Winter 2015 Volume 10, Number 3

Complimentary Continuing Education Credit for Nurses Counseling Points

Enhancing Patient Communication for the MS Nurse

Advising Patients About Disease-Modifying Therapy Selection and Switching

Series Editor

Amy Perrin Ross, APN, MSN, CNRN, MSCN

Faculty Panel

Constance B. Easterling, RN, MSN, ARNP, MSCN Mary Kay Fink, RN, ACNS-BC, MSCN Elida J. Santos de Greinel, RN, BS, MSCN

This continuing education publication is supported by an educational grant from Teva CNS.

FACULTY:

Series Editor

Amy Perrin Ross, APN, MSN, CNRN, MSCN Neuroscience Program Coordinator Loyola University Medical Center Maywood, IL

Faculty Panel

Constance B. Easterling, RN, MSN, ARNP, MSCN Clinical Coordinator MS Care Center of Neurological

Services of Orlando Orlando, FL

Mary Kay Fink, RN, ACNS-BC, MSCN

Clinical Supervisor MS Center of Saint Louis St Louis, MO

Elida J. Santos de Greinel, RN, BSN, CNS, MSCN

Clinical Coordinator, Multiple Sclerosis Specialty Clinic University of New Mexico Health Sciences Center Albuquerque, NM

Faculty Disclosure Statements

Amy Perrin Ross has received honoraria for consulting and participating on the Speakers' Bureaus for Acorda Therapeutics, Bayer HealthCare, Inc., Biogen Idec, EMD Serono, Genzyme, Novartis, Questcor, Pfizer Inc, and Teva CNS.

Constance Easterling has received honoraria for participating on the Speakers' Bureaus for Biogen Idec, Genzyme, Mallinckrodt, and Teva CNS and for consulting for Acorda Therapeutics, Mallinckrodt, and Teva CNS.

Mary Kay Fink has received honoraria for participating on the Speakers' Bureaus for Acorda Therapeutics, Biogen Idec, EMD Serono, Genzyme, Novartis, and Teva CNS and for consulting for Novartis.

Elida J. Santos de Greinel has disclosed no relevant financial relationships.

Planners and Managers

The following planners and managers have declared no relevant financial relationships: Joseph J. D'Onofrio, Frank Marino, Katherine Wandersee.

PUBLISHING INFORMATION:

Publishers

Joseph J. D'Onofrio Frank M. Marino Delaware Media Group 66 South Maple Avenue Ridgewood, NJ 07450 Tel: 201-612-7676 Fax: 201-612-8282 Websites: www.delmedgroup.com www.counselingpoints.com

Medical Writer

Katherine Wandersee

Art Director

James Ticchio

Cover photo credit: © Stuart Jenner / Veer

Copyright © 2015, Delaware Media Group, Inc. All rights reserved. None of the contents may be reproduced in any form without prior written permission from the publisher. The opinions expressed in this publication are those of the faculty and do not necessarily reflect the opinions or recommendations of their affiliated institutions, the publisher, or Teva CNS.

Counseling Points™ Advising Patients About Disease-Modifying Therapy Selection and Switching

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 assist nurses who treat patients with MS to counsel patients in the decision-making process involved in disease-modifying therapy selection and switching.

Learning Objectives

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

- Analyze the role and benefits of patient participation in selection of diseasemodifying therapies (DMTs)
- Review other factors that affect therapeutic selection (e.g. payer limitations, medical contraindications)
- Discuss situations leading to switches in DMTs and patient involvement in decision making

Continuing Education Credit

This continuing nursing education activity is developed under the joint providership of Delaware Media Group and NP Alternatives.

NP Alternatives is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

Laurie Scudder, DNP, NP, served as nurse planner and reviewer for this activity. She has declared no relevant financial relationships.

This activity has been awarded 1.0 contact hours (1.0 contact hours are in the area of pharmacology). Code: MSCP01015.

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.

This program expires January 31, 2017.

Disclosure of Unlabeled Use

This educational activity may contain discussion of published and/or investigational uses of agents that are not approved by the FDA. Teva CNS and Delaware Media Group do not recommend the use of any agent outside of the labeled indications. The opinions expressed in the educational activity are those of the faculty and do not necessarily represent the views of Teva CNS and Delaware Media Group.

Disclaimer

Participants have an implied responsibility to use the newly acquired information to enhance patient outcomes and their own professional development. The information presented in this activity is not meant to serve as a guideline for patient management. Any medications, diagnostic procedures, or treatments discussed in this publication should not be used by clinicians or other health care professionals without first evaluating their patients' conditions, considering possible contraindications or risks, reviewing any applicable manufacturer's product information, and comparing any therapeutic approach with the recommendations of other authorities.

welcome

Dear Colleague,

How to help patients plan for a switch in disease-modifying therapy (DMT) is one of the most common questions we encounter as multiple sclerosis (MS) nurses. Today many more therapeutic options are available for our patients, but there are often several hurdles to clear before a person can successfully switch to a different DMT. These may include verifying the safety of the new therapy, arranging for necessary monitoring, educating the patient about dosage and adherence and—perhaps the biggest challenge—ensuring financial coverage from a third-party payer.

