

Rehabilitation Research at the National Institutes of Health (NIH): Moving the Field Forward Conference Summary

Natcher Conference Center

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Welcome

Catherine Y. Spong, M.D.

Acting Director

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

Dr. Spong welcomed members and said that the goal of the meeting was to address the scope of National Institutes of Health (NIH) rehabilitation research and to provide the scientific community and the public the opportunity to provide input into the development of the NIH Rehabilitation Research Plan. The meeting would highlight research opportunities, gaps, infrastructure needs, and career and training opportunities. Those in attendance would help shape the future of medical rehabilitation research.

The first day of the 2-day meeting would include presentations from researchers who represent the range of rehabilitation research. There would also be a performance by the Same Sky Project, a musical performance by youth with disabilities. The day would also include a series of panels to discuss various aspects of rehabilitation research.

The second day of the meeting would include workshops and a town hall meeting to get the ideas of the attendees. The participation of everybody at the meeting is vital. She asked attendees to use their Twitter accounts during the day, with hashtag #NIHRehab.

Relevance and Importance of Rehabilitation to NIH and Introduction of Keynote

Francis S. Collins, M.D., Ph.D.

Director

National Institutes of Health

Dr. Collins thanked attendees for coming to the conference.

NIH's total investment in rehabilitation research is seven times the budget of the National Center for Medical Rehabilitation Research (NCMRR). NIH has 17 Institutes invested in rehabilitation research, with a total budget of \$514 million in fiscal year 2015. New technology is bringing about advances in rehabilitation that might not have been dreamed possible a few decades ago. NCMRR is in a good position to apply these advances and to move rehabilitation forward. These improvements and this research is important because it will affect so many people in the United States, where 53 million people have a disability and 43 million people take care of somebody with a disability.

Dr. Collins said that he convened a blue ribbon panel on rehabilitation in 2012 to suggest ways to advance rehabilitation research. The panel made recommendations, and this conference is a direct response to those recommendations. The conference attendees will help formulate the research plan, its themes, and what NIH can do with the resources available to move the field forward.

The visibility of rehabilitation research has increased at NIH under the leadership of former NICHD Director Alan Guttmacher, M.D.; NICHD Acting Director Dr. Spong; and NCMRR Director Alison Cernich, Ph.D. Dr. Collins said that he hoped attendees would help NCMRR further crystallize ideas about the research that will lead to better solutions.

Dr. Collins introduced the consumer keynote, the Same Sky Project, a group of youth from Northern Virginia who have disabilities. The group composes and performs songs to explain their disabilities and their struggles.

Consumer Keynote: The Same Sky Project

Kim Tapper provided information about A Place to Be, a company that helps individuals overcome life obstacles through the therapeutic arts. The company is open to anybody, including people with disabilities. The group uses performance-based methods.

Tom Sweitzer, the executive director of A Place to Be, said that music therapy has been found to reduce the anxiety of individuals waiting for chemotherapy. It has been used successfully in palliative care. The students involved in the Same Sky Project wrote the songs and performed them at the meeting.

Following the performance, there was a panel that included one of the performers, three parents of the performers, and Mr. Sweitzer. Dr. Cernich moderated the panel. The panelists made the following points:

- A young woman with cerebral palsy who was a member of the group said that consumers are willing to learn about their conditions if providers are willing to teach them. She often asks providers about the meaning of a technical term. She asked that providers talk to her, not at her.

- The mother of a girl with a traumatic brain injury (TBI) said that the whole family has been affected by her daughter's injury. For example, the mother has left work and become a full-time caregiver.
- The father of a girl with diabetes said that consumers can benefit from new devices like the continuous glucose monitoring device his daughter wears. The device has been a lifesaver for his daughter.
- The father of a girl with cerebral palsy asked that researchers find the fastest ways to get their findings to the people who need it.
- The woman with cerebral palsy discussed the value she has found in music therapy. She has learned to talk more naturally and now enjoys dancing. She also said that she hopes that others will see individuals with disabilities as people and reach out to them.

Discussion

An attendee asked about the use of music therapy in acute rehabilitation. Mr. Sweitzer said that A Place to Be has used music therapy successfully in medical settings including a psychiatric ward with youth who recently have attempted suicide. Music therapy is also effective for people with chronic obstructive pulmonary disease, increasing lung capacity by 40 percent. Dr. Cernich said that NIH has funded studies on the benefits of dance and how it can help improve gait. These and other studies can be found on *NIH RePORTER*.

A woman asked about the barriers to improving insurance coverage for music therapy. Dr. Cernich said that insurance coverage is one of the challenges in the field of rehabilitation. Developing the evidence to show the effectiveness and the need for these services is one of the tasks that must be undertaken.

An attendee said that she helped start a new journal, the *Journal of Humanities and Rehabilitation*. She said that researchers, providers, and consumers are invited to submit to the journal.

Dr. Cernich asked panelists about their biggest challenges. One parent said that the focus is on physical healing but that there is so much more to the picture. The challenge is to give the child the strength and confidence to face life. Another parent said that the biggest challenge is finding tools to allow his daughter the greatest possible independence. His daughter said that she wants the tools to be able to live independently.

Mr. Sweitzer said that mental health is a big issue for parents and the young people with disabilities. Nearly all have a need for mental health services because of the stresses involved. Insurance does not pay for many of the mental health-related services.

A researcher asked what types of technology researchers should develop to improve the quality of life of consumers and their families. A parent said that his family has obtained software for voice control of

lights and thermostats. He would like voice control to be extended to opening elevator doors. He also said that technology that was developed for a general audience and can be adapted for the needs of those with disabilities is the most useful and affordable.

A parent said that tablets have revolutionized communication. He suggested the development of mobile phone apps to provide messages of emotional support while also providing practical help such as providing appointment reminders. Another panelist said that there is a need for technology that is small and unobtrusive. His teenage daughter does not want to wear a medical device that others can see. The smaller a device is, the better. A mother seconded that and said that children want the same thing that their peers have.

Rehabilitation Across the Lifespan

Moderator: Alan Jette, Ph.D.

*Professor of Health Law, and Policy Management
Boston University*

Dr. Jette said that the panel would focus on integrating rehabilitation into the mainstream of health care for various populations.

Toward Integrated Models of Rehabilitation: Chronic Disease

Andrea L. Cheville, M.D.

*Professor and Research Chair
Mayo Clinic*

Dr. Cheville discussed how people with cancer cope with chronic disease.

People with cancer show a slow decline until they become housebound with some mobility but little ability to be out in the community. In the late stages, people with cancer are confined to bed. Her work aims to maximize the time that these patients can be mobile in the community and the home.

Society pays a high cost to support people with a serious chronic disease. These include the indirect costs and the costs of institutionalization. There is also a heavy burden on caregivers who spend, on average, more than 8 hours daily for 13 months taking care of the patient. They have higher rates of depression, tend to neglect their own health, and have higher mortality rates. Challenges include identifying the point at which patients need additional interventions.

Most patients will progressively lose functionality. Some experts have suggested all patients should be embedded in rehabilitation therapy; others have said cancer patients should be included only at the end

of treatment. There is little empirical validation of the best approach, so the default approach of the conventional delivery system is used.

The conventional system is not working well, because 66 percent of cancer patients have at least one functional impairment at the time of discharge; 92 percent of women with stage IV breast cancer have impairments, but only 2 percent of patients receive rehabilitation. The odds of receiving outpatient care for a physical impairment are 1 in 88. The odds of getting a physician-directed intervention are 1 in 500.

Screening is part of the answer. There are many screening methods, including patient-reported outcomes, clinician-reported outcomes, objective performance measures, and activity monitoring. There is increased precision and efficiency of screening, including electronic medical record (EMR) capabilities and remote assessments.

These are sound methods of monitoring patients and functions. But in chronic disease, treatment is not as clear-cut, because it is less prescriptive, more negotiable, and subject to patient preferences.

How should interventions be conducted? In the past 5 years, there have been 40 systematic reviews on the benefits of physical activity, but patients do not receive prescriptive counseling in how to be active. There is good evidence that physical activity works to reduce cancer-related fatigue, but only 10 percent of patients received counseling on prescriptive treatment. There is a paucity of efficacy and effectiveness trials on impairment-directed therapy, but when tested, rehabilitation services have been found to be effective.

Linear models also have their limitations. Linear models look at pathology and how it leads to impairments, then functional limitations, and then disability. This model does not work well in cancer, because cancer involves multiple impairments. There is a need to see how well the International Classification of Functioning (ICF) can serve the field and guide clinics.

The current care delivery system emphasizes disease management, but cancer patients may need rehabilitation as a result of their cancer treatment. Patients may be focused only on the cancer treatment and unwilling to give up their time and travel for rehabilitation.

Dr. Cheville was involved in the Collaborative Care to Preserve Performance in Cancer study. This approach included a nurse coordinator, a fitness care manager, and physical therapists located near the patient's home. The care manager received information from the patient, including a report on pain, over the phone. The nurse adjusted medications based on information from the patient and provided information to the care team.

The lessons learned are that treatments should be negotiated with the patients, who should help decide where they want to receive rehabilitation. The treatment is relationship based, and accountability is very important.

Preventing Mobility Decline and Disability Among Older Adults

Jonathan F. Bean, M.D., M.S., M.P.H.

*Associate Professor in the Department of Physical Medicine and Rehabilitation
Harvard Medical School*

Director of the New England Geriatric Research Education and Clinical Center

Veterans Affairs Boston Healthcare System

Medical Director of Spaulding Cambridge Outpatient Center

Spaulding Rehabilitation Hospital

The population is aging, bringing more focus to older adult issues. Elderly adults are at risk of losing their mobility skills. A commentary in the *Journal of the American Medical Association* in April 2014 noted that the slower an individual's gait, the greater their risk for mobility disabilities. Rehabilitation should be employed in the primary care setting to prevent mobility decline and disability.

Dr. Bean's group developed an approach, based on the ICF model, to include rehabilitative care in primary care. Primary care doctors identify people with chronic conditions that adversely affect mobility, such as arthritis, stroke, diabetes, osteoporosis, and congestive heart disease, and refer those individuals to rehabilitation. His group conducted a longitudinal cohort study of the approach and found that four impairments are predictive of unfavorable mobility outcomes:

- Leg strength
- Leg speed
- Leg range of motion
- Trunk extensor muscle endurance

The findings on the importance of leg speed and trunk extensor muscle endurance are new.

Musculoskeletal pain and cognitive decline, particularly declines in executive function, are predictive of falls and mobility declines and must be considered in caring for the patients.

In 2010, Dr. Bean's group developed the Live Long Walk Strong program, which is eligible for reimbursement from insurers (including Medicare). The program begins with a primary care screen. Patients who need services are referred to a physiatrist. The program manager may refer the patient to physical therapy or occupational therapy, as well as community exercise and activity programs.

Those who completed the program showed statistically significant and clinically meaningful improvement as measured by the Short Physical Performance Battery. Participants responded positively to the program but asked for more in-home services. As a result, Dr. Bean's group developed the Rehabilitation Enhancing Aging through Connected Health (REACH). This program involves extended multisetting treatment and is in the pilot phase.

Integrating Rehabilitation for Children into Ongoing Care: The Role of Child Development

Shari L. Wade, Ph.D.

Professor of Pediatrics

Cincinnati Children's Hospital Medical Center

Dr. Wade said that one of the challenges with pediatric patients is that rehabilitation occurs in the context of the developing and changing brain. It is necessary for the patient to both regain lost skills and develop new skills. (This is also an opportunity because if optimal periods of plasticity are identified, providers can deliver more effective interventions.) Children's therapy must also exist within the broader context of families, schools, and peers.

TBI has been viewed as a discrete event with time-limited consequences. However, the TBI Model Systems longitudinal study shows there are lifelong physical and cognitive consequences of TBI. Chronic disease and elevated mortality are more common in adult TBI survivors. There is little data of the long-term outcomes of TBI for pediatric survivors. Because they are not considered innovative, natural history studies of pediatric TBI are not highly scored by NIH grant reviewers.

Children with TBI are unlikely to receive ongoing rehabilitation after post-acute recovery. They may display emerging problems because of the increased demands on them to develop new skills. Teachers may not know that the child has TBI, and the child may be labeled as having other problems, such as psychiatric disorders. Families and schools are important to ongoing rehabilitation and later habilitation. One of the challenges is to include habilitation in the child's school.

Family-centered intervention is an important part of the integrated approach to rehabilitation. Families exert a powerful influence on the recovery trajectory. Interventions must be developmentally tailored and address the child's developmental and neural condition. Some examples include parent skills training and problem-solving therapy for adolescents and young adults.

Dr. Wade's group is studying problem-solving therapy for adolescents with TBI. This therapy has the potential to be very flexible and can be used with a wide range of populations, not just with those who have a TBI. The therapy includes the family and allows parents and adolescents to identify problems and develop solutions. One of the values of the therapy is that it accounts for executive dysfunction, and it provides the adolescent a model for problem solving that they can take out into the world.

Dr. Wade is conducting six trials, three multicenter randomized controlled trials and three pilot trials involving more than 500 children. The intervention takes the form of online modules that provide information about TBI and videos of teens and families sharing their experiences, as well as exercises to practice skills. The intervention also includes video conference meetings with a therapist to review the module and implement the problem-solving process around a goal identified by the teen or family.

These studies have found that online delivery of service is acceptable and feasible with individuals with a wide range of education, cognitive abilities, socioeconomic backgrounds, and technology expertise. The approach has shown significant improvements in externalizing behavior, executive function, and overall function. These studies found greater improvement in older children, those from lower socioeconomic backgrounds, and those with greater injuries. That is, the children who most needed the inventions accrued the most benefit.

These studies suggest that rehabilitation can be delivered outside the context of traditional medical settings and that telehealth reduces traditional barriers to care such as time constraints, distance, and the lack of health care providers. Challenges that remain include that rehabilitation must be framed as an ongoing process with “tune-ups” at various developmental stages.

Future research should focus on understanding the outcomes for TBI children when they reach adulthood, including their level of disability and quality of life. Also, a better way to categorize initial injury so that outcomes can be better predicted is needed. Finally, there is a need for a better understanding of the injury’s effects on neurodevelopment and how it relates to long-term function.

Future research should include consortia and multicenter clinical trials to support large outcome studies. Partnerships will help move the field forward. Research centers could link schools and medical data. They could also study interventions and management practices more efficiently.

