

NARCOMS

Fall 2015

www.narcoms.org

NOW

Vol. 4, Issue 4



RESEARCH INSIGHTS

In June, The University of Alabama at Birmingham hosted an “Etiopathogenetic, Immunological and Clinical Concepts” MS Symposium. NARCOMS was there and asked noted MS researchers:

What’s the next BIG thing in MS research?



**Howard Weiner, MD, Professor
Department of Neurology, Brigham and Women’s Hospital
Harvard Medical School**

“The microbiome is a big one. Also, increased efforts in understanding progressive MS, as well as individualized care for people living with MS. We’re too heterogeneous in our current approach to treating the disease.”

**John Rinker, MD, Associate Professor
Department of Neurology, UAB**

“Neurotreatments that have greater effectiveness and more aggressive early treatment, or we will continue to have a ‘wait and see’ approach, until something bad happens.”



**Stephen Miller, PhD, Professor
Department of Microbiology-Immunology
Northwestern University**

“Developing antigen-specific therapies to avoid the side effects of the drugs that patients are currently using.”



**Tika Beneviste, PhD, Professor and Chairman
Department of Cell, Developmental and Integrative Biology, UAB**

“We are trying to train your cells to be protective cells against MS.”



A project of the Consortium of Multiple Sclerosis Centers



THE CONSORTIUM OF
MULTIPLE SCLEROSIS CENTERS

- 02 **Letter from the Director:** Fall Survey and Research Updates
- 03 **NARCOMS Info Corner**
- 04 **Feature Focus:** Researching Research; MS in Song & Print
- 11 **MS Apps:** Women With MS
- 12 **Survey 101:** Fall Update New Questions
- 14 **Q&A:** From Data Collection to Publication
- 15 **NARCOMS Messenger:** Let's Vote!
- 16 **MS Reflections:** Uncertainty in MS
- 18 **NARCOMS Snapshot:** Comorbidities in MS and NARCOMS
- 20 **MS News:** Gilenya Gets FDA Warning for PML; ADA Turns 25
- 24 **Play:** Fall Word Find
- 25 **Faces of NARCOMS:** My MS Diagnosis Journey

NARCOMS NOW

STAFF

Robert Fox, MD
Managing Director

Ruth Ann Marrie, MD, PhD
Scientific Director

Gary R Cutter, PhD
Coordinating Center Director

Stacey S Cofield, PhD
Executive Editor

Christina Crowe, MA
Managing Editor & Media Specialist

Shawn Avery Stokes
Creative Director

NARCOMS Now acknowledges and appreciates the companies listed below who 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.

Genentech
A Member of the Roche Group

Teva Neuroscience

genzyme
A SANOFI COMPANY

The Performance Scales (Mobility, Hand Function, Vision, Fatigue, Cognitive Symptoms, Bladder/Bowel, Sensory, and Spasticity) have a filed copyright assigned to DeltaQuest Foundation, Inc., effective October 1, 2005. U.S. Copyright law governs terms of use. TXu000743629 / 1996-04-04.

A Letter from the Director - Fall 2015

Greetings,

Welcome back to *NARCOMS Now*. We've had a busy summer starting with the Consortium of Multiple Sclerosis Centers annual meeting in late May, followed by our Spring Survey showing fantastic response rates—thank you! Our researchers are continually working on manuscripts for publication or abstracts for presentations based on the data you provide for studies. We're looking forward to several NARCOMS-related presentations at the forthcoming annual congress meeting of the European Committee for Treatment and Research in MS (ECTRIMS).

How do you research your MS? Where do you look? What should you look for when you're reading about the latest findings in MS research news? We tackle these topics in this issue's "**Feature Focus**" story on interpreting research results.

Also in this issue, we enjoy a conversation with **David Osmond**, musician and MS patient, on how he's using music to share positive messages about his MS life. **James Hall**, an author with more than 19 novels to his credit, spoke to us about one of his books, which highlights MS both in a main character living with it, and as a plot line.

"**MS News**" this issue discusses the recent anniversary of the Americans with Disabilities Act, as well as the Supreme Court's decision to uphold President Barack Obama's Affordable Care Act, and its implications for those living with MS. "**MS Apps & Blogs**" highlight several women bloggers writing about and representing MS in their lives and their work.

"**Snapshot**" discusses the results of a review by myself and other researchers of published research on MS and comorbidities—living with two or more chronic conditions, highlighting NARCOMS results to questions about "Other Conditions" in each Spring update.

In "**MS Reflections**," **Dr. Cheri Roseberry**, Clinical Instructor at the University of Arizona, discusses her research on NARCOMS data looking at depression, fatigue, and declines in cognitive function in women with MS.

Fall will be here before we know it, and with it our Fall Survey. We extend our sincerest thanks to you, our participants, for all the input you provide on a regular basis.

Best,



Dr. Ruth Ann Marrie
Managing Director, NARCOMS



Dr. Ruth Ann Marrie is a Don Paty Career Scientist, practicing neurologist and Director of MS Clinic at University of Manitoba Health Sciences Center in Winnipeg, Canada.

NARCOMS INFORMATION CORNER



Have an idea?

We would love to hear from you!
Send us your questions,
comments & suggestions.

Call: **1-800-253-7884** (toll-free US)

Email: narcomsnow@narcoms.org
Online: www.narcoms.org/contact

Who you'll hear on the phone:
Chad or Chasity



NARCOMS Promise

Your personal information is always confidential.

The NARCOMS Global MS Patient Registry facilitates multi-center research on multiple sclerosis, developing collaboration between MS centers of excellence throughout the world to increase knowledge, improve clinical care, and enhance the quality of life for persons with MS.



View Past Surveys

Go to: www.narcoms.org

Click on: Participant Log in Here

Enter your username and password.
Select the correct picture, click Login.
Click the Form Summary link.

Choose the survey you would like to view from the drop down menus and click the **View Summary** link.
Print like you would any document.



En Español

Para acceder a nuestro sistema a línea:

www.narcoms.org/es

Nuestro sitio de web es de alto seguridad a para su confidencialidad.

Para solicitar la envía de un cuestionario de inscripción por correo, llame al Registro NARCOMS al (800) 253-7884.



Become a part of NARCOMS:

WWW.NARCOMS.ORG / 1-800-253-7884

Reminder When Completing Paper Surveys:

Please use pen rather than pencil when filling out NARCOMS paper surveys. Responses are scanned to electronic files for data capture and pen is easier to read. Thanks!

Interpreting Research Results: What to Look for and What it Means

Research results are published every day, along with news stories designed to grab the reader's interest. Reading and interpreting the actual published results can be difficult, even with a research background or detailed knowledge of MS, research, or statistics.

There are some clues you can look for that can help you interpret the results and what they mean for you. There is a lot of research taking place, just like there are a lot of different people living with MS. Just because the letters "MS" are the headline, not every study will apply to every person with the disease. Some important factors to consider is whether enough people were involved, were they studied for an appropriate amount of time, and with a meaningful measurement.

Consider this example:

Does exercise improve MS? This question is very general and actually hard to measure.

What kind of exercise? How is "improvement" defined and measured? If there is improvement, who improved? When did the improvement happen? How long did the improvement last? And how does this apply to you?

What was the study question?

