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CONTRACTING ORGANIZATION: National Rehabilitation Hospital
Washington, DC 20010-2949

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13. Abstract ***(Maximum 200 Words)*** *(abstract should contain no proprietary or confidential information)*

The NRH Neuroscience Research Center (NRC) mission is to *promote and accomplish rehabilitation-related basic and applied neuroscience research.* 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 2 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; facilities construction; supporting pilot projects; and educating through lecture series.

Staffing:

- Principal investigator- Tresa Roebuck-Spencer, PhD was added as a principal investigator as part of our pilot project research
- Principal investigator - Lauro Halstead MD was added as to assist with the oversight and study Design of project D2
- Co-investigator- Mark Lin, MD, Zachary Levine, MD, where added to assist with specifics of study design and subject recruitment for project A1.
- Research Investigator- Justin Carter, M.S., has been hired as a biomedical engineer to assist with project A1.
- Research Investigator- Dee O'Neill was hire in March to assist administrative and implementation of project B1.
- Research Investigator- Emily Olmstead, MS was hire in January to assist administrative and implementation of project B2.
- Research Investigator- Melissa Richman and Thilo Kroll PhD where added to assist subject recruitment and Statistical support for project D1.
- Research Investigator- Lorraine Priestley RN will be added to assist subject recruitment and serve as study coordinator for project D2.

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)

Developing related projects:

- Submitted
  - NIDRR –RERC, FIR
- Grants awarded during past year
  - NIDRR- RRTC. Lead institution ("RRTC on SCI: Promoting Health and Preventing Complications through Exercise")

- NIDRR-RERC. Subcontract with RIC (Project- "Gait restoration in hemiparetic stroke patients using goal-directed, robotic-assisted treadmill training")

- Currently performing
  - Clinical trials
    - Acorda Therapeutics
    - Aventis
    - Amphetamine (Duke)
    - Modafinil (USUHS)
  - NIDRR- RRTC
  - NIH- tDCS

Facilities construction:
The effort to create a geographically defined Neuroscience Research Center at NRH devoted to rehabilitation-related neuroscience research has made considerable progress over the past year. The major accomplishments in the past year are as follows:

1. *Relocating Researchers during construction for new physical space.* Research staff with out direct clinical contact where relocated during construction and renovation of the new physical space.
2. *Construction started in December 2003.* The DC government approved all plans for construction and renovation of the new physical space and project was initiated.
3. *Completion of the construction for the new physical space.* It is anticipated that the construction will be completed by August 2004 and research staff will initiate occupation of new physical space.

The anticipated completion date for the new physical space should be completed by the beginning of year 3 of the NRH Neuroscience Research Center Cooperative Agreement.

Pilot projects:
This years pilot project was awarded to Dr. Tresa Roebuck-Spencer. Please see project D3 for detail.

Lecture series:

- " Mechanisms of neural cell death: implications for the treatment of acute and chronic neurodegenerative disorders" Alan I Faden, M.D.
- "Inflammation in Atherosclerosis: Emerging Concepts of Pathophysiology and Implication on Therapy" Thomas James DeGraba, MD

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

Funding period: Year 1 of 3-year funding period

Status: Ongoing

Principal Investigator: Joseph Bleiberg, Ph.D.
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:
The primary progress this past year has taken two forms. First, has been the recruitment of a biomedical engineer (Justin Carter, M.S.) who has made significant progress programming the motor tasks that are an essential component of this project. Progress in this area is described in more detail below. Second, has been the identification of settings and patient populations to be used for validating the procedures and instruments developed in this proposal. This has included incorporating Parkinson's disease and movement disorders clinical programs which simply were nonexistent at the time the original proposal was written. For example, as described in greater detail below, the Washington Hospital Center recently has developed clinical programs for Parkinson's disease and movement disorders, including deep brain stimulation and other advanced services, and two of the physicians directing these services, Drs. Lin and Levine, have joined this project as investigators. A clinical protocol to begin testing the instruments developed as part of the present proposal was submitted to the Medstar IRB early this year and has been approved, and has been pending before the DOD IRB for approximately the past six months.

The primary obstacle to progress described in our prior progress report, the lack of availability of a biomedical engineer with sufficient time commitment to develop novel motor tasks, was solved this year. Justin Carter, M.S., has been 10% from August 2003 through December 2003, increasing to 50% from December 2003 until the present, and with the intention of increasing to 100% on August 1, 2004. While this still puts the project clearly behind schedule, we rapidly are "catching up" and expect to be on schedule by the middle of this coming year. Since the engineering funding schedule for the first-year, as well as other related funding, was not expended, the plan is to move the project schedule foreword by one year, thus permitting completion of all original objectives.

The following elements of the originally proposed motor tasks have been completed. First, a "shell" providing a common foundation and infrastructure for the motor tasks has been designed and created. This shell is cosmetically similar to the existing ANAM shell and is designed so that the user (subject or patient) experiences continuity when moving from the existing ANAM cognitive tasks to the presently developed motor tasks. While these tasks can be integrated within the current ANAM shell using the "alias" feature of the .lst file, these tasks will be submitted to Kathy Winter, SPAWAR, to optimize integration within existing ANAM technology.

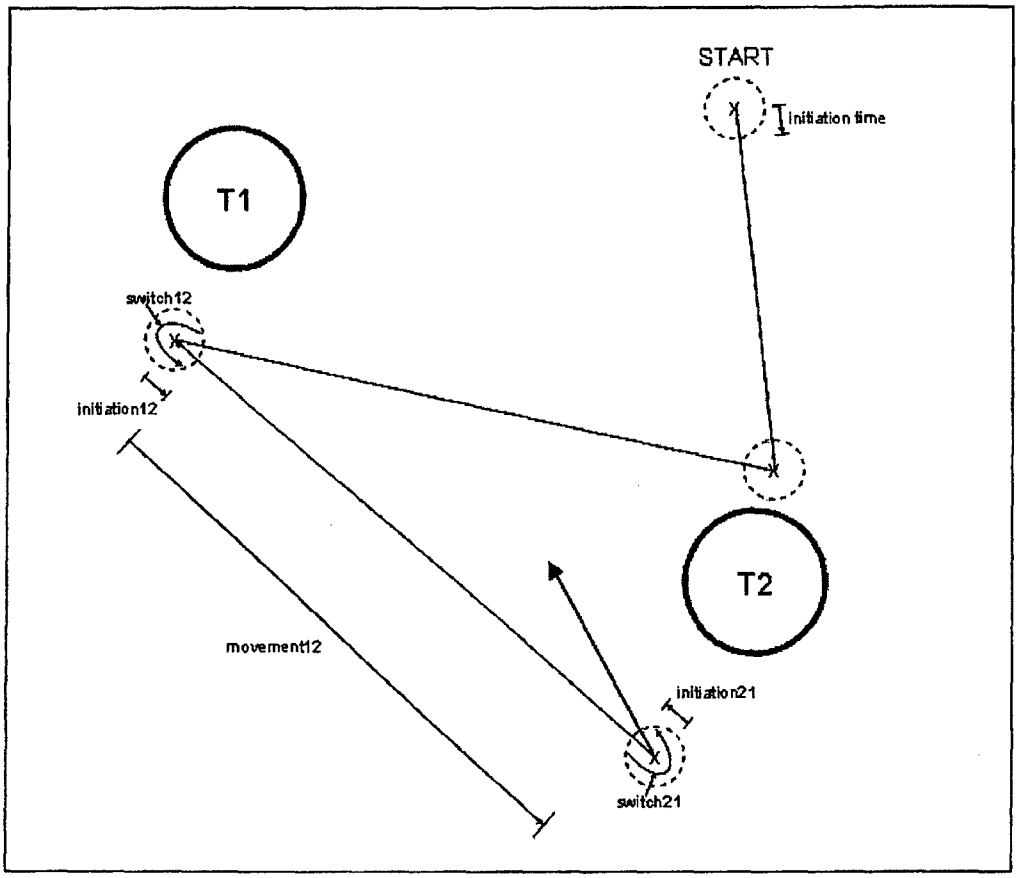
An overall strategy and architecture for motor task development was developed in order to maximize compatibility across newly developed tests and facilitate future modifications. Consistent with ANAM philosophy, the motor test development strategy emphasizes flexibility for the examiner to modify test parameters and to select and aggregate specific motor tests into "batteries." Following development of the framework, the first motor task was prototyped. This task, the Alternating Two-point Target Acquisition subtest (ATPTA) has been completed.

Another element of test design strategy and architecture has focused on data structure and design, and automation of transfer of test data from data files to databases. Tests are designed using three programming logic groups, or "layers": user interface logic, business logic, and data logic. This was done so that future changes, whether they be in test parameters, operating systems, data management systems, etc., would not require complete redesign of the test, but only redesign of the specific logic section. We also have completed design and programming of preliminary templates for each logic section. These templates specify code requirements for new subtests, such that the additional motor tasks in our proposal already have a code "template" to assure that they will integrate seamlessly into our framework, as well as to provide a development map to expedite and increase the efficiency with which the additional tests will be developed. Moreover, since motor tasks can yield a nearly infinite number of test "scores," we have identified a set of preliminary output variables, listed below:

Figure 1

tblATPTA : Table

Field Name	Description
SubjID	subject ID
Dat	date of the subtest
Tim	time of the subtest
ATPTAtrialnum	trial number
ATPTAtimInit	initiation time
ATPTAtimInitAvg12	average initiation time moving from Target1 -> Target2
ATPTAtimInitAvg21	average initiation time moving from Target2 -> Target1
ATPTAtimInitAvgTot	total average initiation time
ATPTAtimSwitchAvg12	average switch time moving from Target1 -> Target2
ATPTAtimSwitchAvg21	average switch time moving from Target2 -> Target1
ATPTAtimSwitchAvgTot	total average switch time
ATPTAtimMvmtAvg12	average movement time moving from Target1 -> Target2
ATPTAtimMvmtAvg21	average movement time moving from Target2 -> Target1
ATPTAtimMvmtAvgTot	total average movement time
ATPTAclickMean	average time between clicks
ATPTAclickSD	std dev of click times
ATPTAnumClicks1	number of clicks attempting Target1
ATPTAnumClicks2	number of clicks attempting Target2
ATPTAnumClicksTot	total number of clicks attempting either Target
ATPTAnumCorr1	number of clicks INSIDE Target1
ATPTAnumCorr2	number of clicks INSIDE Target2
ATPTAnumCorrTot	number of clicks INSIDE either Target
ATPTAnumIncorr1	number of clicks OUTSIDE Target1
ATPTAnumIncorr2	number of clicks OUTSIDE Target2
ATPTAnumIncorrTot	number of clicks OUTSIDE either Target
ATPTApctCorr1	percent of clicks INSIDE Target1 when aiming for Target1
ATPTApctCorr2	percent of clicks INSIDE Target2 when aiming for Target2
ATPTApctCorrTot	percent of clicks INSIDE either Target
ATPTApctIncorr1	percent of clicks OUTSIDE Target1
ATPTApctIncorr2	percent of clicks OUTSIDE Target2
ATPTApctIncorrTot	percent of clicks OUTSIDE either Target
ATPTAavgIncorrDist1	average distance (percent radial) of incorrect responses to Target1
ATPTAavgIncorrDist2	average distance (percent radial) of incorrect responses to Target2
ATPTAavgIncorrDistTot	average distance (percent radial) of total incorrect responses
ATPTAnumFreeze1	number of freezes on Target 1
ATPTAnumFreeze2	number of freezes on Target 2
ATPTAnumFreezeTot	total number of freezes
ATPTAaccel	acceleration
ATPTAtremor	tremor



In addition to task development, progress has been made regarding developing several approaches to validating the tests currently being developed. A test validation protocol was written last autumn and submitted and approved by the Medstar IRB. The protocol emphasizes demonstration of test sensitivity to the symptoms of Parkinson's disease using pre-and post-treatment symptom comparisons, both following pharmacologic and deep-brain magnetic stimulation. Specifics of study design and subject recruitment have been finalized with our new collaborators at the Washington Hospital Center, Drs. Mark Lin and Zachary Levine. In addition to assessing the efficacy of the newly developed motor tasks, the protocol includes the cognitive and affective symptoms common to Parkinson's disease. Application for IRB approval was submitted to the NRH Research Committee and MRI IRB, with final approval from MRI received on 12/15/03. An application for IRB approval from DoD was submitted to the DoD on 1/8/04 and is pending approval.

All clerical and administrative tasks have been completed in anticipation of this IRB approval, including finalizing plans for subject recruitment, ordering of all testing and office supplies, training of research assistants, and database construction.

Barriers and Solutions:
As noted previously, this program is heavily dependent upon biomedical engineering technology development, and the primary obstacle during the first year and first few months of the second year was the absence of such resources. This obstacle has been overcome and substantial progress has been made. The primary consequence has been to delay achievement of project milestones, though these milestones currently are being met at a rapid pace and the completion of all proposed technology development activities is without current barriers.

The primary barrier to clinical validation of the motor measures has been the long duration required for DOD IRB approval. As noted previously, a clinical protocol approved by the MRI IRB was submitted to DoD approximately six months ago and a response still is pending. IRB approval is necessary in order to begin pilot testing the motor tasks, the first of which already has been completed, and the remainder of which will be completed within several months now that a framework and architecture has been created.

Plan:
As noted above, the primary tasks this coming year are completion of the motor task development and 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.
The next steps in developing the motor subtests will be to design and implement the next set of our subtests. First will be a Finger Tapping subtest (condition 1 – Simple Tapping), followed by Target Acquisition, Form Tracing (both regular and mirror feedback trials), the final three conditions of ATPTA, and the final two conditions of Finger Tapping.

Upon completion of programming the motor tasks, they will be incorporated 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 if modifications are necessary when testing older adults. Once the computerized battery has been finalized, we will begin recruitment of and data collection from controls and patients with PD and Alzheimer's disease.

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

Funding period: Year 1 of 3-year funding period

Status: Collecting data

Principal Investigators: William Garmoe, PhD
Co-investigators: Michael O'Connell, Ph.D., 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:
During the present funding year the focus of effort on this project has been securing final approval from all Institutional Review Boards (IRB) that have oversight. Following approval from Medstar Research Institute (MRI), the project was submitted to the DoD IRB. This was a very lengthy process due to the time it takes projects to be reviewed by the DoD IRB. Additionally, because this project involves subjects with impaired decisional capacity, additional requirements had to be met. Specifically, DoD regulations stipulate that the protocol has to promise benefit to participants when decisionally-impaired subjects are included. Most civilian IRBs, including Medstar, consider it unethical to promise benefit to research participants. Thus significant effort needed to be expended in order to make the protocol acceptable to both IRBs with jurisdiction over the project.

Following conditional approval from the DoD IRB, the project was submitted for final review with the Medstar IRB. This will (hopefully) be received in the next two weeks. The final approval letter from Medstar then needs to be submitted back to DoD for their approval to change from conditional to final. Data collection will be initiated as soon as final approval is gained.

Plan:
Attain final approval and collect data.

Publication and Presentations:
Premature. However, this researcher has been invited to submit to the Journal of Head Trauma Rehabilitation for a special issue on self-awareness.

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

Funding period: Year 1 of 4-year funding period

Status: Ongoing

Principal Investigators: Joseph Hidler, PhD
Co-investigators: Edward Healton, MD, MPH

Research Assistant: Emily Olmstead, MS

Sub-contracts/consultants:

- Dr. Anthony Ricamato, Developmental Innovations, West Chicago, IL

Abstract:
The overall goal of this study is to determine whether robotic-assisted gait training is superior to conventional rehabilitation treatments for facilitating the recovery of stable walking patterns in individuals following stroke and spinal cord injury.

The subject sample will consist of 80 patients, 40 with sub-acute hemiparetic stroke and 40 with incomplete spinal cord injury, randomly assigned to one of 2 experimental groups for each patient population (4 total groups total). One group of stroke subjects (n=20) and one group of SCI subjects (n=20) will receive one hour of conventional rehabilitation, consisting of a standardized regimen of lower extremity strengthening exercises and full weight bearing ambulation as tolerated, with appropriate physical assistance and feedback as necessary. The other 2 groups will receive body-weight supported treadmill training (BWSTT) with robotic-assistance using the Lokomat® System (Hocoma, Inc., Zurich, Switzerland). The Lokomat is an exo-skeletal robotic orthosis that attaches to a person's legs and assists the subject in achieving normal gait patterns while walking on a treadmill. During training sessions, patients will receive bio-feedback of their performance, allowing for goal-directed therapy. Both groups will be trained for 24 sessions, with 1 hr allocated for all training paradigms.

The re-acquisition of natural gait patterns and lower limb motor function will be evaluated at bi-weekly intervals and will be based on numerous measures, including the speed and variability of unassisted walking, step lengths and cadence, postural balance, assessment of spasticity, and various strength measures. Using these criteria, we will determine the form of therapy which best promotes the restoration of walking capabilities in patients with incomplete SCI and stroke.

Progress and Outcomes:
In anticipation of receiving DOD IRB approval to run the project, we continued to develop the necessary infrastructure for running the protocol outlined above. Specifically, our first main goal was to develop electronic subject training logs which document all subject outcome measures digitally. For this study, we utilize 14 different outcome assessments (e.g. Berg Balance, SF-36 Quality of Life, etc.) which encompass 212 data entries. In order to minimize errors in managing data, we wanted to design a program that would record and store these outcome assessments.

Working with Dr. Tony Ricamato of Developmental Innovations of Chicago IL, we created a software program using the VB.net framework that links into an Access database that stores and manages all data obtained during the trial for each subject. The software contains digital versions of 14 clinical scales used to evaluate each subject's improvements in motor function and quality of life. The software contains error checking and automatic calculations of performance which will be used to determine which intervention is more effective.

