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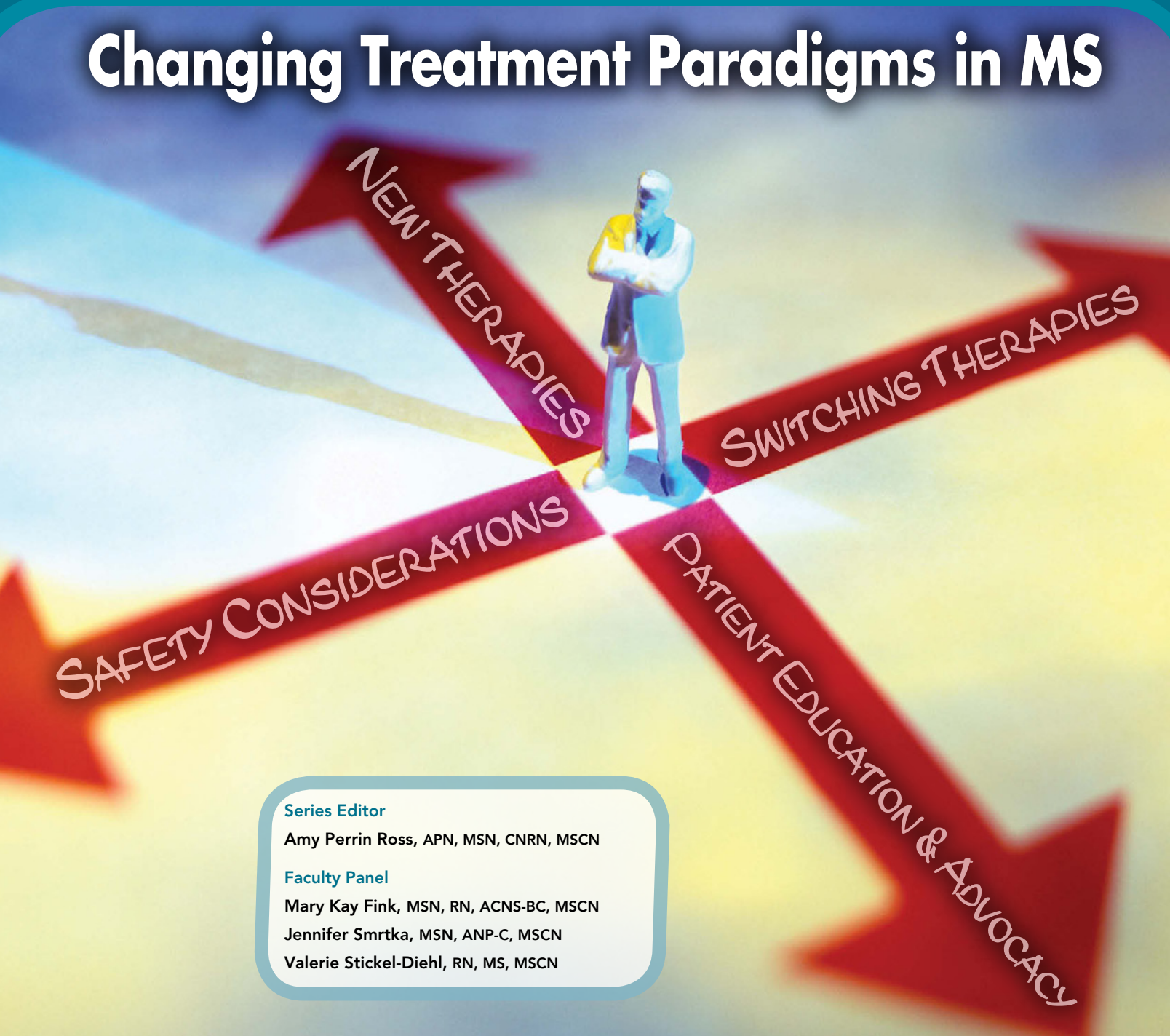
Changing Treatment Paradigms in MS



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Counseling Points™

Changing Treatment Paradigms in MS

Continuing Education Information

Target Audience

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

Purpose

To inform MS nurses about current changes and trends in clinical practice with a focus on MS disease-modifying therapies (DMTs).

