This project would not have been possible without the commitment and expertise of many individuals, but in particular Jocelyn Baudista, MD; Irene Katzan, MD; Christine Moore; and John Urchek.
To promote quality improvement, Cleveland Clinic has created a series of Outcomes books similar to this one for many of its institutes. Designed for a physician audience, the Outcomes books contain a summary of our surgical and medical trends and approaches, data on patient volumes and outcomes, and a review of new technologies and innovations.

Although we are unable to report all outcomes for all treatments provided at Cleveland Clinic — omission of outcomes for a particular treatment does not necessarily mean we do not offer that treatment — our goal is to increase outcomes reporting each year. When outcomes for a specific treatment are unavailable, we often report process measures associated with improved outcomes. When process measures are unavailable, we may report volume measures; a volume/outcome relationship has been demonstrated for many treatments, particularly those involving surgical techniques.

In addition to our internal efforts to measure clinical quality, Cleveland Clinic supports transparent public reporting of healthcare quality data and participates in the following public reporting initiatives:

- Joint Commission Performance Measurement Initiative (qualitycheck.org)
- Centers for Medicare & Medicaid (CMS) Hospital Compare (hospitalcompare.hhs.gov)
- Ohio Department of Health (ohiohospitalcompare.ohio.gov)
- Cleveland Clinic Quality Performance Report (clevelandclinic.org/QPR)

Our commitment to providing accurate, timely information about patient care also will help patients and referring physicians make informed healthcare decisions.

We hope you find these data valuable. To view all our Outcomes books, please visit Cleveland Clinic's Quality and Patient Safety website at clevelandclinic.org/quality/outcomes.
Dear Colleague:

It is my great pleasure to present Cleveland Clinic’s annual Outcomes books. The current edition includes outcomes and volumes along with recent innovations and publications for Cleveland Clinic’s clinical services through calendar year 2010.

Cleveland Clinic is celebrating its 90th Anniversary in 2011. Our founders were innovators. They created a unique model of medicine based on patient care, enhanced by research and education. We honor this legacy, measuring quality, reporting outcomes and continuously improving the value of medical services.

Cleveland Clinic Outcomes books are offered in print and online. Additional data is available through our online Quality Performance Report (clevelandclinic.org/QPR). The site offers data in advance of national and state public reporting sites, in key areas including heart attack, heart failure, stroke and infection prevention.

Thank you for your interest in Cleveland Clinic Outcomes books. We hope you will find them useful and informative.

Sincerely,

Delos M. Cosgrove, MD
CEO and President
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Dear Colleagues,

I am pleased to again share with you Cleveland Clinic Neurological Institute’s annual outcomes data. This report reflects an ongoing effort to collect validated health status measures through our Knowledge Program© to track care longitudinally across venues. The process is facilitated by disease-specific care paths that bridge geography, unifying our institute and ensuring utilization of standardized, evidence-based practices throughout our health system.

To date, our stroke care path is the most advanced, integrated in the patient’s electronic medical record to guide stroke management from the Emergency Department through home care. We gather health status measures at admission, discharge and when our stroke patients return for ambulatory care. In addition to driving improvements in quality and outcomes, this exhaustive data collection is enabling better understanding and documentation of stroke etiology in the individuals we see.

We are developing the same structured approach to traumatic brain injury, another common neurodegenerative disorder that has ignited an intensive interdisciplinary research initiative at Cleveland Clinic. In collaboration with our colleagues in the Orthopaedic & Rheumatologic Institute and Cleveland Clinic Lerner Research Institute, we have embarked on a multi-pronged effort to address prevention, diagnosis and treatment of concussion, whether it occurs on the playing field or the battlefield.
Among several research projects under way is a longitudinal study of cognitive and physical function in mixed martial artists and boxers. The Neurological Institute’s Lou Ruvo Center for Brain Health, co-located in Cleveland and Las Vegas, is working with the Nevada Athletic Commission to administer annual physical exams, including brain scans, to volunteer fighters. We expect this information to aid in advancing knowledge of brain trauma, concussive injury and neurological health among athletes in combative sports.

While acute episodes of traumatic brain injury tend to occur in youth, chronic traumatic encephalopathy and other forms of dementia linked with head trauma are typically diagnosed later in life. The common denominator is cognitive dysfunction. Our boxing study reinforces the need for a surveillance system to evaluate concussion patients over years, not just in the moments after impact.

As a result, we are increasingly migrating toward disease management across both venues and time. Continued development and refinement of tools such as care paths and the Knowledge Program enable more accurate measurement and reporting of our performance. The message to our patients is more visceral: We will be there whenever and wherever you need us, and you can trust us with your healthcare.

Please let us know if we can assist with your patients’ neurological needs. As always, we welcome your comments.

Michael T. Modic, MD, FACR
Chairman, Neurological Institute
The multidisciplinary Cleveland Clinic Neurological Institute includes more than 300 medical, surgical and research specialists dedicated to the diagnosis, treatment and rehabilitation of adult and pediatric patients with neurological and psychiatric disorders. The institute model allows patients to access the care they need through specialized, disease-specific centers that integrate the expertise of neurologists, neurosurgeons, orthopaedic surgeons, psychiatrists, psychologists, physiatrists, neuroradiologists and allied health professionals. This model also facilitates collaboration and improved measurement of quality and outcomes on a continuing basis.

*U.S. News & World Report’s “America’s Best Hospitals” survey has consistently ranked both our adult and pediatric neurology and neurosurgery programs among the top 10 in the nation. Our neurology, neurosurgery, pediatric neurology/neurosurgery and psychiatry programs also hold top ranking in Ohio.*

The Neurological Institute comprises the following centers as well as departments that integrate resident training, academics and research:

<table>
<thead>
<tr>
<th>Center Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rose Ella Burkhardt Brain Tumor and Neuro-Oncology Center</td>
</tr>
<tr>
<td>Center for Behavioral Health</td>
</tr>
<tr>
<td>Lou Ruvo Center for Brain Health</td>
</tr>
<tr>
<td>Cerebrovascular Center</td>
</tr>
<tr>
<td>Cleveland Clinic at Home</td>
</tr>
<tr>
<td>Epilepsy Center</td>
</tr>
<tr>
<td>Mellen Center for Multiple Sclerosis Treatment and Research</td>
</tr>
<tr>
<td>Center for Neuroimaging</td>
</tr>
<tr>
<td>Center for Neurological Restoration</td>
</tr>
<tr>
<td>Neurological Center for Pain</td>
</tr>
<tr>
<td>Neuromuscular Center</td>
</tr>
<tr>
<td>Center for Pediatric Neurology and Neurosurgery</td>
</tr>
<tr>
<td>Department of Physical Medicine and Rehabilitation</td>
</tr>
<tr>
<td>Center for Regional Neurosciences</td>
</tr>
<tr>
<td>Sleep Disorders Center</td>
</tr>
<tr>
<td>Center for Spine Health</td>
</tr>
</tbody>
</table>
We provide care across the spectrum of neurological and psychiatric disorders, including primary and metastatic tumors of the brain, spine and nerves; pediatric and adult epilepsy; headache, facial pain syndromes and associated disorders; movement disorders such as Parkinson’s disease, essential tremor and dystonia; neurocognitive disorders; cerebral palsy and spasticity; hydrocephalus; metabolic and mitochondrial disease; fetal and neonatal neurological problems; multiple sclerosis; stroke; cerebral aneurysm; brain and spinal vascular malformations; carotid stenosis; intracranial atherosclerosis; nerve and muscle diseases, including amyotrophic lateral sclerosis, peripheral neuropathy, myasthenia gravis and myopathies; sleep disorders; mental/behavioral health disorders and chemical dependency; impairments and disabilities in the areas of mobility, self-care, communication, swallowing and cognition.

**Expert, Specialized Diagnosis**

Our Neurological Institute physicians draw on advanced diagnostic capabilities and experience. Our imaging services include structural and functional MRI, CT, PET, myelography, diagnostic cerebral/spinal angiography, interventional neuroradiology, and carotid and transcranial Doppler ultrasound. Our neuroimaging staff subspecializes in specific disease entities such as epilepsy and cerebrovascular disease, ensuring accurate, in-depth interpretations.

Additional diagnostic tools are found in our epilepsy monitoring units, sleep laboratories, neuropsychological testing facilities, electromyography laboratory, autonomic laboratory and cutaneous nerve laboratory.

**The Latest Treatment Modalities**

Patients receive leading-edge treatment options at the Neurological Institute, where we continue to advance such innovations as deep brain stimulation (DBS), laser interstitial thermal therapy (LITT) for brain tumors, epilepsy surgery, stereotactic spine radiosurgery, endovascular treatment of cerebral aneurysms and vascular malformations, and neuroendoscopy. The Rose Ella Burkhardt Brain Tumor and Neuro-Oncology Center was one of the first such facilities worldwide to integrate the newest intraoperative MRI technology with its pioneering LITT capability to enhance brain tumor treatment. The interventional MRI suite accommodates many other neurosurgical procedures as well, including DBS surgery.

Our main campus and four Cleveland Clinic regional hospitals are Joint Commission-designated Primary Stroke Centers, in line with our initiative to standardize stroke treatment protocols across our health system so that patients in Northeast Ohio have access to the same high-quality stroke care no matter where they live. We are developing structured care paths for additional disorders – a critical step in bridging geography to deliver high-quality, patient-centered care and to function as an integrated enterprise.
Relevant Research

We conduct research directly related to conditions experienced by our patients. A prime example is concussion, a signature injury of athletes at all levels of competition as well as military veterans who have served in Iraq and Afghanistan. Neurological Institute investigators are active participants in an intense interdisciplinary research effort at Cleveland Clinic to better prevent, diagnose and treat concussion. Much of this work is going forward in our Spine Research Laboratory.

Our neuroscientists pursue translational research, clinical trials of drug and device interventions, neuroimaging research, epidemiology and health outcomes, behavioral and psychiatric research, and research into better diagnostic methods. Typically, more than 200 clinical research trials are under way in the Neurological Institute. In 2010, we were awarded more than $19 million in neurologically based research grants and contracts.

Convenient Care in the Community

We are committed to making access to world-class care convenient for all patients. Regional facilities extend advanced treatments, technologies and the expertise of Neurological Institute physicians to community hospitals and family health centers throughout the Cleveland Clinic health system. As a result, patients can easily access specialists who treat the most complex neurological conditions.

Key components in our regional network include:

- Cleveland Clinic Neurological Institute at Lakewood and Hillcrest hospitals, which provides comprehensive services to Cleveland’s suburban residents.
- Cleveland Clinic Rehabilitation Hospitals, with a total of 98 adult acute inpatient rehabilitation beds at our main campus and two suburban hospitals.
- Cleveland Clinic Rehabilitation and Sports Therapy, a unique consortium with Cleveland Clinic Orthopaedic & Rheumatologic Institute that engages 650-plus physical and occupational therapists throughout the region.
- Cleveland Clinic at Home, which brings in-home and distance healthcare to individuals in an expansive area comprising 14 Ohio counties and provides home infusion/pharmacy services in eight states.
- Our Sleep Disorders Center, which conducts overnight sleep studies at nine locations throughout the community, including eight conveniently located hotels.
- Cleveland Clinic Pediatric Neurology and Neurosurgery services are provided at Fairview and Hillcrest hospitals, as well as several family health centers, our pediatric rehabilitation hospital at Shaker Campus, and the Lerner Autism School.
Extending Our Services

Neurological Institute services extend beyond the region. The Lou Ruvo Center for Brain Health diagnoses, treats and researches Alzheimer’s disease and other neurocognitive disorders from locations in Cleveland and Lakewood, Ohio, and Las Vegas and Reno, Nevada. Diagnostic tests performed in Nevada are digitally transferred to Cleveland and other Cleveland Clinic sites for interpretation by one of the world’s leading neuroimaging centers. At Cleveland Clinic Florida, epileptologists work with their colleagues at the Cleveland Clinic Epilepsy Center to diagnose and treat adults with epilepsy. All Florida epileptologists have dual appointments with the Neurological Institute in Cleveland.

In addition, our Cerebrovascular Center’s Telestroke Network offers medical staff at other hospitals remote access to patient consultation services from our neurological specialists. The network is enabled with a mobile, two-way videoconference system and a dedicated link for transmitting imaging studies.

Integrated Nursing

Nurses in the Neurological Institute rank as respected members of the care team. As such, they are encouraged to offer input to physicians and administrators and to engage in problem solving and process improvement. Patients benefit from this integration through improved coordination of care and commonly held provider goals.

Opportunities for further education and career advancement are readily available to institute nurses. Their participation is welcomed in all continuing education programs, and those with at least two years’ experience in the institute can aspire to certification in neuroscience nursing. These subspecialists staff areas such as the neurological intensive care and stepdown units that treat the most complex patients.

Each November, Cleveland Clinic’s “Innovations in Neuroscience” conference convenes in Cleveland. This meeting, originally limited to nurses, now includes physician assistants and medical assistants as organizers continue to work toward increased provider collaboration.

Pioneering the Collection of Data and Outcomes

The Neurological Institute’s Knowledge Program® has captured data from more than one million self-administered patient questionnaires. One of the world’s first interactive clinical patient databases, the Knowledge Program® is demonstrating its value as it evolves, with collection and correlation of electronic information on patient health status, quality of life and outcomes.

We are aggregating this patient-generated data with information from other sources, such as imaging results and information collected during patient encounters, to optimize clinical decision making, quality improvement and research opportunities.

All these data are accessible to physicians through an interface with the patient’s electronic medical record. The Knowledge Program® is proving to be among our most constructive tools for delivering individualized care to improve outcomes and quality of life, in line with Cleveland Clinic’s guiding principle: Patients First.
### 2010 Statistical Highlights

<table>
<thead>
<tr>
<th>Position</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff Physicians</td>
<td>225</td>
</tr>
<tr>
<td>Clinical Residents and Fellows</td>
<td>145</td>
</tr>
<tr>
<td>Research Fellows</td>
<td>17</td>
</tr>
<tr>
<td>Advanced Practice Nurses</td>
<td>38</td>
</tr>
<tr>
<td>Physician Assistants</td>
<td>15</td>
</tr>
<tr>
<td>Medical Students (NI Rotation)</td>
<td>85</td>
</tr>
</tbody>
</table>

### Inpatient Facilities (Main Campus)

<table>
<thead>
<tr>
<th>Facility Type</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatient General Neuro Beds</td>
<td>50</td>
</tr>
<tr>
<td>Neuro ICU Beds</td>
<td>22</td>
</tr>
<tr>
<td>Neuro Stepdown Beds</td>
<td>17</td>
</tr>
<tr>
<td>EMU Beds – Pediatrics</td>
<td>9</td>
</tr>
<tr>
<td>EMU Beds – Adult</td>
<td>14</td>
</tr>
<tr>
<td>Chemical Dependency Unit Beds</td>
<td>13</td>
</tr>
<tr>
<td>Inpatient Rehab Beds</td>
<td>12*</td>
</tr>
</tbody>
</table>

### Inpatient Facilities (Regional)

<table>
<thead>
<tr>
<th>Facility Type</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychiatric Unit Beds</td>
<td>254</td>
</tr>
<tr>
<td>Rehabilitation Beds</td>
<td>81*</td>
</tr>
<tr>
<td>Skilled Nursing Units</td>
<td>96</td>
</tr>
</tbody>
</table>

* As of March 2011
<table>
<thead>
<tr>
<th>Initial Outpatient Visits**</th>
<th>10,627</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brain Health</td>
<td>911</td>
</tr>
<tr>
<td>Brain Tumor Neuro-Oncology</td>
<td>405</td>
</tr>
<tr>
<td>Cerebrovascular</td>
<td>353</td>
</tr>
<tr>
<td>Epilepsy</td>
<td>746</td>
</tr>
<tr>
<td>Headache and Pain</td>
<td>920</td>
</tr>
<tr>
<td>Mellen Center</td>
<td>754</td>
</tr>
<tr>
<td>Neurological Restoration</td>
<td>419</td>
</tr>
<tr>
<td>Neurology</td>
<td>654</td>
</tr>
<tr>
<td>Neuromuscular</td>
<td>872</td>
</tr>
<tr>
<td>Pediatric Neurology***</td>
<td>915</td>
</tr>
<tr>
<td>Pediatric Neurosurgery***</td>
<td>286</td>
</tr>
<tr>
<td>Physical Medicine and Rehabilitation</td>
<td>429</td>
</tr>
<tr>
<td>Psychiatry and Psychology</td>
<td>334</td>
</tr>
<tr>
<td>Regional Neurological Institute</td>
<td>932</td>
</tr>
<tr>
<td>Spine</td>
<td>1,503</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total Outpatient Visits</th>
<th>154,944</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brain Health</td>
<td>4,214</td>
</tr>
<tr>
<td>Brain Tumor Neuro-Oncology</td>
<td>7,049</td>
</tr>
<tr>
<td>Cerebrovascular</td>
<td>3,141</td>
</tr>
<tr>
<td>Epilepsy</td>
<td>7,384</td>
</tr>
<tr>
<td>Headache and Pain</td>
<td>11,367</td>
</tr>
<tr>
<td>Mellen Center</td>
<td>6,033</td>
</tr>
<tr>
<td>Neurological Restoration</td>
<td>5,237</td>
</tr>
<tr>
<td>Neurology</td>
<td>4,228</td>
</tr>
<tr>
<td>Neuromuscular</td>
<td>5,293</td>
</tr>
<tr>
<td>Pediatric Neurology***</td>
<td>8,810</td>
</tr>
<tr>
<td>Pediatric Neurosurgery***</td>
<td>2,841</td>
</tr>
<tr>
<td>Physical Medicine and Rehabilitation</td>
<td>5,465</td>
</tr>
<tr>
<td>Psychiatry and Psychology</td>
<td>31,655</td>
</tr>
<tr>
<td>Regional Neurological Institute</td>
<td>19,769</td>
</tr>
<tr>
<td>Sleep</td>
<td>5,131</td>
</tr>
<tr>
<td>Spine</td>
<td>27,327</td>
</tr>
</tbody>
</table>

** Initial visits for patients new to Cleveland Clinic

*** Children and adolescents are also included under Epilepsy, Psychiatry and Psychology, and Sleep
## Institute Overview

### Admissions

<table>
<thead>
<tr>
<th>Service</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brain Tumor Neuro-Oncology</td>
<td>1,036</td>
</tr>
<tr>
<td>Cerebrovascular</td>
<td>1,178</td>
</tr>
<tr>
<td>Epilepsy</td>
<td>1,482</td>
</tr>
<tr>
<td>Neurological Restoration</td>
<td>192</td>
</tr>
<tr>
<td>Neurology</td>
<td>695</td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>360</td>
</tr>
<tr>
<td>Pediatric Neurology*</td>
<td>140</td>
</tr>
<tr>
<td>Pediatric Neurosurgery*</td>
<td>210</td>
</tr>
<tr>
<td>Psychiatry and Psychology</td>
<td>8,617**</td>
</tr>
<tr>
<td>Regional Neurological Institute</td>
<td>203</td>
</tr>
<tr>
<td>Spine</td>
<td>1,378</td>
</tr>
</tbody>
</table>

### Inpatient Days

<table>
<thead>
<tr>
<th>Service</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brain Tumor Neuro-Oncology</td>
<td>4,976</td>
</tr>
<tr>
<td>Cerebrovascular</td>
<td>7,044</td>
</tr>
<tr>
<td>Epilepsy</td>
<td>9,025</td>
</tr>
<tr>
<td>Neurological Restoration</td>
<td>726</td>
</tr>
<tr>
<td>Neurology</td>
<td>3,770</td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>1,891</td>
</tr>
<tr>
<td>Pediatric Neurology*</td>
<td>491</td>
</tr>
<tr>
<td>Pediatric Neurosurgery*</td>
<td>960</td>
</tr>
<tr>
<td>Psychiatry and Psychology</td>
<td>60,188**</td>
</tr>
<tr>
<td>Regional Neurological Institute</td>
<td>1,213</td>
</tr>
<tr>
<td>Spine</td>
<td>6,524</td>
</tr>
</tbody>
</table>

* Children and adolescents are also included under Epilepsy, Psychiatry and Psychology

** Includes totals from the following Cleveland Clinic regional hospitals: Euclid, Fairview, Huron, Lakewood, Lutheran, Marymount and South Pointe
<table>
<thead>
<tr>
<th>Surgical/Interventional Procedures</th>
<th>8,230</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brain Tumor Neuro-Oncology</td>
<td>912</td>
</tr>
<tr>
<td>Cerebrovascular</td>
<td>1,095</td>
</tr>
<tr>
<td>Epilepsy</td>
<td>617</td>
</tr>
<tr>
<td>Headache and Pain</td>
<td>19</td>
</tr>
<tr>
<td>Neurological Restoration</td>
<td>374</td>
</tr>
<tr>
<td>Neuromuscular</td>
<td>91</td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>444</td>
</tr>
<tr>
<td>Pediatric Neurology*</td>
<td>46</td>
</tr>
<tr>
<td>Pediatric Neurosurgery*</td>
<td>394</td>
</tr>
<tr>
<td>Physical Medicine and Rehabilitation</td>
<td>21</td>
</tr>
<tr>
<td>Regional Neurological Institute</td>
<td>317</td>
</tr>
<tr>
<td>Spine</td>
<td>3,900</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Neuroimaging Studies***</th>
<th>98,276</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total CT Brain Scans</td>
<td>37,000</td>
</tr>
<tr>
<td>Total MR Brain Procedures</td>
<td>56,000</td>
</tr>
<tr>
<td>Total Cerebral Angio Procedures</td>
<td>5,276</td>
</tr>
</tbody>
</table>

*** Studies performed across the entire Cleveland Clinic health system
Recognizing that the presence of significant comorbidity affects overall care and eventual disease outcome, all Cleveland Clinic Neurological Institute patients are assessed for overall health status, including quality of life and presence of psychiatric comorbidity such as depression.

