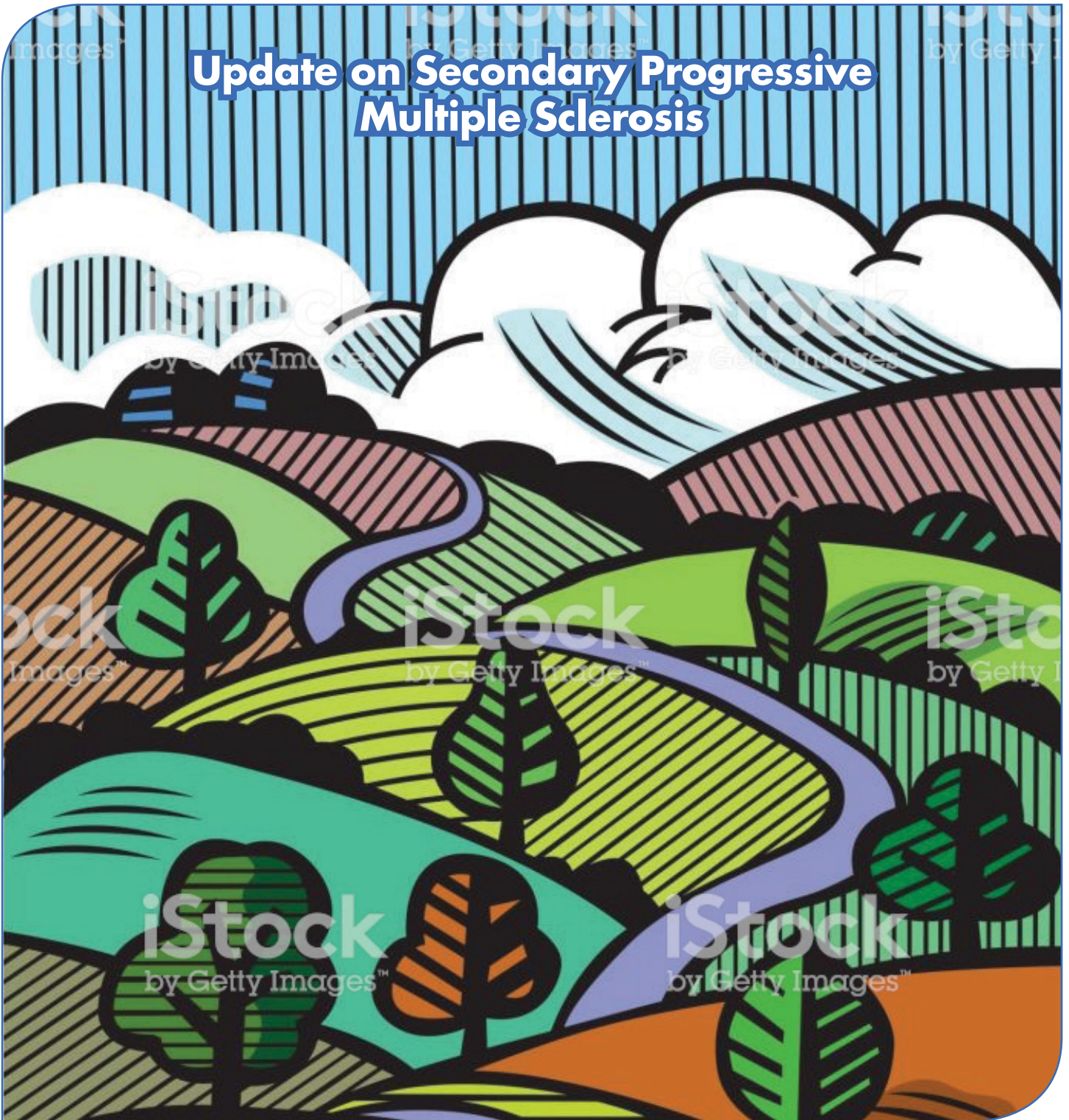


NARCOMS NOW

www.narcoms.org

Vol. 8, Issue 4, 2019

Update on Secondary Progressive Multiple Sclerosis



A Publication of the North American Research Committee on Multiple Sclerosis

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INFOCORNER



What is NARCOMS?

NARCOMS is a registry for people who have multiple sclerosis (MS). Registry participants complete two surveys each year to provide information about themselves and their experience of having MS. Data from these surveys are used in research studies and to help further our understanding of MS. Participation in the registry is voluntary, and responders' identity and privacy are carefully secured.



What is the Goal of NARCOMS?

The NARCOMS Global MS Patient Registry helps to facilitate research about multiple sclerosis in North America and around the world. Collaboration between MS centers of excellence throughout the world helps to increase knowledge, improve clinical care, and enhance the quality of life for persons with MS.



