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CONTRACTING ORGANIZATION: National Rehabilitation Hospital
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14. ABSTRACT The NRH Neuroscience Research Center (NRC) mission is to <i>promote and accomplish rehabilitation-related basic and applied neuroscience research</i> . As part of this mission, the NRC: (1) develops new clinical interventions for patients with neurologically based impairments, (2) evaluates the effectiveness of new and existing rehabilitation-related interventions, (3) enhances our understanding of the neurophysiological and neuropsychological basis of impairment and disability, and (4) develops new methods to assess human function and performance. In order to be successful with our mission, the NRC is comprised of five research areas. They are as follows: a) High Resolution and Neuromotor Assessment; b) Mechanisms Underlying Recovery from Neurological Illness and Injury; c) Treatment of Neurological Diseases and Injury; d) Pilot Projects; and e) Annual Conference and Expert Panel Projects. Year 3 progress is discussed in detail in this report.					
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Introduction:

The NRH Neuroscience Research Center (NRC) grant continues to assist the NRH with the infrastructure to support core elements associated the development of a Neuroscience Research Center. These elements include expansion of staffing; collaborating with other organizations; developing related projects; completion of the facilities construction; supporting pilot projects; and educating through lecture series.

Staffing:

- Co-investigators- Gerard Gioia, PhD and Laura Kenealy, PhD from Children's National Medical Center were added to assist with the study design and subject recruitment for project D3.
- Consultant- Jose Contreras-Vidal PhD is a neuroscientist specializing in the neural networks of motor control. He is on faculty at the University Maryland. Dr. Contreras-Vidal is working with Dr Bleiberg on Project A1.
- Research Investigator- Dr. Hamm was hired as a Senior Research Scientist in the Neuroscience Research Center and Program Director of Cardiac Rehabilitation. Prior to coming to NRH, he had a 28-year history in the areas of cardiovascular disease, cardiac rehabilitation, and clinical exercise testing. Dr. Hamm's expertise is being used as a co-investigator in project D2 "*Metabolic Studies Individuals with Chronic Spinal Cord Injury: The Effects of an Oral Anabolic Steroid and Conjugated Linoleic Acid*" of this NRC grant. In addition he is currently the Principal Investigator of three research projects involving persons with spinal cord injury. Two of the studies are funded by the National Institute for Disability and Rehabilitation Research – *Cardiovascular Risk Stratification Across Injury Levels after Spinal Cord Injury: Assessment of Need for Intervention and Its Predictors* and *Effect of Robotic Body-Weight Supported Treadmill Training on Bone Mineral Density and Selected Secondary Characteristics in Individuals with Spinal Cord Injury*. He is also a Principal Investigator for *Comparison of Physiological Responses to Three Standard Modes of Exercise Testing in Persons with Spinal Cord Injury* funded by the Assistive Technology and Research Center. (curriculum vitae attached)
- Principle investigator and codirector of the NRC-Alexander W. Dromerick, MD, a highly respected scientist in the field of stroke and brain injury, will join the research team at NRH this summer. Dr. Dromerick will serve with Dr Heaton as co-director of the Neuroscience Research Center and will also lead the hospital's new Comprehensive Stroke Research Program. Dr. Dromerick's role as co-director is to share responsibilities with Dr. Heaton for the oversight of the grant and continued growth of the NRC. This is in part due to the increased responsibilities that Dr. Heaton has assume as principle investigator of the Assistive Technology Research Center grant and his resent appointment as interim chair of Neurology at Georgetown University Hospital. Dr. Dromerick comes to NRH from Washington University in St. Louis, MO, where he most recently co-directed the Washington University Stroke Center and served as an associate professor of Neurology, Occupational, and Physical Therapy. Widely published, Dr. Dromerick's research activities focus on stroke

and traumatic brain injury. He served as a co-principal investigator and was Core Director on *Brain Recovery: Return of Cognitive and Social Function*, a project funded by the McDonnell Foundation. He is principal investigator on *Very Early Constraint-Induced Movement for Stroke*, a National Institute of Neurological Disorders and Stroke-sponsored study which he will continue to develop when he assumes duties at NRH. (curriculum vitae attached)

Collaborating with other organizations:

- National Institutes of Health (NIH)
- Uniformed Services University Health Sciences (USUHS)
- Duke University
- Georgetown University Medical Center/GUH
- National Institute on Disability and Rehabilitation Research (NIDRR)
- The Miami Project
- The Rehabilitation Institute of Chicago (RIC)
- University Maryland
- Children's National Medical Center

Developing related projects:

- Submitted
 - NIH R01: "Effects of Early Niacin-Statin Multi-Therapy on Dyslipidemia, Pre-Clinical Vascular Disease, and Early Osteopenia After SCI: A Two-Center Randomized Clinical Trial" Co-investigators: Groah and Hamm.
 - National Science Foundation: "CAREER: Robotic Assessment of Walking Ability in Individuals with Neurological Disorders" Principal Investigator: Joseph Hidler
 - NIDRR: "Smart over-ground body weight support system" Principal Investigator: Joseph Hidler
 - NIH-NCMRR R24: "National Capital Area Rehabilitation Research Network (NCARRN)" Co-Principal Investigator: Joseph Hidler
- Currently performing
 - Clinical trials
 - Aventis
 - IMPAX
 - Amphetamine (Duke)
 - Modafinil (USUHS)
 - NIDRR- Rehabilitation Training Center for Spinal Cord Injury
 - NIH- Transcranial Direct Current Stimulation study in individuals with stroke.

Facilities construction:

The effort to create a geographically defined Neuroscience Research Center at NRH devoted to rehabilitation-related neuroscience research was completed over the past year. In addition, the entire NRH research division is now centrally located at NRH.

In the late summer of 2004, expanded research efforts took up residence in the Research Division's new 7000 sq.ft. dedicated facility. Ten months in construction and more than two years in planning, rising from the hospital's north face, the newly constructed research area is now home to more than 30 research scientists and staff. A tribute to modernity and accessibility, the new building houses internet-wired laboratory facilities, office space and a demonstration center showcasing state-of-the-art assistive technologies. A 500 sq. ft. conference center allows multimedia consultation over a full array of broadband wired and wireless technologies.



Pilot development project:

When describing and identifying the current patient population of individuals seen at NRH that have sustained a spinal cord injury, an obvious void has been noted. We have been unable to appropriately describe important information of these individuals that we see at NRH. Thus, the need for the development of a Spinal Cord Injury database was requested: 1) to improve the description of those we serve by tracking key clinical and research events that occur during their stay; 2) assist with finding appropriate individuals to recruit for research projects; and 3) to better position NRH to receive future funding.

For the above mention reasons, we developed a Spinal Cord Injury (SCI) database that was modeled after the NIDRR funded Model Systems Database. Medical records on all SCI patients are reviewed and pertinent SCI related data is extracted. SCI- specific demographic data included age at SCI, ethnicity, gender, employment status, marital status, level of spinal cord injury as well as completeness of injury (according to the American Spinal Injury Association classification scale). SCI related medical complications are also captured including: pneumonia, deep venous thrombosis, pulmonary embolism, autonomic dysreflexia, and wound infection. Other variables include functional outcome measures such as: Functional Impairment Measurement,

length of hospital stay and return to home rates. This database is maintained on a secure computer and uses a Microsoft Access program.

Lecture series:

- "Ventilatory Management for the Patient with Spinal Cord Injury" Peter Peterson, M.D
- "Neurophysiology as a Tool to Understand Brain Function in Children" Marjorie Garvey, MD
- "Clinical Trials in Constraint Induced Therapy in Individuals with Stroke" Steven L. Wolf, PhD, PT, FAPTA
- "Clinical Development of Autologous Cell Based Therapy in Acute Complete Spinal Cord Injury" Dr. David Snyder

Project A1: A Computerized Neuropsychological Battery for Parkinson's Disease: Application for Population Surveillance, Early Detection, and Monitoring Disease Progression

Funding period: Year 3 of 3-year funding period

Status: Waiting IRB Approval

Principal Investigators: Joseph Bleiberg, PhD

Co-investigators: Tresa Roebuck-Spencer, Ph.D. (project coordinator), Mark Lin, M.D., Zachary Levine, M.D., and Robert Kane, Ph.D.

Consultants: Dennis Reeves, PH.D., and Kathy Winter, M.S.

Abstract:

Parkinson's disease (PD) is a neurodegenerative disorder that presents with a specific set of motor symptoms, including tremor, rigidity and bradykinesia. PD also typically affects cognition and mood similar to that observed in other subcortical neurodegenerative diseases. Approximately 1% of the population over age 50 suffers from PD. Although 40% of patients with PD are between the ages of 50 and 60, there is evidence that "early-onset" PD is on the rise, with an estimated 10% of recently diagnosed patients under age 40. Current therapies for PD focus on amelioration of PD symptoms and slowing disease progression. Future therapies, however, will focus on arresting and even reversing the disease process. Since substantial neuropathologic change, as indicated by greater than 60% loss of dopaminergic neurons, typically precedes manifestation of clinical symptoms in PD, future therapies likely will create a compelling need for early identification in order to permit initiation of treatment prior to the occurrence of extensive CNS insult. The early loss of dopaminergic neurons in PD suggests that subtle neurocognitive changes and subclinical motor symptoms may be seen early in the disorder, possibly before the onset of symptoms necessary for a clinical diagnosis. A test battery sensitive to subtle cognitive dysfunction and subclinical motor symptoms will aid in early detection of PD and monitoring of disease progression. The DoD-developed Automated Neuropsychological Assessment Metrics (ANAM) provides a well-developed starting point. Sensitivity of this measure to cognitive change has been demonstrated in sports concussion, fatigue, exposure to altitude, systemic illness, and pain secondary to headache. The primary objective of the present study is to develop an effective and highly efficient computerized testing system for population surveillance, early identification, and clinical monitoring in PD, using ANAM as the cognitive component. PD symptom specific measures of mood and motor functioning will be developed and added to the current ANAM test battery. Special emphasis will be placed on measures that target the earliest subclinical symptoms of PD that would normally go undetected in the typical neurological exam. Not only will this new ANAM battery be the first of its kind to focus on subtle cognitive change in neurodegenerative disease, it will continue to

be both cost- and time-efficient and able to be universally administered via a simple computer and mouse interface.

Progress and Outcomes:

Primary progress made over the last year has been made to finalize the selection and specifications of the primary tasks to be used in the ANAM motor assessment battery. This progress built upon the gains made last year, which included programming a "shell" or common foundation and infrastructure for the motor tasks, developing an overall strategy and architecture for motor task development to maximize compatibility across newly developed tests, and automating transfer of task data from data files to databases. With this framework in place we were able to focus on designing specific motor tasks known from the scientific literature to be sensitive to motor anomalies resulting from damage to the subcortical motor system, as seen with Parkinson's disease. Descriptions of the tasks and task components to be included in the final ANAM motor battery and progress on each to date is included below.

1. Mouse and Computer Orientation: This component will orient the subject to the computer and mouse. Subjects will be asked in a "free form" stage to move the mouse to all quadrants of the computer screen while observing corresponding cursor movement. Subjects will then be asked to move the cursor to specific targets located at various points across the screen. This orientation is particularly important for older individuals who may have had limited real-life exposure to computers and computer peripherals.

2. Tapping Tasks: Two finger tapping tasks will be included. The first will measure simple fine-motor speed by having the subject tap the space bar as quickly as possible with the index finger of one hand then the other. This task will provide a baseline measurement of fine-motor speed in the absence of specific task demands. The second tapping task will measure a subject's ability to follow external versus internal cues by having them tap in synchrony with a tone and then try to mimic that rhythm once the external tone has disappeared.

3. Target Acquisition Tasks: This set of five tasks allows for measurement of the subject's reaction and movement time when specific task parameters are in place. Each task within this section requires the subject to move the mouse cursor when cued to click a circle target located in one of eight positions encircling a central starting point. Each task component is designed to build in complexity so that the various cognitive and motor components of each can be statistically determined. These tasks are as follows:

a) Target Acquisition without visual feedback: For this task, the subject will not receive visual confirmation of where the cursor is located on the computer screen and their hand will be obstructed from view. The subject will be asked to move the mouse to the cued target but must estimate the distance based on their experience with a set of earlier presented practice trials. This task will measure estimation of dynamic movement, a function known to be impaired in patients with Parkinson's disease.

b) Target Acquisition with visual feedback: This task will measure a subject's initiation and movement time when asked to move the visible cursor to a cued target as quickly as possible.

c) Continuous Target Acquisition (2 parts): This task is similar to that above with the exception that cued targets will occur in a random self-paced sequence. That is, a new target will be cued in a random location as soon as a subject responds to the last target. This task will measure a subject's speed and accuracy of movement when required to continuously monitor and move to targets. In the first part of this task, targets will be cued at random to measure dynamic motor speed and accuracy. In the second part of this task, targets will occur in a repeating sequence to measure a subject's implicit motor learning.

d) Reverse Target Acquisition: In this task, subjects will be instructed to move only to targets cued with a specific color (different from the color used to cue targets in previous aspects of this task) and to ignore all other colors. In addition to motor speed and accuracy, this task will provide a measure of cognitive flexibility and response inhibition.

4. Alternating Two-Point Target Acquisition: This task requires the subject to move the mouse back and forth between two fixed targets as quickly as possible for a fixed duration of time and provides a measure of speed and accuracy of dynamic movement. This task has been widely used in the scientific literature as a measure of bradykinesia in Parkinson's disease.

5. Handwriting/Adaptation: This task requires that the subject draw a series of loops or spirals on the computer screen using the mouse. This task consists of three conditions. In the first condition, visual feedback on the computer mirrors the subject's movement in a 1 to 1 fashion. For the second and third conditions, visual feedback is modified so that cursor movements are either smaller (condition 2) or larger (condition 3) than that produced by the subject's actual movement. This task measures a subjects ability to adapt movement in response to changes in the environment. Specific difficulties in this area have been noted in patients with Parkinson's disease and may be related to handwriting impairments seen in this population.

6. Sequence Learning: For this task, the subject must learn a sequence of doors leading them through four rooms to a final reward. Within each room a subject is presented with three doors and must chose the correct one. Correct doors lead either to the next room or the treasure, whereas incorrect doors lead to a brick wall after which trials repeat until a correct response is made. Subjects must learn the correct sequence of doors through a trial and error process. This task measures trial and error sequence learning, a function shown to be impaired in patients with Parkinson's disease.

Progress to date also includes addition of a consultant Dr. Jose Contreras-Vidal, a neuroscientist specializing in the neural networks of motor control from the University of Maryland. Dr. Contreras-Vidal has been extremely helpful in planning and adapting the above tasks in conjunction with current study investigators.

Initiation of the validation protocol has not begun as we continue to await final IRB approval. Approval with minor revisions was received from the DOD IRB last month, and the modifications have been completed and have been sent to the MedStar IRB, which originally approved the project 15 months ago, for final approval. We are awaiting

Medstar's response. Once received we will be able to begin pilot testing of the motor battery.

Barriers and Solutions:

The primary barrier to clinical validation of the motor measures has been the long duration required for DOD IRB approval. We did not receive approval until last month, approximately 15 months from original submission. We are currently awaiting response from MedStar for modifications requested by the DOD IRB. Pending this final approval, pilot data and subsequent data collection should be able to proceed.

Plan:

The above described motor and psychomotor tasks will be combined with mood measures and the existing ANAM software to create a multidimensional computerized testing system. Pending IRB approvals, pilot testing of the new computerized testing system will begin to determine its suitability for testing older adults and to make any necessary modifications. Our expectation is that pilot testing will be quick, and that we will rapidly move into implementation of the validation protocol. The validation protocol combines the newly developed motor tasks, existing ANAM cognitive tasks, and mood measures, and examines their performance across three groups of subjects, healthy controls, patients with early Alzheimer's disease, and patients with Parkinson's disease.

Publication and Presentations:

n/a

**Project B1: The Impact of Self-Awareness on Functional Outcomes
Following Moderate and Severe Traumatic Brain Injury**

Funding period: Year 3 of 3-year funding period

Status: Collecting data

Principal Investigators: William Garmoe

Co-investigators: Anne Newman, Ph.D.

Research Assistant: Dee O'Neill

Abstract:

The purpose of the present study is to examine the relationship of self-awareness following traumatic brain injury (TBI) to functional outcome six months after inpatient rehabilitation. It is hypothesized that self-awareness is a salient variable affecting functional outcome. The present study represents one of a series of follow-up studies designed to gain further understanding of self-awareness deficits following brain injury.

Progress and Outcomes:

The lengthy process of obtaining IRB approval from all oversight bodies was achieved during 2004 and data collection commenced. Up to the present time approximately 16 subjects have been enrolled, and of these 16 3 have returned for the six month follow-up component of the study. The project was recently reviewed for annual continuation by the Medstar IRB and was approved with minor stipulations regarding consent form language. An initial qualitative review of the data suggests that results from prior studies are being replicated. There are too few subjects thus far at the six-month endpoint to determine whether study hypotheses are being supported.

Barriers and Solutions:

Data collection is approximately a year behind initial expectations, which was due to the prolonged IRB approval process within the Department of Defense. Presently the primary limiting factor is a lower-than-anticipated census of eligible subjects in the NRH Brain Injury Program. The research assistant screens all admissions to the program and reviews potential subjects with the PI. There have been very few, if any, refusals to provide consent by families approached. Thus there are thorough steps in place for recruiting subjects.

Plan:

Complete data collection and present finding.

Publication and Presentations:

Garmoe, Newman, & O'Connell. Self-Awareness Early Following Traumatic Brain Injury: Comparison of Brain Injury and Orthopedic Inpatients Using the Functional

Self-Assessment Scale (FSAS). Accepted for publication as invited article in Journal of Head Trauma Rehabilitation (JHTR).

**Project B2: Gait Restoration in Stroke and Incomplete SCI Patients Using
the Lokomat Robotic Treadmill System**

Funding period: Year 3 of 4-year funding period

Status: Ongoing

Principal Investigators: Joseph Hidler, PhD

Co-investigators: Edward Heaton, MD, MPH

Sub-contracts/consultants:
Scientific Solutions, LLC., Falls Church, VA

Abstract

As stated in the original proposal, the two overall objectives of this project are to determine whether robotic-assisted gait training using the Lokomat (Hocoma AG, Zurich, Switzerland) improves the walking capabilities in stroke and incomplete SCI subjects, and to investigate whether secondary complications following these injuries such as spasticity and excessive muscle tone are influenced by prolonged gait training. After lesions to certain descending motor pathways, patients often experience a loss of motor control, weakness, and an inability to initiate and coordinate movements. Furthermore, the excitability of certain reflex pathways is often enhanced to the point that involuntary, unwarranted movements occur. We believe that repetitive training with the Lokomat will lead to the restoration of normal gait patterns beyond what can be expected using traditional therapies. Because the patient is secured in the Lokomat which will assist in guiding their legs through smooth kinematic trajectories, it is believed that the subjects will be able to concentrate on re-establishing their natural gait patterns and effectively re-train neuronal circuits, rather than having to walk in such a way that falls will not occur. We also believe that because the Lokomat can provide therapy to the subject for periods of time well beyond what a therapist is capable of, secondary effects such as spasticity and muscle tone will be reduced, allowing the patients to walk without experiencing dysfunctional involuntary movements. Finally, it is our hypothesis that repetitive training may aid in developing central pattern generators which could potentially overcome weakness and inappropriate synergies commonly experienced in stroke subjects.

To test these hypotheses, we proposed to test 40 stroke and 40 SCI patients, half of which would receive conventional gait training while the other half would receive Lokomat gait training. Furthermore, all subjects had to be within 30 days of their stroke or spinal cord injury. All subjects were to undergo training 5 days per week for 20-30 minutes each day, for a total of 4 weeks. Evaluations of improvements in function ranged from walking speed to strength and endurance.

Progress and Outcomes:

On June 7, 2004, we requested permission from the DOD to alter the study in two specific ways. For the sake of clarity, we will repeat our original requests and justifications here.

Limitation with Stroke Component of the Study

A serious flaw with our original study design that we quickly recognized after acquiring the Lokomat robotic gait orthosis was that we intended to do all the training at NRH and found that finding subjects that fit the study criteria was difficult (mostly due to other health conditions that prohibit them from participating). As a result, we do not believe that we can train a sufficient amount of subjects to demonstrate statistically significant effects in the limited funding cycle of the grant. Furthermore, it also became apparent early that it would be nearly impossible to start training stroke subjects within 30 days after their stroke since most of these individuals are plagued with other co-morbidities whereby starting their training within this period would place them at significant risk for further complications. It should be noted that the original proposal was written before acquiring a Lokomat so that that it wasn't until after using the device that these problems became apparent.

Resolution:

After noting these problems, we decided to submit a multi-center proposal to the National Institute on Disability and Rehabilitation Research (NIDRR) with our colleagues at the Rehabilitation Institute of Chicago to look at the effects of the Lokomat in the stroke population, in an effort to bolster our sample size. This grant was awarded to us last year and we have subsequently started training subjects. The NIDRR study is slightly different to the proposed study under the NRC where the stroke inclusion criteria is now within 6 months following their stroke rather than 30 days and instead of receiving training 5 days per week for 4 weeks, training occurs 3 days per week for 8 weeks. Unfortunately the NIDRR award amount is not sufficient to carry out the proposed study as we seriously underestimated the costs involved with running this study. We did not allocate sufficient funds for therapist support, a study coordinator, or subject travel. As a result, it will be difficult if not impossible to carry out the proposed study with the current funding stream.

Our hope is to cost share the study between our NIDRR funding and NRC funding which should be sufficient to execute the study. We would follow the protocol outlined in the NIDRR study in that we would train stroke subjects for 8 weeks, 3 days per week. All other aspects of the study would remain in tact. Funding from both NIDRR and the NRC will allow us to provide subject transportation to all of our participants, as well as the therapist and study coordinator costs. In addition, because this is a multi-center effort, our stroke sample size will now be 100 participants, 50 of which will be trained at NRH.

Limitation with SCI Component of the Study

Based on recently published results from the NIH funded body-weight supported treadmill training study that compared conventional gait training with manually-assisted body-weight supported treadmill training, it was reported that to show statistically significant group effects, a sample size of 200 acute SCI patients would be necessary. We had had proposed to

train 40 subjects which would not provide sufficient power to make statistical conclusions. And unlike the stroke leg of this study, we do not have any additional funding to increase the sample size to a critical level, which would also take multiple centers to reach the necessary numbers.

Resolution:

We propose to change the original focus of this study from comparing conventional gait training with robotic-assisted gait training in incomplete SCI subjects to one which will investigate the health benefits of robotic-assisted gait training in individuals with chronic motor complete spinal cord injuries. Across rehab settings in the United States and Europe, locomotion therapy is not being pursued in this patient group because it is considered “maintenance therapy” which is not reimbursable by health care providers. We believe that intensive locomotor therapy will result in tremendous health benefits in these individuals such as increased bone-density, better circulation, cardiovascular effects, improved bowel/bladder function, and decreased cholesterol levels. These benefits may ultimately allow these individuals to better execute activities of daily living and reintegrate back into society. We have chosen to pursue this study in chronic subjects so that they can act as their own control. That is, beyond 2 years post-injury, studies have shown that changes in motor function are exceptionally rare. If we are able to detect before-after changes, we can attribute them to our intervention rather than spontaneous recovery. As a result, the sample size does not need to be large to make statistical conclusions.

For this change, we propose to test 5 SCI subjects with motor-complete injuries for up to 6 months of robotic-assisted gait training, 3 days per week. We will evaluate the outcome measures listed in table 1 bi-monthly using the assessment tools also listed in table 1.

Table 1. Outcome measures and assessment tools

Outcome	Measurement Tools
1. Functional Limitation	1. Spinal Cord Index Measure (SCIM)
2. Strength	2. American Spinal Cord Injury Association (ASIA) scale
3. Sensation	3. ASIA
4. Spasticity	4. Modified Ashworth
5. Muscle Mass	5. Circumferential leg measurements
6. Range of Motion	6. Direct measurement
7. Skin Integrity	7. Visual Inspection
8. Cardiopulmonary Function	8. Direct measurement/Parvo Machine
9. Total Lipid Profile*	9. Direct measurement
10. Bone Density*	10. Dexascan
11. Pain	11. 0-10 scale
12. Dysreflexia	12. Subjective Journal
13. Sitting Balance	13. Modified Functional Reach Test

14. Degree of Handicap/Health	14. Short-form health survey
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* These outcome measures will be evaluated at 0, 6, and 12 months only.

We believe that a study of this sort is extremely important clinically since there are no current rehab centers providing motor complete SCI patients with this form of therapy, and if it does in fact prove to be effective at improving important health measures, health care providers will be forced to change their existing policies.

SUMMARY

We originally proposed to compare conventional gait training with robotic-assisted gait training in 40 stroke and 40 incomplete SCI subjects for 1 month, 5 days per week. We would like to modify the stroke protocol to test sub-acute subjects (rather than acute) for 8 weeks, 3 days per week and cost share the study with other existing funding sources. We would like to change the SCI component of the study to train chronic motor complete SCI patients and evaluate whether 6 months of robotic-assisted gait training leads to improvements in important health measures which may ultimately improve their quality of life. We believe these changes will allow us to best utilize the existing funding sources under the Neuroscience Research Center at NRH while at the same time make significant contributions to the scientific community.

Barriers and Solutions:

The DOD approved of these changes in December 2004 after requesting a response to some concerns (see attached). We then submitted a revised IRB for the SCI portion of the study which was discussed with the DOD IRB on May 11. We are currently waiting for approval from the DOD IRB to begin training SCI subjects. The stroke leg of the study required an amendment to our original approved IRB for this study, which is just now being submitted to the DOD IRB.

Plan:

We anticipate that IRB approval will be granted for the SCI portion of the study by the end of this fiscal year, after which we will begin training patients. We also anticipate that the amendment for the stroke portion of the study will be approved by early summer so that we can also start training stroke patients under this study.

Publication and Presentations:

A number of presentations and publications have resulted from pilot work done over the past funding cycle that was affiliated with this study:

J. M. Hidler, D. Nichols, M. Pelliccio, and K. Brady, "Advances in the understanding and treatment of stroke impairment using robotic devices." *Top Stroke Rehabil*, vol. 12(2): 21-33, 2005.

J. M. Hidler and A.E. Wall, "Changes in muscle activation patterns during robotic-assisted walking." *Clinical Biomechanics*, vol. 20(2): 184-193, 2005.

- A. Ricamato and J. M. Hidler, "Quantification of dynamic properties of EMG patterns during gait." *Journal of Electromyography and Kinesiology*, vol. 15(4) pp. 387-395, 2005.
- J. M. Hidler, "What's next for locomotor-based studies." *Journal of Rehabilitation Research & Development*, Guest Editorial, vol. 42(1), pp. xi-xiv, January/February, 2005.

Conference Proceedings

- J. Hidler, "Robotic-Assessment of Walking in Individuals with Gait Disorders", *IEEE Engineering in Medicine and Biology Society*, 2004.
- A. Wall and J. Hidler, "Alterations in EMG patterns during robotic-assisted walking", *Northeast Bioengineering Annual Conference*, 2004.

Abstracts

- A. Ricamato and J. Hidler, "A Tool to Quantify the Temporal and Spatial Properties of EMG Patterns during Gait", *ISEK Annual Conference*, Boston, MA, 2004.
- A. Lichy, J. Hidler, J. Cisper, and A. Wall. "Changes in muscle activation patterns during robotic assisted gait training." *APTA Annual Conference*, Chicago, IL, 2004.

INVITED PRESENTATIONS

- "Development of robotic devices to facilitate motor recovery in stroke and spinal cord injury", Innovations in Neurorehabilitation, Jewish Rehabilitation Hospital Annual Conference, Montreal Canada, April 2005 (KEYNOTE SPEAKER)
- "Robotic-assisted gait training following spinal cord injury: influence of training parameters on walking ability", University of Maryland Baltimore, November 2004.
- "Robotic-assessment of walking ability in individuals with neurological disorders", Arizona State University, BioDesign Institute, Tempe Arizona, November 2004.
- "Gait restoration in hemiparetic stroke patients using goal-directed, robotic-assisted treadmill training", Lokomat Symposium, Zurich Switzerland, September 2004.
- "Contemporary Issues Surrounding Robotic-Assisted Locomotor Training", Neural Prosthesis Seminar Series, Cleveland FES Center, Cleveland, Ohio, 2004.
- "Advances in the understanding and treatment of stroke impairment using robotic devices", CME Symposium - Stroke Rehabilitation: Outstanding Outcomes and Best Practices, National Rehabilitation Hospital, Washington, DC, 2004.

Trainees affiliated with the project

Undergraduate Students – Catholic University

Anji Wall
Lindsay Diromualdo
Cathryn Jensen
Megan Payne
Gloryvee Rivera
Erin Blair

Graduate Students – Catholic University

Iian Black
Nathan Neckel

Project C1: Stroke Performance Recovery and Outcomes Study

Funding period: Year 3 of 4-year funding period

Status: Ongoing

Principal Investigators: Brendan Conroy, MD

Co-investigators: Gerben DeJong, PhD,¹ FACRM; Susan Horn, PhD

Sub-contracts/consultants:

Institute for Clinical Outcomes Studies (ICOR), Salt Lake City, UT

Abstract:

Stroke Performance Recovery and Outcomes Study examines specific patient characteristics and rehabilitation interventions and their relationship to outcomes. All together, six inpatient rehabilitation facilities in the U.S. and one in New Zealand contributed detailed patient-level data on 1,383 patients--approximately 200 consecutively admitted stroke patients at each site. The study entails the development of a detailed taxonomy of interventions, the creation of extensive in-depth data collection protocols, the creation of a study database, data analyses, publications, presentations, and project spin-offs to exploit the database. The study is made possible by a cohesive leadership team, the commitment by participating clinical sites, and a number of volunteer investigators who have joined the study as it became better known throughout the country and abroad.

Progress and Outcomes:

1. Continued to analyze the very large database created by the study. The findings are now finding their way into the manuscripts cited below.
2. Prepared or published *17 manuscripts* for publication in various health science journals. See list of publications and presentations. This includes the preparation of 12 manuscripts for a special supplement of the *Archives of Physical Medicine & Rehabilitation*, the field's most widely cited publication. The *Archives of PM&R* will be publishing this special supplement in December 2005 devoted entirely to the findings of this study. These 12 manuscripts are currently undergoing peer review. Final copy will be going to the journal in mid July. Currently, the 12 papers consists of 342 pages of manuscript text that will be compressed to 100 pages of published text. Drs. DeJong, Horn, and Conroy are the editors for the supplement.

¹ At this time last year, Dr. DeJong was a professor at the University of Florida's College of Public Health & Health Professions and the Associate Directors for the University of Florida Brooks Center for Rehabilitation Studies. In November 2004, Dr. DeJong rejoined the NRH team and currently serves as a senior fellow in the NRH Research Division and the NRH Neuroscience Center.

3. Assembled a team to organize a 1½-day conference to be held in January 2006 based on the study, its methods, and findings. A copy of the conference agenda can be found in the appendix to this report.
4. Developed plans to merge the study's database with an almost identical study database being assembled in 4 European countries from 5 rehabilitation centers. The European study was discovered only this past year.
5. Assisted Koen Putman, PhD, PT, of the Free University of Brussels, the European study project director, to apply for a European Community Maria Currie Fellowship and for a Fulbright Scholarship. Dr. Putman was successful in acquiring the Fulbright Scholar designation and will be joining the NRH group in April 2006. Dr. Putman's faculty liaison at the NRH will be Dr. DeJong.
6. Sought supplementary funding to further examine the study's extensive database. Submitted a field-initiated research proposal to the National Institute on Disability & Rehabilitation Research (NIDRR). Submitted an original R01 proposal and resubmitted 2 other R01 proposals to NIH this past year. Submitted 2 fellowship proposals for a European investigator to join NRH to continue work on the study. See Item 5 above.
7. A request to develop of a Clinical Stroke Research database at NRH has been approval. This database will allow us to understand how modifications to practice will effect specific areas of stoke rehabilitation and improve patient outcomes. This project has been initiated and data collection is planned to start on July 1st.

Barriers and Solutions:

There were no unusual or insurmountable barriers other than usual prodding to get contributing authors to finalize their manuscripts for the *Archives* supplement. The overall task of assembling a unified and coherent supplement proved to be more arduous than expected but was successful.

Plan:

1. Promote secondary uses of the *Archives of Physical Medicine & Rehabilitation* supplement that incorporates the principal findings from the study.
2. Host Fulbright Scholar from Free University of Brussels in working to combine and analyze data from both the American (project database) and European databases that include data on 1,800 stroke patients from the U.S. New Zealand, Germany, Belgium, Switzerland, and the United Kingdom.
3. Continue to submit papers to other journals and conferences as opportunities arise and as papers are accepted. Target conferences include the annual meetings of the:

- American Congress of Rehabilitation Medicine (ACRM)
- American Society for Neurorehabilitation (ASNR)
- American Academy of Physical Medicine & Rehabilitation (AAPM&R)
- International Stroke Association (ISA)
- American Physical Therapy Association (APTA)
- American Occupational Therapy Association (AOTA)
- American Speech & Hearing Association (ASHA)

Publications:

1. DeJong G, Horn SD, Gassaway J, Dijkers M, Slavin M. Toward a Taxonomy of Rehabilitation Interventions: Using an Inductive Approach to Examine the 'Black Box' of Rehabilitation. *Archives of Physical Medicine & Rehabilitation*. 55 (April 2004), 678-686
2. Jette DU, Latham NK, Smout RJ, Gassaway JV, Slavin MD, Horn SD. Physical therapy interventions for patients with stroke in in-patient rehabilitation facilities. *Physical Therapy* 2005 March; 85:238-248.
3. Latham NK, Jette DU, Coster W, Richards L, Smout RJ, James RA, Gassaway J, Horn SD. Occupational Therapy Interventions for Clients with Stroke in an Acute Rehabilitation Setting. *American Journal of Occupational Therapy*. Submitted
4. DeJong, Gerben and Susan Horn 2005 "Randomized Controlled Trials in Rehabilitation Research." *New Zealand Journal of Disability Studies*. Vol. 11: 120-124.
5. B Conroy, B Hatfield, D Nichols (2005). Opening the Black Box of Inpatient Stroke Rehabilitation. *Topics in Stroke Rehabilitation*, P Rao, ed. May; Vol. 12:2, 36-48.

Special Edition, *Archives of Physical Medicine and Rehabilitation*, December 2005:

6. DeJong G, Horn SD, Conroy BC, Nichols D, Heaton EB. Opening the Black Box of Post-Stroke Rehabilitation: Stroke Rehabilitation Patients, Processes, and Outcomes. *Archives of Physical Medicine & Rehabilitation*. December 2005 Supplement
7. Horn SD, DeJong G, Ryser D, Veazie P, Teraoka, J. Another Look at Observational Studies in Rehabilitation Research: Going Beyond the Holy Grail of the Randomized Controlled Trial. *Archives of Physical Medicine & Rehabilitation*. December 2005 Supplement

8. Gassaway JV, Horn SD, DeJong G, Smout RJ, Clark C. Applying the CPI Approach to Stroke Rehabilitation: Methods Used And Baseline Results. *Archives PM&R*, December 2005 supplement.
9. McNaughton H, DeJong G, Smout R. A comparison of stroke rehabilitation practice and outcomes between New Zealand and United States facilities. *Archives of Physical Medicine & Rehabilitation*. December 2005 Supplement.
10. Conroy B, Zorowitz R, Horn S, Ryser D, Teraoka J, Smout R. Variation in Use of Medications in Stroke Rehabilitation *Archives of Physical Medicine & Rehabilitation*. December 2005 Supplement.
11. James R, Gines D, Horn SD, Gassaway J, Smout R. Nutrition as a Rehabilitation Intervention. *Archives of Physical Medicine & Rehabilitation*. December 2005 Supplement.
12. Latham N, Jette D, Slavin M, Richards L, Smout R, Horn S. Characterizing Physical Therapy Practice in Stroke Rehabilitation. *Archives of Physical Medicine & Rehabilitation*. December 2005 Supplement.
13. Richards L, Latham N, Jette D, Rosenberg, L, Smout R, DeJong G. Characterizing Occupational Therapy Practice in Stroke Rehabilitation. *Archives of Physical Medicine & Rehabilitation*. December 2005 Supplement.
14. Hatfield B, Millet D, Coles J, Gassaway J, Conroy B, Smout R. Characterizing Speech and Language Therapy in Stroke Rehabilitation. *Archives of Physical Medicine & Rehabilitation*. December 2005 Supplement.
15. Maulden S, Gassaway J, Horn SD, Smout R, DeJong G. Timing of Rehabilitation After Stroke. *Archives of Physical Medicine & Rehabilitation*. December 2005 Supplement.
16. DeJong G, Smout R, Horn SD, Smout R. The Early Effects of the IRF-PPS on Stroke Rehabilitation Case-mix and Utilization. *Archives of Physical Medicine & Rehabilitation*. December 2005 Supplement.
17. Horn SD, DeJong G, Smout R, Gassaway J, James R, Conroy B. Associations of Patient Characteristics and Interventions on Rehabilitation Outcomes. *Archives of Physical Medicine & Rehabilitation*. December 2005 Supplement.

Project C2: Role of Eye Movements in Activities of Daily Living

Funding period: Year 3 of 1-year funding period

Status: Completed

Principal Investigators: Cheryl Trepagnier

Co-investigators: Marc M. Sebrechts, Willie Stewart, Jr., Andreas Finkelmeyer

Abstract:

The major objective of this pilot project was to identify, adapt and modify a mobile eye-tracking system in order to assess the feasibility of such a system for use with patients recovering from brain injury, and to assess the potential value of such instrumentation.

Mobile eye-tracking technology provided assessment of eye-gaze during tasks of everyday living without interfering with task performance. Planning was evidenced by substantial numbers and duration of look-ahead gazes that were correlated with reduction of gaze at the same objects during the time participants were actually performing the steps involving those objects. The approach to executive function assessment appears to have promise for assessment of executive function including use with patients recovering from brain injury.

Progress and Outcomes:

Total and relative task performance time indicated little or no effect on task performance of wearing the equipment involved in monitoring eye gaze with mobile eye-tracking technology. This approach therefore presents a useful way to assess planning activities. Look-ahead gaze behavior indicated that participants do exhibit substantial planning while performing tasks of everyday living. Negative correlations of look-aheads and step-relevant gazes indicate that planning eye-gaze decreases the need for repeating those eye movements during actual task performance. Due to difficulties of patient access, only a single participant was an individual recovering from brain injury. This individual responded similarly to the other participants in the study, suggesting that the mobile eye-tracking technique may be useful in assessment of recovery of executive function.

Barriers and Solutions:

The study encountered a barrier in regards to the recruitment of experimental participants (brain-injured participants). The protocol specified that enrollment of clinical participants would be limited to persons identified by and known to the vocational rehabilitation counselors at NRH. The protocol also required that participants have stable balance and not be at any risk of falls. Consequently, the eligible clinical population was largely restricted to individuals voluntarily returning to the hospital to participate in the study, or who had other reasons for visiting the hospital. Intensive telephone efforts to connect with patients identified by the vocational counselors had minimal yield.

Plan:

The project is no longer funded, and access to the testing site (the model kitchen at the hospital) is terminated. Further analyses of data are still in progress. A poster has been presented (below) and a paper is in progress.

Publication and Presentations:

Sebrechts, M. M., Stewart, W. C., Finkelmeyer, A., & Trepagnier, C. Y. (2005). **Eye-Gaze Demonstrates Planning in Activities of Daily Living**. *Posterpresented at the 17th Annual Convention of the American Psychological Society, May 26-29, Los Angeles, CA.*

Project D1: Determining the Psychometric Properties of the NRH Pragmatic Communication Skills Rating Scale

Funding period: Year 2 of 1-year funding period

Status: Collecting data

Principal Investigators: Christine Baron

Co-investigators: Melissa Richman, Thilo Kroll

Abstract:

Speech-language pathologists (SLPs) complete the NRH Pragmatic Communication Skills Clinician Rating Scale as part of their evaluation of right-hemisphere stroke survivors. Family members or significant others are asked to fill out the version of the same scale that has been designed for their use. Both of these rating scales have been used clinically without benefit of reliability or validity testing. Reviews of work done with this scale to date have been extremely encouraging, with the caveat that the psychometric properties of the Scale need to be examined. The objective of this project is to determine the reliability and validity of the clinician scale in order to contribute to the profession, current clinical practice and the ability to conduct applied research regarding pragmatic communication changes after stroke in a multi-cultural population.

Progress and Outcomes:

Data collection began April 26, 2004. Data for 20/50 subjects has been collected. Preliminary data analysis suggests that original sample size projection (N = 50) is on target.

Barriers and Solutions:

Data collection has been interrupted for extended periods due to unavoidable events (relocation of the SLP Service; death in PI's family) which have twice required the temporary halting of data collection.

Plan:

Continue data collection. Estimate 4-5 months once IRB continuation approval has been received. Results will be submitted to the Clinical Aphasiology Conference, and if accepted, presented at the conference in May 2006.

Publication and Presentations:

Prior research in this area and the current research design and rationale were published: Baron, C., Hatfield, B. and Georgeadis, A. (2005). Management of communication disorders using family member input, group treatment and telerehabilitation. Topics in Stroke Rehabilitation, 12(2), 47-54.

Project D2: **Effect of an oral anabolic steroid on pulmonary function and body composition in individuals with chronic spinal cord injury: a pilot study**

Funding period: Year 2 of a 1-year funding period.

Status: Awaiting IRB from DOD

Principal Investigators: Lauro Halstead, MD MPH

Co-investigators: Suzanne Groah, MD, MSPH and Larry Hamm, PhD

Abstract:

This is a 1 year study to investigate the effects of 2 agents—oxandrolone and conjugated linoleic acid (CLA)—in individuals with chronic spinal cord injury (SCI). Oxandrolone is an oral anabolic steroid that has been shown to increase lean body mass and improve pulmonary function. CLA (brand name Tonalin) is a group of polyunsaturated fatty acids found in animal meat, dairy products and other natural sources and has been shown to decrease body fat mass. The purpose of this project is to determine whether oxandrolone, CLA, or both improve body composition and pulmonary function in individuals with C8-C4 ASIA A or B of at least 1 year duration. Subjects will be randomized to either the oxandrolone (n=15), CLA (n=15), or control (n=15) groups. All 45 participants will receive baseline liver function tests (LFTs), lipid panel, pulmonary function testing (PFTs) and dual x-ray absorptiometry (DEXA) for body composition analysis. Subjects will then receive either 8 weeks of oxandrolone, 12 weeks of CLA, or neither. Participants will have laboratory studies including lipid panel, LFTs, PFTs, and DEXA during and immediately after the intervention period and 3 months later to determine if any changes are maintained.

Progress and Outcomes:

There have been 2 major developments since the last report. The first development occurred in late 2004, when we received notification of funding for one-year by the Cognis Corp. of LaGrange, IL to support the inclusion of conjugated linoleic acid (CLA) and a control group in the study. CLA is a group of polyunsaturated fatty acids found in animal meat, dairy products and other natural sources and has been shown to decrease body fat mass. The purpose of the project and protocol have been expanded to determine whether oxandrolone, CLA, or both improve body composition and pulmonary function in individuals with C8-C4 ASIA A or B of at least 1 year duration. Subjects will be randomized to either the oxandrolone (n=15), CLA (n=15), or control (n=15) groups. All 45 participants will receive baseline liver function tests (LFTs), lipid panel, pulmonary function testing (PFTs) and dual x-ray absorptiometry (DEXA) for body composition analysis. Subjects will then receive either 8 weeks of oxandrolone, 12 weeks of CLA, or neither. Participants will then have laboratory studies including lipid panel, LFTs, PFTs,

and DEXA during and immediately after the intervention period and then 3 months later to determine if any changes are maintained.

As a result of this first development, the project now has co-funding from 2 separate sources with 2 separate budgets. The first source of funding is from the Army (HSRRB Log Number A-11230.13) and is restricted to supporting the oxandrolone (oral anabolic steroid) arm of the study (15 subjects) and one half of the control group (7 subjects).

The second source of funding is from Cognis Corporation and is restricted to supporting the conjugated linoleic acid arm of the study (15 subjects) and one half of the control group (8 subjects). None of the funds from Cognis Corporation will be used to finance any portion of the oxandrolone arm of the research and associated control subjects. Conversely, none of the funds from the Army will be used to finance any portion of the conjugated linoleic acid arm of the project and associated study subjects.

Because of these changes to the protocol, we have changed the title from "Effect of an oral anabolic steroid on pulmonary function and body composition in individuals with chronic spinal cord injury: a pilot study" to the current title "Metabolic Studies in Individuals with Chronic Spinal Cord Injury: The Effects of an Oral Anabolic Steroid and Conjugated Linoleic Acid". CLA may have complementary effects to oxandrolone in individuals with SCI, potentially decreasing fat mass. By adding a control group the study has been markedly strengthened and is now a true experimental study with 2 drugs of interest and 2 primary functions of interest (body composition and pulmonary function), thereby increasing the potential for future funding.

The second major development since the last report was the approval of the new protocol and informed consent by the MRI Institutional Review Board (IRB) in February 2005.

Barriers and Solutions:

We have been unable to initiate the study due to delay in IRB approval by the Army/DOD. During this period, the study has been modified as outlined above. It has become necessary to transition a portion of the PI duties since Dr. Groah is the PI and Center Director of NRH's new NIDRR-funded Rehabilitation Research and Training Center (RRTC) on Secondary Conditions After Spinal Cord Injury. The RRTC is a large, multi-year, collaborative center grant that is comprised of 5 research projects and 4 training projects. Lauro Halstead will take over most of Dr. Groah's responsibilities as PI of this current project. Dr. Groah will remain as Co-PI in a small role and will assist with analysis of data, manuscript and presentation preparations.

Plan:

Anticipate initiation of study as soon as approved by the Army IRB.

Publication and Presentations:

None.

**Project D3: Development and Clinical Validation of a Children's
Version of the Automated Neuropsychological
Assessment Metrics (ANAM)**

Funding period: Year 2 of 1-year funding period

Status: Waiting IRB Approval from DOD

Principal Investigators: Tresa Roebuck-Spencer, PhD

Co-investigators: Joseph Bleiberg, Ph.D. (NRH); Gerard Gioia, Ph.D. (Children's
National Medical Center - CNMC); Laura Kenealy, Ph.D. (CNMC)

Sub-contracts/consultants:

- Investigators at CNMC will be paid via a subcontract to CNMC

Abstract:

Every day children experience illnesses, injuries, or take medicines that may change their ability to think quickly and remember things. This study will adapt and validate a group of computerized tests, called the Automated Neuropsychologic Assessment Metrics (ANAM), in order to inform doctors and other health care providers when a child had a change in his or her cognitive functioning. The ANAM battery was originally developed by the US Army to measure changes in thinking abilities in adults. While ANAM has been used with young adults and adolescents in high school, it has not been used with children younger than 13 and a comparable measure in this age group does not exist.

The current study includes three stages. The first stage includes development and pilot testing of a pediatric version of ANAM (ped-ANAM) with children between the ages of 10-12, to demonstrate that children at this age can understand and complete the test. During the second stage, a group of middle school children (between the ages of 10-12) will take ped-ANAM. This phase of the study will establish expected levels of performance in normally developing children and will test for differences in performance between boys and girls and across the three age ranges. In the last stage of this project, sensitivity of ped-ANAM to detect cognitive change in two pediatric clinical groups will be examined using a series of single subject studies. First, children with a diagnosis of ADHD will be tested with ped-ANAM prior to and after receiving medication in order to determine if performance on ped-ANAM changes after receiving medication. Second, children with recent (< 24 hours) history of concussion or mild traumatic brain injury will be tested with ped-ANAM multiple times over several days to 1) demonstrate its use within an emergency medical setting and 2) document its ability to track recovery of cognitive functioning. Data collected from this study will provide evidence of ped-ANAM's use with normal and clinical samples of children and document its sensitivity to cognitive change in children.

Progress and Outcomes:

This project is still awaiting approval from the Army Human Subjects Research Review Board (HSRRB), thus no data collection or human subject accrual has begun. The project previously received full approval from the MRI and CNMC IRB committees and was recently reviewed by the HSRRB committee on April 27. We are currently awaiting response from HSRRB.

Significant progress has been made regarding development of the pediatric ANAM battery over the past year, thus bringing us near completion of Phase One or the Development Phase of this project. Over the last year, regular meetings have continued between NRH and CNMC study investigators to modify and adapt the current ANAM testing battery for use with children aged 10 to 12. The goal was to create a testing battery that was both developmentally appropriate and engaging for children in this age group. This was accomplished through modification of the ANAM test process, instructions, and stimuli. In addition, "child-friendly" tests were added to the battery. When appropriate, efforts were made to keep the pediatric ANAM battery as consistent as possible with the standard version of ANAM so that a core set of tests could be used throughout the lifespan.

Modification of Test Process: Traditionally, responses to ANAM subtests occur as a button press of one of the two mouse buttons. In the adult version, test directions refer either to the "right" and "left" buttons or to the "1" and "2" buttons. To avoid confusion, we have color coded the mouse buttons as blue or red using stickers and will refer to them as such both verbally and pictorally throughout the directions.

Modification of Test Instructions: To make current ANAM instructions developmentally appropriate, we have shortened and simplified sentence structure of all verbally presented instructions. We have restricted reading level to no greater than third grade and have added pictures as illustration of test directions in addition to words wherever possible. For all tests, multiple examples of appropriate responses are provided in contrast to only one example in original ANAM test instructions. Finally, for all tests both positive and negative feedback are provided during the practice trials.

Modification of Test Stimuli: In consultation with CNMC pediatric neuropsychologists all ANAM subtests were reviewed for developmental appropriateness. Specifically, complexity of individual subtest stimuli and amount of information to be visually scanned or learned was carefully reviewed with respect to the current developmental literature. Where necessary test stimuli were modified to be more developmentally appropriate for children. Specifically, stimuli were simplified to less abstract symbols for the Code Substitution Learning and Delayed subtests. Additionally, a pictorial sleepiness scale validated for use with children was substituted for the Stanford Sleepiness Scale, which was determined to be too verbally complex for children in our target age range.

Addition of "Child-Friendly" Tests: Through consultation with CNMC pediatric neuropsychologists the current Mathematical Processing and Logical Reasoning subtests were deemed to be too complex for children in our target age range. These tests were

modified and new stimuli were created to create two new ANAM subtests for specific use with children.

NRH study investigators modified ANAM test instructions and created new ANAM stimuli in preparation for final creation of the pediatric ANAM install program. A beta version of this program was created by ANAM programmers at Pensacola. Several researchers outside of NRH network have expressed interest in using the pediatric ANAM and plan to incorporate this measure into their own ongoing research projects. Collaboration with these individuals will help to expand our sample of normally developing children to other geographic regions and will provide reference group data for the pediatric ANAM to other clinical samples.

Barriers and Solutions:

The primary barrier to progress on this study has been the delay in receiving IRB approval from MRMC. Although this protocol was submitted to them in January of 2004, it was not reviewed by the HSRRB until April 27, 2005. We have completed Phase One of this project and will be ready to initiate Phases Two and Three as soon as we receive final approval from the HSRRB.

Plan:

Once the final IRB approval is received from MRMC HSRRB any necessary modifications requested by HSRRB will be filed with both the MRI and CNMC IRBs. Once these modifications are approved by internal IRBs, pilot testing will begin with the beta version of the pediatric ANAM battery. Upon completion of pilot testing, any changes to the battery deemed necessary will be made in conjunction with current ANAM programmers. Once a final pediatric version of ANAM is ready, data collection from the normally developing and clinical groups will begin and continue for 6-9 months. Databases will be created for data storage. At the completion of data collection, statistical analysis will begin with plans to present these analyses at a national conference to be followed by manuscript preparation and submission to a peer-reviewed journal.

Publication and Presentations:

n/a

Project E1: Annual Joint NRH/NIH/ACRM/AAMPM&R/NIDRR Conference

Funding period: Year 3 of 4-year funding period

Status: Postponed until January 2006

Principal Investigators: N/A

Abstract:

The purpose of this conference is to discuss the leading opportunities in neuro-rehabilitation, emerging practices in multi-center trials, and best practices research administration. It is cosponsored with several other organizations and will produce an annual report that summarizes the meeting.

Progress and Outcomes:

The conference for year 3 was postponed until year 4 in order to more appropriately utilize resources.

As a follow-up to the year 2 E1 project, "Stroke Rehabilitation: Outstanding Outcomes and Best Practices," the Spring 2005 addition of the "Topics in Stroke Rehabilitation" publication was inspired by this project. Please see the publication in the appendix.

Barriers and Solutions:

N/A

Plan:

Host a national invitational conference in January 2006 based on the results of the study using the manuscripts for the special issue of the *Archives* as the basis for conference content. Please see below for details.

A Working Conference

**Rethinking Stroke Rehabilitation Practice:
Is Earlier and More Aggressive Therapy Better?**

Findings from the Post-stroke Rehabilitation Outcomes Project

Potential Agenda Version5

January 12 & 13, 2006 (1st choice)
January 9 & 10 (2nd choice)
1½-day meeting
National Rehabilitation Hospital
Washington, DC

DAY 1

07:30 Registration & Breakfast

08:30 Welcoming Remarks²
Edward Heaton, MD, MPH
National Rehabilitation Hospital
Washington, DC

08:45 Introduction: Purpose & Scope of PSROP and Meeting Expectations
Gerben DeJong, PhD
National Rehabilitation Hospital
Washington, DC

09:05 Going Beyond the Holy Grail of the RCT
Susan Horn, PhD
Institute for Clinical Outcomes Research
Salt Lake City, UT

09:45 Break

10:00 PSROP Taxonomy, Methods, & Baseline Results
Julie Gassaway, MPH
Institute for Clinical Outcomes Research
Annapolis, MD

10:40 Commentary & Group Discussion
Alex Dromerick, MD³

² The meeting will be recorded and edited for web viewing. This will also assist us in developing a report that will include recommendations for practice and future research.

National Rehabilitation Hospital
Washington, DC

11:10 The Leap-frog Hypothesis: Is Early & More Aggressive Therapy Better?

Susan Horn, PhD
Institute for Clinical Outcomes Research
Salt Lake City, UT

Brendan Conroy, MD
National Rehabilitation Hospital
Washington, DC

12:00 Lunch

Remarks by Ruth Brannon, MA, MSPH, NIDRR project officer
Remarks by Mary Lopez, PhD, OTR, DOD project officer

13:00 Commentary & Group Discussion

Elliot Roth, MD
Hilary Siebens, MD
Deborah Wilkerson, MA
Dale Strasser, MD
John Melvin, MD
Patrick Murray, MD
Cathy Ellis, PT

13:45 Workgroup organization and instructions

Instructions to the workgroups, Gerben DeJong, PhD

14:00 Workgroups

14:10 Presentations by authors (about 14 min each)

15:00 Break

15:20 Designated discussants (2-3 discussants/workgroup)

15:50 Workgroup discussion

16:30 Workgroup consensus discussion

16:50 Adjourn

Topics covered by each workgroup:

- Practice patterns and variation across sites
- Is earlier and more aggressive better?
- Recommendations for practice, policy, and research
- Recommendation for stroke rehabilitation quality and accreditation standards
- What are the next steps?

³ Dr. Dromerick will begin with a 5-10 min commentary before the discussion would be open to the floor.

