

Comprehensive Care in Multiple Sclerosis – A Patient-centred Approach

a report by
June Halper

Executive Director, Consortium of Multiple Sclerosis Centers (CMSC)

DOI:10.17925/ENR.2008.03.02.72

Multiple sclerosis (MS) is a complex neurological disease with a far-reaching impact on patients and families throughout a lifetime with the disease. Its hallmark is uncertainty; it has physical, emotional, financial and psychosocial implications throughout its course. Care in MS has evolved from a wait-and-see attitude during the mid-1900s to a more proactive stance with the advent of effective disease-modifying and symptomatic therapies. Therefore, interactions with the healthcare community have become more intense and increasingly frequent for patients and their providers. Today, patients are impelled to make emotionally charged decisions regarding their healthcare virtually from the time of their diagnosis and with each change in their condition.

The inflammatory pathology of MS includes damage to the myelin and axon in the white matter of the brain and spinal cord.¹ Recently, there have been reports of grey matter involvement resulting from different pathological mechanisms that have been shown to contribute to long-term disability in MS.² There are implications of MS that involve not only the symptoms but also the adjustment of living with a chronic illness that may bring disability, lifestyle changes and significant alterations in quality of life. With the advent of disease-modifying therapy, patients with relapsing forms of MS must follow treatment regimens, monitor their condition, adapt to changes and regularly make decisions about whether they need to seek care or are able to handle their problem on their own. Functioning as a self-care manager requires a high level of knowledge, skill and confidence.

The History of Disease Modification in Multiple Sclerosis

In the 20th century, treatment focused on symptomatic care, as well as relapse management. The use of corticosteroids was the hallmark of relapse management, although there was no evidence that this therapy brought any long-term permanent benefit. During the 1980s, researchers began studying interferons as a possible treatment for

people with MS because it was believed that intercurrent viral infections may trigger MS attacks and beta-interferons might have an immunomodulating effect on this process.³ During the same period there were investigations into the use of a synthetic polypeptide, co-polymer I, to modify MS relapses. As a result of four pivotal trials that demonstrated effective outcomes in relapsing forms of MS, Betaseron was approved for use in the US in 1993; Avonex and Copaxone entered the marketplace for relapsing–remitting MS in 1996; and Rebif, although approved in many countries throughout the world, finally entered the US market in 2002.

In 2008 Extavia (interferon beta 1β) was approved for use in Europe, and it may enter the North American market in 2009. A chemotherapeutic agent, mitoxantrone, became available for worsening relapsing forms of MS in 2000. This treatment, as opposed to the earlier therapies, is administered by infusion, whereas the others are via self-injection. As opposed to a philosophy of care during the early part of the 20th century, a new model of care included a great deal of self-management by the patient and family. Adverse-effect strategies, injection technique, follow-up laboratory work and self-monitoring were added to the responsibilities of the person diagnosed with MS. Issues related to adherence and factors related to quality of life gained increasing importance in MS care. During the early part of the 21st century, natalizumab was also approved for relapsing forms of MS. Administered by infusion, natalizumab has a different safety profile from the injectable agents, and some people view the convenience of infusions versus self-injection as a viable option. Thus, MS patients currently have seven approved treatment options that can support hope for the future and control of their disease.

It is obvious that healthcare professionals worldwide are now presented with challenges that include extensive patient and family education about these therapies, assisting patients to start treatment, sustaining compliance/adherence to treatments and evaluating outcomes through clinical assessments and other methods to appraise treatment response. In addition, these patient and family education efforts include provision of accurate information and education, presenting reasonable expectations and outcomes of therapy, sustaining the patient's belief in his or her treatment, promoting adherence and preventing premature discontinuation of an effective treatment for more 'convenient' types of administration. It is this author's opinion that these challenges will continue with current choices and will be increased with the introduction (in the future) of an approved oral medication for MS.