How Private Is My Information?

We will keep the information that you provide us private and confidential by storing your data in a secure database. All information will be used for research purposes only. We do not share any personally identifying information with any person or research institution. We follow all Federal (HIPAA) laws regarding confidentiality.



Not Yet a NARCOMS Participant?

Please contact us at www.NARCOMS.org to enroll online, or call toll free at 1-800-253-7884.



Tell Us Your Thoughts!

Have an idea? We would love to hear from you!
Send us your questions, comments, and suggestions.

Call: 1-800-253-7884 (toll-free U.S.)

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This publication is supported
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NARCOMS is a project of the Consortium of Multiple Sclerosis Centers (CMSC).

For more information on the CMSC visit www.ms-care.org.

NARCOMS Now acknowledges and appreciates the companies listed on the bottom of page 2, which have provided unrestricted educational grants through the Foundation of the CMSC toward production costs of *NARCOMS Now*, including printing and mailing. None of these companies have any control or influence over the content of *NARCOMS Now* and are not provided access to NARCOMS data in return for their support. For any questions regarding *NARCOMS Now* funding please call 1-800-253-7884.

DIRECTOR'S LETTER

Dear *NARCOMS Now* Readers:

The study and treatment of progressive forms of multiple sclerosis (MS) have been an important focus for me. This includes participating on the Scientific Steering Committee of the International Progressive MS Alliance, an organization formed to stimulate advances in the treatment of progressive forms of MS. I am gratified to see that we are making progress.

This issue of *NARCOMS Now* discusses secondary progressive MS (SPMS), a stage that occurs later in the disease course for many people with MS. During SPMS, relapses may be reduced or stop completely. On MRI, we tend to see fewer new lesions in the white matter, but research studies suggest there are changes in grey matter in SPMS which may equate with cognitive changes and other signs of progression. The Feature Focus in this issue provides an update on SPMS. The MS News section contains some reports from recent MS meetings, along with an overview of Cannabis research and use in MS. Your role in the NARCOMS registry has made many advances in MS possible. Thank you for your continued participation!



Robert Fox, MD

Sincerely,

A handwritten signature in black ink that reads "Robert Fox, MD".

Robert Fox, MD

Managing Director, NARCOMS



Update on Secondary Progressive Multiple Sclerosis

Progress is Being Made Toward Understanding and Treating SPMS

Many scientific advances have helped improve the treatment of relapsing MS (RRMS). But, some people feel that progressive forms of MS have been overlooked. Speaking at a national MS conference, Cynthia Zagieboylo, President and CEO of the National Multiple Sclerosis Society (NMSS), said “People with progressive MS often feel left out. It’s painful to hear about wonderful new discoveries that are for someone else and not for them.”

In truth, progressive MS is not overlooked in MS research. However, this form of MS can be quite hard to study and treat. In the past 5 years, research efforts have led to new drug approvals, many ongoing treatment trials, and a better understanding of what happens in the brains and bodies of people with progressive MS. This article will discuss updates about secondary progressive MS (SPMS).



What is SPMS?

SPMS is a stage of the disease that occurs after a person has had relapsing-remitting MS (RRMS) for several years. In SPMS, relapses and new brain lesions seen on magnetic resonance imaging (MRI) scans may slow or even stop. “This suggests that some of the active inflammation that was driving the MS disease process is beginning to slow down,” explained NARCOMS Managing Director Robert Fox, MD. “With SPMS, other changes can increase, including atrophy (brain shrinkage) in different regions of the brain. Compared to RRMS, these brain tissue changes are believed to have different underlying causes that are not just inflammatory. But we still don’t know exactly what triggers the start of this degenerative phase, why it occurs, and how we can prevent it from occurring,” Dr. Fox said.

Who Gets SPMS?

SPMS has a gradual onset, usually starting between the ages of 45 and 55 years. During this transitional phase, a person may still experience MS relapses. However, for most people with SPMS relapses and new MRI lesions become less frequent after age 55 years. Studies show that SPMS is more likely

after a person with MS reaches a certain level of disability. This is often defined by a score over 4.0 on the Expanded Disability Status Scale (EDSS). A few important points to note:

- Not everyone with RRMS will necessarily transition to SPMS.
- Some people with SPMS continue to have occasional relapses or other signs of “active” inflammation.
- A small number of people may be diagnosed initially with SPMS without ever being diagnosed with RRMS. This may mean that the person had a mild form of RRMS earlier in life that went unnoticed or was mistaken for another condition.