Discussion

Nancy Baker, Sc.D., M.P.H., of the University of Pittsburgh, said that the population is very heterogeneous and that researchers must find better ways to deal with that heterogeneity in the data. Adaptive design is needed in the research. Dr. Wade agreed, saying that it will be important to find ways to deal with heterogeneity within clinical trials.

An attendee asked whether the children in Dr. Wade’s studies continued to use their new skills after the study ended. Dr. Wade said that they informally noted ongoing improvements up to 18 months post-treatment, giving her hope that the treatments were long lasting, but there is no data to support that. The attendee said that she is working with brain-injured adults on anger management. When the study team follows up later, the participants do not remember the intervention, and it is difficult to tell whether they are using the skills they learned.

Peter Esselman, M.D., of the University of Washington, asked how to provide the treatments discussed in the session in a cost-effective way. Dr. Cheville said that they are measuring costs right now, recognizing that they must show that the interventions help patients and that they save money before they will be implemented. Dr. Bean said that there is an ongoing study to measure the costs of the REACH study.

Technology in Rehabilitation

Moderator: Ranu Jung, Ph.D.

Professor of Biomedical Engineering

Florida International University

Dr. Jung gave an overview of the session before beginning the panel discussion. She said that the presentation would focus on neural interfaces. The development of neural interfaces is a field in which engineering, the life sciences, and rehabilitation overlap. The purpose of neural interfaces is to improve the quality of life through technology that can replace and repair damaged neuromechanical systems.

One of the challenges is that neurotechnology must interact with the changing nervous system. But this is also an opportunity because successful intervention at one stage can create a cascade of positive effects at later stages.

Dr. Jung said that the presenters would discuss neurotechnology that is becoming more integrated with biological systems, more adaptive, more targeted to neural sensing and activation, and more personalized. Dr. Jung provided background on each of the panelists and their work, all of which was done in partnership with industry.

Cochlear Implants

Mario Svirsky, Ph.D., is the Noel L. Cohen Professor of Hearing Science at the New York University School of Medicine. His research includes the study of communication outcomes after cochlear implantation and the development of tools to optimize cochlear implant fitting. He is interested in both the clinical and scientific aspects of cochlear implantation.

Cochlear implants are the first successful example of replacing a human sense. They work best with patients who have lost hearing after age 3 and for congenitally deaf children who receive the implant early in life. Cochlear implants bypass the nonfunctional hair cells of the ear and deliver electrical signals directly to the auditory nerve, which then sends them to the brain. The brain recognizes the signals as sound. Provision of cochlear implants is a form of rehabilitation. It is not known whether auditory training after implantation is helpful. Most adults say the signals seem distorted. Over time speech perception improves, but differences among patients remain.

Retinal Implants

Joseph F. Rizzo III, M.D., is the David G. Cogan Professor of Ophthalmology at Harvard Medical School and the director of Neuro-Ophthalmology Service at the Massachusetts Eye and Ear Infirmary. He is the founder of the Boston Retinal Implant Project, a multidisciplinary research program between the

Massachusetts Eye and Ear Infirmary and the Massachusetts Institute of Technology. The goal is to develop an implantable retinal prosthesis to restore vision to patients with outer retinal degeneration. The system, now being tested, includes a small external camera that is hard-wired to a small wearable processor. A primary coil delivers wireless power and digital signal to a secondary implant. Penetrating electrodes are implanted into the thin retina.

Prostheses with Sensorimotor Integration

Dr. Jung is the Wallace H. Coulter Eminent Scholar Chair, a professor of biomedical engineering, and the interim dean of the College of Engineering and Computing at Florida International University. She has been working on a project to restore the sense of touch and hand-closing ability in a prosthetic for upper arm amputees. The device includes an implantable, wirelessly controlled, direct neural interface system.

Brain-Computer Interface

Leigh Hochberg, M.D., Ph.D., is a neuroscientist and critical care neurologist at Brown University, Massachusetts General Hospital, and the Providence Veterans Affairs Medical Center. He directs the pilot clinical trials of the BrainGate Neural Interface System. The team is developing and testing a neuroprosthetic system to help people with paralysis regain communication, mobility, and independence. Microelectrodes are implanted on the motor cortex of the brain. The goal is to allow people with quadriplegia to intuitively control external devices by simply thinking to move their hand or arm. The research is conducted in the homes of the users.

Recovery of Function Following Spine Injury

V. Reggie Edgerton, Ph.D., is the director of the Neuromuscular Research Laboratory, Distinguished Professor, and a member of Brain Research Institute at the University of California, Los Angeles. He is also the president and chairman of the board of NeuroRecovery Technologies, Inc. He is interested in the recovery of sensory motor and autonomic functions following complete paralysis. He investigates how motor functions can be modified through activity-dependent interventions after spinal cord injury (SCI). This work has produced improvements in function, even when the injury occurred up to 15 years before the training. The improvements occurred in voluntary movement, standing and balance, and assisted stepping.

Discussion

Following the presentation of this overview, Dr. Jung and the panelists asked questions of each other. Dr. Jung asked Dr. Svirsky whether his work on cochlear implants fits with the Precision Medicine Initiative.

Dr. Svirsky said that his work begins with the general principle that the human brain is sufficiently plastic to make sense of the input from cochlear implants. The individualization comes in that there is a lot to be done to fit the device to the individual.

Dr. Jung asked whether it is possible to combine neurotechnology with other technologies such as cell therapies. Dr. Svirsky said that gene therapy has the potential to regenerate the human system without the assistance of technology, but that will take a long time to achieve. In the meantime, it is likely that there will be a combined approach that uses technology and gene therapy. For example, there is usually too much space between the electrodes and the nerves that they are meant to stimulate. One solution is to use gene therapy to grow dendrites nearer to the electrodes.

Dr. Edgerton agreed that the use of stem cells to restore function is likely to be a therapy of the distant future. Much more must be learned about the biology of spinal paralysis. It is not yet clear that the axons could be stimulated to grow. The approaches of improving function through activity and using stem cells to regrow damaged nerves will likely be combined to get the best result.

Dr. Jung asked Dr. Rizzo what approaches could be used to collect scientific data when the technology is still under development and the science is still new. Dr. Rizzo said that this is a complex area that encompasses a range of disciplines. Experts from these disciplines will need to work together to collect the data.

Dr. Hochberg said that there are regulatory and scientific hurdles to getting these technologies to market, but it must be done as quickly as possible because people need them now. There are challenges but also opportunities to get the devices out more quickly.

Dr. Jung asked about technologies that are multipurpose. Dr. Edgerton said that some devices are diagnostic, are assistive, and improve function. Dr. Rizzo said that retinal implants are both assistive and restorative.

Dr. Jung asked at what point new devices should be introduced for wider use. Dr. Edgerton said that they should be introduced when there is good evidence that they will be useful, even if the biology is not understood. Conventional wisdom has always been that individuals who are paralyzed cannot improve function after 1 year, but now they see patients improve beyond that point. Investigators will learn more about the biology even as the technology is in use and advances. Dr. Svirsky agreed and said that the sooner the technology can be given to the patients, the better. This is particularly important for

children who are deaf because there are critical periods to learn speech. Learning is slower when treatment is given later.

Dr. Jung said that the challenge is that only a small number of individuals will need an implant. How do investigators find out whether the technology is effective? Dr. Hochberg said that small clinical trials can be run on the devices using the individual as his or her own control. Investigators hope that these technical advances will have such a dramatic effect that their usefulness will be clear. Prosthetics can have a very dramatic effect. Dr. Jung asked what happens when the gain is not dramatic. Dr. Edgerton said that some devices can be slightly modified for use for a variety of conditions. That helps increase the number of individuals who can test it.

Dr. Jung asked about leveraging partners when the hope of commercialization is not imminent. Dr. Hochberg said that it is a fact of life that universities do not make medical technologies and market them, so they must partner with a company. It is important for the university to secure the intellectual property rights first. Dr. Rizzo said that industry partners want investigators to “de-risk” the program before they invest. Universities have to develop their own multidisciplinary teams to do that. The government could help by de-risking long-term development efforts.

Dr. Jung asked about logistical, safety, and regulatory concerns. Dr. Rizzo said that some devices allow the patient greater autonomy and the ability to use a technology in different ways to improve their function. The first step for his retinal implant patients is to help them navigate on their own without risk to themselves or others.

An audience member asked whether there is a host response to implants and, if so, how it affects the lifetime of the therapy. If electrodes degrade, how is that handled? Dr. Hochberg said that there is a host response to everything put in the body, but the question is whether it changes the performance of the device. Implant electrodes have not been used for very long, so the question is still open. The other thing to consider is that this may be a material science question as opposed to a host-response problem. Dr. Svirsky said that cochlear implants have been around for three decades and have been highly reliable. It appears that lifetime use is feasible, but it is also possible to replace a cochlear implant without negatively affecting the patient.

An audience member asked whether it is possible to increase the number of electrodes in cochlear implants. Dr. Svirsky said that cochlear implants use between 12 and 22 electrodes. The reason it works at all is because the human brain is so good at interpreting the signals. An increase in the number of electrodes would not help very much, but other steps are being taken to improve sound quality.

The next questioner asked about collaborations between scientists and industry. Dr. Jung said that researchers need industry to help move their discoveries from the laboratory to the public. It is possible to do this and to publish the work, but it is important to take steps to protect the university’s intellectual

property. That will play a role in the timing of the publication. NIH can help investigators by helping them form these partnerships.

Mechanisms and Markers of Activity and Function: Exercise, Plasticity and Mechanism—How Is Rehabilitation Happening?

Introduction and Issues in Neurorehabilitation: Some of the Problems of Having a Spinal Cord Injury

Moderator: Keith E. Tansey, M.D., Ph.D.

Senior Scientist

Center for Neuroscience and Neurological Recovery

Methodist Rehabilitation Center

Dr. Tansey began by saying that rehabilitation is different from other types of medicine. Patients hope that their conditions will be cured as opposed to controlled, there are few Food and Drug Administration–approved interventions, and there is a desperate search for more evidence-based standards.

Improvements in technology are improving the ability to function in daily life. Researchers also hope to bring about more improvements in neural plasticity and neural repair.

Dr. Tansey also said that focusing on one molecule will not produce behavioral changes; researchers must match the biological target to the patient profile. They must ask the right question about the right system; otherwise, the treatment may not fit the patient. Physiological measures such as electrophysiology and functional imaging can bridge the gap from molecules to behavior.

Dr. Tansey discussed some issues that must be considered in neurorehabilitation. There is a need for better phenotyping of patients as a way to differentiate responders from nonresponders. If the 10 percent who have a 90 percent improvement are mixed in with the 90 percent who have a 10 percent improvement, the intervention’s efficacy for the 10 percent will be masked. Patients who are most likely to respond should be prioritized to detect the benefits of a treatment.

Another consideration has to do with patient heterogeneity including differences in genetics and the biology of their injuries. These all can affect recovery, and clinical scales are limited in their ability to differentiate changes in status. Behavioral assessments are also limited in terms of knowing how an improvement occurred. They cannot differentiate compensation versus recovery or responder versus nonresponder.

Other considerations are how to target rehabilitation therapeutics. Should one “teach to the test” of a particular task, aim for optimal compensation, or aim for the best neurological improvement? There are also considerations of differences between a clinical trial and a therapeutic intervention. Both approaches investigate dose and timing in individuals. Medical rehabilitation does not often use algorithms, but they should be used.

Therapeutic and research methods should be fused to produce interventions tailored to the patient profile and treatment effect over time. Both gain of function and loss of function must be addressed. Poor gait speed can be due to weakness or stiffness.

Skeletal Muscle Plasticity in Rehabilitation Studies

Richard L. Lieber, Ph.D.

Chief Scientific Officer

Rehabilitation Institute of Chicago

Dr. Lieber began by providing some background on muscle structure and physiology. Knowing the sarcomere length of muscles during a task would provide valuable information about the patient’s muscle function. But these are microscopic properties, and they are not easily measured.

Many muscle studies are done using electromyography, which is an imperfect measure because it picks up movement artifacts. Over the past 10 years, researchers have begun using ultrasound to study muscle structure and to measure contractions.

The gold standard of muscle studies is a muscle biopsy, which gets directly to the muscle tissue. It is the best way to diagnose myopathy, but it is invasive. Because of its invasiveness, it is rarely used in a longitudinal study.

Measuring muscle contraction often involves a histochemical analysis of muscle fiber type. Fiber types range from fast to slow, high endurance to low endurance. But fiber type is not very important to function.

Another way to measure muscle is through fiber size. Large fibers deliver high force; small fibers deliver low force. This measure is a functional parameter of muscle performance. The variability in fiber size is highly diagnostic, but measurements are obtainable only by muscle biopsy.

Physiologists have focused their studies on active muscle function and much less on the passive function. But passive muscle force is important. In children with cerebral palsy, it is the passive muscle function that is the most variable. However, little is understood about passive mechanics. In neuromuscular conditions, collagen and stiffness are elevated, but how these conditions relate to

muscle function is not understood. Without knowing what causes changes in passive properties, it is not possible to know how to treat the patient. Studies to understand tissue physiology are needed here.

In children with spasticity, the muscles are shortened and have high amounts of passive tension, but the sarcomere length of the muscle is very long. In other words, the muscle is extremely short and under tension, but the muscle's internal structures are stretched. This must be better understood to develop therapies.

A recent finding has been that the number of satellite cells among children with cerebral palsy is very low. These cells play a role in muscle growth, repair, and regeneration. This finding has implications for rehabilitation. Simply stretching the muscle will not be helpful. This illustrates why mechanistic studies are needed, including studies of fibroblasts, satellite cells, collagen, and intermediate filaments.

Rehabilitation in Renal Disease: Effects on Physical and Cognitive Performance

Stephen Seliger, M.D., M.S.

Associate Professor of Medicine

University of Maryland School of Medicine

Veterans Affairs Maryland Healthcare System

Dr. Seliger is a nephrologist who works with patients with kidney failure. Chronic kidney disease is prevalent and is a disease of aging. About one-quarter of U.S. adults who are 60 years or older have evidence of the disease.

One study found that more dialysis patients are severely debilitated than had been expected. A study of physical activity and employment status of patients on maintenance dialysis—nearly half of whom were younger than 50 years—found that only 25 percent were working outside the home.

