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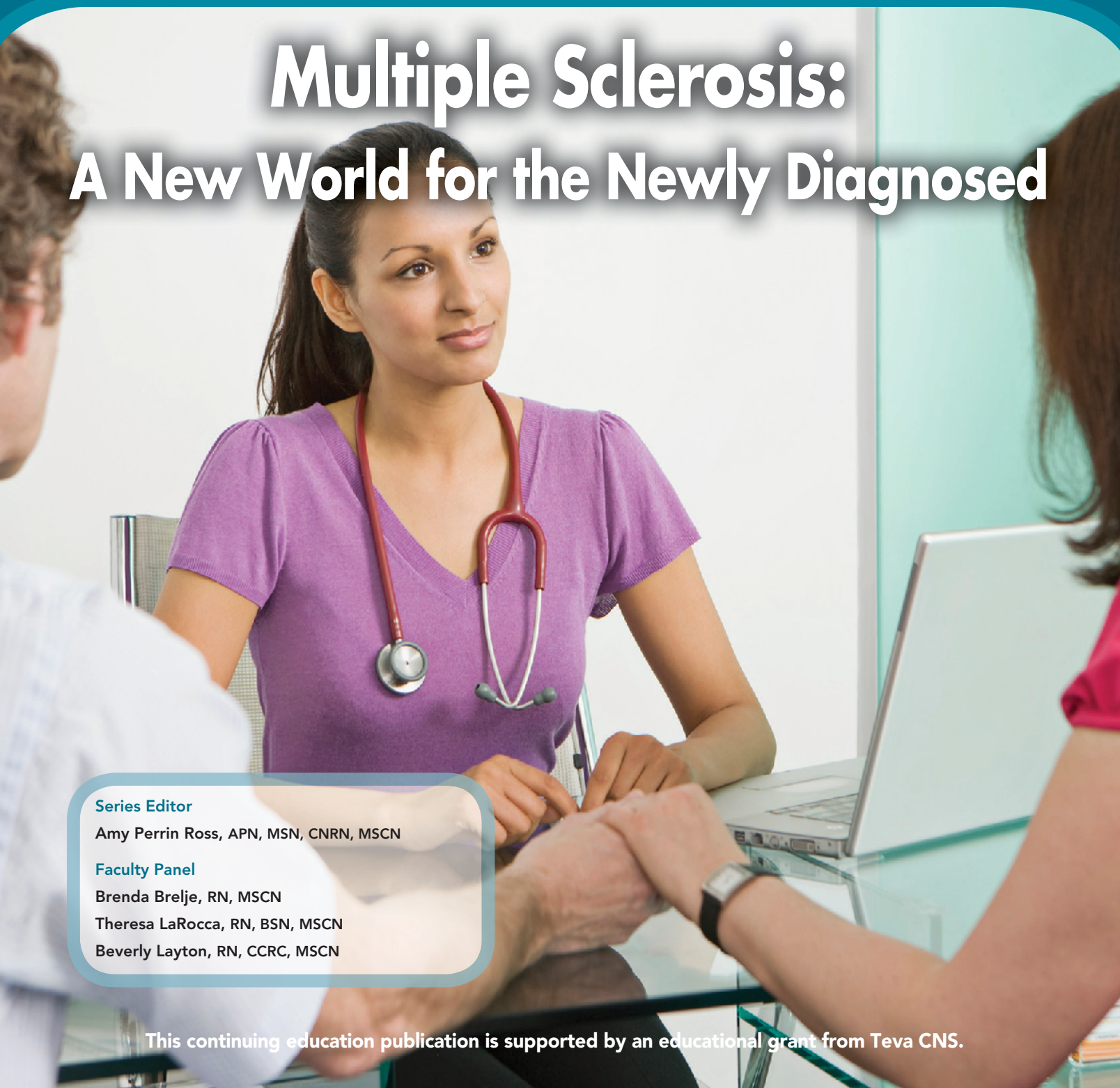

Multiple Sclerosis:
A New World for the Newly Diagnosed

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Counseling Points™

Multiple Sclerosis: A New World for the Newly Diagnosed

Continuing Education Information

Target Audience

This educational activity is designed to meet the needs of nurses who treat or who have an interest in patients with multiple sclerosis (MS).

Purpose

To provide nurses with up-to-date information and strategies for counseling patients who have been newly diagnosed with MS.

Learning Objectives

Upon completion of this educational activity, the participant should be able to:

- Analyze changes in the diagnosis and assessment of newly diagnosed patients with MS and clinically isolated syndrome
- Describe projected paradigm shifts in outcomes and prognosis for patients who receive early treatment for MS
- Develop strategies for educating patients about whether early treatment is right for them
- Review recommended protocols for starting patients on MS therapy

Continuing Education Credit

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welcome

Dear Colleague,

Is it really a "new world" for a person newly diagnosed with multiple sclerosis (MS)? From the perspective of the faculty panelists for this issue of Counseling Points™, the answer is yes. MS nurses who began practicing before disease-modifying therapies (DMTs) were widely used in MS can remember very different initial discussions with their newly diagnosed patients, and very different outcomes after these patients had lived with the disease for 10 or 15 years. As many veteran MS nurses describe it, there were a lot more wheelchairs in the waiting room back then, and there is much more hope to offer patients today.