Workgroup A—Therapy Activities

Convener/moderator/facilitator:

Paul Rao, PhD

Recorder:

Julie Gassaway, MPH

Discussants:

Diane Nichols, PT

Deborah Millet, MS, CCC-SLP

Lauren Rosenberg, OTR

Physical Therapy

Nancy Latham, PT, PhD

Occupational Therapy

Lorie Richards, PhD

Speech & Language Therapy

Brooke Hatfield, MS, CCC-SLP

Workgroup B—Timing, Medications, Nutrition, IRF-PPS in Stroke Rehabilitation

Moderator/convener/facilitator:

Richard Zorowitz, MD

Recorder:

David Ryser, MD

Discussants:

Lee Ann Simms, RN

Jeffrey Teraoka, MD

Timing of Rehabilitation after Stroke

Sarah Maulden, MD, MS

Neurotropic Medications

Brendan Conroy, MD

Nutrition

Roberta James, MStat

Early Effects of the IRF-PPS on Stroke Rehabilitation

Gerben DeJong, PhD

16:50 Adjourn for the day

DAY 2

07:00 Breakfast

08:00 Stroke Rehabilitation Practice in New Zealand & the United States

Harry McNaughton, MD

08:50 The CERISE Study (5 centers in Europe)

Koen Putman, ABD

Willy De Weerd, MD

09:40 Group Discussion on the International Dimension

Murray Brandstater, MD

10:05 Break

10:20 Workgroup Reports & Group Discussion

Moderator, e.g., Gerben DeJong, PhD

Each workshop will present its findings/implications/recommendations followed by a brief Q & A from the audience followed by:

Implications for practice

Implications for accreditation standards

Implications for policy

Implications for future publications

Implications for future research & funding

Recommendations: What are the next steps?

12:15 Closing remarks

G DeJong, PhD

E Heaton, MD

**Project E2: Expert Panel on Neuroprotectant Treatment of Mild
Brain Injury**

Funding period: Year 3 of 1-year funding period

Status: Project is starting on June 21, 2005

Principal Investigators: Joseph Bleiberg, PhD

Abstract:

In the late 1970s and 1980s there was a rush of clinical trials using neuroprotectants as treatment for traumatic brain injury. Unfortunately, the initial excitement and optimism gave way to disappointment in the face of poor results, with several agents actually appearing to exacerbate the injury they were designed to treat. The present project will assemble a multidisciplinary group of experts to review newer generation neuroprotectants and determine whether there is a sound scientific rationale to reconsider a neuroprotectant clinical trial. Specifically, the panel will review candidate neuroprotectants in order to produce one of two actions: 1) a state-of-the-art literature review of neuroprotectants, with the conclusion that none are promising for current clinical trials, or, 2) the identification of one or more promising neuroprotectants, with the conclusion that a clinical trial should be undertaken. In the event of the latter conclusion, the literature review will serve as the introduction for a clinical trial research proposal.

Progress and Outcomes:

This project originally was written with the intention that it would be chaired by COL Andres Salazar, M.D., who retired before implementation of the project. The past year has been devoted to establishing new leadership for the project. This has been accomplished.

The Expert Panel will be chaired by James P. Kelly, M.D., Professor of Neurosurgery, University of Colorado Medical School. Edward Healton, M.D., will be a member of the Panel. Drs. Kelly and Bleiberg have a meeting scheduled June 21 and 22, 2005 to develop a detailed Statement of Work for a subcontract to University of Colorado to conduct the Panel. Drs. Kelly and Bleiberg have a meeting scheduled with Dr. Healton on June 23, 2005 to finalize the SOW.

Barriers and Solutions:

None remaining and the project will be completed this upcoming year.

Budget/Staffing changes:

Dr. Kelly, as noted above, will chair the Panel.

Plan: Unchanged with respect to Expert Panel. However, a dissemination plan for the results of the panel has been developed. It consists of applying for private funds to devote an Aspen Institute to the findings of the Panel. This is *in addition* to the original plan regarding publication. Dr. Kelly has been successful in creating several Aspen Institutes on brain injury in the past.

Project E3: Expert Panel to Explore Feasibility of Neuro-imaging Studies

Funding period: Year 2 of 2-year funding period

Status: Completed

Principal Investigators: William Garmoe, PhD

Abstract:

Progress and Outcomes:

Plan:

Appendix:

Advances in the Understanding and Treatment of Stroke Impairment Using Robotic Devices

Joseph Hidler, Diane Nichols, Marlena Pelliccio, and Kathy Brady

The presence of robotic devices in rehabilitation centers is now becoming commonplace across the world, challenging health care professionals to rethink treatment strategies for motor impairment in hemiparetic stroke patients. In this article, we will discuss some of the motivations for using these devices, review clinical outcomes following robotic-assisted training in both the upper and lower extremities, and detail how these devices can provide quantitative evaluations of function. We will also address the clinical issues that need to be considered when using robotic devices to treat stroke patients, and finally a vision of where this field is heading will be discussed. **Key words:** *gait, stroke, rehabilitation, robotics*

Over the last decade, the integration of robotic devices into neurorehabilitation centers across the world has reshaped clinical strategies when considering treatment options for individuals with motor impairments resulting from neurological injuries. What began as proof-of-concept testing in the 1990s has evolved into widespread acceptance among many researchers and clinicians. Today, robotic devices are being used as rehabilitative tools for treating physical impairments in both the upper and lower limbs. Because these devices have precise instrumentation that measures variables such as position and forces, they are also being used to diagnose and assess motor impairments such as spasticity, tone, and strength with great accuracy. Because they are driven with mechanical motors, these devices can automate repetitive tasks such as passive ranging, active reaching, and gait training in time-unlimited durations. Furthermore, in instances where more than one therapist is necessary to provide a therapeutic intervention, such as gait training a severely impaired acute stroke patient, robotic devices may also help reduce health care costs. It must be emphasized that the goal of introducing rehabilitation robots into clinics is not to replace physical and occupational therapists, but rather robots are a complement to existing treatment options.

Although there are numerous potential benefits to adopting these technologies into the rehabilita-

tion setting, there are also some potential drawbacks, including safety, clinician and patient acceptance, and the ability to bill for time on these devices. Because rehabilitation robots come with state-of-the-art technology, the up-front costs can be overwhelming for smaller centers.

In this review article, we will discuss some of the key findings and contemporary issues surrounding the introduction of robotic devices into

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neurorehabilitation programs targeting hemiparetic stroke patients. First, the motivation and potential benefits of using rehabilitation robotics will be discussed. Then, clinical outcomes following robotic training programs will be presented and interpreted for both the upper and lower extremities. Next, we will discuss how these devices can be used as diagnostic tools that provide quantitative evaluations of function. A discussion of the clinical considerations that need to be taken into account when using robotic devices to treat stroke patients will be outlined, and finally a vision of where this field is heading will be proposed.

Motivation

The idea of massed-practice therapy is not a new concept in the world of rehabilitation professionals; it is used in various forms throughout occupational and physical therapy. One obvious limitation with this type of intervention from a health care cost perspective is that it is often quite labor intensive, requiring one-on-one therapist-patient interactions for highly impaired individuals. For example, manual-assisted gait training often requires multiple therapists, and even then it places excessive physical demands on the therapists that sometimes result in repetitive strain injuries, lower back problems, and extreme fatigue. It would be difficult if not impossible for even the most proficient and skilled therapist to maintain high-quality therapy across a full case load of patients who require this type of attention.

One of the main motivations for developing rehabilitation devices is to automate or assist interventions that normally require multiple therapists or that are extremely physically demanding. For example, during reach-to-grasp tasks, the robot can provide visual cues to the patient and then assist the movement if they are unable to complete the task.¹ As the patient regains function, the robot can make the task more challenging by adding resistance during the movements or perhaps adding obstacles the patient must navigate through or avoid. Because the movements are guided by an actuated device, the number of reaches is not limited in time or duration.

Another potential benefit of integrating these

devices into rehabilitation clinics is that rehabilitation robots are able to accurately measure and track the patient's impairments over the course of a therapeutic intervention. Clinical scales such as FIM™,² Ashworth,³ and others are subjective and often suffer from poor interrater reliability.⁴ Robotic devices can monitor or measure numerous behaviors within a session and across sessions, making it possible for the therapist to track improvements and also justify their time to health care providers and payers.

There is little doubt that our population is aging; it is projected that the size of the elderly population (those 65 years or older) will rise from approximately 33+ million (12.7% of US population in 1999) to 53 million in 2020 and 77 million by 2040.⁵ From a health care cost perspective, this trend is troubling because, after the age of 55, the probability of suffering a stroke doubles with each decade,⁶ and more than half of all stroke survivors are left with some long-term disability.⁶ In parallel, economic pressures are forcing rehabilitation centers to treat patients in shorter periods of time. Often patients are discharged while they are continuing to make functional gains. Because the duration of inpatient stays at rehabilitation hospitals is decreasing and the number of outpatient therapy sessions is being continuously reduced, it is imperative to optimize the therapy patients are able to receive in the limited time window available to our clinicians and therapists.

Robot Therapy Clinical Outcomes

Since the concept of using robotic devices to deliver goal-directed physical therapy was first explored through a number of small controlled studies in the mid 1990s,^{7,8} dozens of trials have been conducted in both the upper and lower limbs. Here, we present summaries of both upper and lower limb studies that have looked at the effectiveness of robotic rehabilitation in facilitating the restoration of function in hemiparetic stroke survivors (see also refs. 9, 10, and 11 for reviews).

*FIM™ is a trademark of the Uniform Data System for Medical Rehabilitation, a division of UB Foundation Activities, Inc.

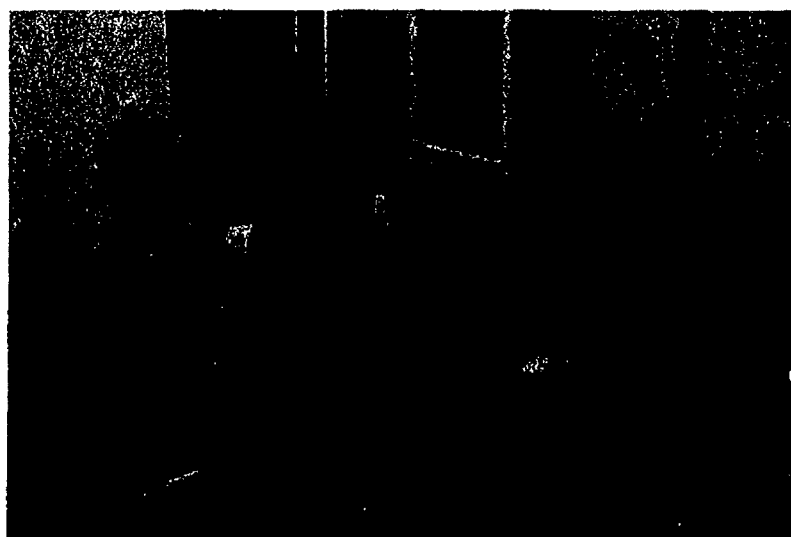


Figure 1. MIT-MANUS (Interactive Motion Technologies, Cambridge, MA).

Upper limb robotic rehabilitation

Although there have been numerous devices designed to deliver arm therapy in individuals with neurological injuries, we highlight three that have undergone extensive testing with hemiparetic stroke subjects: MIT-MANUS,^{8,12,13} ARM-GUIDE,¹⁴ and MIME.^{15,16}

MIT-MANUS

The MIT-MANUS was developed at the Massachusetts Institute of Technology in the early 1990s¹² with the goal of determining whether repetitive reaching exercises using a robotic device can enhance recovery of the arm function in hemiparetic stroke survivors. The MANUS, as shown in **Figure 1**, allows subjects to execute reaching movements in the horizontal plane. During movements, the device can assist or resist the subject and monitor arm position and applied forces. The manner in which the MANUS interacts with the subject is intended to be safe, stable, and compliant throughout the training paradigm.

A collection of cumulative studies utilizing the MIT-MANUS have been published for acute^{8,13,17-19} hemiparetic stroke subjects with the goal of determining whether subjects who receive robotic-assisted arm therapy coincident with their conven-

tional therapy make greater improvements in upper limb function than those who receive "sham" robot therapy along with their conventional therapy. In each of these studies, the robot-trained subjects used the MANUS to reach toward various targets across their workspace; if they were unable to complete the movement, the robot assisted them. On average, three packets of 20 repetitions were done with the impaired limb, totaling 4-5 hours per week over a 7-week period. The sham group received 1 hour of additional therapy per week, where they used the device for 30 minutes with their unimpaired arm and the other 30 minutes with their impaired arm. The motors on the MANUS were not turned on so that if these subjects did not complete their intended movement, they used their unaffected limb to assist the affected limb complete the task.

Evaluation of upper limb motor impairment and ability to carry out functional tasks was done before and after the intervention and included the FIM²; subset of the upper limb Fugl-Meyer (FM) functional impairment scale²⁰; strength in the biceps, triceps, anterior, and posterior deltoid muscles using the Medical Research Council Motor Power (MP) scale; and Motor Status Score (MSS) for the shoulder-elbow complex (MSS-SE) and wrist-hand complex (MSS-WH).²¹

After testing 96 acute stroke subjects (average of 2

weeks post stroke at enrollment) at the Burke Rehabilitation Hospital (White Plains, NY) through a double-blinded study, it was found that the robot-trained group demonstrated significantly greater gains in elbow and shoulder motor function (MSS-SE, $p < .001$) and elbow and shoulder strength (MP, $p < .005$) than the sham control group. No significant differences were between groups were observed in Fugl-Meyer scores at the shoulder, elbow, wrist, or hand nor were there differences in FIM or motor function (MSS-WH) at the wrist and hand. A 3-year follow-up study evaluating 12 of the first 20 subjects enrolled in the study found that there were no significant differences in any of the outcome measures described earlier except for shoulder-elbow motor status score (MSS-SE, $p < .05$).

Recent studies have explored the idea of using the MIT-MANUS in chronic subjects^{22,23} and have found similar trends. That is, even in the chronic stages of their injury, subjects are able to improve shoulder and elbow function after training for 6 weeks with the robot. Furthermore, these gains were sustainable for at least 4 months, which suggests that long-term improvements in function are achievable even in the chronic stages of stroke.

Even though these studies demonstrate functional improvements in both acute and chronic stroke subjects following training on the MIT-MANUS arm robot, a few points of contention need to be raised. First, in the acute studies presented here, the control group only received 1 hour of extra therapy per week while the robot-trained group received approximately 5 hours. Of this 1 hour of therapy, 30 minutes were spent training the unimpaired arm. So it is questionable whether true comparisons should be drawn between the two types of interventions. Furthermore, Volpe et al.¹⁸ noted that the control group had significantly lower FIM motor and cognitive scores, and, while not statistically significant, there was a trend for the lesion volumes to be larger in the control group than in the robot-trained group. Each of these issues may raise questions about whether robot therapy with the MIT-MANUS is more effective than conventional therapy, but there is little doubt that the robot-trained group demonstrated statistically significant gains in function after repeated sessions with the device.

ARM-GUIDE

One possible limitation with the MIT-MANUS is that it emphasizes training within the horizontal plane. Subjects who trained on the MANUS did demonstrate improvements in shoulder strength and function, but some researchers have hypothesized that training in a three-dimensional workspace may enhance these functional gains. Reinkensmeyer et al.^{14,24,25} developed a trombone-like device called the Assisted Rehabilitation and Measurement Guide (ARM-GUIDE) that allows stroke subjects to reach along a rail, which in turn can be positioned so that the subjects' reaching motion can be neutral to gravity or can work against gravity (Figure 2). Like the MIT-MANUS, the device is actuated with a motor that can assist or resist the subject's motion and is also instrumented to monitor hand position and speed. A 6-degree of freedom force sensor is mounted just below the handle so that forces exerted by the subject along the rail and also orthogonal to the desired motion can be quantified. The device can be adjusted in the elevation and yaw axes, and the extent of the movement can also be controlled. The device continues to be used as both a diagnostic tool (see the section, "Robot Therapy Clinical Outcomes") and a treatment tool for addressing arm impairment in hemiparetic stroke subjects.

A small controlled study was carried out that compared long-term arm training on the ARM-GUIDE to a control group that executed free-reaching movements.²⁶ In this study, a group of chronic stroke subjects (more than 1-year post stroke) were trained; six subjects used the ARM-GUIDE and four acted as controls. The ARM-GUIDE group reached toward targets arranged across their reaching workspace with their impaired arm. In this setting, the ARM-GUIDE was pointed toward the selected target; after receiving a visual cue, the subject was instructed to try and reach toward the target as fast as possible. If the hand velocity of the subject followed a predetermined hand trajectory, then the motor on the ARM-GUIDE provided no assistance. However, if the subject reached either too fast or too slow, the device resisted or assisted the movement, respectively. In this setting, the subjects' goal was to

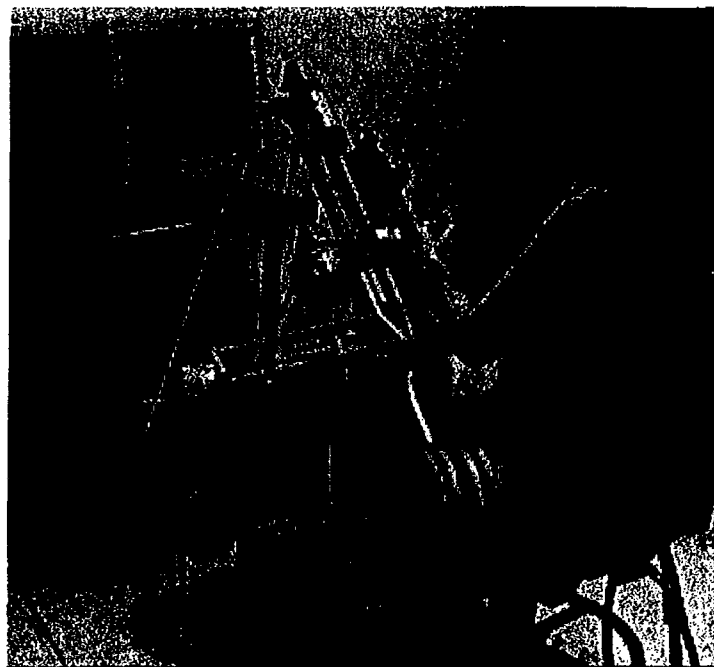


Figure 2. Assisted Rehabilitation and Measurement Guide (ARM-GUIDE).

follow a prescribed velocity path that spanned their range of motion. Graphical feedback of their hand position was provided during each reach.

The control group executed free reaching toward targets arranged on a wall that were similar in direction as the targets used in the ARM-GUIDE group. Here, the subjects were not constrained to move along any path; they were simply asked to reach toward the various targets at a comfortable speed. Each trial began with the hand of their impaired arm resting on their lap. A Flock of Birds (Ascension Technology Corporation, Milton, VT) sensor was placed on the back of the subjects' hand to monitor their reach trajectory. Visual feedback was also provided to this group after they completed a sequence of reaches.

Both groups were trained 3 days per week for 8 weeks, totaling 24 sessions. Evaluations of performance were done prior to and following training using the Chedoke-McMaster Upper Extremity Stroke Assessment Scale²⁷ for monitoring arm function and the Rancho Los Amigos Test²⁸ for evaluating each subject's ability to carryout everyday tasks. Subjects also carried out passive and active tests on the ARM-GUIDE to measure passive

limb mechanics and voluntary reach range and speed.

It was found that both subject groups improved in the Chedoke-McMaster and Rancho Los Amigos Tests; however, there were no statistical differences between the improvements across groups. Furthermore, both groups demonstrated statistically significant improvements in active range of reach and reaching speed and demonstrated decreased passive resistance to movement ($p < .05$). However again, there were no statistical differences between groups, which indicated that both therapeutic interventions had similar effects.

While this study only consisted of 10 chronic stroke subjects, it raises questions about whether it is the mode of therapy or the amount of therapy that is ultimately important in restoring arm function to hemiparetic stroke subjects. It should be noted that the starting impairment level in the ARM-GUIDE group was slightly greater than that of the control subjects, which may slightly skew the results. However, it appears from this study that the results can be interpreted in at least two ways: robotic-assisted therapy is no more effective than conventional therapy, or the type of robotic-

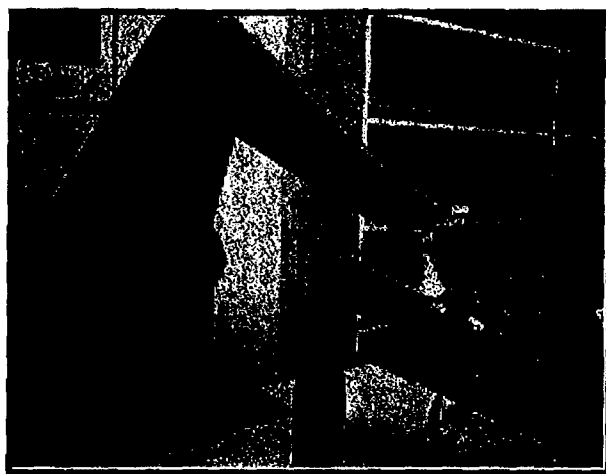


Figure 3. Mirror Image Movement Enabler (MIME).

assisted therapy used in this study is not optimal for addressing arm impairment in this patient population. This group is currently exploring a variation of the ARM-GUIDE protocol to try and address this issue.²⁹

MIME

The final upper limb training protocol based on robotic-assisted movements that will be discussed was designed through a collaborative effort between the Veteran Administration Medical Center in Palo Alto and Stanford University and is called MIME (Mirror-Image Movement Enabler).^{1,15} The robot utilized in this protocol, a PUMA 560 industrial device (Staubli Corporation, Duncan, SC), was modified so that it could interact with subjects in a stable and repeatable manner. The subject's impaired limb was placed in a splint, which in turn was connected to the robot through a 6-degree of freedom force-torque sensor (Figure 3). This sensor is able to measure the interaction forces between the subject and the device during reaching tasks. The device is fully instrumented so that the position of the subject's limb can be inferred through the robot's position. The idea behind this protocol was to explore the effectiveness of restoring arm function in stroke subjects by having them execute movements that mirror one another in both of their upper limbs.

In these studies, four different modes of operation were explored. In the first mode, the subject's arm was passively moved by the robot from a starting position to a target along some predetermined kinematic trajectory. During these movements, the subject was asked to relax the paretic limb and allow the device to passively move the arm. In the second mode of therapy, the subject would attempt to move to a target while the robot would stabilize the limb. The subject was only allowed to move in the direction of the target and not back toward the starting position. If the subject attempted to move toward the target and could not make it, the robot would support the limb and assist the movement. In the third mode of operation, the robot was programmed to provide some viscous resistance as the subject reached for the targets across the workspace. Finally, the fourth mode of training was developed to be bimanual in nature, where the subject would reach for symmetric targets using both arms at the same time, one connected to the robot and the other connected to a position-sensing digitizer. Here, the motion of the unimpaired forearm dictated the range and rate of the movements of the impaired arm that was assisted by the robot. The idea was that in the bimanual mode the subject had full control over the path and rate of movements of both arms.

To evaluate the effects of these robot modes of therapy in comparison to NeuroDevelopmental

Therapy (NDT), 27 chronic stroke subject (more than 6 months post stroke) were tested, where each subject received 24 one-hour sessions over a 2-month period.¹¹ For the robot group, subjects practiced shoulder and elbow movements that were assisted by the robot. Here, targets were placed away from the subject so that the emphasis was placed on reaching movements to various points in the workspace. All subjects spent approximately 12 minutes in bimanual mode, 5 minutes in passive mode, and the remainder of the session in practicing active-assisted or active-resisted modes depending on their functional level. For the control group, subjects were trained using NDT; the subjects practiced various tasks with their arm that focused on functional or self-care tasks.

Evaluations of intervention effects were done at months 0, 1, and 2 and at a 6-month follow-up session and included Fugl-Meyer testing,²⁰ Barthel Index,³⁰ FIM,² and maximum strength testing under isometric conditions. Evaluation of active reach was also examined by having the subject make reaches to targets positioned at various places in a three-dimensional space, during which arm position and orientation were quantified using a lightweight, instrumented forearm splint.

Following 24 sessions of training, it was found that the subjects who received MIME therapy made statistically higher gains in proximal arm function (Fugl-Meyer scores), strength (elbow extension, shoulder flexion, and shoulder abduction and adduction), and the amount of active reach. The robot group made statistically faster gains in proximal arm function during the 2 months of training; however, at the 6-month follow-up, there were no statistical differences in function between the two groups. No changes were found between subjects in distal arm function or ability to perform activities of daily living (ADLs; Barthel Index or FIM).

In a similar study that only focused on subjects trained using the MIME protocol,¹⁶ it was found that the amount of work the subjects were able to perform during active reaches had significantly increased. In subjects with low levels of function, the extent of reach had improved; in high-functioning subjects, the movement velocity was significantly higher. Improvements in elbow and

shoulder muscle activation patterns were also observed in subjects who performed reaches against gravity, but no improvements were noted during table-top movements.

Preliminary summary: arm devices

This study, like the MIT-MANUS study, provides evidence that training with a robotic device can improve arm function in hemiparetic stroke subjects, but it is task specific. That is, both of these studies found that proximal arm function improved more rapidly and to a greater extent in the robot group, however distal arm function did not experience these same gains. Both devices used in these studies emphasize proximal tasks, so it is not surprising that changes in wrist and hand function were no different from those in the control groups.

What is somewhat disappointing in these studies is that subjects experienced improvements in function according to scales such as Fugl-Meyer and Motor Status Score, but changes in the subjects' ability to perform ADLs were no greater in the robot-trained group than they were in the control groups. One has to consider which aspect of recovery is more important to the consumer; the ability to perform things at home that would make them more independent or tests that are supposed to be indicative of their ability to perform ADLs. We postulate that future studies using these and other robotic devices must demonstrate clear benefits to the subjects' ability to perform ADLs, otherwise acceptance of these devices by the clinical community and the consumer will be significantly compromised.

Lower limb robotic rehabilitation

The concept of body weight-supported locomotor training is now being used extensively in most neurorehabilitation centers and is demonstrating promising results. Over the last 10 years, it has been shown that subjects who receive body weight-supported treadmill training after spinal cord injury³¹⁻³³ and stroke³⁴⁻³⁶ demonstrate improved EMG activation patterns,^{31,37} more natural walking characteristics,³⁵ are able to bear more weight on their legs,³² and demonstrate functional



Figure 4. Lokomat gait orthosis (Hocoma AG, Volketswil, Switzerland).

improvement in walking ability.^{33,37} Furthermore, there are also reports of reductions in spasticity³³ and increases in cardiopulmonary efficiency³⁸ after body weight-supported locomotor training.

The major drawback of manual-assisted locomotor training is that it places large physical demands on the therapists, which limits the consistency and duration of training sessions. Furthermore, from a health care cost basis, manual-assisted locomotor training is quite expensive, as it often requires multiple therapists to properly administer. To address these limitations, a number of robotic gait trainers have been developed, all having the goal of delivering time-unlimited, consistent gait training in individuals with neurological injuries. We highlight two such de-

vices that are currently being used in various clinics around the world: the Lokomat³⁹ and the Gait Trainer.⁴⁰

Lokomat gait orthosis

The Lokomat robotic gait orthosis has been in development since the mid 1990s in order to automate the delivery of locomotor training for individuals with neurological injuries.³⁹ This system is comprised of a treadmill, a body weight-support system, and two lightweight robotic arms that attach to the subject's legs (Figure 4). The Lokomat is fully programmable, including control of knee and hip kinematic trajectories, the amount of assistance the system provides to the

subject, and the speed at which the subject ambulates. This high-level dynamic control is achieved by small direct current (DC) motors and linear ball screw assemblies at the hip and knee joints that are tightly synchronized with the timing of the treadmill. Hip and knee angles are monitored through high-precision potentiometers while dorsiflexion is provided at the ankle of the subject through two passive elastic straps. Unloading of the patient is achieved by connecting the shoulder straps on a harness to a counterweight system. Furthermore, force sensors mounted in series with the motors sense the amount of resistance/assistance the subject is generating while walking in the device, which can be used as biofeedback for motivational purposes. The Lokomat is an FDA-approved medical device.

Because the Lokomat has only been commercially available since 2002 (Hocoma AG, Volketswil, Switzerland), no large-scale studies have been published comparing the effects of Lokomat gait training to conventional gait training in hemiparetic stroke subjects. A multicenter study currently being conducted by the National Rehabilitation Hospital and the Rehabilitation Institute of Chicago is investigating this question in subacute stroke subjects (less than 6 months post stroke), where it is anticipated that the results of more than 100 participants will be reported in the fall of 2007. That study is being sponsored by the National Institute on Disability and Rehabilitation Research (NIDRR) under Rehabilitation Engineering Research Center (RERC) "Machines Assisting Recovery from Stroke (MARS)."

Mechanized Gait Trainer

Another robotic device that targets gait training in stroke subjects is the Gait Trainer^{40,41} developed in Germany, which works very similarly to traditional elliptical trainers. In this setting, the subject's feet are strapped to two footplates, which in turn are connected to a linkage system that moves the foot through a trajectory quasi-similar to the gait cycle. The foot is always connected to the platforms, and the positioning and loading of the foot on the Gait Trainer is comparable to the stance and swing phases of the gait cycle, with a ratio of 60% and 40% for each phase, respectively.

The stride length and phase durations can be adjusted by using different gear ratios on the linkage system, while the step velocity is modulated between 0 to 1.12 m/s. Furthermore, the linkages connected to the footplates are connected to a motor that can provide varying levels of assistance throughout the gait cycle, ranging from full support when the subject provides no assistance to little or no support when the subject actively propels his or her legs. Similar to the Lokomat, the forces generated by the subject can be used as biofeedback during training.

A randomized crossover design was performed to evaluate the effectiveness of using the mechanized Gait Trainer in a group of nonambulatory stroke subjects ($n = 30$; 4–12 weeks poststroke).³⁶ Subjects enrolled in the study were randomly assigned to one of two groups: a group that received treatments A-B-A and a group that received treatments B-A-B. Intervention A consisted of 15–20 minutes of daily locomotor training on the Gait Trainer for 2 weeks; intervention B consisted of the same doses of therapy only on the treadmill. In the robot and treadmill interventions, a portion of the subject's body weight was supported using an overhead unloading system. Furthermore, assistance with weight shifts and leg kinematics (e.g., foot placement and knee control) was provided by a therapist in both groups as required for each subject. Evaluations of walking ability consisted of the Functional Ambulation Category (FAC),⁴² gait velocity, and Rivermead Motor Assessment Score,⁴³ and ankle spasticity was quantified using the modified Ashworth scale.³ Assessments were performed by an independent evaluator blinded to the subject's treatment group before training, weekly, and finally at a 6-month follow-up visit.

After 6 weeks of therapy, both the A-B-A group and B-A-B group demonstrated improvements in walking ability (FAC), walking speed, and Rivermead scores. FAC scores were found to be statistically higher in the A-B-A group than the B-A-B group, however there were no group differences in walking speed or Rivermead scores. No changes in ankle spasticity were found in either group. By the 6-month follow-up evaluation, none of the outcome measures were statistically different across groups.

For the robot intervention, therapy sessions

could be carried out by one therapist even in highly impaired subjects; whereas for the treadmill training intervention, sometimes three therapists were needed to properly train low-functioning subjects. This likely cost productivity highlights one of the benefits of robotic rehabilitation, particularly with the current health care economic pressures.

A potential limitation with the Gait Trainer is that the system does not directly control the knee or hip joints nor is the trunk supported. In acute stroke subjects, weakness across the knee and hip joints often results in poor joint stability, so that hyperextension may occur unless otherwise controlled by a therapist or trainer. Furthermore, because the subject's feet are always attached to the pedals, unnatural cutaneous inputs to the bottom of the feet may alter sensory inputs normally experienced during gait. Nevertheless, the outcomes of this study provide promising indications that robotic-assisted gait training may result in positive returns in walking ability.

Preliminary summary: gait training devices

Although there are limited experimental results supporting the effectiveness of robotic-assisted devices in restoring walking function in hemiparetic stroke subjects, the need for gait-specific devices is of high importance because training subjects with significant motor impairment is labor intensive and often requires multiple therapists. If devices such as the Lokomat or Gait Trainer can replicate results in neurological subjects that are similar to the results experienced after manual-assisted locomotor training, the cost benefits of robotic devices may ultimately help facilitate their adoption into rehabilitation centers.

Quantifying Impairment Using Robotic Devices

The section "Robot Therapy Clinical Outcomes" highlighted various studies of the effectiveness of robotic devices as therapeutic tools for upper and lower limb rehabilitation, but these devices are also well-suited to quantify motor function and impairments in hemiparetic stroke subjects. Because all of the devices discussed previously are

fully instrumented with sensors that measure limb position, velocities, and forces, these variables can be used to study impairment with a high degree of precision. Furthermore, this information can also be used to track recovery and perhaps even dose therapy. By better understanding the mechanisms underlying impairment, more effective treatments may ultimately be developed. In this section, we discuss a few examples of robotic devices used to evaluate arm and leg function in hemiparetic stroke survivors.

Previously, we highlighted the MIT-MANUS (Figure 1) as a therapeutic tool for aiding in the recovery of arm function in stroke subjects. The MIT-MANUS has also been used to track changes in smoothness during arm movements^{8,44} and the ability to execute continuous arm movements.⁴⁵ Both of these characteristics, smoothness and continuity, are inherent characteristics of coordinated human movement.⁴⁶ In these studies, stroke subjects were instructed to either make point-to-point linear movements or draw a circle. The resulting hand movements were examined for the number of corrective movements made, the shape of the velocity profile, and other metrics of smoothness. It was found that throughout the course of recovery, stroke subjects demonstrate improvements in their ability to execute smooth, continuous movements that are similar to nonneurologically impaired subjects. For example, Krebs et al.⁸ showed that prior to robot training, when subjects attempted to draw circles, the shape of the circle was highly distorted and a large number of corrective movements were made. However, through the progression of the intervention, the shape of each movement became more circular and the velocity profile began resembling a bell-shape with less corrective movements, both being normal characteristics.

Reinkensmeyer et al.^{24,25} utilized the ARM-GUIDE (Figure 2) to study active and passive restraints exhibited by chronic stroke subjects during guided reaching. Subjects were instructed to reach as far and as fast as possible along the guide and to try not to push up or down or left or right against the device. The arm was also moved through the entire range of motion by the device while the subject relaxed in order to evaluate passive tissue properties. It was found that during ac-

tive reaches subjects generate large and significant forces against the rail perpendicular to the desired movement. These forces were consistent with the synergy patterns previously reported in chronic stroke subjects.^{47,48} Furthermore, it was found that passive tissue constraints were significantly higher in the impaired arm and that deficits in active reach extent were attributable to spasticity and weakness. These studies demonstrate the utility of robotic devices to investigate the mechanisms underlying arm dysfunction in stroke subjects.

Techniques are also being developed to evaluate walking ability and gait impairments using robotic devices.⁴⁹ The goal of this work is to establish the optimal set of training parameters, such as walking speed and level of body weight support, for maximizing the effectiveness of the therapy. A standard Lokomat (Figure 4) has been modified in two distinct ways. First, the cuffs that couple the subject's legs to the Lokomat have been customized to contain 6-degree of freedom load sensors that allow for the accurate measurement of the assistance or resistance the device provides the subject. Second, a split belt treadmill that resides under the Lokomat contains sensors that allow for the calculation of ground reaction forces and centers of pressure. Utilizing the leg-Lokomat interaction forces, the ground reaction forces, and the kinematic data (e.g., position and velocity of the legs), a modified inverse-dynamics technique is used to estimate the ankle, knee, and hip moments the subject generates under any set of training parameters. Combining this information with electromyographic (EMG) information, the role of impairments such as weakness, spasticity, and abnormal synergies on walking ability can be studied, and the set of training parameters through which the subject steps to generate the best joint moments and muscle activation patterns can be identified. The goal is to train subjects under conditions that may lead to higher returns in walking ability after long-term locomotor training.

Clinical Considerations When Incorporating Robotic Devices into Rehabilitation Centers

A major consideration of most facilities with regard to using robotics will be the cost effectiveness of treatment. The purchase of robotic systems

such as the Lokomat or MIT-MANUS presents a significant expense for any clinical facility. There are numerous administrative costs related to clinical use of the robotic as well. Therapists and aides must be trained to use the equipment safely and effectively; this is nonreimbursable time for the department. Training not only involves learning how to properly set-up the patients into the device but also gaining a detailed understanding of both the hardware and software that accompany the robot. Once the proper fit has been determined, an aide might be able to perform any necessary set-up of the robot prior to the patient getting into the robotic system, but the therapist should check the set-up before any training begins.

Unlike most physical therapy settings where a therapist might see more than one patient at a time, robotic training currently requires one-on-one treatment. While this may soon change for some devices (see the section, "Future Directions"), currently group therapy with these devices is not possible and therefore impacts department revenue. In some robotic devices, particularly the gait trainers, an additional person in the lab is often necessary for efficiency and safety purposes. For example, due to co-morbidities in the patient populations using the Lokomat (typically SCI, CVA, and TBI), blood pressure, cardiac, or diabetic issues can arise during training sessions. Although training can be accomplished safely with one person, it often requires a minimum of two people to get a patient safely out of the device when time is critical. With the proven benefit of robotics, the potential to increase referrals to therapy and the increased revenue generated from those referrals might offset some costs.

In addition to cost issues, there are numerous treatment considerations with robotic therapy. For such interventions to be used in the clinic, the benefit must be established through ongoing clinical research trials. Currently, a motor learning approach is the generally accepted method to retraining movement with neurologically impaired individuals. Motor learning theory has been incorporated into therapy practice since the 1990s when Carr and Shepard advocated its use with NDT.⁵⁰ Regardless of the treatment philosophy, in general the adopted strategy is a principle of active, high repetition, task-specific practice.

Before bringing a robot into the clinic as a training tool, a clinician might ask if the robot can provide these needed practice conditions. Therapists will also want to know that adequate and/or varied learning conditions can be provided with a robotic device.

Another hurdle to overcome before robotics become a standardized treatment tool may be acceptance from the clinicians themselves. Therapists pride themselves on their ability to use their hands for evaluation and treatment. Their hands are the "tools of the trade." Clinicians may feel that the robot eliminates this aspect of practice that they feel is implicit to their profession. Other clinicians may fear that new technology could replace them in the clinic. Yet, the ability to assess and plan for the patient's individual needs is still dependent on the therapist's expertise and judgment. Robotics are technologies that are developed to assist therapists in attaining optimal outcomes for patients. In treatment, a robot may replace the therapist's hands to assist with heavy, challenging, or repetitious movement and ease physical strain on the therapist. A robot could also be used as a tool to allow for massed or varied practice of a difficult movement task. The therapist's hands and eyes will continue to provide the information that is used to evaluate the patient's movement strategies. Data from the robot can quantify what clinicians may be seeing and feeling (see the section, "Quantifying Impairment Using Robotic Devices") and can provide them with objective information on current performance that can be compared to past and future performance.

Future Directions

Whereas the last decade has taken rehabilitation robotics from concept to reality, the upcoming years will test these devices with extreme rigor to determine whether they should be considered as daily treatment options across various patient populations. Furthermore, advances in technology will result in these machines becoming lighter and more powerful, perhaps opening up new opportunities and therapies. Before devices like those profiled in this article can be made more effective, we must first understand which interventions best promote recovery. Once a particular mode of in-

tervention has been shown to be effective, it only makes sense to then wonder whether a robotic device can help deliver it more effectively. The design and construction of devices that are not based on evidence-based practice or on solid therapeutic principles shown to be effective will surely lead to failure.

Robotic devices must also overcome the cost hurdles discussed in the section "Clinical Considerations When Incorporating Robotic Devices into Rehabilitation Centers." Krebs et al.¹³ proposed that the MIT-MANUS could be used in a classroom fashion, where one therapist could oversee multiple patients who were each using the device. Such practice is currently being performed in Austria with the Lokomat, where one technician simultaneously trains more than one subject at a time on two devices side by side. Ultimately, the safety of these devices must be shown to be such that the occurrence of patient injuries is no higher than what is seen routinely in clinics.

We must also evaluate patient satisfaction and therapist satisfaction with the clinical use of rehabilitation robots. Krebs et al.⁸ surveyed their research subjects; even though all subjects felt that the robot training was productive and assisted their recovery, they all preferred the therapist to the robot. Even though clinical rehabilitation robots mostly work in tandem with therapists rather than autonomously, issues such as patient comfort, anxiety, and tolerance must be taken into account.

Finally, we propose that clinical acceptance in this field will come only after well-controlled studies are performed demonstrating the effectiveness of robotic devices. For each device, these studies will need to identify which patients are appropriate and will likely demonstrate improvements in function, training parameters, training dosages, and other determinants surrounding the therapeutic intervention. To date, we have relied on heuristic rules for establishing parameters and dosing the therapies, because there were little or no foundations from which to work. Now that there is a growing body of literature in the field of rehabilitation robotics, our next steps must be to design, build, and test devices based on evidence and not assumption.

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Alterations in muscle activation patterns during robotic-assisted walking

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Abstract

Objective. The goal of this study was to compare the muscle activation patterns in various major leg muscles during treadmill ambulation with those exhibited during robotic-assisted walking.

Background. Robotic devices are now being integrated into neurorehabilitation programs with promising results. The influence of these devices on altering naturally occurring muscle activation patterns utilized during walking have not been quantified.

Methods. Muscle activity measured during 60 s of walking was broken up into individual stride cycles, averaged, and normalized. The stride cycle was then broken up into seven distinct phases and the integrated muscle activity during each phase was compared between treadmill and robotic-assisted walking using a multi-factor ANOVA.

Results. Significant differences in the spatial and temporal muscle activation patterns were observed across various portions of the gait cycle between treadmill and robotic-assisted walking. Activity in the quadriceps and hamstrings was significantly higher during the swing phase of Lokomat walking than treadmill walking, while activity in the ankle flexor and extensor muscles was reduced throughout most of the gait cycle in the Lokomat.

Conclusions. Walking within a robotic orthosis that limits the degrees of freedom of leg and pelvis movement leads to changes in naturally occurring muscle activation patterns.

Relevance

An understanding of how robotic-assisted walking alters muscle activation patterns is necessary clinically in order to establish baseline patterns against which subject's with neurological disorders can be compared. Furthermore, this information will guide further developments in robotic devices targeting gait training.

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1. Introduction

Over the last decade, there has been growing support for the use of manual-assisted treadmill training in neurorehabilitation programs (Dobkin, 1999). Preliminary studies have found that individuals who receive body-

weight supported treadmill training following stroke (Hesse et al., 1994, 1997) and spinal cord injury (Wernig and Muller, 1992; Wernig et al., 1999; Dietz et al., 1995) demonstrate improved electromyographic (EMG) activity during locomotion (Visintin et al., 1998; Dietz et al., 1995), walk more symmetrically (Hassid et al., 1997; Hesse et al., 1997), are able to bear more weight on their legs (Wernig and Muller, 1992) and experience higher returns in functional walking ability when compared to patients who receive conventional gait training (Wernig

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et al., 1999; Visintin et al., 1998). It is postulated that treadmill training is a therapeutic paradigm that effectively activates afferent receptors in the lower limbs, generating the necessary sensory feedback needed to train central pattern generators in the spinal cord believed to underlie locomotion (Forssberg, 1979; Grillner, 1979, 1981).

The primary limitation with manual-assisted, body-weight supported treadmill therapy is that a training session relies on several physical therapists to manually assist the patient's leg movements through the gait cycle, a protocol that is not cost effective in the current health care system. Furthermore, training sessions tend to be short because of the physical demands on the therapists, which may limit the full potential of the treatment.

Recent advances in robotics attempt to combat this problem by automating gait training with actuated devices (Colombo et al., 2000; Hesse and Uhlenbrock, 2000). These systems, used in conjunction with a body-weight support system, help move the individual's legs through well-specified and consistent gait patterns as s/he walks on a treadmill (Colombo et al., 2000). The potential advantages of using robotic devices include patient safety, repeatability, unlimited duration of training, and hands-free operation by a single therapist. In addition, because the patient is secure in the device removing the potential for falls, s/he is more apt to adopt a natural gait pattern rather than a guarded, cautious gait in order to ensure stability and prevent falls.

One potential limitation with robotic-assisted gait training is that the degrees of freedom through which the subject is able to walk is necessarily limited due to safety and control complexity. As a result, individuals are unable to execute some of the key gait determinants (Saunders et al., 1953) which may alter the set of muscle activation patterns required for stable over-ground walking.

The objective of this study was to determine whether muscle activation patterns exhibited while walking within a robotic orthosis are different from those demonstrated during treadmill ambulation. Furthermore, we sought to establish a set of "normative" muscle activation patterns which could be used as baseline measures against which the muscle activation patterns exhibited by individuals with gait disorders could be compared to. Portions of this work have been previously reported in abstract form (Hidler et al., 2003).

2. Methods

2.1. Subjects

A total of seven healthy subjects (3 male, 4 female) with no known neurological injuries or gait disorders participated in the study (mean age: 26.8 years; range:

24–30). All experimental procedures were approved by the Research Review Board at the National Rehabilitation Hospital and the Institutional Review Board of Medstar Research Institute.

2.2. Experimental apparatus

The primary equipment utilized in this study was the Lokomat robotic orthosis manufactured by Hocoma AG (Volketswil, Switzerland). This system is comprised of a treadmill and body-weight support system (Woodway Inc., Waukesha, WI, USA), and two light-weight robotic actuators that attach to the subject's legs (Fig. 1). The Lokomat is fully programmable, including control of knee and hip kinematic trajectories, the amount of assistance the system provides to the patient, and the speed at which the patient ambulates. This high-level dynamic control is achieved by small DC motors and linear ball screw assemblies at the hip and knee joints, tightly synchronized with the timing of the treadmill. The knee and hip joints have position sensors and force sensors that are monitored by the control computer throughout the training. The entire Lokomat assembly resides on a parallelogram structure which in turn is counter-balanced by a large spring. The pretension in the spring is adjusted so that the weight of the Lokomat is compensated for, preventing upward or downward external forces to the subject during training.

For the portion of the study where subjects walked on the treadmill without the Lokomat, knee flexion–extension and varus–valgus angles, as well as hip flexion–extension and abduction–adduction angles were measured using goniometers (XM180, Biometrics Ltd., Ladysmith, VA, USA) while heel contact information was acquired using foot-switches (MA-150, Motion Labs, Baton Rouge, LA, USA). The foot-switch was taped directly to the subject's heel, while the

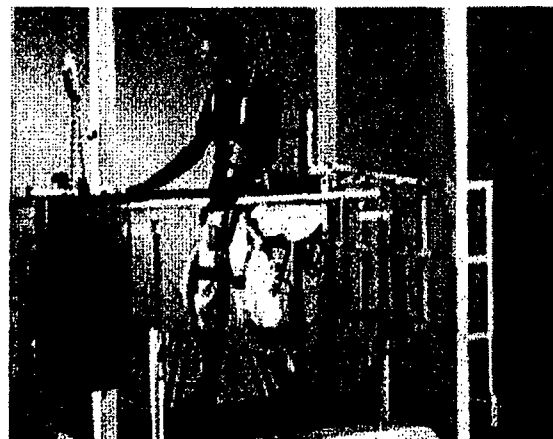


Fig. 1. Lokomat[®] robotic-orthosis (Hocoma AG, Volketswil, Switzerland).

goniometers were taped to the skin using double sided medical tape.

During both Lokomat and treadmill walking, surface EMGs were recorded differentially from the gastrocnemius, tibialis anterior, hamstrings, rectus femoris, adductor longus, vastus lateralis, and gluteus medius and maximus muscles using a Bagnoli-8 EMG system (Delsys, Inc., Boston, MA, USA). Only one leg was instrumented with EMG electrodes since none of the subjects had any gait disorders and walked symmetrically. Knee and hip angles, foot-switch data, and EMG signals were all anti-alias filtered at 500 Hz prior to sampling at 1000 Hz using a 16-bit data acquisition board (Measurement Computing, PCI-DAS 6402, Middleboro, MA, USA) and custom software (Matlab, Mathworks Inc., Natick, MA, USA).

2.3. Protocol

After providing informed consent, EMG electrodes and goniometers were attached to the subject's leg, which was then wrapped with ace-bandages to ensure the wires did not impede the subject's gait pattern. After the subject was fully instrumented, they were asked to walk at a self-selected speed on the treadmill for approximately 5 min in order to acclimate to the treadmill. After this acclimation phase, each subject walked at four different walking speeds (0.42, 0.53, 0.64, 0.75 m/s), with the order randomly selected in order to eliminate any bias associated with the order in which speeds were tested. With each change in treadmill speed, the subject walked for 1 min acclimation phase, after which EMG and kinematic data was collected for 60 s.

After walking at the four different speeds on the treadmill, the subject was placed inside the Lokomat described above. The Lokomat linkages were adjusted to the leg lengths of each subject, so that the hip and knee joints of the Lokomat were aligned with those of the subject. The ankle of the subject was held in a neutral position ($\approx 90^\circ$) using cloth straps with elastic properties. This was done to replicate the training setup commonly used with individuals with neurological injuries, where the straps are used to assist with dorsiflexion for adequate toe-clearance during swing.

After the device was adjusted to the subject's geometry, the Lokomat initiated stepping, after which the subject was instructed to try and match the kinematic trajectories dictated by the device. In this sense, the Lokomat is run in a position control mode, where the legs of the Lokomat move through a pre-determined gait pattern. At the onset of walking within the Lokomat, the hip and knee trajectories of the Lokomat were adjusted to best match the joint angles the subject utilized during the treadmill ambulation portion of the study at an intermediate speed. The peak error between the knee and hip trajectories was always within $\pm 10^\circ$ across the

gait cycle. It should be noted that since the kinematics of the subject used during treadmill walking were necessary for adjusting the Lokomat's kinematic pattern, all subjects first walked on the treadmill followed by the Lokomat.

The subject was first allowed to walk in the Lokomat for 5 min in order to acclimate to the device. After this acclimation period, the Lokomat walking speed was then randomly set to one of the four speeds used during treadmill ambulation, and after 1 min acclimation phase, EMG and kinematic data was collected for a 60-s step sequence. This same procedure was repeated for all four speeds (0.42, 0.53, 0.64, 0.75 m/s). In addition to the experimental signals outlined in Section 2.2, the interaction forces exerted by the subject on the Lokomat were also measured using six degrees of freedom load cells (JR3 Inc, Woodland CA, USA) mounted between the Lokomat and the leg cuffs attached to the subject. Similar to all other signals, the load cell signals were anti-alias filtered at 500 Hz prior to sampling at 1000 Hz using a 16-bit data acquisition board (Measurement Computing) and custom software (Matlab, Mathworks Inc.).

It should be noted that the subject was not provided any body-weight support while walking in the Lokomat as is commonly done when training individuals with neurological injuries. We chose not to use body-weight support since none of the test subjects had any gait disorders and consequently did not require external support. Furthermore, since body-weight support has also been shown to alter muscle activation patterns (Ferris et al., 2001; Finch et al., 1976; Harkema et al., 1997; Dietz et al., 2002; Ivanenko et al., 2002), we did not want to introduce any other biases that could potentially influence the behavior exhibited while walking in the Lokomat.

2.4. Data analysis

Individual stride cycles were determined using the foot-switch data, where each stride was considered the period between successive heel-strikes in the same leg. The muscle activation (EMG) pattern for each stride was then time normalized, expressed as a percentage of the total gait cycle (e.g., 0–100%) and up-sampled using a cubic spline for averaging purposes (Giakas and Baltzopoulos, 1997). EMGs for each stride were then smoothed using a 50-point root-mean-square (RMS) algorithm (Kenney and Keeping, 1962), after which the mean EMG pattern generated for the gait cycle was computed by averaging all the individual stride cycles taken by the subject during the 60-s data collection sequence ($n > 20$). Finally, each mean EMG trace was normalized to the maximum observed EMG amplitude for each specific muscle across all trials. This allowed for general comparisons across subjects.

Table 1
Phases of the gait cycle

Phase	Percent of gait cycle
Initial loading	0–12
Mid-stance	12–30
Terminal-stance	30–50
Pre-swing	50–62
Initial-swing	62–75
Mid-swing	75–87
Terminal-swing	87–100

After the average EMG profile for each muscle was calculated for all eight trials (4 treadmill, 4 Lokomat), the data was broken up into seven phases as outlined in Table 1 (Perry, 1992). Within each of these phases, the integrated EMG activity was calculated for each muscle.

2.5. Statistical analysis

The amount of EMG activity generated within each of the seven phases of the gait cycle for each muscle was compared between treadmill and Lokomat walking using a two-factor analysis of variance (ANOVA). The fixed factors were the type of walking (i.e. treadmill or Lokomat) and the speed of ambulation while the dependent variable was the integrated normalized EMG activity for each respective phase.

3. Results

3.1. General observations

Despite subjects reporting that walking within the Lokomat was extremely comfortable and felt natural, significant changes in the muscle activation patterns were observed in numerous muscles. Average muscle activation profiles for each muscle group across speeds and conditions are shown in Figs. 2 and 3. Interestingly, there was typically higher muscle activation in the quadriceps muscles (e.g., rectus femoris and vastus lateralis) and the gluteus muscle groups during Lokomat walking than during treadmill walking, while there was often less activation in the gastrocnemius, adductor longus, and tibialis anterior during Lokomat walking. For the gastrocnemius and tibialis anterior muscle groups, the drop in muscle activity may be attributable to the foot lifters placed on the subject's forefoot which assists ankle dorsiflexion for toe clearance during swing (see Section 2.3 for description).

Mean integrated muscle activity in each of the seven gait phases is shown in Fig. 4, where it is demonstrated that in some muscles, the two walking conditions produce quite similar activation levels while in others, there is consistent over-activity or under-activity, depending on the muscle and phase of the gait cycle. A summary

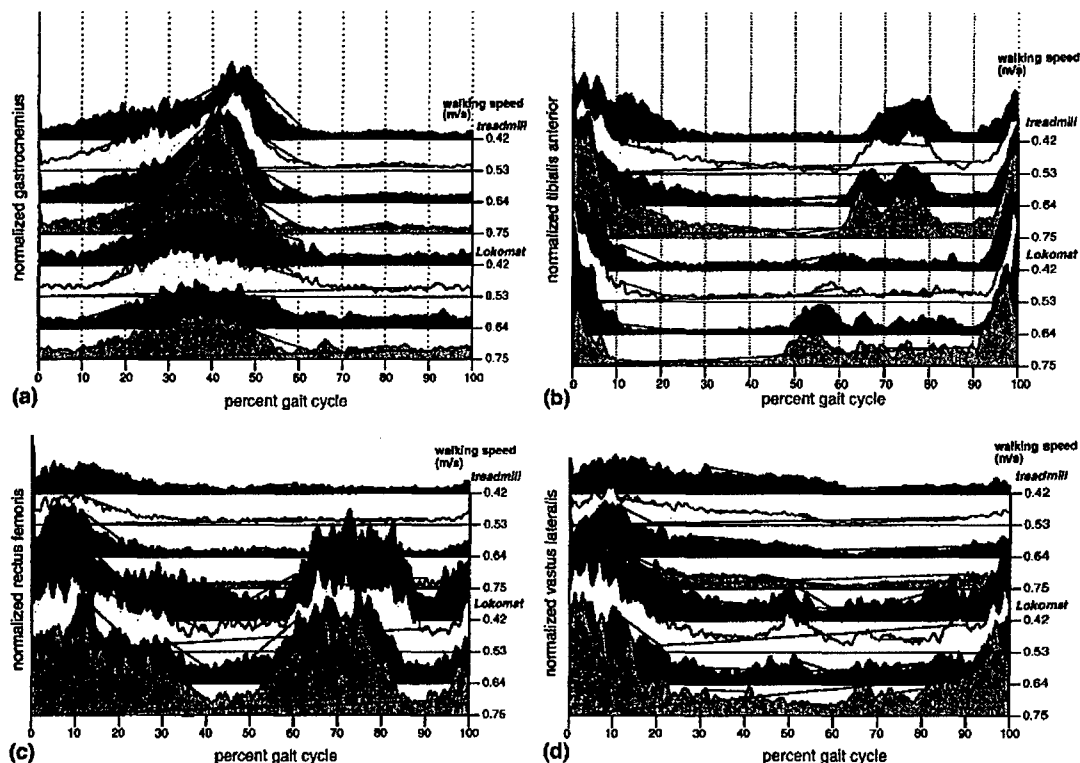


Fig. 2. Average normalized gastrocnemius (a), tibialis anterior (b), rectus femoris (c) and vastus lateralis (d) activity across speeds for both treadmill and Lokomat walking.