Our second main goal was to investigate how walking in the Lokomat affected normal muscle activation patterns (EMGs) utilized during gait. This information is critical because when we train subjects in the Lokomat, we are interested in observing how their muscles fire. And if the Lokomat changes normal muscle patterns, then comparing EMG profiles to those observed during healthy over-ground walking would be inappropriate. Therefore, because this project is cost-shared with other funding sources separate from the Department of Defense, we have run a small number of related experiments on healthy subjects comparing EMG profiles while they walked in the Lokomat with those demonstrated on the treadmill. In parallel with this work, we have developed an analytical technique for quantifying the magnitude and phase characteristics of EMG patterns during gait.

IRB approval was granted for this project in May 2004 and as such, we are currently running 3 stroke subjects in the study. With this IRB approval, we now anticipate running at least 3 subjects in parallel for the remainder of the study.

Dr. Lauro Halstead who was originally part of this project is no longer working in this area.

Barriers and Solutions:
The main barrier in this project has been acquiring IRB approval for this project from the DOD. We had a review in September 2003 with the IRB committee and after making and submitting the requested modifications, IRB approval was finally granted in May 2004. We are now training subjects and anticipate no further barriers for the remainder of the funding cycle.

Due to the complexity of coordinating this research effort, we have increased the effort level of our study coordinator to assist in arranging transportation, assisting with the training, and all other aspects of the study.

Plan:
Now that IRB approval has been granted, we plan on testing at least 3 patients in each group in parallel for the remainder of the grant. Now that all the necessary instrumentation, software, and documentation has been established, we do not anticipate any additional barriers for the remainder of the project.

Publication and Presentations:
A number of presentation and publications resulting from the work affiliated with this project include:

Journal Papers

J. M. Hidler and A. Wall, "Changes in muscle activation patterns during robotic-assisted walking" In review.

A. Ricamato and J. M. Hidler, "Quantification of dynamic properties of EMG patterns during gait." In review.

Conference Proceedings

J. Hidler, "Robotic-Assessment of Walking in Individuals with Gait Disorders", ***IEEE Engineering in Medicine and Biology Society,*** submitted.

A. Wall and J. Hidler, "Alterations in EMG patterns during robotic-assisted walking", ***Northeast Bioengineering Annual Conference***, April 2004.

Abstracts

A. Ricamato and J. Hidler, "A Tool to Quantify the Temporal and Spatial Properties of EMG Patterns during Gait", ***ISEK Annual Conference***, Accepted for June 2004.

A. Lichy, J. Hidler, J. Cisper, and A. Wall. "Changes in muscle activation patterns during robotic assisted gait training." ***APTA Annual Conference***, Accepted for July 2004.

Invited Presentations

- "Contemporary Issues Surrounding Robotic-Assisted Locomotor Training", Neural Prosthesis Seminar Series, Cleveland FES Center, Cleveland, Ohio, May 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, May 2004.

- "Emerging technologies for understanding and treating motor-impairment in stroke and spinal cord injury", Neurosurgery Lecture Series, Washington Hospital Center, Washington DC, April 2004.
- "Loss of differential muscle control leads to weakness and discoordination in individuals with acute hemiparetic stroke", IEEE Engineering in Medicine and Biology Society, Cancun, Mexico, September 2003.

Trainees Affiliated with the Project:

Undergraduate students

- Anji Wall
- Lindsay Diromualdo

Graduate students

- Iian Black
- Nathan Neckel

Project C1: Stroke Performance Recovery and Outcomes Study

Funding period: Year 2 of 4-year funding period

Status: Ongoing

Principal Investigators: Brendan Conroy, MD
Co-investigators: Gerben DeJong, PhD, FACRM; Susan Horn, PhD; Thilo Kroll 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 have 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. Completed data collection on1,383 patients from 7 sites—6 in the U.S. and 1 in New Zealand.

2. Continue to hold weekly conference calls (Fridays at 1:00 PM) with project staff, participating sites, and others to review progress, edit and clean data, make decisions about how best to partition the data, review data analyses and findings on a therapy-by-therapy basis, identify and review manuscripts for publication.

3. Conducted a 3-day analysis meeting with project stakeholders (i.e., study team, participating sites, invited clinical experts and researchers) in July 2003, in Washington, DC, with project stakeholders to review initial findings and to agree on a data analysis plan, an authorship protocol, and dissemination plan. See attached "Executive Summary" provided in the project appendix to this report.

4. Prepared a proposal to the *Archives of Physical Medicine & Rehabilitation* for a special issue of the journal devoted entirely to the findings of this project. Proposal accepted. Special issue to be published in December 2005, with 12 peer-reviewed papers (100 pages of published text; 300 pages of double-spaced text). See project appendix for copy of proposal.

5. Published 1 peer-reviewed paper; another was accepted this past year.

6. Submitted 3 R0-1 proposals to NIH this past year for supplementary data analyses of the study's very large database. Still undergoing review.

Barriers and Solutions:
The main barrier this past year was completing data collection at the University of Pennsylvania site. U Penn converted to an electronic patient record system and as a result we were unable to obtain supplementary medical record data on about 60 patients (These data are in addition to the therapy data we had already collected in the course of treatment). We thought we would loose even more data because of the conversion but were able to obtain about half the medical record data that we still needed. Patients with missing data are not included in the data analysis.

Our weekly conference calls have enabled us to problem-solve effectively.

Phil Beatty, MA has left for new employment and Thilo Kroll, PhD has agreed to take over his role on the stroke follow-up portion of the study.

Plan:
1. Continue to conduct weekly conference calls as noted above.

2. Prepare and edit manuscripts for the special issue *Archives of Physical Medicine & Rehabilitation* as outlined above.

3. Organize a national invitational conference to be held in 2005 on the results of the study using the manuscripts for the special issue of the *Archives* as the basis for conference content.

4. 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)

5. A request to develop of a Clinical Stroke Research database at NRH has been sent for approval. This database will allow us to understand how modifications to practice will effect specific areas of stoke rehabilitation and improve patient outcomes. This request does not change the current objectives of the project; but rather, will add to the wealth of information that is being studied.

Publications:

Gerben DeJong, Susan Horn, Julie Gassaway, Mary Slavin, & Marcel Dijkers (2003). "Toward a Taxonomy of Rehabilitation Interventions: Using an Inductive Approach to Examine the 'Black Box' of Rehabilitation." ***Archives of Physical Medicine & Rehabilitation.*** 55(April), 678-686.

DeJong, Gerben and Susan Horn (2004). "Randomized Controlled Trials in Rehabilitation Research." ***New Zealand Journal of Disability & Rehabilitation Research.*** Submitted.

Diane Jette, Nancy Latham, Randall Smout, Julie Gassaway, Mary Slavin, Susan Horn (2004)
"Physical Therapy Interventions for Patients with Stroke in an Acute Rehabilitation Setting," ***Journal of the American Therapy Association.*** Submitted.

Project C1 Appendix

STROKE PERFORMANCE RECOVERY AND OUTCOMES STUDY

[AKA Post-stroke Rehabilitation Outcomes Project]

Analysis Meeting
July 23-25, 2003
Washington, DC

EXECUTIVE SUMMARY

Sponsor:

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POST-STROKE REHABILITATION OUTCOMES PROJECT

Analysis Meeting

July 23-25, 2003

Washington, DC

EXECUTIVE SUMMARY

The Post-Stroke Rehabilitation Outcomes Project analysis meeting was hosted by the National Rehabilitation Hospital in Washington DC on July 23-25, 2003. Mr. Edward Eckenhoff, President and CEO, and Dr. Edward Healton, Medical Director, NRH, welcomed participating facility representatives and other clinical and research experts in post-stroke rehabilitation to the Washington Hospital Center/National Rehabilitation Hospital campus.

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MEETING GOALS

1. Understand the Clinical Practice Improvement research methodology.
2. Understand the stroke study and its complex database that will provide answers to research questions for many years to come.
3. Define patient, process, and outcome variables
4. Begin to discover best processes and outcomes for specific types of patients.
5. Identify dissemination vehicles and potential manuscripts.

PROJECT GOAL

This study addresses the need for scientific data supporting the effectiveness of acute inpatient rehabilitation treatments in improving post-stroke outcomes. Most previous studies have looked at post-stroke rehabilitation in the aggregate without trying to disassemble the components to determine which of them are actually contributing to the outcome. This study peers into the "black box" of rehabilitation.

DISCUSSIONS

1. CLINICAL PRACTICE IMPROVEMENT (CPI) METHODOLOGY

Clinical Practice Improvement is a study methodology that analyzes each component of the process of care and then determines how and to what degree each component—individually and in concert with others—contributes to outcomes, taking into account patient differences. This approach—the CPI approach—involves five elements:

1. Create a multi-site, multidisciplinary Project Clinical Team (referred to as Team) whose tasks are to (a) identify outcomes of interest, (b) identify individual components of the care process, (c) create a common intervention vocabulary and dictionary, (d) suggest key patient characteristics and risk factors, (e) propose hypotheses for testing, (f) participate in project meetings and conference calls, and (g) take ownership of study processes and findings needed to implement clinical practice improvements.

2. Use the Comprehensive Severity Index to control for differences in patient severity of illness. CSI severity is an age- and disease-specific measure of physiologic and psychosocial complexity comprised of over 2,100 signs, symptoms, and physical findings. CPI uses the CSI as a case-mix adjuster.

3. Use data on patient characteristics, care processes, and outcomes drawn from medical records and study-specific data collection instruments. These instruments are tested for inter-rater reliability, and variables are tested for predictive validity.

4. Create a study database suitable for statistical analyses.

5. Successively test hypotheses based on questions that motivated the study originally, previous studies, existing guidelines, and, above all, new hypotheses proposed by the Team using bivariate and multivariate analyses including multiple regression, analysis of variance, logistic regression, and other methods consistent with measurement properties of key variables.

The CPI approach offers a naturalistic view of rehabilitation treatment by examining what actually happens in the care process. It does not alter the treatment regime to evaluate efficacy of a particular intervention as one might in a randomized controlled trial (RCT). The CPI approach also offers the advantage of large numbers—numbers that often cannot be attained in an RCT constrained by stringent selection criteria. Yet, the CPI approach controls for patient differences by taking into account important patient covariates, such as initial severity of illness and functional status. Moreover, CPI's detailed data on rehabilitation interventions allow researchers to penetrate to the most meaningful level of resolution regarding the types of care rendered—consistent with current knowledge and insights offered by Team participants. Thus, the CPI approach can answer study questions and hypotheses initially at a fairly basic level of resolution but also allows researchers to drill down into the data with the help of additional insights offered by Team participants.

2. STROKE STUDY DATABASE

Seven (6 in the United States and one in New Zealand) not-for-profit hospital-based rehabilitation centers are participating in the Post-stroke Rehabilitation Outcomes Project and provide a geographically diverse sample of post-stroke hospital-based rehabilitation care. See Table 1. Each site is contributing 200 consecutive post-stroke patients—total sample size upon completion will be 1,400 patients. These facilities are a convenience sample, but were selected based on their diverse geographic locations and their willingness to participate. We included one international site (from New Zealand) to permit inclusion of somewhat different approaches to rehabilitation care. Since the analyses are performed at the patient level, controlling for micro differences in patients, treatments, etc., inclusion of facilities that may use different approaches to rehabilitation care allows for much richer analyses and faster discovery of better practices. Analyses will be performed with and without data from New Zealand.

Table 1—Participating Clinical Sites

Facility	Location	Site Director (s)	# Rehab beds

National Rehabilitation Hospital	Washington, DC	Brendan Conroy, MD	128
Univ. of Pennsylvania Med Center	Philadelphia, PA	Richard Zorowitz, MD	24
LDS Hospital Rehabilitation Center	Salt Lake City, UT	David Ryser, MD	26
Legacy Health Systems	Portland, OR	Frank Wong, MD Lee Ann Simms, RN	33
Stanford Univ. Hospital	Palo Alto, CA	Jeffrey Teraoka, MD	17
Loma Linda Univ. Medical Center	Loma Linda, CA	Murray Brandstater, MD	40
Wellington & Kenepuru Hospitals	Wellington, NZ	Harry McNaughton, MD	25 & 20

Patient Inclusion Criteria

Patient selection criteria include:

1. *Diagnosis.* **Rehabilitation diagnosis of 430-438.99, 997.02, or 852-853: One of these diagnosis codes must appear in the list of ICD-9 codes in the rehabilitation record.**

2. ***Age.*** Age >18 years

3. ***Reason for admission.*** First rehabilitation admission following current stroke; the principal reason for admission must be the stroke. The patient may have had previous strokes and previous rehabilitation admissions for the previous stroke(s), but this is the first admission for the current stroke. Current stroke must have occurred within one year of this rehabilitation admission.

4. ***Transfers.*** If patient is transferred to another setting of care, e.g., acute hospital, and returns to the rehabilitation center/unit within 30 days, the patient remains a study patient. If patient is transferred to another setting of care, e.g., acute hospital, and returns to the rehabilitation center/unit after 30 days, the patient is no longer a study patient. Participation in the study ends on the day the patient was transferred.

Each site obtained IRB approval, and in addition, the New Zealand hospitals obtained a Federalwide Assurance (FWA) number for the protection of human subjects for international (non-US) institutions.

Data Types

The duration of the enrollment period varies with the number of stroke admissions at each facility. All study patients survived their stroke and entered hospital-based rehabilitation. For each study patient we are collecting 4 types of information:

1. **Rehabilitation intervention data** documented by clinicians for each therapy session and nursing day during each patient's rehabilitation stay. Notebook Tab 4.

2. **Clinician profile information** for all rehabilitation providers that contain information about the clinician's education, years of experience, clinical expertise, research experience, etc., and depict changes/advancements in training over time. Notebook Tab 5.

3. **Disease-specific severity of illness data** (signs and symptoms) for each of a patient's diagnoses obtained from post-discharge chart review in both acute care and rehabilitation settings. Notebook Tab 3.

4. **Patient, process, and outcome data** obtained from chart review in both acute care and rehabilitation settings. The CSI system allows for the creation of auxiliary data modules (ADMs), which are sets of study-specific data elements that are collected along with patient severity information. Notebook Tab 3.

3. DEFINE PATIENT, OUTCOME, AND PROCESS VARIABLES

3.a PATIENT VARIABLES

Section 6 of the Meeting Notebook contains demographic (age, gender, race, religion, education, career status) distributions by site for the existing sample of 897 patients. Payer source data reveal that approximately 50% of the US sample is Medicare patients. Risk factors are also presented. Approximately 50% of the sample has no documented use of alcohol or tobacco.

Cardiovascular history was obtained both from chart review and from comorbidity diagnosis codes. 78% of the sample has hypertension, 26% have a history of stroke, and 21% have pulmonary disease. In addition, 24% have arthritis and 44% have documented mental disorders.

Severity distributions were significantly different among sites for hospital, admission rehab, and maximum (overall) rehab as scored with the Comprehensive Severity Index (CSI®). Site average maximum rehab CSI scores ranged from 18.3 to 45.6. The average number of diagnosis codes entered per patient also varied by site from 4.6 to 15.0, but did not correlate significantly with average severity scores (Spearman correlation $r = .634$, p (2-tail) $= .16$) using site as the unit of analysis.

Details about types of strokes in study patients are contained on pages 27-42 in Section 6. 81% of the strokes were ischemic; 19% were hemorrhagic. The patients were further stratified by location of stroke.

Action Steps to follow meeting (some done in Breakout Groups):

a. Review ICD-9 codes for rehab and for hospitalization to determine percentage of codes found in chart documentation vs. those coded by the data collector. This will provide a picture of ICD-9 code availability and association with severity. Also control for type of hospital chart that was available to the data collector (full, partial) for CSI and number of ICD-9 codes comparisons by site.
b. CV history:
   - Separate atrial arrhythmias from the conduct disorders/arrhythmias group
   - Add hyperlipidemia as a CV risk factor (using ICD-9 code for identification = 31% of patients)
   - Identify number of patients who had previous MI and CABG – 29 patients
c. Calculate BMI for all patients where height and weight are known. Do not estimate obesity based on weight alone.
d. Define hierarchical groupings for type of stroke. See Breakout Group report.
e. Mental Disorders: Examine mental disorders by types: See Breakout Group report. Also include signs and symptoms of mental disorders from CSI criteria.

3.b. OUTCOME VARIABLES

Section 7 of the Meeting Notebook contains initial outcome variable definitions.

Length of Stay (LOS) in the rehabilitation units varies significantly by site, ranging from an average of 14.8 to 29.4 days.

FIM scores and components were presented for patients pre-PPS and post-PPS implementation. Original data contained zeros for both time periods even though the rules for pre-PPS FIM stated no zeros were to be used. Data presented in the notebook had zeros converted to ones for the pre-PPS time period. Mean admission FIM scores did vary significantly across sites for patients pre- and post-PPS implementation. Mean discharge FIM scores did not vary significantly across sites. Post-PPS severity of illness scores were statistically significantly higher than pre-PPS.

Mean **increases in CSI** severity from rehab admission to rehab maximum (full stay) varied significantly by site.

Complications occurring during the rehab stay are presented in Section 7, pages 13-20. Conference participants suggested we change the name of this section to 'Rehab associated conditions'. Each condition identified by ICD-9 code is presented by site and whether it is coded in the hospital diagnosis list, the rehab diagnosis list, or both hospital and rehab diagnosis lists. Some conditions (e.g., DVT, pressure ulcer, falls, etc.) are also found in chart review data. Cross tabs for these conditions depict the frequency that conditions are ICD-9 coded vs. found in chart documentation.

