Encouraging Monitoring and Follow-up in MS Care

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Counseling Points™

Encouraging Monitoring and Follow-up in MS Care

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 who treat patients with MS with information and practice advice related to safety monitoring and follow-up associated with MS disease-modifying therapies.

Learning Objectives

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

- Discuss current challenges associated with pre-treatment monitoring for MS disease-modifying therapies (DMTs)
- Assess methods for recommending and encouraging regular follow-up while on MS DMT
- Review how appropriate monitoring can prevent complications of MS DMTs

Continuing Education Credit

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This activity has been awarded 1.0 contact hours (1.0 contact hours are in the area of pharmacology). Code: MSCP04015.

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Dear Colleague,

Discussing safety risks and monitoring patients for potential adverse effects of treatment are increasingly important parts of management of MS. We want each patient with MS to receive the most efficacious therapy that is appropriate for that individual. But we also need to balance the potential for efficacy with safety, tolerability, and willingness to adhere to therapy.

The growing number of therapeutic options for MS has broadened this decision-making process greatly. In most respects, this is a positive step forward. At the same time, MS nurses need to apply a more comprehensive approach to preparing patients for treatment and following patients on treatment. We need to be aware of how a DMT affects other aspects of a patient’s health. We need to educate and inform our patients about the potential risks involved with some treatment approaches. And, we need to make sure that patients are evaluated to determine whether the therapy is achieving its goals for suppression of MS disease activity.

Most MS nurses face the challenges of increased time constraints, paperwork burden, and frustration when a therapeutic plan does not go forward as intended. Our nurse panelists discuss the challenges they are facing now, and those anticipated for the future as more new DMT categories are introduced. I hope you are able to benefit from these insights.

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Encouraging Monitoring and Follow-up in MS Care

In a neurology clinic that manages approximately 200 patients with multiple sclerosis (MS), a newly hired neurology nurse practitioner (NP) is asked to review the charts of all active patients with a diagnosis of MS, to determine if they are up-to-date with the monitoring requirements needed to ensure safe and effective use of their disease-modifying therapies (DMTs). This sounds like a fairly straightforward task, so the NP begins with the practice’s electronic medical record system to see if there is a system in place for keeping track of patients’ blood test results, necessary eye exams, MRI data, etc. Unfortunately, the amount of information entered into this system seems to differ for each patient, and is incomplete for many of them. The NP starts making a list of the common problem areas where more information or follow-up appears to be needed:

- Some patients with MS have not had a follow-up appointment at the clinic for at least a year.
- In some cases, it’s not clear whether patients are actually taking the most recent MS DMT prescribed, if they ever filled the initial prescription, or if they have returned to obtain appropriate refills.
- There is no single place to look to review current results of safety monitoring. Patients appear to be “on their own” to obtain most lab tests, eye exams, and follow-up MRI studies. Only a few patients regularly report back or bring copies of their lab results to the clinic.
- Notes in the charts indicate that many patients have encountered significant delays in obtaining their DMT due to difficulties getting through the prior authorization system.
- When some patients have tried to refill their medications, they are sometimes told by the pharmacy they need a particular test first. It’s not clear from the chart whether the person completed these steps and was able to refill the medication.

This practice may sound particularly disorganized, but in fact it may be closer to the norm than the exception. Rapid changes in the MS therapeutic environment have demanded a much more personalized system for initiating and following patients on their therapies. However, increasing complexity in both reimbursement and patient monitoring and follow-up have made it difficult for MS care providers in most practice settings to keep up with the demand for more hands-on care. This is true not only in MS, but also in other disease states such as cancer and rheumatoid arthritis, where personalized medicine goals are coupled with higher-cost specialty pharmaceuticals. In these settings, nurses face increasing challenges for communication, support, and advocacy for patients.

Balancing the best possible treatment outcomes with the need to minimize complications, maximize adherence to therapy, and control costs often
presents a set of conflicting goals. How to help patients accomplish these goals in a day-to-day MS care setting is the focus of this discussion.