Cognitive impairment and dementia are more common among this group, and the prevalence of cognitive impairment is not reduced with more frequent dialysis. Cognitive decline begins earlier in the course of kidney disease, not simply with kidney failure. Those who showed early signs of kidney impairment were 40 percent more likely to develop dementia during the following 8-years. Also, they were more likely to develop vascular dementia rather than Alzheimer's disease.

Studies show that cardiorespiratory fitness in patients with kidney failure is much lower when compared to patients who are in rehabilitation for reasons unrelated to kidney failure. Early studies suggest that cardiorespiratory fitness is reduced by half in patients with dialysis.

Lower extremity performance—the 6-minute walk test, gait speed, and timed up and go—is impaired by 20 percent to 45 percent among patients with chronic kidney disease who are not receiving dialysis.

However, grip strength is preserved. Lower extremity performance was predictive of 3-year mortality and was a better predictor than biochemical measures such as hemoglobin levels.

There are a multiplicity of physiological processes that contribute to the outcome of frailty and decreased function in kidney failure patients. The lack of physical activity among the patients contributes significantly to these functional outcomes.

Dr. Seliger showed that dialysis adversely affects muscle strength and function and cardiorespiratory function. A study of physical activity training in people with kidney failure found modest improvements in aerobic capacity and respiratory fitness. Resistance training helps improve muscle function.

Dr. Seliger concluded by discussing how cognitive function in kidney patients could be improved through physical activity and other rehabilitation interventions. He said that the mechanisms of improvement are related to vascular function, neurotrophic factors, and indirect mechanisms such as reduced sleep disturbance and reduced depression. Dr. Seliger is currently studying exercise training as a way to improve cognitive function in older adults with chronic kidney disease.

The Added Value of Stress Management in Cardiac Rehabilitation: Results from the ENHANCED Trial

James A. Blumenthal, Ph.D.

J.P. Gibbons Professor of Psychiatry

Duke University Medical Center

Physical activity training is a cornerstone of cardiac rehabilitation. Medication management, smoking cessation, and healthy eating habits are also important. Stress is also associated with a poor prognosis in cardiac patients. Its effects appear to be independent of traditional risk factors such as high blood pressure, smoking, and cholesterol. Importantly, stress can be modified or reduced with pharmacologic and behavioral interventions.

However, managing stress is a challenge because there is no consensus definition of stress, no gold standard for measuring it, and no established treatment. A 5-year study done in 1991 found that the level of an individual's psychological stress predicts increased cardiac-related mortality. The study also found that level of depression was predictive of cardiac death. The American Heart Association recently recognized depression as a risk factor for heart disease.

A 2012 study from the United Kingdom found no benefit in cardiac rehabilitation as it is practiced there. The program included either weekly or biweekly sessions of physical activity, relaxation, and stress management over about 8 weeks. (This is a less intensive rehabilitation program than is used in the United States.) There were no differences in morbidity or mortality, anxiety, depression, or quality of life between patients who received cardiac rehabilitation and those who did not.

With that as background, Dr. Blumenthal's group launched the Enhancing Standard Cardiac Rehabilitation (ENHANCED) randomized clinical trial. This trial evaluates the benefit of stress management training when coupled with comprehensive cardiac rehabilitation. The outcomes for the group that received stress management training were compared to a group that received comprehensive cardiac rehabilitation alone and to a group who declined to participate in cardiac rehabilitation. The participants were all 35 years or older and had stable coronary heart disease.

The 12-week stress management training included weekly 1.5-hour small-group sessions that included education, group support, and skills training. Outcome measures included psychological stress, exercise tolerance and physical activity, heart disease biomarkers such as heart rate variability, and a composite measure of stress from several standardized scales.

The study found that the participants in the rehabilitation-alone group and the group that had rehabilitation plus stress management showed improvement in aerobic fitness, leisure-time activity, and the number of accelerometer-measured steps. Participants in both groups also exhibited improved coronary heart disease biomarkers, including lipid levels, and improved exercise tolerance and physical activity. In addition, those in the group that also received stress management showed greater reductions in patient-reported stress and in clinical events than those who had rehabilitation alone.

The overarching conclusion is that stress management provides added value to the standard cardiac rehabilitation. However, fewer than 30 percent of those who were eligible for cardiac rehabilitation took part.

Discussion

An audience member asked about mindfulness approaches and the role of motivation. Dr. Blumenthal said that there is an interest in other approaches such as mindfulness and meditation, but those studies have not yet been conducted in the context of cardiac rehabilitation.

The next question concerned whether rehabilitation research should be structured around a uniform conceptual model. This would make it possible to compare rehabilitation research across different organ systems.

Dr. Tansey said that patients with spinal cord injuries often develop dysfunction in multiple organs. There is a tendency to look at dysfunction in one organ at a time, not at the relationships among them. So this is an important point. It is difficult to find a clinical trial that includes both locomotive recovery and neurological control. Investigators probably have to take a broader approach.

Individuals, Families, and Community

Moderator: Linda Ehrlich-Jones, Ph.D., RN

Clinical Research Scientist

Rehabilitation Institute of Chicago

Dr. Ehrlich-Jones said that this session would focus on rehabilitation interventions that help people with disabilities be actively engaged and achieve increased independence and better quality of life. The session would also focus on ways to help caregivers of people with disabilities.

Home Health Care Strategies for Improving Rehabilitation Outcomes

Christopher M. Murtaugh, Ph.D.

Director

Visiting Nurse Service of the New York Center for Home Care Policy and Research

As background, Dr. Murtaugh said that most of the patients at the Center for Home Care Policy and Research are older and are Medicare recipients. He discussed Medicare requirements to qualify for home health care and the types of services provided. The center's staff take care of patients with widely varying conditions and levels of disability.

Dr. Murtaugh summarized five studies done at the Center for Home Care Policy and Research. One study focused on the intensity level of in-home therapy. Two studies involved expanding access to effective outpatient programs. And two studies involved including families and home health aides to achieve rehabilitation goals.

The first study, which focused on the intensity of home therapy, was conducted in conjunction with a hospital that referred patients with knee replacements for home therapy. The study compared the effectiveness of intensive home health rehabilitation (an average of five visits a week) versus the usual rehabilitation care of two visits per week. There was also a historical control group composed of patients who had their knee replacements before the intensive home care was implemented. There were 1,000 patients in each group.

The baseline and outcomes were assessed using the Outcome and Assessment Information Set (OASIS), a clinical assessment instrument. They found that the intensive rehabilitation improved ambulation and bathing compared to both control groups. There was no effect on the outcomes of hospital readmission or frequency of pain.

The second study was a randomized controlled trial to test the effectiveness of usual care plus cognitive behavioral self-management for persons with activity-limiting pain. The aim was to reduce disability

among older home health patients. The cognitive behavioral intervention included activities such as deep breathing and using imagery.

There was no difference between usual care and usual care plus cognitive behavioral pain self-management in reducing pain intensity or pain-related disability. However, both groups improved substantially from baseline. It appears that both the usual care therapy and the intervention have a positive effect.

A third study involved an investigation of the feasibility of a home-based interdisciplinary cardiac rehabilitation program. The investigator did a literature review; interviewed home care patients, many with implantable devices; and did focus groups with home care nurses and rehabilitation therapists.

This clinician training program included background on cardiac rehabilitation, motivational interviewing, physical activity prescriptions, guidance on nutrition, and information about cardiovascular diseases, risk reduction, and development of emergency plans. Fifty-four clinicians from a range of disciplines received the training, and the principal investigator (PI) is now recruiting patients.

The final two studies that Dr. Murtaugh presented focused on including family caregivers and paraprofessionals in a falls prevention program. The aim was to reduce falls of older adults receiving services by increasing family caregiver involvement in falls prevention.

This was a prospective, quasi-experimental study in which the investigators instructed physical therapists on the importance of involving family in falls prevention. They also distributed materials developed for patients and families on falls prevention. The key outcomes included whether the physical therapists contacted family members and how many patients reported having a fall. The data were obtained from caregiver and patient interviews and from OASIS.

This intervention did not increase the percentage of physical therapists who contacted caregivers, nor did it change the number of patient falls. However, the number of physical therapists who contacted caregivers was high for both the intervention and the control group (around 75 percent for both groups). Barriers to involving family members included caregiver work schedules. Also, caregivers feared that the role of the physical therapist would be reduced as a result of caregiver involvement.

The final study was to determine the impact that a home health aide training program would have on patient compliance with home exercises and improvement in activities of daily living. This was a prospective, quasi-experimental study. The intervention included 4 days of classroom training for the home health aides during the first year of the study. The investigators made some process changes in the second year, giving the aides mobile phones, introducing them at rehabilitation team meetings, and notifying the therapist when a health aide was assigned to a patient.

At the end of the first year, the intervention group improved the number of activities of daily living that patients reached. Patients also were more likely to agree that the home health aide had guided the patient through exercises.

Dr. Murtaugh said that the effectiveness of home health therapy is still uncertain. The pilot project showing that intensive rehabilitation improves short-term outcomes of knee replacement patients should receive further study. The extent to which nonclinicians can extend the reach of this therapy has yet to be explored. There is a need to move beyond the “one-and-done” model of rehabilitation, to improve transition to other community-based services, and to explore the potential of bundled and capitated payment models.

Psychosocial Interventions for Post-Stroke Depression

George S. Alexopoulos, M.D.

S.P. Tobin and A.M. Cooper Professor

Director

Weill-Cornell Institute of Geriatric Psychiatry

Dr. Alexopoulos said that nearly 50 percent of stroke patients have depression after the stroke. Depression worsens patient outcomes, lowers their mobility, and increases mortality. Preventing depression could improve patient outcomes.

A profile of major depression among patients of stroke includes mood disorders, ideational disturbances including suicidal thoughts, cyclic function disturbance including insomnia, motor disturbances such as agitation, and somatic symptoms such as loss of libido.

Patients with post-stroke major depression show more problems than the nondepressed in memory and executive functions. They also are likely to have a wide range of disabilities such as mobility problems, are less likely to participate in society, and are likely have problems with life activities.

Antidepressants have been found to have some benefit. For example, antidepressants reduce mortality in post-stroke patients who are depressed. A drawback of antidepressants is that studies as a whole show that they have only a small benefit. The question is why that would be. It appears that the impairment of the patient’s executive function plays a role. Also, the antidepressants themselves can increase the risk of stroke.

Dr. Alexopoulos has developed a post-stroke model of depression that includes etiological factors such as vascular changes, repair responses, and inflammation. These combine with predisposing factors such as frontolimbic compromise and neurobiological responses to stress such as inflammation and reactive oxygen species. Dr. Alexopoulos said that his approach to help patients with post-stroke depression is called ecosystem focused therapy (EFT).

The organizing principles of EFT are that adaptive behavior is a function of the person's competence and the demands of the environment and that interventions should be personalized to the patient's abilities, ecosystem resources, and the trajectory of their changing needs. In EFT, the patient selects a rehabilitation goal that is meaningful and is possible to achieve.

EFT enhances treatment through an action plan that helps mitigate the effects of resignation, executive dysfunction, and motivational disturbance. The family and caregivers also participate in the therapy.

EFT also re-engineers family goals to accommodate the patient's disability and its impact on the family. The program combines specialized therapies and community resources, such as support groups and recreational services. EFT has been found to be effective in decreasing depression compared to education about stroke.

The Role of Family Caregivers in Supporting Individuals with Disabilities or Chronic Conditions

Sara J. Czaja, Ph.D.

Leonard M. Miller Professor of Psychiatry and Behavioral Sciences

Scientific Director

Center on Aging

University of Miami Miller School of Medicine

Dr. Czaja outlined the significance of family caregiving, saying that there is more outpatient care and patients are expected to be more actively involved in their own care. There is also more reliance on family to help provide care.

Family members provide a significant source of support for people who have a chronic illness or disability. About 30 percent of the U.S. adult population is providing care for somebody who is ill. Two-thirds of caregivers are caring for people who are age 50 or older. The health needs of family caregivers are overlooked, and the demands of family caregiving are becoming more complex.

Most caregivers are engaged in a wide variety of tasks that include care coordination, personal care tasks, household tasks, medical or nursing tasks, and emotional, cognitive, and behavioral support. The caretaker's role is complex, and they are expected to do a lot while juggling other responsibilities.

The potential consequences of caregiving include some positive impacts such as personal growth and an opportunity to give back to someone such as a parent. Negative impacts include depression, risks to health, and disruptions in employment, family, and social relationships.

Because of the negative effects on caregiver health, numerous studies aimed at developing interventions for caregivers have been funded. These studies aim to reduce caregiver burden and

negative outcomes. They provide skill building, education, counseling, and support. Many caregivers do not have access to these programs, but technology is being used to deliver interventions.

Dr. Czaja described one of her studies, the Resources to Enhance Alzheimer's Caregiver Health intervention, which is a tailored technology intervention for diverse family caregivers of Alzheimer's disease patients. The study used a video cell phone technology to deliver psychosocial support to caregivers. The caregivers were mostly from lower socioeconomic groups who were caring for Alzheimer's disease patients. The technology showed positive effects in terms of reducing caregivers' sense of burden and enhancing their social support. The caregivers also felt more confident in their caregiving skills.

The investigators are now doing an enhanced version of that intervention using video conferencing and tablet technology. The caregivers receive individual skill-building sessions via video and video conferencing support groups from the comfort of their own homes. The aims are to determine the acceptability of the intervention to the caregivers, to evaluate its impact on outcomes such as emotional distress, and to gather data on ethnic differences in response to the intervention.

The study has enrolled 182 dyads and has a low attrition rate of 13 percent. Caregivers easily adapt to the technology, and they enjoy the video support group sessions. The investigators find the technology is an effective way to deliver the intervention.

The study so far indicates that technology-based interventions have the potential to benefit caregivers and care recipients. More information is needed on cost effectiveness, the relative advantages of different technologies, the preferred formats for monitoring, privacy issues, and the challenges of technology use.

More information is needed on effective intervention approaches for other caregiver populations, including those with mental illness, adults with developmental disabilities, adults with comorbid conditions, and minority and ethnic populations, including lesbian, gay, bisexual, and transgender caregivers. Also needed are more biological markers as caregiver outcomes.

Discussion

The first question was about language and culture. Dr. Czaja said that she works with a diverse population of caregivers. Her team is multiethnic and multilingual. Language is only one piece of providing culturally appropriate support. It is also important to determine community values concerning things such as family and caregiving. Investigators may have to establish trust with the community. Her team has been working to strengthen its relationship with the Haitian community by forming community advisory boards, among other steps.