Discharge locations by site are presented in groups (expired, SNF or other facility, home health or other assistance, and home).

Action Steps to follow meeting:

LOS

a. Re-do the length of stay analysis for US sites only.
b. Correlate LOS with time from stroke onset to time of admission to rehab.
c. Identify which lengths of stay include combined rehab admissions (interruptions of <30 days).
d. Consider lengths of stay <7 and >33 days outliers for some analyses.
e. Examine short LOS (<7 days) for FIM, CSI, social support, and interventions especially patient/family education. Do the same for the top and bottom 3% of LOS patients.
f. Identify whether long lengths of stay may be due to placement issues. Does rehab continue until end of stay? Are long LOS patients related to type of stroke? Discharge FIM?
g. Compare LOS for patients discharged to home vs. other placement settings.
h. Compare number of patients with LOS <4 days by site.

FIM

i. Marcel Dijkers suggests we do Rasch analyses on all FIM data to estimate value for missing FIM components
j. Consider reverting to original pre-PPS data that contain zeros – do not force zeros to ones.
k. Consider for some analyses, using motor and social/cognition component scores separately instead of total FIM scores. Other analyses can use the combined score.
l. We speculated that changes in FIM pre- and post-PPS could be due to changes in coding and documentation, since PPS emphasized more accurate coding and increased documentation of severity. Alternatively, it could be that sicker patients are being admitted post-PPS. We will look at changes in coding, FIM, and severity for patients pre- and post-PPS by site. Correlate FIM with CSI for patients overall and for patients in each site separately.
m. Investigate where missing FIM scores are found: non-Medicare patients? By site? In expected content areas, such as incontinence, stair climbing?

Severity

n. Examine and correlate number of ICD-9 codes and CSI maximum score for patients pre- and post-PPS separately in each site. We will repeat the correlation between number of diagnosis codes and maximum CSI at the patient level overall and also separately for patients within each site. Pearson correlations will be used for larger sample sizes. Also we will repeat the correlation between number of diagnosis codes and maximum CSI at the patient level overall and also separately for patients within each site dividing into pre- and post-PPS time periods.
o. Calculate CMG for each patient. Examine CMGs by LOS.
p. Examine LOS, admission and discharge FIM, and max CSI in various CMG groups.
q. Are CMGs by site related to average CSI and average FIM components?

Associated rehab conditions (previously called complications)

r. UTIs: examine relationship with use of Foley in hospital and in rehab, look at relevant symptoms (temperature, WBC, urgency, frequency, burning), steroid use, and listed reason for high WBC
s. Pneumonia: examine relationship with feeding tube use, diet types, and swallowing descriptions and interventions from SLP. Examine tube placement before pneumonia.
t. DVTs: combine DVTs and PEs as thromboembolism group, separate DVTs by distal and proximal
u. Pressure Ulcer: look at start date of ulcers to determine if started in hospital or in rehab, stage of PU, location of PU (heel vs. sacral)
v. Malnutrition: calculate BMI for all patients and compare with levels of malnutrition and weight loss.
w. Seizures: examine by type of stroke (infarct vs. hemorrhage, and cortical vs. subcortical).
x. Falls: look at date/time of fall and examine risk factors. See Breakout Group report.
y. Elevated WBC: relationship of high WBC and steroid use; also related to complications.
z. Altered mental status: identify groups by ICD-9 code. See Breakout Group report.
aa. Examine incontinence and association with discharge location and LOS

Discharge location

bb. Breakout Group provided hierarchical stratification so that varying levels of detail can be used for specific analyses:
    - A. Home
        - Own home
        - Relative's/friend's home
    - B. Community
        - Assisted living
        - Group home
        - Foster home
    - C. Institutional
        - SNF
        - Non-SNF: ICF, LTC, rest home, transitional care, sub-acute facility, nursing home
    - D. Acute care hospital/acute inpatient rehabilitation
    - E. Expired
cc. Examine discharge location with location of care prior to stroke: same place, more or less dependent?
dd. Examine patients with no indicated discharge therapies (405 patients) and discharge location.

Review discharge therapy list to be sure all descriptions have been included in selection lists.

ee. Separate patients who go home into 2 groups: independent and requiring care (look in recommended services, discharge destination, and discharge FIM to see how dependent patient is)
ff. Examine discharge FIM score and discharge CSI by discharge location
gg. Examine actual vs. projected discharge location

3.c. PROCESS VARIABLES

Meeting participants suggested we look at interventions on a trajectory from time of injury. Examine the time of onset of symptoms to admission to acute care, and to admission to rehab. How do these correlate with payer and by type of stroke?

Section 8 of the Meeting Notebook contains selected process variables. This section contains sub-tabs for: Physical Therapy, Occupational Therapy, Speech Language Pathology, Physician, Nursing, Medications, and Nutrition.

Physical Therapy, sub tab #1

Data are presented for average time per PT session by functional activity, mean number of PT sessions per patient over whole rehab stay by site, and mean number of PT sessions per patient per day by site. Significant differences by site were found. The frequency of number of PT sessions where specific interventions were used for each functional activity is also displayed.

Patients and data were then separated into length of stay groups – each group represented one week of rehab stay. Frequency of functional activities and minutes/day spent on each functional activity in each LOS group was displayed and summarized on page 19. Interventions were displayed in a similar manner and summarized on page 47.

Action Steps to follow meeting:

a. Examine group therapy vs. not group therapy sessions. Compare for: breadth of activities, payer (regular Medicare vs. managed Medicare (HMO)), psychiatric codes, change in mood, FIM, CSI, type of provider (PT, aide, etc). Group therapy can be defined as sessions with duration ≥1.5 hours
b. Compare date of formal assessment to date of admission for patients pre- and post-PPS
c. Capture number of sequential sessions before a break of any number of days. If more breaks, is LOS longer?
d. Examine missed therapies by day of week and by reason of fatigue
e. Examine duration of session by day of week – particularly Monday and Friday
f. Examine use of aide/assistant by day of week
g. Examine number of days of PT to total number of days in rehab
h. Examine number of patients who received therapy on weekends and separately for Saturdays and Sundays, by site. Much weekend therapy data may be missing as some sites use temporary staff who did not use TELEforms.
i. Stratify prefunctional activities by FIM and LOS
j. For patients who received no PT in last week of stay, what therapies did they receive? N=897-776=121 patients.
k. Examine type of functional activity and intervention by site
l. Examine consistency (continuity) of therapist: total number and frequency of intervention sessions for each therapist by patient: (> 80% same therapist = good; 50% same therapist = ok; 25% same therapist = poor)
m. Missed therapies: correlate with discharge disposition, tube count, LOS, discharge FIM, day of week.

n. Redo Tables on pages 19 and 47 for frequent CMGs. Do results differ?

Occupational Therapy, sub tab #2
Occupational Therapy data displays that are similar to the PT data displays are presented in Section 8, sub tab #2.

Action Steps to follow meeting:
a. The suggestions listed above for Physical Therapy will be performed for Occupational Therapy.

Speech Language Pathology, sub tab #3
Speech Language Pathology data displays that are similar to the PT and OT data displays are presented in Section 8, sub tab #3.

Action Steps to follow meeting:
a. The suggestions listed above for Physical Therapy will be performed for SLP.
b. Examine use of swallowing interventions by site.

Nursing, sub tab #4
We did not discuss the nursing section during the meeting. This will be done on sub-group conference calls. We will also present each site's nursing patient hours that were sent to Julie.

Sub tab #5
Sub tab #5 is empty. Contents (physician TELEform data) will be supplied separately.

Medications, sub tab #6
Frequency distributions by medication class were presented for selected medication classes. Additional definitions for medication classes were discussed in Breakout Group - see report below.

Action steps to follow meeting:
See Breakout Group report. We will consider adding a pharmacist to our team. Preliminary suggestions include:

a. Assemble a comprehensive list of anti-hypertensive medications and examine association with BP control.
b. Look at use of combination therapy, e.g., beta-blockers and diuretics for BP control.
c. Examine anti-platelet medications (Persantine, Dipyridamole, Ticlodipine, Plavix, Clopidogril, Aspirin, Aggrenox) and anticoagulants (Heparin, Coumadin, Warfarin, Lovenox, Fragmin, Enoxaparin) in detail.
d. Examine dopamine agonists/stimulants: Provigil, Amphelamine, Dexedrine, Ritalin, Amantadine.
e. 305 patients received 387 different anti-depression medications. 100 of these 387 are Trazadone. Look at dose, as different doses are used for different reasons.
f. Examine pain medications and outcomes.

Nutrition, sub tab #7

Albumin levels are available on about 52% of the sample. Participants urged caution in interpreting low albumin levels as nephritic syndrome may cause abnormal albumin. Only 10% of the sample (in only three sites) had pre-albumin levels. Weights are available on 91% of the sample.

Significant variation by site is seen in the use of feeding tubes. Site #5 used feeding tubes for 41% of their stroke study patients; other sites were between 5-13%. Most tubes were placed for dysphagia. Use of supplements also was statistically significantly different among sites, ranging from 11% to 35% with an average of 22%.

Action steps

a. Calculate BMI for all patients who have a weight and height. Do not estimate BMI for patients with no height entered in the database. The following BMI obesity classes were provided after the meeting:

Underweight:	<18.5
Normal:	18.5-24.9
Overweight:	25-29.9
Obese Class I:	30-34.9
Obese Class II:	35-39.9
Extreme Obesity:	>40

Create a weight (# pounds) frequency distribution (with height displayed when available) to examine the upper and lower tails. Also display presence of ICD-9 code for morbid obesity (278.0) and gender.

b. Examine discharge location and other outcomes by BMI class.

c. How is BMI related to number of therapies provided of various types? Are there fewer sessions per stay for higher BMI patients? Are there more missed therapies for higher BMI patients?

d. Examine the use of feeding tubes with FIM, CSI, and discharge disposition. Include all tubes.

e. Look at the timing (dates of insertion and removal of feeding tubes). Did a swallowing evaluation happen prior to insertion?

f. Examine diet type for patients with feeding tubes, including hydration with water.

g. Determine how many patients in our database had a calorie count. Any association with use of tubes?

h. Look at types of feeding tubes used.

i. Examine supplement list to determine which items should 'count' as supplements. Snacks and bowel agents such as yogurt and fiber rich should not count as dietary supplements.

j. For patients who had calorie counts, look at diet type, supplements, BUN, and Creatinine.

k. Is there an association with diet type, particularly thickened liquids, and complications or missed therapy?

l. Hydration can be examined by looking at fluid orders in 'diet type,' BUN, and Creatinine. What is association between fluid orders and BUN and Creatinine?

BREAKOUT GROUPS

The team formed Breakout Groups to accelerate work in defining variables and initiate ideas for regression analyses. Participants self-selected groups in which to participate based on their expertise and interest.

Variable: Stroke Type (Section 6, pages 27-42)

Breakout Group provided hierarchical stratification so that varying levels of detail can be used for specific analyses:

A. Side of stroke
- Right
- Left
- Bilateral

B. Location

B.1. Cortical
- Frontal
- Parietal
- Temporal
- Occipital

B.2. Brainstem
- Peduncles
- Midbrain
- Pons
- Medulla
- Cerebellum, cerebellar

B.3. Subcortical

Basal ganglia	Corpus Striatum
Caudate	Small vessel ischemic disease
Internal capsule	Post limb of IC
Corona radiata	Lateral thalamic
White matter	Corpus callosum
Putamen	Paraventricular/periventricular
Thalamus	Deep grey nuclei
Lacunar	Posterior Fossa
External capsule	Ventricle
Lentiform/lenticular nucleus	Geniculate
Centrum semiovale	Microvascular disease
Paramedian	Lenticulostriate

C. Ischemic (non-hemorrhagic)	**vs.**	**Hemorrhagic/Bleed/Rupture**
Embolic		Intraparenchymal hemorrhage
Infarct/thrombotic/ischemic		Intraventricular (ventricle)
Lacunar		Subarachnoid
Hemorrhagic conversion		Subdural

D. Vascular

Anterior cerebral
Middle cerebral
Posterior cerebral
Anterior inferior cerebellar
Posterior inferior cerebellar
Vertebral
Basilar
Internal carotid

Variable: Medications (Section 8, sub tab 6)
The following groups were defined:

Dopamine Receptor Antagonists (anti psychotics)
Alpha-1 Antagonists: Prazosin, Hytrin, Cardura,
Alpha-2 Agonists: Clonidine, Tizanidine
Anti-spasticity: Baclofen, Dantrolene, Tizanidine
Anti-epileptics: Phenobarbital, Phenytoin, Gabapentin, Tegretol, Depakote, Klonopin, Keppra, Lamictal
Stimulants:
Adrenergics: Methylphenidate, Provigil (Modafinil), Dexedrine (Dextroamphetamine), Adderall, Cylert
Dopaminergics: Amantadine, Sinemet, Levodopa, Carbidura, Bromocriptine
Cholinergics: Aricept, Reminyl, Cognex, Exelon, Tacrine, Antiplatelet, Aspirin, Persantine, Aggrenox, Plavix, Ticlid
Stroke Prophylactics
MVI (Multivitamins), Folate, Thiamine, Vitamin B, B_6, B_{12}

Variable: Falls
Define: Date and time of fall, assisted vs. unassisted, witnessed vs. non-witnessed
Other variables to look at in relation to fall:

Perceptual, balance, and cognition deficits at time of fall
FIM and CSI scores – change in scores for patients who fall vs. no fall
Mental status
Communication deficits
Restraints – electronic, chemical (need to define medications), and physical
Location of stroke
Nursing staffing patterns
Use of DMEs
Repeat falls
Psychotropic drugs

In some institutions, falls may be recorded on incidence reports, which do not become part of the chart; thus, we may not have complete data. We will look at ICD-9 codes (fractures) that may indicate falls.

Variable: Mental Disorders

This Breakout Group reviewed all ICD-9 code in the Mental Disorder chapter of the ICD-9 code book and suggested the following groupings and associated ICD-9 codes

Dementia	290; 294.1
Depression	296.2; 296.3; 300.4; 309.0; 309.1; 311
Psychoses	
Chronic	291; 292; 294.0; 295-296.1; 296.4-299
Transient	293
Adjustment/Anxiety	300.0-300.3; 300.5-302.9; 306, 307, 308, 309.2 – 309.9
Organic Brain Damage	294.8; 294.9; 310
Substance Abuse	303, 304, 305

Regression Analyses

The team separated into different Breakout Groups on Friday morning to make suggestions to begin regression analyses. Groups focused on five human functional domains (mobility, self care, communication/ cognition, psychosocial, prevention/health maintenance).

Mobility and Self Care

Question: What patient and process variables affect mobility and self-care?

Outcomes of interest: discharge disposition, LOS, total FIM, FIM motor and cognition components, FIM stages – mobility, ADLs, bowel and bladder, executive functioning

Patient variables	Process variables – medications and nutrition	Process variables - therapies
Age	Ritalin	Site
Gender	SSRIs	Length of stay
Education	Dexedrine	Total minutes in each therapy
Race	TCAs	**Overall for all patients/site**
Career	Trazadone	1st, 2nd, 3rd phase of episode
Financial stressors (yes/no)	Amantadine	for patients in subcategories
CV history (yes/no)	Sinemet	a. ≤6 days LOS
BMI	Ambien	b. 7-28 days LOS
Time from stroke to rehab admission	Clonidine	c. >28 days LOS
Payer	Benzodiazepines	d. CMGs
ICD-9 – specific diseases:	Beta blockers	e. Stroke type
Prior CVA	Narcotics	f. Admit FIM score categories
MI	Anti-depressants	Therapist experience, degree,
CABG	Tranquilizers stopped in rehab	specialty certification
PTCA	(y/n)	# patients seen per day by therapist
Dialysis	Drug serum levels in rehab	Size of rehab hospital/# of beds
Emphysema or COPD	Dilantin	# missed therapy sessions
Chronic bronchitis	Depokine	Weekend vs. no weekend therapy

CHF History of TBI Stroke Type: Right vs. left Hemorrhagic vs. ischemic Cortical vs. subcortical Bowel or bladder amnol (yes/no) DVT in rehab Living situation PTA Ambulation PTA PT, OT, SLP in rehab (yes/no) Albumin (normal, mild, severe malnutrition) Acute hospital medications Clonidine Benzodiazepines Narcotics Beta blockers Anti-depressants Tranquillizers DMEs PTA (≥3 or <3) Highest CSIC in rehab Pressure ulcer on admission to rehab (<stage 3 or ≥ stage 3) Highest CSI score in rehab for: Altered movement Coordination/balance Strength Ambulation status Perceptual deficits Sensory alterations C-difficile (yes/no) Admit motor FIM Admit cognitive FIM	Tegretol Digoxin	Overall by site: PT/OT/SLP practice: Describe activities provided Interventions given in activity Overall total episode By 1st, 2nd, 3rd phase of episode Consistency of therapist Typical constellation of interventions for each activity Utilization of therapies Professional vs. assistant For what % of sessions For what types of activities For what types of interventions Overall By 1st, 2nd, 3rd phase of episode By CSI and CMG

Psychosocial

Patient variables	Process variables – medications and nutrition	Process variables - therapies
Race Religion Stroke location Family involvement History of CVA, DME use, ADLs Incontinence Depression and anxiety (mental status, ICD-9) # complications through hospital stay History of substance abuse Discharge disposition: change from anticipated to actual level of independence Use of PEG/feeding tubes Ratio of patients to therapists by site Consistency of therapists Change in patient's communication during rehab as predictor of d/c disp Intubation History of falls during rehab High FIM mobility score, low cognitive score	Pain meds correlate with 'pain' in treatment topic on 4 forms	# missed therapy sessions due to fatigue, depressive signs Community settings correlated to change in mental status Group therapy Use by any discipline with higher social FIM score Amount of time in group Size of groups (# patients) Presence/absence of social worker and rec therapist and amount of intervention time On SW form – psychosocial eval

Cognition/Communication

Questions: What patient and process variables affect cognition and communication?