A common theme emerged as our *Counseling Points* nurse panelists discussed the issue of therapeutic selection and switching: the nurse–patient relationship. This concept may seem counterintuitive in a time of rushed office visits and larger patient caseloads. But we all agreed that making the effort to establish a trusting relationship with the patient early in the course of treatment (or when the patient enters your practice) can save time by preventing misunderstandings and potential complications down the road.

Unfortunately, MS is not necessarily a condition in which the patient "gets better" with therapy—our goal for treatment is usually for the disease to remain stable rather than worsen, with other improvements arising through functional therapies and life-style changes. Helping patients to set expectations for their existing therapy, or a new one, is an important part of the nurse's job, along with evaluating the reasons behind the patient's request for a switch.

The close of 2014 represents 10 years of continuous publication for the *MS Counseling Points* program. We sincerely hope you find the insights presented here to be helpful in your practice.

Omy former Ress

Amy Perrin Ross, APN, MSN, CNRN, MSCN (series editor) Neuroscience Program Coordinator Loyola University Medical Center Maywood, IL

Advising Patients About Disease-Modifying Therapy Selection and Switching

t's already scheduled to be a busy day in the office, but you notice on your patient roster that a 15-minute appointment has been slotted in with R, a 28-year-old woman with a diagnosis of multiple sclerosis (MS) whom you had seen just a few months ago. The reason for the visit was stated as, "Wants to discuss change from her current therapy to a different drug."

R is receiving an oral disease-modifying therapy (DMT) that required some negotiation with payers to get approved, and she has fulfilled all the recommended safety monitoring. It may be a bit too early to determine whether her current therapy is working for her. When you see R, you plan to explore a number of possible reasons why she might be requesting the switch. (You also recognize that a 15-minute appointment is probably not realistic for this purpose.)

Patterns of Switching

A study on switching patterns based on data from 2005 showed that 75% of patients with MS had switched DMTs at least once and 14% had switched 3 or more times.¹ This study was completed well before the approval of most of the newer therapies available today. With an even greater variety of DMT choices available, switches in therapy are likely to become increasingly common. In this older analysis, younger patients (age 34 or under) and female patients were more likely to switch.¹ Only a small percentage (11%) of those who switched did so without a break between therapies. One-third had a lapse between therapies that lasted longer than 90 days. This is significant because other studies show that treatment gaps of 90 days or longer gaps may double the probability of a relapse occurring.²

A more recent study derived from a North American Research Committee on Multiple Sclerosis (NARCOMS) registry survey explored patients' perspectives on the reasons for switching MS therapies.³ The study looked at patterns from 308 NARCOMS registry participants who had reported a recent switch in DMT the 2011 general survey (**Table 1**).

Table 1. Patient Factors Associatedwith Switching³

| 308 NARCOMS registry participants (83.4% female) | | | |
|---|-------|--|--|
| Median PDDS score | 4 | | |
| Therapy at time of switch: | | | |
| Injectable | 35.4% | | |
| Infusion | 23.1% | | |
| Oral* | 41.6% | | |
| On DMT \geq 1 year before switch | 75% | | |
| Switch initiated by: | | | |
| Patient | 49% | | |
| Physician | 48.7% | | |
| Both | 1.3% | | |
| Reasons for switching: | | | |
| Patients with no disease activity | | | |
| Doctor's recommendation | 21.1% | | |
| Dislike of injections | 17.5% | | |
| Patients with some disease activity | | | |
| Doctor's recommendation | 27.5% | | |
| Adverse effects | 15.7% | | |
| Perceived lack of efficacy | 13.7% | | |

PDSS=Patient-Determined Disease Steps (4 indicates need for a cane) *Fingolimod (Gilenya®) was the only approved oral therapy at the time of the study.

