

 **NorthShore**
University HealthSystem

Neurological Institute

Neurological care for what's next.

2018 ANNUAL REPORT

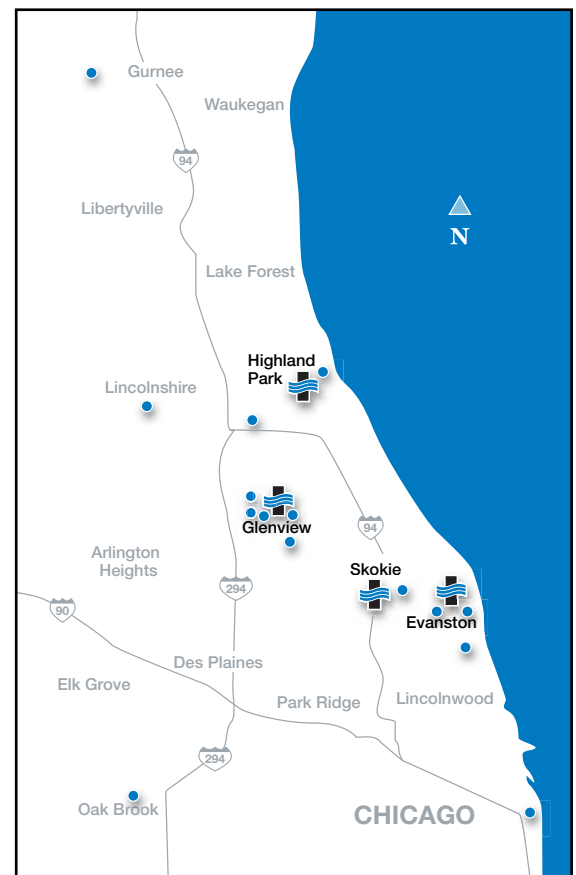


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NorthShore University HealthSystem (NorthShore) Neurological Institute offers unparalleled access throughout the Chicago area, including at each of our four award-winning hospitals. Our expert team of neurospecialists offers comprehensive care for a wide range of neurological conditions.



Call **(877) 570-7020** for more information or to schedule an appointment.

OUR LEADERSHIP

Susan M. Rubin, MD

*Medical Director, NorthShore Neurological Institute
Interim Chair, Department of Neurology*

Dr. Rubin is a neurologist at NorthShore Neurological Institute, specializing in multiple sclerosis, women's neurological issues and headaches. She is the director of NorthShore's Women's Neurology Program and a Clinical Associate Professor at University of Chicago Pritzker School of Medicine.

She completed her medical degree at University of Illinois at Rockford and her internship at Lutheran General Hospital in Park Ridge, Illinois. She completed both her residency and fellowship training at Northwestern Feinberg School of Medicine in Chicago. For over a decade, she has been recognized as a "Top Doctor" by *Chicago* magazine and as one of "America's Top Doctors" in a list compiled by Castle Connolly.

Additionally, Dr. Rubin is conducting promising multiple sclerosis (MS) research looking at better medications, new approaches toward relapses and the lifestyle modifications making a difference toward living a better life with MS. She also acts as principal investigator in clinical trials that look at new drugs, as well as research on genes. Her research will provide clinicians with the information needed to better diagnose and manage patients with this chronic, lifelong disease.



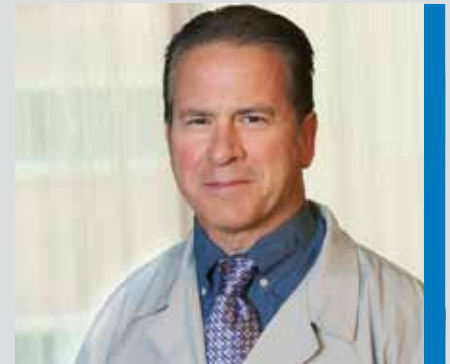
Julian E. Bailes, MD

*Surgical Director, NorthShore Neurological Institute
Bennett-Tarkington Chair, Department of Neurosurgery*

Dr. Bailes is a nationally recognized leader in neurosurgery, with special emphasis on brain tumors and the impact of brain injury on brain function. He is also one of the first neurosurgeons in the Chicago area to use the minimally-invasive NICO BrainPath® as part of the Six Pillars approach, offering promising outcomes for patients with otherwise inoperable brain tumors using the most advanced imaging and intervention technologies.

As a national authority in neurosurgery, Dr. Bailes is President of the Subcortical Surgery Group, neurological consultant to the NFL Players' Association (NFLPA), Chair of Pop Warner Football Medical Advisory Committee and an adviser to the NCAA. He is also a member of the NFL Head, Neck, and Spine Committee and the NFLPA Mackey-White Health and Safety Committee. Dr. Bailes has been honored as one of the nation's best surgeons and recently has been recognized as a 2016 "Chicago Top Neurosurgeon" by *Chicago* magazine.

Dr. Bailes' current research focuses on innovative new strategies for treating and preventing the impact of traumatic brain injury. His research has been instrumental in the understanding of the clinical evidence of chronic traumatic encephalopathy (CTE), a progressive degenerative disease found in individuals who have been subjected to multiple concussions and other forms of head injury. The research done by Dr. Bailes as it relates to the discovery of CTE in football players was featured in the movie *Concussion*.



Joseph T. Alleva, MD, MBA

Chief, Division of Physical Medicine and Rehabilitation

Dr. Alleva has spent his entire career at NorthShore since completing his specialty training in 1994 at the Rehabilitation Institute of Chicago (RIC), where he was chief resident. Dr. Alleva directs a team of physiatrists and therapists (physical, occupational and speech-language) experienced in treating patients with brain and spine disorders.

Dr. Alleva holds an MD degree from the Chicago Medical School and completed an internship in internal medicine and neurology at Northwestern University Medical School. His expertise in the field most recently landed him on the "America's Best Doctors" list compiled by *U.S. News & World Report*, and for more than a decade, he has consistently been lauded in Castle Connolly Guide's *The Best Chicago Doctors*. In 2011, *Chicago* magazine featured Dr. Alleva on its "Best Sports Medicine Doctors" list.



RECOGNITION AND ACHIEVEMENTS

11 NorthShore Neurological Institute Specialists Listed as Castle Connolly "Top Doctors"

First Certified ALS Clinic in the Northern Chicago Suburbs by the ALS Association

Accredited Epilepsy Center by the National Association of Epilepsy Centers

Systemwide Magnet® Recognition by American Nurses Credentialing Center

Sleep Center Certification and A-STEP Accreditation by American Academy of Sleep Medicine

Systemwide Certification by Joint Commission as Primary Stroke Center

Designated Center for Comprehensive and Coordinated Multiple Sclerosis Care

Blue Distinction® Centers+ for Spine Surgery Recognized by Blue Cross Blue Shield

ABOUT THE INSTITUTE

A Personalized and Team Approach to Advanced Neurological Care

NorthShore Neurological Institute's comprehensive programs offer patients and their families proven expertise, advanced technology and outstanding care coordination to treat a variety of neurological diseases and conditions.

As one of the region's preeminent providers of neurological care, we are actively engaged in clinical trials and translational research. We regularly launch new research studies to ensure that the latest technology, clinical treatments and techniques are available for our patients.

The foundation of our excellence in neurological care is the personalized and multidisciplinary approach that is essential to achieving the best possible outcomes. Each program in the center circle has a team of medical, surgical and rehabilitative members with unique expertise that maintains open lines of communication. These members often collaborate face-to-face in real time, as well as through one of the most advanced Electronic Medical Record (EMR) systems in the country, to deliver care effectively for complex neurological diseases.



KEY CLINICAL SERVICES

Brain Health

- Clinical services for patients at higher risk of Alzheimer's, Parkinson's disease or chronic traumatic encephalopathy (CTE).
- Assessment of familial, genetic, lifestyle and comorbidity risks.
- Medical, physical, cognitive, dietary and integrative therapies to reduce risk.
- Annual visits to preserve and improve brain health, and to prevent dementia and other aging-related brain disorders.

Concussion/Brain Injury

- A multidisciplinary and nationally recognized team of concussion and head injury specialists.
- Multipronged approach to the diagnosis and management of acute concussion, postconcussion syndrome and chronic consequences of brain injury.
- Sports Concussion Program with neurological and neuropsychological assessment.

Epilepsy and Central Neurophysiology

- Complete diagnostic services to identify the likelihood and cause of seizures and assess the patient's candidacy for admission to our accredited Epilepsy Monitoring Unit (EMU).
- Medication management and surgical options (for suitable candidates) that include laser interstitial thermal therapy, responsive neurostimulation and vagus nerve stimulation.

“Pharma and non-pharma treatments of epilepsy can not only be life-saving, but also contribute to significant improvements in quality of life.”

— Dr. Jaishree Narayanan,
Division Chief,
Neurophysiology



General Neurology

- Evaluation, diagnosis, treatment and management of a variety of acute and chronic neurological conditions such as pain, tingling, numbness, weakness, dizziness, fainting and problems with speech, vision, hearing, swallowing or balance/coordination.

Memory and Cognitive Disorders

- Care team of neurologists, neuropsychologists, nurses and a medical social worker who embrace the highest standard of care, continuously seeking and offering new and innovative treatments, cutting-edge imaging techniques and neuropsychological evaluation tools.

Migraine and Other Headache Disorders

- Evaluation of headache disorders by specialized neurologists in consultation with experts in psychiatry, psychology or neurosurgery to aid in the treatment.
- Chronic headache specialists who may recommend Botox® therapy, integrative medicine such as acupuncture, and patient education to recognize triggers and modify habits.

Multiple Sclerosis

- Services at our designated Center for Comprehensive Multiple Sclerosis Care that begin with a diagnosis involving in-depth clinical, laboratory and neuroimaging evaluations.
- Treatments that use new “disease modifying” oral medications, and infusion therapies such as intravenous corticosteroids, plasma exchange and baclofen via intrathecal pump.
- Several active clinical trials that explore the efficacy and safety of new treatments.

Neuro-Oncology/Brain and Spine Tumors

- Complete diagnostic evaluation leveraging advanced neuroimaging and molecular neuropathology.
- Multidisciplinary care team that reviews each patient's case at regular tumor conferences and in consultation with the patient and family to develop a personalized treatment plan.
- Clinical trials offering patients access to promising new methods of cancer detection and treatment.

Neuromuscular Disorders

- Diagnostic work-ups incorporating electromyography and an advanced Autonomics Laboratory.
- Amyotrophic lateral sclerosis clinic offering treatment modalities to optimize quality of life.

Neuropathology

- Diagnostic services for neurosurgical specimens, including molecular testing to determine customized care.

(continued)

Neurophysiology

- High-quality diagnostic testing available including electroencephalography (EEG), nerve conduction studies, electromyography, evoked potentials (somatosensory, visual, acoustic brain stem), home and continuous inpatient EEG monitoring, intracranial monitoring, Wada test, functional brain mapping, deep brain stimulation (DBS) testing and video EEG in the EMU.
- Intraoperative monitoring where our team of physicians and technologists work with surgeons, monitoring the central and peripheral nervous system in order to avoid preventable complications.

Neuropsychology

- Consultation and evaluation services to a broad range of inpatients and outpatients with a variety of adult and pediatric neurological disorders.
- Cognitive rehabilitation and psychological care based on a patient-specific treatment plan that is coordinated with and provided by speech therapists, occupational therapists, learning disability specialists and clinical psychologists.

Neuroradiology

- High-resolution neuroimaging with CT, MRI and PET scanning used to diagnose the full range of brain, spine and head/neck diseases.
- Advanced MRI and PET techniques that are leveraged to guide treatment and monitor treatment response.
- Nine neuroradiologists with Certificates of Added Qualification (CAQs) who collaborate to ensure the highest level of imaging performance and interpretation.



Dr. Julian Bailes, Chair of Neurosurgery and Surgical Director of NorthShore Neurological Institute, prepping his team for surgery.