Does depression increase with initiation of medications (status improves) due to increased awareness?

Does use of memory books alone or in combination with other strategies improve outcomes?

Outcome variables: FIM memory score, dysphagia, discharge location, LOS

Patient variables	Process variables – medications and nutrition	Process variables - therapies
Dementia Depression History CVA Level of malnutrition Stroke location Time of symptom onset to rehab	Onset of meds for depression Total number of medications Use of Ambien or other sleeping agent (PRN or routine) Feeding tube insert and removal dates	Total time of family education Use of motor speech strategies Time clinician spends with supervisor Use of (across sites): EMG

admission Patient education Patient occupation Patient currently employed? Yes/no Age Motor FIM score (admit) Cognitive FIM score (admit) CSI Aphasia + cognitive Aphasia +dysarthria Communication Impairment+depression Trach status Family involvement Change in aphasia ICD-9 for dementia Perceptual deficits Memory deficits	Diet modification timing	Electrical stimulation Any communication device Nasal manometer DPNS Memory books Time of use Change in orientation as they start Use in combination with other strategies Use of co-treatment Total time in all therapies OT vs. SLP provide cognitive-based treatments Time spent on swallowing (especially with malnutrition) Frequency of groups Consistency of therapists Number of treatments

Prevention/health maintenance

Questions: How do reasons for missed therapies relate to medications, complications, and other outcomes?

What is the relationship of tube count (feeding tubes, urinary catheters, trachs, etc.) to discharge disposition, complications, LOS?

What is relationship of behavioral problems to interventions (use of restraints, medications, use of sitter, nursing intensity), sleep problems, missed therapies, and other outcomes?

Does number of education minutes by discipline relate to function and outcomes?

Does education about skin integrity and use of pressure-relieving devices result in better outcomes?

Do bowel and bladder incontinence education and bowel/bladder training programs result in better outcomes?

How do pulmonary problems (use of oxygen, respiratory treatments, trach) relate to outcomes?

Is intensity of treatments associated with to nutrition, fatigue, depression, and other complications?

How do pain and pain management measures relate to outcomes?

Do dysphagia and nutritional problems (use of tubes and supplements) relate to FIM scores?

Compare CSI to PPS tier system to predict LOS.

Medical consultants – number of minutes physicians spend on consults and talking with care team

What is the relationship of physician visit (total # minutes) to medical complexity and complications?

Outcomes: LOS, missed therapy, number of minutes per day of therapy, overall number of minutes of therapy, FIM and FIM components, complications/morbidity (type and intensity), disposition

Patient variables	Process variables – medications and nutrition	Process variables - therapies
BMI Albumin DVT Alcohol, tobacco, other drug use High/low blood pressure Stroke location Education level Continence level (bowel and bladder) Diabetes, Hypertension LOS in acute hospital Therapy initiated in acute hospital	Vaccines (flu shot, pneumovax) Use of meds (harmful and helpful groups) DVT measures – A/C, pneumatic compression, TED, mobility, DX tests Use of nutritional supplements Use of feeding tube Use of stroke prevention medications: anti-platelet, lipid lowering, Folate, B12,	Education minutes by discipline # of dietary consults Total minutes family conference

OPENING THE "BLACK BOX" OF STROKE REHABILITATION

AND WHAT IT MEANS FOR REHABILITATION RESEARCH

The proposed editors and authors are pleased to submit their proposal for the 2005 ACRM Supplement in the *Archives of Physical Medicine & Rehabilitation,* hereafter, the *Archives* supplement. We propose a thematic supplement that seeks to tear off the cover of stroke rehabilitation's proverbial black box using the experience of an unparalleled major multi-site stroke outcomes study. The proposed supplement provides a discipline-by discipline characterization of stroke rehabilitation practice and their effects on stroke rehabilitation outcome. The supplement also examines practice variation in medications and nutrition, international variation, and the effect of excess body weight on stroke rehabilitation practice and outcome.

Equally important, and perhaps more so from the standpoint of rehabilitation research theory and practice, the proposed supplement addresses fundamental issues in rehabilitation research design and epistemology.[1] The proposed supplement will present an alternative to the research paradigm that dominates biomedical research and one that rehabilitation research has sought to emulate. We believe that the experiences of the multi-site stroke study noted above offers an approach that, in many instances, may be better suited to the multi-disciplinary and the multi-factoral nature of the rehabilitation enterprise.

The proposed editors and authors comprise a ***pre-existing team*** of investigators and clinical experts who already have a strong and abiding working relationship that bodes well for the success of the proposed supplement. This team has delivered on every aspect on one of the most demanding research protocols in rehabilitation research history. We stand ready to deliver on the proposed supplement as well.

Theme and Its Importance

One of the great challenges in rehabilitation has been the ability to characterize the multi-faceted and multi-disciplinary interventions that comprise the rehabilitation process. "What does rehabilitation actually do?" one might ask. Historically, rehabilitation has tried to answer this question mainly by specifying its outcomes—enhanced function, discharge to home, participation in family and community life—instead of its processes. And rightfully so. A field needs to know first and foremost what its goals and intended outcomes are. For

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References

[1] Epistemology refers to "the study or a theory of the nature and grounds of knowledge especially with reference to its limits and validity" (Merriam-Webster on-line dictionary at http://www.m-w.com/cgi-bin/dictionary.

many years, the field presumed that by keeping its eye on the prize, i.e., the outcome, that the processes of care would self-organize to achieve the desired outcomes.

Events over the last two decades have brought increasing attention to the process of care as well as the outcome of care. First is the increased focus on practice guidelines and evidence-based practice as in the case of the AHCPR Post-stroke Practice Guideline project. Second is the increased use of non-hospital settings for rehabilitation care that has forced the question of what makes the process of care in one setting different than another. Third is the increased concern about the quality of care, i.e., the absence or presence of sentinel processes of care. Fourth is the increased scrutiny of third-party payers regarding the duration and process of care. And fifth is the inception of prospective payment for post-acute rehabilitation that has forced providers to re-examine their processes of care in order to deliver care more efficiently.

In each of these instances, rehabilitation providers have been limited by the lack of a taxonomy to characterize rehabilitation processes, the lack of an adequate documentation system to capture what actually transpires in the treatment setting, and the lack of a research paradigm and corresponding research method that could capture the diversity and range of rehabilitation practice.

This *Archives* supplement addresses these challenges and presents an alternative approach to the research paradigms that dominate research today. We use the vehicle of a very large multi-center observational study in stroke rehabilitation to address and illustrate the challenges and alternatives that are currently available to rehabilitation research today. We do not seek to be definitive in all our observations but we do seek to illustrate how one very large data-intensive stroke rehabilitation study is managing to break through many of the barriers that have limited rehabilitation research in the past.

Relevance to ACRM's Mission

> "The mission of the American Congress of Rehabilitation Medicine (ACRM) is to promote the art, science, and practice of rehabilitation care for people with disabilities. This mission challenges us to be responsive to the rapidly changing environment of health care and the increasing diversity of rehabilitation service delivered by healthcare professionals from all disciplines and venues within the continuum of rehabilitation care. . . . ACRM recognizes the urgent need for an organization that will address the crucial issues of outcomes, efficacy of treatment, managed care, best practices, and reimbursement . . ."

The proposed supplement fits squarely with ACRM's mission. It addresses rehabilitation practice and uses scientific methods to understand practice variation in one rehabilitation impairment group, namely stroke survivors who comprise 20% of all inpatient rehabilitation admissions. We believe that the proposed supplement breaks new ground in rehabilitation methods and approaches and for the first time will really be able to provide a detailed characterization of stroke rehabilitation intervention.

Literature Review

Over the years, rehabilitation has expended enormous intellectual energy conceptualizing models of disability, identifying relevant outcome domains, and developing outcome measures, including psychometric and clinometric 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: There has been little systematic disaggregation (conceptualizing, measuring, and counting) of interventions used in rehabilitation. While 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 little 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 (e.g., rehabilitation team culture). Most previous studies 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.[2,3] 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.[4,5,6] Rarely are individual interventions examined in the

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[2] Keith RA, Wilson DB, Gutierrez P. Acute and subacute rehabilitation for stroke: a comparison. *Arch Phys Med Rehabil* 1995;76:495-500.

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[4] Heinemann AW, Hamilton B, Linacre JM, Wright BD, Granger C. Functional status and therapeutic intensity during inpatient rehabilitation. *Am J Phys Med Rehabil.* 1995 Jul-Aug;74(4):315-26.

[5] Heinemann AW, Kirk P, Hastie BA, Semik P, Hamilton BB, Linacre JM, Wright BD, Granger C. Relationships between disability measures and nursing effort during medical rehabilitation for patients with traumatic brain and spinal cord injury. *Arch Phys Med Rehabil.* 1997 Feb;78(2):143-9.

[6] Baker JG, Fiedler RC, Ottenbacher KJ, Czyrny JJ, Heinemann AW. Predicting follow-up functional outcomes in outpatient rehabilitation. *Am J Phys Med Rehabil.* 1998 May-Jun;77(3):202-12.

context of the entire array of interdisciplinary interventions used and within the structural arrangements (such as 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.[7,8,9,10] 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 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 one another. Optimal interventions may be different for various diagnoses, admission functional levels, or co-morbidities.

Several have called for a taxonomy of treatments that will bring 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.[11 12 13]

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[7] Reker DM, Hoenig H, Zolkewitz MA, Sloane R, Horner RD, Hamilton BB, Duncan PW. The structure and structural effects of VA rehabilitation bed service care for stroke. *J Rehabil Res Dev.* 2000 Jul-Aug;37(4):483-91.

[8] Reker DM, Duncan PW, Horner RD, Hoenig H, Samsa GP, Hamilton BB, Dudley TK. Postacute stroke guideline compliance is associated with greater patient satisfaction. *Arch Phys Med Rehabil.* 2002 Jun;83(6):750-756.

[9] Hoenig H, Sloane R, Horner RD, Zolkewitz M, Reker D. Differences in rehabilitation services and outcomes among stroke patients cared for in veterans hospitals. *Health Serv Res.* 2001 Feb;35(6):1293-318.

[10] Duncan PW, Horner RD, Reker DM, Samsa GP, Hoenig H, Hamilton B, LaClair BJ, Dudley TK. Adherence to postacute rehabilitation guidelines is associated with functional recovery in stroke. *Stroke.* 2002 Jan;33(1):167-77.

[11] Dijkers MP. A taxonomy of rehabilitation interventions: Feasibility and development suggestions. Presentation at the 2001 annual meetings of the American Congress of Rehabilitation Medicine, Tucson, AZ, October 25-28, 2001.

[12] Dijkers, MP. ACRM presentation in October 2003

[13] Hart, T. ACRM presentation in October 2003 and presentation to the NIH National Advisory Board on Medical Rehabilitation Research in December 2003.

[14 15] In fact, the matter of a taxonomy of rehabilitation interventions has been the subject of many recent conversations in rehabilitation research especially within the ACRM as noted by the vigorous discussions of the ACRM Task Force on Rehabilitation Taxonomy. Some have labeled this extended conversation as a rehabilitation zeitgeist. The proposed supplement is not primarily about rehabilitation taxonomy development, however. That is the subject of another soon-to-be-published paper that emerged from the study that motivates this proposal. The proposed supplement does report on how a stroke rehabilitation taxonomy became an inevitable byproduct of the attempt to identify more clearly and precisely the interventions that comprise the stroke rehabilitation process (Paper 3). It certainly is not the only taxonomy—and a different taxonomy might emerge using a different level of resolution. Nonetheless, the taxonomy used in this supplement is one developed by many clinicians working within and across disciplines with colleagues and researchers from several different sites.

Armed with a workable taxonomy, one can begin to examine what actually transpires in the rehabilitation process—within disciplines, across disciplines, and across sites of care. Studies
suggest that there is large variation in stroke rehabilitation practice.[16 17 18 19 20 21 22 23 24 25] There is also variation practice between countries.[26 27 28] Unfortunately, many of these

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[14] Whyte J, Hart T. It's more than a black box; it's a Russian doll: Defining rehabilitation treatments. *Am J Phys Med Rehabil* 20003; 82:639-652.

[15] DeJong G, Horn S, Gassaway J, Dijkers M, Slavin S. Toward a taxonomy of rehabilitation interventions: using an inductive approach to examine the 'black box' of rehabilitation. *Archives of Physical Medicine & Rehabilitation* (in press), 2004.

[16] Kwan J, Sandercock P. In-hospital care pathways for stroke: a Cochrane systematic review. *Stroke* 2003; 34: 587-8.

[17] Jette D, Smout R, James R, Gassaway J, Horn S. (unpublished manuscript). Physical therapy interventions for patients with stroke in an acute rehabilitation setting.

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[23] Ballinger C, Ashburn A, Low J, Roderick P. Unpacking the black box of therapy -- a pilot study to describe occupational therapy and physiotherapy interventions for people with stroke. *Clin Rehabil* 1999; 13: 301-9.

studies report on only one domain of therapy, such as gait training or activities of daily living (ADL).[29] Rarely do studies examine the full range of therapeutic interventions simultaneously.

The multi-factorial character of rehabilitation interventions has proved daunting in rehabilitation research. Building on our introductory observations and at the risk of oversimplification, one can characterize rehabilitation effectiveness or outcomes research as existing along a continuum. At one end of the continuum, rehabilitation research attempts to compare bundled packages of services without differentiating the content of the package. As noted earlier, a classic comparison is the comparison between the outcomes of rehabilitation care in skilled nursing facilities (SNF) versus care provided in inpatient rehabilitation facilities (IRFs). No clear differentiation of individual therapies is made at this aggregate level of analysis. At the other end of the continuum, rehabilitation research attempts to examine the efficacy of a single intervention (or closely but limited array of interventions) compared to another single intervention or to placebo or sham intervention as in the case of a randomized controlled trial (RCT).

The proposed supplement will argue that this dichotomy, at one level, presents a false choice—a choice made necessary in the absence of a taxonomy that can adequately characterize rehabilitation care. Yes, there have been studies that have been conducted near the middle of this continuum as in studies that examine the differential effects of hours of physical or occupational therapy affect outcome. In the final analysis, this middle-ground type of study remains inherently unsatisfying because it does not characterize what therapists in fact do during the therapy encounter. Single-bullet RCTs also remain unsatisfying due to their logistical challenges and the opportunity for generalization. More importantly, there simply is not enough money in the nation's entire biomedical research budget to examine all the variation of practice in rehabilitation care.

The proposed supplement presents an alternative to this false-choice state of affairs. We do not deny the important role that other types of research can have but we believe that

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[24] Snels I, Beckerman H, Lankhorst GJ, Bouter L. Treatment of hemiplegic shoulder pain in the Netherlands: results of a national survey. *Clin Rehabil* 2000; 14: 20-7.

[25] Rothi L. A reminiscence of the first two years, current practice, and a renewal of our purpose. *Invited presentation at the Academy of Neurologic Communication Disorders and Sciences*. Washington, DC, 2000.

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rehabilitation research has not taken full advantage of multivariate statistical approaches that can power today's observational studies. With the aid of a taxonomy, large clinical databases, and partnering with front-line clinicians, researchers can finally address some of the methodological limitations that have bedeviled rehabilitation research all of these years. We do not suggest that the evidence resulting from our research is necessarily definitive. "[O]ne . . . feature of medical evidence is its inherently provisional nature. . . [E]vidence is emergent and therefore expected to change with time."[30]

Objectives

In short, the proposed supplement has several objectives:

1. Addresses some of the larger epistemological issues in rehabilitation and biomedical research (Paper 2);

2. Introduces the concept of a clinical practice improvement (CPI) study and where it fits in the pantheon of rehabilitation research (Paper 2);

3. Describes how a CPI approach has been operationalized and applied in a multi-site stroke rehabilitation study (Paper 3);

4. Uses CPI to characterize rehabilitation practice and practice variation and explain rehabilitation outcomes (Papers 4-8);

5. Explain the impact of the IRF-PPS on stroke rehabilitation practice using the study's ability to actually characterize rehabilitation practice (Paper 9);

6. Apply CPI to help understand the role of obesity in stroke rehabilitation practice and outcome (Paper 10);

7. Characterize some international differences in stroke rehabilitation practice and their differential effects on outcomes (Paper 11); and

8. Determine the extent to which rehabilitation practices that affect outcomes at discharge also affect longer-term 6-month outcomes (Paper 11).

The proposed supplement concludes with brief commentaries from several leaders in the field of rehabilitation and stroke rehabilitation who can address the epistemologic, methodologic, clinical, and policy issues raised by the 11 papers presented in the supplement.

Intended Audience

This supplement addresses fundamental issues of concern to all ACRM and rehabilitation stakeholders—researchers, providers, large purchasers, and payers—who are

[30] Ross EG. Seven characteristics of medical evidence. *J Evaluation in Clinical Practice* 2000; 6: 2, 93-97.

concerned with issues related to evidence-based practice in stroke rehabilitation. It is not designed to address the decision needs of consumers although it will address issues facing consumers who may want to understand the nature of evidence-based practice and how it can help inform their choices about rehabilitation alternatives.