Learning Objectives

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

- Discuss changes in MS patient care related to increasing treatment options and more complex safety issues
- Evaluate the considerations involved in making a switch between DMTs for MS
- Identify steps involved in safety monitoring of current DMTs
- Improve strategies for patient education and advocacy in the selection of DMTs

Continuing Education Credit

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In order to earn credit, please read the entire activity and complete the posttest and evaluation at the end. Approximate time to complete this activity is 60 minutes.

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welcome

Dear Colleague,

A year ago, many of us thought treatment of multiple sclerosis (MS) as we know it would be turned on its head by the end of 2011. In some respects, it has; in other ways, the paradigm shift has only just begun. In this issue of *Counseling Points*™, our panelists examined five changing aspects of our MS nursing practice, and what these changes mean for us and for our patients. Some of the biggest adjustments relate to how patients are monitored for adverse effects or complications of disease-modifying therapies. Another area that seems to be shifting is our protocol for switching therapy if a patient has exacerbations or exhibits radiologic evidence of disease progression.

Although we still spend a significant amount of time counseling patients about their MS therapies, much of this time is now focused on discussing new medication options, anticipated therapies in the pipeline, orals versus injectables (or infusions), and other new concepts. Helping patients to maintain realistic expectations is still an important part of this process because, despite all of the media hype, no drug or procedure has yet been shown to eliminate the effects of MS or stop all disease progression.

As we read the literature, we are aware that MS treatment of the future may be vastly different, with biomarkers and genetic indicators to guide therapeutic choices. But for most of us, the waiting area is full of patients who need the best MS care we are able to offer based on the options we have available today.

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Changing Treatment Paradigms in MS

Paradigm shift has been defined as "an intellectually violent revolution," in which "one conceptual view is replaced by another."[1] Is a paradigm shift under way in multiple sclerosis (MS), and if so, what changes have affected the practice of MS nursing? Recently, a panel of *Counseling Points*™ nurses explored changes occurring in five major areas:

1. new therapies and changing modes of administration;
2. considerations for switching therapies;
3. monitoring and safety considerations for therapy;
4. patient education and expectations; and
5. the approach to patient advocacy.

1 New Therapies and Administration Methods

MS nurses who were practicing in the early 1990s when the first disease-modifying therapies (DMTs) were launched may remember patients saying, "Be sure to call me when this is available in a pill." At that time, many practitioners envisioned having oral versions of interferon beta (IFNβ) or glatiramer acetate (GA) to prescribe for their patients. But the current shift has taken DMTs in another direction, with novel forms of oral and infusion therapies being introduced that differ significantly from IFNβ and GA **(Table 1).**

A major part of this shift has been the creation of a need to take new and potentially serious safety considerations into account.[2,3] To some extent, MS practitioners may have fallen into a habit of taking the overall safety of DMTs for granted, as no unexpected or serious safety risks emerged in over 15 years of clinical use of either GA or the interferons.[4] Currently, the challenge in choosing a DMT for any patient with MS is to balance efficacy goals with the potential risks associated with a given therapy. In addition, while many of the newer and emerging agents have shown high efficacy scores in large clinical trials, there is currently no way to predict how effective a particular therapy will be for an individual patient.[5-7] A question that must be asked is, "How well is the patient doing on his or her current therapy?" Many practitioners employ the "if it's not broken, don't fix it," philosophy to answer this question.

