

HENRY FORD

SYNAPSE

Neurosurgery

Fall 2016



A Look Inside

- Letter from the Chair
- Epilepsy Symposium
- Skull Base Program
- Cancer Moonshot Initiative
- Neurosurgical Technology
- Clinical Trials

LETTER FROM THE CHAIR



Dear Colleagues and Friends,

The Henry Ford Department of Neurosurgery has a long history of an unrelenting pursuit of innovation and academic discovery. The latest issue of Synapse underscores the many ways that our dedicated team is achieving this vision.

Leadership and Collaboration

The Henry Ford Hospital Stroke and Neurovascular Center was recently awarded certification as a Comprehensive Stroke Center from The Joint Commission -- one of a select few institutions to receive this prestigious designation. This spring we also held our epilepsy symposium, where our faculty worked with other renowned experts to share the latest innovations in epilepsy treatments. In addition, Henry Ford is collaborating on broader projects that will have global impact - including our leadership role in the GBM-AGILE initiative - which seeks to use the latest techniques, such as crowd-sourcing informatics, to pool resources in the fight against glioblastoma.

Committed to Safer Surgery

As a national leader in the use of technologies that make surgery safer, we have helped pioneer the use of intraoperative MRI and neuro-navigation systems over the last two decades. Recently, we added to this heritage with the introduction of the new BrightMatter functional imaging platform from Synaptive and also a new intraoperative mobile CT scanner. We were the first in Michigan to offer the new BrightMatter imaging, navigation and robotic optical

platform, a groundbreaking system that is transforming neurosurgery as we know it. Ultimately, all of these technologies help to make surgery safer while ensuring better outcomes for our patients.

Advancing Skull Base Care

Some of these technologies are also used in our innovative Skull Base, Pituitary and Endoscopy Center, a multidisciplinary program that receives referrals from throughout the Midwest. Through this program, we diagnose and treat all skull base and intracranial conditions, offering the latest techniques in tumor embolization, stereotactic radiation therapy and surgery.

A Focus on Spine Surgery

At the first quarterly meeting of the Michigan Spine Surgery Improvement Collaborative (MSSIC), we took another huge step toward our goal of improving spine care by targeting three key quality improvement focus areas for the coming year. More than 20,000 cases have been entered into the collaborative registry so far.

I could not be more proud of what our team has done to push the boundaries of what is possible in neurosurgical care, and I look forward to all of the ways we will continue to provide our patients with hope in the future.

STEVEN N. KALKANIS, M.D.

Professor and Chair, Department of Neurosurgery and Co-Director, Neuroscience Institute; Mark Rosenblum Endowed Chair in Neurosurgery, Henry Ford Health System

WHY GO TO A COMPREHENSIVE STROKE CENTER?

Henry Ford Hospital Stroke and Neurovascular Center was awarded certification as a Comprehensive Stroke Center from The Joint Commission. We are one of a select few institutions to become certified as a comprehensive stroke center, one of five in Michigan, and the only hospital in Wayne County. This new level of certification recognizes the significant resources in staff and training that Comprehensive Stroke Centers must have to treat complex stroke cases.

Joint Commission-certified Comprehensive Stroke Centers are required to have:

- Advanced resources for the acute treatment of stroke patients available 24 hours a day, 7 days a week

- A dedicated neurocritical care unit
- A high volume of stroke cases
- Certified vascular neurologists, neurosurgeons, neuroradiologists and vascular surgeons
- Advanced practice nurses
- Advanced neurodiagnostic tools
- A system that optimizes the benefits of carotid artery procedures
- Participation in stroke research

In addition to this prestigious designation, the Henry Ford Hospital Stroke and Neurovascular Center is a recipient of the following awards from the American Heart Association/American Stroke Association for its commitment to and success in



The Joint Commission



American Heart Association
American Stroke Association

CERTIFICATION

Meets standards for

Comprehensive Stroke Center

implementing excellent care for stroke patients:

- Get With The Guidelines Gold Plus Quality Achievement Award
- Get With The Guidelines Target: Stroke Honor Roll Award

EPILEPSY SYMPOSIUM

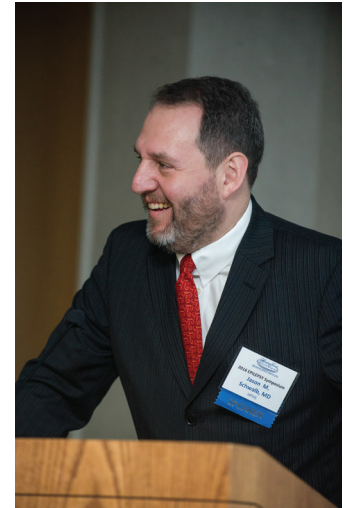
TO REFER A PATIENT, GO TO
henryford.com/neuro or call (313) 916-1340

Epilepsy is the fourth most common neurological disorder in the United States, affecting an estimated 2.2 million Americans. The Comprehensive Epilepsy Center at Henry Ford provides one of the nation's leading medical teams focused on the diagnosis, treatment, and research of epilepsy and seizure disorders. Henry Ford epileptologists and neurosurgeons offer novel therapies to help patients achieve a seizure-free life.