Content

1. **Gerben DeJong, Brendan Conroy, Edward Healton, Susan Horn.** "Introduction to this *Archives Supplement*." 3 published pages

This will be a brief overview of purpose and scope of the supplement and how the supplement unfolds from paper to paper. This article will also reference our earlier previously in-press work on stroke rehabilitation taxonomy.

2. **Susan Horn, Gerben DeJong, David Ryser, Peter Veazie, Jeff Teraoka, *et al.*** "Another Look at Observational Studies in Rehabilitation Research: Going Beyond the Holy Grail of the Randomized Controlled Trial." [This is a more theoretical paper]. 12 published pages.

The randomized controlled trial (RCT) is considered the gold standard in bio-medical research. It is held as the highest level of evidence for efficacy and best practice or what Miettinen calls "all purpose RCTism."[31] The RCT is, unfortunately, an expensive and unwieldy, if not clumsy, tool for discovering and establishing best practice in rehabilitation. RCTs work well when the intervention is singular, the timing is well established, and the dosage is fairly clear. RCTs do not work as well with rehabilitation where the interventions are multi-faceted and multidisciplinary, where timing is in doubt, and the dosage will have to vary with patient tolerance and other factors. In short, RCTs do not lend themselves well to black-box research. There simply is not enough money in the biomedical research world to subject all the variations of rehabilitation practice to an endless array of RCTs. In the interim, we have to rely more on observational studies that are more naturalistic and where the interventions are not as contrived for experimental purposes. Many argue that observational cohort studies are well down the hierarchy of scientific evidence. This paper challenges this assumption by introducing the concept of a clinical practice improvement (CPI) study. One of the strengths of CPI studies is its attention to defining and characterizing the black box of clinical practice. One downside is that CPI studies require demanding data collection protocols but the upside is that they offer the one of the best opportunities to uncover best practices more quickly and still achieve many of the advantages that RCTs are presumed to have. The paper juxtaposes RCT and CPI approaches, evaluates their relative advantages and disadvantages, and discusses their implications for rehabilitation research and evidence-based practice.

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3. **Julie Gassaway, Susan Horn, Crystal Clark, Mary Slavin, and other interested parties.** "Applying the CPI approach to Stroke Rehabilitation: Methods Used to Define and Evaluate the Black Box of Stroke Rehabilitation." 10 published pages.

This paper provides an introduction to the research methods used in the Post-stroke Rehabilitation Outcome Project. It discusses how the CPI approach was operationalized in the case of a multi-site stroke rehabilitation outcomes study, the results of which are discussed in subsequent papers. One of the singular contributions of the PSROP has been its attention to defining and measuring the interventions used in stroke rehabilitation, i.e., characterizing the interventions in the proverbial black box. The study attempted to address not only the variation in practice but also the variation in language and vocabulary the study uncovered when it attempted to describe stroke rehabilitation practice. The paper also describes the project's clinical sites, study population, the participation of clinicians in identifying practice parameters, the data collection protocols, and the database that is the basis for the papers that follow.

Note: There is one combined abstract for Papers 4, 5, & 6. See bullet following Paper 6.

4. **Diane Jette, Randal Smout, Nancy Latham, Gerben DeJong, Diane Nichols, Jaime Lees, Adam Procino, Brad Zollinger, Shelley Howe, Murray Brandstater, Marti Carroll, *et al.*** "Characterizing Physical Therapy Practice in Stroke Rehabilitation. 8 published pages.

5. **Nancy Latham, Randal Smout, Diane Jette, Lori Richards, Cathy Goodman, Lauren Rosenberg, Heather Welch, Murray Brandstater, Gerben DeJong, *et al.*** "Characterizing Occupational Therapy Practice in Stroke Rehabilitation." 8 published pages.

6. **Brook Hatfield, Randal Smout, Janice Coles, Debbie Millet, Joyce Maughn, Andrew Dodds, *et al.*** "Characterizing Speech and Language Therapy in Stroke Rehabilitation." 8 published pages.

- There is currently little research to describe the specific therapy interventions that are used in stroke rehabilitation, and how the use of these interventions changes over a rehabilitation episode. Most studies to date have included only gross descriptions of stroke therapy interventions, such as the minutes of therapy provided by each profession. Our ability to describe specific physical therapy (PT), occupational therapy (OT) and speech language pathology (SLP) interventions has been hampered by the lack of clear definitions of therapy interventions. To overcome this problem, a taxonomy of interventions used in PT, OT and SLP was created for the Post Stroke Rehabilitation Outcomes Project (PSROP). The PSROP provides enormous detail about the treatments and therapeutic activities that therapists used throughout the entire length of stay on a rehabilitation unit. The aim of these three

papers is to describe the interventions that were used by PT, OT and SLP and to describe how these interventions changed during the initial, middle and final third of each patient's therapy episode. The analyses for these three papers will be carried out in parallel, to allow comparisons about how the nature of the interventions, including the type of activities, the duration of the sessions and the frequency that each intervention was selected varies over time and across the therapy professions. These papers will provide information about the specific interventions and activities that PT's, OT's and SLP's use in stroke rehabilitation with more detail and precision than any previous publications.

7. **Brendan Conroy, Richard Zorowitz, Susan Horn, Jeff Teraoka, Jim Young, David Ryser, Sarah Maulden, Andrew Dodds, Jeff Randle, *et al.*.** "Variation in Use of Medications in Stroke Rehabilitation." 8 published pages.

The PSROP uncovered significant variation in the use of medications from one clinical site to another that cannot be explained due to patient differences but to differences in physician preferences (that may also be shaped by drug formularies and other factors). There appears to be wide variation in outcome associated with variation in medication use and this paper explores the associations between drug therapy and outcomes and its implications for practice and future validation studies.

8. **Sarah Maulden, Randy Smout, Susan Horn, *et al.*.** "Nutrition as a Rehabilitation Intervention." 8 published pages.

Malnutrition's association with poor outcomes was reported as far back as 1936.[32] Hospital associated malnutrition was reported in the middle and late 1970's.[33] [34] Early enteral feeding in trauma patients has been espoused for nearly two decades. Traditional rehabilitation therapies require much time and effort by stroke patients who often have attendant swallowing difficulties. Nutrition is rarely regarded as a rehabilitation intervention. Yet, we observed that nutritional support varied greatly from patient to patient and from site to site. This paper characterizes differences in the timing and the amount of nutritional intake and their relationship to intensiveness of therapy and rehabilitation outcomes.

9. **Gerben DeJong, David Ryser, John Melvin, Susan Horn, *et al.*** "The Impact of the Inpatient Rehabilitation Facility Prospective Payment System (IRF-PPS) on Stroke Rehabilitation Practice." 9 published pages.

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[32] Studley HO. Percentage of weight loss: a basic indicator of surgical risk in patients with chronic peptic ulcer. *JAMA* 1936: 106:458-60.

[33] Weinsier RL, Hunker EM, Krumdieck CL, Butterworth CE. Hospital malnutrition: a prospective evaluation of general medical patients during the course of hospitalization. *Am. J. Clin. Nutr.* 1979; 32:418-26.

[34] Bistrian, BR, Blackburn GL, Vitale J, Cochran D, Naylor J. Prevalence of malnutrition in general medical patients. *JAMA* 1976; 235:1567-70.

The PSROP was conducted over a 3-year period from 2001-2003, a period that predates and postdates the implementation of the IRF-PPS in 2002. We were able to observe significant differences in practice patterns including changes in lengths of stay. More importantly, we are able to observe very specifically how PPS affected the mix, intensity, and duration of individual therapies. In short, this paper reports on how PPS has reshaped the black box of stroke rehabilitation.

10. **Crystal Clark *et al.*** "The Effect of Body Weight on Rehabilitation Practice and Outcomes." 8 published pages.

Recent studies have clarified the relationship between obesity and stroke. While the relationship between obesity and coronary artery disease, diabetes, and hypertension have been well established, the evidence establishing obesity as an independent risk factor for stroke has only recently been established. Abdominal obesity appears to predict the risk of stroke in men and obesity and weight gain appear to be risk factors for ischemic stroke in women.[35] As obesity's independent role in stroke has come to light, there appears to be a need for basic statistics on the prevalence of obesity in stroke patients, its impact on rehabilitation practice, and its effect on rehabilitation outcomes.

This paper provides bodyweight and/or body mass index (BMI) on over 750 stroke patients enrolled in the Post Stroke Rehabilitation Outcomes Project (PSROP). The PSROP enrolled over 1218 patients from 7 clinical sites of diverse geographic representation to gather information on the critical patient, provider, and process elements associated with optimal outcomes in post-stroke rehabilitation. To date, the evidence linking bodyweight to rehabilitation outcomes has been primarily limited to cardiopulmonary rehabilitation and therapy following orthopedic procedures. In these areas a higher BMI was associated with relative quadriceps weakness which impacts on patient-level outcomes.[36] Using bivariate and multivariate analyses, we examine the impact of bodyweight and/or BMI on care processes and practices, as well as selected outcomes (length of stay, FIM, complications, and discharge location) in this multi-site rehabilitation study.

11. **Harry McNaughton, Gerben DeJong, Nancy Latham, Phillip Beatty, Melinda Neri, John Melvin, Murray Brandstater, *et al.*.** "International Variation in Stroke Rehabilitation Practice and their Impact on Short- and Long-term Outcomes." 10 published pages.

One of the PSROP's 7 clinical sites is in New Zealand. The study uncovered significant differences in practice patterns between the New Zealand site and the 6 American sites. One strength of the CPI approach—compared to RCTs, for example—is its ability to uncover and accommodate wide practice variation. This paper makes 2 sets of

[35] Seung-Han S. Abdominal obesity and risk of ischemic stroke. *Stroke* 2003; 34:1586-1592.

[36] Silva M. Knee strength after total knee arthroplasty. *J Arthroplasy* 2003 Aug; 18(5): 605-11.

comparisons: The first compares NZ with the U.S. centers combined making adjustments for case-mix differences; the second compares NZ with one of the U.S. centers that also obtained 6-month outcome data. The paper describes variation in case mix, practice patterns, and outcomes. The New Zealand site is also one of two sites in the study that acquired data on 6-month outcomes. Hence, the paper also examines the impact on longer-term outcomes that relate to activity and participation. We may decide to make the matter of longer-term outcomes a separate paper.

12. **John Melvin, Edward Healton, Pamela Duncan, Alan Jette, *et al.*** "Commentary." 2 published pages for each commentary. (Unlike the papers listed above, the proposed commentators are examples of the kinds of expertise we wish to invite as potential commentators.)

This portion of the supplement will include a series of short commentaries by experts in the field. The commentaries will be preceded by a short summary of the papers' sentinel findings and their collective implications for rehabilitation research, practice, and policy.

Qualifications of Guest Editors

The three proposed editors have worked together intensely over the last 4 years in developing the Post-stroke Rehabilitation Outcomes Project (PSROP) and have collaborated on several manuscripts that are now finding their way into the literature. They enjoy a high degree of mutual trust and sharing of responsibility. Dr. DeJong and Dr. Horn had a previous professional relationship more than 20 years ago. Drs. DeJong and Horn are experienced writers and editors; Dr. Conroy's strengths are in editing.

Gerben DeJong, PhD is the Associate Director for Health Policy & Health Services Research with the University of Florida Brooks Center for Rehabilitation Studies. He also serves as a professor in the Department of Health Services Administration within the University of Florida's College of Health Professions and concurrently serves as a Senior Fellow with the NRH Neuroscience Research Center. Prior to coming to the University of Florida in 2002, Dr. DeJong served for 16 years (1985-2001) as the Director of Research for the National Rehabilitation Hospital (NRH) in Washington, DC and as the Founding Director of hospital's Center for Health & Disability Research located in the MedStar Research Institute. While at NRH, he served as a professor in the Department of Family Medicine at Georgetown University. From 2001-2002, Dr. DeJong served as a Senior Fellow with the NRH Center for Health and Disability Research while based in Prague in the Czech Republic. During his tenure with NRH and the MedStar Research Institute, Dr. DeJong also served as the Co-director of the federally funded Research and Training Center (RTC) on Managed Care & Disability (1997-2002) and previously served as the Director of the RTC on Medical Rehabilitation and Health Policy (1993-97). Dr. DeJong's academic training is in economics and public policy studies (MA and MPA, University of Michigan; PhD, Brandeis University). His main research interests are in health outcomes, health care utilization, health payment policy, evidence-based practice in rehabilitation, disability policy, income maintenance policy, and national health policy. He is the

author or co-author of more than 200 papers on health, income maintenance, disability, and medical rehabilitation.

Susan D. Horn, PhD is Senior Scientist with the Institute for Clinical Outcomes Research (ICOR) and Vice President for research for International Severity Information Systems, Inc. (ISIS), and Adjunct Professor in the Department of Medical Informatics at the University of Utah School of Medicine in Salt Lake City. From 1968-1991, Dr. Horn was a full-time faculty member at The Johns Hopkins University in Baltimore, Maryland. From 1991-1995, she was senior scientist at Intermountain Health Care in Salt Lake City. In 1982, Dr. Horn and colleagues began developing the Comprehensive Severity Index (CSI®), with inpatient, ambulatory, hospice, rehabilitation, and long-term care components for adult and pediatric patients. CSI software collects disease-specific, physiologic severity data for Clinical Practice Improvement (CPI) and risk-adjusted outcomes. Dr. Horn has conducted CPI projects in cost-containment practices in HMOs, pediatric severity of illness, asthma, and bronchiolitis, GI surgery, congestive heart failure, pressure ulcers in long-term-care, ambulatory diabetes, hospice, post-stroke rehabilitation, falls, and women's health. She has authored over 140 publications on statistical methods, health services research, severity measurement, clinical practice improvement, and quality of care. Dr. Horn edited *Clinical Practice Improvement Methodology: Implementation and Evaluation,* 1997. She is the PI for the NIDRR-funded Post-Stroke Rehabilitation Outcomes Project that is addressing the need for scientific data supporting the effectiveness of rehabilitation treatments. Dr. Horn earned a B.A. in mathematics at Cornell University and a Ph.D. in statistics at Stanford University.

Brendan Conroy, MD has been intimately involved in the development and management of the Post-Stroke Rehabilitation Outcomes Project (PSROP) since its inception. He has been the Medical Director of the National Rehabilitation Hospital's Stroke Rehabilitation Program since January of 1998. He is Board Certified in Physical Medicine and Rehabilitation. He has been involved in several other stroke rehabilitation research projects on the use of medications and natural substances, the provision of rehabilitation services using telemedicine technology, and the use of robotics in stroke rehabilitation (e.g., Lokomat/Robotic Gait Training, self-powered Self Range of Motion for plegic arms). He has authored several published papers and chapters.

Qualifications of contributing authors

See **Appendix A** for an alphabetical listing of individual author bios. See **Appendix B** for letters of commitment from individuals authors. Some bios and letters of commitment are not included.

Action Plan: Project Team, Proposed Conference, Timetable, and Funding (Feasibility and Probability of Success)

Project Team

The proposed editors and nearly all of the proposed authors have worked together as a project team for 3 or more years under the auspices of the Post-stroke Rehabilitation Outcome Project (PSROP) cited earlier. Some of the proposed authors joined the project team somewhat later in its history but all are committed to its success and the publication of its findings. The overall Project Team meets each Friday morning via conference call and subteams of clinicians and investigators meet on an as-needed basis. We propose to continue the weekly conference calls for the Project Team as a whole and propose additional as-needed teams for select topics. True to the ACRM spirit of interdisciplinary rehabilitation, the Project Team, i.e., the proposed authors, consists of physicians, therapists, nurses, and others from each of the 7 stroke rehabilitation sites and an array of several other investigators who have gravitated toward the project over time. The PSROP has succeeded in fostering ownership and commitment among Project Team members, the individual clinical sites, and among proposed authors that bode well for the success of the proposed supplement.

The proposed authors met as a group in Washington, DC this past July to map out potential papers, possible authors, and subteams to work on individuals papers.

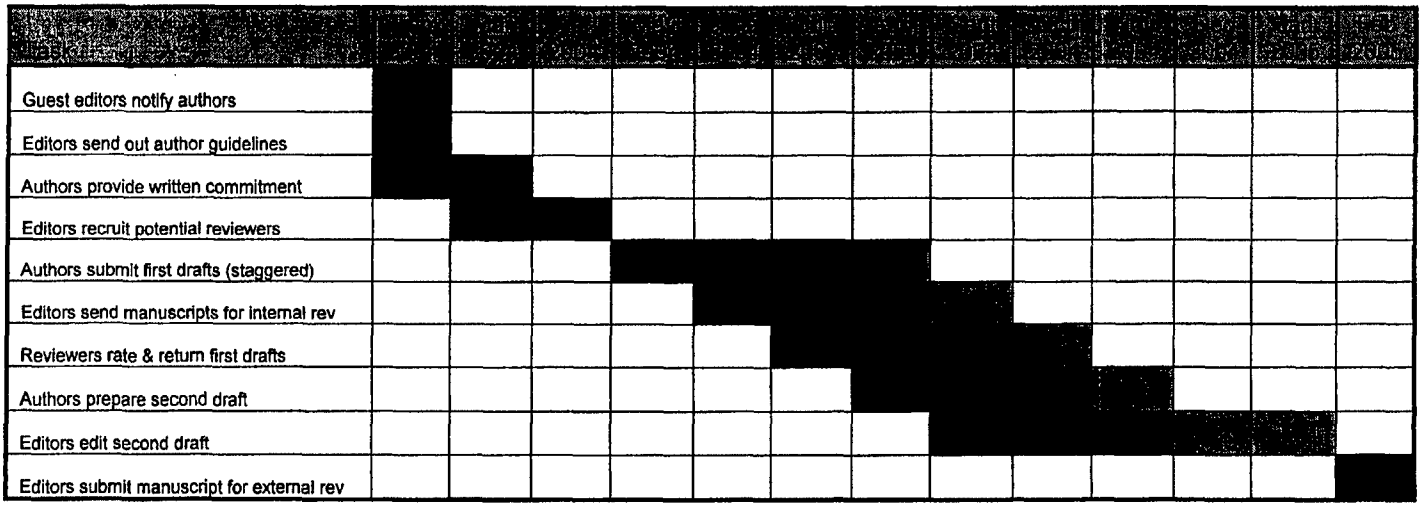
Funding & sponsorship

The original PSROP was funded under the auspices of a NIDRR-funded project as part of the Rehabilitation Research and Training Center on Medical Rehabilitation Outcomes at Boston University's Sargent College (PI: A Jette, PhD) with subcontracts to the Institute on Clinical Outcomes Research (ICOR) (S Horn, PhD) and the National Rehabilitation Hospital Center for Health & Disability Research (G DeJong). The NRH group was fortunate to obtain supplemental funding for the project from the National Blue Cross Blue Shield Association and through the NRH Neuroscience Research Center with a grant from the Department of Defense funded under a cooperative agreement with the U.S. Army & Materiel Command (Cooperative Agreement Award # DAMD17-02-2-0032, Cheryl R. Miles, project officer).

