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State of Our Profession Over the Decades

This special supplement of the IV STEP Conference Proceedings 2016 marks the continuation of a process that began in 1966 with The Northwestern University Special Therapeutic Exercise Project (NUSTEP). This original conference brought together many of the leaders in rehabilitation for a series of lectures and demonstrations representing the state of the art for neurologic rehabilitation for children and adults. The proceedings from that conference served as the text for physical therapy education for many years. My personal copy of that 1200-page tome is creased and battered after many long hours of study as a physical therapy student at the University of Wisconsin-Madison.

It has been a privilege to participate in and experience the growth of physical therapy since those early student experiences. The initial NUSTEP conference 50 years ago was followed in 1990 with II STEP Special Therapeutic Exercise Project, in 2005 with III STEP Symposium on Translating Evidence into Practice, and now the most recent conference held in 2016, IV STEP Prevention, Prediction, Plasticity, and Participation. These last 3 conferences have been jointly sponsored by the Academy of Pediatric Physical Therapy and the Academy of Neurologic Physical Therapy. Our thanks for all the extraordinary efforts given by members of both academies to plan and implement these conferences. The Academies are jointly publishing these proceedings. Our thanks to the authors for their contributions. You can access all of the manuscripts at:

- http://journals.lww.com/pedpt
- http://journals.lww.com/jnpt

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The Past, Present, and Future of Neurorehabilitation: From NUSTEP Through IV STEP and Beyond

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Purposes: To present the history and aims of the STEP conferences; describe the interdependence of prevention, prediction, plasticity, and participation; reflect on where we stand today regarding those 4 Ps; and discuss how future neurorehabilitation should look for individuals with movement disorders.

Key Points: Physical therapists have focused primarily on tertiary prevention, emphasizing primary/secondary prevention far less. Predicting optimal response to intervention is essential for primary prevention. Research examining neurorehabilitation effects mediated by brain plasticity is evolving from an emphasis on impairment outcomes toward examination of participation outcomes.

Clinical Practice Recommendations: (1) Capitalize on primary and secondary prevention. (2) Administer simple, environmentally relevant predictive measures. (3) Partner with researchers to examine exercise-induced brain plasticity effects via neuroimaging. (4) Encourage physical activity to promote secondary prevention of lifestyle-related diseases and enhance participation. (5) Integrate psychological/social sciences with physiological sciences to move forward with advances in mindful health and patient-centered practices. (Pediatr Phys Ther 2017;29:S2–S9)

Key words: neuroplasticity, neurorehabilitation, participation, prediction, prevention

HISTORY AND PURPOSES OF THE STEP CONFERENCES

The inaugural STEP conference took place 50 years ago in Chicago. The Northwestern University Special Therapeutic Exercise Project (NUSTEP) lasted 4 weeks (July 25 to August 19, 1966) and the conference proceedings, published in the American Journal of Physical Medicine and as a stand-alone textbook, totaled nearly 1200 pages.1 Developed primarily for physical therapy (PT) educators who taught adult and pediatric neurology courses,2 the goal of NUSTEP was “to analyze older and newer methods of therapeutic exercise and to search for ways to meet future needs of physical therapy students through reconsideration of objectives and of curriculum content.”1(p19) Neurofacilitation approaches of the prevailing gurus were presented (eg, Bobath, Brunnstrom, Knott and Voss, Rood), and overall content included the basic sciences of neurophysiology, motor development, motor learning and motor behavior.2 The NUSTEP conference proceedings became a primary textbook for PT students in the latter 1960s, 1970s, and into the 1980s.

Not until 1990 was the concept of a STEP conference revisited when the Neurology Section and the Section on Pediatrics of the APTA collaborated to present II STEP (Special Therapeutic Exercise Project)—an 8-day conference (July 6 through 13) at the University of Oklahoma’s continuing education center in Norman. Modeled after NUSTEP, the purpose of II STEP was “to bring new theory and knowledge arising from the same content areas addressed at NUSTEP to an audience of physical therapy educators who work in both academic and clinical settings.”2(pvii) The proceedings were published by the Foundation for Physical Therapy in a 29-chapter book in the sequence in which plenary sessions, panel discussions, and small-group discussions were given.3

Fifteen years after II STEP, the neurology and pediatric sections organized and presented III STEP (Symposium on Translating Evidence into Practice) at the University of Utah in Salt Lake City, Utah (July 15-21, 2005). More so than the previous 2 STEP conferences, III STEP included a heightened emphasis on neuroplasticity, motor learning, and motivation, with a theme...
of linking movement science to intervention.\textsuperscript{4} Furthermore, III STEP was specifically aimed at translating knowledge about movement science into effective clinical interventions.\textsuperscript{3} Articles based on III STEP plenary and breakout sessions were published as a special series in *Physical Therapy* (2006-2007).\textsuperscript{6-17} Five additional articles based on III STEP presentations\textsuperscript{18-22} as well as a perspective on the effect of the conference on clinical practice\textsuperscript{23} appeared in a special issue of the *Journal of Neurologic Physical Therapy*.