In May, Henry Ford hosted **EVALUATION OF EPILEPSY AND MODERN MANAGEMENT**. The symposium, held at Henry Ford Hospital, featured nationally recognized epilepsy experts, including Aatif Husain, M.D., and Gregory Holmes, M.D. These speakers joined the distinguished Henry Ford faculty to present on several areas of epilepsy treatment and trends, including pediatric epilepsy, neuroimaging, treatment for special populations, hospital seizures and status epilepticus, drug-resistant epilepsy and epilepsy surgery.



MARIANNA SPANAKI-VARELAS, M.D., PH.D.



JASON SCHWALB, M.D.



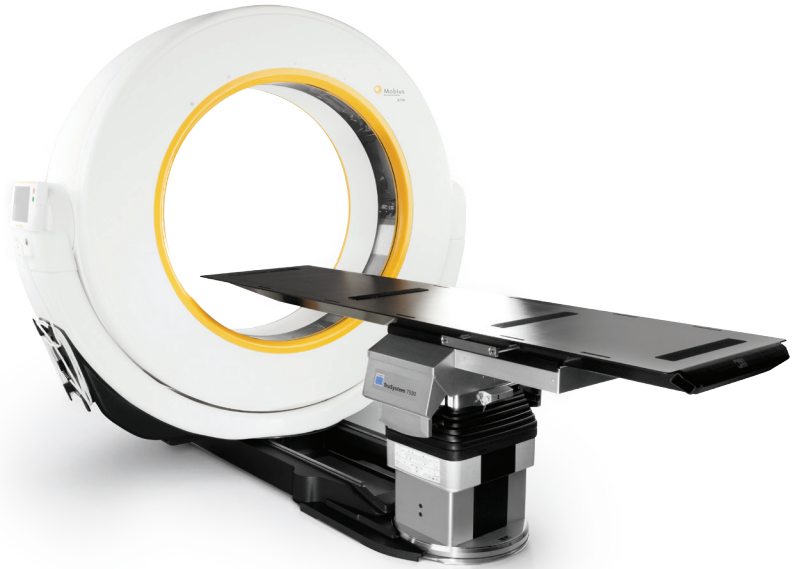
ANDREW ZILLGITT, M.D., ADDRESSES THE SYMPOSIUM CROWD.

AIRO[®] iCT: REAL-TIME PATIENT IMAGES DURING SURGERY

Intraoperative CT Offers the Latest Imaging Technology for Safer Surgery

Our new Airo[®] iCT technology has the potential to change daily life in the surgical space, expanding the use of CT technology for both diagnostic imaging and intraoperative use. The new portable, 32-slice scanner aids in decision-making in the operating room – without the need to wait for postoperative images to verify results. It also offers unprecedented mobility and access, including significant flexibility in patient positioning.

Ultimately, this technology may help to reduce re-operation rates and decrease overall costs, and can help to reduce trauma to patients. In addition, procedures conducted with iCT typically feature less recovery time and shorter hospital stays. Along with our investments in iMRI and minimally invasive brain surgery, this technology assists our team in providing exceptional patient outcomes.



MSSIC UPDATE



The Michigan Spine Surgery Improvement Collaborative (MSSIC) is an initiative that aims to improve spine surgery for patients in Michigan by reviewing patient outcomes and using this data to update treatment protocols. Henry Ford Health System is the Coordinating Center for MSSIC.

Work with MSSIC has continued in earnest, with a new year bringing new members. MSSIC has recently welcomed the five new hospitals joining the collaborative as part of Wave 3. Currently there are 27 hospitals participating in MSSIC, representing nearly all of the major spine surgery programs in Michigan. The collaborative currently includes 158 orthopaedic surgeons and neurosurgeons, 55 data abstractors and 27 quality administrative leads.

Registry Update

Data collection for the project registry is underway at 23 of the 27 sites, with more than 20,000 surgery cases entered into the

registry since live data collection began in the spring of 2014. The data being collected includes details about surgical procedures, surgical outcomes (including patient self-reported outcomes) and complications.

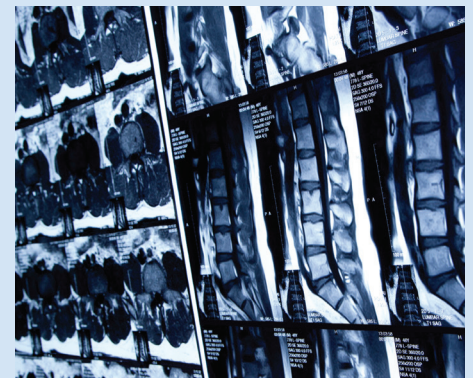
MSSIC Promotion

An article describing MSSIC was published in the December 2015 issue of *Neurosurgical Focus: Defining, Measuring, and Predicting Quality in Neurosurgery* (tinyurl.com/mssicnf15). This issue also featured other national spine surgery initiatives, including the National Neurosurgery Quality and Outcomes Database (N2QOD) as well as the National Surgery Quality Improvement Program (NSQIP).

