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Counseling Points
Enhancing Patient Communication for the MS Nurse

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Disease-Modifying Therapy: What Are the Long-Term Benefits?

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Counseling Points™
Disease-Modifying Therapy: What Are the Long-Term Benefits?

Continuing Education Information

Target Audience
This activity is designed to meet the educational needs of nursing professionals who manage patients with multiple sclerosis (MS).

Purpose
To provide nurses with information and tools to counsel patients about the potential benefits of long-term disease modifying therapies for multiple sclerosis (MS).

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

• Review long-term findings of existing and emerging MS DMTs
• Assess how new knowledge and long-term evidence affect decision making in MS
• Integrate current and long-term management into patient education discussions

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

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Dear Colleague,

“How long do I need to be on treatment for MS, and how will it benefit me?” These questions are among the most common that we, as multiple sclerosis (MS) nurses, receive from patients. Many people understand relatively little about this condition when they are given a diagnosis, and are often surprised to hear that they will need to undergo treatment indefinitely. In my practice, I sometimes find that patients are feeling better after recovery from an acute relapse, so they don’t see the value in a preventive therapy that will significantly change their lives. For these discussions, I want to use the best available evidence to discuss the known benefits of DMT for MS and the best choices for that individual.

Questions about the duration of therapy also arise as patients get older and have undergone treatment for many years. We are just beginning to explore the issue of whether and when to discontinue DMT, as our patients with MS live longer and maintain healthier, more active lifestyles. Is there a time when the disease activity is reduced and we can risk discontinuing DMT? Or should we continue under the assumption that the treatment may be helping to maintain control of the disease?

Of course, we know the facts about how often patients with MS discontinue their treatment. Supporting our patients in staying on therapy is a challenge that must be tailored for each individual. This issue is designed to provide MS nurses with information and guidance to be used in these discussions.

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Disease-Modifying Therapy: What Are the Long-Term Benefits?

Elena, a schoolteacher, was diagnosed with multiple sclerosis (MS) 20 years ago and is now about to celebrate her 50th birthday. She has taken a variety of disease-modifying therapies (DMTs) for MS over the years. After giving birth to a son in her mid-30s, she stopped all treatment for a period of about 18 months, but went back on a new therapy after experiencing a sudden increase in relapse pattern and worsening of some of her MS symptoms. At a recent office visit, Elena tells you that after she turns 50 she might discontinue her treatment to see if perhaps “the disease has settled down a bit.” She has read that relapse frequency in MS tends to drop off with age and for those with long-standing disease. She believes that she “did her time” on DMTs when it mattered most, and now she is ready to “let her body stabilize.” You are asked to help Elena make a treatment decision based on this information.

Introduction

“How long do I have to be on my disease-modifying therapy (DMT)?” This is a question commonly asked of multiple sclerosis (MS) nurses and other MS care professionals, and the response can be a difficult one. Is the answer, forever? Until you develop secondary progressive disease and are no longer benefitting from the DMT? Or, until a better therapy is available for your particular disease presentation?

The best answer might be a combination of these responses, and is likely to be a bit different for every patient. The benefits of long-term DMT use for patients with MS have long been in question. Treatment guidelines and medication product labels do not specifically define a recommended duration for treatment.1, 2 Because pivotal trials for DMTs are placebo-controlled and usually extend only 1 or 2 years, these studies provide limited information about how patients may respond to treatment over the long term. However, there is a substantial accumulation of data on the long-term benefits of many MS therapies, based on clinical use and long-term extension trials of DMTs.3-7 Now that a wider range of treatments are available, nurses who care for patients with MS may find it challenging to keep up with current data on safety risks, efficacy findings, and longer-term outcomes. This issue will take a closer, updated look at the “how long?” question and discuss the currently available information.

How Do We Educate Patients about the Benefits of Long-Term Therapy?

The case example of Elena highlights several key issues in discussing long-term therapy with patients. As patients have more choices and become more involved in their treatment decisions, it is necessary to empower them to better understand both the complexity of the disease and their individual goals.2