The NRH Neuroscience Center has agreed to sponsor a national conference in late 2004 or in 2005 that will feature the papers proposed here. The NRH Neuroscience Center will support Dr. Conroy's participation in this effort and Dr. DeJong's editorial role under a subcontract to the University of Florida Brooks Center for Rehabilitation Studies. The NRH Neuroscience Center will also provide a limited support to ICOR to conduct additional analyses pursuant to the preparation of the proposed papers. Because of NRH's overall financial support for the supplement under the auspices of its Neuroscience Research Center and the conference tie-in, it will be identified as a sponsor for the supplement. If ACRM and the *Archives* approve our application, we will also seek support from two other organizations—a federal source and a private one that will remain unmentioned for now. We believe that the proposed financial backing for the proposed supplement will help to ensure the success of the proposed supplement.

Timetable

The ACRM RFP already provides the timeline for the external review that will commence in February 2005 but leaves it to the proposed editor(s) to specify the timeline for February 1, 2004 to 2005. Figure 1 outlines our proposed timeline for this period.



Timeline

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

Funding period: Year 1 of 1-year funding period

Status: Collecting data

Principal Investigators: Cheryl Trepagnier, PhD
Co-investigators: Marc M. Sebrechts, Willie Stewart, Andreas Finkelmeyer

Abstract:
This is a feasibility study with the long-term goal of identifying and characterizing deficits in the integration of manual and gaze behavior, by individuals recovering from brain injury, in activities of daily living, in order to target rehabilitative and assistive interventions.
The immediate goals of this pilot study are
to determine whether the body-worn, mobile eye tracking technology can be used without itself unduly affecting people's behavior; and,
whether data acquired by using this technology shows promise of uncovering, and providing a way to quantify, interesting differences between the gaze behavior of brain-injured individuals and non-disabled controls.

Progress and Outcomes:
Several control participants were enrolled first, so that any difficulties with the procedure would come to light before experimental group participants took part. As of June 15, 2004, 10 controls and one individual recovering from brain injury have completed the study.

Transcription of the data from the videotapes, an extremely time-intensive process since the protocol requires obscuring the faces of all participants throught the videotaped records of their task performance, is nearly complete.

Graphical and matrix-based methods have been tried as means of reducing the data. An example of graphical representation is attached to this report as an appendix. The analysis presented below employs a matrix to represent the data. In this matrix, each glance is classified according to its relationship to the task-step (the sub-part of the task) to which it pertains. Each glance is coded according to whether it occurs in advance of manual contact with the object at which it is directed; at the same time as or during manual contact; or after the manual action has been completed; or the glance is directed at some object not relevant to the task. Each gaze is coded only once, for the first step to which it is is relevant. For example, if in the Hand-Washing task the individual looks at the paper towel while s/he is turning on the water, that glance is coded as occurring in advance of the step to which it pertains. This allows compilation of summary statistics for each task as performed by each participant.

Previous research utilized body-worn, mobile eye tracking to examine the relationship of gaze behavior to action in the performance of novel and familiar tasks. This study is the first to attempt to apply this technology to study task performance by individuals who are recovering from brain injury, and who are at risk for residual executive function (EF) deficits.

Following are preliminary results and discussion for 7 controls and 1 experimental participant.

The participants included 3 females; 3 were Black and 5 were Caucasian; Mean age was 26.25 (SD=8.03); with a mean of 15.5 years of education (SD=2.07).

Use of the mobile eye tracking system was readily accepted by all of the study participants. Several clinicians also tried out the equipment, in order to gain an understanding of what patients would be asked to do. Of these, one person who was of slight build and short stature found the equipment uncomfortable.

One basic measure of the impact of wearing the backpack and headset of the ASL (American Science Laboratories) mobile eye tracking system is whether and to what extent wearing the equipment interferes with carrying out the assigned task. To the extent it interferes, it is reasonable to expect the task to require more time to complete. To assess this, participants were shown how to do the task, and then asked to carry it out three times: the first time prior to putting on the equipment, the second time while they were wearing the equipment, and then finally after they had removed the equipment. Table 1, below, presents the means for the seven controls whose data were analyzed, for the three iterations of Task 1, and the corresponding times for the experimental participant.

	Pre (Time 1) (no equip.)	With (Time 2) equipment	Post (Time 3) (no equip.)
Controls (Mean)	30.5	26.0	32.7
Experimental Participant	50.0	50.7	51.0

Table 1. Task duration (sec) for each iteration of Task 1

While these data represent only one task, there is at this point no indication that wearing the equipment slows task performance. The fact that the post-equipment iteration of the task does not show a learning effect supports the inference that the lack of slowing in the plus-equipment repetition is due to gain in task familiarity.

Table 2, below, provides the means and standard deviations characterizing gaze behavior in performing Task 1, Handwashing. "Look-ahead" gazes are identified when the participant's line of gaze intersects an object that will be involved in the task prior to contacting or utilizing that object. "% Look-aheads" refers to the percentage of glances that are look-aheads. "# Steps looked ahead" refers to the breakdown of the task into steps, such as turning on the water, wetting one's hands, picking up the soap, etc. If the individual looks at the soap while turning on the water, that represents a look-ahead of 2 steps. If the soap is not looked at until the hands are under the running water, that is a one-step look-ahead. If the eyes go to the soap as the hands contact it, a 0 is contributed to the calculation of the mean number of look-aheads.

	# Glances	# Look-aheads	% Look aheads	# Steps lookedahead
Controls' Mean	45.286	15.429	33.5%	2.089
Controls' SD	14.256	6.630	9.3%	0.341
Experimental Participant	102	18	17.6%	2.360

Table 2: Comparison of control and experimental gaze parameter values

The experimental subject does not appear to differ from controls in the performance of this particular task in regard to gaze behavior, apart from taking longer and performing a much lower proportion of look-aheads.

Participants (including controls) were given the Wisconsin Card Sorting Test, a widely-used clinical test that taps some aspects of the executive functions, in particular ability to maintain and to shift set in response to environmental contingencies.

The Wisconsin was utilized because of the hypothesis that the executive functions play a role in planning and therefore in the temporal relationship of gaze with actions. Accordingly, correlations were computed between Wisconsin scores and measures of gaze behavior in relation to task performance, for Task 1. Tables 3a and 3b, below, display the correlation values obtained. The information is presented in two parts because of formatting constraints. The data represent the seven controls whose Task 1 performance has been analyzed and the experimental individual (N=8). Number and percentage of perseverative responses and perseverative errors refer to the neurological phenomenon of perseveration, the increase in probability that a behavior that has just been produced will be the one produced again, without regard to contingencies, a frequent effect of brain dysfunction.

	# trials	# correct	% respns	# errors	% persev respns	# persev respns	% persev errors	persev errors
total duration of task		-0.19	-0.22	-0.15	-0.13	-0.29	-0.35	-0.33
# glances for task	0.16	-0.06	0.21	0.27	0.13	0.10	0.11	
# look-aheads	0.50	0.06	0.58	0.54	0.51	0.41	0.42	
# steps looked ahead	-0.23		-0.13	-0.24	-0.22	-0.29	-0.29	-0.24
% look aheads		0.27	0.17	0.27	0.17	0.26	0.17	0.17

Table 3a: Relationship between Wisconsin scores and gaze behavior, part 1.

In Table 3b, below "conceptual" responses refer to responses consistent with the organizing concept being reinforced, i.e., responses indicating that the testee has grasped the current organizing principle. "Learning to learn" is an index of the testee's ability to generalize so that it becomes progressively easier to shift sets with the changing contingencies provided by the examiner.

	# non-persev errors	% non-persev errors	# conceptual responses	% conceptual responses	'learning to learn' score
total duration of task	-0.05	0.00	-0.06	0.12	-0.33
# glances for task	0.27	0.34	-0.18	-0.25	0.08
# look-aheads		0.63	0.62	-0.65	-0.60	0.18
# steps looked ahead	-0.22	-0.21	0.15	0.24	-0.46
% look aheads		0.28	0.21	-0.37	-0.26	0.04

Table 3b: Relationship between Wisconsin scores and gaze behavior, part 2.

There is a sizeable correlation, of .5 or greater, between number of look-aheads (glances at an object to be used in the task, in advance of contacting it, as shown in the third row of each of the two tables) and the majority of the Wisconsin scores. The scores indicative of poorer Wisconsin performance (e.g., % of perseverative responses) correlate positively with number of look-aheads, and the Wisconsin scores indicative of success (e.g., % Conceptual responses) correlate negatively. This at first appears counter-intuitive, since it seems to suggest that persons with relatively poor executive functions (EF) carry out more planning than persons with 'better' EF skills! Further examination of Tables 3a and 3b offer a possible account of this finding: In terms of the NUMBERof steps looked ahead, the correlations, while small (.2 or greater), are in the opposite direction. Persons with lower EF scores do perform look-ahead glances, but they tend to perform them just prior to acting upon the objects. In contrast there is a

tendency for people with higher EF to carry out planning gazes earlier on in the course of the task, two or more steps in advance of contact, rather than just one. While this advance gaze behavior might be expected to place more demand on working memory, it may also have the effect of contributing to smoother task performance.

The data that have been analyzed so far are intriguing, in that there is some indication of a relationship between Wisconsin performance, considered primarily as an index of flexibility, and evidence from gaze behavior of planning, in what is, in all but one case, a non-clinical population! These data are of course highly preliminary. It will be interesting to determine whether this apparent relationship between test scores of EF and use of gaze in planning will hold up in this non-clinical population. However, it is only by testing groups known to be at risk for EF deficits that the value of this technology for investigation and rehabilitation of EF impairments can be explored. Recent progress in studying and teasing apart the various executive functions and pursuing their role in numerous acquired and congenital neurological disorders makes this a potentially exciting tool for rehabilitation research.

In the attached appendix, E001 Task 1 Bar Chart, the time axis runs from left to right, and bar length represents duration. The red bars in the upper half of the page represent the steps into which the task is broken down. The blue bars in the lower half of the page represent gazes at the objects referred to on the y axis (e.g., So stands for soap). The chart is created by two transcription passes through the videotape (in addition to the identity-masking process). On one transcription pass time of each step is noted, and the other is to record time of each gaze. These are entered in an excel file from which this chart is produced. Page 2 of the appendix provides the legend for the Steps and objects.

Barriers and Solutions:
The study experienced delays due to the multi-stage IRB process and in particular the (understandable) delay in review by the AMRMC IRB.

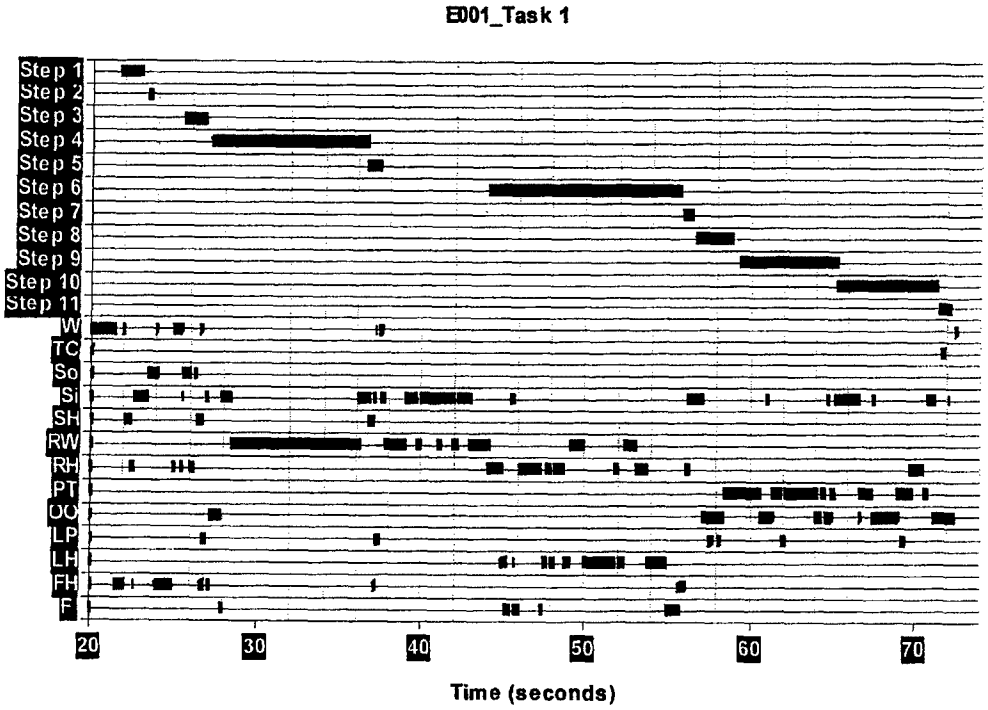
A related barrier has been the difficulty identifying and contacting prospective experimental participants. Many prospective participants initially identified by the Vocational Rehab therapists were no longer available by the time permission was granted, at the end of January, 2004, to proceed with the studies that had already undergone initial review by the AMRMC IRB, without the requirement of an additional review for continuation approval.

Recruitment efforts have continued, and will resume if and when continuation is approved. The Voc Rehab therapists have contacted other NRH clinicians who are in contact with their former clients, and it is anticipated that some of these individuals will be available to us.

The USAMRMC's permission to proceed is understood to mean that the study can proceed AS APPROVED. In view of the low success rate of recruitment of patients according to the approved protocol, it is desirable to modify the recruitment procedure so that persons recovering from brain injury can be recruited from other sources, and so that some inducement (small sum of money, movie tickets, or other token reward) can be offered. If NRH permits continued use of the ASL equipment and Independence Square facility, and MRI approves continuation, an amendment will then be submitted to this effect. If approval is obtained from MedStar IRB and from the Army to amend the protocol, we anticipate rapid completion of data collection.

Plan:
Completion of data reduction and analysis for the data already acquired. As discussed above, completion of data collection, pending the necessary approvals.

Project C2 Appendix



Legend:

Task 1	Steps required to complete task.
• Window • Trashcan • Soap • Sink • Soap Holder • Running water • Right hand • Left hand • Paper towel • Faucet handle • Faucet • Other object • Lost point	1. Turn on the water 2. Rinse hands before soaping 3. Gather soap 4. Soap hands under water 5. Place soap back 6. Rinse hands after soaping 7. Turn off faucet 8. Shake water from hands 9. Gather towel 10. Dry hands 11. Throw towel away

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:
On October 24, 2002, the MedStar Research Institute (MRI) IRB approved the research protocol and informed consent form. The protocol was then forwarded to Dr. Vern Jimmerson, Human Subjects Protection Scientist at the Office of Regulatory Compliance and Quality at the U.S. Army Medical Research and Materiel Command for review by the Human Subjects Research Review Board (HSRRB). Response from the HSRRB was received March 26, 2003. Since last renewal (June, 2003), proposal revision which addresses the HSRRB's recommendations was completed and resubmitted September 26, 2003. Approval was received from the HSRRB on November 19, 2003. MRI's IRB approval was reapplied for on November 14, 2003 and received on January 27, 2003. An approved consent form was received approximately one month later. Data collection began in April 26, 2004. To date, data for 7/50 subjects has been collected.

Barriers and Solutions:
Once begun, data collection has proceeded smoothly. Some patients approached (2 of 9 to date) have indicated a refusal to sign the consent form. It's suspected that other stroke researchers may be contacting these same

patients within the first few days after admission to NRH. Should an adequate supply of right-hemisphere-damaged stroke patients not be available and/or the proportion of refusals grow, the reasons for the refusals will be obtained, analyzed and any possible action will be taken to improve enrollment in this study.

Plan:
Continue data collection, estimated to be completed in February, 2005. Submit results to the Clinical Aphasiology Conference, and if accepted, present results analyzed to date at the conference in May, 2005.

Publication and Presentations:
Prior research in this area and the current research design and rationale were presented at the Washington Hospital Center's Continuing Medical Education Symposium: Stroke Rehabilitation: Outstanding Outcomes and Best Practices, Washington, D.C., May, 2004.

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: Funding will initiate in year 3 of the NRH-NRC grant. This is a one-year pilot study.

