APPENDIX 4

1. FACTOR VIII

CAPACITY, PRODUCTION AND DEMAND 1973 - 1990

-	[ ]	denotes the source document from the CBLA List of Documents dated 11.06.90
-	*	estimate based on the available figures
-		bold type indicates the best figure/estimate for the year (where this is possible to establish from the documents)
-	E	England
-	FFP	fresh frozen plasma
-	L	Litre
-	MSC	Re-Amended Main Statement of Claim (figures for approximate consumption of Factor VIII)
-	NI	Northern Ireland
-	S	Scotland
-	TEP	time expired plasma
-	W	Wales
Note 1:		Figures for "Plasma Fractionated" may include stock in hand from previous year.
Note 2:		Early figures should be treated with caution as the units of production/volume etc are expressed in varying ways.

1973

1 BPL/PFL Capacity

200L plasma for Factor VIII per week, 10,000 doses (ie vials?) per year [70]

2 Plasma Fractionated

BPL fractionated 5,457L plasma [104]
PFL fractionated 4,262L plasma [102]
(NB No of bottles per L of plasma decreased in 1972 and 1973 due to lower Factor VIII yield.)

Factor VIII?

Remove whole comment.

3 BPL/PFL Actual *

2,389,075 (Approx 2.4m) Factor VIII units in 1973 [172]

Is this right? What have 400 iu from each.

BPL: 4,049 bottles (400 iu each) [103]
604 bottles failed pyrogen test or await retesting [105]
therefore net bottles issued = 3,445 @ 400 iu each = 1,378,000 iu.

PFL: 4,252 bottles (300-400 i.u. each) no figure for the number of failed bottles = 4,252 @ 350 each = 1,488,200 iu (= 2,866,200 iu?) [105]
3,751 bottles (300-400 iu) = 1,312,850 iu [176]

2·4m iu made.
∴ 240 iu per bottle
∴ not 400 iu.

* **Total from the above figures is approx 2,690,850 to 2,866,200 iu/yr.**

(Published) of plasma demand.

4 Estimated Demand

275,000 donations (5 donations = 1.0L plasma) [84]
365,000 donations for E & N.I. estimate of future need is supply unlimited [72]
250,000 donations by 1975, 400,000-700,000 over next 10 yrs [268]

5 Actual Consumption - Factor VIII. (all products)

In UK and NI total including concentrate and cryo = 15.829×10^6 units.
NHS concentrate = 2.481×10^6 units.
Commercial concentrate = 0.875×10^6 units.
Total concentrate 3.356×10^6 units. (MSC)

NB separate the info:
1. Fractionation data
2. External data.

* ACTUAL
1. No. of containers from (1) BPL (2) PFL.
2. Actual total of iu as calculated
3. iu must agree with annualised vial yield rates (see above).

1974

1 BPL/PFL Capacity

900,000L (not clear whether this is for FFP or FFP + TEP) [141]
90,000 L. - must be FFP + TEP. ∴ need to work out how much was FFP. Nearer 13,500 litres

2 Plasma Fractionated

1402L for 1974 Jan-Mar [168] → This doesn't help. Need annual rate.

3 BPL/PFL Actual

Dr Maycock said double the amount of NHS concentrate had been made in 1974 as compared with 1973? [162] [This is not supported by the figures].

2,568,015 Factor VIII units for 1974 approx 2.6×10^6 [172]

4,296 x 300-400 iu bottles = 1.5×10^6 iu [176]

5,493 kg plasma equivalent to 1,241,373 iu went into 4879 x 250 iu = 1,219,750 iu = approx 1.2×10^6 iu [366]
4,879 x 250 iu = 1,219,750 iu = 1.2×10^6 iu [594] [366]

* **Best figure from the above is to add the number of 300-400 iu bottles to 250 iu bottles for a total of approx 2.7×10^6 iu**

↑ if this is right, the yield isn't as good as the previous yr.

4 Estimated Demand — Plasma.

Minimum estimated demand, assuming no backlog of surgery cases is 40 million units of Factor VIII = 500,000 donations, assuming 40% recovery and that 5 donations = 1L plasma [112]

500,000 to 750,000 donations per year for next 5 years [117]

Use same format as 1975.

275,000 donations by 1975 [162]

home therapy patients 25,000 iu/patient/yr [172] (but how many patients were on home therapy?

5 Actual Consumption

UK and NI:- Total concentrate and cryoprecipitate, 20. 548 x 10^6 iu
broadly carried out on figure. — **NHS concentrate - 2.732 x 10^6 iu,**
Commercial concentrate - 2.681 x 10^6 iu,
Total concentrate - 5.413 x 10^6 iu
(MSC)

NB. Must check figs. correspond with Haemoph. D's. figs.

NB. compile separate file of notes for each year.

Nos don't tally!

1975

Must represent what BPL/PFL could do. There was ↓ but no apparent change in capacity.