One challenge in clinical practice is that it is difficult to predict the course of MS given the variability of disease factors in each individual patient. MS does not progress in the same way in any two individuals, but rather each patient has a unique underlying disease “topography.” A visual tool developed by Stephen Kriger, MD, of the Corrine Dickinson Center for MS at Mount Sinai Medical Center, New York, depicts the evolution of MS symptoms over time as a “topographical map” (Figures 1 and 2).8 In this 3D computer
simulation, the central nervous system (CNS) is depicted as a swimming pool with a deep end and a shallow end. The surface of the water represents the “clinical threshold” or the point at which MS lesions become clinically evident (this is dark blue water on 1A to show the effects that are hidden, and clear on 1B to show what is “under the surface”). Much of the time, new inflammatory CNS lesions (shown as white “peaks” on the model) remain silent, or under the water’s surface and are kept in check to some degree by functional reserve. Over the course of time, more peaks begin to crop up, and an increasing number of them break the water’s surface. In the animated model, the water level is gradually lower each year, representing the clinical threshold being lowered due to the effects of time and aging. Events such as acute exacerbations tilt the balance and increase the body’s vulnerability to the neurologic effects of MS. In Dr. Krieger’s model, described in a paper published in *Neurology* in October 2016, the effects of MS are divided according to three CNS areas: 1) spinal cord/optic nerve, 2) brainstem/cerebellum, and 3) the cerebral hemispheres. The model can also be modified to represent other MS phenotypes such as secondary progressive MS (SPMS) and highly active disease (Figure 2A and B). An app for computer and mobile devices is under development, but currently is available only for the iPad.

How can these tools be used to educate patients, and what is the take-home message? According to Dr. Krieger, the model can help patients to understand why some lesions, because of their location and/or their severity, cause relapses and symptoms. Meanwhile, others remain hidden below the “clinical threshold.” Symptoms manifest differently over the course of the disease. Some result from acute relapses caused by new inflammatory lesions; some occur due to a temporary worsening of symptoms brought on by stress, infection or fever. Others worsen as the disease progresses and may evolve to chronic disability. “Understanding the differences in these
clinical experiences can help with overall management of MS and to address patients’ emotions, fear and uncertainty that pervades this condition,” he stated in an interview. “We are not making new claims about the biology of MS... [the model] shows the heterogeneity of this disease—and how much of its propensity to cause disability is hidden from view.”

What Can We Learn from Extension Studies of MS DMTs?

Clearly, long-term, placebo-controlled studies in MS are not feasible. But for most MS therapies, we now have a substantial amount of longer-term data. Extension studies have been established for many agents to evaluate how subjects fared in the years following the pivotal placebo-controlled studies.

There are a few caveats to keep in mind when looking at long-term MS data. Head-to-head comparisons of DMTs are limited, so it is important to be aware of major differences the trial designs, outcome measures, and baseline characteristics of the patients enrolled in the studies.
In some long-term trials, data were collected after long intervals during which patients were not monitored; many had discontinued, switched, or added other immunomodulating therapies. In the open-label trials we can’t determine whether outcomes are directly related to a therapeutic effect of the drug, or possibly due to differences in the natural expression of the disease among individuals. It is logical that the patients who remain in a trial of a particular therapy over many years are those who are continuing to respond well to that agent, so there may be an inherent bias in the sample. Meanwhile, those who withdrew from the trial are likely to be those who had a suboptimal response and/or a more aggressive course of MS.

The following figures provide a sampling of recent long-term data of DMTs, including some studies conducted in “real world” clinical settings outside of the strict protocols of clinical trials. Figure 3 shows findings from a “real world” observational study of natalizumab involving 5,808 patients. The treatment showed a sustained benefit in preventing disease worsening on the Expanded Disability Status Scale (EDSS) over 6 years, regardless of the patients’ baseline level of disability, including those with low disability (EDSS ≤ 1.5) and higher disability (EDSS ≥ 6). Among those with EDSS ≤ 5.5, patients were more likely to improve than worsen. In this study, annualized relapse rates also were reduced at all levels of disability (85–92%, P < 0.0001).

Five-year open-label extension study data from daclizumab, a recently approved MS DMT administered as a once-a-month subcutaneous therapy, are shown in Figure 4. This study compared efficacy of daclizumab versus interferon beta-1a (IFNβ-1a) at reducing confirmed disability progression (based on the MS Functional Composite Scale) and time elapsed before the first relapse on therapy. A significantly higher proportion of patients treated with daclizumab were relapse-free over the course of 168 weeks (3.2 years; P<0.0001). Both therapies delayed confirmed disability progression as shown in Figure 4B.

Extension study data were analyzed for alemtuzumab, which had high 6-year retention rates in the CARE-MS I trial in treatment-naive patients (93% retention) and CARE-MS II conducted in patients who had continued disease activity on first-line therapies (88% retention). Annualized relapse rates (ARR) remained low over 6 years as shown in Figures 5A and 5B. In addition, most of the study participants (81% in CARE-MS I and 77% in CARE-MS II) had

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**Figure 3. Multinational Observational Study of Natalizumab in Patients With RRMS Treated in Clinical Practice Settings**

NTZ=natalizumab; EDSS=Expanded Disability Status Scale.

stable or improved EDSS scores.\textsuperscript{14,15} The authors noted that a distinct pattern of T-cell and B-cell repopulation may contribute to durable efficacy of this agent.