Today, more than ever, there is no "one size fits all" approach to MS treatment. There are more choices, but also greater complexity in decision-making and often a need for compromise. For example, some patients may need to accept additional safety risks to benefit from the potential of improved control of MS.[8,9] Some of the key factors

Table 1. New and Emerging Therapies for MS: Administration Methods

Oral Agents	
Fingolimod (Gilenya™)	Approved as a first-line therapy in 2010
Cladribine	Withdrawn from trials in MS
BG-12/fumarate	Phase III study results released
Laquinimod	Phase III studies ongoing
Teriflunomide	Phase III studies ongoing
Infusible Agents	
Natalizumab (Tysabri®)	Reapproved in 2006 as a second-line therapy
Alemtuzumab	Phase III studies ongoing
Ocrelizumab	Phase III studies ongoing
Daclizumab	Phase III studies ongoing

that go into therapeutic selection are outlined in **Table 2.**

Table 2. Factors to Consider in Selection of Disease-modifying Therapy

- Stage of MS (CIS, RRMS, progressive forms)
- Recent stability of disease course (e.g., relapses, changes in enhancing lesions on MRI)
- Patient's readiness for starting/committing to the therapy
- Availability of reimbursement for therapies
- Previous therapies used and safety/efficacy/adherence history
- Patient's comfort level with mode of administration
- Patient's commitment level to necessary monitoring
- Reproductive goals (e.g., desire for future pregnancies)
- Comorbid diseases or contraindications

CIS=clinically isolated syndrome; MRI=magnetic resonance imaging; MS=multiple sclerosis; RRMS=relapsing-remitting multiple sclerosis.

Working with patients collaboratively to make treatment decisions has become the accepted approach in MS care.[10,11] It is important for MS nurses to avoid pushing their own opinions or values about health and lifestyle goals on patients, but rather to support and assist patients in making informed decisions. Some patients have a high risk-taking threshold; others may value a greater assurance of safety or comfort with an existing therapy above other issues. Recommended questions to help facilitate these discussions with patients are included in **Table 3**.[11]

2 Considerations for Switching Therapies

"Should I switch to something newer?" This question weighs on the minds of many people with MS as they peruse new possibilities in MS treatment. Some MS nurses have observed that the benchmark for considering a switch in therapy is shifting—neurologists may evaluate patients more frequently, or order additional magnetic resonance imaging (MRI) scans to monitor disease activity. This trend will probably continue as more new choices are introduced.[10,12] What constitutes an acceptable change in gadolinium-enhancing lesions on MRI or number of exacerbations in a given time period? This must be individualized for each patient, but many clinicians are evaluating these signs of disease breakthrough earlier and considering a change in therapy when possible.

Rather than switching among therapies arbitrarily, it is important to explore the reasons for the

Table 3. Questions that Provide Insight Into a Patient's Decision-making Process[11]

- What questions or concerns do you have about MS—for instance, its long-term impact?
- What experiences have you had with other people who have MS?
- How do you feel about the available treatment options (e.g., which attributes of each agent are appealing or not appealing)?
- Can you imagine self-injecting a medication on a daily or weekly basis?
- How would you like to participate in the treatment decision (e.g., do you want to consider the options and select a therapy, do you want to rely on your medical team's recommendation, or a combination of the two)?
- What would help you feel like you're making the right decision about treatment (e.g., involvement in the decision-making process, detailed information about the therapy choice)?
- Do you perceive making a decision as losing or gaining control?
- What would help you make this treatment plan a success (e.g., minimal impact on your lifestyle, short- and long-term reduction in relapses)?
- Would you like more time to think about your options? (Try to establish a time frame in which the decision will be made without making the patient feel rushed.)

