



Carolinas HealthCare System

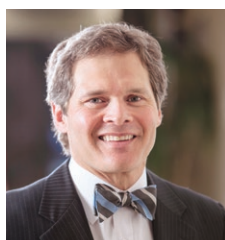
The Neuro Report

Spring 2014

Research Update

TRACKING QUALITY AND DEFINING APPROPRIATENESS OF CARE

Reaching the right patient with the right treatment at the right time takes on special meaning in the quality-based research underway at Carolinas HealthCare System Neurosciences Institute.



Anthony L. Asher, MD, FACS, Neurosurgeon and Co-Medical Director, Carolinas HealthCare System Neurosciences Institute

“Clinical science asks very specific questions about the efficacy of various therapeutic maneuvers in controlled settings,” said Anthony L. Asher, MD, co-medical director of Carolinas Healthcare System Neurosciences Institute, who has long been involved in clinical research and efforts to support quality science. “The problem is we’ve been left with a lot of medical science that cannot be generalized. It

cannot be applied to individual patients or to care in the real world. We need different scientific tools that

yield information about what individual patients will experience in different care settings.”

REDEFINING PATIENT-CENTERED HEALTHCARE

A registry is one such tool, defined in recent medical literature as a “disruptive technology,” because registries will be utilized to redefine care based on patient level data. Dr. Asher, who also serves as director of the National Neurosurgery Quality and Outcomes Database, is leading organized neurosurgery on a national level to develop a registry to coordinate the technology-driven acquisition, analysis and reporting of clinical data from neurosurgery practices.

“This is one of the most comprehensive surgical registries yet devised. It will be a real game changer,” said Dr. Asher. “We’re looking at the longitudinal outcomes of care – the durability of treatment responses. And for the first time we’re heavily relying on patient-reported outcomes, not just outcomes from the perspective of clinicians. This is absolutely what we need to do to build a patient-centered healthcare system and differentiable Neurosciences Institute.”

CONTINUED ON PAGE 2

Transforming to Meet a Changing Healthcare Climate

A Leader in the Field of Multiple Sclerosis

Neurology Clinical Updates Symposium

A National Leader in Spine Surgery

LEVERAGING THE STRENGTH OF THE SYSTEM

By leveraging the National Neurosurgery Quality and Outcomes registry, Dr. Asher sees the registry as a springboard for expanding the healthcare System's involvement in the national quality effort, building a center for scientific innovation and developing novel healthcare services.

"We've been able to coordinate several excellent resources," said Dr. Asher. "Carolinas HealthCare System's size, the sophistication of our informatics systems and clinical services, the expertise of our staff and our geographic reach position us to be leaders in this effort, both regionally and nationally,"

BENCHMARKING CARE IMPROVES PATIENT OUTCOMES

The effort to improve outcomes in neurosurgery and related specialties will define the appropriateness of care on an individualized level in a way that wasn't previously possible.

CONNECT WITH OUR RESEARCH

For more information about the National Neurosurgery Quality and Outcomes Database, visit CarolinasHealthCare.org/NeuroReport2.

"We are building the ability to tell patients their individualized risk, not based on some national average but based on matched individuals who have similar characteristics and similar previous experiences," said Dr. Asher. "We'll be able to tell patients their chance of success with any therapeutic intervention based on their own past medical history and demographic features. In this way, we can put the power back into the patient's hands to create a truly patient-centered method for determining the best types of care. I know we'll come up with something unique and impactful in healthcare, the marketplace and the clinical realm."



WE'LL BE ABLE TO TELL PATIENTS THEIR CHANCE OF SUCCESS WITH ANY THERAPEUTIC INTERVENTION BASED ON THEIR OWN PAST MEDICAL HISTORY AND DEMOGRAPHIC FEATURES. IN THIS WAY, WE CAN PUT THE POWER BACK INTO PATIENTS' HANDS TO CREATE A TRULY PATIENT-CENTERED METHOD FOR DETERMINING THE BEST TYPES OF CARE. I KNOW WE'LL COME UP WITH SOMETHING UNIQUE AND IMPACTFUL IN HEALTHCARE, THE MARKETPLACE AND THE CLINICAL REALM.

– Anthony L. Asher, MD, FACS



Transforming to Meet a Changing Healthcare Climate

CMC-NEUROLOGY AND NORTHEAST NEUROLOGY MERGE

The merger of CMC-Neurology and NorthEast Neurology, the two largest neurology groups within Carolinas HealthCare System, is a positive, proactive response to the rapidly changing national healthcare environment.