1 BPL/PFL Capacity

PFL July-Dec 1975 did not reach capacity for Factor VIII - 200L per week [299]

> 25,000 litres per annum (combined).

2 Plasma Fractionated

127,000 donations [217]

PFL 2476.1. kg FFP was fractionated in 25 pools to recover Factor VIII (81P) and Factor IX (DE(1) concentrates [ ]

PFL - 2476.1 kg plasma [ ]

BPL - 5348.6 kg plasma gross, 108.2 kg plasma rejected because donor had lymphosarcoma) [366]

* **Approximately 7,824.7 kg plasma**

7,800 litres fractionated i.e. < the 2 previous yrs.

3 BPL/PFL Actual

PFL Factor VIII 2476.1. kg plasma = 614.3×10^3 iu [ ]

BPL 5348.6 kg of plasma = 126,470 iu of Factor VIII (108.2 kg of plasma approx 49,000 iu was rejected because donor had lymphosarcoma) = 4450 bottles = 1,215,670 iu [366]

8770 x 250 iu = 2,192,500 iu [594] [366]

Figs. for cable & rejects are too small.

4 Estimated Demand

275,000 donations by 1975 [162]

MRC Working Party 15,000-20,000 iu/ patient/year.
Scottish estimate 18,000 iu/patient/year.
Home therapy requirements 25,000iu/patient/year.
275,000 donations for Factor VIII + 75,000 donations for cryo [240]

5 Actual Consumption

Public?

NHS - 3,085,465 iu/year
Commercial - 5,151,935 iu/year
Total - 24,886,000 iu/year
Approx - 14,902 iu/patient/year [611(b)]

Total including concentrate and cryoprecipitate - 24.886×10^6 iu
NHS Concentrate - 3.085×10^6 iu
Commercial concentrate - 5.152×10^6 iu
Total concentrate - 8.237×10^6 iu
(MSC)

NR. add figs. for total no. of reqd. Haem. A & B patients for the year.

→ undo heading with estimated use per patient.

1976

1 BPL/PFL Capacity

PFL 5,000 kg plasma p.a., limited by plasma supply. Potentially approx 10,000 kg plasma p.a. (but need shelf freezer).
BPL (to June 77) 50,000 kg plasma. Could do more.
Edinburgh 50,000 p.a. Total capability 110,000 kg (from 593,340 donations). Greatly in excess of 343,100 donations planned for June 77 but about 50% of estimated demand [266]

2 Plasma Fractionated

.75 or .66 of target of 45,000-50,000 x 250 iu containers by Autumn 1976 (optimistic). Will not reach target of 275,000 donations until late 1977 at earliest. [246]

140,000 donations [217]

Estimated 343,100 donations by June 1977 ie 67,755 kg or 12.35 x 10^6 iu ie 30% of total requirement for Factor VIII as dried concentrate [266].

FFP to BPL and PFL 46,580kg [2126]

3 BPL/PFL Actual

BPL and PFL combined output 30,000 x 250 iu containers = 7.5 x 10^6 iu [273]

42,000 x 250 iu = 10.5 x 10^6 iu [285]

13.7 x 10^6 iu from 343,100 donations (307,100 donations to BPL, 36,000 to PFL) = 61,760 litres plasma = 54,800 x 250 iu per year (49,050 BPL, 5,750 PFL) [332]

Commercial concentrate available (E&W) in January-June 1976 = 5.4 x 10^6 iu NHS - 10.8 x 10^4 [336]

January-June 12,268 (incl 695 vials) x 250 iu [366]

28,104 x 250 iu = 7,026,000 iu [594]

* **BPL/PFL Factor VIII 25,429 @ 240 iu, issued for clinical use equivalent to 6,102,960 iu. This figure should be approx 7 million iu [2126]**

4 Estimated Demand

Average 12-15,000 iu/patient/yr.
Total requirement 36M -45M iu per year.
36 x 10^6 iu/yr = 180,000 kg plasma - 970,920 donations.
45 x 10^6 iu/yr = 225,000 kg = 1,213,650 donations [266]

35 x 10^6 iu/yr [332]

With introduction of home treatment it is estimated demand will increase until 40 x 10^6 iu/yr is reached [338]

E, W and NI = 36,481,890 units
S = 3,741,917 units
Total; = 40,223,807 units [403]

5 Actual Consumption

1976 - 46% of Factor VIII used was freeze-dried NHS intermediate potency concentrate
14% of all Factor VIII was commercial [ ]
34 x 10^6 iu [822] and [880]

Total including concentrate and cryoprecipitate 33.716 x 10^6 iu
NHS Concentrate - 6.915 x 10^6 iu
Commercial Concentrate - 11.069 x 10^6 iu
Total concentrate - 17.984 x 10^6 iu
(MSC)

1977

1 BPL/PFL Capacity

BPL Target of 14 x 10^6 should be reached by Autumn 1977
PFL Target of 2.5 x 10^6 10,000 x 250 iu in 1977/78 [366]

PFC Liberton potential capacity 60 x 10^6 iu [485].
14-15 x 10^6 iu was the maximum capacity for Elstree in the present plant and buildings. This included Oxford and was a final figure after current expansion was completed [485].

