufacturing elements remain:

Compatibility with the total regional blood supply programme. Growth in plasma supply needs is almost parallelled by increasing platelet demand. There are marked regional differences, but there remains one main source material, i.e. whole blood, which no longer can meet total requirements for components in all cases. Alternative primary sources of materials need defining e.g. cell separation systems for platelets which incorporate the quality and economic advantages of plasmapheresis for both platelets and FFP.

Ultimately, economic analysis of different plasma collection systems will strongly influence decisions. Quality of plasma from different sources, as it affects fractionation yield, may be a determining factor on economics, but it must be said that excellent frozen fresh recovered plasma can be obtained from CPD-A and SAG-M systems as well as Source Plasma (Human) from plasmapheresis systems.

With special regard to blood separation into SAG-M, the increased output of plasma presents an obvious economic advantage provided this is not neutralised by the increased system cost and associated extra technical overheads. These have to be properly set down and the cost centres have not yet been agreed. Should red cells cost any more because they are taken into SAG-M? The question is widely asked and, if the answer is NO, then the added on-cost of SAG-M systems falls onto plasma. One important advantage of SAG-M blood collection which cannot be disputed is that it allows a significant proportion of NBTS plasma requirement to be met without recourse to excess blood donations, where the outcome is mounting wastage of red cells.

A potential disadvantage of SAG-M-collected plasma is that it remains Recovered Plasma by definition and makes only limited impact on donor pool size entering into large-pool plasma protein concentrates. Here the potential of plasmapheresis is unchallenged if, as yet, it remains unexploited.

(2) ANTICOAGULANT

SAG-M systems for blood collection depend upon SAG-M for the red cell preservation. Therefore, the primary donation can be taken into an anti-coagulant solution where the volume and formulation relate more to security of coagulation factors than to cellular elements. Such a study is now under way, and it is hoped that results will be available by August.

(3) PACKS

At full capacity, the new fractionation factory will be calling into process single donation frozen fresh plasma at the rate of 5600 units per day for 250 days each year. Automated opening systems are now available which can strip plasma packs at 2400 per hour. The International Plasma Pack is designed to hold up to 250 ml plasma and will be enlarged, if necessary, to hold the higher volume of plasma from SAG-M blood. Here, the volume of primary anticoagulant water becomes significant and there are some potential savings in this area. The anticoagulant study in progress seeks to provide information on this problem.