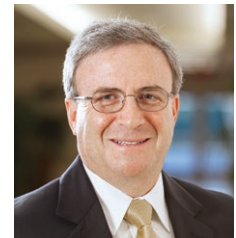
CREATING AN EFFICIENT, EFFECTIVE ENTITY

“As we looked at how healthcare is changing – moving toward an outcomes-based methodology and a value-based world, as opposed to a volume-based world – we saw challenges that might occur if we continued to have physician groups operating within their own silos,” said Sanjay Iyer, MD, co-medical director of Carolinas HealthCare System Neurosciences Institute. “Our collective expertise, ability and scope to transform patient care is going to be paramount in bringing these groups together. We have to continue to work together.”

Together, the two neurology groups include more than 40 providers, 7 outpatient locations and 5 hospitals around the Metro area reaching approximately 20,000 inpatient visits per year and almost 80,000 outpatient visits per year. Specialists across both groups complement each other within all major conditions, including Epilepsy, Parkinson’s disease, Neuromuscular and Stroke. “We saw clear synergies and recognized that we can be better together,” said Robert Mitchell, MD, associate medical director of Carolinas HealthCare System Neurosciences Institute.



Sanjay Iyer, MD
Co-medical director of
Carolinas HealthCare System
Neurosciences Institute



Robert Mitchell, MD
Associate Medical Director,
Carolinas HealthCare System
Neurosciences Institute



**WE SAW CLEAR SYNERGIES AND
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– Robert Mitchell, MD



RESOURCE SHARING BENEFITS PATIENTS

The merger enables sharing of resources and opportunities that will significantly benefit patients. Instead of each group taking care of patients in their respective geographies and developing their own methodologies, the drive is to understand how to take care of patients in a more coordinated effort throughout the entire geographic area.

As healthcare and reimbursement models evolve and new care pathways are developed, the merger represents the best opportunity to improve access to care, control costs and deliver the high-quality care that distinguishes neurological services within Carolinas HealthCare System.

INFORMATION FOR REFERRING PHYSICIANS

Visit CarolinasHealthCare.org/neuroscience if you would like more information about referring patients to the programs and services available at Carolinas HealthCare System Neurosciences Institute.



A Leader in the Field of Multiple Sclerosis

HONORING MICHAEL D. KAUFMAN, MD

In December 2013, Michael D. Kaufman, MD, retired after a long and distinguished career serving as clinical assistant professor of medicine and director of the Multiple Sclerosis Center at Carolinas Medical Center in Charlotte, NC. As one of the leading clinicians in the field of multiple sclerosis (MS), Dr. Kaufman’s list of accomplishments is extensive. He is a nationally recognized clinical researcher, a fellow of the American Academy of Neurology, an inductee in the National Multiple Sclerosis Society Hall of Fame and former president of the Consortium of MS Centers and Chairman of the Integrative Panel of the Congressionally Directed MS Research Program. Just as important, he is also recognized by his patients for his clinical expertise, personalized care and compassion in treating Multiple Sclerosis.

RESEARCH LEADS TO DRUG DEVELOPMENT

The field of MS treatment and research was a perfect fit from the start for Dr. Kaufman, who has devoted his career to exploring this chronic, disabling autoimmune disease of the central nervous system.

“I had an interest in neuromuscular disease when I left training in 1976, and began using chemotherapy agents,” said Dr. Kaufman. “In the late 1980s, chemotherapy was used to treat MS. In our practice, I was the one who understood the use of these agents to treat neurological conditions.” Dr. Kaufman quickly

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developed a practice that included 400 MS patients, enough to run research studies.

“That was the most fun, being right on the ground floor of developing a drug,” he said, describing the practice’s early and ongoing participation in clinical trials. The drug, monoclonal antibody natalizumab (Tysabri), was approved for the treatment of patients with relapsing forms of MS, to reduce the frequency of clinical exacerbations. Dr. Kaufman cites his involvement in these studies as one of the highlights of his career.

A CHAMPION FOR PATIENTS WITH MS

“Dr. Kaufman has been a leader in the field of neurology for 30 years,” said Sanjay Iyer, MD, co-medical director of Carolinas HealthCare System Neurosciences Institute. “He has an uncanny ability to listen intently to patients and address all of their needs.”