The initial injectable or “platform” therapies have extensive long-term data, some extending 20 years or longer and showing continued benefit of these agents in controlling MS.\textsuperscript{16-18} A multicenter retrospective cohort study conducted in Spain assessed the long-term efficacy of glatiramer acetate in clinical practice conditions.\textsuperscript{19} The trial followed 149 patients with RRMS treated for at least 5 years (mean 6.9 ± 1.4 years), with 21 patients followed for 9 years. The primary endpoint, long-term clinical effectiveness, was defined as absence of disability progression (based on EDSS) for at least 5 consecutive years. More than 85% of treated patients remained free from disability progression through years 1 to 9, and 75.2% showed absence of disability progression for at least 5 consecutive years. Most patients had stable or improved EDSS scores, and over 90% sustained an EDSS score of less than 6 (Figures 6A and 6B).\textsuperscript{19} Other significant outcomes that were sustained over the treatment period included decreased ARR, increased proportion of relapse-free patients, and decreased gadolinium-enhanced T1-weighted lesions.\textsuperscript{19}

**Educating Patients About Staying on Long-Term Therapy**

Perceived lack of efficacy, side effects, method of administration, and disease-related factors all affect how consistently patients remain on long-term therapy in MS.\textsuperscript{20} A given patient’s ability to maintain long-term therapy for MS is highly specific, but much depends on the level of education and support received from the MS care team.\textsuperscript{21} In addition to knowing what works for an individual patient, understanding when and why people with MS discontinue therapy can help the MS care team to provide appropriate monitoring and support.\textsuperscript{22}

Patients are most likely to discontinue therapy in the first 6 months after treatment initiation.\textsuperscript{23} A retrospective analysis of 5,722 MS patients in

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**Figure 4. Daclizumab 5-Year Efficacy and Safety from the EXTEND Study**\textsuperscript{13}

Open-label extension study in patients with RRMS completing daclizumab pivotal trials (DECIDE, SELECTED, or OBSERVE Trials)

DAC=daclizumab; CDP=confirmed disability progression; IFN=interferon beta-1a, HR=hazard ratio; MSFCS=Multiple Sclerosis Functional Composite Scale; AEs=adverse events.

a managed care setting showed that up to 41% of patients ultimately discontinue therapy, most in first 2 years:24

- 30–50% discontinued due to perceived lack of efficacy
- 22–70% discontinued due to adverse events
- 75% switched to another DMT one time
- 11% switched 2 times
- 14% switch 3 or more times

Some patients believe they can take “drug holidays,” and may be told by a clinician that such breaks are healthy. While limited data exist on the long-term effects of treatment gaps, the few studies that provide such information suggest that patients staying on therapy continuously fare significantly better over the long term than those who take drug holidays.1,25 A study using data from a national managed-care database examined the effect of treatment gaps on rates of severe relapse in MS. Patients with gaps in therapy lasting $\geq 90$ days had nearly double the chance of having a severe relapse than patients with shorter gaps.26

The degree to which DMTs are effective in patients who have stopped having relapses remains an important unanswered question in the field of MS.27 Is the lack of relapses due to secondary progressive MS, or to the anti-inflammatory effects of therapy? Is the patient willing to take a chance on worsening disease if therapy is discontinued? Other methods of intervention may help to support patients at this time, including specialized exercise programs or additional physical therapy support.

Counseling patients with MS in decisions about long-term therapy often involves helping the patient to set expectations about therapy. No existing therapy can guarantee that the patient will cease all disease activity, although NEDA measures show that this degree of “remission” may be possible for many patients. We cannot always accurately predict which patients will have a more benign course, although there are some prognostic clues. For example, a low EDSS in the first 5 years after diagnosis is predictive of a less-aggressive course and better outcomes on treatment.1 Helping patients with MS to set and understand their own expectations is not a one-time event, but an ongoing process as changes occur in the disease state, the patient’s life, and the available therapeutic options. Over time, expectations must be refocused and new strategies tried.28
Should Older Patients Stay on Therapy?