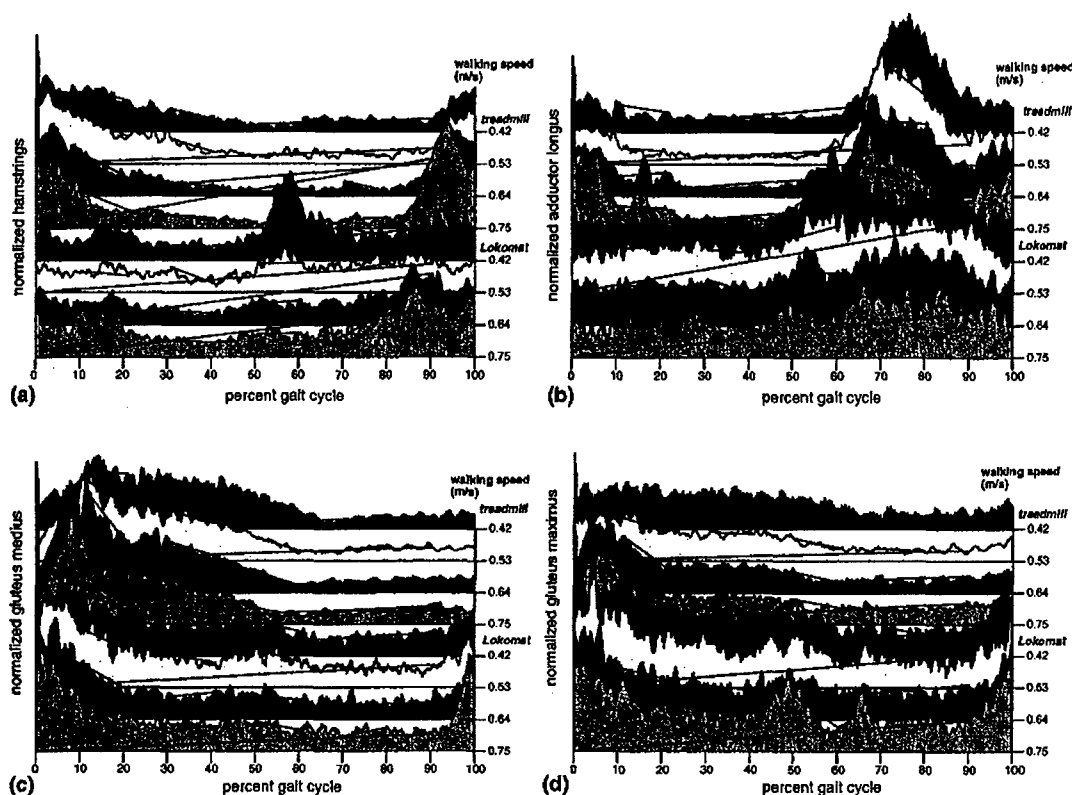


Fig. 3. Average normalized hamstrings (a), adductor longus (b), gluteus medius (c) and gluteus maximus (d) activity across speeds for both treadmill and Lokomat walking.

of the statistical differences between the two conditions for each muscle is shown in Table 2.

3.2. Influence of walking speed on EMG activity

The influence of walking speed on the magnitude of EMG activity across the gait cycle was also examined since previous studies have demonstrated a tight correlation between these two factors (Hof et al., 2002; Murray et al., 1894; Nilsson et al., 1985; Ricamato and Hidler, 2004; Shiavi and Griffin, 1983; Shiavi et al., 1987; Yang and Winter, 1985). For the narrow range of speeds tested (0.42–0.75 m/s), there were no statistical differences in the magnitude of EMG for any of the muscles observed in each of the seven phases of the gait cycle, nor were there inter-dependencies between speed and type of walking (e.g., treadmill or Lokomat).

3.3. Interaction forces between subject and robot

Because the EMG patterns of some muscles were different between treadmill and Lokomat walking, we examined the interaction forces between the subject's legs and the Lokomat to see how closely the subject was able to match the gait patterns prescribed by the Lokomat. As stated previously, prior to collecting any

experimental data, we adjusted the kinematic pattern of the Lokomat to best match the kinematic pattern measured at an intermediate speed while walking on the treadmill for that subject so that their step patterns were as comfortable and natural as possible.

We observed that throughout all trials, subjects were able to walk with a similar gait pattern as the Lokomat, however there were always some interaction forces present. In fact, the interaction forces coincided with the measured muscle activity during the gait cycle. Fig. 5 illustrates the mean forces exerted on the upper, middle, and lower Lokomat leg cuffs across all walking speeds and subjects. The left panel depicts the forces along the flexion–extension axis while the right plot is along the abduction–adduction axis. See figure legend for explanation of force effects on leg.

Examining the flexion–extension panel of interaction forces, the thigh cuff illustrates that after heel-strike, the subject drives their leg back into the Lokomat such that the Lokomat resists the desired movement. This behavior correlates with increased muscle activity observed in the hamstrings (Fig. 4). As the leg moves through stance, the direction of the forces reverse and the Lokomat starts to assist the motion of the limb. Surprisingly, there was still significantly more activity in the hamstrings during these phases than during treadmill walking, and also

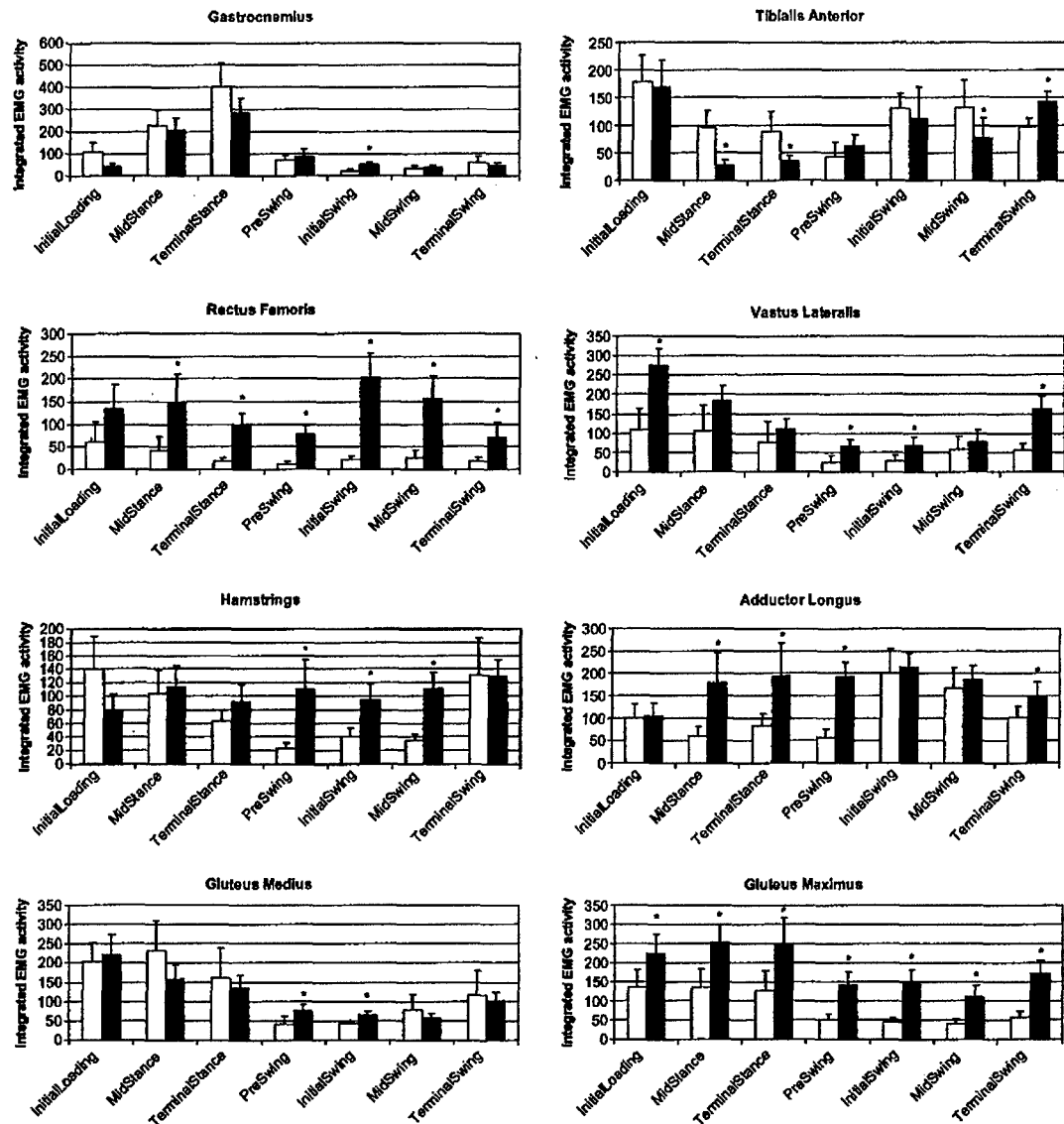


Fig. 4. Summary of the mean integrated muscle activity and 95% confidence interval for each of the eight muscles during treadmill (white) and Lokomat (black) walking in the seven gait phases (arbitrary units). Note * indicates $P < 0.05$ or less, summarized in Table 2.

Table 2
Statistical comparison of muscle activity for treadmill and Lokomat walking

Muscle	Initial loading	Mid-stance	Terminal-stance	Pre-swing	Initial-swing	Mid-swing	Terminal-swing
Gastrocnemius	*	—	—	—	***	—	—
Tibialis anterior	—	***	*	—	—	*	**
Adductor longus	—	**	*	***	—	—	*
Rectus femoris	—	**	***	***	***	***	**
Hamstrings	—	—	—	***	***	***	—
Vastus lateralis	***	—	—	**	**	—	***
Gluteus medius	—	—	—	*	**	—	—
Gluteus maximus	*	*	*	***	***	***	***

— Not significant, * $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$.

there was increased activation in the quadriceps. At the end of stance and throughout most of swing, the subject

pulls on the Lokomat while at the end of swing, the Lokomat again assists the motion of the subject's leg. This is

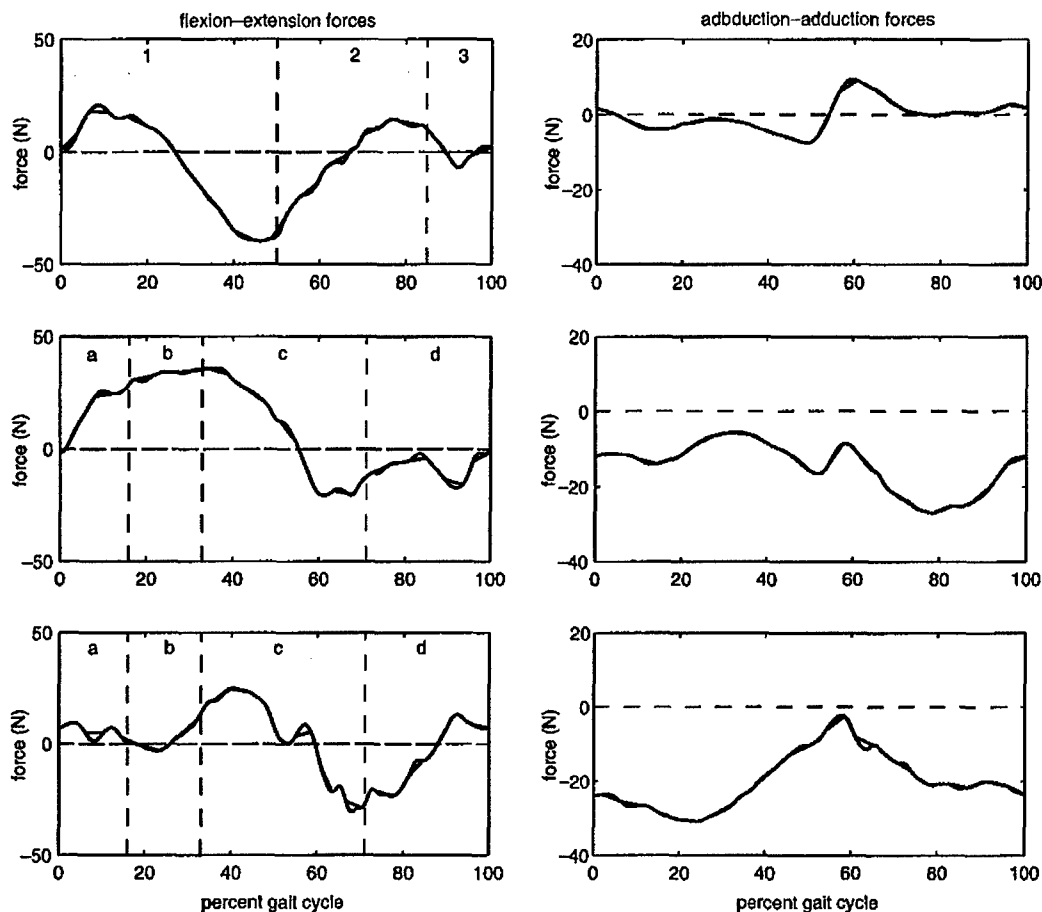


Fig. 5. Mean interaction forces between the subject's leg and the Lokomat cuffs along the flexion-extension plane (left column) and the abduction-adduction plane (right column). For the thigh cuff in the flexion-extension plane (upper trace), positive forces in sections 1 and 3 and negative forces in section 2 represent Lokomat resistance. For the shank cuffs in the flexion-extension plane (middle and lower traces), positive forces in sections a and c and negative forces in sections b and d represent Lokomat resistance. For the abduction-adduction plan (right column), positive values represent abduction forces against the leg cuff while negative values represent adduction forces against the cuff.

reflected in the large amount of EMG activity in the quadriceps (see rectus and vastus in Fig. 4).

For the lower cuff interaction forces shown in the middle and lower traces in the left column, the subject's routinely push back on the Lokomat throughout stance and also pull on the Lokomat during swing. In essence the shank is being resisted throughout the gait cycle. It should be noted that while there are interaction forces present despite the subjects trying to match the Lokomat gait pattern, the amplitude of the forces are quite small. This demonstrates their ability to adapt their gait pattern and walk with similar kinematic trajectories as the Lokomat.

For the abduction-adduction forces as shown on the right panel in Fig. 5, throughout most of the gait cycle, the subject exerts a net adduction force on the leg attachment cuffs which corresponds to the significant activity in the adductor longus (Fig. 4). The only portion of the gait cycle in which the subject generates abduction forces occurred during early swing and only for the

thigh cuff. Interpretation of these interaction forces are discussed below.

4. Discussion

Comparisons of muscle activation patterns measured during treadmill ambulation with those exhibited while ambulating within a commercially available robotic orthosis demonstrate significant differences in both spatial and temporal properties for most muscles in the lower extremities. The robotic orthosis used in this study, called the Lokomat, restricts leg movements to the sagittal plane and does not allow for substantial hip rotation or listing, all of which are present in normal walking. Yet despite these restrictions, subjects who participated in this study routinely stated that they did not feel uncomfortable or too restricted when walking within the Lokomat but instead felt as though they were walking normally. We hypothesize that after walking

inside the device for just a short period, subjects are able to adapt their gait pattern and learn a new set of motor commands necessary for the restricted movement imposed by the robot (e.g., lack of leg movements along the abduction–adduction axis or pelvic movements such as rotation or listing). This is supported by the small interaction forces between the leg and Lokomat (see Fig. 5).

It is not surprising that differences in the activation patterns of some muscles were found since the device imposes numerous restrictions on the gait pattern. Reducing the degrees of freedom through which the person is allowed to move is necessary for safety reasons, as well as to simplify the complexity of the device so physical therapists can quickly setup the patient. Furthermore, until a wide scale clinical trial of the device of varying complexity is undertaken, it is unclear whether additional degrees of freedom are necessary to promote gains in functional walking ability in individuals with neurological injuries.

4.1. Interpretation of findings

We believe that the observed changes in muscle activity can be explained primarily due to the restriction of leg movements to the sagittal plane and restrictions on pelvic movement. That is, during the swing phase of the gait cycle, subjects normally rotate and list their hips and also abduct their leg to allow the toe to clear the floor. Because the Lokomat limits movement of the pelvis and prevents abduction movement, the subject will exert excessive muscle activity in the quads to help elevate the foot and prevent toe stubbing. In the extreme case, this can be equated to the gait patterns exhibited by a member of a marching band.

In the current study, we did not examine whether subjects could “learn” the Lokomat’s gait pattern over an extended period of time and thereby reduce the amount of coactivation of antagonistic muscles. This may be an important point since training with a device like the Lokomat often involves repeated exposure thereby allowing the subject to adapt and feel more comfortable which may lead to reductions in cocontraction of antagonistic muscles.

Finally, we believe that because the test subjects tended to walk with their feet spread slightly wider than normal to accommodate for the leg cuffs on the Lokomat, this may help explain why there is excessive activation in the adductor longus across the gait cycle. This is a slight artifact with the current study as we tested young healthy individuals with significant muscle bulk. As a result, the leg cuffs that couple the subject to the Lokomat needed to be larger and spread wider than would normally be done in subjects with neurological injuries and atrophied muscle. This resulted in the spacing between the legs to be slightly wider than what

would normally be used in individuals with neurological injuries (e.g., spinal cord injury).

4.2. Failure to induce changes in EMG patterns with speed

While the finding that variations in EMG patterns were not dependent on speed contradicts previous studies (Hof et al., 2002; Shavi and Griffin, 1983; Shavi et al., 1987; Yang and Winter, 1985), we believe this is attributed to the extremely slow speeds through which our test subjects walked. That is, in our study, due to limitations with the Lokomat, the speeds subjects walked at ranged from 0.42 to 0.75 m/s. In previous studies that found EMG scaling with speeds, speed ranges were always higher, for example ranging from 0.75 to 1.75 m/s in the study by Hof et al. (2002). At these low walking speeds, it was visually observable that there was significantly more pelvic motion than at normal walking speeds, which could result in decreases in leg muscle activity due to forward propulsion of the legs from pelvis rotation. We also believe that the slow walking speeds resulted in a higher variability in EMG patterns than previously reported (Hof et al., 2002). Reductions in walking speed have been shown to result in both increased pelvic motion and walking variability (Dingwell et al., 2001; Savelberg et al., 1998). As a result of these factors, EMG patterns tended to be smaller and more variable than is commonly observed in normal ranges of walking speeds. It should be stressed that there were observable differences in EMG patterns with walking speed (see Figs. 2 and 3), however the differences were not statistically significant.

4.3. Clinical significance

While the present findings imply that muscle activation patterns exhibited during robotic-assisted gait training are significantly different than those observed during treadmill ambulation, the clinical implications of this are not necessarily negative. That is, during early neurorehabilitation, it is often helpful if not mandatory to reduce the degrees of freedom through which a person can move since neurologically impaired patients can easily become overwhelmed with the amount of tasks to perform. Training in a robotic orthosis allows non-ambulatory patients to start practicing patterned movements through consistent, time-unlimited training sessions earlier in their rehabilitation program. Therefore, simply because the Lokomat restricts movements and alters some muscle EMG patterns should not diminish the fact that the device allows patients to execute mass-practiced movements in a highly consistent manner.

It should be stressed that the findings in this study cannot necessarily be extrapolated to individuals with neurological injuries. Presumably these individuals will

exhibit much different patterns of activity than non-disabled individuals due to the loss of descending motor commands. However the EMG patterns measured in this study do provide a basis of comparison against which the muscle activation patterns exhibited by subjects with neurological injuries while walking in the Lokomat can be compared. New quantitative methods of analyzing muscle activation patterns during gait require normative EMG profiles to evaluate the temporal and spatial properties (Ricamato and Hidler, 2004). The findings in this study suggest that comparing EMG's demonstrated during robotic-assisted gait training with those collected from healthy subjects walking on a treadmill or over-ground will produce biased results.

4.4. Future directions

While the focus of this study was on the Lokomat robotic-gait orthosis, a number of other devices are either already commercially available (Hesse and Uhlenbrock, 2000) or being developed (Reinkensmeyer et al., 2002). Each of these devices work in different ways, however the principle objective of each is the same: to deliver mass-practice gait training to subjects who are unable to ambulate without significant external assistance from physical therapists. Future advances in the robotic-gait orthosis industry may include adding degrees of freedom to the pelvis and the leg, as well as adding complex control strategies to guide leg movements such as adaptive or impedance control. Each of these advances may result in more normative muscle activation patterns and provide new challenges to the patient during neurorehabilitation.

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Quantification of the dynamic properties of EMG patterns during gait

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Abstract

A technique for analyzing and comparing the dynamic properties of electromyographic (EMG) patterns collected during gait is presented. A gait metric is computed, consisting of both magnitude (amplitude) and phase (timing) components. For the magnitude component, the processed EMG pattern is compared to a normative EMG pattern obtained under similar walking conditions, where the metric is incremented if the muscle is firing during expected active regions or is silent during expected inactive regions. The magnitude metric is penalized when the EMG is silent during phases of expected activity or when the EMG is active in regions of expected inactivity. The phase component of the metric computes the percentage of the gait cycle when the muscle is firing appropriately, that is, active in expected active regions and silent in expected inactive regions. The magnitude and phase components of the metric are normalized and combined to yield the EMG pattern that demonstrates the closest characteristics compared to normative gait data collected under similar walking conditions. Using experimental data, the proposed gait metric was tested and accurately reflects the observed changes in the EMG patterns. Clinical uses for the gait metric are discussed in relation to gait therapies, such as determining optimal gait training conditions in individuals following stroke and spinal cord injury.

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Keywords: Locomotor training; Muscle; Spinal cord injury

1. Introduction

Monitoring electromyographic (EMG) activity during gait therapies such as body-weight supported treadmill training (BWSTT) can play an important role in evaluating walking performance in individuals with neurological injuries. It can also be used to establish key training parameters for facilitating optimal stepping patterns. For example, following stroke, subjects who have

difficulty bearing their full body-weight while walking tend to co-contract antagonistic muscles spanning the knee and ankle joints in order to increase their stability [16,17]. These co-activation patterns often lead to poor functional gait, and at the same time, significantly enhance the rate of fatigue [3]. Monitoring EMG patterns during gait training can be used to determine the minimum amount of body-weight support given to a subject without the presence of co-activation of antagonistic muscles. Similar techniques can be used to establish the walking speed where the subject demonstrates the most appropriate EMG activation patterns throughout the gait cycle. Both of these variables (body-weight support and walking speed) have been shown to play

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important roles in altering muscle activation patterns in both healthy [14,15] and disabled [11] individuals, as well as influencing the outcomes of neurorehabilitation programs [20,22]. Therefore, developing a way to monitor the appropriateness of muscle activation patterns with changes in training conditions may lead to greater gains in motor recovery.

The objective of this study was to develop a standardized way of quantifying and comparing EMG patterns generated during the gait cycle. We describe a gait metric that compares the dynamic properties (amplitude and timing) of locomotor EMG patterns to normative gait-related EMG patterns generated under comparable walking conditions. We then present a validation of the gait metric using experimental locomotor EMG patterns collected from a group of healthy subjects. This gait metric may provide clinicians and therapists a rational basis for first selecting and then progressing training conditions for neurologically impaired individuals by evaluating the appropriateness of the EMG patterns with changing conditions.

2. Methods

2.1. Description of algorithm

The proposed algorithm compares EMG activity across the gait cycle with normative gait-related EMG data collected during similar walking conditions. This new metric provides a quantitative measure of the EMG pattern by calculating two parameters: (1) the magnitude of the 'area of normative activation' and (2) the phase shift in regard to the normative gait-related EMG pattern. Prior to the application of the metric two preliminary steps need to be completed: (1) pre-processing of the raw EMG data and (2) establishing normative gait-related EMG patterns.

2.1.1. Pre-processing of EMG signals

The metric was evaluated by examining four different muscles and five different conditions using averaged EMG profiles reported by Hof et al. [14]. The data consists of averaged surface EMG profiles from the gastrocnemius medialis (GM), rectus femoris (RF), soleus (SO), and tibialis anterior (TA) muscles of healthy subjects under five different walking speeds of 0.75, 1.00, 1.25, 1.50, and 1.75 ms⁻¹. For complete details on the methods and procedures utilized to obtain muscle activation patterns during human walking, see Hof et al. [14]. The data for each muscle is plotted in Fig. 1.

Prior to applying the metric, conventional EMG pre-processing is employed. This involves smoothing the raw EMG data using a root mean square (RMS) algorithm [2] and then examining the data to verify it is free from artifacts (e.g., equipment noise, electrode movement,

etc.). Trials that contain artifacts should not be used for further analysis. Next, the EMG pattern is broken up into individual stride cycles, which are considered the period between successive heel-strikes in the same leg. The individual EMG stride patterns are then time normalized, expressed as a percentage of total cycle [5], for averaging purposes [10]. The mean EMG profile generated over the gait cycle is then computed by averaging all the individual strides within the sequence. In all trials examined, a minimum of 20 trials were used. It should be noted that the proposed metric can be used on individual strides cycles as well as ensemble averaged data sets.

The final EMG pre-processing stage is amplitude normalization. Perhaps the most widely used amplitude normalization technique is normalizing to the maximum voluntary contraction (MVC) under isometric conditions. In cases where an MVC is unavailable, for example in subjects that cannot voluntarily contract their muscles, or if the activity is higher under dynamic conditions than during isometric conditions, one can use the maximum level of the time-normalized, averaged EMG signal across all trials. For this study, the maximum EMG level from each specific muscle was identified during the entire set of walking conditions and then used to normalize the muscle's activity to this value. It should be stressed that the maximum EMG level for each muscle is always the average peak RMS EMG value of numerous steps, preventing normalization by spurious EMG spikes (e.g., a spastic EMG burst).

2.1.2. Normative gait-related EMG data

The next step is to identify the normative active and inactive portions of the gait cycle for each muscle studied. For the most accurate comparisons, the normative EMG data should be obtained using the same conditions as those which the gait metric will be calculated against. This includes matching the task of interest as closely as possible in terms of speed, surface, grade, etc. For example, differences in EMG activity are expected between treadmill walking as compared to over-ground walking [7], therefore if the metric is to be computed while subjects walk on a treadmill, then the normative data must also be collected on the treadmill under the same walking conditions. When normative task-matching data is not available, the metric can still provide some insight by comparing the experimental data to values obtained from the literature (e.g., from [23]). While the metric values obtained by comparing experimental data to normative data obtained from the literature may not yield the most accurate results for the given task under study, the metric will still provide an excellent way to compare walking conditions by providing a comparison to a known pattern of activity. This can be very useful when collecting pilot data or testing possible new treatment conditions.

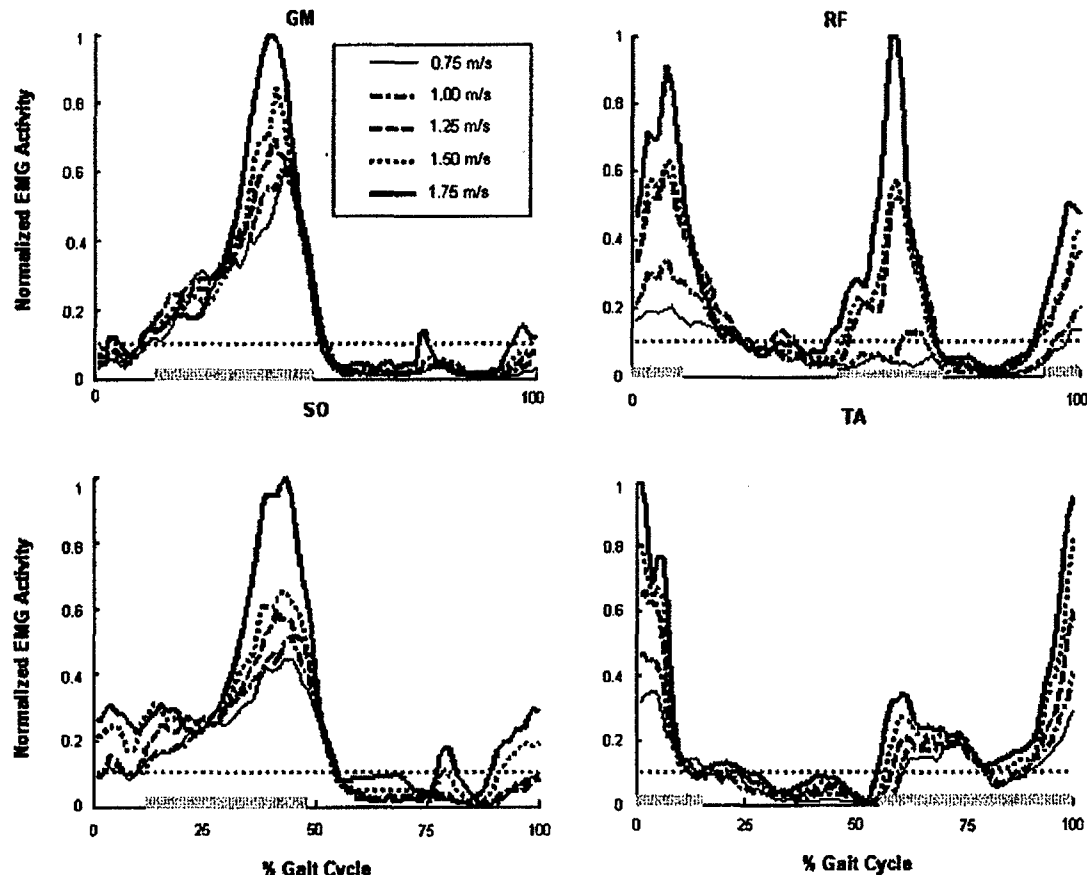


Fig. 1. Averaged surface EMG profiles for each of the four muscles in walking at speeds of 0.75, 1.00, 1.25, 1.50, 1.75 ms^{-1} . Data from Hof et al. [14]. Used with permission.

2.1.3. Application of EMG gait metric

The EMG gait metric quantifies how similar the recorded pattern of EMG activity is to the normative gait-related EMG pattern for a given muscle. The metric is comprised of two components: a magnitude component and a phase component. Specifically, the metric rewards EMG activity when the muscle is active (greater than a given threshold) in the portion of the gait cycle where it is normally 'active' and also when EMG activity is inactive (below the threshold) when the muscle is in the portion of the gait cycle where it is normally 'inactive'. In the case of the magnitude component, the metric also penalizes the opposite conditions, i.e., when the muscle is active when it should be silent and when it is silent but should be active.

2.2. EMG gait metric: magnitude component

2.2.1. Individual muscles

The magnitude component of the metric represents the amount of activation in phase with the normative EMG pattern over the entire gait cycle for each muscle studied. A pre-specified threshold value determines

when the muscle is considered on or off. Typical threshold values are on the order of two standard deviations of the noise level [18,21]. The magnitude component is then calculated by determining the area of EMG above the threshold in the portions of the gait cycle when the muscle should be active plus the area below the threshold when it should be inactive (see Fig. 2). The active and inactive regions are based upon normative EMG data previously collected from the same task or from the values obtained from the literature. The Magnitude Component for an individual muscle ($\text{MagComponent}_{\text{muscle}}$) is expressed mathematically as follows:

$$\text{MagComponent}_{\text{muscle}} = \sum_{p=1}^{100} (\text{NormAct}(p)) (\text{EMG}_{\text{muscle}}(p) - \text{threshold}_{\text{muscle}}), \quad (1)$$

where p represents the phase in the gait cycle ($p = 1-100$), $\text{EMG}_{\text{muscle}}(p)$ represents the normalized EMG activity of a given muscle at phase index, p , $\text{threshold}_{\text{muscle}}$ is the user-defined value that determines whether the muscle is on or off and $\text{NormAct}(p)$ repre-

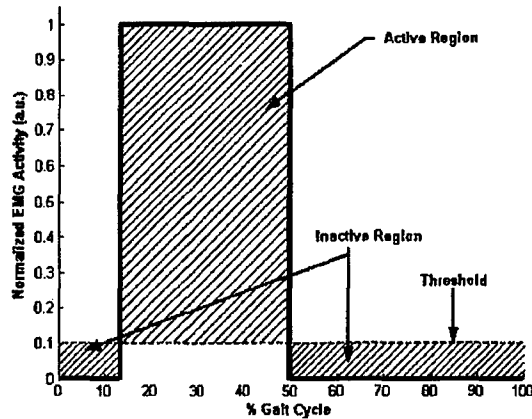


Fig. 2. The magnitude component is equal to the area above the threshold when it should be active plus the area below the threshold when it should be inactive. This area is indicated on the figure as diagonal lines.

sents whether the normative EMG data for phase index, p , is either active or inactive and is assigned a value as given below:

$$\text{NormAct}(p) = \begin{cases} 1 & \text{Active Portions,} \\ -1 & \text{Inactive Portions.} \end{cases} \quad (2)$$

It can be shown in Eq. (1) that when the muscle is firing during inactive regions or is silent during expected active regions, the metric is reduced by the amount of inappropriate muscle excitation.

2.2.2. Normalizing the magnitude metric

The maximum and minimum values of the metric are likely to be different for each muscle since they are a function of two factors: (1) the percentage of active and inactive portions of the muscle during the gait cycle; and (2) the threshold value, expressed as a percentage of normalized maximum EMG activity, which may vary from muscle to muscle. In order to make comparisons across different muscle groups, the *magnitude metric* can be normalized. The maximum (metricMax) and minimum (metricMin) metric values for a given muscle can be calculated as:

$$\text{metricMax} = ((1 - \text{threshold}) * n\text{Active}) + (\text{threshold} * n\text{Inactive}), \quad (3)$$

$$\text{metricMin} = -1 * (100 - \text{metricMax}), \quad (4)$$

where $n\text{Active}$ is the total number of portions of the normative EMG pattern where the given muscle is typically 'on' and $n\text{Inactive}$ is the total number for portions of the normative EMG pattern where the given muscle is typically 'off'.

Using these values, the metric is normalized for a given muscle ($\text{MagComponentNorm}_{\text{muscle}}$) using the following equation:

$$\text{MagComponentNorm}_{\text{muscle}} = \frac{\text{MagComponent}_{\text{muscle}} - \text{metricMin}_{\text{muscle}}}{\text{metricMax}_{\text{muscle}} - \text{metricMin}_{\text{muscle}}}, \quad (5)$$

where the denominator represents the maximum possible area of activation. Therefore, the normalized magnitude component can have values between 0 and 1. If the value is zero, then the EMG pattern under study is exactly opposite of the normative pattern (i.e., it is 'off' when it should be 'on' and vice versa). If the value is equal to 1, then the EMG amplitude is at its maximum level during phases of the gait cycle where it should be active, and below the threshold at phases of the gait cycle where it should be inactive.

2.2.3. Multiple muscles

The metric can also be used to quantify the overall EMG activity (across all muscles for any one training condition, $\text{MagComponent}_{\text{overall}}$) by simply summing the normalized metrics obtained from each of the individual muscles and dividing by the total number of muscles ($n\text{Muscles}$):

$$\text{MagComponent}_{\text{overall}} = \frac{\sum_{\text{muscle}=1}^N \text{MagComponentNorm}_{\text{muscle}}}{n\text{Muscles}}. \quad (6)$$

2.3. EMG gait metric: phase component

The phase component evaluates the timing properties of the EMG pattern by determining how similar the recorded EMG activity fires in-phase with the pattern of the normative gait data. This Phase Component for an individual muscle ($\text{PhaseComponent}_{\text{muscle}}$) is expressed mathematically as follows:

$$\text{PhaseComponent}_{\text{muscle}} = \sum_{i=1}^{100} \text{MatchValue}, \quad (7)$$

where

$$\text{MatchValue} = \begin{cases} 1 & (\text{EMG}_{\text{muscle}}(p) > \text{threshold}) \\ & \text{and } (\text{NormAct}(p) = 1) \\ \text{or} \\ & (\text{EMG}_{\text{muscle}}(p) < \text{threshold}) \\ & \text{and } (\text{NormAct}(p) = -1) \\ 0 & \text{Otherwise} \end{cases} \quad (8)$$

where $p = 1-100$ representing each phase of the gait cycle.

2.3.1. Normalizing the phase metric

To normalize the phase metric for an individual muscle ($\text{PhaseComponentNorm}_{\text{muscle}}$), simply divide by the total number of gait phases ($n = 100$):

$$\text{PhaseComponentNorm}_{\text{muscle}} = \frac{\text{PhaseComponent}_{\text{muscle}}}{100}, \quad (9)$$

where the value ranges from 0 where the timing properties of the EMG pattern do not match the normative gait pattern to 1 where there is an exact match in phasing between the EMG pattern and the normative pattern. While the phase component accurately quantifies the amount of phase shift relative to the normative condition, it does not yield specific information regarding the type of shift (i.e., leading or lagging). Once a poor phase component value is obtained for a given muscle, other traditional methods such as cross-correlation can then be used to quantify the exact nature of the phase shift.

2.3.2. Multiple muscles

The phase metric can also be used to quantify the overall timing properties of EMG activity (across all muscles, $\text{PhaseComponent}_{\text{overall}}$) by simply summing the normalized phase metrics obtained from each of the individual muscles and dividing by the total number of muscles ($n\text{Muscles}$):

$$\text{PhaseComponent}_{\text{overall}} = \frac{\sum_{\text{muscle}=1}^N \text{PhaseComponentNorm}_{\text{muscle}}}{n\text{Muscles}}. \quad (10)$$

2.4. Complete EMG gait metric

The complete gait-related EMG metric is the combination of both the magnitude and phase components and is given as:

$$\text{EMGMetric} = \frac{\sum (\text{MagnitudeComponent} + \text{PhaseComponent})}{2}. \quad (11)$$

The gait-related EMG metric provides a single quantitative measure which can be used to compare gait-related EMG patterns to the normative gait-related EMG patterns generated under comparable walking conditions.

3. Results

The metric described above was evaluated by examining four different muscles and five different conditions using averaged EMG profiles reported by Hof et al. [14]. Examining each of the four muscles, one can see that the EMG activity for each of the speeds is similar in pattern with increasing amplitude as the speed increases. We applied our metric to each muscle to determine the walking speed which resulted in EMG patterns

with the greatest intensity and in-phase with EMG patterns reported previously [23].

From the results displayed in Table 1, we see that the overall (across all the muscles) metric for the second highest speed (1.5 ms^{-1}) has the greatest value and thus represents the most similar EMG profile in terms of both magnitude and phase to the 'normative' condition than any other walking speed studied. Specifically, when examining the overall magnitude and phase components, the results illustrate that while the fastest walking speed generates a higher magnitude metric, the corresponding phase metric is much lower than the forth highest speed. For a more in-depth evaluation, it is important to examine the individual muscles. For the GM muscle, the magnitude component increases with increasing speed, however, the phase components for the first four speeds are nearly identical. For the highest speed, the timing properties of the EMG pattern deviate from the normative pattern as evidenced by the decreasing phase component. In the other four muscles, similar results are observed. Specifically, the soleus (SO) also clearly demonstrates this characteristic; for the two fastest speeds, the muscle does not turn off during phases of the gait cycle in which it would be expected to be inactive (0–14% and 90–100%) as reported by Winter [23]. While the interpretation of these results are beyond the scope of this paper, this example demonstrates the ability of the proposed metric to quantify the overall (multiple-muscle) similarity of gait-related EMG profiles to a normative condition as well as pin-point the condition(s) and the muscle(s) where the EMG activity deviates from expected 'normative' activity.

3.1. Sensitivity of the metric

The sensitivity of the gait metric to changes in threshold value was evaluated using a single condition (1.5 ms^{-1} walking speed) of the GM muscle from the experimental data set. Note, similar results were observed using each muscle and each walking speed; thus the GM muscle is a representative example of all the muscles and conditions studied. Three threshold values (0.1, 0.2, and 0.3) and three phases (0, 10%, and 20%) were studied. These testing conditions are illustrated in Fig. 3.

As shown in Table 2, the normalized magnitude component of the metric is independent of threshold level for a given phase. This is due to the fact that the metric itself is normalized which neutralizes the effect of the threshold. It should be noted that without normalizing the magnitude metric, the values produced are affected by the level of the threshold, however, the relationships between the conditions are still maintained.

The influence of threshold on the phase component of the metric is also shown in Table 2. It is demonstrated that across the 3 phases, as expected, changes in thresh-

Table 1
Metric results from the experimental data set

Speed (ms^{-1})	Muscle								Overall		
	GM		RF		SO		TA		Mag.	Phase	Metric
	Mag.	Phase	Mag.	Phase	Mag.	Phase	Mag.	Phase			
0.75	0.738	0.97	0.546	0.56	0.695	0.86	0.469	0.82	0.612	0.803	0.708
1.00	0.742	0.96	0.566	0.65	0.705	0.87	0.481	0.81	0.624	0.823	0.724
1.25	0.747	0.95	0.628	0.72	0.719	0.87	0.503	0.85	0.649	0.848	0.749
1.50	0.750	0.96	0.645	0.82	0.705	0.73	0.529	0.92	0.657	0.858	0.758
1.75	0.760	0.85	0.704	0.81	0.720	0.67	0.556	0.88	0.686	0.803	0.745

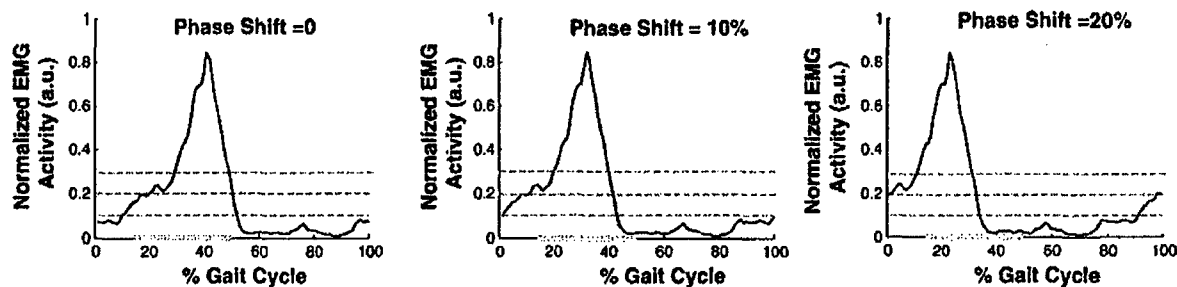


Fig. 3. Averaged surface EMG profile displaying the 1.5 ms^{-1} walking speed condition for the GM muscle from Hof et al. [14] (Used with permission.) The metric was evaluated by using three threshold levels of 0.1, 0.2, and 0.3 which are depicted as the horizontal dashed lines. The sensitivity of the metric to phase shifts relative to the normative gait-related EMG pattern (upper left) was also examined using a 10% (upper right) and 20% (lower left) phase shift.

Table 2
Sensitivity of metric to variations in threshold for the GM muscle at the 1.7 ms^{-1} walking speed

Threshold	Phase shift = 0			Phase shift = 10%			Phase shift = 20%		
	Mag.	Phase	Total	Mag.	Phase	Total	Mag.	Phase	Total
0.1	0.750	0.960	0.855	0.724	0.800	0.762	0.671	0.590	0.630
0.2	0.750	0.940	0.845	0.724	0.880	0.802	0.671	0.670	0.670
0.3	0.750	0.830	0.790	0.724	0.830	0.777	0.671	0.770	0.720

old do in fact influence the phase metric. In this setting, the metric determines the percentage of the gait cycle in which the muscle is firing appropriately. When activation levels cross the threshold level, this directly influences the estimated on–off times. While the phase metric and consequently overall gait metric are influenced by the threshold level, it is shown in Tables 1 and 2 that the metric is still able to appropriately identify shifts in amplitude and phase for a constant threshold value.

4. Discussion

There are few established quantitative methods of analyzing EMG activity during gait training that can be used to assess gait performance in individuals with neurological injuries. Erni and Colombo [8] described an approach that compares the similarity between EMG patterns obtained during locomotor training in individuals with complete and incomplete paraplegia

to those obtained in non-disabled subjects. However, in their analysis, they purposefully phase-shift the patient data and then correlate it with the healthy subject data to obtain the highest variation ratio. Thus, their reported variation ratio does not take into account poor temporal properties of the patient's EMG patterns. Fung and Barbeau [9] introduced a dynamic EMG profile index to quantify inappropriate muscle activation patterns in spastic paretic gait. The index calculates the ratio of activity in the expected "off" regions to the activity in the expected "on" regions, where on and off regions were based on EMG patterns collected from healthy control subjects. While the dynamic index was able to detect out of phase firing in spastic patients, and even corresponded to improvements in a patient's performance following anti-spasticity medication, the EMG on–off regions of the gait cycle were limited to just three, and the index did separate the percentage of the gait cycle where the muscles were firing appropriately. Specifically, the index is restricted to equal 'on' and

'off' phases (50% on and 50% off) for each muscle which may not be appropriate for every muscle studied. When removing this restriction, it is unclear how their index would perform with arbitrary 'on' and 'off' window sizes.

The gait metric presented here demonstrates a quantitative method of assessing the amplitude and timing (dynamic) characteristics of EMG patterns during gait that does not possess the above limitations. The method has been shown to reflect both the magnitude and phase of EMG activity relative to a normative condition during gait. The strengths of the method include: (1) it quantifies the EMG activity of the entire gait cycle using a single value that facilitates interpretation of the quality of the walking condition; and (2) the metric values for each muscle can be examined to determine if it is activated appropriately relative to the normative condition.

5. Applying the metric

There are two important issues to be considered when applying this metric to gait-related EMG data. First, while the metric has been shown to be robust to the threshold level used, it does not imply that the threshold level should be chosen arbitrarily. Similar to other EMG analysis methods, the choice of activation threshold is critical to determining when the muscle is 'on' and thus in the case of gait-related activity will greatly influence the timing or phase of the muscle as quantified by this method. Therefore, it is essential to objectively determine the threshold level for each muscle prior to applying this method. Second, although the method assigns larger values to high amplitude EMGs that are above the threshold provided that the timing is correct, it is important to realize that higher metric values are not necessarily 'better'. High EMG amplitudes may result from high muscles forces which could lead to a loss of metabolic energy and fatigue in the short term and possibly degenerative joint problems in the long term. Therefore, the importance of creating a gait-related EMG metric is its ability to provide quantitative information of muscle activity to help the researcher/clinician determine the optimal *amplitude and timing* of muscle activation during the gait cycle. The usefulness of the metric in addressing these issues in the clinical setting is discussed below.

5.1. Subject training

The proposed gait metric is extremely useful for comparing the EMG patterns demonstrated in subjects while trained under various conditions, for example with changes in body-weight support or walking speeds. This is clinically important in patients with neurological injuries who often demonstrate poor coordination among muscle groups, particularly if the walking conditions

are too difficult [4,13,16,19]. Using the metric presented in this study, clinicians can assess both the magnitude and timing of the subject's muscle activation patterns while they are trained, choosing the set of conditions resulting in the most appropriate EMG patterns across the gait cycle. For example, it has been shown that in incomplete spinal cord injured subjects, changing training conditions such as walking speed can significantly influence ambulation properties (e.g., joint moments & EMG firing patterns) [19]. In that study, it was shown that each subject was able to properly coordinate the timing and amplitude of EMG's in numerous leg muscles at a unique walking speed. Subjects trained at speeds faster and slower than the subject's "preferred" speed exhibited EMG's that were significantly attenuated in amplitude or the phase characteristics were not consistent with the kinematics of the limbs. Without adequate assessment procedures, establishing "optimal" training conditions for each subject remains elusive, resulting in therapeutic interventions that may not be maximizing recovery. Quantifying muscle activation patterns utilizing procedures like that proposed in this study may allow clinicians and therapists to determine the preferred set of training conditions which subjects should be trained. This technique also complements procedures being developed that examines joint moments during gait in neurologically impaired subjects [12].

It should be noted that although combining the magnitude and phase components into a single metric provides an overall assessment of the EMG pattern (see Eq. (11)); it is also useful clinically to track each component separately. That is, in some patient populations, it may be more important to have the subject step with the most appropriate muscle timing (using the phase component of the metric), and then once this is achieved, they can then work on altering the levels of activation (using the magnitude component). Thus the ability to separately explore training conditions that stress activation level and/or phasing presents another strength of the proposed technique.

5.2. Comparing patient gait-related EMG profiles to 'normative' gait-related EMG profiles

In addition to quantifying within-subject training performance, that is, how the subject's EMG patterns change across walking conditions, the EMG gait metric also provides a relative comparison of the EMG patterns generated by impaired subjects during gait to those exhibited by healthy individuals under similar walking conditions. It is important to note that in order to maximize the accuracy and utility of these comparisons, the active and inactive regions of the gait cycle determined from subjects with normal gait function must be identified under similar conditions. It is well established that EMG patterns exhibited during treadmill walking are

different than those demonstrated during over-ground walking [1], so if the subject is being trained on the treadmill, then the normative patterns must have also originated from treadmill stepping. Furthermore, recent developments in robotic-technology now allow for hands-free assisted gait training [6]. These devices assist the movement of the subject's legs, often through kinematic trajectories that reduce the number of degrees of freedom normally used in human walking. Due to these restrictions, it is even more important when evaluating the stepping patterns during robotic-assisted training, as the EMGs exhibited in healthy subjects during treadmill walking have been shown to be different than when these subjects walk within the robotic orthosis [11].

6. Conclusion

In summary, a quantitative tool has been established for assessing the amplitude and timing properties of EMG patterns during gait. This information is especially important during step training in subjects with some form of walking disorder, where the training conditions in which the subject exhibits the most appropriate muscle activation patterns can be identified. Future work will explore the effectiveness of the metric to quantify pathological conditions. For example, two questions to be addressed are: (1) Can the metric be used to detect specific levels of impairment? (2) How well does the metric correlate with clinical scales used to evaluate functional behavior?

Finally, the introduction of instrumented robotic gait devices [6] allows clinicians to monitor joint moments produced by the subject during step training. This information can be combined with an assessment of EMG patterns using the gait metric presented in this study to determine the set of training conditions in which the subject steps with the least amount of robotic-assistance and demonstrates the most appropriate muscle activation patterns. This in turn may allow patients with gait disorders to achieve higher levels of functional gains following long-term intensive gait training.

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Guest Editorial

What is next for locomotor-based studies?

The scientific community has launched an aggressive campaign to investigate new therapeutic interventions that focus on restoring walking function in individuals with neurological injuries. For more than a decade now, we have seen the proliferation of scientific studies focusing on body-weight-supported locomotor training paradigms, many of which have demonstrated promising results. But where are we now? What have we learned from all of these studies and in which direction should we head next? These are the questions the scientific community needs to ask, perhaps in a large forum, so that we stop the circular nature of our investigations. With this editorial, I would like to raise a few issues that we need to examine to move this therapeutic intervention forward. Before jumping into this discussion, I want to describe some of the key concepts and findings in this field to date.

As eloquently outlined in a review by Prochazka and Yakovenko [1], we have been aware of locomotor patterns originating from segmental circuits for well more than 250 years. But the work of Sherrington [2] and Brown [3] in 1910–11 truly moved this field forward. In these studies, they found that with appropriate sensory cues from the periphery, spinalized, deafferented cats generated patterned movements that mimicked those exhibited during the flexion and extension phases of locomotion. What they originally termed “the intrinsic factor” has now become known as the central pattern generator (CPG), a cluster of neuronal networks in the central nervous system that can generate basic rhythmical motor patterns involved in tasks such as walking, breathing, chewing, and more [4]. These early studies motivated others to investigate whether appropriate training paradigms could enhance these CPGs to execute specific tasks, such as walking.

After extensive animal research demonstrated that spinalized cats can be trained to step, Barbeau and his colleagues [5] extended the concept of body-weight-supported locomotor training to humans, and since then, this area of research has taken off. Over



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the last 10 years, studies have shown that subjects who receive body-weight-supported treadmill training following spinal cord injury (SCI) [6–8] and stroke [9–10] demonstrate improved electromyographic (EMG) activation patterns [8,11] and more natural walking characteristics [10,12], are able to bear more weight on their legs [6], and have higher returns in functional walking ability when compared with subjects who received standard physiotherapy [7,13]. Furthermore, studies have also shown reductions in spasticity [7] and increases in cardiopulmonary

efficiency [14] following body-weight-supported locomotor training. Note that most of these studies have focused on subjects with subacute or chronic injuries. The recently completed multicenter randomized clinical trial comparing manual-assist, body-weight-supported locomotor training with conventional gait training included a much more acute subject population (within 8 weeks post-SCI) and did not find any statistical differences between groups [15].

While these studies have laid the foundation for where we are today, it is now time to ask, "Where do we go from here?" One aspect of locomotor training that has not been properly studied in human subjects is how we should train subjects. I constantly read articles and reviews by scientists and therapists involved in locomotor training who describe the proper training paradigms, sometimes referred to as the "rules of locomotion." But the question I have always asked is, "Where did these rules come from?" Show me some quantitative evidence that supports these "rules" and you will convince me. Tell me it is based on experience, and I will listen and respect it, but I will want to see more sufficient evidence that proves these rules are true. We all know that experience and intuition by themselves do not always lead to the correct conclusion. Let me highlight just a couple of key aspects of human locomotor training that are essential, yet lack sufficient understanding.

HOW FAST SHOULD SUBJECTS BE TRAINED?

The typical treadmill training speeds used in the United States sharply contrast to those used in Europe and sometimes Canada. The philosophy of many researchers in the United States is that training speeds at or close to normal are necessary for eliciting the sensory feedback to help drive segmental circuits [16]. Those who favor this philosophy might argue that if you train too slowly, the afferent drive to the spinal cord would be reduced, effectively attenuating the locomotor pattern. In contrast, those who favor slower training speeds often argue that the subject's level of function needs to guide

walking speed so that the subject can execute proper, coordinated movements without relying principally on the therapist to generate them. So, how fast should we train subjects?

Training speeds need to be set to the limit of each subject's ability to retain adequate control over leg movements. In our laboratory at the National Rehabilitation Hospital, we have found in preliminary experiments that if you train subjects too slowly, their muscle activation patterns are significantly attenuated throughout the gait cycle. Furthermore, most of our subjects report that they do not like to walk slowly because it feels more comfortable at moderate rates. In contrast, when subjects are trained too quickly, we see that the EMG patterns do get larger, but the timing of the firing patterns is so asynchronous with the movement of the legs that the subject's ability to control the leg movements is all but absent. It would be difficult to support any training paradigm in which muscle activity is lagging leg movements so that, for example, the ankle plantar flexors are highly active during midswing.

To first establish baseline training parameters for each patient and then progress training speed, we need good quantitative measures of walking ability based on joint moments exhibited by the subject as well as a solid analysis of muscle firing patterns. Without being able to quantify these behaviors, one could be misled easily into believing that certain training paradigms are facilitating locomotor patterns when, in fact, they may not be. A classic example reported throughout the literature is that training at higher speeds results in the subject stepping better, as evidenced by the reduced need for therapist assistance. But it is easy to show that at higher walking speeds, passive joint mechanics (e.g., the spring-like properties of musculotendon structures) play a progressively larger role in generating joint moments [17]. It is no wonder that subjects like training at higher speeds: They are doing less active work! This may not be the best neurorehabilitation strategy for all subjects, however, since it does not train active, coordinated control over leg movements.

