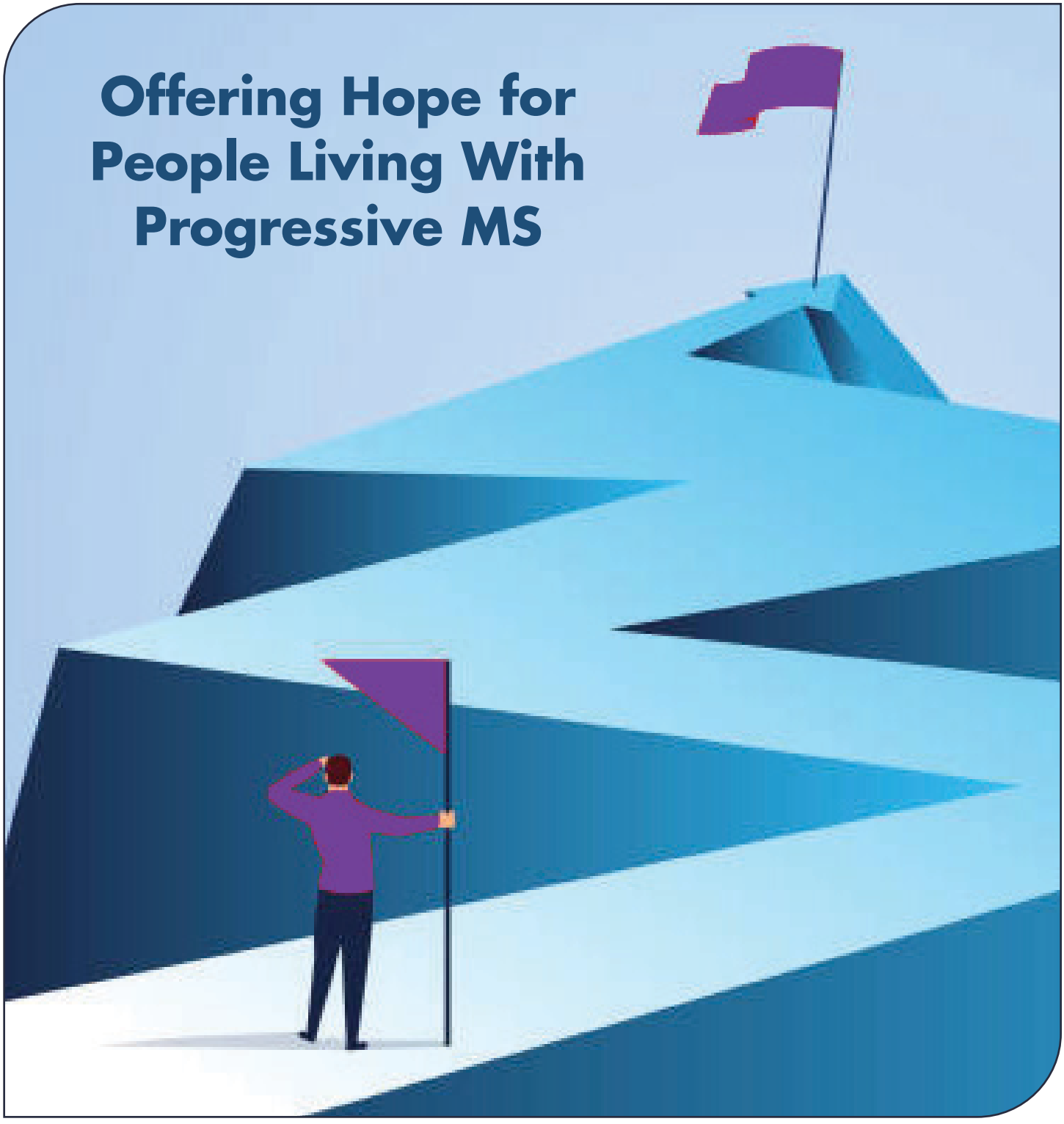
NARCOMS NOW

www.narcoms.org

Vol. 10, Issue 1, 2021

Offering Hope for People Living With Progressive MS



CMSC NARCOMS

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 living with 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.)
Email: MSRegistry@narcoms.org
Online: www.narcoms.org/contact-us

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DIRECTOR'S **LETTER**

Ruth Ann Marrie, MD, PhD

Dear *NARCOMS Now* Readers:

In this issue of *NARCOMS Now*, we focus on the concept of repurposing existing drugs that were developed for other conditions as possible treatments for progressive multiple sclerosis (MS). Drug repurposing avoids some of the challenges faced by newly developed treatments when entering clinical trials for progressive MS. As an example, we look at the repurposing of simvastatin, a drug commonly used to reduce blood cholesterol levels, as a possible treatment for progressive MS. High doses of simvastatin have been shown to reduce brain tissue loss in people with secondary progressive MS. The MS News section discusses investigations into the use of metformin, a drug approved for the treatment of diabetes, to enhance remyelination in people with relapsing MS.