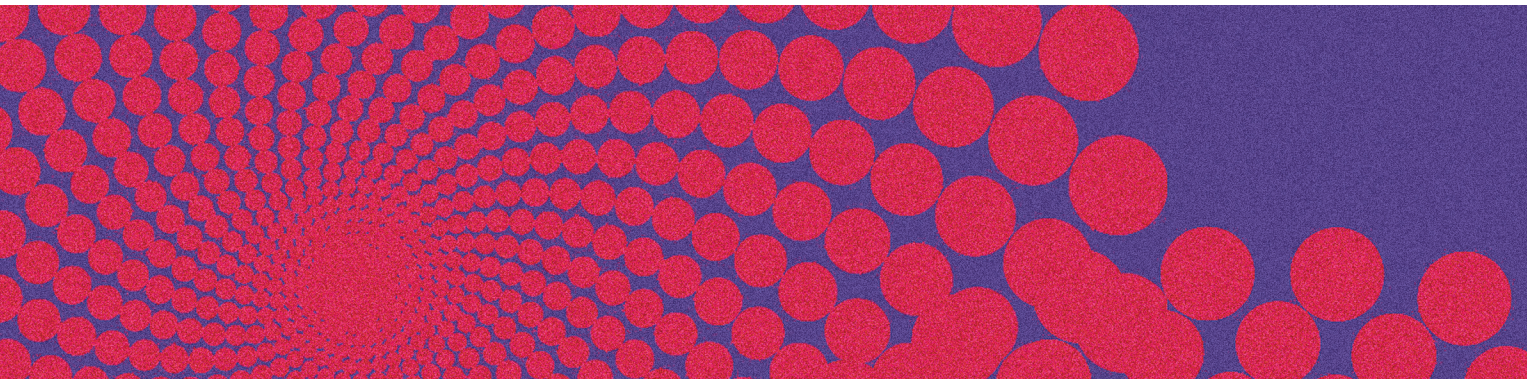
It may seem obvious that a report on exercise improving MS came from a study about exercise and MS, but this is not always the case. It could be that in a drug study, after the study was analyzed, some additional analyses were conducted which looked at who improved and who didn't, and found an association between exercise and improvement. These after-the-fact (or **post-hoc**) **observations** are useful and important, but they are less informative than the primary question the study asks.

These are the types of questions that should come to mind when seeing or hearing about new research results. Some things you can look for when reading research are:

- What was the study question?
- Who is in the study?
- What was measured?
- How long did the study last?
- What do the results mean for you?

It is much more difficult to state in advance what you are trying to show (what researchers call their **hypothesis** or their **specific aims**) than it is to collect data and ask, what is the difference between those who improve and those who don't.

A study that starts with a question and answers that question is more believable because it is more like what will happen if you follow the same exercise routine.



Who is in the Study?

An exercise study conducted only in men, or only in people with relapsing-remitting MS might not mean as much for you if you are a woman, or have progressive MS. It is important to pay attention to the types of people who were in the study, for example: their gender, age, MS type, length of MS, or mobility levels. It may be that while a study is done only with relapsing MS, it could still apply, but you should ask questions about who took part in the study and who did not. These are called **inclusion** or **exclusion** criteria.

When reading about research, pay attention to who was studied and think about how the inclusion and exclusion criteria may impact the results, and whether that is relevant to you.

What was measured?

The measurement used—also called the **outcome** or **endpoint**—should be clearly defined and consistently measurable. In our exercise example, improvement can mean many things: improved walking, greater leg strength, the individuals feeling better. Improved walking is a physical measurement, but even here do we mean walking faster, or easier, or more steadily?

Another key component of measured results is how **reproducible** the measurements are. That is, if someone else ran the same study again, the same clearly defined measurement could be used with different people, without difficulty.

Cross-Sectional or Longitudinal? If a study was conducted at one point in time, then the study was looking for associations or relationships, this is called **cross-sectional**. This type of research does not show cause-and-effect since all measures were collected at the same time. For example, measuring body weight and a timed 25-foot walk and asking whether higher or lower body weight is associated with longer walking times.

If the study was many time points, also called **longitudinal** research, then the study allows for studying patterns over time and cause-and-effect. Instead of just looking at the change in time of the 25-foot walk, you can see if the change happens earlier, later or steadily over time.

How long did the study last?

This is really two questions: how long were the people studied and how long did the whole study last?

• *How long were the people studied?*

Studies looking for an immediate or short-term result can be shorter duration. Studies looking for long-term results would need to be long enough to measure those types of changes. For example, if researchers are interested in long-term effects of exercise, studying participants for one week does not address “long-term effects.”

• *How long did the whole study last?*

Pay attention to when the study took place and how long it lasted. Study results from 1965 might not be as relevant as results from 2015—the definitions of MS have changed a lot since then, so the people included 50 years ago would be different than those included today. Studies that lasted 10 years may show different results from the first 5 years and the last 5 years if there was a change to the types of walking assistive devices used during the study follow-up time.

Looking for Proof?

Keep in mind that research generally can't “PROVE” something. For example, to prove one treatment is better than another, you would really need to study every person with MS on both treatments for a very long period of time (many, many, many years). This really isn't possible. What research will try to do is study enough people for enough time to come to a conclusion about what has happened.

Interventional or Observational?

Interventional research is when participants are assigned an intervention, such as trying a drug or a lifestyle change. These include clinical trials. **Observational** research, like NARCOMS, collects information without assigning an intervention like a drug or lifestyle change. Asking participants about their exercise is observational; assigning them a specific exercise routine is interventional.

What do the results mean for you?

To answer this, first consider all of the questions above: Was the study designed to ask and answer a specific question, or is it an observation that may be important to you, but really requires more data? Is the group of people studied relevant to you? Is the question being studied meaningful to you?

If there was an intervention, like an exercise program, is it something you can do? Were enough people studied to give the results meaning? Weighing the answer to all of these questions along with your health professionals can help you determine if research results are applicable to you.

Recent NARCOMS research can be found at: www.narcoms.org/publications. If you have any questions about NARCOMS research, please email us at: narcomsnow@narcoms.org.

DAVID OSMOND HOPE THROUGH SONG



You’ve heard of the Osmonds, no matter your age—they’re a famous American singing family who successfully transitioned from child stars to adult performers, both on stage and on the television screen. What you may not know about the Osmonds is that multiple sclerosis is also a part of their family.

David Osmond, a younger member of this extended family, is the son of Alan Osmond, one of the original Osmond family singers. David, like his father, has multiple sclerosis—in fact at 26, he was even younger than his father was when he learned of his diagnosis.

“It was in what I thought was the prime of my life,” David says.

But now a decade into his life with MS, David continues to radiate the positive spirit his family has always embodied. With an “MS anthem” of sorts, a song called “I Can Do This,” David works with the pharmaceutical company Novartis (maker of Gilenya) to represent the “Our Voice in Song” campaign.

Osmond’s father, Alan was diagnosed with MS in his 30s, so David says he “was raised up around it. Since I was a kid I knew these terms relating to MS because of my dad’s diagnosis.”

But that didn’t lessen his shock when he began experiencing MS symptoms. “I thought I was an expert on the disease, so after a series of so many tests when they finally said it looks like MS, I didn’t believe it,” he recalls

David has relapsing remitting multiple sclerosis (RRMS), a different form than his father’s MS, which is primary progressive MS. “I was worse off than my dad had been in decades,” he says. “I was in a wheelchair for about eight months.” David had been dating the woman who became his wife, Valerie, for about six months before he had any complications.