While some recent evidence in the stroke literature favors higher training speeds [10,12,18–20], we need to investigate this question with larger sample sizes to determine whether there are, in fact, better outcomes across neurological populations that are statistically significant and, if so, which groups are likely to benefit most (e.g., those with initial motor deficits, lesion sites, etc.). Furthermore, one should be cautious about generalizing the findings of these studies for all neurological patients, particularly from stroke populations into SCI populations, since within 6 months, more than 85 percent of stroke subjects are walking while only 10 to 13 percent of SCI subjects ambulate within that period [21–22].

HOW MUCH BODY-WEIGHT SUPPORT SHOULD BE USED?

The amount of body-weight support is another variable, along with walking speed, that has not been adequately addressed yet profoundly influences walking ability. Visintin and Barbeau [11] first demonstrated that the timing of muscle activation patterns improved as did joint and trunk kinematics in individuals following SCI with up to 40 percent body-weight support. Harkema et al. [23] found that in a small group of SCI subjects, muscle activation patterns were modulated by loading on the lower limbs rather than by stretching the muscle tendon structure. In terms of improving walking ability, in both SCI and stroke patients, positive effects from using body-weight support during locomotor training have been reported (see Barbeau et al. for a complete review [24]).

Yet in spite of the results of these studies, we still do not know how to first establish baseline training parameters and then progress the level of body-weight support for each subject. I stress each subject because the motor deficits exhibited in most patients are quite unique, such that a training paradigm that works for one person may be quite different from those necessary for others. We have found that in SCI subjects, too little body-weight support results in significant cocontraction of antagonistic muscle groups, while too much body-weight sup-

port results in significant attenuation of EMG activity [25]. Many times, we see that providing too little or too much body-weight support results in poor, if any, ambulation. Just as with walking speed, we need to develop quantitative methods of evaluating walking performance at varying levels of body-weight support, in terms of both muscle activation patterns and joint moments. While subjects may be able to walk under heavy loads, it may be more important to train them to coordinate leg movements through properly timed muscle-firing sequences and, subsequently, active joint moments. To select training paradigms by simply looking at average muscle activation amplitudes across the entire gait cycle is insufficient, because such a method does not penalize for coactivation or poor muscle firing sequences [26].

SUMMARY

Locomotor training techniques can be improved and, consequently, better functional gains can be realized if we develop quantitative methods of evaluating walking performance, such that we can establish baseline training parameters for each patient and then progress each patient in an optimal fashion. Until now, quantitative assessments were thought to be elusive, because a standard gait analysis is not always possible, since many SCI and stroke patients do not ambulate without assistance. The instrumentation now available with gait-training robotics [27–28] makes quantitative methods possible.

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Toward a Taxonomy of Rehabilitation Interventions: Using an Inductive Approach to Examine the "Black Box" of Rehabilitation

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A barrier in outcomes and effectiveness research is the ability to characterize the interventions under review. This has been the case especially in rehabilitation in which interventions are commonly multidisciplinary, customized to the patient, and lack standardization in definition and measurement. This commentary describes how investigators and clinicians, working together, in a major multisite stroke rehabilitation outcome study were able to define and characterize diverse stroke rehabilitation interventions in a comprehensive, yet parsimonious, fashion and thus capture what actually transpires in a hospital-based stroke rehabilitation program. We consider the implications of the study's classification system for a more comprehensive taxonomy of rehabilitation interventions and the potential utility of such a taxonomy in operationalizing practice standards, medical record keeping, and rehabilitation research.

Key Words: Classification; Rehabilitation; Taxonomy.

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AN ENDURING QUESTION in rehabilitation—and health care in general—is whether and to what extent interventions used are effective, and, if so, whether they are efficient. In answering these questions, one must know the ends that are

being sought—outcomes that are of value to patients, payers, and society as a whole. Over the years, rehabilitation has expended enormous intellectual energy conceptualizing models of disability, identifying relevant outcome domains, and developing outcome measures, including psychometric (clinimetric) research on validity, reliability, scaling, and interpretation of these measures.

By contrast, little energy has been expended on issues related to the processes of care and interventions used in rehabilitation. The *input side* (patient, treatment, and environment characteristics) has not been subjected to the same level of conceptual and methodologic rigor as the *output side* in the effectiveness equation, and there has been little systematic disaggregation (conceptualizing, measuring, counting) of interventions used in rehabilitation. Although there is research of individual treatments, focusing on their effectiveness either as "stand alone" interventions in an outpatient setting or as part of a larger package of inpatient or outpatient services, there is no research that investigates the contribution of all individual components of a rehabilitation program to the outcomes, individually and combined.

Typically, outcomes research or effectiveness research has examined "unopened" packages of services, gross settings of care, or organizational milieus (eg, rehabilitation team culture). Most previous studies^{1,2} have examined rehabilitation in the aggregate; investigators have looked at rehabilitation as a whole, such as comparing outcomes of patients treated in hospital rehabilitation centers versus those treated in skilled nursing facilities. Quantifying the amount of therapy that a patient receives usually does not go beyond length of stay or hours of each type of therapy delivered.³⁻⁵ Rarely are individual interventions examined in the context of the entire array of interdisciplinary interventions used and within the structural arrangements (ie, care settings) in which care is delivered. In the case of stroke rehabilitation, for example, no study has investigated the effects of multiple aspects of stroke rehabilitation simultaneously, although some explorations of the effects of structural and process characteristics of the treatment environment have been published.⁶⁻⁹ In short, we have yet to disassemble the "black box" of rehabilitation.

As a result of our failure to disaggregate, we cannot identify those interventions that truly contribute to rehabilitation outcomes. Even if we could distinguish the "active ingredients" in rehabilitation, we would still need to quantify them, which depends on adequate measurement. Each intervention presents its own measurement challenge and rehabilitation interventions often are not mutually exclusive. For example, a physical therapist may combine motor learning strategies with balance training while working with a patient on sit-to-stand activities. Both are important related components of therapy and sometimes difficult to differentiate. Separating the effects of individual interventions and their multiple interactions is an analytical and statistical challenge. Rehabilitation practitioners

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claim that rehabilitation is an interdisciplinary process that is more than the sum of its parts. That may be the case, but without identifying and measuring the parts, we cannot begin to evaluate the whole. Some parts may not be necessary or can be substituted for each another. Optimal interventions may be different for various diagnoses, admission functional levels, or comorbidities.

Some¹⁰ have called for a taxonomy of treatments that will bring systemization, greater clarity, and more precision to describing and quantifying what happens in the rehabilitation process, and thus serve as the basis for measuring interventions used in conjunction with outcomes. The notion of a taxonomy suggests creation of a system of concept categories, classes, or groups into which individual observations can be lumped. For our purposes, a taxonomy is not a grand classification scheme, such as Linnaeus's historic organization of the plant and animal kingdoms of the world, but a typology that brings order and rigor to the description of myriad rehabilitation interventions. The purpose of a rehabilitation interventions taxonomy is to characterize systematically the many treatments, procedures, and interventions used in rehabilitation, taking into account their multidimensionality with respect to content (type), purpose, intensity, duration, sequence, frequency, and other characteristics of care rendered.

The purpose of the present article is to sketch an approach to the development of a taxonomy of rehabilitation interventions. The approach is the byproduct of a major outcomes study in stroke rehabilitation. Although we did not intend to develop a grand and comprehensive rehabilitation taxonomy, the approach used in the study can inform the development of such a scheme. Thus, our purpose was not to propose a definitive taxonomy but to share our experiences that can help inform more definitive attempts in the future. Our article (1) outlines experiences in developing taxonomies in other health care fields, such as nursing, (2) considers 2 main approaches to developing a rehabilitation intervention taxonomy, (3) describes the larger study on stroke rehabilitation outcomes that led to our approach, (4) presents an example of the classification scheme used in that study, (5) introduces proposed criteria for an intervention classification system and discusses the limitations of the current study relative to these criteria, (6) discusses the implications for the development of clinical practice guidelines (CPGs) and electronic medical records, and (7) identifies some of the implications for rehabilitation research.

TAXONOMY DEVELOPMENT IN OTHER HEALTH CARE FIELDS

Taxonomies have been part of health care for many years. The *International Classification of Diseases, 9th Revision*¹¹ is a taxonomy of diseases and health conditions. The *International Classification of Impairments, Disabilities and Handicaps*,¹² now the *International Classification of Function*, is a taxonomy to address the multiple dimensions of disability. Current Procedural Terminology codes are a billing taxonomy used in health care.¹³ A number of taxonomies have been developed for nursing, of which the Nursing Intervention Classification (NIC) is the most extensive and best known.

The NIC addresses the range of activities that nurses carry out in daily routines.¹⁴ The NIC developers started with extensive listings of specific nursing activities as found in nursing textbooks, care planning guides, and information systems. These were grouped into interventions using expert opinion, focus groups, and other methods. "Purification" was achieved by using Delphi processes with experts who rated domains and classes on clarity, homogeneity, inclusiveness, mutual exclusiveness, and theory neutrality.

In its current edition, the NIC consists of 486 interventions. Each is comprised of a label, a definition, and a set of activities (as many as 20) that together characterize the intervention. Each intervention is in turn classified within 1 of 30 classes within 7 domains: physiologic, basic; physiologic, complex; behavioral; safety; family; health system; and community. Examples of nursing interventions are the following: *epidural analgesia administration* is defined as "preparation and delivery of narcotic analgesics into the epidural space," *cough enhancement* refers to a group of nursing activities intended to help respiration, and *airway management* includes activities such as endotracheal and nasotracheal suctioning. Some nursing interventions in the NIC include activities that overlap with other interventions. Many, if not most, interventions and their component activities cut across medical diagnostic categories.^{14,15}

The NIC authors specify that the list of interventions can be used to make visible and legitimate the work that nurses do. However, other uses are described also: standardizing and defining the knowledge base for nursing education and practice, facilitating communication among nurses and of nurses with other care providers, teaching clinical decision making, staff needs planning by administrators, and investigating the effectiveness and cost of nursing care.¹⁴ The NIC's editors assert that "NIC, although still relatively young, promises to be a major rallying point for nurses in the decades to come."¹⁵ A little over a decade in the making, the NIC's research applications appear secondary to its clinical, educational, and administrative uses. To date, we do not have a large body of research studies that use the NIC as the principal means of characterizing the nursing interventions under review, and even fewer studies that use the NIC to describe interventions that are compared on their impact on patient outcomes.

APPROACHES TO REHABILITATION TAXONOMY DEVELOPMENT

Deductive Approach

There are 2 main approaches one can take to develop a taxonomy of rehabilitation interventions. The first is a theory-driven, top-down, deductive approach led by expert opinion and scientific evidence (where such evidence is available). The approach stems from a profession's or practice area's view of its self-identity and its professional belief system. Good theory is believed to be the precursor to good science and is important to the legitimacy of a profession or area of practice. The natural inclination is to assemble a group of experts and to define deductively a rational ordering of interventions within their scope of practice with little attention to whether the distinctions made correspond to differentiations visible in the practice of rehabilitation.

Inductive Approach

The second approach is an experience-driven, bottom-up, inductive approach led by front-line opinion and scientific evidence (where such evidence is available). This approach starts with what people do in the clinical setting, taking into account the multidimensionality of each intervention and multidisciplinary interaction. It gathers front-line clinicians to describe and characterize what they actually do and then categorizes meaningfully the various interventions using a common language. An even more empirical method is to cull from existing materials (eg, medical records, textbooks, articles in the literature) descriptive terms and statements referring to activities, to sort them, and then to summarize them as a first step toward development of conceptual classes—the approach taken by the developers of the NIC.^{13,14}

These 2 approaches are not mutually exclusive. A limitation of the deductive method is that theory may overlook important behaviors and distinctions that may not fit the theory. Presently, rehabilitation lacks theory, particularly a comprehensive theory that encompasses the links between impairments, treatments, and outcomes for all patient problems in all diagnostic groups. A limitation of the inductive approach is that one may not see how disparate interventions fit together. Thus, the second approach needs to incorporate theory at some level.

A taxonomy developed using either approach needs to show its value. Later we describe the development of a limited taxonomy that uses the second approach to characterize interventions in stroke rehabilitation. The taxonomy was developed as part of a stroke outcomes study by using the clinical practice improvement (CPI) study method. This taxonomy is being implemented at clinical sites around the United States and abroad. We describe the process and discuss potential implications for a broader, more cohesive medical rehabilitation taxonomy.

THE STROKE REHABILITATION OUTCOME STUDY

Purpose, Scope, and Approach

The stroke rehabilitation outcomes study addressed the need for scientific data that support the effectiveness of rehabilitation treatments. The study included 7 clinical sites, 6 in the United States and 1 in New Zealand. Each site contributed 200 stroke survivors for a total of 1400 study participants.

The study used what has come to be called the CPI study method because it allows one to identify and analyze specific components of the stroke rehabilitation process to determine how each component contributes to outcomes.¹⁶ The CPI analyzes the content and timing of individual steps of the health care process, with the goal of improving clinical outcomes at the lowest necessary cost. It involves the development of a comprehensive database linking patient characteristics, treatment factors, environmental factors, and outcomes to examine simultaneously all factors that influence the care process.¹⁶

Because the effects of stroke can be wide ranging, it is a challenge to make the right match between a stroke survivor's needs and rehabilitation services. Failure to find the right fit can result in the wrong type of therapy or too little or too much of the right type of care for a patient. But we cannot allocate appropriate rehabilitation services to stroke patients responsibly (clinically and fiscally) if there is little scientific evidence showing the effectiveness of specific poststroke rehabilitation interventions for specific deficits. The main goal of the CPI stroke project is to identify empirically the patient factors and specific interventions in poststroke rehabilitation that are associated with better outcomes. Only those aspects of the project that are directly relevant to taxonomy development are described here.

Patient Characteristics, Processes of Care, and Outcomes

In a CPI study, practicing front-line professionals define the patient characteristics, the treatment processes, environmental variables, and outcomes (eg, change in FIMTM instrument score) to be studied.¹⁶

Patient characteristics. The study team selected a large array of relevant patient characteristics that also took into account the patient's prestroke history, social support, and cognitive functioning. The Comprehensive Severity Index (CSI) was our primary severity adjustment method.¹⁶⁻²⁵ The CSI provides an objective, consistent method to quantify patient severity of illness levels based on signs, symptoms, and physical findings of a patient's disease(s).¹⁷⁻²⁵

Processes of care. Details about therapist treatments, their intensity, duration, and so forth, were collected along with information about other treatment steps including use of intermittent pneumatic compression, time to first mobilization, time to first rehabilitation, pain management, presence and amount of psychiatric intervention, functional electric stimulation, bowel and bladder training programs, Foley catheter use, change position schedule, seating devices—pressure relief, review of imaging results, use of durable medical equipment, medications, nutritional support, and patient and family education topics.

Development of Standardized Documentation Forms

The initial intent of the stroke rehabilitation outcome study was to use information contained in existing rehabilitation patient chart documentation to examine process variables for poststroke patients. However, clinical representatives from the participating sites pointed out that detailed information about therapist treatments, their intensity, and duration are not typically available in current charts. They recommended strongly that if we were to succeed in determining best care (ie, most effective for a specific set of deficits), we must first have each member of the rehabilitation team describe precisely what he/she does. The participating sites recommended extensive clinical intervention documentation in a standardized format, something that had not been done before in rehabilitation care. The goal of this standard documentation format was to provide clinicians with a tool that would assist them in recording what treatments and interactions with the patient and/or family and/or other members of the care team occur during a treatment session, shift, or day. In developing and finalizing the documentation forms, great care was taken not to duplicate documentation that clinicians routinely record in other parts of the chart. The purpose of the new documentation forms was to document actual practice—not necessarily what will generate reimbursement or satisfy outside review boards.

Multidisciplinary teams of clinical specialists from participating study sites met weekly via telephone conference calls from the beginning of the study (March 2000) to discuss study issues, including how to conceptualize and design a specific intervention documentation form for each rehabilitation discipline. In addition, subcommittees of physicians, nurses, psychologists, social workers, and physical, occupational, recreational, and speech-language pathology therapists conducted conference calls for a period of 8 months to develop a documentation form to capture details about intervention nature, intensity, duration, sequence of care, and frequency of care necessary to create an accurate picture of the contribution made by that discipline to rehabilitation care.

As these subcommittees discussed interventions to include, it became apparent that clinicians in different parts of the United States practice differently. For example, some physical therapists use constrained-induced movement therapy; others never use this therapy. Following the CPI methodology, we included all interventions that were possible in any of the participating sites. This approach preempted disagreement among therapists during the development process as to what practices are best and allowed all therapists using the forms to document all therapies they performed.

As the subcommittees of clinical specialists from different centers worked together in developing the documentation forms, it also became apparent that practitioners in the same discipline from different institutions or parts of the United States use various terms to describe similar treatments. This required the subcommittees to develop common definitions of terms that could be used on the forms and thus ensure that the

data collected were based on a common vocabulary. Further, each clinical subcommittee decided on the frequency with which their form would be completed to have an adequate picture of changes in the type or intensity of therapies rendered over a patient's stay. Some of the forms are used for every patient encounter (physical therapy [PT], occupational therapy [OT], recreational therapy, speech-language pathology therapy), others for every shift (nursing), and others are multiday forms (medicine, social work).

When the subcommittees completed the "final first" draft of their form, each site representative used the form with actual patients. Form utility and content were then tested on a limited basis; comments were brought back to the subcommittee and used to continue form revision. This preliminary testing went on for about a month before the forms underwent a 1-month pilot test in which clinicians used the forms on many unidentified patients. Again, comments contributed to form revisions.

Each subcommittee developed the content of their documentation form as they deemed appropriate, not based on burden of completion; however, completion burden was a big concern. The pilot test at the end of the development process found that documentation forms for each therapy session took between 30 seconds and 3 minutes to complete. Clinical staff members did not find them overly burdensome. After approximately 9 months of use, clinicians in each rehabilitation specialty estimated the average number of minutes to complete the standardized documentation for 1 therapy session was less than 2 minutes with a median of less than 1 minute.

Each study site received a syllabus cum training manual that contained paper and electronic copies of each clinical discipline's intervention documentation form, instructions for completing each form, and definitions for all terms used on each form. Written case studies were also included to show how to complete each form based on a patient scenario. Additional case studies were used to evaluate the trainees' understanding of the instructions. Representatives from each site's clinical disciplines participated in telephone training sessions specific to that discipline. After the telephone training session, each site's clinical leaders conducted on-site training sessions for their coworkers. Follow-up telephone conference calls for each clinical specialty group were conducted during the 2 months after training to provide an opportunity for clinicians to discuss implementation issues and ask questions of their peers in other institutions.

To show the process used by each of the 8 clinical specialty groups, we describe the development of the PT classification scheme.

The PT Classification Scheme Development and Use

The PT intervention classification scheme was developed through the combined effort of 1 or more physical therapists from each of the study's initial 5 participating rehabilitation centers in different regions of the United States. The process began with discussions of the conceptual framework for PT interventions used in poststroke rehabilitation and consideration of potential classification schemes. The subcommittee began by examining the *Guide to Physical Therapist Practice*,²⁶ which is a thorough description of practice developed by the American Physical Therapy Association using expert consensus. The *Guide* was not developed as an intervention classification scheme, but it does provide an extensive list of interventions used by physical therapists for various patient and client diagnostic groups, which are termed practice patterns. The practice pattern that includes the diagnosis of stroke lists 48 major intervention categories. However, after careful review, the PT subcommittee determined that the interventions

listed in the *Guide* were not organized to allow for a clear and distinct classification of interventions and lacked a conceptual framework that was suitable to reflect actual practice. Therefore, we did not use the interventions listed in the *Guide*, but we used the *Guide*'s terminology and definitions whenever possible.

Subcommittee members discussed the theoretical underpinnings of the various therapeutic approaches used in stroke rehabilitation to identify appropriate organizing themes for classifying PT interventions. Our goal was to develop a stroke intervention classification scheme that captured the complexity of treatment with sufficient detail to distinguish different interventions while simultaneously maintaining parsimony. The group agreed on using functional activities as a key organizing theme or classification dimension for PT interventions because this approach emphasizes the importance of functional activities as a critical component in various therapeutic approaches. Figure 1²⁷⁻²⁹ is a schematic diagram of the conceptual framework underlying the intervention classification system for PT. It identifies 10 functional activities that serve as the core organizing feature. These 10 functional activities are important to patient goals and functional outcome measures and include key activities with a range of difficulty from elemental (bed mobility) to advanced (community mobility).

We identified body systems as a second classification dimension. The neuromuscular, musculoskeletal, cardiopulmonary, and cognitive/perceptual/sensory body system dimensions further classify various interventions because, after a stroke, impairments in any or all of these systems can impede performance of functional activities and PT interventions are directed at minimizing these affects. Figure 1 also shows the classification of PT interventions organized by the body systems they target. The 2 main dimensions, functional activities and body systems, when combined, maximize the level of detail that can be captured. These dimensions also yield numerous combinations that capture the multidimensionality of clinical practice. They are a conceptually sound and efficient way to categorize PT interventions. A therapy session is often structured around functional activities that appropriately challenge a patient's functional ability, and, in the context of these activities, interventions are directed at ameliorating the specific impairments that limit function. Thus, the functional activity and body system dimensions of the classification system reflect critical aspects of clinical practice. As figure 1 shows, neuromuscular interventions (1-8) are always done in the context of a functional activity. Musculoskeletal interventions (9-13) and modalities (27-29) can be done in the context of a functional activity or separate from a functional activity and directed toward a specific area of the body, such as the upper extremity (60), lower extremity (61), trunk (62), or head and neck (63). Interventions for impairments in cardiopulmonary (14, 15) or cognitive/perceptual/sensory systems (16-19) can be done in the context of a functional activity or separately. Other generic interventions, such as education (20-22), pet therapy (30, 31), and assistive devices (32-58), are not specific to a body system and can be done in the context of a functional activity or separately, whereas interventions related to equipment (23-26) and patient assessments are always documented separate from functional activities.

The documentation form in use. To complete the documentation grid, a therapist records the duration of each activity in 5-minute intervals and lists codes for the interventions used. Time for formal assessments, home evaluation, and work site evaluations are recorded separately. We describe interventions and demonstrate coding of a PT treatment session for a patient with left-sided hemiparesis and hemi-inattention. The 45-

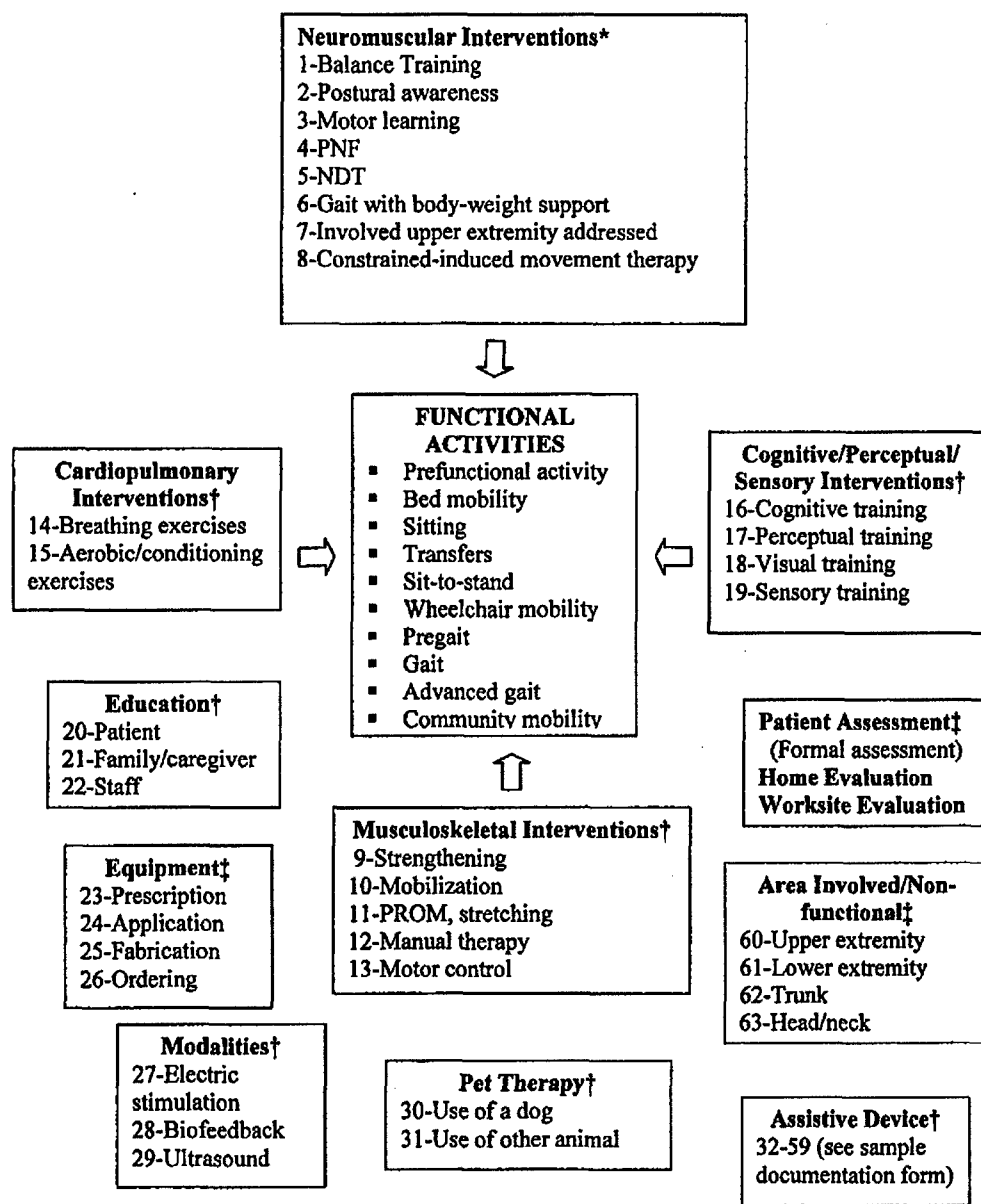


Fig 1. Framework of the intervention classification system in poststroke PT. *Always documented in the context of functional activities. †Documented in the context of functional activities or separately. ‡Always documented separate from functional activities. Abbreviations: NDT, neurodevelopmental treatment; PNF, proprioceptive neuromuscular facilitation; PROM, passive range of motion.

minute treatment session consisted of 4 functional activities directed at impairments in 4 body systems and shows the complexity and multidimensionality that is captured by the intervention classification system. Figure 2 presents a completed documentation form that shows intervention coding. As the example illustrates, the documentation form provides an efficient method to describe the details of a complex PT intervention.

The PT session began with a transfer from the wheelchair to the mat table (duration of transfers activity, 5min). The therapist and patient discussed the steps involved in transferring safely (patient education is code 20) and awareness of the left arm and leg during the transfer was emphasized (perceptual training is code 17). After the transfer, the therapist worked on sitting balance (duration of sitting activity, 15min) by having the patient clasp the involved and noninvolved hands together and reach targets placed to the left, right, and forward (balance training is code 01; involved upper extremity addressed is code

07). Targets to the left were emphasized and the patient was instructed to visually scan the left visual field to find the targets (code 17). Initially, the therapist used manual and verbal cues to encourage proper alignment of the trunk (neurodevelopmental treatment is code 05) and then encouraged the patient to self-assess and correct alignment (motor learning is code 03). During the forward weight shift, the activity transitioned into preparation for standing (duration of sit-to-stand activity, 10min) and the therapist used manual and verbal cues to encourage the patient to maintain midline alignment of the trunk (code 17; code 05). The involved lower extremity was positioned to bear more weight on the left, and the patient completed 10 repetitions of moving from the seated position to holding in a squat position for a few seconds (strengthening is code 09). The patient was asked to remember the steps required for a safe transfer and transferred back to the wheelchair. The patient then worked on walking (duration of gait activity, 15min) with body-weight support (gait with body-weight sup-

port is code 06; assistive devices, ankle dorsiflexion assist is code 32; lite gait is code 44). While walking, the patient used a target on the floor to guide placement of the left foot during stepping (code 03) and was instructed to work to fatigue before resting (aerobic/conditioning exercises is code 15).

Integration Across Disciplines

The study team sought a high level of conceptual integration across the disciplines. The 2 main conceptual dimensions used in PT, functional activity and body system, also served as the 2 main axes for the other 2 main rehabilitation therapies, OT and speech therapy. Every effort was made to use, wherever possible, a common language and nomenclature allowing for differences to occur in describing activities that are specific to each of the 3 therapies.

Documentation forms for other disciplines were designed somewhat differently and sought to capture intervention information that might not relate to the 2 dimensions noted earlier. For example, physicians, nurses, and social workers are heavily involved in care coordination activities,—for example, dealing with payers, discharge planning, and community reentry—and thus, care coordination became a principal component across these disciplines.

One drawback in some of the study's documentation forms was that—in an effort to minimize clinical staff burden—they were intended to supplement information already collected. The next step would be to integrate intervention classification schemes with typical assessments and intervention documentation into a comprehensive documentation format that would replace fragmented documentation processes that currently exist. The study's database, however, lets investigators integrate data from all known sources in a conceptually consistent manner.

CRITERIA FOR AN INTERVENTION CLASSIFICATION SYSTEM

Various observers^{10,30,31} have proposed criteria for a sound intervention classification system. Building on their suggestions, we propose several potential criteria that can help put the findings of the present study into a broader perspective and help lay the foundation for a future rehabilitation classification system.

1. Theoretical integrity. The classification, whether developed deductively or inductively, makes theoretical and conceptual sense.
2. Domain completeness. The system addresses all the key domains of clinical intervention under review.
3. Multiple dimensions. The system captures the multidimensionality of the interventions where such multidimensionality exists.
4. Granularity. The system provides a sufficient level of detail to adequately describe and characterize the group of interventions under review.
5. Parsimony and nonredundancy. The system describes the interventions, including complex interventions, in an efficient, nonburdensome, and nonredundant way.
6. Clinical and research utility. The system is viewed as useful in the everyday practice of clinicians, researchers, and third-party users.
7. Reliability. The system is used and interpreted similarly across different treatment settings, different users, different diagnoses, and across time.
8. Future development. The system allows for growth and development as new interventions are developed and introduced into clinical practice.

Few, if any, classification systems can meet all the criteria simultaneously. Although the criteria are not necessarily mutually exclusive, future rehabilitation classification systems will entail some degree of trade-off. For example, the domains completeness (criterion 2) and granularity (criterion 4) are likely to compete with parsimony (criterion 5). The selection of criteria should be dictated by the primary purpose or application of the taxonomy under development: scientific description of practice, routine documentation, and billing for services.

Study Limitations

We cannot state with certainty that our approach to rehabilitation intervention description and classification meets all of these proposed criteria. Most of them are inherently subjective. We lack external benchmarks by which to determine whether the proposed criteria have been partially or fully attained. We can, at this time, report the subjective views of our study investigators and clinicians who used the study's classification and documentation system. They report, for example, that the complexity of rehabilitation (ie, criteria 2, 3, 4) was easier to capture than was first thought. In other words, despite the complexity, we were able to characterize interventions in a fairly parsimonious way (criterion 5). Participating clinicians believe that the classification and documentation system developed for stroke rehabilitation study can greatly improve traditional clinical documentation systems when these process recordings are added to traditional recordings of patient functional status and disease progression. We do not know whether this classification and documentation system can be generalized to other diagnostic groups served by rehabilitation or to different settings (eg, subacute or outpatient care). Nor is there evidence at this time that all significant interventions used in stroke rehabilitation are captured, or captured with sufficient detail, by the taxonomy as developed to date.

Empirical research is also needed to provide evidence of reliability (eg, interobserver reliability, recall bias), completeness of data, and the intervention data's relevance to patient outcomes. Many of these issues must be addressed before the study's approach can be recommended for widespread clinical use. Nonetheless, the study investigators obtained a high level of clinical input and consensus, sought a high level of conceptual and linguistic integration, conducted extensive pilot testing, prepared supplementary materials (eg, user guides), and provided extensive training—all of which bode well for both validity and interrater reliability.

IMPLICATIONS FOR FUTURE DEVELOPMENT

Clinical Practice Guidelines

The degree to which the participating clinicians have embraced the study's classification and documentation systems as addressing what they do in everyday practice bodes well for the development of future rehabilitation classification systems. And a sound rehabilitation classification system may, for example, help overcome the lack of specificity that often characterizes CPGs and best practice standards, thus reducing their utility in actual practice.³² In the future, rehabilitation classification systems may aid in the development of decidable and executable CPGs and best-practice standards, that is, CPGs and standards with specific process steps to follow based on deviations of a patient's signs and symptoms from normal values and deficits.

Electronic Medical Records

Further, parsimonious classification and documentation systems may aid the development of electronic medical records in

rehabilitation. Rehabilitation's inter- and multidimensional approach presents a daunting challenge to the development of an electronic medical record for medical rehabilitation. The initial results from the present study suggest that the task may not be quite as conceptually intimidating as first feared, although one should never underestimate the challenges of creating an electronic medical record.

Rehabilitation Research

The implications of intervention taxonomies for rehabilitation research are far reaching. They may help to standardize data collection on treatment interventions that will enable us to compare results across studies and across sites. Rehabilitation researchers have achieved a fairly high degree of standardization with respect to outcome measurement with the FIM instrument already an industry standard. Standardization on the input side will greatly strengthen our ability to make comparisons across an even wider range of interventions and outcomes.

In some investigations, the treatment administered may not be an independent variable, as in our stroke outcome study, but a dependent variable. For example, with a rehabilitation treatment taxonomy and measurement system, it becomes possible to examine the effects of independent variables such as organizational change (eg, hospital reorganization, new management information system) and health policy change (eg, new reporting systems, new payment systems) on the mix of services actually rendered. Front-line clinicians often assert that external changes adversely alter their daily practice patterns, but the ability to document these changes is lacking. A rehabilitation taxonomy and measurement system may enable us, for the first time, to quantify what changes really happen in the clinical setting when structural changes are imposed from the outside. It may enable us to eliminate our reliance on time-and-motion studies, billing office data, and other surrogate measures—that many find lacking—for what happens in the clinical setting.

CONCLUSIONS

Our approach to developing a study-specific rehabilitation taxonomy suggests that an inductive or bottoms-up approach is a promising, but not fully tested, way to develop a comprehensive rehabilitation taxonomy. The development of rehabilitation intervention taxonomies is currently in its infancy and promises to grow into a more mature intellectual and research enterprise in the years ahead. As the rehabilitation research community embarks in this area of research, we hope that our experiences in the present study may help inform the options for future research and development in rehabilitation intervention taxonomy.

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Research Report

Physical Therapy Interventions for Patients With Stroke in Inpatient Rehabilitation Facilities**Diane U Jette, Nancy K Latham, Randall J Smout, Julie Gassaway, Mary D Slavin, and Susan D Horn****Invited Commentary | Related Letters**[Click here for the PDF version of this article.](#)

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Background and Purpose. The purpose of this study was to describe physical therapy provided to patients with stroke in inpatient rehabilitation facilities. **Subjects and Methods.** Data were collected from 972 patients with stroke receiving physical therapy services at 6 rehabilitation facilities in the United States. Descriptive statistics were derived to describe physical therapy sessions, including proportion of therapy time spent in specific functional activities and proportion of those activities that included any of 59 interventions. **Results.** Mean length of stay was 18.7 days (SD=10.3), and patients received physical therapy, on average, 13.6 days (SD=7.8). Patients attended, on average, 1.5 (SD=0.3) physical therapy sessions per day, with each session lasting 38.1 minutes (SD=17.1). Gait and prefunctional activities were performed most frequently (31.3% and 19.7% of total treatment time, respectively). For gait activity, physical therapists used balance and postural awareness training in more than 50% of sessions and used strength training for more than 50% of sessions of prefunctional activities. Eighty-six percent of the patients received evaluation, and 84% of the patients and families received education. **Discussion and Conclusion.** Therapists selected an eclectic approach to intervention rather than specific intervention techniques. The approach to patients' care included interventions to remediate impairments and to compensate for functional limitations. Therapists also reported frequently using motor control and motor learning approaches to facilitate all activities. This approach to care is largely consistent with existing stroke care guidelines and advances in the scientific theories of motor control and motor learning. [Jette DU, Latham NK, Smout RJ, et al. Physical therapy interventions for patients with stroke in inpatient rehabilitation facilities. *Phys Ther*. 2005;85:238-248.]

Key Words: *Physical therapy, Rehabilitation, Stroke*

According to data from the National Health and Nutrition Examination Survey (NHANES I, II, and III), there were 3.7 million people aged 25 years or older reporting a history of stroke in the United States in 1991.¹ In 1994 alone, there were 457,000 patients aged 25 to 74 years discharged from hospitals with an underlying diagnosis of stroke.¹ Only 8.9% of those patients were discharged to a long-term care facility,² suggesting that the remainder were discharged to rehabilitation settings or to their home. Indeed, in a study using data from the Uniform Data System for Medical Rehabilitation (UDSmr) in 1999, Tesio et al² found that approximately 58,000 patients with stroke who survived and had a

rehabilitation admission of less than 1-year duration had been admitted to rehabilitation facilities within 90 days of symptom onset. On admission to a rehabilitation facility, these patients scored, on average, less than 5 ("completing a task with supervision," where 1="total assistance" and 7="complete independence") on all 13 motor items of the Functional Independence Measure (FIM).⁴

The 1995 Agency for Health Care Policy and Research (AHCPR)⁴ clinical practice guideline for poststroke rehabilitation³ and the 1999 Royal College of Physicians (RCP) *National Clinical Guidelines for Stroke*¹ recommend that patients with acute stroke receive care provided by rehabilitation professionals who are experts. Furthermore, a systematic review of the literature published in 1999 showed support for early implementation of rehabilitation interventions for improving functional outcomes for patients with stroke.⁵ A study conducted in Switzerland and Belgium in 2000 showed that, following stroke, patients engaged in therapeutic activities 28% of the working day in Belgium and 45% of the working day in Switzerland.⁶ Physical therapy accounted for 77% and 70% of the therapeutic activity time in each country, respectively. Taken together, the information from these sources suggests that many patients with stroke each year are likely to receive physical therapy and that physical therapy comprises an important and a relatively large component of their rehabilitation.

The AHCPR³ and RCP¹ guidelines provide a framework for understanding the recommended strategies for physical therapists in providing care to patients with stroke. Several recommendations are particularly salient:

1. Examination/evaluation for all patients to determine baseline motor impairments and function.
2. For patients who have some voluntary control over movement of the involved limbs, exercises and training for remediation of impairments, including those to improve "strength" (the term used in the guidelines) and motor control and function and those designed to help the patient relearn sensory-motor relationships.
3. For patients with persistent movement and sensory deficits that cannot be remediated, teaching of alternative or compensatory methods for performing functional tasks and activities, including gait re-education, practice of activities of daily living (ADL), and community activities.
4. Patient and family education as an integral part of the rehabilitation process, particularly in moving and handling patients safely at home.
5. Individualized decisions about the prescription of adaptive and assistive devices (eg, ankle-foot orthosis, cane) only if other methods are not possible for completing an activity.

Despite evidence suggesting that physical therapy may be useful in rehabilitation of patients with stroke and recommendations for broad classifications of interventions based on clinical guidelines,^{3,4} the literature contains little information describing the precise nature of interventions provided by physical therapists. For the most part, reported studies have been conducted in countries outside the United States,⁸⁻¹¹ have described intervention only in terms of duration or frequency,^{7,8} have involved a limited number of patients,^{6,9,10} or have asked therapists about intervention choices for hypothetical patients.¹¹

Given the limitations of reported studies and a lack of information about how patients with stroke are managed by physical therapists in the United States, we undertook a study to describe the care provided by physical therapists for patients with stroke in 6 inpatient rehabilitation facilities in the United States. Our purpose was to describe the physical therapy plan of care in terms of the types of therapeutic activities engaged in by patients during physical therapy sessions; the interventions used by physical therapists during the activities; the duration,

frequency, and intensity of physical therapy sessions; and the personnel who provided them. We also examined the percentage of sessions that included examination/evaluation, the combinations of activities used most commonly during physical therapy sessions, and the percentage of patients or families who received some education from the physical therapist.

Method

Subjects

Data were collected between March 2001 and August 2003 from consecutive patients with stroke seen at 6 rehabilitation hospitals in the United States. This care was provided by 86 physical therapists, physical therapist assistants, physical therapy aides, and students. Data were collected as part of a large multicenter study of stroke rehabilitation. One thousand twenty-six patients were enrolled in the study at the 6 US sites. Sites were in northern California, southern California, Oregon, Utah, Pennsylvania, and Washington, DC. Inclusion criteria included a diagnosis code (ICD-9 CM)³² of 430 to 438.99, age greater than 18 years, recent stroke (within 1 year of admission) as the reason for admission, and no interruption in rehabilitation services of greater than 30 days. The data analyses in this article are based on 972 patients who received physical therapy during their rehabilitation stay. The mean age of those patients was 66.1 years (SD=13.3, range=18-95). Men comprised 50.7% and women comprised 49.3% of the sample. Fifty-six percent of the patients were white, 24.4% were African American, 4.7% were Asian, and the remaining patients were of other races. Forty-three percent of the patients had left-sided hemiplegia, 44% had right-sided hemiplegia, 10% had bilateral involvement, and the remainder had other types of involvement.

Procedure

Similar to a previous observational study related to physical therapist practice,³³ therapists used data collection forms to record interventions they used during each physical therapy session with a patient across the episode of care. Physical therapy data collection forms and definitions were developed by physical therapists from the centers involved in the study to describe processes of care and interventions used in physical therapy across settings. The interventions were largely derived from the *Guide to Physical Therapist Practice*³⁴; however, the therapists were encouraged to identify the full scope of interventions that they used in their practice. Instructions for completing the forms and definitions of all terms related to activities and interventions listed on the forms were supplied in a training manual to those individuals providing care. One physical therapist at each site participated in a train-the-trainer session under the direction of the project team and then provided training to other therapists in his or her rehabilitation unit. Training consisted of sessions with colleagues using specific case examples to identify, correct, and confirm interventions checked by the various therapists attending. The physical therapists in charge of training at each site were designated as resources for questions related to data collection and recording as the forms were used on a daily basis. Each site developed internal auditing methods to ensure that data collection forms were used as intended. Verbal reports of progress and challenges or questions about form use were discussed during weekly telephone conferences that included the project team and at least one clinical representative from each site.

Data collection forms allowed physical therapy providers to describe treatment sessions in terms of categories of activities: prefunctional, bed mobility, sitting, transfers, sit-to-stand, wheelchair mobility, pre-gait, gait, advanced gait, and community mobility. Therapists could identify one or more activities that they worked on with the patient within a session. Within each of these activity categories, therapists recorded the amount of time spent on the activity with the

patient and up to 5 specific interventions that they used during the performance of that activity. Therapists could select from 59 interventions, including 8 neuromuscular, 5 musculoskeletal, 2 cardiopulmonary, 4 cognitive/perceptual, 3 educational, 4 equipment related, 3 modalities, and 2 pet therapy interventions.

Interventions reflected both specific techniques, such as proprioceptive neuromuscular facilitation (PNF) or neurodevelopmental treatment (NDT), as well as general theoretical approaches to intervention, such as motor relearning. Twenty-seven types of equipment were listed. One category was provided for writing in interventions not provided on the form. This large list of interventions, developed through the effort of those providing care at the sites involved in the study, allowed therapists to choose from a broad range of possible interventions defined by them in ways that they would understand. The forms also allowed therapists to record the amount of time patients spent being examined and evaluated, in co-treatment with other disciplines and in therapy sessions that included more than one patient. Additional information was reported regarding which providers gave the care during the session, including physical therapists, physical therapist assistants, and students (Figure). Data regarding patient characteristics were collected from patients' medical records following their discharge by trained data abstractors from each institution.

Data Analysis

Descriptive statistics were derived to examine characteristics of the patients and characteristics of their episodes of care, including length of stay, number of days physical therapy was provided, number of physical therapy sessions per day, and number of days physical therapy was provided divided by the total length of stay. The content of treatment sessions was described by determining the duration of each session, the proportion of all physical therapy time spent directed to the activities listed above, and the proportion of those activities that included specific interventions. We also examined the proportion of all physical therapy sessions in which more than one patient was treated by a single provider and the proportion of sessions for which physical therapists, physical therapist assistants, or students were involved in care. In addition, we determined combinations of activities provided to patients during sessions, the proportion of sessions that included examination/evaluation, and the proportion of patients and families who received an educational intervention.

Results

The 972 patients included in this study participated in 21,192 physical therapy sessions during inpatient rehabilitation. The mean length of stay in the rehabilitation setting, or episode of care, was 18.7 days (SD=10.3, range=1-75) (Tab. 1). Patients received physical therapy, on average, 13.6 days (SD=7.8, range=1-54) during an episode of care, or 73% of the days during their stay in the rehabilitation hospital. The average number of physical therapy sessions per day was 1.5 (SD=0.3, range=1-3), and the average time for each session was 38.1 minutes (SD=17.1, range=5-360). Approximately 64% of the sessions were attended by physical therapists, 30% by physical therapist assistants, 9% by physical therapy aides, and 7% by students. In approximately 93% of sessions, only one physical therapy provider was present. In addition, approximately 4% of sessions consisted of co-treatment with another discipline. In approximately 10% of sessions more than one patient was treated by a single provider at one time (Tab. 2).

Eighty-six percent of the patients had some examination/evaluation time recorded. Approximately 7% of all sessions included some examination/evaluation, and 5% of all sessions included only examination/evaluation. Table 3 provides data on the types of interventions therapists used in facilitating therapeutic activities with their patients. Only those interventions included in at least 5% of the sessions for any

activity are included in the table. Of a total of 18 types of procedural interventions from which therapists could choose to characterize their care of patients, 13 were used during at least 5% of the sessions that included a particular activity. Equipment interventions, pet interventions, and modality interventions were done during less than 5% of the sessions for each activity.

In approximately 78% of the sessions, patients engaged in training in more than one activity. Gait training, prefunctional activities, and transfer training activities were the most frequently addressed activities (31.3%, 19.7%, and 10% of total treatment time, respectively). *Gait activities* were defined as activities focusing on skills needed for ambulation over level surfaces and stairs. Interventions provided most frequently to address gait were balance training, postural awareness training, and motor learning (included in 60.5%, 50.2%, and 40.5% of the gait activities, respectively). *Balance training* was identified as intervention designed to help maintain the body in equilibrium with gravity both statically and dynamically. *Postural awareness training* was defined as an intervention designed to improve awareness of the alignment and position of the body in relationship to gravity, center of mass, and base of support. *Motor learning* was defined as providing practice or experiences leading to change in the capability for producing skilled actions.

Prefunctional activities were those determined to be in preparation for later functional activity or activities that physical therapists provided on behalf of the patient without necessarily having direct contact with the patient. In all sessions that addressed prefunctional activities, the interventions most frequently provided were strengthening exercises, balance training, and motor learning (included in 58.2%, 24.4%, and 24.3% of prefunctional activities, respectively). *Strengthening exercises* were described as interventions where muscular contractions were resisted by an outside force applied manually or mechanically.

Transfer activities were defined as activities focusing on relocating the body from one surface to another. The interventions most frequently provided to address transfer ability were balance training, postural awareness training, and motor learning (included in 49.6%, 48.0%, and 51.0% of transfer activities, respectively).

Equipment was used most commonly during gait activities and included 4-wheeled walker, ankle-foot orthosis (AFO), and straight cane (included in 22.9%, 17.0%, and 20.2% of gait activities, respectively). During at least one physical therapy session during their admission, 32% of the patients used an AFO, 62% used a form of cane, 55% used a walker, and 30% used a wheelchair. Wheelchair mobility activities were included during less than 2% of the total treatment time.

Overall, 84% of patients or their families received some educational intervention. Patient and caregiver education was most frequently included during transfer activities, advanced gait activities, and community mobility activities.

Discussion

To our knowledge, this study is the first to describe physical therapist management of patients with stroke in terms of specific interventions provided during an episode of care in multiple inpatient rehabilitation settings in the United States. Over the past 30 years, the literature on physical therapy interventions for patients with stroke has described these interventions largely in a nonspecific and qualitative manner.¹⁵⁻¹⁷ A report from 1969 describes the elements of physical therapist management for patients with stroke as including many of the interventions used frequently by the physical therapists in this study: strengthening exercises, bed mobility and sitting activities, transfer and gait training activities, facilitation of motor control, and use of equipment such as AFOs

and straight and wide-based canes with patients.¹⁶ In 1978, a similar descriptive report included recommendations for most of the same interventions as those described in 1969.¹⁵

The finding that some interventions described in our study have been used in stroke rehabilitation for the past 30 years is not surprising because the basic armamentaria of physical therapists have not changed dramatically and the focus of care continues to be directed toward reducing impairments and facilitating function or adaptation to impairments. Our findings, however, are consistent with a shift in the physical therapy approach to management of patients with stroke from the specific reflex-based neurofacilitation techniques advocated in the 1960s, such as Bobath, Brunnström, Rood, and PNF, to an approach based on motor control and motor learning theories. In our study, physical therapists identified and defined interventions that they used in practice and could choose up to 5 different interventions to describe their approach to an activity. Although the therapists in our study listed PNF as an intervention, it was used in less than 5% of the sessions. Neurodevelopmental treatment, based on the Bobath approach, was listed as an intervention and used frequently in activities (6%-28%). Other generic interventions, such as balance training, postural awareness, and motor learning interventions, however, were selected more often. The fact that the physical therapists in our study infrequently chose techniques such as PNF during their sessions with patients provides evidence of this shift in therapeutic approach to management of patients with stroke.^{18,19} Our data do not allow us to fully explore which theories of motor learning or motor control influenced the physical therapists' therapeutic approach to care. The results suggest, however, that advances in scientific theories of motor control and motor learning may have had an influence on physical therapist practice.

The results of our study indicate that functional activities are a focus for physical therapist practice in stroke rehabilitation. That is, the majority of physical therapy session time was spent in functional activities. We also observed that many procedural interventions were integrated into more than one functional activity. Therapists used interventions to address a range of impairments in the context of functional activities. For example, the following procedural interventions were incorporated into transfer activities: balance training, postural awareness, motor learning, NDT, upper-limb activities, strengthening, motor control, cognitive training, and perceptual training. Thus, an approach in which functional training and neurofacilitation were separate activities¹⁹ seems to have been replaced by functional training that incorporates a multidimensional approach. An approach to neurorehabilitation focused on functional activities, as advocated by Carr and Shepherd,²⁰ disseminated via the proceedings of the II-STEP Conference in 1991,^{21,22} and interpreted by Shumway-Cook and Woollacott,²³ seems to have been adopted by physical therapists involved in stroke rehabilitation.

The AHCPR clinical practice guideline for rehabilitation of people after stroke noted that physical therapy interventions for patients with stroke could be classified into 3 categories: (1) "remediation," exemplified by use of neuromuscular facilitation, sensory stimulation, and resistive training to redress impairments; (2) "compensation," emphasizing independence in basic ADL by teaching patients adaptive techniques using the noninvolved side when they are unable to use the involved side; and (3) "motor control," encouraging practice of activities under specific, real-life conditions.³ The guidelines provided recommendations that supported physical therapy interventions based on each of these approaches. The guidelines from the RCP⁴ recommended that patients see a therapist "each working day if possible" and that patients receive as much therapy as they could tolerate. They further recommended that gait re-education be offered, although no specific techniques could be recommended on the basis of evidence. Duncan et al²⁴ reported that adherence to AHCPR guidelines was associated with improved functional outcomes in patients.

The recommendations from both sets of guidelines are broad and recognize the patient's impairments as important factors in determining the appropriate approach to intervention. If the 3 approaches to intervention suggested in the AHCPR guidelines are valid, however, our findings indicate that therapists use all 3 approaches in their care of patients. Moreover, most sessions (~78%) addressed more than one activity. This "eclectic" approach seems consistent with the RCP guidelines,⁴ which note that there is no evidence to support the superiority of one approach over another. An approach to care that includes several activities at each session is consistent with findings related to care provided by physical therapists to patients with musculoskeletal conditions.¹⁰ An "eclectic" approach to management of stroke also has been reported by therapists practicing in the United Kingdom.²⁴

A "motor control" approach is suggested by the high percentage of therapy time (~54%) spent with the patient engaged in one of the following functional activities: bed mobility, sitting, transfers, sit-to-stand, or gait. Therapists indicated that they frequently incorporated a motor learning (~53%) or motor control (30%) approach as a procedural intervention. In our study, *motor learning interventions* were defined by consensus among the participating therapists as targeting impairments in the neuromuscular system and providing practice or an experience leading to change in the capability for producing skilled action. *Motor control interventions* were defined as targeting impairments in the musculoskeletal system and encouraging purposeful movement and postural adjustment by selective allocation of muscle tension across joint segments. Some people might argue that the definitions of motor control and motor learning are inadequate because they could define the basis for many types of interventions such as NDT or wheelchair mobility. Because a therapist in our study could identify up to 5 types of interventions for each activity, motor control, motor learning, and NDT, for example, could have been selected to describe a therapist's approach to facilitating an activity with a patient. The literature supports the fact that a lack of a conceptually sound, theory-driven system for classifying interventions is a problem that limits advances in the understanding of rehabilitation in stroke.²⁵

A "remediation" approach to rehabilitation was suggested by prefunctional and pre-gait activities. Almost 20% of all therapy time was spent on prefunctional activities such as strengthening and range-of-motion exercises that were not part of a functional activity. A remediation approach also might include the use of modalities such as biofeedback or functional electrical stimulation. Despite some evidence suggesting the efficacy of electromyographic biofeedback^{26,27} and functional electrical stimulation^{28,29} in stroke rehabilitation, these interventions, which were first introduced in the late 1970s, are not supported by the guidelines and appear not to have been adopted widely by therapists in our study. Data indicate that biofeedback and functional electrical stimulation were used in less than 1% of the interventions.

Recently, there has been interest in 2 new approaches to stroke rehabilitation that might be considered to represent a remediation approach to intervention. These approaches include constraint-induced movement therapy, extensive practice for involved upper-limb rehabilitation,¹⁷ and weight-supported gait training.³⁰ Therapists in our study used constraint-induced movement therapy infrequently (<1% of sessions), and, despite a large percentage of time devoted to gait training by therapists in our study, weight-supported gait training was used in less than 5% of all sessions.

In our opinion, the use of an AFO, cane, and walker for gait activity by some patients may indicate the use of a "compensatory" approach, as suggested by the AHCPR guidelines.³ A high proportion of treatment time also was spent on transfer training. In some patients, this activity may involve teaching the patient a compensatory strategy for safely moving from surface to surface. Interestingly, in patients with stroke, the greatest functional impairment as well as the greatest

Improvement has been shown to be in locomotion and transfer ability.³² Therapists in our study may have addressed these activities frequently because patients displayed low levels of ability in these areas at admission and disability in these areas is amenable to improvement. The focus on gait training also is supported by the RCP guidelines.⁴ Our findings also indicate that therapists spend a great deal of time in therapy working on balance training, but this intervention is not directly supported by the AHCPR guidelines.

Education of the patient and family was included in a fairly low percentage of sessions for each activity and in only approximately 7% of the sessions overall. At first glance, this finding does not appear consistent with either set of guidelines. In our opinion, however, teaching the family can often be accomplished in relatively few sessions, and we would not expect family members to be present during most sessions. Overall, 84% of the patients or their families received some educational intervention, thereby suggesting adherence to the guidelines. Education of patients and families in our study tended to be most prevalent in addressing high-level (advanced gait and community mobility) and low-level (transfers) activities. In our opinion, these are activities for which patients may require the most input or help when they return home, depending on their level of mobility skills.

