Developing Performance Metrics for Prosthetic Utility

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Dear Colleagues,

We’re starting a new PM&R residency program at Cleveland Clinic. The first class will arrive in July 2016.

Our fellowship programs that recruit PM&R graduates and host visiting residents have been a source of pride for decades. We’ve welcomed some of the best young doctors in the country for advanced training in electromyography, multiple sclerosis, pain management, spine medicine, sports medicine and musculoskeletal medicine.

The ratio of staff attention units to work productivity units is relatively low for fellows. Starting a residency training program will flip that ratio; we are blessed with a faculty that is ready to take this on. We are equally fortunate to work for physician leaders here who recognize the importance of the post-acute medical space and are willing to support these efforts in the face of declining hospital reimbursement for teaching activities.

I hope that we can encourage more residents to choose inpatient rehab as a career. With the inpatient rehab experience provided in many PM&R residencies, it’s no wonder that so many of our graduates choose to pursue pain management or musculoskeletal medicine. Our labyrinthine teaching hospitals tend to collect the most complicated and demanding patients and families. Trainees measure themselves against the rare faculty mentors who are up to the task of treating these patients, then many rush toward jobs with less traction, less call and fewer unhappy customers.

As a result, hundreds of rehab hospitals across the country are staffed by interns and family practitioners. It’s a shame that most PM&R trainees are not exposed to practice in community-based hospital settings. These are jobs that are diverse, stable, well-paying, manageable and, most of all, gratifying. As much as possible, we hope to show this to our new residents.

As our new residency program’s director, John Lee, MD, explains on P. 16, the diversity of Cleveland Clinic’s healthcare system and the breadth of rehab experiences and patients that our PM&R residents will encounter during their instruction should help achieve this goal.

One of the settings where our new residents and their mentors will care for patients is the 60-bed adult rehab hospital that Cleveland Clinic is building next to our Avon, Ohio, medical campus, in a joint venture with Select Medical. The hospital is nearing completion, as you’ll see in the photos on P. 22, and should open later this year. We’re excited by the project, which is a testament to our plans to expand rehab services regionally, nationally and internationally.

Elsewhere in Frontiers in Rehabilitation, you’ll read accounts that demonstrate the broad scope of our clinical and academic efforts. Ela Plow, PhD, Andre Machado, MD, PhD, and colleagues describe brain stimulation’s potential to, respectively, restore post-stroke upper limb function and alleviate post-stroke refractory thalamic pain syndrome. Paul Marasco, PhD, reports on his team’s efforts to devise performance measures to aid the development of advanced prosthetic limbs. Ian Stephens, PT, DPT, OCS, writes about our creation of a physical therapy care path for patients with lower back pain that should make treatment more efficient and effective. And Mary Stilphen, PT, DPT, explains an ambitious project to integrate our 6 Clicks patient functional assessment tool into Cleveland Clinic’s electronic medical record, enabling the seamless provision of rehab services across all treatment settings.

Projects such as these collectively show our Department of Physical Medicine and Rehabilitation’s drive to put our patients first, to train those who serve them and to investigate their problems in a rigorous scientific environment. There is a palpable, positive energy when you enter our buildings; we’re anxious to share that with PM&R trainees.

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Prosthetic limb technology has significantly advanced in recent years, but there is currently no standardized set of metrics to evaluate these technologies. This lack of objective information leaves insufficient evidence to guide research and medical decision-making. It also hinders the ability to communicate benefits to patients and demonstrate improved outcomes to insurance payers.

A Cleveland Clinic-led research team has been awarded up to $2.5 million through a contract from the Defense Advanced Research Projects Agency (DARPA) to develop a suite of outcome metrics for advanced prosthetic limbs that are clinically relevant and rooted in cutting-edge science.

Our project’s goal is to inform future prosthetics development; help physical medicine and rehabilitation physicians make better clinical care decisions regarding prosthetic selection; justify to payers the need for advanced prosthetic devices; and ultimately improve the quality of life for patients with upper limb amputations. Clinical practice will not change until it can be demonstrated to insurers that technological advances in prosthetics actually improve outcomes.

The contract is through DARPA’s new Hand Proprioception and Touch Interfaces (HAPTIX) program, which aims to deliver naturalistic sensations to amputees and enable better control over their prosthetic limbs.

The research team of neuroscientists, clinicians and engineers intends to develop and validate a battery of functional metrics for advanced prosthetic limb systems that are integrated with the nervous system to provide intuitive motor control and relevant feedback for tactile and proprioceptive sensation.

This Sensory-Motor Prosthetic Evaluation Suite will focus on the assessment of the amputee-prosthetic system in clinical application. Using functional tasks, videography, virtual/augmented reality, motion-capture equipment and analytic software, the various metrics will quantify key

**KEY POINTS**

Current prosthetics lack sensitive, standardized, objective performance metrics to guide future development and clinical use.

A Cleveland Clinic-led research team is developing a suite of outcome metrics for existing and advanced prosthetic limbs.
aspects of sensory-motor functional performance to provide evidence on effectiveness. The group of tests will be correlated to current standard outcome metrics for upper limb prosthetic users, and will require minimal technical expertise to operate.

Getting a GRIP

The metrics will include the following approaches:

• Grasping Relative Index of Performance (GRIP)

Principal tasks for prosthesis use involve grasping, gripping, or squeezing. Quick and accurate application of desired forces is critical for manual manipulation, from holding hands to heavy lifting, and is necessary for obtaining fluid, natural prosthetic use. Fitts’ law is a widely applicable descriptive model relating the time required to achieve a target to movement size and accuracy. Applying this law to grip forces across the dynamic range of a terminal device is expected to quantify a relative effective accuracy and index of performance, irrespective of the prosthetic control scheme or feedback modality.

• Prosthesis Efficiency and Profitability (PEP)

Humans use their hands to acquire and manipulate objects for a multitude of activities of daily living. This involves seamless interaction between motor control, touch and proprioception. Upper limb prosthetics replace this lost functionality, and their intrinsic utility is reflected in relative efficiency of use. Accepted methodologies from evolutionary ecology provide a mathematical model-based framework for assessing efficiency and profitability in complex biological systems. Optimal foraging theory, a model that helps predict an animal’s food-searching behavior, will be used as a platform to objectively assess the searching, reaching, grasping, manipulating and decision-making movements involved with prosthesis use.

