Workshop to Develop a Research Agenda on Appropriate Settings for Rehabilitation

BETHESDA, MD
FEBRUARY 14-15, 2005

Workshop Summary

WORKSHOP ORGANZING SPONSORS:

National Institute of Child Health and Human Development, National Institutes of Health
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services

The statements, conclusions, and recommendations contained in this document reflect both individual and collective opinions of the symposium participants and are not intended to represent the official position of the U.S. Department of Health and Human Services, the National Institutes of Health, or the Centers for Medicare and Medicaid Services.

National Institute of Child Health and Human Development (NICHD) and Centers for Medicare & Medicaid Services (CMS)

Workshop to Develop a Research Agenda on Appropriate Settings for Rehabilitation

National Institutes of Health (NIH)
Bethesda, Maryland
February 14–15, 2005

Summary Report

Introductions and Charge

Bob Kuhl, director of the Division of Institutional Post Acute Care in the Chronic Care Policy Group of CMS, welcomed participants to the Workshop to Develop a Research Agenda on Appropriate Settings for Rehabilitation. Michael Weinrich, M.D., director of the National Center for Medical Rehabilitation Research (NCMRR) within the NICHD, explained that the workshop constituted the meeting specified in the CMS final rule (69 FR 25752) on the classification criteria for qualification as an inpatient rehabilitation facility (IRF).

With the help of the NICHD, the CMS was convening the panel of experts to help develop a research agenda on appropriate settings for providing rehabilitation care. Dr. Weinrich clarified that, as part of the NIH, the NICHD is charged with improving the nation's health through research; the Institute is not authorized to advise other federal agencies on policy. Similarly, the workshop was not convened under Federal Advisory Committee Act rules, so the expert panel would not be providing consensus recommendations to the CMS. However, Dr. Weinrich encouraged all participants to voice their opinions and to focus on the topic of a research agenda, rather than on the CMS final 75-percent rule. Specifically, he asked the panel to consider patients in six categories—total joint replacement, pulmonary and cardiac rehabilitation, cancer and transplant rehabilitation, back surgery rehabilitation, hip fracture rehabilitation, and chronic pain. For each category, Dr. Weinrich asked participants to identify the current research issues, the most pressing research questions that need to be answered, and the best ways to answer those questions. He also asked for input on subgroups of patients in each group that might benefit from intensive inpatient rehabilitation.

Overview of the Agency for Healthcare Research and Quality (AHRQ) Study

At the request of the CMS, the AHRQ conducted an assessment to determine the scope of the medical literature evaluating intensive IRF programs on specific conditions, primarily those not currently covered by the CMS 75-percent rule. Stanley Ip, M.D., assistant director of Evidence-Based Practice Center at the Tufts-New England Medical Center, presented the results of the assessment, which considered the following conditions of interest:

- Cardiac (e.g., ischemic heart disease, bypass surgery, heart failure)
- Pulmonary (e.g., chronic obstructive pulmonary disease [COPD], restrictive lung disease)
- Transplant surgery
- Total joint (knee or hip) replacement
- Back surgery
- Cancer

Rehabilitation settings of interest included:

- IRFs
- Skilled nursing facilities (SNFs)
- Home health rehabilitation conducted in a home by a therapist
- Outpatient rehabilitation

Dr. Ip reported that searches of the MEDLINE and CINAHL [Cumulative Index to Nursing and Allied Health Literature] databases yielded more than 4,000 abstracts on these topics. A review of 240 full articles identified 30 studies that met specific inclusion criteria (see AHRQ Technology Assessment[1] http://www.nichd.nih.gov/about/ncmrr/AHRQ-companion-report.pdf). These studies were grouped into the following three categories:

- **Category I**—Studies comparing intensive IRFs with alternative care settings, including comparisons of specialized inpatient rehabilitation centers with other facilities
- **Category II**—Other comparison studies, including SNFs versus home health rehabilitation and SNFs versus outpatient rehabilitation
- **Category III**—Non-comparative single-arm cohort studies in any rehabilitation setting.

Dr. Ip noted that although the primary interest was comparison studies in the first two categories, the paucity of such research in the literature led to the creation of the third, single-arm category.

The assessment concluded that few comparative studies had been conducted on the conditions of interest, and that few studies had been conducted in the United States during the past 10 years. Only one randomized controlled trial (RCT) specifically asked whether inpatient rehabilitation made any difference compared to outpatient rehabilitation. The studies were heterogeneous in terms of research questions, conditions of interest, types of facilities, countries of origin, interventions, follow-up durations, and outcomes assessed (Hill, 2000[2]).

In a discussion of search strategies, participants made the following suggestions:

- Use terms other than "rehabilitation" (e.g., "early exercise intervention") to find additional studies in database searches of the literature.

[1] Lau, et al. (2005) An assment of medical literature evaluating inpatient rehabilitation facility programs on conditions of interest. AHRQ Technology Assessment Program. Available at http://www.nichd.nih.gov/about/ncmrr/AHRQ-companion-report.pdf

[2] Hill SP et al. (2000) Early discharge following total knee replacement—a trial of patient satisfaction and outcomes using and orthopaedic outreach team. *Journal of Orthopaedic Nursing 4*(3):121-126.