The EuroQOL (EQ-5D) is a five-item, validated, self-reported generic health-related quality-of-life measure that has been used to assess individuals with a variety of medical conditions as well as the general population. The EQ-5D assesses five domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. An EQ-5D index score of 1.0 indicates perfect health.

**Quality of Life by Neurological Disease Category**

A cross-sectional analysis of quality of life across multiple neurological disease categories suggests the lowest quality of life for patients with chronic pain and the highest for those with sleep disorders.
The Patient Health Questionnaire (PHQ-9) is a nine-item, validated, self-reported measure of depression that is based on the nine diagnostic criteria for depressive disorders according to the DSM-IV and yields a measure of depression severity. Scores range from 0 to 27 and scores of 5, 10, 15 and 20 reflect mild, moderate, moderately severe and severe depression, respectively.

**Depressive Symptoms by Neurological Disease Category**

2010

A cross-sectional analysis of depressive symptoms across multiple neurological disease categories suggests at least mild depression in all neurological diseases, with the most severe depression in those with chronic pain.
The Rose Ella Burkhardt Brain Tumor and Neuro-Oncology Center (BBTC) of the Neurological Institute is one of the largest and most comprehensive programs in the country and is dedicated to providing exceptional patient care including surgery, radiation, chemotherapy and clinical research trials for brain tumor patients. Patient care is provided by a multidisciplinary team consisting of neurosurgeons, radiation oncologists, neuro-oncologists, medical oncologists, psychiatrists and neuropsychologists, along with nurses, physician assistants, case managers and social workers who all specialize in treating patients with brain tumors. The BBTC is dedicated to bringing novel treatment options emerging from the institute’s extensive basic and translational research programs. The center’s primary missions are to offer excellent care through state-of-the-art surgical intervention and to conduct clinical research to enhance patient outcomes. BBTC enrolled 233 patients in research trials in the last five years (2006 – 2010).

### Brain Tumor Diagnosis Distribution (N = 1,999)

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Percentage</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glioma</td>
<td>44%</td>
<td>889</td>
</tr>
<tr>
<td>Schwannoma</td>
<td>7%</td>
<td>141</td>
</tr>
<tr>
<td>Pituitary Tumor</td>
<td>8%</td>
<td>165</td>
</tr>
<tr>
<td>Meningioma</td>
<td>18%</td>
<td>354</td>
</tr>
<tr>
<td>Metastasis</td>
<td>23%</td>
<td>450</td>
</tr>
<tr>
<td>Total</td>
<td>100%</td>
<td>1,999</td>
</tr>
</tbody>
</table>

Gliomas remain the most common brain tumor seen in patients, accounting for 44 percent of cases.

### Brain Tumor Procedures (N = 790)

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Percentage</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brain Biopsy</td>
<td>5%</td>
<td>38</td>
</tr>
<tr>
<td>Infratentorial Craniotomy</td>
<td>6%</td>
<td>48</td>
</tr>
<tr>
<td>Pituitary Surgery</td>
<td>10%</td>
<td>78</td>
</tr>
<tr>
<td>Novalis® Radiosurgery</td>
<td>14%</td>
<td>108</td>
</tr>
<tr>
<td>Supratentorial Craniotomy</td>
<td>22%</td>
<td>177</td>
</tr>
<tr>
<td>Gamma Knife® Radiosurgery</td>
<td>43%</td>
<td>341</td>
</tr>
</tbody>
</table>

Gamma Knife® radiosurgery was the most common procedure in 2010, followed by supratentorial craniotomy, and Novalis® stereotactic radiosurgery.
Brain Tumor Surgical Site Infection Rates

Surgical site infection rates remained under 5 percent in 2010. N = number of clean cases per year. Per Centers for Disease Control and Prevention (CDC) guidelines, “clean cases” are defined as uninfected operative wounds in which no inflammation is encountered and, in the case of brain tumor surgery, neither the respiratory nor the alimentary tract is entered.
Thirty- and 180-day (for first six months of 2010) survival rates for brain biopsies continued to improve, reaching 100 percent in both categories. \( N \) = number of brain biopsies per year.
**Supratentorial Craniotomy**

**Supratentorial Craniotomy: Inpatient Mortality**

<table>
<thead>
<tr>
<th>Year</th>
<th>N</th>
<th>Actual</th>
<th>Expected</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>298</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2007</td>
<td>273</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2008</td>
<td>230</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2009</td>
<td>277</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td>243</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Inpatient mortality remained significantly lower than predicted, continuing the trend over the past five years. N = number of supratentorial craniotomies performed for brain tumor per year. For this and all subsequent graphs, expected mortality is based on national normative data and All Patient Refined Diagnosis Related Groups (APR-DRGs), a method of adjusting for severity of patient illness.¹

**Supratentorial Craniotomy: Length of Stay (LOS)**

<table>
<thead>
<tr>
<th>Year</th>
<th>N</th>
<th>Actual</th>
<th>Expected</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>298</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2007</td>
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<td></td>
</tr>
<tr>
<td>2008</td>
<td>230</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2009</td>
<td>277</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td>243</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Mean length of stay (LOS) remained lower than expected. For this and all subsequent graphs, expected mean LOS is based on national normative data and APR-DRGs, a method of adjusting for severity of patient illness.¹

¹. [http://solutions.3m.com/wps/portal/3M/en_US/3M_Hash_Information_Systems/HIS/Products/APRDRG_Software/](http://solutions.3m.com/wps/portal/3M/en_US/3M_Hash_Information_Systems/HIS/Products/APRDRG_Software/)
Supratentorial Craniotomy: Karnofsky Performance Scale (KPS) (N = 139)

Change in KPS Status within 30 Days of Operative Procedure

2010

Performance status, as measured by the KPS, was stable or improved in over 90 percent of patients immediately after supratentorial craniotomy. Change in KPS was defined as a change of 20 points or more.
Supratentorial Craniotomy: Survival by Tumor Type

Glioma: Survival

Survival (%)

<table>
<thead>
<tr>
<th>Year</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>112</td>
<td>115</td>
<td>88</td>
<td>113</td>
<td>76</td>
</tr>
</tbody>
</table>

Meningioma: Survival

Survival (%)

<table>
<thead>
<tr>
<th>Year</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>34</td>
<td>30</td>
<td>25</td>
<td>35</td>
<td>29</td>
</tr>
</tbody>
</table>

Metastasis: Survival

Survival (%)

<table>
<thead>
<tr>
<th>Year</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>32</td>
<td>32</td>
<td>23</td>
<td>29</td>
<td>18</td>
</tr>
</tbody>
</table>

Thirty- and 180-day (for the first six months of 2010) survival rates remained robust in 2010 for supratentorial craniotomy independent of tumor type.
Infratentorial Craniotomy

Infratentorial Craniotomy: Inpatient Mortality

There have been only four deaths in patients undergoing infratentorial craniotomy at Cleveland Clinic in the past five years, which is below the expected number based on national averages. \( N \) = number of infratentorial craniotomies performed for brain tumor per year.

Infratentorial Craniotomy: Length of Stay (LOS)

There have been only four deaths in patients undergoing infratentorial craniotomy at Cleveland Clinic in the past five years, which is below the expected number based on national averages. \( N \) = number of infratentorial craniotomies performed for brain tumor per year.
Infratentorial Craniotomy: Change in KPS Status within 30 Days of Operative Procedure (N = 36)

2010

<table>
<thead>
<tr>
<th>Patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
</tr>
<tr>
<td>80</td>
</tr>
<tr>
<td>60</td>
</tr>
<tr>
<td>40</td>
</tr>
<tr>
<td>20</td>
</tr>
<tr>
<td>0</td>
</tr>
</tbody>
</table>

- Declined
- Improved
- No Change

Performance status, as measured by the KPS, was stable or improved in over 94 percent of patients undergoing infratentorial craniotomy in 2010. Change in KPS status was defined as a change of 20 points or more.
Infratentorial Craniotomy: Survival by Tumor Type

Glioma: Survival

Survival (%)

<table>
<thead>
<tr>
<th>Year</th>
<th>30-Day</th>
<th>180-Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>2007</td>
<td>75</td>
<td>75</td>
</tr>
<tr>
<td>2008</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>2009</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>2010</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

N = 5

Meningioma: Survival

Survival (%)

<table>
<thead>
<tr>
<th>Year</th>
<th>30-Day</th>
<th>180-Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>2007</td>
<td>75</td>
<td>75</td>
</tr>
<tr>
<td>2008</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>2009</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>2010</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

N = 9
Metastasis: Survival

Survival (%)

<table>
<thead>
<tr>
<th>Year</th>
<th>N</th>
<th>30-Day</th>
<th>180-Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2007</td>
<td>6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2008</td>
<td>15</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2009</td>
<td>11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td>7</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Pituitary Surgery

Survival (%)

Thirty- and 180-day (for the first six months of 2010) survival rates were 100 percent in both categories. N = number of pituitary tumor surgeries per year.

Mortality (%)

There have been no inpatient deaths following pituitary surgery over the past five years.
Actual mean LOS continues to remain close to target LOS.

In 100 percent of patients, performance status, as measured by the KPS, remained stable or improved after pituitary surgery. Change in KPS status was defined as a change of 20 points or more.
**Stereotactic Radiosurgery: Gamma Knife®**

Thirty- and 180-day (for the first six months of 2010) survival rates remained robust in 2010 for Gamma Knife® radiosurgery treatment, independent of tumor type.

**Gamma Knife® Radiosurgery: Meningioma Survival**

![Survival graph for Meningioma](image)

**Gamma Knife® Radiosurgery: Schwannoma Survival**

![Survival graph for Schwannoma](image)
Gamma Knife® Radiosurgery: Metastasis Survival

Survival (%)


Survival (%)


Gamma Knife® Radiosurgery: Pituitary Tumor Survival
In 2010, 108 patients were treated with Novalis® stereotactic radiosurgery. Thirty- and 180-day (for the first six months of 2010) survival rates for this type of treatment, which is mainly used to treat malignant and metastatic tumors to the spine, were 100 percent and 96.3 percent, respectively.
Novalis® Stereotactic Radiosurgery: Treatment of Painful Spinal Metastases

Pain Scores after Stereotactic Spine Radiosurgery for Metastatic Renal Cell Carcinoma (N = 53)

The graph demonstrates pain scores in renal cell carcinoma patients with spinal metastases treated with single fraction spine radiosurgery (53 patients at baseline). There is a marked decrease in patient-reported pain scores as early as week one post-treatment. Further, this improved pain outcome score persists and pain scores of zero at the treated levels were reported by the available patients at both 18 and 24 months.
In 2010, 73 patients with newly diagnosed glioblastoma, the most common type of malignant primary brain tumor, underwent initial surgical resection and treatment at Cleveland Clinic. Approximately 12,000 cases of glioblastoma are diagnosed each year in the United States.

**Glioblastoma Multiforme**

In the graph above, the reference data represent relative survival, while Cleveland Clinic data are observed survival, which prevents formal statistical comparison.

**CC = Cleveland Clinic**

## Get With The Guidelines® (GWTG) Stroke Performance and Quality Measures

<table>
<thead>
<tr>
<th>Clinical Measure</th>
<th>Measure Description</th>
<th>GWTG Stroke Performance Award Goal</th>
<th>National Average*</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>IV rt-PA 2 Hour</td>
<td>Acute stroke patients who arrive at the hospital within 120 minutes (2 hours) of time last known well and for whom IV rt-PA was initiated at this hospital within 180 minutes (3 hours) of time last known well.</td>
<td>85.0%</td>
<td>75.9%</td>
<td>66.7% (4/6)</td>
<td>88.9% (8/9)</td>
<td>78.6% (11/14)</td>
<td>86.7% (13/15)</td>
</tr>
<tr>
<td>Early Antithrombotics</td>
<td>Patients with ischemic stroke or TIA who receive antithrombotic therapy by the end of hospital day 2.</td>
<td>85.0%</td>
<td>96.7%</td>
<td>97.7% (173/177)</td>
<td>95.3% (261/274)</td>
<td>97.5% (392/402)</td>
<td>95.7% (396/414)</td>
</tr>
<tr>
<td>Antithrombotics at Discharge</td>
<td>Patients with ischemic stroke or TIA prescribed antithrombotic therapy at discharge (e.g., warfarin, aspirin, other antiplatelet drug).</td>
<td>85.0%</td>
<td>97.8%</td>
<td>98.6% (352/357)</td>
<td>99.7% (346/347)</td>
<td>99.3% (534/538)</td>
<td>99.6% (562/564)</td>
</tr>
<tr>
<td>Anticoagulation for Atrial Fibrillation/ Atrial Flutter</td>
<td>Patients with ischemic stroke or TIA with atrial fibrillation/flutter who are discharged on anticoagulation therapy.</td>
<td>85.0%</td>
<td>93.5%</td>
<td>97.2% (35/36)</td>
<td>98.4% (62/63)</td>
<td>98.7% (78/79)</td>
<td>97.7% (84/86)</td>
</tr>
<tr>
<td>DVT Prophylaxis</td>
<td>Patients with ischemic stroke, TIA or a hemorrhagic stroke and who are non-ambulatory who receive DVT prophylaxis by end of hospital day 2.</td>
<td>85.0%</td>
<td>91.8%</td>
<td>93.5% (217/232)</td>
<td>97.4% (261/268)</td>
<td>94.8% (507/535)</td>
<td>93.8% (410/437)</td>
</tr>
<tr>
<td>Lipids Measure (Statin at Discharge)</td>
<td>Ischemic stroke or TIA patients with LDL &gt; 100, or LDL not measured, or on cholesterol-reducer prior to admission, discharged on cholesterol-reducing drugs.</td>
<td>85.0%</td>
<td>89.2%</td>
<td>83.2% (228/274)</td>
<td>88.1% (230/261)</td>
<td>97.2% (350/360)</td>
<td>97.1% (370/381)</td>
</tr>
<tr>
<td>Smoking Cessation Counseling</td>
<td>Patients with ischemic, TIA or hemorrhagic stroke with a history of smoking cigarettes, who are, or whose caregivers are, given smoking cessation counseling during hospital stay.</td>
<td>85.0%</td>
<td>96.8%</td>
<td>100% (101/101)</td>
<td>92.4% (109/118)</td>
<td>92.9% (234/252)</td>
<td>99.5% (204/205)</td>
</tr>
<tr>
<td>Dysphagia Screening</td>
<td>Patients with ischemic or hemorrhagic stroke who undergo screen for dysphagia with an evidence-based bedside testing protocol approved by the hospital before being given any food, fluids, or medications by mouth.</td>
<td>85.0%</td>
<td>78.5%</td>
<td>--</td>
<td>67.9% (256/377)</td>
<td>73.7% (490/665)</td>
<td>84.8% (519/612)</td>
</tr>
<tr>
<td>Stroke Education</td>
<td>Patients with ischemic, TIA or hemorrhagic stroke or their caregivers who were given education and/or educational materials during the hospital stay.</td>
<td>85.0%</td>
<td>81.3%</td>
<td>--</td>
<td>41.4% (164/396)</td>
<td>80.6% (286/355)</td>
<td>89.9% (310/345)</td>
</tr>
<tr>
<td>Rehabilitation Considered</td>
<td>Patients with ischemic or hemorrhagic stroke who were assessed for rehabilitation services.</td>
<td>85.0%</td>
<td>96.6%</td>
<td>83.3% (30/36)</td>
<td>98.5% (393/399)</td>
<td>96.5% (684/709)</td>
<td>92.5% (593/641)</td>
</tr>
</tbody>
</table>

*Get With The Guidelines® (GWTG) is the premier hospital-based quality improvement program for the American Heart Association and the American Stroke Association, empowering healthcare provider teams to consistently treat stroke patients using current evidence-based guidelines. Cleveland Clinic is the recipient of the GWTG Stroke Gold Plus Performance Achievement Award and uses the GWTG aggregate comparative data for internal quality improvement. Rates are taken from the GWTG-Joint Commission Primary Stroke Center Reporting Tool, “Consensus-GWTG/PAA set,” as of February 15, 2011.