• Gaze and Movement (GAM)

The movement of our eyes to specific locations is intimately tied to the demands of a task and is an excellent correlate of our mental focus point. Visual attention is an integral component of motor performance that is expected to change with accurate sensory feedback from the prosthesis and intuitive motor control. The combination of movement and eye tracking during simulated real-world tasks will identify the motion of the prosthesis, compensatory body movements and simultaneous visual gaze behavior. This test will assess the effect of advanced motor control systems and tactile and kinesthetic feedback on movement and visual attention.

• 3-D Gaze and Movement (3-D GAM)

The function of a prosthesis is defined not only by the movement of the device and the body, but also by the movement of grasped objects within their environmental context. Expanding on the gaze and movement tracking described above, goal-directed tasks will be assessed in a real-world environment. The movement of task-critical objects will be joined with 3-D gaze points rendered into a workspace that includes a full breadth of active reaching, grasping and placement tasks. This will use simultaneous tracking of how an object is moved, where the gaze is centered in space, and how the body and prosthesis move during relevant goal-oriented functional tasks to evaluate the benefits of enhanced motor control, including proprioceptive and tactile sensory feedback.

• Prosthesis Incorporation (PIC)

Measuring how much a prosthesis has been incorporated into the body schema is likely a good indication that control and sensory feedback are intuitive, synchronized and meaningful. We will use the cross-modal congruency effect (which tracks reaction time as the brain “figures out” which
different stimuli to combine to feel integrated across vision, touch and movement) to evaluate prosthesis incorporation and assess the ability of a person to ignore one form of feedback in favor of another. We seek to develop an index that can be assessed quickly and accurately, using a simple standardized setup, while being sensitive to control source, tactile feedback fidelity and kinesthetic feedback.

- **Control Bottleneck Index (CBI)**
  Brain signals can be corrupted by noise from many sources. To counteract this, the brain forms models that help it predict limb control and interpret feedback. Good prosthetic performance can be achieved with many combinations of control and feedback, but performance may be limited by system bottlenecks such as noisy control signals, or errors in feedback with respect to touch or movement. Improvements in feedback and control may not lead to significant improvements in performance until these constriction points are relieved. This work will identify the processing bottlenecks for given tasks, and evaluate the contribution of particular control strategies or sensory feedback modalities independent of the specific impediments.

**Paving the Way for Lifelike Robotic Limbs?**

These metrics could conceivably change the way that prosthetic devices are defined. With the Sensory-Motor Prosthetic Evaluation Suite, we want to help usher in a new era of prosthetic limb replacement by having our evaluation approaches be sensitive to testing advanced multifunctional robotic prosthetic limbs with sensory feedback directly connected to the prosthetic user.

Along the way, we want to substantially advance how we demonstrate the benefits of currently available standard-of-care prosthetic limb systems.

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Enterprise Care Transformation: Integrating 6 Clicks and the Electronic Medical Record

By Mary Stilphen, PT, DPT

As part of its ongoing efforts to reduce healthcare costs and improve the quality of care that patients receive, Cleveland Clinic has established the Clinical Transformation initiative, led by Chief Clinical Transformation Officer Michael Modic, MD. The initiative’s intent is to develop and execute a system of integrated, highly coordinated, value-based treatment whose components include:

- Care path clinical guidelines derived from the latest research
- Seamless, accessible electronic medical records
- Interdisciplinary care teams organized to address individual patients’ needs
- Discharge planning that appropriately assigns rehabilitative services to avoid unnecessary readmissions and restore physical functioning

Dr. Modic has drawn the theoretical model for this transformative process from his experience as Chairman of Cleveland Clinic’s Neurological Institute and his oversight of its Department of Physical Medicine and Rehabilitation. This theoretical model is meant to change the healthcare system’s focus from treating illness to restoring and sustaining health. That will require incorporation of the biopsychosocial model of medicine, which stresses a broadened, holistic conception of health defined by a patient’s physical, mental and sociological status. Rehabilitation is a vital component of the care transformation process.

Cleveland Clinic’s enterprisewide approach involves the precise tracking, collation and analysis of physical, psychological and cognitive functioning and environmental vectors that affect an individual’s health. The ultimate goal is creation of a comprehensive, digitally captured patient phenotype that allows us to better understand...
the complex factors affecting health and to direct resources accordingly.

A recent but valuable addition to this growing data set is the 6 Clicks tool, a pair of electronic questionnaires administered by Cleveland Clinic physical therapists and occupational therapists to measure the functional status of patients in the acute care hospital. The tool is a short-form version of Boston University’s Activity Measure for Post-Acute Care™, developed and validated at Cleveland Clinic.

Hospitals are adept at measuring burden of illness with case mix index, but physical function is what drives the provision of most post-acute services.

Since its inception in 2011, 6 Clicks has been used to assess nearly 600,000 patients. It is a functional measurement tool designed for the hospital. It helps determine appropriate referrals for physical and/or occupational therapy, aids in discharge planning and improves allocation of treatment resources and personnel in the acute care hospital.

In April 2015, we completed an enormous project that brought together Cleveland Clinic information technology experts and rehabilitation leaders with the goal of full integration of our 6 Clicks rehabilitation outcomes platforms into the enterprisewide electronic medical record (EMR).

To illustrate the order of magnitude of this effort, the 6 Clicks tool measuring a patient’s physical capabilities is but one of a dozen discrete biopsychosocial elements culled from the EMR. Just one of those elements involves data analysis of hundreds of patients and millions of data points.

The response to the biopsychosocial element/EMR integration from treating physicians and rehabilitation professionals has been overwhelmingly positive. Before long, physicians will be able to assess, at a glance, the variety of factors (e.g., family support, physical function, mood, financial resources) that truly determine health outcomes.

The result is that our healthcare providers are able to minimize the time they must spend typing and retrieving information from the computer and maximize the time interacting with patients. They can measure and manage the provision of rehab services from the emergency department through the acute care hospital and into every post-acute setting.

Ms. Stilphen (stilphm@ccf.org; 216.444.8610) is Senior Director, Rehabilitation Services, in the Department of Physical Medicine and Rehabilitation.