In March, information about MSSIC was presented at the 2016 Annual Meeting of the AANS/CNS Joint Section on Disorders of Spine and Peripheral Nerve in Orlando, Florida. It was also presented at the Minimally Invasive Neurosurgical Society on Mackinac Island in August.

Key Quality Improvement (QI) Focus Areas

In addition, MSSIC recently completed its first quarterly meeting of 2016. Among the topics discussed were goals for statewide



quality improvement. MSSIC has targeted three key outcomes of QI focus for the coming year:

- 90-day hospital readmissions
- Surgical site infections (SSI)
- Urinary retention (UR)

As part of the initial analysis, the Coordinating Center identified risk factors predisposing to each adverse event, and is in the process of creating a risk adjustment model to standardize comparisons among hospitals. Once established, this will allow MSSIC to identify high-performing centers from which to identify “best practices” that can be implemented across the collaborative.



EXPERT, MULTIDISCIPLINARY CARE FOR SKULL BASE AND RELATED CONDITIONS



JACK ROCK, M.D.



JOHN CRAIG, M.D.

The Henry Ford Skull Base, Pituitary and Endoscopy Center treats all types of skull base and intracranial conditions. Led by co-directors Jack Rock, M.D. (Neurosurgery) and John Craig, M.D. (Otolaryngology – Head and Neck Surgery), the center offers your patients a guaranteed appointment with a neurosurgeon or otolaryngologist within 24 business hours.

A Comprehensive Approach

In addition to experts from Neurosurgery and Otolaryngology, the team features Henry Ford Medical Group experts from other specialties, including ophthalmology, endocrinology, plastics, medical oncology, radiation oncology and interventional neuroradiology.

“Each new tumor case is reviewed by our multidisciplinary Skull Base Tumor Board to determine the best treatment options for the patient,” Dr. Rock says. “Depending on the case, this may include tumor embolization, stereotactic radiation therapy or surgery.”

Henry Ford also offers the latest diagnostic imaging and other techniques, including:

- 3-D MR spectroscopy
- 3-D neuroimaging
- High-field 3-T MRI
- Speech language evaluations
- Carotid angiography
- CT, MR and nuclear cisternography

Advanced Skull Base Surgery

When surgery is recommended, surgeons from various departments may participate in the procedure to ensure the best possible outcome. In addition, the Henry Ford team:

- Utilizes the most advanced minimally invasive endoscopic approaches
- Offers special expertise in skull base reconstruction – improving functional and cosmetic outcomes and reducing the risk of CSF leaks and infection
- Features highly skilled interventional neuroradiologists who may perform preoperative carotid and vertebral artery occlusion tests, and tumor embolization

Skull Base Tumor Research

The Henry Ford team also participates in a number of research protocols for meningioma and other skull base tumors as well as laboratory work that focuses on surgical techniques and strategies.

CONDITIONS TREATED

- Acoustic neuroma (vestibular schwannoma)
- Adenoma
- Cerebrospinal fluid leak
- Chondroma
- Chondrosarcoma
- Chordoma
- Craniopharyngioma
- Encephaloceles
- Fibrous dysplasia
- Giant cell tumor
- Hemangiopericytoma
- Meningioma
- Metastatic brain tumors
- Nasopharyngeal angiofibroma
- Neurofibroma
- Olfactory neuroblastoma (esthesioneuroblastoma)
- Osteoma
- Paranasal sinus cancer
- Petrous apex lesions
- Rathke’s cleft cyst
- Rhabdomyosarcoma

HENRY FORD SELECTED AS LEADING GBM-AGILE SITE

The GBM-AGILE (Glioblastoma Multiforme-Adaptive Global Innovative Learning Environment) program is a new global initiative that combines several elements to fight glioblastomas, including a new mechanism for new drug development and a new way of doing clinical trials, advanced precision medicine genetic testing, crowd-sourcing informatics and telecommunications. It is part of President Obama's new National Cancer Moonshot Initiative led by Vice President Joe Biden, whose son recently died from a GBM.

GBM-AGILE is led by Dr. Anna Barker, Executive Committee Chair for GBM-AGILE and ex Deputy Director of the National Cancer Institute and now Director, National Biomarker Development Alliance; Executive Committee Chair, GBM-AGILE Trial; Co-Director, Complex Adaptive Systems; and Professor, School of Life Sciences, Arizona State University. In this new program:

- Any new patient or recurrent patient with a glioblastoma will undergo specific biomarker and genetic testing.
- All clinical information will then be entered into a global informatics platform.
- In a process called "adaptive randomization," patients with similar gene deletions and clinical scenarios from around the world will be assigned to one of multiple study arms. The idea will be to remove those treatments not meeting the standard and rapidly promoting those which do better.
- The poorest survival groups (unmethylated GBMs) may even bypass the standard temozolomide arms so that these patients can have earlier access to newer and second-line treatments.

