

**DRAFT**

PLASMA FRACTIONATION

IN THE

UNITED KINGDOM .

A PERSONAL APPRAISAL

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## CONTENTS

	Page
1.00 <u>Introduction</u>	1
2.00 <u>Scottish Plasma Availability</u>	1
2.10 Antihaemophilic Globulin	1
2.20 Plasma Protein Solution	2
3.00 <u>Summary of Scottish Need</u>	3
3.10 Commercial Equivalent Value	3
4.00 <u>Estimate of English Need</u>	3
5.00 <u>United Kingdom Need</u>	3
5.10 Commercial Equivalent Value	4
5.20 Summary of Need for Plasma	4
6.00 <u>Fractionation Capacity in the U.K. for P.P.S.</u>	4
6.10 Third Fractionation Facility - A Non-sequitur	5
6.20 Liberton Expansion Feasibility	5
6.30 Consequences of Rapid Decision	5

## Need for Plasma Fractions in the United Kingdom - A Personal Appraisal

1.00 Introduction

This critique is based on observations and conversation with producers and users in Europe, North America and Australasia as well as discussions within the Blood Transfusion Service in Scotland. Observations regarding B.P.L., Elstree are based on one visit and discussions with Mr Vallet, Dr Ellis and Mr Wesley; they may, for this reason, prove only superficial in value.

The population of the United Kingdom is estimated at 60 million. Of this, for purposes of discussion, the Scottish population is estimated at 5 million. The number of haemophilic patients in the U.K. is estimated as 3000 (5/100,000).

2.00 Scottish Plasma Availability

Discussion on the probable need for plasma for fractionation indicates that, of all fractions prepared, the main limiting consideration is the need for Plasma Protein Solution. The need for specific immune globulin and salt poor albumin will create errors in calculation but, in a coherent policy of overall balanced use of blood and its fractions, these errors practically cancel each other out to make a net error factor of less than 1% in the total estimate.

Following prolonged discussion during late 1972 and 1973 the Scottish Regional Transfusion Centres have embarked on a policy of use of cellular components and balanced blood intake which has resulted in the making available of plasma at a rate slightly in excess of 6000 litres (30,000 donations) per million population per annum. Slightly less than 30% of this plasma (the period has been too short for accurate assessment) is available as fresh frozen plasma.

2.10 Antihaemophilic Globulin

The official estimate of the need for fresh frozen plasma for AHG preparations is given as 10 donations/1000 population. On this basis the Scottish plasma availability is correct. It is my personal belief that this figure/

-2-

figure is probably 30% too low since it presupposes an overall process yield of 40%. These calculations do not allow for :-

- a) Increased use in domestic therapy.
- b) The need for a proportion of the production as low yielding, high purity fractions.
- c) A probable drop in yield, of Intermediate concentrate, to 30% when made on a realistic scale.

Allowing that this argument is correct, Scottish need for F.F.P. becomes 15,000 donations/million rather than the 10,000 donations now becoming available. This would provide (at 30% yield) about 4.8 million plasma units of A.H.G. per annum for the countries' need; approximately one million p.u./million population or 20,000 p.u./haemophiliac/annum.

It is my belief that a production of 15,000 litres of fresh frozen plasma is well within the capacity of the Scottish Regional Centres without recourse to plasmapheresis.

## 2.20 Plasma Protein Solution

Production figures from the P.F.C. indicate that 4 litres of input plasma will yield 6 x 400 ml units of P.P.S. with a protein concentration of 4.3% and albumin purity greater than 85% (>90% by moving boundary electrophoresis). The total plasma input to P.F.C. in 1974 will probably be slightly in excess of 35,000 litres and should provide approximately 50,000 units of P.P.S., i.e. 10 units/1000 population.

From international experience this figure is probably about 20% too low. Production may have to rise to about 12 units/1000 population or 60,000 units for Scotland; requiring a plasma input of just over 40,000 litres (200,000 donations). It is doubtful if this higher figure can be reached by simple reliance on good housekeeping and may require an increase in blood collection.

## 3.00 Summary of Scottish Need

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-3-

From chapter 2.00 it is seen that Scotland has available 35,000 litres of plasma of which 10,000 is as F.F.P. These figures may have to increase to 40,000 and 15,000 respectively to meet the full national requirements for Antihaemophilic globulin and Plasma Protein Solution.