An attendee asked whether it would be possible to generalize the findings regarding the efficacy of certain technologies to people with other disabilities and conditions. It would be nice to avoid having to reinvent the wheel. Dr. Czaja said that her group has already done that by widening their findings to people with SCI and their caregivers. Every condition has its unique needs and challenges, but it is possible make generalizations; for example, multicomponent interventions tailored to the caregiver are the most helpful.

A woman said that these studies illustrate that this is a good time for multidisciplinary work because there are now so many shared constructs across the disciplines.

Dr. Alexopoulos said that it would be a good idea to look more at the clinical level than at the science level. He also said that although much of the discussion was about families that help interventions, family members can also interfere with interventions and the therapeutic process. Addressing them head on and setting them right is important.

Access to the Lived Environment

Moderator: Melanie B. Fried-Oken, Ph.D.

*Professor of Neurology, Pediatrics, Biomedical Engineering, and Otolaryngology
Oregon Health & Science University*

Dr. Fried-Oken said that this panel would focus on the development, use, and measurement of assistive technologies for functional outcomes in the lives of people with disabilities. The panel members would describe their NIH-funded research and then introduce a major challenge posed when introducing new assistive technology. The panel would discuss those challenges together and answer questions about assistive technologies.

GoBabyGo!

James C. (Cole) Galloway, Ph.D.

*Professor and Associate Chair
Department of Physical Therapy
University of Delaware*

Dr. Galloway introduced himself as a participatory action researcher who makes assistive devices accessible at low cost.

GoBabyGo! has more than 60 chapters and holds 50 hands-on workshops annually. They have modified more than 5,000 toy cars for children as young as 6 months old. Powered wheelchairs for young children are very expensive, but a modified toy car can cost about \$200. The devices are individualized to the

user by volunteers. The cars allow very young children to explore their environment, something that they often do not have the opportunity to do because of mobility limitations.

Another of his projects, A Harnessed Life, uses easily available materials such as reinforced shower curtains to create harnesses for people of all ages. The harnesses can be set up in the home, giving the individual mobility and independence they would not have had otherwise.

Dr. Galloway showed videos of the harnesses and cars being made and used by individuals. Not only do the devices increase the quality of life for the people using them, but they can often improve the users' physical and, possibly, neurophysiological, functioning.

Developing Smart Environments for Older Adults

Maureen Schmitter-Edgecombe, Ph.D.

Professor of Psychology

Washington State University

By 2030, more than 20 percent of the population will be over age 65. Aging brings chronic disabilities that society will have to care for. Dr. Schmitter-Edgecombe's laboratory has been developing monitoring technology to allow people to live independently in their own home for longer.

The monitors provide a more complete health assessment because they provide continuous information that is needed to make a good assessment. Clinicians can more quickly pick up changes that could go unnoticed, such as a change in how long it takes to complete tasks of daily living. Dr. Schmitter-Edgecombe's work centers on using infrared motion sensors to monitor the activities of adults with cognitive disabilities.

The Washington State University Center for Advanced Studies in Adaptive Systems uses its "smart-home-in-a-box" to test the technology on adults with cognitive impairments. The sensors monitor, for example, the opening and closing of cabinet doors, the use of a sponge to wash a countertop, the watering of plants, and so forth. The investigators have found that there is a correlation between the monitoring data and the individual's functional status.

They have also developed automated interventions to prompt individuals to engage in certain behaviors. One example of the possibilities of this technology is that an individual with mild cognitive impairment who forgets to take medications with breakfast can be cued to take it. The cue is not given if the person has taken the medication. The technology can be "activity aware."

Using Computer Vision to Support Accessibility for People with Visual Impairments

James Coughlan, Ph.D.

Senior Scientist

Smith-Kettlewell Eye Research Institute

Computer vision, which was at first very limited, has now advanced to the point of having many commercial applications, including the development of self-driving motor vehicles. Dr. Coughlan's laboratory has been working to develop computer vision for those who are visually impaired. Smartphones and tablets are now powerful enough to apply computer vision.

One application that Dr. Coughlan's laboratory first developed was a product barcode reader to enable a blind person to read the labels on canned foods. This has now been superseded by more modern approaches, such as object recognition technology.

People who are blind can have difficulty orienting themselves, so the laboratory developed technology that enables a blind person to accurately align with the crosswalk at an intersection. The laboratory is also working on technology to read the time remaining on the walk light.

Another application the laboratory is working on involves audio interactions with objects, allowing a user to point to an object to hear information about it. The laboratory is also developing cell phone camera technology to enable people with low vision to read electronic displays, which are often low contrast and difficult to read even for people with normal vision. One challenge is to be able to properly aim the camera to the display so that it can be read. This will require further work to provide the best user interface.

Discussion

The panel next identified three issues to discuss. The first was to define participatory action research (PAR) and discuss how to incorporate PAR into rehabilitation science.

PAR seeks to understand and improve the environment by modifying it. It is a collaborative process involving a range of disciplines. PAR gives individuals increased control over their lives.

The PAR process is as follows:

- Engage with the real world
- Define the issue
- Plan an intervention with users and stakeholders
- Carry out the intervention
- Reflect on the action both quantitatively and qualitatively

- Repeat the intervention, modified if necessary

Incorporating PAR into rehabilitation science requires answering questions such as who would be critical to the research effort, that is, whose expertise is needed. PAR also requires the PI to involve community members, including subject populations, as collaborators. It is important for PIs to ask what they would study if they were a member of the community for whom they are designing.

Dr. Coughlan said that it is important to talk to the end users, who can help generate ideas about the types of assistive devices needed. Too often, solutions are devised that the user population does not want. Also, PIs should talk to a wide range of people before deciding on their project. This includes not only the end users but also teachers, families, and rehabilitation specialists.

Dr. Fried-Oken said that assistive technology must be individualized by embracing single-subject design. Her team designed an assistive technology for people with aphasia by including an individual with aphasia and her husband on the research team. The users helped test the design before data collection began. They were paid members of the team, and investigators met with them every 6 weeks.

The next challenge the panel discussed was how to scale technology so that it is practical and affordable.

Dr. Schmitter-Edgecombe recounted that the technology in her smart home requires that the individual have a cell phone and an Internet connection and that they pay those costs. However, the cost of the sensors has come down. In addition, a clinician must examine the data coming in, and that represents an expense for the health care facility.

Getting out the word about these new technologies to users, their families, and their caregivers is an issue. There was also discussion of establishing lending libraries of assistive technology. One of the challenges is that the library must be staffed by individuals who can maintain the technology and who can train those who borrow it in how to use it.

An audience member said that end users are becoming involved in the design of products. Will they be included in the intellectual property protections? Dr. Galloway said that the whole process should be open source instead of developing intellectual property. GoBabyGo! became well known with the help of social media. Many people saw the idea and ran with it, which is part of the participatory design idea. They then made their own videos with improvements and advancements to share with others. These videos come from many different countries and are available globally. He also said that researchers must leave their laboratories and go into the real world.

How can you convince individuals that there are solutions to help with activities of daily living that would help to keep them at home? The utility of an assistive technology should be demonstrated as a value added to users and professionals. One way is to compare performance with and without the assistive device. User satisfaction surveys are important, as is measuring quality of life.

Other challenges discussed were that the user population is heterogeneous in terms of needs, abilities, and preferences. The variability of the user population and task conditions can make it very hard and costly to get good statistics on utility. The degree of satisfaction can be hard to measure. In some cases, the technology may not work, may work unreliably, or may be too challenging to use.

An audience member asked whether the potential for a security breach by hackers is a concern for the smart home. Dr. Schmitter-Edgecombe said that they intend to test security before the smart home becomes widely available.

An audience member asked how to reach a wider audience of people who have had a stroke. Most people who are in studies of stroke survivors are receiving outpatient treatment or attending a support group, but there is a much broader population out there. How does a researcher find them?

Dr. Galloway reiterated that it is important to get out into the community where the people are. Dr. Fried-Oken said that accessing the EMR through primary care physicians is another route.

Development of an NIH Rehabilitation Research Plan

Alison Cernich, Ph.D.

Director, NCMRR

Lyn Jakeman, Ph.D.

Program Director, NINDS

Dr. Cernich and Dr. Jakeman detailed the development of the new 5-year trans-NIH Rehabilitation Research Plan. Work on the plan began in 2015. The trans-NIH Medical Rehabilitation Coordinating Committee (MRCC) developed the priorities in consultation with the National Advisory Board on Medical Rehabilitation Research and the directors of the NIH ICs. NCMRR published a draft of the plan asking for public comment.

Most of the public comments received (66 percent) were submitted by individuals; 30 percent were submitted by organizations, associations, foundations, companies, and private hospitals; and 3 percent were submitted by individuals.

Staff analyzed the comments and further modified the plan based on those comments. The suggestions included developing new methods to foster interdisciplinary research, placing greater emphasis on health disparities, and encouraging the development of new technologies. As a result of the comments, the MRCC added two priority areas and revised and refined other priority areas including Family and Community, Technology Use and Development, and Research Design and Methodology.

The plan was to be finalized in June. Those who wanted to give further input were asked to email their comments to rehabilitation1@mail.nih.gov.

Discussion

One commenter suggested that the plan should focus more on prevention. Dr. Cernich said that prevention is included in the plan. The plan also addresses permanent and temporary disabilities. The plan focuses on rehabilitation, but it is hard to be specific because of the range of disabilities that exist.

Another attendee asked whether there would be outreach to the study sections once the plan is finalized. It is important to inform the reviewers of the priorities when they are considering grant applications. Dr. Cernich said that she has met with the Center for Scientific Review and they have the plan. NCMRR will recommend individuals with expertise in rehabilitation be appointed to study sections.

An attendee asked whether there is an established definition of medical rehabilitation research. Dr. Cernich said that there is wording in the plan about what rehabilitation research encompasses. The definition is broad, covering everything from mechanisms to community-based research. The document also includes implementation and dissemination research.

A participant asked whether there are common terms or a conceptual model to guide the work. Dr. Cernich said that NCMRR is looking for ways to harmonize the terms that would be used across the field of rehabilitation research. Common data elements (CDEs) and the Patient-Centered Outcomes Research Institute (PCORI) definitions are being examined. At this point, it does not appear that there is an overarching conceptual model. Most of the projects funded by NIH and NCMRR are investigator initiated.

Understanding the Context: Environmental Impacts in Rehabilitation

Moderator: Michael Mueller, Ph.D.

*Professor, Program in Physical Therapy and Department of Radiology
Washington University*

Dr. Mueller introduced the session by noting that environmental factors could be facilitators or barriers, but emphasized that the key is that they are modifiable.

Conceptual Relationship of Rehabilitation and Environment

James Burke, M.D., M.S.

*Clinical Lecturer in the Department of Neurology
University of Michigan*

Dr. Burke presented a number of conceptual models for the ways that race and socioeconomic factors may interact with contextual factors such as caregiver support, transportation, neighborhood environment and social network to limit access to rehabilitation. A clear, validated model does not exist.

In discussing these models, he pointed out that Medicare data from the National Health and Aging Trends Study (NHATS) provides evidence that African-Americans get more time in acute rehabilitation. In additional analyses, he points out that the differences in outcomes for activity between African Americans and other ethnic groups seem more to do with post-stroke environment (e.g., caregiver, home, neighborhood, and community).

Dr. Burke ended his session by asking how to interest members of NIH study sections in the role that environmental factors may play in rehabilitation and in the use of qualitative research to investigate common themes related to environmental factors.

Findings and Implications from Studying Community Effects on Rehabilitation Outcomes

Amanda Botticello, Ph.D., M.P.H.

Research Scientist

Kessler Foundation

Dr. Botticello introduced her talk by noting that the built environment shapes opportunities for health and outcomes, especially in the disability community. Using data from the Spinal Cord Injury Model Systems database, she outlined the geographic differences in outcomes and the usefulness of environmental measures in examining the ability to integrate into the community.

Findings from her studies suggest that the location and socioeconomic status of an individual with spinal cord injury are important to employment outcomes, with the best prospect for work re-entry among high socioeconomic status individuals in urban environments. She also noted that in areas with mixed and dense populations, individuals with spinal cord injury are more likely to be out of the home and in the community. Finally, she pointed out that the overall socioeconomic status of the person's neighborhood tends to affect health and well-being over and above personal characteristics.

Dr. Botticello concluded her talk with a discussion of the need for research in particular communities and settings because of limitations in generalizability. She also noted the need to include people with disabilities in population studies so that the effect of these larger variables could be determined.

Considerations for Working with Individuals in Rural Communities

Patrick Kitzman, Ph.D., PT

Professor of Physical Therapy

Department of Rehabilitation Sciences

University of Kentucky

Director, Kentucky Appalachian Rural Rehabilitation Network

Dr. Kitzman began by noting that in rural regions, a higher percentage of persons with disability report their health as poor and have less access to care. They also have fewer hospital visits and lower rates of participation in preventative care.

The key finding is that many health facilities use a hub-and-spoke model which requires travel to centralized facilities. This a particular limitation for rural communities due to long travel times and limited access to transportation. Patients with trauma are released to home where they receive less specialized support and have decreased accessibility to their built environment. Their follow-up educational needs are often not met because of their readiness level at discharge from care and their lack of access to providers when they move home.

Dr. Kitzman provided examples of a model in which they work with the rural community and demonstrate a long-term commitment to the community and individual. There is a tendency for rural communities to feel that “they take care of their own” and being a partner with them in this is important to establish. Use of telehealth, assistive technologies, and biomechanical engineering support is critical to the continued success of these partnerships.

Discussion

The audience noted that attitudinal barriers could be important, and that the difficulty is how to capture and measure these. There may be a disconnect between the attitude of the provider and the client that impact outcome. Another audience member pointed out a need for longitudinal studies of outcomes, particularly regarding what reinforces and sustains attitudes in families and communities.

An attendee asked about the potential for ecological studies of the activities of people with disabilities in their respective of environments, including key surrogate measures like zip code and socioeconomic status. Setting was further discussed as difficult to define as an “independent variable” because living in rural communities could be chosen because of the person’s alignment with specific community values or attitudes. Finally an attendee noted the need for professional organizations to provide appropriate access to specialists, especially in rural regions.