Some NARCOMS surveys ask participants what type of MS they have. In the most recent data available, 8,004 participants with MS

responded. Of these, 6,774 indicated their MS type or disease course; 1,700 (25%) had SPMS (see **Figure 1**). A paper published in *Multiple Sclerosis Journal* in 2018 by NARCOMS researcher Amber Salter and colleagues gave more details about each type. Some of the details about NARCOMS participants with SPMS are shown in **Table 1**.

Why is SPMS Harder to Study?

Many challenges related to SPMS have caused delays in the discovery of new and effective treatments. First, we do not know enough about the mechanisms of this type of MS—the underlying causes and main drivers. Researchers believe that RRMS is mainly inflammatory, while SPMS is “neurodegenerative,” with nervous system damage occurring by different pathways.

To study SPMS, researchers must use different ways to measure whether a treatment is helping.

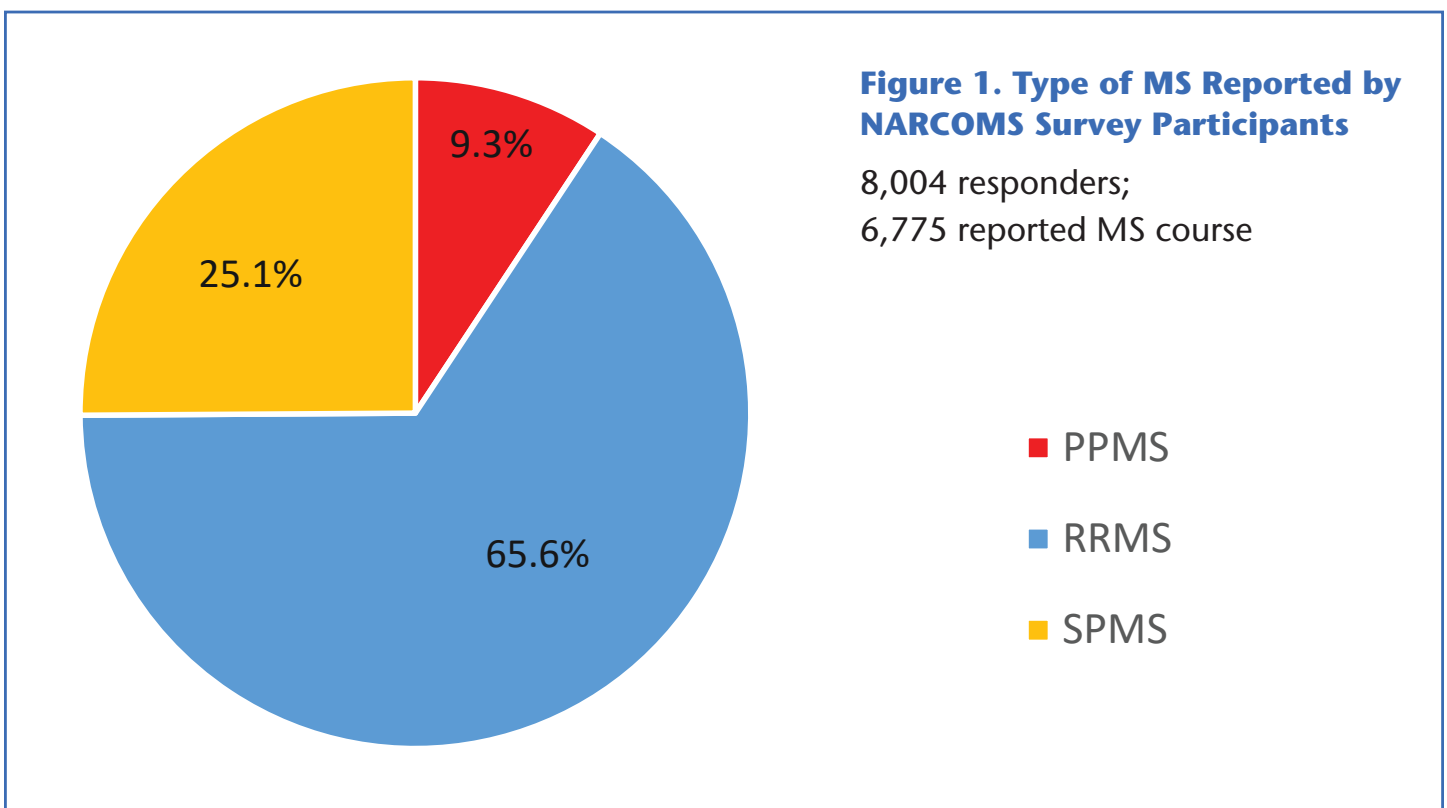


Table 1. NARCOMS Survey Responders with SPMS

MEAN AGE: 62.4 YEARS



73.5% FEMALE



MS DURATION (MEAN): 24 YEARS



EDUCATION

High school or less	28%	Postgraduate degree	26%
Associate's degree	14%	Technical degree	2%
Bachelor's degree	30%		