MS=multiple sclerosis.
Reprinted with permission from Halper J. *Int J MS Care*. 2011; 13(Suppl 1):3-4.

switch, whether it is for suboptimal response to the present therapy, tolerability issues, injection-related problems, or reimbursement factors. Is the patient actually using the prescribed therapy as directed? According to a National Multiple Sclerosis Society task force, "treatment failure" can be any combination of transient response, partial response, and poor adherence.[7,10] Many factors can be mistaken for treatment failure, including low persistence and adherence, certain side effects, and a combination of hidden symptoms such as depression or infection.[9,13] Patients may assume that their treatment is not working if their symptoms do not abate with regular use of their DMT or if they experience any new symptoms.[14] "Treatment failure" is also often related to patient difficulties in coping with drug side effects or having to regularly inject their medications, rather than strict failure in efficacy, the NMSS task force points out.[10] As many as one-quarter of people with MS discontinue therapy within the first 6 months of treatment, with studies showing that perceived lack of efficacy counts for 30% to 52% of therapy discontinuation.[13,15]

Neutralizing Antibodies

For a patient using an interferon therapy, neutralizing antibodies (NABs) may contribute to lack of efficacy. NABs have been shown to occur in 30% to 40% of patients receiving IFNβ-1b, 12% and 25% of those receiving subcutaneous IFNβ-1a, and 2% to 6% of those using intramuscular IFNβ-1a.[16-18] The true impact of NABs on treatment response is controversial. Some studies have shown NABs to have a negligible effect on clinical outcomes, while others have demonstrated a correlation between reduced efficacy and NAB positivity.[19] The current consensus appears to be that high, persistent titers of NABs can reduce IFNβ efficacy.[16,20,21]

NABs typically occur during the first year of therapy, although their development may range anywhere from 3 months after the beginning of therapy to 18 months.[22] To add to the confusion, some patients who develop NABs have been found to revert to NAB-negative status, although this usually happens in those with a relatively low titer of antibodies.[17,18] Based on an American Academy of Neurology (AAN) consensus paper on NABs, NAB-positive status begins at >20 NU/mL, with high titers defined as ≥100 NU/mL.[20]

The AAN subcommittee determined that there is "insufficient information to state definitively whether IFNβ should be halted on the basis of a positive NAB test."[20] A 2005 European Federation of Neurological Societies report is more direct in its recommendations, suggesting NAB testing after 12 and 24 months of IFNβ treatment, and discontinuation of therapy when high NAB titers are sustained at repeated measurements with 3- to 6-month intervals.[21]

Switching Between GA and IFNβ

Patients who do not respond well to one class of DMT may respond to another class with a different mechanism of action. This was demonstrated in an open-label study by Caon and colleagues.[23] Eighty-five consecutive patients with relapsing-remitting MS (RRMS) were initially treated with IFNβ-1a and switched to GA therapy after 18 to 24 months due to either persistent clinical disease activity (n=62) or intolerance to therapy (n=23). After switching, patients were followed for a mean of 37 months. For those patients switched for efficacy reasons, the mean annualized relapse rate decreased from 1.32 with IFNβ-1a to 0.52 with GA (P=0.0001). No significant differences in relapse rate were noted among patients who switched because

of tolerability problems.[23] This was an open-label study and thus the findings should be interpreted accordingly. Likewise, patients not responding to GA therapy may benefit from switching to an interferon.[7,9]

Effect of Switching Therapies on Immune Function

One aspect of the changing paradigm that remains unclear is how long a patient should stay on a new therapy, and whether a "washout period" is warranted before transitioning from one treatment to another. Drugs used in MS may have unknown immune system effects that are triggered or compounded when moving from one therapy to another.[24,25] For example, among patients receiving natalizumab who have contracted progressive multifocal leukoencephalopathy (PML), approximately 50% had been treated previously with an immunosuppressant such as mitoxantrone.[26] Likewise, some newer immunomodulators may have long-lasting effects relating to the depletion of lymphocytes that predispose patients to infection or malignancy.[8,27] And some experimental MS therapies have secondary effects that may have life-long consequences, such as the elevated risk of autoimmune thyroiditis (Hashimoto's or Grave's disease) associated with some monoclonal antibody treatments.[28]

Further research and additional clinical experience are beginning to shed light on some of these questions. In the case of natalizumab (originally introduced in 2004, then withdrawn from the market and re-introduced in 2006 under tighter monitoring requirements), antibody testing for the JC virus is now available as a tool for risk stratification for PML.[26] However, a positive antibody test to the JC virus does not always require that the patient immediately discontinue natalizumab therapy. Some patients may feel the disease control they receive from the drug outweighs the risk. These patients should be closely monitored with regular visits, frequent MRIs, and close monitoring for PML as delineated in the natalizumab TOUCH Prescribing Program.