We also examine the mission of the International Progressive MS Alliance. This organization seeks to develop effective treatments for people with progressive MS and to improve their quality of life. We speak with Dr. Alan Thompson, the outgoing Chair of the Alliance, as well as Jon Strum, a member of the Alliance's Scientific Committee and a strong advocate for improving the lives of people with MS. Finally, we review a study that identifies a link between gut bacteria and activity of some cells in the brain. The Snapshot returns in this issue to provide information about the use of statins among NARCOMS participants, as well as treatments for other medical conditions (often called "comorbidities").

We thank you for your continued participation in the NARCOMS registry! Your involvement in this registry is critical in advancing our knowledge of MS. We also want to reiterate the importance of wellness during these difficult times and to follow safe practices during this pandemic.

Sincerely,

Ruth Ann Marrie

Ruth Ann Marrie, MD, PhD
Scientific Director, NARCOMS

International Progressive MS Alliance Offers Progress and Hope for People Living With Progressive MS

International Progressive MS Alliance Accelerates Progress in Developing Treatments for People Living with Progressive MS

A decade ago, many people with progressive forms of multiple sclerosis (MS) felt overlooked by the research community. At that time, many new therapies for relapsing MS were approved, but none for progressive MS. "It was a bit like watching a parade go by, but there's nothing there for you to celebrate," explains Jon Strum, an MS advocate whose wife suffered from an aggressive form of primary progressive MS before passing away last year. Having more effective therapies for relapsing MS is cause for celebration, but more focus on progressive MS was long overdue.

The International Progressive MS Alliance was formed with this focus in mind, says Professor Alan Thompson, MD, chair of the Alliance's Scientific Steering Committee and a founder of the organization. "One of the main reasons for establishing the Alliance was to bring progressive MS to center stage, to raise the profile. I think that is something that has really happened." The other main purpose was to inspire, encourage, and financially support research to address the need for effective disease-modifying therapies (DMTs) for progressive MS. "We needed the best brains in the world to come together and focus on this mission," Prof. Thompson noted. Some DMTs have now received approval for treating progressive forms of the disease. Nonetheless, there remains an urgent need for therapies that can remyelinate nerve cells and potentially restore damaged areas of the brain. After chairing the Scientific Steering Committee for over a decade, Prof. Thompson will step aside in early 2022 when the leadership will transition to Robert Fox, MD (as Chair), and Ruth Ann Marrie, MD, PhD (as Vice Chair). Both are also part of NARCOMS leadership.

Challenges in Progressive MS

Prof. Thompson discussed some of the challenges that make researching progressive MS difficult. "When treating MS, we're really very good at stopping attacks, or relapses," he said. MS relapses are caused by inflammation, and most available DMTs are effective at halting or preventing inflammation, he said. "It's much more difficult to stop or delay progression or neurodegeneration. That is

partly because we don't fully understand the underlying mechanisms."

Progression in MS appears to involve gradual deterioration of the nerve cells and nerve fibers. This is a prolonged and often silent process. "We used to think of relapsing MS as being the earlier stage of MS and progression as happening later. We now believe that both occur at the same time," Prof. Thompson explained. "It's a balance, and in some people the progressive part is more evident."

Bolstering Research Projects in Progressive MS

To meet the challenges of better understanding MS progression and identifying ways to stop it, the Alliance has established a series of collaborative research networks.

- **Drug Discovery International Collaborative Research Networks**. These networks bring together leading scientists from MS research institutions across multiple countries to drive innovation and expedite results. The networks are supported by over $9.5 million in research funding from the Alliance. One network is aiming to identify compounds for neuroprotection and repair. Another network is focused on finding ways to prevent the degenerative process.
- **Research Awards**. This program provides grant funding for scientists to better understand the causes of progression and to identify new pathways for treatment. In 2021 up to 20 awards totaling $1.8 million in funding will be

International Progressive MS Alliance

Mission:

Accelerate the development of effective treatments for people with progressive forms of multiple sclerosis to improve quality of life worldwide

Values:

Collaboration

Be Bold

Excellence

Inclusivity

Transparency

Acting with Urgency

For more information, visit progressivemsalliance.org

granted for progressive MS research. Grant awards will prioritize high-risk proposals that have the potential to result in a major shift in the approach to progressive MS treatment.