In today's "new world" of MS, patients typically receive a diagnosis much earlier in the disease course than in the past. This can present counseling challenges, but overall provides a more optimal window of time in which to begin early treatment. We know through established research that patients who are started on DMTs earlier have fewer relapses, less disease progression, and better long-term outcomes than those who delay the start of treatment.

The nurse's role at the time of an MS diagnosis is especially critical. Nurses often have the primary responsibility of helping patients to accept and understand the diagnosis, educating patients and families about the disease, and helping to select and acclimate patients to their initial treatment course. With the availability of several new DMTs, the latter task is becoming more complex. MS nurses can learn from one another as we venture into this new world, which we hope will be a brighter one for our patients newly diagnosed with MS.

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Multiple Sclerosis: A New World for the Newly Diagnosed

In the "old days" of multiple sclerosis (MS), people typically waited many years and often had to seek opinions from several medical specialists before receiving a definitive diagnosis of MS. Today, clearer diagnostic criteria and access to advanced imaging techniques make the diagnostic process more straightforward for most patients. Back then, treatment focused mainly on symptom management, and some doctors took a "wait and see" approach after delivering the diagnosis (an approach ominously termed "diagnose and adios"). Today, patients are urged to start on disease-modifying therapy (DMT) soon after—or even before—receiving a diagnosis of clinically definite MS (CDMS), with the goal of preventing unseen, irreversible neurologic deterioration. For many years, the available DMTs had limited options for administration: either subcutaneous or intramuscular injections. Today, three oral agents are on the market, an infusible DMT is available for some patients, and the longstanding injectable agents remain a viable choice for many.

By some accounts, we have finally arrived in the "new world" of MS treatment. But with it comes a period of adjustment for MS practitioners that involves learning new languages and exploring uncharted territories. Today's MS management requires a more sophisticated understanding of immunologic disease processes and the ability to conduct a risk-benefit analysis for a wide range of therapies with very different mechanisms. Because patients are essential partners in the successful management of MS, it is necessary to educate them in these complex areas as well.

What Is the New World of MS Diagnosis?

The diagnostic process in MS has come a long way in the past decade. A survey of 50 patients conducted in 2003 revealed that patients were referred to at least two other specialists before seeing a neurologist and learned of their diagnosis an average of 3.5 years after the onset of symptoms.[1] Over half (58%) were initially given wrong diagnoses. Women were more likely than men to receive a misdiagnosis of a mental disorder, while men were more likely to be referred for orthopedic workups.[1]

In the past, MS was called a "great imitator," and the disease may still be mistaken for a variety of other conditions, particularly when the initial presenting symptoms are nonspecific.[1-3] Wider availability of magnetic resonance imaging (MRI) technology has greatly advanced the process of diagnosis.[4] The current diagnostic criteria for MS allow for a diagnosis to be made after a single clinical episode in some cases, whereas previous diagnostic criteria required two clinical episodes **(Table 1)**.[5] This helps to reduce the duration of the difficult "limbo" period for many patients.

Natural History of MS

Outdated perceptions about MS—such as the notion that most people with the disease end up using a wheelchair—are being replaced with the new reality of MS. At the time when no effective treatments were available for MS, about 50% of people with relapsing-remitting MS (RRMS) entered a progressive phase of disease within 10 years after diagnosis, according to a large-scale natural history study based in Ontario, Canada.[6,7] Another classic natural history from Lyons, France showed that people with RRMS progressed to "relatively severe disability"—represented by an Expanded Disability Status Scale (EDSS) score of 4—in an average of 11.4 years after diagnosis.[8]

The London Ontario Natural History Study enrolled a large cohort of patients with MS (1,023 total; 806 with RRMS) in the 1970s and 1980s,

Table 1. Revised McDonald Criteria for Clinically Definite MS (CDMS)[5]

Clinical Presentation	Additional Data Needed for Diagnosis
≥2 attacks (relapses) ≥2 objective clinical lesions Reasonable historical evidence of a prior attack	None; clinical evidence will suffice (Additional evidence is desirable, but must be consistent with MS)
≥2 attacks Objective clinical evidence of 1 lesion	Dissemination in space, demonstrated by: • ≥1 T2 lesions in at least 2 of 4 MS-typical regions of CNS *or* • Await a second clinical attack
1 attack Objective clinical evidence of ≥2 lesions	Dissemination in time, demonstrated by: • Simultaneous presence of asymptomatic Gd+ and nonenhancing lesions *or* • New T2 and/or Gd+ lesion(s) vs. baseline *or* • Second clinical attack
1 attack Objective clinical evidence of 1 lesion (CIS)	Dissemination in space, demonstrated by: • ≥1 T2 lesion in at least 2 of 4 MS-typical regions of CNS *or* • Await a second clinical attack at different CNS site Dissemination in time, demonstrated by • Simultaneous presence of asymptomatic Gd+ and nonenhancing lesions *or* • New T2 and/or Gd+ lesion(s) vs. baseline *or* • Second clinical attack
Insidious neurological progression suggestive of MS (primary progressive MS)	1 year of disease progression (retrospectively or prospectively determined) plus 2 of 3 of the following: 1. Evidence for dissemination in space in brain: ≥1 T2 lesion(s) in MS-characteristic regions 2. Evidence for dissemination in space in spinal cord: >2 T2 lesions in cord 3. positive CSF