“We knew we wanted to get married, then this hit and she stuck by my side,” he says. “I proposed from a wheelchair, and she said yes.”

The couple now has three children.

FEATURE FOCUS

In 2010 David received the National Multiple Sclerosis Society's "Spirit of Life Award," and it was a turning point for he and his family.

"It made me realize I have to look at the abilities, the things I still can do, and that I have so much more to live for and fight for," he says.

REACHING OUT THROUGH SONG

It's no surprise that David, already an accomplished performer, turned to music to help spread a message of hope to others living with MS. David entered into the "Our Voice in Song" campaign last year with a song called "I Can Do This." The song, he says, is inspired by his grandfather who, "was kind of a stubborn guy, and I hope some of that tenacity rubs off on me."

The message David hopes listeners take from it is, "I can do this, keep going, keep fighting. Early detection and treatment is key. Be in charge and don't make the same mistakes I did, which was holding off and waiting and letting time pass before taking the bull by the horns."

The song and video's message is for everyone, he says. "It's for the caretakers and for anyone just going through a hard time. The message is universal."

He says he continues to be awed by the support and warmth of the MS community.

"MS is a crazy way to meet great people—this community has given so much to me. As each of us make noise and get out and share our stories, we lift each other up, support each other, and snowball this dialogue of what's happening with MS—and it's getting louder." David encourages others living with MS not to be shy about it

"I'm so grateful to be at this point where the best way I can give back is through music," he says. "Each person with MS is affected differently. My advice is to be your own advocate, and don't live in the shadows. We need to share our stories and be empowered—we'll be better off. Some advice my dad gave me is that it's not the disease that gets you down; it's the lack of hope. Get out there and be hopeful, and share your story."

Check out David's song, "I Can Do This" on the "Our Voice in Song" website: www.ourvoiceinsong.com.



James W. Hall is the author of 19 novels of a genre that may best be described as “racy thrillers.” Fourteen of those center around a character named Thorn who, with his private eye pal, Sugarman, act to thwart assorted villains. Many of Hall’s books are set in south Florida, including Miami and the Keys.

In 1992, Hall published a novel called *Bones of Coral*, which features a paramedic named Shaw Chandler as the main character and is set in the Florida Keys. Another of the book’s main characters (and Chandler’s love interest) Trula Montoya is living with—and coping with her diagnosis of—multiple sclerosis.

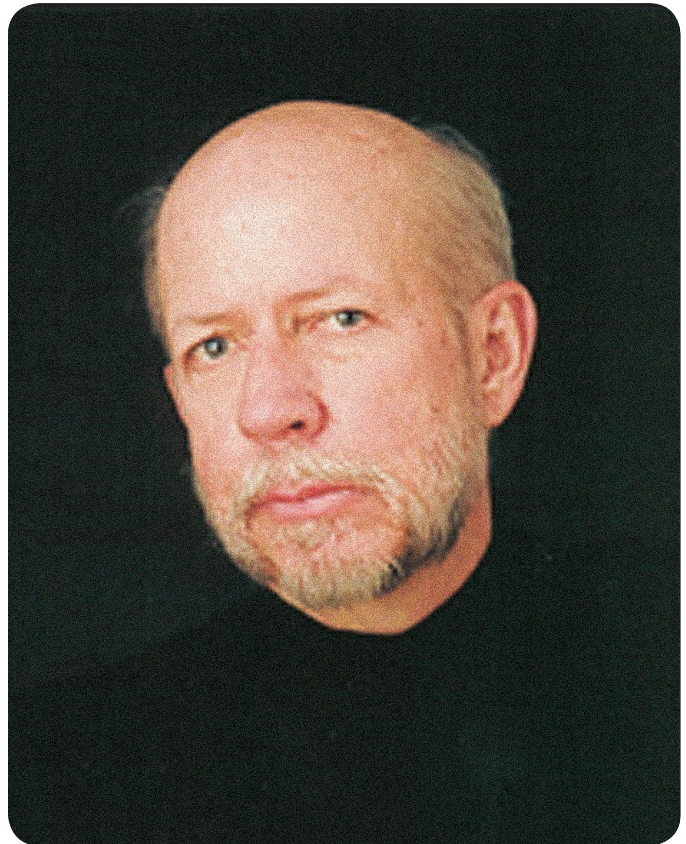
Hall does not have MS, but his descriptions of Trula’s feelings, fears, and symptoms are strikingly detailed. *NARCOMS Now* interviewed Hall about his choice to build a character with MS, and the disease itself, into one of his novels.

One of your book’s central characters, Trula Montoya, is a young actor living with multiple sclerosis. Why did you decide to include this disease in your book?

I wanted to write a novel set in Key West, where I had spent a lot of time over the years, and was researching subjects that had an environmental aspect to them. My novels have mostly focused on something that had to do with ecological issues of one kind or another. I stumbled across an article that mentioned that Key West had a very high incidence of MS and the reasons might have some environmental basis.

So I began to do more research and came across a congressional report about MS in Key West and its possible connection to an Army

experiment back in the 1950s that involved aerial spraying of non-pathogenic substances over unsuspecting civilian populations including Key West. That connection was never proved but the whole episode lit up my imagination, and I was off to the races.



Author James W. Hall: Hall is also the author of two collections of short stories. *Paper Products* (W.W. Norton), and *Over Exposure*, an ebook that contains his Edgar Award winning short story, “The Catch.”

Your descriptions of the symptoms of MS are very detailed and well informed (using terms such as “exacerbation” and asking about most recent MRI, for example). Do you have friends, family or some other personal experience with MS?

I don't have any family members with MS but in the course of my research I went to a couple of meetings in South Florida of recently diagnosed folks and interviewed them. I was deeply moved and the whole novel writing experience changed for me, becoming far more serious.

Do characters with MS or other neurological diseases show up in your other books, and if so, why?

No, I've not used MS again, but I have used other chronic diseases, including chronic pain, in other books. I've also tried in several books to portray the ravages and emotional costs of dementia. I guess I have more of an interest in medical issues than I've admitted to myself. I'm not sure why exactly. But people who are struggling to overcome medical issues in real life have often struck me as quite heroic and inspiring.

What do you hope that your readers might learn about MS from reading your book?

A small bit of understanding of how it feels to have the illness—both the physical and emotional costs.

For more on Character development, visit:
www.narcoms.org/narcomsnow/featurefocus/fall2015/page4.

“What’s the next BIG thing in MS research?”



**Kottil Rammohan, MD, Professor
Department of Neurology,
University of Miami**

“Of course progressive MS and the use of biotin. Biogen has already filed for Zinbryta and is conducting Phase III trials on it for relapsing remitting MS—it's subcutaneous, administered once a month. We need to come up with low-cost therapies—why do pills still cost \$30 per month?”



**Chander Raman, PhD, Professor
Department of Medicine,
Division of Clinical Immunology
and Rheumatology, UAB**

“Asking questions such as, ‘What drives progressive MS?’ The answer will probably be discovery based. We're also interested to find an immune network that links rheumatoid arthritis and multiple sclerosis.”

MS APPS (& BLOGS)

This installment of “MS Apps & Blogs” focuses on multiple sclerosis–themed blogs written by women living with the disease. Check back in our Winter 2016 issue for blogs by men with MS.