Neurosurgery

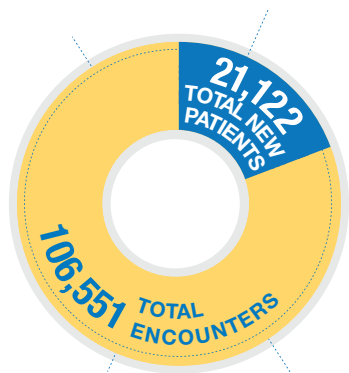
- Surgical intervention for disorders of the brain and spine by highly trained and specialized neurosurgeons using the latest technology for optimal patient outcomes.
- Minimally invasive procedures for epilepsy, neurovascular conditions and brain tumors of the skull base.
- One of the few centers nationwide to use the NICO 6 Pillar Approach for removing tumors and blood clots located deep within the brain.

Parkinson's Disease and Other Movement Disorders

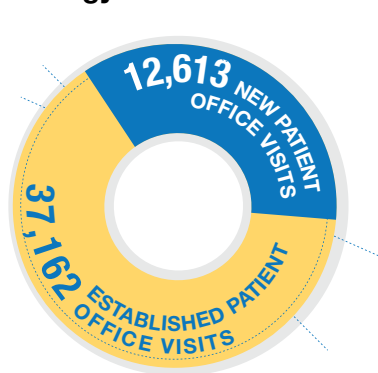
- Pharmacological management, patient education, rehabilitative services to optimize functional independence and improve quality of life.
- Deep brain stimulation (DBS), a surgical therapy used for the treatment of Parkinson's disease.

2018 VOLUME DATA

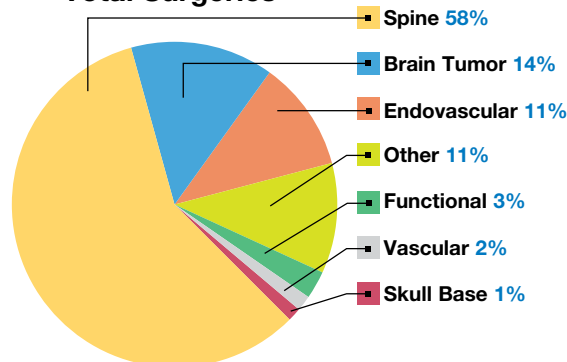
Total Patient Office Visits



Neurology Patient Office Visits



Total Surgeries





Dr. Takijah Heard, Division Chief of Pediatric Neurology, reviewing her patient's medical record.

Pediatric Neurology

- Family-centered diagnosis and care for children with disorders of the brain and nervous system, such as headache and seizures.
- Close collaboration with the pediatricians, behavioral and developmental specialists, neuropsychologists and clinical psychologists.

Physical Medicine and Rehabilitation

- Nonsurgical expert care delivered by our physiatrists, fellowship-trained physicians specializing in the musculoskeletal system who diagnose and treat acute and chronic pain.
- Inpatient and outpatient rehabilitation plans that best help patients improve physical function and achieve rehabilitation goals.
- Fluoroscopic guided injection for spine pain, Sports Medicine Program that offers ultrasound-guided peripheral joint injections and regenerative procedures, and specialized procedures including radiofrequency ablation and spinal cord stimulators.

Sleep Disorders

- Two Sleep Laboratories accredited by the American Academy of Sleep Medicine.
- Staffed by one of the largest teams of board-certified sleep neurologists, pulmonologists and nurse specialists in Chicagoland.
- Full range of services, including consultations, nocturnal polysomnograms and home sleep apnea testing.

Spine Center

- Comprehensive nonsurgical pain management techniques by our fellowship-trained physiatrists, including physical therapy, targeted pain-relieving medicine injections and integrative medicine.
- Advanced minimally invasive (using epidural steroid injections) and complex surgical expertise.

Stroke

- Management of acute stroke, prevention of future strokes and post-stroke rehabilitation using a combination of medications; surgical interventions; physical, occupational and speech therapies; and lifestyle changes.
- Acute stroke team that is available 24/7 to make quick decisions regarding intravenous tissue plasminogen activator administration and/or minimally invasive intra-arterial interventions.
- Endovascular thrombectomy, minimally invasive surgical removal of a blood clot for patients experiencing an ischemic stroke, proven by the latest research to substantially reduce disability.
- Utilization of advanced telemedicine technologies to reduce door-to-needle or intervention times (best outcomes).

2018 RESEARCH SUMMARY

Human Subject Studies

62 Open Studies

33 Studies Enrolling
Subjects in 2018

2,451 Subjects Consented

DNA Study (DodoNA)

2,175 New Participants

7,649 Total Participants

5,493 Samples Genotyped

KEY CLINICAL SERVICES

Neuro-Oncology Program

NorthShore’s neuro-oncology program uses the latest minimally invasive techniques and a collaborative team of specialists for treating brain tumors. Neuro-oncologists and neurosurgeons collaborate with top experts at NorthShore Kellogg Cancer Center to develop customized treatment plans for brain tumors—whether medical, surgical or both—with the goal of preserving neurologic function.

Led by Julian Bailes, MD, Chair of Neurosurgery, and Ryan Merrell, MD, Section Head of Neuro-Oncology, NorthShore’s neuro-oncology program provides experienced and compassionate care backed by leading research and a cohort of multi-disciplinary specialists.

Neurological specialists work closely with experts from the Kellogg Cancer Center in radiology, medical oncology, nursing, social work and rehab medicine to give patients the advantage of an entire team of caregivers. When surgery is necessary, the team determines the best minimally invasive surgical approach.

NorthShore neuro-oncology is the only program in Chicago to offer Synaptive BrightMatter™, a robotic technology that improves access, precision and visualization. Synaptive, along with NICO BrainPath, Surgical Theater (which allows us to create 3D representations of the patient’s specific condition), and

our extraordinary skull base endoscopic program, led by Ricky Wong, MD, are transforming accessibility to tumors and lesions previously deemed inoperable.

These new approaches and technologies are just part of the personalized treatment plan created for every patient. A multi-disciplinary team holds regular tumor board meetings to discuss the range of treatment options for each case, from incision-free stereotactic radiosurgery performed by Shakeel Chowdhry, MD, to integrative medicine treatments to unique clinical trials led by Dr. Ryan Merrell.

To facilitate communication between a patient’s care team, physicians use our award-winning EMR system.

Advances in How Brain Tumors and Lesions Are Treated

Advanced technology allows our neurosurgeons to see detailed images of structures deep within the brain. This benefits patients by making their procedures less invasive, and in some cases, affords those with inoperable conditions new avenues for treatment, including laser ablation of tumors.

“Patients who need surgery for strokes, intracranial brain bleeding and a wide range of brain tumors may now have less-invasive procedures in some cases,” said Dr. Julian Bailes.

Our neurosurgeons also use Modus V—a high-resolution, high-powered digital microscope available only at NorthShore—which increases the range of movement in complex operations. This microscope features a robotically controlled arm that comes equipped with advanced optics and magnification.

“We’re the only program in Chicagoland with these advanced surgical tools,” said Dr. Bailes. “They combine real-time imaging, navigation, advanced optics and robotic positioning to help reduce operative time and improve outcomes.”

For your patient, this means a markedly faster recovery, shorter hospital stay, and improved surgical and cosmetic outcomes. Just a few years ago, these procedures meant a long stay in the hospital; today, they often mean only a one- or two-day stay.



KEY CLINICAL SERVICES

Skull Base Surgery (Pituitary Tumors)

Defined by location, tumors that develop at the base of the skull are called skull base tumors. While they are often benign and slow growing, they can become a concern when they impact function by compressing sensitive anatomy in the brain such as the brainstem, cranial nerves and blood vessels. They are among the most challenging tumors to surgically treat and demand experienced and highly skilled surgeons.

Our NorthShore Neurological Institute multidisciplinary specialists are nationally renowned in the medical and surgical treatment of a variety of skull base tumors such as pituitary tumors (adenomas, craniopharyngiomas) and blood vessel diseases. Our commitment to patient care and use of advanced, minimally invasive surgical techniques distinguish our program from others across the region.

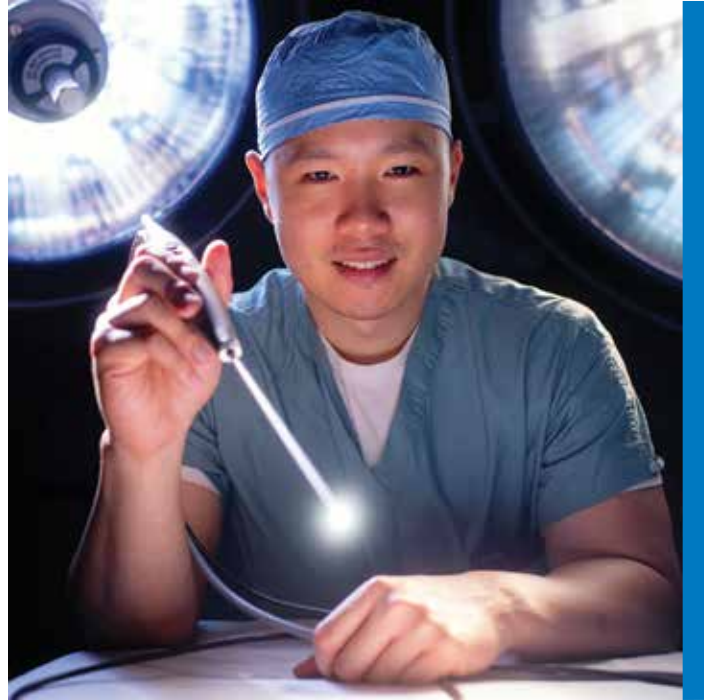
Our fellowship-trained team, among the most experienced in the country, provides expert diagnosis and innovative treatment options to patients with a variety of skull base tumors and conditions including:

- Meningioma
- Acoustic neuroma
- Chordoma
- Cholesteatoma
- Esthesioneuroblastoma
- Cerebrospinal fluid (CSF) leak
- Trigeminal neuralgia
- Hemifacial spasm
- Brain aneurysm

Advanced Surgical Techniques

We have extensive experience employing minimally invasive surgical approaches for the following:

- **Pituitary tumors**—growths that develop in the pituitary gland and can affect hormone production or press on the optic nerves and cause vision problems.
- **Acoustic neuromas**—tumors that grow around the vestibulocochlear nerve, potentially leading to hearing loss, ringing in the ear and vertigo.



Dr. Ricky Wong, Neurosurgery Department

- **Vascular compression syndromes**—compression of the trigeminal nerve that can cause intense facial pain (trigeminal neuralgia) or compression of the facial nerve leading to hemifacial spasm.

Advanced surgical techniques allow for these tumors to be successfully removed through very small incisions hidden in either the eyebrow or hair, or through the nose. The two most common approaches include:

- **Endoscopic endonasal approach**—a technique that involves placing specialized surgical instruments inside the nasal cavity to gain access to certain areas of the brain, skull and upper spine.
- **Keyhole approach**—a technique that uses a combination of microscopes and endoscopes placed behind the eyebrow or hair line to gain access to the brain and skull base.

KEY CLINICAL SERVICES

Deep Brain Stimulation for Parkinson's Disease

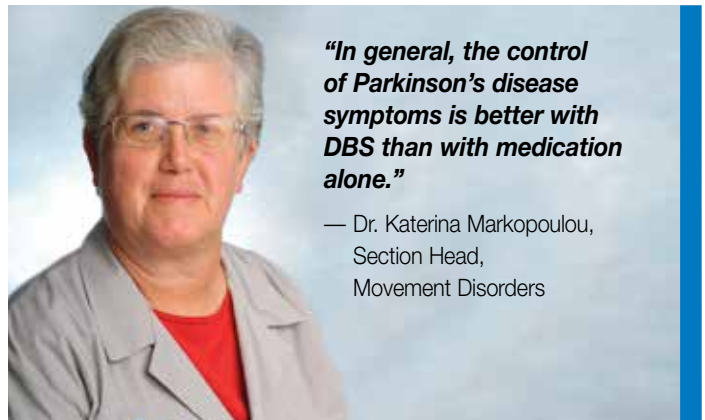
Parkinson's disease is a progressive condition that impairs the control of movement and can cause tremor, slowness of movement, muscle stiffness and balance problems.