CIS=clinically isolated syndrome; CSF=cerebrospinal fluid; CNS=central nervous system; Gd+=gadolinium-enhancing; MRI=magnetic resonance imaging; MS=multiple sclerosis; VEP=visually evoked potential.
Adapted with permission from: Polman CR, et al. *Ann Neurol.* 2011;69:292-302.[5]

before DMTs became available, and followed them annually.[6,7] Analysis of these data offer a rare glimpse into the natural history of the disease. Of interest were findings about how the number of relapses that occurred early in the course of disease influenced long-term disability in MS.[6] As shown in **Figure 1**, patients who had one relapse in the first 2 years after diagnosis had 22.7 years before they reached a score of 6 on EDSS, which represents need for a cane for ambulation. For patients who had three or more relapses during this time period, the time to this level of disability was considerably shorter, at 15.1 years.[6] Thus, it is reasonable to expect that suppressing relapses early in the disease course has the potential to delay disease progression in MS.

Data from natural history studies of MS cannot always be compared directly with new data because of differences in the populations studied. However, the evidence does show that the drugs work by limiting the number of relapses, reducing the progression of black holes on MRI, and extending the length of time for people with MS to advance to high stages of disability.

Benefits of Treatment in Early MS

The first 5 years have been shown to be a critical window of time for treating MS. While research findings have been less clear about the long-term benefits of DMTs (in part because placebo-controlled, long-term trials are not feasible), treatment during the first few years after diagnosis has been shown to offer significant benefits compared with no

Table 2. Benefits of Early Treatment in MS*

- Reductions in annualized relapse rates
- Slowed progression to disability milestones as measured by EDSS
- Slower progression to secondary progressive MS
- Reduced gadolinium-enhancing lesions on MRI
- Reduced T2 weighted lesions on MRI
- Reduced evidence of brain atrophy
- Fewer cognitive changes

*Relative to placebo
EDSS=Expanded Disability Status Scale; MRI=magnetic resonance imaging; MS=multiple sclerosis.

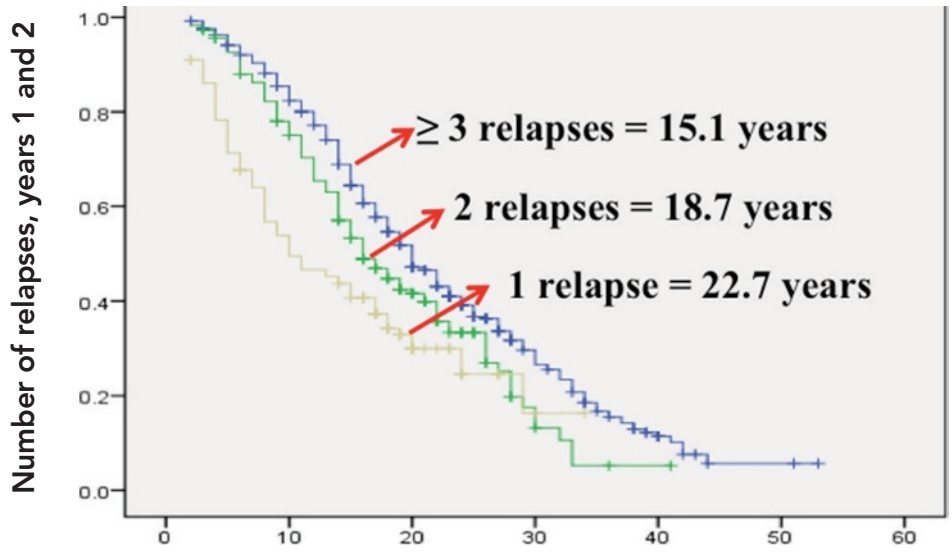

Figure 1. Early Relapses (Years 1 and 2) and Effect on Time to Cane (EDSS 6)

EDSS=Expanded Disability Status Scale. From: Scalfari A, et al. *Brain*. 2010;133:1914-1929.[6]

treatment (placebo) (**Tables 2 and 3**). People who receive DMTs early in the course of MS are significantly more likely to forestall and/or limit disability. For example, in the BENEFIT study of patients using interferon beta-1b, only 6.9% converted to a progressive course after 10 years.[9,10] Patients who were on active treatment during the first 3 years of randomization in this study had a 40% reduced risk of confirmed EDSS progression versus those who received placebo during that phase.[9]