What 6 Clicks Tracks

The 6 Clicks tool, conceived and designed at Cleveland Clinic in collaboration with Boston University’s Rehabilitation Outcomes Center, standardizes the assessment of hospitalized patients’ mobility and self-care abilities. Hospital patients in need of formal post-discharge care are scored on the following functional areas:

**Basic mobility**
- Bed mobility
- Chair sit/stand
- Moving to sit on edge of bed
- Bed/Chair transfer
- Walk in room
- 3-5 stairs

**Daily activity**
- Lower body dressing
- Bathing
- Toileting
- Upper body dressing
- Personal grooming
- Eating

**KEY POINTS**

Hospitals are adept at measuring burden of illness with case mix index, but patients’ physical function is what drives the provision of most post-acute services.

Since 2011, Cleveland Clinic has used the 6 Clicks functional measurement tool to determine appropriate referrals for physical and/or occupational therapy, aid in discharge planning and improve allocation of treatment resources and personnel in the acute care hospital.

The integration of 6 Clicks into Cleveland Clinic’s enterprisewide electronic medical record as real-time discrete data allows us to measure and manage rehab services throughout the acute care hospital and into all post-acute settings.
My colleagues and I recently conducted a 10-patient study at Cleveland Clinic that stands as the first-ever prospective, randomized, double-blind, controlled clinical trial of deep brain stimulation (DBS) for the management of chronic pain.

While the literature offers many case series reporting the effects of DBS in patients with various chronic pain conditions, most studies are limited by failure to account for placebo effects, which can be significant in this population. Furthermore, neurostimulation techniques such as DBS and spinal cord stimulation have thus far been largely aimed at the sensory pathways, which mediate only a portion of the overall pain experience.

In our initial human study, we aimed to alleviate pain-related suffering in patients with thalamic pain syndrome (TPS), a devastating and often refractory condition that can follow a stroke. The study was funded by the NIH Director’s New Innovator Award.

TPS: A Disruption of Sensory Pathways and the Neuromatrix

Chronic neuropathic pain in TPS is associated with lesions of somatosensory thalamic nuclei or somatosensory thalamocortical projections, typically from a stroke. TPS is characterized by unrelenting, disabling anesthesia dolorosa (painful numbness) on one side of the body, with or without associated allodynia. Patients often limit use of the affected extremity due to pain, which is frequently intractable and proves extraordinarily frustrating for patients and physicians alike. However, pain is not simply a sensory experience.

The neuromatrix theory, first described by Melzack, proposes that pain is processed by an integrated network of somatosensory, limbic and cognitive pathways. Therefore, targeting only the sensory pathways may not be a viable option, particularly when little substrate may be available after extensive lesions to this network.

A New DBS Target for Chronic Pain

Our study targeted structures representing emotion and affective behavior: the ventral striatum/anterior limb of the internal capsule. We had experience with this target from studies evaluating DBS for treatment-refractory depression led by Donald Malone, MD, Chairman of Psychiatry and Psychology at Cleveland Clinic.
While previous studies examined DBS for chronic pain conditions, all of them targeted sensory pathways of the brain rather than emotional ones. These traditional approaches targeting sensorimotor substrates have mostly failed to produce pain relief or improve disability. The offending lesion in TPS that almost invariably destroys sensory pain pathways may render these classical approaches ineffective. Our novel approach focuses instead on alleviating the affective sphere of pain to reduce pain-related disability from TPS.3

The lessons we learned from the initial phase of our ongoing study have paved the way for future research in this area. We presented preliminary findings as an invited lecture at the most recent Biennial Meeting of the American Society for Stereotactic and Functional Neurosurgery. Those findings will be published in a forthcoming peer-reviewed article.

**Study Design**

As detailed previously,4 inclusion criteria for our 10-patient, six-month study of ventral striatal/ventral capsular stimulation for TPS included:

- Severe hemibody pain for more than six months
- Lesion in the thalamic region (or immediately ventral or dorsal to the thalamus)
- Failure of at least one antidepressant, one antiseizure medication and one narcotic

After implantation, patients were randomized to receive active DBS to the ventral striatum/anterior limb of the internal capsule or sham stimulation for three months, followed by crossover. The crossover approach was used to mitigate the ethical/scientific dilemma of a control group that would not receive a potentially beneficial intervention as well as to control for placebo effects.

The primary end points were the Pain Disability Index and a visual analog scale of pain. Additional end points included quality-of-life measures, functional neuroimaging, and depression and anxiety inventories.

**Lessons from the First Randomized Trial of DBS for TPS**

While more research clearly lies ahead, our study provided important lessons. Most notably:

- We demonstrated for the first time that it is safe to surgically intervene with DBS on the emotional networks of the brain in patients with chronic pain.
- We showed that it is possible to successfully complete a randomized controlled trial in patients with chronic pain.
- Our preliminary results show that patients with severe and refractory TPS can respond to DBS of the ventral-striatal and ventral-capsular pathways. Patients have shown improvements in pain levels and changes in depression scores.
- These findings are particularly relevant because they were achieved under a double-blind design, thus largely controlling for placebo- and study-related effects.
- We showed that it is possible to safely conduct functional MRI studies in patients with fully implanted DBS systems. fMRI data were acquired during the blinded phase of the study and can therefore be correlated with the observed clinical improvements.

The figure shows an example of how fMRI can detect patterns of brain activity in patients with implanted DBS systems. A striking difference is noted when comparing the fMRI data acquired when DBS was “on” vs. “off.”

**Next Steps: More Centers, More Pain Types**

Shifting attention from the sensory pathways of the nervous system to target areas that modulate emotion could provide a clinical breakthrough with potential to help many patients. When patients are disabled by long-standing chronic pain, their pain can be magnified by desperation, frustration and anxiety. Patients tend to become consumed not so much by their pain in the moment as by its relentlessness and the expectation that they may remain in pain indefinitely.

It’s incumbent on the field to incorporate well-controlled, blinded trial designs into ongoing research to explore current and novel DBS targets for chronic neuropathic pain conditions like TPS. Our study serves as an example of the feasibility of creating protocols that improve the quality of the evidence base.
Cleveland Clinic researchers recently completed the first human clinical trial of DBS for refractory thalamic pain syndrome (TPS), which also represents the first prospective randomized controlled trial of DBS in any chronic neuropathic pain condition.