- Look for studies based on scores that measure the level of disability or on rehabilitation of medical conditions, rather than on specific diagnoses. Diagnosis often has little to do with a patient's functional status or need for rehabilitation services, and comorbidities may be as important as primary diagnoses.
- Consider studies with a more integrated use of different levels of care, rather than the current dichotomy of comparing one rehabilitation setting with one other setting.
- Look at the components of the interventions at the different rehabilitation settings (e.g., in the Hill study, a significant factor in outpatient rehabilitation was a pre-operation home visit to assess the environment).

Conditions of Interest

Participants considered the literature and discussed issues in each of the six conditions of interest. The group identified aspects of a research agenda that were common to all areas as well as considerations specific to each condition. Highlights of the discussions are summarized below.

Total Joint Replacement

Participants noted that patients with total joint replacement constitute a large and growing population for which substantial variations in treatment exist. The literature on this area of rehabilitation was not robust, and most studies looked at only single aspects of this complex issue.

It was suggested that studies should characterize patients in the following key domains:

- Medical conditions, including comorbidities
- Mental/cognitive status (e.g., dementia, depression, anxiety, problem-solving abilities)
- Functional status (e.g., deconditioning, malnutrition)
- Postoperative complication risk (e.g., dizziness)
- Home environment (e.g., availability of family support, stairs versus elevators)
- Access to specific health care settings in the community

In addition to these patient attributes, other variables need to be measured and characterized, including:

- Components of the intervention or treatment (e.g., surgical procedure or technique)
- The setting of care (e.g., hours of therapy provided, availability of physical training, provision of home environment and family assessment, team process approaches)

- Time value of the intervention (e.g., importance of a faster recovery)
- Time of year (e.g., specific problems associated with the winter season)

Many of the above-mentioned variables, however, were based on observation in clinical practice. Epidemiological studies to identify risk factors for poor outcomes or predictors of success are limited for most of the conditions of interest (An exception is a sufficiency of studies on acute depression and dementia/delirium as risk factors for poor outcomes). Some evidence suggests the importance of early intervention in promoting recovery. One crucial question is whether functional status is more valuable than diagnosis in predicting outcome.

It was suggested that many of the factors identified by the group would be applicable to research on all conditions of interest. Additional subsets of elements for each specific condition might also be identified.

In the orthopedic literature, factors that have been identified specifically in the orthopedic literature as affecting outcomes for total joint replacement include age, obesity, preoperative pain or knee stiffness, implant time and type, and specific surgical characteristics.

Participants suggested that the following attributes would be important to characterize, specifically in *patients* with total joint replacements:

- Presence of osteoarthritis in other joints; alternatively, a gradual deterioration of function over a long period of time
- Cardiac and pulmonary status
- Cognitive function (e.g., problem-solving ability)
- Neurological impairments (e.g., prior stroke, Parkinson's disease, severe neuropathies)
- Obesity measured by body mass index (BMI)
- Level of conditioning (suggested measures included Guralnik's short battery of tests and efforts to determine cardiovascular conditioning)

Characteristics of the *interventions* that need specific attention for total joint replacement patients include:

- The elective nature of intervention
- Pain management
- Type of prosthesis

Participants suggested that the following *outcomes* should be used to measure success for total joint replacement:

- Scores for joint replacement (e.g., Knee Society Score, Harris Hip Score)
- Pain scores
- Patient satisfaction with the outcome
- Quality-of-life scores
- Distance ambulated

- Return to work and certain vocational skills
- Complication rates in the first six months
- Ultimate disposition of the patient, such as change in residence (e.g., move to a nursing home)
- Decline in outpatient utilization
- Level of physical activity before and after the operation as a broad integrative value (measured by an activity monitor or survey such as the Yale Physical Activity Survey)
- Caregiver burden

Risk factors in the early postoperative period also could help identify patients who need inpatient rehabilitation. For example, by postoperative day 2, patients needing more intensive and supervised care include those who have delirium, deconditioning, a catheter still in place, inability to walk 15 to 20 feet, dizziness when getting up, inadequate pain management or diabetes control, and a caregiver incapable of following precautions and instructions.

A potential group for study might be patients who have elective surgery, but fall off the normal pathway for recovery (e.g., patients who experience problems such as depression or admission to the intensive care unit [ICU]). These individuals are the types of patients who are usually managed most effectively with more intensive, multidisciplinary rehabilitation services.

A suggested research agenda for total joint replacement could include the following components:

- A retrospective analysis using secondary data (e.g., Medicare claims and clinical data sets) to determine the types of patients treated in different settings and the extent of variations
- A retrospective study or possibly a prospective study comparing outcomes between settings that treat similar patients and characterizing levels and intensity of service Prospective data might be necessary to characterize patients and to adjust for selection bias.
- Selective randomized trial(s) on treatment alternatives that are carefully specified

Participants suggested that other items of interest included the:

- Total cost of care across multiple settings
- Quality of preoperative assessment and acute hospital care
- Characteristics of the family or other caregivers and any associated interventions (e.g., special teams that train caregivers)

Pulmonary and Cardiac Rehabilitation

Dr. Weinrich advised the panel that the AHRQ assessment had excluded outpatient cardiac rehabilitation because the extensive literature on this topic is not germane to the current discussion. He added that although, in theory, large populations of patients might benefit from cardiac and pulmonary inpatient rehabilitation, few published studies exist in this area.