MARRIED: 62%



EMPLOYED FULL TIME: 8%
EMPLOYED PART TIME: 7%



RECEIVING DISABILITY BENEFITS: 66.3%

MS SEVERITY

Patient Determined Disease Steps (PDDS) Score

Mild	5%
Moderate	20%
Severe	75%

**TAKING AN
MS DISEASE-
MODIFYING
THERAPY**



50%

**DATA FROM THE SPRING 2015 NARCOMS
SURVEY UPDATE**

Trials of RRMS therapies focus on changes in the number of relapses and new MRI lesions. But in SPMS, these changes are less frequent. This can make it more difficult to prove whether the drug has made a difference. Now, newer ways to measure treatment effects in SPMS are being explored. One way is to measure change in the overall size of the brain and in certain brain regions. Cognitive function and disability progression are other measures used in SPMS. Substances in blood or spinal fluid that signal the breakdown of nerve cells (called neurofilaments) might also be used to determine whether a treatment for SPMS is effective.

Delaying Onset of SPMS

A major reason for using a disease-modifying therapy (DMT) to treat MS is to delay SPMS for as many years as possible. Most of the approved DMTs used in RRMS are thought to delay the onset of SPMS, as well as other signs of disability such as need to use a cane or need to rest while walking. Before DMTs were available, about half of people with relapsing MS could be expected to transition to SPMS within 10 to 15 years of their diagnosis—and 90% within 25 years. However, with effective treatment we see a very different picture. One study followed over 500 people with RRMS for 17 years and found that only 18% of them had transitioned to SPMS in that time period. Starting DMT early in the course of MS (soon after diagnosis) has been shown to delay the transition to SPMS for some people.

Drug Therapies for SPMS

In the past few years we have finally seen approval of DMTs tested in SPMS. Among the approved drugs used in RRMS, most now

state in their labeling that they can be used for treatment of “active secondary progressive disease” (with relapses or certain types of MRI activity). **Table 2** reviews some medications with evidence trials involving SPMS patients.

Should a Person with SPMS Stop Disease-Modifying Treatment?

The “old school” approach was to stop DMT after a person with MS reached the secondary progressive phase. This is not necessarily the standard anymore. Inflammation may continue in SPMS and continue to cause subtle, even silent, damage to the central nervous system. Stopping the DMT could cause that activity to restart or increase. “When a person is on an effective treatment and has few relapses or new lesions, we never really know if the disease

was relatively quiet, if the drug is working as it should, or maybe if SPMS has started,” Dr. Fox said. “But we don’t want to take a chance as long as the person’s MS is well controlled.”

For patients with SPMS who are on DMT but have no active inflammation, discontinuation of DMT could be considered in some situations. Some providers will consider stopping DMT in a person who:

- Is over age 55 or 60, and
- Has no ongoing relapses or new MRI lesions in the past several years.

An ongoing trial (Discontinuation of Disease Modifying Therapies in Multiple Sclerosis; DISCOMS) is looking to answer that question and should have results sometime in 2021.

Table 2. Therapies Showing Positive Results in SPMS

Therapy	Trials in SPMS	Methodology	Key Findings
Siponimod <ul style="list-style-type: none"> • S1P modulator • Approved by FDA for relapsing forms of MS, including SPMS with disease activity 	Siponimod in SPMS EXPAND trial	Randomized double-blind placebo-controlled trial in SPMS (with or without relapses)	Siponimod reduced the risk of disability progression; safety profile similar to other S1P modulators (e.g, fingolimod)
Ibudilast <ul style="list-style-type: none"> • Nonselective phosphodiesterase inhibitor • Not FDA approved in the U.S. 	Ibudilast in Progressive MS SPRINT-MS trial	Randomized double-blind phase II clinical trial of ibudilast in PPMS and SPMS	Ibudilast was associated with reduction in progression of brain atrophy

Kappos L, Bar-Or A, Cree BAC, et al. Siponimod versus placebo in secondary progressive multiple sclerosis (EXPAND): a double-blind, randomised, phase 3 study. *Lancet*. 2018;391(10127):1263-1273.

Fox RJ, Coffey CS, Conwit R, et al. Phase 2 trial of ibudilast in multiple sclerosis. *N Engl J Med*. 2018;379:846-855.

For some people, “de-escalating” (switching from a higher-efficacy DMT to a more moderate agent with perhaps lower safety risks) may be considered. And, even if SPMS is confirmed, it is important to continue to have medical supervision with clinic visits and imaging, to see whether the condition has changed or progressed.