Inpatient Rehabilitation for Stroke

Length of Stay Efficiency for Stroke Inpatient Rehabilitation

2007 – 2010

Change in FIM Score/LOS

Outcomes are shown for all stroke patients at Cleveland Clinic Rehabilitation Hospitals using the Uniform Data System for Medical Rehabilitation (UDS-MR) data set (Rehabilitation Impairment Category/RIC Group 01). Length of stay (LOS) efficiency compares the functional improvement (FIM) gains made during the rehab stay with the length of stay required to make the gains (FIM change/LOS). Data are aggregated from Cleveland Clinic Rehabilitation Hospitals at Fairview (25 beds), Lakewood (15 beds) and Euclid (46 beds) hospitals, compared to the national average, and are case-mix adjusted by the UDS-MR database. Case mix values for each unit are: 1.51 at Euclid, 1.31 at Fairview and 1.4 at Lakewood. Data suggest that Cleveland Clinic Rehabilitation Hospitals return patients to a higher level of function in a shorter time than the national average.
Change in Outcomes after Stroke

2009 – 2010

The graph illustrates changes between first score after stroke and the last follow-up visit. Mean duration of follow-up was 187 days. The Barthel Index is a measure of disability widely used for stroke. The Stroke Impact Scale (SIS-16) assesses physical function. The National Institutes of Health Stroke Scale (NIHSS) is a brief, reliable measure of severity of neurological impairment following stroke. The Rankin Scale is a global disability scale for overall assessment of disability.
Cerebrovascular Disease

Change in Neurological Impairment over Acute Hospital Course (N = 128)

September – December 2010

Number of Patients

<table>
<thead>
<tr>
<th>Change in NIHSS Scores from Admission to Hospital Discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Patients</td>
</tr>
<tr>
<td>-10 -6 -3 -2 -1 0 1 2 3 4 5 6 7 8 9 10 11 16 2012 13 14</td>
</tr>
</tbody>
</table>

71.9% of stroke patients improved
18.7% remained stable
9.4% of stroke patients worsened

NIHSS = National Institutes of Health Stroke Scale

Change in Neurological Impairment 30 to 90 Days Postdischarge (N = 128)

September – December 2010

NIHSS

<table>
<thead>
<tr>
<th>NIHSS</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
</tr>
<tr>
<td>8</td>
</tr>
<tr>
<td>6</td>
</tr>
<tr>
<td>4</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Small Vessel</th>
<th>Large Artery Atherosclerosis</th>
<th>Cardioembolism</th>
<th>Combined</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 23</td>
<td>40</td>
<td>40</td>
<td>103</td>
</tr>
</tbody>
</table>

The graph illustrates the change in NIHSS score from acute presentation (Baseline) to follow-up 30 to 90 days after hospital discharge (Postdischarge), compared across stroke subtype. Lower scores reflect less impairment.
**Ischemic Stroke**

**Ischemic Stroke: Length of Stay (LOS)**

**Mean LOS (Days)**

<table>
<thead>
<tr>
<th>Year</th>
<th>N</th>
<th>Actual</th>
<th>Expected</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>434</td>
<td>8.0</td>
<td>8.6</td>
</tr>
<tr>
<td>2008</td>
<td>498</td>
<td>7.5</td>
<td>8.0</td>
</tr>
<tr>
<td>2009</td>
<td>561</td>
<td>7.0</td>
<td>7.5</td>
</tr>
<tr>
<td>2010</td>
<td>550</td>
<td>6.5</td>
<td>7.0</td>
</tr>
</tbody>
</table>

Actual mean LOS has remained shorter than expected for ischemic stroke. For this and subsequent graphs, expected mean LOS is based on national normative data and APR-DRGs.¹

**Ischemic Stroke: Inpatient Mortality**

**Number of Deaths**

<table>
<thead>
<tr>
<th>Year</th>
<th>N</th>
<th>Actual Deaths</th>
<th>Expected Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>434</td>
<td>20</td>
<td>25</td>
</tr>
<tr>
<td>2008</td>
<td>498</td>
<td>18</td>
<td>20</td>
</tr>
<tr>
<td>2009</td>
<td>561</td>
<td>16</td>
<td>18</td>
</tr>
<tr>
<td>2010</td>
<td>550</td>
<td>14</td>
<td>16</td>
</tr>
</tbody>
</table>

Among inpatients treated for ischemic stroke at Cleveland Clinic, actual mortality remained below expected. For this and subsequent graphs, expected mortality is based on national normative data and APR-DRGs.¹

¹. [http://solutions.3m.com/wps/portal/3M/en_US/3M_Health_Information_Systems/HIS/Products/APRDRG_Software/](http://solutions.3m.com/wps/portal/3M/en_US/3M_Health_Information_Systems/HIS/Products/APRDRG_Software/)
Hemorrhagic Stroke

Intracerebral Hemorrhage: Length of Stay (LOS)

Mean LOS (Days)

<table>
<thead>
<tr>
<th>Year</th>
<th>N</th>
<th>Actual</th>
<th>Expected</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>139</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2008</td>
<td>161</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2009</td>
<td>172</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td>167</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Among inpatients treated for intracerebral hemorrhage at Cleveland Clinic, actual mean LOS was lower than expected.

Intracerebral Hemorrhage: Inpatient Mortality

Number of Deaths

<table>
<thead>
<tr>
<th>Year</th>
<th>Actual Deaths</th>
<th>Expected Deaths</th>
<th>SMR</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>139</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2008</td>
<td>161</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2009</td>
<td>172</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td>167</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Actual mortality was below expected in 2008, 2009 and 2010.
**Subarachnoid Hemorrhage**

**Subarachnoid Hemorrhage: LOS**

**Mean LOS (Days)**

<table>
<thead>
<tr>
<th>Year</th>
<th>Actual</th>
<th>Expected</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>110</td>
<td>128</td>
</tr>
<tr>
<td>2008</td>
<td>128</td>
<td>143</td>
</tr>
<tr>
<td>2009</td>
<td>143</td>
<td>157</td>
</tr>
<tr>
<td>2010</td>
<td>157</td>
<td>143</td>
</tr>
</tbody>
</table>

**Subarachnoid Hemorrhage: Inpatient Mortality**

**Number of Deaths**

<table>
<thead>
<tr>
<th>Year</th>
<th>Actual</th>
<th>Expected</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>110</td>
<td>128</td>
</tr>
<tr>
<td>2008</td>
<td>128</td>
<td>143</td>
</tr>
<tr>
<td>2009</td>
<td>143</td>
<td>157</td>
</tr>
<tr>
<td>2010</td>
<td>157</td>
<td>143</td>
</tr>
</tbody>
</table>

Inpatient mortality due to subarachnoid hemorrhage has been consistently below the expected rate.
### Intracerebral Hemorrhage, Subarachnoid Hemorrhage and Ischemic Stroke: Discharge Status

#### 2010

<table>
<thead>
<tr>
<th></th>
<th>Intracerebral Hemorrhage</th>
<th>Subarachnoid Hemorrhage</th>
<th>Ischemic Stroke</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Rehab</td>
<td>21%</td>
<td>15%</td>
<td>25%</td>
</tr>
<tr>
<td>Home</td>
<td>22%</td>
<td>36%</td>
<td>34%</td>
</tr>
<tr>
<td>Home with Home Health Services</td>
<td>6%</td>
<td>8%</td>
<td>10%</td>
</tr>
<tr>
<td>Skilled Nursing Facility/Interim Care</td>
<td>24%</td>
<td>22%</td>
<td>24%</td>
</tr>
<tr>
<td>Death</td>
<td>25%</td>
<td>15%</td>
<td>7%</td>
</tr>
<tr>
<td>Other</td>
<td>3%</td>
<td>4%</td>
<td>1%</td>
</tr>
<tr>
<td>Total Number of Patients</td>
<td>167</td>
<td>157</td>
<td>550</td>
</tr>
</tbody>
</table>

The national average for inpatient death following subarachnoid hemorrhage (ruptured aneurysm) was 29.4 percent in 1990-1991 and 26.5 percent in 2000-2001.²

---

Cleveland Clinic’s Lou Ruvo Center for Brain Health (CCLRCBH) provides state-of-the-art care for cognitive disorders and for the family members of those who suffer from them. The physicians and staff at the CCLRCBH are working toward the development of early diagnosis, conducting clinical trials of promising new medications and advancing understanding of cognitive disorders. The ultimate goal is to delay the onset of or prevent Alzheimer’s disease.

Quality of Life Compared across Different Cognitive Disorders

2010

Mean EQ-5D Index

<table>
<thead>
<tr>
<th>Disorder</th>
<th>Mean EQ-5D Index</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alzheimer’s Disease</td>
<td>0.93</td>
<td>158</td>
</tr>
<tr>
<td>Mild Cognitive Impairment</td>
<td>0.82</td>
<td>83</td>
</tr>
<tr>
<td>Frontotemporal Dementia</td>
<td>0.68</td>
<td>26</td>
</tr>
<tr>
<td>Other Dementia</td>
<td>0.67</td>
<td>27</td>
</tr>
</tbody>
</table>

Over a one-year observation period, patients with Alzheimer’s disease and mild cognitive impairment tended to have an improvement or stabilization of their quality of life, as measured with the EQ-5D, while those with frontotemporal dementia or other dementia syndromes tended to have worsening quality of life. Mean interval between first and last visits in 2010 was 97, 64, 96 and 158 days for those with Alzheimer’s disease, mild cognitive impairment, frontotemporal dementia and other dementia, respectively. Improvement was defined as any positive change in score.
Depressive symptoms, as measured with the Geriatric Depression Scale (GDS-SF), are common across all cognitive disorders and show great variability when followed over time. These symptoms are an important management focus, and patients with more severe mood changes should be treated with antidepressants. Mean interval between first and last visits in 2010 was 105, 106, 68 and 126 days for those with Alzheimer’s disease, mild cognitive impairment, frontotemporal dementia and other dementia, respectively.

### Depression Compared across Different Cognitive Disorders

#### Mean GDS-SF Score

<table>
<thead>
<tr>
<th>Disorder</th>
<th>Mean GDS-SF Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alzheimer's Disease</td>
<td>145</td>
</tr>
<tr>
<td>Mild Cognitive Impairment</td>
<td>73</td>
</tr>
<tr>
<td>Frontotemporal Dementia</td>
<td>22</td>
</tr>
<tr>
<td>Other Dementia</td>
<td>21</td>
</tr>
</tbody>
</table>

#### Change in Depression Compared across Different Cognitive Disorders

<table>
<thead>
<tr>
<th>Disorder</th>
<th>Patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alzheimer's Disease</td>
<td>0.32</td>
</tr>
<tr>
<td>Mild Cognitive Impairment</td>
<td>0.15</td>
</tr>
<tr>
<td>Frontotemporal Dementia</td>
<td>0.60</td>
</tr>
<tr>
<td>Other Dementia</td>
<td>0.13</td>
</tr>
</tbody>
</table>
Epilepsy is a chronic condition, with a wide array of symptoms and implications. Its main effects are determined by the frequency and severity of seizures. Cleveland Clinic’s Epilepsy Center is a national and international leader for the diagnosis and management of patients with epilepsy. The outcomes below highlight our treatment results using our highly integrated multidisciplinary approach. We are reporting our seizure outcomes for the large subgroups of patients treated only with medications, as well as the relatively smaller subgroups also treated with epilepsy surgery.

**Seizure Frequency and Severity**

The effect of medical treatment on seizure severity and frequency was assessed using the Liverpool Seizure Severity Scale (LSSS),¹ a validated, patient-completed questionnaire developed to quantify the patient’s own perception of change in seizure severity. Higher scores reflect more severe seizures.

**Seizure Severity in Medically Treated Adult Epilepsy Patients (N = 723)**

2008 – 2010

Seizure severity improved significantly on medical therapy, with the mean LSSS score improving from 31.3 (± 1.1 s.e.) at initial visit to 18.7 (± 1.1 s.e.) at last follow-up (P < 0.0001). Mean duration of follow-up was 15.6 months; minimum duration was six months.

Seizure Frequency in Medically Treated Adult Epilepsy Patients (N = 765)

2007 – 2010

<table>
<thead>
<tr>
<th></th>
<th>Cleveland Clinic</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responder Rate (≥ 50% reduction in seizure frequency)</td>
<td>64%</td>
<td>12-29%</td>
</tr>
<tr>
<td>Percent Seizure-free at 6 Months</td>
<td>44%</td>
<td>--</td>
</tr>
<tr>
<td>Percent Seizure-free at 12 Months</td>
<td>53%</td>
<td>17-29%</td>
</tr>
</tbody>
</table>

Sixty-four percent of our patients seen from 2007 through 2010 and treated with medications alone (N = 765 patients) showed a 50 percent or greater reduction in seizure frequency by last follow-up visit (mean duration of follow-up = 10 months), compared to 12 to 29 percent of patients in a recent meta-analysis of series published from multiple epilepsy centers. In terms of seizure freedom, 44 percent of our patients were completely seizure-free at six months and 53 percent were completely seizure-free at 12 months. Half of these patients had long-standing intractable epilepsy, and their rate of seizure freedom at 12 months based on national data is only 5 to 8 percent, and half were newly diagnosed, and their rate of seizure freedom at 12 months based on national data varies from 29 to 50 percent. As such, the expected rate of seizure freedom in our patients at one year based on national data should have been 17 to 29 percent. Instead, we achieved seizure freedom in 53 percent.

Seizure Severity in Medically Treated Pediatric Epilepsy Patients (N = 85)

2009 – 2010

In the pediatric age group, the LSSS also showed a significant improvement from the initial visit to the last follow-up in patients treated with medications alone (reduction in mean LSSS from 36.4 (± 2.6 s.e. of the mean) to 21.5 (± 2.6 s.e.) (P < 0.0001)). N = the number of patients with greater than three months of follow-up. Mean duration of follow-up was 6.8 months.

Seizure Frequency in Medically Treated Pediatric Epilepsy Patients (N = 120)

2009 – 2010

<table>
<thead>
<tr>
<th></th>
<th>Cleveland Clinic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responder Rate (≥ 50% reduction in seizure frequency)</td>
<td>61%</td>
</tr>
<tr>
<td>Percent Seizure-free at 6 Months</td>
<td>44%</td>
</tr>
<tr>
<td>Percent Seizure-free at 12 Months</td>
<td>53%</td>
</tr>
</tbody>
</table>

Pediatric patients also saw a reduction in seizure frequency: 61 percent of the patients seen from 2009 through 2010 had a 50 percent or greater reduction in seizure frequency. N = 120 patients with mean duration of follow-up of 5.3 months. Forty-four percent became completely seizure-free at six months of follow-up after their initial visit.
Seizure Outcomes Following Epilepsy Surgery (Adult and Pediatric Patients)

Long-term chances of achieving and maintaining seizure freedom following various types of epilepsy surgery are shown in the following graphs. Whenever possible, our data were compared to national published data. We used the widely accepted Engel classification of seizure freedom to classify our seizure outcomes (seizure-free = Engel class 1).

Long-Term Seizure Freedom in Adult and Pediatric Patients Following Epilepsy Surgery (N = 1,594)

Surgical Dates: 1996 – 2010

<table>
<thead>
<tr>
<th>Years from Surgery</th>
<th>1 Year</th>
<th>2 Years</th>
<th>5 Years</th>
<th>10 Years</th>
<th>12 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Seizure-free (overall group)</td>
<td>76%</td>
<td>71%</td>
<td>62%</td>
<td>50%</td>
<td>44%</td>
</tr>
<tr>
<td>% Seizure-free (adult epilepsy)</td>
<td>72%</td>
<td>66%</td>
<td>56%</td>
<td>48%</td>
<td>43%</td>
</tr>
<tr>
<td>% Seizure-free (pediatric epilepsy)</td>
<td>80%</td>
<td>76%</td>
<td>67%</td>
<td>50%</td>
<td>44%</td>
</tr>
</tbody>
</table>

Forty-four percent of patients with previously medically intractable epilepsy remained seizure-free 12 years after surgical treatment at Cleveland Clinic’s Epilepsy Center. The overall curve of seizure outcomes shows similar long-term chances of seizure freedom in adult and pediatric patients who underwent epilepsy surgery at the center from 1996 through 2010.

Long-Term Seizure Freedom Following Temporal Lobe Epilepsy Surgery (N = 830)

Surgical Dates: 1996 – 2010

Temporal lobe epilepsy surgery is the most common type of brain surgery performed for the treatment of intractable epilepsy. The graph illustrates the percent of adult and pediatric patients who were seizure-free up to 10 – 15 years following a temporal lobe resection. National averages represent a weighted average of recent studies conducted in the United States.⁷-¹³

<table>
<thead>
<tr>
<th>Years from Surgery</th>
<th>1 Year</th>
<th>2 Years</th>
<th>5 Years</th>
<th>10 Years</th>
<th>15 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Seizure-free (Cleveland Clinic)</td>
<td>77%</td>
<td>72%</td>
<td>63%</td>
<td>57%</td>
<td>40%</td>
</tr>
<tr>
<td>% Seizure-free (national average)</td>
<td>72%</td>
<td>54%</td>
<td>59%</td>
<td>51%</td>
<td>NA</td>
</tr>
</tbody>
</table>


Frontal lobe resection is the second most commonly performed epilepsy surgery procedure. This type of epilepsy surgery is traditionally considered the most challenging. The graph reflects seizure outcome in 324 adult and pediatric patients with previously medically intractable frontal lobe epilepsy operated on between 1997 and 2010.

**Long-Term Seizure Freedom Following Frontal Lobe Epilepsy Surgery (N = 324)**

**Surgical Dates: 1997 – 2010**

<table>
<thead>
<tr>
<th>Years from Surgery</th>
<th>1 Year</th>
<th>2 Years</th>
<th>5 Years</th>
<th>10 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Seizure-free</td>
<td>63%</td>
<td>56%</td>
<td>45%</td>
<td>31%</td>
</tr>
</tbody>
</table>
Surgical outcomes for frontal lobe epilepsy surgery have improved over time, likely due to the introduction and use of state-of-the-art diagnostic and surgical techniques. Close to one-half of the patients operated on after 2000 are seizure-free at five years, compared to one-third of those operated on before 2000.

<table>
<thead>
<tr>
<th>Years from Surgery</th>
<th>1 Year</th>
<th>2 Years</th>
<th>5 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Seizure-free - 2000 or After</td>
<td>65%</td>
<td>58%</td>
<td>47%</td>
</tr>
<tr>
<td>% Seizure-free - Before 2000</td>
<td>53%</td>
<td>48%</td>
<td>33%</td>
</tr>
</tbody>
</table>
Long-Term Seizure Freedom Following Posterior Quadrant Resection (N = 111)

Surgical Dates: 1997 – 2010

Posterior quadrant resection is used to treat intractable epilepsy involving the posterior temporal, parietal, and/or occipital regions. The graph reflects the percent of patients who continue to be completely seizure-free up to eight years following a posterior quadrant resection.

<table>
<thead>
<tr>
<th>Years from Surgery</th>
<th>1 Year</th>
<th>2 Years</th>
<th>5 Years</th>
<th>8 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Seizure-free</td>
<td>81%</td>
<td>79%</td>
<td>75%</td>
<td>75%</td>
</tr>
</tbody>
</table>
Long-Term Seizure Freedom Following *Hemispherectomy* (N = 207)

**Surgical Dates: 1997 – 2010**

Patients with life-threatening, catastrophic epilepsy may be candidates for hemispherectomy, one of the most demanding types of epilepsy surgery. The graph reflects the percent of patients who continue to be completely seizure-free up to eight years following a hemispherectomy.

<table>
<thead>
<tr>
<th>Years from Surgery</th>
<th>1 Year</th>
<th>2 Years</th>
<th>5 Years</th>
<th>8 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Seizure-free</td>
<td>88%</td>
<td>83%</td>
<td>75%</td>
<td>69%</td>
</tr>
</tbody>
</table>
Epilepsy Outcomes Beyond Seizure Frequency and Severity

At the Epilepsy Center, we strongly believe that the burden of epilepsy extends beyond a “seizure count” and that the effect of the multidisciplinary and highly integrated care we provide (either medical or surgical) should be long-lasting and extend beyond simply treating seizures. As a result, the Outcomes Research Program was established in 2008 to provide a systematic long-term follow-up of patients undergoing epilepsy surgery and to create a mechanism for a comprehensive 360° assessment of our treatment outcomes during every outpatient clinic visit, including an evaluation of quality of life, mood and psychosocial functioning, in addition to seizure frequency and severity.

Adult Epilepsy: Effect of Treatment on Quality of Life

A successful epilepsy treatment should translate into a better quality of life, and not simply fewer seizures. We assess quality of life in every outpatient clinic visit using the Quality of Life in Epilepsy questionnaire (QOLIE-10), a 10-item validated patient-completed questionnaire covering general and epilepsy-specific domains: epilepsy effects (memory, physical effects and mental effects of medication), mental health (energy, depression, overall quality of life) and role functioning (seizure worry, work, driving, social limits). Lower scores reflect a better quality of life. Quality of life improved in both the medical and surgical groups.

Quality of Life in Medically Treated Adult Epilepsy Patients (N = 595)

2008 – 2010

In the medically treated group, the mean QOLIE-10 score improved from 23.1 (± 0.4) at the initial visit to 20.9 (± 0.4) at the last follow-up (P < 0.0001). The standard box plots reflect the median and the 25th and 75th quartiles. N = adult epilepsy patients treated with medications only and with greater than six months of follow-up. Mean duration of follow-up was 15.2 months.
Quality of Life in Surgically Treated Adult Epilepsy Patients (N = 168)

2008 – 2010

In the surgically treated patients, the mean QOLIE-10 score also improved from 27.9 (± 0.7) at the initial visit to
22.3 (± 0.6) at the last follow-up (P < 0.0001). The standard box plots reflect the median and the 25th and 75th quartiles. N = adult epilepsy patients with greater than six months of follow-up after epilepsy surgery. Mean duration of follow-up was 15.7 months.
Adult Epilepsy: Effect of Treatment on Mood

Mood disorders, especially depression, are very common in patients with epilepsy. We routinely screen for depressive symptoms using the PHQ-9 in order to identify and actively treat depression as soon as possible, using Primary Care Depression Treatment Guidelines. Early identification and treatment should result in improvement in our patients’ care, given the significant impact of depression on quality of life. In fact, mood did improve in both the medical and surgical groups.