The study involved stimulation of the ventral striatum/anterior limb of the internal capsule, structures representing emotion and affective behavior, in recognition that pain is not solely a somatosensory phenomenon.

Results from this phase 1 study revealed that intervening in the emotional networks of the brain in patients with chronic pain is safe and can be effective in some patients with TPS.

We are now working to secure funding for a larger multicenter study, which could take several years to complete. As our research continues, we hope to expand it to additional medical centers and extrapolate our findings to populations with chronic pain conditions beyond TPS. This work goes hand in hand with current nationwide efforts to reduce opioid use in the management of non-cancer chronic pain.

Dr. Machado (machada@ccf.org; 216.444.4270) is Director of the Center for Neurological Restoration in the Neurological Institute.

References
Personalizing Rehabilitation and Brain Stimulation: The Patient as a Guide to Maximizing Neurologic Recovery

By Ela Plow, PhD, PT; Vishwanath Sankarasubramanian, PhD; David Cunningham, MS; Kelsey Potter-Baker, PhD; Ken Sakaie, PhD; and Andre Machado, MD, PhD

Personalized medicine is an emerging medical model emphasizing interventions that are biologically or genetically tailored to maximize outcomes upon initial use, without the need for trial and error.

The great challenge facing neurologic rehabilitation, however, is the lack of information about which clinical or diagnostic characteristics are appropriate for deriving tailored therapies. A project called the BRAIN initiative (Brain Research through Advancing Innovative Neurotechnologies℠), recently launched by the federal government in conjunction with the National Institutes of Health, promises to yield the first interactive map of the neural circuitry of the human brain. This type of mapping may provide the key to tailored rehabilitation treatments.

In our work at Cleveland Clinic, we are leveraging the concepts of the BRAIN initiative to develop personalized rehabilitation care programs. This work is based on our creation of an interactive map of the diseased or damaged brain.

Confronting Variance in Brain Plasticity

Despite the fact that stroke is the most common and well-studied condition leading to persistent disability, the field of stroke rehabilitation is plagued with generic, non-specific therapies. The best example of this scatter-shot approach is seen with noninvasive brain stimulation.

Although the technology was initially considered promising as a means to increase adaptive neuroplasticity, the latest clinical trials have failed to demonstrate a consistent improvement in outcomes. Noninvasive brain stimulation using magnetic fields or direct current may ultimately prove helpful, but its current indiscriminate...
use — driven by a one-size-fits-all approach based on the assumption of a generic substrate for brain plasticity — is likely to produce inconsistent outcomes, given differences in the nature and extent of stroke-related disability among individual patients.

Rather than discounting the potential of brain stimulation to dramatically maximize and accelerate outcomes of rehabilitation in stroke, we instead operate on a conceptual framework based on tailoring the stimulation to an individual’s neurological characteristics.

Guided by our empirical understanding that mechanisms of neuroplasticity actually vary from patient to patient, we use advanced imaging neurotechnologies to investigate individual characteristics that generate such variance. These techniques include functional MRI to illustrate brain perfusion and function during real-time limb movement; diffusion tensor imaging to visualize the structure of white matter pathways devoted to moving the paralyzed limb; and transcranial magnetic stimulation to map the physiology of pathways and cortices.

Through these imaging innovations, we are able to determine which substrates remain spared in the damaged brain, how they interact with other regions and how they contribute to the potential to move paralyzed limbs. We process this information in concert with information regarding the patient’s pattern and severity of impairment, collected using validated clinical scales that track deficit and recovery.

Next, we process these neural and clinical characteristics via a hypothesis-driven decision tree, with the goal of developing treatment interventions unique to the patient’s pathology. The goal is to identify whether substrates on the injured or damaged side of the brain are spared adequately to be entrained with rehabilitation of the paretic upper limb, or if they are disrupted to such a degree that it would be best to rely on compensatory therapies such as those involving use of the less-affected side.

Figure 1. Advanced diffusion tensor imaging methods help reconstruct all surviving pathways in the lesioned areas of the stroke-affected hemisphere. Differences between integrity of pathways in the affected vs. the unaffected hemisphere serve as an important baseline characteristic to predict levels of recovery and the types of brain stimulation therapies that can be employed. The images at top right represent pivot points used for the analysis — internal capsule and motor cortices. Pathways are reconstructed between these nodes to form the analyses.

Figure 2. Similarly to Figure 1, this image illustrates the ability to reconstruct all surviving pathways in the lesioned areas of the stroke-affected hemisphere. The image also demonstrates the ability to map key transcallosal pathways that collect bilateral motor cortices. Survival and physiology of these pathways are key to dictating chronic stroke recovery.
**Figure 3.** This image illustrates the ability to interface two mapping methodologies. Cuboid cells in blue and red represent points on the surface of the brain that are mapped with a neurophysiologic technique (transcranial magnetic stimulation, or TMS); red cells represent sites on the surface that were responsive to TMS, i.e., sites that are able to elicit neurophysiologic responses in the corresponding muscles of the hand. Pathways emerging from these sites have been reconstructed with diffusion tensor imaging (DTI). A combined TMS-DTI approach demonstrates regions of the brain that offer structurally and neurophysiologically sound pathways.

**Figure 4.** This image shows sites on the surface of the brain that are mapped with transcranial magnetic stimulation.
Considering that rehabilitation interventions are patient-specific, customized to individual impairment and etiology, it is necessary to similarly customize stimulation therapies. After all, stimulation therapies seek to facilitate processes adopted in recovery with rehabilitation. Brain stimulation customized to a patient’s pathology will likely offer the most consistent boost to paired rehabilitative therapy.

In a clinical trial and two other clinical studies underway at Cleveland Clinic, we are attempting to understand how clinical and neural characteristics predict what substrates likely are inherent to a patient’s expression of plasticity. We are testing stimulation of such candidate substrates against the traditional approaches and validating whether stimulation of the “patient-specific” substrate is most effective for recovery.

**Tailoring Stimulation for a Range of Deficits**

If successful in stroke, there is potential across other disease states; our framework could be translated to tailor stimulation in conditions such as pain, vision loss and depression, and to potentiate therapies in brain injury, cerebral palsy and multiple sclerosis, where generic approaches have rendered rehabilitation arduous, varying effective and poorly funded.

In a much larger context, using a simple, noninvasive, inexpensive treatment tailored to what NIH Director Francis Collins, MD, PhD, has termed “brain types,” we challenge the long-standing assumption of generic plasticity.