BPL 1,200 litres FFP per week approx to 15.0 x 10^6 iu per year = 60,000 x 250 iu = 15.0 x 10^6 iu
PFL - 10,000 x 250 iu = 2.5 x 10^6 iu.
Total 17.5 x 10^6 iu/yr [594 Appendix A2]

BPL - 14 x 10^6 iu [611]

2 Plasma Fractionated

Target of 1000L plasma fractionated per week was reached in July 1977 [594]
BPL prepares approximately .25% of the Factor VIII used in England and Wales [619]

343,100 (307,100 Elstree, 36,000 Oxford) donations plasma [631]

340,000 donations p.a. by 1977 (target) [285]

BTS could supply enough plasma for fractionation to provide a minimum of 40 x 10^6 units/year. 125,000 single FFP donations p.a. [641]

1217L plasma fractionated and equivalent to about 227m iu/wk was being released for use [803]

* **FFP to BPL and PFL - 64,306kg [2126]**

3 BPL/PFL Actual

12.5 x 10^6 iu Factor VIII for 1977 [837]

Intention to achieve NHS self sufficiency by the middle of 1977 [273]

Estimated output for 1977 - 14 x 10^6 iu [285]

It was estimated that by mid 1977 when current production target for Factor VIII was expected to be achieved, the NHS supply of Factor VIII might be of the order of 31-34 x 10^6 iu/yr (ie 12-15 x 10^6 iu of concentrate in England and Wales, 15 x 10^6 iu in form of cryoprecipitate and 4 x 10^6 10 of Factor VIII (in all forms) produced in Scotland) [338]

46,005 x 250 iu = 11.05 x 10^6 [803]

52,507 x 250 iu = 13.1 x 10^6 iu [928]

Factor VIII 48,242 @ 240 iu, issued for clinical use = 11,578,080 iu [2126]

Best figure is 52,507 x 250 iu = 13.1 x 10^6 iu [928]

4 Estimated Demand

50 x 10^6 p.a. [515]

1,000 iu per 1,000 population per annum, calculations based on achieving an annual donor collection rate of 50/1000 population, an annual plasma yield of 8L/1000 population and that half of the plasma (4L/1000 population) is processed fresh for Factor VIII [602]

50 x 10^6 iu [611]

Estimate in [611] possibly too low [701]

Trends Working Party estimated use of Factor VIII to rise to 50m iu per annum over the decade 1977-1987 and this was subsequently revised to 60m iu by the Standing Medical Advisory Committee (SMAC). The approved SMAC estimate has probably been exceeded already in 1978 [822]

5 Actual Consumption

48.6 x 10^6 units [807]

48.4. x 10^6 [822]

Commercial Factor VIII purchase increased by £1.2m [822]
48.5 x 10^6 iu [836 and 878 (same document)]

48.4. x 10^6 iu [880]

Total concentrate and cryoprecipitate 43.193 x 10^6 iu
NHS concentrate 12.949 x 10^6 iu
Commercial concentrate - 15.017 x 10^6 iu
Total concentrate - 27.966 x 10^6 iu
(MSC)

1978

1 BPL/PFL Capacity

1,200L per week equivalent to 320,000 donations over a 48 week year [668]

Stop Gap Targets: 62,500 - 93,600 - 124,000 litres plasma p.a. (12m iu to 24m iu) [830]

2 Plasma Fractionated

BPL received 67,178 litres of plasma (373,211 donations at 180 ml per donation) [846]

FFP received at BPL Jan-May 1978 - 143,136 donations [733]

Total donations = 1.9m blood donations annually - approx 360,000 (9%) are converted to FFP for Factor VIII concentrate production = 65,000 litres plasma [822]

Stop Gap Target of 28m iu Factor VIII requires approx 750,000 donations of FFP [836]

344,000 donations fractionated at BPL [837]

FFP to BPL and PFL - 76,182 kgs [2126]

* Last 2 are best figures

3 BPL/PFL Actual

65,000 litres plasma - processed at approx 1,200 litres/week = 12m iu/yr [822]

January 1979 - currently fractionated at 1,200 litres/week to provide 12.5M-15M iu/yr [836]

13.5m iu/year - increase of over 1m over 1977 despite static intake of FFP [837]

62,236 x 250 iu - 15.6 x 10^6 iu [928]

Factor VIII 58,679 @ 240 iu, issued for clinical use = 14,082,960 iu [2126]

* **Best figure probably 15.6 x 10^6 iu**

4 Estimated Demand

60-65 m iu [822]

5 Actual Consumption

increase in commercial Factor VIII purchase of £1.9m projected [822]

Figure of 60m iu/yr probably exceeded in 1978 [822]

60 x 10^6 iu [880]

NHS concentrate 14,964,000 iu
Commercial concentrate 19,459,000 iu [957 (a)]