(4) PLASMAPHERESIS

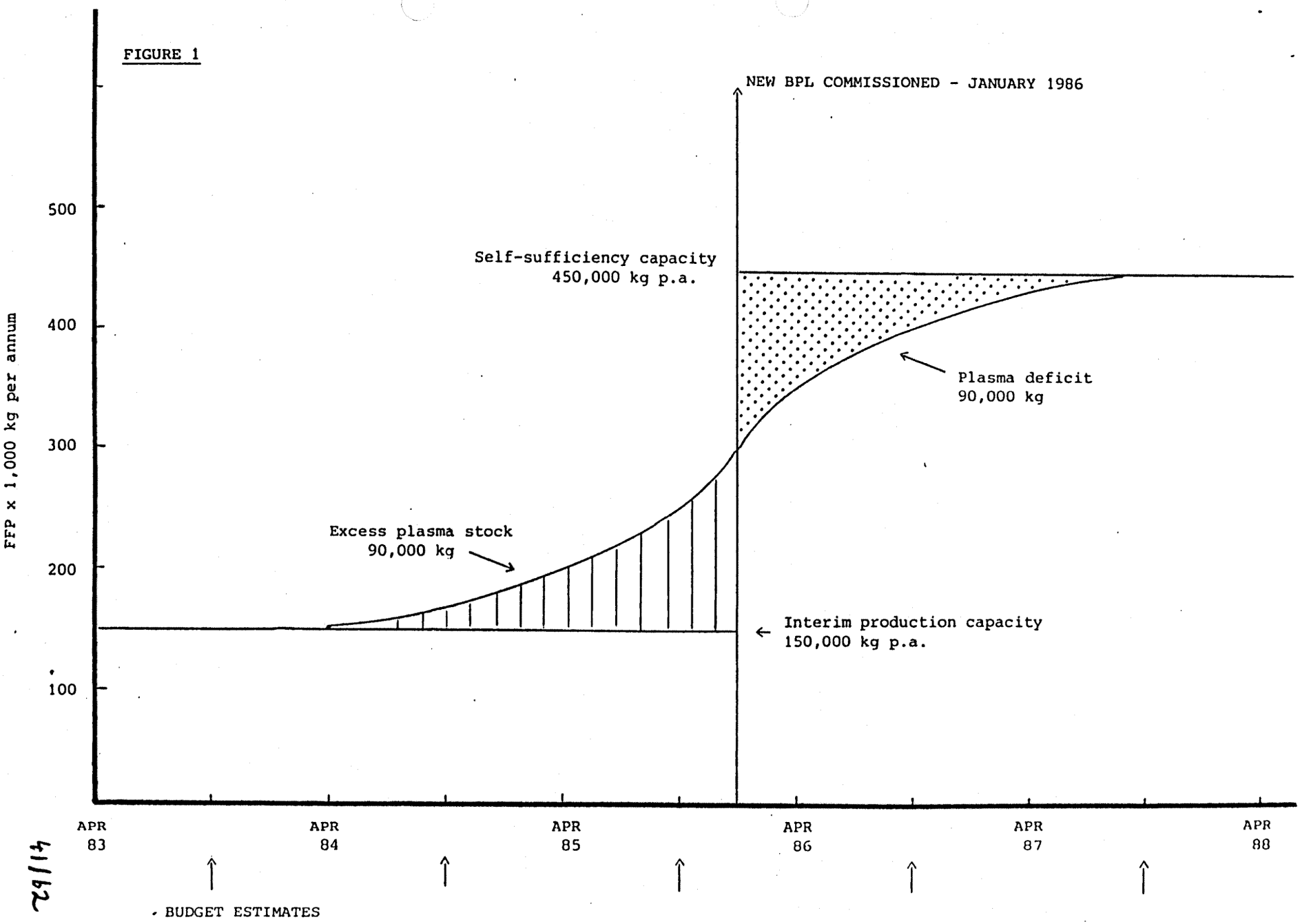
The limited study of SAG-M blood and plasma collection has shown that a considerable role still exists for growth in collection of SOURCE PLASMA (Human) by plasmapheresis, if self-sufficiency of blood products is to be achieved in England and Wales. The intrinsic benefits of plasmapheresis remain to be properly analysed and exploited.

CONCLUSION:

Provided SAG-M suspended red cells are accepted in large part by clinicians, then the resultant plasma yield will have a major impact on plasma procurement by NBTS. A substantial lack of data exists on many aspects of use of the system and its products and on its technical and logistical interaction with existing and future Blood Transfusion Centre practices. Detailed information is currently being sought from transfusion centres which is vital to developing assurance about this system of blood collection.

41/61.

FIGURE 1



79/14

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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

41/63

FIGURE 2

100 tonnes = 22.5 M iu F.VIII

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

	Routine %	0	10	20	30	40	50	60	7
SAG.M %	SAG.M				-	-	-	-	-
	Routine				118	157	196	235	27
0	Total				118	157	196	235	27
	P/P				326	287	248	209	16
				60	60	60	60	60	6
10				78	118	157	196	235	27
				138	178	217	256	295	33
				306	266	227	188	149	10
		120	120	120	120	120	120	120	12
20		-	40	78	118	157	196	235	27
		120	160	198	238	277	316	355	39
		324	284	246	206	167	128	89	4
		180	180	180	180	180	180	180	18
30		-	40	78	118	157	196	235	27
		180	220	258	298	337	376	415	45
		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

41/64

TABLE 2

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.

