

DEVELOPMENT OF THE GUIDELINE

1 Introduction

1.1 Guideline aim

Multiple sclerosis (MS) is a condition of the central nervous system (brain and spinal cord) that usually starts in early adult life. Once present the disease never goes; there is no cure and the person lives with the condition for life but a significant proportion of people have few or no problems. The impact of MS on the individual is variable but one constant feature is uncertainty. The condition also has an impact on family members

Many people with MS may need to make extensive use of health services and social services. Consequently, the aim of this guideline is to ensure that people with MS benefit from a coherent and consistent response from services, to minimise their problems as far as can be achieved.

1.2 Who is the guideline intended for?

A guideline has been defined as ‘a systematically developed statement that assists clinicians and patients in making decisions about appropriate treatment for a specific condition.’¹

These guidelines are aimed at helping health care professionals provide optimal services for those with MS by:

- providing individual clinicians with a set of explicit statements on the best way to manage most common clinical problems to maximise the effectiveness of the service
- providing commissioning organisations and provider services with specific guidance on the best way to organise complex services, to maximise efficiency and equity.

Others, including the general public, may find the guideline of use in understanding the clinical approach to MS. Separate short-form documents for a) the public and b) clinical staff are available which summarise the recommendations without full details of the supporting evidence.

1.3 Clinical context

MS is diagnosed in 3.5 to 6.6 people per 100,000 of the population each year, equivalent to about 1,820 to 3,380 new people being diagnosed each year in England and Wales (population 52 million). Life expectancy in the majority is more or less normal. The prevalence (frequency in the population) is between 100 to 120 per 100,000, equivalent to two people for each general practitioner or 52,000 to 62,400 people in total in England and Wales.²⁻⁴ In comparison, the incidence of stroke is 240 per 100,000 each year, equivalent to about 124,800 new cases each year in England and Wales. The prevalence is about 700 per 100,000, equivalent to about 14 per GP or 364,000 people in England and Wales in total.

Multiple sclerosis is usually diagnosed between the ages of 20 and 50 years. Once diagnosed, people often recognise that they have had the condition for many years. It affects two women for each man affected. The cause is unknown, but it is thought to have several different ‘causes’ because the evidence suggests that there are both genetic (inherited) and environmental factors at play.

The disease process involves episodes where white matter within the brain or spinal cord becomes inflamed and then damaged by the person's own immune system. These inflamed areas become scarred, giving the disease its name: *multiple* areas of hardening (*sclerosis*) within the brain and spinal cord. Many episodes do not cause any symptoms, but when sudden symptoms occur the person is said to have had a relapse. In some people there is simply a slow progressive increase in symptoms.

Although there is no cure, there are positive roles for the health service. These include making the correct diagnosis, trying to reduce the disease progression, and trying to help the person (if necessary) experience as few symptoms and functional problems as possible.

1.4 The challenge

The challenge facing both organisations and individual clinicians is major. MS is an extremely variable condition. The specific symptoms or signs experienced by an individual can vary. Each person will have a unique combination of symptoms, signs, personal circumstances and wishes. Furthermore, the prognosis for an individual patient is unpredictable. Through their disease pathway people with MS may present to any one of a wide range of health care professionals in any one of a wide range of specialist services. They also present to a wide range of non-health care professionals with their problems, and these professionals may know little or nothing about the condition and yet need to make decisions. Moreover, the evidence needed by a professional to make an informed decision is often difficult to find. Consequently many people with MS are seen by individuals who have relatively little expertise or knowledge, and who cannot find relevant advice easily, and who often are working in isolation away from co-ordinated services, and the service is suboptimal both for the patient in terms of effectiveness and for society in terms of efficiency and equity.

Several studies have highlighted the poor provision of services to people with MS in the UK. Freeman and Thompson surveyed an opportunity sample of 150 patients in contact with the NHS, and found many people with significant disability failed to receive services.⁵ An audit of services in Oxfordshire showed the extent of the disorganisation, and the problems faced by individual patients.⁶

Large resources are needed to help people with MS. A recent survey of people with MS at three specialist centres in England estimates a mean total cost per patient of £17,000 per year, suggesting a total burden to society of around £1.34 billion per year.⁷ Informal care accounts for 26% of this total, and direct medical cost only 16%. A cost of approximately £3,400 per patient per year falls on the NHS, and the remainder is borne by patients and their families and carers. As well as this financial cost, the quality of life of people with MS is affected by the physical limitations imposed by the disease, and also by the social limitations that follow from this and the emotional problems that may also arise.

1.5 Underlying guideline principles

The main principles behind the development of these guidelines were that they should:

- consider all issues that are important in the health care of people with MS
- use published evidence wherever this is available
- be useful to and usable by all professionals

- take full account of the perspective of the person with MS and their family
- indicate areas of uncertainty or controversy needing further research.