Future Goals for Progressive MS

In many MS drug trials, success is measured by whether a treatment stops the development of new brain lesions seen on MRI or reduces the frequency of clinical relapses. These measures are not as informative in progressive MS. Observing how a drug affects progression can take many years, a frustrating problem for people who are living with progressive MS now. Speeding up clinical trials and improving their design is another goal of the Alliance. To do this, there is a need for better biomarkers. An example of a biomarker might be a blood test that shows when nerve damage

NARCOMS Now Talks With International Progressive MS Alliance Scientific Committee Member Jon Strum

Jon Strum was thrust into the world of progressive MS (MS) when his wife Jeanne was diagnosed with an aggressive primary progressive form of the disease. Prior to her illness, Jeanne was a writer, hiker, and avid cyclist. While Jeanne became more disabled and eventually bedbound, Jon worked as an advocate and voice for other families affected by progressive MS. In addition to his role representing people affected by MS on the Scientific Steering Committee of the International Progressive MS Alliance, Strum is an ambassador for the Patient-Centered Outcomes Research Institute (PCORI).

What has it meant to you to represent people with progressive MS as part of the International Progressive MS Alliance?

Being part of the International Progressive MS Alliance has been some of the most gratifying work I've ever done, without question. The Scientific Steering Committee includes about 20 members who are scientists and neurologists, and three of us who are directly affected (myself and two people who have progressive MS). We quickly bonded, naming ourselves the Three MS-keteers. We don't just have token seats on the committee, but full participation in every way. We vote along with the other members on what research directions should be encouraged and what projects should be funded. It has been a phenomenal experience.

Do you believe that we are beginning to see more progress for treating progressive MS?

I think for a long time people were frustrated about the lack of research in this area. Progressive MS and related topics have moved much closer to the top of the neurological research agenda than it ever was before. The Alliance has helped to focus attention and gain momentum by creating what I call *global synergy* around progressive MS research. These actions have really changed the game when it comes to interest in, and pursuit of, research in progressive MS.

is occurring. Research into new biomarkers is ongoing, including a blood test known as neurofilament light chain (NfL). Another innovation of the Alliance has been allowing people with progressive MS and family members to have a voice in how research is planned and conducted (see interview with Jon Strum, below).

Continued focus must also be placed on the symptoms that people with progressive MS experience every day. The Alliance is working to establish a global research strategy that can lead to proven methods for rehabilitation and symptom management to improve the lives of people living with progressive MS. "We have always had hope for progressive MS, but now we can combine that hope with progress. We are on an upward trajectory," Prof. Thompson stressed.

When you speak to people with progressive MS or their family members, what messages do they want you to convey?

First and foremost, we want to be recognized. We want to make sure that the MS community remembers to count us among its population. We also need more disease-modifying therapies for progressive MS. There is a lot of interest in topics like myelin repair. This is a big conversation because it implies being able to restore lost function. People also have an interest in stem cell research, although we haven't really seen evidence showing that stem cell therapies are particularly effective in people with advanced disability.

NARCOMS registry participants have an interest in furthering MS research. As someone involved in MS advocacy efforts, what would you want to convey to them?

That things are changing—in fact, today I would say things *have* changed. We now have treatments approved for progressive MS and I believe we will see more to follow. The Alliance is funding some ongoing international research collaborations. The year of the pandemic has been quite challenging for research, to say the least. But I can say unequivocally that these projects will provide us with foundations for new treatments and new ways of doing things. And that to me is most exciting.

Can you tell us about your involvement with PCORI?

Yes. The Patient-Centered Outcomes Research Institute (PCORI) is an independent nonprofit, nongovernmental organization in Washington, DC. PCORI was authorized by Congress in 2010 to close gaps between patients and healthcare providers. I think PCORI is a great example of an ongoing evolution in health care. The voices of patients and caregivers are being moved to the center rather than the periphery. PCORI allows people who are actually affected by diseases like MS to help design better trials that study the outcomes that matter most to us. PCORI is a great reflection of this new way of thinking.

What has it meant to you personally to give back to the MS community through your involvement?

Progressive MS has impacted my family in every imaginable way. It has profoundly affected us financially, emotionally, you name it. As I often say, it takes no prisoners. My wife lost her battle with progressive MS one year ago in February. My fondest wish—and why I am so committed to the mission that the Alliance has undertaken—is that other families never have to experience all the challenges that we had to face.

Repurposing: Using Existing Drugs to Treat Progressive MS

What if an effective new treatment for progressive multiple sclerosis (MS) was hiding in plain sight? This idea is being explored as MS researchers look at existing drugs, used for different conditions, as possible therapies for MS. "Repurposing," or using an 'old' drug to treat a different disease or condition, has potential to open new avenues of research.

