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Paper 3

PROVISION OF HAEMOPHILIA TREATMENT AND CARE

Introduction

This guidance sets out the background to haemophilia treatment and care, highlights the particular features and requirements of patients suffering from haemophilia and related conditions and reminds health authorities of the considerations which they will need to take into account in order to secure continuity of access to comprehensive treatment and care for these patients.

Background

- The Haemophilic Condition

The haemophilic population in the United Kingdom comprises a group of patients whose medical management is both complex and costly. Some of the complexity arises due to the rarity of the condition, its lifelong nature, its variable severity and the fact that the patients do not appear "ill" in the accepted sense of that term. Generally, medical experience of the condition can be sparse and expertise in the management of the more complex situations tends to be concentrated in the larger Centres. It may not always be understood that the lack of prompt/appropriate treatment can cause a multiplicity of undesirable effects, for example, in those most severely affected there is a potential for crippling deformities to ensue, necessitating a need for more costly treatment at a later stage. This may also lead to inappropriate prolonged hospitalisation, the misuse or even on occasion, the wastage of expensive blood products.

- **Evolverment of the present mode of patient reveral**

Since 1968 arrangements have been in place under which Centres have provided diagnosis, treatment and registration of patients suffering from haemophilia and related conditions. Centres have offered different levels of service according to skills, knowledge and experience of staff in haemophilia treatment and facilities available to them. HC 76(4) revised and updated the arrangements for haemophilia treatment and care which led to the current situation of Reference Centres, Haemophilia Centres and Associate Haemophilia Centres.

Haemophilia patients have built up relationships with a chosen Centre for various reasons, including convenience or special services and facilities offered and the Centre may not be within their home district. In many cases patients have travelled long distances to visit these Centres and in some cases patients have chosen to live near the Centre of their choice. Haemophilia patients have tended to refer themselves direct to a particular haemophilia treatment Centre and have in many cases, though not universally, by-passed the customary consultation with the general practitioner because of the specialised knowledge required for their treatment.

Patterns of Contracting for Haemophilia Services

- **Established patterns**

Patients have already established a pattern of self-referral which health authorities will want to accommodate, taking into account professional advice and patient preference. It is a most important priority that access to fully comprehensive services is secured.

- **Considerations**

By virtue of special need and special practice, districts will need to take account of the fact that patients will refer themselves direct to these specialist Centres and will not normally be referred by the general practitioner. However, there is marked variation in the frequency and nature of need for treatment of individual patients. Districts may only become aware of a haemophilia patient within its district when it receives a bid for an extra contractual referral from a provider.

Health authorities will need to take into account in contracting for services for their haemophilia patients that there are a number of considerations:

- the variable numbers of haemophilia patients in each district and the complexity of their condition
- severity of the condition which ranges from very mild to most severe and particularly complicated. Those with mild or moderate haemophilia usually only experience bleeding problems after significant injury or surgical intervention. In the severely affected cases, bleeding episodes will be more frequent and can occur up to 2-3 times per week.
- complexity of the condition which may require a diverse and complex range of services. Given the nature of the condition, the amount of treatment required by some patients will be unpredictable. Even within a district a different pattern of care may be indicated for different individuals;

- the need for ease of access to supplies of blood products to support home treatment programmes;
- the incidence of HIV, which is a significant problem in this group of patients and the need for HIV counselling for infected haemophilia patients.
- expertise in treatment of haemophilia patients is not uniformly available across the country.

District health authorities have responsibility for securing access to comprehensive treatment and care for their haemophilia patients. Each health authority will need to identify the extent of these patients' requirements and will need to take professional advice in planning for provision of services for their treatment and care. Examples of the sources of professional advice are contained in the DHA project discussion paper **Professional Advice for Purchasers (EL(91)21)**. For this group of patients, this would normally include the local consultant haematologist.