Current NARCOMS data trends show a greater proportion of patients starting oral therapies, and in this study patients on an oral DMT were somewhat more likely to prefer staying on their current therapy (81.3%) compared with those on an infusion therapy (77.5%) or first-line injectable (63.6%).³ However, patients on oral therapies were also more likely than their physician to have initiated the discussion to switch. Interestingly, only 14% of those surveyed said they had used information obtained from the Internet as a basis for initiating the discussion. As shown in Figure 1, a large proportion of patients switched even though there was an absence of relapse activity (1A) or worsening of MS symptoms in the prior year (1B).³

Initial Therapy Selection

The goal for therapy in MS

remains to select the best initial treatment based on the disease presentation, the patient's baseline characteristics, and other individual factors.⁴ However, there is no exact formula that presents us with a clear choice based on patient characteristics or medical history. With many potential options available now for each patient, this decision-mak-



Figure 1. Patients Switching Despite Absence of Relapse Activity (A) or Absence of Symptom Worsening (B)

Reprinted from: Salter AR, Marrie RA, Agashivala N, et al. Patient perspectives on switching disease-modifying therapies in the NARCOMS registry. *Patient Prefer Adherence*. 2014;8:971-979. Creative Commons License 3.0 (http://creativecommons.org/licenses/by-nc/3.0/#)

ing process has become more complex (Table 2).

Discussing initial therapy with the patient

Presenting a patient who is newly diagnosed with MS with too many DMT choices is likely to be confusing or overwhelming. A better way may be to start with a general overview and then nar-

| Injectable | Interferon beta-1a (IM) Interferon beta-1a (SC) Interferon beta-1b (SC) Peginterferon beta-1a | Avonex Rebif Betaseron Extavia Plegridy |
|------------|--|---|
| Infusion | Natalizumab Alemtuzumab | Tysabri Lemtrada |
| Oral | Fingolimod Teriflunomide Dimethyl fumarate | Gilenya Aubagio Tecfidera |

Table 2. Approved* Therapies forRelapsing-Remitting MS

*as of December 2014.

row the options down to 2 or 3 that appear to be most appropriate for that individual. This allows the person and his or her family or support person to go home, absorb the information, and think about the options more concretely. Although therapy should be started as soon as is realistically possible, rushing into an initial choice before the person is truly ready may be counterproductive in the long run. A person who starts treatment before he or she is ready or has considered his or her options carefully is more likely to stop therapy or be nonadherent initially or early in the course of treatment.⁵ Data show that between 17% and 41% of patients with MS ultimately discontinue DMT and most do so in the first 1 to 2 years of treatment.5-9

Studies have established that most patients with MS want to be part of shared decision-making process in therapeutic selection.¹⁰ People who feel they have a "say" in their therapeutic decisions are more likely to adhere to therapy.¹¹⁻¹³ Shared decision-making involves the exchange of information, in which the healthcare provider contributes experience and information, and the patient com-

municates details about values, risk tolerance, and goals for treatment.¹⁴ But, how much of the initial choice in therapeutic selection truly rests with the patient? Even with an ideal give-and-take process there are typically some limitations on what therapies are appropriate for the individual, based on contraindications or safety issues. The patient should be made aware if he or she is not a candidate for a certain drug. An algorithm for initial therapeutic selection in relapsing-remitting MS (RRMS) was recently developed by a consensus group convened among Consortium of Multiple Sclerosis Centers (CMSC) members and published in the *International Journal of MS Care* (**Figure 2**).¹⁵

In addition, it may be necessary to determine initially which therapeutic choices are covered under the patient's health insurance or other medical plan. If one of these therapies is an appropriate fit for the patient, this can help to streamline the initial approval process. If a certain therapy is not covered, it may also help for the patient to be aware up front. Many payers require patients to start with a trial of a medication that falls within preferred formulary categories and to have a documented "failure" on one or more of these therapies before switching to one on a second tier. The nurse may need to document the presence of intolerable adverse effects or adverse laboratory findings to justify a switch to a second-tier medication.

Determining Patient Reasons for Switches

There are many reasons supporting a change in DMT for people with MS. Switching to a different therapy may be warranted for efficacy, safety, or tolerability reasons, but problems with adherence to therapy are also a concern that should be



evaluated and addressed.^{4,16,17} Assessing a patient's reasons for a change in therapy is an important step in the shared decision-making process between the MS nurse, the prescribing physician, and the patient. A variety of possible reasons for switching were outlined recently in the *International Journal of MS Care* (**Table 3**).¹⁸

Clinical attacks may occur relatively infrequently in patients receiving DMT, making it difficult to establish the efficacy of a new agent in a time period of less than 6 months.¹⁹ In addition, some agents may require a number of months after start-up to reach full therapeutic efficacy.

Sometimes, a need to change therapy may arise because the current therapy is no longer reimbursed by the insurer or third-party payer. In these cases it may be up to the MS nurse to help determine whether such a change is appropriate for the patient therapeutically. For prior authorization to change a patient's therapy, insurers may require documentation of new MS symptoms, MRI changes, or ancillary evaluations such as lab results or eye examination findings.