Similar findings occurred in a long-term follow-up of the pivotal glatiramer acetate study.[11] While all patients were given the option of switching to active treatment after 3 years, a significantly greater proportion of those receiving active treatment from the start of the trial had stable or improved EDSS scores (65.3%) compared with those starting therapy later (50.4%).[11]

Natalizumab is the treatment thus far showing the highest reduction in relapse rates (54% and 68% in clinical trials versus placebo), with the oral agent fingolimod in the range of 55%.[12-14] Newer controlled trials also provide a more sophisticated comparison of radiologic changes than in the past, such as measures of brain atrophy and lesion volume between active treatments and placebo. For example, study reports for the recently approved oral agent dimethyl fumarate showed an effect of the drug in increasing whole brain volume by 21% to 30% versus placebo in the CONFIRM trial, and a 73% to 90% reduction in gadolinium-positive MRI lesions in the DEFINE trial.[15,16]

In the 20 years since DMT pivotal trials began, there has been an overall change in the profile of patients enrolled in these studies. Observers have noted that current trials are able to enroll patients much earlier in the disease course, thus studying a population with lower levels of disability and clinical symptoms.[17] This difference can be noted in baseline patient characteristics and is also reflected in relapse rates of both the active treatment and placebo groups. Earlier diagnosis and wider patient acceptance of MS therapies are likely reasons for this shift in research to enrollment of younger and less-disabled people with MS.[17] Thus, relapse-rate reductions may not be comparable across clinical trials, or, as author Klawiter questioned, "Is the new 66% just the old 33%?"[18]

Clinically Isolated Syndrome: What Are the Odds It Will Become MS?

Clinically isolated syndrome (CIS) is a designation given to patients who exhibit clinical symptoms suggestive of MS without the required radiologic findings to confirm a diagnosis. In contrast, patients who have MRI results suggestive of MS but without the clinical symptoms are said to have "radiologically isolated syndrome" (RIS).

Table 3. Summary of RRMS Pivotal Trials Results

Agent/Trial Name	Design	Relapse Reduction	Relapse-Free	Disease Progression
IFNβ-1b[19]	2 doses vs placebo	33%		
IFNβ-1a IM[20]	Placebo	18%		21.9% vs 34.9%
IFNβ-1a SC[21]	2 doses vs placebo	33%		
Glatiramer acetate[22]	Placebo	29%	27% vs 34%	21% vs 29%
Natalizumab (SENTINEL)[12]	Add-on to IFNβ-1b IM	54%		23% vs 29%
Natalizumab (AFFIRM)[13]	Placebo	68%		17% vs 29%
Fingolimod (FREEDOMS)[14]	2 doses vs. placebo	55%		18% vs 24%
Fingolimod (TRANSFORMS)[23]	vs IFNβ-1a IM	52%		6% vs 8%
Teriflunomide (TEMSO)[24]	2 doses vs placebo	31%		20% vs 27
Dimethyl fumarate (CONFIRM)[16]	Placebo Glatiramer acetate	45% 24%		13% vs 17 13% vs 16
Dimethyl fumarate (DEFINE)[15]	Placebo	41%	73% vs 54%	16% vs 27

IFNβ=interferon beta; IM=intramuscular; SC=subcutaneous.

CIS is defined as a "*first neurologic event suggestive of MS, lasting for at least 24 hours, with symptoms and signs indicating either a single lesion (monofocal) or more than one lesion (multifocal) within the central nervous system.*"[25] CIS usually occurs in young adults and affects the optic nerves, the brainstem, or the spinal cord. Most patients recover from the initial episode, but a large percentage go on to develop CDMS, often within just a few years.[26,27] In a 14-year longitudinal study by Brex and colleagues of patients presenting with CIS, 30% progressed to CDMS within 12 months, while 88% who also had an abnormal baseline MRI developed CDMS over that extended follow-up period.[28]

Early MRI findings have been shown to be more predictive than clinical symptoms of the future risk of developing CDMS. A study by Barkhof and colleagues showed that patients with more than eight T2-weighted hyperintense lesions and at least one gadolinium-enhancing lesion on MRI had a greater risk of converting to CDMS.[29] In addition, the presence of oligoclonal bands in the cerebrospinal fluid is highly prognostic for CDMS.[30]

Benefits of Treatment in CIS

Large-scale controlled trials of DMTs have shown that treatment during CIS extends the mean time for conversion to CDMS and minimizes MRI signs of MS progression. These pivotal trials resulted in approval of injectable interferons and glatiramer acetate for CIS. PreCISe was a 3-year, randomized, double-blind trial enrolling 481 patients with an initial demyelinating event, monofocal presentation, and at least two T2-weighted lesions.[31] This study compared the effects of glatiramer acetate treatment to placebo over 36 months or until conversion to CDMS. (Patients who converted to CDMS during the trial were placed on the active treatment as part of the extension study.) Results after 36 months showed that 43% of the placebo group had converted to CDMS, versus 25% of the active treatment group ($P<0.0001$). Mean time for conversion to CDMS was 722 days for glatiramer acetate compared with 366 days for placebo (115% longer). Active treatment reduced the number of new T2 lesions by 58% ($P<0.0001$).[31]