Oral Options for MS

Fingolimod has now been on the market for over a year with no additional side effects seen beyond those observed in clinical trials. Safety issues observed during clinical trials of fingolimod in MS are outlined in **Table 4**.[27,29,30] With continued postmarketing surveillance and careful patient selection, confidence among practitioners and patients about this agent should increase. More long-term surveillance is needed, but the attractiveness of fingolimod and other anticipated oral therapies for MS is evident.

Table 4. Fingolimod Adverse Effects[27,29,30]

Common, minor side effects

- Nasopharyngitis
- Headache
- Diarrhea
- Nausea
- Clinically asymptomatic lymphopenia (drop in peripheral lymphocyte counts of 20% to 30% from baseline)

Uncommon, serious side effects

- Cardic effects: bradycardia, atrioventricular block, nonsustained ventricular tachycardia
- Abnormal liver enzyme levels
- Macular edema
- Infections, including potentially fatal varicella zoster, herpes simplex encephalitis

Pregnancy

- No data are available on the safety of fingolimod during pregnancy or effects on fertility

"Injection fatigue" is a common reason for patients wanting to switch to a different form of MS therapy, and for nonadherence to therapy.[31] Now that an oral option is available, MS nurses report that some patients have come forward to admit they have not been using their injection therapy as prescribed. In counseling patients about the mode of therapy, the nurse needs to get across that ingesting something orally does not make it benign or guarantee that it will be well tolerated.

3 Monitoring

Regardless of what disease-modifying agent is used, safety monitoring is a necessary step that cannot be overlooked by people with MS or those involved in their care. Increasingly, insurance companies and health care practitioners are requiring that patients be up to date on blood work and other necessary tests before authorizing prescription refills for MS drugs. All MS therapies require follow-up and monitoring to ensure safety and tolerability **(Table 5)**, but

Table 5. Safety Monitoring Steps of Approved Disease-Modifying Therapies[32-37]

IFNß-1b, IFNß-1a SC, IFNß-1a IM[32-34]

- Blood chemistry values, including liver function tests, hemoglobin, platelet count, white blood cell count, and complete and differential blood count; monitor blood levels at 1- to 3-month intervals during the first year of therapy and every 6 months thereafter if stable
- Monitor for skin reactions, including lipoatrophy, skin necrosis

Glatiramer acetate[35]

- Monitor for signs of lipoatrophy, skin necrosis

Natalizumab[36]

Under the terms of the TOUCH Prescribing Program, follow up:

- Once every 4 weeks (at each infusion visit)
- 3 and 6 months after the first infusion and at least once every 6 months thereafter
- Treatment must be reauthorized every 6 months

Fingolimod[37]

- Observe patients for 6 hours after the first dose for signs and/or symptoms of bradycardia
- Obtain ECG prior to starting fingolimod if a recent (within 6 months) test result is not available in patients taking antiarrhythmics, with cardiac risk factors, and among those who have a slow or irregular heartbeat
- Monitor BP
- Before initiating treatment, obtain a recent CBC (within 6 months)
- Patients without a history of chickenpox or who have not been vaccinated against varicella zoster virus should be tested for VZV antibodies. Monitor for infection during treatment and for at least 2 months after discontinuing therapy
- Perform ophthalmic evaluation at baseline and 3 to 4 months after treatment initiation
- If patients report visual disturbances at any time during treatment, order additional ophthalmologic evaluation. Patients with diabetes mellitus or a history of uveitis should have regular ophthalmologic evaluations while receiving fingolimod
- Perform spirometric evaluation of respiratory function and evaluation of diffusing capacity of lungs for carbon monoxide during therapy if clinically indicated
- Obtain recent (within 6 months) transaminase and bilirubin levels before initiation of treatment; monitor liver enzymes in patients who develop symptoms suggestive of hepatic dysfunction