With recent, drastic Medicare cuts for reimbursement of therapies, neurologic rehabilitative practice demands more effective, precise and accelerated outcomes. Brain stimulation guided by characteristics that maximize individual patients’ mechanisms of neuroplasticity would enable promising, consistent and prompt gains in neurologic rehabilitation.

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Cleveland Clinic’s New PM&R Residency Program: Training the Next Generation of Physiatrists

The urgent need for more physiatrists is clear.

By the mid-21st century, the number of Americans 65 or older is projected to nearly double present levels, with the youngest of the baby boom generation well into their 80s and their children reaching retirement age. Longer life spans will result in more people with disabling conditions. Continuing military conflicts will ensure a steady stream of wounded soldiers with ongoing physical medicine and rehabilitation requirements.

These increasing healthcare demands are the rationale for Cleveland Clinic’s decision to launch a PM&R residency program. Recruitment is underway, with the first pair of residents in the three-year program expected to arrive in July 2016.

“Our residency program will mirror our unique clinical environment,” says Frederick S. Frost, MD, Chairman of the Department of Physical Medicine and Rehabilitation. “We are building a curriculum to train physicians to provide rehab care to the most challenging and complex patients.”

“We are energized and look forward to providing a first-rate training experience,” says program Director John Lee, MD. “Cleveland Clinic’s motto, ‘Patients First,’ will be our guiding principle in training the next generation of physiatrists to become excellent clinicians, researchers and teachers.”

Individual Attention, Wide-Ranging Patient Exposure

Incoming residents will benefit from exposure to Cleveland Clinic’s large volume and diverse mix of patients, Dr. Lee says, with wide-ranging rehabilitation needs in both acute care and outpatient settings. The residency program’s small size will allow for close interaction with PM&R faculty and increased individual attention.

As a tertiary and quaternary referral center, Cleveland Clinic cares for regional, national and international patients with high medical complexity, providing unique learning opportunities for PM&R residents. Many patients have impairments leading to disabilities that require rehabilitation. These include neurological disorders such as stroke, multiple sclerosis, Parkinson disease and spinal cord injuries; medical conditions such as heart failure and cancer; and surgical procedures such as solid organ and bone marrow transplants, left ventricular assist device implantations, amputations and joint replacements.

Cleveland Clinic also has high clinical volume and demand for interventional pain procedures, musculoskeletal ultrasound, spasticity management and inpatient PM&R consultative services, Dr. Lee says — all of which present valuable and varied educational experiences for the new residents.

Seeing Patients Throughout the Continuum of Care

Cleveland Clinic’s Department of Physical Medicine and Rehabilitation has more than 40 staff physicians, six researchers and more than 700 therapists, and received more than $5.5 million in research funding in 2014. The new residency program will contribute to ongoing faculty development in clinical care, teaching and research, Dr. Lee says, as well as increase the presence of PM&R throughout the healthcare system.
In addition to rotations at Cleveland Clinic’s main campus, its two community rehabilitation hospitals and its various family health centers, residents will serve rotations at Cleveland Clinic Children’s Hospital for Rehabilitation, the MetroHealth Rehabilitation Institute of Ohio, the Louis Stokes Cleveland VA Medical Center, and the new inpatient rehab hospital Cleveland Clinic is building in Avon, Ohio, west of Cleveland, in a joint venture with Select Medical. This will enable the residents to follow patients throughout the continuum of care, Dr. Lee says.

The residency’s electrodiagnostic rotation will be taught in partnership with the Neuromuscular Center within Cleveland Clinic’s Department of Neurology. Cleveland Clinic PM&R residents will share several rotations with residents from Cleveland’s MetroHealth Medical Center PM&R program. The two groups will participate in joint didactic sessions, facilitating a closer collaboration between residents and faculty at the institutions.

“We are so fortunate to have the enthusiastic and magnanimous support of the other teaching hospitals in Cleveland. Everyone stands to benefit from this endeavor. There will be a multitude of opportunities for learning and the exchange of ideas,” Dr. Lee says.

For additional information about Cleveland Clinic’s PM&R residency program, contact Dr. Lee at leej4@ccf.org or 216.445.9987.
Low back pain (LBP) is one of the most common reasons patients seek healthcare.

The national direct and indirect cost of care for patients with LBP continues to escalate. This increased cost of care has not been shown to correlate with improved outcomes.1 For most patients, expensive imaging, opiate drugs, injections and extended treatment courses are not medically necessary.

Healthcare reform is driving transition from a volume-based reimbursement system to a value-based one. Organizations that are able to standardize care around best-practice patterns are better positioned to maximize clinical outcomes. Currently, significant opportunity exists to improve the management of LBP via standardization of care.

Physical therapists are healthcare providers who are frequently involved in the management of patients with LBP. Early access to physical therapy services for these patients has been reported to result in reduced healthcare utilization and costs.2,3

Recent research on physical therapy management of LBP has focused on classifying patients into subgroups based on clusters of signs and symptoms and providing targeted physical therapy interventions for each subgroup. Studies that emphasize interventions based on subgroup classification have reported improved treatment effect sizes compared with studies that deliver physical therapy interventions using a one-size-fits-all model.4,5

Subgrouping to Boost Effectiveness

In 2013, Cleveland Clinic developed an evidence-based care path to standardize physical therapist management of patients with LBP. The care path emphasizes the use of subgrouping to match patients with treatment interventions that have the highest probability of effectiveness.

The state of Ohio allows physical therapists to evaluate and treat patients without a physician’s referral. The care path was developed to guide physical therapists’ management of LBP patients in a direct-access model. The care path and direct access system was built with full integration into the physician-based multispecialty spine group, which employs nine PM&R physicians.

The care path initially guides the therapist through a standardized red-flag screening process to identify patients who are at high risk for serious pathology. Physical therapists are instructed to refer to a physician if they identify clusters of red-flag findings that are suggestive of serious pathology such as fractures, cancer or infection. Once red-flag screening is completed, the care path guides the physical therapist to screen for yellow flags.

Assessment of yellow flags in individuals with LBP is an important part of the examination process. Kendall et al. used the term “yellow flags” to detail how psychological, social and environmental factors could place someone at increased risk for prolonged disability.6 Early identification of yellow flags helps identify patients who may have increased risk for prolonged disability.