In July 2016, a half century after the seminal NUSTEP conference, the APTA neurology and pediatric sections joined forces again to organize and host IV STEP: “a summer institute for clinicians, educators, and researchers designed to explore new theory and research evidence related to movement science, and to translate this theory and evidence into physical therapy practice for individuals of all ages with neurologic disorders.”\textsuperscript{24} Held at Ohio State University in Columbus from July 14 to 19, IV STEP focused on 4 Ps: prevention, prediction, plasticity, and participation, relating those Ps to roles and responsibilities of today’s PTs and designed to guide PT practice over the next decade.\textsuperscript{24}

In the following sections of this article, we list the objectives of IV STEP, define the 4 Ps and describe their interdependence, and provide thoughts and reflections on where we stand today with regard to prevention, prediction, plasticity, and participation. Finally, we discuss what we believe the future should look like for neurorehabilitation of children and adults.

**IV STEP OBJECTIVES**

The IV STEP Planning Committee developed 4 objectives for the conference, each relating to 1 of the 4 Ps:

1. Explore physical therapists’ role(s) in preventing disabling conditions among at-risk and preclinical populations.
2. Evaluate ways to classify individuals’ movement disorders, as well as strategies to link classification with accurate predicted outcomes.
3. Summarize critical periods for the emergence of neuroplasticity and strategies, including dosage, timing, and technology, for maximizing experience-dependent plasticity.
4. Analyze and apply emerging measures and interventions to optimize participation within the patient-centered care model.

These objectives will be integrated into our definitions of the 4 Ps and their interdependence.

**DEFINITIONS AND INTERDEPENDENCE OF PREVENTION, PREDICTION, PLASTICITY, AND PARTICIPATION**

**Definitions of the 4 Ps**

With the goal of advancing PT practice, IVSTEP defined prevention, prediction, plasticity, and participation and explored their interdependence as related to the roles and responsibilities of today’s therapists.

**Prevention.** The term *prevention* refers to actions taken to prevent the onset of disease (or disability), to stop its progress, and to minimize its consequences.\textsuperscript{25} Primary prevention aims to prevent specific diseases or disabilities through risk-reduction strategies, such as modifying lifestyle behaviors. In both children and adults, for example, we know that wearing bicycle helmets can reduce the risk of traumatic brain injury (TBI) if the cyclist falls or is hit by a car. In *secondary prevention*, procedures to “detect and treat pre-clinical pathological changes” for the control of progression to disability are implemented.\textsuperscript{25} Examples of secondary prevention include screening premature infants for cerebral palsy (CP) or prescribing graded aerobic exercise for individuals at risk for stroke because of hypertension.

**Tertiary prevention**, with the goal of minimizing the effect of movement disorders on the patient’s activity, participation, and quality of life, is the type of prevention with which most PTs are currently involved. For example, studies have shown that gait and step perturbation training reduces falls in persons with Parkinson disease (PD)\textsuperscript{26} and that adaptive seating systems may improve home-based activity and participation in children with severe CP.\textsuperscript{27}

**Prediction.** According to the IV STEP Planning Committee: “*Prediction of optimal response to intervention* choice is fundamental to effective practice. It begins with meaningful movement system diagnoses and measurement. *Prediction is also essential as it relates to primary prevention.*” At IV STEP, classification of movement disorders was discussed, as well as *strategies to link classification with predicted outcomes*.

One of the best-known systems for classifying children with movement disorders, used in hundreds of studies around the world, is the Gross Motor Function Classification System (GMFCS), a 5-level, ordinal system based primarily upon sitting, walking, and wheeled mobility.\textsuperscript{28} Developed initially for children with CP,\textsuperscript{28} the GMFCS has been also used to classify children with Down syndrome.\textsuperscript{29} In 2007, the GMFCS was revised and expanded to include an age band for children 12 to 18 years and to encompass environmental and personal factors that influence mobility, now referred to as the GMFCS—Expanded and Revised (GMFCS-E&R).\textsuperscript{30}

Classification on the GMFCS has been linked to predictions of type of mobility used (walking, wheeled mobility, or assisted mobility) in different environments (home, school, and outdoors) at different ages by children and young adults with CP\textsuperscript{31} and the rate of developmental gain in mobility and self-care activities in preschool-aged children with CP.\textsuperscript{32}

Classification of adults with movement disorders into fallers and nonfallers has been a focus of predictive neurorehabilitation research for the past 25 years, with introduction of the Berg Balance Scale\textsuperscript{33} (developed by PTs) and the Timed Up & Go\textsuperscript{34} in the early 1990s. One or both of these simple tests have been used to accurately predict falls in persons with multiple sclerosis,\textsuperscript{35} individuals poststroke,\textsuperscript{36} and those with PD.\textsuperscript{37, 38}

Another type of classification system, the American Spinal Injury Association Impairment Scale (AIS)\textsuperscript{39} is the international standard for categorizing injury severity in persons with spinal cord injury (SCI). A multicenter study of more than 1000 patients indicated that AIS classification at admission to inpatient rehabilitation was the strongest predictor of overall
physical functioning at 1 year postdischarge. In another large multicenter study, AIS also predicted likely walking function at 1 year postinjury based on scores obtained within the first 2 weeks of SCI.