Improvement in Depressive Symptoms in Surgically Treated Patients (N = 116)

2008 – 2010

The mean PHQ-9 score was 8.4 (± 0.6) before surgery as opposed to 6.5 (± 0.6) at the last follow-up visit, reflecting a 23 percent reduction in score severity (P = 0.03). The main improvement was observed in patients with moderate to severe depression at their initial visit. The standard box plots reflect the median and the 25th and 75th quartiles. N = adult epilepsy patients with greater than six months of follow-up after epilepsy surgery. Mean duration of follow-up was 13.1 months.

Improvement in Depressive Symptoms in Medically Treated Patients (N = 447)

2008 – 2010

The mean PHQ-9 score improved from 7.9 (± 0.3) at the initial visit to 6.0 (± 0.3) at the last follow-up visit, reflecting a 25 percent reduction in depression score severity (P < 0.0001). The standard box plots reflect the median and the 25th and 75th quartiles. N = adult epilepsy patients treated with medications only and with greater than six months of follow-up. Mean duration of follow-up was 12.4 months.
Anxiety was assessed using the Generalized Anxiety Disorder questionnaire (GAD-7), a patient-completed validated measure screening for symptoms of anxiety. The mean GAD-7 score improved from 6.2 (± 0.6) before surgery to 4.7 (± 0.6) at the last follow-up visit in patients who underwent epilepsy surgery (P = 0.09). The standard box plots reflect the median and the 25th and 75th quartiles. N = adult epilepsy patients with greater than six months of follow-up. Mean duration of follow-up was 11.7 months.
Anxiety also improved in adult patients treated with medications alone: the mean GAD-7 score at the initial visit was 5.7 (± 0.3), significantly higher than the mean score of 4.5 (± 0.3) seen at last follow-up (P = 0.007). The standard box plots reflect the median and the 25th and 75th quartiles. N = adult epilepsy patients with greater than six months of follow-up. Mean duration of follow-up was 11.2 months.
Change in Driving Status in Adult Epilepsy Patients

Driving Status in Surgically Treated Patients (N = 205)

2008 – 2010

Driving restrictions are a significant limitation for patients with uncontrolled epilepsy. Recovering the ability to drive is mostly dependent on the ability to regain seizure control. While only 9 percent of our surgical patients were driving before surgery, 29 percent were doing so after six months (P < 0.0001). N = adult epilepsy patients with greater than six months of follow-up. Mean duration of follow-up was 15.4 months.
Driving Status in Medically Treated Patients (N = 784)

2008 – 2010

In the medical group, 37 percent were driving at their first visit as opposed to 48 percent at last follow-up (P < 0.0001). N = adult epilepsy patients with greater than six months of follow-up. Mean duration of follow-up was 15.1 months.
Pediatric Epilepsy: Effect of Treatment on Healthcare Utilization

Treatment benefits for patients in the pediatric age group also extended beyond the improvements seen in seizure frequency and severity.

Hospitalizations in Surgically Treated Pediatric Epilepsy Patients (N = 66)

2009 – 2010

Number of Hospitalizations

Healthcare utilization improved significantly from the initial visit to the last follow-up. This was determined based on a reduction in the number of hospitalizations in the three months preceding the visit, which decreased from a mean of 0.41 hospitalizations over three months (± 0.07) at initial visit to a mean of 0.11 (± 0.01) at last visit (P = 0.0034). This represents an approximately 75 percent reduction in frequency of hospitalization. N = pediatric patients with greater than three months of follow-up. Mean duration of follow-up was 10.5 months.
Emergency Room Visits in Surgically Treated Pediatric Epilepsy Patients (N = 65)

2009 – 2010

Although not statistically significant, there was a reduction in the frequency of emergency room visits, from a mean of 0.22 emergency room visits (± 0.07) in the three months preceding the initial visit to 0.05 (± 0.07) at last follow-up visit (P = 0.11). N = pediatric patients with greater than three months of follow-up. Mean duration of follow-up was 10.5 months.
Pediatric Epilepsy: Effect of Treatment on Functional Outcome

School Days Missed in Surgically Treated Pediatric Epilepsy Patients (N = 47)

2009 – 2010

Following surgery, there was a nearly 75 percent reduction in the number of days a child missed from school in the three months preceding the initial visit, from a mean of 6.3 days (± 1.3) at initial visit to 1.5 days (± 1.3) at last follow-up visit (P = 0.009). N = pediatric patients with greater than six months of follow-up.
Improvement in Motor Symptoms of Parkinson’s Disease before and after Deep Brain Stimulation (N = 42)

Surgical Dates: January 2010 – February 2011

The Unified Parkinson’s Disease Rating Scale Part II (UPDRS II) is a self-administered scale with items covering activities of daily living, including speech, swallowing, washing, dressing, feeding, writing, hobbies and work-related activities, moving in bed, standing from a chair and walking. The scale also includes items more related to common movement disorders: functional impact of tremor, drooling, and freezing of gait. Higher numbers reflect worse symptoms. There is improvement in Parkinson’s disease motor symptoms following deep brain stimulation (DBS) surgery. The graph shows UPDRS II scores (mean and s.e.) preoperatively and at most recent follow-up. Average duration of follow-up was 113 days.
Change in Motor Symptoms over Time for All Movement Disorder Patients

2010

The top graph shows the change in UPDRS II activities of daily living score, from visit one to visit two, for all movement disorder diagnoses; the bottom graph depicts the change from visit one to visit three. Most diagnoses are progressive conditions with symptoms expected to worsen over time. Despite this, evaluation and treatment in Movement Disorders clinic, on average, improves symptoms, as assessed by ability to perform daily activities. Average interval between visits was 85 days between visits 1 and 2, and 174 days between visits 1 and 3. Mean change for visit 2 was 20 percent improvement, and the mean change for visit 3 was 29 percent.
Botulinum toxin injection was used for four indications: hemifacial spasm (HFS), blepharospasm, sialorrhea and torticollis (cervical dystonia). Each circle represents one patient. At the time of their most recent follow-up appointment, patients rated the overall improvement in symptoms since the last injection using the Global Improvement Score (GIS), which ranges from 0 to 100 percent, with 0 percent indicating no improvement and 100 percent indicating complete resolution of symptoms.
Multiple Sclerosis

Mellen Center Patient Characteristics

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Patients (N = 3,369)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>73%</td>
</tr>
<tr>
<td>Caucasian</td>
<td>84%</td>
</tr>
<tr>
<td>Mean Age</td>
<td>48 years</td>
</tr>
<tr>
<td>Married</td>
<td>64%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Multiple Sclerosis Subtype</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Relapsing-Remitting</td>
<td>61%</td>
</tr>
<tr>
<td>Secondary Progressive without Relapses</td>
<td>14%</td>
</tr>
<tr>
<td>Secondary Progressive with Relapses</td>
<td>7%</td>
</tr>
<tr>
<td>Primary Progressive</td>
<td>6%</td>
</tr>
</tbody>
</table>

Changes in Health Status over Time

Multiple sclerosis (MS) is a disease of great variability and it is difficult to advise individuals about how their disease will progress over time. To better understand how health status and well-being change over time, we collected and analyzed five health status measures (EQ-5D, PHQ-9, Multiple Sclerosis Performance Scale (MSPS), Timed 25-Foot Walk (T25FW) and Timed 9-Hole Peg Test) in 2010 and segmented that data by time since diagnosis in five-year increments.
Cross-sectional analysis of PHQ-9 scores shows gradual decline in depression scores by years since diagnosis with significantly worse values in individuals with disease duration of 10 to 14.99 years compared to those who have had MS for five years or less (P = 0.007).

EQ-5D scores gradually decline by years since diagnosis, with significantly worse values in individuals with disease duration of 15 to 19.99 years, compared to those who have had MS for five years or less (P = 0.025).
The MSPS is a validated measure of MS-related disability with higher scores indicating worse functioning. In this cohort, scores are significantly worsened with every five-year increment from time of diagnosis.

The T25FW is a measure of lower extremity disability with higher scores indicating worse functioning. In this cohort, scores are significantly worsened with every five-year increment from time of diagnosis.
Upper Extremity Function in 5-Year Increments since MS Diagnosis

2010

The 9-Hole Peg Test is a measure of upper extremity disability with higher scores indicating worse functioning. These data demonstrate gradual worsening in upper extremity function by years since diagnosis; such function is significantly worse for individuals with disease duration of 10 to 14.99 years compared to those who have had MS for five years or less (P = 0.007).
Establishing Health Status Measure Benchmarks for Multiple Sclerosis

There are no established health status measure benchmarks for clinical MS populations. Development and confirmation of such benchmarks are important for purposes of comparative effectiveness research and the development of symptom severity comparisons across different sites. Here we compare the relative stability of the overall scores for the PHQ-9, EQ-5D, MSPS, T25FW and 9-Hole Peg Test, health status measures used at the Mellen Center, over a three-year period. A mixed model ANOVA was used to make these comparisons.

Consistency of Depression Scores over Years

<table>
<thead>
<tr>
<th>Mean PHQ-9 Score</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>743</td>
<td>3,138</td>
<td>3,324</td>
</tr>
</tbody>
</table>

PHQ-9 scores were significantly higher in 2008 (P = 0.002), while the scores remained stable over 2009 and 2010. The increasing sample size and longitudinal data are informative for interpreting these results.
Quality of Life Scores over Years

Quality of life, as measured with the EQ-5D, remained stable over the three-year period (overall $P = 0.335$).

MS-Related Disability Scores over Years

MS-related disability scores, as measured with the MSPS, remained stable over the three-year period (overall $P = 0.086$).
Gait or lower extremity function, as measured with the T25FW, was significantly worse in 2010 (overall P = 0.009), but the actual change in value was relatively low.

Arm function, as measured by the 9-Hole Peg Test, remained stable over the three-year period (overall P = 0.065).
Disease-Modifying Therapy for Multiple Sclerosis

A major initiative at the Mellen Center is to monitor and document patients' self-reported adherence to their MS disease-modifying therapies (DMT). These medications, most of which are injectable, are proven to slow disease progression, and it is important that they are taken routinely. We set a target goal of patients achieving greater than 75 percent adherence from one office visit to the next, usually at six-month intervals.

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Patients</td>
<td>1,058</td>
<td></td>
</tr>
<tr>
<td>Patients not Receiving DMT</td>
<td>367</td>
<td>35%</td>
</tr>
<tr>
<td>Patients Receiving DMT</td>
<td>691</td>
<td>65%</td>
</tr>
<tr>
<td>No Doses Missed</td>
<td>570</td>
<td>82.5%</td>
</tr>
<tr>
<td>At Least 75% Adherent</td>
<td>677</td>
<td>97%</td>
</tr>
</tbody>
</table>

Adherence to MS Disease-Modifying Therapy (N = 691)

As expected, patients experiencing side effects from therapy are less likely to be adherent.
## Treatment with Natalizumab (Tysabri®)

Natalizumab (Tysabri®) is an FDA-approved disease-modifying therapy for multiple sclerosis, which is often used when other MS treatments have failed. It is infused on a monthly basis. While it is associated with a rare complication (progressive multifocal leukoencephalopathy) that has occurred in 1 in 1,000 cases, it has also demonstrated the ability to improve MS health status. We evaluated health status before treatment initiation and again six months after, using the EQ-5D, PHQ-9, MSPS, T25FW and 9-Hole Peg Test. Our inability to demonstrate significant change on any of these measures is most likely due to the small sample size.

### Quality of Life before and after Tysabri® Treatment (N = 29)

Treatment Start Dates: July 1, 2009 – June 30, 2010

Quality of life, as measured with the EQ-5D, was stable after six months of treatment ($P = 0.24$).
Depressive Symptoms before and after Tysabri® Treatment (N = 29)

Treatment Start Dates: July 1, 2009 – June 30, 2010

Likewise, depressive symptoms, as measured with the PHQ-9, were less after six months of treatment, but the difference did not reach statistical significance (P = 0.28).

Disability before and after Tysabri® Treatment (N = 27)

Treatment Start Dates: July 1, 2009 – June 30, 2010

Data suggest an improvement in MS-related disability (lower scores indicate less disability) after six months of treatment, but did not reach statistical significance (P = 0.06).
Multiple Sclerosis

Walking Times before and after Tysabri® Treatment (N = 29)

Treatment Start Dates: July 1, 2009 – June 30, 2010

Mean T25FW Score (Seconds)

Data suggest an improvement in gait (decrease in walking times with the T25FW) following six months of treatment, but we were not able to demonstrate a statistically significant change (P = 0.23), likely due to the small sample size.

Arm Function before and after Tysabri® Treatment (N = 29)

Treatment Start Dates: July 1, 2009 – June 30, 2010

Mean 9-Hole Peg Test Score

Arm function, as measured with the 9-Hole Peg Test, was stable after six months of treatment (P = 0.57).
Treatment with Dalfampridine (Ampyra®)

Walking is limited in most MS patients, and lower limb function has been rated the most important bodily function by MS patients. Dalfampridine (Ampyra®) is an extended-release form of 4-aminopyridine, which was approved by the FDA to improve walking in patients with MS, based on an improvement of walking speed in two phase III clinical trials. Walking speed was measured with the T25FW. The average improvement in T25FW among responders to dalfampridine was 25 percent. A change of 20 percent on the T25FW has been identified as clinically significant.¹

We analyzed data on 122 Mellen Center patients with MS who started dalfampridine since FDA approval, and who had at least one follow-up visit after starting the medication. The T25FW was systematically performed and collected at all clinic visits, as part of routine clinical care. We analyzed the change in T25FW between baseline and the first follow-up visit on treatment.

Dalfampridine Patient Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Subjects</td>
<td>122</td>
</tr>
<tr>
<td>Age</td>
<td>Mean = 53.1, range = 28 - 74</td>
</tr>
<tr>
<td>Gender</td>
<td>Females = 73 (60%)</td>
</tr>
<tr>
<td></td>
<td>Males = 49 (40%)</td>
</tr>
<tr>
<td>MS Subtype</td>
<td>Relapsing-Remitting = 31 (25%)</td>
</tr>
<tr>
<td></td>
<td>Secondary Progressive = 68 (56%)</td>
</tr>
<tr>
<td></td>
<td>Primary Progressive = 19 (16%)</td>
</tr>
<tr>
<td></td>
<td>Progressive-Relapsing = 4 (3%)</td>
</tr>
<tr>
<td>Disease Duration</td>
<td>Mean = 18.0 years, range = 2 - 51</td>
</tr>
<tr>
<td>Time on Dalfampridine before Assessment</td>
<td>Mean = 77.8 days, range = 3 - 246</td>
</tr>
<tr>
<td>Time between Gait Assessments (pre/post)</td>
<td>Mean = 164.2 days, range = 23 - 658</td>
</tr>
<tr>
<td>Pre-dalfampridine T25FW Score</td>
<td>Mean = 17.6 seconds; range = 3.9 - 194.2</td>
</tr>
</tbody>
</table>

Using a 20 percent change as clinically significant, 22 percent of patients (N = 27) exhibited a clinically significant improvement on the T25FW between baseline and the first follow-up visit on treatment. A logistic regression analysis showed that baseline walking time is a significant predictor of response to dalfampridine (P = 0.003), with slower walkers at baseline being more likely to have a clinically significant improvement (5 percent increase for each second).
Intrathecal Baclofen Therapy

Intrathecal baclofen (ITB) therapy is approved by the FDA for the treatment of severe spasticity of spinal or cerebral origin refractory to other treatment modalities. The Mellen Center has been using this therapeutic modality since its approval, with over 300 patients treated since 1990. The intrathecal infusion device (baclofen pump) is implanted by neurosurgeons in the Center for Neurological Restoration at Cleveland Clinic. Patient selection, testing and postoperative management are performed in the Mellen Center Spasticity Clinic.

From January 2007 to October 2010, 81 patients underwent implantation of a baclofen pump.

<table>
<thead>
<tr>
<th>Diagnosis/Indication for ITB</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiple Sclerosis</td>
<td>41</td>
</tr>
<tr>
<td>Motor Neuron Disease</td>
<td>5</td>
</tr>
<tr>
<td>Cerebral Palsy</td>
<td>8</td>
</tr>
<tr>
<td>Traumatic Brain Injury</td>
<td>2</td>
</tr>
<tr>
<td>Spinal Cord Injury</td>
<td>6</td>
</tr>
<tr>
<td>Stroke</td>
<td>4</td>
</tr>
<tr>
<td>Myelopathy</td>
<td>10</td>
</tr>
<tr>
<td>Other (stiff person syndrome, cerebral arteritis, anoxic brain injury, adrenomyeloneuropathy)</td>
<td>5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>81</strong></td>
</tr>
</tbody>
</table>
Spasticity before and after Intrathecal Baclofen

January 2007 – October 2010

Mean Spasticity Score

Spasticity scores on the Modified Ashworth Scale (0 = no increase in tone, 4 = severe increase in tone) indicate improvement after ITB therapy. There was a statistically significant (P < 0.0001, paired t-test) reduction in spasticity at early follow-up. Average follow-up was 145 and 718 days for early and last follow-up, respectively.

Spasm Frequency before and after Intrathecal Baclofen

January 2007 – October 2010

Mean Spasm Frequency Score

Spasm Frequency Scale scores (0 = no spasms, 4 = more than 10 spasms/hour) before treatment, at early follow-up and at last follow-up show statistically significant reductions after ITB treatment (P < 0.0001). Average follow-up was 145 and 718 days for early and last follow-up, respectively.
**Pain Score before and after Intrathecal Baclofen**

January 2007 – October 2010

<table>
<thead>
<tr>
<th>Mean Pain Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
</tr>
<tr>
<td>8</td>
</tr>
<tr>
<td>6</td>
</tr>
<tr>
<td>4</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>0</td>
</tr>
</tbody>
</table>

- **Before Treatment**: 81
- **Early Follow-up**: 77
- **Last Follow-up**: 46

Pain scores (0 = no pain, 10 = worst pain possible) before and after ITB therapy show a statistically significant reduction in pain at early follow-up ($P = 0.007$). Average follow-up was 145 and 718 days for early and last follow-up, respectively.

---

**Ambulating Following ITB**

The Mellen Center has developed expertise in the use of ITB therapy in ambulatory patients. ITB therapy in this population has the same potential benefits in terms of reduction of bothersome spasticity that may interfere with activities of daily living, sleep and quality of life in general. However, a common concern about ITB is that it may cause increased weakness with loss of function.

**Gait Speed before and after Intrathecal Baclofen**

January 2007 – October 2010

<table>
<thead>
<tr>
<th>Mean T25FW Score (Seconds)</th>
</tr>
</thead>
<tbody>
<tr>
<td>30</td>
</tr>
<tr>
<td>20</td>
</tr>
<tr>
<td>10</td>
</tr>
<tr>
<td>0</td>
</tr>
</tbody>
</table>

- **Before Treatment**: 81
- **Early Follow-up**: 77
- **Last Follow-up**: 46

Following ITB, there was no statistically significant change in mean gait speed, as measured with the T25FW for the patients who remained ambulatory.
Quality of Life in Myasthenia Gravis Patients (N = 26)

2010

Mean MG-QOL15 Score

The MG-QOL15 is a quality-of-life questionnaire specific to myasthenia gravis (MG) that assesses both physical and psychological aspects of function. The MG-QOL15 has been shown to correlate well with clinical outcomes using physician impression as the gold standard. There is a reduction in mean MG-QOL15 from first to last visit. Average time between visits was 88 days.

Myasthenia Gravis Functional Status (N = 95)

2009 – 2010

Mean MG-ADL Score

The MG-ADL profile is a simple eight-item questionnaire that focuses on common symptoms reported in MG. The graph shows the average score of 95 patients with MG who were seen in the outpatient clinic by neuromuscular staff and who had complete MG-ADL assessments on at least two occasions in 2009-2010. There was a significant reduction in MG-related symptoms (P < 0.0001). Average time between visits was 189 days. Higher scores indicate greater disability.
The Headache Program, within the Neurological Center for Pain, utilizes the Headache Impact Test™ (HIT-6™) as a standard health status measure for all patients treated in the center. HIT-6 is a disease-specific survey that captures the effects of headache and its treatment on functional health and well-being.