In the CHAMPS trial, 382 patients with clinical CIS and at least three suspicious brain MRI lesions were randomized to receive either placebo or intramuscular (IM) interferon beta-1a.[32] The primary endpoint was time to second clinical relapse. In an interim analysis, 35% of patients receiving interferon therapy met the criteria for CDMS versus 50% of patients receiving placebo, for a 49% risk reduction (P=0.02). The trial was stopped after the interim analysis, but an extension study (CHAMPIONS) crossed over all patients to active therapy and compared the groups after another 2 years.[33] Those who received interferon from the start had a 36% lesser risk of developing CDMS, compared with 59% for those originally receiving placebo (P=0.03), demonstrating the benefits of early treatment.

The BENEFIT trial enrolled patients with a first demyelinating event and at least two clinically silent brain MRI lesions, and measured time to CDMS over 2 years among those treated with subcutaneous (SC) interferon beta-1b (n=292) and placebo (n=176).[34] Among those receiving interferon, 28% had a second attack confirming a CDMS diagnosis during the study period, versus 45% of those in the placebo group (a 50% risk reduction, P<0.0001). When the data were analyzed using a more current definition of CDMS, an even greater percentage of placebo-treated patients were shown to have converted in 2 years (85% versus 46% of actively treated subjects, P<0.00001). BENEFIT results showed rapid conversion to CDMS among untreated patients, with 51% meeting McDonald criteria for CDMS by 6 months into the trial.[34]

What is "Benign MS"?

Are there cases when it is still okay to "wait and see?" Every MS case is different, and many experts have lamented the fact that we don't know the possible outcomes of any cases of untreated MS. And what about patients with so-called "benign MS" or BMS? Several groups of investigators have followed these patients (classified as benign based on their lack of apparent progression on the EDSS) and have found that, over time, these patients do exhibit changes consistent with progressive disease. A study by Correale and colleagues prospectively followed 342 patients with MS for over 10 years, including 43 who met BMS criteria of an EDSS score <3 after at least 10 years' disease duration.[35] By the conclusion of the follow-up period, 47% of benign patients had signs of cognitive impairment, 53.3% had depression, 48.8% had changes in pain intensity, 33% had changes in fatigue, and 74% showed significant increases in the number of new or enlarging T2 lesions, gadolinium-enhanced lesions, and persistent black holes.[35] As these authors suggest, "the definition of BMS currently applied in clinical practice requires reassessment."[35,36]

Educating Patients About Treatment Choices

The "new world of MS" exists in the age of the Internet. Many people who are newly diagnosed with MS are likely to surf the Web and arrive armed with information (some accurate, some not) and ideas about the disease and their own preferences for management. At the same time, there is a huge range in the level of sophistication and complexity of information that patients desire and are able to absorb. Some want only simple overviews, while others are ready for complex scientific explanations and examination of the data. Some basic "starter" kits and collections of web materials are recommended in **Table 4**.

While information about the wide range of available treatment options is readily available on the Web, determining which of the available options is right for any individual is a much more daunting task that requires communication and personalized attention. Some of the questions to consider are outlined in **Table 5**.

The relative importance of each of these factors is going to differ for each individual. For some, the need to get the inflammatory and demyelinating aspect of the disease under control may override some of the convenience aspects. At the same time, the therapy that a patient is most apt to consistently adhere to is likely to be the most efficacious for that individual.[37]

Table 4. Resources for Patients Newly Diagnosed with MS

National Multiple Sclerosis Society (*www.nationalMSsociety.org*)
Knowledge is Power educational series
Register online at NMSS website, or call 800-FIGHTMS (800-344-4867)

The Multiple Sclerosis Association of America (www.myMSAA.org)
Information for Newly Diagnosed

Multiple Sclerosis Foundation (www.MSfocus.org)
Coping with MS – Newly Diagnosed

Consortium of Multiple Sclerosis Centers (CMSC)
CMSC Essential Elements program (www.MSpatientcare.com)

*Relative to placebo

EDSS=Expanded Disability Status Scale; MRI=magnetic resonance imaging; MS=multiple sclerosis.

Are Injectable Agents Still an Option?

The introduction of three oral therapies for MS is a long-awaited and welcome change that provides a dramatic improvement for many, particularly for those patients who have difficulty self-injecting or have experienced adverse effects associated with injectable agents. Some people may assume that, with the array of new options for MS, the older "platform" therapies might be retired, especially for a newly diagnosed patient. However, many MS nurses are finding that these therapies have a place alongside the other options for new and continuing patients. One of the advantages is their documented history of long-term safety in patients with MS. The interferon beta formulations and glatiramer acetate have a demonstrated safety record extending over time periods of many years, with no unexpected or serious safety risks emerging subsequent to the original pivotal trials.[38-40]