However, ,for a selected subgroup of patients, the availability and provision of acute rehabilitation services have been invaluable for reducing complications and length of stay, and in improving outcomes. Based primarily on observation, the types of patients who require these more intensive services include:

- Patients with comorbidities (e.g., stroke, Parkinson's disease, other neurological deficits)
- Patients with complicated courses (e.g., prolonged postoperative intubation) that require more interventions such as ICU stays and computed axial tomography (CAT) scans
- Very elderly patients undergoing advanced cardiac procedures
- Patients with severe deconditioning who are waiting for transplants or other advanced treatments but must meet certain criteria to be eligible; inpatient rehabilitation can help maximize care for these patients and optimize their window of opportunity for advance treatment
- Patients with left ventricular assistive devices (LVAD) who need specialized medical support and interdisciplinary rehabilitation; it was suggested that LVAD patients and transplant patients—both diagnostic groups that were not available in the early 1980s—might constitute ideal study populations

Several participants noted that although diagnostic categories were important, they were not necessarily the best starting point for asking research questions related to rehabilitation. Dr. Weinrich asked whether it would make more sense to describe cardiac and pulmonary patients in terms of deconditioning, malnourishment, or qualifying lengths of acute hospitalization with a certain number of ICU days and complications, rather than focusing on organ system diagnosis. Participants generally agreed but noted that these patients also had special post-surgical requirements (e.g., telemetry and oxygenation issues) that might require study in specialized centers. In addition, cachexia is another issue that often needs to be addressed in heart failure patients.

In general, the panel's discussion indicated that research questions need to address deconditioning and the larger issue of the functional status of patients, rather than diagnosis. However, because payers may view deconditioning as a subjective category, a major challenge will be to identify objective measures. Participants noted that reasonably good tools exist to look specifically at deconditioned patients, including some modified ways to assess severely deconditioned patients. Elements of a definition of deconditioning should include significant functional impairment (e.g., not ambulatory at the home level), a relatively recent decline in function (e.g., within the past couple of months), and expectations of improvement.

One research priority might be to study the fit between different levels of deconditioning and the best setting for rehabilitation in patients at the various levels. Separate comorbidities (e.g., cachexia, anemia) could be addressed through different targeted interventions. Acuity of deconditioning could be studied as an independent variable and could be an important predictor of the level of the setting that best fits the patient. Because the status of patients with acute deconditioning can change rapidly, the capability of facilities to make interim reassessments and adjust the course of activities is a crucial setting attribute.

Participants identified the following special populations of pulmonary patients who could benefit from rehabilitation for deconditioning:

- Pre-transplant patients
- Pulmonary surgical patients who are not necessarily deconditioned but are very pulmonary limited
- Ventilator-dependent individuals with pulmonary disease

The medical literature seems to indicate that the rehabilitation setting does not matter for patients with severe COPD and functional limitations. However, some clinicians have observed that COPD patients who are stable and functional and then become deconditioned after an acute medical exacerbation can benefit from intensive rehabilitation. These patients might be addressed by a natural history observational study in long-term care facilities care for medically complex pulmonary patients.

Cancer and Transplant Rehabilitation

Cancer and transplant rehabilitation patients are highly complex and fragile populations with special multidisciplinary needs (e.g., chemotherapy, biopsies), some of which can be delivered on an outpatient basis. Some types of transplant patients (e.g., heart, lung) can go home within seven to 10 days after surgery. However, when these patients do need rehabilitation, care is often complex.

Participants suggested that studies consider the following subgroups of cancer and transplant patients:

- *End-stage cancer patients who have finished their oncology workup and are moving closer to the hospice setting*--These individuals may have special needs related to pain management, malnutrition, and family issues. Rehabilitation could help address these issues and prevent bouncebacks to the hospital or emergency department for unmanaged pain.
- *Transplant patients*--These patients have had costly, life-changing interventions that were not available in the 1980s when regulations concerning the appropriate diagnoses for inpatient rehabilitation facilities were promulgated. They may also have multiple comorbidities that need to be managed. It is important to determine the efficacy and cost-effectiveness of thess high-stakes interventions and to study this well-defined population within the next several years, before the number of sites with these patients decreases. In addition, RCTs of transplant patients are problematic because of the difficulty of randomizing patients to less-than-optimal care.

Suggested types of studies included:

- A study to examine the cost-effectiveness of different levels of rehabilitation care for cancer and transplant patients, followed by a study to look at the right setting in which this care can be provided

- Head-to-head studies of these patients involving rehabilitation in long-term acute care facilities versus acute intensive rehabilitation.

Hip Fracture Rehabilitation

Laurie Feinberg, M.D., of the Office of the Assistant Secretary for Planning and Evaluation, DHHS, presented results of a literature review on hip fracture rehabilitation. She noted that few prospective studies exist in this area, and that methodological problems limit the usefulness of some studies. Dr. Feinberg cited an article (Deutsch et al.[3]) that attempted to control for multiple covariables, such as type of fracture, comorbidities, geographic location, pre-hospital living arrangements, and Medicare reimbursement. It was noted that although the study is a good example of the acute deconditioning model and what could be done in other patient types using, some important measures have not been included.

