EXPLORING YOUR OPTIONS:
Considering Risks and Benefits of MS Medications
The MS Society would like to thank the following Canadian MS clinics nurses for their practical advice and invaluable assistance in the preparation of this booklet:

Bonnie Blain, Red Deer, AB; Annie Bourbeau, Charny, QC; Line Boutin, Québec City, QC; Janice Britz, Saskatoon, SK; Janet Brown, St. John’s, NL; Jennifer Boyd, Toronto, ON; Kathleen Carr, Toronto, ON; Sheryl Clarke, Toronto, ON; Cathy Edgar, Kingston, ON; Sheila Frost, Victoria, BC; Colleen Harris, Calgary, AB; Michael Kehoe, Halifax, NS; Connie Lamotthe, Thunder Bay, ON; Victoria Landry, Winnipeg, MB; Diane Lowden, Montréal, QC; Lynn MacMillan, Toronto, ON; Lynn McEwan, London, ON; Michelle Milot, Greenfield Park, QC; Linda Plasche, Kelowna, BC; Josée Poirier, Montréal, QC; Maria Skrypka, Hamilton, ON; Nancy Soucy, Ottawa, ON.


Special thanks to Dr. Paul O’Connor, Colleen Harris, Janet Brown and Nadia Pestrak for reviewing the 2012 version.

Revisions and printing of the 2012 version of Exploring Your Options: Considering Risks and Benefits of MS Medications was supported by an unrestricted educational grant from Novartis Pharmaceuticals Canada Inc.

© Multiple Sclerosis Society of Canada 2012. All rights reserved.
None of the contents may be reproduced in any form without prior written permission of the Multiple Sclerosis Society of Canada.

The opinions expressed do not necessarily reflect the opinions or recommendations of the sponsors. Consult full prescribing information before initiating any medication described herein.

Printed in Canada
Living with MS

Multiple sclerosis is believed to be an immune-mediated disease, in which cells of a person’s immune system attack the protective covering (called myelin) around nerve fibres in the central nervous system (the brain and spinal cord). In the short term, periodic flare-ups (called relapses) of inflammation result in a variety of symptoms relating to sensation (e.g. numbness and tingling or “pins and needles”), muscle function (e.g. stiffness, weakness or paralysis of any part of the body), unusual and extreme fatigue, visual disturbances, speech problems, urinary or bowel dysfunction, loss of coordination or balance and mood or cognitive changes. Relapses are defined as the appearance of new symptoms or a worsening of old symptoms lasting at least 24 hours. In the longer term, progressive nerve damage (called neurodegeneration) can result in permanent disability.

Most people with MS are diagnosed when they are 20–40 years old and have relapsing-remitting MS. This means that they have occasional relapses when symptoms are worse, followed by periods of remission, when symptoms typically improve. Over the course of time, there is a slow accumulation of nerve damage and many will progress to a secondary-progressive phase of the disease. Relapses are often less frequent during this phase, but there is a steady worsening of function.

Unlike relapsing-remitting MS, in which symptoms subside and you often return to your previous level of functioning, the setbacks you experience during the secondary-progressive phase may become the “new normal”. If you were accustomed to walking two blocks without difficulty, the new limit may be one block or less. If you develop a new symptom, such as an area of numbness, this change may not improve. Relapses often don’t occur with the progressive forms of MS, which means that the current disease-modifying therapies – designed to treat the inflammation in MS that leads to relapses – are not effective or helpful. This does not mean that people with progressive forms of MS cannot take an active role in their health. There are many symptom management medications and wellness strategies that can make a big difference in how you feel. For more information on progressive MS visit www.mssociety.ca
MS is an illness of uncertainty. The disease is highly variable and affects everyone differently. Relapses may strike every few months, or may occur years apart. Relapses range from mild to severe and will have a differing impact on a person’s function and quality of life. Some people will find that they get much worse from year to year. Others may live with MS for decades with relatively little impact on their day-to-day functioning. Living with uncertainty is one of the greatest challenges of MS. It is very difficult not knowing when a relapse will strike, how well you will feel on a given day, or what you will be like in a few years from now. Educating yourself about how to manage and treat your disease might offer you some sense of control and enable you to better cope with this uncertainty.

The Importance of Treatment

Left unchecked, MS can do permanent damage to the brain and spinal cord. That is why treating MS is so important. Medications can provide some measure of control over the inflammation that injures nerve fibres, improve the inflammation seen on MRI, and generally reduce the frequency and severity of MS relapses. Slowing the accumulation of nerve damage may also prevent some of the disability seen during the lifetime course of MS. That is why your doctor has probably advised you to start treatment as soon as possible. The best course of action is to prevent tissue damage early on before any problems occur and become irreversible.