In 2011, the MS Society of the United Kingdom (UK) encouraged researchers to study existing oral drugs to identify possible neuroprotective effects in secondary progressive MS (SPMS). Several drugs were studied. From this initiative, three medicines were tested in a phase II trial in people with SPMS: riluzole (a drug for ALS), amiloride (a diuretic), and fluoxetine (an antidepressant commonly known as Prozac). None of the three medicines were shown to be beneficial in slowing the progression of brain atrophy (shrinkage) as measured by MRI.

In 2018, the UK MS Society set up a consortium of expert clinicians, laboratory scientists, pharmaceutical scientists, and people with MS. Their goal was to identify existing drugs that:

1) show possible relevance to MS progression, including remyelination;
2) have the ability to enter the brain; and
3) show benefit in at least one animal model of MS.

Monoclonal antibodies (such as B cell therapies) were not included, mainly because there is already a great deal of research focus in this area. The group produced a list of its

Neuroprotection is the ability of a disease therapy to preserve the cells, structure, and/or function of the nervous system.

Remyelination is the generation of new myelin sheaths (or coverings) on nerves that have lost their myelin sheath.

Table 1. Drugs Prioritized for Repurposing for Progressive MS

Drug	What it is	Possible properties in MS
R-alpha-lipoic acid	Dietary supplement; Approved in Germany for nerve damage in diabetes (neuropathy)	Antioxidant, anti-inflammatory; may be neuroprotective
Metformin	Common diabetes treatment, lowers blood sugar	Anti-inflammatory; may promote remyelination and neuroprotection
R-alpha-lipoic acid plus metformin	(Combination)	The combination of these drugs may be of more benefit than either drug alone
Slow-release niacin	Cholesterol-lowering agent	May promote proliferation of oligodendrocytes (cells that produce myelin) remyelination, neuroprotection
Clemastine	Antihistamine used for seasonal/ nasal allergies	May promote oligodendrocyte progenitor differentiation, remyelination
Lamotrigine	Sodium channel antagonist used as anticonvulsant	Possible neuroprotective effects
Nimodipine	Calcium channel antagonist, used to treat narrowing of blood vessels in brain associated with bleeding	May promote remyelination, neuroprotection, restore passage of oxygen and fluids through central nervous system
Flunarizine	Calcium entry blocker; used in prevention of migraine	Neuroprotective effects

Source: Cunniffe N, Vuong KA, Ainslie D, et al. Systematic approach to selecting licensed drugs for repurposing in the treatment of progressive multiple sclerosis. *J Neurol Neurosurg Psychiatry*. 2021;92:295-302.

top 8 choices of existing drugs to target for further research in progressive MS (Table 1). Research findings for the diabetes drug metformin are discussed in this issue's MS News column, page 11.

"Finding drugs to treat progression remains the greatest unmet need for people with MS," the consortium authors stated in a recent medical journal article. Drug repurposing is attractive because there are fewer hurdles before the drug can reach clinical trials, they said, but it is important to carefully consider why a drug is being investigated and how it might offer benefits in progressive MS.

MSMESSENGER

NARCOMS Survey Updates and Tips

The NARCOMS Spring 2021 Update Survey has been sent to all of our participants. If you have not received your copy, please let us know. Due to the COVID-19 pandemic our physical offices have been closed since last March, but NARCOMS staff continues to work from home. Email is the best way to reach us, but we can also receive phone calls. Please continue reaching out to us; we love hearing from our participants!

On the completed surveys, we are always interested to read your comments and the questions. The most common questions we receive are:

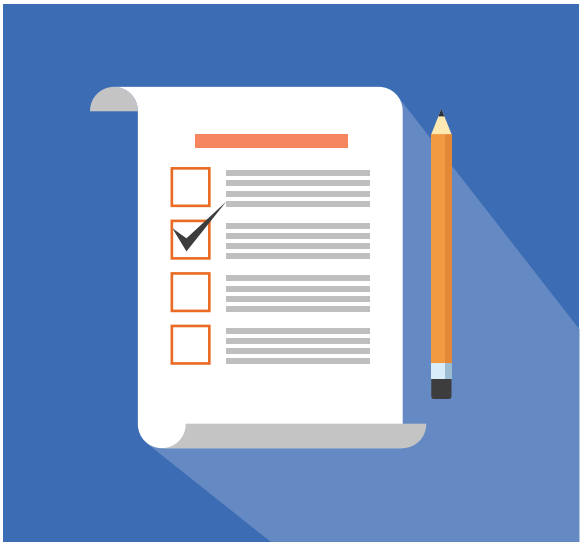
Should I continue to complete the surveys even though I haven't had any changes in the past few years?"

The answer to that is YES! Even if you have not had changes for decades, it is important for us to know that you are stable. These data are vital to researchers. All of your information is important. We appreciate the information about you, and how you access and use healthcare. Additionally, we try to include current, one-time topics in each survey and we want examine these areas with as much representation as possible from our participants.