As he reaches the end of his career, many long-time patients are reaching out to thank Dr. Kaufman. “The relationships I’ve built with patients mark another highlight of my career. I just saw a woman who has been my patient for 30 years. It has been a privilege to know her.”

Dr. Kaufman will remain active on advisory boards for clinical investigations in MS. Within five years, he anticipates advances in the development of monoclonal antibodies and stem cells to treat the disease. From his highly informed perspective, for patients who are in the early stages and are not averse to risk, Dr. Kaufman optimistically foresees therapies on the horizon that will render MS less a disabling disease than a nuisance.



DR. KAUFMAN HAS BEEN A LEADER IN THE FIELD OF NEUROLOGY FOR 30 YEARS.

– Sanjay Iyer, MD



Clinical Trials Underway for Intracerebral Hemorrhage, Alzheimer's Disease

Two innovative Phase III clinical trials are in the initial stages of recruitment at Carolinas HealthCare System Neurosciences Institute.

MINIMALLY INVASIVE INTERVENTION FOR INTRACEREBRAL HEMORRHAGE

CMC has some of the highest volumes of ICH (intracerebral hemorrhage) patients in the Carolinas. Typical treatment for non-operative ICH is medical management. The MISTIE III trial may lead to an alternative minimally invasive surgical intervention option for ICH patients.

The MISTIE III trial (Minimally Invasive Surgery Plus rt-PA for ICH Evacuation Phase III) will include 500 subjects ages 18 to 80 in a randomized, controlled study of ICH patients who have a clot size of 30 mL or greater. Carolinas HealthCare System Neurosciences Institute will follow up to 10 patients who come into the emergency department, are admitted to the hospital and enroll in the year-long study. The trial will run from December 2013 through September 2018.

"Patients will be randomized to medical management alone or to the study protocol, which involves minimally invasive surgical intervention with a catheter inserted into the clot site and intravenous administration of nine doses of tissue plasminogen activator rt-PA injected every eight hours into the clot to break it up and drain it," said Megan Kramer, a clinical research nurse at the Neurosciences Institute.

The Study is a partnership between neurology and neurosurgery. Jason Todd, MD, neurology, with Anthony L. Asher, MD, and Joseph David Bernard, MD, neurosurgery will be lead investigators. Outcomes will be measured using the modified Rankin Scale and other neurological testing. "We hope to improve patient outcomes and decrease the length of hospital stays," Kramer said.

IMMUNIZATION FOR PATIENTS WITH ALZHEIMER'S DISEASE

The EXPEDITION 3 study (Progress of Mild Alzheimer's Disease in Participants on Solanezumab Versus Placebo) for Alzheimer's dementia will investigate passive immunization

with a monoclonal antibody that is first in its class to move to a Phase III trial.

"We've been trying to address this disorder for 20 years and so far only three indications have been approved, with modest therapeutic effect," said Oleg Tcheremissine, MD, psychiatrist and lead investigator at the Neurosciences Institute.

The System will enroll up to 10 of the 2,100 patients for the trial, which runs from June 2013 through December 2016. Otherwise healthy patients ages 55 to 90 must have a diagnosis of Alzheimer's disease confirmed by MRI or CT scan, amyloid pathology confirmed by PET scan or cerebrospinal fluid, scores of 20 to 26 on the Mini-Mental State Examination and less than six on the Geriatric Depression Scale. Most will already be on a stable dose of donepezil and/or memantine and will be randomized to continue standard treatment plus intravenous placebo or solanezumab every four weeks for 18 months.

Outcomes will be measured using the Alzheimer's Disease Assessment Scale-Cognitive 14 item subscore and the Alzheimer's Disease Cooperative Study-Instrumental Activities of Daily Living score.

"Aiming at a cure for Alzheimer's disease is an honorable goal, but in my view the steps to defeating it will be incremental," said Dr. Tcheremissine. "The hope of this study is to move the progression of this disorder to another decade of life."

"This trial provides another treatment option for patients and their families who battle Alzheimer's disease. It also exemplifies the increasing cross-specialty collaboration among our providers," said Robert Mitchell, MD, associate medical director, Carolinas HealthCare System Neurosciences Institute.

IS YOUR PATIENT A CANDIDATE?