**Plasticity.** The third P, plasticity, has been defined as “the capacity of cerebral neurons and neural circuits to change, structurally and functionally, in response to experience.” Brain plasticity is critical not only for sensory function maturation during development and behavioral adaptability to the environment but also for brain repair resulting from injury or disease. Exposure to enriched environments including cognitive, sensory, and motor interventions, for example, is one noninvasive approach to enhancing brain plasticity. In a meta-analysis comparing the effects of enriched environments to standard care in infants at high risk for CP, Morgan and colleagues found a small positive effect on motor outcomes (standard mean difference = 0.39; 95% confidence interval = 0.05-0.72) in favor of the infants exposed to enriched environments. Enriched environments were defined as “interventions that aim to enrich at least 1 of the motor, cognitive, sensory, or social aspects of the infant’s environment for the purposes of promoting learning.” One example was to adapt the infant’s physical and play environment to provide opportunities for self-initiated motor activity.

Another interesting area of adult neuroplasticity research is examining the effects of aerobic exercise on brain changes poststroke, suggesting that aerobic exercise can “enhance the neuroplastic milieu.” Two recent systematic reviews (SR) involving animal studies showed that daily, moderate, forced exercise initiated within 48 hours after stroke reduced the volume of the stroke lesion, protected the surrounding tissue against damage and inflammation for at least 4 weeks, and enhanced synaptogenesis in multiple brain regions. Researchers in this area suggest that combining aerobic exercise with task training “may enhance activity-induced plasticity” in humans.

**Participation.** The most widely known definition of participation comes from the World Health Organization’s International Classification of Functioning, Disability and Health: the “involvement of people in all areas of life” or the “functioning of a person as a member of society”; participation restrictions are “problems an individual may experience in involvement in life situations.” Functioning within society is as important for children and adults with movement disorders as for individuals who can move easily within their environment. Unfortunately, however, there has been less emphasis in rehabilitation research on interventions to affect participation outcomes than on strategies to improve the neurological impairments that characterize individuals with movement disorders.

A 2015 SR examined the effects of interventions aimed at improving participation for children with disabilities. Adair and colleagues were able to identify only 3 studies that included participation as a primary outcome. Participants included children with hemiplegia, Down syndrome, and those with a variety of other intellectual, emotional, or physical disabilities. Studies were limited to randomized controlled or pseudo-randomized trials. Not surprisingly, the authors of this review concluded that “few high-quality studies have reported favor-
The infant scored in the 70th percentile rank on the AIMS, suggesting motor performance within normal limits for her corrected age. Although this result allayed some of the parents’ concern, their son’s PT suggested that they might want to enroll their daughter in the center’s inclusionary day care program to enhance her participation with other infants developing typically as well as those with special needs. This example illustrates how physical therapists can capitalize on the interactions among prevention, participation, plasticity, and participation to facilitate optimal outcomes in our clients.

Figure 1 depicts the interdependence of the 4 Ps, with definitions of each construct. The arrow direction depicts the hypothetical effect each would be expected to impart on central nervous system plasticity. Participation and prevention are expected to directly impact central nervous system plasticity through behavior change, whereas prediction variables are not thought to directly impact plasticity. Instead, the arrow points from plasticity toward prediction to capture a growing body of research showing that measures of structural brain impairment such as diffusion tensor imaging can be used to predict response to motor therapies in stroke.33,34

**WHERE DO WE STAND TODAY WITH REGARD TO PREVENTION, PREDICTION, PLASTICITY, AND PARTICIPATION?**

**Thoughts and Reflections on Where We Stand Today**

**Prevention.** PTs have been more involved in tertiary prevention than in primary or secondary prevention. One intervention aimed at tertiary prevention that has been studied extensively in recent years is functional electrical stimulation (FES). Three recent SRs examining the effects of FES in persons post-stroke have shown that (1) stimulation of the peroneal nerve for foot drop is more effective than ankle-foot orthoses in decreasing physiological cost and is preferred by patients;55 (2) FES in combination with conventional therapy is more effective than therapy alone in preventing or reducing early shoulder subluxation (less than 6 months after stroke);56 and (3) compared with placebo or no treatment, FES improves activity and is more beneficial in combination with activity training than training alone.57 Two recent reviews, albeit not SRs, described evidence for the use of FES in tertiary prevention in adults58 and children with SCI.59 For children with spastic CP, a recent SR showed that FES was more effective than no FES in enhancing activity but that specific activity training was as effective as FES for activity enhancement.60

**Prediction.** Walking is one very simple and clinically relevant activity, used both as a predictor variable and as an outcome measure. Using attainment of independent walking (≥3 steps) as the desired outcome in 80 young children with CP, Begnoche and colleagues61 found that the most important predictor was functional strength, as operationalized by transitions from sit to stand and stand to sit.