The answer selections on the survey do not fit my condition exactly.

We recognize that all question/answer combinations do not fit all people. It can be difficult at times to pick the "correct" answer. Please remember that there are no right or wrong answers to the survey questions. If you can't find an option that exactly fits your situation, please choose the answer that fits most closely. We welcome any explanation in the comment section at the end of each survey.

Enjoy the upcoming change in seasons and stay well!



New Study Suggests Gut May Control Cells That Fight Brain Inflammation

Which organ is really in charge, the gut or the brain? Many previous research studies have suggested about 70% of the immune system resides in the "gut," which consists of the intestines and digestive organs. A new study led by Francisco Quintana, MD, from Harvard's Brigham and Women's Hospital, reports that a type of brain cell called *astrocytes* may be receiving directions from bacteria in the gut (also known as the microbiome) that help to reduce brain inflammation. The study was conducted through the International Progressive MS Alliance's Collaborative Research Network and also funded by the National Institutes of Health (NIH).

Astrocytes are abundant in the brain and spinal cord. They support other brain cells. Also, they may be capable of promoting inflammation and nerve degeneration. A specific subtype of astrocytes can turn off inflammation within the brain, based (at least in part) on signals regulated by bacteria that reside in the gut. By finding out more about these processes, investigators may be able to develop new ways to combat MS.

"This is a very novel mechanism by which the gut controls inflammation in the brain," said Dr. Quintana. "We have a list of other populations of astrocytes, and we're working to see how the gut flora may control them," he added. Determining how to harness this beneficial activity may lead to new treatment approaches for MS, including probiotics to alter the balance of gut bacteria.

Reference: Sanmarco LM, Wheeler MA, Gutierrez-Vazquez C, et al. Gut-licensed IFNγ + NK cells drive LAMP1 + TRAIL + anti-inflammatory astrocytes. *Nature.* 2021 Feb;590(7846):473-479.

Can An Old Diabetes Drug Be Taught New Tricks for Remyelination in MS?

Oligodendrocytes are the cells in the brain and spinal cord that generate myelin. Myelin is the coating on the nerves that is destroyed by the immune system in people with multiple sclerosis (MS). Treatments that preserve oligodendrocyte function might help to restore myelin, a concept known as "remyelination."

An important stage of oligodendrocyte formation happens in a type of stem cell known as "oligodendrocyte precursor cells," or OPCs. In people with MS, these OPCs may fail to change into oligodendrocytes. This problem may worsen with age. A group of investigators from the United Kingdom (UK) and Australia studied the diabetes drug metformin in ratsrodents to see if the treatment would help the OPCs to differentiate into oligodendrocytes. In a paper published in the journal Cell Stem Cell, the researchers reported that metformin appeared to enhance remyelination in aging rats.

Metformin is an oral drug used for diabetes as far back as the 1950s. It has also been shown to reduce inflammation in animal models of MS. Other studies have suggested that it may be neuroprotective. In the UK, Prof. Alasdair Coles is embarking on a clinical trial to test

metformin. The trial will enroll 50 people with relapsing MS who will be given either a combination of metformin and clemastine (an antihistamine), or placebo. The goal of this study will be to see if this combination promotes myelin repair in humans.

Reference: Neumann B, Baror R, Zhao C, et al. Metformin restores CNS remyelination capacity by rejuvenating aged stem cells. *Cell Stem Cell*. 2019;25(4):473-485. [Free article]

Cholesterol Lowering Agents for Progressive MS—Beneficial, or Not?

The term "statin" refers generally to a group of drugs used to lower cholesterol levels. Some of these drugs are named simvastatin, atorvastatin, and lovastatin. Some investigators are exploring whether statins can have any benefit in multiple sclerosis (MS), especially progressive MS. New research studies suggest statins may protect the brain and spinal cord against damage in MS.

In addition to lowering cholesterol, statins appear to have other actions that may be relevant in MS. Statins are thought to:

- help to prevent the activation and proliferation of T cells, a type of white blood cell important in immune system function
- shift T cells from a proinflammatory function to an anti-inflammatory function
- inhibit travel of certain immune cells across the blood-brain barrier.

In 2014, simvastatin (known by the brand name Zocor®) was studied in a randomized double-blind controlled trial at three UK centers among 140 people with secondary progressive MS (SPMS). Half of the study participants received placebo and half received 80 mg simvastatin per day (a higher dose than is normally used to lower cholesterol). At the two-year follow-up period, patients in the high-dose simvastatin group had significantly less brain atrophy (loss of brain tissue) compared to those receiving placebo—a 43% reduction in annualized brain atrophy rate. There were no differences between the groups in terms of serious side effects. The authors cautioned, however, that brain imaging findings like atrophy can be difficult hard to interpret. They might not necessarily translate into clinical benefits.