**Need for Safety Monitoring in MS Therapies**

At one time, a complete blood count (CBC), a complete metabolic panel (CMP), and regular magnetic resonance imaging (MRI) studies made up the mainstay of lab and radiologic tests for most patients with MS. Today, depending upon which DMT is prescribed, many other types of monitoring could be part of the required protocols, including pulmonary function tests, tuberculin skin tests, negative pregnancy test, serum JC virus (JCV) and varicella antibodies, ECG and heart rate monitoring, and ophthalmic screening for macular edema. Regardless of which DMT is selected, safety monitoring is a necessary step that cannot be overlooked by people with MS or those involved in their care. Increasingly, payers and health care organizations require that patients remain current on blood monitoring and other necessary evaluations before they will approve prescription refills for MS drugs or authorize reimbursement. All MS therapies require follow-up and monitoring to ensure safety and tolerability. However, many of the more newly introduced therapies have prompted different types of monitoring that were not previously needed in MS care practices. As more new agents are introduced (including the newly approved drug, alemtuzumab, and other biologic therapies in the pipeline), a greater variety of tests will be needed to detect early signs of potential serious adverse effects in patients receiving these treatments.

The specific monitoring requirements and/or “risk evaluation and mitigation strategy” (REMS) for each of the approved MS agents have been subject to frequent changes and updates. Thus it is advisable for practitioners who treat patients with MS to keep track of the most current labeling information for each drug and to check for updates regularly. REMS systems for some of the higher-risk agents (such as alemtuzumab or natalizumab) include careful monitoring and record keeping among the requirements for prescribing the drug. For example, according to the Lemtrada (alemtuzumab) REMS program, “prescribers are required to keep track of laboratory monitoring status of all patients who have been infused with Lemtrada from the first infusion until 48 months after the last infusion.” Monitoring of CBC, serum creatinine, and urinalysis with urine cell counts must be completed monthly for 4 years after the last infusion of alemtuzumab, and tests of thyroid function status are required every 3 months. Patient status forms must be completed by prescribers every 6 months. For other MS DMTs, the individual clinic or practice may need to create its own systems to better track patient monitoring information. Some of the monitoring steps for each of the agents are listed in Table 1.
In many practices, keeping up with this information will warrant a need for new in-office protocols for testing and surveillance of patients with MS to ensure that they are tolerating therapy and receiving the recommended tests to monitor for potential adverse events. Some practices also ask patients to document in writing that they have received education about the risks of MS therapies and that they are aware of their own responsibilities for monitoring and follow-up while receiving the drug. Determining the patient’s level of health literacy is an important aspect of this process. The Agency for Healthcare Research and Quality (AHRQ) offers an online Health Literacy Toolkit that includes a number of useful resources toward this goal, including:

- Health Literacy Assessment Tool and User’s Guide
- Training Program for Healthcare Staff on Communication
- Telephone Reminder Tool to Help Refill Medicines on Time

### Infectious Complications of MS Therapies

The development of newer immunomodulating therapies for MS has introduced new infectious risks and immune-mediated effects that are not normally encountered in patients with MS. These include opportunistic infections, which are defined as “illnesses caused by organisms that would not usually cause disease in a person with a normally functioning immune system.” Immuno-modulation in MS may also lead to unexpected presentations of more typical infections (such as herpesvirus), development of malignancies, and risk of autoimmune conditions such as thyroid disease.

Natalizumab increases the risk of opportunistic infections because it prevents inflammatory cells from performing immunosurveillance of the central nervous system. This risk appears to be largely confined to one serious CNS infectious
disorder, progressive multifocal leukoencephalopathy (PML). PML is a demyelinating white matter disease caused when the JC polyomavirus (JCV) proliferates in the CNS. The virus infects the oligodendrocytes and causes their death by necrosis and demyelination. PML may develop in patients with underlying immunosuppressive conditions (e.g., Hodgkin’s lymphoma, AIDS), but its incidence has been steadily increasing in people with MS treated with monoclonal antibodies such as natalizumab. PML risk stratification has been discussed extensively in other literature, including a comprehensive Supplement to the International Journal of MS Care. 

Infectious complications associated with MS therapies are summarized in Table 2. For some drugs, the reported infectious complications have been observed mainly in other disease states such as rheumatoid arthritis or leukemia.

Use of interferons or glatiramer acetate are not associated with increased risk of infections, as demonstrated through more than 20 years of use. Treatment with interferon may result in mild leukopenia, but there are no reports of opportunistic infections in patients with MS treated with these agents. A study by Miller and colleagues to determine whether treatment with any interferon or glatiramer acetate would decrease expression of JC virus did not show an