Henry Ford was chosen as one of only six institutions to serve on the executive team of leading sites for this global initiative. The other leading institutions include MD Anderson, Memorial Sloan Kettering, Dana Farber - Harvard, University of California - Los Angeles and the University of Utah. In addition, these sites will work together to further expand into Europe, Australia and China to have a truly worldwide effort and impact.



STEVEN N. KALKANIS, M.D., AND JONATHAN HIRSCH, FOUNDER AND PRESIDENT OF SYAPSE



BRIGHTMATTER PLATFORM: A GAME

"This is the future of not only neurosurgery, but what technology can do for medicine. The level of detail allows us to think of surgery and visualize the brain in an entirely new way." – Steven N. Kalkanis, M.D., Chairman of Neurosurgery at Henry Ford Hospital and Co-director of the Hermelin Brain Tumor Center

Building on a heritage of innovation in neurosurgery, the Hermelin Brain Tumor Center at Henry Ford Hospital is the first in Michigan – and one of the first in the United States – to offer BrightMatter™ Surgical Solutions technology. This state-of-the-art imaging, navigation and robotic optical platform can transform surgeries previously deemed inoperable to operable with great outcomes. BrightMatter surgeries also can be performed through smaller incisions.

BrightMatter can be used to treat a variety of conditions, including:

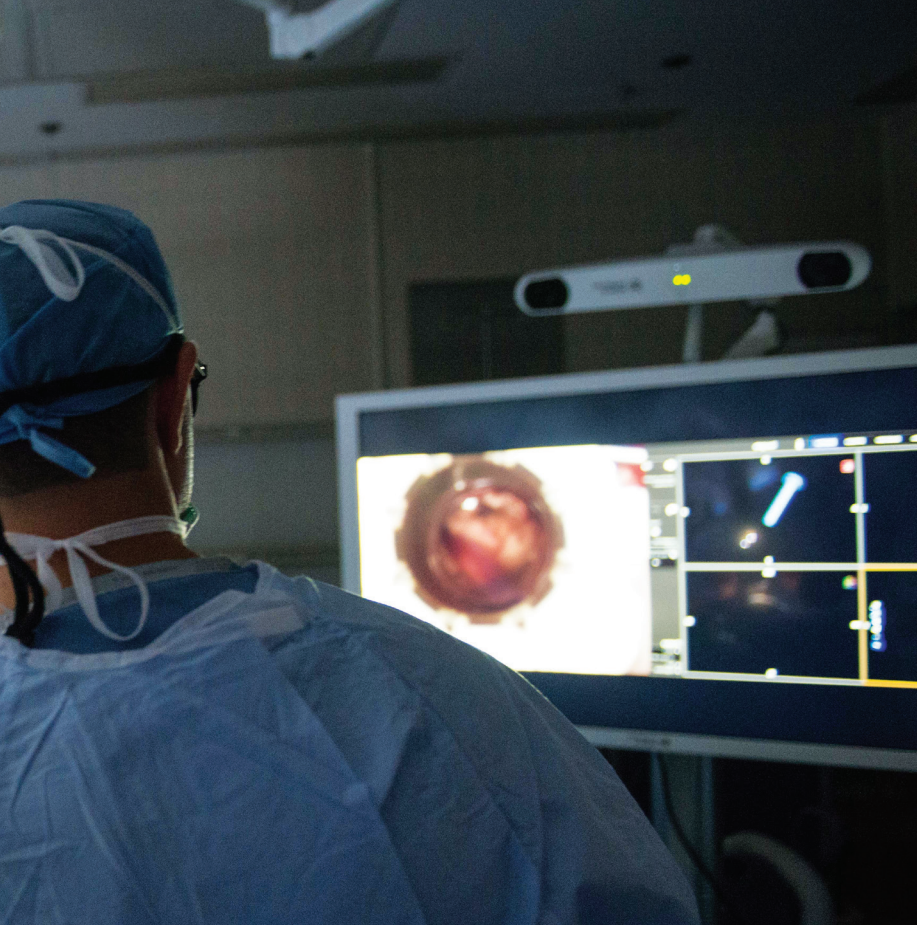
- Brain tumors
- Aneurysms
- Vascular lesions
- Skull-based issues

In addition, the imaging elements of the system can be used during minimally invasive spine surgery.