As the process of entering into contractual arrangements for provision of health care services evolves following the first year of "steady state", Districts should:

- identify the number of haemophilia patients for which it is responsible, their needs, current treatment patterns and the services which are currently provided in their own locality. These might include Associate Haemophilia Centres, Haemophilia Centres and Haemophilia Comprehensive Care Centres (formerly termed Reference

Centres). It is recommended that purchasing health authorities should build into contracts with haemophilia treatment Centres requirements to provide information on the numbers of individuals treated who live in the district.

- enter into contracts with haemophilia treatment Centres providing care for people with haemophilia which will ensure that proper provision is made for treatment and care of these patients.

Given the numbers found in each district, it is probable that at least some will require these services. Districts should ensure that access to those services is available through contract when required.

Options to consider when purchasing care for haemophilics
Districts should secure access to comprehensive care for their haemophilia patients through the contracting process and not rely on extra-contractual referrals. Given the pattern of haemophilia treatment Centres across the country, this could be done in a number of ways:

Haemophilia Comprehensive Care Centre in the District

A health authority with a Haemophilia Comprehensive Care Centre in its district will normally wish to contract with that Comprehensive Care Centre for the full range of services for haemophilia patients in the district.

- **Other Haemophilia Treatment Centre in the District**

A health authority with a Haemophilia Centre or Associate Haemophilia Centre in the District will be able to contract with that Centre for routine treatment and additionally with a Haemophilia Comprehensive Care Centre for the more specialised services which cannot be provided by the local Centre.

However, in certain circumstances a health authority may decide to place the contract for all haemophilia services in respect of a particular patient with a Comprehensive Care Centre.

- **No Haemophilia Treatment Centre in the District**

A health authority with no haemophilia treatment Centre in the district will normally be able to contract for its haemophilia services with a Comprehensive Care Centre. Factors such as distance and difficulty of travel to a Comprehensive Care Centre may indicate that contractual arrangements for routine treatment should be made with an appropriate Centre in a neighbouring District. It is advised that in such cases contractual arrangements be entered into with a treatment Centre able to provide more specialised services as and when patients required them, rather than rely on extra-contractual referrals.

- **Extra-Contractual Referrals**

Districts will need to arrange continuing access to services for the haemophilia population as a whole. In the interests of continuity of patient care, access to those services is better secured on a planned basis rather than relying on extra-contractual referrals (ECRs). ECRs should be reserved

for unpredictable treatment needs or for accidents, etc. occurring when the patient is in another district, for instance on holiday.

Medical Audit

As part of the contracting process, health authorities will be seeking quality as well as cost-effective services for their haemophilia patients. In keeping with the general movement towards peer review, the Haemophilia Regional Centre Districts' Committee has prepared a scheme of Medical Audit for all haemophilia treatment Centres. Medical Audit will play an essential part in enabling haemophilia treatment Centres to ensure quality of haemophilia treatment and care.

ANNEX

Drafting Note: The Annex will need to be redrafted once we have received responses from the Haemophilia Regional Centre Directors' Organisation on the proposals that the existing pattern of Haemophilia and Associate Centres should be replaced with a flexible system of self-ranking by treatment Centres according to the facilities and services which they can offer to purchasers.

Haemophilia Treatment Centres

The categorisation of haemophilia treatment Centres is based on the facilities which are offered by the Centres. Haemophilia treatment and care is currently provided at three levels in haemophilia treatment Centres:

1. Associate Haemophilia Treatment Units
2. Haemophilia Centres
3. Haemophilia Comprehensive Care Centres

The definition of the services provided by these Centres are described in greater detail below.

The United Kingdom Haemophilia Centre Directors Regional Committee will review the facilities provided by all categories of Centre and periodically may revise their designation in order to fulfil the aims and objectives of the Organisation as laid down in its Constitution.

1. Associate Haemophilia Treatment Units

An Associate Haemophilia Treatment Unit is defined as a diagnostic and treatment facility providing primary responsibility for the care and treatment for less than ten severely affected haemophilic patients per year.