The session was summarized by Dr. Mueller who stated that there are complex interactions between the environment and outcomes but conceptual frameworks are developing to help understand the

relationship between these variables. The field needs more consistent outcome measures. He considered the benefit of “big” data sets to understand the overall framework, but noted that there is a need to support qualitative studies and longitudinal data to understand common themes in apparently diverse environmental situations and how these change over time. Dr. Mueller concluded by saying that research can help target policy changes to help make environmental factors a positive modifier in rehabilitation outcomes.

Effective Pathways to Evidence for Rehabilitation

Moderator: James Malec, Ph.D., ABPP-Cn, Rp

Professor and Research Director

Department of Physical Medicine and Rehabilitation

Indiana University School of Medicine

Rehabilitation Hospital of Indiana

Dr. Malec began by reviewing the traditional trajectory of rehabilitation research as described by Whyte and Barrett in their 2012 publication. He then outlined the challenges of randomized controlled trials (RCT) in rehabilitation research, such as blinding of researchers and participants and the heterogeneity of participants and diversity in treatment. He voiced a plea for better measurement in rehabilitation research. Dr. Malec said other challenges include identifying the effective dose and maintaining fidelity of treatment and control conditions. He further acknowledged the delicate balance between internal and external validity and the influence on generalizability or certainty of mechanism. He then listed several alternatives to using RCT in rehabilitation research. These include large observational studies, practice-based evidence, and single case design.

Incorporating Mechanisms into Trials

Lynn Snyder-Mackler, Sc.D., PT

Professor in the Department of Physical Therapy

University of Delaware

Dr. Snyder-Mackler presented and discussed challenges with and approaches to embedding mechanistic investigation in clinical trials. She followed with a description of the use of observational quasi-experimental design studies in rehabilitation. Dr. Snyder-Mackler named the challenges in rehabilitation research: defining the intervention, ensuring the intervention is applied reliably, and identifying the active component. She then compared and contrasted rehabilitation research with drug trials, noting that while drug trials typically have a single active component, rehabilitation interventions are typically multi-modal. Dr. Snyder-Mackler then cited examples of rehabilitation studies that were successful in investigating the mechanism of action of the rehabilitation intervention and concluded that meaningful mechanistic studies can be embedded in rehabilitation clinical trials.

Dosing for Rehabilitation Trials

Catherine Lang, Ph.D., PT

Professor of Physical Therapy, Neurology, and Occupational Therapy

Program in Physical Therapy

Washington University in St. Louis

Dr. Lang introduced the topic of dosing for rehabilitation trials by dividing it into two major segments: 1) why it is important to address dose; 2) how to address dose in rehabilitation studies. She noted that dose was critical in pharmacology and made a strong point that it needed to be considered in rehabilitation research. Dr. Lang indicated that lack of consideration of dose equaled waste in patient's time, clinician's time, opportunities, money, and future collaborative innovation with other disciplines. Dr. Lang contrasted what is known about interventions that required Food and Drug Administration (FDA) approval with what is known (or unknown) about rehabilitation research. Dr. Lang ended her talk by giving examples of how dose can be studied early in the clinical trial via thoughtful methodology.

How Do We Define Standard Care?

Susan Horn, Ph.D., FACRM

Adjunct Professor of Biomedical Informatics, Family and Preventive Medicine, Nursing, Physical Therapy, and Population Health Sciences

University of Utah School of Medicine

Dr. Horn emphasized the importance of personalization, which is how to determine the best care for patients with specified characteristics. She began her presentation by highlighting the basic problem in non-randomized studies, statistical adjustments, and the ongoing debate about adequacy of these adjustments. Dr. Horn introduced practice-based evidence and its methodology. She gave examples of severity systems used to address selection bias/confounding with some attention to the TBI Complex Severity Index. Finally, Dr. Horn compared the merits of RCTs, observational cohort studies, and practice-based evidence.

Discussion

After the presentations, the panel entertained comments and questions from the audience. It was noted that there is a place for various designs based on the research questions and that the rehabilitation field should strive to match the design to the research question. An attendee highlighted the need to address what is necessary and sufficient in rehabilitation care. There were a few comments on international research and the gains made through foreign research and collaboration across the globe. There was also discussion centered on the difficulty of blinding for RCTs in rehabilitation and that this was not unique to rehabilitation as other specialties are also challenged by blinding, e.g. surgery.

Central and Peripheral Mechanisms of Rehabilitation

Moderator: Rick Lieber, Ph.D.

Chief Scientist

Senior Vice President of Research

Rehabilitation Institute of Chicago

Dr. Lieber provided a historical background to his research and started by describing the understanding of sarcomere length. He discussed some of the basic studies that defined how sarcomeres function and the range over which they can function, including their optimal length. He then discussed the implications of studies about how the extensor and flexor systems operate and the design of joint systems related to peak force and power and their implications for studies with individuals with disability. A key example he provided was related to children diagnosed with cerebral palsy with flexor carpi ulnaris wrist flexion contractures. Because children with CP have shorter muscles, the sarcomeres are longer, and as they grow the sarcomere continues to be compromised. He concluded with a discussion of the extracellular matrix, content in the muscle cells (myocytes and phagocytes), and the effect of satellite cells on function for individuals with cerebral palsy and the implications of this basic biology for growth, repair, regeneration, hypertrophy, and therapy. He then introduced the panelists and noted the emphasis on the mechanisms underlying function and how to increase the evidence underlying interventions.

Transitions between Clinical and Basic, Fundamental Studies

D. Michelle Basso, Ed.D., PT

Associate Director

School of Health and Rehabilitation Sciences

Associate Professor

Physical Therapy

The Ohio State University College of Medicine

Dr. Basso began with a video of movement of a clinical participant on a treadmill with body weight-supported treadmill training (BSWTT) over many sessions and noted the problems with toe drag and balance at discharge. She then discussed the data related to individuals with spinal cord injury at the American Spinal Injury Association C and D levels who were motor incomplete and their rates of community ambulation pre- and post- BSWTT training. The overall conclusion of this study was that BSWTT training alone is not enough even for those that respond, and is not beneficial for everyone with SCI. To understand why, she looked at animal models and determined three key factors: 1) task specific rehabilitation, 2) timing and potential for toxicity, 3) injury site and injury response. In looking at the mechanism in mice, there is a relationship between neuroinflammation and timing of rehabilitation with a focus on MMP9. The central challenge is timing. If the training is too late, there is no effect, but if it is

too early, the inflammation can be detrimental. Looking clinically then, the efficacy of the intervention depends on the interaction between the type and timing of training and the state of the cellular microenvironment. Moving to animal studies, she examined the source of inflammation and this appears to come from the peripheral bone marrow cells. This helped to identify a potential target; peripheral inflammatory sources may be more effective than targeting epicenter inflammation.

This leads to clinical applications for persons who are non-responders. There is a need to consider the timing of the intervention. There is also a potential to monitor peripheral inflammation and to train more specifically to the task. In response to questions, Dr. Basso noted that it is difficult to predict who will or will not walk following injury, and that it is also difficult to study walking and standing in those who cannot walk or stand. There are also challenges in outcome measures for clinical studies. Also in response to questions, Dr. Basso noted that the lumbar spine changes are bilateral, but the injury is in the central core. The inflammatory response is different in the cervical cord as there is no evidence of heightened inflammation there.

Neuroplasticity in Rehabilitation

Monica Perez, Ph.D., PT

Associate Professor

Department of Neurological Surgery

The Miami Project to Cure Paralysis

University of Miami

Dr. Perez discussed how the brain and spinal cord manage movement and how to use these mechanisms to guide therapeutic interventions. Her focus is on corticospinal tract (CST), the major descending tract involved in control of movement. The plasticity of this tract may benefit recovery, and in humans one can assess activity in this pathway with electrophysiology. She discussed how to assess transmission within the pathway and gave examples of plasticity.

Using transcranial direct current stimulation (tDCS) positioned on the surface of the skull, one can activate the CST and create a motor evoked potential. If one stimulates at the pyramidal decussation, one can evoke a biphasic response. If one stimulates motor axons at the cervical anterior root and at the ulnar nerve it will evoke different motor responses. tDCS directs currents in different positions and the handle position can change with different thresholds. Given the angle and amplitude, one can detect changes in the organization of the pathways. She then presented group data from individuals with SCI that demonstrated that the amplitude of the signal is decreased. At the first peak there is no delay in latency of response, but after the second and third stimulation, there are longer latencies. The duration of the response is more pronounced, with longer temporal delay and the response lasts longer.

Dr. Perez then discussed recent research that demonstrates the ways in which investigators can examine plasticity using tDCS. She emphasized the need to select a single mechanism, target it, and then demonstrate proof of principle. In addition, she outlined how to study a targeted intervention in the spinal cord and monitor activity. She emphasized the need to verify what the intervention is doing, at what level the intervention is targeted, and what the distinct responses are with the different parameters (e.g., single pulse vs. combined pulse). She further discussed how to look at stimulation and functional improvement on specific voluntary tasks.

Dr. Perez reached two conclusions: 1) targeted plasticity can improve function for people with SCI but we first need to understand the mechanisms; 2) to monitor mechanisms, non-invasive electrophysiology can be used. In response to a question regarding changes in the cortex as a result of tDCS and its effect on post-injury plasticity or leveraging post-injury plasticity to increase effect, Dr. Perez noted that the studies are in chronic phase and that it would be interesting to look at this longitudinally. When asked if these therapies are ready for clinical use and application, Dr. Perez noted that we can get activation in multiple muscles, but until we understand mechanisms it would be difficult to guide therapy.

Regenerative Rehabilitation

Michael L. Boninger, M.D.

Professor and Endowed Chair

University of Pittsburgh Medical Center

Department of Physical Medicine and Rehabilitation

Director

University of Pittsburgh Medical Center Rehabilitation Institute

Dr. Boninger started his presentation by noting that he would discuss a conceptual model related to regenerative rehabilitation. He introduced the initial excitement that surrounded stem cells that started with Christopher Reeve and his proposal that it could be used for spinal cord injury. Dr. Boninger noted that stem cells can be used, but there are multiple problems including differentiation in the local environment, migration of the cells, engrafting, and function in the environment with little evidence of functional gain.

However, he pivoted to an interesting development. Therese Ambrosia started to work in vitro through regenerative medicine techniques to create living, functional tissue to repair or replace tissue or organ function. Integration of that tissue could increase the efficacy of recovery. There were studies that looked at the combination of neuromuscular electrical stimulation to enhance the efficacy of therapies for muscular dystrophy, specifically on the number of dystrophin positive fibers and major histocompatibility complex positive fibers. He cited other examples of combination therapies using exercise in combination with stem cells in traumatic brain injury and stroke with improvement in

neurologic function. It appears that adding rehabilitation interventions to regenerative therapies enhances recovery.

Dr. Boninger then described a project from his lab, using extracellular matrix implantation in combination with exercise to enhance functional recovery after volumetric muscle loss. With a large volume injury like traumatic amputation, simply injecting cells cannot do the job. Attaching an extracellular matrix to viable tissue and casting it, produces no integration. However, functional improvement occurred in an individual controlled trial in which investigators inserted the matrix and exercised in recovery.

Citing the work of Todd McDevitt's 3-D microstructures for stem cell growth and Tom Rando's in vivo bioluminescence in mice to look at the response of stem cell activity, Dr. Boninger said that regenerative rehabilitation must model exercise or physical therapy in vitro and in vivo. In addition, more individuals must come into the field and apply for grants using these approaches. He highlighted the availability of resources through the Alliance for Regenerative Rehabilitation Research and Training.

In response to questions, Dr. Boninger noted that it is important to get basic science researchers who are engaged in stem cell work to be interested in rehabilitation. Scientists need to pay attention to the routine being incorporated after the implantation. What is happening when scientists move from animal to clinical studies where expertise from stem cell and rehabilitation scientists are combined?

Discussion

The panel discussed the challenge of when to move these methods into human studies or into populations of individual with more chronic injury. They noted that this depends on the level of intervention, the amount of scientific evidence, and the chronicity of the injury. Many of the studies are still in mice and at the acute injury stage. There was also a discussion of the ability to conduct these studies in humans and whether they should be done in humans. One solution is educating patients about levels of evidence for intervention therapies in early stages so they can make informed decisions. In addition, FDA is working to get human studies done sooner and is developing fast tracks for consideration of safety and efficacy. There was also a discussion about the timing of the intervention and how it affects effectiveness. The panel noted that the window of effectiveness has to be defined.

Audience members said that there is a need to look at these interventions in multiple species. In addition, there was a discussion of the mechanisms of training. If there is no understanding of the interaction between training and function and healthy and impaired conditions it would be difficult to replicate. The panel noted that sometimes understanding the mechanism is less critical if the intervention works. The audience also asked the panel to define plasticity. The panel answered that plasticity involves changes to the cellular structure and/or function that be adaptive and/or maladaptive. Plasticity can be measured in many ways. One could also define plasticity as temporary

changes in excitability and outcome; the difficulty is there is no understanding of the effect of the timing of the intervention and type of intervention.

Bending the Arc of Technology Toward Rehabilitation and Health

Moderator: Aiko Thompson, Ph.D.

Associate Professor

Medical University of South Carolina

Dr. Thompson introduced the session by demonstrating a need for continuum of care using new strategies for remote rehabilitation training. This would be illustrated by the talks within the session including telerehabilitation (provider directed care), eHealth (telecoaching with interaction with a provider), and mHealth (self-directed care with potential access to a telecoach). These techniques provide rehabilitation and health care opportunities for patients including equity, access, and patient empowerment. Electronic health approaches are changing what is possible and making us rethink what could be possible. The full potential of telehealth, eHealth, or mHealth technologies to reach a large number of people with disabilities who exhibit a range of physical and psychosocial secondary health conditions has yet to be realized. The expansion of smartphone use and app design is placing sophisticated rehabilitation interventions in the hands of individuals with disabilities.

Going to the Home: Telerehabilitation Research

Steven Cramer, M.D.

