MEMORANDUM

To : Dr R.S. Lane   From: N. Pettet

cc : Dr J.K. Smith
     Mr E.D. Wesley   9th January, 1981

PRO-RATA OF DISTRIBUTION OF PRODUCTS

Introduction

"Blood products from BPL are currently distributed broadly on the basis of an assessment of Regional requirements for patient treatment".

In a recent document to all RHA's, the DHSS proposed "that with effect from 1st April, 1981, Regions should receive from the BPL, factor VIII, factor IX and albumin containing fractions in quantities proportional to the amount sent for processing, account being taken of the yield from each batch of plasma". There was also a requirement "that the supply of blood products for Regions with special units is maintained".

Regions should note that this will not mean 100% return of blood products in proportion to their input of plasma. Account has to be taken, not only of special unit requirements but also of quality control and national stock requirements.

As the intention of pro-rata is to make all Regions aware of the necessity for improved quality and quantity of plasma as FFP, the scheme should be supported by a programme to reduce the input levels of time-expired plasma. Any system to be used for pro-rata should be as simple and straightforward in operation as possible to eliminate the necessity for major clerical calculations. This can be achieved provided all Departments can agree on a basic methodology, and would mean that the distributions for factor VIII, factor IX, and albumin be treated separately.

a) **Factor IX**

At the present time, this product should continue to be issued from PFL using their existing system. I am not sure as to whether factor IX requires a pro-rata distribution as I believe we are self-sufficient in this product.

b) **Albumin**

Referring to the document enclosed from E.D. Wesley, there are some difficult problems concerning the pro-rata distribution of albumin:-

1. Annual issue 1979 of PPF (134,420 bottles) is well below the level that would be achieved if all incoming "plasma" i.e. TE, CF CPS, and Oxford CPS was being fractionated.

1164

16-96

2. The percent of actual issue (column 7) compared to 100% pro-rata return (column 2), includes freeze-dried Plasma, which is being phased out over 1981/1982, therefore when this happens, the percent figures will be reduced for those centres using Dried Plasma, unless sufficient extra PPF is available as a replacement.

3. Column 7, shows a wide range of percent issue (33.9-127.3) with a mean of 68.1%, for the Regions.

4. Oxford "plasma intake" includes some Wessex CPS which has been incorrectly credited to Oxford, thereby falsely increasing their return and reducing that of Wessex to 93%.

Thus, as the 1981 issue rate for PPF is expected to be of the order of 135,000 bottles (plus 11,000 Dried Plasma) compared to a theoretical input rate of 220,000 bottles.

RTD's should consider:-

1. Pro-rata distribution of albumin can be no greater than 68% for all centres at the present time.

2. Because of the way that the present distribution system operates, some centres grossly exceed this figure (68%) now, whilst others receive considerably less. Thus NET and SET, whilst expecting an increase in supplies of albumin as surmised from the DHSS document will in fact receive less from April 1980, if the debit centres are to be brought into line.

3. Hammersmith Hospital and Northwick Park Hospital should be treated as 'special units'.

4. Pro-rata will continue to be based on 1.25 bottles of PPF per litre of 'plasma'.

5. Where one centre increases its production of 'plasma' significantly, this will not result in an equivalent increase in its supplies of albumin. The resultant affect would be to decrease supplies to all other centres because of the present fixed annual issue rate.

6. It will not be practical to distinguish between 'plasma' from one centre to another because of the way in which production of albumin is dependent on two sources of raw material - T.E and CPS.

7. As output of PPF increases through increased production 1982/1983, using the scheme above, the initial pro-rata figure of 68% will be increased in line with increased production. This will depend, however, on whether the total 'plasma' intake (TE and CPS) increases at a rate higher than the increased rate of production. This should be alleviated to some degree as the percent input of time-expired plasma decreases with increasing FFP input.

16- 97

8. The time-scale over which calculations are adjusted - probably six-monthly i.e. percent pro-rata for April-September 1981 would equal <u>April-September total issue</u>/input during preceding June-December 1980.

9. Should a pro-rata system be based on the Regional population rather than a percent <u>issue</u> as proposed above.
   input

10. Finally, the Committee should be aware of the co-operation and understanding which is required from all RTD's if a more fair distribution is to be achieved.