Models of Care in Multiple Sclerosis – The Comprehensive Care Approach

MS care has changed a great deal in the late 20th and early 21st century. The most recent model, the comprehensive care approach to

June Halper is Executive Director of the Consortium of Multiple Sclerosis Centers (CMSC), a position she has held since 1992, and served as the Consortium's President from 1995 to 1997. A certified adult nurse practitioner who has specialised in multiple sclerosis (MS) since 1978, she was a founder of the MS Center in Teaneck, New Jersey, and served as its Executive Director until 2008. Ms Halper has published and lectured extensively on MS and its ramifications. She chaired the first Multiple Sclerosis Nurse Specialist Consensus Committee's development of a monograph on the nurse's role in adherence to complex protocols, the impact of cognitive impairment in MS nursing care and the nurse's role in the patient's and family's quality of life. She is a member of the American Academy of Nurse Practitioners (AANP), a Founding Director of the International Organization of MS Nurses (IOMSN) and the recipient of the IOMSN's first June Halper Award for Excellence in Nursing in Multiple Sclerosis. She was inducted as a Fellow into the American Academy of Nursing in November 1999. In 2000, Ms Halper spearheaded the establishment of the Multiple Sclerosis International Credentialing Board, which developed the first international certification examination in MS nursing, first offered in June 2002 and bi-annually thereafter. As Executive Director of the CMSC, in 2004 she initiated the first certification examination for multidisciplinary MS specialists.

this lifelong and complex illness, has become more widely adopted during the past three decades. This is an organised system to address the complex and dynamic challenges of medical, social, vocational, emotional and educational needs of patients and their families and is provided by a team of professionals either in one facility or within a comprehensive care system. This approach ensures that the direction and goals of treatment are consistent, logical and progressive.⁴ The team approach facilitates co-ordination of services and continuity of care and avoids duplication and fragmentation of programmes. The MS team usually consists of neurologists, nurses, rehabilitation specialists, counsellors, advocates and educators. Most recently, with the advent of injectable and infusible therapies, specialists in self-injection or infusions have become leading members of the healthcare team.

An active rather than a passive role fits the current treatment patterns in MS because patients must learn to adapt to changing circumstances and assume responsibilities for skills needed for new and emerging pharmaceutical MS management. Comprehensive care embraces a philosophy of empowerment in which the patient takes an active role in planning healthcare and self-care activities and acts as a part of the team. Those with progressive courses need a comprehensive team approach to meet their needs. They will benefit from counselling, education, symptomatic care and prevention of complications of their disease.

Services Required for Successful Management

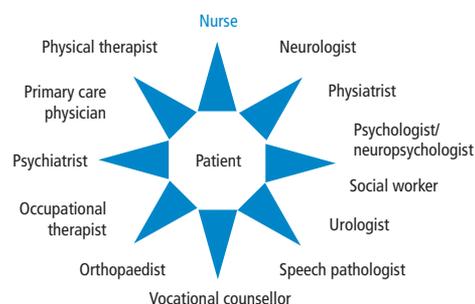
The basis of successful management of MS lies within the foundation of a productive relationship with the patient's healthcare team. Communication with the neurologist is crucial to establishing trust and belief on the part of the patient and family. It is essential that there is an understanding of MS itself and the rationale for all prescribed treatments. Nursing support during the initiation and continuation of disease-modifying therapies has also emerged as an important factor to sustain

The most recent model, the comprehensive care approach to this lifelong and complex illness, has become more widely adopted during the past three decades.

adherence. Primarily, it is the patient who requires education and training, yet, frequently, care partners such as family members must be included in this process. Most people have access to training kits prior to starting therapy, although it is obvious that personalised sessions, either one-to-one or group programmes, best accomplish the goal of successful patient and family education.⁵

Because MS is a chronic, unpredictable disease, sustaining adherence is a challenge that should be addressed throughout the patient's experiences with injections. Adherence has been defined as active, voluntary and collaborative in an acceptable course of behaviour.⁶ Nurses and other healthcare professionals must assess for barriers that may contribute to non-adherence. These include physical, psychological and financial issues that might impede successful adherence to these complex protocols. For instance, some patients

Figure 1: Transdisciplinary Team Approach



require several sessions to learn new administration techniques, whereas others need only frequent telephone calls or additional visits to facilitate their newly developed skills.