### 3.10 Commercial Equivalent Value

Scotland has available plasma to make 50,000 units of P.P.S. at a C.E.V. of £10/unit and 4.8 million p.u. of A.H.G. at a C.E.V. of £0.10/unit. Bought on the commercial market this would cost £980,000.00 per annum.

If my estimate of increased need is accurate this cost will increase to £1.1 million at present day prices by 1980.

### 4.00 Estimate of English Need

Since there should be little difference between the community need of England and Scotland on a proportional basis it would appear that the Scottish figures should be applicable to England; especially since these figures are in close agreement with those established in other countries.

On this basis the English need would be :

P.P.S. 550,000 x 400 ml units.

A.H.G. 48 million plasma units.

### 5.00 United Kingdom Need

The total U.K. requirement for the two plasma fractions would appear to be :

P.P.S. 600,000 x 400 ml units

A.H.G. 53,000,000 plasma units

This would require some 400,000 - 500,000 litres of plasma per annum of which 150,000 would be required as fresh frozen plasma. The total volume is difficult to judge since the conversion estimate of P.F.C. is 4 litres of/

-4-

of plasma is equivalent to 6 units of P.P.S. whilst that of B.P.L. appears to be 5 litres equivalent to 6 units.

#### 5.10 Commercial Equivalent Value

Calculated as at 3.10 on modest present day figures.

U.K. P.P.S. requirement	6,000,000
A.H.G. requirement	5,300,000
Estimate of other fractions	<u>4,600,000</u>
Total	<del>£</del> 15,900,000

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This estimate of value could be low by 20%.

#### 5.20 Summary of Need for Plasma

The amount of plasma (200,000 litres or 1 million donations) required for A.H.G. preparation is of no account in consideration of overall need. Scottish experience shows that determined efforts to promote component therapy can produce this volume from within the existing blood collection programme without material increase in the total volume of blood collected.

The critical figure of 400,000 litres required for P.P.S. production should, similarly, be available from within existing programmes but, since the number of donations/million population is lower in England than in Scotland, it may be necessary to increase the total number of donations collected.

#### 6.00 Fractionation Capacity in the U.K. for P.P.S.

B.P.L. and P.F.C. are each specified for 70,000 - 80,000 litres of plasma per year. It is my opinion that B.P.L. production could be increased to about 150,000 litres but further increase would appear impossible on the present site and could hardly<sup>be</sup> justified. The difference of more than 250,000 litres includes 35,000 to 40,000 which the P.F.C. must process for Scotland.

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Assuming that Scotland's resources will not be <sup>MISUSED</sup> increased to subsidise England a dual standard of clinical availability could come to exist.

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-5-

In my opinion this intolerable situation could not be maintained, enough plasma to meet real need will be collected in England and, unless prompt action is taken, U.K. fractionation and finishing capacity will be inadequate to meet demand.

#### 6.10 Third Fractionation Facility - A Non-sequitur

Strong arguments can be advanced in favour of opening a third Fractionation Centre, properly designed for a realistic capacity.

- X However, I do not consider that the U.K. possesses<sup>es</sup> the managerial and scientific talent in fractionation to justify such a centre in the present decade.
- X Similarly, the time-scale of planning and building<sup>c</sup> would be substantially greater than that of need.

#### 6.20 Liberton Expansion Feasibility

The P.F.C. at Liberton has process potential to handle up to 300,000 litres of plasma per year but is unable to finish P.P.S. at equivalent rates. However, the construction of premises equal to this task on the Liberton site would appear to be the most economic and most rapid means of achieving adequate fractionation capacity in the U.K.

#### 6.30 Consequences of Rapid Decision

If, as seems certain, the additional facilities should be available as soon as the specified capacity of Liberton is exceeded (i.e. by the end of 1974) planning would be required to start immediately, despite the fact that some technical questions remain unresolved. Obviously, this time-scale is impossible but it would seem feasible that, provided planning detail started at once, the increased facilities could be available on the Liberton site by the end of 1975. Such a programme could be costly since it would involve persuading the existing contractors to accept a new contract which, since they would be in a nominated position, would not be capable of submission to competitive tender. However, in comparison with the global sums involved, this/

-6-

this additional expenditure could be recouped in a period of months since each month "saved" has a current financial implication of approximately £1 million.

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