Total including concentrate and cryoprecipitate = 45.050 x 10^6 iu
NHS concentrate = 14.600 x 10^6 iu
Commercial concentrate = 19.273 x 10^6 iu
Total concentrate = 33.873 x 10^6 iu
(MSC)

1979

1 BPL/PFL Capacity

4 x 600 litres FFP pools per week [836]

Maximum production in BPL could be 124,800 litres/year (693,333 donations) with present site and machinery [846]

2 Plasma Fractionated

BPL 1978/79 target 15 m iu requiring 112,000 litres FFP [887]

75,051 kg plasma equivalent to 367,000 donations of FFP with yield per unit 220 iu/kg plasma (net yield to patient) with annual production of 15 m iu (including PFL) [1004]

Target of 40,000 donations FFP independent of time expired plasma [600]

Total whole blood donations p.a. = 1.9m.
No of donations used for TEP = 0.37m (20%).
No of donations used for FFP and TEP and other plasma eg specific immune = 0.78m (41%)
Therefore total plasma input into BPL = approx. 160,000 litres.
Total plasma available for Factor VIII = 75,000 litres.
Maximum Factor VIII obtainable from 75,000 litres FFP at gross yield of 250 iu/litre - 19m iu; if BPL received all its plasma as FFP, the maximum Factor VIII obtainable with current yields would be 38m iu.
1985 target of 90m iu would require an FFP input of 360,000 litres [1004]

1979 "all Plasma" intake (litres) - 169,693 litres [1164 Table 1]

FFP to BPL and PFL - 77,264 kg [2126]

3 BPL/PFL Actual

BPL output stationary since early 1977 [853]

NHS-14,678,000 iu/year [1090]

NHS - 14,668,000 iu [1174]

59,844 vials of Factor VIII @ 240 iu, issued for clinical use [2126]

4 Estimated Demand

In excess of 60 m iu this year and to an amount in excess of 80 m over next five years [853]

Predict demand to be 100 m iu/year by mid-80's with upper limit of 150m/year by 1990 [1276]

5 Actual Consumption

Commercial Factor VIII purchase increase of £2.5m is projected [822]

69 x 10^6 iu [880]

Total 46 x 10^6 iu (BPL-15m iu, Cryoprecipitate 17m iu, Commercial 14m iu) [1004]

Average per patient 22,200 iu/year [1090]

NHS-14,668,000, Commercial-24,739,000 iu Total-48,678,000 [1174]

Total- 48,678,000
NHS -14,668,000
Commercial -24,793,000
Average per patient 22,200 iu/year

23,000 iu/patient/year, 52 x 10^6 iu/year [1276]

Total including concentrate and cryoprecipitate - 50.716x 10^6 [1090] [1174]
NHS concentrate = 15.092 x 10^6 iu
Commercial concentrate = 26.178 x 10^6 iu
Total concentrate = 41.27 x 10^6 iu
(MSC)

1980

1 BPL/PFL Capacity

2 Plasma Fractionated

Target of 47,000 donations FFP independent of TEP [600]

National Self Sufficiency would require 450,000 kg FFP/year approx 90,000 donations [1056]

1980 BPL received 68,400 litres FFP/year [1082 Appendix 12]

January-September annual input of FFP - 71,000 kg to BPL, 12,000kg to PFL (total 83,000 kg) - sufficient for 78,000 x 140 iu vials [ ]

16,298 x 5 litre packs FFP [1258]

During 1980 2.032 million donations of whole blood collected at RTC's [1307]

* **FFP to BPL and PFL - 85,940 kg [2126]**

3 BPL/PFL Actual

62,000 x 250 iu = 15.5 x 10^6 iu [1155]

PFL issued 1,827,480 iu to Oxford, 919,750 iu to Wessex, Total 11,303 @ 243 iu per bottle = 2,747,230 iu [1171]

57,790 x 240 iu = approx 14 x 10^6 iu/yr, annual allocation [1258]

NHS -14,505,000 iu [1392]

Factor VIII 49,428, vials @ 240 iu, issued for clinical use approx 11,862,720 iu. [2126]

4 Estimated Demand

77 x 10^6 iu [880]

Estimated demand during life of new lab 120 x 10^6 iu from 700,000 litres plasma [1057]

By end of decade, the UK would need one million litres of FFP [1188]

5 Actual Consumption

Commercial Factor VIII purchase increase of £3.0m projected [822]

NHS concentrate - 14,505,000 iu

Commercial concentrate - 35,095,000 iu
Average 24,312iu/patient/year [1392]

Total (including Cryo) = 57.0 x 10^6 iu - 60% of this commercial, 14% cryoprecipitate, no percentage given for NHS. Approx 27,181 iu/patient/year [1617]

Total Concentrate and Cryoprecipitate = 57.271 x 10^6 iu
NHS Concentrate = 14.364.10^6 iu
Commercial Concentrate = 34.749 x 10^6 iu
Total concentrate = 49.113 x 10^6 iu
(MSC)