Acute relapses while a patient is on therapy may indicate a suboptimal response.²⁰ Does a single acute attack represent a treatment failure, regardless of the patient's prior relapse rate? Expectations that DMT should completely eliminate MS relapses have been raised with the availability of newer therapies showing high relapse-reduction rates in controlled clinical trials. However, DMTs should not be regarded as conferring complete protection from relapses, and no existing DMT is thought to cure MS. At the same time, any relapse that a patient experiences while on therapy should

Table 3. Reasons for Switching DMTsin MS18

| Efficacy | No response or suboptimal therapeutic response Initial response followed by breakthrough disease Neutralizing antibodies leading to suboptimal response Introduction of new therapy that may offer better management of disease |
|--|---|
| Safety | Significant adverse events such as liver toxicity or decreased blood counts Comorbid condition or new safety consideration (e.g., pregnancy, development of renal disease) Change in patient's risk profile for adverse events (e.g., JC virus antibody conversion) Development of tolerability problems over time (e.g., skin damage) Introduction of new therapy that may offer better safety |
| Patient-related Reasons | Difficulties with adherence to therapy Desire to try different administration method Perceived lack of efficacy of current therapy Introduction of new therapy that may offer better tolerability |
| Prescriber- or Payer-related Reasons | Patient has new prescriber who switches therapy related Reasons Changes in practice of existing prescriber Change in payer or payer formulary choices forces switch due to lack of coverage |

prompt an increased level of monitoring, if not a treatment switch.¹⁸

Perceived lack of efficacy is a primary reason for patients to request a switch in therapy.^{21,22} This may be because the patient had anticipated that most or all MS symptoms (e.g., numbness, tingling, fatigue, or weakness) would be resolved with treatment. The perception that DMT should "cure" MS or eliminate any signs or possible progression persists and may even be conveyed by a healthcare provider by or misleading medical or web-based media. One of the most difficult aspects involved in educating the person with MS is conveying that *absence of change* (e.g., no worsening of disease) is the primary goal. It may be helpful to explain that the goal is to "freeze the person in time" with respect to MS worsening or progression.

In contrast, there are patients who believe that their therapy is working well for them, even when there are signs of worsening disease. These people may become accustomed to a DMT and the effects of MS and fail to notice subtle signs of disease worsening that may warrant further exploration. In these cases, giving the patient an opportunity to view new enhancing lesions on an MRI or other evidence of advancing disease may help the person to accept the need to explore a switch to a different DMT.

The issue of discontinuing DMT is controversial, especially in light of a recent Agency for Healthcare Research and Quality (AHRQ) report that claimed little evidence of efficacy for longterm treatment.²³ The AHRQ report has drawn much criticism from MS organizations such as the National Multiple Sclerosis Society, the Multiple Sclerosis Coalition, and others, which argued that healthcare providers and patients may misinterpret the document as justification to go off of treatment when they should not.²⁴ While this issue continues to be debated, it is important that patients not discontinue DMT unless advised by their healthcare professional.

The Role of Patient Adherence in Switching

Is the best MS therapy simply one that the individual will use correctly and consistently? Efficacy and safety matters must be given precedence, but considerations of adherence are tied closely to both of these issues. Obviously, if the drug is not being taken at therapeutic levels, its efficacy is a moot point. Similarly, problems with tolerability or worries about adverse effects are among the chief reason for patients to skip doses or discontinue therapy. In controlled clinical trials of MS therapies, efficacy rates appear to be reasonably high, but the available "real life" data tell another story, as shown in **Table 4**.^{5,6,9,25-28}

Most of the adherence analyses done in MS to date were performed in patient groups receiving injectable therapies. Limited data are available adherence to oral therapies, but one study suggested that medication possession ratio was higher in patients receiving fingolimod (versus injectable therapies) and rates of discontinuation were lower.²⁹ While taking a pill is easier for most people than administering an injection, it is common for patients on oral MS therapies (and oral therapies in general) to miss doses or discontinue.²¹ For example, if an oral drug has a twicedaily dosage schedule, patients admit they often skip the second dose because of forgetfulness or to avoid adverse effects such as gastrointestinal upset.

True adherence to therapy is difficult to measure because it relies on a person's honest recounting of medication doses taken. Most patients overreport their adherence,³⁰ while physicians and other healthcare providers tend to over-estimate the degree to which their patients are taking the