Symptom Management in SPMS

For many people with SPMS, symptom management becomes a greater priority. Symptoms that may occur or worsen during SPMS include spasticity, mobility issues, bladder and bowel control problems, pain, and fatigue. These issues can occur at any stage of MS but may worsen in SPMS. Because SPMS usually affects an older population, it is often easy to

“blame the MS” if a new symptom occurs, instead of looking for other possible causes. Examples might be other age-related conditions like arthritis, diabetes and thyroid disorders.

What’s Next for SPMS Research?

Research is ongoing for all types of MS. There has been increased funding and focus on research for progressive MS. Therefore, we hope that many more advances will be seen in SPMS in the coming years. This may include more treatments to improve function and quality of life for people with SPMS. The research has not yet led to methods for repairing or reversing damaged nervous system tissue yet, but several studies are aiming to reach that goal.



A Global Push to Advance Research Goals in Progressive MS

MS organizations in several countries have joined forces to address unmet needs affecting people with progressive MS. In 2012, a new organization was created to focus on progressive MS globally. That group is called the International Progressive MS Alliance. The “Alliance” has accomplished much since its formation, says NARCOMS Managing Director Robert Fox, MD, who is a member of Alliance’s Scientific Steering Committee. The three overarching goals of the Alliance are to:

1. Understand what progression means in MS;

2. Encourage and support clinical trials in this area; and
3. Enhance the well-being of people affected by progressive MS.

The Alliance has set many ambitious goals, including a goal to see more approved treatments for PMS by 2025. More information about the International Progressive MS Alliance, including yearly progress reports and educational webcasts, can be found on the website: <https://www.progressivemsalliance.org/>