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<th>Therapy</th>
<th>Potential Infectious Complications in MS</th>
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<tr>
<td>Interferon beta-1a</td>
<td>May cause neutropenia or lymphopenia. Rarely of clinical significance in MS.</td>
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<tr>
<td>Interferon beta-1b</td>
<td>None¹</td>
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<tr>
<td>Glatiramer acetate</td>
<td>Risk of opportunistic infection from severe leukopenia.²⁴ Urinary tract infection, pneumonia, varicella zoster, herpes simplex (0.6% of treated patients)</td>
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<tr>
<td>Mitoxantrone</td>
<td>Varicella zoster encephalitis and vasculopathy, herpes simplex encephalitis, PML (rare; cases may be associated with prior natalizumab use)²⁵-²⁷</td>
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<tr>
<td>Fingolimod</td>
<td>PML, herpes simplex, varicella zoster, CNS and ocular toxoplasmosis, human herpesvirus 6 (HHV6) reactivation²²,²⁸-³¹</td>
</tr>
<tr>
<td>Natalizumab</td>
<td>Hepatitis B reactivation, Pneumocystis pneumonia, about 80 cases of PML. Serious infections are rare among large populations treated for RA²²,³³</td>
</tr>
<tr>
<td>Rituximab*</td>
<td>Similar to placebo³⁴</td>
</tr>
<tr>
<td>Teriflunomide</td>
<td>None noted in pivotal trials. Rare cases of PML in psoriasis patients treated with fumarate. One PML case in patient with MS taking drug for 4.5 years (lymphopenia 3.5 years)³⁵,³⁶</td>
</tr>
<tr>
<td>Dimethyl fumarate</td>
<td>None noted in pivotal trials. Rare cases of PML in psoriasis patients treated with fumarate. One PML case in patient with MS taking drug for 4.5 years (lymphopenia 3.5 years)³⁵,³⁶</td>
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<tr>
<td>Alemtuzumab**</td>
<td>In organ transplant population, 50% greater risk of opportunistic infection; 2X risk of CMV reactivation; increased risk of fungal infections; 7 cases of PML in patients with immunosuppression (lung transplant, chronic lymphocytic leukemia). Prophylaxis is recommended to limit varicella zoster or herpes simplex activation or reactivation. ⁷-⁹</td>
</tr>
</tbody>
</table>

CMV=cytomegalovirus; PML= progressive multifocal leukoencephalopathy; RA=rheumatoid arthritis
*Not approved for use in MS; data based on use in rheumatoid arthritis
**Infectious complications based on use in organ transplant population
### How Well Do People With MS Understand Risk of Therapies?

**Survey Results from the NARCOMS Registry**

**Goal of Study:** To determine how well MS patients understand risks of serious complications related to therapies.

**Methods:** 10,259 people with MS in the NARCOMS Registry were invited to complete a web-based questionnaire on treatment decision-making. Several standard “gambling paradigms” were used to identify maximal risk tolerance, with risk described numerically (i.e. 1:1000) and graphically. Two scenarios presented to patients were “completely cure MS” and “prevent a one-step progression of disability on the Patient Defined Disease Steps (PDDS) scale.” The researchers used logistic regression analysis to study inconsistency among the responses.

**Results:** 5,446 people with MS completed the survey. Demographics included:
- Mean age: 52.7 years
- % female: 78
- Mean disease duration: 13.9 years
- Mean PDDS score: 3.2
- % on MS DMT: 74%

Female sex and higher education were, to the investigators’ surprise, associated with “illogical pairings,” which suggested a disconnect between the level of risk presented and the hypothetical decision made by the patient. In another analysis of the same data, increased risk tolerance was associated with higher levels of disability, male sex, and among patients not currently on an MS DMT.

**Conclusion:** “These observations suggest that additional attention is needed by clinicians in explaining risk of serious complications to MS therapies.”


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**How Prepared are Patients to Take Risks?**

As the therapeutic options for MS have expanded, we have begun to learn more about acceptance of risk as it relates to the disease. For patients, this means knowingly accepting potential health risks that could be permanent (e.g., thyroid dysfunction) or even fatal (e.g., PML) as part of achieving control over the disease process. This concept may be akin to patients with cancer who accept the risks and potential long-term health effects associated with aggressive chemotherapy regimens in exchange for a chance at remission. These are difficult decisions to make for a person who may still be trying to grapple with the shock of an MS diagnosis and what it means for one’s future. In addition, many people experience changes in their belief sets and risk acceptance as they age and enter different life stages.

For patients who experience worsening disease or a particularly aggressive MS disease course, a greater degree of risk may be needed to gain control over the disease and may override other factors. A 2010 survey by Heesen and colleagues of 69 natalizumab-treated patients treated and 66 neurologists suggested that patients with MS were willing to accept higher risks related to potential development of PML than were the physicians surveyed. Only 17% of patients said they would stop treatment with natalizumab when the risk of
PML reached 2 in 10,000 persons (compared with 49% of physicians who would stop the therapy). The authors also concluded that “patients had a significantly worse perception of MS as a malignant disease,” than did the neurologists surveyed. Patients also indicated being open to information about treatment-related risk and the shared decision-making process.