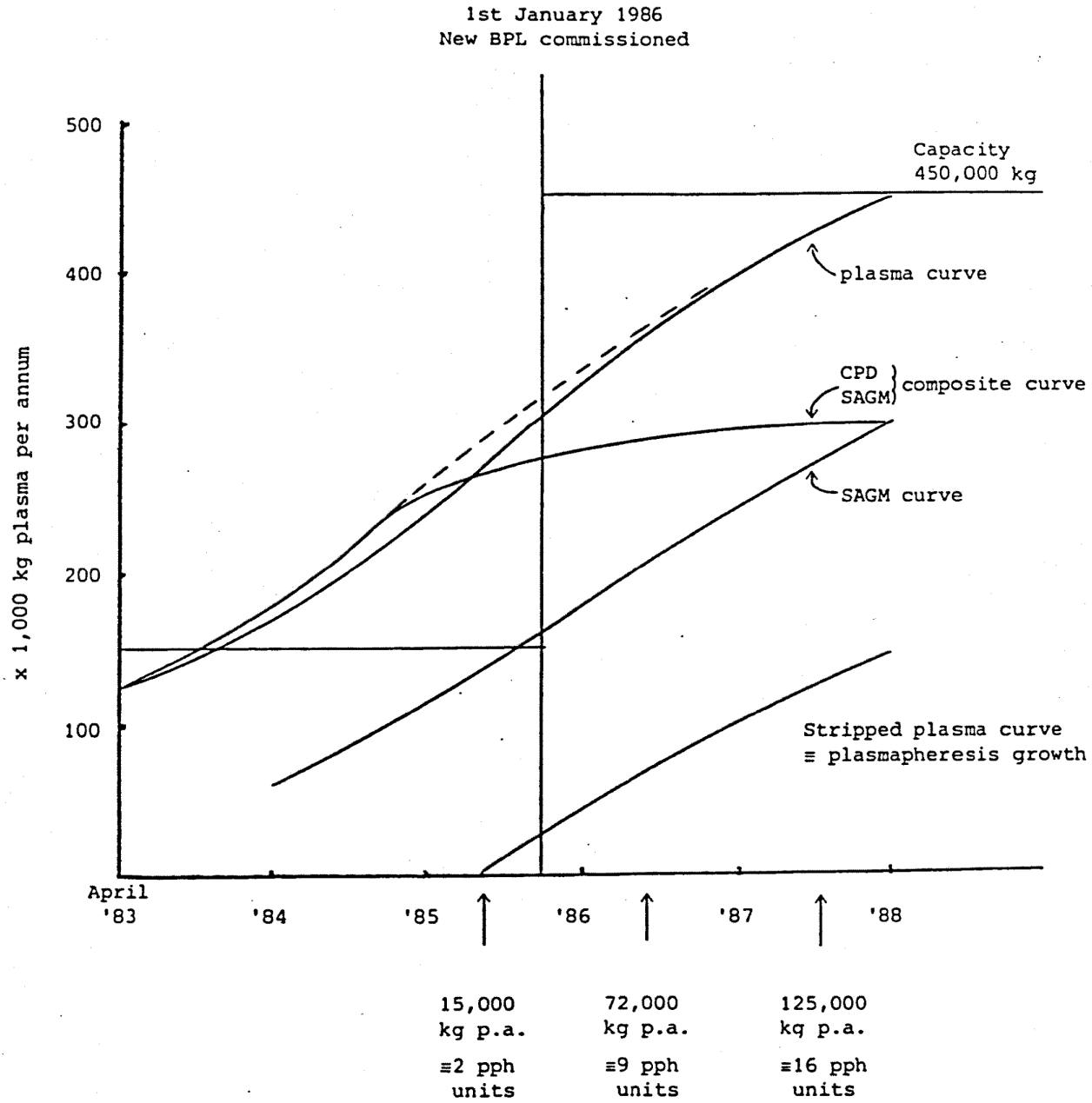
TABLE 3

SPECIMEN PLASMA COLLECTION PROGRAMME

YEAR	PLASMA SOURCE	YIELD (tonnes)	TOTAL (tonnes)
1983/84	30% CPD	118	178
	10% SAG-M	60	
1984/85	20% CPD	78	258
	30% SAG-M	180	
1985/86	10% CPD	40	280
	40% SAG-M	240	
1986/87	50% SAG-M	300	300
1987/88	50% SAG-M	300	300

4/6b.

FIGURE 3



41/67.

INDEX - RTD PAPERS - 1983.

D(83)1.	Antenatal Anti-D Programmes.
RTD(83)2.	REVISED BLOOD TRANSFUSION SERVICE COST FORMS.
RTD(83)3.	Anti-HBs Immunoglobulin.
RTD(83)4.	NBTS Working Party on Donor Recruitment
RTD(83)5.	Draft of Notes on Transfusion (distributed 5.4.83
RTD(83)6a.	Record-Keeping & Stock Control Arrangements: Draft Health Circular
6b.	Report of the Director of Audit - Blood and Blood Products.
RTD(83)7	Plasma Supply NBTS (Draft 11.4.83)

47/345