SNAPSHOT

WHAT WE CAN LEARN FROM NARCOMS SURVEYS

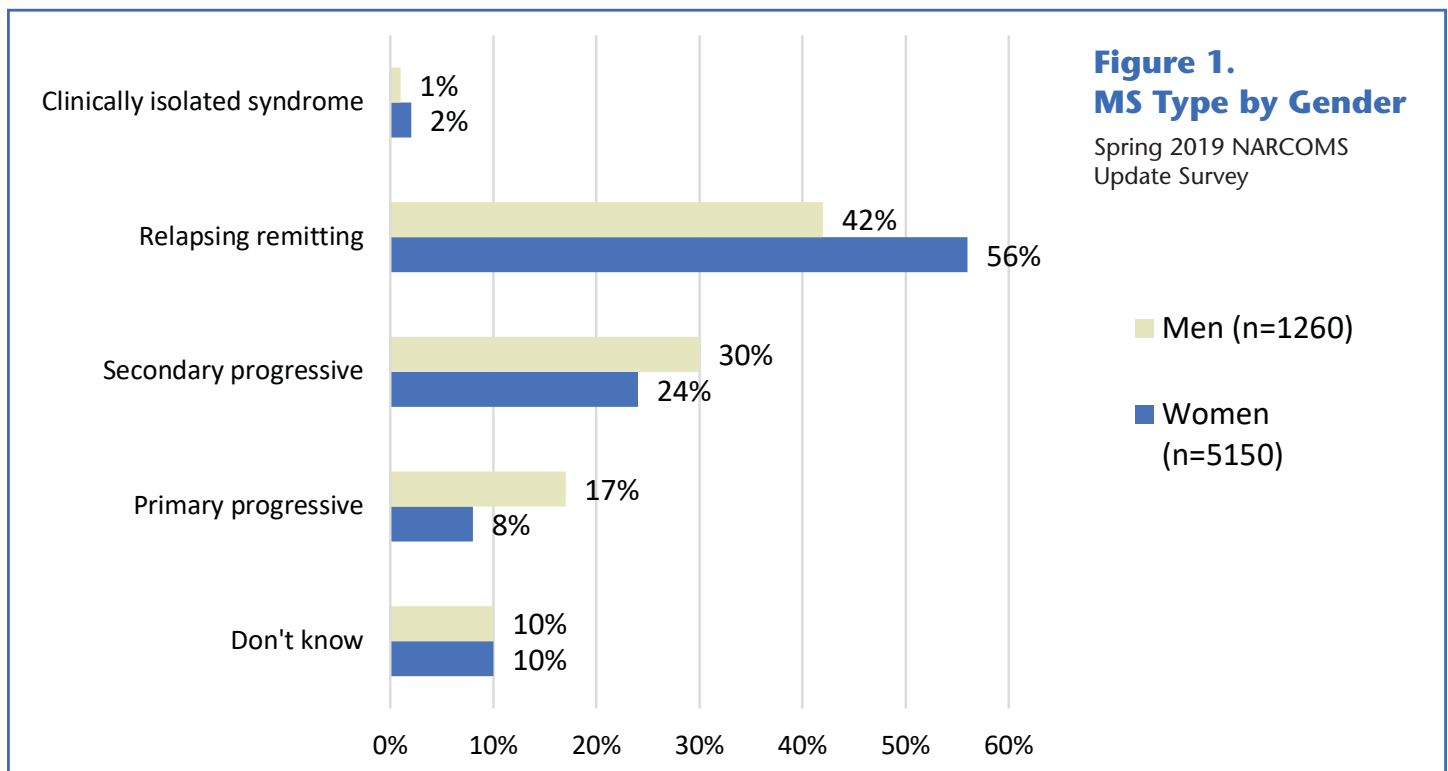
MS Type in the NARCOMS Registry

In each NARCOMS update survey, we ask participants what type (clinical course) of MS they have, according to their healthcare provider. This information is important for several reasons:

1. MS type can affect answers to many of the questions that we ask. So – we need to account for this when we analyze the answers;
2. When recruiting participants for additional studies, MS type is often one of the inclusion criteria. We try to send notifications only to participants who would qualify for that study;

3. Monitoring changes in MS type over time helps researchers and clinicians better understand the MS disease course.

For this Snapshot, we looked at what participants reported as their MS type in the Spring 2019 update survey. **Figure 1** shows the results separately for men and women in. Of the 6,410 responders who answered the question about MS type, about 80% were women. A higher percentage of men than women reported having progressive forms of MS. One in ten responders reported uncertainty in MS type or MS diagnosis. Determining MS type can be tricky even for clinicians, especially during the transition period to secondary progressive MS.





Cannabis: Miracle Drug, or Still a Mystery?

Few plants are surrounded with as much mystique as *Cannabis sativa*, or the marijuana plant. Among more than 400 chemicals in this plant, many are thought to have medicinal properties. The two most widely known chemicals in the plant are cannabidiol (CBD) and delta-9-tetrahydrocannabinol (THC). THC is the substance that causes a “high” feeling, while CBD may provide medicinal benefits without causing this “high” or altered mental state.

- “Medical marijuana” is a broad umbrella term that may refer to substances containing THC and CBD.
- Hemp is a Cannabis plant variety that naturally contains low THC levels and high CBD levels.
- Plants that have higher THC levels are often classified as marijuana.

How to isolate, purify, and administer these substances—and what health conditions they actually benefit—is currently the subject of a tremendous amount of debate and confusion.

What Is CBD Oil, and What Does It Do?

Since December 2018, Federal law allows for distribution and sale of CBD hemp oils that contain less than 0.3% THC. Since these restrictions were removed, the popularity of CBD oils has exploded, for a huge variety of

purposes. Consumers can get CBD at their local coffee shop, in the form of chewing gum, in drinks such as seltzers, and in oils used as dietary supplements, skin softeners, stress relievers, and sleep aids. CBD is being touted as a miracle drug. While CBD might have medical benefits, few consumers and even healthcare professionals truly understand how to use these substances or whether they really work.

Scientific Research in CBD

CBD is currently being studied extensively for its pharmacologic properties in many disease states. The FDA recently approved a highly purified oral CBD solution for treatment of two severe types of seizures (Lennox Gastaut and Dravet syndromes). Other controlled research in CBD is being done in neurologic



and psychiatric conditions. These include schizophrenia, anxiety disorders, depression, autism, and Parkinson's disease. However, the scientific evidence is not yet in, and there are many unsubstantiated claims.

The purity and strength of the substances purchased in health food stores is not equivalent to the FDA-approved CBD medicine. The oils come from a plant, which can draw impurities from the soil, and also may have additives that contain harmful substances. In theory, CBD oils found in stores should contain only very small amounts of THC, but some samples tested have been shown to have higher levels than the law allows. There is little oversight, and no real way for consumers to know what they are actually getting in their CBD product.

People with multiple sclerosis (MS) who want to try CBD oils to treat various conditions such as pain or anxiety should consult their MS care provider and be aware of the variability between these products.

Stopping Regular Cannabis Use Improves Cognitive Function in People with MS

Some people with multiple sclerosis (MS) smoke cannabis (marijuana) to relieve symptoms such as pain or spasticity, or to improve sleep. To find out how smoking marijuana might be affecting their cognitive function, psychiatrist Anthony Feinstein, MD, conducted a study among people with MS who were habitual marijuana users (at least 4 days a week over many years). Dr. Feinstein recruited 40 patients from the MS clinic at the



University of Toronto who had some problems with cognition (thinking and memory). The researchers randomly divided them into two groups. One half continued to smoke marijuana regularly over a 28-day period, while the other half discontinued marijuana entirely during that time. Those who stopped using marijuana did not experience worsening MS symptoms, other than sleep problems which were treated with other methods.