Cleveland Clinic’s care path uses the STarT Back Screening Tool (SBST) to assess for psychosocial factors that could impede progress.7,8 The SBST stratifies patients into low, moderate or high risk for prolonged disability. Patients who score high via the SBST are considered to have a high level of psychosocial prognostic risk factors. Physical therapists are expected to manage these patients following principles described in the graded activity/exposure subgroup detailed later in this article and/or refer for medical or psychological management.

The care path also guides physical therapists to use a two-item depression screen to identify patients with elevated risk for depression.9,10 Patients who are positive are referred for further medical and/or psychological management.

Once red- and yellow-flag screening has been completed, the care path guides the physical therapist to complete the objective assessment. The therapist uses the findings to classify the patient in one of five treatment subgroups. Each subgroup is named based on the primary physical
therapy treatment intervention that should be emphasized in patient management. The subgroups are:

- Specific exercise
- Mobilization/manipulation
- Stabilization exercise
- Graded exercise/activity
- Unweighting

Following are brief descriptions of each subgroup.

Specific Exercise
This subgroup uses repeated movement testing to determine whether patients present with a directional preference for exercise. The presence of centralization and/or symptomatic or mechanical response to end-range therapeutic loading strategies is used to determine whether a directional preference is present, and to guide what exercises patients are instructed in for their home exercise program.

Mobilization/Manipulation
Patients in this subgroup often benefit from skilled mobilization or manipulation of their lumbar spine to restore normal mobility and reduce pain. Patients often present with symptoms of stiffness or loss of lumbar motion, sharp pain at end range of motion, no pain below the knee, and recent onset of LBP.

Stabilization Exercise
Patients in this subgroup frequently lack strength, endurance and coordination of the muscles that provide support and stability to the lumbar spine. Interventions that

Figure 1. Physical therapy low back pain care path algorithm.
The direct and indirect costs of low back pain (LBP) continue to rise. Increased expenditures have not been shown to correlate with improved outcomes.

Physical therapists’ management of patients with LBP has been shown to be associated with decreased health care utilization.

Physical therapists’ management of LBP is most effective when a subgrouping approach is used to guide patient care.

Cleveland Clinic has developed and implemented a physical therapy care path for patients with LBP to improve value-based care.

**References**


<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Description</th>
<th>Meaningful Change in Score</th>
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| NPRS<sup>12</sup> | Rate pain from 0-10  
0 = no pain  
10 = worst possible pain | Minimal detectable change (MDC) decrease of 2 points<sup>12</sup> |
| OSW<sup>13</sup> | 10 items addressing different aspects of function  
Each item scored 0-5 | MDC decrease of 6 points or 12%<sup>13</sup> |
| AM-PAC<sup>14</sup> | Activity limitation instrument, Basic Mobility Version  
Age > 65 years  
• 13 items  
• Each item scored 1 (unable) to 4 (no difficulty)  
Age < 65  
• 18 items  
• Each item scored 1 (unable) to 4 (no difficulty) | MDC increase of 4.28 points<sup>14</sup> |

Figure 1. These standardized outcome measures are collected during a low back pain patient’s initial evaluation and at subsequent intervals to track progress as part of Cleveland Clinic’s low back pain care path. NPRS = Numeric Pain Rating Scale; OSW = Modified Oswestry Disability Index; AM-PAC = Activity Measure for Post-Acute Care

NEW REHAB HOSPITAL PREPARES TO OPEN

Construction of Cleveland Clinic's new adult inpatient rehabilitation hospital in Avon, Ohio, 20 miles west of Cleveland, is nearly complete. The 60-bed facility, shown below in architectural renderings and a construction site photo, is part of a joint venture with rehab services provider Select Medical that will expand Cleveland Clinic’s rehab capabilities regionally, nationally and internationally. The Avon hospital is scheduled to begin admitting patients in early December. Cleveland Clinic currently provides acute inpatient rehab care at its main campus, its regional hospitals in Euclid and Lakewood, and at Cleveland Clinic Children’s Hospital for Rehabilitation.
New Center for Pediatric Integrative Medicine Enhances Options for Hard-to-Manage Chronic Conditions

About 12 percent of American children use some form of complementary medicine, according to the National Institutes of Health’s National Center for Complementary and Integrative Health. As evidence in support of complementary and integrative medical techniques mounts, that percentage is likely to climb.

To meet this demand, Cleveland Clinic Children’s has launched a Center for Pediatric Integrative Medicine to complement traditional medical care for patients with a range of difficult-to-manage chronic conditions.

**Conceived as Complementary Care**

“Going beyond a child’s physical needs to address lifestyle and emotional needs can reduce the frequency of disease episodes, decrease the stress related to chronic illness and improve quality of life,” says Center Director Benjamin Katholi, MD, a pediatric physiatrist.

The center is built on a rehabilitation model, employing a team approach when appropriate to enhance patient care. Team assessments are also offered to develop treatment plans for complex conditions.

Dr. Katholi emphasizes that the center's treatments are intended as a complement to — not a replacement for — traditional medical therapies. “Our aim is to enhance patients’ existing medical care, to work in tandem with their traditional providers and to ensure that patients are maintaining their relationships with those traditional providers,” he says.

**Treating a Variety of Conditions**

The center — located at Cleveland Clinic Children’s Hospital for Rehabilitation — treats a range of difficult-to-manage chronic conditions in children and adolescents, including:

- Anxiety and depression due to chronic illness
- Arthritis and musculoskeletal pain
- Asthma, allergies and other pulmonary problems
- Concussions and other brain injuries
- Chronic pain, including abdominal, nerve and myofascial pain
- Delayed wound healing
- Headache
- Sports and traumatic injuries
- Vocal cord dysfunction
- Torticollis

The center is staffed by a multidisciplinary team of pediatric specialists in behavioral medicine, physical medicine and rehabilitation, pain management, pulmonary medicine, general pediatrics, and nutrition, along with dedicated pediatric occupational and physical therapists.