Nursing support programs associated with MS agents assist new patients in adapting to medication use and managing adverse effects, and by answering basic questions about the disease. These programs have evolved into a significant support system for patients and a useful extra set of eyes and hands for the MS nurse in a clinic or neurology practice (**Table 6**). Research has shown the utility of these programs in helping patients maintain continuous adherence to therapy over 24 months; in a study of over 5,825 individuals using an injectable therapy, patients were 40% more likely to achieve their goal when using the manufacturer-provided support program.[41]

Counseling Newly Diagnosed Patients: More Options, Greater Complexity

Nurses working in neurology settings are often responsible for helping newly diagnosed patients to understand the disease. In this "new world," there is usually more definitive information that can be

Table 5. Considerations for Therapeutic Selection in MS

- How severe does the initial presentation appear to be? Some people with a particularly aggressive onset may respond better to an escalated course of therapy.
- What does the person's insurance coverage (if available) allow, and how does this influence the selection of therapy?
- Are there comorbidities, such as liver dysfunction or heart rhythm abnormalities, that could influence the selection of therapies?
- What previous treatments (including immunosuppression with steroids or chemotherapy) might influence selection of therapy?
- How important is future fertility to the patient (male or female)?
- Is the person likely to adhere to pre-therapy testing and ongoing monitoring required for treatment with some DMTs?
- How important is the dosage form (oral, injection, infusion) and does the patient understand the overall repercussions of these choices (e.g., the fact that all therapies have potential risks and adverse events)?
- Is the person a risk-taker who will assume the risks of potential serious adverse events? Or is he or she someone who wants to take a more balanced approach between safety and efficacy?
- What support systems are available to help the person administer medications correctly and ensure adherence to DMT regimens and monitoring?

DMT=disease-modifying therapy.

Table 6. Nursing Support Programs for MS Injectable Agents

IFNβ-1a IM	Avonex®	MS ActiveSource	800-456-2255
IFNβ-1b	Betaseron®	BetaPlus Beta Nurses	800-788-1467
IFNβ-1a SC	Rebif®	MS LifeLines	877-447-3243
Glatiramer acetate	Copaxone®	Shared Solutions	800-887-8100

MS=multiple sclerosis; SC=subcutaneous.

given to patients about their diagnosis and possibly even their prognosis, but also much more extensive educating that needs to be done. Today, in order for patients to have a general understanding of how the available DMTs work and why they should be receiving therapy, the nurse educator needs to provide a background that includes immunology, mechanisms of action, and even explanation of brain injury terms such as axonal transection and atrophy. This is a considerable challenge given time constraints related to reimbursement and tight scheduling. While it is sensible to spread MS patient education across several meetings rather than trying to provide too much complex and overwhelming information at once, nurses must balance this need against the potential risk of losing a patient to follow-up before they begin a course of treatment.[42]

Breaking the News of an MS Diagnosis

The manner in which patients are told about their diagnosis of MS is important in the process of acceptance and adjustment. A study by researchers in Australia suggested that the news of an MS diagnosis could trigger symptoms of post-traumatic stress disorder (PTSD) in some individuals.[43] Of 58 patients with MS evaluated for PTSD, nine (16%) met symptom criteria. Another study group interviewed neurologists, nurses, psychologists, and people with MS in Italy to determine how patients respond to the news of an MS diagnosis.[44] All 23 people with MS reported the discovery of their diagnosis as a powerfully evocative and unforgettable moment. Many noted poor levels of support and information surrounding the moment. The authors suggested that further improvements are needed in communicating about difficult subjects such as an MS diagnosis, including choosing an appropriate setting (privacy, no interruptions, sufficient time to talk), presenting the information at a level appropriate for the individual, and ensuring that appropriate follow-up is done.[44]

At the same time, patients need to be told directly and honestly about their diagnosis of MS, rather than "cushioning the blow" by delaying the information. A large-scale study conducted in Greece reached out to 1,200 people with MS and received responses from 657. Of those responding, 91% said they would have preferred to be told immediately about their MS diagnosis, but only 44% said this was consistent with their actual experience. The study was published in 2004 and referred to experiences of patients prior to that year, but 29% of those interviewed said they were informed within 1 to 3 years of their diagnosis, and 27% said they were informed beyond 3 years.[45]

A possible reason for the delay in notifying patients may be uncertainty about the diagnosis, especially for patients who have what is now termed CIS, because their condition looks like MS but does not meet the strict definition in the diagnostic criteria.

Adjusting to a Diagnosis of MS

A person's initial reaction upon receiving an MS diagnosis is more likely to be "Why me?" than "When do I start treatment?" There is a normal period of adjusting to the idea of having MS, accepting the fact that the diagnosis is not a mistake or a fleeting event that will soon pass, and finally, adapting to physical, emotional, and lifestyle changes that may be involved for those living with the disease. As a patient website for the newly diagnosed offered by the Consortium of Multiple Sclerosis Centers (CMSC) advises, "Adapting to MS is an ongoing and challenging process that requires patience, understanding, and good communication with your loved ones, friends, colleagues, and your MS healthcare team."[46]

For some people, the early post-diagnosis phase resembles that of the grieving process. Patients are coping with a loss—often the loss of hopes and aspirations they may have had, and the assumption that they will not be able to pursue their goals now that they have MS. This is often not the case: there are many inspiring stories of people with MS meeting and far exceeding their goals, and in fact many people find new and more meaningful goals as they accept and adapt to their condition.