The researchers compared MRI and cognitive test results for both groups at the beginning of the study and at the end of 28 days. These included tests of verbal and visual memory, processing speed and executive functioning. "At the end of the study, the group that withdrew from marijuana performed significantly better on every cognitive index we measured," Dr. Feinstein reported. The withdrawal group completed more tests correctly and had faster reaction times. These improvements were associated with increased activation in brain regions known to be

associated with performance of these tests. “Our results showed that patients with MS who are frequent, long-term cannabis users can show significant improvements in memory, processing speed and executive function after 28 days of drug abstinence,” he stated.

In an interview with *NARCOMS Now*, Dr. Feinstein said he believed the cognitive challenges seen in cannabis users are linked to THC. “That’s a preliminary statement, and we would need to do a study looking at the respective effects of THC versus CBD. That has not yet been done in MS,” he said. He noted that the study participants who had discontinued medical marijuana elected to go back on it afterward, even with the knowledge that it affected their cognitive abilities, as a “lifestyle choice.”

Asked about whether marijuana or CBD can be beneficial treatments for people with MS, Dr. Feinstein remarked, “The expectations are way ahead of the evidence.”

Feinstein A, Meza C, Stefan C, et al. Coming off cannabis: a cognitive and magnetic resonance imaging study in patients with multiple sclerosis. *Brain*. 2019;Sep 1;142(9):2800-2812.

Should People With MS Take Vitamin D? How Much and How Often?

The vitamin D question is not a new one in multiple sclerosis (MS), but there is a growing body of information that can help shed light on how and whether people with MS should use vitamin D supplements.

Alberto Ascherio, MD, PhD, a pioneer in vitamin D research in MS, discussed this issue at the ECTRIMS 2019 Congress in Stockholm. “Do we know for a fact that vitamin D supplementation will do more good than harm?” asked Dr. Ascherio, of Harvard University’s T.H. Chan School of Public Health. Results of large studies include an analysis of over 40 million blood samples from people with or without MS, showing clear health benefits among those individuals whose vitamin D levels were in the normal range (50 nmol/L).

Neurologist Ellen Mowry, MD, of Johns Hopkins University School of Medicine in Baltimore, MD, provided practical advice for the use of vitamin D for people with MS. Dr. Mowry noted that studies have not proven



whether treatment with vitamin D can lead to a change in disability status in people with MS. And, it remains unknown whether the connection between vitamin D and the risk of developing MS may be related to lower blood levels of vitamin D, or due to other factors such as exposure to ultraviolet (UV) radiation.

How much vitamin D should a person with MS be taking to maintain health? Dr. Ascherio said he advocates a dose of 3,000 IU vitamin D per day. Dr. Mowry usually treats patients with MS who have low serum vitamin D levels to reach a target blood level of 40 to 60 nmol/L. To achieve this, she suggests oral daily supplementation at doses ranging between 2,000 and 5,000 IU. Higher doses are not recommended due to risk of toxicity. "You can get to the same levels reasonably quickly with a moderate daily dose," she said.

Hot Topic 3: Should we recommend vitamin D supplementation to our MS patients? Presented atECTRIMS, Stockholm, Sweden, Sept 11, 2019. Abstract 27.

European and U.S. Meetings Show MS Treatments Reduce Loss of Brain Volume

Research results reported at multiple sclerosis (MS) meetings in 2019 have shown that disease-modifying treatment (DMT) can reduce loss of brain tissue, or *atrophy*, that occurs in both relapsing and progressive forms of MS.

Oral Treatment for MS Reduces Loss of Grey Matter in People With SPMS

Grey matter is brain tissue with essential roles in many functions such as sight, hearing, memory, and speech. Atrophy, or shrinkage, of grey matter has been linked to cognitive

decline in people with MS. Grey matter atrophy increases in secondary progressive MS (SPMS). A poster presented atECTRIMS reported 1-year and 2-year results of an analysis from theEXPAND study of siponimod, an oral therapy approved in the U.S. in 2019. These investigators showed that, compared with placebo, siponimod reduced grey matter loss in the cortex region of the brain by 88% and reduced whole brain volume loss by 40%.

Arnold DL, Fox R, Bar-Or A, et al. Effect of siponimod on cortical grey matter and thalamic volume in patients with secondary progressive multiple sclerosis - Results of theEXPAND Study. Presented atECTRIMS, Stockholm, Sweden, Sept 11, 2019. Poster P382.