Most of these symptoms can be treated effectively with medications. However, these medications come with side effects that include involuntary movements and/or wearing off of the beneficial effect of the medication after prolonged use.

Deep brain stimulation (DBS) is an FDA-approved surgical treatment for Parkinson's disease that can help treat the Parkinson's disease symptoms and the complications that may arise from long-term use of medications. It also allows for a reduction in the medication requirements to treat the symptoms, thus decreasing the chance for medication-related side effects.

DBS surgery involves the insertion of electrodes targeted to stimulate specific structures deep inside the brain that are involved in the control of movement. For the right patients, DBS surgery has been shown to be a more effective treatment of Parkinson's disease

symptoms than medications alone. The DBS benefit is long-lasting. DBS treats the symptoms of Parkinson's but unfortunately cannot halt the disease's progression.



"In general, the control of Parkinson's disease symptoms is better with DBS than with medication alone."

— Dr. Katerina Markopoulou,
Section Head,
Movement Disorders

Concussion Program

Slipping and falling at home. Injuring yourself at work. Being involved in a motor vehicle accident. These situations as well as others from daily life can put people of all ages at risk for concussion, traumatic brain injury (TBI) or other head injuries. The experts at the Neurological Institute draw upon the collaborative strength of neurologists, neuropsychologists, neurosurgeons, physiatrists, and physical, occupational and speech therapists as well as others to diagnose and treat brain injuries—from the very mild to the most severe.

Our neurological team offers a full spectrum of concussion and head injury assessment and treatment strategies and helps

promote long-term brain health with appropriate counseling, testing and reduction of risk factors.

Upon diagnosis, our skilled team develops a personalized treatment plan employing an array of options from medication to speech therapy. However, most mild brain injuries are self-limiting conditions that can be resolved through rest and medical observation and monitoring of your condition.

When left undiagnosed, the brain may not have the proper time needed to heal, which can lead to more serious, long-term effects if another head injury is sustained.

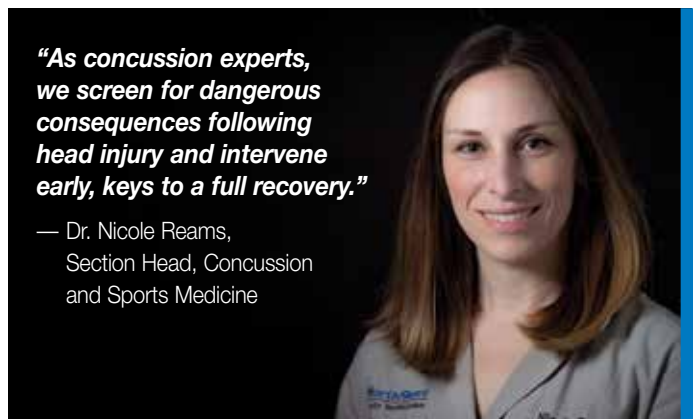
Concussion Symptoms and Diagnosis

A head injury or concussion can occur with or without a direct hit to the head, and symptoms can linger for days to weeks.

Symptoms of concussions are often very subtle and may not be immediately evident after the head injury is sustained, making a diagnosis more difficult. This diagnosis can be increasingly hard to identify given that the majority of concussions do not result in loss of consciousness or being classically "knocked out."

Some of the most common head injury and concussion symptoms include:

- Headaches
- Memory loss or confusion
- Dizziness
- Difficulty concentrating
- Neck pain
- Sensitivity to light or sound



"As concussion experts, we screen for dangerous consequences following head injury and intervene early, keys to a full recovery."

— Dr. Nicole Reams,
Section Head, Concussion
and Sports Medicine

KEY CLINICAL SERVICES

Center for Brain Health

The Center for Brain Health at NorthShore Neurological Institute aspires to preserve and improve brain health by preventing dementia, Alzheimer’s disease, Parkinson’s disease and other aging brain disorders. Experts use results of genetic testing, assessments of modifiable lifestyle factors and advanced diagnostics to equip patients with personalized prevention strategies to maintain brain health and avoid Alzheimer’s disease and related neurodegenerative disorders.

Primary Prevention of Alzheimer’s and Other Neurodegenerative Disorders

Research has shown that the pathological changes in the brain that may lead to dementia due to Alzheimer’s disease begin decades before the onset of symptoms. It is during this “preclinical” stage that we aim to intervene. The same may hold true for Parkinson’s disease and chronic traumatic encephalopathy (CTE). Alzheimer’s disease causes problems with memory, thinking and behavior; disrupts daily living; and robs people of their independence.



Dr. Smita Patel, Director, Center for Brain Health (CBH), assessing for a neurodegenerative brain disorder in the Center for Brain Health clinic.

One in five women and one in 10 men will develop symptoms of Alzheimer’s in their lifetime. Parkinson’s disease impacts 1 million Americans and results in tremors, stiff muscles, slow movement, and difficulties with walking or balance. CTE is a progressive, degenerative brain disorder associated with traumatic brain injury that is increasingly recognized in professional athletes and military personnel.

The Center for Brain Health is directed by Smita Patel, DO. At the Center, patients may elect to receive genetic testing and advanced diagnostics while specialists focus on lifestyle and medical factors to predict and protect against dementia due to Alzheimer’s disease and related disorders. Longer life expectancy and unhealthy lifestyles and behaviors have combined to result in an expected epidemic of Alzheimer’s. Risks for this disease include genetic, medical and lifestyle factors.

Our patients are individuals with normal cognition at an increased risk due to a family history or the presence of risk factors. Our experts identified the factors listed below as having strong evidence in the literature as increasing or decreasing the risk for Alzheimer’s disease and related disorders.

Personalized Brain Health Care

By proactively participating with our team of brain health experts, at-risk individuals get the support needed to delay—and possibly prevent—brain disorders. NorthShore’s team of specialists at the Center includes neurologists, neuropsychologists, neuroradiologists, genetic counselors, physical therapists, dietitians, health psychologists, social workers, lifestyle coaches and researchers.

We implement personalized, evidence-based interventions to mitigate risk factors and maximize protective factors, as well as evidence-based interventions with the potential to benefit all patients. These interventions include lifestyle and behavioral changes, medications, and management of diseases associated with increased risk of Alzheimer’s disease.

We maintain compliance-focused follow-up via interval visits with a physician assistant. Annual follow-up visits with the neurologist focus on updating risk profiles and modifying interventions according to outcomes and the latest evidence.

If patients develop aging brain disorders despite our best efforts, they are transitioned at the earliest point to relevant neurology subspecialty practices. To identify at-risk individuals, we provide education to primary care providers for relevant referrals and have developed informatics tools built into the Electronic Medical Record (EMR) system including a web- and paper-based Brain Health Quiz. The Brain Health Quiz is an educational list of evidence-based risk factors for Alzheimer’s disease, Parkinson’s disease and CTE by which individuals can learn about their risk factors and self-refer.

We built into the EMR Best Practice Advisories that prompt neurologists to enroll patients into a DNA biobank (each patient is genotyped for 1 million single nucleotide polymorphism markers), which will enable genomic discoveries related to brain health.

KEY CLINICAL SERVICES

Amyotrophic Lateral Sclerosis (ALS) Clinic

NorthShore Neurological Institute has opened the first ALS Association certified ALS treatment center in the Northern Chicago suburbs.

ALS, also known as Lou Gehrig's Disease, is a progressive disease that affects nerve cells in the brain and spinal cord.



Speech, swallowing and movement gradually deteriorate in ALS patients.

NorthShore's ALS Clinic—led by Octavia Kincaid, MD—specializes in the management, care and support of people with ALS, providing resources and clinical expertise that make it easier for patients to cope effectively with ALS and optimize the quality of daily life.

A collaborative multidisciplinary team including neurologists; pulmonologists; occupational, physical and speech therapists; social workers; and nutritionists works together to provide answers and solutions to patients and their families.

This approach ensures that team members work closely together and consult with one another regularly to help ensure the highest level of care possible.

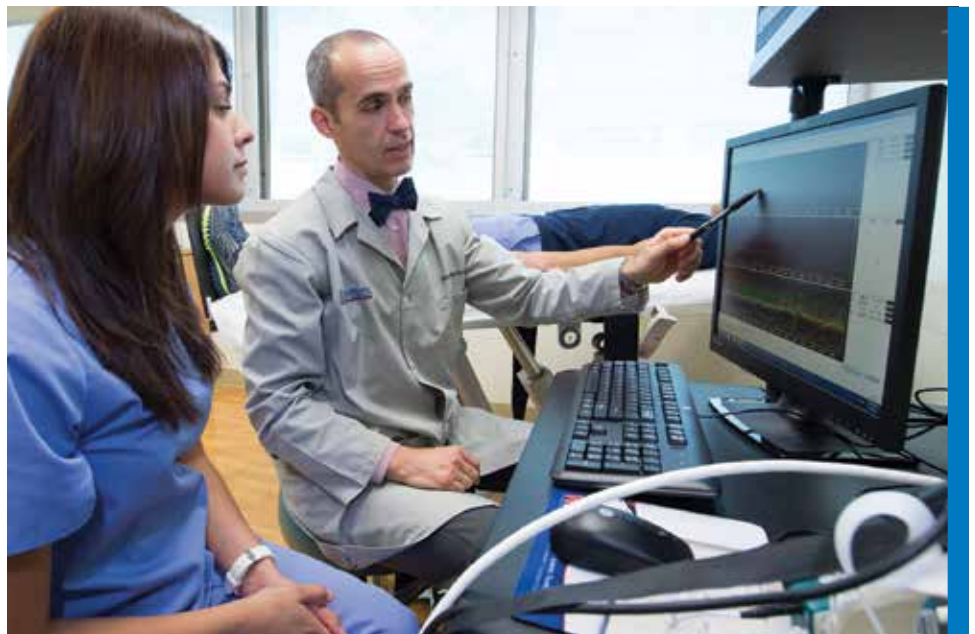
Sponsored by the ALS Association Greater Chicago Chapter, our full-service clinic offers a personalized coordinated care experience all in one convenient location. A dedicated neurology nurse specialist and a home care representative from the ALS Association are also available.

Autonomics Laboratory

The autonomic nervous system is part of the peripheral nervous system, which regulates subconscious activities such as heart rate, digestion, respiratory rate, salivation, perspiration, swallowing and more. Disorders of the autonomic nervous system are often complex and disabling conditions that are a challenge to diagnose.

As one of the most comprehensive labs of its type in the region, NorthShore's Autonomic Testing Lab includes the most advanced, state-of-the-art technology and equipment to diagnose these disorders.

Led by fellowship-trained physician and director of the Neuromuscular Program, Alexandru Barboi, MD, the lab assists Dr. Barboi in making a comprehensive diagnosis of autonomic system disorders.



Dr. Alexandru Barboi, Section Head, Neuromuscular (right) reviews a patient's diagnostic tests with a technician in our state-of-the-art autonomic laboratory.

KEY CLINICAL SERVICES

Spine Program

Back and neck conditions are some of the most common causes of pain and disability in the United States. This kind of pain can be recurring and incredibly disabling, preventing people from performing and enjoying everyday tasks and activities. NorthShore Spine Center specialists help minimize back and neck pain and return patients to a full, healthy life as quickly as possible.

With a holistic approach toward our patients, we consider each patient's ability to manage pain, which can vary from individual to individual and is often impacted by anxiety or depression.

Moreover, stress or fear associated with pain, such as how it affects day-to-day functioning or mobility, also influences a patient's pain, overall psyche and attitude toward treatment options.

Our multispecialty team devises the best neck and back pain treatment plan for each patient. Our goal is not just to treat the pain, but to treat the whole person.