Cathy Chester: An Empowered Spirit— www.anempoweredspirit.com

Blogger Cathy Chester writes about “living a healthy and vibrant life after 50,” and many of her posts focus on her life with MS. Chester, who diagnosed in 1987, was featured in our Winter 2015 issue (<http://www.narcoms.org/narcomsnow/featurefocus/winter2015/page3>) and has written articles about her MS life for the Huffington Post, as well as for MultipleSclerosis.net. She writes candidly about life with MS and even attends major MS-related conferences, including the recent Consortium of Multiple Sclerosis Centers annual meeting, to share the latest research news with her readers. Healthline named her blog a top multiple sclerosis blog.

Laura Kolackzakowski: Inside My Story — www.insidemystory.com

Like Cathy, Laura Kolackzakowski is a blogger who hasn't let MS slow her down—in fact she may be more active online since receiving her dual diagnosis of MS and myocardial infarction in 2008. She is the Lead Patient Representative on the Governing Board for iConquerMS, The Accelerated Cure Project's Patient Powered Research Network; she has served as a Patient Reviewer for the Patient Centered Outcome Research Institute (PCORI); and is certified as a PCORI Science-trained Ambassador. Laura is actively involved with the online MS community, using social media to share experiences and knowledge, and attended

the Mayo Clinic Center for Social Media's Residency program to view the use of these tools from the perspective of medical providers. She has participated in pharmaceutical-sponsored MS focus groups and is active with her local American Heart Association GO RED for Women heart health passion committee.

Laura, like Cathy, covered the recent CMSC meeting, including articles about NARCOMS research presented there, posted on our “In the Media” page (www.narcoms.org/inthemedial).

Nicole Lemelle: My New Normals — www.mynewnormals.com

Nicole's website, My New Normals, boasts a clean and lovely layout and strives in its content to explain to readers what it's like to live with MS. Nicole has served as a contributor to many sites, as well as been featured in such outlets as the New Orleans *Times Picayune* and the National Multiple Sclerosis Society's website. As she says on the site, “MNN provides an outlet to families, friends, caregivers and anyone living with MS or any other debilitating disease. Our goals are to raise national awareness and educate the public about MS. We want to generate conversation, promote advocacy, highlight resources and inspire hope.”

Nicole often guest speaks and has been active in her local community to increase awareness of accessibility issues—inspiring modifications to local chain restaurant restrooms and parking lots, for example.

To read about additional MS bloggers, visit our website, www.narcoms.org/narcomsnow/msapps/fall2015

In the Fall 2015 Update, we ask about the new MS disease definitions and in the special sections there are questions about non-medical insurance and nutrition.

New MS Definitions:

The main categories of MS types will look very similar to the old groups, the biggest change is that Primary Relapsing MS (PRMS) is no longer a category. So if you were PRMS, you are likely now Secondary Progressive MS or Primary Progressive MS. This new MS definitions ask you for a class of MS (1-7) in the left-side column and then also about your relapse and MRI activity in the right-side column.

Start here & Pick 1 - 7	then	Pick Activity Level Here
<input type="checkbox"/> 1. Clinically Isolated Syndrome (CIS): Had only one attack, without further attacks or new MRI activity	→	N/A
<input type="checkbox"/> 2. Relapsing Remitting: Periods of worsening with all or some recovery	→	1. Activity - relapses, new MRI activity or both in the past year <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unsure
<input type="checkbox"/> 3. Secondary Progressive: Started with relapsing remitting MS but developed gradually increasing disability even between relapses	→	1. Activity - relapses, new MRI activity or both in the past year <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unsure
	→	2. Progression – gradual worsening of symptoms independent of a relapse: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unsure
<input type="checkbox"/> 4. Primary Progressive: Increasing disability from onset without relapses	→	1. Activity - relapses, new MRI activity or both in the past year <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unsure
	→	2. Progression – gradual worsening of symptoms independent of a relapse: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unsure
<input type="checkbox"/> 5. Don't know/Unsure	→	N/A
<input type="checkbox"/> 6. MS diagnosis not confirmed by a physician	→	N/A
<input type="checkbox"/> 7. Other: _____	→	N/A

For more information see Page 14 in the Spring 2015 NARCOMS Now:
www.narcoms.org/narcomsnow/pdfs/NARCOMSNowSpring2015.pdf

Non-Medical Insurance:

In the Spring 2015 Update, the special section asked about medical insurance. This is insurance that covers medical care at your doctor, clinic, hospital, and/or pharmacy. In the Fall 2015 Update, there are questions about other types of insurance that are available either through your job or a policy that you can get on your own. The goal of these questions is to determine the awareness of these types of additional insurance policies described below:

- » **Short-Term Disability Insurance (STD):** This type of policy pays benefits when a person is unable to work due to disability or illness. These policies have a waiting period of 0 to 14 days with a maximum benefit period of no longer than two years.
- » **Long-Term Disability Insurance (LTD):** This type of policy pays benefits when a person is unable to work due to disability or illness. These policies have a waiting period of several weeks to several months with a maximum benefit period ranging from a few years to the rest of your life.
- » **Long-Term Care Insurance (LTCI):** This type of policy is designed to cover long-term services and supports, including personal and non-medical care in many settings like your home, a community organization, or other facility.
- » **Life Insurance (LI):** This type of policy provides a lump-sum payment, known as a death benefit, to beneficiaries (e.g. spouse, partner, children, or other named person) when the policy holder dies.

Nutrition and Wellness:

Healthy eating is especially important when you have a chronic illness like MS. Good nutrition can provide energy and help with bowel function. There are 3 sets of nutrition and wellness questions:

1. How often do your healthcare providers ask you about your nutrition and level of physical activity.
2. You will be asked if you have tried any of the named diets like Paleo or Atkins™ or follow any eating plans such as Jenny Craig® or vegetarian or low-calorie diets. If you have not tried any of the diets or eating plans, you can simply check “No” to Question 35 and skip to the next section. If you have tried any of the diets, then you can tell us which ones and if you thought they were helpful for you weight, general health and/or your MS.
3. The third set of questions asks you to recall how often in the past month you have eaten certain types of foods. This questionnaire is from the National Health and Nutrition Examination Survey (NHANES) and will allow us to determine your nutritional intake and compare that to other groups of people with and without illnesses. All of the questions are check box questions where you select an option except the cereal question. If you take the online survey, you will type the cereal name. If you complete the paper survey, we ask that you write in all capital letters to make the cereal names easier to read.



Q: What happens to the NARCOMS data once the update survey closes?

A: We start working with the data long before data collection ends. From the day the survey opens we monitor incoming data for potential trouble spots or technical issues. For example, the web-based survey may have specific questions or response options that need clarification to make it easier and faster for people to move forward. We also review the paper surveys as soon as they start coming in to look for any questions that appear to have been confusing or difficult to answer. If we detect any particular problem areas we can make immediate adjustments to the survey form, mail out more detailed instructions, and refine the instructions on the website.

After the data-collection phase closes, we review every question for out-of-the-ordinary responses that can then be double-checked by contacting the participant. From there, the data is added to the database for use in several ongoing and future projects. For each project the data are prepared for statistical analysis by creating specific, de-identified datasets. Subject-level data are often combined with data from other updates and enrollment, using a study specific code rather than any personal information, which means your information remains confidential. The final steps in the process are analysis for results and, ultimately, presentation and publication. Which leads to the next question...