Status: Ongoing

Principal Investigators: Suzanne Groah, MD, MSPH, Lauro S. Halstead, MD, MPH
Co-investigators: Larry Hamm, PhD

Abstract:
Oxandrolone is an oral anabolic steroid that has been shown to increase lean body mass. Tonalin CLA (conjugated linoleic acid) 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 pilot project is to determine whether oxandrolone, CLA, or both improve body composition and pulmonary function in individuals with chronic spinal cord injury (SCI). Individuals with C8 ASIA A or B or higher SCI of at least 1 year will be randomized to either the Oxandrolone, CLA, or Control groups. All 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, CLA, or neither. Participants will then have laboratory studies including lipid panel, LFTs, PFTs, and DEXA immediately after the intervention period and then 3 months later to determine if any changes are maintained.

Progress and Outcomes:
Project has been approved by the Medstar IRB (as of December 2003).

Project is now being modified and expanded to include a control group and an additional intervention group that will receive Tonalin CLA (conjugated linoleic acid). Tonalin CLA may have complementary effects of 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.

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.

Changes in study protocol, staffing and budget should not delay the initiation of the study further, as these will be incorporated in the next month and then will be sent to MedStar IRB for approval. This, in turn, will be forwarded to Army IRB. We anticipate this process to be complete prior to review by the Army IRB.

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 PI in a small role and will assist with analysis of data, manuscript and presentation preparations.

Lorraine Priestley has been added as the project coordinator.

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

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

Funding period: Funding will initiate in year 3 of the NRH-NRC grant. This is a one-year pilot study.

Status: ongoing

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)

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:
Approvals from the NRH Research Committee and MRI IRB have been received. Final approval from the MRI IRB was received on January 12, 2004 and a proposal was submitted on 2/03/04 for review by the MRMC Human Subjects Review Board. IRB approval from MRMC is pending, thus pilot testing and data collection has not begun for this study. We anticipate approval from the CNMC IRB in July. Regular meetings (1 to 2 per month) have been held since August of 2003 between CNMC and NRH investigators to prepare IRB proposals and discuss plans for ANAM development and subject recruitment strategies. Dr. Gioia has established contacts within several local school districts, which we will pursue as options for subject recruitment. Options for recruitment outside school districts have been researched and contacts within the community have been established. Evaluation of the current ANAM software for developmental appropriateness is ongoing and has included selection of appropriate ANAM subtests, determination of the reading level of subtest instructions, and evaluation of complexity of subtest stimuli. Several pediatric researchers outside the NRH network have approached Drs. Roebuck-Spencer and Bleiberg with interest in the pediatric ANAM and have made offers to incorporate the measure into their ongoing research projects, thus increasing the sample of normally developing children and expanding the normative sample to other geographic regions (New York and Ohio). These options will be considered once IRB approval has been received from MRMC.

Barriers and Solutions:
The original IRB proposal was submitted to the NRH Research Committee on 7/16/03, but was postponed from review until September of 2003 due to the potential conflicts of interest that arose when Drs. Gioia and Janusz were awarded a CDC grant that included modification of a commercial software program similar to ANAM for use with children. Resolutions included a staff change from Dr. Jennifer Janusz, whose responsbilties will be solely directed to the CDC grant, to Dr. Laura Kenealy who has comparable experience in pediatric neuropsychology and a strong background in ADHD research. Dr. Gioia has agreed to sign a mutual non-disclosure statement in order to keep separate intellectual property between the two similar grants. The primary barrier to progress on this study is the delay in receiving IRB approval from MRMC. At the current time, it has been approximately 4.5 months since submission of this IRB proposal to MRMC. Because we cannot anticipate when we will receive approval from MRMC, we have delayed the official start date for the project so that funding will coincide with a 12-month timeline.

Plan:
Investigators will meet weekly to continue evaluation of developmental appropriateness of ANAM subtests, instructions, and stimuli. Based on the consensus of the investigators necessary modifications will be made to the

current ANAM software so that it is developmentally appropriate for children ages 10-12. When approval has been received from MRMC IRB, pilot testing of the pediatric ANAM will begin and if necessary further modifications to the software will be made. During this time frame, recruitment via local school districts and community groups will begin. At the completion of pilot testing, 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 anlyses at a national conference to be followed by manuscript preparation and submission to a peer-reviewed journal.

Project E1: "Stroke Rehabilitation: Outstanding Outcomes and Best Practices"

Funding period: Year 2 of 4-year funding period

Status: Complete

Principal Investigators: Brendan E. Conroy, MD

Abstract: The NRH Neuroscience Center featured a program designed to provide clinicians with a comprehensive, current and practical approach to post stroke management. Functional approaches and innovative management techniques were emphasized. The program included didactic lectures, question and answer sessions, panel discussions, workshops, and patient management case studies. Participants were encouraged to bring problem or innovative cases from their own practices for discussion.

Objectives for this program were as follows:

- Describe a best practice research methodology to investigate stroke rehab
- Describe the challenges rehab providers face in adapting to a Prospective Payment System
- Identify a variety of appropriate outcome measurement tools to document the benefits of stroke rehab
- Apply systematic assessments of tone and related problems in your practice.

Progress and Outcomes:
On May 14-15, 2004, Brendan E. Conroy, MD, Medical Director, Stroke Recovery Program, National Rehabilitation Hospital, convened the CME symposium, **"Stroke Rehabilitation: Outstanding Outcomes and Best Practices"** which was designed to provide clinicians with a comprehensive, current and practical approach to post stroke management. This two-day symposium was jointly sponsored by Washington Hospital Center (WHC) and National Rehabilitation Hospital (NRH) and was held at NRH. The activity featured national speakers (Pamela W. Duncan, PhD, and Gerber DeJong, PhD, both of University of Florida, Brooks Center for Rehabilitation Studies; and, Susan J. Ryerson, PT, MA, National Rehabilitation Hospital, in addition to participating MedStar Health faculty). The audience of approximately 125 attendees was a regional one of physicians, nurses, and allied health professionals, as well as physical therapists, occupational therapists, speech language pathologists, and case managers. Attendees represented the DC and Baltimore metropolitan areas and areas as far away as North Carolina, Missouri, Oklahoma, Massachusetts, and Tennessee.

Barriers and Solutions: The original center grant application called for a Year 1 conference as outlined above. The main barrier was the delay in funding of the Center grant proposal. We had anticipated a much earlier start date for the Center grant and planed accordingly. Part of this planning process entailed the participation of several co-sponsors in order to secure additional funding and to secure greater stakeholder ownership of conference findings. Given the momentum in planning the conference, we proceeded with the conference in advance of the Center grant's final approval for fear of loosing the interest that we had developed in the conference. Our ability to proceed was a result of the funding we obtained from other sources. We have used Center funding to support the production and dissemination of the conference's final report.

Plan: We are now in the process of selecting the principal conference theme for the coming year.

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

Funding period: Year 2 of 1-year funding period

Status: Deferred to year 3

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 has been deferred to Year 3.

Plan:
The project will proceed as planned under the modified timeframe noted above.

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

Funding period: Year 2 of 2-year funding period

Status: Completed

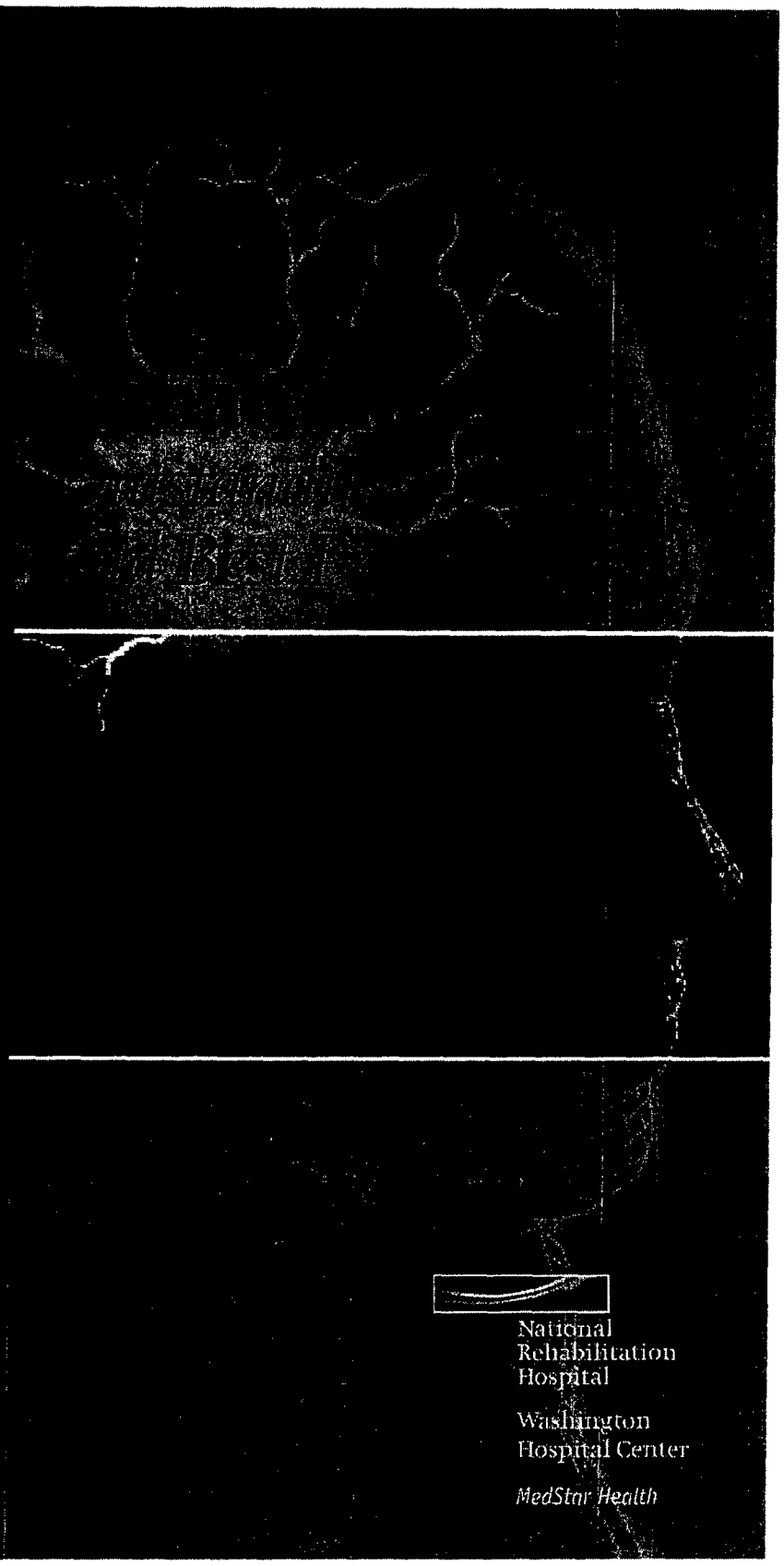
Principal Investigators: William Garmoe, PhD

Abstract:
There has been very little work to date addressing the anatomic substrates of self-awareness in adults with brain injury. Functional neuro-imaging has become widely used in research applications, though clinical uses for this technology remains very limited at this point. The purpose of this project is to consult with experienced investigators in the area of functional neuro-imaging, with the goal of determining the feasibility of applying such techniques to self-awareness studies following brain injury. Consultations will be done on the basis of individual contacts rather than a convened panel. A written summary of conclusions that emerge from this project will be prepared, and used to guide possible future functional neuro-imaging studies.

Progress and Outcomes:
The Principal Investigator (Dr. Garmoe) attended fMRI workshops at the National Academy of Neuropsychology annual conference in 2003. In addition, he met with Dr. Frank Hillary, an experienced fMRI researcher (who at the time was at Kessler), to discuss feasibility of fMRI designs. Dr. Hillary affirmed the feasibility of fMRI protocols to investigate self-awareness, and possible collaboration was discussed. In early 2004 Dr. Garmoe initiated discussion with the director of the functional neuroimaging lab at Georgetown University (Dr. Zeffiro), who agreed to collaborate on designing studies. Following initial discussions, the project needed to be put on hold because of the priority of finalizing IRB approval for project B1 (which has been very lengthy through the Army IRB).

Plan:
Having concluded that the project is feasible, the plan is to develop a research protocol for functional imaging studies with subjects from the self-awareness project. Initial contacts have been made with the neuro-imaging lab at Georgetown University.

Appendix:



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SYMPOSIUM DESCRIPTION

This program is designed to provide clinicians with a comprehensive, current and practical approach to post stroke management. Functional approaches and innovative management techniques will be emphasized. The program will include didactic lectures, question and answer sessions, panel discussions, workshops, and patient management case studies. Participants are encouraged to bring problem or innovative cases from their own practices for discussion.

LEARNING OBJECTIVES

At the end of this Symposium, attendees should be able to:

- Describe a best practice research methodology to investigate stroke rehabilitation;
- Describe the challenges rehabilitation providers face in adapting to a Prospective Payment System;
- Identify a variety of appropriate outcome measurement tools to document the benefits of stroke rehabilitation; and
- Apply systematic assessments of muscle tone and related problems in your practice.

AUDIENCE

This Symposium is intended for physicians (Physiatry and Neurology), Physical Therapists, Occupational Therapists, Speech Language Pathologists, Case Managers and Rehabilitation Nurses.

P R O G R A M

THURSDAY, MAY 13, 2004

7:30 a.m. Registration/Continental Breakfast

8:00 – 8:10 a.m. Welcoming Remarks and Introductions
Edward Ellis, Jr., MD

8:10 – 8:15 a.m. Conference Overview & Statement of Objectives
Paul R. Rao, PhD

8:15 – 9:15 a.m. Keynote Address: Beyond Lives Saved: Improving Stroke Outcomes
Pamela Duncan, PhD

9:45 – 10:30 a.m. Minister's Chat Cast: Medicare Reimbursement for Stroke Rehabilitation
Gerben DeJong, PhD

10:30 a.m. Refreshment Break

10:45 – 11:30 a.m. Outcome Management: Program Evaluation in Stroke Rehabilitation
Jacqueline Jones, PhD and Paul R. Rao, PhD

11:30 a.m. Lunch Break

12:00 – 1:00 p.m. Grand Rounds — Inflammation in Atherosclerosis: Emerging Concepts of Pathophysiology and Implications of Therapy
Thomas Jones, DeBakey, MD

1:15 – 2:15 p.m. The Black Box of Science: Rehabilitation: Exploring What Makes a Difference
Brendan E. Conroy, MD

2:15 p.m. Refreshment Break

2:30 – 4:00 p.m. BREAKOUT SESSIONS

- Cortical Reorganization and Function
  Pamela Duncan, PhD
- Community Re-Entry: Adding Life to Years
  Joan Boyce, CRRN
- Policy Issues and Pragmatic Approaches to Coping with Medicare Reform
  Gerben DeJong, PhD
- Managing Co-morbidities Post Stroke
  Brendan E. Conroy, MD
- Stroke Communication: Lessons Learned from the Rehab Group, Stroke Out, Stay Home, in Rural Ohio
  Amy Gonzales, MS CCC
  Jacqueline Jones, MS CCC

4:00 – 4:30 p.m. Day One Panel Discussion & Wrap Up
Chris Burnett, MS CCC
Edward Ellis, Jr., MD
Gerben DeJong, PhD
Pamela Duncan, PhD
Joan Boyce, CRRN

SATURDAY, APRIL 15, 2004

8:00 a.m. Registration/Continental Breakfast

8:30 – 9:30 a.m. The SCI Team Approach to Stroke Rehabilitation
Carol Berliner, MSW
Brendan E. Conroy, MD

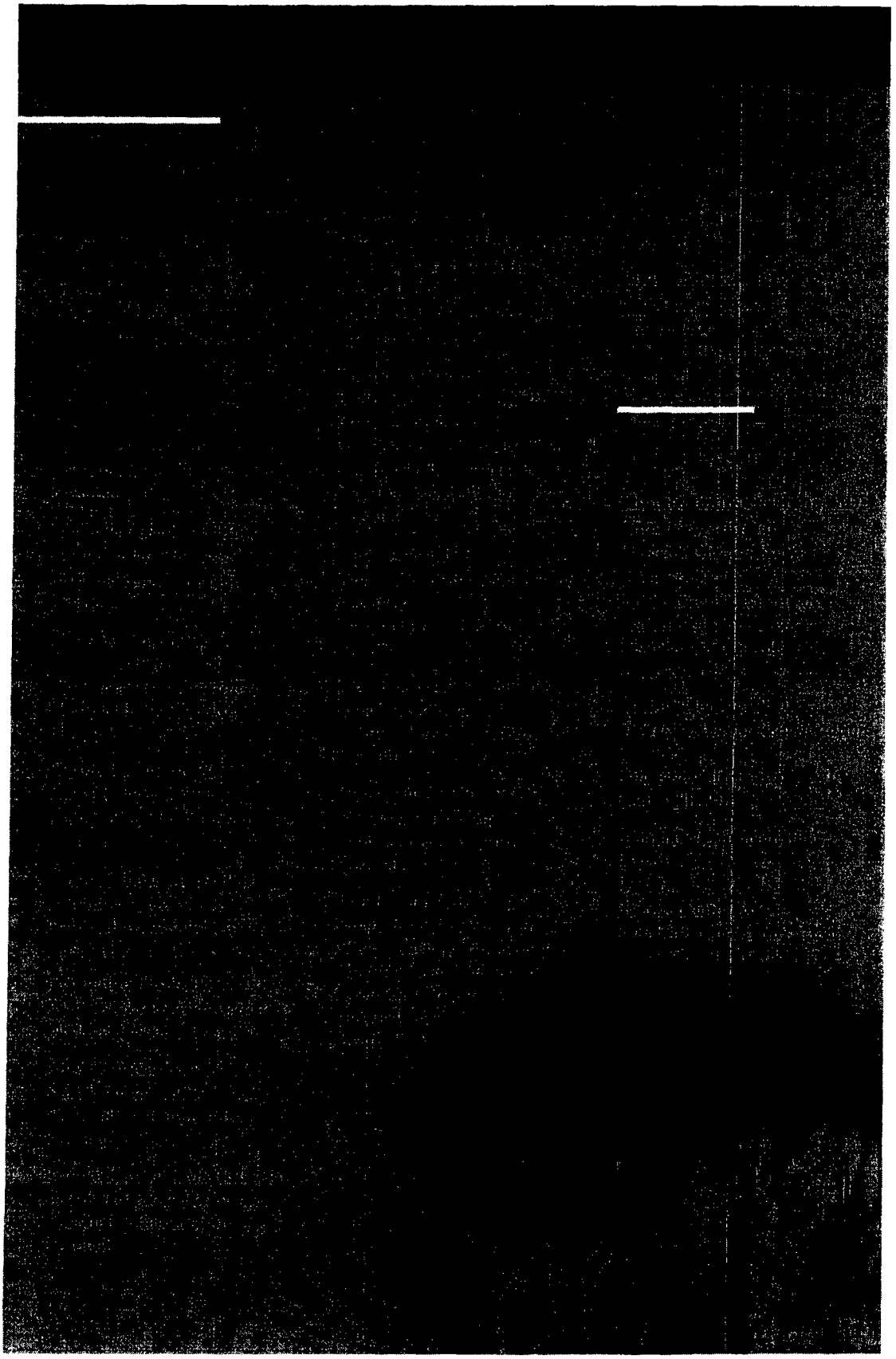
9:30 – 10:45 a.m. Consumer Speak Out — The Person Served Perspective on Stroke Rehabilitation
Lessons Learned
Moderator: Paul Rao, PhD