**Chronic Migraine**

Chronic migraine refers to migraine headaches occurring at least 15 days per month, frequently associated with significant functional impairment and depression. Patients with chronic migraine often present for treatment with excessive and prolonged use of opioids, triptans or other analgesics, which can exacerbate the headache in the long term.

**Functional Impairment: New Chronic Migraine Patients with and without Medication Overuse Headache (MOH)**

2009 – 2010

Functional impairment, as measured with the HIT-6, in chronic migraine patients seen for the first time at Cleveland Clinic's Neurological Center for Pain in 2009 and followed into 2010 showed improvement over time, in patients with medication overuse headache (MOH) as well as those without (P < 0.0001). Those patients with MOH were more impaired, in general, than those without.

**Depression: New Chronic Migraine Patients with and without MOH**

2009 – 2010

Depressive symptoms, as measured with the PHQ-9, improved in chronic migraine patients initially seen in 2009 and followed into 2010 in patients with MOH as well as those without (P < 0.0001).
Infusion Therapy for Headache

Headache patients with status migrainosis, transformed migraine, cluster headache and MOH may receive intravenous infusion therapy with a number of different medications, including dihydroergotamine, magnesium, antiemetics, Robaxin®, Depacon®, Toradol® and/or steroids, lasting one to five days. This treatment provides a less expensive alternative to emergency department care and can be useful as a component of a comprehensive headache management strategy.

Pain Ratings before and after Infusion Therapy (N = 454)

2009 – 2010

Pain Score
(0 = No Pain, 10 = Worst Possible Pain)

Headache severity decreased following infusion therapy (P < 0.0001). Average treatment duration was 2.2 days.
**Interdisciplinary Method for the Assessment and Treatment of Chronic Headache (IMATCH)**

One of only a few such programs in the country, IMATCH is an intensive, multidisciplinary outpatient program for chronic headache patients who have exhausted other treatment options.

**Pain Ratings before and after IMATCH (N = 92)**

Pain scores (mean ± s.d.) decreased following completion of the IMATCH program (P < 0.0001). To obtain a more comprehensive assessment of their pain, patients were asked to rate their current pain as well as pain over the preceding week. Current pain is the level of pain at that moment; average, least and worst levels of pain are reported for the preceding week. Information is based on patients who completed IMATCH in 2010.
Depression, Anxiety and Stress before and after IMATCH (N = 92)

Scores on measures of stress, anxiety and depression all decreased following IMATCH, indicating improvement (P < 0.0001). Mean DASS-42 subscale scores are plotted with their standard deviations.

Patient Satisfaction with IMATCH (N = 92)

Average scores on the Treatment Helpfulness Questionnaire (maximum score = 5) indicate high rates of patient satisfaction.
As part of IMATCH, patients are seen daily by physical therapists in the Department of Physical Medicine and Rehabilitation for group cardiovascular, strengthening and stretching exercises. Patients also meet twice each week with physical therapists specially trained in the treatment of headaches and neck pain for individualized exercise and manual techniques aimed at reducing their symptoms. In addition to the Headache Impact Test and Pain Disability Index, disability is measured with the Headache Disability Index (HDI), the Dizziness Handicap Index (DHI) and the Neck Disability Index (NDI).

Disability Status before and after Physical Therapy with IMATCH (N = 92)

2010

Disability Score

<table>
<thead>
<tr>
<th>Index</th>
<th>Admission</th>
<th>Discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache Impact Test (36-72)</td>
<td>70</td>
<td>40</td>
</tr>
<tr>
<td>Pain Disability (0-70)</td>
<td>60</td>
<td>40</td>
</tr>
<tr>
<td>Headache Disability (0-100)</td>
<td>80</td>
<td>50</td>
</tr>
<tr>
<td>Dizziness Handicap (0-100)</td>
<td>60</td>
<td>30</td>
</tr>
<tr>
<td>Neck Disability (0-100)</td>
<td>70</td>
<td>30</td>
</tr>
</tbody>
</table>

Pain disability, measured across multiple instruments, decreased following completion of the IMATCH program (all $P < 0.0001$). Lower scores indicate less severe disability.
Cleveland Clinic Chronic Pain Rehabilitation Program

The Chronic Pain Rehabilitation Program (CPRP), within the Neurological Center for Pain, is a comprehensive, interdisciplinary program designed to treat patients with disabling chronic pain.

<table>
<thead>
<tr>
<th>CPRP Patient Characteristics</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Patients Enrolled</td>
<td>207</td>
<td>229</td>
<td>287</td>
</tr>
<tr>
<td>Number of Patients Completing</td>
<td>184</td>
<td>171</td>
<td>230</td>
</tr>
<tr>
<td>Number of Patients Identified with Addiction</td>
<td>71</td>
<td>85</td>
<td>86</td>
</tr>
<tr>
<td>Percent Female</td>
<td>62.8</td>
<td>65.1</td>
<td>66.2</td>
</tr>
<tr>
<td>Mean Age (s.d.)</td>
<td>43.4 (15.02)</td>
<td>48.1 (13.09)</td>
<td>46.7 (12.58)</td>
</tr>
</tbody>
</table>

Each year, a number of patients enroll in the CPRP but fail to complete the full daily, three- to four-week program for a variety of medical and nonmedical reasons.

In recognition of the increasing number of patients with both chronic pain and addiction, and the dearth of pain treatment programs to address the needs of this population, the CPRP in late 2009 started a treatment track designed specifically to help patients with both pain and addiction. Although this is not a chemical dependency treatment program, patients in this track receive education about addiction and the role it has played in their lives and their pain. This education helps them start to plan the substance abuse treatment that follows completion of the CPRP.
Pain Intensity before and after CPRP

Mean Pain Score
(0 = No Pain, 10 = Worst Possible Pain)

Mean pain scores decreased following participation in the CPRP. A two-point change is considered clinically significant. One-year follow-up was not yet available for 2010. N = number of patients enrolled in the program.

Depression before and after CPRP

Mean Depression Score

Depressive symptoms, as measured with the DASS depression subscale, improved following participation in the CPRP. Higher scores on the 0 to 36 scale indicate more severe depression. Mean admission scores suggest moderate depression, while all discharge and follow-up scores suggest mild depression or no depression. One-year follow-up was not yet available for 2010. N = number of patients enrolled in the program.
Anxiety before and after CPRP

Mean Anxiety Score

Anxiety symptoms, as measured with the DASS anxiety subscale, improved following participation in the CPRP. Higher scores on the 0 to 26 scale indicate more severe anxiety. Mean admission scores suggest moderate anxiety, while mean discharge scores are in the normal range or show mild anxiety. One-year follow-up was not yet available for 2010. N = number of patients enrolled in the program.

Pain Disability before and after CPRP

Mean Pain Disability Index Score

Functional status, as measured with the Pain Disability Index (PDI), improved at discharge, six months and one year after participation in the CPRP compared with prior to treatment. Higher scores on the 0 to 70 scale indicate greater disability. One-year follow-up was not yet available for 2010. N = number of patients enrolled in the program.
CPRP Outcomes in Patients with Fibromyalgia

Pain Intensity before and after CPRP for Fibromyalgia vs. Other Chronic Pain

Mean Pain Score
(0 = No Pain, 10 = Worst Possible Pain)

Both patients with fibromyalgia and patients with other chronic pain disorders attained clinically significant reductions in pain following participation in CPRP.

Pain Disability before and after CPRP for Fibromyalgia vs. Other Chronic Pain

Mean Pain Disability Index Score

Both patients with fibromyalgia and patients with other chronic pain disorders attained clinically significant reductions in disability due to pain following participation in CPRP.
CPRP Outcomes in Multiple Sclerosis Patients

<table>
<thead>
<tr>
<th>Multiple Sclerosis Patient Characteristics: 2000 - 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of MS Patients Enrolled</td>
</tr>
<tr>
<td>Mean Age at Diagnosis of MS</td>
</tr>
<tr>
<td>Mean Age at Enrollment</td>
</tr>
<tr>
<td>Percent Female</td>
</tr>
<tr>
<td>MS Subtype</td>
</tr>
<tr>
<td>Relapsing-Remitting</td>
</tr>
<tr>
<td>Primary Progressive</td>
</tr>
<tr>
<td>Secondary Progressive</td>
</tr>
<tr>
<td>Comorbid Pain Diagnosis</td>
</tr>
<tr>
<td>Neuropathic Pain</td>
</tr>
<tr>
<td>Fibromyalgia</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>Comorbid Psychiatric Diagnosis</td>
</tr>
<tr>
<td>Depression</td>
</tr>
<tr>
<td>Substance Abuse</td>
</tr>
<tr>
<td>Other</td>
</tr>
</tbody>
</table>

Depression before and after CPRP in MS Patients (N = 12)

Mood was measured with either the DASS or Beck Depression Inventory (BDI) and categorized as normal mood, mild depression, moderate depression or severe depression. A change in mood was defined as a change of two or more categories. Among those with depressive symptoms before CPRP, 67 percent showed improvement of mood following completion of the program. N = number of patients who completed both admission and discharge mood data and who had evidence of depression on admission.
Pain Intensity before and after CPRP for MS Patients vs. All CPRP Patients

2000 – 2009

Mean Pain Score
(0 = No Pain, 10 = Worst Possible Pain)

Pain Disability before and after CPRP for MS Patients vs. All CPRP Patients

2000 – 2009

Mean PDI Score

MS Patients (N = 21)
All Patients (N = 2,030)
CPRP Outcomes in Patients with Low Back Pain

Depression, Anxiety and Stress before and after CPRP for Patients with Low Back Pain

2010

DASS Subscale Score

- Depression
- Anxiety
- Stress

Pain Intensity and Pain Disability before and after CPRP for Patients with Low Back Pain

2010

Mean Pain Score
(0 = No Pain, 10 = Worst Possible Pain)

Mean PDI Score
CPRP Outcomes in Patients at Risk for Substance Use Disorders

Program Completion Rates in Patients at Risk for Substance Use Disorders

Program completion rates tend to be lower for those identified at risk for substance use disorders. N = total number of patients initially enrolled in CPRP in 2009 and 2010. Although patients with substance use disorders are much more likely to drop out of treatment, those who complete treatment do as well as patients without comorbidity. The program is making efforts to understand and improve the problem of program dropout. In fact, Cleveland Clinic data suggest that 30 percent of patients with substance abuse disorders who drop out of CPRP do so because they do not want to give up the addictive substance.

Depression before and after CPRP in Patients at Risk for Substance Use Disorders

Depressive symptoms, as measured with the DASS depression subscale, improve following participation in CPRP. Higher scores on the 0 to 36 scale indicate more severe depression. Depressive symptoms tend to be higher in those patients identified at risk for substance use disorders. For this and subsequent graphs, SUD = patients enrolled in a Substance Use Disorders Education Track for those identified at risk for substance use disorders.
Anxiety symptoms, as measured with the DASS anxiety subscale, improve following participation in CPRP. Higher scores on the 0 to 26 scale indicate more severe anxiety. Again, anxiety symptoms tend to be higher in those patients identified at risk for substance use disorders.

Clinically significant change in average pain intensity ratings (a 3-point change or more) occurred from admission to discharge in both groups, but at no other times.

Functional status is measured here with the Pain Disability Index. Higher scores on the 0 to 70 scale indicate greater disability. Clinically significant improvement, a shift from one category to another (for instance, from moderate to mild disability) occurred in both SUD and non-SUD groups at all intervals following admission.
**Pediatric Neurometabolic Clinic**

The term “idiopathic developmental delay” is used to define some 3 percent of the population that has unexplained neurologic and developmental symptoms, including autism and epilepsy. Until recently, this population of children and adults, some with progression of their symptoms for unexplained reasons, remained largely without a diagnosis. With advances in technology and improving diagnostic skills, the ability to reach a conclusive diagnosis in this population has steadily improved. While there is no national standard, tertiary care centers such as ours have the potential to reach a diagnosis 30 to 50 percent of the time.¹

**Neurometabolic Clinic Diagnostic Yield**

**2010**

<table>
<thead>
<tr>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Patient Consults</td>
</tr>
<tr>
<td>Diagnosis Established via Muscle, Genetic or Cerebrospinal Fluid Testing</td>
</tr>
<tr>
<td>250</td>
</tr>
<tr>
<td>200</td>
</tr>
<tr>
<td>150</td>
</tr>
<tr>
<td>100</td>
</tr>
<tr>
<td>50</td>
</tr>
</tbody>
</table>

In 2010 our Neurometabolic Clinic evaluated 232 patients presenting with unexplained neurologic and/or developmental symptoms, and we were able to establish a diagnosis in 67 patients (31 genetic/syndromic and 36 metabolic), or 29 percent.

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There are only a few medical centers in the country that provide high-quality EMG for the pediatric population with the option of EMG under sedation, resulting in a more comprehensive examination and less discomfort for the patient.

Pediatric patients treated for headache in 2010 showed an improvement in PedsMIDAS (Migraine Disability Assessment Score) of 39 percent. There was also a 50 percent reduction in school days missed in the preceding three months. Mean duration of follow-up was 160 days.
Pediatric Spasticity and Dystonia

Spasm before and after Botulinum Toxin Injection (N = 47)

July 2010 – February 2011

Mean Spasm Score

Data reflect the outcome of botulinum toxin injection for spasticity and dystonia in children treated since July 2010. The decrease in spasm score between first and second visits was not statistically significant (P = 0.095). Mean duration of follow-up between first and second visits is 105 days.

Pain Intensity before and after Botulinum Toxin Injection (N = 47)

July 2010 – February 2011

Mean Pain Score
(0 = No Pain, 10 = Worst Possible Pain)

Data reflect the mean pain score decreases following botulinum toxin injection (P = 0.019). Mean duration of follow-up between first and second visits is 105 days.
Goal Attainment Scale (GAS) after Botulinum Toxin Injection (N = 47)

July 2010 – February 2011

The GAS measures how well goals were satisfied after the last botulinum toxin injection, with the scale ranging from 
-3 = much worse than expected to 2 = much better than expected. Goal satisfaction was as expected or above in all but three patients (who had minimal worsening of spasticity).

Outcomes for pediatric epilepsy are included in the epilepsy section. Children and adolescents are also seen in the Center for Behavioral Health and the Sleep Disorders Center.
Pediatric Neurosurgery

Surgical site infection rates decreased in 2010, at least partly due to efforts to improve perioperative antibiotic timing. Infection rates in primary shunts decreased from 12 percent in 2009 to zero in 2010.

Surgical Site Infection Rate for Primary Shunts

Rate per 100 Clean Cases (%)

<table>
<thead>
<tr>
<th>Year</th>
<th>Rate</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>15</td>
<td>18</td>
</tr>
<tr>
<td>2008</td>
<td>10</td>
<td>15</td>
</tr>
<tr>
<td>2009</td>
<td>17</td>
<td>17</td>
</tr>
<tr>
<td>2010</td>
<td>0</td>
<td>12</td>
</tr>
</tbody>
</table>

N = number of clean cases per year. Per Centers for Disease Control and Prevention (CDC) guidelines, “clean cases” are defined as uninfected operative wounds in which no inflammation is encountered and, in the case of brain tumor surgery, neither the respiratory nor the alimentary tract is entered.

Surgical Site Infection Rate for Shunt Revisions

Rate per 100 Clean Cases (%)

<table>
<thead>
<tr>
<th>Year</th>
<th>Rate</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>5</td>
<td>34</td>
</tr>
<tr>
<td>2008</td>
<td>26</td>
<td>18</td>
</tr>
<tr>
<td>2009</td>
<td>28</td>
<td>26</td>
</tr>
<tr>
<td>2010</td>
<td>0</td>
<td>28</td>
</tr>
</tbody>
</table>
More than 50 percent of adult outpatients demonstrated improvement in depressive symptoms, severity of illness and overall quality of life based on the change in PHQ-9 scores (Patient Health Questionnaire), CGI (Clinical Global Impression Scale) and EQ-5D (European Quality of Life Scale), respectively, from initial evaluation for major depression to the last follow-up visit (defined as occurring 90 or more days from the initial evaluation). Improvement is defined as a 50 percent or greater reduction in score. Patients were treated with outpatient psychotherapy and/or medication management.

N = all patients seen for initial evaluation of major depression from January 1 through December 31, 2010, for whom both initial and follow-up data were available. Mean duration of follow-up was 90 days.
Consultation Liaison Inpatient Psychiatry Service

The Consultation Liaison (CL) Psychiatry Service specializes in the interface between medicine and psychiatry. The role of the consultation-liaison psychiatrist is to evaluate patients currently admitted as a general medical inpatient at the request of the treating medical or surgical team. The reasons for consultation are varied and may include assistance in the management of delirium, mood, anxiety and adjustment disorders, as well as addiction and capacity evaluations. At Cleveland Clinic, the CL Psychiatry Service provides over 3,000 consults annually to adult and pediatric inpatients admitted to medical services.

Reduction in Illness Severity following Inpatient Psychiatry Consultation (N = 110)

November – December 2010

The Clinical Global Impression (CGI) Severity of Illness is a standardized clinician-rated seven-point metric widely used in behavioral health to measure severity of mental symptoms, with higher scores indicating greater severity of illness. Mean group scores at baseline inpatient assessment and at last follow-up inpatient visit are displayed for all adult inpatients evaluated and treated by the CL service from November 1 to December 30, 2010. The most common reasons for psychiatric consultation in this patient sample are depression/anxiety in 50 percent, delirium in 40 percent and a combination of substance abuse, adjustment disorders and capacity evaluations in the remainder. On average, patients experienced a significant reduction in overall severity of illness following psychiatric consultation (P = 0.0001). Mean duration of follow-up from initial consultation to last inpatient psychiatric evaluation was four days.
Women’s Mental Health Management Group for Depression (N = 62)
January – July 2010

The data reflect patients’ perception of improvement with Shared Medical Appointments for Depression based on the Clinical Global Impression-Improvement (CGI-I) scale, a seven-point, self-rated, widely used instrument that requires the patient to assess improvement or worsening of symptoms relative to a baseline state at the beginning of the intervention. Aggregate results are presented as proportions of patients who reported improvement (very much improved, much improved or minimally improved), no change or worsening of symptoms (minimally worse, much worse or very much worse). Mean duration of intervention was three months.
Inpatient Treatment for Depression

The Mood Disorders Inpatient Unit at Lutheran Hospital opened in late January 2008. Data are presented for patients admitted to this unit in 2010 who consented to complete admission and discharge mood rating scales as part of an IRB-approved research mood disorder registry. Nearly 70 percent of patients were diagnosed with major depression and 23 percent with bipolar disorder (Type I, II, NOS).

Change in Depressive Symptoms before and after Treatment (N = 251)

2010

Mean Score

Both the Hamilton Depression Scale (Ham-D) and the Montgomery-Asberg Depression Rating Scale (MADRS) are widely accepted and validated instruments to measure severity of depression and response to treatment. Mean group scores on admission and discharge are displayed for patients admitted to the Mood Disorders Unit from January 1 through December 31, 2010. For both scales, there was a statistically significant reduction in mean severity of depression from admission to discharge (P = 0.001). Mean duration of hospitalization was 5.6 days.
In 2010, patients treated on the Mood Disorders Unit experienced, on average, a reduction of more than two points on the CGI severity of illness scale (P = 0.0001). A CGI severity of illness score of 2 equates with “minimally ill.” The Young Mania Rating Scale (YMRS) measures the presence of manic or hypomanic symptoms. In this sample, the majority of patients did not experience excessive activation either at presentation or with treatment as reflected by low YMRS scores at admission and on discharge. YMRS scores of less than 8 are considered normal.
Electroconvulsive Therapy (ECT)

Cleveland Clinic offers electroconvulsive therapy (ECT) services at its main campus as well as at Lutheran Hospital for both inpatients and outpatients. ECT is an effective, safe, traditional form of neuromodulation therapy. ECT may be recommended for individuals with a diagnosis of depression, mania, psychosis or schizophrenia. The ECT service includes a team of specially trained professionals, including psychiatrists, anesthesiologists and nurses.