Given our lack of data on specific impairments, we were unable to determine if the AHCPR³ and RCP⁴ guidelines' recommendations for use of adaptive and assistive devices were followed. The finding that 30% of the patients used a wheelchair during at least one physical therapy session and the finding that only 2% of total treatment time was used for wheelchair mobility training suggest that the patients may have used wheelchairs for a short period of time during their rehabilitation stay. It seems likely, given the focus on gait training, that physical therapists would work to transition patients from wheelchair to walking mobility. This finding would be consistent with guidelines that suggest adaptive and assistive devices be used only if other methods are not possible for completing an activity. The majority of patients used a cane or a walker during at least some of the treatment sessions.

In our study, physical therapy was provided to patients on 73% of the days during their rehabilitation stay. This finding is consistent with an approach to rehabilitation in which physical therapy is provided on weekdays and not on weekends and appears to be consistent with the RCP guidelines that provide a level B recommendation for therapy every "working day."⁴ The RCP guidelines also provide a level A recommendation for patients receiving as much therapy as they can tolerate. In our study, patients received approximately 38 minutes of physical therapy per session and an average of 1.5 sessions of physical therapy on those days that they received physical therapy. Ninety-eight percent of the patients also received occupational therapy for an average of 41 minutes per day across the entire length of stay. It is unclear whether this amount of therapy represents the limits of patients' tolerance. The finding is interesting, however, in light of the Medicare requirement for acute rehabilitation admission that the patient be able to tolerate 3 hours of therapy per day.³²

Our study has some important limitations. Although detailed information about stroke severity and medical condition was collected, we did not have data on patients' specific impairments such as loss of voluntary motor control. We were unable, therefore, to relate the choice of interventions to impairment as suggested by the stroke guidelines.^{3,4} Because our aim was to describe physical therapy activities and interventions, this report does not suggest that any one intervention or combination of activities results in better functional outcomes for patients. Two previous studies^{23,32} have shown that better outcomes for patients are associated with settings' higher rates of adherence to clinical practice guidelines.

Another limitation is that we did not specifically test the reliability of the data collection within or among providers. Although physical therapists in the settings

we studied were trained in the use of data collection forms and written definitions were provided in a training manual, there are potential limitations in data reliability due to interpretation of the categories of interventions and activities. A problem with interpretation may have resulted in some misclassification of interventions and activities. In our opinion, these random errors are likely to have a small effect on the overall findings because data were collected from a large number of participants (N=972) over many sessions (>20,000). Insofar as any definitions may have inaccurately represented the interventions, however, there is a chance for systematic error. Definitions provided to therapists were somewhat broad and did not allow identification of very specific and detailed descriptions of treatment that might include, for example, how a physical therapist approaches balance training with a patient, what tone of voice is used, how much rest is given, or how challenging the activity is for an individual. Despite this lack of specific detail, to our knowledge there is no other published study that reports this degree of description of physical therapy for a large number of patients with stroke who received care in multiple facilities. This approach to data collection may be considered a first step to further refining descriptions of physical therapy interventions.

Conclusion

Physical therapy provided to patients with stroke in inpatient rehabilitation facilities reflected an integration of treatment approaches with inclusion of interventions to remediate impairments and compensate for functional limitations as well as to improve motor control. The care appears to adhere, in general, to stroke guidelines published in the literature. The largest percentage of time in physical therapy sessions was spent on gait activities. Balance training, postural awareness training, and motor learning were included in a majority of treatment sessions. Nearly all patients were provided with an examination/evaluation, and they or their families were provided with education by the physical therapy providers.

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*Although currently called the Agency for Healthcare Research and Quality, the guidelines were developed by the agency under the name held by it in 1995. We will refer to the guidelines by the AHCPR acronym.

Opening the Black Box of Stroke Rehabilitation with Clinical Practice Improvement Methodology

Brendan E. Conroy, Brooke Hatfield, and Diane Nichols

Although stroke survivors are the largest consumer group for postacute rehabilitation services, there has been little quantification of the details of poststroke rehabilitation (PSR), with the major exception of the AHCPR Clinical Practice Guidelines #16 of 1995. The gold standard research methodology of a randomized controlled trial cannot practically encompass PSR. Using clinical practice improvement (CPI), a statistically based, validated research methodology, a mathematical representation of the inpatient stroke rehabilitation experience has been constructed. This article examines the principle aspects of CPI methodology and how it was adapted to a multicenter study of inpatient PSR. **Key words:** *best practice, clinical practice improvement, Comprehensive Severity Index, methodology, outcome(s), practice variation, regression, rehabilitation, stroke, TeleForm*

Poststroke rehabilitation (PSR) is a powerful, complex, and expensive medical therapy that is provided for many thousands of stroke survivors each year. The American Medical Rehabilitation Providers Association (AMRPA) eRehab database¹ has data on 25,853 patients for calendar year 2004, with an average cost of \$18,000 per stay, worth approximately \$465,354,000. Even though prescribing providers may write orders for a stroke rehabilitation program to include 5–6 days per week of physical therapy (PT), occupational therapy (OT), speech language pathology (SLP), psychology, and around-the-clock rehabilitation nursing care, the full extent of what the patient receives is not exactly known. Acute inpatient stroke rehabilitation is a “black box” into which the prescriber and the insurer place a patient, money, and a team of rehabilitation providers, mix them up, let the black box work its magic, and, 18–20 days later, out pops a patient on their way home (usually) and with the money consumed. Even the prescriber, who usually follows the patient during the rehabilitation stay, has no precise, quantified idea of what the patient is experiencing. Insurance carriers typically must be satisfied with weekly progress reports and a projection of the expected discharge date and disposition.

Background

With health care costs escalating dramatically through the 1980s, there was a major change in the way hospital beds were utilized and how hospitals were reimbursed. Health care providers were held more accountable for their clinical decisions and resource consumption through guidelines put in place by payers. Payers required increased documentation from clinicians to justify what was being done with patients to ensure quality of care and to justify the cost of care. Then, in an effort to contain costs, payers wanted to know that the treatment provided was actually necessary. And,

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more than that, payers wanted the treatment to be cost effective. In 1982, Lind² reviewed seven studies on the effectiveness of stroke rehabilitation. The results were conflicting. Three studies showed a positive effect as a result of rehabilitation; three studies showed no effect; and the seventh study showed a negative effect, also noting that physical therapy was associated with creating shoulder-hand syndrome.² In the 1980s, there were little data to justify the effectiveness of medical rehabilitation services. Twenty years later, the research on stroke rehabilitation outcomes and efficacy remains scarce and still shows conflicting data.³ However, rehabilitation appears to be moving consistently in the direction of evidence-based practice, with more and more clinical research being performed. Just as important, a critical look is being taken at the research that is being done.³ In the current health care market, where reimbursement is capped, the maximum number of treatment days and types of services covered are often specified at the outset. Clinicians have had to become much more efficient and effective in the care they provide to patients in order to have good outcomes, keep costs down, and be competitive with other providers.

Since the late 1980s, there has been a greater commitment through research to justify treatment, contain health care costs, and improve patient care. In 1988, Dombrov and Bach-y-Rita addressed the need for more research into stroke recovery to enhance services and reduce costs. The following goals were outlined: (a) address the mechanisms of stroke recovery in human participants with imaging or pathologic correlation; (b) design therapeutic techniques based on neurophysiology and assess their effectiveness in groups of patients; (c) determine if intensive rehabilitation reduces functional dependency resulting in decreased long-term social and economic costs; (d) determine when rehabilitation should begin, where rehabilitation should take place, and how rehabilitation programs should be organized; and (e) enable selection of patients most likely to succeed in rehabilitation programs.⁴

There has been a concerted effort in the neuroscience, radiology, medical, and pharmacology fields to address the issues related to stroke management in recent years. TPA treatment protocols

are progressively becoming part of the routine, standard of care for the initial presentation of an acute stroke in the emergency department.^{5,6} Deep vein thrombosis (DVT) prophylaxis is now routine and includes combinations of Doppler screening, use of various antithrombotic drugs, and compression devices.⁷⁻⁹ Finding better methods to prevent initial and recurrent cerebrovascular accidents (CVAs) is an ongoing challenge to the medical and research communities.¹⁰⁻¹² In the actual arena of stroke rehabilitation, research has been intense in the applications of constraint-induced movement therapies of Taub,^{13,14} and modified versions of the initial protocol are also proving effective.^{15,16} Research on mental and physical practice, applications of learning theory,¹⁷ task-specific training,¹⁸ and functional imaging and neuroplasticity have all contributed important concepts to the treatment of stroke patients in the clinic today.¹⁹⁻²³ Some of the newer technology being tested involves virtual reality and robotics to aid in the recovery of lost function.²⁴⁻³⁴ Functional imaging allows us to see activation patterns of the brain to help understand motor recovery. We hope the knowledge gained will lead to the development of training approaches. The basis and understanding of the techniques used in rehabilitation are evolving from clinical lore to data and science. See the article by Hidler et al. on the use of robotics and the article by Hodics and Cohen on improvements in neuroimaging in this issue of *Topics in Stroke Rehabilitation*.

For therapy to be cost effective, it has been necessary to identify who will benefit the most from therapy, under what circumstances, and which type of treatment. Much of the current outcomes research has been devoted to determining which factors will lead to a favorable outcome (i.e., return home) after rehabilitation. These outcome studies are trying to open up and examine the black box of rehabilitation.³⁵⁻³⁷ To predict which patients will benefit the most from PSR, patient characteristics such as age, sex, side and site of lesion, social supports, type of dwelling prior to CVA, job status, socioeconomic level, prior level of function, impairments, co-morbidities, cognition, admission FIM™,* and level of injury (acute vs. chronic) have been subjected to analysis of variance (ANOVA) and reduced to regression formu-

lae, which have not been clinically practical. The processes or circumstances under which the patients are treated (e.g., length of stay [LOS] in acute care, LOS in rehabilitation, treatment on a stroke interdisciplinary unit vs. general med-surg unit vs. home care, intensity of therapy) are also compared to the results of care. Efficacy studies that compare which treatment interventions are most effective for managing various problems under differing circumstances have also been conducted. Because researchers choose different study designs and methods in their attempt to determine the influence of one factor on another in their research, it is often difficult to compare results of one study to another. Both the Spring and Summer 2003 volumes of *Topics in Stroke Rehabilitation*^{38,39} contained detailed evidence-based reviews on numerous outcome and efficacy studies in rehabilitation medicine. The reader is encouraged to review the contents of these two volumes for much greater depth of material on stroke rehabilitation. The studies were rated based on the number and quality of randomized controlled trial studies that supported findings. Below is list of clinical findings based on RCTs found to have strong evidence³:

- Stroke rehabilitation improves functional outcomes.
- Stroke rehabilitation does not reduce mortality of all strokes.
- Stroke rehabilitation reduces the length of hospital stay.
- Stroke rehabilitation does not reduce rates of institutionalization.
- Greater intensity of therapy results in improved functional outcomes.
- Greater functional improvements by patients rehabilitated on specialized stroke units vs. general medical ward are maintained for up to 1 year.
- High-level patients discharged early from acute care can be rehabilitated successfully in the community by an interdisciplinary stroke team.
- Treatment of visual neglect and perceptual disorders improves visual neglect functioning.

- Treatment utilizing primarily enhanced visual scanning techniques improves visual neglect post stroke with associated improvement of function.
- Exercise therapies do not improve arm function.
- Constraint-induced movement therapies improve outcomes vs. traditional therapy.
- Functional electrical stimulation (FES) improves muscle function, pain, subluxation, and range of motion of the hemiplegic shoulder.
- FES and gait training improve hemiplegic gait.
- Biofeedback training improves gait and standing post stroke.
- Higher intensity aphasia training improves outcomes.
- Trained volunteers can provide speech and language therapy with similar results.
- There is a positive benefit of family education if it involves an active educational and counseling approach.
- Information packages and a workbook approach to family education do not alter outcomes.

The rehabilitation black box is an analogy, used previously by Ballinger,³⁷ DeJong,³⁵ and others, from airplane technology. An airplane's black box is an impregnable device that is able to make a multimedia record of what happens during each flight of the airplane. The content of the recording is typically not reviewed unless there is a catastrophe or major problem during the flight. A great deal of resources and information end up inside the box during the flight. If all goes well, the exact details of the contents never need to be examined.

The idea of examining the contents of the black box of PSR was developed based on three major problems: the ever-shrinking number of health care dollars, the need to maintain outcomes in spite of reduced resources, and the reasonable demands of the payers to know what was being done with their money. Additionally, both the providers and payers are interested in knowing what the opportunities are for increased efficiency and decreased costs while maintaining or even improving outcomes. This resulted in the formation of the Post Stroke Rehabilitation Outcomes Project (PSROP) study team, led by Drs. Gerben DeJong

*FIM™ is a trademark of the Uniform Data System for Medical Rehabilitation, a division of UB Foundation Activities, Inc.

and Susan Horn. The study team has worked under the auspices of the Research and Training Center on Medical Rehabilitation Outcomes at Sargent College, Boston University. The initial findings of this group will be forthcoming as the project continues, but the study design itself has already proved to be exciting and innovative when applied to the poststroke population.

Clinical practice improvement (CPI) methodology is a validated, scientific method of data collection and analysis, which looks for associations between patients, their characteristics, their experiences in a health care environment, and their outcomes.⁴⁰ Horn has developed and validated this software-based data collection and analysis research methodology to quantify and examine the process and demographic and clinical variables of inpatient medical care.⁴⁰ CPI has been used in multiple inpatient clinical settings including pediatric intensive care, prostate resection surgery, and nursing home resident's management. It cannot establish causality, but it can say that a certain group of patients who have certain characteristics and had a certain type or group of medical processes ended up with a certain outcome. The CPI methodology has two major conceptual tools that are used to organize the data in meaningful and clinically relevant ways: the Comprehensive Severity Index (CSI®) score and the Auxiliary Data Module (ADM). The CSI is a validated measurement tool of how sick patients may be, which quantifies the minimal and maximal degrees of illness a patient experienced during a hospitalization as well as a daily illness score and subscores of the degree of illness in different physiologic systems. The CSI scores can be expressed as a cumulative score that has no upper limit or an averaged score of 1-4, 1 meaning in *normal health* and 4 signifying *critically ill*. Clinical severity variables include co-morbidities such as fevers, blood pressures, seizures, pain, finger stick values, infections, fractures, syncope, constipations, and arrhythmias, all of which are calculated into the CSI score.

The ADM is the other major tool of CPI research. It is a set of variables that quantifies the experiences or processes a patient has during hospitalization. Some of those variables are the timing of medications; consultative care received; time spent

in ICU; the number of days between acute care admission and admission to PSR; amount of PT, OT, SLP, rehabilitation nursing care, psychology, vocational rehabilitation, and therapeutic recreation services received; whether the PSR unit was located in a freestanding rehabilitation center or in a unit of an acute care hospital; medical and rehabilitation therapies received while in acute care; antibiotics received for infection; billing and cost data; number of group or individual therapy treatments received per day and per week; experience level of their therapists; and others. The therapeutic interventions were examined with a high degree of detail via a data-recording sheet named the TeleForm. Each specialty area developed its own TeleForm through teleconferencing discussions that led to consensus among other rehabilitation teams from around the country. This will be discussed at greater length later in this article. The CPI patient demographic variables include age, race, sex, education, and social support system. Outcome variables include LOS, FIM at discharge, FIM change, and discharge destination. Process, demographic, and outcomes variables are all contained within the ADM.

The TeleForm was used across all sites to record time spent with the patient and was divided into skill areas and interventions. Any clinician who encountered the patient completed the TeleForm and provided such information as time spent in evaluation versus time spent in working with the patient in the targeted areas (i.e., gait, grooming, etc.) while using a specific intervention (i.e., balance training, adaptive equipment) for each session. Clinical profiles were obtained from persons who completed TeleForm as a means of capturing data on individual practitioner variability and included such information as education, years of experience, and completion of specialized training programs (see Appendix for an example of a PT TeleForm).

In terms of sample collection, there were virtually no exclusion criteria. There was no attempt to standardize the treatment regimens. There were no placebo therapies. Almost any stroke survivor who was admitted to one of the participating rehabilitation centers was included in this study, unless they were younger than 18 or had had their stroke over a year before the rehabilitation admission. This

was the entrée to the black box stroke research study.

CPI methodology is a contradistinctive way of carrying out research on human participants from randomized, double-blinded, placebo-controlled trials (RCTs). RCTs have very strict rules of study design that allow researchers to establish causality between an intervention, such as an experimental drug, and a patient outcome by minimizing the number of independent variables in the experimental design. These rules include the establishment of strict inclusion and exclusion criteria for which patients can or cannot be included in the sample, which creates a very homogenous group of participants in the sample. Persons who are included are then subjected to a highly formalized, standardized process of receiving the active substance in question or a nonactive placebo sugar pill. The whole patient experience is rigorously controlled so that any differences in the participants' eventual outcomes can be ascribed to either the active substance or the fact that they did not receive that active substance. This methodology is notoriously expensive (estimated at \$15,000/patient or \$15M/1000 patient study),⁴¹ and, if scientific rigor is to be maintained, conclusions reached can only be applied to patients who meet the original inclusion and exclusion criteria. This design rigor also allows for replication and some generalization of results.

The problems with RCTs are the cost, the limited applications of the conclusions, the whole notion of the use of a "placebo" in the process of blinding, and the facts that inpatient rehabilitation is not a pill and that rehabilitation participants talk to each other. The word "placebo" is the Anglicized first person future version of the Latin verb "placere" which means "to please," meaning, "I will please." In the medical research context, *placebo* is defined as: "A substance which has no effects on the test subject, given to members of the control group during experimental trials that test the effects of a drug or other substance. The control group is the group which does not receive the experimental drug or substance and is used to compare what happens to the test group or groups," according to www.hyperdictionary.com.⁴² Pharmacological research traditionally uses a sugar pill camouflaged

to look exactly like the tablet of the experimental drug as the placebo. The camouflaging allows the participants to be "blind" to what they may be receiving. Ideally, the researcher is also totally unaware of what the participant is receiving. This creates the Holy Grail of "double blinding," so that knowledge of the intervention by those directly involved does not affect the outcome. Unfortunately, there really is nothing to disguise in the physical process of rehabilitation: there is no pill and neither the patients nor the therapists are blind to the physical processes they are experiencing.

Rehabilitation is not the only field that has difficulty with placebo. Kirsch⁴³ describes a similar frustration with the research community's otherwise dismissive insistence on having placebo-controlled study design when he wants to research the effects of psychoanalysis. Surgeons struggle with creating sham interventions,⁴⁴ and a lot of surgical research is composed of case reports and case series. There is also extensive literature on the fact the placebo effect is a 25%–30% positive response rate⁴⁵ to the nonactive substance in exactly the way the experimental drug is supposed to work. Not to mention the additional fact that research participants who receive placebo also experience side effects! Thus, to have a placebo, you must create a nonactive intervention with your patient, which pleases them, which is physically indistinguishable from "real" rehabilitation, and which might even help them to a limited, unexpected degree. Given the shortcomings of RCTs for use in the inpatient PSR setting and the need for evidence-based practice and efficacy data, another approach to opening the black box that had been successful in other medical settings with other impairments was identified.^{46,47}

CPI studies are not randomized (except that humans are very random) nor are they blinded. No patient receives any placebo. The data collected are a large number of variables about a large number of patients. The CPI data analysis process, tailored to the PSROP, is to look at cross-sections of the patients, who are similar in terms of medical status and severity of stroke and who are similar, for example, in terms of having all started at a FIM transfer score of 2, and subdivide them into those who progressed to a discharge FIM transfer score of 4 or higher and those who did not make it. Then

the remaining variables of those two subgroups of the cross-section are examined to determine what may have made significant differences. The database may contain variables about those patients that will help discriminate patients who progress from those who do not and to say that applying a certain type or group of therapies will enhance the chance of a patient making the desired progress. The database may not contain what is needed to provide the discrimination. The set of variables was developed by a group of well-intentioned but perfectly fallible human beings, who might have unknowingly omitted significant variables or were not cognizant of a particular and very important process that was happening. Dr. Horn performed a multicenter study of pediatric ICUs several years ago and found that patients of one of the units among the group were having shorter lengths of stay, reduced frequency of tracheotomy, reduced complication rates, and reduced use of antibiotics,⁴⁶ but nothing else seemed to discriminate between the successful unit and the others, except for the smaller volume of antibiotics. Antibiotic use ended up being an outcome, not a process variable. A second, very intensive study of the same pediatric ICUs as in the first study revealed one small but apparently meaningful difference in the processes experienced by the children on the most successful unit: the nurses had a routine of going around to their child-patients on a regular basis and tickling the children's feet!⁴⁶ This tickling apparently prompted more frequent diaphragmatic inspiration and enhanced respiratory capacity and control in these young ICU patients, allowing for better outcomes.

The conclusions achieved through use of a CPI study are relatively inexpensive to achieve because most of the data collection is carried out through retrospective chart review. Data collection is performed by trained clinicians who use a software program named CSI, which helps maintain intercollector consistency and keeps the data HIPAA compliant.

The development team for the PSROP study agreed that the typical variables collected for a CPI study, structured for examining acute hospitalization med-surgical care, would not capture the full extent of processes experienced by a PSR patient. The planning team spent several months develop-

ing a new subset of ADM variables, using a consensus panel approach among the nurses, therapists, doctors, and researchers of the various rehabilitation institutions participating in the study to agree on which variables appeared to quantify a PSR patient's experiences. There is no existing research that might have provided guidance as to what these variables should be. The literature that does exist is primarily summarized in AHCPR'S Stroke Guidelines,⁴⁸ which only tell, based primarily on consensus panels, what the patient should receive, not what they actually did receive.

This research work was planned and developed through a weekly series of telephone teleconferences during which we discussed issues such as the variables to be included in the ADM, as well as many logistical issues involved in carrying out the data collection and planning for the eventual data analysis.

The justifications for pursuing such an exhaustive look at the details of PSR are multiple. First of all, it is an opportunity to determine what happens, and it is a chance to look for correlations between the frequency of different patient and process variables and their associations with the outcomes. If a situation in data analysis is found such that all the available variables between two PSR centers are not statistically different and yet their outcomes are, it is an opportunity to go back to those centers and re-examine what might be making the difference. It is a chance to look in detail at the effects of individual and cumulative co-morbidities on outcomes as well as the effects of individual and cumulative medications. It is a chance to do a detailed resource utilization review of certain groups of patients and of patients cared for in different areas of the county. In short, it is a chance to discover "tickle" phenomena, such as the one discovered in the pediatric ICU study, which may exist in each of the PSR centers involved in this study.

The CPI approach is an excellent match for studying the process of poststroke inpatient rehabilitation, because of its ability to include and appreciate the diverse poststroke population. In RCTs, co-morbidities are exclusion criteria, resulting in a small percentage of patients being included in a given design. In CPI, all patients can be

included with the co-morbidities as part of the analysis or controlled for at the level of severity. In RCTs, change is based on fact and the result shows the efficacy of the studied intervention, whereas in CPI improvement is still based on fact but the result shows effectiveness of the intervention. In RCTs, all aspects are highly controlled, eliminating the impact of the practitioner's knowledge, treatment philosophy, and decision making and resulting in small effects. In CPI, everyday practice is analyzed in the place and manner in which it has always taken place, with a myriad of individualized approaches to the various patients, resulting in large effects and capturing the practitioner's dynamic role in the process.

Overall Data Summary

A geographically diverse sample was collected from seven inpatient rehabilitation facilities (IRFs) across the United States and in New Zealand, with each site planning on collecting data on 200 poststroke patients for an expected database of 1,400 patients. Data were collected for patients more than 18 years old, who were admitted for inpatient rehabilitation for primary management of a stroke (ICD-9 codes of 430-438.99, 997.02, or 852-853). Patients with a past medical history of stroke were included as long as the rehabilitation stay was targeting a stroke within 1 year of onset.

A preliminary review of the demographic makeup of the eventual 1,291 patients who were collected supported trends previously reported in the literature of the "typical" stroke survivor. The average stroke survivor in the PSROP database was slightly more likely to be male, had an average age of 67.0, and had co-morbidities of hypertension, diabetes mellitus, and coronary artery disease. The stroke itself was as likely to be in the left hemisphere as in the right and was an infarct 67.1% of the time, a hemorrhage 22.9% of the time, and a lacunar infarct 10.9% of the time. During rehabilitation, the average patient showed an increase in motor FIM score of 21.94 and an increase in cognitive FIM score of 4.057. The average survivor stayed in an acute care hospital for 11.6 days before transferring to acute rehabilitation for an additional 19.8 days. This is very similar to existing demographic data on stroke survivor popu-

Table 1. Patient demographics

Demographics	
No. of participants	1291
Male/female	51%/49.9%
Average age	67.0 years
Typical co-morbidities	Hypertension, diabetes mellitus, coronary artery disease
Average length of time between acute care admission and admission to rehabilitation	11.6 days
Average length of stay	19.8 days
Stroke type distribution	
Infarct	67.1%
Lacunar infarct	10.9%
Hemorrhage	22.9%

Table 2. Racial demographics

Race	Individual frequency	%	Cumulative frequency	%
Black or African American	256	21.92	256	21.92
Other	91	7.79	347	29.71
Unknown or missing	139	11.90	486	41.61
White	682	58.39	1168	100.00

lations who undergo inpatient stroke rehabilitation (Tables 1-4).

Analyses

The development of this 1,291 poststroke patient database provided the study team with an infinite number of potential hypotheses by providing highly detailed information for individual patients from the time immediately following the onset of the stroke through each day of the inpatient rehabilitation stay through the hour of discharge from inpatient rehabilitation. Using bivariate and multivariate analyses consistent with measurement properties of key variables, preliminary examinations of the data indicate that this data set allows for infinite combinations of vari-

Table 3. Side of brain

Stroke side	Frequency	%	Cumulative frequency	Cumulative %
1. Right	516	44.18	516	44.18
2. Left	505	43.24	1021	87.41
3. Bilateral	109	9.33	1130	96.75
4. Unknown	38	3.25	1168	100.00

Table 4. Case Mix Group (CMG) classification on admission distribution

CMG admission	Frequency	Cumulative %	Cumulative frequency	%
101 Motor 69-84 Cog 23-35	15	1.38	15	1.38
102 Motor 59-68 Cog 23-35	46	4.24	61	5.62
103 Motor 59-84 Cog 5-22	19	1.75	80	7.37
104 Motor 53-58	95	8.75	175	16.11
105 Motor 47-52	149	13.72	324	29.83
106 Motor 42-46	109	10.04	433	39.87
107 Motor 39-41	98	9.02	531	48.90
108 Motor 34-38 Age >82	13	1.20	544	50.09
109 Motor 34-38 Age <83	109	10.04	653	60.13
110 Motor 12-33 Age >88	21	1.93	674	62.06
111 Motor 27-33 Age 82-88	15	1.38	689	63.44
112 Motor 12-26 Age 82-88	31	2.85	720	66.30
113 Motor 27-33 Age <82	133	12.25	853	78.55
114 Motor 12-26 Age <82	233	21.45	1086	100.00

ables so the study team is limited only by their imagination for querying the data.

The analyses are performed and conclusions are developed for multiple different subgroups, which are created by choosing different inclusion and exclusion criteria that are clinically relevant. For example, the computer software can be instructed to look only for patients who have a right middle cerebral artery infarct, who have diabetes and hypertension but no known coronary disease, and who are continent of bowel and bladder and who are a FIM level 3 (moderate assistance) for toileting. The controls are created retrospectively after data are collected in a manner that allows for human variability, rather than trying prospectively to reduce the variability of humans by an RCT study design. The principle analysis technique is

regression with ANOVA, also referred to as multivariate regression. It is a chance to look at the use of certain therapy techniques, or medicines, and to see if they have an associated improved or diminished outcome. This provided the study team with an opportunity to look for best practices and to develop hypotheses for future RCT studies. The group of patients selected can be subdivided into those who achieved a discharge FIM score of 5 (supervision) for toileting and those who did not. The subsequent analysis is to determine if there are statistically significant differences between the successful and the unsuccessful subgroups.

The CPI methodology consists of a wide range of data types, including rehabilitation intervention, clinician profiles, disease-specific severity of illness data in both acute care and acute rehabilitation, as

well as patient, process, and outcome data. In the specific context of inpatient PSR, the goal of using CPI is to identify patient factors and rehabilitation interventions that are associated with better outcomes as well as to determine the optimal intensity and duration of poststroke interventions and ultimately the utilization of health care resources.

Specific observations

The elegance of the CPI methodology is its ability to describe interventions that were used during PSR and how they changed across a patient's LOS to investigate best practices when patient factors such as demographic information and severity of disease are controlled. As the study group continues its analyses, the CPI methodology will provide information to fill in the blanks of the statement, "If you want to improve (deficit area), clinicians do (activity) using (intervention) during (time frame during length of stay)." The nature of the data collected through the CSI and ADM allows the study team to investigate the relationship between activities/interventions and functional change in performance.

Once preliminary patient factors were identified and controlled, some surprising differences in outcomes began to emerge that demonstrate why the CPI methodology is an exciting, cutting-edge technique for analyzing practices of PSR programs. Tremendous areas of practice variation were identified across sites as well as across practitioners that, as the study team proceeds with analysis, will likely be connected to favorable or unfavorable outcomes in patient performance. Detailed descriptions of these practice variations with an eye toward best practices are forthcoming as the study team develops discipline-specific papers via indepth analyses. However, to show the vast potential for the use of the CPI methodology in PSR, some examples of preliminary looks at the data are as follows.

In PT, significant variability was found in practice regarding the use of neuromuscular re-education techniques across practitioners; the ratio of professional staff to nonprofessional staff and the ratio of individual to group therapy emerged as points of difference across sites. There has been strong support in the data analyzed so far for

starting gait training as early as possible, even in patients whose FIM scores for transfers may only be 1 (*dependent*) or 2 (*maximal assistance*). In OT, practice variability emerged in which interventions were used to address the target area of toilet transfers and across clinicians who used different neuromuscular re-education approaches. In a preliminary finding conceptually similar to PT, the initiation of high-level self-care activities as early as possible, perhaps even earlier than currently thought possible, may lead to better outcomes in terms of discharge FIM scores for all ADLs. In SLP, practice variability in the approach to dysphagia emerged in the areas of the timing of modified barium swallows across a patient's LOS, the recommendation for use of feeding tubes, the frequency of use of fiberoptic endoscopy for swallowing evaluation, frequency and timing of the bedside clinical evaluation, and use of graded solid and liquid food consistencies. Across all three clinical groups, variations across sites existed in the time spent in evaluation and time spent in individual sessions versus group treatment. Significant variability in when a particular deficit area was addressed during the LOS was observed as well. We look forward to examining what appear to be universal practices, such as the apparent lack of significant differences across the sites in management of communication disorders.

One of the differences in practice across physicians emerged in the type of medication used for depression. The medication olanzepine was used regularly at one site, sporadically at two others, and rarely or not at all at the remaining sites. A closer look at functional outcomes, when patient factors such as clinical severity and severity of initial level of disability were controlled for, indicated LOS, discharge disposition, and FIM improvement were significantly better in patients who received olanzepine versus another drug for treatment of depression post stroke.

Conclusion

As the PSROP study team looks more closely at these differences in practice, the applicability of RCTs to determine best practices increases. The CPI methodology is a way to narrow down what microprocesses should be examined via RCTs, as it

identifies a correlation between factors or processes that would have otherwise gone undetected or unnoticed. The process acts as a research "imagination" supported by strong, reliable analytic measures.

Given the richness of the data set and the ability to control for severity, co-morbidities, and a wealth of patient factors, the CPI methodology lends itself to analysis of practices in PSR. However, this methodology is not without limitations. As the study team continues to analyze the data and discuss the significance of the findings, the picture frequently becomes blurred. There are subjective decisions that must be made by the study group to control for a given factor, such as what degree of FIM change is considered "successful," what factors may or may not contribute to a given outcome, and the data components that can or cannot be condensed to provide a sufficient amount of data for analysis. Use of the FIM as the outcomes measure has also proved limiting, because this scale simply does not capture all of the nuances of change that may be achieved through different practices and it is limited in the concrete measurement of complex tasks such as ambulation (i.e., a patient is rated a FIM of 1 in ambulation if they are not able to ambulate at all and if they ambulate less than 50 feet). Another limitation of the study design lies in the TeleForms used for recording interventions and activities performed during therapy. Although the consensus panels agreed upon a standardized interpretation of the terms on the TeleForms and a standardized in-service approach to be used at all the sites participating in the study, the completion of these forms had no actual interrater reliability checks. Finally, there is no standardized use of a measure of impairment, such as the NIH Stroke Scale, upon admission to an IRF.

Given the number of patients who participate in PSR, the number of facilities who provide rehabilitation services, and the number of third-party payers who support this level of care, there is a paucity of research that shows what practitioners were, are, and should be doing in the day-to-day management of stroke survivors. Despite its limitations, the CPI methodology used to investigate the black box of PSR appears to be a valid and revolutionary way to examine the microprocesses and

interventions that patients experience across their LOS and to assist in determining best practices for provision of care. Although the CPI methodology and the PSROP study group have generated an enormous amount of data, it will take time to sift through it to see what best practices and or correlations between interventions and outcomes rise above the noise that a data set of this size creates. Additional research is needed across all disciplines and across different clinical sites, as examining variability in practice is at the heart of this methodology. In designing this research, the CPI methodology should be considered a worthwhile approach that embraces and manages the limitations inherent in RCTs. CPI is a methodology for examining the big picture of a clinical care system, feasibly capable of quantitatively encompassing the wide variation of human responses to illness and the variation in practice of health care providers in order to establish correlations between those patients, their experiences, and their outcomes.

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ISSUE EDITOR

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Post PPS: Practices and Perspectives

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- Functional Neuroimaging in Motor Recovery After Stroke *Hodics & Cohen*
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Foreword

This issue commences with a topical refrain: Shift happens! There is no question but that administrators and clinicians in the rehabilitation industry have seen their share of radical changes from the Balanced Budget Amendment of 1997 to the controversial legislation dictating a reinterpretation and implementation of the 75% rule in 2004. It may be a truism, but more change is coming with tighter payment schedules and an age wave of boomers requiring rehabilitation. We will see even more patients "shifted to home care and outpatient," even more patients moving to and from long-term acute care facilities to skilled nursing facilities, and acute rehabilitation facilities attempting to cope with a rationing rule that may indeed shift entire diagnoses from a given facility. Perhaps the bigger shift on the horizon is the seismic shift to technology. President Bush has given the health care industry a decade to become safer and more efficient through the adoption of electronic records. Frankly, it is my opinion that rehabilitation has half that time to become more technologically savvy and to achieve the efficiencies promised through the integration of information technology into every practice and process. Nearly every industry except health care has experienced the technology shift, and they all are better for it.

Based on the changing landscape of stroke rehabilitation, one unavoidable, underlying challenge to every professional in the stroke rehabilitation field is to adopt an advocacy posture within their facility, state, and nation. Reimbursement, accessibility, and patient safety will be drivers for the foreseeable future. Thus the industry requires each of us to be more involved in the policy aspects of stroke rehabilitation than ever before. CARF, the Rehabilitation Accreditation Commission, obviously perceives a unique and urgent need for elevating stroke rehabilitation to the level of a special program; it summoned an international panel of experts in late 2004 to roll out stroke rehabilitation standards throughout the continuum of care in late 2005.

Rao et al. accept the challenge of change; in this issue they propose the use of different metrics and methods to evaluate our programs in order to increase accountability and transparency of outcomes to all of our various stakeholders. How will the stroke rehabilitation programs of tomorrow translate their outcomes into con-

sumer information that provides understandable comparisons and guides to best practices? In acute rehabilitation, stroke has become the bread-and-butter compliance category upon which small and large providers can rely and even thrive in a white-water market. Unique outcomes may well be the key to survival of some providers and the market niche for others.

DeJong argues that the Medicare Modernization Act of 2003 with its highly touted prescription drug benefit must be understood in the context of the "American devolution"—a much larger shift in American health and social policy that is changing how Americans manage their health and wealth as more tasks and responsibilities devolve to them in managing their affairs and their lives in the workplace. DeJong argues that the devolution presents a special challenge to those who have diminished capacities for self-direction, including many stroke survivors with aphasia or other cognitive language impairments who are especially dependent on the Medicare program for their rehabilitation and management of their diminished health status. Consonant with the point made earlier regarding a call to invest in technology, DeJong calls for a massive investment in information technology and brokerage that will enable all Americans to effectively navigate the challenging changes in the Medicare program that are envisioned.

Two topics that are discussed in this issue of *Topics in Stroke Rehabilitation* that fall on the high technology end of the rehabilitation continuum are robotics and neuroimaging. Hidler et al. discuss some of the motivations for using robotic devices on persons with stroke, review clinical outcomes following robotic-assisted training in both upper and lower extremities, detail how these devices can provide quantitative evaluation of function in persons with stroke, and finally share a vision of where the robotic field is heading vis á vis stroke rehabilitation. Hodics and Cohen provide a state-of-the-art review of neuroimaging techniques that provide information on the neural substrates underlying functional recovery after stroke. This methodology presents information that could lead to the development of new, targeted interventions to maximize recovery.

Three articles in this issue address research and treatment issues concerning acute rehabilitation

and its sequelae. Conroy et al. attempt to glimpse into the black box of stroke rehabilitation by using a clinical practice improvement methodology to determine what variables make a difference in stroke outcomes. It is hoped that the results of this multicenter study will result in sufficient statistical significance so that a randomized controlled study would be the logical next step. Before we can infer what really goes on in stroke rehabilitation that makes a difference, we also need a process in place that gathers the necessary information from the team and makes the prioritized decisions necessary to optimize the functional outcomes of persons with stroke. Newman et al. describe in replicable detail a patient-centered approach to conferencing persons with stroke that has reportedly resulted in improved patient outcomes, increased efficiency and productivity, and enhanced patient and team member satisfaction. Baron et al. expand on patient care by describing unconventional approaches to managing communication disorders. With shortened lengths of stay and patients' demands for increased involvement in their own care becoming ever more prominent, the simplest and most straightforward speech-language pathology (SLP) intervention is to more actively and more immediately engage the patient's spouse or significant other in the communication therapy program. This consumer

approach is increasingly evident in acute care and has become a sine qua non in acute rehabilitation and outpatient levels of care. The speech-language pathologist must take advantage of every possible venue to maximize outcomes, and special group treatment interventions have been found to make a difference in functional communication. Once the patient is discharged and outside the radius of accessibility for outpatient, telerehabilitation approaches are described that demonstrate the efficacy and efficiency of this high-tech and unconventional approach to follow-up care.

With the national emphasis on patient safety in health care and falls prevention in rehabilitation, Zdobysz et al. provide a timely review of the literature with a predictive approach to tease out who is at risk for falling and suffering serious injury. In addition to advocating for quality care and functional outcomes, each of us is responsible for advocating to "do no harm." Falls and medication errors are the top two risk factors for injury in acute rehabilitation, so we all benefit from becoming acutely aware of the predictive factors and preventive interventions that should be considered for the person with stroke.

—Paul R. Rao, PhD, CCC, CPHQ, CHE
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Shift Happens: Using Outcomes to Survive and Thrive Under PPS

Paul Rao, Purvi Boradia, and Jacqueline Ennis

In the post prospective payment system (PPS) era, acute rehabilitation providers are presented with multiple challenges and opportunities. All inpatient rehabilitation facilities (IRFs) face the requisite demands for improved efficiency (e.g., reduced length of stay for persons with stroke) and the re-institution of monitoring for compliance with the 75% rule. However IRFs also now have a dramatic opportunity to shift the paradigm of "how we do business" by adopting cutting edge technology and continuous quality improvement methodology and by rethinking and revising how we evaluate a stroke program. Today, more than ever before in our industry, providers have an opportunity to evolve to a consumer-driven program evaluation model with the resultant modification of rehabilitation outcomes, indicators, and metrics. The article argues for a climactic and dramatic change in how acute rehabilitation providers market for patients, deliver care, and report on their outcomes. In the current context of PPS and the 75% rule, we are quite literally considering the survival of the industry as we know it. Improved rehabilitation processes and revised rehabilitation report cards (customized for the various stakeholders) hold the key to market share and organizational success. If patient access, quality outcomes, patient safety, and functional gains are to be achieved, the industry needs to change the way it does business and as a consequence the way it evaluates its programs. **Key words:** PPS, program evaluation, stroke outcomes

In this issue of Topics in Stroke Rehabilitation, our author contributors will be sharing their perspectives and expertise on a broad range of clinical and administrative topics about stroke rehabilitation. Gerben DeJong discusses Medicare reform and offers new insights on trends that shape US health and social policy and how they increasingly impact the lives of stroke patients and service providers. Brendan Conroy discusses the care techniques, outcomes measurements, and patient demographic factors affecting patient care as they evolve in an environment with decreased resources and increased demands from payers.

Common among the authors in this issue is recognition of the role and importance of 21st century technology in advances in treatment and administrative management of stroke populations. Another common theme among the articles is patient-centered care and clinical management, a concept often described but sometimes unachieved.

As I read these contributions and reflect on my own experiences as an administrator, a CARF Surveyor, and a speech-language pathologist, I am struck by the profound resource challenges that we face in improving care and outcomes for persons with stroke. The challenges of meeting a 21st century technology imperative and developing patient-centered care are tempered by the realities of prospective payment. While the pro-

spective payment system (PPS) has forced providers to increase the efficiency with which they deliver care, it has also posed challenges to all aspects of stroke rehabilitation.

Reimbursement methodology changes have an indirect influence on staffing. In its most minimal impact, prospective payment has required new staffing strategies that address timely assessment and filing of FIM™ data to the Centers for Medicare & Medicaid Services (CMS). A recent survey of providers suggests that mean time spent performing assessment evaluations has increased from 84 to 109 minutes (33% increase). In the aforementioned survey, the majority of the respondents reported a change in staffing post PPS. Hence, acute rehabilitation has seen an increase in nondirect care; more human resources are needed to simply cope with the new payment system.

Direct care providers are experiencing less-than-

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ideal schedules and burnout in a field in which professional shortages create more therapist employment options and higher vacancy rates at inpatient rehabilitation facilities (IRFs). In 1997 following the Balanced Budget Amendment, nursing homes witnessed an exodus of rehabilitation therapists. Acute rehabilitation post PPS (January 2002) has experienced a similar therapy crisis. Because the postacute venues of nursing home, outpatient, and home care are now under PPS and are rebounding financially, today's therapists have many more employment options. Acute rehabilitation therapy recruiters now find themselves in a virtual bidding war with all of the other rehabilitation levels of care.

Historically, acute rehabilitation outcome was defined by aggregate measures of length of stay (LOS), gains and changes in functional independence, and noninstitutional discharge placement. Ten years ago, it was not uncommon for a patient undergoing stroke rehabilitation to experience a LOS of 30 or more days. Patients at that time also experienced a net FIM gain of slightly more than 1 point per day of stay. By comparison, patients in most IRFs can expect to gain nearly 2 FIM points per day of stay in a significantly compressed LOS averaging less than 18 days. The realities of payer pressures, including those of CMS, have contributed to greater outcome achievement in a shorter time span.

In the past, FIM assessments resulted in detailed data on specific measures of functionality, but these specific measures were rarely used as a comparator or outcome measure. Recent research interest has focused on the potential value of specific FIM measures to produce a more refined and robust perspective of outcome in the context of functional independence. The article on falls by Zdobysz and colleagues in the current issue underscores the value of this approach.

Notwithstanding improved LOS efficiency, shortened LOS challenges the goal of community discharge for persons with stroke. In 1995, on average more than 80% of discharges from stroke rehabilitation programs were discharged to home or community. Recent data however show that discharge to community has declined to a range of 60%–70%, while discharges to skilled nursing facilities have correspondingly increased.

A nonscientific survey of rehabilitation provid-

ers suggests that shorter LOS leads to higher rates of discharge to nursing homes or other institutional placement. There was unanimity in belief among survey respondents that family education and support mitigate the potential institutional placement outcome associated with shortened LOS. In addition, discharge to an acute unit because of medical complications by definition reduces the percentage of persons with stroke discharged to the community. At the National Rehabilitation Hospital, for example, our discharge to an acute unit (understood as an unplanned/emergent discharge) averages 11% of our patients. In addition to the unfortunate medical complication for the person with stroke, this unplanned process translates into numerous system inefficiencies such as missed therapy appointments on the day of emergent discharge, reassessment upon return to acute rehabilitation, and an extension of the planned discharge date.

These observations are borne out by our survey respondents who unanimously agree that patients have a greater number and degree of comorbidities than in the past. As a result, rehabilitation hospitals are admitting patients with a higher medical acuity. A higher level of severity and lower level of functional independence at admission is reported to correlate with a higher likelihood of emergent discharges to acute care. These transfers back to acute care and the resultant system inefficiencies exaggerate the burden on the patient, family, and clinical staff from both health management and customer service perspectives.

The role of outcomes measurement and program evaluation has become increasingly valuable and challenging under these circumstances. A variety of stakeholders have a variety of perplexing and professional questions and needs. Program evaluation and outcomes management must attempt to address these needs and questions in a systematic and comprehensive fashion.

Because of PPS, the care delivery team must deal with an entirely new set of outcome trends. The increased rates of discharge to acute care and other noncommunity discharges have placed a burden on the care delivery team as they must deal with missed appointments and reevaluations upon readmission. Applied research into these issues may

help define the problem. For example, outcomes measures have shown us that there are differences in the rates of discharge to the community among specific impairment groups within the stroke rehabilitation impairment class. Identifying these impairment groups or targeting patients with high co-morbidities may help rehabilitation providers reduce the number of patients who profile as high risk.

Physicians have also become more technologically savvy and have a better appreciation for the business aspects of health care. They should quickly be able to know who their patients are, the status of the patients with respect to LOS, and the empirical factors that influence LOS. The outcome data we can provide them will also give them an indication of how they are doing in respect to PPS.

Outcomes measurements will help us address the typical questions and informational needs of our various other consumers/stakeholders. Our primary consumer and family member(s) will want to know what their life is going to be like post discharge, and we should also be able to convey our expectations on their treatment progress. By continuing our 90-day post discharge follow-up assessments, we can track how other patients have done. Surveying the patients' perspective on their satisfaction with the care they received will allow the care delivery team to make adjustments or improvements as needed. These patient-centered indicators can be disseminated via a consumer report card. Our institutional partners will want to know what added clinical benefits we can offer their patients and whether we are getting their patients out soon enough. A referral source report card with appropriate outcomes metrics will answer their questions. Finally, our payers will also want to know if an expense for acute rehabilitation today will reduce downstream costs and co-morbidities tomorrow.

For years, the means to assess and improve quality in health care included ongoing monitoring and simple evaluation. In the future, a continued emphasis will be placed on care provider accountability that will be supported by increased reliability and validity of assessment tools and data. Improvement in the outcomes of stroke rehabilitation will be reflected not only through FIM gains,

shorter LOS, and increased patient safety but also through consumer empowerment and family member input as they become vital components of our approach to patient care.

If our providers can use the assessment tools and technologies of continuous quality improvement (CQI) to achieve greater efficiencies in the delivery of rehabilitation services, they will also alleviate the burden on our staff of overcoming any of the regulatory issues found in Medicare rules and managed care contracts. Today's technology and CQI approaches will assist providers in achieving compliance with the ever-changing and increasing licensure, accreditation, and reimbursement rules and regulations.

What does all this mean to program evaluation and outcomes management today and tomorrow? The acute rehabilitation industry appears to be riveted on CMS's enforcement of the 75% rule, judging that without success in this endeavor the very survival of the industry is at stake. If certain diagnostic categories are not allowed to be admitted to acute rehabilitation because these diagnoses/impairments are not on the CMS compliance list, then the industry is de facto rationing care. The fiscal impact of noncompliance with the 75% rule may have unintended negative consequences to the availability of rehabilitation programs for persons with stroke. In some instances, noncompliant admissions balance the revenue distribution and the fiscal viability of some IRFs. In short, the industry must look not only at outcomes data, but also their current service mix and revenue distributions to manage the challenges posed by sometimes disparate service imperatives. For example, professionals charged with screening admissions for an IRF may need to have the facility's case mix for all patients and for Medicare only before deciding to admit a "paying patient" who does not meet the 75% rule.

The ultimate goal of advancing technology, clinical management, and outcomes measurement should result in the continuous cycle of assessment and improvement in stroke rehabilitation and overall clinical care. If the "black box" of rehabilitation works well, access, safety, quality, and functional gains should be the common denominator for acute rehabilitation outcomes.

Medicare Reform and the American Devolution

Gerben DeJong

The Medicare Modernization Act of 2003 (MMA'03) did more than introduce a prescription drug benefit for Medicare beneficiaries; it also laid the groundwork for several far-reaching changes in the Medicare program. These changes must be considered in the context of the "American devolution"—a much larger shift in American health and social policy that is changing how Americans manage their health and wealth as more tasks and responsibilities devolve to individuals in managing their personal affairs and their lives in the workplace. The devolution presents a special challenge to those who have diminished capacities for self-direction, including many stroke survivors who are especially dependent on the Medicare program for their rehabilitation and management of their diminished health status. This article calls for a massive investment in information technology and brokerage that will enable all Americans to effectively navigate the brave new world that the changes in the Medicare program portend. **Key words:** *devolution, information brokerage, Medicare, Medicare Modernization Act, prescription drugs, rehabilitation, stroke*

On December 8, 2003, the President signed into law the Medicare Prescription Drug Improvement and Modernization Act of 2003, commonly cited as the Medicare Modernization Act of 2003 (MMA'03). To most people, this 680-page bill is known for adding a long-awaited prescription drug benefit to the Medicare program. The Act actually represents a new divide in American social policy for older and disabled Americans that is not well understood. It is a divide that places a much higher burden on individuals in navigating information and making complex choices about health and income benefits that even the best-educated and most-informed persons are not well-equipped to make. For those with less education and less capacity for processing information, MMA'03 will be especially burdensome. For many people who have had a stroke, the choices will be especially difficult to navigate.

In this article, I want to focus less on the specific provisions of the MMA'03 and more on the larger trends that shape American health and social policy and what they mean for American individuals and families as they think about their future

and plan for their older years. I will argue that the MMA'03 is part of a larger shift in the American economy that is only now affecting the twin towers of Social Security and Medicare. The new challenges that face Americans in general are particularly daunting for those who must cope with the limitations that arise from having had a stroke.

Main Provisions

What are some of the main provisions of MMA'03 that shape the choices facing older Americans and individuals with disabilities? There are four provisions or benefits that will eventually touch every American in one form or another: (a) the new prescription drug benefit, (b) new funding for Medicare managed care, (c) the premium support demonstration, and (d) health savings accounts. There are numerous other provisions aimed at providers, health plans, durable medical equipment vendors, and others. There are also provisions that address health care quality, the interface between Medicare and Medicaid, the development of care coordination demonstration

Editor's Note: This article reaches well beyond stroke rehabilitation to touch on how changes in the Medicare program are emblematic of larger changes that affect all of us. Dr. DeJong provides new insights about how these changes shape the lives of stroke patients, the work of service providers, and the roles that we have as individuals responsible for managing our personal and professional affairs.

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projects for those with chronic health conditions, temporary fiscal relief for academic health centers, and a wide range of esoteric payment issues of concern mainly to providers and health plans. This article is written primarily from the vantage point of a prospective Medicare beneficiary and less from the perspective of providers and health plans.

Collectively, the new Medicare provisions represent the most significant change in the scope of the Medicare program since the program's inception in the mid 1960s. Yes, in 1988, Congress did pass the Medicare Catastrophic Coverage Act that provided an outpatient drug benefit and catastrophic coverage for extended hospital stays. This act was, however, repealed a year later when well-to-do seniors rebelled after they found themselves paying for a benefit that was expensive and accrued mainly to those of lower socioeconomic status. This experience, as I note later, also shaped the prescription drug benefit provided in the MMA'03.

Prescription drugs

The prescription drug benefit, now Part D of the Medicare program, is the most widely advertised provision of MMA'03. It was touted by the Bush Administration during the 2004 election to gain a stronger foothold among seniors who were prone to view Medicare as a signature Democratic policy

issue. The Administration wanted in on the Medicare franchise that had been long associated with Democrats, much like the Clinton Administration had usurped the welfare reform issue that had long been associated with Republicans a decade earlier. The White House was so determined and the House vote was so close that the roll call vote on the bill continued for 3 hours during the middle of the night (November 22, 2003) until enough Republican votes could be secured in an arm-twisting 220 to 215 vote that remains controversial to this day.

The prescription drug benefit features several controversial provisions. Most controversial is the structure of the benefit itself. Unlike most health benefits, the main deductible oddly occurs near the middle of benefit not at the front-end where the heavy deductibles usually appear, resulting in an odd contribution-and-benefit structure (see also Figure 1):

- A \$35 per month premium.
- A \$250 deductible.
- A 25% copayment from \$251 to \$2,250 of total drug costs.
- A \$2,850 deductible or gap in coverage from \$2,250 to \$5,100 of total drug costs. This gap cannot be filled by a Medigap plan or by Medicaid coverage, and employer contributions will not count toward meeting out-of-pocket expenditures. This \$2,850 gap is com-

Total spending by beneficiary

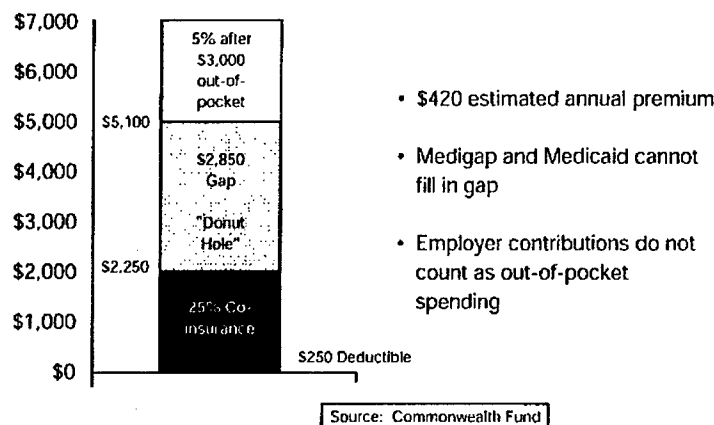


Figure 1. Prescription drug benefit 2006: beneficiary cost-sharing.

monly referred to as the "donut hole" in the benefit.

- A 5% copayment for amounts over \$5,100 per year. In other words, this part of the benefit kicks in once the beneficiary has incurred a total of \$3,600 in out-of-pocket expenses.

This odd benefit structure can be attributed to three factors. First is the experience of the 1988 Catastrophic Coverage Act cited earlier. This act was highly redistributive and only a few people received any benefit at all, which thus undermined any sustainable political constituency for the program. With the prescription drug benefit, Congress wanted to make sure that a lot of people received at least some benefit, no matter how small, in order to avert the kind of backlash seen 15 years earlier with the repeal of the 1988 Catastrophic Coverage Act. Second, Congress wanted to retain the catastrophic protection feature of the plan in keeping with basic insurance principles (premium for low-incident but high-cost events, not for ordinary and predictable events). And third, Congress wanted to keep the cost below a 10-year \$400 billion price tag—a price tag that would appeal to fiscal conservatives but that later proved to be a phony one. As odd as this benefit may appear, its features and complexity mirror a larger trend in health and income benefits to be discussed later.