Investigational Drug Showed Reduced Loss of Cortical Grey Matter Volume Compared With Interferon

Loss of grey matter volume has also been studied in a clinical trial of another drug, ozanimod. This oral drug is currently under consideration by the FDA for approval in MS. Findings from the Phase 3 RADIANCE trial of ozanimod were reported earlier in 2019 at the American Academy of Neurology (AAN) meeting. They showed that people with relapsing MS treated with ozanimod had less grey matter volume loss compared with those treated with interferon beta-1a. People aged 25 or younger had larger brain volume at the start of the study, but experienced greater brain volume loss over the course of the 2-year study. Ozanimod was associated with less grey matter volume loss in the cortex region in all age groups, compared with interferon.

Schippling S, Cree BAC, Montalban X, et al. Gray matter volume loss is increased in younger patients with relapsing multiple sclerosis but minimized by ozanimod: experience from the ozanimod phase 3 program. Presented at: AAN 2019 Annual Meeting; May 4-11, 2019; Philadelphia. Abstract S2.059.



MS MESSENGER

WHAT TO EXPECT ON THE NEXT NARCOMS SURVEY

Spring Survey Planning

Happy New Year 2020! We all hope you are enjoying a wonderful holiday season. At NARCOMS we are already busy getting ready for the spring survey. As usual, it will be sent out in early April. Plans for other projects in early 2020 are also in progress; so please stay tuned!

Thank you for completing and returning the fall update survey. We appreciate your taking the time to advance MS research. You may have noticed that we changed some of the survey questions in the fall update. Based on your feedback, we removed the Performance Scales® and replaced them with the shorter SymptoMScreen® and Health Utilities Index®. We are planning to continue with these new scales in the spring survey too. Many of you have told us that these questions allow you to better represent

your conditions and symptoms.

One of the most common calls we get from NARCOMS participants is to clarify whether to include other illnesses when answering those symptom questions on the surveys. For example, if a participant has recently fractured a hip, should they consider that injury when reporting their ability to walk? The answer is yes. We are asking about your **current** abilities; your condition over the last 4 weeks. We will capture your progress and healing in the next survey.

If you ever feel the need to clarify your answers, please explain your unique situation in the comment section at the end of your survey. We understand that it is sometimes difficult to make your circumstances fit one choice; we welcome more information about YOU!

As always, please feel free to reach out via email or our toll-free number.

Patient Forum to Be Held at 2020 CMSC Annual Meeting

The Consortium of Multiple Sclerosis Centers (CMSC) will be hosting the second annual patient forum at its upcoming conference, scheduled for May 27–30, 2020 in Orlando, Florida. If you are planning to be in that area at the time, we would love to see you there. More details will be provided in the upcoming issue of *NARCOMS Now* or available from the CMSC (www.MScare.org/2020).



Play **WORDSEARCH**

Find the following hidden words relating to a Happy New Year!

BEGINNING
FAMILY
RESOLUTION
SLEDDING

TWENTY
CENTURY
FREEZE
SKATING

SOLSTICE
VALENTINES
DECADE
JANUARY

SKIING
TRANSFORMATION
WINTER

J	Z	F	V	P	E	E	E	T	L	O	H	X	T	G
U	A	G	E	K	V	C	D	R	O	O	T	R	C	N
A	J	N	W	C	I	N	Y	A	L	Y	A	E	E	I
B	L	R	U	T	Q	L	A	I	C	N	X	T	N	N
S	O	N	S	A	I	M	S	L	S	E	D	N	T	N
X	E	L	W	M	R	S	I	F	A	B	D	I	U	I
H	O	N	A	M	K	Y	O	H	I	N	Y	W	R	G
S	Y	F	I	A	F	R	E	E	Z	E	M	U	Y	E
S	B	Z	T	T	M	S	L	E	D	D	I	N	G	B
K	K	I	B	A	N	O	I	T	U	L	O	S	E	R
L	N	I	T	R	D	E	Y	T	N	E	W	T	S	B
G	D	I	I	D	A	R	L	D	U	H	L	H	E	V
V	O	G	D	N	U	T	I	A	L	I	Z	K	K	E
N	Q	X	N	G	G	K	D	R	V	P	H	X	E	Q
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NARCOMS NOW

BE PART OF NARCOMS—HELP TO ADVANCE RESEARCH IN MS

Whether you were recently diagnosed with multiple sclerosis (MS) or have lived with it for years, your personal history with the disease helps contribute to improving the lives of others with MS.

Participation in the NARCOMS registry allows you to be part of the process. The data provided by participants gives researchers a clearer picture of how a condition like MS impacts the lives of those affected.

Participation in NARCOMS is confidential—your information is kept secure and completely private. If you have MS and are not yet participating in NARCOMS, or have been out of touch for a while, we would love to hear from you! Contact us at 1-800-253-7884 (toll-free U.S.) or via email at MSRegistry@narcoms.org.



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