Patient Concerns

Because the underlying disease process is not easily observed or monitored, it is very important to educate the patient about realistic outcomes from disease-modifying therapy. It is equally important to emphasise that persistent symptoms unrelated to the disease course (ongoing pain, spasticity or fatigue) may not be altered by injectable or infusible therapy. These symptoms require separate, individualised management. It is hard, however, for the patient to differentiate between relapses and MS-related difficulties that may interfere with function and affect his or her quality of life. Frequently asked questions are: How do you know my therapy is working? Why am I still fatigued? Why am I not able to complete a full day at work? I have not had a relapse but why am I not feeling better? The healthcare professional must be prepared to explain the difference between disease activity (relapses and progression) versus symptoms that occur as a result of underlying damage that most likely occurred prior to the initiation of therapy. It is important that the patient be treated for symptoms, referred to appropriate rehabilitation services and/or counselling and educated and re-educated (when necessary) in self-injection, site rotation, skin care and adverse-effects management. Although healthcare professionals assume that patients understand the difference between the disease state and its consequences, they really must try to address these concerns seriously with a wide variety of educational strategies and tools. The primary objective should be to encourage patients to stay on their prescribed therapy, provided that it continues to deliver benefit.

Switching Therapies

The MS nurse will proactively and rigorously screen adherence to injections and injection technique. It has been reported that some patients have been successfully treated with injectables for as long as 17 years. However, there are situations when switching therapies is called for. A number of studies have identified parameters for suboptimal response using MS disease-modifying therapies. One study by Carra et al. defined inadequate effectiveness as greater than two relapses per year, disability progression of one Expanded Disability Status Scale point from baseline lasting more than six months and continued disease activity on magnetic resonance imaging (MRI).⁷

A consensus publication by the MS Trust has listed frequency and severity of relapses, the lack of relapse reduction compared with the previous two years and new and enhancing lesions on MRI as a

rationale for discontinuing treatment. This publication also cites the development of non-relapsing secondary progressive symptoms, including losing the ability to ambulate as a rationale for discontinuation of treatment.⁸ Freedman et al. list relapse frequency and severity, recovery from relapses and MRI activity as outcomes measures with a rationale for switching and/or discontinuation of therapy.⁹ O'Rourke and Hutchinson determined that patients who stopped interferon therapy mainly stopped treatment due to adverse effects.¹⁰ Weinstock-Guttman et al. focused on the challenges of

The basis of successful management of multiple sclerosis lies within the foundation of a productive relationship with the patient's healthcare team.

switching therapies in MS and pointed out that there are numerous challenges in this process. Included are clinical appraisals supported by neuroimaging that would determine breakthrough disease versus actual disease progression.¹¹

In any event, switching or discontinuing therapies should be based on professional expertise/assessment, along with evidence documenting the need to change or discontinue therapies. There should be serious discussions between patients and healthcare professionals before the change is made.

Practical Issues with the Use of Disease-modifying Therapies

Clinicians need to be alert for cues that patients are experiencing difficulty with their MS and their related quality of life. Careful assessment can identify 'red flags' when problems are occurring. For example, is the patient having problems at home or at work, missing injections or becoming tired of his or her therapy? A recent study examined the factors that influence problems at work. Women had more lost days than men, particularly those on interferon therapy.¹² These data probably reflect the fact that more women than men have MS and are under treatment. Once problems are discussed and recognised, clinicians can counsel patients and ensure that they have access to ancillary services within the community to help overcome these problems. In addition, nursing support

to counsel and re-educate the patient and family may be helpful during this time of concern, as well as questioning the rationale for therapy and the burdens that therapy presents to patients' quality of life. Nurses and other healthcare professionals can:

- empower patients by educating them about their disease;
- routinely assess quality-of-life issues;
- be alert for red flags such as needle fatigue, financial strain and employment problems;
- encourage patients to communicate openly;
- be aware of changes in physical and emotional status;
- routinely screen for adherence to treatments; and
- refer patients to support services and community programmes when indicated.¹³