Unparalleled Surgical Precision and Control

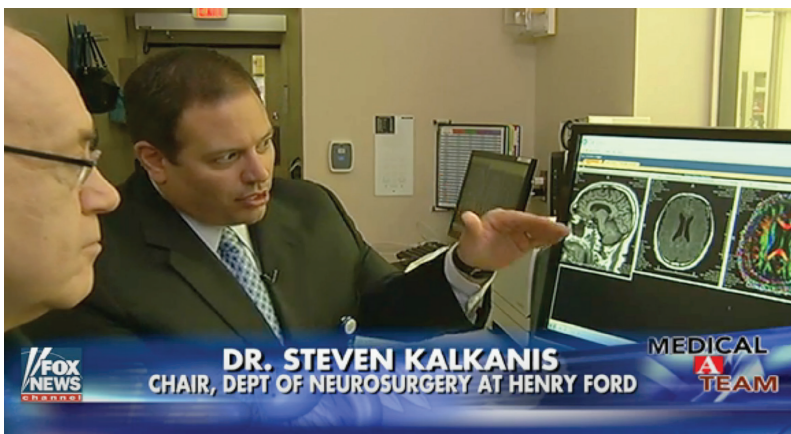
More information supports better outcomes, and with BrightMatter, Henry Ford surgeons are able to visualize patient-specific fiber tracts to plan and navigate through important structures in the brain:

INSTITUTE WELCOMES NEW TEAM MEMBERS

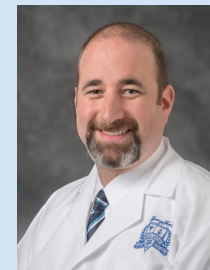


E-CHANGER FOR NEUROSURGERY

- **PREOPERATIVE PLANNING:** The system creates patient-specific, 3-D images before surgery, and automatically processes Diffusion Tensor Images with whole-brain tractography. These images allow a surgeon to plan the best route by seeing important structures.
- **AUTOMATED, HIGH-RESOLUTION IMAGES:** An unprecedented level of magnification and detail allows surgeons to see structures in the surgical field clearly. The system also offers unrivaled optical component alignment and high maneuverability.
- **NEURO-NAVIGATION:** An automated tracking system accurately positions and tracks the optical component, hands-free, and tracks the surgeon's tools in real time – while the robotic arm aligns to the surgeon's tools and keeps the surgical field in focus.



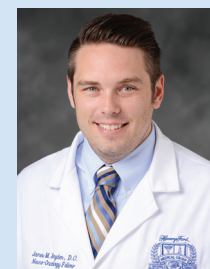
DR. KALKANIS WITH DR. MARC SIEGEL FROM FOX NEWS.



**TODD B. FRANCIS,
M.D., PH.D.**

Spinal Surgery

Dr. Francis earned his medical degree from Wayne State University School of Medicine, where he also completed his residency training in Neurosurgery and earned a doctorate in Physiology. He completed his fellowship in Clinical Spine Surgery at the Cleveland Clinic Foundation. He specializes in the treatment of all spinal disorders, including degenerative disease, deformities, tumor and trauma.



JAMES N. SNYDER, D.O.

Neuro-oncology

Dr. Snyder earned his Doctor of Osteopathic Medicine degree from Michigan State University in 2010. He completed his residency training in Neurology at Huron Valley-Sinai Hospital and St. John Providence Health System. Following his residency, he continued on to specialized training by completing a neuro-oncology fellowship in the Henry Ford Department of Neurosurgery. He is board certified in Neurology.



**HOUTAN NOUSHMEHR,
PH.D.**

Bioinformatics

Dr. Noushmehr received his doctorate degree in Genetics, Molecular and Cellular Biology from University of Southern California, Keck School of Medicine. He also completed his post doctorate research fellowship from USC, Keck School of Medicine. Most recently Dr. Noushmehr was the Director and Founder of the Los Angeles Bioinformatics Foundation, LLC in California. Dr. Noushmehr will be joining the Hermelin Brain Tumor Center's Bioinformatics Lab in September.

NEUROINTENSIVIST RECEIVES TOP AWARD



**PANAYIOTIS
VARELAS, M.D.**

At the 2015 Neurocritical Care Society annual meeting, Panayiotis Varelas, M.D., was presented with the Society's Presidential Service Award.

Dr. Varelas, Director of Henry Ford's Neuro Intensive Care Unit, received the award for his record fundraising of more than half a million dollars in a single year. For the last three years he has served as Chair of the Society's Fundraising Committee, and during his tenure contributions have more than doubled. Dr. Varelas also served as a member of the NCS Board of Directors for the last four years, and this service was another contributing factor for his award.

Dr. Varelas received the award at the 13th Annual Neurocritical Care Society Meeting, which was held in Scottsdale, Arizona, in October 2015.

Brain Death Policies

Dr. Varelas also recently published a paper in *JAMA Neurology*, which reported the results of an investigation into the variability of brain death policies at U.S. hospitals. The American Academy of Neurology (AAN) issued new guidelines in 2010 on the determination

of brain death. It is imperative that brain death be diagnosed accurately in every patient.

Over the course of three years, from June 2012 to July 2015, Dr. Varelas and his team analyzed almost 500 unique hospital policies, representing the majority of hospitals in the United States that would be eligible and equipped to evaluate brain death in a patient. Policies were evaluated for summary statistics across the following five categories of data:

- Who is qualified to perform the determination of brain death
- What are the necessary prerequisites for testing
- Details of the clinical examination
- Details of apnea testing
- Details of ancillary testing

The team concluded that hospital policies in the United States for the determination of brain death are still widely variable and not fully congruent with contemporary practice parameters.