Nonsurgical Back Pain Treatment Options

We begin by treating back pain as conservatively as possible, exploring nonsurgical options where appropriate. Our fellowship-trained physiatrists, including several who specialize in chronic pain management, offer an extensive variety of treatment options based on any patient's specific needs, including:

- **Physical therapy**—Physiatrists and therapists educate patients on proper body mechanics and establish individualized exercise programs they can follow at home.
- **Interventional procedures**—Image-guided pain-relieving injections of medicine straight to the source of the pain can make a huge difference for a patient's comfort.
- **Medication management**—Our experienced physicians and staff work closely with patients to regulate and monitor any oral medications they take to treat their back pain.
- **Integrative medicine**—NorthShore's Integrative Medicine Program can complement a patient's holistic back pain treatment plan, in conjunction with any other therapies. Options include acupuncture, chiropractic care, yoga, biofeedback and more.

Surgical Treatment Options

When conditions require surgery, one of the most experienced surgical teams in the region offers the most advanced minimally invasive and complex surgical techniques available.

Minimally invasive procedures offered include:

- Anterior lumbar interbody fusion
- Direct lateral interbody fusion
- Transforaminal lumbar interbody fusion
- Spinal cord/nerve root decompression
- Cervical interbody fusion
- Foraminotomy
- Total disc replacement
- Microdiscectomy
- Kyphoplasty
- Lumbar disc replacement
- Cervical disc replacement
- Lumbar interbody fusion

Use of state-of-the-art minimally invasive techniques, instrumentation and imaging helps patients recover in a shorter period of time and allows for a quicker return home.



“After surgery, I’ve seen patients go from being impeded in their daily activities by severe back pain to being able to play sports again and resume an active lifestyle.”

— Dr. Michael Musacchio,
Neurosurgery Department

RESEARCH HIGHLIGHTS

Traumatic Brain Injury

Traumatic brain injury (TBI) remains a major public health challenge, causing an estimated 57,000 deaths and 288,000 hospitalizations annually in the United States.

There are limited therapeutic options for TBI since more than 30 clinical trials have been conducted in TBI, and all have failed. This may be because preclinical tools capable of screening potential therapeutic compounds are not currently available for TBI. At the TBI Laboratory at NorthShore Neurological Institute, researchers have developed a new tool to address this gap that is hoped to accelerate new discoveries in TBI therapeutics.

John Finan, PhD, is the biomedical engineer in the Department of Neurosurgery and principal investigator on the project. Dr. Finan was awarded federal funding from the National Institute of Neurological Disorders and Stroke to further develop this model. “The human brain is soft and heavy, and it shears under its own

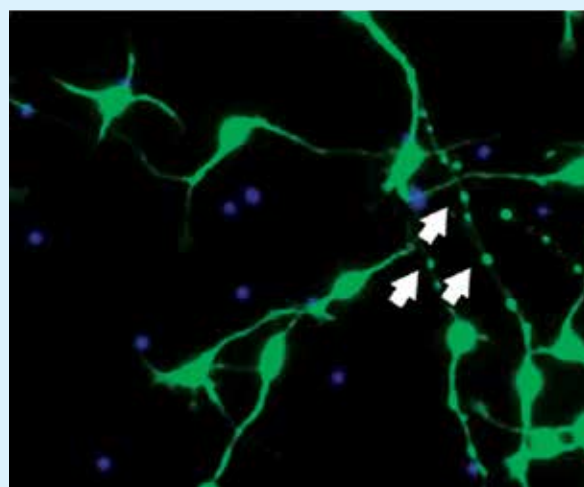
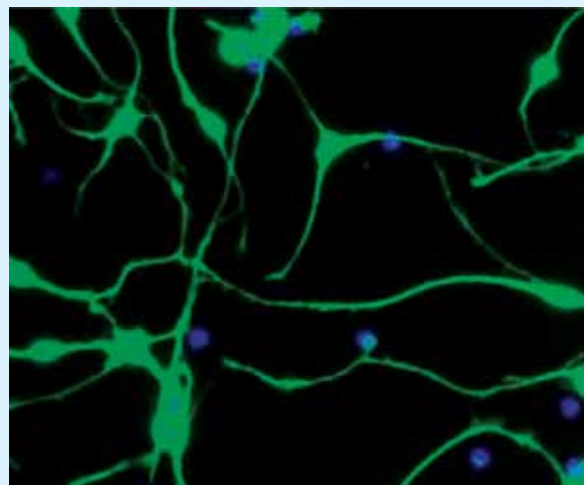


weight when the head is violently accelerated,” said Dr. Finan. “This motion stretches neurites, causing a traumatic axonal injury (TAI)—an important component of severe TBI pathology.”

The custom-built tool is engineered to mimic this stretching injury in a cell-based test (see the image to the right). Dr. Finan plans to convert this test into a high-throughput screening (HTS) method that can be used for drug discovery. HTS assays are performed in “automation-friendly” microtiter plates with a 96-well format so as to quickly test the biological or biochemical activity of a large number of compounds. Even the image analysis is computerized to track the injury. “This tool will allow us to screen thousands of potential therapeutic compounds to identify those that can rescue neurons after traumatic injury,” continued Dr. Finan. “We’ll start by screening for all the current FDA-approved drugs—and if we identify a candidate that has potential, we’ll move to the next stage in its testing.”

The TBI Laboratory at NorthShore Neurological Institute has a number of well-established models and researchers with the experience to use them to take a potential therapeutic com-

High-Throughput Screening for TBI Therapeutics



(Top panel) Image of live (green) and dead (purple) neurons in a 96-well microtiter plate before a stretching injury was applied. The neurites (projections from the neurons) are large and thick. (Bottom panel) Same cells four hours after a stretch injury results in an increase in neuronal cell death and shorter and thinner neurites with beads (arrows). From Scientific Reports 2016;6:34097.

pound all the way through to human clinical trials. Julian Bailes, MD, Surgical Director of NorthShore Neurological Institute and a nationally recognized leader in research on the impact of brain injury on brain function, describes the TBI Laboratory as “one of the select few places in the country with multiple modalities and expertise to advance new solutions to the TBI problem.”

RESEARCH HIGHLIGHTS

Clinical Trials

For an up-to-date list of clinical trials currently enrolling patients at NorthShore Neurological Institute, go to: northshore.org/neurological-institute/research-innovation

The DodoNA Project

The DodoNA Project: DNA Predictions to Improve Neurological Health

Aims: “DodoNA” is a metaphor. Dodona was an oracle of ancient Greece, where priestesses interpreted the rustling leaves of a sacred oak tree to predict the future and to guide actions to improve fate. Just as at Dodona, we can interpret subtle variations in DNA, the “tree of life,” to improve neurological health. Specifically, we are developing medical informatics tools to capture standardized data via routine office visits that measure the progression and outcomes of patients with the following neurological disorders: brain tumors, epilepsy, memory disorders, migraine, mild traumatic brain injury, multiple sclerosis, neuropathy, Parkinson’s disease, restless legs syndrome and stroke. We are also studying persons who are neurologically healthy but at increased risk for Alzheimer’s disease and related brain disorders.

DodoNA is a clinical practice initiative (note-writing and workflow efficiencies) and a quality initiative (best practices). It is also a research initiative. We will invite up to 1,000 subjects for each of the 11 projects (11,000 subjects in total) to provide, via informed consent, a blood sample for DNA extraction and storage. We then will ask permission to associate information in their blood with information in their medical record (for the purposes of developing molecular prognostics and therapeutics).

Principal Investigator: Katerina Markopoulou, MD
NorthShore Project Number: EH10-139
Contact: Call (847) 503-4344 with questions regarding the study.

Practice-Based Research

Quality Improvement and Practice-Based Research in Neurology Using the EMR System

Aims: The purpose of this study is to advance quality improvement and practice-based research in neurology using the Electronic Medical Record (EMR) system. The Department of Neurology at NorthShore has built into its commercial EMR (called “Epic”) structured clinical documentation support (SCDS) and clinical decision support (CDS) tools that standardize care, write progress notes, and capture ~1,000 discrete and cascading fields of neurological data per office visit. The specific aims of this project are to first create a Neurology Practice-Based Research Network (NPBRN) by sharing SCDS and CDS tools for 10 common neurological disorders (brain tumors, epilepsy, migraine, mild cognitive impairment, mild traumatic brain injury, multiple sclerosis, neuropathy, Parkinson’s disease, restless legs syndrome and stroke) and for brain health (11 projects total) with seven other Neurology Departments nationwide that also use the Epic EMR platform (eight sites total). Secondly, we will individualize medicine at the point of care by conducting pragmatic trials using subgroup-based adaptive designs, comparing the effectiveness of available treatments for common neurological disorders.

Site Principal Investigator: Steven Meyers, MD
NorthShore Project Number: EH14-355
Contact: Call (847) 503-4344 with questions regarding the study.

Brain Aneurysm Clinical Trials

Humanitarian Use Device: Neuroform Microdelivery Stent System

Aims: The Neuroform Microdelivery Stent System is used with coils for treating wide-neck aneurysms in the brain that cannot be treated with open brain surgery.

Principal Investigator: Shakeel Chowdhry, MD
NorthShore Project Number: EH12-352
Contact: Call (847) 570-4224 with questions regarding the device.

Humanitarian Use Device: CODMAN ENTERPRISE Vascular Reconstructive Device and Delivery System

Aims: This device is used for treatment of wide-neck aneurysms. A stent is placed across the opening or neck of the aneurysm to secure the placement of coils and to maintain blood flow through the artery in which the stent is placed.

Principal Investigator: Shakeel Chowdhry, MD
NorthShore Project Number: EH12-354
Contact: Call (847) 570-4224 with questions regarding the device.

Humanitarian Use Device: Wingspan Stent System with Gateway PTA Balloon Catheter

Aims: This device is used to increase cerebral artery blood flow in patients with intracranial atherosclerotic disease. A stent is placed in the affected area and is deployed by inflation of a very small balloon, which widens the occluded vessel.

Principal Investigator: Shakeel Chowdhry, MD
NorthShore Project Number: EH12-355
Contact: Call (847) 570-4224 with questions regarding the device.

Humanitarian Use Device: The PulseRider® Aneurysm Neck Reconstruction Device (ANRD)

Aims: This device acts as a support for the treatment of unruptured, wide-neck bifurcation aneurysms in the brain. A bifurcation aneurysm is a specific type of aneurysm that arises at the point at which there is a division of one major vessel into two branches.

Principal Investigator: Shakeel Chowdhry, MD
NorthShore Project Number: EH17-313
Contact: Call (847) 570-4224 with questions regarding the device.

Brain and Spine Tumor Clinical Trials

A Phase III Randomized, Double-Blind, Placebo-Controlled Study of Armodafinil (Nuvigil) to Reduce Cancer-Related Fatigue in Patients with High-Grade Glioma

Aims: The purpose of this study is to determine whether taking the drug armodafinil will improve problems with fatigue in patients with glioma and to evaluate the effects of taking armodafinil as compared to a placebo on cancer-related fatigue and on cognitive function.

Principal Investigator: Ryan Merrell, MD
NorthShore Project Number: EH13-248
Contact: Call (847) 570-2025 with questions regarding the study.

(continued)

Brain and Spine Tumor Clinical Trials *(continued)*

YELLOW 560 Microscope for Intraoperative Visualization of Fluorescein-Stained High-Grade Gliomas

Aims: The purpose of this study is to assess the use of a yellow, fluorescent dye in combination with a specialized microscope during brain surgery for the removal of a specific type of tumor called a high-grade glioma. Objectives include measuring patient outcomes and measuring the extent of tumor removal.

Principal Investigator: Julian Bailes, MD
NorthShore Project Number: EH13-331
Contact: Call **(847) 570-4224** with questions regarding the study.

Compassionate Use of ABT-414 for the Treatment of Glioblastoma Multiforme

Aims: The purpose of this study is to provide the drug currently being studied in an ongoing research study to patients who do not meet the criteria to participate in the main study.