To what degree can people with MS—or even health professionals—understand the complex balance of risk and benefit associated with medical treatment? People watching consumer drug advertisements on television are often overwhelmed (or even bemused) by the long array of potential adverse effects that seem to overshadow any possible benefit of the drug. Research shows that these ads often lack the basic contextual information that could help a consumer to make an informed decision. Thus, most people “tune out” the information without being able to consider what it may mean for them.

The North American Research Committee on Multiple Sclerosis (NARCOMS) Registry allows researchers to tap into real-world views and experiences of a large population of people with MS. Using NARCOMS data, Robert Fox and colleagues recently explored how people with MS who are using a variety of therapies view the concept of risk. As described in the Sidebar, these authors found a wide spectrum of risk tolerance, with some variation based on gender, patient age, and severity of disease.

Expanding Patient Communication and Counseling Skills

Communicating risk and risk assessment is crucial to enable shared decision making with patients. Shared decision making is a concept that focuses on patient–provider communication in the medical decision-making process. In the exchange of information between the provider and the patient, the patient is encouraged to communicate values, risk attitudes, and treatment goals. Research about medication-taking risks in general indicates that patients tend to underestimate common risks, but overestimate the rarer risks. Furthermore, patients may respond to risks primarily on the basis of emotion rather than facts. “Individual patients do not experience ‘likelihood,’ or population-level rates of events. They experience single outcomes (something happens or does not).”

Statistical representations are often used to describe the risks of certain treatments, but patients’ have a limited ability to understand concepts such as relative risk reduction (RRR). It is also important to consider that each patient will have different priorities and risk tolerance and may change his or her perception and tolerance of risk over time. Key issues related to discussion of treatment risks with patients are summarized in Table 3.

Patients often answer “No” when asked if they
have any questions about their medications. This is usually not because they understand everything about the treatment—they simply don’t know enough about the medication to ask the right kinds of questions.\textsuperscript{50} In addition, patients may sense that the nurse or other healthcare provider doesn’t have time to answer all of their questions.

\section*{Effect of Reimbursement and Prior Authorization on Monitoring Needs}

As most healthcare providers know, prior authorization systems do not necessarily promote quick turnarounds. An analysis by Cohen and colleagues from Tufts University Medical School describes barriers related to reimbursement and diagnostic tests as “bottlenecks” that keep patients from getting the treatments prescribed for them.\textsuperscript{51} Many MS nurses have made a 3-month follow-up appointment and/or MRI appointment for a patient who was started on a new therapy, only to find that the person had not yet begun using the new agent within that time period. Is a 6-month follow-up time period more realistic? Some nurses recommend that the patient return in 6 months, regardless of whether a therapy has been started, to determine whether and why a delay has occurred. Some practices use automated software systems such as Covermymeds.com to help streamline prior authorization paperwork.\textsuperscript{52}

\section*{Conclusion}

New and emerging therapies will continue to have a major impact on the treatment of MS.
Even as safety concerns increase, it is important to keep in mind that control of the disease is also a crucial issue, and the standards for what constitutes successful therapy are on the rise. Further data are required on long-term safety profiles of new therapies to establish their exact role in treating different stages and forms of MS (early vs. established, mild vs. severe) and their placement in relation to the established treatments. Appropriate programs for monitoring adverse events for specific therapies will continue to be enhanced with increased knowledge of the specific dangers that each may present, and thus help to minimize potentially serious and life-threatening consequences while creating a higher standard of efficacy and improved outcomes for MS patients.