BP=blood pressure; CBC=complete blood count; ECG=electrocardiogram; IFNß=interferon beta; IM=intramuscular; SC=subcutaneous; VZV=varicella zoster virus.

newly introduced therapies have prompted different types of monitoring not previously used in MS care practices. These include the TOUCH Prescribing Program for natalizumab and cardiac and respiratory monitoring for patients receiving fingolimod. As more new agents are introduced, this list will likely expand with a greater variety of tests needed to ensure the safety of patients receiving these treatments.

Often, monitoring practices are dictated by what is required by insurance companies for reimbursement of a drug. Depending upon where blood work and other monitoring tests such as eye exams are done, patients may need to keep track of results and provide the records to their MS center or practice. This adds to the already-confusing aspects of MS care, especially for patients who have cognitive impairments. MS nurses can assist by developing spreadsheets, checklists, or reminder systems according to the type of therapy and the monitoring needs. However, patients need to be counseled to accept responsibility for their care and take on the onus of monitoring and follow-up when possible.

In addition to monitoring and follow-up associated with DMTs, a more comprehensive array of screening steps is evolving as more is learned about MS and its interactions with body systems.[38-40] Vitamin D, herpes virus, and thyroid function tests are moving to the forefront as this paradigm evolves. Some of the screening steps receiving heightened interest in MS are outlined in **Table 6**.

4 Patient Education & Expectations

Patient education has always been a central focus of MS nurses, and today's changing environment only heightens the need for informed and high-quality education.[31,41,42] Faced with increasingly complex

Table 6. Screening Tests for Patients with MS

- Varicella zoster virus antibodies (when considering fingolimod treatment)
- JC virus (when considering natalizumab treatment)
- Epstein-Barr virus
- Vitamin D levels
- Thyroid function
- Sleep evaluations
- Neuromyelitis optica antibodies
- Interferon neutralizing antibody testing (with IFNß treatment)

IFNß = interferon beta.

decisions, patients need up-to-date, evidence-based information and decision-support systems in order to make informed decisions.[43] These days, managing miscommunication is almost as important as initiating communication. Patients are exposed to multiple sources of varying credibility and much hearsay through chat rooms and internet sites such as YouTube. Clearly, these types of communication have their pros and cons. Many internet-based services can offer a great deal of comfort and support for people with MS. However, a bit of web browsing should be on the MS nurse's recommended reading list, to provide insight into what people are seeing and how they are reacting to information.

Managing patients' expectations is an ongoing challenge.[42,44] Media attention to new MS drugs raises hope, but also may offer unrealistic expectations about what a given therapy can do for an individual. To date, none of the DMTs available for MS is 100% effective curative. Managing expectations often means walking a fine line between being realistic about specific treatment approaches while not killing a person's hopes for a better lifestyle and a more healthful future.

5 Approach to Advocacy for People with MS

Part of a paradigm shift for medicine in general is the tension between the higher costs of diagnostic tests, drugs, and other therapeutic interventions on one hand and the tighter, more stringent cost-control measures by payers on the other. As MS therapies become more advanced, the expense of administering these agents has increased accordingly. Added to the cost of extensive preclinical and clinical studies, many MS drugs are derived from biologic methods or processes that are particularly expensive to develop. As a result, maintaining the best and most appropriate therapy for a given patient often comes down to how effectively the health care provider (often, the MS nurse) can advocate for reimbursement by insurers.