Table 4. Adherence Studies for MS Disease-Modifying Therapies

| Author (Location, years studied) | Agents/Reporting methods | Findings |
|---|--|--|
| Correlative Analyses of Adherence in RRMS (CAIR, Netherlands) ⁵ | Glatiramer acetate Patient self-report | Patients reported missing 30% of doses 6-month discontinuation rate 27% Most patients discontinued in first 12 months |
| Tremlett 2003 (British Columbia, 1995–2001) ⁶ | Interferon beta-1b Chart review for interruptions in therapy | Most interruptions occurred in first 6 months Most common reason was perceived lack of efficacy |
| Tremlett 2008 (Southern Tasmania, 2002–2005) ²⁵ | Injectable agents Prospective, population-based study | 73% of patients missed doses 1 in 10 patients missed > 10 doses in any 6-month period History of missed doses predicted future missed doses (<i>P</i><0.0005) |
| Wong 2011 (Ontario, Canada, 2006–2008) ⁹ | Injectable agents Retrospective cohort study | 74%–79% patients remained on therapy at 6 months 60% remained on therapy at 1 year 41%–47% remained on therapy at 2 years Rates of discontinuation were similar for all injectable DMTs |
| Halpern 2011 (Claims database for major US health plan, 2000–2008) ²⁶ | Injectable agents Medication possession ratio (MPR) | • Between 40% and 50% were nonadherent (defined as MPR < 80%) |
| Treadaway 2009 (US) ²⁷ | Web-based survey of MS patients | 36%–39% reported missing ≥1 dose in previous 4 weeks Forgetfulness was cited as most common reason for nonadherence (58% of patients) |
| de Seze 2012 (France) ²⁸ | Injectable agents, patient surveys | 42% reported missing injections "from time to time"17% reported taking "drug holidays" |

therapies they prescribe.³¹ In a study based on a survey of 331 patients with MS and 280 physicians in 7 countries, the proportion of patients who admitted to taking a treatment "break" (31%) was nearly twice the proportion estimated by physicians (17%).³²

When asking patients about their adherence to therapy, open-ended questions ("How many of your doses would you say you have skipped?") are generally more effective than closed-ended questions (e.g., "Are you taking your medicine?"). Patients may exaggerate their adherence in order to avoid confrontation with their doctor or to avoid appearing uncooperative.²⁸ It is usually helpful for the MS nurse to acknowledge how common adherence problems are for other patients—stressing for patients that they're not alone in facing these challenges. A first step to addressing adherence problems is to help patients identify their own specific barriers to using their therapy as directed. (**Table 5**).^{22,33}

An increasing number of reminder systems are available to help increase patient adherence to medication therapies. Studies in other health conditions such as diabetes, smoking cessation, and hypertension have shown that cell-phone text messaging systems that prompt patients with reminders are effective at increasing adherence.34-36 Some MS-specific Web-based and smart-phone technologies are available, some of which include medication reminders. These include Track-MyShots and the Multiple Sclerosis Association of America's mobile phone app, "Multiple Sclerosis Self-Care Manager." Even a simple electronic alert programmed into a smartphone may be helpful to signal the time for taking a medication. However, one must bear in mind that these "novelty factor" of these technologies may wear off over time for some patients.

Conclusion

Switching therapies is expected to become more common with the introduction of more therapeu-

Table 5. Common Barriers toAdherence in MS22,33

- Unrealistic expectations about the impact of therapy on MS
- Lack of belief in the benefits of therapy
- Fear of or intolerance to injection (with injectable agents)
- Adverse effects/tolerability problems
- Complacency, "treatment fatigue"
- Cognitive decline or declining motor skills
- Change in family or financial circumstances

tic options for MS. Some newer therapies being introduced in MS present greater long-term health risks and higher needs for safety monitoring than the original injectable therapies. When initiating conversations with patients about starting a new DMT or a potential switch in therapy, it is important to keep in mind the patient's level of health literacy and what he or she is able to comprehend and accept in a given encounter. Concepts related to MS treatment will be totally unfamiliar to most patients, so starting from the beginning is necessary whether discussing a new treatment or switch until the patient has become educated about MS treatments. Discussions about switching therapies should be initiated with an open mind to the patient's reason for a switch, potential barriers to certain therapies, and what is practical from a reimbursement standpoint.

References

- 1. Reynolds MW, Stephen R, Seaman C, et al. Healthcare resource utilization following switch or discontinuation in multiple sclerosis patients on disease modifying drugs. *J Med Econ.* 2010;13(1):90-98.
- Schafer JA, Gunderson BW, Gleason PP. Price increases and new drugs drive increased expenditures for multiple sclerosis. J Manag Care Pharm. 2010;16(9):713-717.
- Salter AR, Marrie RA, Agashivala N, et al. Patient perspectives on switching disease-modifying therapies in the NARCOMS registry. *Patient Prefer Adherence*. 2014;8:971-979.
- 4. Coyle PK. Switching therapies in multiple sclerosis. CNS Drugs. 2013; 27(4):239-247.
- Jongen PJ, Hengstman G, Hupperts R, et al. Drug adherence and multidisciplinary care in patients with multiple sclerosis: protocol of a prospective, web-based, patient-centred, nation-wide, Dutch cohort study in glatiramer acetate treated patients (CAIR study). *BMC Neurol.* 2011;11:40.
- 6. Tremlett HL, Oger J. Interrupted therapy: stopping and switching of the beta-interferons prescribed for MS. *Neurology*. 2003;61(4):551-554.
- Rio J, Porcel J, Tellez N, et al. Factors related with treatment adherence to interferon beta and glatiramer acetate therapy in multiple sclerosis. *Mult Scler.* 2005;11(3):306-309.
- Giovannoni G, Southam E, Waubant E. Systematic review of disease-modifying therapies to assess unmet needs in multiple sclerosis: tolerability and adherence. *Mult Scler.* 2012;18(7):932-946.
- Wong J, Gomes T, Mamdani M, et al. Adherence to multiple sclerosis disease-modifying therapies in Ontario is low. *Can J Neurol Sci.* 2011; 38(3):429-433.
- Heesen C, Kasper J, Kopke S, et al. Informed shared decision making in multiple sclerosis--inevitable or impossible? J Neurol Sci. 2007;259(1-2):109-117.
- Caon C, Saunders C, Smrtka J, et al. Injectable disease-modifying therapy for relapsing-remitting multiple sclerosis: a review of adherence data. J Neurosci Nurs. 2010;42(5 Suppl):S5-9.