Q: How long does it take for a NARCOMS research project to get published?

A: The time from the start of data collection to presentation or publication will vary depending on project size. Results from smaller projects, based on a single update with a link to enrollment information, are often presented at a meeting within a few months of an update and then published in a paper within a year or two. Longer projects that require data from multiple updates can take many years to be presented or published. Once data collection ends, the data will be cleaned (errors fixed, groups created) and analyzed, the paper drafted, submitted, reviewed, changes and edits made, and finally published.

The publication phase, including the often lengthy scientific peer-review process, can take up to a year. The average time from the start of NARCOMS data collection to publication in a peer-reviewed journal is four years but has ranged from as short as six months for short projects to as long as seven years for projects that followed participants over a period of several years. It can be a long road—we cannot thank you enough for your patience and continued participation in NARCOMS!

**To submit a question for Q&A
please email -
narcomsnow@narcoms.org**

NARCOMS Social Media Poll

Since 2013 NARCOMS has been on Twitter as [@NARCOMS](#). Two years later we have nearly 500 followers - thanks! As we look forward to expanding our social media presence, we'd like your help on picking our NARCOMS social media logo (also called an icon or avatar). There are two images up for vote:



#1globe



#noglobe

You can vote in two ways:

1. Follow us on Twitter and tweet #1globe or #noglobe.
2. Or go online and vote at our website, www.narcoms.org/narcomsnow/globepoll to pick your favorite.

NARCOMS will be increasing our social media presence in 2016, so look to our Winter 2016 issue for details on even more ways you can interact with us at NARCOMS.

Your MS Story – Seeking New Faces of NARCOMS

Sharing your MS journey is personal but it can also help other people living with MS. We are so grateful to you for sharing your personal perspectives in “FACES of NARCOMS,” and know many of more of you have amazing tales to tell. We're making it easier for you to submit your stories to *NARCOMS Now*.

- » You can email your story to narcomsnow@narcoms.org.
- » Or you now can send it in online! www.narcoms.org/narcomsnow/faces and tell us about your journey!

Tell us about your diagnosis story, your MS inspiration, or your MS “A-ha” moment.

Depression, Fatigue, Declines in Cognitive Function and Uncertainty in Women with MS

Cheri Roseberry, PhD, RN, Faculty, University of Arizona College of Nursing

While most individuals with multiple sclerosis (MS) are diagnosed between the ages of 20 and 40, diagnosis at a younger age doesn't necessarily mean less severe disease course. Multiple sclerosis is recognized as a leading cause of neurologic disability among young adults, and the most prevalent neurologic disease among young and middle-aged adults¹. Healthcare costs associated with MS are estimated at over \$10 billion annually in the United States alone². Those living with can MS face many uncertainties in symptoms, diagnosis, disease exacerbation, relapse, and even disability, and that uncertainty can cause stress.

Cheri Roseberry, PhD, a faculty member at University of Arizona, College of Nursing, conducted a study to describe the relationships between fatigue, depression, and declines in cognitive function in women with MS using a modified version of Braden's Self Help Model. As part of the research for her doctorate degree, Dr. Roseberry sought to evaluate whether depression, fatigue, and declines in cognitive function, uncertainty and self-management influenced quality of life in women with MS.

Through NARCOMS, 215 women with MS living in the southwest United States were invited to participate in the study, by providing:

- 1) Demographic and Disease Characteristics
- 2) The Modified Fatigue Impact Scale
- 3) Perceived Deficits Questionnaire
- 4) Patient Health Questionnaire-9
- 5) Mishel's Uncertainty in Illness Scale-Adult
- 6) Rosenbaums' Self-Control Scale- Modified
- 7) COPE Inventory- Brief
- 8) SF-36 Health Status Questionnaire

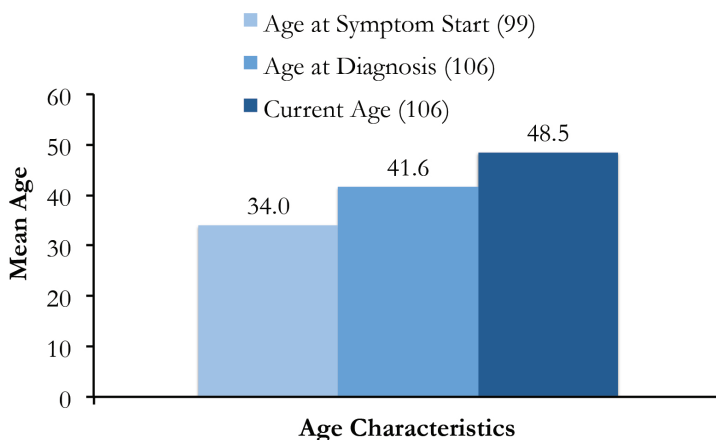


Figure 1. Mean at Symptom Start, Diagnosis and Survey

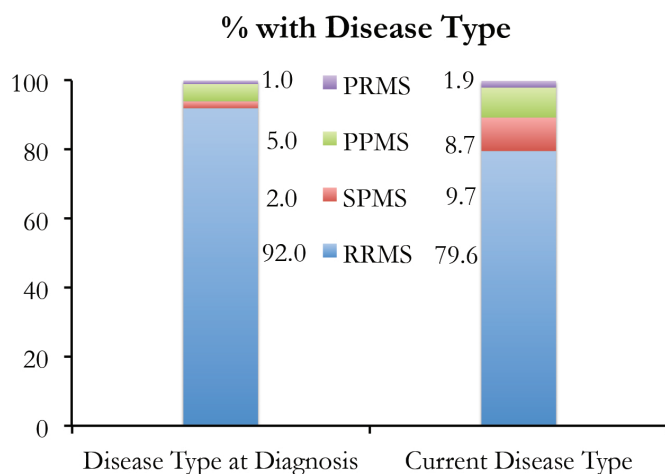


Figure 2. Disease Status at Diagnosis and Survey

References: 1. National Institute of Neurological Disorders and Stroke [NINDS]. NINDS MS information page. Retrieved April 23, 2008: http://www.ninds.nih.gov/disorders/multiple_sclerosis/multiple_sclerosis.htm

2. Adelman, et al. 2013. The cost burden of multiple sclerosis in the United States: a systematic review of the literature. <http://informahealthcare.com/doi/abs/10.3111/13696998.2013.778268>

RESULTS

The 106 participants were on average 14.5 years older at the time of this survey compared to diagnosis (Figure 1) and the majority reported relapsing remitting MS (Figure 2). They reported having a moderate level of uncertainty, defined as a condition that induces stress. Since their diagnosis, they reported mild depression, perceived mild declines in cognitive function, and moderate levels of fatigue.

There was also a moderate-to-strong relationship between depression and fatigue, depression and perceived declines in cognitive function, and fatigue and perceived declines in cognitive function (Figure 3). The research also showed a relationship between depression and uncertainty, perceived declines in cognitive function and uncertainty, and fatigue and uncertainty.