A follow-up analysis from this same trial looked at how simvastatin affected cognition and health-related quality of life. One of the cognitive tests measured "executive" function, which is the ability organize thoughts and actions. The simvastatin group performed better on the Frontal Assessment Battery, a test of executive function, at the end of the study than the placebo group. Physical quality of life was also better in the simvastatin group. There was no observed benefit of simvastatin versus placebo in any of the other outcome measures studied. "These potential effects warrant confirmation and underline the importance of fully assessing cognition and quality of life in progressive multiple sclerosis treatment trials," the authors concluded.

Based on these findings, a larger phase 3 trial of simvastatin in 1,050 people with SPMS is under way in the UK, with an estimated completion date of 2024.

References: Chataway J, Schuerer N, Alsanousi A, et al. Effect of high-dose simvastatin on brain atrophy and disability in secondary progressive multiple sclerosis (MS-STAT): a randomised, placebo-controlled, phase 2 trial. *Lancet*. 2014;383:2213-2221.

Chan B, Binks S, Nicholas JM, et al. Effect of high-dose simvastatin on cognitive, neuropsychiatric, and health-related quality-of-life measures in secondary progressive multiple sclerosis: secondary analyses from the MS-STAT randomised, placebo-controlled trial. *Lancet Neurol*. 2017;16(8):591-600.

Survey: The use of statins among NARCOMS participants

Survey results in the past show that many NARCOMS participants are taking anti-cholesterol medications known as statins (e.g., Lipitor®, Lescol®, Mevacor®, Pravachol®, Crestor®, and Zocor®). Statins reduce blood levels of cholesterol by limiting the activity of an enzyme important in the production of cholesterol. They reduce the risk of heart disease and stroke linked to high cholesterol levels. However, statins can also reduce inflammation and pass through the blood-brain barrier, both of which suggest a possible application as an MS treatment. One of the MS News articles in this issue describes a study looking at repurposing of statins in the treatment of progressive MS.

We examined your answers to the "statin use" question in the Fall 2019 survey. In that survey, nearly one in three NARCOMS participants reported taking statins. Statin use among NARCOMS participants increased with age (Figure 1) which also aligns with the general

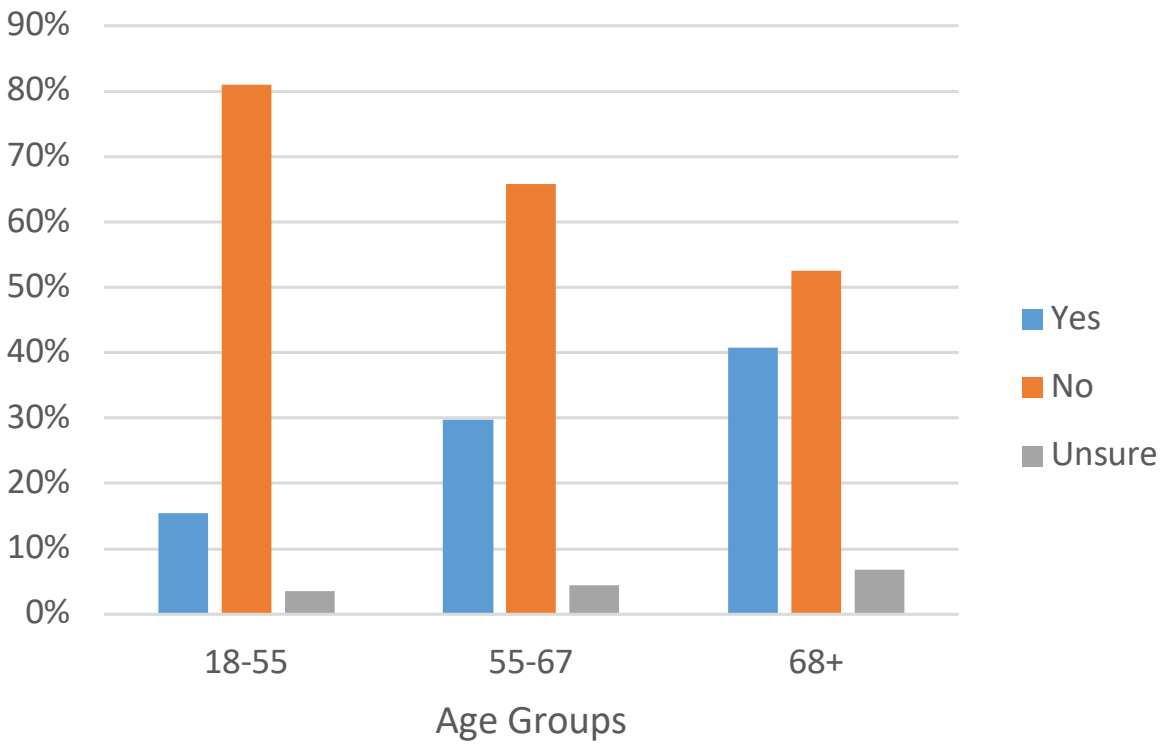


Figure 1. Statin use in NARCOMS participants by age group.

