

Dr Maycock.

*I do not propose to circulate generally
until you & Dr White have had chance to consider*

AMF

Dr Waiter

GRO-C:
Dutton

cc Dr Maycock
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FACTOR VIII SUPPLIES

1. At the meeting of the Expert Group on the Treatment of Haemophilia and Allied Conditions held on 4 May, the experts maintained that there was still some way to go before they had all the Factor VIII required for the optimum treatment of their patients and that this requirement would continue to rise until, in Dr Biggs' opinion, something over 40 million international units were being administered per annum. In the ensuing discussion the consensus view which emerged was that the Department must certainly plan for 35 million international units per annum if all the haemophiliacs who would benefit from home treatment in the next 5 years were to be so treated. It was estimated that by mid-1977, when the current production target for Factor VIII was expected to be achieved, the NHS supply of Factor VIII might be of the order of 31 million to 34 million international units a year (ie 12-15 million IU of concentrate in England and Wales; 15 million IU in the form of cryoprecipitate and 4 million IU of Factor VIII (in all forms) produced in Scotland.

2. The information on potency ie units per donation contained in the paper prepared for the meeting of Regional Transfusion Directors (RTD(76)17) on 21 July 1976 has enabled the current uptake of Factor VIII to be expressed in terms of international units, see tables A and B annexed. Even if it is assumed that the yield of cryoprecipitate is, on average, no more than 60 units per donation, the 35 million IU figure for total annual requirement of Factor VIII discussed at the meeting is already being attained, mainly due to the success of RTCs in maintaining a high level of output of cryoprecipitate and at the same time providing the plasma needed for processing for freeze dried concentrate.

3. When the AHG freeze dried concentrate production programme was planned it was assumed that the output of cryoprecipitate would be scaled down in order to release more plasma for the preparation of the freeze dried concentrate which most clinicians seemed to prefer. It was assumed that by the time the target figure of 375,000 donations for all forms of Factor VIII (England and Wales) was achieved by mid-1977, the number of donations of blood devoted to cryoprecipitate production would have fallen to 100,000 donations per annum. However, in the 6 months January-June 1976 the annual rate of production of cryoprecipitate has been at about twice this level while the output of freeze dried concentrate has continued to rise at the anticipated rate.

4. The situation which the figures in the annexed tables reveal throw some doubt on the recent assessment of the experts which, while emphasising that the present level of treatment of haemophiliacs is well below what it should be according to the best clinical practice, maintained that 35-40 million units per annum would be required if all the patients who can benefit from home treatment were to receive it. Unless haemophilia centres are accumulating supplies of Factor VIII faster than they are using it, clinicians are already administering the component at an annual rate of 35 million units. The figures also highlight the cost of treating haemophilia. The cost of commercial concentrate (10-12p per unit) appears to be more or less steady at about £1.25 million per annum. The cost of the NHS factor is difficult to assess without detailed calculations which will take some time to prepare.

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Nevertheless

Nevertheless, it is unlikely to be much below 5p per unit even after due allowance is made for all the other components obtained from the blood, which represents a level of expenditure of about £2.5 million per annum at present levels of usage. *low calc*

5. With expenditure possibly of this order now being incurred in the NHS production of Factor VIII, yields become of considerable importance. The current yield of NHS freeze dried concentrate is approximately 30% of the factor available in the plasma as received at the processing laboratories. The yield of cryoprecipitate per donation is up to twice as high but is known to vary very widely.

6. It is theoretically possible to replace all the Factor VIII at present being purchased from commercial sources (at a cost of over £1 million per annum) by improving the yield per donation of cryoprecipitate and freeze dried concentrate. It is well recognised that Factor VIII is highly labile and that losses occur at all stages from taking the blood donation through the various processing stages to the reconstitution before administration. Also, that in the processing of biological products theoretically possible yields are rarely approached, far less attained. Nevertheless, the prospect of replacing a significant part of the commercial Factor VIII without the need to increase the number of donations is sufficiently attractive financially and rewarding technologically to merit careful consideration.

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