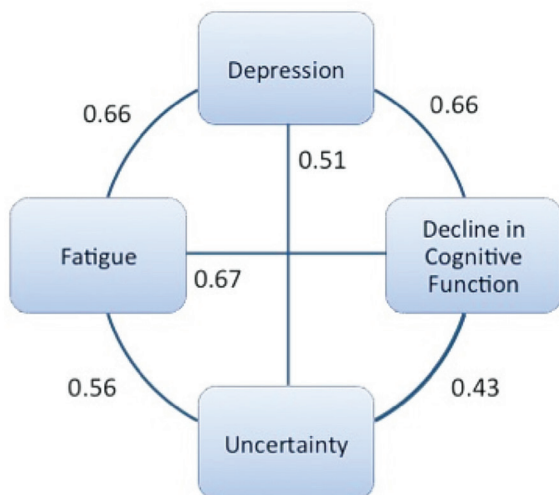


Figure 3. Relationships between Uncertainty, Depression, Cognitive Function, and Fatigue. Numbers are on a scale of 0-1, with higher numbers reflecting a stronger relationship.

About the Researcher:

Cheri Roseberry, PhD, RN, completed her PhD in Nursing and an interest in multiple sclerosis in 2014. She is full-time clinical faculty with the University of Arizona College of Nursing and teaches in the Masters in Entry to Practice Nursing (MEPN) program.

Dr. Roseberry's lifelong passion for MS evolved from growing up caring for a mother who was diagnosed with MS in her 20s.

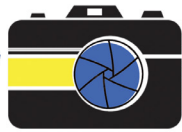
Those who reported lower physical and mental health, and overall diminished quality of life, showed higher perception of uncertainty.

Higher depression scores, greater perceived declines in cognitive function, and higher fatigue scores were associated with lower physical and mental health and poorer quality-of-life outcomes.

CONCLUSIONS

The findings of this study suggest a number of symptoms are related to feelings of uncertainty for this population involving depression, fatigue and declines in cognitive function. A larger study involving more women with MS—living across the United States and not just the southwest—is needed to learn more.

Roseberry plans to begin designing a larger study in 2016, with the hope of eventually providing enough information to facilitate interventions for patients and healthcare providers aimed at recognizing and assessing all three symptoms early after diagnosis. This could help identify self-management and coping techniques to help improve quality-of-life outcomes in individuals with MS.



Some people with MS also have another (co-existing) health condition such as diabetes or high blood pressure. These co-existing conditions are called comorbidities. It is important for us to know more about co-existing conditions in MS for several reasons. First, they may make it harder to diagnose MS. Second, they may affect how well MS treatments work or the risk of serious side effects. Third, they affect quality of life, pain and disease progression in MS.

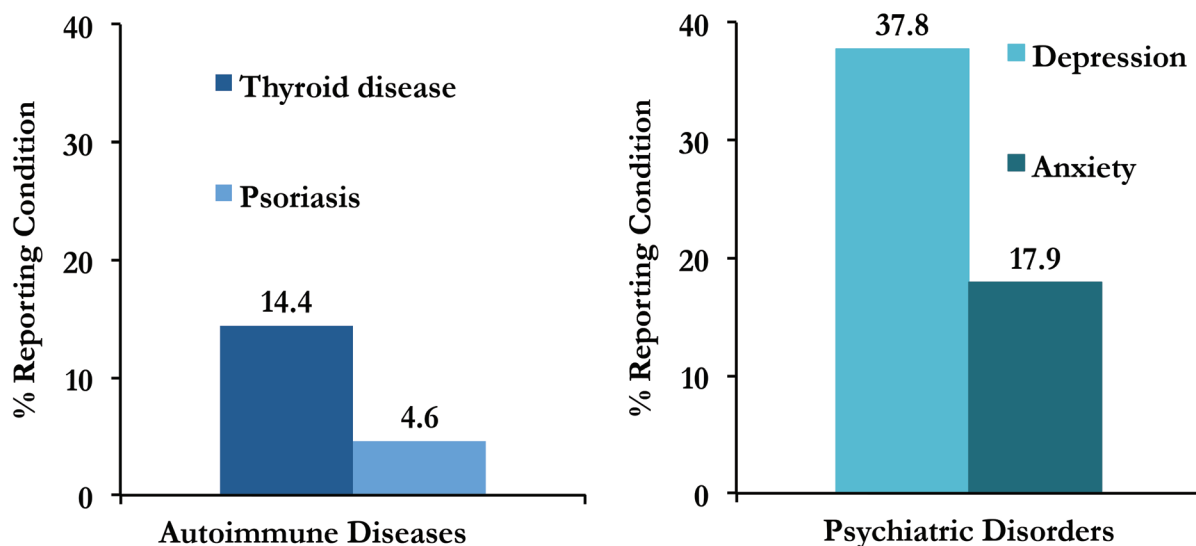
Recently, a group of MS researchers conducted, “A systematic review of the incidence and prevalence of comorbidity in multiple sclerosis,” that was published as a special edition in the journal *Multiple Sclerosis* in March 2015. The panel was lead by Dr. Ruth Ann Marrie, Scientific Director of NARCOMS, and also included Dr. Gary Cutter, Director of the NARCOMS Coordinating Center, and the work was commissioned by the International Advisory Committee on Clinical Trials in Multiple Sclerosis, an organization sponsored by the National Multiple Sclerosis Society and the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS).

Dr. Marrie and her colleagues reviewed published research about MS and co-existing conditions from around the world. They grouped the conditions reviewed into six major areas:

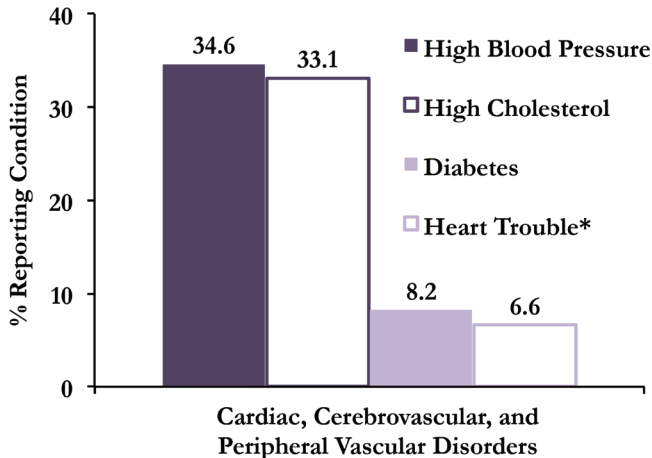
- Autoimmune conditions
- Psychiatric disorders
- Cardiac, cerebrovascular, and peripheral vascular diseases
- Gastrointestinal, musculoskeletal, ocular, pulmonary, and renal disorders
- Sleep disorders
- Cancer

While the group researched hundreds of co-existing conditions, in each Spring update NARCOMS currently asks about 16 of the most common comorbidities or “Other Conditions.” So what did NARCOMS participants report in Spring 2015?

Percentages of MS Patients in NARCOMS Reporting Comorbidities:



Note: Percentages reported out of the number of participants that responded to the “Other Conditions” questions in the Spring 2015 Update, N ranges from 7601 to 7804.