Participants that the following patient characteristics were most predictive of outcome:

- Pre-fracture functionalNunctional Independence Measure™)
- Mental health status (e.g., depression)
- Age
- Caregiver

Level of disability was considered more predictive than comorbidities.

It was noted that unlike many of the other conditions discussed, hip fracture rehabilitation had generated a body of literature that might provide a good foundation for moving from observational studies toward RCTs. One research question that would be important to answer is whether patients who receive rehabilitation in inpatient rehabilitation facilities have comparable outcomes to those who receive rehabilitation at skilled nursing facilities. .Data from earlier observational studies could be used to classify patients and the intensity of care. Another suggested priority was clarifying whether weight-bearing status is a useful criterion for assigning patients to specific rehabilitation interventions. It would also be useful to test rehabilitation pathways (e.g., step-down rehabilitation) that would forge new care alternatives.

[3] Deutsch A et al. (in press) Outcomes and reimbursement of inpatient rehabilitation facilities and subacute rehabilitation programs for Medicare beneficiaries with hip fracture.

Back Surgery Rehabilitation

No observational or other data exist on intensive inpatient rehabilitation for back surgery. Although back surgery patients do not have specific high-intensity acute needs, they do have deconditioning. The patient population is heterogeneous, with different levels of neurogenic weakness, as well as different kinds of previous surgery, comorbidities, pain, and neurological deficits. Younger patients who are covered by workers compensation rather than Medicare present different methodologic issues and require different mechanisms for capturing information.

It will be important to identify the specific surgical procedures (e.g., fusion) devices (e.g., artificial discs)- - when studying back surgery rehabilitation. There has been an explosion of innovation in this area, and many new interventions are being used without supportive data. Although standardization of surgery and physical therapy might be possible for prospective studies, retrospective studies pose a problem unless they involve large numbers of patients. Partnerships with orthopedic colleagues will be crucial to the success of back surgery rehabilitation studies.

Participants suggested supporting the following types of research:

- Proactive observational studies to learn what types of back surgery are being performed, on what types of patient, followed by studies on the rehabilitation possibilities in different settings
- Design of a template or paradigm that allows testing of a broad range of new technologies for efficacy and cost-effectiveness; the different conditions of interest could be then substituted in the template.

Chronic Pain

Dr. Feinberg reported that the literature on inpatient rehabilitation for chronic pain was scarce. She found only a few U.S. studies which were prospective studies on back pain from the early 1990s. However, none of the studies did comparisons. Although data exist on the visual analog scale, other proxy measures (e.g., how much medication patients take, what patients are able to do) may be more reliable than self-reported pain. Dr. Feinberg noted that, starting in 2006, Medicare outpatient drug data from new drug benefit claims should facilitate research on the amount of drugs patients are using for pain. Participants indicated that earlier studies on chronic pain describe clinically successful approaches, such as the operant condition pain behavior model, which has a structured rehabilitation program. Although these studies might not be comparative, they do describe standardized programmatic activities.

Participants they also described the following challenges posed by current practices involving patients with chronic pain.

- These patients often are treated in psychiatric units through outpatient chronic pain programs. However, it was difficult to find outpatient-based, multidisciplinary chronic pain programs that really worked.

- Institution-based programs and a rehabilitation focus on physical restoration are lacking.
- Anesthesia-based pain management centers are proliferating and are appropriate for some patients. However, patients with long-term, widespread body pain often receive many procedures that make no long-lasting difference in their functional outcomes.
- The practice of providing narcotics over the long term has become widespread, even though only a small number of patients require it. Moreover, many patients who receive this type of treatment are often not getting into rehabilitation-based programs.
- Anesthesia-based programs do not have a functional or standardized pain reporting system that would be useful in studies.
- The current diagnostic coding system for pain syndromes does not allow for precise coding of many specific syndromes.

One participant described an inpatient, psychiatric-based, short-term pain rehabilitation program at the Mayo Clinic that has physical and occupational therapists. Patients in the psychiatric unit who are appropriately shifted to the inpatient rehabilitation program include those whose major needs are rehabilitative (e.g., they are functionally impaired and not ambulatory in the psychiatric setting). However, rehabilitation uses a team approach, with psychiatric support still provided for pharmacologic management of chronic pain.

Dr. Weinrich noted that a potential research effort could be undertaken to determine whether inpatient rehabilitation was more effective than outpatient programs for some subpopulations of patients whose primary diagnosis is chronic pain. He suggested that an observational study could be conducted to determine how chronic pain patients utilize medical resources. Researchers could then design a small-scale trial to compare usual care with an inpatient pain-management program. Participants suggested that an important aspect of the observational study would be to determine what injections patients received and whether any type of rehabilitation (e.g., conditioning or stretching exercises) followed the injections. Observational studies also could also collect data to help determine whether any patient profile could predict the success or failure of pain treatment. Subsequent prospective studies could address the identified cofactors.