1981

1 BPL/PFL Capacity

Combined BPL and PFL capacity is 15 M iu/yr [ ]

2 Plasma Fractionated

January-March 1981 net weight plasma to BPL - 41,557 kg [1164]

Target for NHS in England and Wales is to fractionate 450,000 litres/yr, present - 70,000 litres FFP p.a. [1223]

Need 500,000 kg plasma to meet mid-80's estimated demand for 100m iu/yr [1307]

Approx 28,500 kg plasma required for 10M iu cryoprecipitate so net plasma required for concentrates is approx 470,000 kg/year [1307]

Total required plasma estimate of 500,000 kg lowered to 435,000 kg to supply 100 m iu/yr [1378]

435,000 kg FFP/yr would produce 95m iu of intermediate Factor VIII and 5m iu cryoprecipitate and also enough to meet requirement for high purity Factor VIII [1387]

Combined BPL and PFL fractionation 100,000 kg FFP [1384]

FFP sent to BPL during 1981 - 109,403 kg [1495(a)]

Plasma intake 1981/82 was 116.2 tonnes, 26% increase on 1980/81 [1500]

FFP to BPL and PFL - 109,403 kg [2126]

3 BPL/PFL Actual

By end of 1982 short-term up-grading programme of BPL, production will increase from 15m iu to 30m iu [1200]

Approaching 20m iu BPL and PFL - [1384]

15 m iu p.a. from 350,000 donations FFP [1453]

22 m iu - combined BPL and PFL output first major increase in production since plateau in production in 1977
1981/82 increase in released Factor VIII product of 39% [1500]

86,101 @ 250 iu = 21,525,250 iu production 1981/82 [1511(a)]

NHS - 22,474,000 iu [1542]

Factor VIII 83,192 @ 240iu, issued for clinical use = approx 19,966,080 iu [2126]

4 Estimated Demand

82 x 10^6 iu [880]

600 iu /1000 population [1164]

90 M iu by mid-80's [1200]

Predict mid-80's demand to be 100m iu/yr with 1990 upper limit of 150m/yr - a minimum of 80% of Factor VIII requirement would need to be in the form of intermediate purity concentrate - a maximum of 10% of total Factor VIII requirement would need to be high purity concentrate [1276]

NB [1276] figures criticised as "off top of head" by Dr Lane and Dr Smith in [1288]

100m iu/yr by mid-80's intermediate purity concentrate
80 m iu/yr, high purity concentrate
10m iu/yr frozen/freeze dried cryoprecipitate
[1307]

5 Actual Consumption

Commercial Factor VIII purchase increase of £3.4m projected [822]

55M iu in England and Wales [1200]

BPL - 14m iu,
cryoprecipitate - 12m iu,
commercial - 29m iu,
Total 55m iu/yr [1224]

Total 60m iu p.a.:-
NHS 15M iu,
commercial 45M iu
therefore national deficit = 1,050,000 donations FFP [1453]

No change in amount of commercial Factor VIII used from 1980 to 1981 [1549]

NHS Concentrate = 22,472,000 iu
Commercial Concentrate = 35,524,000 iu
Total including cryo and plasma = 65,701,000 [1542]

Total concentrate and cryoprecipitate = 65.7 x 10^6
NHS Concentrate = 22.472 x 10^6 iu
Commercial Concentrate = 35.5 x 10^6 iu
Total concentrate = 57.972 x 10^6 iu
(MSC)

1982

1 BPL/PFL Capacity

Short term upgrade of BPL to double capacity from 15M iu/yr to 30M iu/yr expected to be complete mid-82 [1307]

2 Plasma Fractionated

Target 1982/83 requires 800,000 donations [1037]

National Target for FFP to BPL in 1982 = 131,648 kg [1495(a)]

FFP sent to BPL in 1982 = 127,634 kg [1688(b)]

FFP to BPL - 128,302kg [2126]

3 BPL/PFL Actual

BPL only, target is 28.75 million iu as 115,000 @ 250 iu [878]

1982/83 target is 30m iu (equivalent to 800,000 donations) [1037]

22,892,000 iu - NHS [1686(a)]

Products dispatched for clinical use 1981/82 - Factor VIII - 86,101 @ 250 iu = approx. 21,525,250 iu [1716]

88,000, Factor VIII @ 240 iu, issued for clinical use = approx. 21,120,000 iu [2126]

* **Best Figure is 21,525,250**

4 Estimated Demand

85 x 10^6 iu [880]

5 Actual Consumption

Commercial Factor VIII purchase increase of £3.7 projected [822]

NHS - 22,892,000 iu
Commercial - 45,644,000
Total 73,1732,000 iu [1686(a)]

Total concentrate and cryoprecipitate = 73.732 x 10^6 iu
NHS Concentrate = 22.892 x 10^6 iu
Commercial Concentrate = 45.644 x 10^6 iu
Total concentrate = 68.536 x 10^6 iu
[MSC]