Greer DM, Wang HH, Robinson JD, Varelas PN, Henderson GV, Wijdicks EF. Variability of brain death policies in the United States. *JAMA Neurol.* 2016 Feb 1;73(2):213-8. PMID: 26719912.



GHAUS MALIK, M.D.

NEUROSURGEON HONORED

Congratulations to Dr. Ghaus Malik, Executive Vice Chair of the Henry Ford Department of Neurosurgery, who was awarded the 2015 Dandy Medal based on three main qualifications: has achieved mastery within a discipline of neurosurgery, produced seminal scholarly work within that discipline of neurosurgery and has been a mentor to a whole generation of neurosurgeons. Dr. Malik is a noted authority in cerebrovascular surgery and a recognized master in arteriovenous malformation (AVM) surgery.

COMMITTED TO ONCOLOGY CARE

Longtime neuro-oncology coordinator for the Hermelin Brain Tumor Center has received her latest oncology certification - for a total of 33 years certified.

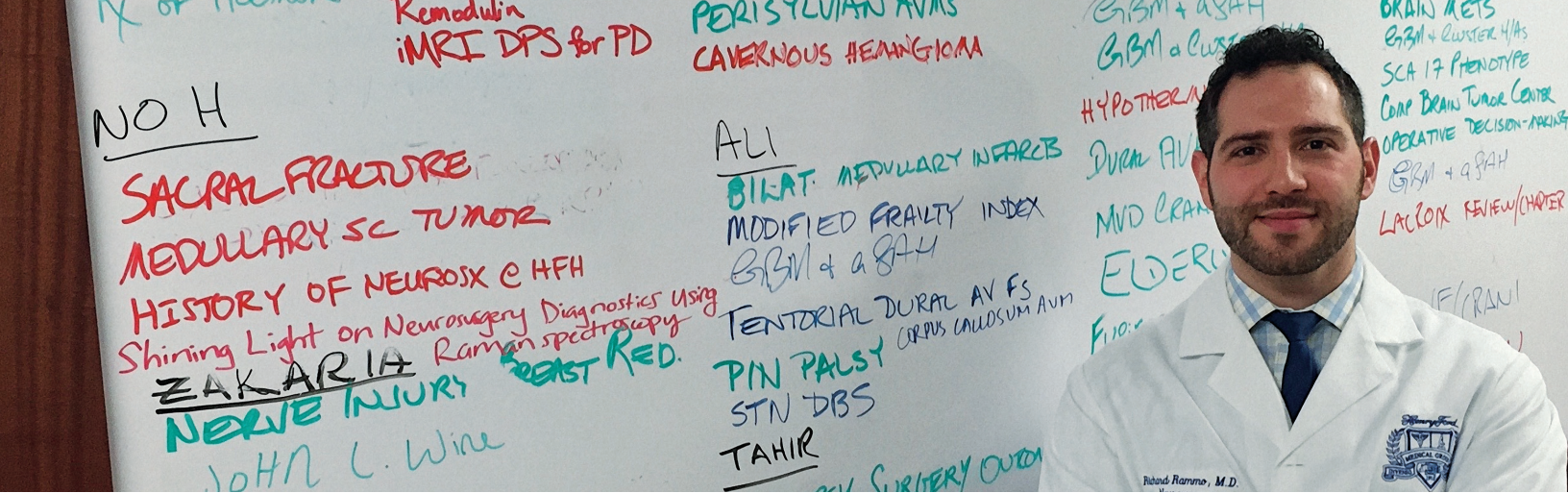
At our Center, we understand that helping patients through the process is key to their long-term well-being and quality of life. An important component of our treatment approach is the neuro-oncology coordination efforts of Sandra Remer, RN, MSN.

For more than two decades, Remer has helped manage the complex medical care of thousands of brain tumor patients we treat every year. Working with caregivers at each stage of the process, she assists patients with testing, setting up appointments and overall comprehension of their care. She also actively participates in research that focuses on new treatments as well as new understanding about the approaches caregivers take to communicate with their patients.

With her latest OCN® renewal from the Oncology Nursing Certification Corporation, Remer has held continuous oncology certification from 1987 to 2019. Her commitment to her profession and her patients has helped to shape the care we provide at our center every day.



SANDRA REMER, R.N.



RESIDENTS' CORNER

Dr. Richard A. Rammo is a senior neurological surgery resident at Henry Ford Hospital. He obtained his undergraduate degree in neurobiology at the University of Miami, where he also continued his training to attain his medical doctorate. He is a member of AANS and CNS. His clinical research interests include intractable epilepsy, deep brain stimulation, meningiomas and brain metastases. He is currently interested in pursuing a fellowship in functional/stereotactic neurosurgery and epilepsy. Here, he describes his personal experience with carrying out research as an integral part of the neurosurgical training program at Henry Ford.