Accessing Medicare claims data on patients with chronic pain syndrome using current diagnostic codes is difficult. Participants suggested the following potential alternative sources of data:

- Long-term acute care facilities provide a possible source of inpatient pain rehabilitation patients.
- Health systems such as Oxford Health Plans®, Kaiser Permanente®, or the Mayo Clinic might have databases of patients that would include data elements of interest.
- Skilled nursing facilities probably have pain-management protocols for the many patients who have pain associated with their primary diagnosis.
- The Department of Veterans Affairs health care system provides inpatient drug rehabilitation to patients and may maintain data of interest.

Potential subgroups of chronic pain patients who might benefit from inpatient rehabilitation include:

- Patients for whom injection of narcotics, long-term, are not working

- Patients who have a pump, for initial medication management and to keep them mobilized after implants
- Deconditioned and malnourished patients with a subtype of pain

Research Methodologies

Throughout both days of discussion, participants offered their insights on the types of studies that might be included in the research agenda. During the initial discussion on total joint replacement, Dr. Weinrich emphasized that the purpose of the Workshop was to identify the necessary steps in priority order to advance knowledge that ultimately will help policy makers make decisions in regard to appropriate settings for rehabilitation. A wide range of studies in addition to RCTs should be considered for inclusion in the research agenda.

Participants suggested considering where and when RCTs fit within the broad spectrum of the research agenda. The field might not be ready for RCTs in all areas. Types of studies suggested by participants included:

- A retrospective analysis of key variables, which might facilitate the identification of subcohorts of patients who benefit from rehabilitation from both medical efficacy and cost perspectives
- Studies designed to take advantage of natural variability, such as geographic variations in treatment
- Studies of rehabilitation outcomes and diagnoses conducted within a network of centers. These studies would use certain base parameters for all conditions and separate variable questions for specific conditions. Participating centers would need to comply with standardized therapy. The network might include specialized centers that have met specific criteria and quality standards to perform special procedures.

Participants suggested that some prerequisites for an RCT include:

- A scoring mechanism to classify patients according to measures of the severity of medical and mental functional status
- A well-defined intervention to study
- Better ways to operationalize and classify the intervention (One crucial consideration is identifying the treatment components for which variability must be characterized. The interdisciplinary nature of the treatment team is a key factor irrespective of setting.)
- Standardization of therapy using scripted protocols for various settings (Researchers would need to identify the key elements of therapy that must be standardized.)
- Articulation and characterization of facility attributes and actual differences between the various types of facilities
- Standard, objective measures of the types of care that are available and provided in each rehabilitation setting (In addition to specific activities, other aspects that need to be considered include the proximity of the rehabilitation gym to patients' bedrooms, the interaction between rehabilitation and nursing staff, and the subspecialty expertise of the physician.)

- Definitions of terms such as *intensive*, *early*, and *aggressive* therapy as well as terms such as *frailty*
- Ways to measure the intensity of service (New sophisticated scores of patient satisfaction may be a better measure than therapy hours.)

Participants identified the following types of information that might be obtained by analyzing Medicare claims data linked to other databases, such as the Inpatient Rehabilitation Facility Patient Assessment Instrument (),minimum datasets skilled nursing facilities

- Number of outpatient visits
- Frequency of visits (not readily available with skilled nursing facilities)
- Relatively comparable functional and cognitive data
- Comorbidities (by examining past claims for an extended period of time, rather than just the last hospitalization)
- Standard outcome measures based on community residence at 30/60/90 days, but not based on function
- Outcome measures, such as mortality and hospital readmission

Obtaining data to measure factors such as depression, family support, and duration of onset of illness (e.g., progressive, slow, disabling decline versus acute onset of illness) was considered more problematic.

Participants agreed that it was important to identify the measures and predictors of those outcomes that would be most useful in helping payers make decisions about coverage. Ideally, researchers should develop a predictive profile that would help identify the types of patients who are most in need of, or likely to benefit most from, appropriate types of rehabilitation in various settings. It was suggested that study designs for all conditions should address the following questions:

- What are the appropriate screens to identify high-risk individuals?
- What are the predictors of good outcomes?
- What are the best outcomes from the best settings (after the stratification of individuals)?

An interesting next step would be relating the risk profile to the rehabilitation setting to determine whether a relationship existed among a particular risk profile, the setting, and the ultimate outcome. Such a relationship, if found, could be a springboard to future trials. This type of sequence of studies needs to be done for all the conditions of interest.

Research Priorities

On the final day of discussion, Dr. Weinrich asked participants to consider the most important research questions that need to be answered and the methodologies needed, in priority order, to obtain the answers.

Hip Fracture

Participants agreed that hip fracture rehabilitation was one of the few areas of the field ready for RCTs that would answer setting-specific questions. Suggested questions included:

- Is inpatient rehabilitation superior to care in skilled nursing facilities for patients who are at risk (based on identifiable preoperative characteristics)?
- How should the standard postoperative rehabilitation protocol be defined? (The efficacy of various interventions could then be studied based on that protocol.)

The study would need to define what constitutes success. Outcome measures should be describable, objective, and reproducible. Outcomes should include a cost component to allow assessment of the ratios of cost versus the speed of recovery, maximum recovery, and duration of recovery. Fortunately, the literature has characterized the trajectory of recovery from hip fracture and different ways to quantify outcome following rehabilitation.