Future Horizons

The future for MS care and therapies is quite hopeful. As of the time of this writing, numerous oral and infusible and several injectable medications are under investigation. Oral studies in phase III investigation are cladribine, fingolimod, BG 00012, teriflunomide and laquinimod; those given by infusion are alemtuzumab, MBP8298 and rituximab. There are also several genetic studies under way and investigations into the role of stem cell therapies, biological markers that may predict response to therapies and plasmapheresis. As new treatments may enter the market, the role of the nurse will likely expand from a focus on injection training and adherence to managing pre-screening of patients, initiation of therapy, frequent health checks and aspects of safety monitoring to stay on therapy. Benefits for patients will include more frequent checks and closer contact with healthcare professionals, less anxiety as potential problems will be identified early and reassurance that their disease is being actively supervised.

MS has become very important both in the improvement of care models and in basic research and clinical trials. This positive outlook in the healthcare arena must be imparted to patients and their families by the healthcare community. During the past two decades there have been many breakthroughs that have not identified the cause or cure for MS but are providing important clues for the future. In the meantime, it is imperative that we keep hope alive in our patients and their families. As stated by the late Linda Morgante: "Hope is experiencing a sense of unlimited possibility and potential."¹⁴ Morgante continues by stating that "nurses share an intimate space with patients and their families... Nurses who care for people with MS can transform an uncertain experience into one of comfort and hope."¹⁴ ■

1. Vollmer T, Multiple sclerosis: the disease and its diagnosis, In vanden Noort and Holland, *Multiple Sclerosis in Clinical Practice*, New York: Demos, 1999.
2. Fisniku LK, Chard DT, Jackson JS, et al., Gray matter atrophy is related to long-term disability in multiple sclerosis, *Ann Neurol*, 2008;64:247–54.
3. Ross AP, The evolution of disease management. In Halper J, *Advanced Concepts in Multiple Sclerosis Nursing*, 2nd Edition, New York: Demos Medical Publishing, 2007:53–68.
4. Cobble ND, Burks JS, The team approach to the management of multiple sclerosis. In Maloney F, Burks JS, Ringel SR (eds), *Interdisciplinary Rehabilitation of Multiple Sclerosis and Neuromuscular Disorders*, Philadelphia: JB Lippincott Co, 1985:11–31.
5. Ross AP, The evolution of disease management, In Halper J (ed.), *Advanced Concepts of Multiple Sclerosis Nursing*, New York: Demos Medical Publishing, 2007:62–3.
6. Multiple Sclerosis Nurse Specialist Consensus Committee, *Multiple sclerosis: key issues in nursing management, Adherence, Cognitive Function, Quality of Life*, New York: Bioscience, 2004.
7. Carra A, Onaha P, Luetig G, et al., Therapeutic outcome 3 years after switching of immunomodulatory therapies in patients with relapsing-remitting MS in Argentina, *Eur J Neurol*, 2008;15:386–93.
8. MS Trust, *Disease Modifying Therapy. What you need to know*, Letchworth Garden City, UK.
9. Freedman MS, Patry DG, Grand'Maison F, et al., Treatment optimization in multiple sclerosis, *Can J Neurol Sci*, 2004;31:157–68.
10. O'Rourke KET, Hutchinson M, Stopping beta-interferon therapy in multiple sclerosis: an analysis of stopping patterns, *Mult Scler*, 2005;11:46–50.
11. Weinstock-Guttman B, Ramanathan M, Switching therapy in multiple sclerosis: challenge and potential, *Medscape Neurology and Neurosurgery*, 2007.
12. Lage MJ, Castelli-Haley J, Oleen-Burkey MA, Effect of immunomodulatory therapy and other factors on employment loss time in multiple sclerosis, *Work*, 2006;27:143–51.
13. Bishop B, Easterling CB, Greinel E, et al., *Counseling Points: Quality of Life Issues in MS*, Ridgewood, NJ: Delaware Media Group, 2007;2:4.
14. Morgante L, Integrating the concept of hope into clinical practice, In Halper J, Holland N, Editors, *Comprehensive Nursing Care in Multiple Sclerosis*, 2nd Edition, New York: Demos, 2002.