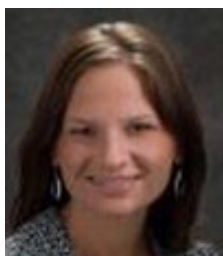
For more information about these and other clinical trials at Carolinas HealthCare System Neurosciences Institute, visit CarolinasHealthCare.org/NeuroReport2 or call 704-512-5603.

Neurology Clinical Updates Symposium

REACHING OUT TO PRIMARY CARE PHYSICIANS



Christopher Connelly, MD, Neurologist
Carolinas HealthCare System Neurosciences Institute



Danielle Englert, MD, Neurologist
Carolinas HealthCare System Neurosciences Institute



Sanjay Iyer, MD
Co-Medical Director
Carolinas HealthCare System Neurosciences Institute

A faculty of neurologists from CMC-Neurology, NE Neurology and Carolina Neurological Clinic delivered lectures covering topics that included new onset seizures, headache management, Alzheimer's disease and dementia,

Since the inception of Carolinas HealthCare System Neurosciences Institute a year ago, its leadership, comprised of Co-Medical Directors Anthony L. Asher, MD, Sanjay Iyer, MD, and Associate Medical Director Robert Mitchell, MD, have been examining and organizing the assets within the service line. Reaching out to key stakeholders, such as primary care physicians, was an important step in understanding how neurosciences can support the medical community. The goal was to determine their needs and increase opportunities for interaction.

"With the guidance of Carmen Teague, MD, director of internal medicine for Carolinas HealthCare System, we were able to construct a curriculum of the eight to 10 topics her physicians face on a daily basis," said Dr. Iyer. That curriculum evolved into the Neurology Clinical Updates Symposium, which was presented September 14, 2013, with 50 primary care providers in attendance.

The symposium was co-chaired by Christopher Connelly, MD, and Danielle Englert, MD, neurologists with the Neurosciences Institute.



WE PLAN TO HOST THIS EVENT ON A YEARLY BASIS.

– Sanjay Iyer, MD



movement disorders, peripheral neuropathy, insomnia, vertigo, stroke and multiple sclerosis. The symposium also included and facilitated a panel discussion with a Q-and-A session to offer a forum for attendees to ask presenters about clinical cases they have encountered in their own practices.

A lecture by Dr. Connelly about a patient who presented with various types of vertigo, exemplifies how presenters tailored their material to be of most benefit to the audience of primary care providers. "I provided an outline of approaches – what you look for in the history and exam," said Dr. Connelly. In particular, he addressed benign paroxysmal positional vertigo, a condition that's not serious but affects a patient's quality of life. "Treatment is a series of exercises primary care physicians can instruct patients on that are curative for the condition. There's no need to incur the cost of an MRI of the brain or a visit to an ENT."

"The symposium was our first attempt at offering primary care a forum to learn about best practice patient care management strategies for neurological conditions they see in their practices. We wanted to provide valuable information and be a resource to primary care practitioners that would ultimately help them in their environment."

RESOURCES FOR REFERRING PHYSICIANS

For more information about the symposium, visit CarolinasHealthCare.org/NeuroReport2. To refer a patient, call 704-512-5603.

A National Leader in Spine Surgery

Carolinas HealthCare System Neurosciences Institute is widely recognized for its comprehensive capabilities and diverse expertise in diagnosing and treating adult spinal disorders. The highly regarded staff is actively involved in the development and use of the most advanced techniques available. Both open and minimally invasive surgical approaches are used to treat and repair a variety of conditions, including cervical and lumbar disc herniation, spinal cord compression, spinal instability, spinal tumors, scoliosis, trauma and infection.

OFFERING LEADING-EDGE PROCEDURES

"I don't think there's any type of patient or case our group can't handle in terms of spine surgery care," said Kevin Cahill, MD, a neurosurgeon specializing in advanced surgical procedures for adults with spinal deformities or prior spinal fusions, adult scoliosis, complex tumors and complex spine trauma.

The expertise of the team extends to patients with certain malignant spinal tumors. These tumors can be addressed by en bloc resections to remove the entire tumor along with healthy tissue, which optimizes survival.

Another complex procedure employed by the team uses a relatively new, FDA-approved artificial disc replacement as an alternative to spinal fusion. "In fusion, the good news is that by restricting movement you've eliminated the disc as a potential pain source," said Domagoj Coric, MD, Medical Director chief of neurosurgery. "The bad news is the disc is supposed to move, but after fusion you've lost function at that level and put stress on the levels above and below it, which can lead to more problems. The artificial disc maintains motion and doesn't put stress on adjacent levels."