As a predictive measure, self-paced walking (gait speed) was shown in a pooled analysis of 7 studies of community-dwelling elderly adults to significantly predict future disability and mortality.62 A comfortable gait speed has also been shown to predict success in community ambulation for adults with PD of mild-to-moderate severity, with fear of falling adding further to the predictive capability of gait speed.63 In a scoping review, Kikkert and colleagues64 identified 20 longitudinal studies that examined the predictive relationship between walking ability at ages 65 years or more and later cognitive abilities; gait speed was the predictor variable in 18 of the studies. Slow gait speed at baseline (1.00 m/s) predicted cognitive decline and/or dementia an average of 4.3 years later. As Perera and colleagues65,66 commented: “gait speed is a simple, clinically feasible independent indicator of risk of future disability.”

**Plasticity.** Research examining the effects of neurorehabilitation on brain plasticity has been most notable in studies involving adults poststroke and children with unilateral CP, with constraint-induced movement therapy being the prime intervention example for both groups.65,66 But what about other neurological patient populations and other types of interventions?

Fisher and colleagues67 studied 30 people with mild PD who were within 2 years of diagnosis, and showed that high-intensity treadmill training increased corticomotor excitability and improved self-selected walking speed and other gait parameters. Later, Fisher and colleagues68 reported that intensive treadmill training (3 times per week for 8 weeks) resulted in an increase of striatal D2 dopamine-binding receptor as well as improved postural control in adults with early-stage PD.

In a study of 19 children with moderate-to-severe TBI (ages 8.5-19 years) and 28 similar-aged children who had typical development, Drijkoningen and colleagues69 examined whether an 8-week, home-based balance training program could enhance balance and whether it was associated with neuropsychological patient populations and other types of interventions?

In adults with moderate-to-severe neurologic disabilities, we know that a 10-week, community-based exercise program designed by PTs and aimed at leading to independent exercising resulted in significant improvements in health-related quality of life, with 44% of participants becoming independent exercisers.70

**Participation.** Where do we stand today with regard to participation? We know from recent research that school-aged children with disabilities are just as good as their parents in setting and attaining task-oriented goals, and that the children’s goals were directed primarily at participation (ie, activities of daily living, school work, and leisure), whereas the parents’ goals focused primarily on activities of daily living.71 We know also from children and young persons with physical disabilities that leisure for them is composed of elements of fun, freedom of choice, fulfillment, and friendships—and that participation in leisure activities enhances quality of life and overall health.72

In adults with moderate-to-severe neurologic disabilities, we know that a 10-week, community-based exercise program designed by PTs and aimed at leading to independent exercising resulted in significant improvements in health-related quality of life, with 44% of participants becoming independent exercisers.73

**WHERE DO WE GO FROM HERE? WHAT SHOULD THE FUTURE LOOK LIKE FOR NEUROREHABILITATION OF CHILDREN AND ADULTS?**

There is an urgent need for PTs to become more involved in primary and secondary prevention for persons with movement...
disorders. What can we do as clinicians to help in preventing, for example, concussion in children and adults?

Based on results of 2 recent SRs,\textsuperscript{75,76} there is insufficient high-quality evidence that lifestyle interventions (eg, aerobic exercise, health education, and life management skills) will reduce the incidence of further cardiovascular events or lower the risks for such events in persons who have sustained strokes or transient ischemic attacks—leading the PT authors of these reviews to call for robust, high-quality, longer term trials to investigate this focus of secondary prevention.\textsuperscript{75,76}

The future of PT clinical practice should include administration of simple and environmentally relevant measures shown to be predictive of later performance, such as transitions from sit to stand and stand to sit as a measure of functional strength and a predictor of independent walking for young children with CP.\textsuperscript{61}

Scores on the AIMS administered to infants at 4 months of age have been shown to be predictive of motor performance at age 4 years in very preterm children; not surprisingly, the predictive accuracy improved with serial assessments (at 4, 8, and 12 months).\textsuperscript{51} For very preterm infants, clinicians should consider also using the Neuro-Sensory Motor Development Assessment\textsuperscript{77} to accurately predict later CP in infants at 1 year of age.\textsuperscript{81}

Speed of self-paced walking is a very reliable and simple measure to capture in the clinic, having been shown to predict community walking ability in adults with PD,\textsuperscript{63} dementia in older adults,\textsuperscript{64} and future disability and mortality in the elderly living in the community.\textsuperscript{62} Self-selected walking speed has also been shown to predict the ability to run in adults who have experienced TBI, the vast majority of whom had sustained severe injury, and was a stronger predictor than postural stability or quality of gait performance.\textsuperscript{78} As Perera and colleagues\textsuperscript{82(70)} commented: “Physical performance measures, including gait speed, may serve as examples of universal outcomes to monitor health and function, evaluate novel interventions, and test innovations in the organization of health care.”