1983

1 BPL/PFL Capacity

30M iu during 1983 [1493]

New BPL Capacity 450 tonnes p.a., date of commissioning Dec 1985 [1638]

Max capacity of BPL during remaining interim period approx 150,000 kg FFP/yr [1704]

Now at maximum capacity in the old building fractionating in a full year 150 tonnes of FFP - 1982/83 Annual Report [1894]

2 Plasma Fractionated

April 1983 - FFP received 10,698 kg
processed 11,569 kg
Factor VIII (245 iu) 2.62 x 10^6 iu
May FFP received 12,840 kg
FFP processed 13,228 kg
Factor VIII (245 iu) 2.52 x 10^6 iu [1639]

1st quarter 83/84 FFP received 36,961 kg
FFP processed 40,307 kg
Factor VIII = 7.93 x 10^6 iu [1650]

FFP received: July 1983 11,410 kg
August 11,156 kg
FFP processed: July 10,936 kg
August 13,988 kg
Factor VIII 2.53 x 10^6 [166]

Third quarter 1983/84 - FFP received = 110,169 kg
FFP processed = 113,620 kg
Factor VIII (245iu) - 23.83 x 10^6 iu [1715]

Target FFP from 800,000 donations p.a. by 1983/84 [1037]

FFP stocks and supplies = currently 125 tonnes p.a. are received at BPL. Target is 150 tonnes p.a. [1637]

FFP sent to BPL in January-June 1983 = 73,704 kg [1688(b)]

Estimated FFP to BPL during 82/83 financial year will be 125,000 kg [1704]

Production 1982/83 - Plasma Processed FFP (BPL) 116,890 kg
FFP (PFL) 14,209 kg
FFP Total 131,099 kg [1716]

FFP to BPL = 148,171 kg [2126]

The amount of FFP being received has now risen to 150 tonnes per year (150,000kg) Any plasma received in addition to 150 tonnes will be stock piled to assist commissioning of new BPL production building [1894]

FFP (BPL) - 116,890kg
FFP (PFL) - 14,209kg
FFP total - 131,099kg
TEP - 53,791kg
Total Plasma Processed 184,890kg [1894]

3 BPL/PFL Actual

Target of 30 x 10^6 by 1983/84. Production target is less than 50% of the annual use rate for Factor VIII [1037]

Annual output doubled to 30m iu [1716]

Production 82/83 Products passed to Free Stock -
Factor VIII (BPL) 80,002 units @ 250 iu
Factor VIII (PFL) 8,405 units @ 250 iu

Products dispatched for Clinical Use: 1982/83
Factor VIII 250 iu @ 90,594

Products dispatched for clinical use April-December 1983
Factor VIII 250 iu @ 108,308 [1716]

Factor VIII (BPL) @ 80,002 units, 250 iu
(PFL) 8,405 units, @ 250 iu
Total 88,407 units @ 250 iu = approx. 22,101,750 iu - [1894]

* **Factor VIII @ 240 iu, 123,364 vials issued for clinical use = approx. 29,607,360 iu [2126]**

4 Estimated Demand

85 x 10^6 iu for 1983 [ ]

5 Actual Consumption

NHS - 30,018,000 iu,
Commercial 36,217,000 iu,
Total including concentrate and cryo - 71,008,000 iu [1810(a)]

Total concentrate and cryoprecipitate = 71.008 x 10^6
NHS Concentrate = 30.018 x 10^6 iu
Commercial Concentrate = 26.217 x 10^6 iu
Total concentrate = 56.235 x 10^6 iu
[MSC]

1984

1 BPL/PFL Capacity

2 Plasma Fractionated

Target FFP from 800,000 donations p.a. by 1983/84 [1037]

Minimum Plasma Collection Schedule for 1983/84 is 150,000 kg FFP [1705]

Report to the CBLA by Dr H. Gunson re Plasma Supply for Self-Sufficiency: "it would be unwise to assume that the necessary quantity of plasma will be available for the successful operation of the new BPL" [1726]

April 1983/March 1984
FFP intake 153,987kg
FFP Fractionation - 159,181kg [1755]

Target figure of 205 tonnes likely to be met by March 1985 [1817]

FFP stock increased by 1,500 kg in current financial year against a targeted 10,400kg [1861]

Performance April - December 1984;
FFP receipts 134,661kg;
FFP fractionated -113,007kg
FFP in store - 47,185kg [1909]

*** At the beginning 179,850 litres plasma per year to BPL.
By introducing optimal additive solutions to allow the collection of 50% more plasma from each unit of whole blood this figure should increase to between 200,000 and 250,000 litres plasma per year by 1986.
This latter figure should be regarded as a maximum.
The target (set in 1983) to allow the new BPL to function at full capacity was 450,000 litres by 1987.
To attain this target it will be necessary to supplement the plasma derived from whole blood by the acquisition of an additional 200,000-250,000 litres of plasma per year [1910]