Depressive Symptoms before and after ECT (N = 93)

2010

Mean Score

Patients show a significant decrease in depressive symptoms with ECT based on the PHQ-9 and MADRS scores (P < 0.0001).
Alcohol and Drug Rehabilitation

The Alcohol and Drug Rehabilitation Center (ADRC) provides a multidisciplinary team approach to the evaluation and treatment of chemical dependency. The ADRC is designed to help patients confront and overcome their chemical and/or alcohol dependency, and to assist in developing strategies for maintaining a chemical-free lifestyle.

Treatment of Opioid Dependence

Buprenorphine (Subutex®) and buprenorphine/naloxone (Suboxone®) offer a safer and arguably more effective treatment alternative to methadone for dependence on opioids such as heroin, Oxycontin®, Percocet® and Vicodin®. Buprenorphine attenuates withdrawal symptoms and decreases cravings by partially stimulating the opioid receptor while blocking the effects of other opioids. To further support the recovery of patients in medication-assisted treatment with buprenorphine and buprenorphine/naloxone, support group sessions targeted to the special challenges of this population are required for those early in treatment and encouraged for those with more established sobriety.

Depressive Symptoms in Patients Newly Admitted for Chemical Dependency (N = 410) vs. Patients Treated with Buprenorphine (N = 436)

July – December 2010

Mean PHQ-9 Score

Patients already participating in the outpatient buprenorphine or buprenorphine/naloxone program show less depressive symptomatology, as measured with the PHQ-9, compared to patients newly admitted to the ADRC not currently treated with buprenorphine or buprenorphine/naloxone (P < 0.0001).
Cleveland Clinic’s Sleep Disorders Center provides multidisciplinary care for patients of all ages with sleep and wake disorders. Comprehensive care is provided through integration of specialists in Neurology, Internal Medicine, Pulmonary and Critical Care Medicine, Psychiatry and Psychology, Pediatrics, Otolaryngology and Dentistry.

**Adult Sleep Studies**

2010

**Number of Studies**

<table>
<thead>
<tr>
<th>Year</th>
<th>PSG/EEG</th>
<th>CPAP/BiPAP</th>
<th>Split</th>
<th>MSLT/MWT</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>1,000</td>
<td>500</td>
<td>200</td>
<td>100</td>
</tr>
<tr>
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<td>1,000</td>
<td>1,000</td>
<td>500</td>
</tr>
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<td>3,000</td>
<td>2,000</td>
<td>2,000</td>
<td>1,000</td>
</tr>
<tr>
<td>2009</td>
<td>4,000</td>
<td>3,000</td>
<td>3,000</td>
<td>2,000</td>
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<tr>
<td>2010</td>
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<td>4,000</td>
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</tr>
</tbody>
</table>

The number of adult sleep studies performed in nine locations across Northeast Ohio has continued to increase over the past five years.

**Pediatric Sleep Studies**

2010

**Number of Studies**

<table>
<thead>
<tr>
<th>Year</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>100</td>
</tr>
<tr>
<td>2007</td>
<td>200</td>
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<tr>
<td>2008</td>
<td>300</td>
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<tr>
<td>2009</td>
<td>400</td>
</tr>
<tr>
<td>2010</td>
<td>500</td>
</tr>
</tbody>
</table>

The number of pediatric sleep studies continually increased during each of the past five years. Children ages 12 and older without special needs may be tested in any one of the nine sleep laboratory locations.
Sleep Disorders

Sleep Apnea

Obstructive sleep apnea syndrome affects millions of people, with an estimated prevalence of 24 percent in men and 9 percent in women. Untreated sleep apnea is associated with a variety of medical and psychosocial problems, including hypertension, heart disease, depression and obesity, as well as daytime sleepiness, occupational and academic difficulties and motor vehicle accidents. Positive airway pressure (PAP) therapy is a first-line treatment for sleep apnea, shown to reduce or reverse these adverse consequences.

Positive Airway Pressure (PAP) Compliance in Patients with Sleep Apnea

2010

<table>
<thead>
<tr>
<th>Compliance Rate</th>
<th>Cleveland Clinic</th>
<th>National Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>(percent of sleep apnea patients using PAP ≥ 4 hours/night)</td>
<td>78%</td>
<td>50%</td>
</tr>
</tbody>
</table>

PAP therapy compliance is most commonly defined as four or more hours of use per night. Most studies report PAP compliance rates in the range of 50 percent in patients with sleep apnea. Patients with sleep apnea treated in the Sleep Disorders Center in 2010 had higher compliance rates compared to the national average, due in part to the implementation of a standardized care pathway that ensures regular follow-up visits with health status assessments, aggressive troubleshooting for challenging cases and integration of Cleveland Clinic Home Care therapists into the treatment team.

Sleepiness and Fatigue before and after Treatment

2010

Daytime sleepiness, as measured with the Epworth Sleepiness Scale (ESS), decreased in sleep apnea patients who were compliant with PAP therapy (P < 0.0001). Lower ESS scores indicate less sleepiness (ESS < 10 is considered normal). Similarly, fatigue, as measured with the Fatigue Severity Scale (FSS), decreased in sleep apnea patients who were compliant with PAP therapy (P < 0.0001). Lower FSS scores suggest lower fatigue levels during the day.
Functional status, as measured by the Functional Outcomes of Sleep Questionnaire (FOSQ), improved among sleep apnea patients who were compliant with PAP treatment ($P < 0.0001$). The FOSQ is a condition-specific functional status measure designed to evaluate the effects of sleep disorders on activities of daily living. Higher scores indicate higher levels of quality of life. Depressive symptoms, as measured with the PHQ-9, improved in sleep apnea patients who were compliant with PAP therapy ($P < 0.0001$). Lower scores indicate fewer depressive symptoms. A score less than 5 is considered normal.

Sleep apnea patients who were compliant with PAP therapy showed improvement in all five domains of functional status as measured by the FOSQ subscales ($P < 0.0001$). Higher scores indicate higher levels of functioning.
The 2011 National Sleep Foundation's Sleep in America poll found that during the week, 39 percent of respondents sleep less than seven hours per night, and 14 percent sleep less than six hours per night. Sleep disorders, such as sleep apnea and insomnia, increase the risk for inadequate sleep. Chronic sleep deprivation is associated with a variety of health and social consequences including cognitive impairment, mood disorders, obesity, reduced productivity and drowsy driving.

Total Sleep Time before and after Treatment (N = 398)

Patients with sleep apnea who were compliant with PAP therapy slept an average of 30 minutes more per night after treatment (P < 0.0001). A multifaceted treatment plan that includes lifestyle changes, good sleep hygiene and PAP therapy is required to optimize sleep quality and quantity in patients with sleep apnea.
Sleepiness and Fatigue in Patients with REM-Related Sleep Apnea before and after Treatment

2010

In approximately 25 percent of cases, sleep apnea occurs exclusively or nearly so in rapid eye movement (REM) sleep, a stage that is believed to be important for cognitive restoration and memory consolidation. Patients with REM-related sleep apnea are often not offered the same treatment options. No studies have addressed functional outcomes in this subset of sleep apnea. Investigators at Cleveland Clinic analyzed health status measures before and after PAP therapy in patients with REM-related sleep apnea. Improvements in sleepiness, as measured by the ESS, and fatigue, as measured by the FSS, were observed in patients with REM-related sleep apnea, comparable to those observed in sleep apnea patients overall (P < 0.0005).

Functional Status and Depressive Symptoms in Patients with REM-Related Sleep Apnea before and after Treatment

2010

Similarly, patients with REM-related sleep apnea treated with PAP experienced a significant increase in FOSQ scores, suggesting improved quality of life, and a significant decrease in depressive symptoms as measured by the PHQ-9 (P < 0.0005).
Insomnia

It is estimated that as many as 50 percent of adults have occasional episodes of insomnia and that 10 percent of adults experience chronic insomnia. Insomnia is associated with many comorbidities, both psychiatric and medical, and it imposes an economic burden related to increased healthcare utilization and time away from work.

Total Sleep Time before and after Cognitive Behavioral Therapy for Insomnia (N = 249)

Patients who were evaluated and treated for insomnia by a behavioral sleep medicine expert experienced an increase in total sleep time of over 30 minutes per night (P < 0.0001) after three months of treatment. Over an average of five visits, patients were treated with a variety of Cognitive Behavioral Therapy for Insomnia (CBT-I) strategies, including progressive muscle relaxation, stimulus control, sleep restriction, sleep hygiene education and biofeedback. CBT-I can be individualized or can take place in a group setting. Meta-analyses report better outcomes in insomnia patients using CBT-I than sedative-hypnotic medications alone.
The Center for Spine Health provides a comprehensive continuum of care for spinal disorders, including medical management, surgical interventions, minimally invasive injection procedures, specialized exercise programs, acupuncture, osteopathic manipulation and referral to functional restoration programs, all of which are intended to maximize return to participation in vocational, family and recreational activities. In 2010, Cleveland Clinic began a comprehensive attempt to extend computerized outcomes data gathering to all centers throughout the entire system with a phase-in of data gathering capabilities for all visits and targeted outcomes monitoring for continuous practice improvement within the Center for Spine Health.

### Lumbar Disc Herniation

**Improvement in Functional Status Following Lumbar Microdiskectomy for Disc Herniation**

**2010**

<table>
<thead>
<tr>
<th>Patients (%)</th>
<th>EQ-5D</th>
<th>PHQ-9</th>
<th>PDQ</th>
<th>Rankin</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>92</td>
<td>89</td>
<td>54</td>
<td>121</td>
</tr>
</tbody>
</table>

The EQ-5D and PHQ-9 measure quality of life and depressive symptoms, respectively, as explained in more detail in the Outcomes Overview. The PDQ (Pain Disability Questionnaire) measures the effects of pain on 15 aspects of function including work, recreation, travel, need for medical visits, reliance on social support, income, lifting, and personal care. On each item, patients rate their performance from 0 to 10 (worst), with cumulative scores ranging from 0 to 150. Higher scores indicate greater disability due to pain. The Rankin is a commonly used scale for measuring the degree of disability or dependence in daily activities. Over 80 percent of patients experienced greater-than-expected functional improvement after surgery (elective lumbar microdiskectomy for disc herniation), based on two separate measures of functional status, the EuroQOL (EQ-5D) and the Pain Disability Questionnaire (PDQ). The specific degrees of improvement are shown in subsequent graphs.
Improvement in Quality of Life Following Lumbar Microdiskectomy for Disc Herniation (N = 92)

Patients reported improvement in quality of life after lumbar microdiskectomy for disc herniation.

Improvement in Pain Disability Following Lumbar Microdiskectomy for Disc Herniation (N = 54)

Patients reported improvement in pain disability, as measured with the PDQ, after lumbar spine surgery. Higher scores indicate greater disability.
Cervical Myelopathy

An area of special interest is treatment of patients with cervical spondylotic myelopathy (CSM). This disease tends to be a progressive, often painless, loss of hand, leg and bladder function related to compression of the spinal cord from degenerative change in the cervical spine. The diagnosis of CSM requires a high index of suspicion and generally requires surgical decompression to minimize the risk of irreversible damage.

Improvement in Quality of Life Following Spinal Decompression for Cervical Myelopathy (N = 48)

2010

Mean EQ-5D Score

Quality of life improved following spinal decompression.

Improvement in Pain Disability Following Spinal Decompression for Cervical Myelopathy (N = 48)

2010

Mean PDQ Score

Objective measures of function improved after surgical decompression of the cervical spinal cord with greater function in almost all domains.
Degenerative Spondylolisthesis and Spinal Stenosis

Surgical Treatment

Lumbar degenerative spondylolisthesis is a slippage of one or more vertebral bodies relative to the adjacent vertebral body. This slippage may cause back and leg pain from neurological compression (stenosis) that may impair walking, standing and many aspects of daily function. Surgical treatment typically involves decompression and instrumented fusion.

Improvement in Quality of Life Following Laminectomy and Fusion for Spinal Stenosis (N = 37)

![Quality of life improved following spinal surgery for spinal stenosis.]

Improvement in Depressive Symptoms Following Laminectomy and Fusion for Spinal Stenosis (N = 37)

Loss of normal function is often associated with distress. This distress can be measured on psychological tests and often manifests as increased family strife, negative self-perception, trouble sleeping and depression. Following lumbar laminectomy and fusion for symptomatic stenosis, distress associated with functional impairments, as measured by PHQ-9, decreased to levels near those seen in the general population.
Spinal Injections
Symptomatic lumbar spinal stenosis may produce leg pain with walking or standing. In carefully selected patients, particularly those who are older and have significant comorbidities, spinal epidural steroid injections performed by a Center for Spine Health interventionalist may provide an effective alternative to surgery.

Improvement in Quality of Life Following Spinal Injections for Spinal Stenosis (N = 36)

![Graph showing mean EQ-5D score before and after treatment.]

Improvement in Depressive Symptoms Following Spinal Injections for Spinal Stenosis (N = 32)

![Graph showing mean PHQ-9 score before and after treatment.]

Depressive symptoms and psychological distress would be expected due to loss of independence related to difficulty walking from spinal stenosis. Depressive symptoms, as measured by the PHQ-9, were reduced following spinal injections and nearly returned to baseline based on age-related comorbidities.

Improvement in Functional Status Following Injections for Spinal Stenosis

![Graph showing patients' percentage by functional status.]

Patients had improved objective measurements of function more than two months following spinal injection for lumbar spinal stenosis.
Outpatient Physical Medicine and Rehabilitation

Improvement in Quality of Life Following Outpatient Physical Medicine and Rehabilitation

Both the Musculoskeletal and Neurological patient groups experienced statistically significant (P < 0.05) improvement in quality of life, as measured with the EQ-5D. Mean duration between visits was 86.1 days for Musculoskeletal and 111.4 days for Neurological patient groups. Musculoskeletal diagnoses include spondylosis, lumbago, back pain, disc disorders, spinal stenosis, and joint disorders, with spine-related disorders accounting for more than 45 percent of all outpatient encounters with board-certified physiatrists. Neurological conditions include disorders of the central nervous system (hemiplegia, multiple sclerosis, cerebral palsy, movement disorders), disorders of the peripheral nervous system (muscular dystrophy, peripheral neuropathy, mononeuritis), and pain.

Improvement in Depressive Symptoms Following Outpatient Physical Medicine and Rehabilitation

At last follow-up visit, both the Musculoskeletal and Neurological patient groups experienced statistically significant (P < 0.05) improvement in depressive symptoms, as measured with the PHQ-9. Mean duration between visits was 96.2 days for Musculoskeletal and 120.1 days for Neurological patient groups.
Occupational Rehabilitation Program

The Work Conditioning Program is accredited by the Commission on Accreditation of Rehabilitation Facilities (CARF). Meeting three to five times per week for up to eight weeks, the program uses physical reconditioning and job simulation/real work tasks to help injured workers regain optimal function so they can return to work.

The Occupational Rehabilitation Program is a CARF-accredited multidisciplinary, individualized therapy program (five days per week, up to eight weeks). The program assists injured workers in returning to work through progressive physical conditioning, work simulation and vocational and psychosocial interventions. An on-site job analysis is performed and recommendations for accommodation to the work environment are made to minimize the risk of reinjury.

Work Readiness Following the Work Conditioning and Occupational Rehabilitation Programs

2010

<table>
<thead>
<tr>
<th>Patients Work Ready (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
</tr>
<tr>
<td>80</td>
</tr>
<tr>
<td>60</td>
</tr>
<tr>
<td>40</td>
</tr>
<tr>
<td>20</td>
</tr>
<tr>
<td>0</td>
</tr>
</tbody>
</table>

N = 23 After Completing Work Conditioning
N = 15 After Completing Occupational Rehabilitation

Patients in both programs had primarily musculoskeletal (spine, upper extremity and lower extremity) diagnoses. “Work ready” indicates the percentage of patients who either returned to work, are in search of a job or are otherwise unemployed but capable of working upon discharge from their respective program. Some patients progress from the Work Conditioning Program to an occupational rehabilitation program prior to returning to work.
Inpatient Physical Therapy

Improvement in Functional Status Following Inpatient Physical Therapy

2010

The graph illustrates the changes in our patients’ ability to perform certain functional tasks such as bed mobility, dressing and transfer. Patients admitted to the acute hospital were evaluated at admission to the acute care unit and at discharge. Fifty percent of our acute care patients improved their ability to perform the three functional tasks. Data were obtained from MediLinks rehabilitation clinical information system.

For the following three graphs, the patient’s ability to independently perform these tasks was scored as follows: independent or supervised = patient was able to perform the task independently or with some supervision; moderate to minimum assist = patient required assistance; and total or maximum assist = patient required total to maximum assistance from caregivers to perform the task. The goal of rehabilitation is to enable patients to become more independent in performing activities of daily living. Data were obtained from MediLinks rehabilitation clinical information system.

Improvement in Bed Mobility Following Inpatient Acute Rehabilitation (N = 4,026)

2010

The ability to perform bed mobility, a functional task, was evaluated at admission to the acute care unit and at discharge from the unit. At the end of the acute hospital stay, the number of patients with a high level of independence doubled and the number of patients with a medium level of independence decreased from 85 percent at admission to 68 percent.
Improvement in Ability to Dress Following Inpatient Acute Rehabilitation (N = 1,786)

The ability to dress independently, a functional task, was evaluated at admission to the acute care unit and at discharge from the unit. At the end of the acute hospital stay, the number of patients with a high level of independence increased three-fold, and the number of patients with a medium level of independence decreased from 91 percent at admission to 70 percent.

Improvement in Ability to Perform Transfers Following Inpatient Acute Rehabilitation (N = 519)

The ability to transfer, a functional task, was evaluated at admission to the acute care unit and at discharge from the unit. At the end of the acute hospital stay, the number of patients with a high level of independence doubled and the number of patients with a medium level of independence decreased from 75 percent at admission to 49 percent.
QuickDASH (Disabilities of the Arm, Shoulder and Hand) is a widely used tool in both clinical and research settings and has proven to be a useful self-report outcome measure for people with musculoskeletal upper-limb disorders. The QuickDASH uses 11 items to measure physical function and symptoms in people with one or more multiple musculoskeletal disorders of the upper limb. The scores range from 0 to 100, and a higher score indicates greater disability. Patients seen by Cleveland Clinic occupational therapists had an initial QuickDASH score of 45.6. At discharge, the score had decreased significantly (P < 0.005) to 13.9. Mean duration between visits was 85 days.
Cleveland Clinic Care at Home compared favorably with other home healthcare providers nationally and within the state of Ohio, in terms of percent of home healthcare patients requiring readmission to the hospital. The leading causes for readmission were cardiopulmonary disease and wound complications. On average, 2,880 patients per quarter are served by Cleveland Clinic Care at Home. Transitional Care Programs, such as Heart Care at Home and Go Right Home focus care on transitioning patients successfully to the home after acute care discharge. The data above demonstrate a level of success in our ability to keep our patients at home once they are discharged from the hospital.

Source: www.medicare.gov/HomeHealthCompare
Cleveland Clinic Hospice at Home

Patient Satisfaction (N = 10)

December 2010

Patients Responding Favorably (%)

Providing information and communicating with patients and families are critical for optimal patient outcomes. Hospice at Home has met or exceeded all national benchmarks from the National Hospice and Palliative Care Organization (NHPCO).
Traditional respiratory services include home oxygen, nebulizers and aerosol medications for treatment of obstructive sleep apnea, emphysema, chronic bronchitis, asthma and compromised heart function. Cleveland Clinic provides a growing population of sleep apnea patients with CPAP and BiPAP equipment and supplies.
Current guidelines dictate that a patient presenting with an acute stroke (brain attack) should receive a noncontrast head CT within 25 minutes of arrival and the study must be interpreted within 20 minutes of exam completion. Because inpatients are also commonly entered into the same algorithm when they present with symptoms of an acute stroke, our goal is to provide test results within 45 minutes from the time the head CT is ordered. In 2010, the exam-to-notification metric was met in 95 percent of cases and the order-to-notification metric in 96 percent.
Although a number of neuroradiology results yield information urgently important to clinical care, Cleveland Clinic has determined that acute intracranial hemorrhage and severe intracranial mass effect are considered “critical,” and results should be communicated to a responsible licensed caregiver within 90 minutes of test interpretation. Compliance with these guidelines was 99 percent for 168 cases across the entire year, with only two studies in February and July that failed to meet these targets.