In a review article titled “How Can You Mend a Broken Brain?” members of the Canadian Partnership for Stroke Recovery posited that enriched rehabilitation, composed of environmental enrichment and task-specific therapy, provides a very promising combination for improving recovery after stroke.\textsuperscript{79} Based on animal research over the past 2 decades, these authors suggested that “stroke recreates a cerebral milieu similar to that of early brain development, a period characterized by rapid brain growth and remodeling of synaptic connections.”\textsuperscript{79(234)} A pilot study involving people poststroke in an inpatient rehabilitation unit supports the beneficial effects of an enriched environment (ie, those in the experimental group were more likely to participate in cognitive and social activities whereas the control group participants were more likely to be inactive, alone, or asleep).\textsuperscript{80} These results parallel those of Morgan and colleagues\textsuperscript{43} SR, showing that enriched environments were beneficial for infants at high risk for CP.

The future of neurorehabilitation for children and adults must also include greater emphasis on physical activity (PA), to promote secondary prevention of lifestyle-related diseases as well as provide strategies for enhancing participation.\textsuperscript{81} On the basis of a comprehensive literature review, expert opinion, and longstanding clinical experience, Verschuren and colleagues\textsuperscript{82} recently published exercise and PA recommendations for children and adults with CP that could be incorporated into clinical settings or research protocols. Similarly, the American Heart Association and American Stroke Association’s recently released Guidelines for Adult Stroke Rehabilitation and Recovery made the following recommendation: Following successful screening, an individually tailored exercise program is indicated to enhance cardiorespiratory fitness and reduce the risk of stroke recurrence (class 1A for improved fitness; 1B for reduction of stroke risk).\textsuperscript{83}

In qualitative interviews of 19 adults with a range of movement disorders (eg, stroke, SCI, PD, and multiple sclerosis), Mulligan and colleagues\textsuperscript{84} reported that PA was best promoted (and more apt to be maintained) when individuals chose their own preferred form of recreational exercise. The authors proposed that future research could include intervention studies to test the effectiveness of these findings. In a sample of 260 individuals living in the community with PD, Ellis and colleagues\textsuperscript{85} investigated the barriers to exercise participation using the self-report barriers subscale of the Physical Fitness and Exercise Activity Levels of Older Adults Scale. Their findings that low expectation of exercise, lack of time to exercise, and fear of falling appeared to present barriers to exercise engagement provide important insights about issues that can be targeted for application in people with PD who do not regularly exercise.

Finally, a concerted effort to integrate the psychological and social sciences with the physiological sciences\textsuperscript{86} in our entry-level and residency programs, elegantly exemplified by new theoretical models,\textsuperscript{87} intervention practices,\textsuperscript{4} and approaches\textsuperscript{88,89} will be critical for moving forward in concert with recent advances in understanding the importance of mindful health\textsuperscript{90} and patient-centered health care practices.\textsuperscript{91,92}

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S6 Harris and Winston Pediatric Physical Therapy


Regenerative Rehabilitation: Combining Stem Cell Therapies and Activity-Dependent Stimulation

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The number of clinical trials in regenerative medicine is burgeoning, and stem cell/tissue engineering technologies hold the possibility of becoming the standard of care for a multitude of diseases and injuries. Advances in regenerative biology reveal novel molecular and cellular targets, with potential to optimize tissue healing and functional recovery, thereby refining rehabilitation clinical practice. The purpose of this review is to (1) highlight the potential for synergy between the fields of regenerative medicine and rehabilitation, a convergence of disciplines known as regenerative rehabilitation; (2) provide translational examples of regenerative rehabilitation within the context of neuromuscular injuries and diseases; and (3) offer recommendations for ways to leverage activity dependence via combined therapy and technology, with the goal of enhancing long-term recovery. The potential clinical benefits of regenerative rehabilitation will likely become a critical aspect in the standard of care for many neurological and musculoskeletal disorders. (Pediatr Phys Ther 2017;29:S10–S15)

Key words: neural engineering, neuroplasticity, neuroprosthesis, regeneration, regenerative rehabilitation, stem cells, tissue engineering

INTRODUCTION

The combination of rehabilitation together with engineered devices and regenerative therapies holds potential to improve quality of life after neuromuscular injury or disease. The field of regenerative medicine is based on the assumption that the health of our population would benefit from a paradigm shift in the way we approach the treatment of acute and chronic conditions so as to maximize clinical outcomes. As proposed by Daar and Greenwood¹:

Regenerative medicine is an interdisciplinary field of research and clinical applications focused on the repair, replacement or regeneration of cells, tissues or organs to restore impaired function resulting from any cause, including congenital defects, disease, trauma and ageing. It uses a combination of several converging technological approaches, both existing and newly emerging, that moves it beyond traditional transplantation and replacement therapies. The approaches often stimulate and support the body's own self-healing capacity.