- Fraser C, Hadjimichael O, Vollmer T. Predictors of adherence to Copaxone therapy in individuals with relapsing-remitting multiple sclerosis. J Neurosci Nurs. 2001;33(5):231-239.
- Saunders C, Caon C, Smrtka J, et al. Factors that influence adherence and strategies to maintain adherence to injected therapies for patients with multiple sclerosis. J Neurosci Nurs. 2010;42(5 Suppl):S10-18.
- Kasper J, Heesen C, Köpke S, et al. Patients' and observers' perceptions of involvement differ. Validation study on inter-relating measures for shared decision making. *PloS One*. 2011;6(10):e26255.
- 15. Best practices for therapeutic selection in remitting relapsing multiple sclerosis. Int J MS Care. 2014;16(Suppl 5):6-12.
- Healy BC, Glanz BI, Stankiewicz J, et al. A method for evaluating treatment switching criteria in multiple sclerosis. *Mult Scler.* 2010;16(12): 1483-1489.
- Clerico M, Barbero P, Contessa G, et al. Adherence to interferon-beta treatment and results of therapy switching. J Neurol Sci. 2007;259(1-2):104-108.
- Switching disease-modifying therapies due to lack of efficacy. Int J MS Care. 2014;16(Suppl 5):6-12.
- Haynes RB, McDonald H, Garg AX, et al. Interventions for helping patients to follow prescriptions for medications. *Cochrane Database Syst Rev.* 2002(2):CD000011.
- 20. Cohen BA, Khan O, Jeffery DR, et al. Identifying and treating patients with suboptimal responses. *Neurology*. 2004;63(12 Suppl 6):S33-40.
- 21. Patti F. Optimizing the benefit of multiple sclerosis therapy: the importance of treatment adherence. *Patient Prefer Adherence*. 2010;4:1-9.
- Costello K, Kennedy P, Scanzillo J. Recognizing nonadherence in patients with multiple sclerosis and maintaining treatment adherence in the long term. *Medscape J Med.* 2008;10(9):225.
- Agency for Healthcare Research and Quality. Discontinuation of Disease-Modifying Treatment for Multiple Sclerosis. Research Protocol – Dec 17, 2013. Available at: http://effectivehealthcare.ahrq.gov/index.cfm/searchfor-guides-reviews-and-reports/?productid=1833&pageaction=displaypro duct.
- McKelvey C. MS community flares over AHRQ report: controversy erupts over review of MS drug discontinuation strategies. *MedPage Today*. Nov 17, 2014. Available at: http://www.medpagetoday.com/Neurology/MultipleSclerosis/48649.