References

33. van Vollenhoven RF, Emery P, Bingham CO, 3rd, et al. Long-term safety of rituximab in rheumatoid arthritis: 9.5-year follow-up of the global...
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- MS nurses need to apply a comprehensive approach to preparing patients for treatment and monitoring patients on treatment.
- Selection of the most efficacious therapy for each individual with MS must be balanced with issues relating to safety, tolerability, and willingness to adhere to therapy.
- While all MS therapies require monitoring to ensure safety and tolerability, some newer therapies may require monitoring practices not previously required for MS.
- Risk evaluation and mitigation strategies (REMS) for the approved MS agents are subject to frequent changes, so it is advisable to keep track of the most current labeling updates.
- Some practices may implement in-office protocols for testing and surveillance of patients with MS to ensure that they are tolerating therapy and receiving the recommended monitoring.
- Reimbursement procedures such as prior authorization may delay the start of new treatment or a switch in therapy, so monitoring procedures may need to be adjusted to account for possible delays.
- Communicating risk is crucial to enable shared decision-making with patients. Some practices may ask patients to document in writing that they have received education about the risks of MS therapies.
- Patients’ acceptance of the complex balance of risk and benefit associated with medical treatment varies widely. Studies in MS show that patients are open to discussing risk and view MS as a serious enough disease to accept risk.
1. Patients with multiple sclerosis (MS) who are on disease-modifying therapy (DMT) should be monitored for safety and adverse effects of therapy:
   a. at initiation of therapy and after 6 months
   b. at initiation of therapy, after 3 months, and then every 6 months thereafter
   c. only if the patient complains about adverse effects or if lab results are abnormal
   d. this determination must be individualized for the specific DMT and the patient’s circumstances

2. A patient with MS in your practice has been prescribed a DMT, but 3 months later has not yet filled the prescription. An appropriate course of action would be:
   a. call the pharmacy and ask them to contact the patient
   b. wait another 3 months and then follow up to see if the patient has started on the drug
   c. follow up to determine whether insurance limitations or prior authorization requirements may be causing a delay
   d. assume that the patient is not yet ready to commit to regular use of a DMT

3. Electrocardiogram (ECG) and heart rate monitoring are part of the safety monitoring protocol for:
   a. fingolimod (Gilenya)
   b. natalizumab (Tysabri)
   c. alemtuzumab (Lemtrada)
   d. teriflunomide (Aubagio)

4. Monthly liver function testing is recommended for patients receiving which of the following DMTs?
   a. glatiramer acetate (Copaxone)
   b. interferon beta 1b (Betaseron)
   c. dimethyl fumarate (Tecfidera)
   d. teriflunomide (Aubagio)

5. Among patients receiving a DMT, complete blood count (CBC) is recommended:
   a. mainly for those on an immunosuppressive agent such as alemtuzumab
   b. only for those receiving an interferon
   c. for most patients, as a way to monitor immune cell response and infection risk
   d. primarily for patients with low white blood cell counts at initiation of therapy

6. Progressive multifocal leukoencephalopathy (PML) is caused when:
   a. immunosurveillance of the central nervous system (CNS) is blocked or inhibited
   b. JC virus proliferates in the CNS
   c. JC virus invades oligodendrocytes in the CNS
   d. all of the above

7. True or False? Leukopenia due to treatment with interferon-based DMTs has been associated with serious opportunistic infections among patients with MS.
   a. True
   b. False

8. In discussing risk acceptance with a patient in regard to a new MS therapy, the MS nurse should always:
   a. recognize that younger people are more open to accepting risk
   b. take into account the patient’s level of health literacy
   c. try to play down some of the least-likely, serious risks of DMTs
   d. encourage the patient that it’s worth taking on some greater health risks for better disease control

9. Research about medication use in general shows that patients:
   a. underestimate common risks
   b. overestimate serious risks
   c. have an accurate view of how adverse effects may impact their health
   d. both (a) and (b) above

10. Potential adverse effects of MS DMTs:
    a. are well understood based on pre-approval clinical trial data
    b. may not become apparent until after several years of postmarketing use
    c. are usually outweighed by the efficacy potential of the drug
    d. can always be detected early through monitoring
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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 current challenges associated with pre-treatment monitoring for MS disease-modifying therapies (DMTs) ................................................................. 5 4 3 2 1
2) Assess methods for recommending and encouraging regular follow-up while on MS DMT ........................................................................................................... 5 4 3 2 1
3) Review how appropriate monitoring can prevent complications of MS DMTs ...................................................................................................................... 5 4 3 2 1

To what extent was the content:

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

General Comments

8) 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?)
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   ☐ The program reinforces my current practice.
   ☐ No barriers
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   ☐ Lack of opportunity (patients)
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   ☐ 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
   ☐ Other (please specify)

9) Please indicate any barriers you perceive in implementing these changes (check all that apply):
   ☐ 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
   ☐ Other (please specify)

10) Will you attempt to address these barriers in order to implement changes in your knowledge, skills, and/or patients’ outcomes?
   ☐ Yes. How?
   ☐ No. Why not?

Suggestions for future topics/additional comments:

___________________________________________________________________________________________________________________________________

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☐ 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.

Post-test Answer Key

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