Professor, Neurology, Anatomy, Neurobiology, and Physical Medicine and Rehabilitation

Clinical Director, Sue and Bill Gross Stem Cell Research Center

Associate Director, Institute for Clinical and Translational Sciences

University of California, Irvine

StrokeNet, funded by the National Institute of Neurological Disease and Stroke, is providing an unprecedented opportunity for stroke rehabilitation research. Currently, most medical care for stroke is provided in the emergency room in the first hour. However, only 5 percent of patients receive tissue plasminogen activator. Now the focus needs to be on the 95 percent who do not get these treatments. Dr. Cramer noted that the post-stroke brain is ready to learn; based on animal models there is a great deal of plasticity. At this point, 44 percent of patients leave the hospital having received no therapy or low-intensity therapy, they return to an area where they have no access to therapy, and they do not comply with the home exercise they are given. What is critical is monitoring compliance to the exercises. The newly funded TeleRehab project is a non-inferiority design trial, meaning that the telerehabilitation intervention is not inferior to standard care. The trial allows for variability so that one can match the right therapy to the right patient.

REHABILITATION RESEARCH AT NIH
MOVING THE FIELD FORWARD

Research, Technology Development, and Business Opportunities

James Rimmer, Ph.D.

Director

Lakeshore Foundation and University of Alabama at Birmingham Research Collaborative

Endowed Chair

Health Promotion and Rehabilitation Sciences

Dr. Rimmer started by discussing the necessity of health promotion in individuals with disability which the traditional system of rehabilitation care does not provide. In 2009, the U.S. National Council on Disability concluded that “significant architectural and programmatic accessibility barriers remain, and health care providers continue to lack awareness about steps necessary to ensure that individuals with disabilities have access to appropriate, culturally competent care.” This provides an opportunity to integrate health and fitness into the system given the availability of fitness centers and the potential for social connection through these programs.

The gaps that need to be filled for individuals with disabilities are changing the emphasis of care to self-care and the development of partnerships between the individual and provider. These gaps are also stimulating the development of eHealth/mHealth platforms that are customized for people with physical, cognitive, or sensory disabilities. There is a need to ensure that specific energy intake requirements or recovery from illness, or identification and mitigation of potential barriers are in these platforms. Dr. Rimmer discussed the potential use of big data and nontraditional sources of data (Twitter, Google search) for disease surveillance and for clinical interaction. Telehealth encompasses preventive, promotive, and curative aspects. Telerehabilitation involves delivery of rehabilitation services over telecommunication networks and the internet with the services falling into two categories: clinical assessment and clinical therapy.

The question is how to get beyond the plateau of recovery; exercise is important to achieving that. Dr. Rimmer stressed that technology can help compensate for shorter lengths of stay in rehabilitation hospitals and help to continue sustainable community exercise. Another question is how to help people learn to manage their own health in the community. This involves a transition from rehabilitation provider to telecoach to trainer. Dr. Rimmer discussed a study funded by the National Institute on Disability, Independent Living, and Rehabilitation Research the Telehealth Exercise Training for Monitoring and Evaluation of Home-based Exercise (TEXT-ME) study, which is a telehealth exercise training study to demonstrate safety and feasibility. Because of the availability of current technologies that can measure heart rate, blood pressure, respiratory rate, temperature, weight, glucose, other blood chemistries and physical activity and the ability of those devices to transmit to the provider, there is a great deal that can be done in the community. The benefits of these approaches include reduced barriers related to travel and time, increased confidence and reduced fear of being in the community.

Putting Rehabilitation in the Hands of Consumers

Susan Magasi, Ph.D.

Assistant Professor

Department of Occupational Therapy

University of Chicago

The challenge of living with a disability does not end with functional improvements; there is an ongoing need for long-term, community-based supports. Dr. Magasi noted that the field of mHealth allows the community to capitalize on mainstream technologies and innovation. The World Health Organization defines mHealth as “medical and public health practice supported by mobile devices such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices.” The goal for this is to put tools for living in the hands of consumers for symptom monitoring, real-time data capture, real-time navigation, and to monitor their environmental barriers, support, and social connectedness. There is a tremendous amount of accumulated knowledge in the disability community but there is not a lot that is evidence-based. The results of literature reviews are promising, and Dr. Magasi discussed the preliminary findings from meta-analysis of 462 articles. Generally there is a strong bias towards exercise-based interventions with telemonitoring, and an emphasis on cardiac, pulmonary, and stroke rehabilitation. There are promising results from trials but they are not robust. There is limited evidence for mental health, social support, and cognitive rehabilitation, and there is a lack of interdisciplinary focus.

An app takes advantage of the platform, but the context is the science. The development should be iterative and collaborative and the app should be used to enhance and augment rehabilitation. There are specific barriers to mHealth use including limited scientific evidence; lack of integration to support clinical decision making; limited connectivity and integration into workflow; slow paradigm for reimbursement; concerns over data confidentiality, privacy and security; and a continued need to bridge the digital divide. Dr. Magasi emphasized a hallmark of the development of these apps is the emphasis on community-identified needs and priorities and early and ongoing attention to access and accessibility.

With respect to access, according to the Pew Research Center, nearly two-thirds of Americans have a smartphone and for 10 percent of individuals who own a smartphone have no other form of high-speed internet access. Sixty-two percent of smartphone owners use their phone to get health information, with higher rates among young adults. Certain populations, for example African-Americans and Hispanics, are more likely to have a cellphone but do not have high-speed subscriptions. There are underserved populations that have to be considered in developing mHealth applications.

Dr. Magasi concluded by noting the tremendous potential for mHealth to expand rehabilitation and address community identified needs. She identified a need for effectiveness research to build confidence in referrals and support reimbursement. There is a need for greater integration with health

care providers and systems and a need to capitalize on the full functionality of mHealth applications. She finished by pointing out the paramount importance of data privacy, consumer safety, and accessibility.

Panel Discussion

The panel discussed how the use of information and communication technologies eliminates distance barriers and can make rehabilitation and health care services available to people who have limited access to transportation or have other access issues. In recent years, digital health (e.g., telehealth, telerehabilitation, eHealth, and mHealth) has become a significant part of health care and the health care economy. Digital health funding has been steadily increasing. Tools for developing and implementing mobile health care services and research applications are becoming more available. It is clear that the use of information and communication technologies can broaden rehabilitation and health care research opportunities for researchers, and serve as opportunities for patients. In this session, the panel speakers described three levels of remote rehabilitation training management: full management (by health care professions), middle-level management, and self-management (by patients). These different levels are not mutually exclusive, but allow the patient to transition from one level of management to another based on progress in recovery and changes in needs for care and services.

Dr. Cramer emphasized that many patients do not receive enough doses of rehabilitation therapy after stroke. He presented his pilot study and ongoing clinical trial on a home-based telerehabilitation system for patients with stroke and said that telerehabilitation is ideally suited to maximize the gains from therapy. For example, telerehabilitation can increase the duration and intensity of therapy and therefore contribute to greater functional gains. Telerehabilitation also offers the option for a holistic approach to patient care, for example, incorporating education, sensor data collection, and regular structured interactions with therapists.

Dr. Rimmer discussed the contribution of eHealth and mHealth to health promotion. With eHealth and mHealth, the emphasis is on self-care rather than expert care. In furthering the view that digital health technologies can help to overcome existing healthcare problems (e.g., lack of integration and coordination across different disciplines and accessibility barriers), he suggested that telerehabilitation may prevent well-known post-rehabilitation health decline as the patient transitions from dependence to independence. He presented preliminary findings from his ongoing project, "TEXT-ME and pointed out that home-based teleexercise interventions can achieve better participant adherence than conventional onsite exercise programs, leading to better health benefits. Participants in this teleexercise program reported that the convenience and online interaction with a telecoach enhanced their motivation to attend the sessions. This telecoaching (i.e., mid-management) model may become a precursor to self-management and mHealth for optimizing recovery in people with neuromuscular disability.

Dr. Magasi reviewed how the expansion of smartphone use and the app design is literally placing sophisticated rehabilitation interventions in the hands of people with disabilities. Potential of mRehab applications include symptom monitoring, real-time data capture, real-time access to information about navigating the community, social connectedness through peer-to-peer support, and bidirectional communication. However, there exist barriers to use of mHealth, such as limited scientific evidence, lack of integration of multiple perspectives and disciplines into workflow, concerns over data confidentiality, privacy and security, and lack of provisions for reimbursement. Of particular concern for the disability community is how factors at the human-technology interface can impose barriers to use. She emphasized that an iterative inter-disciplinary design process that brings together content accessibility and information technology experts and people with disabilities can help ensure the needs and priorities of the disability community (including accessibility and usability of mRehab interventions) are integrated throughout the app development.

Implications and Gaps: After acquiring a disability, many patients are unable to receive the optimal amount of rehabilitation and healthcare services due to a number of challenging barriers. With continuing growth in the internet and use of smartphones, the development of digital health applications can significantly broaden rehabilitation and healthcare opportunities for patients. The full potential of digital health technologies to reach a large number of people with disabilities who exhibit a range of physical and psychosocial secondary health conditions and provide them with effective dose of interventions has yet to be realized.

Transitions Across the Lifespan

Moderator: Walter Frontera, M.D., Ph.D.

*Chair and Professor, Physical Medicine and Rehabilitation
Vanderbilt University*

Medical Director, Rehabilitation Services

Vanderbilt Stallworth Rehabilitation Hospital

Dr. Frontera provided a brief introduction of the session and speakers.

Implementation Science: Using Rigorous Scientific Designs and Methods to Move from Efficacy Evidence to Effective Clinical Implementation

Sharon Landesman Ramey, Ph.D.

Professor and Distinguished Research Scholar

Virginia Tech Carilion Research Institute

Research Professor, Psychology

Virginia Tech

Professor of Psychiatry and Behavioral Medicine

Virginia Tech Carilion School of Medicine

Dr. Ramey introduced the topic of implementation science as the least studied but potentially most impactful branch of the translational science framework. She began with the main question of how to increase the number of implementation science trials to advance the field. This does not fall into the regular trials framework of safety monitoring or effectiveness of the therapy. This approach investigates obstacles that impede effective implementation of effective therapies, identifies facilitators that promote implementation, and tests new approaches to improve health care delivery. Dr. Ramey emphasized the need for treatment fidelity, the degree to which the treatment delivered to patients matches the treatment specifications from the tested protocol. This requires a guide on training clinicians, a way to monitor clinical performance, and methods to address planned deviations in the treatment to potentially derive extra benefit without compromising expected benefits.

Implementation science approaches can maximize the ability to look at the economics of the approach and the effect of health disparities on adoption of effective treatments. This approach allows for the rapid adoption of high-fidelity science to put research into practice. This requires two things of the field: 1) that clinicians be willing to drop current practice or the “innocuous treatment,” and 2) that the scientific community explore barriers and obstacles to implementation and disseminate the results of fidelity and implementation measures so efficacy can be demonstrated.

Self-surveillance and Integrated Health Care: Transition to Adulthood

Ellen Giarelli, Ed.D., RN, CNRP

Associate Professor

Drexel University

Dr. Giarelli began by placing chronic disorders or illnesses in the context of rehabilitation and discussing how self-management can be a major component of rehabilitation. She noted that her examples would concentrate on Marfan’s syndrome (MFS) and Autism Spectrum Disorder (ASD).

MFS is a complex disorder that leads to functional deficits that benefit from rehabilitation, especially at the early stages following diagnosis. However, there is a need to constantly monitor symptoms and look

for long-term effects or changes in specific symptoms (e.g., prevention of bone injury, care of joints, and cardiovascular symptoms). Self-management allows people with MFS to recover faster with better prognosis and to use self-monitoring to record observations of their symptoms and potentially help them to interpret these observations.

For life-long disorders like ASD that have significant impact on health and well-being with multiple etiologies, there is a need for strategies to be multi-factorial. These disorders need to be thought of as long-term with a focus on adaptation instead of recovery. Information from an integrated team of professionals is required. The most important aspect of this is to target transitions of care. Success in transitioning relies on believing the diagnosis, wanting to know or understand the symptoms, and willingness of the provider and the patient to share problem solving. There is a need to determine obstacles for the person with the disorder, the parent or family, and within the system of care. Dr. Giarelli noted that there are areas of focus that enable transition, including what to monitor and when to report changes. She provided an overview of measures used to assess and promote self-surveillance that were developed through in-depth interviews. These interviews were specific to MFS, but the concepts could be extended. She then concluded with practical tips for youth at transition age for income supports, health care coverage, and vocational and educational supports that should be considered in research programs to determine how they can be used to enable success.

Enhanced Medical Rehabilitation

Eric Lenze, M.D.

Professor of Psychiatry

Washington University School of Medicine

Through his presentation, Dr. Lenze emphasized that the two main points that need to be considered in rehabilitation are patient engagement and therapy intensity. He noted that in post-acute rehabilitation, which is an incredible period of transition, there is a narrow window of opportunity to regain function or become permanently disabled. He noted that depression is a common finding in this setting but it is hard to measure and conceptualize in the older population because of multiple comorbid conditions that overlap. It is then difficult to determine the best therapy for older to people to use, especially in light of multiple comorbidities.

Dr. Lenze outlined his approach, which combines the science of behavior change and the science of rehabilitation intensity. He posited three principles that underlie this enhanced medical rehabilitation (EMR) approach: 1) the patient is the boss; 2) link therapy activity to goals that the patient identifies and prioritizes; and 3) optimize intensity. Through EMR, Dr. Lenze and colleagues reinforce effort and progress during therapy and use a systematic depiction of progress to talk with patients. This helps the patient to see progress and get and give feedback, which enhances patient engagement. He presented the status of their ongoing R01 project to test the effectiveness of EMR vs. standard-of-care therapy.

This is focused on patients in skilled nursing facilities at the post-acute phase. The project uses the clinical staff at those facilities and monitors for adherence and competence to the approach. Initial results are promising. Dr. Lenze concluded by noting that clinicians can use these techniques to increase patient engagement and increase therapy intensity.

Panel Discussion

The panel was asked about goal setting. There was a discussion of how to change medical understanding, not just to therapy, to ensure appropriate goal setting and engagement in therapy. This leads to differences in motivation for the patient and may tie in with care delivery models. There was also a discussion of how there is too much information provided to the patient during discharge from acute care and that more appropriate transitions of care and timing of information sharing might benefit the patient. There was a discussion of how to hear the voice of the patient and important caregivers, both in pediatric patients and the elderly. For diseases that start early in life the panel discussed the need to follow-up with patients throughout adulthood to determine if the therapy provided was effective. There also needed to be a consideration of the major barriers that had to be overcome to plan effective therapy.