- Tremlett H, Van der Mei I, Pittas F, et al. Adherence to the immunomodulatory drugs for multiple sclerosis: contrasting factors affect stopping drug and missing doses. *Pharmacoepidemiol Drug Safety*. 2008;17(6):565-576.
- 26. Halpern R, Agarwal S, Dembek C, et al. Comparison of adherence and persistence among multiple sclerosis patients treated with diseasemodifying therapies: a retrospective administrative claims analysis. *Patient Prefer Adherence*. 2011;5:73-84.
- 27. Treadaway K, Cutter G, Salter A, et al. Factors that influence adherence with disease-modifying therapy in MS. J Neurol. 2009;256(4):568-576.
- de Seze J, Borgel F, Brudon F. Patient perceptions of multiple sclerosis and its treatment. *Patient Prefer Adherence*. 2012;6:263-273.
- Agashivala N, Wu N, Abouzaid S, et al. Compliance to fingolimod and other disease modifying treatments in multiple sclerosis patients, a retrospective cohort study. *BMC Neurol.* 2013;13:138.
- Zeller A, Ramseier E, Teagtmeyer A, et al. Patients' self-reported adherence to cardiovascular medication using electronic monitors as comparators. *Hypertens Res.* 2008;31(11):2037-2043.
- Lugaresi A, Ziemssen T, Oreja-Guevara C, et al. Improving patient-physician dialog: commentary on the results of the MS Choices survey. *Patient Prefer Adherence*. 2012;6:143-152.
- Rinon A, Buch M, Holley D, et al. The MS Choices Survey: findings of a study assessing physician and patient perspectives on living with and managing multiple sclerosis. *Patient Prefer Adherence*. 2011;5:629-643.
- Bayas A. Improving adherence to injectable disease-modifying drugs in multiple sclerosis. Expert Opin Drug Deliv. 2013;10(3):285-287.
- Derose SF, Green K, Marrett E, et al. Automated outreach to increase primary adherence to cholesterol-lowering medications. JAMA Intern Med. 2013;173(1):38-43.
- Vervloet M, van Dijk L, Santen-Reestman J, et al. SMS reminders improve adherence to oral medication in type 2 diabetes patients who are real time electronically monitored. *Int J Med Inform.* 2012;81(9):594-604.
- Lin H, Wu X. Intervention strategies for improving patient adherence to follow-up in the era of mobile information technology: a systematic review and meta-analysis. *PLoS One.* 2014;9(8):e104266.

Advising Patients About Disease-Modifying Therapy Selection and Switching

Counseling Points^m

- Presenting a newly diagnosed patient with too many disease-modifying therapy (DMT) choices is likely to be overwhelming. A better way may be to start with a general overview and then narrow the options down to 2 or 3 that appear to be most appropriate for that individual.
- Rushing into an initial choice before the person is ready may be counterproductive. If this occurs, the patient may be more likely to discontinue or have low adherence early in the course of treatment.
- In the selection of therapy, it may be necessary to determine up front which therapeutic choices are covered under the patient's health insurance or other medical plan.
- Assessing a patient's reasons for requesting a change in therapy is an important step in the shared decision-making process between the MS nurse, the prescribing physician, and the patient.
- Switching to a different therapy may be warranted for efficacy, safety, or tolerability reasons. Sometimes, a need to switch may arise because the therapy is no longer reimbursed by the insurer or third-party payer.
- Perceived lack of efficacy is a primary reason for patients to request a switch in therapy. The patient may have thought that MS symptoms (such as numbness or weakness) would be resolved with treatment.
- It is important to convey to patients that *absence of change* (no worsening of disease) is the primary goal for DMT in MS.
- True adherence to therapy is difficult to measure because it relies on a person's honest recounting of medication doses taken. Most patients over-report their adherence.
- A first step to addressing adherence problems is to help patients identify their own specific barriers to using MS therapies as directed. These barriers should be discussed at every encounter with the patient.
- Electronic reminders (including apps on smartphones or tablets) can be a good way for patients to track doses and adhere to monitoring requirements for MS therapies.

Counseling Points[™]

Advising Patients About Disease-Modifying Therapy Selection and Switching

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% (8 correct) or better. A certificate will be mailed within 4 to 6 weeks. There is no charge for CNE credit.

By Mail: Delaware Media Group, 66 S. Maple Ave., Ridgewood, NJ 07450. 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 Educational Materials > Publications > *Counseling Points* and follow the instructions to complete the online post-test and application forms.

PLEASE SELECT THE BEST ANSWER

- 1. Research on patterns of switching in multiple sclerosis (MS) shows that most patients who switch:
 - a. have a lapse (period of no treatment) between therapies, which may increase risk of relapse
 - b. transition from one therapy to the next with no break in between
 - c. are advised by their physicians to have a "washout period" of 3 to 5 months between therapies
 - d. wait until they have a relapse of MS before starting a new therapy
- 2. North American Research Committee on Multiple Sclerosis (NARCOMS) registry data show that switches in therapy are usually initiated by:
 - a. the person with MS
 - b. the physician
 - c. the person with MS or the physician at equal rates
 - d.the insurer or third-party payer
- 3. True or False: According to the recent NARCOMS survey on switching therapies, most people with MS who decided to switch did so because of something they read on the Internet.
 - a. True
 - b. False
- 4. When discussing an initial disease-modifying therapy (DMT), the faculty recommends that patients be given: a. information about the one DMT that seems best for that person's medical history and lifestyle
 - b. comprehensive information about all of the approved MS DMTs
 - c. information about 2 or 3 therapies to take home and consider before making a decision
 - d.a choice between a few DMTs for a decision that same day, to ensure that the person starts therapy immediately
- 5. The concept of shared decision-making in MS is important because:
 - a. people who have a say in therapeutic decisions are more likely to stay on a DMT
 - b. patients benefit from the healthcare professional's insight when making an informed decision
 - c. patients' values, risk tolerance, and goals for treatment should be considered
 - d.all of the above
- 6. When advising patients about the role of reimbursement in DMT selection, it is generally accurate to state that:
 - a. if a therapy is deemed medically appropriate for the patient, most payers will cover its cost
 - b. payers are required to provide coverage for all FDAapproved drugs for MS