As previously mentioned, other requirements for an RCT include strict protocols and defined settings. Participation in patient registries such as the National Joint Registry might save time and money, but this approach would require certain types of approval (e.g., institutional review boards) and ways to link to other data sets while ensuring confidentiality.

Time-Sensitive Studies

Some participants suggested that studies on the following types of patients were urgently needed before a window of opportunity for collecting data closes:

- Patients with low-incidence transplants who were not included in diagnostic groups available in 1983 (e.g., liver transplant patients)--A priority research question is whether intensive inpatient rehabilitation can help these patients get out of the acute hospital setting sooner.
- Patients with major joint replacements who no longer qualify for acute inpatient rehabilitation under the 75%-rule--The priority question would be whether intensive inpatient rehabilitation is effective for these patients. An initial observational study could compare the outcomes of these patients to the outcomes of patients in the past (before the change in policy) or patients at skilled nursing facilities to determine whether there has been a significant change in outcomes.
- Patients with cardiac and pulmonary disability

Representatives of provider groups were particularly interested in outcome studies on patients who lost access to rehabilitation care because of Medicare reimbursement policies.

It was noted that some small, but important patient groups are representative of a growing population of patients who will undergo new procedures that result from technological innovations. It will be important to learn which patients require and benefit from intensive rehabilitation after receiving these new interventions.

Deconditioning versus Diagnosis

Another important research topic is the extent to which the complexity, severity, and acuity of a patient's deconditioning is a useful model for determining the appropriate level of rehabilitation care. A suggested approach to addressing this topic was an observational study with three separate diagnoses and a good measure of deconditioning obtained at entry into the study, followed by a regression on outcomes. Such a study could start to examine any relationship between diagnosis and deconditioning versus independent effects on setting and outcomes. It was noted that patients are more likely to report fatigue than deconditioning, but the underlying physiologic cause of fatigue is often deconditioning, secondary to diagnosis-specific conditions such as cachexia, anemia, malnutrition, or joint pain. It was suggested that outcome measures need to go beyond length-of-stay and acute measures to include long-term follow-up information. Physical activity was considered a good integrative measure of how well patients have done.

Definition of Variables

Participants generally agreed that was work needed to be done to examine existing epidemiological evidence and identify key measures (e.g., functional status, cognitive impairment, depression) that would cut across studies of all the conditions of interest. The definitions of these variables could inform research and perhaps impact the design of day-to-day care. Definitions are also needed for the components of care used as variables to describe different rehabilitation settings. However, participants differed on whether consensus panels or study investigators should decide on these definitions.

Characterization of Rehabilitation Setting

Research is also needed to better characterize the rehabilitation facilities. Important topics include the extent to which these settings are unique and different, as well as the areas in which they overlap. An observational or survey study could be conducted to characterize the nature and distribution of activities in each setting. Attributes of interest that might help describe the environments include average size, average number of beds dedicated to rehabilitation, nurse-to-patient ratio, and the extent of physician involvement (e.g., frequency of visits from the physician). Some of these questions might be answered using Medicare data or a database on nursing homes and rehabilitation hospitals developed by Horn and colleagues.[4] Panelists

[4] Dejong G, Horn SD, Gassaway JA, Slavin MD & Dijkers MP. (2004) Toward a taxonomy of rehabilitation interventions: Using an inductive approach to examine the "black box" of rehabilitation. *Arch Phys Med Rehabil. Apr;85*(4)678-686.

emphasized the need to standardize treatments for RCTs and the large variations in service provision across skilled nursing facilities that could potentially confound observational studies. The need to include long-term care hospitals was also emphasized.

Dr. Weinrich presented what he considered a feasible approach to organizing a study. He suggested a government/provider partnership in which the NIH and the CMS would provide the infrastructure by jointly funding both a clinical research organization to recruit and randomize patients, and a data coordination center to collect and analyze data. Providers would be reimbursed for providing patient care and supporting data collection. Dr. Weinrich estimated that, within two to three years, a study might have enough patients to answer the primary question of comparing the benefit of inpatient rehabilitation facilities and skilled nursing facilities and a secondary question of which specific patient subpopulations benefit from each type of care. Such a study might be funded at $5 million per year.

Next Steps/Closing Remarks

Dr. Weinrich thanked participants for their valuable input and noted that a report summarizing the Workshop would be issued within two months. The report will be submitted to the NIH, the CMS, and the AHRQ and would be posted on the Internet. Dr. Weinrich said that he would personally work to obtain resources for a targeted initiative of some kind and hoped that his CMS colleagues would do the same. However, he advised that any resulting initiative would not have the funds to support a large number of rehabilitation sites with independent principal investigators at each site. Providers might have to give some protected time for investigators to participate in and help collect data for the study. Dr. Weinrich also suggested that, for some issues, providers could conduct their own small population studies without waiting for a federal initiative.

