



Pond Street
Hampstead
London NW3 2QG

The Royal Free Hospital

THE KATHARINE DORMANDY HAEMOPHILIA CENTRE

Telephone
01-794 0500

Ext GRO-C

PK/HP

27 April 1979

Dr B. Colvin
Secretary
NETR Association of Haematologists
Department of Haematology, London Hospital
Whitechapel
LONDON E1

Dear Brian,

Regional Funding of factor VIII

I am writing to you at the request of the members' of the NETR Haematologists Haemophilia Working Party to ask for the formal approval and support of the Association of our efforts to establish a more rational and financially equitable system for the distribution and purchase of factor VIII in the NETR than that which exists at present.

You will know that the Regional Treasurer has recently refused our request to institute a system of central funding for factor VIII. As a compromise measure it has been proposed that all requests for purchase of factor VIII should be channelled through a single Area Supplies Officer and that only the Directors of the two major Haemophilia Centres in the Region - at the Royal Free and London Hospitals - should be authorised to make such requests. The members of the working party find this proposal quite unacceptable, and indeed a retrograde step. It is also felt that there is a lack of understanding at Regional level of the special problems of treating haemophiliacs, and in particular, the problem of obtaining adequate supplies of factor VIII. This problem will not be solved by stop-gap measures and will be with us for at least several years to come. The members of the working party feel an obligation to ensure that the Regional Authorities are fully aware of the current position, and are also aware of the need for more long-term planning to take place than has been the case up to now.

THE CURRENT POSITION

1. The organization of care for haemophiliacs

Haemophilia is a rare disorder. Because of this and for sound economic, logistic and clinical reasons, the care of haemophiliacs on a national basis is undertaken at DHSS - designated Haemophilia Centres. The development of Centres at different institutions has largely depended on the interest and enthusiasm of individual physicians and not upon arbitrary administrative boundaries. The numbers of patients receiving care at different Centres varies markedly from several hundred at the Royal Free and London Hospitals to less than 10 at some of the 4 smaller 'Associate' Centres in NETR. Particularly in the case of the larger Centres, it is quite impracticable to observe strict catchment areas. The majority of registered patients at major Centres do not live in the

continued -

same District as the hospital which delivers their treatment, and very often not in the same Area or Region. This is particularly the case at the Royal Free Hospital where, largely for historical reasons, more than half the registered patients live in NWTR. The nub of the financial problem is this: it is the hospital District which has to bear the total cost of treatment, and the Districts do not receive any special funds for this purpose.

2. Types of therapeutic material available

The only way to stop a haemophiliac bleeding is to give him factor VIII. Although factor VIII can be considered to be a drug, it cannot be synthesized. The only source is human blood and the extraction process is both difficult and expensive. There are 3 factor VIII-containing preparations available: cryoprecipitate, semi-purified factor VIII concentrate made by the NHS and semi-purified factor VIII concentrate made by commercial companies. Cryoprecipitate, although relatively cheap to produce, has serious clinical disadvantages and in the U.K, as in all developed countries, is being superseded by semi-purified factor VIII concentrates. Since the amount of concentrate being made by the NHS is at present quite inadequate to satisfy needs, the shortfall has to be met by buying commercial concentrate. Not only is commercial concentrate expensive, but there are both clinical and moral reasons for preferring the N.H.S. material. The clinical reason is the growing awareness of the probability that commercial concentrates have a higher risk of transmitting non-A non-B hepatitis than NHS material. This is a serious disease with long-term consequences which, as far as is known, is at present much less common in the U.K. than in those parts of the world - particularly the U.S.A. - where donor blood for commercial concentrates is collected. We may, therefore, be introducing diseases which are not yet endemic in the U.K. The moral reason for preferring N.H.S. material is that it seems inappropriate to many that the maintenance of adequate standards of treatment to NHS patients should be dependent on blood obtained from paid donors in foreign countries.

The only medium to long-term solution to these problems is for the NHS to markedly increase production of factor VIII.

3. Usage of factor VIII in NETR

Calculations about future needs for factor VIII are necessarily imprecise. It is clear to all involved in the care of haemophiliacs, however, that usage is increasing and will continue to do so for some years to come. The principle reason for this increased usage is that until commercial concentrates became available in the last few years the demand for factor VIII was artificially suppressed by the limited availability of supplies. Now that such concentrates are available increasing numbers of patients are being treated, in accord with modern practice, much more aggressively than has hitherto been the case. In 1977, the most recent year for which figures are available, approximately 4.6 million units of factor VIII were used in NETR (excluding Great Ormond Street Hospital). Our projections for the financial year 1979/80 indicate a figure of 7.0 million units. The optimum amount of material needed is not known with any certainty, but North American experience suggests that a figure of 10-13 million units annually would be a not unreasonable projection for the NETR. Our expectation that only 1 million units of NHS-produced concentrate will be available for use in the NETR this year gives an idea of the extent of the problem.

continued -

4. Financial arrangements

With the exception of those institutions in the NETR which obtain supplies of blood products from the North London BTS, and have to pay not inconsiderable sums for cryoprecipitate, NHS-produced cryoprecipitate and factor VIII concentrate are distributed without charge to Haemophilia Centres in NETR. Since distribution is from the BTS, either at Brentwood or Edware, it is possible to know with accuracy how much of these materials are used in NETR. The problem, from both financial and data collection points of view, is with commercial concentrate which, as I have already indicated, is being needed and is being bought in increasing quantities.