In the case example described earlier, Elena wondered whether 50 was about the right age to stop her therapy. Use of DMTs in older patients with MS (e.g., in their 50s or 60s) remains an uncertainty. For some patients, it may be appropriate to discontinue DMTs, although we still lack sufficient data to support this recommendation. In clinical practice, some MS nurses describe patients in their 80s who are maintaining or even switching therapies. Unfortunately, most randomized controlled trials of MS agents exclude patients over age 60, so the efficacy and safety of immunomodulatory and especially immunosuppressive therapies in older patients is largely unknown. Many people with longstanding MS have advanced to a secondary-progressive course (SPMS) where the benefits of DMT are less certain.

However, data are beginning to accumulate on the health and well-being of older patients with MS. Researchers from Newfoundland, Canada surveyed a group of patients over age 55 and received 683 responses (78% female). The average age of the group was 64 years (±6.2) with MS symptoms for 32.9 years (±9.4). Most respondents (n=657) lived in their own homes with a spouse or partner. Among the 7 determinants of healthy aging with MS, having positive “social connections” was the factor that contributed most to healthy aging, along with attitude and outlook on life, and lifestyle choices.

What Do We Know About the Effect of MS on Survival?

The proportion of people with MS who are

older adults is increasing, likely due to improved longevity and the wider range of effective treatments.\textsuperscript{33} Population-based registries from the time before DMT was available showed that untreated people with MS have a mean decreased survival time of 6 to 12 years compared to age- and sex-matched population controls.\textsuperscript{34-38}

Long-term (21-year) follow-up data from patients enrolled in the initial pivotal trial of interferon beta-1b provide a hopeful message of improving long-term prognosis with treatment.\textsuperscript{39,40} This trial had an exceptionally high ascertainment rate of 98.4%—meaning that after approximately 21 years, 366 of the 372 RRMS patients enrolled in the pivotal study were located for assessment of the primary endpoint (vital status) and, if deceased, the secondary endpoint of cause of death.\textsuperscript{39-41}

Study participants who were initially treated with a placebo had significantly higher mortality rates than patients treated initially with IFNb-1b. Patients whose treatment was initiated early in the course of their disease had a 46.8% decrease in all-cause mortality.\textsuperscript{39} This suggests that even a 5-year delay in starting interferon therapy affected mortality outcomes. Because details of post-study therapy were not precisely known, one cannot definitively conclude that early treatment with IFNb-1b was solely responsible for the difference in death rates, and not early treatment followed by subsequent treatment with other disease-modifying therapies (DMTs). This is likely applicable to other DMTs, with the take-home message that people with MS should be encouraged to start treatment early and maintain therapy with effective agents.\textsuperscript{42}

Despite certain predictors such as high baseline MRI lesion load or higher baseline EDSS, the hazard ratio (reduction of risk of dying over 21 years) in the treated group versus the placebo group remained relatively consistent at approximately 0.5 across all the baseline variables.\textsuperscript{43} This finding suggests that treating patients with MS within 8 years of disease onset improved survival, regardless of whether patient had other indicators of poor prognosis.\textsuperscript{43}

\textbf{Summary and Conclusions}

It is important that we consider MS treatment with a long-term view. In the absence of a cure, we are supporting patients with the goal to “live with MS” and minimize relapses and disability over long periods of time, which could mean 40 or 50 years. Issues such as effectiveness, tolerability, adverse effects, effects of immunosuppression, and access must be considered over the long term.

\textbf{References}


Pivotal trials for DMTs are placebo-controlled and usually extend only a few years, so these studies provide limited information about how patients may respond to treatment over the long term.

A model of MS “topography” can be used to convey to patients how MS progresses differently among individuals. This model is useful in showing patients how subclinical damage affects disease progression, becoming more prominent as the patient’s compensatory reserve is reduced.

Use caution when comparing DMT clinical trial results head-to-head, because of major differences in trial design, outcome measures, and baseline characteristics of the patients enrolled in the studies.

Despite the proven benefits of long-term therapy, many patients discontinue treatment, often within the first 6 months to 2 years of treatment.

Counseling patients with MS in decisions about long-term therapy often involves helping the patient to set expectations about therapy. No existing therapy can guarantee that the patient will experience an end to all disease activity.

However, gaps in treatment or “drug holidays” significantly increase the risk of relapse and disease progression.

We don’t have clear guidance on when to advise patients about stopping therapy later in the disease course. Many patients stay on therapy and continue to do well into their sixth and even seventh decades.

Survival data in MS among untreated patients shows that the disease reduces life expectancy by 6 to 12 years, while use of DMT confers a significant survival benefit regardless of other baseline disease characteristics.
Counseling Points™
Disease-Modifying Therapy: What Are the Long-Term Benefits?