2. Haemophilia Centres

A Haemophilia Centre is defined as a diagnostic and treatment facility existing either autonomously or as a component of a larger department which provides primary responsibility for the care and treatment for at least ten severely affected (less than 0.02 units per decilitre clotting factor present in the blood) haemophilia patients per year.

The function of the Haemophilia Centres and Associated Haemophilia Treatment Units acting in conjunction with the most convenient Haemophilia Comprehensive Care Centre is to

provide full diagnostic, therapeutic and advisory services to patients. These functions include:

A. A Laboratory Service

i. Capable of carrying out all tests necessary (where appropriate in conjunction with Haemophilia Comprehensive Care Centres) for the definitive diagnosis of haemophilia and all inherited haemorrhagic disorders, including the identification and assay of specific haemostatic factors, platelet function abnormalities and inhibitors of haemostasis. Further, capable of monitoring the levels of haemostatic factors and inhibitors during therapy. (Although laboratories other than Haemophilia Centres or Associate Haemophilia Treatment Units may wish to investigate inherited haemostatic disorders unrelated to haemophilia, it is implicit, particularly in the condition of recognition of a Haemophilia Comprehensive Care Centre that diagnostic facilities are available for all inherited disorders of haemostasis.)

ii. where appropriate and indicated, to conduct in collaboration with other Haemophilia Centres, the further laboratory investigation of relatives or patients with haemophilia or other haemostatic disorders.

iii. to maintain satisfactory quality control and assurance for all laboratory tests offered in relation to clinical services, both by establishing appropriate internal procedures and by participation in the UK National External Quality Assessment Scheme in Blood Coagulation (NEQAS), or other relevant approved external quality assessment schemes.

B. A clinical service provided by experienced staff for the treatment of patients with haemostatic disorders and their families at short notice at any time of the day or night. Facilities must exist for the immediate treatment of patients and counselling in privacy of patients and their relatives.

C. An Advisory Service to patients and close relatives (and in the case of children, to their parents) on matters of concern to them, such as preventative medicine and dentistry, education, employment, genetic, HIV and other relevant counselling services. Advice should also be given to general practitioners about the emergency treatment of haemophilic patients and patients with other haemostatic disorders on their list and the procedure for securing the admission of these patients to hospital when required, including what the patient should do to obtain ambulance transport in an emergency.

D. Maintenance of Medical Records

Records must be maintained of all treatment administered. Special medical cards are to be issued and a register kept of all patients attending the Centre. Annual information is to be sent to the Secretariat of the United Kingdom Haemophilia Centre Directors' Organisation for analysis and provision of statistics.

3. Haemophilia Comprehensive Care Centres

The Haemophilia Comprehensive Care Centre is defined as one fulfilling all services in the preceding paragraphs. Additionally it is required to treat 40 or more severely

affected patients per year and it requires to be capable of providing the following facilities:

- i. The provision of a 24-hour advisory service to Haemophilia Centres and Associate Haemophilia Treatment Units and to support them, particularly during holiday periods.
- ii. The provision of a specialist consultant service for all surgery including orthopaedic and dental, for infectious diseases, for paediatric and social care and for genetic, HIV and other counselling services.
- iii. The provision and organisation , as required, of home therapy and prophylactic treatment programmes for patients with haemophilia and other haemostatic disorders.
- iv. The provision of a reference laboratory service for Haemophilia Centres and Associate Haemophilia Treatment Units. The services should include the diagnosis of atypical cases, genotypic analysis, the assay of inhibitors and other haemostatic factors, the diagnosis of hereditary platelet disorders, the supply of assay standards and reagents and when requested, advice and recommendations concerning analytical procedures and laboratory health and safety.
- v. The provision of educational facilities for medical staff, nurses, MLSOs, counsellors and other personnel as required in order to promote optimal comprehensive care of patients and an extensive laboratory diagnostic service for disorders of haemostasis.

vi. To coordinate meetings and undertake research programmes, including the conduct of clinical trials and to establish and participate in suitable regional and national programmes of Clinical Audit.

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