The prescription drug benefit becomes effective in January 2006 with enrollment beginning in 2005. Seniors will have a powerful incentive to sign up, because beneficiaries who delay enrollment after the initial enrollment period will face a 1.0% premium increase for each month of delay. One purpose of this provision is to avert "adverse risk selection" that is prone to occur when only those who perceive a need for the benefit sign up and those who do not perceive a need do not sign up. In other words, high-need beneficiaries self-select into the program, which creates a pool of higher cost beneficiaries that force health plans and prescription drug plans to raise premiums and thus make the benefit all but unaffordable to the large mass of beneficiaries. The cost of participation may, however, go up if the Centers for Medicare and Medicaid Services (CMS) determine that the actuarial costs are higher than projected. More-

over, the program contains low-income provisions designed to assist those who are dually eligible for Medicare and Medicaid and those who are not eligible for Medicaid but have incomes that hover near the federal poverty line. Complicating matters further are provisions that allow employer-sponsored retiree prescription drug benefits to be supplemented with Medicare dollars.

Bowing to the presumed competence and efficiency of the private sector, Congress provided that the drug benefit be administered through private prescription drug benefit management companies (PBMs) or through health maintenance organizations (HMOs) that participate under Part C of the Medicare program, now relabeled *Medicare Advantage*. The federal government will offer a Medicare prescription drug plan of its own in those geographic regions that fail to attract participation by a PBM or a Medicare HMO. When choosing a drug benefit plan, seniors will also have to consider the drug formularies that PBMs and Medicare HMOs offer to make sure that the drugs they need are included on the formulary. Drug formularies are not straightforward. Formularies, as well as classes of drugs within a formulary (e.g., beta blockers), can be "open" or "closed." Moreover, some drugs may be on the formulary but may require preauthorization. PBMs and HMOs may change their formularies at will, which adds to the uncertainty for seniors.

Until 2006 when the prescription drug benefit becomes effective, Congress has provided for a transitional drug discount card that will enable beneficiaries to experience some fiscal relief. Although the transitional drug benefit will have ended by the time this article is published, the experience of the transitional drug benefit has much to tell us about the administration of the Medicare drug benefit. Congress insisted that there be choice, but with choice comes the need for information. With many drug discount cards to choose from, CMS established a telephone hotline and a website where seniors could compare prices within their geographic area. Many seniors obtained incorrect information from the hotline and found that the website information was not always up to date. We will return to this experience later in the article.

Two other features of the drug benefit are worth

noting. First, Congress, in deference to the drug lobby, refused to authorize CMS to use the clout of its large purchasing power to negotiate lower prescription drug prices for its 41 million Medicare beneficiaries much like the Department of Veterans Affairs does on behalf of veterans. A Republican Congress believed that the market competition between PBMs and HMOs would lower prices without questioning why competition in today's markets had failed to do so. Second, Congress, in deference to vocal senior groups, allowed for the reimportation of drugs from Canada where prices for the same drugs are cheaper but essentially nullified the provision when requiring, in deference to the pharmaceutical lobby again, that the Department of Health and Human Services (HHS) certify the safety of such drugs. Thus far, HHS and the FDA have refused to provide such certification, thus rendering the drug reimportation provision moot.

Medicare Advantage (Medicare managed care)

Congressional Republicans and some Democrats have long believed that managed care in the form of HMOs would bring fiscal discipline to the Medicare program and added several sweeteners to the MMA'03 to induce greater participation by HMOs in the Medicare program, many of whom had exited the program in recent years. Recall that in the 1990s HMOs stepped up their participation in the Medicare program and doubled their share of the Medicare market from 8% at mid decade to 16% by the end of the decade (see **Figure 2**). Previously, Medicare paid HMOs a premium that was 95% of the amount spent on traditional or fee-for-service (FFS) Medicare on the presumption that HMOs would manage their patients more efficiently. At first, HMOs did well even when offering a prescription drug benefit mainly because it was able to appeal on average to younger and healthier Medicare beneficiaries. As the program succeeded and grew, its subscriber mix changed and HMOs could no longer make the margins they once did and began withdrawing from the Medicare market.

To reverse this trend, Congress agreed to have Medicare pay HMOs 100% of the amount spent by FFS Medicare and created a \$10- to \$12-billion slush fund for HMOs referred to as a *stabilization*

fund that would be used to shore up HMO participation in the Medicare market. The actual amounts Medicare will pay HMOs will be between 108% and 116% of the amount spent for FFS Medicare.^{1,2} These provisions have led some critics to dub the MMA'03 as the "No HMO Left-behind Act of 2003." These provisions will not be transparent to seniors except that seniors will see more choices including HMO options that had become less available to them in recent years. To seniors, these choices will come under the rubric of Medicare Advantage that previously had been known to them as Medicare + Choice. For seniors, the choice, unfortunately, will be little more than an old wine in a new bottle.

If the HMO sweeteners do result in a resurgence of Medicare managed care, we may well see a situation similar to the mid 1990s when Medicare HMOs were in their ascendancy and redefined much of the postacute rehabilitation landscape because of HMOs' preference for skilled nursing facilities (SNFs) over hospital-based rehabilitation facilities as the venue for rehabilitation. In the case of stroke rehabilitation, for example, we may see a resurgence of SNF-based rehabilitation as we had in the 1990s until HMOs started to withdraw from the Medicare market. Since then, stroke rehabilitation patients have returned to the traditional venue of hospital-based rehabilitation centers. Since 1998, many hospital-based SNFs found stroke rehabilitation patients much less attractive financially³ because of a new fixed per diem payment system authorized by the Balanced Budget Act of 1997 (BBA'97). IRFs continued to be paid on a cost basis and remained exempt from any prospective payment system until 2002. Thus, for seniors, choices for rehabilitation may be shaped by the extent to which HMOs reenter the Medicare market—a choice that may not always be transparent to individuals when they make their health plan choices during open enrollment periods.

Premium support demonstration

The premium support demonstration will have no immediate implications for Medicare beneficiaries, but it does portend what is to come. *Premium support* is simply a fancy term for private health insurance or private health plan and is a code word

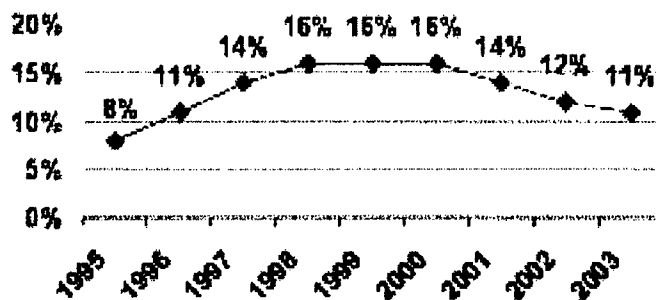


Figure 2. Medicare managed care enrollment.

for privatizing Medicare. In Congressional parlance, it means that private health plans could compete with traditional Medicare much like Medicare HMOs have done and that Medicare would provide beneficiaries a fixed payment with which beneficiaries would purchase their own private plan. In short, the Medicare program would become a defined contribution plan rather than a defined benefit plan. The implicit assumption in the premium support model is that Medicare is inherently inefficient and that if beneficiaries were offered a voucher of sorts with which to purchase their own health plan, traditional Medicare as we have known it would eventually wither away as market forces presumably favor private plans.

The premium support concept has been simmering in Republican think tanks and Congressional circles for a long time. In fact, Congressional Republicans did not want to offer a prescription drug plan unless the premium support concept came with it, because they knew that a premium support plan would not pass without the votes that a prescription drug benefit would garner if both were in the same package. In the end, Congressional Republicans only got half a loaf. Instead of a premium support program, they got a premium support demonstration that will not start until 2010 and will be limited to six markets. The demonstration authorization was a major disappointment to many Congressional Republicans who wanted a full-fledged premium support program, but the White House also wanted to have a prescription drug benefit to run on in the 2004 election.

Much could happen between now and 2010 when the demonstrations are rolled out. More im-

portant is the overall shift in the Medicare program that the premium support model portends. Congressional Republicans very much want Medicare to resemble the private health plan market. They also argue that the Medicare benefit package is outdated and is based too much on what health insurance plans looked like back in the 1960s, as in the case of Blue Cross/Blue Shield plans that included a Part A for hospitalization and Part B for outpatient services. Hence, the notion of Medicare "modernization" that one finds in the title of the MMA'03.

Health savings accounts (HSAs)

A favorite and recurring Republican concept is the idea of the health savings account (HSA), previously known as the medical savings account (MSA). This provision applies to all individuals, not just Medicare beneficiaries, and is not likely to be taken up by Medicare beneficiaries, given their cost and utilization profiles relative to the structure of the HSA outlined in the MMA'03. I mention them here because, like some of the other provisions, HSAs portend a larger shift in American health and social policy that I address later in this article. Discussing it here provides some of the empirical evidence for the larger argument that I want to make later.

An HSA is a tax-free health-related account analogous to individual retirement accounts (IRAs). Individuals, employers, or family members can make tax-free contributions to an account whose earnings and distributions remain tax-free. The HSA follows the individual and does not dissi-

pate when an individual leaves an employer, as does his or her group health insurance. It remains in perpetuity with the individual. The amount that can be put into an HSA is up to 100% of a deductible associated with a catastrophic health plan. Such health plans typically have upwards to a \$5,000-deductible before the health plan begins to make outlays. The notion is that the individual is "self-insured" for the amount of the deductible, and, when responsible for the deductible, individual HSA participants will be more judicious consumers of health services and thus limit utilization and costs and slow the overall growth of health spending in the American economy. The minimum deductible under a qualified HSA is \$1,000 for individual coverage and \$2,000 for family coverage. Moreover, individuals 55–65 years old can make additional tax-free "catch-up" contributions of \$1,000 analogous to the way near-retirement age individuals can make catch-up contributions to an IRA or to a 401(k) or 403(b) plan. Individuals and families can use their HSAs to pay for unreimbursed medical expenses, retiree health insurance, and other items not covered by their health plan. This presumes, of course, that a qualified medical expense under an HSA is broader than one defined by Medicare or a private health plan.

The downside to HSAs is the problem of adverse risk selection where younger and healthier persons are more prone to select an HSA and older and less healthy individuals are prone to select an alternative plan. The adverse risk selection problem can result in a downward spiral for conventional health plans as premiums become more expensive and healthier people opt out for other plans that feature HSAs with lower premiums. This is one of the reasons why MSAs and HSAs have not been embraced in the group health markets up till now and remain largely a feature of the individual and small business health insurance market.

The Devolution

Aside from its potential advantages or disadvantages, the larger message in HSAs as in other provisions of the MMA'03 is that the onus will shift to the individual to make informed choices and take

more responsibility for health care expenditures. This is the defining feature in the other provisions as well—in the prescription drug benefit, the Medicare Advantage program, and the premium support concept. Some may look at the Medicare reform legislation and cast it into the traditional left–right debate about the role of the individual and government, with one side favoring greater individual responsibility and the role of markets and the other side favoring greater individual protections and the role of government. Casting the debate in these dichotomous terms may have some heuristic continuity with past debates about American social policy, but it masks other important trends in American life and economy that cannot be reduced to simple left–right dichotomies. My central thesis is that the MMA'03, as illustrated by the provisions outlined earlier, is part of a larger "devolution" of American life and economic behavior.

Devolution, as it is traditionally understood, refers to the transfer of power, authority, responsibility, duties, and accountability to a subsidiary entity or person. It is a term that is most commonly used to characterize the devolving of responsibility and accountability from higher levels of government to lower levels of government, from the federal government to state and local governments. The term is now widely used in the United Kingdom where there has been a vigorous debate about the extent to which government responsibilities previously anchored in London should be reallocated to the UK's constituent governments in Scotland, Wales, and Northern Ireland.

I am referring to devolution in its broader meaning, that is, the devolving of responsibilities, duties, tasks, and accountability to the individual citizen, the consumer, the beneficiary, the user, and the individual employee. I would argue that this is one of the defining features of our time, and yet it is not adequately recognized or understood. Thus, when applied to social policy, devolution risks creating mischief as well as new opportunities for individual empowerment.

The American devolution is perhaps most evident in the self-help economy that has emerged over the last 25 or more years as illustrated in **Tables 1 and 2**. Organizations are increasingly outsourcing their work to their customers and

Table 1. Examples of devolution in the American economy

Activity	Previously	Now or in the future
Pumping gas	Attendant	Driver/consumer
Checking in at airport	Ticket agent	Kiosk
Checking out at store	Cashier	Consumer check out
Banking	Teller	ATM
Computer trouble shooting	Original vendor	Consumer or 800 number in India
Employer-employee transactions	Went to human resources dept; submitted travel reimbursement to administrative support staff	Enroll online for health benefits; manage travel reimbursement online using Oracle or PeopleSoft software

clients and "outsourcing" their administrative tasks to their employees. Many of the examples cited in Tables 1 and 2 precede the rise of the Internet during the 1990s, but the Internet has become the facilitator, if not the great accelerator, of the American devolution. More important, I believe, is the way the devolution is spreading to the management of income and health benefits, both private and public.

On the income benefits side, employers have, over the last few decades, shifted from defined-benefit to defined-contribution retirement plans such as 401(k), 403(b), and cash-balance plans that place most of the burden on the individual to make investment choices. The choices involve not only asset allocation decisions between stocks and bonds (complex in themselves), but they also require extensive research with regard to third-party administrators (e.g., TIAA-CREF, AIG-VALIC, Fidelity Mutual), their fee structures, hidden insurance charges, withdrawal options, and tax implications. For the most part, employers have abdicated their role as honest information brokers and sometimes have conflicts of interests that are not transparent to employees. Some companies require that employees invest a significant portion of their 401(k) investments into the company itself—sometimes leading to disastrous results as in the case of the Enron scandal.

If the current Administration and Republican Congress prevail, Social Security will also shift from a strictly defined-benefit program to more of a defined-contribution plan as suggested by the

proposals for individual private Social Security accounts. The transformation of portions of the Social Security program into a series of giant 401(k)- or 403(b)-like retirement programs will present individuals with enormously complex choices that are already difficult to make in the private sector.

On the health insurance side, employers are diversifying their offerings that allow employees to choose health plans that more nearly match their needs and health care consumption patterns. Increasingly, we hear about cafeteria plans and consumer-driven health plans that also come with donut holes, that is, plans that come with first-dollar coverage and deductibles around the mean annual health spending.⁴ These plans are difficult for employees to evaluate because many employees cannot ascertain in advance their risk of reaching the donut hole. My more cynical side wonders whether donut-hole plans are merely another surreptitious method of risk selection that will attract consumers whose health care expenditures will remain well below the mean.

The devolution has now reached nearly every aspect of American life, including areas that may not be immediately apparent to those caught up in the devolution. At the workplace, for example, employers are shifting more of the administrative burden for human resource activities, time reporting, benefit management, travel and expense reimbursement, research grants management, and so on from support staff to line staff through the use of Internet or Intranet protocols made available from software vendors such as IBM, Oracle, and its

Table 2. Examples of devolution in American health and social policy

Program area	Previously	Now or in the future
Employer-sponsored retirement programs	Fixed employer pensions Defined-benefit programs	Cash balance plans & defined-contribution plans, e.g., 401(k), 403(b)
Government sponsored retirement programs	Fixed pension Defined-benefit program Social Security as we have known it	Individual retirement accounts (IRAs) Individual Social Security Accounts akin to 401(k) and 403(b)
Employer-sponsored health benefits	Fixed benefit plan Defined coverages	Flexible spending accounts (FSAs) Consumer-directed health plans Health savings accounts (HSAs)
Government-sponsored health benefits, e.g., Medicare	Fixed benefit Fee-for-service (FFS) Medicare Medicare as we have known it	Medicare + Choice Medicare Advantage Premium support

recently absorbed rival, PeopleSoft. These protocols are expected to save organizations millions of dollars as whole layers of support staff are eliminated. This streamlining can be efficient but also enormously frustrating to individual employees who need to make transactions that do not conform to the protocols or transactions that are sufficiently infrequent and thus require the employees to relearn the protocol upon each application.

Organizations are similarly shifting more of the administrative burden for service dispute and account resolution to the individual or another member of the individual's family. Each time a consumer calls an 800 telephone number that triages the caller with a series of touch-tone options, the organization is essentially outsourcing an administrative burden from it to the caller. American companies have become leaner and meaner, but the presumed savings may also mean that costs are hidden on the consumer side of the equation and fail to get factored into most measures of economic activity and productivity. The reported productivity gains in the American economy in recent years may merely represent a shift in the cost of production from the supply side to the demand side of the market and may not represent any real productivity gain at all.

Embedded in the American devolution is tremendous lip service to the notions of consumer choice, consumer direction, and consumer empowerment—all terms used to legitimize public policy choices with respect to income and health benefits. But as neoclassical economic theory sug-

gests, these terms have little meaning unless certain preconditions are met. For consumer choice to be meaningful, there has to be transparency and a means to compare apples with apples and oranges with oranges. In the economic theory of the perfectly competitive market, there must be a homogenous product, that is, meaningful comparisons should be made within a class of similar goods and services. In health care, this argues for a standard health-plan benefit package or groups of standardized packages as is currently present in the Medicare Medigap market where beneficiaries can choose from 1 of 10 different standardized plans and thus make genuine comparisons about price and scope of service. Apart from the Medigap market, this kind of standardization is not widespread in health care. When plans and offerings are not standardized, there is an even greater need for transparency and side-by-side comparisons with respect to benefits, costs, and fees that might otherwise be hidden from the consumer.

Equally important, consumers need honest and disinterested third-party brokers of information. Employers could do a lot more to be honest brokers of health plan information, although they are not always disinterested parties. In the case of Medicare, government has attempted to be an honest broker of information with the development of hotlines and beneficiary-oriented websites. CMS staff have made near-heroic efforts in rolling out the new prescription drug benefit to Medicare beneficiaries, but CMS's record in educating the public about an interim discount card for prescription

drugs has not been encouraging. A test of the Medicare hotline (800-Medicare) for discount prescription drug cards—run by a private contractor—found that 29% of callers received inaccurate information and another 10% received no information at all.⁵ One can only imagine the confusion that is bound to follow as more choices become available in the Medicare program. The problem is neither CMS nor call center operators but a Congress that has created a nonstandardized benefit program with thousands of variables that even the best-educated and well-informed can never fully understand.

Government has already made some important strides in this area. For many years, the Agency for Health Care Research & Quality (AHRQ), the nation's lead health services research agency, has worked with its contractors and CMS to develop the CAHPS (Consumer Assessment of Health Plans) technology that enables consumers to compare health plans on the basis of subscriber satisfaction scores. MMA'03 also provides support for the Hospital Quality Initiative (HQI), a joint effort of American Hospital Association, the Federation of American Hospitals, and the Association of Academic Medical Centers (AAMC). At this stage of its development, the HQI remains limited to the development of 10 quality measures on only three sentinel health conditions: myocardial infarction, heart failure, and pneumonia.⁶ As a financial incentive to participate, hospitals that participate in the HQI and meet all the reporting requirements will receive a full inflation-adjusted update in the amount in their payment schedule under Medicare and those that do not will receive 1.4% less. CMS has already developed analogous quality measures for nursing homes (10 quality measures) under the auspices of the Nursing Home Quality Initiative⁷ and for home health agencies (11 quality measures) under the auspices of the Home Health Quality Initiative. CMS publishes these quality measures on its websites to enable beneficiaries and consumers to compare facilities and agencies in their home areas. Some of these measures, admittedly embryonic, are controversial and reflect some of the inherent limitations of administrative databases such as the minimum data set (MDS) for nursing homes and OASIS for home health agencies.

This kind of information can help beneficiaries

make more informed choices about health plans and providers, but it does not address many other basic questions. Many of the questions center on how the changed Medicare program will interface with other income and health benefit programs. For example:

- If I have a Medigap policy with a drug benefit, should I enroll in the new Medicare prescription drug plan or would I be better off with a Medicare Advantage plan (Medicare HMO plan) that offers a drug benefit?
- If I am eligible to participate in a state-sponsored pharmacy assistance program, how will it affect my out-of-pocket expenses for the new Medicare prescription drug program?
- Will the new federal subsidy for company-sponsored retiree health benefits provide the level of drug benefit that is as good as the stand-alone Medicare benefit? If so, what are my risks if my former employer decides to discontinue the retiree health benefit as many employers are now doing? To what extent does my employer-sponsored health plan provide "wrap-around" coverage for my Medicare benefit?

These are not easy questions even for the best-informed and most-educated beneficiaries or soon-to-be beneficiaries. Only the Internet can provide an adequate platform for managing these kinds of choices. With or without the Internet, these choices presume that Medicare beneficiaries have the navigational skills to sort out the choices and make informed decisions. There remains a great generational divide that separates older Americans from many of their younger counterparts in knowing how to navigate the information that is already on the Web. For many older Americans, even the old QWERT keyboard—so essential to the navigation process—represents foreign and frustrating territory.

The American Association for Retired Persons (AARP) addresses many of these issues and underscores many of the challenges that seniors face as consumers and financial managers in the rapidly changing marketplace. A recently released report entitled *Beyond 50: A Report to the Nation on Consumers in the Marketplace* notes that consumers have less time to make more decisions, they face increasingly complex products and services, and they must do

so with low levels of financial literacy.⁸ AARP makes three sweeping recommendations:

- Make product information, labeling, and disclosures easier to understand, more accurate, and useful;
- Increase the quality and integrity of advice to consumers; and
- Empower consumers with new tools and technology.

Overlooked in this discussion are the millions of younger and older Americans who lack the cognitive skills needed to process the information and make good choices. Each year, for example, there are 700,000 new stroke survivors, many of whom come away with diminished capacities for self-determination. We can add to this number the larger number of under-educated seniors and a subset of seniors who experience varying degrees of dementia and cognitive degradation in the final years of life.

The increasing complexity of choices presents a challenge for individual beneficiaries and their family members but also for providers who depend on third-party payment such as Medicare. Providers are going to have to learn much more about the benefit coverages that individual patients may or may not have and find ways to assist patients to arrange their financial affairs in a way that will help facilitate the services they need both in the short and long term.

What is essential in decision making is good client representation (which some family members are able to do well) and good and impartial information brokerage. Too much information brokerage is provided by those who have an interest in the outcome of the decision, for example, commission-paid financial advisors and health-plan repre-

sentatives. Providers, though not disinterested, can do more. Steps in this direction, for example, are two publications from the National Rehabilitation Hospital: *A Consumer Guide for People with Stroke: Choosing a Rehabilitation Program*⁹ and *Choosing a High Quality Medical Rehabilitation Program*.¹⁰ These kinds of information brokerage can go a long way in helping to build a franchise with an organization's clientele.

Ultimately, we will have to turn to other organizations that have the impartiality, the command of the issues, and credibility to be honest brokers in the American devolution much like the Consumers' Union in the consumer market. Some organizations that come to mind include AARP, the Medicare Rights Center, and groups such as the National Academy of Social Insurance. Most important is government itself, either as a provider of information or as a facilitator and funder of information-dispensing organizations. To fulfill the promise of the American devolution, we must invest massively in the information infrastructure to make the devolution work effectively for both the sponsors and beneficiaries for both the supply and demand sides of the market. Transparency is essential to well-functioning markets and even more so in markets that are as complex as the future of Medicare portends.

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Functional Neuroimaging in Motor Recovery After Stroke

Timea Hodics and Leonardo G. Cohen

Neuroimaging techniques provide information on the neural substrates underlying functional recovery after stroke, the number one cause of long-term disability. Despite the methodological difficulties, they promise to offer insight into the mechanisms by which therapeutic interventions can modulate human cortical plasticity. This information should lead to the development of new, targeted interventions to maximize recovery. **Key words:** *adult, animal, cerebrovascular accident/stroke, fMRI, functional magnetic resonance imaging, human, motor function, neuroimaging, PET, positron emission tomography, recovery, rehabilitation*

Stroke is the number one cause of long-term disability and the third leading cause of mortality in the United States. There is no universally accepted method to enhance the beneficial effects of rehabilitative therapy after stroke, which leaves more than half the patients with some degree of motor deficit, particularly in the hand.¹ Functional improvement following a debilitating stroke is thought to be due to plastic changes that occur in the brain during the months after the injury. Despite the numerous studies performed in this area, the exact mechanisms and biologic basis for brain plasticity are still largely unknown, making it difficult to design targeted interventions to influence recovery.

Animal Models

In animal models, focal brain damage triggers a number of changes in molecular, cellular, and system levels that in turn result in cerebral reorganization and functional recovery. The dominant mechanism of plasticity likely differs depending on the time frame. Swift changes in motor representations within minutes are likely due to unmasking of latent synaptic connections involving modulation of GABA-ergic inhibition. Within hours of a peripheral nerve transection in adult rats, movements represented in neighboring primary motor cortical areas are evoked from the cortical territory of the affected body part.² Changes over a longer time likely involve other additional mechanisms such as long-term potentiation, axonal regeneration, and sprouting. These morphological changes that occur in the

brain after injury during the recovery process are similar to those described with learning.³ Skill learning in animals is associated with growth of dendrites and axons, dendritic spine development, and formation of new synapses.³⁻⁵ Long-term potentiation and long-term depression are mechanisms to change synaptic efficacy.^{6,7} Motor skill learning is associated with altered strength of connections in the primary motor cortex in animals.⁸ Animal models suggest that widespread cortical areas of the adult brain are able to change structure and function in response to incoming signals after injury, much like in the developing brain. These activity-driven changes can be influenced by pharmacological interventions⁹ or experimental manipulations.¹⁰

Clinical Studies

Methods used to study brain activation

Noninvasive techniques such as electroencephalography (EEG), magnetoencephalography (MEG), transcranial magnetic stimulation (TMS), positron emission tomography (PET), single photon emission computer tomography (SPECT),

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functional magnetic resonance imaging (fMRI), and near infrared spectroscopy (NIRS) are useful tools in exploring specific aspects of plastic changes that occur during the recovery process. The scientific question at hand dictates the choice of the investigative method. The relatively recent discovery that changes in hemodynamics that accompany mental function in the brain can be measured using changes in deoxyhemoglobin content led to the invention of a new imaging technique called fMRI. fMRI examination has proved useful in measuring plastic changes in the human brain with excellent spatial resolution.^{11,12} The so-called blood oxygen level-dependent (BOLD) signal is based on the tight coupling between local brain activation and regional cerebral blood flow. The noninvasiveness, relatively low price, widespread availability, and detailed structural and functional information of fMRI has made it one of the most often used functional neuroimaging modalities.

PET, which uses radioactive tracer, can measure flow similarly to MRI, however it also is capable of measuring tissue metabolism directly and is able to image tissue viability and neurochemistry.

TMS provides information that is not available with other neuroimaging techniques. Conduction velocity, motor evoked potentials, cortical excitability, and cortical inhibition can be evaluated using this technique. TMS is able to noninvasively stimulate one cortical site or create a temporary virtual lesion of a focal brain area with excellent temporal resolution, whereas fMRI and PET give more information on the spatial relations of the neuronal activation with the given task, including involvement of deep cerebral structures. However, fMRI or PET cannot provide information about the role of these activated areas. For example, fMRI or PET reveals an enlargement in the size of the hand representation in the motor cortex; TMS can indicate if temporary disruption of the areas newly recruited after treatment delays motor responses.^{13,14} If so, it would be an indication that the newly recruited region in the motor cortex plays an active role in planning and/or execution of the movement. Therefore, analysis of the behavioral consequences of TMS can provide crucial information on the role of brain regions activated in neuroimaging studies in the process of functional recovery.

EEG, NIRS, and MEG brain-mapping techniques all have excellent temporal resolution to the millisecond level, but they have been used relatively less frequently to study stroke recovery.

Methodological considerations

Patient-related issues

Stroke is a diverse disease. Variability in patient characteristics (see box titled, "Patient-Related Variables Influencing Recovery and Brain Activation and Study Participation") often makes it difficult to make meaningful observations regarding the mechanism of recovery. For example, a young patient is likely to recover better than an elderly person with the same deficit. Hemispheric dominance and handedness influence the activation patterns observed with functional imaging studies. Size and location of stroke as well as severity of the deficit are individually variable. Concomitant medications during the recovery process or scanning may alter the pattern of cortical activation. Co-morbidities such as dementia, depression, severe heart disease, or arthritis may limit a patient's ability to participate in recovery studies. Time passed since stroke onset may influence the ob-

Patient-Related Variables Influencing Recovery and Brain Activation and Study Participation

Prestroke disability and education
Age
Handedness; dominant-nondominant injury
Stroke topography (size, location)
Clinical deficit and disability from stroke
Acute stroke treatment
Time after stroke
Medications
Co-morbidities
Type and amount of rehabilitative therapies
Contraindications to imaging (claustrophobia, pacemaker, metal implant)
Vascular reserve capacity

served cortical activation pattern and further complicate the studies.

Furthermore, patient selection is usually limited by factors such as claustrophobia, metal implants, pacemakers, and the patient's ability to fully cooperate with the task. Vascular stenosis may limit the degree of reactive blood flow increase to the active brain regions. The so-called vascular reserve is the vasculature's capacity to increase the blood flow in response to increased need, and it is essential in the genesis of the BOLD response. Indeed, there is evidence that in patients with limited vascular reserve capacity the BOLD signal may be reduced or negative.¹⁵⁻¹⁷ It is particularly important to assess the functional reserve of the brain surrounding the infarct in stroke patients, where such narrowed arteries may be found more commonly.

Study design

Cross-sectional studies give a snapshot of the cerebral activation at a certain time point after stroke compared to healthy controls, whereas longitudinal studies evaluate the dynamic changes that occur during recovery. Most studies so far have used block design (a block of time with repetitive activity interlaced with rest periods), but some now are using event-related design.¹⁸ In the latter, single movements such as wrist extension are interleaved with long rest periods, and the signal is averaged over multiple single movements.

Choosing the right standard motor task for the degree of disability can be particularly challenging with longitudinal neuroimaging studies. The cortical activation pattern observed with neuroimaging depends on the type, complexity, range, frequency, and force of the motor task. Each patient has to be able to perform the same task at each time to make meaningful comparisons across imaging sessions and patients. However, the concept of "performing the same task" has been interpreted differently. In some publications, effort has been considered important (relative effort compared to the patient's maximum). In others, movements of the same body part with different kinematic parameters, EMG activation patterns, and/or even frequency of motions have been considered comparable. Some have used passive movements to include severely affected

patients and avoid variability in effort and accuracy of willed movements. The motor task should be representative of the patient's disability, yet simple enough to avoid patients using different strategies to execute the task that could confound the study.

There is considerably more intersubject variability in task performance in stroke patients than in healthy individuals due to factors such as attention, cognitive and language issues, and fatigue. Task performance should be carefully monitored to avoid associated unwanted movements in muscles other than the target region as well as coactivation of multiple muscle groups and mirror motions, which are all capable of confounding neuroimaging results. Synkinesis is usually monitored with video and/or surface EMG to ascertain isolated activation of the target muscles. Some studies had the participants rehearse the motor task outside of the scanner prior to imaging to allow careful observation of synkinesis and head movements and to train patients to perform consistent movements once in the scanner. Head movements and other movement artifacts can also confound interpretation of neuroimaging studies, therefore they should be avoided as much as possible.

The clinical outcome measures should be carefully selected to reflect clinically meaningful changes in the disability or deficit and should be sensitive in the disability range examined. Early poststroke studies when the impairment ranges from the most severe to moderate-mild degrees use scales such as the Fugl-Meyer test,¹⁹ whereas studies examining well-recovered chronic stroke patients may use scales such as the Jebsen-Taylor Test (JTT)^{20,21} that require good baseline function and are sensitive to changes at the higher end of functional status.

Imaging outcome measures are variable and take into account the location and intensity of cerebral activity as compared to a baseline or normal controls. One of the most frequently used fMRI outcome measures is the Laterality Index (LI) = $(C-I)/(C+I)$ that compares the contralateral and ipsilateral M1 relative degree of activation, where C is the number of suprathreshold voxels in M1 contralateral to the movement, and I is the number of suprathreshold voxels in M1 ipsilateral to the hand

movement. LI can range from exclusively contralateral to the movement (+1) to exclusively ipsilateral (-1).²² One problem with this type of measure is that it provides limited information on the specific brain regions operating in the recovery process. Other quantitative indices such as displacement of centers of gravity of specific body part representations in the motor or sensory strips and activation/deactivation of new cortical regions in association with task performance may provide more focal information on newly activated/deactivated neural substrates along the recovery process.

What we learned from functional neuroimaging studies

Role of the lesioned hemisphere

PET and fMRI studies have shown activation of a wider neural network in patients with stroke than that identified in healthy volunteers. Functional recruitment of cortical areas that previously were not participating in the motor task is a possible explanation.²²⁻²⁵ It has been proposed that cortical excitability of regions surrounding the infarcted site may increase in the initial phase after injury. In accordance with this, Witte et al.²⁶ found that long-term potentiation increased in the nonischemic periinfarct region early after stroke compared to unaffected brain sites. It is possible that similar mechanisms operate by mediating use-dependent plasticity during motor learning in health and disease.^{27,28} In the case of cortical lesions, it is possible that the infarct unmasks preexisting latent redundant cortical representations through decreased intracortical GABA-ergic inhibitory interactions.^{25,29,30} Brain regions that are connected but distant from the injury may function suboptimally despite the normal resting blood flow and lack of direct damage to the area. This phenomenon is called *diaschisis*, and SPECT or PET can directly image the accompanying metabolic compromise. Recovery from diaschisis³¹ may also contribute to recovery. Additionally, nonprimary motor regions within the affected hemisphere can be recruited to compensate for lesions in the primary motor outflow from M1.³²

The observed pattern of cerebral activation dur-

ing the recovery process depends on a number of conditions. These include lesion location,^{33,34} degree of impairment, time from stroke onset, acute and rehabilitative therapies used, and other patient-related issues (see box titled, "Patient-Related Variables Influencing Recovery and Brain Activation and Study Participation"). Cross-sectional imaging studies using PET^{23,35-37} and fMRI^{18,22,33,38-45} mostly involved chronic subcortical stroke patients with good functional recovery. All dealt with few patients and therefore generalization is uncertain; however, there seems to be a pattern emerging showing a few key features. First, these cross-sectional studies describe changes in affected primary motor cortex (M1), in particular ventral displacement of the cortical representation of the hand. Second, recruitment of secondary motor and sensory areas, normally not participating in the task, was frequently observed. Third, a gradual shift of activation from the bilateral sensorimotor (SM1) and premotor (PM) cortices to the affected hemisphere occurs as recovery takes place.³⁰ In cortical strokes, overactivation shifted to the periinfarct region^{22,33} and the ipsilesional PM cortex.^{37,46} Fourth, recruitment of nonmotor areas such as the prefrontal, posterior parietal, insula, and anterior cingulate cortices may represent the use of alternative compensatory cognitive strategies (for review, see ref. 47).

Only a few longitudinal functional neuroimaging studies so far evaluated the dynamic changes that occur during the subacute and chronic period during motor recovery using neuroimaging techniques, eight of which were fMRI studies.^{24,34,48-58} A few studies investigated the correlation of activation maps with recovery with longitudinal design. Information based on these studies is accumulating, suggesting that patients with overall better functional recovery are the ones that activate preferentially the M1 and dorsal premotor cortex (PMd) of the affected hemisphere.^{30,51,53} An activation shift toward the motor and premotor cortex of the affected hemisphere seems to correlate with better recovery^{52,59} (see ref. 47 for review).

Role of the healthy hemisphere (contralesional side)

Although the involvement of ipsilesional primary motor cortex (M1) in recovery of motor function

after subcortical stroke has been demonstrated,^{32,60} the role of contralesional M1 is incompletely understood.³⁸ Does contralesional M1 participate in recovery? Fridman et al.³² demonstrated the involvement of the ipsilesional premotor cortex in motor recovery using TMS disruption in individuals with good outcome, which supported its potential role in functional recovery. This result is consistent with data showing the involvement of the intact hemisphere in those patients with lesser recovery.^{32,46,53} TMS disruption of contralesional M1 did not cause delays in reaction time in the affected hand, suggesting that increased contralesional M1 activity does not simply represent functional recruitment after brain injury caused by stroke.⁶⁰ Contralesional M1 overactivation occurs in the absence of mirror movements as well, therefore it cannot simply be ascribed to synkinesis in the healthy hand. Cao et al. suggested that overactivation of the undamaged M1 represents uncrossed ipsilateral corticospinal tract recruitment³⁸; however, this seems less likely in light of the marginal physiologic role played by these connections.⁶¹⁻⁶⁵ In cortical strokes, reduced transcallosal inhibition may play a role in the overactivation of the unaffected SM1, while in cortical and subcortical strokes it can result from the increased drive from the overactivated affected side supplementary motor cortex (SMA) and PMd. Additionally, activation within the intact hemisphere could reflect interhemispheric influences on the affected hemisphere.⁶⁶ The occasionally observed synkinesis may be a consequence of this overactivation rather than the cause. In healthy participants, complex and nondominant hand tasks activate bilateral motor regions. Therefore, contralesional SM1, PMd, and SMA overactivation may be the result of the brain's compensatory activation where it processes a "simple" motor task as a "complex" task due to the injury.⁴⁷

Role of Neuroimaging in Influencing Plasticity

Neurorehabilitation studies using noninvasive techniques indicate that the brain's adaptive reorganization can be manipulated using different rehabilitative methods. Cellular therapy, growth factors, pharmacological agents, locomotor and cognitive training, robotics, special physiotherapeutic techniques such as constraint-induced treatment, and central and peripheral stimulation are just a few examples of the avenues that are currently being explored to enhance motor recovery. Neuroimaging studies can also provide information on the neural targets for possible adjuvants to neurorehabilitation like cortical stimulation.⁶⁷

What can neuroimaging tell us about the effects of a treatment? Can fMRI or PET be a surrogate marker to monitor recovery? Noninvasive neuroimaging techniques can provide information on the plastic changes that occur in association with the different interventions. For example, it was demonstrated that constraint-induced therapy increased the size of the motor output area activation and MEP amplitudes in parallel with clinical improvement.⁶⁸ Passive training caused reorganization of the sensorimotor areas in healthy individuals forming the theoretical basis of the effectiveness of proprioceptive training after injury.⁶⁹ Neuroimaging can also demonstrate effects of medications on cortical activity. Fluoxetine with physical therapy (PT) enhanced recovery in hemiplegic patients, and increased activation in the ipsilesional SM1 enhanced speed and force.^{41,70} A single dose of paroxetine altered the activation map for hand movements as measured by fMRI.

The use of therapeutic interventions while monitoring their effects on cortical reorganization should lead to a new, more effective era of neurorehabilitation that is based on targeted, individualized, evidence-based treatments.

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Advances in the Understanding and Treatment of Stroke Impairment Using Robotic Devices

Joseph Hidler, Diane Nichols, Marlena Pelliccio, and Kathy Brady

The presence of robotic devices in rehabilitation centers is now becoming commonplace across the world, challenging health care professionals to rethink treatment strategies for motor impairment in hemiparetic stroke patients. In this article, we will discuss some of the motivations for using these devices, review clinical outcomes following robotic-assisted training in both the upper and lower extremities, and detail how these devices can provide quantitative evaluations of function. We will also address the clinical issues that need to be considered when using robotic devices to treat stroke patients, and finally a vision of where this field is heading will be discussed. **Key words:** *gait, stroke, rehabilitation, robotics*

Over the last decade, the integration of robotic devices into neurorehabilitation centers across the world has reshaped clinical strategies when considering treatment options for individuals with motor impairments resulting from neurological injuries. What began as proof-of-concept testing in the 1990s has evolved into widespread acceptance among many researchers and clinicians. Today, robotic devices are being used as rehabilitative tools for treating physical impairments in both the upper and lower limbs. Because these devices have precise instrumentation that measures variables such as position and forces, they are also being used to diagnose and assess motor impairments such as spasticity, tone, and strength with great accuracy. Because they are driven with mechanical motors, these devices can automate repetitive tasks such as passive ranging, active reaching, and gait training in time-unlimited durations. Furthermore, in instances where more than one therapist is necessary to provide a therapeutic intervention, such as gait training a severely impaired acute stroke patient, robotic devices may also help reduce health care costs. It must be emphasized that the goal of introducing rehabilitation robots into clinics is not to replace physical and occupational therapists, but rather robots are a complement to existing treatment options.

Although there are numerous potential benefits to adopting these technologies into the rehabilita-

tion setting, there are also some potential drawbacks, including safety, clinician and patient acceptance, and the ability to bill for time on these devices. Because rehabilitation robots come with state-of-the-art technology, the up-front costs can be overwhelming for smaller centers.

In this review article, we will discuss some of the key findings and contemporary issues surrounding the introduction of robotic devices into

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neurorehabilitation programs targeting hemiparetic stroke patients. First, the motivation and potential benefits of using rehabilitation robotics will be discussed. Then, clinical outcomes following robotic training programs will be presented and interpreted for both the upper and lower extremities. Next, we will discuss how these devices can be used as diagnostic tools that provide quantitative evaluations of function. A discussion of the clinical considerations that need to be taken into account when using robotic devices to treat stroke patients will be outlined, and finally a vision of where this field is heading will be proposed.

Motivation

The idea of massed-practice therapy is not a new concept in the world of rehabilitation professionals; it is used in various forms throughout occupational and physical therapy. One obvious limitation with this type of intervention from a health care cost perspective is that it is often quite labor intensive, requiring one-on-one therapist-patient interactions for highly impaired individuals. For example, manual-assisted gait training often requires multiple therapists, and even then it places excessive physical demands on the therapists that sometimes result in repetitive strain injuries, lower back problems, and extreme fatigue. It would be difficult if not impossible for even the most proficient and skilled therapist to maintain high-quality therapy across a full case load of patients who require this type of attention.

One of the main motivations for developing rehabilitation devices is to automate or assist interventions that normally require multiple therapists or that are extremely physically demanding. For example, during reach-to-grasp tasks, the robot can provide visual cues to the patient and then assist the movement if they are unable to complete the task.¹ As the patient regains function, the robot can make the task more challenging by adding resistance during the movements or perhaps adding obstacles the patient must navigate through or avoid. Because the movements are guided by an actuated device, the number of reaches is not limited in time or duration.

Another potential benefit of integrating these

devices into rehabilitation clinics is that rehabilitation robots are able to accurately measure and track the patient's impairments over the course of a therapeutic intervention. Clinical scales such as FIM™,^{2*} Ashworth,³ and others are subjective and often suffer from poor interrater reliability.⁴ Robotic devices can monitor or measure numerous behaviors within a session and across sessions, making it possible for the therapist to track improvements and also justify their time to health care providers and payers.

There is little doubt that our population is aging; it is projected that the size of the elderly population (those 65 years or older) will rise from approximately 33+ million (12.7% of US population in 1999) to 53 million in 2020 and 77 million by 2040.⁵ From a health care cost perspective, this trend is troubling because, after the age of 55, the probability of suffering a stroke doubles with each decade,⁶ and more than half of all stroke survivors are left with some long-term disability.⁶ In parallel, economic pressures are forcing rehabilitation centers to treat patients in shorter periods of time. Often patients are discharged while they are continuing to make functional gains. Because the duration of inpatient stays at rehabilitation hospitals is decreasing and the number of outpatient therapy sessions is being continuously reduced, it is imperative to optimize the therapy patients are able to receive in the limited time window available to our clinicians and therapists.

Robot Therapy Clinical Outcomes

Since the concept of using robotic devices to deliver goal-directed physical therapy was first explored through a number of small controlled studies in the mid 1990s,^{7,8} dozens of trials have been conducted in both the upper and lower limbs. Here, we present summaries of both upper and lower limb studies that have looked at the effectiveness of robotic rehabilitation in facilitating the restoration of function in hemiparetic stroke survivors (see also refs. 9, 10, and 11 for reviews).

*FIM™ is a trademark of the Uniform Data System for Medical Rehabilitation, a division of UB Foundation Activities, Inc.

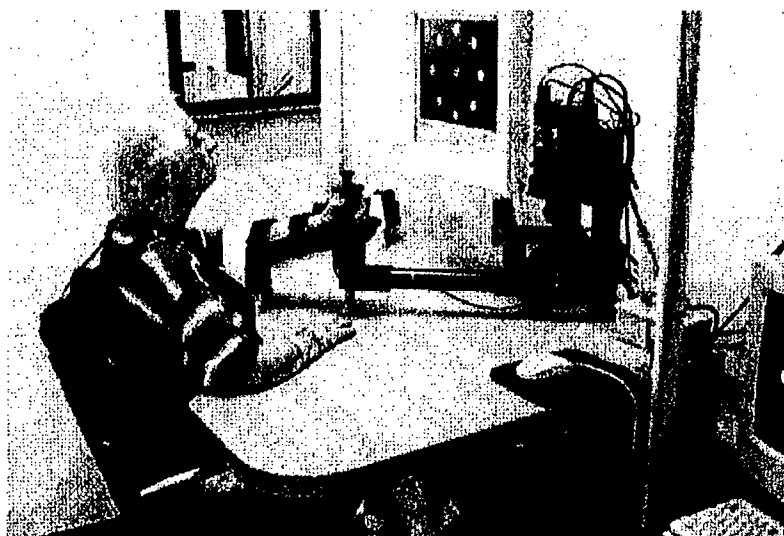


Figure 1. MIT-MANUS (Interactive Motion Technologies, Cambridge, MA).

Upper limb robotic rehabilitation

Although there have been numerous devices designed to deliver arm therapy in individuals with neurological injuries, we highlight three that have undergone extensive testing with hemiparetic stroke subjects: MIT-MANUS,^{8,12,13} ARM-GUIDE,¹⁴ and MIME.^{15,16}

MIT-MANUS

The MIT-MANUS was developed at the Massachusetts Institute of Technology in the early 1990s¹² with the goal of determining whether repetitive reaching exercises using a robotic device can enhance recovery of the arm function in hemiparetic stroke survivors. The MANUS, as shown in Figure 1, allows subjects to execute reaching movements in the horizontal plane. During movements, the device can assist or resist the subject and monitor arm position and applied forces. The manner in which the MANUS interacts with the subject is intended to be safe, stable, and compliant throughout the training paradigm.

A collection of cumulative studies utilizing the MIT-MANUS have been published for acute^{8,13,17-19} hemiparetic stroke subjects with the goal of determining whether subjects who receive robotic-assisted arm therapy coincident with their conven-

tional therapy make greater improvements in upper limb function than those who receive "sham" robot therapy along with their conventional therapy. In each of these studies, the robot-trained subjects used the MANUS to reach toward various targets across their workspace; if they were unable to complete the movement, the robot assisted them. On average, three packets of 20 repetitions were done with the impaired limb, totaling 4–5 hours per week over a 7-week period. The sham group received 1 hour of additional therapy per week, where they used the device for 30 minutes with their unimpaired arm and the other 30 minutes with their impaired arm. The motors on the MANUS were not turned on so that if these subjects did not complete their intended movement, they used their unaffected limb to assist the affected limb complete the task.

Evaluation of upper limb motor impairment and ability to carry out functional tasks was done before and after the intervention and included the FIM²; subset of the upper limb Fugl-Meyer (FM) functional impairment scale²⁰; strength in the biceps, triceps, anterior, and posterior deltoid muscles using the Medical Research Council Motor Power (MP) scale; and Motor Status Score (MSS) for the shoulder-elbow complex (MSS-SE) and wrist-hand complex (MSS-WH).²¹

After testing 96 acute stroke subjects (average of 2

weeks post stroke at enrollment) at the Burke Rehabilitation Hospital (White Plains, NY) through a double-blinded study, it was found that the robot-trained group demonstrated significantly greater gains in elbow and shoulder motor function (MSS-SE, $p < .001$) and elbow and shoulder strength (MP, $p < .005$) than the sham control group. No significant differences between groups were observed in Fugl-Meyer scores at the shoulder, elbow, wrist, or hand nor were there differences in FIM or motor function (MSS-WH) at the wrist and hand. A 3-year follow-up study evaluating 12 of the first 20 subjects enrolled in the study found that there were no significant differences in any of the outcome measures described earlier except for shoulder-elbow motor status score (MSS-SE, $p < .05$).

Recent studies have explored the idea of using the MIT-MANUS in chronic subjects^{22,23} and have found similar trends. That is, even in the chronic stages of their injury, subjects are able to improve shoulder and elbow function after training for 6 weeks with the robot. Furthermore, these gains were sustainable for at least 4 months, which suggests that long-term improvements in function are achievable even in the chronic stages of stroke.

Even though these studies demonstrate functional improvements in both acute and chronic stroke subjects following training on the MIT-MANUS arm robot, a few points of contention need to be raised. First, in the acute studies presented here, the control group only received 1 hour of extra therapy per week while the robot-trained group received approximately 5 hours. Of this 1 hour of therapy, 30 minutes were spent training the unimpaired arm. So it is questionable whether true comparisons should be drawn between the two types of interventions. Furthermore, Volpe et al.¹⁸ noted that the control group had significantly lower FIM motor and cognitive scores, and, while not statistically significant, there was a trend for the lesion volumes to be larger in the control group than in the robot-trained group. Each of these issues may raise questions about whether robot therapy with the MIT-MANUS is more effective than conventional therapy, but there is little doubt that the robot-trained group demonstrated statistically significant gains in function after repeated sessions with the device.

ARM-GUIDE

One possible limitation with the MIT-MANUS is that it emphasizes training within the horizontal plane. Subjects who trained on the MANUS did demonstrate improvements in shoulder strength and function, but some researchers have hypothesized that training in a three-dimensional workspace may enhance these functional gains. Reinkensmeyer et al.^{14,24,25} developed a trombone-like device called the Assisted Rehabilitation and Measurement Guide (ARM-GUIDE) that allows stroke subjects to reach along a rail, which in turn can be positioned so that the subjects' reaching motion can be neutral to gravity or can work against gravity (Figure 2). Like the MIT-MANUS, the device is actuated with a motor that can assist or resist the subject's motion and is also instrumented to monitor hand position and speed. A 6-degree of freedom force sensor is mounted just below the handle so that forces exerted by the subject along the rail and also orthogonal to the desired motion can be quantified. The device can be adjusted in the elevation and yaw axes, and the extent of the movement can also be controlled. The device continues to be used as both a diagnostic tool (see the section, "Robot Therapy Clinical Outcomes") and a treatment tool for addressing arm impairment in hemiparetic stroke subjects.

A small controlled study was carried out that compared long-term arm training on the ARM-GUIDE to a control group that executed free-reaching movements.²⁶ In this study, a group of chronic stroke subjects (more than 1-year post stroke) were trained; six subjects used the ARM-GUIDE and four acted as controls. The ARM-GUIDE group reached toward targets arranged across their reaching workspace with their impaired arm. In this setting, the ARM-GUIDE was pointed toward the selected target; after receiving a visual cue, the subject was instructed to try and reach toward the target as fast as possible. If the hand velocity of the subject followed a predetermined hand trajectory, then the motor on the ARM-GUIDE provided no assistance. However, if the subject reached either too fast or too slow, the device resisted or assisted the movement, respectively. In this setting, the subjects' goal was to

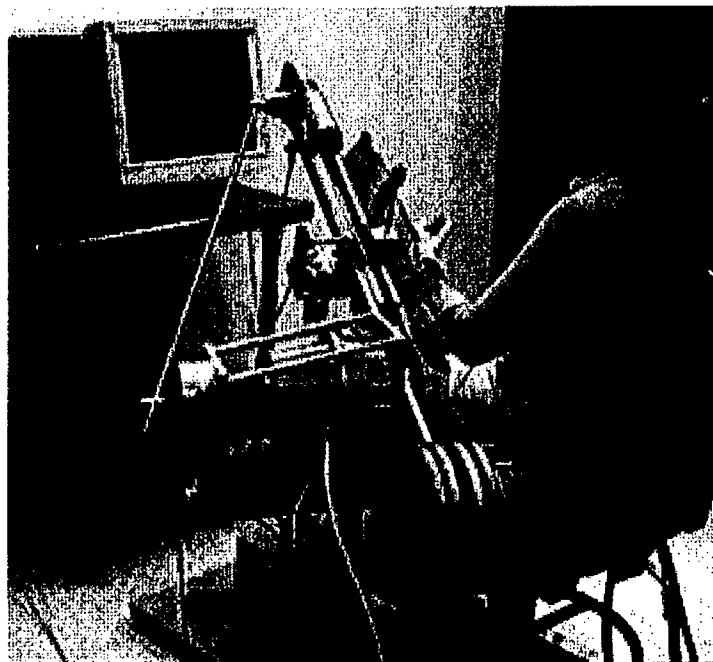


Figure 2. Assisted Rehabilitation and Measurement Guide (ARM-GUIDE).

follow a prescribed velocity path that spanned their range of motion. Graphical feedback of their hand position was provided during each reach.

The control group executed free reaching toward targets arranged on a wall that were similar in direction as the targets used in the ARM-GUIDE group. Here, the subjects were not constrained to move along any path; they were simply asked to reach toward the various targets at a comfortable speed. Each trial began with the hand of their impaired arm resting on their lap. A Flock of Birds (Ascension Technology Corporation, Milton, VT) sensor was placed on the back of the subjects' hand to monitor their reach trajectory. Visual feedback was also provided to this group after they completed a sequence of reaches.

Both groups were trained 3 days per week for 8 weeks, totaling 24 sessions. Evaluations of performance were done prior to and following training using the Chedoke-McMaster Upper Extremity Stroke Assessment Scale²⁷ for monitoring arm function and the Rancho Los Amigos Test²⁸ for evaluating each subject's ability to carryout everyday tasks. Subjects also carried out passive and active tests on the ARM-GUIDE to measure passive

limb mechanics and voluntary reach range and speed.

It was found that both subject groups improved in the Chedoke-McMaster and Rancho Los Amigos Tests; however, there were no statistical differences between the improvements across groups. Furthermore, both groups demonstrated statistically significant improvements in active range of reach and reaching speed and demonstrated decreased passive resistance to movement ($p < .05$). However again, there were no statistical differences between groups, which indicated that both therapeutic interventions had similar effects.

While this study only consisted of 10 chronic stroke subjects, it raises questions about whether it is the mode of therapy or the amount of therapy that is ultimately important in restoring arm function to hemiparetic stroke subjects. It should be noted that the starting impairment level in the ARM-GUIDE group was slightly greater than that of the control subjects, which may slightly skew the results. However, it appears from this study that the results can be interpreted in at least two ways: robotic-assisted therapy is no more effective than conventional therapy, or the type of robotic-



Figure 3. Mirror Image Movement Enabler (MIME).

assisted therapy used in this study is not optimal for addressing arm impairment in this patient population. This group is currently exploring a variation of the ARM-GUIDE protocol to try and address this issue.²⁹

MIME

The final upper limb training protocol based on robotic-assisted movements that will be discussed was designed through a collaborative effort between the Veteran Administration Medical Center in Palo Alto and Stanford University and is called MIME (Mirror-Image Movement Enabler).^{1,15} The robot utilized in this protocol, a PUMA 560 industrial device (Staubli Corporation, Duncan, SC), was modified so that it could interact with subjects in a stable and repeatable manner. The subject's impaired limb was placed in a splint, which in turn was connected to the robot through a 6-degree of freedom force-torque sensor (**Figure 3**). This sensor is able to measure the interaction forces between the subject and the device during reaching tasks. The device is fully instrumented so that the position of the subject's limb can be inferred through the robot's position. The idea behind this protocol was to explore the effectiveness of restoring arm function in stroke subjects by having them execute movements that mirror one another in both of their upper limbs.

In these studies, four different modes of operation were explored. In the first mode, the subject's arm was passively moved by the robot from a starting position to a target along some predetermined kinematic trajectory. During these movements, the subject was asked to relax the paretic limb and allow the device to passively move the arm. In the second mode of therapy, the subject would attempt to move to a target while the robot would stabilize the limb. The subject was only allowed to move in the direction of the target and not back toward the starting position. If the subject attempted to move toward the target and could not make it, the robot would support the limb and assist the movement. In the third mode of operation, the robot was programmed to provide some viscous resistance as the subject reached for the targets across the workspace. Finally, the fourth mode of training was developed to be bimanual in nature, where the subject would reach for symmetric targets using both arms at the same time, one connected to the robot and the other connected to a position-sensing digitizer. Here, the motion of the unimpaired forearm dictated the range and rate of the movements of the impaired arm that was assisted by the robot. The idea was that in the bimanual mode the subject had full control over the path and rate of movements of both arms.