Principal Investigator: Ryan Merrell, MD
NorthShore Project Number: EH16-225
Contact: Call **(847) 570-2025** with questions regarding the study.

A Study of Exploratory Biomarkers in EGFR-Amplified Patient-Derived Xenograft (PDX) Models from Subjects with Glioblastoma Multiforme (GBM) Clinical Study Protocol F15-712

Aims: The purpose of this study is to collect tumor tissue from patients who will receive ABT-414 on the Compassionate Use protocol for use in pre-clinical tumor models.

Principal Investigator: Ryan Merrell, MD
NorthShore Project Number: EH17-148
Contact: Call **(847) 570-2025** with questions regarding the study.

Phase I Study of Safety and Tolerability of Acetazolamide with Temozolomide

Aims: This is a Phase I study that examines the rate of dose-limiting side effects in patients with malignant astrocytoma treated with combination acetazolamide (ACZ) and temozolomide (TMZ). Eligible patients must have histologically proven newly diagnosed, O⁶-methylguanine-DNA methyltransferase (MGMT) methylated WHO grade III or IV astrocytoma and be planning to undergo treatment with standard adjuvant TMZ (after completing treatment with TMZ and ionizing radiation).

Principal Investigator: Ryan Merrell, MD
NorthShore Project Number: EH18-083
Contact: Call **(847) 570-2025** with questions regarding the study.

Phase 3b Study for Management of Ocular Side Effects in Subjects with EGFR-Amplified Glioblastoma Receiving Depatuxizumab Mafodotin (ABT-414)

Aims: This study will evaluate the effect of several ophthalmologic prophylactic treatment strategies for the management of ocular side effects in participants with epidermal growth factor receptor-amplified glioblastoma who are being treated with depatuxizumab mafodotin (ABT-414). The study will include 2 phases during the treatment period: chemoradiation therapy (radiation plus temozolomide [RT/TMZ]) and adjuvant therapy (TMZ). All participants will receive depatuxizumab mafodotin during both phases of the treatment period plus 1 of 3 prophylactic ophthalmologic treatments (standard steroids, standard steroids with vasoconstrictors and cold compress, and enhanced steroids with vasoconstrictors and cooling compress).

Principal Investigator: Ryan Merrell, MD
NorthShore Project Number: EH18-096
Contact: Call **(847) 570-2025** with questions regarding the study.

Brain and Spine Tumor Clinical Trials *(continued)*

Phase III Trial of Observation Versus Irradiation for a Gross Totally Resected Grade II Meningioma

Aims: The purpose of this Phase III study is to finally obtain a clear answer to the long-standing question of which treatment route leads to the best clinical outcome for patients with newly diagnosed WHO grade II meningioma. Subjects will be randomly assigned into one of two groups: Group 1 will be observed following surgery, and Group 2 will receive radiation therapy following surgery.

Principal Investigator: Ryan Merrell, MD
NorthShore Project Number: EH18-270
Contact: Call **(847) 570-2025** with questions regarding the study

A Randomized, Double-Blind, Phase II Trial of Surgery, Radiation Therapy Plus Temozolomide and Pembrolizumab With and Without HSPPC-96 in Newly Diagnosed Glioblastoma (GBM)

Aims: The purpose of this study is to find out if adding immunotherapy (pembrolizumab) with or without a vaccine (HSPPC-96) to standard-of-care treatment for glioblastoma (GBM) improves survival of newly diagnosed GBM subjects. The standard treatment for GBM consists of surgery to remove the brain tumor, radiation and chemotherapy (temozolomide).

Principal Investigator: Ryan Merrell, MD
NorthShore Project Number: EH18-383
Contact: Call **(847) 570-2025** with questions regarding the study.

Epilepsy Clinical Trials

Multicenter 1-Year Observational Study of Patients Who Are Initiating Brivaracetam

Aims: The primary aim of this postmarketing, non-interventional study is to determine brivaracetam (BRV) retention (continuing treatment) in daily clinical practice over a 12-month observation period from the initiation of the medication. BRV will be prescribed according to normal clinical practice. BRV is indicated as adjunctive (add-on) therapy in the treatment of partial onset seizures with or without secondary generalization in patients 16 years of age and older with epilepsy.

Principal Investigator: Jaishree Narayanan, MD
NorthShore Project Number: EH17-366
Contact: Call **(847) 570-4224** with questions regarding the study.

Feasibility of Continuous Pupil Dilation and Other Autonomic Monitoring as Non-Invasive Means of Seizure Prediction and Detection in the Epilepsy Monitoring Unit (EMU)

Aims: People who experience seizures have difficulty recognizing and accurately remembering when and how often they had seizures, and predicting when they will have seizures in the future. There is a need to detect and predict when seizures occur to try to reduce the harm that can come from having them. Researchers have worked on different methods of detecting and predicting seizures by looking at EEGs body movements, sweating, heart rate variability and other things that may change around the time seizures occur. This study for the first time will look at what happens to the pupils of the eye around the time of seizures with the goal of developing another method to detect and predict seizures. This pilot study will focus on the feasibility of monitoring eye dilation in the EMU.

Principal Investigator: Jaishree Narayanan, MD, PhD
NorthShore Project Number: EH18-108
Contact: Call **(847) 570-2547** with questions regarding the study.

Headache Clinical Trials

A Randomized, Multicenter, Double-Blind, Parallel, Sham-Controlled Study of Non-Invasive Vagus Nerve Stimulation (NVNS) for the Prevention of Migraines (PREMIUM II)

Aims: The purpose of this study is to investigate whether a medical device (gammaCore™ Sapphire) can be effective in reducing the frequency and severity of migraine without the use of medication. The device works by stimulating the vagus nerve. It has already been FDA-approved as treatment for use during a migraine attack. This study evaluates whether it is consistent use can prevent future headaches in migraine sufferers.

Principal Investigator: Steven Meyers, MD

NorthShore Project Number: EH19-022

Contact: Call **(847) 503-4344** with questions regarding the study.

Multiple Sclerosis Clinical Trials

A Phase III Study in Subjects with Relapsing Remitting Multiple Sclerosis to Evaluate the Tolerability of ALKS 8700 and Dimethyl Fumarate

Aims: The primary goals of this randomized double-blind trial are to evaluate the safety and tolerability of the study medication (ALKS 8700) and to compare the gastrointestinal (GI) tolerability of ALKS 8700 with another multiple sclerosis (MS) medication, dimethyl fumarate (Tecfidera®). The trial also aims to assess the utility of two gastrointestinal (GI) symptom scales in assessing GI tolerability in adult subjects with relapsing remitting multiple sclerosis (RRMS).

Principal Investigator: Afif Hentati, MD

NorthShore Project Number: EH17-105

Contact: Call **(847) 503-4335** with questions regarding the study.

A Phase III Study in Subjects with Relapsing Remitting Multiple Sclerosis to Evaluate the Tolerability of ALKS 8700 and Dimethyl Fumarate

Aims: The primary goals of this randomized double-blind trial are to evaluate the safety and tolerability of the study medication (ALKS 8700) and to compare the gastrointestinal (GI) tolerability of ALKS 8700 with another multiple sclerosis (MS) medication, dimethyl fumarate (Tecfidera®). The trial also aims to assess the utility of two gastrointestinal (GI) symptom scales in assessing GI tolerability in adult subjects with relapsing remitting multiple sclerosis (RRMS).

Principal Investigator: Afif Hentati, MD

NorthShore Project Number: EH17-105

Contact: Call **(847) 570-2025** with questions regarding the study.



Dr. Afif Hentati, Section Head, Multiple Sclerosis Program

Neuromuscular Disorder Clinical Trials

An Open-Label, Expanded Access Protocol for Firdapse® (Amifampridine Phosphate; 3,4-Diaminopyridine Phosphate) Treatment in Patients with Lambert-Eaton Myasthenic Syndrome (LEMS), Congenital Myasthenic Syndrome (CMS) and Downbeat Nystagmus

Aims: The primary objective of this study is to provide patients with LEMS/CMS/ downbeat nystagmus access to amifampridine phosphate therapy until the product becomes commercially available. The secondary objective of the study is to assess the long-term safety of amifampridine.

Principal Investigator: Alexandru Barboi, MD

NorthShore Project Number: EH16-121

Contact: Call **(847) 271-7415** with questions regarding the study.

RESTORE: A Clinical Study of Patients with Symptomatic Neurogenic Orthostatic Hypotension to Assess Sustained Effects of Droxidopa Therapy

Aims: The purpose of this study is to evaluate the durability, effectiveness and safety of the study drug, droxidopa, in those with neurogenic orthostatic hypotension (NOH). Droxidopa (NORTHERA) has been approved in the United States for treatment of NOH. However, effectiveness beyond 2 weeks has not been demonstrated. This study is placebo-controlled to assess the benefits beyond 2 weeks and is therefore investigational. Total study participation can be up to 36 weeks.

Principal Investigator: Alexandru Barboi, MD

NorthShore Project Number: EH18-106

Contact: **Call (847) 503-4334** with questions regarding the study.

Neuro-Ophthalmology Clinical Trials

A Phase II/III, Randomized, Double-Masked, Sham-Controlled Trial of QPI-1007 Delivered by Single- or Multi-Dose Intravitreal Injection(s) to Subjects with Acute Nonarteritic Anterior Ischemic Optic Neuropathy (NAION)

Aims: This study will test whether the experimental drug QPI-1007 helps prevent visual loss that can occur in NAION. The study will also collect information about whether the experimental drug is safe for humans when it is injected into the eye.

Principal Investigator: John Pula, MD

NorthShore Project Number: EH16-164

Contact: Call **(847) 657-1750** with questions regarding the study.

A Double-Masked Clinical Study Evaluating the Efficacy and Safety of RPh201 Treatment in Participants with Previous NAION

Aims: The primary objective of this Phase III study is to evaluate the efficacy and safety of twice-weekly subcutaneous (below the skin) administration of the study drug (RPh201) over 26 weeks in participants with a prior diagnosis of nonarteritic anterior ischemic optic neuropathy (NAION). Evaluation of efficacy will be based on measuring visual function. Participants will be randomly assigned in a 2:1 active:control ratio to receive RPh201 or a placebo.

Principal Investigator: John Pula, MD

NorthShore Project Number: EH18-294

Contact: Call **(847) 657-1750** with questions regarding the study.

Rapid Number Naming Performance in Myasthenia Gravis (MG) Using the King-Devick (K-D) Test

Aims: The purpose of this study is to investigate the change in K-D rapid eye movement performance test with initiation or change in MG treatment and clinical improvement. This study also aims to define the relation of K-D test performance to standard clinical measures of MG in both visual and MG-specific quality of life scores.

Principal Investigator: John Pula, MD

NorthShore Project Number: EH18-010

Contact: Call **(224) 251-2020** with questions regarding the study. *(continued)*

Parkinson's Disease and Movement Disorder Clinical Trials

An Open-Label, Phase III Study Examining the Long-Term Safety, Tolerability and Efficacy of APL-130277 in Levodopa Responsive Patients with Parkinson's Disease Complicated by Motor Fluctuations ("OFF" Episodes)

Aims: The purpose of this study is to determine whether the study drug, APL-130277, is effective, safe and well-tolerated in patients with Parkinson's disease who have "OFF" episodes. APL-130277 is a fast-acting thin film formulation of apomorphine that is placed under the tongue (sublingual) and is intended to be an alternative to the injectable form of apomorphine.

Principal Investigator: Katerina Markopoulou, MD, PhD
NorthShore Project Number: EH15-170

Contact: Call **(847) 503-4334** with questions regarding the study.

Genetic Analysis of Familial Parkinsonism

Aim: The purpose of this study is to identify inherited factors that may cause Parkinson's disease or parkinsonism.

Principal Investigator: Katerina Markopoulou, MD, PhD
NorthShore Project Number: EH16-166

Contact: Call **(847) 503-4334** with questions regarding the study.