Meeting with a person who has gone through a similar experience can be extremely helpful for a person adjusting to a new diagnosis of MS, and an increasing number of MS centers and pharmaceutical company-sponsored support services offer peer support programs that match patients with an appropriate group or individual mentor.

Managing Expectations

Managing expectations appropriately is a large part of the MS nurse's job at this stage. People who are newly diagnosed may expect that treatment with a DMT is going to erase their MS symptoms (rather than preventing further damage) or eliminate the possibility of further relapses. Not only does the person typically continue to experience some symptoms of MS, but therapies used to treat MS may bring their own set of side effects that require management and adjustment. A system recommended by the National Multiple Sclerosis Society (NMSS) is to provide people with a "contract," encouraging them to communicate their needs and also stating what is expected of them in terms of communication and follow-up. This patient "bill of rights and responsibilities" can be found on the NMSS website under the heading "Making the Most of Your Doctor Visits."[47]

Barriers to Starting Treatment

There are many unknowns remaining about MS, and knowing which patients are most likely to benefit from early treatment is not always predictable. Thus, it can be difficult to convince patients that their particular course will be influenced by use of a DMT. Among the common barriers that MS nurses encounter when encouraging patients to start therapy include:

- fear of the negative aspects of treatment or risks of therapy;
- desire to try alternative treatments, dietary and lifestyle changes;
- lack of belief in the diagnosis (searching for alternative diagnoses);
- trying unproven therapies such as percutaneous transluminal venous angioplasty (PTVA) for chronic cerebrospinal venous insufficiency (CCSVI);
- feeling he or she is not sick enough to initiate a powerful immunomodulatory treatment;
- concern about receiving injections or infusions;
- unwillingness to undergo necessary monitoring or MRI testing;
- drop in interest after a few months or a year on treatment (especially if clinical course is going well);
- lack of insurance coverage/financial reimbursement for therapy; and
- lack of money for insurance copays and non-covered treatment-related costs.

Conclusion

A person who receives a new diagnosis of MS in 2013 faces a future with more hope than in previous decades, but also one with more choices, greater complexity, and, for most, a greater need to weigh the risks and benefits of treating the disease. As the amount of information about this disease increases exponentially, it is easy to understand how a new patient can become overwhelmed with questions about vitamin D, environmental influences, hereditary risks, therapies, and outcomes. The new world has arrived, in the sense that oral therapies are here and there are more choices available to patients, but this has not solved many of the ongoing mysteries about MS that need to be addressed so we can find more effective and safer ways to manage our patients' disease.

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Counseling Points™

A New World for the Newly Diagnosed

- The "new world" for people newly diagnosed with multiple sclerosis (MS) requires a more sophisticated understanding of immunologic disease processes and the ability to conduct a risk-benefit analysis for a wide range of therapies with different mechanisms.
- The first 5 years after diagnosis has been shown to be a critical window of time for preventing neurologic damage in MS, and many studies have shown a difference between patients treated in the first months versus those who start therapy later.
- Patients who receive disease-modifying therapies (DMTs) soon after diagnosis or during the preliminary phase known as clinically isolated syndrome (CIS) are significantly more likely to forestall and/or limit long-term disability.
- Determining which DMT a patient should start with is an individual decision that requires communication and personalized attention.
- Potential efficacy, safety, medical comorbidities, reproductive issues, route of administration, and reimbursement issues are factors that must be considered in the selection of a DMT. Therapy should not necessarily be selected because it is the most convenient for the patient or practitioner if some of these other factors are overriding.
- Educating patients who are newly diagnosed with MS involves empathy and understanding of the adjustment period that is necessary as people cope with the news and the daunting amount of new information.
- Referral to a peer support group or mentor who has a similar background and experience can be helpful to people who are struggling to understand how the disease will affect them, or have unrealistic expectations about their course and the effects of therapy.

Counseling Points™
A New World for the Newly Diagnosed

Continuing Education Post-test

To receive contact hours, please read the program in its entirety, answer the following post-test questions, and complete the program evaluation. A certificate will be awarded for a score of 80% (9 correct) or better. A certificate will be mailed within 4 to 6 weeks. There is no charge for the CNE credit.

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Via the Web: Applicants can access this program at the International Organization of MS Nurses' website, www.IOMSN.org. Click on *Counseling Points* and follow the instructions to complete the online posttest and application forms.