Regenerative medicine technologies have been investigated as a means to enhance the functional capacity of a host tissue when endogenous regenerative mechanisms are inadequate or fail altogether. The enthusiasm surrounding regenerative medicine continues to build, and this enthusiasm is being matched with clinical deliverables at an accelerating pace. Over the next decades, stem cell and tissue engineering protocols hold the possibility of becoming the standard of care for a number of diseases and injuries. Although early stem cell applications were initially limited to the treatment of potentially fatal conditions, clinical trials are increasingly investigating a diverse array of applications, including musculoskeletal and neurological systems. As an example, the Clinical Trials registry (www.clinicaltrials.gov) lists 7 active studies investigating cellular therapies for the treatment of Duchenne muscular dystrophy...
OVERVIEW OF REGENERATIVE REHABILITATION

Physical rehabilitation has foundations in the targeted application of mechanical stimuli to enhance intrinsic tissue healing potential. Mechanobiology is a growing scientific field that seeks to better understand how mechanical forces induce cellular and tissue responses, and how these forces contribute to tissue development, homeostasis, and pathophysiology. A central area of study within mechanobiology is mechanotransduction, the process by which mechanical stimuli are sensed, transmitted, and translated into biologic responses (reviewed in Dunn and Olmedo2 and Thompson et al3). There is robust evidence supporting biologic adaptations in response to both dynamic and static mechanical stimuli. Advances in mechanobiology suggest that changes in cell mechanics, extracellular matrix (ECM) structure and composition, and mechanotransductive sequences may contribute to the pathophysiology of many inheritable and acquired disabling conditions (reviewed in Dunn and Olmedo2 and Thompson et al3). Applied mechanical stimuli represent a potent stimulus to harness intrinsic tissue healing capacity. This concept has served as a foundation for the application of rehabilitation protocols for the treatment of diseased or injured tissues.

Similar mechanical and biological stimuli can also be used to activate the nervous system to induce reorganization and potentially repair. Pairing physical movement with activity in the nervous system is the foundation for many therapies aimed at promoting neuroplasticity. These approaches leverage the phenomenon discovery by Donald Hebb in the 1950s, now paraphrased as “neurons that fire together wire together.”4 Current approaches to physical therapy promote recovery by leveraging this activity-dependent plasticity via assisted movement and stimulation applied to the muscles, nerves, spinal cord, or brain. Going forward, such activity and timing-dependent strategies will be needed in combination with stem cell or tissue engineering solutions to guide the incorporation of tissue grafts or promote the regeneration and functional organization of endogenous stem cells.

Just as endogenous musculoskeletal and neural tissues benefit from the application of rehabilitation protocols to promote functional tissue recovery after injury and with disease, it is increasingly recognized that the functional efficacy of regenerative medicine technologies may be enhanced when coupled with mechanical and electrical stimuli.5-11 The recognized potential for synergy between the fields of regenerative medicine and rehabilitation science has in recent years launched the birth of a new field, regenerative rehabilitation.12-14 The International Consortium for Regenerative Rehabilitation defines regenerative rehabilitation as “the integration of principles and approaches from the fields of rehabilitation science and regenerative medicine. Regenerative medicine focuses on the repair or replacement of tissue lost to injury, disease, or age, primarily via the enhancement of endogenous stem cell function or the transplantation of exogenous stem cells. A focus of Rehabilitation science is the use of mechanical and other physical stimuli to promote functional recovery. The integration of these two approaches will optimize independence and participation of individuals with disabilities” (www.ar3t.pitt.edu).

SUCCESSES IN REGENERATIVE REHABILITATION AND RELATED THERAPIES

Musculoskeletal Regenerative Rehabilitation

Progress in regenerative rehabilitation research has arguably been the greatest when considering musculoskeletal applications, such as the treatment of traumatic skeletal muscle injuries. Although skeletal muscle is capable of remarkable regenerative potential, when the injury or disease is extensive and destroys the underlying architecture, regeneration is aborted and is characterized, instead, by scar tissue formation (reviewed in Huard et al15). The consequence is severely impaired functional capacity of the damaged tissue. In cases such as these, cellular therapies have been investigated as a means to boost tissue regenerative capacity. Unfortunately, the therapeutic benefit of these interventions has often been limited by massive cell death following transplantation and a poor transplantation efficiency,16,17 ultimately resulting in poor functional outcomes. To overcome this barrier, studies have demonstrated that the combination of stem cell transplantation and muscle loading increases the engraftment of donor cells, both in cases of myopathy6,7,18 and injury.5,19

Accordingly, surgical placement of acellular biologic scaffold materials (a tissue engineering approach) composed of mammalian ECM promotes constructive tissue remodeling in cases of volumetric muscle loss.20-22 The mechanisms underlying the reported functional improvements have yet to be elucidated, but it has been hypothesized that donor ECM-mediated response occurs through the recruitment of stem/progenitor cells at the site of implantation.23-26 The application of rehabilitation protocols following ECM implantation has been suggested to be beneficial—even crucial—for providing the needed mechanical signals to encourage site-specific tissue remodeling (reviewed in Gentile et al27 and Badylak et al28). Future randomized studies to determine whether and how optimal rehabilitation protocols may enhance functional outcomes following the application of a tissue engineering device for the treatment of volumetric muscle loss are warranted.