The Longitudinal Clinical and Genetic Study of Parkinson's Disease (LONG-PD Study)

Aims: The clinical and genetic factors that influence motor and nonmotor severity, progression and outcomes in Parkinson's disease are unknown. Identification of these factors may allow us to individualize the care of patients and improve neurological health. The Genetic Epidemiology of Parkinson's Disease (GEO-PD) consortium clinics care for thousands of patients each year. The purpose of this study is to develop a web-based platform for the capture and sharing of standardized data that measure motor and nonmotor severity, progression and outcomes in Parkinson's disease across 25 global sites—from 18 countries, 5 continents and 4,200 cases. These patients will be followed for 15 years for collaborative research studies. Additionally, DNA will be shared in a central repository to conduct genomic studies of severity, progression and outcomes in Parkinson's disease.

Principal Investigator: Katerina Markopoulou, MD, PhD
NorthShore Project Number: EH15-283

Contact: Call **(847) 503-4334** with questions regarding the study.

Spine Surgery Clinical Trials

Confirmatory Clinical Study to Support the Effectiveness and Safety of Oxiplex® for the Reduction of Pain and Symptoms Following Lumbar Surgery

Aims: The objective of this prospective, double-blind, randomized controlled study is to assess the safety and effectiveness of Oxiplex in adult patients for the reduction of pain and symptoms following a single level partial discectomy at L4-L5 or L5-S1 with or without laminotomy for leg pain. Oxiplex is a clear, viscoelastic gel that is applied to the operative site during lumbar spine surgery in order to coat the nerve root with a protective barrier.

Principal Investigator: Michael Musacchio, MD
NorthShore Project Number: EH18-113

Contact: Call **(847) 570-4224** with questions regarding the study.

Sleep Clinical Trial

An Open-Label Expanded Access Program Intended to Provide Treatment with HBS-101 (Pitolisant) to Adult Patients in the U.S. with Excessive Daytime Sleepiness Associated with Narcolepsy with or without Cataplexy

Aims: The purpose of this expanded access program (EAP) is to allow patients who have excessive daytime sleepiness (EDS) associated with narcolepsy with or without cataplexy, access to the medication, pitolisant, prior to FDA marketing approval being granted. This EAP also studies the safety and tolerability of pitolisant in adult patients with this condition.

Principal Investigator: Thomas Freedom, MD
NorthShore Project Number: EH19-028

Contact: Call **(847) 503-4333** with questions regarding the study.

Stroke Program Clinical Trials

ENRICH (Early miNimally-invasive Removal of ICH)

Aims: The purpose of this study is to provide clinical evidence of functional improvement, safety and economic benefit when comparing intracerebral hemorrhage (ICH) evacuation (removal of a blood clot from the brain using the minimally invasive BrainPath access system) to medical treatment.

Principal Investigator: Shakeel Chowdhry, MD
NorthShore Project Number: EH17-038

Contact: Call **(847) 570-4224** with questions regarding the study.

Non-Blinded Data Collection Pilot Study of Acute Stroke Using the BrainPulse™

Aims: The purpose of this pilot study is to collect data from patients experiencing stroke using the BrainPulse device. In the second (current) phase of the study, data will be collected on two groups of patients: those with large vessel occlusion (LVO) acute stroke and non-LVO acute stroke. The data collected from the BrainPulse will be compared across these study groups in an attempt to distinguish stroke from other non-stroke conditions that present with similar symptoms and LVO from non-LVO types of strokes. Further assessments will also be made to evaluate whether the BrainPulse can identify the presence of stroke.

Principal Investigator: Shakeel Chowdhry, MD
NorthShore Project Number: EH19-084

Contact: Call **(847) 570-4224** with questions regarding the study.



"We're participating in cutting-edge national prospective research trials to improve care for patients with ischemic and hemorrhagic stroke."

— Dr. Shakeel Chowdhry,
Neurosurgery Department

RESEARCH HIGHLIGHTS

The DodoNA Project

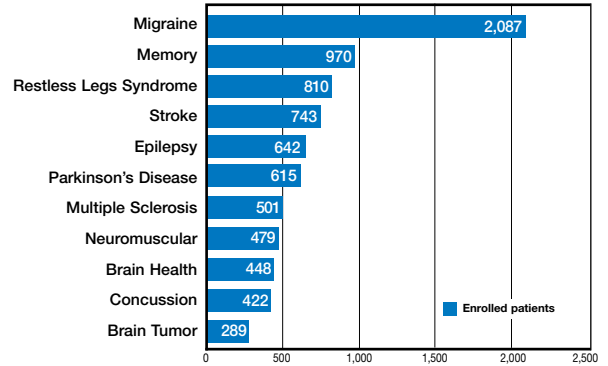
The DodoNA project is one of the major research initiatives of NorthShore Neurological Institute. The purpose of the project is to predict, prevent and halt neurological disorders through the development of DNA-based prognostic tests and therapies.

The DodoNA researchers built customized “toolkits” within NorthShore’s award-winning Electronic Medical Record (EMR) system for each of the 11 disorders that capture and store data from routine office visits. The researchers are also collecting blood and extracting DNA and plasma to be stored in a “biobank.” Laboratory scientists will then perform automated DNA sequencing tests to define DNA fingerprints, which statisticians will then associate with disease outcomes and therapeutic responses. With this information, researchers will be in a better position to deliver methods to predict and modify disease.

Some descriptive data are shown in the graphs below and the following pages.

Research Update

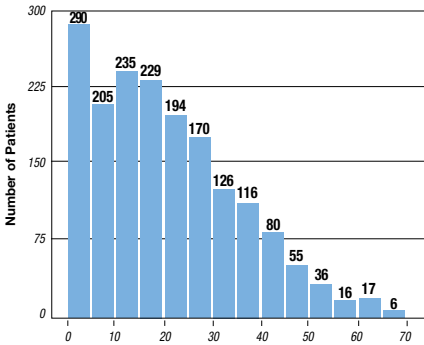
As of January 1, 2019, we have enrolled more than 7,700 patients in the DodoNA project, with a target enrollment of at least 1,000 for each of the disorders.



Migraine Description of our first 2,087 patients enrolled, at their initial visit

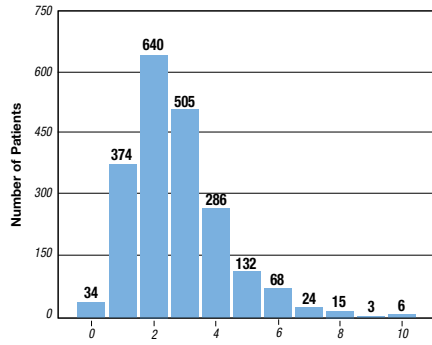
Disease Duration

Measured in years, from year of initial symptom to year of initial visit.



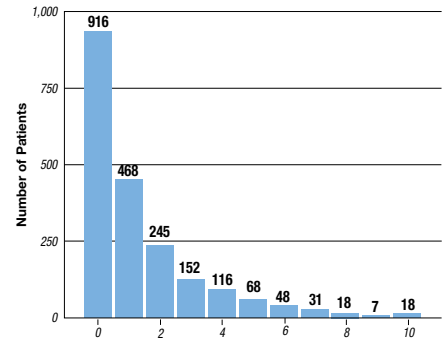
Number of Prior Abortive Medications

Abortive medications are taken at the start of a migraine attack to stop the symptoms.



Number of Prior Preventive Medications

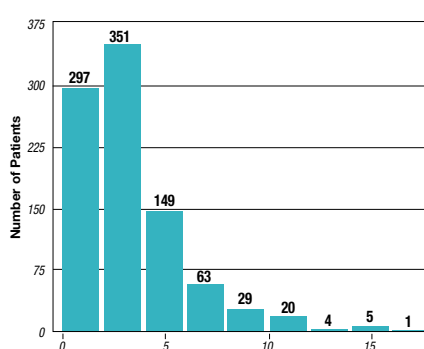
Preventive medications are taken daily to keep migraine attacks from occurring frequently.



Memory Description of our first 970 patients enrolled, at their initial visit

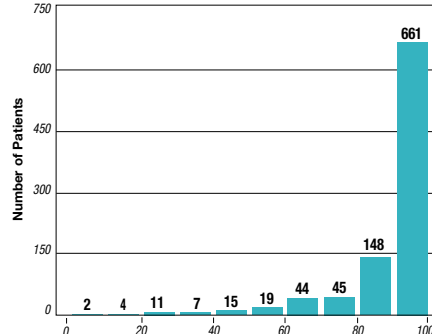
Disease Duration

Measured in years, from year of initial symptom to year of initial visit.



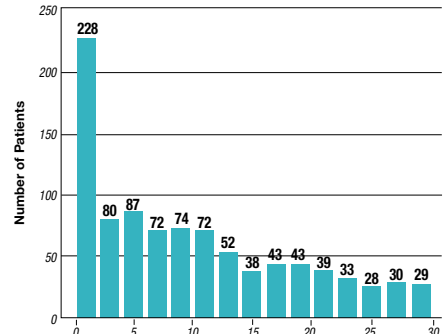
Barthel Index

A measure of performance in activities of daily living (basic activities). 100 = completely independent individual; 0 = completely nonfunctioning individual.



The Functional Activities Questionnaire

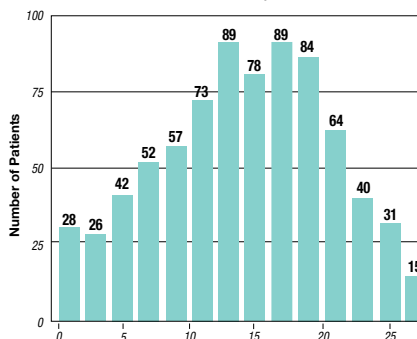
A measure of performance in activities of daily living (complex activities). 0 = person with no limitations; 30 = fully dependent individual.



Restless Legs Syndrome Description of our first 810 patients enrolled, at their initial visit

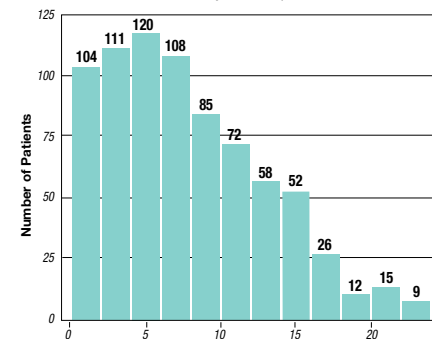
ISI Score

Insomnia Severity Index (ISI), where scores of 15 and over indicate at least moderate severity.



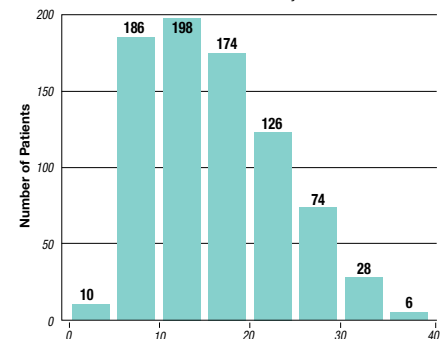
ESS Score

Epworth Sleepiness Scale (ESS), where scores greater than 10 indicate excessive daytime sleepiness.



IRLS Score

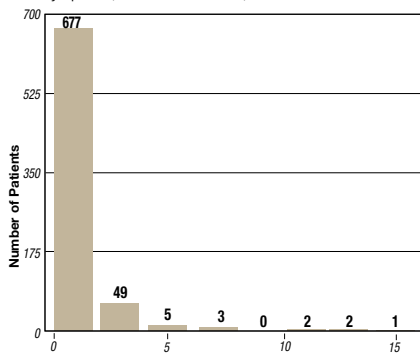
International Restless Legs Scale (IRLS) rating scale, where scores of 0–10 = mild, 11–20 = moderate, 21–30 = severe and 31–40 = very severe.