Appendix A: Invitees

National Institute of Child Health and Human Development (NICHD) and Centers for Medicare & Medicaid Services (CMS)
Workshop To Develop a Research Agenda on Appropriate Settings for Rehabilitation
February 14–15, 2005

Building 31, Room 2A47
National Institutes of Health (NIH)
Bethesda, Maryland

Invitee List

Matthew N. Bartels, M.D., M.P.H.
Associate Professor of Clinical Rehabilitation Medicine
Columbia College of Physicians and Surgeons
Unit #38, 630 West 168th Street
New York, NY 10032
Phone: 212-305-0483
Fax: 212-342-1855
E-mail: mnb4@columbia.edu

Victoria A. Brander, M.D.
Medical Director
Northwestern Arthritis Institute
680 North Lake Shore Drive, Suite 1028
Chicago, IL 60611
Phone: 312-475-5566
Fax: 312-475-5625
E-mail: VictoriaBrander@aol.com

Rebecca L. Craik, Ph.D., P.T.
Professor and Chair
Department of Physical Therapy
Arcadia University
450 S. Easton Road
Glenside, PA 19038-3295
Phone: 215-572-2143
Fax: 215-572-2157
E-mail: craik@arcadia.edu

Albert Esquenazi, M.D.
Department of Physical Medicine and Rehabilitation
Moss Rehabilitation
1200 W. Tabor Road
Philadelphia, PA 19141
Phone: 215-456-9470
Fax: 215-456-9631
E-mail: aesquena@einstein.edu

William J. Evans, Ph.D.
Professor
University of Arkansas for Medical Sciences
4301 West Markham, Slot 806
Little Rock, AR 72205
Phone: 501-526-5701
Fax: 501-526-5710
E-mail: evanswilliamj@uams.edu

Gail Gamble, M.D.
Consultant
Department of Physical Medicine and Rehabilitation
Mayo Clinic
200 First Street, SW
Rochester, MN 55905
Phone: 507-284-2608
Fax: 507-284-3431
E-mail: gamble.gail@mayo.edu or darcy.pamela@mayo.edu

Bruce M. Gans, M.D.
Chief Medical Officer
Kessler Institute for Rehabilitation
1199 Pleasant Valley Way
West Orange, NJ 07052
Phone: 973-324-3658
Fax: 973-324-3656
E-mail: bgans@kessler-rehab.com

David C. Good, M.D.
Professor and Chair
Department of Neurology
Penn State Hershey Medical Center
Department of Neurology, H037
500 University Drive
Hershey, PA 17033
Phone: 717-531-1801
Fax: 717-531-4694
E-mail: dgood@psu.edu

Alan Jette, Ph.D., P.T.
Director
Health and Disability Research Institute
53 Bay State Road
Boston, MA 02215
Phone: 617-358-3472
Fax: 617-358-1355
E-mail: ruchidua@bu.edu

Andrew M. Kramer, M.D.
Head, Division of Health Care Policy
and Research
Professor of Medicine
University of Colorado at Denver
and Health Sciences Center
13611 E. Colfax Avenue, Suite 100
Aurora, CO 80011
Phone: 303-724-2500
Fax: 303-724-2499
E-mail: Andy.Kramer@uchsc.edu

Jay Magaziner, M.S.Hyg., Ph.D.
Professor and Director
Division of Gerontology
Department of Epidemiology and Preventive
Medicine
University of Maryland Baltimore
660 W. Redwood Street, Suite 200
Baltimore, MD 21201
Phone: 410-706-2406
Fax: 410-706-4433
E-mail: jmagazin@epi.umaryland.edu

John L. Melvin, M.D., M.M.Sc.
Michie Professor and Chairman
Department of Rehabilitation Medicine
Jefferson Medical College of Thomas
Jefferson University
25 S. 9th Street
Philadelphia, PA 19107
Phone: 215-955-6574
Fax: 215-955-2311
E-mail: john.melvin@jefferson.edu

Elizabeth Sandel, M.D.
Medical Director
Kaiser Foundation Rehabilitation Center
975 Sereno Drive
Vallejo, CA 94589
Phone: 707-651-3936
Fax: 707-651-4160
E-mail: elizabeth.sandel@kp.org

Richard K. Shields, Ph.D., P.T.
Professor
University of Iowa
1-248 Medical Education Building
Iowa City, IA 52242
Phone: 319-335-9803
Fax: 319-335-9707
E-mail: richard-shields@uiowa.edu

Hilary Siebens, M.D.
Clinical Professor of Physical Medicine
and Rehabilitation
University of Virginia
2015 Los Trancos Drive, Unit C
Irvine, CA 92617
Phone: 949-735-6813
Fax: 949-725-0654
E-mail: hcsiebens@hotmail.com

Ross D. Zafonte, D.O.
Chairman
Department of Physical Medicine
and Rehabilitation
University of Pittsburgh Medical Center
3471 Fifth Avenue, Suite 201
Pittsburgh, PA 15213
Phone: 412-648-6979
Fax: 412-692-4410
E-mail: zafonterd@upmc.edu

Federal Staff

James Bowman, M.D., M.B.A.
Medical Officer
Chronic Care Policy Group
Centers for Medicare & Medicaid Services
C5-07-02, CENT
7500 Security Boulevard, Baltimore MD
21244-1850
410-786-0009
JBowman@cms.hhs.gov