The concept of advocacy evokes the image of a mountain of paperwork. The process is often complicated by the relative lack of understanding about MS drugs among representatives of insurance companies and other payers. Many regulations about which patients are candidates for a particular therapy seem arbitrary. For example, one MS nurse recalled a recent case in which a patient had to be documented as "failing" a standard injectable therapy before receiving authorization for oral therapy. This nurse was told that the requirement for failing the first-line drug was just 2 weeks of therapy—clearly far short of the amount of time needed for an adequate trial of any MS agent.

Other nurses have expressed concerned about attempts by managed-care companies to put MS care decisions into rigid algorithms. MS, as a rule, tends to defy such categorization. Patients usually respond best when therapy is highly individualized and treatment decisions are made on a case-by-case basis.[7,45]

Is the best DMT for a patient the one that the managed care company will reimburse for? Not necessarily, but getting beyond this limitation takes creativity and can be time-consuming. A document that can be especially helpful for the nurse advocate is the Toolkit of Health Insurance Appeal Letters produced by the National Multiple Sclerosis Society.[46] This document, available online in PDF form and also on CD, contains sample appeal letters in the form of templates to aid in the dialogue between clinicians and health plans about disputes over coverage. Other resources in the document include tips about when and how to file and appeal on behalf of a patient **(Table 7).**

Table 7. When Is It Appropriate to File an Appeal?[46]

When a denial of coverage has been made, patients and/or their clinicians should pursue an appeal after considering the following:

1. Is the treatment, service, or rite medically necessary and indicated for this patient at this point in time?
2. Is the treatment, service, or item a covered benefit under the patient's plan? If the desired treatment, service, or item is clearly listed as an uncovered benefit, there is virtually no value in pursuing an appeal. However, if the plan materials are unclear or silent on the matter, an appeal is warranted.
3. Is the denial based on a clerical error or missing information? If the denial has not already been provided in writing, request it immediately and examine it for errors, such as in the member's ID number, diagnostic or service code, or date of service.
4. Has the patient's co-payment or co-insurance amount for a covered service, drug, or item recently risen and become unaffordable to the patient?

Adapted from: National Multiple Sclerosis Society. Health Insurance Appeal Letters: A Toolkit for Clinicians. 2nd ed. 2009. Available at: www.nationalmssociety.org/for-professionals/healthcare-professionals/resources-for-clinicians/index.aspx.

Advocating for the best therapy for an individual may, in fact, save money in the long run if that treatment helps to prevent disability and the inherent costs associated with advanced MS. As stated in the Consortium of Multiple Sclerosis Centers' white paper, *Advocacy in Multiple Sclerosis*, "Improper or delayed access to healthcare impacts financial status, leads to greater risk of secondary complications, deterioration in health status, hampers mobility and activity, affects the ability to hold a job, and leads to depression, stress, and frustration on the part of the patient."[47] The white paper emphasizes that, "Patients may not have the means or ability to address the complexities of the current health system" by themselves.

Summary

With the rapid pace of change in MS care today, many updates are old news almost before the ink is dry on the paper. These paradigm shifts will continue to evolve until, one hopes, MS becomes a disease that is conquered by modern medical advances.

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Counseling Points™

Changing Treatment Paradigms in MS

- Five current paradigm shifts in multiple sclerosis (MS) care include: 1) new therapies and changing modes of administration; 2) considerations for switching therapies; 3) monitoring and safety considerations for therapies; 4) patient education and expectations; and 5) the approach to advocacy.
- Working with patients collaboratively to make treatment decisions is the accepted approach in MS care. Rather than pushing opinions or values about health or lifestyle goals on patients, it is important to assist patients in making informed decisions.
- When considering a switch in therapy, factors to consider include: determining reasons for a switch, including tolerability and possible suboptimal response; whether the patient has antibodies to a therapy or risk factors (such as the JC virus) relevant to therapy; and the potential immune-system impact of new or previous treatments.
- Monitoring requirements for MS drugs have changed considerably in recent years. Regardless of the disease-modifying therapy (DMT) used, safety monitoring is a necessary step that cannot be overlooked by people with MS or those involved in their care.
- Many people with MS are on "information overload" with respect to MS news. Nurses have an important role in helping patients to balance the pros and cons of any therapy and to manage expectations about what a treatment can do for them as individuals.
- With more choices in MS therapies, insurers and other payers have new sets of requirements that are rapidly evolving. MS nurses should take advantage of resources designed to help them streamline patient advocacy steps.