Turnaround time is defined as the time from exam completion to the time the report is finalized. In 2010, more than 37,000 neurological CT and 56,000 neurological MRI exams were completed across the entire Cleveland Clinic health system, with median turnaround times of approximately one hour for both types of exams. This enables our referring services to expedite patient management in inpatient and outpatient settings.
Surgical Care Improvement Program (SCIP) — National Hospital Quality Measures and Overall Appropriateness of Care

2010

Process Measures (often referred to as “core” measures) Surgical care performance measures are available online at hospitalcompare.hhs.gov, a consumer-oriented website hosted by the Centers for Medicare & Medicaid Services (CMS). Hospitals submit surgery process-of-care data that show how consistently recommended care was provided to adult patients, irrespective of payer. Cleveland Clinic’s National Hospital Quality Measure surgical care data appear on the opposite page.

Appropriateness of Care Measure To supplement process-specific measures, Cleveland Clinic generates “appropriateness of care” data. We calculate how often we provided every recommended surgical care process intervention for which each individual patient was eligible. The results, also shown on the opposite page, are generated on a per-patient, “all or nothing” basis.
Cleveland Clinic data source: [hospitalcompare.hhs.gov](http://hospitalcompare.hhs.gov)

Visit [clevelandclinic.org/QPR](http://clevelandclinic.org/QPR) to view Cleveland Clinic’s current Quality Performance Report.


** Applies to all surgical patients, irrespective of age or payer; includes pediatric patients

Notes: A national average for Perioperative Temperature is not available.

An overall “Appropriateness of Care” national average is not available for the group of surgical care measures shown above.

National Hospital Quality Measure (NHQM) volumes are based on NHQM inclusion/exclusion criteria and sampling methodologies.
**National Surgical Quality Improvement Program**

The American College of Surgeons’ National Surgical Quality Improvement Program (NSQIP) is a national program that objectively measures and reports risk-adjusted surgical outcomes based on a defined sampling and abstraction methodology. Cleveland Clinic has participated in multispecialty NSQIP since May 2008, and the outcome data below reflect our surgical cases between July 1, 2009, and June 30, 2010.

### Overall Multispecialty 30-Day Mortality (N = 4,518)

#### July 2009 – June 2010

<table>
<thead>
<tr>
<th>Percent</th>
<th>Observed</th>
<th>Expected</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

Overall multispecialty mortality was lower than expected; however, the difference was not statistically significant.

### Overall Multispecialty 30-Day Morbidity (N = 4,518)

#### July 2009 – June 2010

<table>
<thead>
<tr>
<th>Percent</th>
<th>Observed</th>
<th>Expected</th>
</tr>
</thead>
<tbody>
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<tr>
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</tbody>
</table>

Overall multispecialty morbidity was higher than expected; the difference was statistically significant.
Neurosurgery 30-Day Mortality
July 2009 – June 2010

Percent

16
14
12
10
8
6
4
2
0

Observed
Comparison*
N = 514
N = 3,430

* Academic/teaching facilities with 500 or more beds

Risk-adjusted Neurosurgery-specific NSQIP mortality data is not available. Raw Neurosurgery-specific data is provided.

Neurosurgery 30-Day Morbidity (N = 514)
July 2009 – June 2010

Percent

16
14
12
10
8
6
4
2
0

Observed
Expected

Neurosurgery morbidity was higher than expected; however, the difference was not statistically significant.
“Patients First” is the guiding principle of Cleveland Clinic. Patient experience is a key component of Cleveland Clinic’s strategic plan to achieve a coordinated delivery model that integrates patient and family-centered care with clinical outcomes, quality, safety and employee experience.

The Office of Patient Experience’s mission is to ensure consistent, patient-centered care by partnering with caregivers to exceed the expectations of patients and families. Programs and services include:

- Expertise for critical initiatives throughout the organization to ensure the consistent delivery of patient-centered care
- Patient satisfaction data analysis, HCAHPS education and resources
- Identification and sharing of sustainable best practices
- Support of employee experience and recognition initiatives

- Customer service education programs, including the Respond with H.E.A.R.T.® service recovery program, to positively impact the Cleveland Clinic culture and support caregivers in providing outstanding service to patients, families and colleagues
- Personalized, holistic Healing Services for patients, families and employees including light massage, Reiki, Healing Touch™, reflexology, personal aromatherapy, guided imagery, spiritual support, Code Lavender first-response holistic care service and others
- Health literacy education and solutions
- Voice of the Patient Advisory Councils, an advisory resource that empowers patients and families to take an active role in improving the patient experience by providing real-time feedback and creative solutions to specific challenges
- Ombudsman Office, which serves as a centralized complaint center

Outpatient – Neurological Institute

Overall Rating of Outpatient Care and Services During Outpatient Visit (N = 2,682)

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<tr>
<th>Percent</th>
<th>Very Good</th>
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<th>Fair</th>
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</table>

Source: Press Ganey, a national hospital survey vendor
**Rating of Outpatient Care Provider (N = 2,682)**

2010

**Percent**

- Very Good: 80%
- Good: 10%
- Fair: 5%
- Poor: 2%
- Very Poor: 3%

Source: Press Ganey, a national hospital survey vendor

---

**Likelihood of Recommending Outpatient Care Provider (N = 2,682)**

2010

**Percent**

- Very Good: 80%
- Good: 10%
- Fair: 5%
- Poor: 2%
- Very Poor: 3%

Source: Press Ganey, a national hospital survey vendor
Inpatient – Neurological Institute

With the support of the Centers for Medicare & Medicaid Services (CMS) and its partner organizations, the first national standard patient experience hospital survey (HCAHPS) was implemented in late 2006. Results collected for reporting are available at hospitalcompare.hhs.gov.

HCAHPS Overall Assessment
2009 – 2010

HCAHPS Domains of Care
2009 – 2010

Source: Press Ganey, a national hospital survey vendor
Cleveland Clinic Experience — Our Mission, Vision and Values

In 2010, the Office of Patient Experience worked in collaboration with several departments, including the Office of Learning and Performance Development, to introduce “Cleveland Clinic Experience” to every employee across the organization. Cleveland Clinic Experience is an initiative designed to enhance and transform the culture at Cleveland Clinic by integrating exceptional employee and patient experiences. Interactive learning sessions taught caregivers the Cleveland Clinic expected service behaviors, how to positively respond to patient and family concerns, and what it means to live the Cleveland Clinic mission, vision and values on the job every day.
“The Neurological Institute staff authored more than 650 publications in 2010.”

For a complete list of publications authored by Neurological Institute staff in 2010, go to clevelandclinic.org/quality/outcomes

Brain Tumor and Neuro-Oncology Center


**Cerebrovascular Center**


Selected Publications

**Epilepsy Center**


**Lou Ruvo Center for Brain Health**


**Mellen Center for Multiple Sclerosis Treatment and Research**


Center for Neurological Restoration


Center for Neuroimaging


**Neuromuscular Center**


**Center for Pediatric Neurology and Neurosurgery**


Neurological Center for Pain


Department of Physical Medicine and Rehabilitation


Department of Psychiatry and Psychology


Selected Publications

Sleep Disorders Center


**Center for Spine Health**


**Emergency Services Institute Selected Publications**

Launching a Brain Metastasis Initiative: the B-AwareSM Program

An estimated 140,000 to 170,000 patients with common systemic cancers are diagnosed with brain metastasis every year in the United States. In particular, patients with breast, lung and renal cancers and melanoma are affected. Historically, brain metastasis has been considered a uniformly fatal condition, and treatments have been limited to palliative brain radiation. Over the last two decades, however, more aggressive approaches have been developed that can lead to local cure or sustained control of the disease in some patients. Nevertheless, cancer patients may be poorly informed about the risks of developing brain metastasis, its early warning signs and modern therapeutic options beyond whole brain radiation. Likewise, physicians may not be fully aware of new treatment options.

To address this issue, the Burkhardt Brain Tumor Center has launched the B-AwareSM program, which educates and empowers patients with information on the risks, symptoms and treatment options that may increase their life spans and improve quality of life. In addition, the center is actively engaged in developing physician awareness, and is collaborating with the American Cancer Society to promote the B-AwareSM program on the society’s website. The program is believed to be the first initiative of its kind to directly educate cancer patients on the health issues of brain metastasis.

An important component of the program is educating cancer patients to recognize early warning signs of brain metastasis. Aggressive therapies may improve outcomes when brain metastasis is diagnosed in its early stages. Traditional treatments such as whole brain radiation and glucocorticoids still play important roles in the treatment of brain metastasis. However, for many patients, whole brain radiation is inadequate to achieve sustained control and quality of life. In fact, in some cases, whole brain radiation may best be reserved for later use.

Alternatively, research has shown that aggressive treatments such as minimal access surgery and radiosurgery can help an appreciable number of patients survive up to five years and, in some cases, up to 10 years. For patients with new or recurrent metastatic tumors following radiotherapy, surgery in conjunction with the placement of carmustine wafers in the tumor cavity, or radiosurgery to the tumor cavity, may preclude local recurrence. In addition, Cleveland Clinic Gamma Knife® Center uses state-of-the-art stereotactic radiosurgery to treat metastatic tumors. Lesions are typically small (< 3 cm at presentation) and spherical, so they displace rather than infiltrate the brain. Results from radiosurgery appear comparable to those achieved by surgery with radiotherapy, and allow for effective treatment even of surgically inaccessible secondary brain tumors. Often, by applying a combination of these aggressive therapies, it is possible to control brain metastasis for an extended period of time and improve quality of life.
Developing a Rapid Test for MGMT Activity in Gliomas

Methylguanine methyltransferase (MGMT) is a DNA repair enzyme that is responsible for the resistance of multiple cancers to certain types of chemotherapy. Current methodology for determining the level of MGMT in a tumor specimen requires several days after a tumor sample is submitted to provide useful information. More timely intraoperative assessment of tumor MGMT levels during surgery may provide essential information necessary to determine whether a patient might benefit from instillation into the tumor or tumor cavity of agents aimed at decreasing MGMT activity, or whether the patient is likely to benefit from chemotherapy placed into the surgical cavity.

The Burkhardt Brain Tumor Center has developed a rapid, highly quantitative method for determining the level of MGMT activity in a tumor with use of just a small piece of tumor tissue. This assay, which requires only about one hour for results, can be performed in the operating room or in an adjacent pathology laboratory. The novel technique for performing this assay has been submitted for a patent, and was recently reported in the journal *Analytical Biochemistry*.¹

Cerebrovascular Center

Improving Access to Acute Stroke Care with the Telestroke Network

The Cerebrovascular Center is creating partnerships throughout Northeast Ohio and Pennsylvania with its new Telestroke Network. The network provides round-the-clock specialist coverage to assist medical centers in the assessment and treatment of their stroke patients. Each medical center is outfitted with a two-way portable videoconferencing system as well as a dedicated link between imaging systems, allowing physicians to connect and evaluate the patient within minutes. The Telestroke Network currently partners with Ashtabula County Medical Center, Huron Hospital, and Medina Hospital in Ohio, and Sharon Regional Health System and Saint Vincent Health System in Pennsylvania.
Implementing a Stroke Care Pathway

Cleveland Clinic recently integrated its own Stroke CarePath into the electronic medical record (EMR) to guide the comprehensive care of stroke patients, from acute presentation in the Emergency Department through the hospital stay and post-discharge care. The Stroke CarePath is based on multiple sources, including evidence-based guidelines, practice parameters, regulatory and organizational policies and procedures, as well as local clinical expertise. Clinical documentation and standard orders are defined and relevant outcomes and cost metrics are collected systematically for every patient.

As patients present with acute stroke, providers are offered suggestions, based on the best current evidence relative to patient care. Moreover, disease-specific clinical documents have been developed and incorporated into the EMR so that key processes and clinical variables can be routinely captured and measured. As a result, clinical documentation will mirror the standard of care and provide a common platform for reporting.

Stroke CarePath

Care pathways are a critical component of Cleveland Clinic’s efforts to deliver a broad menu of solutions to a networked community of providers.
Lou Ruvo Center for Brain Health

Building an Innovative Network to Improve Alzheimer’s Disease Care

Cleveland Clinic Lou Ruvo Center for Brain Health is building an innovative network to advance patient care through discovery of new therapies for Alzheimer’s disease and other neurocognitive disorders. The network concept takes advantage of the multisite distribution of Cleveland Clinic. The institution has expanded to Nevada and Florida, creating the opportunity to conduct research at all these sites within the Cleveland Clinic framework, with one leadership, one set of operational guidelines, the same data collection approaches and one institutional review board for research approval.

The center is capitalizing on this infrastructure to establish a clinical trials network that can more rapidly advance the development of new therapies for Alzheimer’s disease and other disorders of cognition. This approach is unique. The Lou Ruvo Center for Brain Health clinical trials network will position the center as a leader in advancing new therapies, developing new biomarkers and initiating novel programs for patients and caregivers. This program will serve as a model for how healthcare systems can embrace clinical trials, empowering patients to help defeat the diseases from which they suffer and helping to solve the problem of slow trial recruitment and slow emergence of new therapies.
**Center for Neuroimaging**

**Introducing a Hyperacute Stroke MRI Protocol**

Our “brain attack” program typically relies on non-contrast computed tomography (CT) of the head, CT angiography (CTA) and CT perfusion (CTP) studies to evaluate for a central ischemic core and a surrounding ischemic penumbra, the latter of which is potentially salvageable through aggressive intravenous and/or intra-arterial intervention. While the distinction between these two regions generally relies, in part, on the CTP study, a host of patient and technical factors makes this exam potentially unreliable. We recently introduced magnetic resonance imaging (MRI) into a hyperacute stroke protocol in an effort to make more informed decisions for therapy and extend the therapeutic window for acute stroke patients. While this strategy places additional logistical and safety demands on the acute workup of these patients, the benefits in patient management seem to outweigh the disadvantages. In view of the success on our main campus, this MRI protocol will shortly be exported to Lakewood and Hillcrest hospitals within our Cleveland Clinic health system.

**Developing an Electronic MR Safety Screening Tool**

Safety demands a careful screening process for patients prior to any MRI exam. Historically, this meant that each patient was required to complete an extensive paper questionnaire. We initiated a pilot project in the Neurological ICU, in which an electronic version was created for the electronic medical record. Preliminary data demonstrate significant reductions in the time intervals from the placement of the MRI order to exam completion and final report. Shortly, this form will be completed by all Neurological Institute inpatients upon admission, and it will travel with them across inpatient and outpatient venues.

**Improving Methods of Mapping White Matter Tracts for Surgical Planning**

Tractography is an advanced application of MR diffusion imaging to map the course of white matter tracts in the brain for surgical planning purposes, most commonly for tumor and epilepsy surgery. While the application performs reasonably well with larger tracts in normal volunteers, results can be quite variable, hence unreliable, in patients with a number of central nervous system disorders. Our physicists developed a probabilistic method to detect the course of eloquent and non-eloquent white matter tracts in the brain, even in the presence of central nervous system disease states that cause lesions in the brain’s white matter, as seen in the figure below. This same group developed a means for quantifying the connectivity or strength of the white matter connections between different areas in the brain. Previously introduced methods for this assessment have been limited by a strong bias that depends on the distance between different structures. The newly introduced normalization procedure permits the assessment of connections between neighboring subcortical regions, which is independent of the conventional biases.
Applying MRI Motion Correction

Researchers have developed two new methods for correcting motion during relatively long MRI exams, which are more prone to compromise by gross patient motion. One retrospective method is a broadly applicable, iterative approach to motion correction. This post-processing technique provides quantitative metrics for the quality of the motion correction, and should prove helpful for long fMRI exams and high-resolution diffusion tensor imaging. The second method is used to perform motion correction and assessment during the data acquisition, and is set up to alarm when the motion rises above a threshold. This latter method provides the technologist the opportunity to interrupt the study, give feedback to the patient and repeat the acquisition to increase the likelihood of producing clinically useful MRI exams.

Using Intraoperative MRI to Guide Insertion of Deep Brain Stimulators

The Section of Neuroradiology recently introduced an interventional MRI suite attached to a conventional operating room. This suite initially was utilized for intraoperative guidance of intracranial tumor surgery. The same technology would seem ideal for the placement of deep brain stimulators, as it would be expected to improve accuracy and greatly reduce the time necessary to place the stimulators compared with standard OR practices. Previously, we conducted extensive testing with industry to identify safe methods for MR scanning of patients who have deep brain stimulators in place. Neuroradiologists have also worked with our functional neurosurgeons to develop methods to implant these deep brain stimulators safely within the MRI environment, thus enabling our colleagues to take full advantage of the new facility.
Implementing High-Resolution Magnetic Resonance Angiography

The resolution of conventional MRI is about 1-2 mm, depending on the MRI sequence used. This size scale is at the limit for diagnostic imaging of most intracranial vessels, particularly the larger cerebral arteries that provide almost all inflow to the brain. Many disease processes affect these vessels and smaller vessels. The current gold standard is conventional angiography, but it carries a non-negligible risk of serious complications, such as stroke. Furthermore, this technique cannot image the vessel wall, only its lumen. Another alternative is computed tomography angiography (CTA), but it carries a radiation burden and cannot easily be repeated.

At Cleveland Clinic, we have implemented a new MRI sequence called high-resolution magnetic resonance angiography (HR-MRA), which utilizes the high-performance capabilities of our cutting-edge MRI machines. With this technique, we can image the lumen and vessel wall of the cerebral arteries, and strikingly show pathologic states that manifest as abnormal wall thickening with concomitant lumenal narrowing. An example of this technique is shown in the figure. The left panel shows a conventional MRA, with an arrow pointing to abnormal narrowing of the basilar artery in a patient with known cerebral vasculopathy. The middle panel shows an axial HR-MRA example through this artery, demonstrating lumenal narrowing with vessel wall thickening and enhancement suggesting inflammation. For comparison, on the right, is an example of a normal basilar artery.
Epilepsy is one of the most common adult brain disorders. In the United States, epilepsy affects 3 million people, with 200,000 new cases per year. In some patients with medically refractory epilepsy, surgery is an option. The ultimate goal of epilepsy surgery is the complete removal of the epileptogenic zone with the preservation of eloquent brain parenchyma. In some patients, invasive brain mapping is required for further characterization of the epileptogenic zone.

At Cleveland Clinic Epilepsy Center, subdural grids and strips or stereotactically placed depth electrodes (stereoelectroencephalography, or SEEG) are the current surgical techniques for invasive brain mapping. As a possible alternative, frameless, image-guided robotic placement of depth electrodes may offer additional advantages, making the implantation of depth electrodes more precise and safer. The technique also allows the combination of subdural grids and stereotactically placed depth electrodes, providing a precise spatial mapping of the superficial and deep structures in the brain, with optimal 3D understanding of the epileptic neuronal network and its relation to cortical brain function.
Collaboration for Outreach and Prevention Education (COPE) for Children and Adolescents with Epilepsy

Empowering patients with epilepsy and their families is a crucial element of continued medical care. As part of Cleveland Clinic Epilepsy Center’s commitment to community outreach, education and improved access to mental healthcare in patients with epilepsy, Project COPE: Collaboration for Outreach and Prevention Education for Children and Adolescents with Epilepsy, received NIH funding and was implemented in 2010. The primary goal of this project is to increase awareness of mental health issues in children with epilepsy; decrease the stigma of accessing mental healthcare; and educate families, children, caregivers, schools, peers and the medical community on the need to refer epileptic youth struggling with mental health problems to the appropriate level of care. The program targets at-risk Latino and African-American children with epilepsy, in addition to the general population of individuals with epilepsy in Greater Cleveland.

The project is designed to improve access to mental healthcare by developing a community-based, culturally and linguistically competent mental healthcare outreach model. It is essential to educate stakeholders (providers and patients) about psychiatric comorbidities in youth with epilepsy. Project COPE consists of a series of educational talks (workshops) for epileptic children and their families, in addition to workshops for classrooms that include children with epilepsy. Another part of Project COPE is an anti-bullying workshop, to be conducted in school for classmates and teachers. Project COPE collaborates with the Epilepsy Association of Cleveland, the Cleveland Metropolitan School District and the National Alliance on Mental Illness – Greater Cleveland to increase knowledge of mental health issues in children with epilepsy.