10:45 a.m. Refreshment Break

10:30 a.m. – 12:00 p.m. BREAKOUT SESSIONS

- Research Funding Post Stroke
  - Functional Neuro Imaging in Stroke Recovery: Review of Current Research
    Arthur Toga, MD
  - Advances in the Understanding and Treatment of Stroke Impairment Using Robotic Devices
    Joseph Hidler, PhD
- Psychological Issues of Stroke Survivors and Their Families
  Carol Billard-Bates, PhD
- Make Doing Possible: Sexuality & Childcare Post Stroke
  Marilyn Sadler, OTR/L
  Kathy Ayers, CTRS/L
- Sensorimotor Research: Implications for Post Stroke Rehabilitation
  Susan J. Ryerson, PT
- Patient Safety and Falls
  Brenda McCall Russell, RN
  Judy Zdobysz, CPHQ

12:00 p.m. Conclusion: Evaluation and Adjournment



ACTIVITY LOCATION

National Rehabilitation Hospital
Main Auditorium *(Ground Floor)*
102 Irving Street, NW
Washington, D.C. 20010
202/877-1000

Directions and Parking

The Symposium will be held in the auditorium on the lower level of the National Rehabilitation Hospital (NRH), which is located on Washington Hospital Center's medical campus. Parking is available in the MPI Garage adjacent to NRH. Symposium attendees may purchase Parking Coupons for $2.75 at the Symposium's Registration Desk.

Registration Information

Physicians: $150
Residents/Fellows: $120
Allied Health Professionals: $150
MedStar Health Employees: $120

On-site Registration Fees:
Please note that on-site registration fees will be $20 more than the advance registration fees listed above.

Cancellation Policy:
Cancellation of registration must be made in writing and received at Washington Hospital Center no later than April 30, 2004. After that date, no refunds will be made. Telephone cancellations will not be accepted. A substitute may be sent to the Symposium.

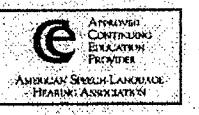
ACCREDITATION

CME ACCREDITATION: This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of Washington Hospital Center and the National Rehabilitation Hospital. Washington Hospital Center is accredited by the ACCME to provide continuing medical education for physicians.

CREDIT DESIGNATION: Washington Hospital Center designates this educational activity for a maximum of 11 category 1 credits towards the AMA Physician's Recognition Award. Each physician should claim only those credits that he/she actually spent in the activity.

CONFLICT OF INTEREST DISCLOSURE:
It is the policy of Washington Hospital Center to ensure balance, independence, objectivity, and scientific rigor in all its sponsored educational programs. All faculty participating in continuing medical education activities sponsored by Washington Hospital Center are required to disclose to the program audience any real or apparent conflict of interest related to the content of their presentations. All faculty are also required to disclose any discussions of unlabeled/unapproved uses of drugs or devices.

CONTINUING EDUCATION CREDIT
The National Rehabilitation Hospital is approved by the Continuing Education Board of the American Speech-Language-Hearing Association (ASHA) to provide continuing education activities in speech-language pathology and audiology. This program is offered for 1.0 CEUs (intermediate level, professional area). ASHA CE Provider approval does not imply endorsement of course content, specific products, or clinical procedures.



Application has been made to Md, DC and VA PT & OT licensing Boards for CEU's.

Washington Hospital Center is accredited as a provider of continuing nursing educaton by the American Nurses Credentialing Center's Commission on Accreditation.

Best Available Copy

SPONSORS

National Rehabilitation Hospital

Located in the nation's capital, National Rehabilitation Hospital treats a complete range of neurological and orthopedic conditions, including spinal cord injury, traumatic brain injury, stroke, arthritis, and amputations among many others. Since 1986, NRH has grown from a single hospital into The NRH Medical Rehabilitation Network. This expanding system now includes more than 30 NRH Regional Rehab outpatient therapy centers throughout the District of Columbia, Maryland, and Northern Virginia; the National Center for Children's Rehabilitation at NRH, the Department of Rehabilitation Medicine at Georgetown University Hospital; rehabilitation services at Washington Hospital Center; and a state-of-the-art research program for people facing disabling injury or illness. National Rehabilitation Hospital is consistently ranked in U.S. News & World Report as one of "America's Best Hospitals" for both Medical Rehabilitation and Rheumatology.
NRHRehab.org

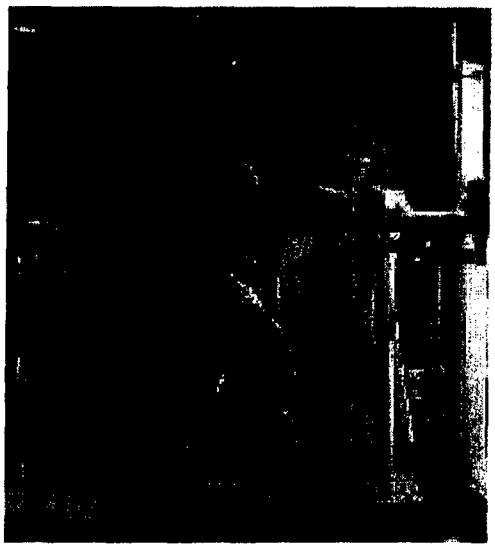
Washington Hospital Center

Washington Hospital Center is a 907-bed, acute care, teaching and research hospital based in Northwest Washington, D.C. It is the largest private, non-profit hospital in the nation's capital and has the 13th highest patient volume in the United States. The Hospital Center is home to one of the largest cardiac programs in the country. It also has a comprehensive Cancer Institute; a full range of women's services; an extensive organ transplantation program; one of the nation's top shock/trauma centers; and the most advanced burn facility in the region. Washington Hospital Center is listed by U.S. News & World Report as one of the best hospitals for heart services, hormonal disorders and urology. http://www.whcenter.org

ACKNOWLEDGEMENTS

National Rehabilitation Hospital gratefully acknowledges the following organizations for their contributions in support of this Symposium:

Boehrlinger-Ingelheim
NRH Neuroscience Research
U.S. Department of the Army



SPECIAL ASSISTANCE

The National Rehabilitation Hospital and Washington Hospital Center wish to ensure that no individual with a disability is excluded, denied services, segregated or otherwise treated differently from other individuals because of the absence of auxiliary aids or services identified in the Americans with Disabilities Act. Please contact (202) 877-8201.

INQUIRIES TO:

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Washington, DC 20010-2975
(202) 877-8201
(202) 877-3374 (fax)
email: ramona.finch@medstar.net

C M E S Y M P O S I U M R E G I S T R A T I O N F O R M

NATIONAL REHABILITATION HOSPITAL

Stroke Rehabilitation: Outstanding Outcomes and Best Practices

Friday and Saturday, May 14-15, 2004

NAME _____ DEGREE _____

TITLE _____ SPECIALTY _____

INSTITUTION _____

ADDRESS / SUITE # _____

CITY _____ STATE _____ ZIP _____

DAYTIME PHONE _____ EVENING PHONE _____

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Please use separate sheet for additional names

I would like to register for the following breakout sessions:

Friday, May 14, 2004 [illegible]

- ☐ Cortical Reorganization and Function
- ☐ Community re-Entry: Independence in the Square
- ☐ Policy Issues and Pragmatic Approaches to Coping with Medicare Reform
- ☐ Managing Co-morbidities Post Stroke
- ☐ Multiplying Communication Impairments via Tele-Rehab Group and Family Member Input

Saturday, May 15, 2004 [illegible]

- ☐ Recent Advances in Stroke Functional Neuroimaging: Implications for Rehabilitation Research
- ☐ Advanced Practice Nursing in Stroke Rehabilitation: Models and Outcomes
- ☐ Psychological Issues: Depression and Anxiety
- ☐ Make Going Home Safe: Security and Children Post Stroke
- ☐ Substance Abuse: Research Implications for Post Stroke Rehabilitation
- ☐ Patient Safety and Falls

☐ **Physicians: $150**

☐ **Residents/Fellows: $120**

☐ **Allied Health Professionals: $150**

☐ **MedStar Health Employee: $120**

Registration includes continental breakfast, lunch, refreshment breaks and a syllabus.

☐ I've enclosed a check or a money order in the amount of _____ payable to NRH Stroke Symposium/CME.

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COMMENTARY

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

Gerben DeJong, PhD, Susan D. Horn, PhD, Julie A. Gassaway, MS, RN, Mary D. Slavin, PT, PhD, Marcel P. Dijkers, PhD

ABSTRACT. DeJong G, Horn SD, Gassaway JA, Slavin MD, Dijkers MP. Toward a taxonomy of rehabilitation interventions: using an inductive approach to examine the "black box" of rehabilitation. Arch Phys Med Rehabil 2004; 85:678-86.

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

From the Brooks Center for Rehabilitation Studies and Department of Health Services Administration, College of Public Health & Health Professions, University of Florida, Gainesville, FL (DeJong); Institute for Clinical Outcomes Research, Salt Lake City, UT (Horn, Gassaway); Department of Medical Informatics, University of Utah, School of Medicine, Salt Lake City, UT (Horn); Center for Rehabilitation Effectiveness, Sargent College of Health and Rehabilitation Sciences, Boston University, Boston, MA (Slavin); and Department of Rehabilitation Medicine, Mount Sinai School of Medicine, New York, NY (Dijkers).

This work was initiated while DeJong was affiliated with the Center for Health & Disability Research and the Neuroscience Research Center, National Rehabilitation Hospital, Washington, DC and Prague, Czech Republic.

Presented in part at the American Congress of Rehabilitation Medicine's annual assembly, October 5, 2002, Philadelphia, PA.

Supported by the National Institute on Disability and Rehabilitation Research (grant no. H133B990005) and the US Army & Materiel Command (cooperative agreement award no. DAMD17-02-2-0032). The views, opinions, and/or findings contained in this article are those of the authors and should not be construed as an official US Department of the Army position, policy, or decision unless so designated by other documentation.

No commercial party having a direct financial interest in the results of the research supporting this article has or will confer a benefit upon the author(s) or upon any organization with which the author(s) is/are associated.

Reprint requests to Gerben DeJong, PhD, Brooks Center for Rehabilitation Studies, University of Florida, College of Public Health & Health Professions, PO Box 100185, Gainesville, FL 32610-0185.

0003-9993/04/8504-8047$30.00/0
doi:10.1016/j.apmr.2003.06.033

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.

Some[10] 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 FIM™ 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 patients' 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 sites' 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 1[27-29] 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-

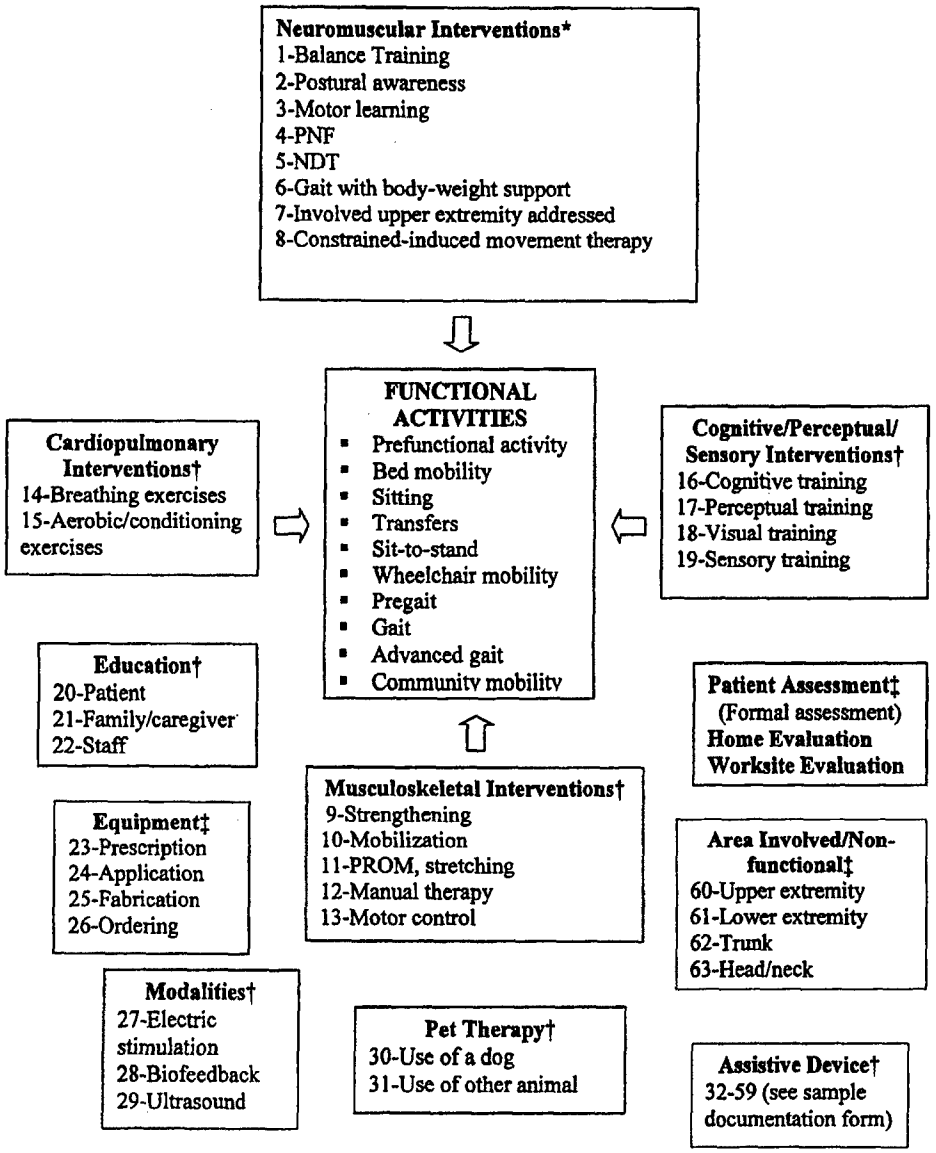

Fig 1. Framework of the intervention classification system in poststroke PT. *Always documented in the context of functional activities. †Documented in the context of functional activities or separately. ‡Always documented separate from functional activities. Abbreviations: NDT, neurodevelopmental treatment;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

Physical Therapy Rehabilitation Activities

6649

Patient ID: Sample19

Date of Therapy Session: 03/15/02

Therapist: DOE

Time session begins: 08:00

INTERVENTION CODES

Neuromuscular Interventions:
01. Balance training
02. Postural awareness
03. Motor learning
04. PNF
05. NDT
06. Gait with body weight support
07. Involved upper extremity addressed
08. Constrained induced movement therapy

Musculoskeletal Interventions:
09. Strengthening
10. Mobilization
11. PROM/Stretching
12. Manual Therapy
13. Motor Control

Cardiopulmonary Intervention:
14. Breathing
15. Aerobic/Conditioning exercises

Cognitive/Perceptual/Sensory Interventions:
16. Cognitive training
17. Perceptual training
18. Visual training
19. Sensory training

Education Interventions:
20. Patient
21. Family/Caregiver
22. Staff

Equipment Interventions:
23. Prescription/Selection
24. Application
25. Fabrication
26. Ordering

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

	Duration of Activity: Enter in 5-minute increments	Interventions: Enter one intervention code per group of boxes.					
Pre-Functional Activity							
Bed Mobility							
Sitting	15	17	05	03	01	07	
Transfers	05	20	17				
Sit-to-Stand	10	17	05	09			
Wheelchair Mobility							
Pre-gait							
Gait	15	06	32	44	03	15	
Advanced Gait							
Community Mobility							
Intervention not related to functional activity							
Intervention #2 not related to functional activity							

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. [ ]

Area Involved/non-functional:
60. Upper Extremity
61. Lower Extremity
62. Trunk
63. Head/Neck

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	PT Assistant	PT Aide/Tech	PT Student
045 minutes	minutes	minutes	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

Fig 2. Example of a completed documentation form. Abbreviations: KAFO, knee-ankle-foot orthosis; FWW, forward-wheel walker.

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 in 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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