For most of the long history of MS, there were no effective medications to treat the disease. That changed in the 1990s with the arrival of the first disease-modifying therapies for MS. Current MS medications are the beta-interferons (Avonex®, Betaseron®, Extavia® and Rebif®), glatiramer acetate (Copaxone®), natalizumab (Tysabri®) and fingolimod (Gilenya®). All of these medications are intended for people with relapsing-remitting disease, although some (Betaseron®, Extavia®, Rebif® as well as other drugs) can also be taken for secondary-progressive MS if there are relapses. More information on these medications is available online at www.mssociety.ca.
Disease modifying therapies are taken by injection, with the exception of Gilenya, which is taken orally. Different ways of combating MS are continually being researched and several other new MS treatments are currently in development. Newer medications may work more effectively, but different mechanisms of action mean that there may be different side-effects, and different risks to be considered.

As the number of MS treatments increases, there will be more options available to you. More choices can sometimes make decision-making more challenging. This publication is intended to help you feel more prepared and confident in assessing your treatment options. It will also help you to have an informed discussion with your healthcare team on the treatment options that may be best for you.

Weighing the Benefits and Risks

MS will affect each person differently, so perhaps it is not surprising that treatment is very individualized. Identifying the treatment option that is best for you will be a decision that will be influenced by many factors. Some of these factors will be medical and these should be discussed with your doctor. For example, a change in your condition may mean that you would benefit from another medication. Other factors will depend on your personal preferences, your lifestyle, and who you are as a person. When assessing your options, it’s important to think about how important the benefits of treatment are to you, and how much the potential risks of therapy will influence your choice.

All medications – even nonprescription pain relievers or supplements – have the potential to cause unwanted effects. A stronger medication may be more effective in controlling a disease, but may also have a greater potential to produce side-effects.
Sometimes there is a trade-off in choosing a medication: to receive the benefits of treatment, you must be prepared to accept the risk of side-effects. Your doctor and/or nurse will be able to review the benefits (e.g. slow the progression of the disease, or prevent a relapse) and the possible side-effects or risks of each medication.

Once you understand the benefits and risks of your treatment options and consider your preferences and lifestyle, the right choice will be the medication that suits all of your needs.

What Are the Possible Benefits of Treatment?

Over the past two decades of MS treatment, the benefits of therapy have become well established. Regardless of whether a treatment is an old or new agent, your healthcare team should be consulted to help you determine what is best for you.

The interferons (Avonex, Rebif, Betaseron and Extavia) and glatiramer acetate (Copaxone), have been shown to reduce the frequency of relapses by about one-third. This means that a person having three relapses a year will hopefully only experience two relapses a year. These medications also reduce inflammation so there is less damage to the delicate nerve fibres of the central nervous system (the brain, spinal cord and optic nerve). The newer therapies, natalizumab (Tysabri) and fingolimod (Gilenya), have been shown to be effective in reducing relapses and disability. Since treatment trials are only two or three years’ duration, it cannot be stated definitively that these benefits will mean a significant reduction in disability over the 20 or 30 years that a person lives with MS (and effective treatments haven’t been available for 30 years). However, it is hoped that by starting treatment as soon as possible, and continuing with regular treatment, the potentially disabling long-term consequences of the disease will be reduced.
The efficacy of a drug is determined by its effects on the body, not on the way it is taken. In your assessment of the benefits of treatment, it is important to note:

• The most important benefit of treatment for many people will be the prevention of disability during the lifetime course of MS. While we know that therapies reduce relapse rates, the long-term impact of treatments on disability is largely unknown. Prevention of disability can only be established once enough people have been on therapy for a long enough time. The hope is that treatment will be effective in this regard, and that more effective medications will result in greater reductions in disability.

• Greater efficacy may also result in greater side-effects. It’s important to understand the nature of the risks involved and if you can minimize them.

• By starting treatment as soon as possible and taking your medication regularly, the potentially disabling long-term consequences of the disease will be reduced.

So let’s look at how to assess the risk of therapies.
What Are the Possible Risks of Treatment?

There is some degree of risk in taking any medication (including nonprescription and alternative medicines). All drugs can produce unwanted side-effects. Some are less severe (e.g. dry mouth), while others can be very serious even if you’re not aware of them (e.g. liver damage).

In assessing the risks of a medication, there are several things to consider:

- **What is the nature of the risk?**
  
  When you receive a prescription for any drug from your doctor, make sure to ask about possible side-effects. A complete list of known side-effects is on the information leaflet provided with the medication packaging or is available from your pharmacist. It is also important to know if the side-effects will go away if the medication is stopped.

- **What are the chances that I will experience side-effects?**
  
  While your doctor cannot predict if you will develop specific side-effects with a medication, he/she can tell you which side-effects are most commonly experienced and, depending on the drug, approximately how long the side-effect has been known to last (e.g. is it a short-term side-effect resulting from an adjustment period to a medication, or is it a long-term side-effect that occurs for as long as the medication is taken?).

- **Can the risks be minimized?**
  
  Doctors have many ways to minimize the risk of developing side-effects, or to minimize the consequences if a side-effect does develop. One important strategy is to monitor you closely, especially in the first few months of starting a treatment. Monitoring may include such things as periodic blood tests. Ask your doctor and nurse which tests are needed. Having these tests is important since they will enable your doctor to respond quickly if a problem does develop.
**Is there anything I can do?**

Once a treatment decision has been made, it is important to be well informed about your medication and to follow the advice of your doctors and your MS nurse, or your pharmacist. This includes taking your medication as directed by your doctor, and showing up for your scheduled appointments (clinic visits and tests). It is essential that you report to your doctor your progress, if you have missed any doses, how you are tolerating your medication and any side-effects you are experiencing (so that effective steps can be taken to minimize them). All this information helps to guide your discussion with your healthcare team.