Stroke Description of our first 743 patients enrolled, at their initial visit

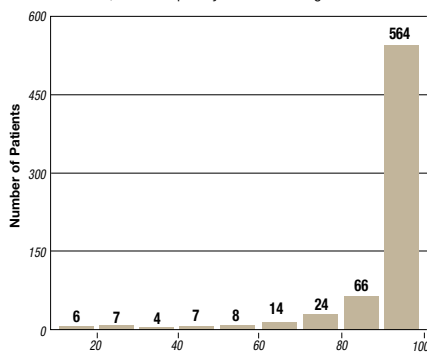
National Institutes of Health Stroke Scale (initial)

An objective measure of the severity of strokes. 0 = no symptoms, 1-4 = mild stroke; 5-15 = moderate stroke.



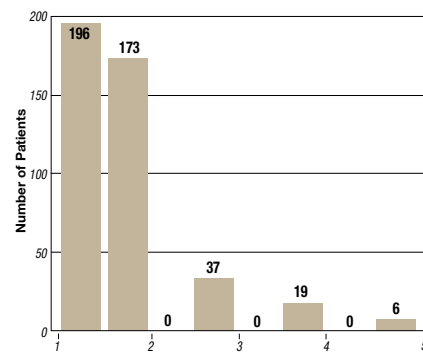
Barthel Index

A measure of performance in activities of daily living (basic activities). 100 = completely independent individual; 0 = completely nonfunctioning individual.



Modified Rankin Index

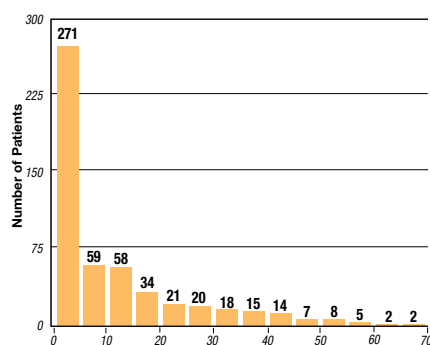
A global disability scale. 0 = no symptoms; 5 = severe disability.



Epilepsy Description of our first 642 patients enrolled, at their initial visit

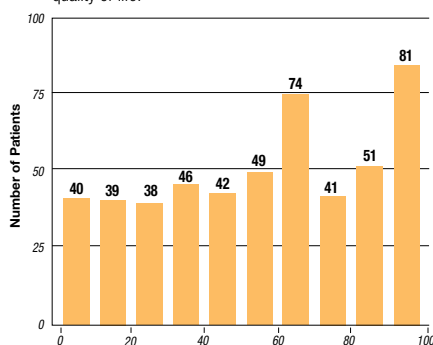
Disease Duration

Measured in years, from year of initial symptom to year of initial visit.



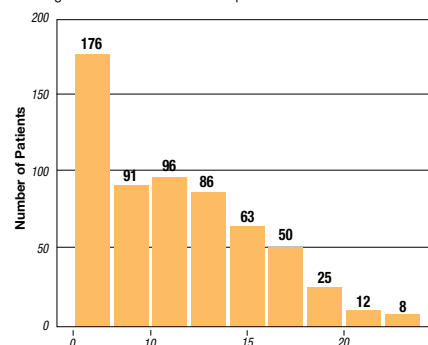
QOLIE Total Score

Quality of Life in Epilepsy (QOLIE-10-P). Lower scores indicate a greater severity and burden of epilepsy on quality of life.



NDDI-E Total Score

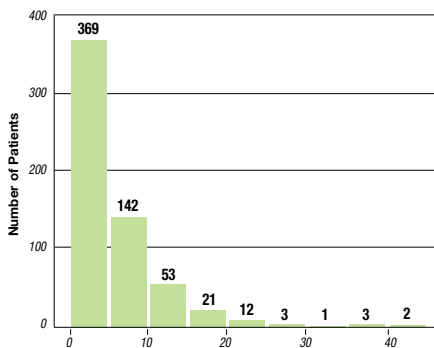
The Neurological Disorders Depression Inventory for Epilepsy (NDDI-E) is a 6-item questionnaire validated to screen for depression in people with epilepsy. Scores greater than 15 indicate depression.



Parkinson's Disease Description of our first 615 patients enrolled, at their initial visit

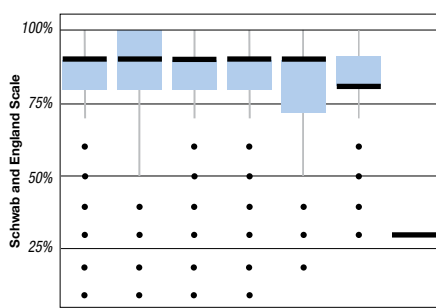
Disease Duration

Measured in years, from year of initial symptom to year of initial visit.



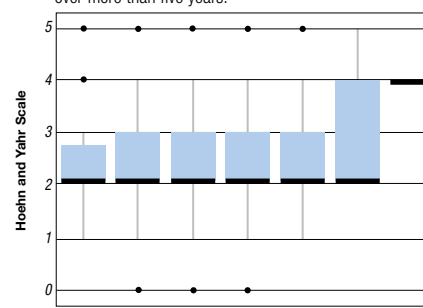
Longitudinal Changes in Schwab and England Scale

Patients self-report their abilities to perform activities of daily living. One hundred percent indicates a completely independent individual, and 0% indicates a completely nonfunctioning individual.



Longitudinal Changes in Hoehn and Yahr Scale

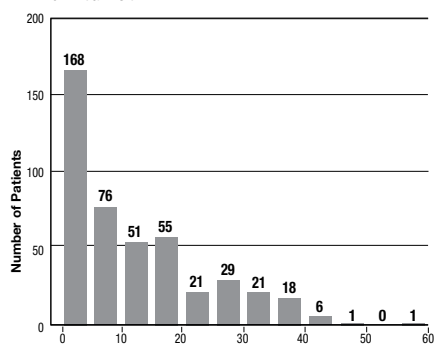
The Hoehn and Yahr scale is a measure of motor impairment; it is an objective measure of disability. As a group, our patients have remained largely stable over more than five years.



Multiple Sclerosis Description of our first 501 patients enrolled, at their initial visit

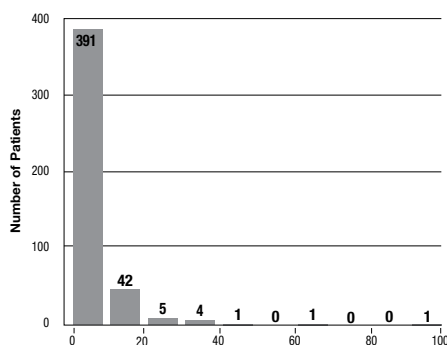
Disease Duration

Measured in years, from year of initial symptom to year of initial visit.



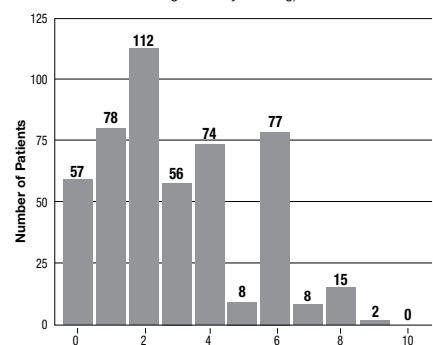
25 ft. Walk

The number of seconds required, on a second attempt, to walk 25 feet.



EDSS Step

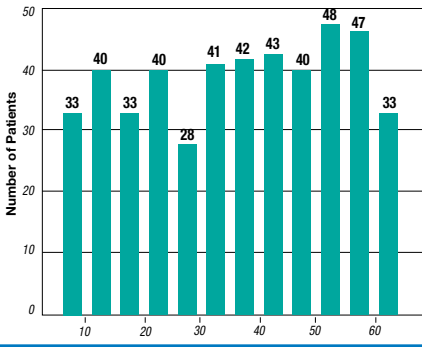
Expanded Disability Status Scale (EDSS), where higher scores are more severe (e.g., scores of 5 and above indicate increasing difficulty walking).



Neuromuscular *Description of our first 479 patients enrolled, at their initial visit*

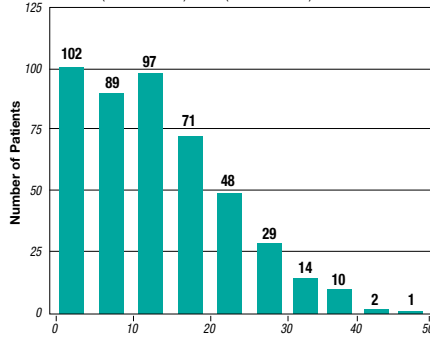
Fatigue Severity Score

A short questionnaire for evaluating the impact of fatigue on patients. A total score of less than 36 suggests that a patient may not be suffering from fatigue.



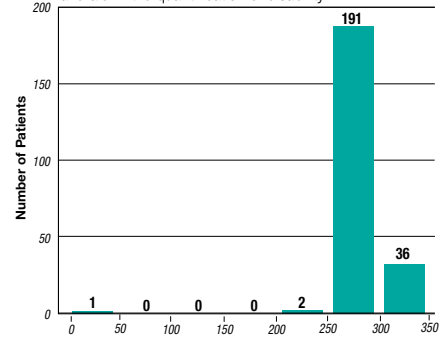
Survey of Autonomic Symptoms

The survey consists of 11 items in women and 12 in men to measure autonomic symptoms in early diabetic neuropathy. Each item is rated by an impact score ranging from 1 (least severe) to 5 (most severe).



NorthShore Neuropathy Impairment Score

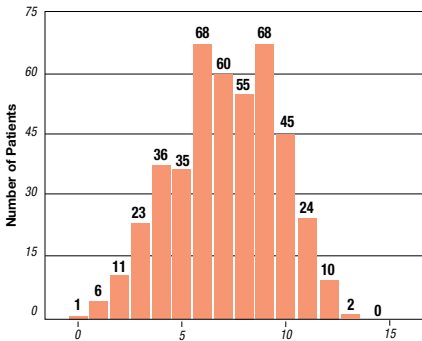
This test was developed by physicians at NorthShore Neurological Institute to parallel severity of involvement and aid in the quantification of disability.



Brain Health *Description of our first 448 patients enrolled, at their initial visit*

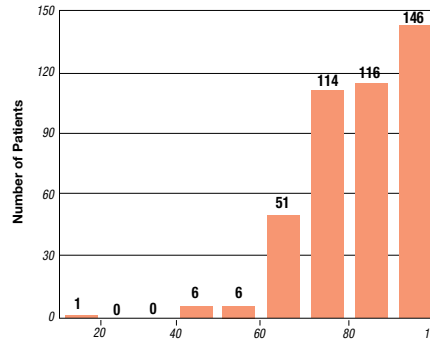
PREDIMED Questionnaire

The PREDIMED questionnaire is a 14-item quiz that defines adherence to the Mediterranean diet. 0–9 = weak adherence; 10–14 = strong adherence.



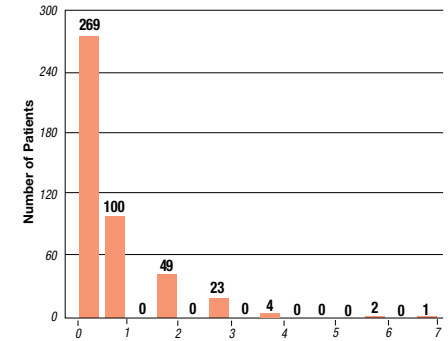
Readiness Questionnaire

The readiness questionnaire indicates readiness to engage in several brain health activities. 100 = very willing for every activity; 0 = very unwilling for all activities.



Brain Health Quiz Score

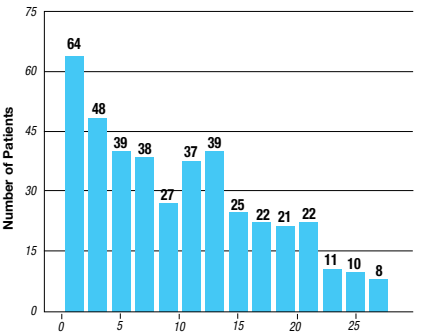
The brain health quiz includes 23 well-defined risk factors for Alzheimer's disease and related disorders. 0 = no risk factors or concerns; 23 = all risk factors and concerns.