US population data. The percentage of people with MS taking statins was not different among MS clinical courses (Figure 2). Of those who reported a diagnosis of high cholesterol, 87% were taking statins.

Also in this issue, another MS News article reported that metformin, an oral drug used for diabetes, has been shown to reduce inflammation in animal models of MS. Other studies have suggested that it may be neuroprotective. In the Fall 2019 survey, approximately one in ten NARCOMS participants reported having diabetes. These data showed little difference between MS type, and the number of NARCOMS participants who reported a diagnosis of diabetes increased only slightly with age.

As we continue to analyze your answers to our recent surveys, we have noticed that a lot of you are experiencing increased anxiety as the COVID-19 global pandemic continues to impact our lives. While we understand that this is a stressful time and this might affect your answers to the survey questions, we greatly appreciate your honesty. We hope that the articles in *NARCOMS Now* about wellness, holistic therapies and exercise can provide some help in reducing anxiety and improve your everyday quality of life. We wish you well in these unprecedented times as we all look to a bright future without quarantines!

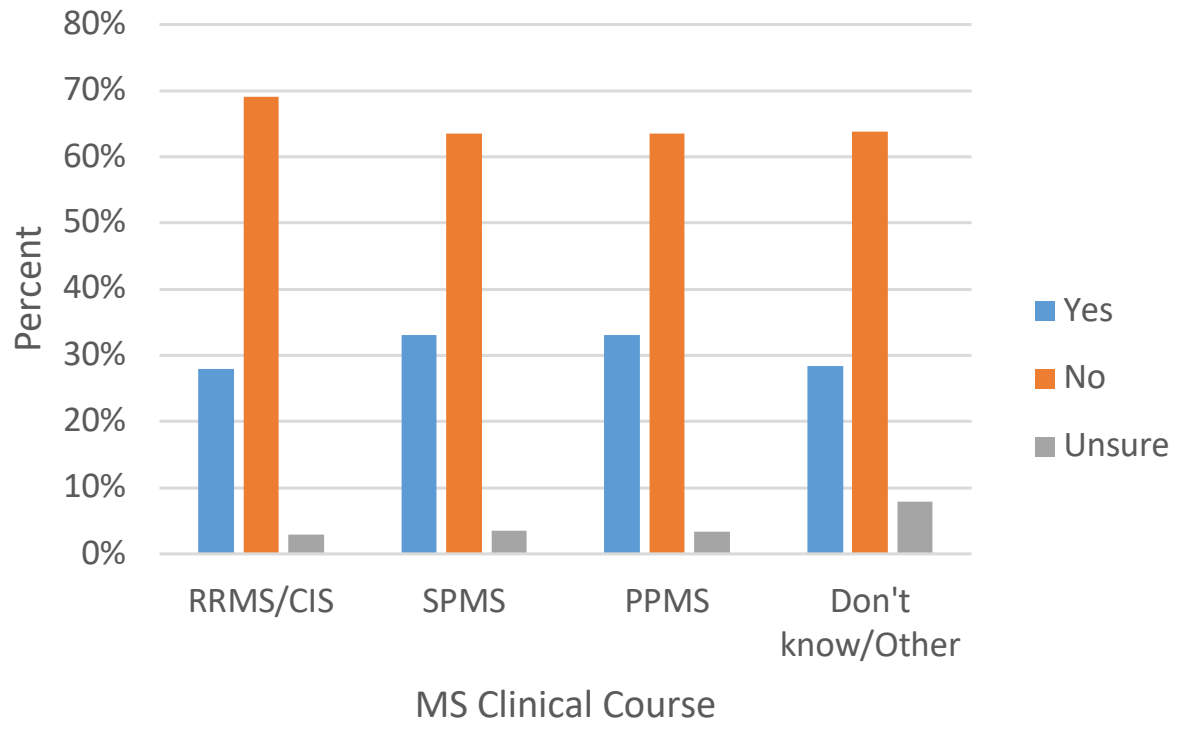
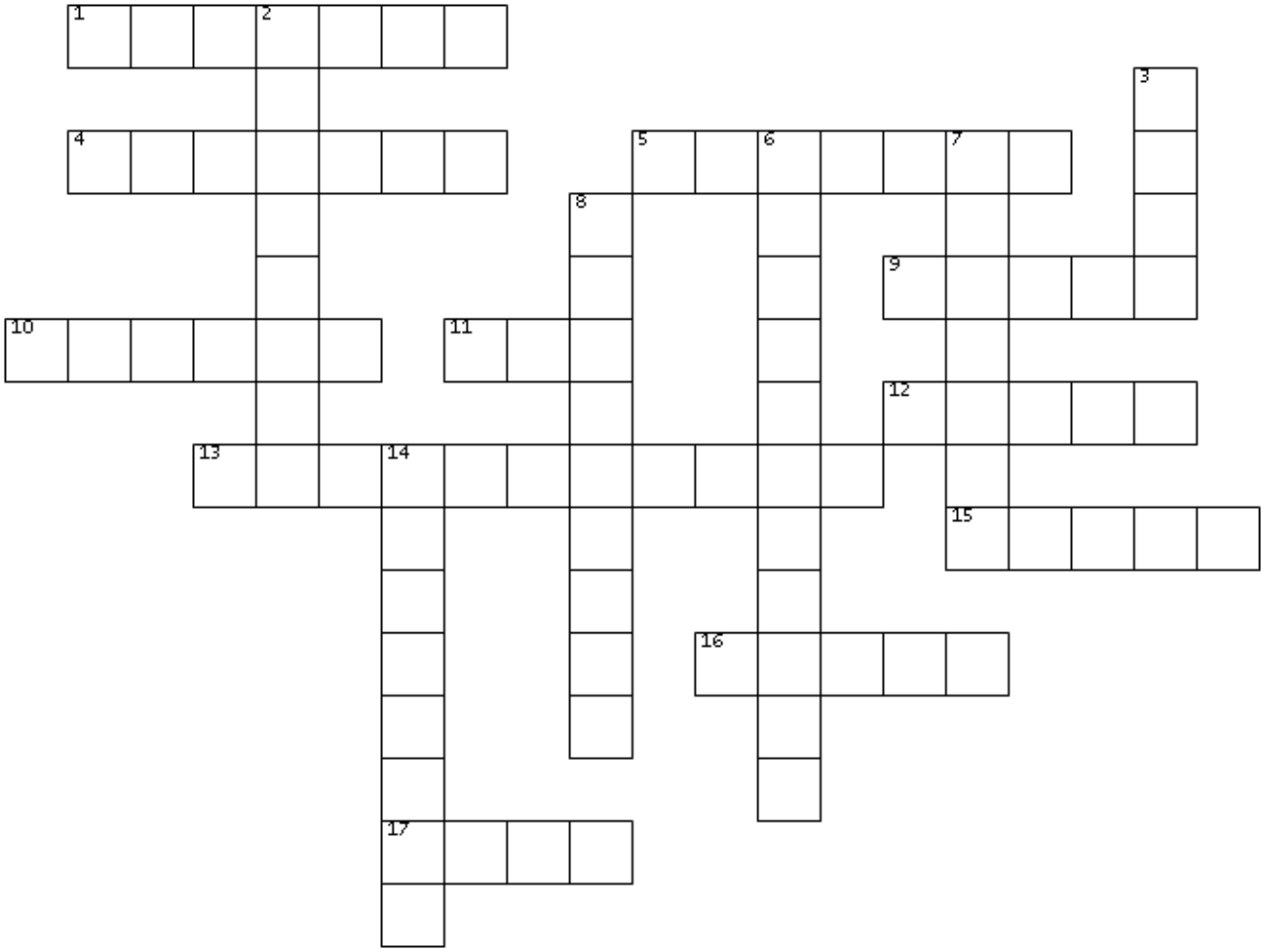


Figure 2. NARCOMS participants who are currently taking any anti-cholesterol drugs

CIS, Clinically Isolated Syndrome; PPMS, Primary Progressive; RRMS, Relapsing Remitting MS; SPMS, Secondary Progressive MS

Play CROSSWORD

NARCOMS Spring Update



ACROSS

1. Temporary worsening of MS
4. Improving the ___ of life for people with MS; goal for MS care
5. Shot to prevent viral illness
9. Another word for clinical research study
10. Season when trees start to bud
11. Term for digestive system
12. Virus causing 2020 pandemic
13. Medical specialist who treats MS
15. Alliance member interviewed in this issue
16. Most MRIs for MS scan this organ
17. Number one goal for MS research

DOWN

2. Advocacy organization for progressive MS
3. When a drug is given by mouth
6. Statins lower levels of this in the blood
7. Registry for people with MS
8. Diabetes drug studied in MS (see MS News)
14. NARCOMS participants help support this for MS

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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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