For $^{3}/_{4}$ of the year, plasma supply remained at 1983 levels.
In the last ¼ and carried through into 1985, plasma input at BPL rose due to increasing collection of blood into optimal additive solutions (SAG-M).
Current annual rate of supply are 220 tonnes [2072]

1984 162,137kg FFP were received at Elstree
14,151kg FFP - Oxford
176,288kg FFP Total
Total processed FFP - 158,826kg
Total FFP in stock - 47,185kg [2072]

FFP to BPL - 179,854kg [2126]

April - October 1984 FFP receipts 99,597kg
FFP fractionated - 91,580kg
FFP in store 33,469, [1861] 5

3 BPL/PFL Actual

Target of 30 x 10^6 by 1983/84.
Production target is less than 50% of the annual use rate for Factor VIII [1037]

Performance April 83 - March 84 Factor VIII
passed to stock 9,428 (PFL)
120,989 (BPL)
Despatched total 138,028
stock to end March 4102 [1755]

Factor VIII issued April - August 1984 = 11.6 x 10^6 iu [1817]

Performance April - December 1984
Factor VIII - 19.8 x 10^6 (+ 1.5 x 10^6 held by PFL for clinical trial) [1909]

145,488kg plasma were processed to Factor VIII
Total no of vials produced 140,631 @ 250 iu = 35,175,750 iu. [2072]

Despatched for Clinical Use
111,782 @ 250 iu = 27,945,500 iu

Remaining in Stock
118,400 @ 250 = 29,600,000 iu

All production targets were achieved
5,533 vials of Factor VIII were "reject batches", this includes product recalled, 4.46% of throughput
[2072]

Factor VIII concentrate 111,782 @ 240 iu, - issued for clinical use [2127]

4. Estimated Demand

85 x 10^6 iu [880]

Dr Gunson says requirement for Factor VIII is now in excess of 100M units/yr [1822]

5 Actual Consumption

Input from Edinburgh PFC = 8320 @ 200 iu = 1,664,000 iu distributed to regions on pro rata against plasma supply [1814]

Total input Edinburgh = 2.12 x 10^6 iu (8300 vials) [1814]

Factor VIII: NHS - 40,192,000 iu;
Comm - 34,033,000,
Total 79,910,000 iu [2204(a)]

Total concentrate and cryoprecipitate = 79.910 x 10^6
NHS concentrate = 40.192 x 10^6 iu
Commercial concentrate = 34.003 x 10^6 iu
Total concentrate = 74.195 x 10^6 iu
[MSC]

1985

1 BPL/PFL Capacity

Intermediate target set in 1978/9 is for 90 x 10^6 iu/yr requiring 315,000 L FFP to be reached by mid-80's. With production ceiling in New Lab of 120 x 10^6 iu = 500,00 L FFP [836]

30 x 10^6 iu (120,000 x 250 iu) per annum, after heat treatment introduced this total reduced to at least 24 x 10^6 iu per annum for a 20% loss in yield [1919]

2 Plasma Fractionated

Forecast of 90m iu would require 5 x 1979 supply of FFP [1004]

Minimum Plasma Collection Schedule 1984-5 - 170,000kg [1705]

Production April - Feb 85:
FFP receipts - 167,934kg
FFP fractionated - 129,499kg
FFP in store 67,396kg [2020] 6.2

3 BPL/PFL Actual

"Currently supplying heat-treated intermediate Factor VIII concentrate at a rate equivalent to 12M iu/yr. From April 1985, this rate will increase up to approx. 25M iu/yr. A full supply of NHS heat treated Factor VIII will not become available until 1986 when the new plant is operational" [2009]

Performance April - Feb 1985 22.7 x 10^6 iu (not including 1.5 x 10^6 iu held by PFL for clinical trial) [2020]

Total units issued January - July 1985:
unheated - 3.9M iu
heated 4.3M iu
total 8.2M iu
expected output 1985 in units = 17.1M iu (unheated 3.9M iu heated HLH 5.7M iu, 8Y 7.5M iu) [2132]

4 Estimated Demand

85 x 10^6 iu [880]

90 x 10^6 iu [1004]

5 Actual Consumption

NHS Factor VIII concentrate - 23,097,000
comm. Factor VIII concentrate - 50,902,000
total 77,344,000 iu [2266]

Total concentrate and cryoprecipitate = 77.344 x 10^6 iu
NHS concentrate = 23.097 x 10^6 iu

Commercial concentrate = 50.902
Total concentrate = 73.999 x 10^6 iu
[MSC]

1986

1 BPL/PFL Capacity

New BPL expected to start in Jan 86: the minimum total plasma requirement will be 265,000kg FFP [1704]

2 Plasma Fractionated

Minimum Plasma Collection Schedule - 1985/6 - 265,000kg FFP [1705]

April 1985 - March 1986:
FFP received (BPL and PFL) = 253,769kg
Total FFP processed - 141,126kg
FFP in stock - 190,444kg [2229] 16 months

FFP input - 300,000 litres [2294]

50 tonnes of untested FFP held in storage from April 1986 [2294]