16-98

TABLE (1)

notional if all q(1) went track.

actual (meet capacity mm)

	(1) 1979 "all Plasma" intake (litres)	(2) "pro rata" PPF return (400 ml)	(3) 400ml PPF	ANNUAL ISSUES (4) 20g Albumin	(5) Freeze-dried Plasma	(6) Total cols (3) (4) (5)	(7) % Col (6) to Col (2)
NORTHERN	11732	14665	9000	360	1200	10560	72.0
YORKSHIRE	8841	11051	7600	400	480	8480	76.7
TRENT	12102	15128	9640	300		9940	65.7
E. ANGLIA	6932	8665	5880	320		6200	71.5
N.W. THAMES	9525	11906	11640	520	3000	15160	127.3
N.E. THAMES	12009	15011	10120	540	720	11380	75.8
). & S.W. THAMES ✳	19008	23760	15960	600	2400	18960	79.7
WESSEX	4506	5632	5040	200		5240	93.0
OXFORD	12532	15665	6880	250	480	7610	48.6
S.WESTERN	19114	23893	9960	680	600	11240	47.0
W. MIDLANDS	18502	23128	10960	500		11460	49.6
MERSEY	7738	9673	7720	440		8160	84.4
N.WESTERN	10458	13073	9000	260	720	9980	76.3
LANCASTER	3288	4110	2040	120		2160	52.6
WALES	6317	7896	4720	260		4980	63.1
P⁻ ⌐ ⌐T	7089	8861	1200	0	1800	3000	33.9
TOTAL	169693	212116	127360	5750	11400	144510	68.1

```
HAMMERSMITH HOSPITAL RPGMS          5760 (approx.)
NORTHWICK PARK HOSPITAL             1300   "
        TOTAL PPF ISSUES (400 ml)   134420
```

NOTES: Col. (1) :   See Table 2 for details.

Col. (2) :   Pro rata return for 400 ml (18g) PPF based upon a yield of 1.25 x 18g containers per litre plasma.

Col. (3) :   If supplies to Hammersmith and Northwick Park were added to supplies to N.W. Thames Region then column (7) for that Region = 186.6%.

16-99

c) <u>Factor VIII</u>

The recent survey made by Chairmen of NBTS Divisions has shown the need for increasing FFP input to enable each region to reach a target of 600 iu/1000 population (I have indicated in a previous memorandum the errors contained in this survey - where there has been confusion over the use of kilogrammes and litres, gross yields and net yields. Also the total of FPP input to PFL as being credited to Oxford RTC, thus duplicating Wessex input figures). There is thus a clear need to define the factors which will be used in determining pro-rata distribution of Factor VIII.

To avoid the need for the setting up of a specialised Stock Control, using lengthy calculations and frequent adjustments, the scheme adopted must be kept simple, with the RTC's fully aware of the time-scales and methodology used. This will require a regular liason with RTC's through this office where BPL policy for all products can be explained and up-dated as necessary, thus avoiding the need for Production Departments to be harassed by any individual centre on problems other than plasma quality and control. Any initial problems arising from the introduction of pro-rata for Factor VIII will have been minimised through the discussions held with the RTD's beforehand. The Advisory Committee must make an early recommendation regarding 'special units' such as Lord Mayor Treloar, Channel Islands and the needs of Northern Ireland as distribution to these it is assumed will come from BPL stocks.

Bearing in mind the comments made by Dr. Smith in his memos of 29th October and 15th December, I suggest that the following points be considered by the Committee:-

1. Decision on allocations to the 'special units' and Northern Ireland.

2. Oxford RTC and Wessex input (to PFL) to be used in the stock calculations at BPL. This would ensure that <u>all</u> regions are treated on the same basis and would allow for Oxford and Wessex to share in the setting up of 'national stock' and 'special unit' commitments. (This may require that the Oxford Haemophilia Centre be considered as a 'special unit' as has been suggested by Dr. Tovey).

3. Should pro-rata distribution be based on numbers of vials or i.u., as current batch variation in iu/vial is 215-280.

4. That there is a need to reduce the input of time-expired plasma in favour of increased FFP input, associated with more efficient methods of cryoprecipitate production, in order to achieve the 'target' figures of 600iu/1000 population.

5. A document to be drawn up for all RTD's explaining the methodology of pro-rata' including a definition of terms used within the scheme.

16-100

BPL Policy for Pro-Rata Distribution of Factor VIII from April 1st, 1981

1. Four factors are to be considered:-

    a) Input of FFP to BPL from each region, and therefore total input for the six - month period July-December, 1980 (for assigned packs only).

    b) As the weight/volume of packs varies from centre to centre, a calculation to be made from production figures (i.e. net weight of stripped plasma divided by number of packs used) in the same period as in a) i.e. July - December, 1980.

    c) Gross yields to be calculated for each RTC for the six-month period July-December 1980, using only those batches considered as 'normal'. This must be assessed by C.F. to take into account unusual processing losses, split-batch experiments, bag-freezing etc.

    d) A factor applied to the final calculation to take into account 'national stock'; special unit; and quality control losses (including a correction for c)) i.e, reducing the pro-rata to below 100%.