Mellen Center for Multiple Sclerosis Treatment and Research

Studying a New Vascular Theory of Multiple Sclerosis

Mellen Center investigators and collaborators from cerebrovascular medicine, radiology, vascular medicine and neuropathology were awarded funding from the National Multiple Sclerosis Society to study a new vascular theory of multiple sclerosis, called chronic cerebrospinal venous insufficiency (CCSVI). This two-year multidisciplinary study will evaluate CCSVI in more than 150 multiple sclerosis (MS) patients and non-MS controls, and will also evaluate vascular tissue obtained at autopsy.
Designing the Hip Flexion Assist Device

The Hip Flexion Assist Device (HFAD) was designed through a collaboration between a Mellen Center physical therapist and local orthotists to help patients with multiple sclerosis who suffer from unilateral or bilateral hip flexor, knee flexor and ankle dorsiflexor weakness. The typical presenting gait includes “dragging” of the leg, which in some cases may be corrected with an ankle foot orthosis (AFO) if the weakness is primarily in the ankle dorsiflexors. In many other cases, however, due to weakness in the flexors of the hip and knee, an AFO is insufficient and the user may still present with an unsatisfactory dragging of the leg. This combination of distal and proximal weakness is the scenario in which the HFAD is most effective.

The HFAD uses elastic tension bands that anchor proximally to a waist belt and attach distally to a strap that fits under the shoelaces. The tension may be adjusted to allow symmetrical toe clearance between each leg as the user swings the leg through during normal gait. The device can be worn with or without a popliteal strap. The popliteal strap connects the tension bands posterior to the knee and improves knee flexion as the toe pushes off from the floor to take a step. For example, the popliteal strap is quite effective for patients with prominent extensor tone in the affected leg, which may impair effective knee flexion. The device is most effective when combined with gait training with a physical therapist.

An uncontrolled pilot study conducted at the Mellen Center found the HFAD to be safe and effective in improving ambulation speed, endurance and quality of life. The Mellen Center is currently enrolling patients in a randomized, controlled study to further examine the safety and efficacy of the HFAD to improve walking in MS patients. This two-year study plans to enroll 88 participants and is funded through a grant from the National Multiple Sclerosis Society.
Center for Neurological Restoration

Treating Chronic Central Pain with Deep Brain Stimulation

The Center for Neurological Restoration has been funded to investigate a novel treatment approach for managing patients with central thalamic pain syndrome, a particularly severe form of pain. In this pilot study, deep brain stimulation (DBS) of the ventral capsular/ventral striatal (VC/VS) area will be utilized to modulate the affective component in patients with refractory pain and, consequently, to reduce pain-related disability. This approach departs from the traditional practice of intervening in the sensory-discriminative neural pathways of pain transmission to produce analgesia. This research marks the first use of DBS of the VC/VS for management of central pain and builds upon the work of a multicenter collaborative, including Cleveland Clinic, that has evaluated stimulation of the VC/VS for treatment of disabling depression and obsessive-compulsive disorders.

Neuromuscular Center

Developing an Interdisciplinary Peripheral Nerve and Plexus Surgery Program

The Cleveland Clinic Peripheral Nerve and Plexus Surgery Program is a specialized, multidisciplinary clinic designed to diagnose and treat brachial and lumbosacral plexus disorders and focal neuropathies of the upper and lower extremities, including peripheral nerve tumors, trauma and entrapment. The program incorporates expert clinical evaluation, world-class electrodiagnostic testing, state-of-the-art imaging technology, cutting-edge surgical management options, and postoperative rehabilitation and pain management services.

The program offers the unique advantage of allowing select patients to undergo a prearranged same-day evaluation, including electrodiagnostic evaluation, imaging, and assessment by a neurologist and neurosurgeon with expertise in treating these disorders. In some cases, evaluation over two days is required. An interdisciplinary approach is utilized in order to provide a tailored treatment plan for each patient.

Assessing the Autonomic Nervous System with the Thermoregulatory Sweat Test

The thermoregulatory sweat test is a measure of a patient’s ability to sweat when stimulated by a warm and humid environment. This test assesses both the central and peripheral autonomic nervous systems’ control of sweating and body temperature regulation (thermoregulation). The pattern of sweating abnormality detected by this test can be helpful in diagnosing a variety of neurological and autonomic disorders that may cause reduced sweating (anhidrosis) or excessive sweating (hyperhidrosis). These disorders include small-fiber and autonomic neuropathies, radiculopathies and central autonomic disorders, including multiple system atrophy, Parkinson’s disease with autonomic dysfunction and pure autonomic failure.
Neurological Center for Pain
Utilizing Sphenopalatine Ganglion Stimulation to Treat Migraine

Outflow of signals from the brainstem to the meninges through the sphenopalatine ganglion (SPG) may lead to the mechanisms of migraine pain. Inhibitory stimulation of the SPG and blocks of the SPG show promise in terminating primary headaches.\textsuperscript{1,2} The Neurological Center for Pain and the Center for Neurological Restoration have teamed with the Department of Pain Management to obtain an Investigational Device Exemption from the Food and Drug Administration for a study of SPG stimulation for acute treatment and prevention of episodic migraine. Patients in the study will be implanted with a permanent SPG stimulator, and they will stimulate acute migraine attacks to see if this device can terminate migraines. After three months, doctors in the study will activate the stimulator chronically to see if continuous stimulation will prevent migraines. Patients will be able to use a second program in the device to terminate any attacks that break through the prevention.

References:


Developing New Methods of Treating Chronic Pain after Spinal Cord Injury

Chronic pain, which disturbs behavioral function and reduces quality of life, has emerged as a major challenge in treating spinal cord injury (SCI). There is currently no cure for chronic pain and oral pharmaceutical interventions are often inadequate, commonly resulting in a slight reduction in pain intensity. Furthermore, addiction and abuse due to continuous administration have become important clinical issues. These facts signal an urgent need to develop a new intervention to treat chronic SCI pain.

After single extracellular matrix (ECM) treatment in the animal SCI model, we developed a novel and effective ECM strategy to inhibit mechanical allodynia, an indicator of chronic SCI pain, over an eight-month observation period. The data, when compared with the vehicle-treated group, showed less blood-spinal cord barrier (BSB) permeability and decreased glial fibrillary acidic protein (GFAP)- and ED1-immunopositive reactivity at the lesion site as well as the areas both rostral and caudal to the lesion site. Additionally, this treatment can modulate the sprouting of 5-HT- and CGRP-positive fibers in laminae I and II of the spinal dorsal horn that mediate pain. Collectively, results from our studies have demonstrated that one-time ECM treatment can modulate nociceptive signaling and lessen inflammation, offering a potential therapeutic strategy to treat chronic pain development after SCI and the neuropathic and/or inflammatory pain caused by other diseases.

Investigating a New Modality to Prevent Deep Vein Thrombosis and Enhance Fibrinolysis

Each year, 600,000 patients experience venous thromboembolism, with at least 50,000 and perhaps as many as 200,000 dying from blood clots that obstruct blood flow to their lungs (pulmonary embolism). The total cost per patient for objective diagnosis and treatment of acute venous thromboembolic disease has been estimated at approximately $4,000, and does not include costs for patients who incur long-term sequelae. Functional magnetic stimulation (FMS) using a magnetic coil and applying a time-varying magnetic field has been demonstrated to be an effective modality for preventing deep vein thrombosis (DVT) and enhancing fibrinolysis.

Vernon Lin, MD, PhD, and his team have demonstrated that FMS can produce a sustained enhancement of systemic fibrinolysis that may prove useful in DVT prophylaxis. The advantages of FMS include painless and noninvasive stimulation because the magnetic field generated can penetrate high-resistance structures such as bone, fat, skin, clothes and leg casts.

However, the device used for FMS is bulky and difficult to secure to a patient during clinical applications. In the case of DVT, the coils must be secured in an optimal location, between the knee and ankle, to provide the desired stimulative effect. Also, the FMS coils generate heat during stimulation and can cause blisters if they touch the patient’s skin.

We have proposed a design that provides a method for securing the coil in an optimal position, prevents any contact with the skin and dissipates the heat generated by the coil during stimulation. The components of this design include magnetic stimulator (any commercially available model), stimulating coil (commercially available circular model), contoured coil positioning and securing system, cooling system and control unit. The proposed design can easily be adjusted to various body sizes and applications and is portable, reusable and easy to maintain.
Measuring Head Impact with the Intelligent Mouthguard

Concussion and traumatic brain injury (TBI) are brain health issues on a geopolitical scale. Almost daily, headlines emerge regarding concussion in football players, deteriorating mental capacity in boxers, TBI in soldiers returning from Iraq and Afghanistan, and the long-term risk of head impact in the forms of dementia, Alzheimer’s disease and Parkinson’s disease. Currently, the only proven method to assess concussion or TBI is a neurological examination by an experienced physician. This method, however, has been hindered by subjective patient input. Absent a robust, accurate and objective concussion and TBI assessment system, clinicians still struggle to answer basic questions about concussion and TBI, such as:

1. When is it necessary to remove an athlete or soldier from competition or military duty after subconcussive or concussive head impacts?

2. How does one identify TBI in an athlete or soldier with normal physical and neurological diagnostic examination and imaging studies?

3. When is it safe to return an athlete or soldier to competition or the battlefield after concussion and/or TBI?

Supported by the Cleveland Clinic Product Development Fund, Cleveland Clinic Spine Research Laboratory and Cleveland Clinic Neurological Institute, the Intelligent Mouthguard was conceived in 2008 as a method to measure head impact dosage via an instrumented mouthguard. Between 2008 and early 2011, work on the project rapidly progressed with the development and delivery of several wireless prototypes.
Prototype ‘V1a’ was a robust laboratory version that incorporated off-the-shelf sensors and Bluetooth data transmission. Prototype ‘V1b’ was approximately 40 percent smaller than ‘V1a.’ Both prototypes, provided valuable insights into clinical data requirements, data collection, Bluetooth proof of concept and measurement algorithm validation from within the laboratory setting. After construction, these prototypes were mounted to a crash test dummy head form and put through a battery of validation experiments, resulting in the July 2010 filing of a provisional patent (“Detection and Characterization of Head Impacts”) based on a proprietary algorithm to wirelessly relate mouth-measured impact dosage to clinically relevant data.

Prototype ‘V2a’ was the first “mouthable” prototype and was delivered in 2010. Whereas both ‘V1a’ and ‘V1b’ were mounted on custom-printed circuit boards and required hand-soldered components, prototype ‘V2a’ incorporated an off-the-shelf mouthguard provided by collaborator Sportsguard Laboratories, Inc., as well as a custom-designed six-degrees-of-freedom microelectromechanical systems (MEMS) sensor package from collaborator Virtus Advanced Sensors. Key differences were that the robust laboratory prototypes ‘V1a’ and ‘V1b’ were high-g (~250g) but could not fit in the mouth, and ‘V2a’ was low-g (~3g) but able to fit into the mouth. In 2011, the Cleveland Clinic Neurological Institute team and collaborators will be conducting further development work to produce additional pre-commercial Intelligent Mouthguard prototypes, such as prototype ‘V3’, which will provide a more favorable mouth form and also collect high-g impacts.

Intelligent Mouthguard wirelessly collects and characterizes head impact dosage.

Intelligent Mouthguard ‘V3’

With the collection of initial head impact dosage data in boxers and football players under an NFL Charities grant, “Examining the Role of Cervical Spine in Football-Related Concussions” (anticipated Fall 2011), the Intelligent Mouthguard will for the first time allow widespread, accurate and objective assessment of the head impact dosage responsible for concussion and TBI.
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Contact Information

**General Patient Referral**
24/7 hospital transfers or physician consults
800.553.5056

**Neurological Institute Appointments/Referrals**
216.636.5860 or toll-free 866.588.2264

On the Web at clevelandclinic.org/neuroscience

**Additional Contact Information**

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216.444.2200

**Hospital Patient Information**
216.444.2000

**General Patient Appointments**
216.444.2273 or 800.223.2273

**Referring Physician Center**
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216.448.0900 or 888.637.0568, or email refdr@ccf.org

**Request for Medical Records**
216.444.2640 or 800.223.2273, ext. 42640

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**Global Patient Services/International Center**
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**Cleveland Clinic Florida**
Toll-free 866.293.7866

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Cleveland Clinic Neurological Institute physicians see patients at the locations below. Please inquire about the availability of specific services at each location when calling.

**Cleveland Clinic Main Campus**
9500 Euclid Ave.
Cleveland, OH 44195
Toll-free 866.588.2264

**Avon Lake Family Health Center**
450 Avon Belden Road
Avon Lake, OH 44012
440.930.6800

**Beachwood Family Health and Surgery Center**
26900 Cedar Road
Beachwood, OH 44122
216.839.3000

**Broadview Heights Family Health Center**
2001 East Royalton Road
Broadview Heights, OH 44147
216.986.4000

**Brunswick Family Health Center**
3574 Center Road
Brunswick, OH 44212
330.225.8886

**Chagrin Falls Family Health Center**
551 E. Washington St.
Chagrin Falls, OH 44022
440.893.9393

**Cleveland Clinic Children’s Hospital Shaker Campus**
2801 Martin Luther King Jr. Drive
Cleveland, OH 44104
216.721.5400

**Cleveland Clinic Nevada**
Lou Ruvo Center for Brain Health
888 W. Bonneville Ave.
Las Vegas, NV 89106
702.483.6000

**Cleveland Clinic Nevada**
Lou Ruvo Center for Brain Health
890 Mill St., Suite 102
Reno, NV 89502
775.337.6200
Institute Locations

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18901 Lake Shore Blvd.
Euclid, OH 44119
216.692.8586

Fairview Hospital
18101 Lorain Ave.
Cleveland, OH 44111
216.476.7000

Hillcrest Hospital
6780 Mayfield Road
Mayfield Heights, OH 44124
440.312.4500

Huron Hospital
13951 Terrace Road
East Cleveland, OH 44112
216.761.3300

Indepedence Family Health Center
5001 Rockside Road
Crown Centre II
Independence, OH 44131
216.986.4000

Lakewood Hospital
14519 Detroit Ave.
Lakewood, OH 44107
216.529.7110

Lorain Family Health and Surgery Center
5700 Cooper Foster Park Road
Lorain, OH 44053
440.204.7400

Lutheran Hospital
1730 W. 25th St.
Cleveland, OH 44113
216.696.4300

Marymount Hospital
12300 McCracken Road
Garfield Heights, OH 44125
216.581.0500

Medina Hospital
1000 E. Washington St.
Medina, OH 44256
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<tr>
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<th>Phone Number</th>
</tr>
</thead>
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About Cleveland Clinic

Overview
Cleveland Clinic is a nonprofit multispecialty academic medical center that integrates clinical and hospital care with research and education. Today, more than 2,500 Cleveland Clinic physicians and scientists practice in more than 100 medical specialties and subspecialties, annually recording more than 1.5 million physician visits and more than 70,000 surgeries. Cleveland Clinic currently has the highest CMS case-mix index in America. Patients come for treatment from every state and from more than 80 countries annually.

Cleveland Clinic’s main campus, with 50 buildings on 180 acres in Cleveland, Ohio, includes a 1,300-bed hospital, outpatient clinic, specialty institutes and supporting labs and facilities. Cleveland Clinic also operates 16 family health centers, nine community hospitals, one affiliate hospital, a rehabilitation hospital for children, Cleveland Clinic Florida, the Lou Ruvo Center for Brain Health in Las Vegas, and Cleveland Clinic Canada. Cleveland Clinic Abu Dhabi (United Arab Emirates), a multispecialty care hospital and clinic, is scheduled to open in 2012. With 41,000 employees, Cleveland Clinic is the second largest employer in Ohio, and is responsible for an estimated $9 billion of economic activity every year.

The Cleveland Clinic Model
Cleveland Clinic was founded in 1921 by four physicians who had served in World War One and hoped to replicate the organizational efficiency of military medicine. The organization has grown through the years by adhering to the model set forth by the founders. All Cleveland Clinic staff physicians receive a straight salary with no bonuses or other financial incentives. The hospital and physicians share a financial interest in controlling costs and profits are reinvested in research and education.

In 2007, Cleveland Clinic restructured its practice, bundling all clinical specialties into integrated practice units called institutes. An institute combines all the specialties surrounding a specific organ or disease system under a single roof. Each institute has a single leader and focuses the energies of multiple professionals onto the patient. From access and communication to billing and point-of-care service, institutes are improving the patient experience at Cleveland Clinic.

Cleveland Clinic Lerner Research Institute
At the Cleveland Clinic Lerner Research Institute, hundreds of principal investigators, project scientists, research associates and postdoctoral fellows are involved in laboratory-based, translational and clinical research. Total annual research expenditures exceed $272 million from federal agencies, non-federal societies and associations, endowment funds and other sources.

Cleveland Clinic physicians, scientists, fellows, residents and other employees are involved in more than 3,000 human-subject research activities at any given time.

Cleveland Clinic Lerner College of Medicine
Now in its seventh year of existence, Cleveland Clinic Lerner College of Medicine of Case Western Reserve University offers all students full-tuition scholarships. The program graduated its first 29 students as physician-scientists in 2009.

U.S. News & World Report Ranking
Cleveland Clinic is consistently ranked among the top hospitals in America by U.S. News & World Report, and our heart and heart surgery program has been ranked No. 1 since 1995.

For more information about Cleveland Clinic, please visit clevelandclinic.org.
Referring Physician Center
For help with service-related issues, information about our clinical specialists and services, details about CME opportunities and more, contact the Referring Physician Center at refdr@ccf.org, or 216.448.0900 or 888.637.0568.

Critical Care Transport Worldwide
Cleveland Clinic's critical care transport team and fleet of mobile ICU vehicles, helicopters and fixed-wing aircraft serve critically ill and highly complex patients across the globe.

To arrange a transfer for STEMI (ST elevated myocardial infarction), acute stroke, ICH (intracerebral hemorrhage), SAH (subarachnoid hemorrhage) or aortic syndromes, call 877.379.CODE (2633).

For all other critical care transfers, call 216.444.8302 or 800.553.5056.

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Track Your Patient's Care Online
DrConnect offers referring physicians secure access to their patients' treatment progress while at Cleveland Clinic. To establish a DrConnect account, visit clevelandclinic.org/drconnect or email drconnect@ccf.org.

Medical Records Online
Cleveland Clinic continues to expand and improve electronic medical records (EMRs) to provide faster, more efficient and accurate care by sharing patient data through a highly secure network. Patients using MyChart can renew prescriptions and review test results and medications from their own personal computer. MyChart offers a secure connection to Google™ Health, where users can securely share personal health information with Cleveland Clinic and record and share details of their Cleveland Clinic treatment with the physicians and healthcare providers of their choice. To establish a MyChart account, visit clevelandclinic.org/mychart.

Remote Consults
Online medical second opinions from Cleveland Clinic's MyConsult are particularly valuable for patients who wish to avoid the time and expense of travel. Cleveland Clinic offers online medical second opinions for more than 1,000 life-threatening and life-altering diagnoses. For more information, visit clevelandclinic.org/myconsult, email eclevelandclinic@ccf.org or call 800.223.2273, ext. 43223.

CME Opportunities: Live and Online
Cleveland Clinic’s Center for Continuing Education operates one of the largest and most successful CME programs in the country. The center’s website (ccfcme.com) is an educational resource for healthcare providers and the public. Available 24/7, it houses programs that cover topics in 30 areas — if not from A to Z, at least from Allergy to Wellness — with a worldwide reach. Among other resources, the website contains a virtual textbook of medicine (Disease Management Project), a medical newsfeed refreshed daily, and myCME, a system for physicians to manage their CME portfolios. Live courses, however, remain the backbone of the center’s CME operation. Most live courses are held in Cleveland, but outreach plans are under way. In 2010, the center offered 11 simultaneous courses at Arab Health, a major world healthcare forum, in Dubai, United Arab Emirates.
This project would not have been possible without the commitment and expertise of many individuals, but in particular Jocelyn Bautista, MD; Irene Katzan, MD; Christine Moore; and John Urchek.
Neurological Institute

2010 Outcomes