

Mr Harris

From: Dr R J Moore

Mr Hart

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cc: Mr Heppell
Dr Harris
Mr Cashman
Dr Pickles
Mr Brown

BLOOD PRODUCTS LABORATORY AND FACTOR VIII REQUIREMENT

1. At the Plasma Supply and Blood Products Working Party chaired by Dr Harris on Wednesday 21st September, Dr Lane of BPL produced new information which has undermined our ability to achieve self-sufficiency in Factor VIII. Since then more information has come to light from BPL which further worsens the position.

2. In summary, stocks of fresh frozen plasma which have been built up at Elstree in preparation for the new laboratory have been recorded as a gross weight (ie including packaging). For planning purposes over the past years however BPL have in error treated the gross weight as a net weight. This means that the plasma stockpile is only 330 tonnes rather than the 450 tonnes expected.

3. Furthermore it has come to light that a 7% plasma loss on opening the packs has not been included in the estimates of net yield. This means that the current net yield for Factor VIII is 130 iu/kg rather than the 140 iu/kg we were told about on the 21st.

4. I have done some preliminary calculations based on these new numbers. It is clear that unless the NBTS can increase plasma input from its current level of 340 tonnes to 490 tonnes from April 1989 and then produce a further increase to 590 tonnes from April 1990, then there will not be enough plasma for BPL to work at maximum capacity. Given the lower yields now admitted by BPL, the Factor VIII production is unlikely to exceed 78 million of international units (m.i.u) per annum (against a current usage of 90 m.i.u) even were the plasma available. (See Option 1 in Appendix 1).

5. In my view it will be impossible for the NBTS to boost supply that fast. We await more detailed information from the NBTS but a more realistic scenario is Option 3 with Option 2 as an optimistic forecast (Appendix 1). It will be seen that in both Option 2 and 3, BPL will be able to fractionate at a 500 tonne level from 89/90 and produce 65 m.i.u of Factor VIII. Whilst this is about three times the output of the old building, it is only 72% of current Factor VIII usage. Until last week we were looking forward to an annual rate of 91 m.i.u from November 1988 onwards. (Appendix 2)

6. We will presumably need to alert Ministers to the changed circumstances since they may not be able to talk of self-sufficiency for a few years. They will want to know how such inept planning has occurred. The finger points clearly at BPL and in particular Dr Lane. It is his figures upon which we have of necessity relied for planning the plasma build-up and his estimates of yield and Factor VIII production. The CBLA Chief Executive and the Finance Director have been instrumental in introducing the accounting systems which have produced the new facts we now have. Before these systems were installed they, like us, had to rely on Dr Lane's figures.

7. The story of the Factor VIII yield estimates demonstrates particular incompetence. At last year's accountability review planning was based on a yield of 185 - 190. Earlier this year Dr Lane explained this was a laboratory derived process yield and stated the true net yield as around 166. At this year's accountability review in July a figure of 166 was used for planning purposes. Last week we were told 140 was more realistic and this week we discovered it did not include a further 7% loss. The true net figure is therefore down to 130. Overall this represents a 30% loss of product over our expectations a year ago.

8. The error in weighing the stockpile is again a management error. Net figures for plasma were available in the commercial department but were not used for the stockpile inventory. Had this error come to light even a year ago, it would have been possible to plan to increase the plasma supply accordingly. Instead many RTCs deliberately held back production because the stockpile and yield figures showed that the haemophilia need would be met.

9. It is hard to estimate the cost to the NHS of the errors in yield and stockpile measurement. However if we assume that the NBTS given correct planning information would have been able to respond in a timely fashion, then the cost could be estimated as the lost opportunity cost of producing 76.7 m.i.u of Factor VIII in the years up to 92/93. On this basis, there may well be a loss totalling 23 m.i.u of Factor VIII alone which would cost the NHS around £6 m. If other blood products are taken into account this figure could double. This debacle must throw doubts on Dr Lane's management competence and his future position with BPL.

10. Dr Gunson's working party are studying the problem of the plasma supply in the light of the new BPL figures, but it will take time to prepare an accurate estimate of what the NBTS can achieve at such short notice.

11. The document prepared for the CBLA Accountability Review last July is now obsolete. Its planning estimates were based on higher yields and sufficient plasma. I would suggest that as a first step CBLA are called once more to account in the near future.