Neurological Regenerative Rehabilitation

In the central nervous system (CNS), electrical and chemical signaling is believed to be the strongest driver of plasticity and remodeling. Following injury to the CNS, fibrosis formation can alter the biophysical tissue properties and may trigger a multitude of downstream cellular responses and strongly influence plasticity and recovery. Indeed, static mechanical and electrical properties of the cellular microenvironment have been shown to exert potent effects on mesenchymal stem cell
regenerative potential.\textsuperscript{20,30} Spinal cord and hippocampal neurons grown on a soft gel substrate were shown to form 3 times as many branches compared with neurons grown on stiffer gels.\textsuperscript{31} Together, these studies suggest that complementary methods to optimize the biophysical microenvironment (eg, through pharmacological or cell-based therapies) may be a critical step in realizing the full potential of rehabilitation protocols after spinal cord injury, stroke, or traumatic brain injury.

More traditional interventions for CNS trauma involve activity-dependent therapies. For example, following spinal cord injury or stroke, assisted locomotor training is used with the goal of delivering synchronous input both above and below a lesion.\textsuperscript{32,33} As reviewed later, such interventions may also employ electrical stimulation of the muscles, peripheral nerves, or spinal cord to activate the affected neuromuscular tissue. In addition to direct efferent activation, such stimulation often also results in activation of sensory afferents, providing coordinated input to the CNS distal to a lesion.\textsuperscript{32-34}

Several methods exist for electrically or magnetically activating the brain and spinal cord after injury. Methods of electrical stimulation include application of current to the dorsal surface of the spinal cord, termed epidural stimulation (Figure 1). Early human studies are possible because of the off-label use of stimulators designed to alleviate chronic pain.\textsuperscript{35-37} Noninvasive methods of spinal stimulation are also possible using magnetic fields, which have improved spasticity following spinal cord injury for up to 24 hours.\textsuperscript{38-40} Magnetic stimulation of the lumbar spinal cord can be triggered by upper extremity movement to create an activity-dependent paradigm where stepping movements are synchronized with arm swing in spinally intact volunteers.\textsuperscript{41}

Parallel work in animals uses hair-like wires within the spinal cord, termed intraspinal microstimulation (Figure 1). Intraspinal microstimulation can evoke functional synergies for walking and reach/grasp.\textsuperscript{42,44} Such stimulation can also lead to long-term improvements in forelimb function in animal models of spinal cord injury,\textsuperscript{11} especially when triggered by residual muscle signals in an activity-dependent paradigm.\textsuperscript{10} Although intraspinal stimulation is more invasive than epidural stimulation, it is currently scheduled for the first human experiments and provides much greater specificity of activation that may benefit the incorporation of regenerative therapies.\textsuperscript{45}

In both the brain and spinal cord, pairing of artificial stimulation can benefit individuals recovering from stroke and spinal cord injury.\textsuperscript{46,47} Application of peripheral nerve stimulation followed by transcranial magnetic stimulation after an appropriate latency can reinforce\textsuperscript{48,49} or inhibit\textsuperscript{47} connections either within the intact brain or for subjects recovering from stroke. Similar mechanisms have been applied to the cervical spinal cord after injury to reinforce weak but spared connections bypassing a lesion. Even stimulation applied directly to the brain surface improves function in animal models of ischemic stroke.\textsuperscript{50,51} Furthermore, paired stimulation delivered to the brain or brain and spinal cord can lead to long-term changes in synaptic strength in the intact brain and injured CNS.\textsuperscript{52} Building on the success of constraint-induced therapy,\textsuperscript{55,56} if such methods of stimulation can incorporate time or activity dependence, they may induce long-term plasticity and recovery. Going forward, efforts are required to ensure that such stimulation methods are effectively combined with physical therapy, and eventually cellular and regenerative therapies, to optimally improve function after injury.

Appropriate neural activity is likely a prerequisite for stem cells to improve function in the damaged CNS. Neural activity is critical for avoiding cell death following insult.\textsuperscript{57,58} Improves blood perfusion and the related health of neurons,\textsuperscript{59} and upregulates brain-derived neurotrophic factor, which is implicated in plasticity and recovery.\textsuperscript{60,61} In contrast, reduced activity such as that observed in models of spinal muscular atrophy is associated with reduced axon growth.\textsuperscript{62} On the basis of this cumulative evidence, one of the most successful stem cell transplant studies coupled brief electrical stimulation of the peripheral nerve with motor neuron cell grafts and demonstrated impressive cell survival and muscle reinnervation.\textsuperscript{63} This landmark study suggests that the combination of regenerative cell therapies and artificial stimulation may be critical for achieving targeted plasticity and functional recovery following injuries or regeneration of the neuromuscular system.

**OBSTACLES AND BARRIERS TO REGENERATIVE REHABILITATION—WHAT IS HOLDING US BACK?**

The clinical translation of regenerative medicine approaches for the enhancement of physical functioning presupposes the existence of a critical mass of basic scientists working in close collaboration with rehabilitation clinicians. Unfortunately,
although interdisciplinary research is conceptually desirable, there are few opportunities providing rehabilitation scientists with the resources and training necessary to become engaged in the field of regenerative medicine. Of the almost 1300 currently funded studies investigating “stem cell transplantation” or “tissue engineering” listed on National Institutes of Health (NIH) reporter, only 8 are housed in rehabilitation departments (Accessed July, 2016).