At the beginning of my residency, like many others in a surgical program, I was focused solely on finessing my technical skills in the operating room. My first year as an intern was spent moving from rotation to rotation, with no attempt to pursue a research project. After having several projects in undergrad and medical school that proved fruitless following months and sometimes years of dedication, I was hesitant in committing to a single venture. With the beginning of my second year, a schedule that was already hectic became even more so, and the idea of publishing was a distant thought left for my fifth year.

This coincided with the arrival of Dr. Walters, who was integrated into the program to assist with resident research education. Her efforts focused on unbridling the residents' hidden research potential. Each time I met with Dr. Walters we would review the same two projects that had made no gains. This continued for a year, until finally in October of my third year there came an intervention. While in Cincinnati on a pediatrics rotation, I had a conference meeting with both Dr. Walters and Dr. Mo Alsaidi (my chief at the time). The clock had run out, and there were no more excuses for my lack of productivity.

It was out of that conversation that Dr. Alsaidi brought me into his epilepsy project and, with Dr. Walters' guidance, my interest in research was rekindled. Within two weeks I had submitted an abstract to the AANS meeting. Feeling energized I began working with Dr. Rock on a case report. Unfortunately, I stalled out again and could not make headway.

During my next meeting with Dr. Walters, we discussed barriers to advancement, including poor time management and writing workflow. This, along with a push from another co-resident, Dr. Aqueel Pabaney, changed my mindset and approach. Within several months, my contributions grew from one written manuscript to six.

Furthermore, I learned the value of collaborating with my fellow residents in a writing group, and in that group I learned how to allocate each author's strength to a different aspect of the paper.

With mentoring from Dr. Walters, senior staff and my co-residents, I have been able to appreciate research in a clinical setting, an area that I was not even aware of at the beginning of residency. The knowledge and fulfillment from publishing and advancing the field of neurosurgery has proven equal to that of operating, a skill that I continue to improve on daily.

DR. RAMMO'S PUBLICATIONS

Published research papers include:

DeFazio MV, Rammo RA, Robles JR, Bramlett HM, Dietrich WD, Bullock MR. The potential utility of blood-derived biochemical markers as indicators of early clinical trends following severe traumatic brain injury. *World Neurosurg.* 2014 Jan;81(1):151-158. PMID: 23313262.

Rammo R, Rock A, Transou A, Raghunathan A, Rock J. Anaplastic meningioma: Octreotide therapy for a case of recurrent and progressive intracranial disease. *J Neurosurg.* 2016 Feb;124(2):496-500. PMID: 26274993.

Rammo RA, Greiner HM, Trout AT, Leach JL, Rozhkov L, Fumiwara H, Rose DF, Mangano FT. False lateralization of pre-surgical work-up in a child with a cortical cavernous malformation and intractable epilepsy. (Scheduled for publication in 2016 in the *Journal of Neurosurgical Sciences.*)

CLINICAL TRIALS

ABI-007-MBC-001 – A Phase 2/3, Multi-Center, Open-Label, Randomized Study of Weekly Nab-Paclitaxel in Combination With Gemcitabine or Carboplatin, Compared to Gemcitabine/Carboplatin, as First-Line Treatment in Subjects with ER, PgR, and HER2-Negative (triple negative) Metastatic Breast Cancer

ABI-007-NSCL-005 – Safety and Efficacy of nab-Paclitaxel (Abraxane) in Combination With Carboplatin as First-Line Treatment in Elderly Subjects With Advanced Non-Small Cell Lung Cancer (NSCLC): A Phase IV, Randomized, Open Label, Multi-Center Study

ABTC 1401 – Phase 1 Dose Escalation and Drug Distribution Study of Oral Terameprocol in Patients With Recurrent High-Grade Glioma

BO28984 – Randomized, Multi-Center, Phase III, Open-Label Study of Alectinib versus Crizotinib in Treatment-Naive Anaplastic Lymphoma Kinase-Positive Advanced Non-Small Cell Lung Cancer

CA209143 – A Randomized Phase IIB Open-Label Study of Nivolumab or Nivolumab in Combination With Ipilimumab versus Bevacizumab in Adult Subjects With Recurrent Glioblastoma (GBM)

CC-122-ST-001 – A Phase 1A/1B, Multi-Center, Open-Label, Dose-Finding Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Efficacy of the Pleiotropic Pathway Modifier CC-122 Administered Orally to Subjects With Advanced Solid Tumors, Non-Hodgkin's Lymphoma or Multiple Myeloma

ET743-SAR-3002 – A Multi-Center, Open-Label Single-Arm Study of YONDELIS (trabectedin) for Subjects With Locally Advanced or Metastatic Soft Tissue Sarcoma Who Have Relapsed or Are Refractory to Standard of Care Treatment

GOG 0278 – Evaluation of Physical Function and Quality of Life (QOL) Before and After Non-Radical Surgical Therapy (Extra Fascial Hysterectomy or Cone Biopsy With Pelvic Lymphadenectomy) for Stage IA1 (LVSI+) and IA2-IB1 (< 2CM) Cervical Cancer