12. The timescale for action will need to take into account the effect the news will have on the Haemophilia community. Dr Lane and several Haemophilia Centre directors are attending a meeting in Dublin at this moment. It is therefore likely that the Haemophilia community and the Society will get wind of the new factors within the next week or two. It is particularly unfortunate that the Society received a positive and reassuring letter from PS(H) only two weeks ago. Once CBLA have given an account of themselves we will be in a position to brief Ministers.

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OPTION 1

YEAR	88/89 (Sept/March)	89/90	90/91	91/92	92/93	93/94
OPENING PLASMA STOCK (tonnes)	330.00	208.80	109.40	110.00	110.60	111.20
PLASMA SUPPLIED BY NBTS	216.80	490.60	590.60	590.60	590.60	590.60
PLASMA FRACTIONATED	338.00	590.00	590.00	590.00	590.00	590.00
FACTOR VIII YIELD (m.i.u./kg)	130.00	130.00	130.00	130.00	130.00	130.00
FACTOR VIII PRODUCED (m.i.u.)	43.94	76.70	76.70	76.70	76.70	76.70

OPTION 2

YEAR	88/89 (Sept/March)	89/90	90/91	91/92	92/93	93/94
OPENING PLASMA STOCK (tonnes)	330.00	210.00	160.00	110.00	110.00	110.00
PLASMA SUPPLIED BY NBTS	210.00	450.00	500.00	550.00	590.00	590.00
PLASMA FRACTIONATED	330.00	500.00	550.00	550.00	590.00	590.00
FACTOR VIII YIELD (m.i.u./kg)	130.00	130.00	130.00	130.00	130.00	130.00
FACTOR VIII PRODUCED (m.i.u.)	42.90	65.00	71.50	71.50	76.70	76.70

OPTION 3

YEAR	88/89 (Sept/March)	89/90	90/91	91/92	92/93	93/94
OPENING PLASMA STOCK (tonnes)	330.00	240.00	160.00	110.00	110.00	110.00
PLASMA SUPPLIED BY NBTS	210.00	420.00	500.00	580.00	590.00	590.00
PLASMA FRACTIONATED	300.00	500.00	550.00	580.00	590.00	590.00
FACTOR VIII YIELD (m.i.u./kg)	130.00	130.00	130.00	130.00	130.00	130.00
FACTOR VIII PRODUCED (m.i.u.)	39.00	65.00	71.50	75.40	76.70	76.70

OPTION 4

YEAR	88/89 (Sept/March)	89/90	90/91	91/92	92/93	93/94
OPENING PLASMA STOCK (tonnes)	330.00	330.00	280.00	230.00	180.00	140.00
PLASMA SUPPLIED BY NBTS	210.00	400.00	450.00	500.00	550.00	590.00
PLASMA FRACTIONATED	210.00	450.00	500.00	550.00	590.00	590.00
FACTOR VIII YIELD (m.i.u./kg)	130.00	130.00	130.00	130.00	130.00	130.00
FACTOR VIII PRODUCED (m.i.u.)	27.30	58.50	65.00	71.50	76.70	76.70

APPENDIX 2

PREVIOUS PLANS

FORWARD ESTIMATE JULY 1987

YEAR	88/89	89/90	90/91	91/92	92/93	93/94
OPENING PLASMA STOCK (tonnes)	450.00	370.00	320.00	320.00	320.00	320.00
PLASMA SUPPLIED BY NBTS	350.00	400.00	450.00	450.00	450.00	450.00
PLASMA FRACTIONATED	430.00	450.00	450.00	450.00	450.00	450.00
FACTOR VIII YIELD (m.i.u./kg)	185.00	185.00	185.00	185.00	185.00	185.00
FACTOR VIII PRODUCED (m.i.u.)	79.55	83.25	83.25	83.25	83.25	83.25

DRAFT PLAN AUGUST 1988

YEAR	88/89	89/90	90/91	91/92	92/93	93/94
OPENING PLASMA STOCK (tonnes)	450.00	370.00	220.00	120.00	70.00	70.00
PLASMA SUPPLIED BY NBTS	350.00	400.00	450.00	500.00	550.00	550.00
PLASMA FRACTIONATED	430.00	550.00	550.00	550.00	550.00	550.00
FACTOR VIII YIELD (m.i.u./kg)	166.00	166.00	166.00	166.00	166.00	166.00
FACTOR VIII PRODUCED (m.i.u.)	71.38	91.30	91.30	91.30	91.30	91.30