The therapy setting was discussed in detail as it related to adherence in trials or in treatment. There was a conversation related to the patient's ability to identify the purpose of the rehabilitation intervention. Others pointed out that motivation might be a factor in adherence at that point in the rehabilitation process. However, the panel pointed out that specific barriers might affect adherence (e.g., transportation, time) or it might be an implementation problem (not using behavior change techniques). The challenge is to do research involving multi-disciplinary teams that can consider transition issues and identify methods to help in transitions of care or transitions due to age. This includes what motivational techniques are best to affect behavior change, how self-evaluation and management assist, what technologies can be used to assist in transition, and the need to engage patients in the research so they have a personal stake in it. The final discussion related to setting was related to where the research took place (clinic, community, home) and how it affects patient engagement and therapy outcome.

The panel concluded with a discussion of how to use proven conceptual theories from other disciplines to help with rehabilitation research. For example, are there methods from behavioral economics that would benefit rehabilitation? Further, the discussion considered the need for standardization of terms and definitions so that if new approaches or methods are adopted, they are universally understood. This would also help to facilitate replication of studies, evidence-based practice studies, and to facilitate partnerships with systems to help with implementation research.

Novel Outcomes in Rehabilitation and Integration into Clinical Care

Moderator: Jonathan Bean, M.D., M.P.H.

Director

VA New England Geriatric Research Education and Clinical Center

Associate Professor, Department of Physical Medicine and Rehabilitation

Harvard Medical School

Dr. Bean highlighted the clinical and scientific relevance of developing novel outcomes in rehabilitation and its potential to favorably impact the changing health care environment. Health care reform and the shifting emphasis on managing health have been coupled with exceptional growth and development in the application of technology and engineering to health measurement. As the mobile health field and technologies evolve, researchers will continually be presented with challenges in the conceptual design and deployment of clinical trials as well as the conduct of clinical care due to the vast array of outcome measures that can be collected.

Interactive Mobile Health and Rehabilitation (iMHere)

Brad Dicianno, M.D.

Associate Professor, Department of Physical Medicine and Rehabilitation

University of Pittsburgh School of Medicine

Dr. Michael Boninger presented the work of Dr. Brad Dicianno on the iMHere system as an example of a mobile health system being used to collect ecological momentary assessment outcomes data from patients with spina bifida. He discussed the functionality required for these types of systems: reminders, medication management, photos for transmission, symptom reporting, and secure messaging. The presentation provided an overview of the facets of the application and the clinician portal. Results from an early feasibility trial were promising with improvements noted in independence and self-management, especially for skin care and bowel and bladder care. Wearable sensors monitoring different aspects of health are becoming more widely used in rehabilitation research as a method of capturing real-world outcomes. He discussed the opportunities and challenges in this research. Finally, Dr. Dicianno's presentation included a discussion of the limitations and opportunities in this area of research including the constant changes in technology, the amount of user reminders that should be provided, how to manage the amount of data collected, and the need for secure data transmission.

Sensor-Based Outcomes

Melissa Morrow, Ph.D.

Assistant Professor, Biomedical Engineering

Mayo Clinic Center for the Science of Health Care Delivery

Dr. Morrow presented her work on sensor-based outcomes used in SCI rehabilitation research and explored the challenges of integrating this “big data” into clinical practice. She provided an overview of wearable sensors and the contrast of active versus passive monitoring of the user and the impact this may have on rehabilitation care. As a case example, she reviewed her project to monitor shoulder pathology in individuals who use manual wheelchairs that uses MRI, motion sensors on the shoulder, and iGlove to track forces at the hand. She then demonstrated how these data could be used to track susceptibility to shoulder injury. She further detailed the potential use of pressure sensors on wheelchair cushions in conjunction with an app that provides feedback to the wheelchair user on pressure distribution, peaks, and average to prevent pressure sores. She concluded by discussing how these technologies could or should be integrated into clinical practice and the need for user centered design of data visualization from these systems to optimize the data they generate for the user.

Patient-Reported Outcomes (PROs) for Distinct Clinical Populations

Brian Hafner, Ph.D.

Associate Professor, Rehabilitation Medicine

University of Washington

Dr. Brian Hafner discussed how new approaches to outcomes measurement have also been applied to the development of patient-reported outcomes. This included a discussion of computerized adaptive testing formats that feature calibrated item banks that can be modified and tailored for specific settings and fixed-length short forms for use in rehabilitation research. National initiatives, like the Patient Reported Outcomes Measurement Information System (PROMIS), have resulted in rigorous frameworks for developing PROs that can evaluate health outcomes across different patient populations. Efforts using these same methods to develop an item bank to measure prosthetic mobility in people with lower-limb loss were described. This included advisory panels, review of existing PROs items, focus groups, large-scale administration, item response theory analyses, development of short forms, and validity and reliability studies for the instrument. Dr. Hafner concluded with the limitations inherent in PROs research, including limitations in knowledge and experience in selecting, administering, and interpreting these measures and challenges to integration of these measures into existing information technology systems. The opportunity to use these measures to evaluate practice efficiency, clinical decision-making, and cost-effectiveness is large, but more efforts are needed to help to integrate these measures into practice.

Panel Discussion

The panel discussion identified a number of issues and challenges. These included general issues such as: 1) the importance of developing a consolidated infrastructure, be that through industry partnerships or academic hubs; 2) using that infrastructure to develop systems that integrate mHealth, wearables, and PROs in ways that optimize assessment and monitoring; 3) developing strategies to integrate these

data elements into measurement systems with which patients and clinicians can optimally engage and interact; and 4) in which the resulting data can then be integrated into the electronic medical record. Specific needs that were discussed included: 1) developing “standards” or “best practices” for wearable sensor technology akin to what PROMIS had done for PROs; 2) developing strategies for extracting the “most important” data from wearable sensors and presenting them in a way that is appropriate for the stakeholder (patients, practitioners, payers); and 3) using these approaches for more optimal management of self-care and thus relieving clinicians of the burden created by interpreting and processing high volumes of data. Lastly, integrated leadership in addressing these concerns was viewed as a priority for NIH, especially in cooperation with other relevant agencies such as PCORI, the Agency for Healthcare Research and Quality, or the Veterans Health Administration.

Using Data to Drive Discovery

Moderator: Ken Ottenbacher, Ph.D.

Russell Shearn Moody Distinguished Chair in Neurological Rehabilitation

Professor and Director, Division of Rehabilitation Sciences

Director, Center for Recovery, Physical Activity and Nutrition

University of Texas Medical Branch at Galveston

Dr. Ottenbacher began by introducing the concept of big data, which is complex and challenging but presents new opportunities for combining analyses. Secondary analysis is helpful for answering questions and for producing hypotheses. He contrasted large data vs. big data by noting that big data is more complex, combining multiple types of data versus data from a single discipline, which would be considered large data. It is critical when using this data to understand the methodology used to collect the data and the methods required to combine them. There is support available to help researchers learn these approaches including from the NCMRR-funded University of Texas Medical Branch Center for Large Data Research and Data Sharing in Rehabilitation (CLDR). This Center makes data from large sources available for analysis, and provides support for investigators to conduct these analyses. The Center also supports researchers in other ways through courses, workshops, and webinars; data sharing and archiving opportunities; pilot projects; visiting scholar programs; and a rehabilitation data directory. More broadly, NIH recognizes the potential that exists in using existing and accumulating data and has instituted the [Big Data to Knowledge](#) (BD2K) to provide the research community with access to the expertise needed. In addition, [PCORI](#) is a robust non-profit, nongovernmental organization that provides quality research evidence to inform health decisions. PCORI offers a variety of research opportunities. Finally, NICHD hosts the [Data and Specimen Hub](#) (DASH) which is a repository for clinical trials data from NICHD-funded grants and contracts. Data sharing will be a requirement for future grants at NIH, and these resources will be of use to our investigators.

Using Publicly Available Data to Enable Discovery

James Graham, D.C., Ph.D.

Associate Professor, Division of Rehabilitation Sciences

University of Texas Medical Branch at Galveston

Exploration of administrative data (electronic medical records, insurance, and census data) is an opportunity for rehabilitation research, and offers a window into what is going on in practice. CLDR and other specialized centers offer the 3 As of data: accessing, analyzing, and archiving. Much of the data used in this work is stored in central repositories and there are often links to other data sources. A skilled team of investigators that include a computer programmer, statisticians, and potentially economists who can explore cost data are necessary for this work. Given the new federal requirements for data sharing, it is best for investigators to understand these policies and the need for a robust team to respond to them. In planning for data sharing it is critical to provide supporting information, including data dictionaries and protocols to allow for secondary use of data by other investigators in a precise and reproducible manner. There are challenges in data sharing, including funding and expertise. Dr. Graham discussed the use of administrative databases for secondary analyses, and the opportunity for researchers to access key drivers of health and cost which potentially include patients' social, environmental, and cultural factors. The conclusions from secondary analyses may be different from those of trials, but the analyses offer the opportunity to test hypotheses about practices and populations, do comparative effectiveness studies, look for morbidities, or perform longitudinal studies. As data science becomes a greater part of rehabilitation research and applications for funding, NIH will need expertise on study sections, and program interest in fostering this area of science.

Using Big Data for Insight: Data Science and Biomechanics for Gait Rehabilitation

Jennifer Hicks, Ph.D.

Director of Data Science, Mobilize Center

Associate Director, National Center for Simulation in Rehabilitation Research

Senior Research Engineer, Department of Bioengineering

Stanford University

Dr. Hicks began by providing an overview of the resources available for investigators to access and use large data relating to musculoskeletal modeling and dynamic simulation through the National Center for Simulation in Rehabilitation Research (NCSRR). Biomechanical data involves large data sets and modeling the data presents opportunities to focus on critical areas for possible intervention. NCSRR shares data and tools to assess the large amounts of data coming in about motion and mobility from phones, wearables, and other devices or systems. The hallmark of the program at NCSRR is the freely available simulation tool, OpenSim, which allows users to assess movement and create kinematic

models. The Center offers a visiting scholars program, as well as workshops, seminars, and pilot grants. Another resource at Stanford is the Mobilize Center whose mission is to improve movement by analyzing data about human movement. This effort combines heterogeneous data and creates tools to perform the analysis. Dr. Hicks provided an example of a project in this center examining archived data from treatment planning with children with cerebral palsy to determine factors that define individuals and how they move. These approaches can identify the phases of pathology in cerebral palsy (CP), for example, crouched gait or success of surgical treatments. In the examples provided, Dr. Hicks provided an overview of individual prediction models based on biomechanics and how to predict movement patterns after surgery. Dr. Hicks provided a final example of a large dataset that used worldwide data from wearable devices to examine patterns of activity and obesity.

Using Health Care Systems Data to Empower Research

Adrian Hernandez, M.D.

Director, Health Services and Outcomes Research

Duke Clinical Research Institute

The NIH Health Care Systems Research Collaboratory is led by Dr. Hernandez. He outlined the opportunities available for researchers to take advantage of this Center including weekly grand rounds and participation in clinical trials. The Collaboratory aims to replace a health system that may rely on “the art of medicine,” not data, by gathering and providing data about real-world health outcomes. The current research system is not fast or efficient enough, with long waits for applications, review, and funding. Everything in clinical research is expensive and unwieldy. The Collaboratory seeks not only to answer questions but also to determine how to translate valuable data into practical solutions. Systems (health, research, payment) are changing; data are available and becoming more linked. Complexity has produced the “system-ness of care.” There are multiple entities that impact the patient so it is necessary to do research in practice. Pragmatic randomized trials are based in the system, with health care systems serving as the source of data. In trials, researchers must consider severity of illness, systems of care, and methods of intervention. Alternative trial designs used by the Collaboratory include: cluster randomized trials (randomization of clinics, hospitals), and stepped wedge design (testing time of introduction of treatment). The Collaboratory can see 200,000 patients by randomizing 200 systems at an average cost of \$1500 per patient. Because the practices define the research, outcomes line up to health systems’ interest. The Collaboratory recognizes that the clinician is critical because they enter data so workflow and information technology integration must be maintained. Another large-scale, community research effort aimed at better health care decisions is The National Patient-Centered Clinical Research Network (PCORnet). Funded by PCORI, PCORnet will be a community of research that includes health systems and patients who will participate in observational studies. The goal is to map a common data model to make a common language that can link to other data. Researchers can query the data center for information, and responses would be sent back with the data staying protected in the system, reducing the intellectual property and security risks. These data will be available in July of 2016.

This has inspired a new model for clinical trials that eliminates the need for special visits and dramatically reduces cost and time. The first trial to use the system, Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-term Effectiveness (ADAPTABLE), is a trial to examine the use of aspirin in heart disease.

Panel Discussion

The panel began with a question from the audience regarding how to fund this type of research, especially use of PCORNet and the NCMRR-funded Centers. There was discussion of the limitations of systems to provide preliminary data because of the number of potential requests and an outline of the availability of pilot funding from the Centers. This was followed by a question regarding the interaction of these systems with big health systems. The panel noted that the common data model is becoming more attractive and the participation of the big health care systems in these types of projects is changing the landscape of health systems research. The challenge of standardization of measures and differences in data and data systems that raise barriers to combining data was raised by an audience member. The panel noted that it is difficult to standardize health care delivery for prospective studies. Standardizing common data models is one potential solution to this problem. There was a discussion of the standards used by the wearable community and how that can assist with standardization. Finally, administrative data sets were noted to have a common data model but in that venue the challenge is harmonizing measures across data sets. Finally, a question was raised about how to address the policy challenges inherent in this type of research. The panel noted that researchers needed to work with their health systems to integrate research and to make it a win/win proposition. The panel suggested that there should be a movement to standardize functional measures across settings and identify the most useful measures for rehabilitation research.

Preventing Secondary Disability

*Moderator: Diane Damiano, Ph.D., PT
Department of Rehabilitation Medicine
National Institutes of Health*

Dr. Damiano began the presentation by using the example of CP and a discussion of their primary symptoms versus problems caused by secondary adaptations. She discussed implications of developmental disorders versus adult-onset disorders. In children with CP, muscles fail to develop normally, bones fail to develop tensile and compressive strength, and the brain is given fewer options for developing appropriate connections or pathways to facilitate movement. There are changes in bone density with age and significant functional decline for people with CP as they move into adulthood. It becomes harder to move muscles and these muscles progressively weaken with inactivity. Dr. Damiano outlined the relationship of muscle structure to motor outcomes. She noted that there was a need to take advantage of early plasticity in infants and children and promote activity early to enhance the

ability of individuals with CP to move later in life. In adulthood, people with CP are less active at follow-up than before 18 years of age. This leads to “normal weight obesity,” higher prevalence of cardiovascular risk factors, and higher levels of fatigue, essentially contributing to an early aging process. The key in preventing these developments is activity, using strength training to address specific muscle groups, and incorporating functional electrical stimulation to assist movement. There is a need to identify how to use activity to preserve joints, reduce pain, and not weaken muscles. To prevent the adult consequences and secondary disability they may cause, Dr. Damiano suggested strategies to reduce the barriers to exercise, increase availability and access to activity, and to research novel treatments that would prevent early maladaptive plasticity or prevent further weakening of muscle. She highlighted the potential of certain technologies to integrate into training and maintenance of function. She concluded by highlighting gaps and opportunities in this area and by introducing the panel speakers.