Gradalis CL-PTL-119 – Double-Blind, Placebo-Controlled Phase III Trial of Maintenance FANG (bi-shRNAfurin and GMCSF Augmented Autologous Tumor Cell Immunotherapy) for High Risk Stage III/IV Ovarian Cancer

INCB 18424-268 – A Randomized, Double-Blind, Phase 2 Study of Ruxolitinib or Placebo in Combination With Capecitabine in Subjects With Advanced or Metastatic HER2-Negative Breast Cancer

Janssen 54767414MMY3008 – A Phase 3 Study Comparing Daratumumab, Lenalidomide, and Dexamethasone (DRd) vs. Lenalidomide and Dexamethasone (Rd) in Subjects With Previously Untreated Multiple Myeloma who are Ineligible for High Dose Therapy

NSABP-FB-11 – A Phase II Randomized Study Evaluating the Biological and Clinical Effects of the Combination of Palbociclib With Letrozole as Neoadjuvant Therapy in Post-Menopausal Women with Estrogen-Receptor Positive Primary Breast Cancer

PROTOCOL M11-089 – Randomized, Double-Blind, Multi-Center, Phase 3 Study Comparing Veliparib Plus Carboplatin and Paclitaxel Versus Placebo Plus Carboplatin and Paclitaxel in Previously Untreated Advanced or Metastatic Squamous Non-Small Cell Lung Cancer (NSCLC)

PROTOCOL M18-007 – A 3-Arm Phase 2 Double-Blind Randomized Study of Carboplatin, Pemetrexed Plus Placebo versus Carboplatin, Pemetrexed plus 1 or 2 Truncated Courses of Demcizumab in Subjects With Non-Squamous Non-Small Cell Lung Cancer

SWOG 1406 – Randomized Phase II Study of Irinotecan and Cetuximab With or Without Vemurafenib in Brax Mutant Metastatic Colorectal Cancer

IRB 4008 – A Prospective, Randomized, Controlled Multicenter Pivotal Clinical Trial of the Artificial Cervical Disc-LP at Two levels for Symptomatic Cervical Disc Disease

IRB 5702 – The Use of Patient Reported Outcomes Measurement Information System (PROMIS) Measures and the PROMIS Assessment Center in Clinical Populations

IRB 5905 – Assessment of Clinical Outcomes in Patients Receiving Combination Anterior-Posterior Cervical Fusion Surgery (Internal Funding)

IRB 5998 – Potential Racial Disparities in Treatment of Trigeminal Neuralgia (Internal Funding)

IRB 6784 – National Neurosurgery Quality and Outcomes Database (N2QOD): A Prospective Registry for Quality Reporting

IRB 7763 – Mechanomyography for Evaluation of Pedicle Screw Placement (Sentio, LLC), Grant# E12101

IRB 8138 – OPTIMISE STUDY: Occipital Nerve Stimulation (ONS) for Migraine (A4003) (Boston Scientific), Grant# E14045

IRB 8179 – Vascular Malformation Registry (John R. Davis Chair) Grant# J90092

IRB 8198 – The Effect of Treating Non Ruptured Cerebral Aneurysms on Confounding Headaches

IRB 8231 – The Development of a Pre-Operative Predictor Model of Outcomes in Patients Undergoing Lumbar Spine Fusion Surgeries (Internal Funding), Grant# Pending

IRB 8436 – Tissue Bank for NPH Patients

IRB 8777 – Efficacy of Vagal Nerve Stimulator for Dravet Syndrome using Social Media

IRB 8787 – Surgical Technique For Repair of Complex Skull Base Defects

IRB 8842 – Phase 1 Trial of Laser Interstitial Thermal Therapy for Cerebral Radiation Necrosis (Harris Grant) H10194

IRB 8924 – A Randomized Cross-over Study for Normal Pressure Hydrocephalus (ARCS-NPH) (Johns Hopkins)

IRB 9053 – Metastatic Cancer Study_ Spine Surgery

IRB 9165 – Three-Dimensional Motion Analysis in Patients' Status Post Anterior Cervical Fusion and Cervical Disc Arthroplasty, a Clinical Study_MOTION STUDY Supported by the Mentored Clinician Scientist program of HFHS

IRB 9229 – The Application of Morphometrics As a Predictor for Peri-operative Complications After Lumbar Spine Surgery (Internal Funding)

IRB 9246 – Comparing Engagement Techniques for Incorporating Patient Input in Research Prioritization_SMARTER

IRB 9251 – PI Initiated: Retrospective Safety and Efficacy Evaluation of Spinal Fusion Procedures Utilizing Autologous Concentrated Bone Marrow Aspirate (cBMA) (Isto Technologies), Grant# E14195

IRB 9405 – Preoperative External Tissue Expansion for Complex Cranial Reconstructions

IRB 9413 – Application of LinkView Telemedicine Device in Senior Post-operative Spine Patients

FOR MORE INFORMATION ABOUT CURRENT CLINICAL TRIALS, PLEASE CALL (313) 916-1756.

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