To evaluate the effects of these robot modes of therapy in comparison to NeuroDevelopmental

Therapy (NDT), 27 chronic stroke subject (more than 6 months post stroke) were tested, where each subject received 24 one-hour sessions over a 2-month period.¹¹ For the robot group, subjects practiced shoulder and elbow movements that were assisted by the robot. Here, targets were placed away from the subject so that the emphasis was placed on reaching movements to various points in the workspace. All subjects spent approximately 12 minutes in bimanual mode, 5 minutes in passive mode, and the remainder of the session in practicing active-assisted or active-resisted modes depending on their functional level. For the control group, subjects were trained using NDT; the subjects practiced various tasks with their arm that focused on functional or self-care tasks.

Evaluations of intervention effects were done at months 0, 1, and 2 and at a 6-month follow-up session and included Fugl-Meyer testing,²⁰ Barthel Index,³⁰ FIM,² and maximum strength testing under isometric conditions. Evaluation of active reach was also examined by having the subject make reaches to targets positioned at various places in a three-dimensional space, during which arm position and orientation were quantified using a lightweight, instrumented forearm splint.

Following 24 sessions of training, it was found that the subjects who received MIME therapy made statistically higher gains in proximal arm function (Fugl-Meyer scores), strength (elbow extension, shoulder flexion, and shoulder abduction and adduction), and the amount of active reach. The robot group made statistically faster gains in proximal arm function during the 2 months of training; however, at the 6-month follow-up, there were no statistical differences in function between the two groups. No changes were found between subjects in distal arm function or ability to perform activities of daily living (ADLs; Barthel Index or FIM).

In a similar study that only focused on subjects trained using the MIME protocol,¹⁶ it was found that the amount of work the subjects were able to perform during active reaches had significantly increased. In subjects with low levels of function, the extent of reach had improved; in high-functioning subjects, the movement velocity was significantly higher. Improvements in elbow and

shoulder muscle activation patterns were also observed in subjects who performed reaches against gravity, but no improvements were noted during table-top movements.

Preliminary summary: arm devices

This study, like the MIT-MANUS study, provides evidence that training with a robotic device can improve arm function in hemiparetic stroke subjects, but it is task specific. That is, both of these studies found that proximal arm function improved more rapidly and to a greater extent in the robot group, however distal arm function did not experience these same gains. Both devices used in these studies emphasize proximal tasks, so it is not surprising that changes in wrist and hand function were no different from those in the control groups.

What is somewhat disappointing in these studies is that subjects experienced improvements in function according to scales such as Fugl-Meyer and Motor Status Score, but changes in the subjects' ability to perform ADLs were no greater in the robot-trained group than they were in the control groups. One has to consider which aspect of recovery is more important to the consumer; the ability to perform things at home that would make them more independent or tests that are supposed to be indicative of their ability to perform ADLs. We postulate that future studies using these and other robotic devices must demonstrate clear benefits to the subjects' ability to perform ADLs, otherwise acceptance of these devices by the clinical community and the consumer will be significantly compromised.

Lower limb robotic rehabilitation

The concept of body weight-supported locomotor training is now being used extensively in most neurorehabilitation centers and is demonstrating promising results. Over the last 10 years, it has been shown that subjects who receive body weight-supported treadmill training after spinal cord injury³¹⁻³³ and stroke³⁴⁻³⁶ demonstrate improved EMG activation patterns,^{31,37} more natural walking characteristics,³⁵ are able to bear more weight on their legs,³² and demonstrate functional

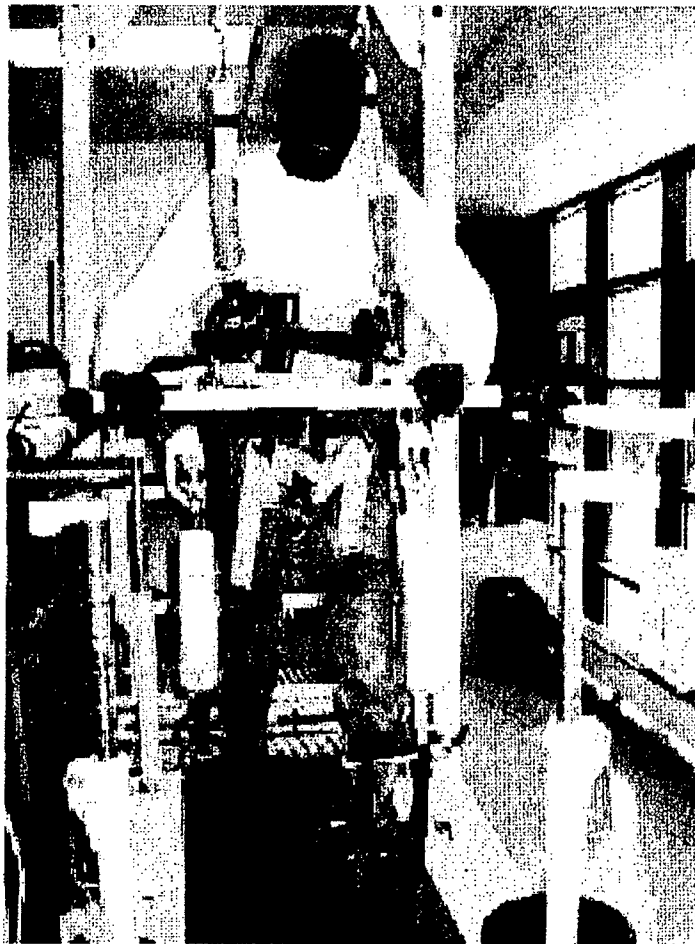


Figure 4. Lokomat gait orthosis (Hocoma AG, Volketswil, Switzerland).

improvement in walking ability.^{33,37} Furthermore, there are also reports of reductions in spasticity³³ and increases in cardiopulmonary efficiency³⁸ after body weight-supported locomotor training.

The major drawback of manual-assisted locomotor training is that it places large physical demands on the therapists, which limits the consistency and duration of training sessions. Furthermore, from a health care cost basis, manual-assisted locomotor training is quite expensive, as it often requires multiple therapists to properly administer. To address these limitations, a number of robotic gait trainers have been developed, all having the goal of delivering time-unlimited, consistent gait training in individuals with neurological injuries. We highlight two such de-

vices that are currently being used in various clinics around the world: the Lokomat³⁹ and the Gait Trainer.⁴⁰

Lokomat gait orthosis

The Lokomat robotic gait orthosis has been in development since the mid 1990s in order to automate the delivery of locomotor training for individuals with neurological injuries.³⁹ This system is comprised of a treadmill, a body weight-support system, and two lightweight robotic arms that attach to the subject's legs (**Figure 4**). The Lokomat is fully programmable, including control of knee and hip kinematic trajectories, the amount of assistance the system provides to the

subject, and the speed at which the subject ambulates. This high-level dynamic control is achieved by small direct current (DC) motors and linear ball screw assemblies at the hip and knee joints that are tightly synchronized with the timing of the treadmill. Hip and knee angles are monitored through high-precision potentiometers while dorsiflexion is provided at the ankle of the subject through two passive elastic straps. Unloading of the patient is achieved by connecting the shoulder straps on a harness to a counterweight system. Furthermore, force sensors mounted in series with the motors sense the amount of resistance/assistance the subject is generating while walking in the device, which can be used as biofeedback for motivational purposes. The Lokomat is an FDA-approved medical device.

Because the Lokomat has only been commercially available since 2002 (Hocoma AG, Volketswil, Switzerland), no large-scale studies have been published comparing the effects of Lokomat gait training to conventional gait training in hemiparetic stroke subjects. A multicenter study currently being conducted by the National Rehabilitation Hospital and the Rehabilitation Institute of Chicago is investigating this question in subacute stroke subjects (less than 6 months post stroke), where it is anticipated that the results of more than 100 participants will be reported in the fall of 2007. That study is being sponsored by the National Institute on Disability and Rehabilitation Research (NIDRR) under Rehabilitation Engineering Research Center (RERC) "Machines Assisting Recovery from Stroke (MARS)."

Mechanized Gait Trainer

Another robotic device that targets gait training in stroke subjects is the Gait Trainer^{40,41} developed in Germany, which works very similarly to traditional elliptical trainers. In this setting, the subject's feet are strapped to two footplates, which in turn are connected to a linkage system that moves the foot through a trajectory quasi-similar to the gait cycle. The foot is always connected to the platforms, and the positioning and loading of the foot on the Gait Trainer is comparable to the stance and swing phases of the gait cycle, with a ratio of 60% and 40% for each phase, respectively.

The stride length and phase durations can be adjusted by using different gear ratios on the linkage system, while the step velocity is modulated between 0 to 1.12 m/s. Furthermore, the linkages connected to the footplates are connected to a motor that can provide varying levels of assistance throughout the gait cycle, ranging from full support when the subject provides no assistance to little or no support when the subject actively propels his or her legs. Similar to the Lokomat, the forces generated by the subject can be used as biofeedback during training.

A randomized crossover design was performed to evaluate the effectiveness of using the mechanized Gait Trainer in a group of nonambulatory stroke subjects ($n = 30$; 4–12 weeks poststroke).³⁶ Subjects enrolled in the study were randomly assigned to one of two groups: a group that received treatments A-B-A and a group that received treatments B-A-B. Intervention A consisted of 15–20 minutes of daily locomotor training on the Gait Trainer for 2 weeks; intervention B consisted of the same doses of therapy only on the treadmill. In the robot and treadmill interventions, a portion of the subject's body weight was supported using an overhead unloading system. Furthermore, assistance with weight shifts and leg kinematics (e.g., foot placement and knee control) was provided by a therapist in both groups as required for each subject. Evaluations of walking ability consisted of the Functional Ambulation Category (FAC),⁴² gait velocity, and Rivermead Motor Assessment Score,⁴³ and ankle spasticity was quantified using the modified Ashworth scale.³ Assessments were performed by an independent evaluator blinded to the subject's treatment group before training, weekly, and finally at a 6-month follow-up visit.

After 6 weeks of therapy, both the A-B-A group and B-A-B group demonstrated improvements in walking ability (FAC), walking speed, and Rivermead scores. FAC scores were found to be statistically higher in the A-B-A group than the B-A-B group, however there were no group differences in walking speed or Rivermead scores. No changes in ankle spasticity were found in either group. By the 6-month follow-up evaluation, none of the outcome measures were statistically different across groups.

For the robot intervention, therapy sessions

could be carried out by one therapist even in highly impaired subjects; whereas for the treadmill training intervention, sometimes three therapists were needed to properly train low-functioning subjects. This likely cost productivity highlights one of the benefits of robotic rehabilitation, particularly with the current health care economic pressures.

A potential limitation with the Gait Trainer is that the system does not directly control the knee or hip joints nor is the trunk supported. In acute stroke subjects, weakness across the knee and hip joints often results in poor joint stability, so that hyperextension may occur unless otherwise controlled by a therapist or trainer. Furthermore, because the subject's feet are always attached to the pedals, unnatural cutaneous inputs to the bottom of the feet may alter sensory inputs normally experienced during gait. Nevertheless, the outcomes of this study provide promising indications that robotic-assisted gait training may result in positive returns in walking ability.

Preliminary summary: gait training devices

Although there are limited experimental results supporting the effectiveness of robotic-assisted devices in restoring walking function in hemiparetic stroke subjects, the need for gait-specific devices is of high importance because training subjects with significant motor impairment is labor intensive and often requires multiple therapists. If devices such as the Lokomat or Gait Trainer can replicate results in neurological subjects that are similar to the results experienced after manual-assisted locomotor training, the cost benefits of robotic devices may ultimately help facilitate their adoption into rehabilitation centers.

Quantifying Impairment Using Robotic Devices

The section "Robot Therapy Clinical Outcomes" highlighted various studies of the effectiveness of robotic devices as therapeutic tools for upper and lower limb rehabilitation, but these devices are also well-suited to quantify motor function and impairments in hemiparetic stroke subjects. Because all of the devices discussed previously are

fully instrumented with sensors that measure limb position, velocities, and forces, these variables can be used to study impairment with a high degree of precision. Furthermore, this information can also be used to track recovery and perhaps even dose therapy. By better understanding the mechanisms underlying impairment, more effective treatments may ultimately be developed. In this section, we discuss a few examples of robotic devices used to evaluate arm and leg function in hemiparetic stroke survivors.

Previously, we highlighted the MIT-MANUS (Figure 1) as a therapeutic tool for aiding in the recovery of arm function in stroke subjects. The MIT-MANUS has also been used to track changes in smoothness during arm movements^{8,44} and the ability to execute continuous arm movements.⁴⁵ Both of these characteristics, smoothness and continuity, are inherent characteristics of coordinated human movement.⁴⁶ In these studies, stroke subjects were instructed to either make point-to-point linear movements or draw a circle. The resulting hand movements were examined for the number of corrective movements made, the shape of the velocity profile, and other metrics of smoothness. It was found that throughout the course of recovery, stroke subjects demonstrate improvements in their ability to execute smooth, continuous movements that are similar to nonneurologically impaired subjects. For example, Krebs et al.⁸ showed that prior to robot training, when subjects attempted to draw circles, the shape of the circle was highly distorted and a large number of corrective movements were made. However, through the progression of the intervention, the shape of each movement became more circular and the velocity profile began resembling a bell-shape with less corrective movements, both being normal characteristics.

Reinkensmeyer et al.^{24,25} utilized the ARM-GUIDE (Figure 2) to study active and passive restraints exhibited by chronic stroke subjects during guided reaching. Subjects were instructed to reach as far and as fast as possible along the guide and to try not to push up or down or left or right against the device. The arm was also moved through the entire range of motion by the device while the subject relaxed in order to evaluate passive tissue properties. It was found that during ac-

tive reaches subjects generate large and significant forces against the rail perpendicular to the desired movement. These forces were consistent with the synergy patterns previously reported in chronic stroke subjects.^{47,48} Furthermore, it was found that passive tissue constraints were significantly higher in the impaired arm and that deficits in active reach extent were attributable to spasticity and weakness. These studies demonstrate the utility of robotic devices to investigate the mechanisms underlying arm dysfunction in stroke subjects.

Techniques are also being developed to evaluate walking ability and gait impairments using robotic devices.⁴⁹ The goal of this work is to establish the optimal set of training parameters, such as walking speed and level of body weight support, for maximizing the effectiveness of the therapy. A standard Lokomat (Figure 4) has been modified in two distinct ways. First, the cuffs that couple the subject's legs to the Lokomat have been customized to contain 6-degree of freedom load sensors that allow for the accurate measurement of the assistance or resistance the device provides the subject. Second, a split belt treadmill that resides under the Lokomat contains sensors that allow for the calculation of ground reaction forces and centers of pressure. Utilizing the leg-Lokomat interaction forces, the ground reaction forces, and the kinematic data (e.g., position and velocity of the legs), a modified inverse-dynamics technique is used to estimate the ankle, knee, and hip moments the subject generates under any set of training parameters. Combining this information with electromyographic (EMG) information, the role of impairments such as weakness, spasticity, and abnormal synergies on walking ability can be studied, and the set of training parameters through which the subject steps to generate the best joint moments and muscle activation patterns can be identified. The goal is to train subjects under conditions that may lead to higher returns in walking ability after long-term locomotor training.

Clinical Considerations When Incorporating Robotic Devices into Rehabilitation Centers

A major consideration of most facilities with regard to using robotics will be the cost effectiveness of treatment. The purchase of robotic systems

such as the Lokomat or MIT-MANUS presents a significant expense for any clinical facility. There are numerous administrative costs related to clinical use of the robotic as well. Therapists and aides must be trained to use the equipment safely and effectively; this is nonreimbursable time for the department. Training not only involves learning how to properly set-up the patients into the device but also gaining a detailed understanding of both the hardware and software that accompany the robot. Once the proper fit has been determined, an aide might be able to perform any necessary set-up of the robot prior to the patient getting into the robotic system, but the therapist should check the set-up before any training begins.

Unlike most physical therapy settings where a therapist might see more than one patient at a time, robotic training currently requires one-on-one treatment. While this may soon change for some devices (see the section, "Future Directions"), currently group therapy with these devices is not possible and therefore impacts department revenue. In some robotic devices, particularly the gait trainers, an additional person in the lab is often necessary for efficiency and safety purposes. For example, due to co-morbidities in the patient populations using the Lokomat (typically SCI, CVA, and TBI), blood pressure, cardiac, or diabetic issues can arise during training sessions. Although training can be accomplished safely with one person, it often requires a minimum of two people to get a patient safely out of the device when time is critical. With the proven benefit of robotics, the potential to increase referrals to therapy and the increased revenue generated from those referrals might offset some costs.

In addition to cost issues, there are numerous treatment considerations with robotic therapy. For such interventions to be used in the clinic, the benefit must be established through ongoing clinical research trials. Currently, a motor learning approach is the generally accepted method to retraining movement with neurologically impaired individuals. Motor learning theory has been incorporated into therapy practice since the 1990s when Carr and Shepard advocated its use with NDT.⁵⁰ Regardless of the treatment philosophy, in general the adopted strategy is a principle of active, high repetition, task-specific practice.

Before bringing a robot into the clinic as a training tool, a clinician might ask if the robot can provide these needed practice conditions. Therapists will also want to know that adequate and/or varied learning conditions can be provided with a robotic device.

Another hurdle to overcome before robotics become a standardized treatment tool may be acceptance from the clinicians themselves. Therapists pride themselves on their ability to use their hands for evaluation and treatment. Their hands are the "tools of the trade." Clinicians may feel that the robot eliminates this aspect of practice that they feel is implicit to their profession. Other clinicians may fear that new technology could replace them in the clinic. Yet, the ability to assess and plan for the patient's individual needs is still dependent on the therapist's expertise and judgment. Robotics are technologies that are developed to assist therapists in attaining optimal outcomes for patients. In treatment, a robot may replace the therapist's hands to assist with heavy, challenging, or repetitious movement and ease physical strain on the therapist. A robot could also be used as a tool to allow for massed or varied practice of a difficult movement task. The therapist's hands and eyes will continue to provide the information that is used to evaluate the patient's movement strategies. Data from the robot can quantify what clinicians may be seeing and feeling (see the section, "Quantifying Impairment Using Robotic Devices") and can provide them with objective information on current performance that can be compared to past and future performance.

Future Directions

Whereas the last decade has taken rehabilitation robotics from concept to reality, the upcoming years will test these devices with extreme rigor to determine whether they should be considered as daily treatment options across various patient populations. Furthermore, advances in technology will result in these machines becoming lighter and more powerful, perhaps opening up new opportunities and therapies. Before devices like those profiled in this article can be made more effective, we must first understand which interventions best promote recovery. Once a particular mode of in-

tervention has been shown to be effective, it only makes sense to then wonder whether a robotic device can help deliver it more effectively. The design and construction of devices that are not based on evidence-based practice or on solid therapeutic principles shown to be effective will surely lead to failure.

Robotic devices must also overcome the cost hurdles discussed in the section "Clinical Considerations When Incorporating Robotic Devices into Rehabilitation Centers." Krebs et al.¹³ proposed that the MIT-MANUS could be used in a classroom fashion, where one therapist could oversee multiple patients who were each using the device. Such practice is currently being performed in Austria with the Lokomat, where one technician simultaneously trains more than one subject at a time on two devices side by side. Ultimately, the safety of these devices must be shown to be such that the occurrence of patient injuries is no higher than what is seen routinely in clinics.

We must also evaluate patient satisfaction and therapist satisfaction with the clinical use of rehabilitation robots. Krebs et al.⁸ surveyed their research subjects; even though all subjects felt that the robot training was productive and assisted their recovery, they all preferred the therapist to the robot. Even though clinical rehabilitation robots mostly work in tandem with therapists rather than autonomously, issues such as patient comfort, anxiety, and tolerance must be taken into account.

Finally, we propose that clinical acceptance in this field will come only after well-controlled studies are performed demonstrating the effectiveness of robotic devices. For each device, these studies will need to identify which patients are appropriate and will likely demonstrate improvements in function, training parameters, training dosages, and other determinants surrounding the therapeutic intervention. To date, we have relied on heuristic rules for establishing parameters and dosing the therapies, because there were little or no foundations from which to work. Now that there is a growing body of literature in the field of rehabilitation robotics, our next steps must be to design, build, and test devices based on evidence and not assumption.

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Opening the Black Box of Stroke Rehabilitation with Clinical Practice Improvement Methodology

Brendan E. Conroy, Brooke Hatfield, and Diane Nichols

Although stroke survivors are the largest consumer group for postacute rehabilitation services, there has been little quantification of the details of poststroke rehabilitation (PSR), with the major exception of the AHCPR Clinical Practice Guidelines #16 of 1995. The gold standard research methodology of a randomized controlled trial cannot practically encompass PSR. Using clinical practice improvement (CPI), a statistically based, validated research methodology, a mathematical representation of the inpatient stroke rehabilitation experience has been constructed. This article examines the principle aspects of CPI methodology and how it was adapted to a multicenter study of inpatient PSR. **Key words:** *best practice, clinical practice improvement, Comprehensive Severity Index, methodology, outcome(s), practice variation, regression, rehabilitation, stroke, TeleForm*

Poststroke rehabilitation (PSR) is a powerful, complex, and expensive medical therapy that is provided for many thousands of stroke survivors each year. The American Medical Rehabilitation Providers Association (AMRPA) eRehab database¹ has data on 25,853 patients for calendar year 2004, with an average cost of \$18,000 per stay, worth approximately \$465,354,000. Even though prescribing providers may write orders for a stroke rehabilitation program to include 5–6 days per week of physical therapy (PT), occupational therapy (OT), speech language pathology (SLP), psychology, and around-the-clock rehabilitation nursing care, the full extent of what the patient receives is not exactly known. Acute inpatient stroke rehabilitation is a "black box" into which the prescriber and the insurer place a patient, money, and a team of rehabilitation providers, mix them up, let the black box work its magic, and, 18–20 days later, out pops a patient on their way home (usually) and with the money consumed. Even the prescriber, who usually follows the patient during the rehabilitation stay, has no precise, quantified idea of what the patient is experiencing. Insurance carriers typically must be satisfied with weekly progress reports and a projection of the expected discharge date and disposition.

Background

With health care costs escalating dramatically through the 1980s, there was a major change in the way hospital beds were utilized and how hospitals were reimbursed. Health care providers were held more accountable for their clinical decisions and resource consumption through guidelines put in place by payers. Payers required increased documentation from clinicians to justify what was being done with patients to ensure quality of care and to justify the cost of care. Then, in an effort to contain costs, payers wanted to know that the treatment provided was actually necessary. And,

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more than that, payers wanted the treatment to be cost effective. In 1982, Lind² reviewed seven studies on the effectiveness of stroke rehabilitation. The results were conflicting. Three studies showed a positive effect as a result of rehabilitation; three studies showed no effect; and the seventh study showed a negative effect, also noting that physical therapy was associated with creating shoulder-hand syndrome.² In the 1980s, there were little data to justify the effectiveness of medical rehabilitation services. Twenty years later, the research on stroke rehabilitation outcomes and efficacy remains scarce and still shows conflicting data.³ However, rehabilitation appears to be moving consistently in the direction of evidence-based practice, with more and more clinical research being performed. Just as important, a critical look is being taken at the research that is being done.³ In the current health care market, where reimbursement is capped, the maximum number of treatment days and types of services covered are often specified at the outset. Clinicians have had to become much more efficient and effective in the care they provide to patients in order to have good outcomes, keep costs down, and be competitive with other providers.

Since the late 1980s, there has been a greater commitment through research to justify treatment, contain health care costs, and improve patient care. In 1988, Dombovy and Bach-y-Rita addressed the need for more research into stroke recovery to enhance services and reduce costs. The following goals were outlined: (a) address the mechanisms of stroke recovery in human participants with imaging or pathologic correlation; (b) design therapeutic techniques based on neurophysiology and assess their effectiveness in groups of patients; (c) determine if intensive rehabilitation reduces functional dependency resulting in decreased long-term social and economic costs; (d) determine when rehabilitation should begin, where rehabilitation should take place, and how rehabilitation programs should be organized; and (e) enable selection of patients most likely to succeed in rehabilitation programs.⁴

There has been a concerted effort in the neuroscience, radiology, medical, and pharmacology fields to address the issues related to stroke management in recent years. TPA treatment protocols

are progressively becoming part of the routine, standard of care for the initial presentation of an acute stroke in the emergency department.^{5,6} Deep vein thrombosis (DVT) prophylaxis is now routine and includes combinations of Doppler screening, use of various antithrombotic drugs, and compression devices.⁷⁻⁹ Finding better methods to prevent initial and recurrent cerebrovascular accidents (CVAs) is an ongoing challenge to the medical and research communities.¹⁰⁻¹² In the actual arena of stroke rehabilitation, research has been intense in the applications of constraint-induced movement therapies of Taub,^{13,14} and modified versions of the initial protocol are also proving effective.^{15,16} Research on mental and physical practice, applications of learning theory,¹⁷ task-specific training,¹⁸ and functional imaging and neuroplasticity have all contributed important concepts to the treatment of stroke patients in the clinic today.¹⁹⁻²³ Some of the newer technology being tested involves virtual reality and robotics to aid in the recovery of lost function.²⁴⁻³⁴ Functional imaging allows us to see activation patterns of the brain to help understand motor recovery. We hope the knowledge gained will lead to the development of training approaches. The basis and understanding of the techniques used in rehabilitation are evolving from clinical lore to data and science. See the article by Hidler et al. on the use of robotics and the article by Hodics and Cohen on improvements in neuroimaging in this issue of *Topics in Stroke Rehabilitation*.

For therapy to be cost effective, it has been necessary to identify who will benefit the most from therapy, under what circumstances, and which type of treatment. Much of the current outcomes research has been devoted to determining which factors will lead to a favorable outcome (i.e., return home) after rehabilitation. These outcome studies are trying to open up and examine the black box of rehabilitation.³⁵⁻³⁷ To predict which patients will benefit the most from PSR, patient characteristics such as age, sex, side and site of lesion, social supports, type of dwelling prior to CVA, job status, socioeconomic level, prior level of function, impairments, co-morbidities, cognition, admission FIMTM,* and level of injury (acute vs. chronic) have been subjected to analysis of variance (ANOVA) and reduced to regression formu-

lae, which have not been clinically practical. The processes or circumstances under which the patients are treated (e.g., length of stay [LOS] in acute care, LOS in rehabilitation, treatment on a stroke interdisciplinary unit vs. general med-surg unit vs. home care, intensity of therapy) are also compared to the results of care. Efficacy studies that compare which treatment interventions are most effective for managing various problems under differing circumstances have also been conducted. Because researchers choose different study designs and methods in their attempt to determine the influence of one factor on another in their research, it is often difficult to compare results of one study to another. Both the Spring and Summer 2003 volumes of *Topics in Stroke Rehabilitation*^{38,39} contained detailed evidence-based reviews on numerous outcome and efficacy studies in rehabilitation medicine. The reader is encouraged to review the contents of these two volumes for much greater depth of material on stroke rehabilitation. The studies were rated based on the number and quality of randomized controlled trial studies that supported findings. Below is list of clinical findings based on RCTs found to have strong evidence³:

- Stroke rehabilitation improves functional outcomes.
- Stroke rehabilitation does not reduce mortality of all strokes.
- Stroke rehabilitation reduces the length of hospital stay.
- Stroke rehabilitation does not reduce rates of institutionalization.
- Greater intensity of therapy results in improved functional outcomes.
- Greater functional improvements by patients rehabilitated on specialized stroke units vs. general medical ward are maintained for up to 1 year.
- High-level patients discharged early from acute care can be rehabilitated successfully in the community by an interdisciplinary stroke team.
- Treatment of visual neglect and perceptual disorders improves visual neglect functioning.

- Treatment utilizing primarily enhanced visual scanning techniques improves visual neglect post stroke with associated improvement of function.
- Exercise therapies do not improve arm function.
- Constraint-induced movement therapies improve outcomes vs. traditional therapy.
- Functional electrical stimulation (FES) improves muscle function, pain, subluxation, and range of motion of the hemiplegic shoulder.
- FES and gait training improve hemiplegic gait.
- Biofeedback training improves gait and standing post stroke.
- Higher intensity aphasia training improves outcomes.
- Trained volunteers can provide speech and language therapy with similar results.
- There is a positive benefit of family education if it involves an active educational and counseling approach.
- Information packages and a workbook approach to family education do not alter outcomes.

The rehabilitation black box is an analogy, used previously by Ballinger,³⁷ DeJong,³⁵ and others, from airplane technology. An airplane's black box is an impregnable device that is able to make a multimedia record of what happens during each flight of the airplane. The content of the recording is typically not reviewed unless there is a catastrophe or major problem during the flight. A great deal of resources and information end up inside the box during the flight. If all goes well, the exact details of the contents never need to be examined.

The idea of examining the contents of the black box of PSR was developed based on three major problems: the ever-shrinking number of health care dollars, the need to maintain outcomes in spite of reduced resources, and the reasonable demands of the payers to know what was being done with their money. Additionally, both the providers and payers are interested in knowing what the opportunities are for increased efficiency and decreased costs while maintaining or even improving outcomes. This resulted in the formation of the Post Stroke Rehabilitation Outcomes Project (PSROP) study team, led by Drs. Gerben DeJong

*FIMTM is a trademark of the Uniform Data System for Medical Rehabilitation, a division of UB Foundation Activities, Inc.

and Susan Horn. The study team has worked under the auspices of the Research and Training Center on Medical Rehabilitation Outcomes at Sargent College, Boston University. The initial findings of this group will be forthcoming as the project continues, but the study design itself has already proved to be exciting and innovative when applied to the poststroke population.

Clinical practice improvement (CPI) methodology is a validated, scientific method of data collection and analysis, which looks for associations between patients, their characteristics, their experiences in a health care environment, and their outcomes.⁴⁰ Horn has developed and validated this software-based data collection and analysis research methodology to quantify and examine the process and demographic and clinical variables of inpatient medical care.⁴⁰ CPI has been used in multiple inpatient clinical settings including pediatric intensive care, prostate resection surgery, and nursing home resident's management. It cannot establish causality, but it can say that a certain group of patients who have certain characteristics and had a certain type or group of medical processes ended up with a certain outcome. The CPI methodology has two major conceptual tools that are used to organize the data in meaningful and clinically relevant ways: the Comprehensive Severity Index (CSI[®]) score and the Auxiliary Data Module (ADM). The CSI is a validated measurement tool of how sick patients may be, which quantifies the minimal and maximal degrees of illness a patient experienced during a hospitalization as well as a daily illness score and subscores of the degree of illness in different physiologic systems. The CSI scores can be expressed as a cumulative score that has no upper limit or an averaged score of 1–4, 1 meaning in *normal health* and 4 signifying *critically ill*. Clinical severity variables include co-morbidities such as fevers, blood pressures, seizures, pain, finger stick values, infections, fractures, syncope, constipations, and arrhythmias, all of which are calculated into the CSI score.

The ADM is the other major tool of CPI research. It is a set of variables that quantifies the experiences or processes a patient has during hospitalization. Some of those variables are the timing of medications; consultative care received; time spent

in ICU; the number of days between acute care admission and admission to PSR; amount of PT, OT, SLP, rehabilitation nursing care, psychology, vocational rehabilitation, and therapeutic recreation services received; whether the PSR unit was located in a freestanding rehabilitation center or in a unit of an acute care hospital; medical and rehabilitation therapies received while in acute care; antibiotics received for infection; billing and cost data; number of group or individual therapy treatments received per day and per week; experience level of their therapists; and others. The therapeutic interventions were examined with a high degree of detail via a data-recording sheet named the TeleForm. Each specialty area developed its own TeleForm through teleconferencing discussions that led to consensus among other rehabilitation teams from around the country. This will be discussed at greater length later in this article. The CPI patient demographic variables include age, race, sex, education, and social support system. Outcome variables include LOS, FIM at discharge, FIM change, and discharge destination. Process, demographic, and outcomes variables are all contained within the ADM.

The TeleForm was used across all sites to record time spent with the patient and was divided into skill areas and interventions. Any clinician who encountered the patient completed the TeleForm and provided such information as time spent in evaluation versus time spent in working with the patient in the targeted areas (i.e., gait, grooming, etc.) while using a specific intervention (i.e., balance training, adaptive equipment) for each session. Clinical profiles were obtained from persons who completed TeleForm as a means of capturing data on individual practitioner variability and included such information as education, years of experience, and completion of specialized training programs (see Appendix for an example of a PT TeleForm).

In terms of sample collection, there were virtually no exclusion criteria. There was no attempt to standardize the treatment regimens. There were no placebo therapies. Almost any stroke survivor who was admitted to one of the participating rehabilitation centers was included in this study, unless they were younger than 18 or had had their stroke over a year before the rehabilitation admission. This

was the entrée to the black box stroke research study.

CPI methodology is a contradistinctive way of carrying out research on human participants from randomized, double-blinded, placebo-controlled trials (RCTs). RCTs have very strict rules of study design that allow researchers to establish causality between an intervention, such as an experimental drug, and a patient outcome by minimizing the number of independent variables in the experimental design. These rules include the establishment of strict inclusion and exclusion criteria for which patients can or cannot be included in the sample, which creates a very homogenous group of participants in the sample. Persons who are included are then subjected to a highly formalized, standardized process of receiving the active substance in question or a nonactive placebo sugar pill. The whole patient experience is rigorously controlled so that any differences in the participants' eventual outcomes can be ascribed to either the active substance or the fact that they did not receive that active substance. This methodology is notoriously expensive (estimated at \$15,000/patient or \$15M/1000 patient study),⁴¹ and, if scientific rigor is to be maintained, conclusions reached can only be applied to patients who meet the original inclusion and exclusion criteria. This design rigor also allows for replication and some generalization of results.

The problems with RCTs are the cost, the limited applications of the conclusions, the whole notion of the use of a "placebo" in the process of blinding, and the facts that inpatient rehabilitation is not a pill and that rehabilitation participants talk to each other. The word "placebo" is the Anglicized first person future version of the Latin verb "placere" which means "to please," meaning, "I will please." In the medical research context, *placebo* is defined as: "A substance which has no effects on the test subject, given to members of the control group during experimental trials that test the effects of a drug or other substance. The control group is the group which does not receive the experimental drug or substance and is used to compare what happens to the test group or groups," according to www.hyperdictionary.com.⁴² Pharmacological research traditionally uses a sugar pill camouflaged

to look exactly like the tablet of the experimental drug as the placebo. The camouflaging allows the participants to be "blind" to what they may be receiving. Ideally, the researcher is also totally unaware of what the participant is receiving. This creates the Holy Grail of "double blinding," so that knowledge of the intervention by those directly involved does not affect the outcome. Unfortunately, there really is nothing to disguise in the physical process of rehabilitation: there is no pill and neither the patients nor the therapists are blind to the physical processes they are experiencing.

Rehabilitation is not the only field that has difficulty with placebo. Kirsch⁴³ describes a similar frustration with the research community's otherwise dismissive insistence on having placebo-controlled study design when he wants to research the effects of psychoanalysis. Surgeons struggle with creating sham interventions,⁴⁴ and a lot of surgical research is composed of case reports and case series. There is also extensive literature on the fact the placebo effect is a 25%–30% positive response rate⁴⁵ to the nonactive substance in exactly the way the experimental drug is supposed to work. Not to mention the additional fact that research participants who receive placebo also experience side effects! Thus, to have a placebo, you must create a nonactive intervention with your patient, which pleases them, which is physically indistinguishable from "real" rehabilitation, and which might even help them to a limited, unexpected degree. Given the shortcomings of RCTs for use in the inpatient PSR setting and the need for evidence-based practice and efficacy data, another approach to opening the black box that had been successful in other medical settings with other impairments was identified.^{46,47}

CPI studies are not randomized (except that humans are very random) nor are they blinded. No patient receives any placebo. The data collected are a large number of variables about a large number of patients. The CPI data analysis process, tailored to the PSROP, is to look at cross-sections of the patients, who are similar in terms of medical status and severity of stroke and who are similar, for example, in terms of having all started at a FIM transfer score of 2, and subdivide them into those who progressed to a discharge FIM transfer score of 4 or higher and those who did not make it. Then

the remaining variables of those two subgroups of the cross-section are examined to determine what may have made significant differences. The database may contain variables about those patients that will help discriminate patients who progress from those who do not and to say that applying a certain type or group of therapies will enhance the chance of a patient making the desired progress. The database may not contain what is needed to provide the discrimination. The set of variables was developed by a group of well-intentioned but perfectly fallible human beings, who might have unknowingly omitted significant variables or were not cognizant of a particular and very important process that was happening. Dr. Horn performed a multicenter study of pediatric ICUs several years ago and found that patients of one of the units among the group were having shorter lengths of stay, reduced frequency of tracheotomy, reduced complication rates, and reduced use of antibiotics,⁴⁶ but nothing else seemed to discriminate between the successful unit and the others, except for the smaller volume of antibiotics. Antibiotic use ended up being an outcome, not a process variable. A second, very intensive study of the same pediatric ICUs as in the first study revealed one small but apparently meaningful difference in the processes experienced by the children on the most successful unit: the nurses had a routine of going around to their child-patients on a regular basis and tickling the children's feet!⁴⁶ This tickling apparently prompted more frequent diaphragmatic inspiration and enhanced respiratory capacity and control in these young ICU patients, allowing for better outcomes.

The conclusions achieved through use of a CPI study are relatively inexpensive to achieve because most of the data collection is carried out through retrospective chart review. Data collection is performed by trained clinicians who use a software program named CSI, which helps maintain intercollector consistency and keeps the data HIPAA compliant.

The development team for the PSROP study agreed that the typical variables collected for a CPI study, structured for examining acute hospitalization med-surgical care, would not capture the full extent of processes experienced by a PSR patient. The planning team spent several months develop-

ing a new subset of ADM variables, using a consensus panel approach among the nurses, therapists, doctors, and researchers of the various rehabilitation institutions participating in the study to agree on which variables appeared to quantify a PSR patient's experiences. There is no existing research that might have provided guidance as to what these variables should be. The literature that does exist is primarily summarized in AHCPR'S Stroke Guidelines,⁴⁸ which only tell, based primarily on consensus panels, what the patient should receive, not what they actually did receive.

This research work was planned and developed through a weekly series of telephone teleconferences during which we discussed issues such as the variables to be included in the ADM, as well as many logistical issues involved in carrying out the data collection and planning for the eventual data analysis.

The justifications for pursuing such an exhaustive look at the details of PSR are multiple. First of all, it is an opportunity to determine what happens, and it is a chance to look for correlations between the frequency of different patient and process variables and their associations with the outcomes. If a situation in data analysis is found such that all the available variables between two PSR centers are not statistically different and yet their outcomes are, it is an opportunity to go back to those centers and re-examine what might be making the difference. It is a chance to look in detail at the effects of individual and cumulative co-morbidities on outcomes as well as the effects of individual and cumulative medications. It is a chance to do a detailed resource utilization review of certain groups of patients and of patients cared for in different areas of the county. In short, it is a chance to discover "tickle" phenomena, such as the one discovered in the pediatric ICU study, which may exist in each of the PSR centers involved in this study.

The CPI approach is an excellent match for studying the process of poststroke inpatient rehabilitation, because of its ability to include and appreciate the diverse poststroke population. In RCTs, co-morbidities are exclusion criteria, resulting in a small percentage of patients being included in a given design. In CPI, all patients can be

included with the co-morbidities as part of the analysis or controlled for at the level of severity. In RCTs, change is based on fact and the result shows the efficacy of the studied intervention, whereas in CPI improvement is still based on fact but the result shows effectiveness of the intervention. In RCTs, all aspects are highly controlled, eliminating the impact of the practitioner's knowledge, treatment philosophy, and decision making and resulting in small effects. In CPI, everyday practice is analyzed in the place and manner in which it has always taken place, with a myriad of individualized approaches to the various patients, resulting in large effects and capturing the practitioner's dynamic role in the process.

Overall Data Summary

A geographically diverse sample was collected from seven inpatient rehabilitation facilities (IRFs) across the United States and in New Zealand, with each site planning on collecting data on 200 poststroke patients for an expected database of 1,400 patients. Data were collected for patients more than 18 years old, who were admitted for inpatient rehabilitation for primary management of a stroke (ICD-9 codes of 430-438.99, 997.02, or 852-853). Patients with a past medical history of stroke were included as long as the rehabilitation stay was targeting a stroke within 1 year of onset.

A preliminary review of the demographic makeup of the eventual 1,291 patients who were collected supported trends previously reported in the literature of the "typical" stroke survivor. The average stroke survivor in the PSROP database was slightly more likely to be male, had an average age of 67.0, and had co-morbidities of hypertension, diabetes mellitus, and coronary artery disease. The stroke itself was as likely to be in the left hemisphere as in the right and was an infarct 67.1% of the time, a hemorrhage 22.9% of the time, and a lacunar infarct 10.9% of the time. During rehabilitation, the average patient showed an increase in motor FIM score of 21.94 and an increase in cognitive FIM score of 4.057. The average survivor stayed in an acute care hospital for 11.6 days before transferring to acute rehabilitation for an additional 19.8 days. This is very similar to existing demographic data on stroke survivor popu-

Table 1. Patient demographics

Demographics	
No. of participants	1291
Male/female	51%/49.9%
Average age	67.0 years
Typical co-morbidities	Hypertension, diabetes mellitus, coronary artery disease
Average length of time between acute care admission and admission to rehabilitation	11.6 days
Average length of stay	19.8 days
Stroke type distribution	
Infarct	67.1%
Lacunar infarct	10.9%
Hemorrhage	22.9%

Table 2. Racial demographics

Race	Individual frequency	%	Cumulative frequency	%
Black or African American	256	21.92	256	21.92
Other	91	7.79	347	29.71
Unknown or missing	139	11.90	486	41.61
White	682	58.39	1168	100.00

lations who undergo inpatient stroke rehabilitation (Tables 1-4).

Analyses

The development of this 1,291 poststroke patient database provided the study team with an infinite number of potential hypotheses by providing highly detailed information for individual patients from the time immediately following the onset of the stroke through each day of the inpatient rehabilitation stay through the hour of discharge from inpatient rehabilitation. Using bivariate and multivariate analyses consistent with measurement properties of key variables, preliminary examinations of the data indicate that this data set allows for infinite combinations of vari-

Table 3. Side of brain

Stroke side	Frequency	%	Cumulative frequency	Cumulative %
1. Right	516	44.18	516	44.18
2. Left	505	43.24	1021	87.41
3. Bilateral	109	9.33	1130	96.75
4. Unknown	38	3.25	1168	100.00

Table 4. Case Mix Group (CMG) classification on admission distribution

CMG admission	Frequency	Cumulative %	Cumulative frequency	%
101 Motor 69-84 Cog 23-35	15	1.38	15	1.38
102 Motor 59-68 Cog 23-35	46	4.24	61	5.62
103 Motor 59-84 Cog 5-22	19	1.75	80	7.37
104 Motor 53-58	95	8.75	175	16.11
105 Motor 47-52	149	13.72	324	29.83
106 Motor 42-46	109	10.04	433	39.87
107 Motor 39-41	98	9.02	531	48.90
108 Motor 34-38 Age >82	13	1.20	544	50.09
109 Motor 34-38 Age <83	109	10.04	653	60.13
110 Motor 12-33 Age >88	21	1.93	674	62.06
111 Motor 27-33 Age 82-88	15	1.38	689	63.44
112 Motor 12-26 Age 82-88	31	2.85	720	66.30
113 Motor 27-33 Age <82	133	12.25	853	78.55
114 Motor 12-26 Age <82	233	21.45	1086	100.00

ables so the study team is limited only by their imagination for querying the data.

The analyses are performed and conclusions are developed for multiple different subgroups, which are created by choosing different inclusion and exclusion criteria that are clinically relevant. For example, the computer software can be instructed to look only for patients who have a right middle cerebral artery infarct, who have diabetes and hypertension but no known coronary disease, and who are continent of bowel and bladder and who are a FIM level 3 (moderate assistance) for toileting. The controls are created retrospectively after data are collected in a manner that allows for human variability, rather than trying prospectively to reduce the variability of humans by an RCT study design. The principle analysis technique is

regression with ANOVA, also referred to as multivariate regression. It is a chance to look at the use of certain therapy techniques, or medicines, and to see if they have an associated improved or diminished outcome. This provided the study team with an opportunity to look for best practices and to develop hypotheses for future RCT studies. The group of patients selected can be subdivided into those who achieved a discharge FIM score of 5 (supervision) for toileting and those who did not. The subsequent analysis is to determine if there are statistically significant differences between the successful and the unsuccessful subgroups.

The CPI methodology consists of a wide range of data types, including rehabilitation intervention, clinician profiles, disease-specific severity of illness data in both acute care and acute rehabilitation, as

well as patient, process, and outcome data. In the specific context of inpatient PSR, the goal of using CPI is to identify patient factors and rehabilitation interventions that are associated with better outcomes as well as to determine the optimal intensity and duration of poststroke interventions and ultimately the utilization of health care resources.

Specific observations

The elegance of the CPI methodology is its ability to describe interventions that were used during PSR and how they changed across a patient's LOS to investigate best practices when patient factors such as demographic information and severity of disease are controlled. As the study group continues its analyses, the CPI methodology will provide information to fill in the blanks of the statement, "If you want to improve (deficit area), clinicians do (activity) using (intervention) during (time frame during length of stay)." The nature of the data collected through the CSI and ADM allows the study team to investigate the relationship between activities/interventions and functional change in performance.

Once preliminary patient factors were identified and controlled, some surprising differences in outcomes began to emerge that demonstrate why the CPI methodology is an exciting, cutting-edge technique for analyzing practices of PSR programs. Tremendous areas of practice variation were identified across sites as well as across practitioners that, as the study team proceeds with analysis, will likely be connected to favorable or unfavorable outcomes in patient performance. Detailed descriptions of these practice variations with an eye toward best practices are forthcoming as the study team develops discipline-specific papers via indepth analyses. However, to show the vast potential for the use of the CPI methodology in PSR, some examples of preliminary looks at the data are as follows.

In PT, significant variability was found in practice regarding the use of neuromuscular re-education techniques across practitioners; the ratio of professional staff to nonprofessional staff and the ratio of individual to group therapy emerged as points of difference across sites. There has been strong support in the data analyzed so far for

starting gait training as early as possible, even in patients whose FIM scores for transfers may only be 1 (*dependent*) or 2 (*maximal assistance*). In OT, practice variability emerged in which interventions were used to address the target area of toilet transfers and across clinicians who used different neuromuscular re-education approaches. In a preliminary finding conceptually similar to PT, the initiation of high-level self-care activities as early as possible, perhaps even earlier than currently thought possible, may lead to better outcomes in terms of discharge FIM scores for all ADLs. In SLP, practice variability in the approach to dysphagia emerged in the areas of the timing of modified barium swallows across a patient's LOS, the recommendation for use of feeding tubes, the frequency of use of fiberoptic endoscopy for swallowing evaluation, frequency and timing of the bedside clinical evaluation, and use of graded solid and liquid food consistencies. Across all three clinical groups, variations across sites existed in the time spent in evaluation and time spent in individual sessions versus group treatment. Significant variability in when a particular deficit area was addressed during the LOS was observed as well. We look forward to examining what appear to be universal practices, such as the apparent lack of significant differences across the sites in management of communication disorders.

One of the differences in practice across physicians emerged in the type of medication used for depression. The medication olanzepine was used regularly at one site, sporadically at two others, and rarely or not at all at the remaining sites. A closer look at functional outcomes, when patient factors such as clinical severity and severity of initial level of disability were controlled for, indicated LOS, discharge disposition, and FIM improvement were significantly better in patients who received olanzepine versus another drug for treatment of depression post stroke.

Conclusion

As the PSROP study team looks more closely at these differences in practice, the applicability of RCTs to determine best practices increases. The CPI methodology is a way to narrow down what microprocesses should be examined via RCTs, as it

identifies a correlation between factors or processes that would have otherwise gone undetected or unnoticed. The process acts as a research "imagination" supported by strong, reliable analytic measures.

Given the richness of the data set and the ability to control for severity, co-morbidities, and a wealth of patient factors, the CPI methodology lends itself to analysis of practices in PSR. However, this methodology is not without limitations. As the study team continues to analyze the data and discuss the significance of the findings, the picture frequently becomes blurred. There are subjective decisions that must be made by the study group to control for a given factor, such as what degree of FIM change is considered "successful," what factors may or may not contribute to a given outcome, and the data components that can or cannot be condensed to provide a sufficient amount of data for analysis. Use of the FIM as the outcomes measure has also proved limiting, because this scale simply does not capture all of the nuances of change that may be achieved through different practices and it is limited in the concrete measurement of complex tasks such as ambulation (i.e., a patient is rated a FIM of 1 in ambulation if they are not able to ambulate at all and if they ambulate less than 50 feet). Another limitation of the study design lies in the TeleForms used for recording interventions and activities performed during therapy. Although the consensus panels agreed upon a standardized interpretation of the terms on the TeleForms and a standardized in-service approach to be used at all the sites participating in the study, the completion of these forms had no actual interrater reliability checks. Finally, there is no standardized use of a measure of impairment, such as the NIH Stroke Scale, upon admission to an IRF.

Given the number of patients who participate in PSR, the number of facilities who provide rehabilitation services, and the number of third-party payers who support this level of care, there is a paucity of research that shows what practitioners were, are, and should be doing in the day-to-day management of stroke survivors. Despite its limitations, the CPI methodology used to investigate the black box of PSR appears to be a valid and revolutionary way to examine the microprocesses and

interventions that patients experience across their LOS and to assist in determining best practices for provision of care. Although the CPI methodology and the PSROP study group have generated an enormous amount of data, it will take time to sift through it to see what best practices and or correlations between interventions and outcomes rise above the noise that a data set of this size creates. Additional research is needed across all disciplines and across different clinical sites, as examining variability in practice is at the heart of this methodology. In designing this research, the CPI methodology should be considered a worthwhile approach that embraces and manages the limitations inherent in RCTs. CPI is a methodology for examining the big picture of a clinical care system, feasibly capable of quantitatively encompassing the wide variation of human responses to illness and the variation in practice of health care providers in order to establish correlations between those patients, their experiences, and their outcomes.

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APPENDIX

PT TELEFORM

Physical Therapy Rehabilitation Activities																								
Patient ID:															Date of Therapy Session:									
N R H															 									
Therapist:															Time session begins:									
 															 									

INTERVENTION CODES	Duration of Activity: Enter in 5 minute increments	Interventions; Enter one intervention code per group of boxes
Neuromuscular Interventions:	Pre-Functional Activity	
01. Balance training		
02. Postural awareness	Bed Mobility	
03. Motor learning		
04. PNF	Sitting	
05. NDT		
06. Gait with body weight support	Transfers	
07. Involved upper extremity addressed		
08. Constrained induced movement therapy	Sit-to-Stand	
Musculoskeletal Interventions:		
09. Strengthening	Wheelchair Mobility	
10. Mobilization		
11. PROM/Stretching	Pre-gait	
12. Manual Therapy		
13. Motor Control	Gait	
Cardiopulmonary Intervention:		
14. Breathing	Advanced Gait	
15. Aerobic/Conditioning exercises		
Cognitive/Perceptual/Sensory Interventions:	Community Mobility	
16. Cognitive training		
17. Perceptual training	Intervention not related to functional activity	
18. Visual training		
19. Sensory training	Intervention #2 not related to functional activity	
Education Interventions:		
20. Patient		
21. Family/Caregiver		
22. Staff		
Equipment Interventions:		
23. Prescription/Selection		
24. Application		
25. Fabrication		
26. Ultrasound		
Modality Interventions:		
27. Electrical Stimulation		
28. Biofeedback		
29. Ultrasound		
Pet Therapy:		
30. Use of dog		
31. Use of other animal		
Assistive Device:		
32. Ankle dorsi flex assist		
33. Cane - Large base		
34. Cane - Small base		
35. Cane - Straight		
36. Crutches - Axillary		
37. Crutches - Forearm		
38. Crutches - Small base forearm		
39. Dowel		
40. Grocery Cart		
41. Hemirail		
42. Ironing Board		
43. KAFO		
44. Lite gait		
45. Mirror		
46. Parallel bars		
47. Platform (parallel bars or FWW)		
48. Standing frame		
49. Steps (various heights)		
50. Step ladder		
51. Swedish knee cage		
52. Swiss ball		
53. Tray table		
54. Walker - FWW		
55. Walker - Hemiwalker		
56. Walker - Rising Star		
57. Walker - Standard		
58. Wheelchair		
Other:		
59.		

Co-Treat:	
No. of minutes: 	Disciplines:
Patient Assessment:	
Formal Assessment (initial, re-evaluation, discharge): 	minutes
Home Evaluation: 	minutes
Work Site Evaluation: 	minutes
Physical Therapy Time:	
Physical Therapist 	minutes
PT Assistant 	minutes
PT Aide/Tech 	minutes
PT Student 	minutes
Group Physical Therapy Time:	
PT Group/Dovetail: 	minutes
Enter the number of each that participated in the Group PT:	
 	
Patients	Therapists
Assistants	Aides/Techs
Students	

Management of Communication Disorders Using Family Member Input, Group Treatment, and Telerehabilitation

Christine Baron, Brooke Hatfield, and Amy Georgeadis

Today, speech-language pathologists (SLPs) practice stroke rehabilitation in environments where they have less time to manage the communication impairments of patients who are more medically fragile than ever before. Many SLPs have creatively adapted their practice to maximize functional outcomes for their patients. This article highlights three techniques designed to enhance functional SLP outcomes: maximizing family member input; providing group treatment; and providing treatment in remote, functional settings via telepractice technology. **Key words:** *communication disorders, family input, group therapy, telerehabilitation*

Today's health care environment finds patients admitted for rehabilitation after stroke with increased medical acuity and decreased insurance coverage benefits to cover the cost of rehabilitation. At the National Rehabilitation Hospital (NRH), average length of stay (LOS) for patients after stroke has decreased nearly a week over the past decade. A typical inpatient rehabilitation stay at NRH averaged 26.4 days in 1994 and has decreased to 20.4 days in 2004. At the same time, patients are admitted to NRH closer to the onset of their stroke with a greater number of complicating medical factors and co-morbidities. Persons with stroke were admitted to NRH an average of 33 days after stroke in 1994 compared with 16 days in 2004.

The current health care environment has had a significant impact on the way that speech-language pathologists (SLPs) practice. SLPs need to work more efficiently and effectively than in the past to assist their patients in achieving early functional outcomes. Evaluation periods are condensed as LOS shortens. Therapeutic techniques that maximize a patient's ability to quickly demonstrate functional therapeutic gains in the real world have taken a dominant role over stimulation techniques in treatment planning. This article describes three techniques that have been proven to enhance functional communication outcomes: maximizing family member input; providing group treatment; and

providing treatment in remote, functional settings via telepractice technology.

The Use of Family Member Input to Drive Therapy

One measure of the success of poststroke SLP intervention is how well the results of treatment translate into the stroke survivor's functional, everyday communication use. SLPs endeavor to maximize this generalization to real-life communication by obtaining input from family members or close friends of the stroke survivor. This input is invaluable for SLPs to quickly learn a patient's prestroke communication skills and to understand the contexts in which communication occurred in the past and is likely to occur in the future. In this regard, family member input not only improves treatment planning but sets the stage for treatment

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that is focused on the concerns of the person and family being served, a requirement for institutions accredited by the Commission on Accreditation of Rehabilitation Facilities (CARF).