Preventing Secondary Disability in Older Adults with Chronic Low Back Pain

Gregory Hicks, Ph.D., PT

*Chair and Associate Professor, Department of Physical Therapy
University of Delaware*

Dr. Hicks began with a discussion of the incidence and prevalence of chronic pain in the United States with a specific focus on lower back pain in the elderly (defined as 75 years of age or older). He outlined data that demonstrates increased costs for these patients are driven not by rehabilitation, but by diagnostic imaging. Advanced age is a risk factor for under-treatment of pain and there are significant knowledge gaps related to optimal pain treatments for older adults due to exclusion of older patients from studies and societal attitudes that pain is a part of aging. He reminded the audience that assumption that function is limited by pain is not absolute. There is a link between pain and function, but it appears that from longitudinal studies, function decreases over time with a steeper decline for those with moderate-to-extreme back pain versus mild-to-no back pain. The goal of the research should be to focus on function in the management of pain. Dr. Hicks noted that there was a need to identify modifiable impairments associated with pain and physical function in older adults with chronic low back pain. Looking at body composition, trunk muscle attenuation decreased with increased pain and there was notable fat infiltration in trunk muscles. In the study he described, poor trunk muscle composition led to worse function three years later. He then outlined a study that examined exercise and low back pain, with a specific focus on Type II fiber atrophy, using an exercise intervention compared with a passive control that received massage, heat, and ultrasound. This study found meaningful change with both groups reporting pain relief, but functional changes and gait speed were noted in the active group. In summary, Dr. Hicks noted that there was improved function with training of the trunk muscles, that pain reduction alone was not enough. He then considered different sub-groups within the low back pain classification that required attention, including those with hip osteoarthritis or hip and spine

degeneration. He concluded by noting that in many of these studies, the needs and challenges of specific populations, such as older adults, must be considered in the design of the research.

Medicaid Patients in Cardiac Rehabilitation: Characteristics and Participation

Diann E. Gaalema, Ph.D.

Assistant Professor, Department of Psychiatry

University of Vermont, College of Medicine

Dr. Gaalema provided an overview of the effectiveness of cardiac rehabilitation to reduce morbidity and mortality in patients with cardiovascular disease. However, she noted that rates of participation in cardiac rehabilitation are not ideal and withdrawal from the programs is too common. To understand this one needs to look at predictors of attendance. Those less likely to comply are younger and older women, current smokers, and individuals of lower socioeconomic status. Her focus is to examine how to increase attendance for people with lower SES as they have higher cardiac risk profiles, worse prognosis following a cardiac event and they are less likely to make needed behavior changes.

She described a program that provided monetary incentives for individuals of lower SES to participate in cardiac rehabilitation. The average earnings over the course of the study were about \$800. There was a 65 percent increase in attendance for those receiving incentives versus 10 percent for those who did not. That equated to attendance at 25 sessions versus 8 sessions. The incentives group was hospitalized less than the control group. The patients themselves have common characteristics that represent barriers to participation in rehabilitation: 1) younger, working age; 2) high rates of smoking; 3) low levels of fitness; 3) high levels of depression; 4) rural residence, which increase time to clinic. Dr. Gaalema concluded by noting that although the incentive-based treatment was successful, there was a need to address the challenges of continued smoking, increasing access to the service, and to determine why there was limited impact on overall fitness for this population.

Secondary Prevention for Individuals with Disabilities: Lessons from Shoulder Pain after Spinal Cord Injury

Sara Mulroy, Ph.D., PT

Director, Rancho Los Amigos National Rehabilitation Center

Assistant Professor, Biokinesiology and Physical Therapy

University of Southern California

Dr. Mulroy began by noting that conditions that lead to major disability impact multiple systems outside of the primary condition and increase risk for secondary impairment. For individuals with SCI, the shoulders are a significant location for development of pain syndromes with an increasing number of

patients reporting pain over the course of their lives following injury that is linked to functional impairment. The shoulder bears upper extremity weight and there is a significant risk for impingement of subacromial structures. Dr. Mulroy examined the effect of alternative wheelchair set ups and measured the forces from the arm and shoulder using fine-wire intramuscular electrodes to record from deep and superficial muscles. If the wheelchair seat was moved backward, it decreased demands on muscle during the push phase.

Using findings from the Strengthening and Optimal Movements for Painful Shoulders trial, Dr. Mulroy provided an overview of the effectiveness of an exercise and movement optimization program to reduce shoulder pain. The targeted program resulted in a 70 percent reduction in pain for the exercise group over the 12 week program which was sustained 4 weeks post-intervention. She followed this by describing a prospective longitudinal study of shoulder pain onset in individuals with SCI. Following these individuals for 3 years she found that 40 percent of them had onset of shoulder pain. The strongest predictor of pain in the shoulder was weaker shoulder muscles. She provided an overview of the value of the individual experience by providing an overview of studies that guided her to look at change events as predictors of risk for shoulder pain onset. These risk factors include unusual wheelchair propulsion (long distance or novel terrain), return to activity after prolonged bed rest, sudden increases in exercise, or altered wheelchair configuration.

Finally, Dr. Mulroy discussed the use of consumer feedback and real-world measurement. She provided an overview of an alternative wheelchair design that is based on lever drivers rather than push rims. She described the development of a functional performance measure to examine how the individual navigates entering and exiting a car in a wheelchair. She also discussed the utilization of technology to provide a window into everyday life in order to inform prevention programs: wheelchair odometers, ecological momentary assessment delivered by smartphone apps, wireless wrist activity monitors, and other systems. She noted that her latest trial is looking at activity to monitor pain and pain coping strategies, to assess activity level in relation to pain and depression, and to examine avenues for future interventions.

Panel Discussion

The panel covered main themes that included: 1) the need to manage and prevent secondary disability to optimize health and function throughout the lifespan; 2) recognizing the major role of pain in limiting function and mechanisms that lead to pain; 3) involving all, especially those at greater risk, to design rehabilitation programs and to develop strategies to increase access and compliance; 4) leveraging technological advances to enhance measurement of rehabilitation outcomes. A question from the audience was directed at the use of incentives and how that would be integrated into health care policy. There was an acknowledgement that Medicaid has now mandated that incentives be part of research. There was a discussion of lack of access to appropriate facilities for exercise and fitness for individuals with disability and challenges for these individuals with wearable monitoring. The group also discussed

the use of positive feedback to encourage adherence and maintain compliance. The panel noted that it is important to understand the trajectories of people who have different types of problems as their functional status or condition may change over time. There was a follow-on discussion about the intensity of these interventions and how to change the model so that this level of intensity could be maintained over time. Finally, there was a discussion of health disparities and who is not participating in studies and how that can limit the generalizability of the findings.

Town Hall

Audience members were invited to make comments or ask questions during this last session of the meeting. The panelists included Lois A. Tully, Ph.D., of the National Institute of Nursing Research (NINR); Teresa Jones, M.D., from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK); Grace Peng, Ph.D., of the National Institute of Biomedical Imaging and Bioengineering (NIBIB); and Ralph M. Nitkin, Ph.D., of NICHD.

The first commenter said that the research programs discussed contribute to the advancement of science. He suggested that these projects, particularly some of those related to measurement, be translated into practice and be incorporated into future research plans.

An audience member said that he appreciated that there was such a broad range of research interests represented at the conference. Many researchers are working in their own silos and do not have the chance to mix with researchers from other fields. He also was pleased to see that rehabilitation related to auditory disabilities was included. Dr. Nitkin said that incorporating deafness and communication disorders should be part of the field. Cochlear implants are appropriate models for rehabilitation. Dr. Cernich said that one of the purposes of the conference was to connect professionals from different fields to give everybody the broader picture.

A commenter said that she was pleased to see discussions related to outcome measurements and the need to measure across the domains of the ICF. There is too much emphasis on specific mechanisms, but more should relate to functional outcomes. The importance of function to rehabilitation research should be translated into review criteria.

An audience member said that the research plan has helped him broaden his understanding of medical rehabilitation and what is happening in other fields. But he asked whether the plan should address habilitation as well as rehabilitation.

Dr. Nitkin said that habilitation is addressed in the plan, especially in terms of treating developmental conditions or preventing secondary conditions. NCMRR is aware of the need to support people who have undergone cancer treatments. He promised to revisit the plan to ensure that habilitation is clearly a part of the plan. Dr. Cernich said that the issue was also raised during the discussion following the

Same Sky Project performance. Those panelists mentioned early intervention, optimization, habilitation, and rehabilitation. There is an issue of nomenclature. It is important to understand what the terms mean and then to ensure they are within the NCMRR mandate, which is medical rehabilitation research.

A question via Twitter asked whether physical activity to treat chronic conditions is considered medical rehabilitation. Dr. Cernich said that physical activity is in the research plan. Physical activity is an effective way to keep people active, it positively affects health, and it improves function, so it is important.

A comment from the audience was that qualitative research, which involves human subjects, is not as easily quantifiable as animal research, but it is a valid tool and should be a part of the research plan. Dr. Peng said that NIH has been emphasizing reproducibility and rigor, and the research must be reproducible. It is necessary to determine what kind of data should be used for human subjects so that the experiments can be reproduced. Dr. Nitkin said that rehabilitation across the lifespan is qualitative research. Knowing the natural history of conditions is important to avoiding secondary conditions.

The next questioner asked whether the research plan would affect how the individual NIH ICs make funding decisions. Will the reviewers within each IC be educated about the rehabilitation research plan? Dr. Cernich said that the trans-NIH group that helped to draft the plan represents the 17 ICs that fund rehabilitation research, including the NIH Office of the Director. The IC directors will also review the plan. There will be discussion about how rehabilitation research grant applications should be reviewed. Those discussions will include the Center for Scientific Review. Dr. Jones suggested that applicants cite the research plan in the significance portion of their applications.

A participant said that it is a challenge to obtain a grant for cancer rehabilitation. There are no champions at NIH for this research. This is a challenge that must be resolved. She also said that many interventions are not implementable. Researchers are reluctant to write an implementation science proposal. Also, is the ICF a useful framework to advance science? It does not appear to be useful clinically. Dr. Tully said that the questioner could reach out to a program officer to help think through a grant application and to help find the best IC for the application. The National Cancer Institute may not be the best IC to receive the cancer rehabilitation application.

An audience member said that heterogeneity—working at the individual level but designing for groups—has been one of the themes of the conference. She said that it is important to identify the common measures that are important to capture. Without the common measures, it will be impossible to compare and contrast what works in different groups of people. Another audience member said that she would suggest educational attainment as a common measure.

An audience member said that one of the themes of the conference was to discuss what was unique about rehabilitation research and what it has in common with other areas of research. She questioned whether the model NCMRR is building fits with the other sciences and the funding model.

A participant suggested that NCMRR encourage other NIH ICs to fund more rehabilitation research. He asked for more funding for auditory rehabilitation research. Perhaps NCMRR could help to fund projects that have just missed the payline. Dr. Jones said that NIH does look at projects just outside the payline and also uses the cofunding strategy. But in the end, it comes down to the paylines, and the review committees determine those. Dr. Tully said that NINR has an interest in topics like self-management, including in rehabilitation. NINR is also “disease agnostic” and partners with NCMRR on some projects including a grant on genomes and stroke interventions. Dr. Peng said that NIBIB also cofunds projects with NCMRR. She suggested that applicants be explicit in their applications about which ICs might be interested in funding their project. That can prompt one IC to reach out to another. Dr. Cernich said that NCMRR is mandated to work with the other ICs.

A member of the audience suggested the development of a good set of metrics to measure the impact of technology on rehabilitation practice. Dr. Peng said that it is important that the metrics be set with the end user in mind. The end user may want faster access or more mobility as endpoints. Those might be the way to measure the impact.

A participant returned to the issue of common characteristics. She said that the National Institute of Neurological Disorders and Stroke (NINDS) CDEs did not include quality-of-life measures. She asked whether the CDEs had been expanded. Dr. Cernich said that NINDS has continued to expand the CDEs in various areas and has updated them across disease categories. NINDS also refreshes the CDEs so that emerging measures become standard.

Addressing the issue of rigor and reproducibility, a participant asked how investigators can gain access to or share data when it is in different formats and time series. How can data be standardized and open science be incentivized? Dr. Peng said that is a big challenge, dealing with the explosion of data that has come out of so many good studies. It is a critical issue because trials must be reproducible. The data standardization should be done on the front end. One idea is to have a platform onto which investigators are required to upload their data. There are good platforms to do this. One of the problems is dealing with intellectual property issues. Dr. Cernich said that NCMRR has funded R13s to allow investigators to put their data into a standard format for inclusion in the NICHD Data and Specimen Hub.

Another commenter suggested that NCMRR consider funding more pragmatic clinical trials. Dr. Cernich said that NCMRR is discussing the use of alternative designs including pragmatic trials.

A participant said that there are physical therapists and occupational therapists who want to do research but have difficulty getting funding because they do not have a doctorate. Dr. Cernich said that this is an issue that she is discussing with the organizations that oversee the education and the training of those professions. This has been a challenge for a number of the fields.

A comment from Twitter said that researchers must support open source so that every advance is shared across the research community.

A questioner asked what direction rehabilitation research funding will take over the next 5 to 10 years. She also asked whether it would be possible for NIH have a rehabilitation research study section. Dr. Nitkin said that the environment is friendlier because there are now study sections getting more rehabilitation applications. Also, those in the field should educate the panels about the importance of rehabilitation and the special issues involved. He said it is better not to have a single rehabilitation panel. As it is now, medical rehabilitation projects can go to a variety of panels, which gives those projects a better chance to receive funding.

Adjournment

Dr. Cernich thanked those in attendance for their presentations and suggestions. She adjourned the meeting at 4:30 p.m.