Concussion *Description of our first 422 patients enrolled, at their initial visit*

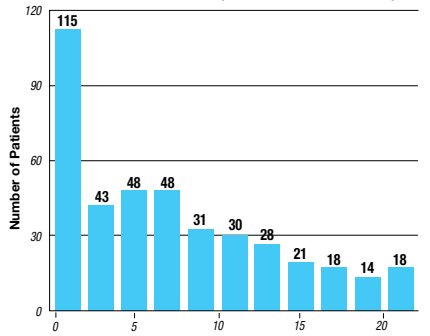
ISI Score

Insomnia Severity Index (ISI), where scores of 15 and over indicate at least moderate severity.



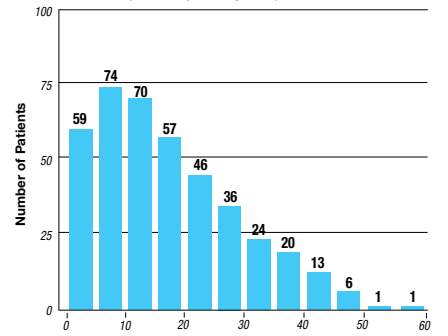
GAD-7 Score

Measuring of generalized anxiety disorder (GAD). 0–4 = minimal anxiety; 5–9 = mild anxiety; 10–14 = moderate anxiety; 15–21 = severe anxiety.



CES-D Score

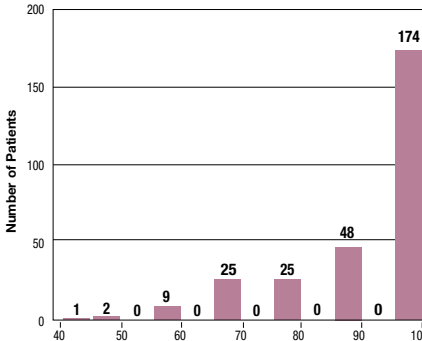
Screening test to determine depression quotient. 15–21 = mild to moderate depression; over 21 = possibility of major depression.



Brain Tumor (primary malignant) *Description of our first 289 patients enrolled, at their initial visit*

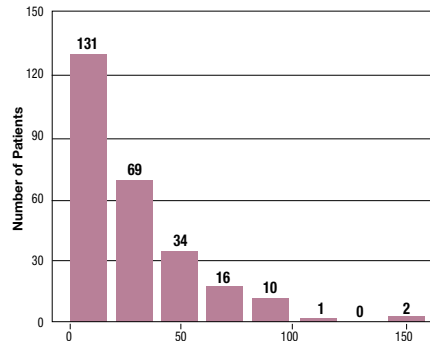
Karnofsky Performance Scale

Classification of functional impairment used to compare effectiveness of different therapies. The lower the score, the worse the survival for most serious illnesses.



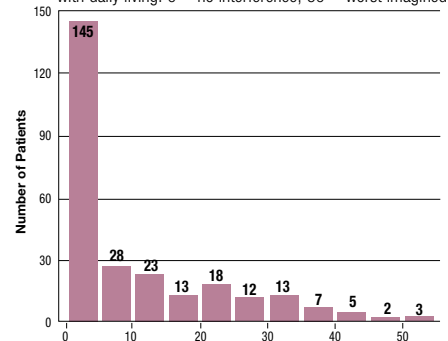
MD Anderson Symptom Inventory—Brain Tumor (Part 1)

Measures a patient's self-reported symptoms severity. 0 = no symptoms; 220 = worst imagined.



MD Anderson Symptom Inventory—Brain Tumor (Part 2)

Measures how a patient's symptoms reportedly interfere with daily living. 0 = no interference; 60 = worst imagined.



RESEARCH HIGHLIGHTS

Neurology Practice-Based Research Network (NPBRN)

From Best Practices to Next Practices

The mission of NorthShore Neurological Institute is to preserve and improve neurological health through clinical practice, education and research. In keeping with this mission, the Neurology Practice-Based Research Network (NPBRN) was launched in June 2015.

The goal of the NPBRN is to advance quality improvement and practice-based research in neurology using the Electronic Medical Record (EMR) system.

Currently, there is a lack of quality initiatives and comparative effectiveness research in neurology. To address this gap, the American Academy of Neurology (AAN) has published evidence-based guidelines, quality improvement measures and resources for treating neurological disorders. However, there are few tools available to standardize neurology office visits according to these guidelines.

In 2003, NorthShore was among the first in the country to successfully launch a systemwide EMR, called “Epic,” with demonstrable benefits in quality, safety, efficiency and service to patients. NorthShore is recognized by multiple national organizations for this notable achievement. The Department

Neurology Practice-Based Research Network Sites Progress

NPBRN Site	Number of Toolkits Planned or Implemented (Out of 11)
Dartmouth-Hitchcock	2
Medical University of South Carolina	3
NorthShore University HealthSystem	11
Ochsner Health System	8
St. Luke’s Hospital (MO)	8
University of Cincinnati	4
University of Connecticut	5
University of Florida	8
University of Kansas	4
University of Michigan	3
University of Nebraska	4
University of Pennsylvania	7
Wake Forest University	4



of Neurology at NorthShore has invested heavily and built, into Epic, tools that meet AAN guidelines, standardize care, write progress notes and capture up to 1,000 discrete data points per office visit. These EMR toolkits have so far been applied to 10 common neurological disorders plus brain health (11 toolkits total).

NPBRN Sites

NorthShore has been successful in obtaining federal support for the NPBRN in the form of a \$1.2 million multiyear award from the Agency for Healthcare Research and Quality (AHRQ). The AHRQ award, titled “Quality Improvement and Practice-Based Research in Neurology Using the EMR,” has two specific aims. The first is to establish the NPBRN at multiple sites by sharing our proprietary EMR tools for 10 common neurological disorders plus brain health (11 toolkits total) with other neurology practices nationwide that also use the Epic EMR system. Sharing EMR tools in this way will not only foster collaboration, but increase the amount of data the project will be able to generate.

In response to the initial call to participate in the NPBRN, seven institutions in addition to NorthShore agreed to join in 2015, and the list currently stands at 13 sites total. The NPBRN is led by Demetrius Maraganore, MD, at the University of Florida, and Steven Meyers, MD, is the principal investigator at the NorthShore site. The table to the left shows the current status of NPBRN sites as of January 1, 2019.

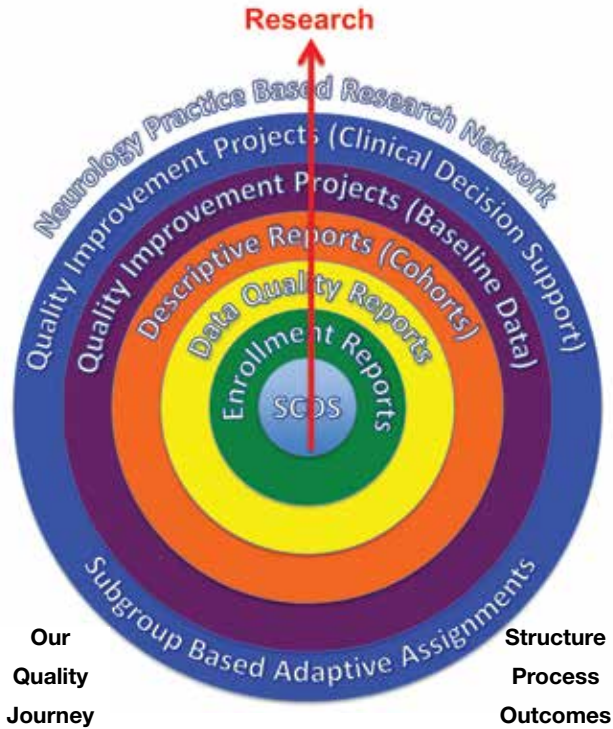


Dr. Steven Meyers, Vice Chair of Quality and Informatics in the Department of Neurology, is site principal investigator of the grant.

Our Quality Journey

The Department of Neurology at NorthShore includes 40 neurologists practicing at four hospitals and multiple outpatient sites in the north suburbs of Chicago.

Below is a graphic and step-by-step description of the establishment of the NPBRN for 11 projects: brain tumors, epilepsy, migraine, memory disorders, mild traumatic brain injury, multiple sclerosis, neuromuscular disorders, Parkinson’s disease, restless legs syndrome, stroke and brain health.



- Step 1:** Development and implementation of structured clinical documentation support (SCDS)–EMR–tools
- Step 2:** Enrollment reports of subjects encountered (up to 1,000 fields of data captured per office visit)
- Step 3:** Data quality reports to identify missing data
- Step 4:** Descriptive reports of group characteristics such as patient reported and physician assessment measure
- Step 5:** Quality improvement projects (baseline data)
- Step 6:** Quality improvement projects (using clinical decision support tools built into the EMR to hardwire patient safety and improved outcomes)
- Step 7:** Dissemination of tools and sharing of data via the NPBRN

Comparative Effectiveness Research

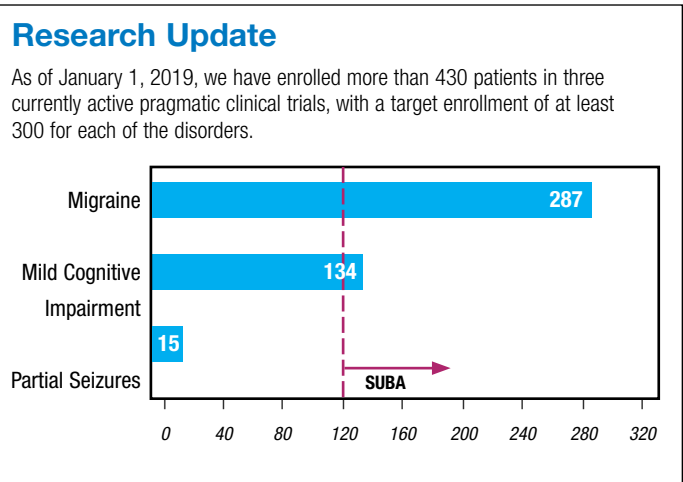
The second aim of the AHRQ award is that we will be able to perform, for the first time, pragmatic clinical trials using the EMR in neurology to compare the effectiveness of several available therapies. These trials will be conducted using a subgroup-based adaptive (SUBA) design, an innovative way to inform healthcare decisions using precision medicine and provide evidence on the effectiveness, benefits and drawbacks of different treatment options. The plan is to perform 11 SUBA trials—one for each NPBRN project—with a total of 3,300+ patients.

For each trial, we are randomly assigning the first 120 patients to one of the currently available medications. We have integrated the SUBA design within the EMR software so that data captured from these first 120 patients will identify subgroup effects and assign 200+ newly enrolled patients—in real time—to the treatments that are expected to be more effective and achieve the best outcomes.

In July 2016, we launched the first of these trials—in migraine—where we are comparing the effectiveness of three preventive medications for migraine headaches. In December 2016, we launched a second pragmatic trial comparing three memory-enhancing drugs in patients with mild cognitive impairment. The third pragmatic trial was launched in July 2017 and compares three anti-epileptic drugs at the point of care in patients with partial seizures. Current enrollment status of these trials is shown below.

To increase the “learning” of the computerized system, we will continually capture outcomes data at initial and annual visits over five years whereas most clinical trials follow patients only up to a year.

Additionally, we will enroll eligible patients to provide a DNA sample and will assay the samples for up to 1 million genetic variations. We will then associate the genotypes with the longitudinal outcomes captured by the EMR tools (see The DodoNA Project on pages 17–19).



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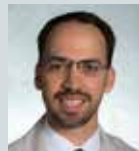
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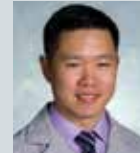
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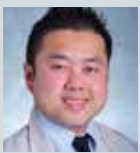
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