- c. patients may need to start on an agent in the payer's "preferred" group or tier, and demonstrate failure on that agent before a switch to a second-tier agent is authorized
- d. the prescribing physician has the final say when it comes to selection of a DMT
- 7. A patient in your practice has requested to change to a different DMT because he feels the therapy is not working for him. He has been using this particular agent for 3 months. The most appropriate response would be:
 - a. tell him he should wait a little longer to see if the drug is working or not
 - b. conduct an examination to detect possible clinical worsening, nonadherence, or need for additional evaluation
 - c. assume that the patient has not been taking the drug as directed
 - d.make arrangements to switch therapies to the agent the patient has requested
- 8. A single acute attack of MS in the course of a year while a patient is on DMT should warrant:
 - a. a change to a different therapy
 - b. a change to a more aggressive therapy
 - c. no change; one relapse is realistic
 - d. an increased level of monitoring and consideration of a switch
- 9. One of your patients appears to be having signs of worsening disease. You suggest a switch, but she says she feels fine and wants to stay on her current therapy. The faculty recommends:
 - a. keeping her on her current therapy; if she's happy, she's more likely to take it
 - b. keeping her on the therapy and suggesting a follow-up in 6 months to see if the worsening condition has continued
 - c. showing the patient an MRI or other evidence of worsening disease to support the discussion about switching
 - d.asking the physician to step in and talk some sense into the patient
- 10. The recent report by the Agency for Healthcare Research and Quality (AHRQ) on discontinuation of MS therapies after 2 years was:
 - a. contested by several large MS organizations as being potentially misleading
 - b. jointly developed by the American Academy of Neurology (AAN) and Consortium of MS Centers (CMSC)
 - c. considered the definitive statement about how long patients should stay on therapy
 - d. republished by the AAN and CMSC as a clinical practice guideline

Counseling Points[™]: **Program Evaluation Form**

Advising Patients About Disease-Modifying Therapy Selection and Switching

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 the role and benefits of patient participation in selection of disease-modifying therapies (DMTs) | | | | | | |
| 2) Review other factors that affect therapeutic selection (e.g. paye | er limitations, medical contraindicat | lons) | | | | |
| 3) Discuss situations leading to switches in DMTs and patient involvement in decision making | | | | | | |
| To what extent was the content: | | | | | | |
| 4) Well-organized and clearly presented | | | | | | |
| 5) Current and relevant to your area of professional interest | | | | | | |
| 6) Free of commercial bias | | | | | | |
| 7) Clear in providing disclosure information | | | | | | |
| General Comments | | | | | | |
| 8) As a result of this continuing education activity (check only | v one): | | | | | |
| \Box I will modify my practice. (If you checked this box, ho | w do you plan to modify your pr | actice?) | | | | |
| I will wait for more information before modifying my | practice. | | | | | |
| The program reinforces my current practice. | 1 | | | | | |
| 9) Please indicate any barriers you perceive in implementing th | hese changes (check all that apply) | : | | | | |
| □ Cost □ Lack of opportunity (patients) | D Patient adherence issues | □ Other (please specify) | | | | |
| □ Lack of administrative support □ Reimbursement/insurance | □ Lack of professional guide | elines | | | | |
| □ Lack of experience □ Lack of time to assess/counsel p | patients 🗖 No barriers | | | | | |
| 10) Will you attempt to address these barriers in order to impl Tyes. How? Not applicable Not applicable | ement changes in your knowledg | e, skills, and/or patients' outcomes? | | | | |
| \Box No. Why not? | | | | | | |
| Suggestions for future topics/additional comments: | | | | | | |
| Follow-up | | | | | | |
| As part of our continuous quality-improvement effort, we continual interventions on professional practice. Please check one | nduct postactivity follow-up surve : ip survey. w-up survey. | ys to assess the impact of our educa- | | | | |
| There is no fee for this educational activity. | | | | | | |
| Post-test Answer Key | 6 4 5 6 | 7 8 9 10 | | | | |
| Request for Credit (Please print clearly) | | | | | | |
| Name | Degree | | | | | |
| Organization | Specialty | | | | | |
| Address | | | | | | |
| City | Chaka | ZID | | | | |
| | State | ZIT | | | | |
| Phone Fax | E-mail | | | | | |

Signature _____

By Mail: Delaware Media Group, 66 S. Maple Ave., Ridgewood, NJ 07450

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 Educational Materials > Publications > Counseling Points and follow the instructions to complete the online post-test and application forms.

_____ Date _____





www.delmedgroup.com