PLEASE SELECT THE BEST ANSWER

1. **Current diagnostic criteria allow for clinically definite multiple sclerosis (MS) to be diagnosed after a single clinical attack in the presence of which of the following additional conditions?**
   A) 1 or more objective clinical lesions on magnetic resonance imaging (MRI)
   B) 2 or more objective clinical lesions on MRI
   C) positive spinal cord MRI
   D) positive cerebrospinal fluid (CSF)

2. **According to current MS diagnostic criteria, dissemination in space can be demonstrated by:**
   A) MRI findings
   B) positive CSF combined with MRI findings
   C) further clinical attack involving a different site
   D) all of the above

3. **In natural history studies of MS, what percentage of patients has disease advancing to a secondary-progressive stage within 10 years?**
   A) 5%
   B) 15%
   C) 50%
   D) 75%

4. **In patients who have not been treated with a disease-modifying therapy (DMT), the number of relapses occurring in the first 2 years after diagnosis affects their quality of life but not their long-term outcomes.**
   A) True
   B) False

5. **Patients in the pivotal clinical trials of glatiramer acetate had more progression of disease if they were randomized to the placebo group for the first 3 years of the trial than if they received the active drug.**
   A) True
   B) False

6. **The approved DMT thus far showing the highest reduction of annualized relapse rate is:**
   A) fingolimod
   B) natalizumab
   C) high-dose interferon beta-1b
   D) teriflunomide

7. **A patient in your clinic presents with neurologic symptoms of left-sided weakness and loss of visual acuity, but the symptoms resolve after 36 hours. Brain MRI reveals a single monofocal lesion. This case is consistent with:**
   A) radiologically isolated syndrome
   B) clinically definite MS
   C) clinically isolated syndrome
   D) a diagnosis other than MS

8. **"Benign MS" refers to a condition in which:**
   A) symptoms are consistent with MS but are not supported by MRI findings
   B) there is an apparent lack of progression on the Expanded Disability Status Scale (EDSS) score over an extended time
   C) radiologic findings are consistent with MS but there are no clinical symptoms
   D) none of the above

9. **Conditions that might influence the selection of a specific DMT for a person newly diagnosed with MS include all of the following *EXCEPT*:**
   A) heart rhythm abnormalities
   B) liver dysfunction
   C) allergies to antibiotics
   D) reproductive issues for male patients

10. **Potential efficacy of a DMT is an overriding factor that is always more important than patient adherence in the selection of therapy.**
    A) True. Efficacy should be the number one factor in therapeutic selection.
    B) False. A medication is only efficacious if a patient is willing to adhere to therapy.

11. **Research has shown that receiving a diagnosis of MS can evoke emotions comparable to that of:**
    A) diagnosis of a terminal illness
    B) the death of a loved one
    C) major depressive disorder
    D) post-traumatic stress disorder

12. **For people newly diagnosed with MS, barriers to starting DMT include all of the following *EXCEPT*:**
    A) severe disease course
    B) concerns about side effects or risks of therapy
    C) unwillingness to undergo necessary monitoring
    D) fear of receiving injections or infusions

Counseling Points™: Program Evaluation Form

A New World for the Newly Diagnosed

Using the scale provided (Strongly Agree = 5 and Strongly Disagree = 1) please complete the program evaluation so that we may continue to provide you with high-quality educational programming. Please fax this form to **(201)612-8282** or complete it online as instructed below.

5 = Strongly Agree 4 = Agree 3 = Neutral 2 = Disagree 1 = Strongly Disagree

At the end of this program, I was able to: *(Please circle the appropriate number on the scale.)*

1) Analyze changes in the diagnosis and assessment of newly diagnosed patients with MS and clinically isolated syndrome 5 4 3 2 1
2) Describe projected paradigm shifts in outcomes and prognosis for patients who receive early treatment for MS 5 4 3 2 1
3) Develop strategies for educating patients about whether early treatment is right for them 5 4 3 2 1
4) Review recommended protocols for starting patients on MS therapy 5 4 3 2 1

To what extent was the content:

5) Well-organized and clearly presented 5 4 3 2 1
6) Current and relevant to your area of professional interest 5 4 3 2 1
7) Free of commercial bias 5 4 3 2 1
8) Clear in providing disclosure information 5 4 3 2 1

General Comments

9) As a result of this continuing education activity (check only one):

❒ I will modify my practice. (If you checked this box, how do you plan to modify your practice?)_____

_____

❒ I will wait for more information before modifying my practice.

❒ The program reinforces my current practice.

Suggestions for future topics/additional comments: _____

_____

10) Please indicate any barriers you perceive in implementing these changes.

❒ Cost ❒ Lack of opportunity (patients) ❒ Patient adherence issues ❒ Other (please specify)_____
❒ Lack of administrative support ❒ Reimbursement/insurance ❒ Lack of professional guidelines _____
❒ Lack of experience ❒ Lack of time to assess/counsel patients ❒ No barriers _____

11) Will you attempt to address these barriers in order to implement changes in your knowledge, skills, and/or patients' outcomes?

❒ Yes. How? _____

❒ Not applicable

❒ No. Why not?_____

Follow-up

As part of our continuous quality-improvement effort, we conduct postactivity follow-up surveys to assess the impact of our educational interventions on professional practice. Please check one:

❒ Yes, I would be interested in participating in a follow-up survey.

❒ No, I would not be interested in participating in a follow-up survey.

There is no fee for this educational activity.

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