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CENTRAL COMMITTEE FOR THE NATIONAL BLOOD TRANSFUSION SERVICE

FACTOR VIII IN THE TREATMENT OF HAEMOPHILIA

Introduction

1. During the past year the Department has been criticised for the fact that clinicians have been unable to obtain sufficient quantities of Factor VIII in the form of human freeze-dried anti-haemophilic globulin (AHG) concentrate which is now the preferred therapeutic agent for the treatment of patients suffering from haemophilia, of whom there are estimated to be some 3000 in Great Britain.

Production of Factor VIII in the NHS

2. Factor VIII in the form of cryoprecipitate can usually be supplied to Haemophilia Centres by Regional Blood Transfusion Centres (RTCs) in England and Wales in sufficient quantities to meet demands. In 1974 some 227,000 blood donations were used at RTCs for the preparation of cryoprecipitate. Factor VIII in the form of the preferred AHG concentrate is produced at the Blood Products Laboratory, Elstree (BPL) and the Plasma Fractionation Laboratory, Oxford (PFL) from plasma sent by RTCs. Although production at the two laboratories rose from 3968 bottles in 1971 to 9624 bottles in 1974, the latter figure represents the plasma from some 65,000 donations only.

AHG Concentrate from commercial firms

3. Adequate stocks of imported AHG concentrate are available from two commercial firms, but the material is very expensive; at 10p a unit a major operation might cost £8,000. In the 17 months between November 1973 and March 1975 Health Authorities spent £500,000 on the purchase of commercial AHG concentrate. This figure contrasts with that of about £2 million a year which it has been estimated would be required to purchase enough AHG concentrate adequately to supplement NHS supplies.

Estimated requirements of Factor VIII

4. An Expert Group on the Treatment of Haemophilia advised the Department that to achieve self-sufficiency in the production of Factor VIII within the NHS the plasma from a minimum of 275,000 donations annually would be required for AHG concentrate and of 100,000 donations annually for cryoprecipitate.

5. In order to reach the target of 275,000 donations for AHG concentrate it is necessary to divert 127,000 of the 227,000 donations at present used for cryoprecipitate and to increase to 148,000 the 65,000 donations at present used for AHG concentrate (see para 2 above).

Steps taken to achieve self-sufficiency

6. Current production of AHG concentrate at the BPL and PFL has been limited by the amount of plasma supplied by RTCs. This amount in turn depends upon (a) the number of blood donations collected and the extent to which clinicians are prepared to use blood in the form of concentrated red cells, and (b) the facilities available at RTCs for separating the whole blood into concentrated red cells and plasma. At present less than 10% of

blood donations in England and Wales are used in the form of concentrated red cells compared with 30-40% in Scotland. It was calculated that if this percentage could be raised to 40% in England and Wales the NHS could meet the demand for AHG concentrate without increasing the number of blood donations from the present figure of 1.6 million per annum.

7. It was recognized that to achieve a 40% use of concentrated red cells would require the full co-operation of clinicians. Clearly no steps could be taken towards this objective unless parallel action had first been taken to ensure that RTCs have sufficient facilities to separate more plasma from whole blood and thus to meet the increased usage of concentrated red cells. If the normal procedure for the financing of health services were to have been followed, Health Authorities would have needed to agree, collectively, to accord blood transfusion priority for additional resources over a period of several years, within a co-ordinated programme of expansion. However, as the extent to which RTCs could increase their production of plasma varies from Centre to Centre, additional expenditure would have been disproportionate as between Regions if realistic Regional targets were to be set. It was therefore decided that since the Department would in any case have to co-ordinate a programme for the increased production of AHG concentrate earmarked finance of up to £.5 million should exceptionally be provided for this purpose.

8. In March the Department gave Regions provisional targets of increased production of plasma and invited them to submit estimates of the additional expenditure which would be incurred. The work involved in collating and clarifying the estimates has been protracted but is now largely completed. £300,000 has been set aside for capital expenditure and up to £200,000 for revenue expenditure in 1975/76. The latter figure will be increased to £400,000 for 1976/77.

9. Nine Regions have been notified of the amounts allocated to them. In the case of three Regions assurances have been sought as to when they would be in a position to start increasing their production of plasma. In one Region the degree of estimated expenditure is, in the light of the total resources available, disproportionate to the amount of plasma to be produced. The Department is, however, anxious that, if it is at all possible, not to leave any Region out of the scheme and is considering this case further.

10. Much preparatory work will have to be done at Regions on structural alteration of RTCs, purchase and installation of equipment and recruitment of staff, and there are unlikely to be significant developments before the end of this year. It is, however, hoped that the goal of self-sufficiency in the production of Factor VIII within the NHS can be achieved within two to three years.

11. This account is presented for the information of the Committee, as an example of the problems involved in the increasing demand for blood products.