The problems presented by people with MS are complex, covering many aspects of illness and lifestyle. As any set of hospital notes will illustrate dramatically, it is difficult to describe their problems in a simple way. This complexity also makes it difficult to construct a set of guidelines.

The solutions to address this complexity in terms of the guidelines are:

- to use a systematic model of illness, the World Health Organization (WHO) International Classification of Functioning (ICF) model
- to consider the different aspects of the management processes separately
- to recognise that
 - people with MS have different needs
 - many people with MS will have very complex needs at different stages of their disease
 - many people may have few or no needs.

The model of illness used is the WHO's International Classification of Functioning, Disability and Health (ICF) framework (see Appendix A).⁸ This allows the description of a person with MS's situation at four levels – disease, symptoms and signs, behaviour, and social situation. It also recognises three different environmental or contextual factors – the social environment, the physical environment, and the person's own internal environment (ie their beliefs, wishes and expectations). It has a specific terminology that has been preferred throughout this document, but the older terminology is also used in places for two reasons: it is sometimes simpler, and it may be more familiar to some readers. More details are given in Appendix A.

1.6 How to use this document

The document is large, covers many topics and gives much background information. The reader is strongly recommended to use the contents page to find his or her way to the relevant part and a glossary is provided at the back of the book to clarify terminology. **The recommendations made in Section 3 apply to all other recommendations, and should be read first.**

Once the relevant part has been found, the reader will probably first look at the recommendations. Generally these follow a logical order from problem identification through simple interventions suitable in most cases, on to complex interventions that will only be used rarely. If the reader wants, he or she can then read the evidence statements above and look at the tables to understand more about why the recommendation was made.

1.7 The structure of the document

The document is divided into sections, each of which covers a set of related topics. For each topic the layout is similar.

The **background** to the topic is described in one or two paragraphs which simply set the recommendations in context.

Then the **evidence statements** are given and these summarise the evidence given in the **evidence tables**, which are Appendix I. In addition, there may be an evidence statement about the health

economic evidence where this is available. In many parts there is a brief statement explaining how recommendations relate to the evidence.

The main **recommendations** follow. These are graded to indicate the strength of the evidence behind the recommendation.

The main recommendations are followed by **local implementation points**: these are specific areas where local clinicians need to develop local policies or guidelines to facilitate the implementation of national guidelines at the local level. They often require collaborative working between NHS services and other local statutory and voluntary sector agencies.

1.8 Guideline limitations

The document and recommendations are subject to various limitations.

The commissioning authority, NICE, is primarily concerned with health services, and so these recommendations only indirectly refer to social services, housing and so on. Nonetheless, the importance of other agencies cannot be overstated and in each locality they should become actively involved.

Not all evidence used comes from MS-specific studies. A systematic approach was used to locate and appraise the evidence. Due to the magnitude of the literature potentially relevant to MS specific inclusion or exclusion criteria were applied. The inclusion/exclusion criteria aimed to limit the included studies to those of a higher quality conducted primarily in people with MS. Where these were not available, well-conducted studies outside MS, or lower-level studies in people with MS, were included.

A general principle behind the search strategy was the use of studies relevant to the clinical situation. Where the situation was specific to MS, for example diagnosis, then the study population was limited to those with MS. However, where the situation was an impairment arising from neurological damage then the search is usually focused upon that impairment when it arose from other neurological diseases causing similar damage. Variation between people with MS is far greater than the variation between people with the same impairment arising from different neurological conditions. Therefore this was not deemed to be extrapolation and the evidence was graded directly.

In areas which primarily relate to organisational matters or general principles such as communication, full systematic searching was not undertaken because priority was given elsewhere. In these areas, existing reviews and other information readily available was considered.

The evidence base was current as of October 2002. Since then additional research findings have become available. However, it is unlikely that these would have a significant impact upon the recommendations.

Using a systematic approach coupled with the grading of evidence used means that some relevant evidence may be omitted. It also means that some recommendations appear without evidence because the recommendation seems self-evident and good practice; no one will consider researching into the area (and ethical considerations might also preclude it). We recognise that much current practice without evidence may in fact be ineffective, but we also recognise that much current practice without evidence may be highly effective and may never

acquire evidence. Consequently, we must emphasise that the lack of evidence cannot be used alone to justify a reduction or withdrawal of resources.

Finally it must be emphasised that these guidelines refer to recommended best clinical practice. It is not the purpose of these guidelines to specify what resources are needed or how appropriate resources are devoted to any particular recommendation.

1.9 Plans for guideline revision

The process of reviewing the evidence is expected to begin four years after the date of issue of this guideline. Reviewing may begin earlier than four years if significant evidence that affects the guideline recommendations is identified.