The scheme would ensure that all Regions would receive an annual issue 'pro-rata' to their input, but would <u>not</u> mean that each centre receives only its own product which would entail a highly complex system of calculation. It would also ensure that for a quarterly period (when up-dating would occur), each RTC would receive a regular supply of factor VIII.

For the scheme to succeed, C.F. would be required to maintain a constant (or increasing) rate of production each quarter above that of quarterly issue i.e. maintenance of set production targets.

16-101

Scheme For Pro-Rata Distribution 1981/1982

1. **PPF**

   Percent pro-rata to be calculated as:-

   a) April 1981 - September 1981

   $$\text{Percent pro-rata} \atop (x) = \frac{0.5 \times \text{proposed annual issue (127.000)}}{1.25 \times \text{all 'plasma' input July-December 1980}}$$

   Each Region would then receive x% of the 100% 'pro-rata' issue
   for PPF. Similar calculations could be applied for 100ml PPF,
   20g albumin, with Freeze-Dried Plasma being treated separately.

   b) October 1981 - March 1982

   $$\text{Percent pro-rata} \atop (x) = \frac{0.5 \times \text{proposed annual issue}}{1.25 \times \text{all 'plasma' input January-June 1981}}$$

2. **Factor VIII**

   a) April 1981 - June 1981

   i) Assigned FFP input for all regions to be calculated for period
      July-December 1980 as numbers of 5 litre packs.

   ii) Average pack weight for each centre to be calculated from
      production figures of period July-December 1980.

   iii) Gross yields for each centre to be calculated from production
      figures of period July-December 1980, with assessment by C.F
      where necessary.

   iv) Calculate the input in kilogrammes for each centre during
      July-December 1980 by multiplying together (i) and (ii).

   v) Multiply (iv) by the gross yield figures (July-December 1980)
      to give the 100% pro-rata in iu. (Then divide by a nominal
      240iu if distribution to be in 'vials' rather than 'iu').

   vi) Multiply (v) by a factor (say 0.8 - 0.9) to account for national
      stock, quality control etc.

   vii) This final figure either in vial equivalents or actual iu to
      be divided by 6 to give the monthly issue for April, May and
      June 1981.

16-102

b) <u>July-September 1981</u>

Repeat (i) to (vii) but using period October 1980 - March 1981 instead of July-December 1980.

Each month, centres will receive, where possible, product obtained from their plasma, but made up by product from other centres or mixed batches. As the system becomes clearer in operation, the factor applied in (vi) may be adjusted to suit BPL and special unit requirements.

16-103

Example COMPARISON OF CURRENT DISTRIBUTION METHOD FOR FACTOR VIII
AND "PRO-RATA" METHOD, FOR ISSUE DURING JAN-MARCH 1981

Note: All calculations are based on data from the period April – Sept. 1980.

Region	(a) No. of 5L packs to BPL	(b) Av. net pack wt fr.prodn data (kg)	(c) Net wt plasma to BPL (a x b) (kg)	(d) gross yield (iu/kg)	(e) 100% pro-rata for ½ yr (c x d) / 240 (vials)	(f) 90% pro-rata	(g) 80% pro-rata	(h) Present alloctn for ½yr
Nor	538	5.03	2706	191	2154	1938	1723	1860
Yor	382	5.37	2051	221	1889	1700	1511	1800
Trent	485	4.87	2362	230	2264	2038	1811	1620
E.A.	261	5.09	1329	219	1213	1092	970	660
NWT	702	5.31	3728	258	4008	3607	3206	2220
NET	803	4.97	3991	223	3708	3337	2966	2220
SET	953	4.63	4412	226	4155	3740	3324	3240
S.West	863	4.96	4281	222	3960	3564	3168	2220
W.Mid	1053	5.01	5276	249	5474	4927	4379	2820
Mers	225	4.98	1121	234	1093	984	874	480
N.West	473	4.90	2318	221	2134	1921	1707	2640
Wales	359	5.10	1831	211	1610	1449	1288	900
Wessex	12160(sd) x 180g		2189	(240)	2189	1970	1751	2340**
Oxford	22037(sd) x 180g		3967	(240)	3967	3570	3174	3300*
TOTAL			41557		39818	35837	31852	28320

MONTHLY ALLOCATION FOR JAN-FEB-MAR WOULD BE 1/6 OF COLUMN (g)

Special arrangements are required for Belfast (540 per ½ yr)
and Jersey (35 per ½ yr) at present allocation levels. /

* Oxford Region receive more than this figure at present as FFP
is sent exclusively to PFL for subsequent return as final product.