**What if I have concerns about my treatment?**

Deciding on the Best Course of Action

Regularly taking a treatment for a life-long disease such as MS requires a commitment – but it is your best course of action to gain some control over the disease process.

With so many treatment choices available, how does someone decide which one will be the best option? Decisions about treatment are best arrived at in consultation with your MS team. They can answer your questions and advise you of the benefits and risks of treatments to help you make an informed decision. It’s important to realize that while your MS team has your best interests in mind, they cannot make the final decision for you. How they assess the risks and benefits of a treatment may differ from how you assess these things. Here are some points to consider as you make your choice:

**What is important to me?**

As part of the coping process, people learn to accept MS and accommodate some degree of impact on their daily life. How acceptable is that to you? Is your goal to be free of symptoms? To keep working? To raise your family? To avoid sleepless nights worrying about the future? To avoid worrying about side-effects? Only you can answer these questions. Take an active role in how you would like your care to be managed.

**What are my hopes and concerns?**

What do you hope to achieve with treatment, and what are your key concerns? Are you worried about what MS may do to your body and your life? Are you concerned about what people will think if you don’t do something about your MS? Discussing your concerns with others may help you feel more in control of the situation.
**How will my decision affect my life?**

Ask your doctor and MS nurse if you won’t be able to do certain things because of starting a particular treatment. Will side-effects or monitoring requirements cause you to miss work or school? If you start on a treatment, will that mean you won’t be able to try another one? What if you decide not to start treatment?

**How will my decision affect the people in my life?**

It can be helpful to discuss your situation with family and friends as you think through your decision. You are an important part of their lives, and your MS affects them as well. Some people will urge you to do everything you can. Others will advise caution. Try to understand their concerns and address them if you can. Ultimately it is your body, and your health and well-being. The final decisions about managing your MS will be up to you.
Deciding on an MS Treatment

The following decision aid may help you consider your treatment options and decide on the best course of action for your situation - whether you are starting treatment for the first time or you are thinking about changing your current therapy. *Adapted from the Ottawa Hospital Research Institute* (www.ohri.ca/DecisionAid/).

1. In thinking through your decision, write down three possible options in the table below.
2. List the benefits for each of the options.
3. List the possible risks for each of the options.

<table>
<thead>
<tr>
<th>BENEFITS</th>
<th>Reasons to choose this option</th>
<th>How much does each benefit matter to me? (insert check marks)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>OPTION 1</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>OPTION 2</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>OPTION 3</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4. Now underline the benefits and risks that you think are most likely to happen.

5. Put a check mark (✓) beside each benefit and risk to indicate how much it means to you. Five check marks means “a lot”, while no check marks means “not at all”.

6. Circle the option with the benefits that matter most to you and which are most likely to happen.

### RISKS

<table>
<thead>
<tr>
<th>Reasons to avoid this option</th>
<th>How much does each risk matter to me? (insert check marks)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Which option did you prefer?

- [ ] OPTION 1
- [ ] OPTION 2
- [ ] OPTION 3
- [ ] Unsure
## Your Decision-Making Needs

### Knowledge:
Do you know the benefits and risks of each option?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

### Values:
Are you clear about which benefits and risks matter most to you?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

### Support:
Do you have enough support and advice from others to make a choice?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

### Certainty:
Do you feel sure about the best choice?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>
People who answer “No” to one or more of these questions have decision-making needs. They are more likely to delay their decision, change their mind, feel regret about their choice, or blame others for bad outcomes. If you answered ‘No’ to any of these questions, try to identify the area(s) where you require additional information or support and discuss them with your MS team. The following questions may help with this exercise.
Questions to Ask Your MS Team

The following are some questions that you may want to discuss with your MS clinic team. Write down additional questions in the space provided or on a separate page.

Multiple sclerosis

1. How will MS affect my life?
2. What are the physical and mental symptoms I could develop?
3. How will I know if my MS is getting worse?
4. What is the likelihood that I’ll end up with physical and/or mental disabilities?
5. Will MS affect my ability to have children, or to raise a family?

Treatment

1. Will treatment be effective for my type of MS?
2. What are the possible benefits of treatment?
3. How will different treatments affect my lifestyle?
4. What side-effects may occur? What is the likelihood that I’ll experience these side-effects?
5. What can I do if these side-effects occur?
6. Is special monitoring needed once I start the medication? How often? Who pays for these tests?

7. How will I know if the medication is working? If it is working, should I continue with my current treatment or switch to something that may be better?

8. What do I do if I forget to take a dose?

9. What if the medication doesn’t work? How will that affect my treatment options later on?

10. Whom do I contact if I run into problems with my medication?

Additional questions:

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________
Contact Numbers:

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

Notes

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________