Counseling Points™
Changing Treatment Paradigms in MS

Continuing Education Posttest

To receive contact hours, please read the program in its entirety, answer the following posttest 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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By Fax: (201) 612-8282

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. When counseling a patient about selection of a disease-modifying therapy (DMT), which of the following considerations should take *less* precedence?
- A. The patient's readiness for starting/committing to the therapy
- B. The availability of reimbursement for therapies
- C. Previous therapies used and safety/efficacy/adherence history
- D. The health care provider's personal preference

2. People with multiple sclerosis (MS) should be asked whether they can envision themselves self-injecting a medication on a daily basis.
- A. True. This should be taken into consideration up front
- B. False. This should be brought up only after a therapy has been selected

3. Factors that can be mistaken for treatment failure include all of the following *except*:
- A. low persistence and adherence
- B. drug side effects
- C. gadolinium-enhancing changes on magnetic resonance imaging (MRI)
- D. hidden symptoms (depression or infection)

4. Of the patients with MS who discontinue therapy, 30% to 52% of discontinuance has been attributed to:
- A. skin side effects
- B. postinjection reactions or flu-like symptoms
- C. perceived lack of efficacy
- D. progression to secondary-progressive MS

5. Patient A has not appeared to respond well to his interferon therapy. The best initial course of action would be to:
- A. try a different interferon preparation
- B. try the patient on a course of natalizumab
- C. explore possible reasons for suboptimal response
- D. manage his expectations about what to expect in MS treatments

6. Among the interferons, the lowest prevalence of neutralizing antibodies (NABs) has been seen in studies of:
- A. IFNβ-1a intramuscular
- B. IFNβ-1a subcutaneous
- C. IFNβ-1b
- D. all agents

7. We know for a fact that NABs reduce the effectiveness of interferon treatment in MS.
- A. True
- B. False

8. Among patients receiving natalizumab who have contracted progressive multifocal leukoencephalopathy (PML), approximately what percentage were previously treated with an immunosuppressant?
- A. 10%
- B. 30%
- C. 50%
- D. 75%

9. An autoimmune disease shown to potentially be triggered by newer immunomodulatory therapies for MS is:
- A. autoimmune thyroiditis
- B. rheumatoid arthritis
- C. Crohn's disease
- D. systemic lupus erythematosus

10. The type of ongoing monitoring recommended for patients using interferon therapies is:
- A. skin examination
- B. blood chemistry values
- C. both of the above
- D. none of the above

11. Which of the following is not part of the recommended monitoring with the use of fingolimod for MS?
- A. recent electrocardiogram
- B. vitamin D levels
- C. vaccination against varicella zoster virus or a positive history of chickenpox
- D. ophthalmic evaluation

12. If a patient's insurance company does not allow coverage of a DMT thought to be appropriate for the patient, the MS nurse should:
- A. only select therapies that are covered under the plan
- B. write an appeal letter stating why the therapy is appropriate
- C. find a clinical trial that might cover the cost of the drug
- D. none of the above

Counseling Points™: Program Evaluation Form

Changing Treatment Paradigms in MS

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) Discuss changes in MS patient care related to increasing treatment options and more complex safety issues 5 4 3 2 1
2) Evaluate the considerations involved in making a switch between DMTs for MS 5 4 3 2 1
3) Identify steps involved in safety monitoring of current DMTs 5 4 3 2 1
4) Improve strategies for patient education and advocacy in the selection of DMTs 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

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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: _____

_____

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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.

Posttest Answer Key	1	2	3	4	5	6	7	8	9	10	11	12

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