Pete Diaz
Inpatient Rehabilitation Facilities Team
Leader
Division of Institutional Post Acute Care
Chronic Care Policy Group
Centers for Medicare & Medicaid Services
C5-07-05, CENT
7500 Security Boulevard, Baltimore MD
21244-1850
410-786-1235
Email: PDiaz@cms.hhs.gov

Martin Erlichman
Senior Health Science Analyst
Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, MD 20850
Phone: 301-427-1610
Fax: 301-427-1639
E-mail: merlichm@ahrq.gov

Laurie Feinberg, M.D., M.P.H.
Office of Health Care Financing Policy
Office of the Assistant Secretary for
Planning and Evaluation
U.S. Department of Health and Human
Services
200 Independence Avenue, SW
Room 443F.7
Washington, DC 20201
Phone: 202-401-8398
E-mail: laurie.feinberg@hhs.gov

Michael Grund
Medical Officer
Chronic Care Policy Group
Centers for Medicare & Medicaid Services
C5-02-25, CENT
7500 Security Boulevard, Baltimore MD
21244-1850
410-786-3116
Email: MGrund@cms.hhs.gov

Jeanette Kranacs
Technical Advisor
Division of Institutional Post Acute Care
Chronic Care Policy Group
Centers for Medicare & Medicaid Services
C5-06-28, CENT
7500 Security Boulevard, Baltimore MD
21244-1850
(410)786-9385
Email: JKranacs@cms.hhs

Bob Kuhl
Director
Division of Institutional Post Acute Care
Chronic Care Policy Group
Centers for Medicare & Medicaid Services
C5-07-17, CENT
7500 Security Boulevard, Baltimore MD
21244-1850
410-786-4597
Email: Robert.Kuhl@cms.hhs.gov

Michael Weinrich, M.D.
Director
National Center for Medical Rehabilitation Research
National Institute of Child Health and Human Development
National Institutes of Health
6100 Executive Boulevard
Room 2A03, MSC 7510
Bethesda, MD 20892-7510
Phone: 301-402-4201
Fax: 301-402-0832
E-mail: weinricm@mail.nih.gov
Fed Ex Address:
Replace last line with Rockville, MD 20852

Laurence Wilson
Director
Chronic Care Policy Group
Centers for Medicare & Medicaid Services
C5-02-17, CENT
7500 Security Boulevard, Baltimore MD
21244-1850
410-786-4603
Email: LWilson1@cms.hhs.gov

Observers

Rochelle Archuleta
Senior Associate Director, Policy
American Hospital Association
325 7th Street, NW
Washington, DC 20004
Phone: 202-626-2320
Fax: 202-626-4626
E-mail: rarchuleta@aha.org

Eileen Gibbons, M.H.A.
Chief Executive Officer
New England Rehabilitation Hospital
2 Rehabilitation Way
Woburn, MA 01801
Phone: 781-935-5080
Fax: 781-935-3555
E-mail: eileen.gibbons@healthsouth.com

Justin Hunter, J.D.
Powers, Pyles, Sutter & Verville
1875 Eye Street, NW
Twelfth Floor
Washington, DC 20007
Phone: 202-466-6550
E-mail: justin.hunter@ppsv.com

Stanley Ip, M.D.
Assistant Director of Evidence-Based Practice Center
Tufts-New England Medical Center
750 Washington Street, NEMC Box 63
Boston, MA 02111
Phone: 617-636-1058
Fax: 617-636-8628
E-mail: sip@tufts-nemc.org

Sally J. Kaplan, Ph.D.
Research Director
Medicare Payment Advisory Commission (MedPAC)
601 New Jersey Avenue, NW, Suite 9000
Washington, DC 20001
Phone: 202-220-3717
Fax: 202-220-3759
E-mail: skaplan@medpac.gov

Malcolm H. Morrison, Ph.D.
President and CEO
Morrison Informatics, Inc.
1150 Lancaster Boulevard, Suite 101
Mechanicsburg, PA 17055
Phone: 717-795-8410
Fax: 717-795-8420
E-mail: informatic@informaticsinc.com

Mary K. Moscato, M.P.H., M.B.A.
Senior Vice President
HEALTHSOUTH Rehabilitation Hospital
New England Rehabilitation Hospital
2 Rehabilitation Way
Woburn, MA 01801
Phone: 781-935-5080
Fax: 781-935-3555
E-mail: mary.moscato@healthsouth.com

Lois Siegelman, M.S.
Director, Contract Services
Spaulding Rehabilitation Hospital
125 Nashua Street
Boston, MA 02118
Phone: 617-573-7154
Fax: 617-573-7159
E-mail: lsiegelman@partners.org

Mary Stuart, Sc.D.
Director
Health Administration and Policy Program
Associate Professor of Sociology and Anthropology
University of Maryland Baltimore County
1000 Hilltop Circle
Baltimore, MD 21250
E-mail: stuart@umbc.edu

Carolyn Zollar, M.A., J.D.
Vice President for Government Relations and Policy Development
American Medical Rehabilitation Providers Association
1710 N Street, NW
Washington, DC 20036
Phone: 202-223-1920
Fax: 202-223-1925
E-mail: czollar@13x.com