3 BPL/PFL Actual

April 1985 - March 1986 units issued:
Intermediate Factor VIII - 3,880,
Intermediate Factor VIII HT - 28,121
High Purity 8Y (Elstree) 67,292
High Purity 8Y (Oxford) 2,909 [2229]

Product released to stock April 85/March 86 - Dried Factor VIII vials- 109,977 (+ 6% relative to April 84/March 85) [2229]

Performance April - March 1986, Factor VIII (250 iu) HT - 100,446 vials [2229]

Reject batches Factor VIII account for 10,373 vials - 10.7% loss (96,644 filled) [2229]

4 Estimated Demand

1986 estimated use of all Factor VIII is above 80M [2296]

5 Actual Consumption

Total usage 88.5M iu, an increase of 11M over 1985 [2321]

NHS Factor VIII - 31,483,000 iu
comm Factor VIII - 53,754,000
total - 88,491,000 iu [2321]

Total concentrate and cryoprecipitate - 88.491 x 10^6 iu
NHS concentrate = 31.483 x 10^6 iu
Commercial concentrate = 53.754. 10^6 iu
Total concentrate = 85.237 x 10^6 iu
[MSC]

1987

1 BPL/PFL Capacity

New BPL to be fully operational by mid 1987 [2237]

2 Plasma Fractionated

Minimum Plasma Collection Schedule 1986-87 - 405,000kg FFP [1705]

April 1986 - March 1987:
FFP intake - 304,665kg
fractionated FFP - 144,672kg
stock end March 1987 354,045kg [2296] 30

The target of 450 tonnes FFP for new BPL would provide 78M iu Factor 8Y and self-sufficiency in all other coagulation products [2296]

3 BPL/PFL Actual

79,003 units (i.e. vials) Factor VIII net issued in 1986/87 = approx 18,960,720 iu [2296]

4 Estimated Demand

5 Actual Consumption

92M iu = total consumption with one Haemophilia Centre being added in as 4M iu (1986 usage) because they could not make a return.
Actual returns figure total was 87.86M iu.
NHS Factor VIII - 25,982,653
comm Factor VIII - 59,186,707
total 87,856,666 iu [2361]

100.69M units, an increase of 12.84M iu over previous year NHS Factor VIII 43,219,029 iu, NHS used rose by 17.24M, Commercial fell by 4M iu Commercial Factor VIII - 55,168,999 iu, total 100,698,570 iu [2375]

Total concentrate and cryoprecipitate = 87.857×10^6 iu
NHS concentrate = 25.982×10^6 iu
Commercial concentrate = 59.186×10^6 iu
Total concentrate = 85.168×10^6 iu
[MSC]

1988

1. BPL/PFL Capacity

Full production by September 1988 - issue of 20,000 vials per month [2334]

Capacity trial proved ability to process plasma at a rate equivalent to 450 tonnes/yr [2343]

2 Plasma Fractionated

Minimum Plasma Collection Schedule 1987/8 - 450,000kg FFP [1705]

In April BPL in a negative plasma supply with fractionation exceeding input by 180 tonnes per annum (stockpile) [2334]

April 1987 - March 1988;
FFP received - 374,069kg
fractionated 258,629kg.
Stock end March 1987 500,376kg including 56,856kg FFP collected before donors were HIV screened [2343] 23

3 BPL/PFL Actual

April 87 - March 88 Factor VIII released 98,787 (vials?) [2343]

4 Estimated Demand

100M iu by 1990 [2343]

5 Actual Consumption

BPL now (Jan 1989) produced 70% of the Factor VIII requirement for England and Wales, compared with around 20% a year ago [2360]

100.69M units, an increase of 12.84M iu over previous year.
NHS used rose by 17.24M
comm fell by 4M iu
NHS Factor VIII 43,219,029 iu
comm Factor VIII - 55,168,999 iu
total 100,698,570 iu [2375]

1989

1 BPL/PFL Capacity

Factory operated at full capacity from April 1988 throughout rest of year [2371]

2 Plasma Fractionated

FFP processed 1988/89 - 470 tonnes
FFP intake 361,498kg
FFP fractionated 485,434kg
closing stock 257,141kg
N.B. 39,877kg (FFP not screened for HIV not included in these figures) [2371]

3 BPL/PFL Actual

Factor 8Y issued increased 2.2 times over the previous year's results.
57M iu by year end.
Factor 8Y (250 iu) passed to stock - 226,107
sales - 210,995
closing stock 16,307 = 0.8 months cover [2371]
Factor 8Y sales achieved 90% of sales plan at 57M iu [2371]

4 Estimated Demand

90M iu [2371]

5 Actual Consumption

90M iu [2371]

BPL became major supplier with over 60% of the market - 57M iu [2371]

1990

1 BPL/PFL Capacity

2 Plasma Fractionated

3 BPL/PFL Actual

4 Estimated Demand

100M iu/yr [2343]

5 Actual Consumption

6 Production