Because commercial material is bought by and delivered to individual institutions, it is difficult to obtain accurate information about regional usage, but our estimates for the current financial year indicate that about 3.65 million units of commercial factor VIII will have to be bought in NETR at a cost of around £365,000. About 75% of this total will be needed at the Royal Free, 15% at the London and the remainder at the smaller Centres in the region. There are two particular problems with current arrangements. The first is the magnitude of the financial burden which falls on 2 Districts, rather than being spread out over the Region as a whole. In the case of the Royal Free, the burden on the District seems particularly inappropriate because, as a DHSS-designated Reference Centre, a supraregional service is offered to patients in the whole of NETR, NWTR and East Anglia regions. Be this as it may, it has been possible for the Royal Free and the London to obtain sufficient supplies of commercial concentrate to satisfy their needs. This is not the case at the smaller Centres, which is the second problem. Directors of these Centres have had considerable difficulties persuading their local administrations to purchase factor VIII. I know of no other instance where supplies of an essential drug have been withheld on the grounds of cost and in my view the refusal of local administrators to purchase commercial factor VIII is a serious interference with the duties and rights of physicians to treat their patients in the most appropriate way they think fit. It has also to be remembered that DHSS-designated Centres have defined functions, one of which is to supply treatment to haemophiliacs. This function cannot be fulfilled without adequate supplies of factor VIII.

At the present time, the Directors of the major Haemophilia Centres in NETR order commercial concentrate direct from the companies concerned, of which there are about five. The price depends on the amount ordered and companies offer different terms at different times. So far as the supply of factor VIII to major Centres is concerned, the present arrangements work well and it has been possible to buy factor VIII considerably cheaper than the 'contract' price arranged by the DHSS. The present arrangements do not, however, solve several of the other problems I have outlined above.

The proposal for Regional Funding of factor VIII

The members of the working party are of the opinion that it would be quite impracticable to attempt to work out a system of cross-District or cross-Area accounting which would resolve the present inequities in the funding and supply of commercial factor VIII in NETR. It is felt that the only sensible solution must be centralized funding at a Regional level. Regional funding is unlikely to save money in the short term, but in the medium to long term will go a long way towards achieving our ultimate objective of total independence from commercially-supplied factor VIII. The reason for this is that along with centralized funding will go more

continued -

27 April 1979

efficient data collection on Regional usage of factor VIII, better forward planning of future needs and more adequate monitoring of the possible adverse effects of therapy. With this information pressure can be brought to bear on the appropriate authorities to make the organizational and financial changes which will be necessary if the production of NHS concentrate is to be massively increased.

Objections to the recently proposed scheme for purchase of commercial factor VIII

Members of the working party have several specific objections to this scheme:

1. It is unacceptable that only the Directors of the Royal Free and the London Hospital Centres should be able to order commercial factor VIII. The Directors of all the Centres in NETR need to do this.
2. The scheme does nothing to spread the financial burden away from the Royal Free and London Hospitals.
3. The scheme does nothing to help Directors of smaller Centres obtain supplies of commercial factor VIII more easily.
4. There will be no financial advantage. The Royal Free and London Hospitals already negotiate the best terms for bulk purchase and since the quantities bought by these Centres account for at least 90% of the total, the price will not come down any further. If the Directors of the major Centres feel they can obtain a better price by direct negotiation, they will have to advise their local finance authorities not to participate in the scheme.
5. Price is not the only determinant of buying policy. There are complexities regarding quality, method of preparation and dosage which are only fully understood by those using the material. If an Area Supplies Officer is to be made responsible for negotiating contracts, it is essential that he works in the closest possible collaboration with the Directors of the major Centres.
6. The Scheme introduces needless complexity without benefit. The Directors of the major Centres are concerned about the logistic problems which may arise if the direct link between themselves and their suppliers is broken.

Yours sincerely

GRO-C

P.B.A. Kernoff, MD, MRCP
Chairman, Haemophilia Working Party
NETR Association of Haematologists

cc Dr O.H.A. Baugh, Secretary, NETR Haemophilia Working Party