Certainly some of this important individualized information is available to SLPs in the inpatient medical record. Information typically gleaned from a medical record review includes basic biographical information, premorbid level of cognitive or communicative functioning, education, occupation, religion, cultural considerations, learning style, and hobbies/interests.

In addition to the information available in the medical record, questionnaires or rating scales designed to solicit more detailed information from the family can be used. A questionnaire soliciting personal biographical information is the most basic of these tools. The questionnaire can be designed to solicit information such as communication style; personality characteristics; likes and dislikes; and names of friends, family members, and pets for incorporation into treatment activities and planning. The information sheet can be tailored to the needs of a specific population of patients or a particular setting.

To solicit family member input in a more detailed manner regarding communication abilities, two tools have been published for use after stroke. The 16-item Communicative Effectiveness Index (CETI)¹ was designed to measure pragmatic communication abilities in individuals with aphasia. The CETI can be completed by a family member, patient, or sometimes both for a comparison of concurrent viewpoints. The CETI solicits input regarding a range of communication behaviors from "getting somebody's attention" to "describing or discussing something in depth" on a continuum from *not at all able* to *as able as before stroke*. Another tool set, the pragmatic communication skills and behavioral observation rating scales of the RIC Evaluation of Communication Problems in Right Hemisphere Dysfunction-Revised (RICE-R),² examines communication and behavioral abilities following right-hemisphere stroke. Nonverbal and verbal communication skills as well as attention, awareness, orientation, and memory are examined. Even though these scales were designed for use by SLPs, they can be completed effectively by some families.

At NRH, SLPs designed a pragmatic communication rating scale for family member input after right-hemisphere stroke. The 18-item NRH Pragmatic Communication Skills Rating Scale was designed with parallel versions for use by families and SLPs (see Baron et al.³ for a description of the creation of these scales). The SLP version uses technical terminology accepted in the profession to denote the pragmatic communication skills, whereas the family version uses lay descriptors. For example, "topic maintenance" was translated to "sticks to the topic when we're discussing something" for the family version. Both versions use a three-point scale to describe each targeted communication behavior. The family version of the rating scale elicits a description of each of the 18 items as either "the same as before," "somewhat different," or "very different," using prestroke behavior as the point of reference. Because clinicians do not possess direct knowledge of premorbid communication behavior as a referent, the clinician version of the rating scale was designed to elicit a rating of each behavior as "consistently appropriate," "sometimes inappropriate," or "usually inappropriate." Both the family and clinician questionnaires offer a fourth response option of "no opportunity to observe" for each of the 18 pragmatic items.

When responses using these scales are examined, it is of particular interest how the SLP and family member perceptions reported with these scales compare to each other. Examination of this comparison reveals that families are more likely to rate behaviors as "unchanged" that SLPs rate as "inappropriate."³ This suggests that without family input SLPs may treat inappropriate pragmatic communication behaviors that are not stroke related.

When comparing perceptions across cultural-linguistic groups, higher levels of agreement are seen between Caucasian SLPs and Caucasian family members when compared to African American family members.⁴ When there is disagreement, SLPs are more likely to rate behaviors as inappropriate that African American families say have not changed and as appropriate that Caucasian families say have changed. This suggests that without family input, Caucasian SLPs may treat communication behaviors in African American right-hemi-

sphere-damaged stroke patients that are not stroke related. Furthermore, Caucasian SLPs may under identify stroke-related pragmatic communication behaviors in Caucasian right-hemisphere-damaged stroke patients. In either case, family member input regarding preconditions is of utmost importance in guiding the SLP in making an efficient and effective diagnosis and treatment plan.

Current research is examining the interrater reliability and concurrent validity of the clinician version of the NRH Pragmatic Communication Skills Rating Scale so that these findings may be viewed with more confidence.

Management of Communication Impairment via Group Treatment

The pioneer of the humanistic school of psychology, Rollo May, wrote, "Communication leads to community; that is, to understanding, intimacy, and mutual valuing"^{5(p36)}. This thought encapsulates the goal of the SLP in the treatment of stroke survivors: The rehabilitation of cognitive-communication function is more about reestablishing access to a community where the person's communication attempts are comfortable and valued than about achieving a given level of performance on an isolated task. The use of group treatment in the management of communication impairments post stroke is a natural adjunct to the individual treatment paradigm, as it creates an instant community of peers and changes the patient's responses from a practice level to a performance level. The benefits of group treatment have been shown in several studies.⁶⁻⁸ Although there is a need for more empirical data regarding the efficacy of group treatment for a variety of neurogenic communication disorders, anecdotal evidence tells us there is benefit from the use of groups even with patients with severe impairments in the acute stage of recovery.

The use of group therapy for the treatment of communication disorders was born out of needs generated after World War II; soldiers with closed head injuries who returned home from battle outnumbered clinicians available to provide services.⁹ As the profession and the health care environment have grown and evolved and the emphasis of treat-

ment has gone from the narrow task-specific emphasis on performance in a highly controlled hierarchy to the much broader rehabilitation emphasis on functional communication by any means necessary, the current role and structure of group therapy has similarly evolved.

Initially, groups were primarily support-based and addressed psychosocial goals for those at a maintenance level. From community-based groups that meet weekly in university clinics for a small charge for maintenance therapy to groups that provide education about many aspects of life post stroke and to groups that target and support specific skills (i.e., book clubs, computer training), SLPs have creatively used their expertise and understanding of functional communication to support stroke survivors long after the onset of their communication impairments. Although this remains a valuable and important format, currently many acute and subacute rehabilitation facilities use the more naturalistic group environment to address specific speech and language targets by maximizing the intrinsic motivation to successfully communicate that group participation may foster in the first few weeks post stroke.

In the acute period of stroke recovery, group treatment can be implemented for patients with mild and moderate communication impairments (i.e., aphasia, apraxia, and dysarthria) as an adjunct to individual SLP treatment. Group therapy is much less often conducted with patients who have severe communication impairments, presumably due to the severity of their functional communication impairments and inability to interact with other group members.

For many years, SLPs at NRH have conducted group therapy for persons with severe communication impairments. Previous literature in this area demonstrates successful implementation of specific interventions in a group setting (i.e., use of Amer-Ind Code¹⁰), and consistent clinical observations suggest that use of group treatment with this patient population has been highly successful. A strong component of this therapy has been the social/peer component of the group setting that appears to result in improved functional communication. Among the perceived benefits of this type of therapy have been improved initiation of com-

munication and speech acts and increased variety of responses. In essence, this form of therapy gives severely impaired people a format in which they can "converse" as well as the experience of seeing a variety of methods being used to get a message across.

Although the field of speech-language pathology commonly accepts the practice of providing communication treatment in group settings, there is variation in the efficacy of SLP group treatment described in the literature depending on the type of communication disorder examined. The current body of literature in aphasia therapy indicates that persons with chronic aphasia improve in both functional communication and linguistic measures after group treatment. The majority of published reports dating back to the 1950s describe anecdotal evidence of benefit from group treatment that focused on support and counseling.¹¹

More recently, published studies have shown that the group paradigm promotes pragmatic skills such as initiation of communication and increases the variety of communication functions and speech acts.⁷ Additionally, the intangibles of the group paradigm (providing a wider array of communication partners, more natural tasks, peer modeling, turn-taking, and support) have been shown to contribute to the improved carryover and generalization of treatment gains.⁷ Psychosocial function is also thought to be impacted, either directly or indirectly, by providing a supportive environment and adjustment to life with aphasia.⁷

As the ever-changing demands of service delivery push clinicians toward creative ways to maximize the patient's gains in treatment in the shortest amount of time, the use of groups creates positive effects for the clinician and facility as well as the patients and their families. A busy clinician frequently has more patients to see than can be seen in a day if only individual sessions are conducted; by using groups and pairings, the clinician can provide quality treatment to a higher census of patients. Even though the charge for group treatment is typically less than the charge for individual treatment, a facility will likely see increased revenue from commercial insurance and Medicaid when groups are used; group treatment results in billing for more total units of therapy and can free

the clinician to see other patients individually by condensing the clinician's schedule. The economy of groups is becoming a prerequisite under a prospective payment system in acute rehabilitation. In this instance, use of groups does not result in increased revenue, but it does result in enhanced efficiency for a larger sample of patients. By participating in group sessions as an adjunct to one-on-one sessions, a patient may receive more overall time in treatment with an increased number of repetitions and opportunities for success, feedback, and carryover. For a stroke survivor at NRH during the inpatient phase of rehabilitation, participation in group treatment across disciplines is the norm rather than the exception. Occupational Therapy offers groups an opportunity to address exercise and activities of daily living as well as cognitive skills. Physical Therapy offers groups an opportunity to exercise, and Psychology offers groups for substance abuse and other adjustment issues.

The framework for providing group communication therapy during acute stroke recovery is dependent on the following: group demographics, the focus of the treatment tasks and goals, the severity of the communication impairments to be addressed, the frequency of service provision, and the method of documentation and communication among clinicians. The composition of a treatment group is a critical component for the success and efficacy of group treatment. If the objective is to create a peer group for more natural communication interactions, the group must have a level of common ground whether it be matched by age, type of impairment, or severity level. At NRH, clinicians use target areas of goals and severity of impairment to enroll patients in groups, generating three to four goals specifically for the group that either underscore the individual treatment goals or address carryover (i.e., increased emphasis on self-cueing, initiating repair, etc.).

Treatment groups may have a cognitive-linguistic focus or a communication skills/strategies focus. Benefits from use of the group model for those targeting cognitive-linguistic skills include the encouragement of mental flexibility via exposure to multiple view points, opportunities for patients to assume leadership roles, and feedback from peers

regarding the accuracy of performance, all embedded in the process of addressing the deficit areas of memory, problem solving, attention, and reasoning. Benefits from the use of the group model for those targeting communication skills include auditory processing of information from a variety of speakers, use of attentive but unfamiliar listeners, and peer modeling of alternative communication approaches, all while addressing specific motor speech and language target areas.

Although it is a long-standing practice to use a group model of treatment for provision of speech and language therapy for patients post stroke in both the acute and chronic phases of recovery, little is known about the best practices for implementation of these groups or the efficacy of the various formats and approaches. Individuals receiving clinical services are entitled to the most appropriate services, meaning treatment that is suitable to the patient's repertoire of behaviors and is consistent with contemporary literature.¹²

The literature concerning group treatment for individuals with chronic aphasia is designed in a treatment group versus no/delayed treatment group format⁷ versus a comparison of performance in group sessions and individual sessions. There is evidence for the superiority of a conversational versus clinician-driven approach to aphasia therapy in the acute period of recovery.¹³ This research was conducted with individual treatment sessions, but it is reasonable to explore this type of approach with aphasia group treatment. The observed difference between the functional communication of a patient with acute communication impairments in group and individual therapies is anecdotal and has not been validated by research. Additional factors in the success of these groups that need to be investigated include the size of the groups, patient-to-clinician ratios, clinician experience and training, and group demographics, including whether significant other participation is a help or hindrance to a favorable outcome.

Although there is still much work to be done to demonstrate the clinical efficacy of group treatment practices in the acute rehabilitation period, anecdotal evidence has repeatedly shown benefits in both performance of isolated skills and in the intangibles of increased number and variation of

interactions, increased motivation to communicate that comes from peer-to-peer feedback and exchanges, and decreased feelings of isolation that frequently accompany changes in communication skills. Successful communication indeed leads to community, but an established community of mutual valuing and intimacy via group treatment also leads to communication, which is the main objective of the provision of SLP services.

Management of Communication Impairments via Telepractice

Telepractice is defined by the American Speech-Language-Hearing Association (ASHA) as "the application of telecommunications technology to deliver professional services at a distance by linking clinician to client, or clinician to clinician for assessment, intervention, and/or consultation"^{14(p11)} Although a relatively new medium for service delivery, the provision of therapy at a distance has been acknowledged for over 25 years. Some of the earliest work exploring this method was conducted with the use of telephone-only contact between clinician and client.¹⁵ As technology evolved, Wertz et al. expanded their research to include audio and video capabilities to assess neurogenic communication impairments at a distance.¹⁶

Since then, telepractice research has expanded to include the exploration of assessment and treatment with a variety of client populations, including adults with brain injury, stroke, and voice disorders and children with speech and language delays, to name only a few. This research has demonstrated that videoconference-based telepractice is a feasible, effective, and appropriate method for providing SLP services to a broad range of clients.¹⁷⁻²¹

There are two main types of information exchange that can occur during a telepractice session: store-and-forward and real-time, alternatively called *clinician interactive*. The store-and-forward telepractice method consists of information from one location being recorded live (typically video and/or still images) and then transmitted, at a later time, to a remote location. This technique is typically used for consultations where

the size of the transmitted information file makes it unsuitable for a live connection.

The second technique, real-time, has greater applicability for the SLP profession as it occurs when both sites are connected using a live interactive communication technique. This is most commonly accomplished via videoconferencing, where live audio and video signals are transmitted between locations. Videoconferencing can occur using high bandwidth connections, which are high in quality and also in cost (e.g., T1, ISDN, DSL, LAN). Alternatives to high bandwidth connections are those that operate using standard phone lines, such as videophones. These systems are markedly less expensive, but they result in decreased audio and video quality as the connection is slower.²²

ASHA states in the technical report on telepractice that "the range of possible models does not limit any setting from being a potential location for the delivery of services via telepractice, including hospitals, satellite clinics, other residential and non-residential healthcare facilities, schools and client's homes"^{14(p3)} A number of current research projects are exploring the "proof of concept" of therapy at a distance. These studies are conducted with the client and clinician in different rooms of the same facility, but they are simulating a distance model.²¹ Other research studies are actually providing the therapy at a distance (e.g., from hospital to a client stationed abroad on military service).²⁰

So what are the benefits of telepractice? The primary advantage is the improved access to care. There are a number of areas in the country where people are unable to receive services due to the distance that they would be required to travel. For clients who do not live in a rural area but who are unable to access local service providers because of mobility issues, telepractice offers a potential solution. Telepractice also affords a reduction in the consumer's cost of care by minimizing travel expenses. Two studies have been completed at NRH that have illustrated two additional potential benefits of telepractice: enhanced outcomes and increased client motivation.^{21,22}

In early NRH telepractice research efforts, a group of adults who sustained either a stroke or traumatic brain injury were asked to complete a

story retelling task in a face-to-face and a videoconference-based session. Across all participants, there was no significant difference in performance between the two settings. In addition, participant variables, such as age, education, and technology experience, did not have a significant effect on participant performance in the videoconference-based versus the face-to-face sessions.²² A number of the participants supported the use of videoconference-based interaction with comments such as, "I was really focused [on the computer] with what was going on! I enjoyed it," "I wasn't intimidated by the computer and usually computers intimidate me," and "It was good and convenient. I could be at my home and do the teleconference with the speech therapist...that would save time."²¹

Although this study was a promising indication that a variety of clients could benefit from diagnostic SLP services delivered at a distance, treatment of communication disorders via telepractice has not been adequately examined, perhaps due, in part, to the limited videoconferencing/treatment materials available to clinicians.

Although treatment provided via videoconferencing alone allows clinicians and clients to have verbal and visual interaction, it does not allow for the use of paper-and-pencil-based treatment tasks. A custom software package was developed at NRH by rehabilitation engineers and SLPs to target the need for interactive treatment tools. The RESPECT (Remote SPEech-language Cognitive-communication Treatment) software package extends basic auditory and visual interaction allotted by videoconferencing and provides the clinician with the ability to deliver a variety of clinically relevant treatment materials to remote clients. RESPECT allows for material, traditionally presented on paper and completed with pen/pencil, to be converted into digital format. During a telepractice session, the clinician controls what is presented on the client's computer. The client is able to interact with the material via the mouse, touchscreen, and/or keyboard. In addition to performing customized therapy tasks, a clinician and client can work interactively on a shared computer application, such as a word processing document, with videoconferencing data sharing tools.²³

Using the RESPECT system, a series of case studies are underway at NRH exploring the effectiveness and patient satisfaction of SLP treatment of neurogenic communication impairments provided via telepractice. To date, one participant has completed the protocol. This patient presented to us with a moderate nonfluent aphasia and a moderate-severe apraxia of speech. Therapy focused on conversational exchange between the clinician and patient with the use of document sharing. Using this model, the clinician was able to clarify what the patient said by typing it on the shared document. In addition, if the patient was unable to process a verbally presented question, the clinician could type the question, which often augmented the patient's comprehension. The shared Word document was also useful for apraxia drills, the other major therapeutic focus. The patient was able to receive graphemic cues (the written word/sentence) while seeing appropriate oral-motor posturing modeled by the clinician, simultaneously. Objective data analysis is underway, but the patient exhibited a marked improvement with reading comprehension scores and spontaneous verbal output. Perhaps the most meaningful outcomes were those that cannot be objectively measured. The patient's family noted a significant difference with his communication at home stating, "My father's speech has improved to the point he is comfortable to participate in and/or add to conversation without being frustrated by the inability to form words." The patient's wife stated, "He is always motivated to come to therapy...he really likes the computer."

Telepractice is not currently widespread, mostly due to the lack of technological support for SLPs. However, it will most likely become more prominent in the not-too-distant future. ASHA has completed a technical report and position statement for SLPs providing clinical services via telepractice. The position statement reads, "Telepractice is an appropriate model of service delivery for the profession of speech-language pathology." It goes on to further explain, "The use of telepractice does not remove any existing responsibilities in delivering services, including adherence to the Code of Ethics, Scope of

Practice, state and federal laws (e.g. licensure, HIPPA, etc.) and ASHA policy documents on professional practices"²⁴ In addition, ASHA is furthering its support for the use of telepractice as a service delivery model by producing a document that provides guidelines for the knowledge and skills a clinician must attain to appropriately provide diagnosis and treatment via telepractice.

The use of telepractice is not applicable to all clients with neurogenic communication impairments. Further research is needed in the field to explore the effectiveness of treatment and identify potential barriers to this type of service provision. As technology expands and becomes less cost prohibitive, the tools required for telepractice will, we hope, become more readily available to clinicians. With changing health care paradigms and the need to exhibit functional gains more efficiently, it is another potential tool for clinicians—one that may not be "as good" as a face-to-face therapy session, but one that may indeed enhance functional outcomes.

Conclusion

With today's changing health care environment, SLPs in rehabilitation settings are being asked to achieve functional outcomes with their patients in shorter amounts of time. This paradigm shift has resulted in clinicians seeking innovative and practical ways to address therapy goals. Facilitating family member involvement via questionnaires and interviews is an important way to access information about the patient's premorbid performance and desired goal areas. Group therapy addresses functional, community-based goals and serves a psychosocial need. Finally, as technology advances, SLPs are able to enlist the assistance of computers. The ability to receive services at a distance has potential not only to increase access to care where it would otherwise be unavailable, but also to address functional community and vocational goals in a motivating manner. As health care continues to change, SLPs will continue to find more efficient ways to help patients make functional gains.

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A New Approach to Patient-Centered Care

Elizabeth Newman, Cathy Ellis, Mary Foley, and Jennifer Hendricks

An opportunity existed at our rehabilitation hospital, in preparation for Medicare's Prospective Payment System (PPS) in acute medical rehabilitation, to develop an integrated inpatient care model using all available resources. The results have been an improved practice of all staff, increased efficiency and productivity, and increased staff and patient satisfaction. This article discusses the drivers for changing the team model within a large rehabilitation hospital. It includes an overview of the process of data gathering prior to changing the team model, how the new team model functions, and follow-up data collection 9 months after to provide evidence on what changes worked and what areas required further change to meet the objectives. **Key words:** *inpatient rehabilitation team, interdisciplinary team, patient-centered care*

In the 1980s and early 1990s, patients received acute inpatient rehabilitative services until the rehabilitation team felt they no longer required intervention. There was little to no pressure from insurance providers, which often resulted in several months of intensive inpatient treatment.¹ Over the last 10 years, there has been a dramatic change in the response from payers to limit reimbursement; we now see patients facing discharge from inpatient service to return to the community before they are ready. Managed care and Medicare's Prospective Payment System (PPS) have forced dramatic changes in the health care system. Therapists are forced to do more with less. Their caseloads have dramatically increased and the patient's length of stay (LOS) has dramatically decreased,¹ which makes it extremely challenging to provide quality care. Changes in health care and reimbursement have dramatically impacted acute rehabilitation. Health care providers now have to analyze operations and outcomes to maximize efficiency and effectiveness in order to provide the best quality of care for their patients.

The National Rehabilitation Hospital (NRH) in Washington, DC, which is a 128-bed, private, non-for-profit acute rehabilitation facility, has established a unique approach to patient-centered care. This was a house-wide effort, which included the Stroke Recovery Program (SRP). The stroke patient population is one of NRH's largest pro-

grams, which includes an average of 22% of the patients served. This program cares for 350–450 stroke patients each year. In the summer of 2000, the SRP was part of a year-long hospital-wide initiative in preparation for the PPS's anticipated impact on acute rehabilitation. The leadership of the SRP consists of a department manager and medical director, with representatives from all services serving on a steering committee. The SRP committee structure also includes a Performance Improvement Committee to manage the program and to address any program issues. The SRP leadership

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joined various teams made up of representatives from all NRH inpatient programs to prepare for PPS by analyzing processes to formulate performance improvement recommendations.

Two PPS teams, the Integrated Patient Care Team and the Discharge Planning Team, identified substantive issues that impacted on patient care such as FIMTM* efficiency, LOS, and team member and patient satisfaction. While these task forces began to explore areas of concern, a mock survey, in preparation for our triennial Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and CARF survey, also noted that the team processes did not clearly demonstrate an integrated, patient-centered approach to care and required corrective actions to meet the accreditation standards. Treatment teams needed to develop an efficient way to document integrated, interdisciplinary treatment plans and more clearly document the patient's response to specific treatment interventions and patient education. The next logical step was to consolidate our PPS teams into a Process Improvement (PI) Team to identify an opportunity for improvement that was data driven. The PI Team clarified and analyzed the current process, selected improvements, and planned and implemented changes. They collected and analyzed data to determine the impact of the changes on an ongoing basis. The PI Team Conference Team was created to improve the quality of patient-centered care and to create a structure to facilitate a cohesive interdisciplinary patient care team.

Evaluation of Current Team Process

The PI Team's goal was to establish a cohesive patient-centered team that follows an integrated, prioritized, patient-focused care plan. The next steps for the PI Team were to clarify and understand the variations in the current process, to collect data from the team members, and to analyze LOS and LOS efficiency FIM data.

All the variations and limitations of the team conference format were identified. Six major barriers

to effective team interventions included the following: Conferences were held during patient treatment time. Team members were unable to attend all conferences due to conflicts in conference schedules; some team members were unable to participate in team conferences at all. Team members spent an enormous amount of time in team conferences (approximately 32 hours across the house not including family conferences). The team conference format varied widely among the various programs, making cross-coverage challenging. Team communication was fragmented due to members not being able to attend conferences. The team was also challenged to actually comply with the requirements of JCAHO to establish prioritized team treatment goals and integrated treatment plans. After completing their initial assessment, the PT Team Conference Team conducted a survey with all staff members about the current process (Table 1). The team member survey confirmed that the aforementioned issues were in fact the most significant obstacles to providing efficient care.

Assessment of Team Processes for Acute Rehabilitation

After developing a clear picture of the current team process and identifying the areas for improvement, the PI Team collected more data to support forthcoming recommendations. The PI Team reviewed the relevant JCAHO and CARF standards. They gathered FIM data and completed a literature search on patient-centered care and team processes. All of the acute rehabilitation industry was facing the same health care market challenges with PPS quickly approaching. The PI Team chose to contact similar facilities and explore current and perhaps "best" practices. Data on patient-centered care and team processes were gathered through questions from phone interviews with a number of major acute rehabilitation centers across the country. The data-gathering stage of the process was actually the impetus for creating and implementing change in patient care practices.

The JCAHO and CARF standards were reviewed to identify specific areas for improvement and to ensure compliance as improvements were planned and implemented.^{2,3} The 2000 JCAHO Hospital and

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Table 1. Data collected from each team member at the outset of process improvement

Questions	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Mean
My interdisciplinary team has a mutual understanding of the patient's weekly goals	22%	48%	19%	9%	2%	3.79
	70%			11%		
My team communicates efficiently and effectively about patient care	17%	53%	19%	8%	2%	3.73
	68%			13%		
My team has a shared vision of the patient's long-term goals	22%	50%	20%	7%	1%	3.86
	72%			8%		
My team effectively includes the patient as a contributing member	23%	44%	10%	13%	10%	3.58
	67%			23%		
All the teams on my program function cohesively	14%	38%	30%	16%	2%	3.46
	52%			18%		

Note: The integrated patient care team survey confirmed the findings of our mock surveys and various task forces' concerns.

CARF Medical Rehabilitation standards included JCAHO Comprehensive Accreditation Manual for Hospitals, Assessment of Patients PE.1 through PE.8 and Care of Patients Tx.1 through Tx.8; CARF Medical Rehabilitation Standards Manual Section 3; and Comprehensive Integrated Inpatient Rehabilitation Programs Standards 1-13.^{2,3}

The PI Team identified that an efficient method was required to document integrated interdisciplinary treatment plans, the patient's response to specific treatment interventions, and patient education.

The PI Team then analyzed FIM data for LOS and LOS efficiency. The rehabilitation LOS is the mean number of days that a patient spent in an acute rehabilitation program. It is an indicator of resource utilization. This measure is calculated by subtracting the admission date from the discharge date. The rehabilitation LOS efficiency is the mean change in functional status for each day spent in an inpatient acute rehabilitation program. The ratio is calculated by subtracting the admission total FIM score from the discharge total FIM score and then dividing this number by the rehabilitation LOS. The PI Team reviewed the JCAHO ORYX data (core measures)

for NRH's LOS efficiency for the period July 2000 to March 2001 against the industry data.⁴ NRH was consistently above the mean for LOS data and consistently below the mean for the total FIM score change. Therefore, these two data ratios automatically result in a lower LOS efficiency (see **Figure 1**).

A literature search was completed to gather existing information on patient-centered care models and team conference formats to help guide the team's recommendations for effective change. The literature provided limited support for the changes that we felt we needed to implement. Halstead in 1976 described the interdisciplinary rehabilitation team as team care requiring coordinated action among experts in an atmosphere with open frank exchanges of information, discussion of options, decision making by consensus, and willingness for critical introspection and self-correction.⁵ The changes in health care that took place in the late 1980s and early 1990s leading to "re-engineering" left a negative impact on staff and as a consequence adversely affected any major change.⁶ In Halstead's view, the team has the ability to change because it functions as a system, capable of learning through

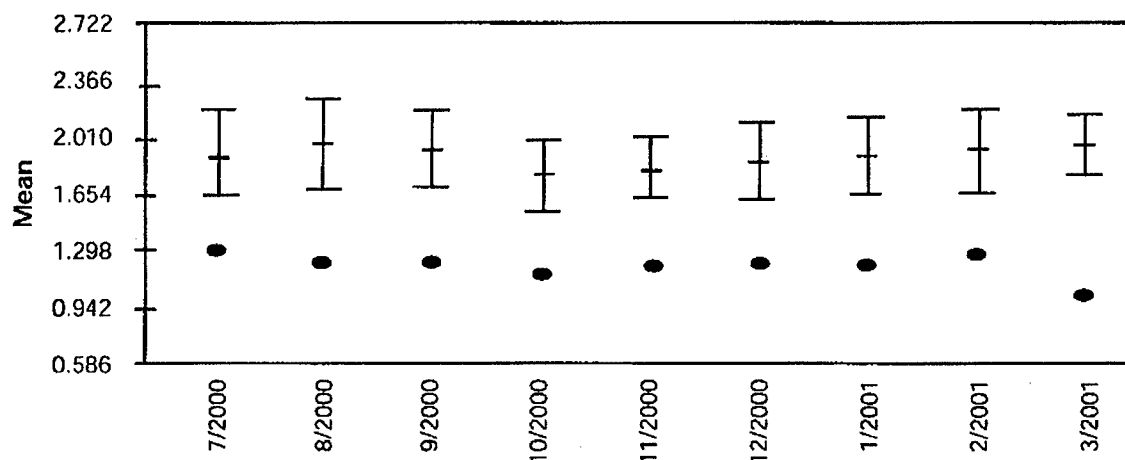


Figure 1. National Rehabilitation Hospital length of stay efficiency data between July 2000 and March 2001.

feedback and self-designing through a continuous process of adjustment, and the team can be challenged to change and objectively assess their input and transformation process and look at their outcomes on a regular basis.⁷ The team engages in continuous system improvement. This reduces task uncertainty and provides timely and effective patient success. This model of a team represents the goal of our PI process. Literature supported the assumption that an interdisciplinary team was a good model for research.⁸ Rehabilitation staff generally endorsed the team approach but were concerned about professional boundaries.⁹ Rehabilitation teams are task-oriented groups.⁹ The next PI step was to access information directly from other rehabilitation institutions similar in size, structure, and case mix to NRH.

A telephone interview was conducted to gather data from 15 facilities on how they monitored LOS data, how communication between nursing and therapy was managed, and how team conference formats and timeframes compared with NRH. Madonna Rehab in Lincoln, Nebraska, was selected for a site visit due to their successful integrated care model. That site visit generated many ideas for implementing a new patient-centered care model.

Selected Improvements

After examining several team models, processes, and data, an integrated patient-centered care

model was developed. This was a major change for all the programs throughout the hospital, starting with the patient's admission through the patient's discharge. A restructuring of patient bed assignments, the make-up of patient care teams, the time and structure of the team conference format, and a new method of documenting and communicating the patient team treatment plan were all parts of the new model.

The NRH's 128 beds are divided into seven teams (covering six major programs, one of which is stroke) based on bed location. The teams are not just given a number of beds or a nursing station, but they are assigned specific rooms with a built-in plan to accommodate fluctuations in census for any diagnostic area. These assignments are planned around an average daily census for the specific programs and geographic room locations. For example, 48 beds are dedicated to the neuro programs; 24 beds for stroke and 24 beds for traumatic brain injury, with 8 of those beds designated as float beds for either traumatic brain injury or stroke patients. Each grouping of beds, based on patient's diagnosis, has a consistent set of assigned team members who form a dedicated patient care team.

Each of the seven teams has the same staffing model structure. The team consists of an attending physician, case manager, nurse coordinator, social worker, and psychologist, and several consistent occupational therapists, physical therapists, and

speech language pathologists. Role expectations for each team member are defined.¹⁰ In this mix, the nurse coordinator position is a newly created position designed to monitor the implementation of the team treatment plan. This nursing position is the key to success of this new model. The nurse coordinator attends all team conferences and is responsible for representing nursing for each patient on the team and communicating the team treatment plan to the patient's nurse. The nurse coordinator and the case manager work closely in managing each case.

Several changes were made in the design of a team conference and in the general rules and expectations of team members. Each team meets daily for a half hour at a set time that is selected to have the least impact on patient care. The scheduled team meetings do not conflict with each other. Attendance at the team meeting is mandatory, even if the staff member's primary patients are not being discussed that day. All documentation must be completed by the designated time.

Each discipline completes their written assessment of the patient and identifies areas for potential team goals prior to the conference. The case manager uses that information to draft a summary with identified goals to be finalized during the team conference. A problem-list structure or format was established for the team conference, and patient-oriented team goals were identified from the problem list. The conference focuses on the team goals for the patient, with the patient's input. The team does not provide the patient status for each discipline, because each discipline has already provided its assessment in the medical record.

A team summary form was designed that incorporated JCAHO and CARF standards for clearly documenting the patient's response to specific treatment interventions, prioritized goals, and patient education.^{2,3} The form, which is in essence the problem list, is placed on an electronic database and is projected on a screen during the team conference. The case manager facilitates the conference proceeding through the form by obtaining team member input to the draft team summary. This draft is finalized during the conference (see **Appendix**). A standard method for posting estimated discharge dates was established so that all team members would know where to find the

correct date. In addition, each patient receives a National Rehabilitation Hospital Calendar on admission. The anticipated date of discharge is prominently displayed on the calendar and thus all team members, the patient, and visitors can see at a glance when the patient is to be discharged. The steps involved in the initial and subsequent team conferences are clearly described for each team member. Each team member is clear on the structure of the conference, is prepared ahead of time, and has all the current information on their patients. This advanced preparation dramatically enhances efficient discharge planning from day one as well as the efficiency of the conference itself.

In summary, to put these pieces of the model together, the team meets for a half hour every day. The case manager facilitates the meeting and starts with issues of the day. These issues include questions, concerns, or information that would affect the team or the patient's discharge from any team member on any patient being treated by that team. Any orders that need to be requested or clarified are completed at the conference. This housekeeping drill usually takes about 10 minutes. The next 10 minutes are dedicated to the patients being conferenced that day. Each patient is conferenced once a week according to a set, predictable schedule based on the day of admission. Three to five patients per team are conferenced each day within the half hour meeting. For an initial conference, the physician will give a brief medical summary of the patient, then the case manager will use the team conference summary form, which has already been drafted prior to conference based on the team's documentation. This form is projected on a screen for the team to review and make suggested changes as the case manager goes through the problem list. At the conclusion of the conference, the prioritized team goals are completed, the discharge plan is finalized, equipment needs are addressed, and the tentative discharge date is set. Any problems that would be barriers to the discharge plan are identified.

Implementation of the Improved Team Process

The implementation for this new team model was carefully planned to ensure success. The new

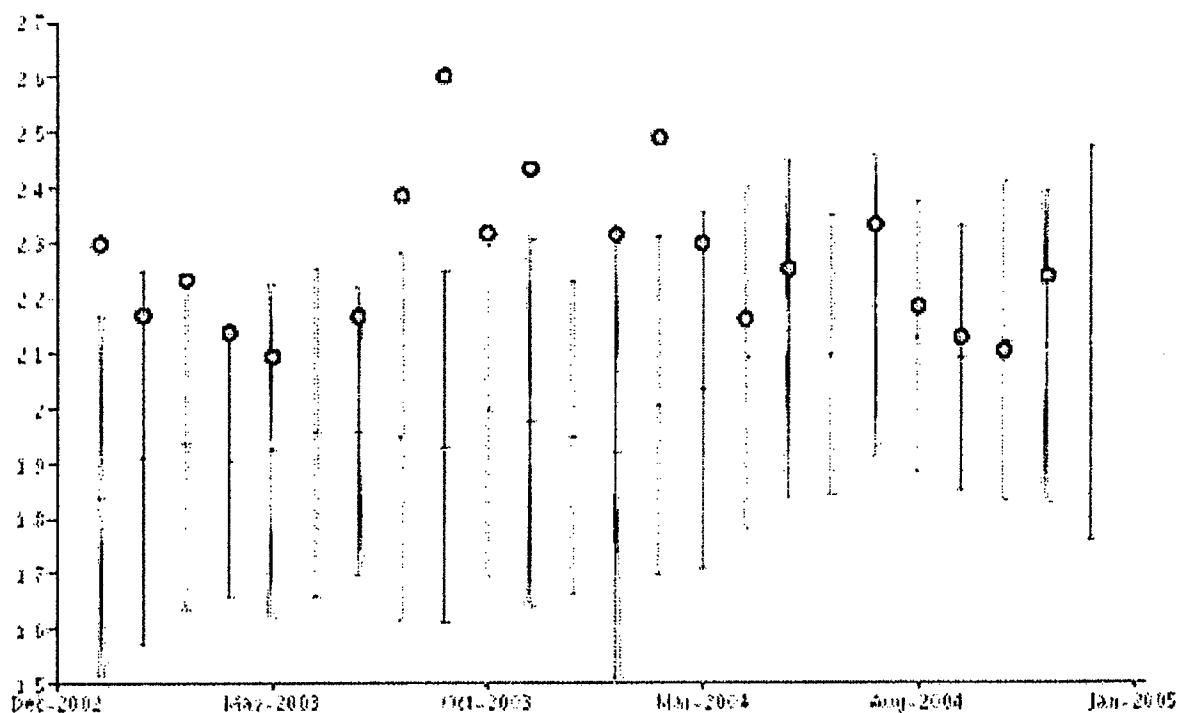


Figure 2. National Rehabilitation Hospital's length of stay efficiency for December 2002 through December 2004.

position of nurse coordinator was created, and nurses were interviewed and selected for each team. Their responsibilities included oversight and implementation of the integrated care plan for all patients on their team. The nurse coordinators do not assume any patient care assignments.

The PI Team developed a comprehensive training packet that was disseminated to each team member of each program. Department supervisors were trained and were given the responsibility of training individual team members. This was followed by a town hall meeting for each program where the PI Team presented the patient-centered care model to all program members to review the training that each member had received through their supervisor. An abbreviated mock team conference was dramatized. Time was also provided for questions and answers.

We knew that without consistent and concerned leadership, the new changes would likely erode and old habits might resume. Thus, each team was assigned a member of the PI team who served as a

coach for each team. This coach was to be present at the team meeting each day. The coach provided a feedback loop to the PI Team and served as a resource for questions. The coach also provided the stability and structure to promote new learning and sustain the gains. The coaching model also ensured consistency of conference format and outcomes throughout all programs. The new team model began on August 27, 2001, only 2 months before our scheduled triennial JCAHO/CARF survey.

Monitoring the Process

The PI Team continues to meet on a monthly basis to address issues and act on suggestions and findings from data collected by team coaches. Ongoing education of role expectations continues for all team members. Because of the feedback from coaches, continued communication and efficiencies have been implemented. Individuals already attending conferences such as case managers have also been trained as coaches. Additional improve-

ments based on issues identified by coaches include an effective manner for communicating the team conference schedule. An improved information management system regarding bed availability based on anticipated discharges was also developed as a result of the feedback from the coaches to the PI Team. One area that continues to be a challenge is coverage for absent team members. Although team members cover for each other and pass on information, at times a breakdown in communication occurs. Attendance of all assigned team members is essential to the success of this team conference model.

Measurements of Success

Measurement of success can be determined from changes in FIM data to patient satisfaction survey data. The amount of time spent in team conference has dramatically changed. To conference all the patients inhouse, a total of 15 hours is scheduled for team conference versus 32 hours being scheduled prior to this model. The manual system for monitoring bed availability remains quite accurate. We are now in the process of developing an electronic version of the pending discharge calendar. Increased patient satisfaction with their rehabilitation team members and outcomes has been evident. The most dramatic change the PI Team has observed has been a change in FIM data.

The JCAHO ORYX data show a dramatic im-

Table 2. JCAHO ORYX outcome measures

	January 2003	February 2003	March 2003
Length of stay	19.3	18.9	18.4
Length of stay efficiency	2.29	2.1	2.2
Change in FIM	30.3	30.8	29.1
Discharge FIM	86.3	89.9	88.7

Table 3. Overall length of stay calendar year (CY)

	CY 2001	CY 2002	CY 2003
Overall length of stay	20.2 days	18 days	18 days

provement in LOS efficiency (see Figure 2). In just 1 year of implementation, overall LOS had decreased by 2 days and discharge FIM scores had improved as well. Therefore, the two data ratios automatically resulted in a higher LOS efficiency (see Tables 2 and 3). The PI data lead to the conclusion that this new approach to patient-centered care has been highly successful. Future patient and team member satisfaction and JCAHO ORYX data will determine if this progress is sustained and if this PI initiative to create a new approach to patient centered care is successful.

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APPENDIX

TEAM CONFERENCE SUMMARY FORM



National
Rehabilitation
Hospital

Team Summary Form

Name:

Medical Record Number:

Patient/ Family states primary goal as:

Patient/ Family involved in
Development of team goals:

☐ Yes

☐ No

Date:

Program:

☐ SCI

☐ CAR

☐ MSK

☐ TBI

☐ CVA

☐ INTP

Priority Team Goal(s)

Problem List	Current Status	Goals	Goal Status + Date	Plan	Team Mbers	Barriers if Goal not Met - Date
Pain:			—			—
Restraints:			—			—
Falls:			—			—
Medical:			—			—
Bowel & Bladder:			—			—
Functional Mobility:			—			—
Daily Living Skills:			—			—
Communication:			—			—
Cognition:			—			—
Psychosocial:			—			—

Estimated Length of Stay:

Follow-up Recommendations:

Nurse Coordinator Statement: New Team Goal(s)/Treatment Plan Discussed with Patient/Family

☐ Yes

☐ No

Other Issues/Comments:

Team:

Nurse Practitioner/ Physician: _____

Date: _____

Case Manager: _____

Date: _____

Nurse Coordinator: _____

Date: _____

The Relationship Between Functional Independence Scores on Admission and Patient Falls After Stroke

Judith A. Zdobysz, Purvi Boradia, Jacqueline Ennis, and Julie Miller

This study explores the relationships between patient admission scores on the FIM™ tool for patients admitted with stroke and their risk for falling within the first 5 days of admission to an acute rehabilitation hospital. **Key words:** *FIM, patient falls, rehabilitation, stroke*

The Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) has asserted patient fall prevention as one of the national patient safety goals for 2005. The goal states that it is necessary for an organization to "assess and periodically reassess each patient's risk for falling, including the potential risk associated with the patient's medication regimen, and take action to address any identified risks."¹ With the increased importance that JCAHO places on formal assessment of patient's risk for falls, health care institutions must understand both the risks and reasons for falls. Reliable and efficient measures of risk for falls are integral to addressing the safety goal.

Patient falls are defined as "any event when the participant unexpectedly came to rest on the ground, floor or another lower level."^{2(p676)} Stroke patients are at particular risk for falling.^{3,4} Mayo et al. found that patients with a diagnosis of stroke had an increased risk of falling during an inpatient rehabilitation episode of care,⁵⁻⁷ and injury from falls is one of the most frequent complications among stroke patients in an acute rehabilitation setting.⁸ An inpatient rehabilitation setting provides a unique set of circumstances in which patients are encouraged to become increasingly mobile and independent, while in some cases the risk of falling is heightened by virtue of increased mobility. The incidence rate of falls among patients

undergoing stroke rehabilitation is reported to be 25%–39%^{8,9}; however, identification of patients who are at risk for falling is difficult.¹⁰ Several studies found that falls occur early in the hospitalization,⁴ although a DeVincenzo and Watkins study reported an increase in patient falls during the fourth week of rehabilitation.⁷ In a recent study conducted by the Department of Veterans Affairs (VA),¹¹ an analysis of 176 root cause analysis (RCA) of patient falls in the VA system was conducted. Of the 745 actions generated that addressed the root cause of the falls, patient safety managers identified a revision with the initial assessment measure from an invalidated measure to a validated measure as the action "having the big-

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gest impact on reducing falls and injuries due to falls."^{11(p30)}

The reported incidence of falls coupled with the heightened attention to falls as a patient safety imperative make identification of fall-prone stroke patients an important priority. Diaz¹² cites a number of independent factors that have been identified with risk of falling. These factors include gender, age, postural sway, medications, cognitive status, changes in motor function, and nocturia. The existence of concurrent multiple risk factors, however, may be of greater significance than the independent effect of each factor alone.¹³ A number of scoring systems that account for the simultaneous effect of multiple factors have been developed as tools to predict the risk for falls. Two such tools recommended by the National Center for Patient Safety (NCPS)¹⁴ are the Morse Fall Risk Assessment and the Hendrich Fall Risk Assessment. Neither of these assessment tools was designed specifically for a rehabilitation patient population, and, as a result, the sensitivity and specificity value is low. In a recent unpublished white paper from a consortium of six free-standing acute rehabilitation hospitals,¹⁵ it is reported that most of the six hospitals have developed their own fall risk assessment tools in an effort to be sensitive to the issues of rehabilitation patients. The validity and reliability of these tools have not been established.

Upon admission to an inpatient rehabilitation hospital, patients undergo an interdisciplinary evaluation to assess their functional ability. Many rehabilitation programs and institutions use the FIMTM* in this assessment process. The FIM is a scale designed to measure the patient's level of disability. The tool is widely used in inpatient rehabilitation settings and has good reliability among testers.¹⁶ Research has shown the FIM to be able to predict patient outcomes after discharge from the hospital.¹⁷ The admission FIM (AFIM) score was found to estimate length of rehabilitation hospitalization,¹⁸ and the motor component of the FIM is a valid and reliable measure of activities of daily living (ADLs) in poststroke outcomes in

patients.¹⁹ Teasell et al. found AFIM scores to be significantly lower among the patients who experienced a fall and patients with multiple falls on an inpatient stroke unit when compared to patients without a fall event.⁶

Under prospective payment reimbursement policies, an FIM assessment is required within the first 72 hours of a rehabilitation stay. During this period, clinicians and nursing caregivers are evaluating functional independence in the context of greatest need. No studies have specifically examined the relationship between FIM subscale or domain scores and the occurrence of falls. Further, little is known about the FIM attributes that may reliably predict those patients who are at (high) risk for falls during their stay.

We believe that there may be a relationship between one or more of the functional deficits and episodes of falls. Further, we believe that prior to the initiation of therapy, the functional measure can predict which patient is at risk for falls. This study seeks to examine the occurrence of falls among a population of stroke patients and to determine those factors, present on admission, that predict a stroke patient's risk of falling. It is our intent to examine the relationship between AFIM score and the incidence of falls during the first 5 days of an inpatient stay.

Method

The prospective data analyzed cover a 2-year period from July 2002 to June 2004. The records of 1,014 discharged patients with an admission rehabilitation impairment category (RIC) of stroke were included in the study. Patients who had experienced a fall or multiple falls and those who did not have a fall during the course of their inpatient rehabilitation stay were included. Patients who were discharged back to an acute hospital were excluded.

Data for the study were analyzed using the FIM, a measure of disability and burden of care. The FIM instrument is used to document the patient's independent function in 18 ADLs to evaluate and monitor function and cognitive status in inpatient rehabilitation settings. The FIM scores are subdivided into a cognitive score and a motor score. The FIM score was created by summing 13 individual

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Table 1. Age, gender, and onset days of stroke patients

Total population	Age		Female		Male		Onset days	
	Mean	SD	n	%	n	%	Mean	SD
Left (1.1)	64.2	14.5	213	52.7	191	47.3	18.8	63.9
Right (1.2)	66.0	14.4	253	54.4	212	45.6	15.1	29.2
Bilateral (1.3)	61.0	16.3	35	46.7	40	53.3	29.2	62.9

motor items covering self-care, sphincter control, transfers, and locomotion and five individual cognitive items covering communication and social cognition. Each of the 18 items is rated on a 7-point ordinal scale from complete dependence with a score of 1 reflecting total assistance needed by a helper or device (or longer time to perform the activity) to complete independence with a score of 7. Numbers between 1 and 7 are assigned to such descriptors to designate minimal, moderate, and maximal assistance. An FIM rating at level 3, or moderate assistance, means that the effort of the task is shared equally between the patient and the helper. Patients' total FIM scores range from a low of 18 (dependent) to a high of 126 (independent). Scoring instructions indicate that the best available information should be used and that direct observation of patient performance is preferred. Safety and the time required to complete an activity also influence scoring. Item scoring is actually fairly complex; although the same seven standard response categories are used for all items, scoring rules do differ somewhat by item.

We computed the number of days from admission to a patient's first fall as occurrence day. We grouped patients into three groups: patients who had occurrence days between admission and 5 days, patients with occurrence days greater than 5 days, and patients with no falls. We counted each occurrence of a fall at the patient level and defined it as total falls. We also computed the number of falls by type. Patients were grouped into age cohorts.

The dependent variable was either total falls or occurrence days. Independent variables used across the analysis included total AFIM, each of the FIM domains, the cognitive and motor subscores, and the 18 individual AFIM items. To account for therapeutic interventions in an inpatient rehabilitation facility (IRF), we evaluated the relationship of a patient's first fall to the AFIM scores within the

first 5 days of admission to the National Rehabilitation Hospital Stroke Program. Analyses included descriptive statistics on the subgroup of patients who fell within the first 5 days of admission ($n = 43$). A univariate linear regression model was used to determine the effect of AFIM on both total falls and when the first fall occurred. We also used a t test to examine the significance of the difference of mean AFIM scores between populations defined by the number of days to first fall.

Results

The study population ranged in age from 20 to 89, with 84% of the patients over the age of 50, and 54% of the patients over the age of 65. More than half (52.5%) of the stroke patients in the study were women. A slight majority of patients were diagnosed with right brain stroke (46%) while few presented bilateral stroke (7%). Demographic characteristics were similar across all three populations; however, the mean onset days to rehabilitation was substantially longer in patients with bilateral involvement. See Table 1 for the demographics of this study.

Assessment of functional independence at admission showed no significant difference in motor or cognitive FIM when comparing patients with left and right brain stroke. AFIM scores, however, of patients with bilateral involvement are lower than those of both the right brain and left brain stroke populations (Table 2).

There is less discernable difference between the three stroke diagnostic subpopulations when AFIM scores are observed across five domain scales: self-care, transfer, locomotion, communication, and social cognition.

In the stroke population of 1,014 patients, 4% experienced a fall during the first 5 days of hospitalization. Of those who fell, 32.5% of the falls

Table 2. Admit FIM (major domain) by stroke diagnosis

	Left (1.1)		Right (1.2)		Bilateral (1.3)	
	Mean AFIM	SD	Mean AFIM	SD	Mean AFIM	SD
Admit Motor FIM	29.4	12.8	28.4	12.8	25.9	12.8
Admit Cognitive FIM	22.8	8.7	19.6	9.3	18.2	9.7

occurred during the first 5 days post admission (Figure 1).

As Table 3 summarizes, the majority of falls (51%) were categorized as a fall from the bed followed by falls from the chair or wheelchair (37%). This distribution is consistent across stroke diagnostic groups and is similarly observed among the patients whose first fall occurred during the first 5 days post admission.

Although older patients had a slightly disproportionate occurrence of falls during the first 3 postadmission days, the observed difference is not statistically significant. The average length of stay for patients who did not fall during their stay was about 4 days less than that of the patients who did fall ($p < .05$). See Tables 4 and 5 for details.

The AFIM scores of patients who did not experience a fall occurrence during their stay were compared with scores of patients who experienced the

first fall in three postadmission ranges. Generally, the AFIM scores of five FIM domains are higher for patients who did not experience a fall during their stay. The difference in mean admit transfer score for patients who experienced their first fall within the first 5 postadmission days and those who experienced the first fall after the first 5 postadmission days is significant ($p < .05$). The lower mean FIM transfer score for the >5-day patient population, however, is counterintuitive. Table 6 summarizes the above data.

We tested the relationship between AFIM domain scores and the number of fall occurrences. Using a linear model, we found a significant ($p < .001$) relationship between the FIM transfer domain and the total number of fall occurrences. A similar test of the relationship between FIM item scores and the number of fall occurrences found no statistically significant relationship. Table 7 illustrates the previously described relationship.

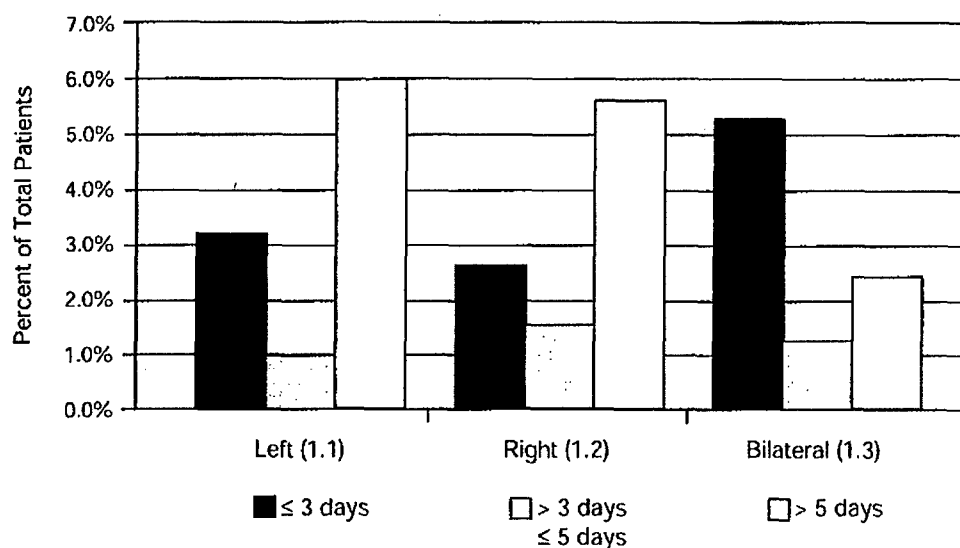
**Figure 1.** Timing of first fall occurrence by stroke type.

Table 3. Occurrence of falls by type and stroke diagnosis

Total population	Left (1.1)	Right (1.2)	Bilateral (1.3)	Total
Lowered to floor	3	5	0	8
From toilet	5	2	0	7
In shower	1	0	0	1
From bed	20	35	8	63
From chair/wheelchair	19	21	6	46
While using equipment	1	1	0	2
While ambulating	3	1	0	4
	52	65	14	131

First fall within 5 days	Left (1.1)	Right (1.2)	Bilateral (1.3)	Total
Lowered to floor	1	1	0	2
From toilet	2	1	0	3
In shower	0	0	0	0
From bed	7	17	5	29
From chair/wheelchair	10	9	4	23
While using equipment	1	1	0	2
While ambulating	3	1	0	4
	24	30	9	63

Table 4. Age and the timing of first fall occurrence

All patients			1st fall within 3 days		1st fall within 5 days	
Age	n	%	n	%	n	%
0-20	12	1.2				
21-35	23	2.3				
36-50	123	12.1	5	16.1	6	14.0
51-65	313	30.9	12	38.7	15	34.9
66-80	401	39.5	13	41.9	18	41.9
80+	142	14.0	1	3.2	4	9.3
Total	1,014	100.0	31	100.0	43	100

Table 5. Average length of stay by timing of first fall occurrence

	Average length of stay				
	n	Minimum	Maximum	Mean	SD
All patients	1,014	1	82	19.47	10.70
1st fall within 3 days	31	6	41	23.65	8.99
1st fall within 5 days	43	6	41	23.42	8.76

Table 6. Mean FIM domain scores by timing of first fall occurrence

	No falls	≤ 3 days	> 3 days and ≤ 5 days	> 5 days
Self-care	15.89	13.00	13.92	12.58
Transfer	5.79	4.90	4.00	3.33
Locomotion	1.73	1.39	0.92	0.69
Communication	8.46	6.81	7.67	7.52
Social-cognition	12.68	9.68	11.92	10.90

Discussion

An accurate and efficient process for identifying fall-prone individuals is essential to implementing prevention strategies early in a stroke patient's rehabilitation stay. Because the FIM evaluation is completed early in the patient's stay, the scores provide information that assists in functional care planning and the organization of strategies to prevent patient falls. In this study, we have identified that there is a significant difference between the mean admit transfer score for patients who had their first fall within the first 5 days of their stay versus those who may have had a fall after the first 5 days. Because transfer ability is significant to a fall within the first 5 days of a patient stay, it is incumbent upon the rehabilitation team to implement care in which pa-

Table 7. Relationship between the number of fall occurrences and FIM domain score at admission.

Source	Univariate analysis of variance		
	F	p	Partial eta squared
Corrected model	13.012	.001	0.123
Intercept	93.255	.000	0.501
Transfer	13.012	.001	0.123

tient transfers are considered. Although this evaluates only the physical aspect of the transfer, the clinician must also manage the cognitive impairments that are associated with transfer. A transfer may result in a fall because the patient does not understand or remember verbal instructions and recommendations regarding ambulation and physical activity. A patient may also demonstrate impulsive behavior and initiate an unplanned transfer. The care for this patient is centered on decreasing unassisted transfers.

Further study regarding other variables combined with FIM transfer might help to explain more of the fall occurrences and may lead to a more effective assessment for patient falls in a rehabilitation setting for stroke patients.

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