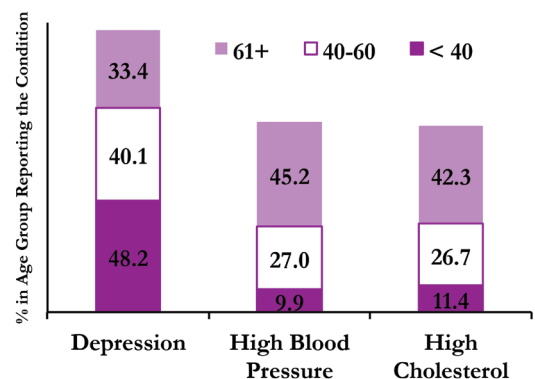
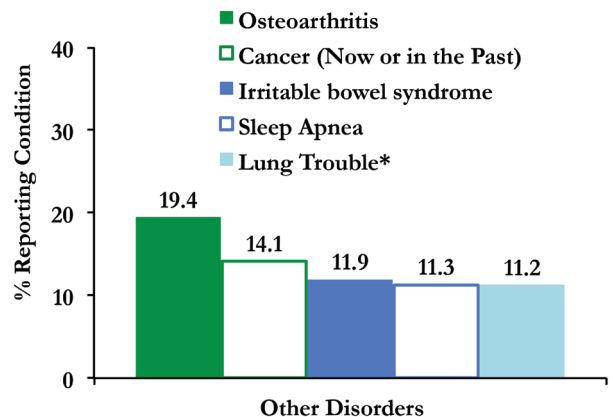
*** In NARCOMS:**

- » **Heart trouble includes:** Angina, congestive heart failure, or coronary artery disease.
- » **Lung trouble includes:** Asthma, emphysema, chronic bronchitis, or COPD.

Results Overall: 81% of participants reported at least one other condition in the Spring 2015 update. Half of the participants reported two or fewer other conditions, and less than 10% reported six or more comorbidities.

Results by Age: Looking at the three most frequently reported conditions, depression seemed to decline with age, with nearly half of those under the age of 40 reporting depression compared to 40% in the 40–60 age range and 33% in the oldest age group, 61 and older. As with the general population, reports of high blood pressure and high cholesterol are higher in older age groups.

Thank you: Considering the effect that other conditions have on MS changes is important and is the reason NARCOMS asks you to update us every Spring. Your contributions to this area of MS research are invaluable!



So what did the panel find? The five most common comorbidities in MS were: depression, anxiety, hypertension (high blood pressure), hypercholesterolemia (high cholesterol) and chronic lung disease. In addition, thyroid disease and psoriasis were the most common comorbid autoimmune diseases. An overview of the six review papers can be found for free at: <http://msj.sagepub.com/content/21/3/263.full>

Third Case of PML in MS Patient Taking Gilenya, Following FDA Warning

A third case of progressive multifocal leukoencephalopathy (PML) in a patient with relapsing multiple sclerosis taking Gilenya (fingolimod) has been reported by Novartis, the drug's manufacturer. This patient did not have prior exposure to natalizumab treatment.

The case follows a warning issued by the Food and Drug Administration on August 4, stating that a definite case of PML—a rare virus of the brain—and a probable case of PML have been reported in patients taking Gilenya. According to the advisory, these are the first cases of PML reported in patients taking Gilenya who had not previously been treated with an immunosuppressant drug for MS or any other condition. As a result, information about these cases is being added to the drug's label.

Gilenya is taken by patients with relapsing forms of MS. Patients taking Gilenya who experience symptoms such as new or worsening weakness; increased trouble using their arms or legs; or changes in concentration, eyesight, strength, or balance are urged to contact their health care provider; but not to stop taking the drug until advised to do so by their physician.

The first case of PML in a patient taking Gilenya was reported in August 2013, but could not be conclusively linked to Gilenya because prior to Gilenya treatment the patient had been treated with an immunosuppressant that can cause PML.

According to the FDA's Drug Safety Communication, "the patient with probable PML did not have clinical signs or symptoms

suggestive of PML, and was diagnosed based on MRI findings compatible with PML and John Cunningham (JC) virus detected in the cerebrospinal fluid (CSF). The other patient was diagnosed with definite PML based on characteristic symptoms, MRI findings, and JC virus in the CSF. Gilenya treatment was stopped in both patients."

The diagnosis of the third case of PML was based on suggestive clinical symptoms, MRI findings, and blood tests for JC Virus. While the patient did not have prior exposure to natalizumab, they did have a history of colorectal cancer that was treated with chemotherapy and radiation, as well as Crohn's disease.

The FDA approved Gilenya to reduce relapses and delay disability progression in patients with relapsing forms of multiple sclerosis (MS) in 2010.

Any adverse effects or side effects from this product should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

ADA'S 25th Anniversary / SCOTUS Saves Affordable Care Act

2015 marks the 25th anniversary of the Americans with Disabilities Act (ADA). This broad civil rights law prohibits discrimination based on disability, adding "disabilities" to the list of prohibited discrimination based on the Civil Rights Act of 1964, which included race, religion, sex, and national origin. The ADA requires employers to provide reasonable accommodations to employees with disabilities, and requires that public buildings be accessible.

“The ADA is celebrating with a series of events that kicked off in July, a quarter century after President George H. W. Bush signed the original law into effect in 1990. The National Council on Disability drafted the law four years prior, and Senator Tom Harkin (D-IA) served as its chief sponsor. Visit the website for more information: www.adaanniversary.org.

On June 25, the Supreme Court of the United States upheld a component of President Barack Obama’s Affordable Care Act, backing tax credits used by millions of Americans to buy insurance. The Court’s 6-3 vote holds that the Affordable Care Act authorized federal tax credits for eligible Americans living not only in states with their own exchanges, but also in the 34 states with federal marketplaces. The ruling prevented a scramble in states that would have needed to act to prevent millions from losing health care coverage.

Five years ago, after nearly a century of talk, decades of trying, a year of bipartisan debate, we finally declared that in America, health care is not a privilege for a few but a right for all,” Obama said from the White House after the ruling. “The Affordable Care Act is here to stay.”

Among other implications, under the ACA insurers can no longer deny coverage to those with pre-existing medical conditions such as MS, or enact caps to annual or lifetime benefits to those enrolled in their plans.

NARCOMS at ECTRIMS Congress 2015

NARCOMS is pleased to have a presence at the 2015 Annual Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS), October 7-10 in Barcelona,

Spain. This scientific meeting for 2015 is designed to “tackle the main topics signaling the path to future MS management.” Our researchers will present four posters on the following topics:

- **Shared Decision Making and Disease Modifying Treatment History in NARCOMS**
- **Characteristics of Continued Tecfidera Use in the NARCOMS Registry**
- **Social Media and Recruitment in the NARCOMS Registry**
- **Differences in Use and Perceptions on Effectiveness of Marijuana for MS: A Survey of NARCOMS Participants**

NARCOMS will also host a booth and report back on research findings presented at this conference. Visit our “In the Media” section of our NARCOMS website for media coverage of NARCOMS research: www.narcoms.org/inthedia.

National MS Society Awards Top Scholars Honors to UAB Student

Ashley Haynes, an undergraduate student in the University of Alabama at Birmingham School of Health Professions and Biomedical Sciences Program was named as the 2015 National Multiple Sclerosis Society’s Presidential Scholar. Haynes is one of only 10 students in the United States to be honored as an NMSS Top Scholar, which indicates they received the highest scores based on review of all components of their application. The NARCOMS Data Coordinating Center is based at the University of Alabama at Birmingham.