**Team members are certified in a host of therapeutic techniques, including:**

- Acupuncture, acupressure and laser acupuncture
- Biofeedback
- Guided imagery and hypnosis
- Integrative dry needling
- Frequency-specific microcurrent therapy
- Craniosacral therapy
- Myofascial release and osteopathic manipulation
- Reiki and therapeutic touch (the latter for infants)
- Relaxation/breathing strategies and yoga

**KEY POINTS**

- Addressing the lifestyle and emotional needs of children with chronic medical conditions can reduce the frequency of disease episodes, decrease stress and improve quality of life.

- Cleveland Clinic’s new Center for Pediatric Integrative Medicine follows a multidisciplinary rehabilitation model, providing therapeutic techniques such as acupuncture, guided imagery, frequency-specific microcurrent therapy and myofascial release as a complement to traditional medical therapies.
The Value of Integrative Medicine in a Complex Case

At left are before-and-after radiographs and photos of a 16-year-old male from overseas who presented with multiple medical problems and severely compromised pulmonary function related to the kyphoscoliotic form of Ehlers-Danlos syndrome.

Spinal fusion was recommended by his multidisciplinary Cleveland Clinic Children’s management team, but the patient was first fitted with a halo brace to elongate his spine to reduce the risk of neurological damage. He was transferred to Cleveland Clinic Children’s Hospital for Rehabilitation for intensive “prehabilitation” for this purpose.

As the patient’s body adapted to his gradual traction regimen, he began to experience pain in his back and sides. His physical therapists noted areas of fascial thickening and started a program of myofascial release therapy using deep dural pulls. The patient’s pain rapidly decreased, and his alignment swiftly improved.

After only two months of intensive therapy, the patient underwent successful posterior spinal fusion from T2 to L4. The next day, he resumed myofascial release therapy, gait training, stretching and taping, and yoga. In 10 days, he was discharged to rehabilitation at the day hospital, with biofeedback for postural retraining added to his regimen. After 12 days, he was discharged to outpatient physical and occupational therapy.

The patient returned to his home country a little more than six months after his initial presentation, with dramatic improvements in his spinal alignment, pulmonary function and overall physical and psychological health. The myofascial release and other integrative therapies used in his rehabilitation regimens are believed to have shortened his length of stay by a full month.

For a fuller profile of this case, visit consultqd.org/pedsintegrative.
Dr. Katholi finds frequency-specific microcurrent (FSM) therapy particularly exciting. “It is subsensory (painless) and noninvasive, and has lasting effects,” he says. “Research suggests that delivering micro-amperage current while using specific frequencies can potentially reduce inflammation, improve ATP production and enhance healing. We’ve found FSM therapy highly effective for nerve and muscle pain, acute and chronic musculoskeletal injuries, and arthritis in children.”

The new center is one of relatively few focused on using integrative medicine specifically in pediatric patients, notes center team member David Burke, DO, a general pediatrician with long-standing interests in osteopathic manipulation and complementary medicine. “While Cleveland Clinic Children’s has offered many integrative medicine services to children for years, creation of a formal center has brought them all under one roof,” he says.

**A Research Mission Too**

Center staff are beginning research on several integrative treatments — including acupuncture, reiki and FSM therapy — to better define their potential benefits for children with various conditions.

“We are committed to providing evidence-based care at this center and helping define the most effective complementary therapies for enhancing traditional care,” says Dr. Katholi. ■

Dr. Katholi (katholb@ccf.org; 216.448.6254) is Medical Director of the Center for Pediatric Integrative Medicine at Cleveland Clinic Children’s Hospital for Rehabilitation.

To refer a patient to the Center for Pediatric Integrative Medicine, call 216.448.6610. For more on the center, visit clevelandclinicchildrens.org/integrativemedicine.
During the past 30 years, the institution of multidisciplinary clinics for children with myelomeningocele has become the standard of care. These clinics integrate neurological, urological and orthopaedic care and social services for patients and families living with this condition.

Extended Life Spans, Distinct Problems
The improvement in care for children affected by myelomeningocele has resulted in prolonged life spans and better quality of life, with more than 85 percent of these children now surviving into adulthood.

Increasing awareness of the disparity of care for this population in adulthood, as well as an understanding that adults with myelomeningocele experience deterioration of function and problems distinct from those encountered in childhood, present a unique opportunity for innovative care models for this population.

Recapturing Adult Patients
In 2014, Cleveland Clinic initiated a multidisciplinary clinic for adults with myelomeningocele. The goals of this effort are threefold:

- To provide ongoing support for patients who have “outgrown” the pediatric myelomeningocele clinic
- To “recapture” and provide ongoing preventive medical care to adult patients who have been lost to routine medical care
- To better understand the unique medical needs and quality of life concerns of these patients as they age

Streamlining Care
The clinic is staffed by physicians and allied healthcare provider representatives from urology, physical medicine and internal medicine. For patients’ convenience, their records are reviewed prior to the clinic so that appropriate screening testing can be ordered on the same day as the appointment.

As needed, referrals to providers in gastroenterology, gynecology, plastic surgery, neurosurgery and other specialties are facilitated.

The effort is labor-intensive, and reimbursement for medical services is poor. In this setting, back-office organization of patient scheduling, test scheduling and pre-visit phone calls is critical. Clinics are offered every four months. In the clinic, maintenance of a critical mass of patients supports intensive staffing and allows for streamlined processes that address orthotics and wheelchair/equipment needs, as well as medical concerns.

Dr. Wood (woodh@ccf.org; 216.444.2146) is a staff physician in Cleveland Clinic’s Department of Urology.

Unique Needs and Concerns of Adult Myelomeningocele Patients Prompt New Multidisciplinary Clinic

By Hadley Wood, MD

Myelomeningocele, also known as spina bifida, is the most common permanent congenital anomaly in the United States. Many adults with this condition feel marginalized by the mainstream healthcare system.

KEY POINTS

- Multidisciplinary clinics for children with myelomeningocele have long been the standard of care.
- The increasing number of children with myelomeningocele who survive into adulthood has highlighted the need for innovative care models for this population.
- Cleveland Clinic has launched a multidisciplinary clinic for adults with myelomeningocele to provide ongoing medical services, rehabilitation services and preventive care, and to better understand these patients’ unique medical needs and quality of life concerns as they age.
Physiatry Augments Upper Extremity Center Care

The addition of a physiatrist to the staff of Cleveland Clinic's Upper Extremity Center has further enhanced the patient care the center provides, especially in diagnostic evaluation, nonsurgical treatment and rehabilitation.