RESEARCH LEADS TO INNOVATIVE CARE

Our team of neurosurgeons are also involved in advancing the science in spine care. Many of the physicians are actively involved in clinical trials, including investigational trials for disc repair in which cartilage or stem cells are injected directly into the affected disc. Outcomes are important, so, in addition to tracking them in our clinical trials, the group tracks routine procedures to assess the

most effective treatments. "Value is a buzzword in healthcare. Value is a combination of quality plus effectiveness plus cost savings," Dr. Coric said. "We don't want cost savings at the expense of patient care, we want to maintain outcomes. So whatever we're doing to improve the efficiency and cost of healthcare we don't want to be at the expense of patients doing well. Furthermore, we look at the efficacy of what we're doing. If we have certain treatments that are more effective than others, we want to identify those. The only way to identify them is to measure outcomes in your everyday surgeries. As we're getting new procedures to do, whether they're less invasive, motion preserving or repair types of procedures, we want to make sure we have efficacy. In this way, value becomes not only less cost but less cost with equal or better outcomes."

Neurosurgeon John Ziewacz, MD, recently joined the team after completing a fellowship in complex and minimally invasive spine surgery, which is well-suited for conditions such as herniated lumbar discs, cervical foraminal stenosis and scoliosis repairs. "Expanding the range into larger scoliosis repairs in adults and finding the best way forward with minimally invasive approaches are my areas of interest," he said.

"Because we conduct research and have members on the American Board of Neurological Surgery, we have access to the latest techniques and literature," said Dr. Ziewacz. "Our size is advantageous. We can use input from several physicians to come to the best collective opinions. Although a patient sees one surgeon, he or she benefits from multiple expert opinions based on the collective knowledge and experience of neurosurgeons located across the system at CMC's main campus, CMC-Pineville, and CMC NorthEast."

EXPERT SPINE CARE

For more information about spine services and clinical research at Carolinas HealthCare System Neurosciences Institute, visit CarolinasHealthCare.org/NeuroReport2.



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Neurosciences Physician Participates in Michael J. Fox Foundation for Parkinson's Research Forum



Sanjay Iyer, MD
Co-Medical Director
Carolinas HealthCare
System Neurosciences
Institute

Sanjay S. Iyer, MD, director of Carolinas Center for Parkinson's disease and Movement Disorders and co-medical director of Carolinas HealthCare

help find a cure. The Charlotte Research Roundtable was held on Jan. 23. Dave Iverson, contributing editor for MJFF, led a panel discussion on "Improving Symptomatic Treatments, Developing Disease-Modifying Therapies and the Role of Biomarkers in Research." Dr. Iyer was joined by Mark Stacey, MD, professor of neurology and vice dean of clinical research at Duke University; Deborah W. Brooks, co-founder and executive vice chairman of MJFF; and Mark Frasier, PhD, vice president of research programs, also with MJFF.

This test is an easy tool that patients and their caregivers can perform on their own and consists of a sequence of sit-to-stand, walking, turning and stand-to-sit tasks. Dr. Iyer said each of these is eventually affected by Parkinson's, especially when performed as a sequence.

System's Neurosciences Institute, participated in a research roundtable for Parkinson's disease hosted by The Michael J. Fox Foundation for Parkinson's Research (MJFF).

Each year, MJFF hosts several Research Roundtables across the United States at no cost to attendees. These educational forums, comprised of expert panelists such as Dr. Iyer, cover topics that matter most to patients and their loved ones – the latest developments in Parkinson's research and what they can do to

Dr. Iyer used his time at the roundtable to discuss treatments and measuring progression of the disease. "To help our patients keep track and to help us determine if they are trending in a negative direction, we've started using predictive analytics to measure a patient's status," he said.

Dr. Iyer and his team are planning to start a pilot program with a test called "Timed Up and Go," used to assess balance and mobility in Parkinson's.

Dr. Iyer wants his patients to routinely perform this test and record their results, which he can then analyze, to determine if the patient may need additional assistance or help. "Over time, we think this is will be a good predictor of when there could be a bad outcome and we can do an intervention to help prevent that from happening," he said.

"Since the audience is mainly composed of patients and their caregivers, this was a perfect opportunity to educate them about what is novel in Parkinson's disease, including what the latest treatments are, how far we've come in terms of research and how close we are to finding a cure," said Dr. Iyer.