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% (5 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

PLEASE SELECT THE BEST ANSWER

1. Your patient, age 45, has been on a disease-modifying therapy (DMT) for approximately 10 years and asks you if he should continue to use the medication. He has not had a relapse for 2 years and thinks he may not need it anymore. The most accurate response for this patient is:
   a. You should probably stay on the medication another 5 years at least. Many patients stop after age 50.
   b. We don’t have any way of knowing whether the medication is preventing relapse activity; if you are tolerating it, it is a good idea to stay on the therapy.
   c. Men tend to have more active disease, so there is a greater need for you to stay on therapy longer.
   d. Since you have not had a relapse for 2 years, we can do a trial off the medication and see if your disease stays under control.

2. Which of the following responses is the most accurate way to explain the idea of the MS “topographical map” with a patient?
   a. MS causes neurological damage that we don’t detect because it is “under the surface” or subclinical.
   b. Your body may have ways to compensate or work around neurologic deficits, but with age or more advanced disease this becomes harder to do.
   c. Every person’s “map” of MS is different because of lesion load and location, type of MS, and many other factors.
   d. All of the above

3. Clinical trial results for the available DMTs in MS:
   a. are generally comparable and can be used to compare their potential efficacy for reducing relapses and disability against each other
   b. do not provide insight about whether a medication will work well for a particular individual
   c. don’t tell us enough about long-term efficacy of these agents
   d. all of the above

4. Data from long-term extension studies of MS clinical trials, in general, show:
   a. MS disease-modifying agents work best in the first 5 years of disease and then efficacy tends to drop off.
   b. MS disease-modifying agents prevent relapses over the long-term, but disability progression continues despite treatment.
   c. The newer high-efficacy agents have benefits that are sustained over a longer time period, compared with “platform” (injectable) therapies.
   d. The available long-term data demonstrate the ability of DMTs to provide sustained efficacy over many years in terms of preventing relapses, disability progression, and other outcome measures in MS.

5. A study using a national managed-care database of patients with MS who took “drug holidays” showed:
   a. patients who had treatment gaps lasting >60 days had a similar level of disease control, compared with patients who stayed on therapy continuously.
   b. because nearly all patients had drug holidays and most did not report gaps in therapy, it was not possible to determine the effect on MS outcomes.
   c. patients with gaps lasting 90 days or more had twice the risk of having an MS relapse compared with patients who had no gaps or shorter gaps.
   d. there was a difference between gaps recommended by the physician and gaps that the patient took on their own.

6. The maximum patient age for which the available MS disease-modifying therapies are approved is:
   a. 65 or older, if the patient has normal kidney function
   b. 75, unless the patient has minimal comorbid conditions that would complicate care
   c. interferons and glatiramer acetate are safe any age but monoclonal antibody therapies should not be used in patients over age 65
   d. Patients over age 65 are usually not included in clinical trials of MS, but the labeling does not restrict their use in older adults

7. Among the determinants of healthy aging with MS identified by Wallack et al, the top 3 “themes” reported by older patients were:
   a. social connections, attitude, lifestyle choices
   b. financial stability, good health, having a significant other
   c. independence, spiritual beliefs, family
   d. maintaining ambulation, living independently, financial independence

8. Survival data derived from the 21-year follow-up data from patients enrolled in the initial pivotal trial of interferon beta-1b showed:
   a. MS causes disability but does not reduce survival times
   b. Untreated patients have about the same life expectancy as patients who have received DMT
   c. Early treatment confers a survival advantage compared with delayed treatment, regardless of other prognostic factors
   d. Early treatment confers a survival advantage compared with delayed treatment only in patients who have mild MS
Counseling Points™: Program Evaluation Form
Disease-Modifying Therapy: What Are the Long-Term Benefits?

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) Review long-term findings of existing and emerging MS DMTs ............................................................. 5 4 3 2 1
2) Assess how new knowledge and long-term evidence affect decision making in MS .............................................. 5 4 3 2 1
3) Integrate current and long-term management into patient education discussions ............................................... 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
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**General Comments**
8) As a result of this continuing education activity (check only one):
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   □ I will wait for more information before modifying my practice.
   □ The program reinforces my current practice.
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
10) Will you attempt to address these barriers in order to implement changes in your knowledge, skills, and/or patients’ outcomes?
    □ Yes. How?
    □ Not applicable
    □ No. Why not?

Suggestions for future topics/additional comments:  
__________________________________________________________________________________

Follow-up

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

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

There is no fee for this educational activity.

**Post-test Answer Key**

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