** Wessex FFP is sent to PFL for processing and final product return.
Shortfall (600 vials per ½ yr) in allocation is made up from BPL
stocks.

Annual input of FFP in 1980, from Jan - Sept. figures, is expected
to be of the order of 71,000 kg to BPL and 12,000 kg to PFL (total
83,000 kg). Thus the input is sufficient to allow for the production
of 78,000 vials (240 iu) at a mean yield of 225 iu/kg for all centres.

The adoption of an 80% pro-rata figure would allow for:
1) the build-up of a national stock to cover emergency requirements,
and special unit requirements, as well as creating sufficient
'shelf-stock' to meet demand in periods of low production through
staff shortages, building contracts, loss of product batches etc.
2) A basis on which to judge the operation of pro-rata in the early
months.

As the operation itself becomes more clear, BPL can raise the figure
to nearer 90%. This may be possible for April-June 1981 or July-Sept.
1981 quarters, but is dependent on the many factors outlined above.

Pro-rata for April - June 1981 would be calculated as above but
using data from July - December 1980. Similarly July - September 1981
ori-rata would be from October 1980 - March 1981 data.

N. PETTET,
14.1.81.

1b-105

IN SUMMARY

REGION	CURRENT MONTHLY ALLOCATION (Vials)	PRO-RATA (80%) MONTHLY (Jan-Mar.81) (Vials)
Nor	310	290
Yor	300	250
Trent	270	300
E.A.	110	160
NWT	370	530
NET	370	490
SET	540	550
S.West	370	530
W.Mid	470	730
Mers	80	150
N.West	440	280
Wales	150	210
Wessex	390	290
Oxford	550+	530
Belfast	90	90
Jersey	6	6
TOTALS	4816	5386
Annual requirement	57792+	64632

16-109

IN SUMMARY

REGION	CURRENT MONTHLY ALLOCATION (Vials)	PRO-RATA (80%) MONTHLY (Jan-Mar.81) (Vials)
Nor	310	290
Yor	300	250
Trent	270	300
E.A.	110	160
NWT	370	530
NET	370	490
SET	540	550
S.West	370	530
W.Mid	470	730
Mers	80	150
N.West	440	280
Wales	150	210
Wessex	390	290
Oxford	550+ ~~(570)~~	530 (590)
Belfast	90	90
Jersey	6	6
TOTALS	4816 +	5386 (+60)
Annual requirement	57792+	64632 (+60)

Example   COMPARISON OF CURRENT DISTRIBUTION METHOD FOR FACTOR VIII
AND "PRO-RATA" METHOD, FOR ISSUE DURING JAN-MARCH 1981

Note: All calculations are based on data from the period April - Sept. 1980.

Region	(a) No. of 5L packs to BPL	(b) Av. net pack wt fr.prodn data (kg)	(c) Net wt plasma to BPL (a x b) (kg)	(d) gross yield (iu/kg)	(e) 100% pro-rata for ½ yr (c x d) 240 (vials)	(f) 90% pro-rata	(g) 80% pro-rata	(h) Present alloctn for ½yr
Nor	538	5.03	2706	191	2154	1938	1723	1860
Yor	382	5.37	2051	221	1889	1700	1511	1800
Trent	485	4.87	2362	230	2264	2038	1811	1620
E.A.	261	5.09	1329	219	1213	1092	970	660
NWT	702	5.31	3728	258	4008	3607	3206	2220
NET	803	4.97	3991	223	3708	3337	2966	2220
SET	953	4.63	4412	226	4155	3740	3324	3240
S.West	863	4.96	4281	222	3960	3564	3168	2220
W.Mid	1053	5.01	5276	249	5474	4927	4379	2820
Mers	225	4.98	1121	234	1093	984	874	480
N.West	473	4.90	2318	221	2134	1921	1707	2640
Wales	359	5.10	1831	211	1610	1449	1288	900
Wessex	12160(sd) x 180g		2189	(240)	2189	1970	1751	2340**
Oxford	22037(sd) x 180g		3967	(240)	3967	3570	3174	3300*
TOTAL			41557		39818	35837	31852	28320

MONTHLY ALLOCATION FOR JAN-FEB-MAR WOULD BE 1/6 OF COLUMN (g)

Special arrangements are required for Belfast (540 per ½ yr)
and Jersey (35 per ½ yr) at present allocation levels.

* Oxford Region receive more than this figure at present as FFP
is sent exclusively to PFL for subsequent return as final product.

** Wessex FFP is sent to PFL for processing and final product return.
Shortfall (600 vials per ½ yr) in allocation is made up from BPL
stocks.

16-107