Haynes works with Dr. Jayne Ness at UAB's Center for Pediatric-Onset Demyelinating Disease (CPODD)—one of six Pediatric Multiple Sclerosis (MS) Centers of Excellence in the country, designated and funded in 2006 by the National Multiple Sclerosis Society. Ashley's drive to get involved in MS research stem from the fact that her mother and grandmother are living with the disease. She plans to become a pediatric neurologist.

“When you grow up with two immediate family members—my mother and grandmother—with MS and you physically witness what this disease can do, you develop a different perspective on life,” said Haynes. “I remember growing up and seeing them fine one day, and then the next unable to move their legs—then the following week they would be walking again.”

CLINICAL TRIALS IN MS

We know you are loyal supporters of and participants in NARCOMS, which is a long-term research study. Following here are several clinical trials that may also be of interest to you.

MAY 2015:

Researchers Nationwide Recruiting Children and Adolescents with MS for a Global Study of Gilenya

Summary: Investigators across the U.S. and in other countries are recruiting 190 children and adolescents with MS (ages 10–17) for a clinical trial comparing the effectiveness of oral fingolimod (Gilenya®, Novartis Pharmaceuticals AG) with interferon beta-1a (Avonex®, Biogen Idec) injected into the muscle.

Sponsor: Novartis. The US arm of the study has been endorsed by the Network of Pediatric MS Centers, which was inaugurated and is supported by the National MS Society.

Rationale: Although MS occurs most commonly in adults, it is also diagnosed in children and adolescents. However, clinical trials have not formally evaluated the safety or effectiveness of these therapies in children with MS.

Eligibility: Anyone ages 10 to 17 with a diagnosis of MS, who has had at least one MS relapse during the previous year or two MS relapses in the previous two years. Participants with significant heart abnormalities upon testing, or severe kidney dysfunction, are excluded.

Participants are being randomly assigned to receive either Gilenya (administered orally daily at a dose of either 0.5 mg or 0.25 mg, depending on body weight) and a placebo injection once weekly intramuscularly; or Avonex injected once weekly intramuscularly, and daily oral placebo. Participants are being treated for 24 months, and receive extensive safety evaluations prior to drug initiation and subsequently during the trial.

The primary outcome being measured is the frequency of relapses. Secondary outcomes include disease activity observed on MRI scans, safety, and how the drug is absorbed by the body.

Contact: To learn more visit: KidsMSResearch.com or call: 1-844-4KIDSMS (1-844-454-3767).

JUNE 2015:

Investigators Recruiting for Study of Oral Laquinimod in Primary-Progressive MS

Summary: Investigators at sites worldwide are recruiting 375 people with primary-progressive MS for a Phase 2 clinical trial comparing oral laquinimod (Teva Pharmaceuticals), an experimental compound that is believed to modify immune function, with inactive placebo in 375 people with primary-progressive MS.

Sponsor: Teva Pharmaceutical Industries Ltd.

Rationale: There are currently no disease-modifying therapies specifically approved for treating the primary-progressive form of MS.

Laquinimod is an immune-modulating compound believed to affect the immune attack on the brain and spinal cord in MS. Previous results of large-scale clinical trials of laquinimod in people with relapsing-remitting MS have had mixed results. (*New England Journal of Medicine* 2012;366:1000-9; *Journal of Neurology* 261:773-83). Analyses of the trials focusing on groups of patients which approximate a progressive MS population, further provide a rationale for studying laquinimod in primary progressive MS. (*Neurology* 2014; 82[10] S4.001; *Multiple Sclerosis Journal* 2014;20[1 suppl]:99)

Eligibility and Details: Be between 25 and 55 years of age, with a diagnosis of primary-progressive MS. Participants will be randomly assigned to receive either laquinimod 0.6 mg, laquinimod 1.5 mg, or inactive placebo, by mouth. The primary goal of the study is to determine the effect of laquinimod on change in brain tissue volume (“atrophy”). Secondary goals are to evaluate its effects on disability progression, mobility, and disease activity as observed on MRI scans.

Contact: For enrollment information, please contact the site nearest you. The principal investigator (PI) and study coordinator (SC) for each US site are available at the National MS Society’s website, www.nationalmssociety.org.

Looking for more trials?

For a comprehensive list of clinical trials in the United States, visit the National Institutes of Health’s website, www.clinicaltrials.org. It can be searched by topic, by location, or even search for a phrase.

play

Find the following hidden words:

care, healing, friendship, conversation, love, laughter, awareness, activism, exercise, relaxation, rest, research, family, sensitivity, hope, happiness

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

FIND THE ANSWERS TO THIS WORD PUZZLE ONLINE:

www.narcoms.org/narcomsnow/play/answers

FACES *of* NARCOMS

“My MS Diagnosis Journey”

My diagnosis journey was a long and confusing road; looking back it really began in the mid- 1980s. I would brush off my body’s strange changes and attribute them to getting older. My wakeup call came in 2006 when I began having trouble walking next to others and turning my head without tripping.

At age 52, I finally went to the doctor’s office when I was unable to walk for more than 15 minutes without sitting down. I would experience lightheadedness, be unable to focus, and lose my balance.

Over the next three years I saw several specialists: a cardiologist for possible blood pressure and blood oxygen issues; an ENT, who was sure it was an inner-ear issue; the neurologist who discovered neuropathy in both legs. Several MRIs indicated “all clear.” Maybe it was vitamin B12 levels? So I endured a year of B12 injections with no change.

At that point I began my research journey to understand why my symptoms were so hard to diagnose. A single online search for lightheadedness on the Mayo Clinic website turned up 2,000 causes. “Wow,” I thought, “they may never figure this out.”

As luck I spoke with a friend’s cousin whose medical history included MS. My friend suggested I speak with him, so I did. We compared notes and the “Big Red” light appeared: so much of what I was going through sounded like MS. That conversation began my MS research and the journey to my diagnosis.

I ordered copies of my medical records and organize them by visits, tests, and test results. I researched each symptom and linked them either to MS or not. Surprisingly, 80% of my symptoms could be associated with MS.

I scheduled an appointment with my neurologist and presented my documents, which gave him a good chuckle. I explained I was sure my problem was in fact MS. He acknowledged my research but said he was 100% sure it was not MS. I then pushed to have him schedule a spinal tap, and after much conversation the procedure was ordered.

A few days after the procedure I received a call from the neurologist, who told me the test indicated MS. At last I had a possible diagnosis. I had a second MRI done at an area MS research center to find out for sure. The test indicated lesions and validated the MS diagnosis.

The moral of my story is to be active in your pursuit of a diagnosis and in your healthcare, no matter how hard it may be. Do your research and push your doctor if you feel more can be done. As for me, I was relieved to know and ready to take the next steps.

-Mike R.

NARCOMS Coordinating Center
The University of Alabama at Birmingham
1720 2nd Ave. South
BIRMINGHAM AL 35294-0022

Non-profit Org.
U.S. Postage
PAID
Permit No. 1256
Birmingham, AL

NOTE: The CMSC has moved.

Please update your records with
our new address and fax number:

3 University Plaza Drive, Suite
116, Hackensack, NJ 07601
Fax: (862) 772-7275

twitter: @narcoms
www.narcoms.org/narcomsnow



Scan for links to online
articles appearing in this issue.



THE CONSORTIUM OF
MULTIPLE SCLEROSIS CENTERS

NARCOMS is a project of
the CMSC. For more
information on the CMSC visit
www.mscares.org.

NARCOMS **NOW**