The Upper Extremity Center, created more than a decade ago, treats injuries, diseases, degenerative conditions, congenital deformities and pain involving the shoulder, elbow, arm, wrist or hand. Its 10 physicians are primarily orthopaedic and plastic surgeons.

Meredith Konya, MD, a physiatrist specializing in nonsurgical upper extremity orthopaedics, collaborates with the rest of the center's surgeons, nurses and therapists to provide comprehensive care and assist with patient access and longitudinal management. “We are very excited about Dr. Konya's addition to the center, as she brings new skills and understanding to the nonoperative care of patients," says Peter Evans, MD, PhD, Director of the Upper Extremity Center.

Managing Nonoperative Treatment

Dr. Konya evaluates new patients, makes referrals for those who need operative care and oversees the treatment of those who don't require surgery, including therapies, medications and bracing for conditions such as arthritis, carpal tunnel syndrome, fractures and tendonitis. She orders and assesses diagnostic imaging and electromyography and performs ultrasound-guided injections.

Her presence helps shorten Upper Extremity Center wait times and helps with patient communication. “I can spend time with them and explain their condition, the pathology and potential treatment options,” she says.

“The goal is to have the physiatrist continue to manage the nonoperative treatments," Dr. Konya says. “After a complete evaluation and nonoperative treatment, when indicated, the patient would then receive an expedited appointment with the most appropriate surgeon. The physiatrist is also able to assist primary care physicians who are uncertain whether a patient is a surgical candidate, by providing the initial consultation.”

Ultrasound-guided Injections

Dr. Konya and other Cleveland Clinic physiatrists are also skilled in the use of musculoskeletal ultrasound for diagnostic and therapeutic purposes. The ultrasound treatment option is in addition to physiatrists’ extensive training in the nonoperative care of musculoskeletal conditions, including osteoarthritis, bursitis, tendinopathy and neuropathy.

Musculoskeletal ultrasound can benefit patients who have failed nonguided injections, are on anticoagulants or require a dynamic assessment. Ultrasound ensures accurate injectate placement and can provide an additional safety margin, making these procedures less painful and more cost-effective, and can often be done on the day of the initial office visit, without the need for an additional appointment.

Physiatrists also are well-versed in spinal conditions and pain management, which often overlap with complex upper extremity issues.

According to Dr. Konya, the Upper Extremity Center's multidisciplinary approach works well for patients and physicians.

“This was recognition that there is a more efficient, effective way to handle patients,” she says. “It's a model that the best programs employ to optimize efficiency and patient service. The teamwork between the nonoperative physicians and surgeons is really the key.”

Dr. Konya (konyam@ccf.org; 330.533.8350) is an associate staff member of Cleveland Clinic’s Department of Orthopaedic Surgery. Dr. Evans (evansp2@ccf.org; 216.444.7973) is Director of the Upper Extremity Center.
Through our three Cleveland Clinic Rehabilitation Hospitals and Cleveland Clinic Children’s Hospital for Rehabilitation, we offer acute inpatient rehab care across 114 beds for patients of any age.

**Department of Physical Medicine and Rehabilitation**

**PM&R AT A GLANCE**

Cleveland Clinic

INPATIENT REHABILITATION

SKILLED NURSING CARE

OUTPATIENT THERAPY

**By the Numbers**

**2014**

1,819..... acute inpatient rehab admissions

4,922..... total rehab hospital days

341,820..... total therapy outpatient visits

400,761..... total therapy inpatient visits

742,581..... total rehab patient visits

**Research Funding by the Numbers**

10 funded research projects

$924K in federal government funding

$95K in corporate and foundation support

$148K in private donations/philanthropy

**Research Staff**

6 (physicians and PhD researchers)

**Specialty-Trained PTs, OTs and Speech Therapists** in Cleveland Clinic Rehabilitation and Sports Therapy, run in conjunction with the Orthopaedic & Rheumatologic Institute

**Research Projects**

60+ funded research projects

$924K in federal government funding

$95K in corporate and foundation support

$148K in private donations/philanthropy

**Outcomes Snapshots** in Acute-Care Hospital Patients (2014)

- **56%** Proportion of patients who exhibited improvement in mobility scores between their first and last physical therapy sessions, as measured by the 6 Clicks functional measurement tool

- **50%** Proportion of patients who exhibited improvement in self-care scores between their first and last occupational therapy sessions, as measured by the 6 Clicks functional measurement tool

**Therapy in the hospital begins the rehab process. The data shown here do not represent a complete cycle of therapy.**
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Physician Directory. View our staff online at clevelandclinic.org/staff.

Same-Day Appointments. Cleveland Clinic offers same-day appointments to help your patients get the care they need, right away. Have your patients call our same-day appointment line, 216.444.CARE (2273) or 800.223.CARE (2273).

Track Your Patients’ Care Online. Establish a secure online DrConnect account for real-time information about your patients’ treatment at Cleveland Clinic at clevelandclinic.org/drconnect.

Critical Care Transport Worldwide. To arrange for a critical care transfer, call 216.448.7000 or 866.547.1467. Learn more at clevelandclinic.org/criticalcaretransport.

CME Opportunities: Live and Online. Visit ccfeme.org to learn about the Cleveland Clinic Center for Continuing Education’s convenient, complimentary learning opportunities.

Outcomes Data. View Outcomes books at clevelandclinic.org/outcomes.

Executive Education. Learn about our Executive Visitors’ Program and two-week Samson Global Leadership Academy immersion program at clevelandclinic.org/executiveeducation.

About Cleveland Clinic

Cleveland Clinic is an integrated healthcare delivery system with local, national and international reach. At Cleveland Clinic, more than 3,200 physicians and researchers represent 120 medical specialties and subspecialties. We are a main campus, more than 90 northern Ohio outpatient locations (including 18 full-service family health centers), Cleveland Clinic Florida, Cleveland Clinic Lou Ruvo Center for Brain Health in Las Vegas, Cleveland Clinic Canada, Sheikh Khalifa Medical City and Cleveland Clinic Abu Dhabi.

In 2015, Cleveland Clinic was ranked one of America’s top five hospitals in U.S. News & World Report’s “Best Hospitals” survey. The survey ranks Cleveland Clinic among the nation’s top 10 hospitals in 13 specialty areas, and the top hospital in heart care (for the 21st consecutive year).