One reason for the disconnect between regenerative biology and rehabilitation studies may be that many rehabilitation programs lack faculty members with the expertise necessary to teach principles and concepts in the domain of cellular and regenerative biology. Physical therapy and occupational therapy departments are often in schools without basic science research programs, thereby limiting opportunities for interaction with basic science colleagues. Similar barriers have impeded those working in the basic sciences from understanding application of their work to clinical practice, as they generally have limited exposure to rehabilitation practice. As a result, regenerative medicine scientists may not consider clinically available approaches, technologies such as robotics and modalities such as neuromuscular electrical stimulation or ultrasound that may be beneficial in targeting the mechanotransductive pathways, so fundamental for driving the tissue regenerative cascade. Moreover, given that functional benefit is the ultimate goal of all translational regenerative therapies, basic scientists stand to benefit from the expertise of rehabilitation specialists in functional outcomes assessment.

There is also a large unmet need for better preclinical models of rehabilitation. Currently, preclinical models of rehabilitation are limited, and the bulk of the studies employ treadmill or wheel running, for example. Yet clinical rehabilitation consists of much more than just the presence or absence of exercise, and investigation into combined rehabilitation modalities such as neuromuscular electrical stimulation and ultrasound to enhance stem cell transplantation or implantation of a tissue engineering device is needed. Finally, timing, dosing, and intensity are all critical variables for both pharmacological and rehabilitation interventions following CNS injury, and work is ongoing to determine the optimal paradigm for combining multiple therapies.

CONCLUSIONS AND CHARGE TO THE FIELD

As is our tradition, rehabilitation practice must continuously evolve such that it may be responsive to scientific and technological innovations that impact clinical practice. Undoubtedly, progress in the field of rehabilitation will increase proportionately with the pace at which rehabilitation professionals keep up with innovations in medical practice. Just as the prescription of rehabilitation is the standard of care following the onset of most musculoskeletal and neurologic injuries and diseases, it is likely that rehabilitation will necessarily be the standard of care, as regenerative medicine technologies increasingly make their way to clinical practice.

To drive knowledge transfer and the technical capabilities of medical rehabilitation researchers to perform cutting-edge regenerative rehabilitation investigations, we must begin to systematically promote the integration of basic scientists with rehabilitation specialists. We must train rehabilitation clinicians who can help oversee the quality, safety, and validity of these innovative regenerative rehabilitation technologies and protocols.

In addition, to be effective in this partnership, there is a need for an improved mechanistic understanding by which mechanical forces and modulation of the tissue microenvironment (eg, through exercise and modalities) may be used to optimize outcomes following a regenerative medicine intervention. Molecular and cellular mechanisms must be the foundation upon which clinical regenerative rehabilitation protocols are derived, and a better understanding of these mechanisms will allow for the more rational design of clinical protocols that elicit targeted and specific cellular and tissue responses. In the absence of these guiding mechanisms, clinical protocols will be left to a trial-and-error approach, an approach that is ineffective in terms of clinical outcomes as well as economics.

Finally, our ability to use engineered devices to interact with the neuromuscular system is beginning to accelerate. Implanted stimulators capable of triggering activity-dependent stimulation are now in early human studies for essential tremor and Parkinson disease. Experimental devices are already capable of delivering electrical, magnetic, optical, and pharmacological stimulation to targeted locations within the brain and spinal cord, as well as the peripheral nerves and muscles. Optogenetics, or light activation of neurons, is currently under trial to treat blindness. This technique may soon be combined with stem cell interventions to enable targeted activation of grafts in situ. Given the current pace of technological advancement, there is tremendous potential to leverage engineered solutions to enhance biological regeneration.

The combination of regenerative therapies such as stem cell or tissue grafts with methods to induce appropriate mechanical or electrical stimuli within the injury or diseased site is likely critical to the success of regenerative rehabilitation. If emerging technologies can be effectively coupled with sound physical therapy practice to induce activity-dependent remodeling of injured tissues, regenerative rehabilitation therapies may soon dramatically improve plasticity and participation for people with injuries to the neuromuscular system.

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Excellence in Promoting Participation: Striving for the 10 Cs—Client-Centered Care, Consideration of Complexity, Collaboration, Coaching, Capacity Building, Contextualization, Creativity, Community, Curricular Changes, and Curiosity

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Participation of children with physical disabilities is critical to optimizing their life roles and lived experiences. This perspective explores the complex and multidimensional construct of participation and presents recommendations for practice, education, and research to transform pediatric physical therapy service delivery. Two models are reviewed of participation-based service delivery grounded in client-centered care and the principles of coaching to engage clients in their rehabilitation. The roles and responsibilities of the physical therapist and the importance of team collaboration are emphasized. Considerations are presented for ecological measurements and interventions to support client participation goals for children of all ages in home and community settings. Practitioners, educators, and researchers are encouraged to be advocates and change agents to ensure that services support meaningful participation for children in real-life contexts.

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Key words: intervention, measurement, participation

Legislation in the United States advocates for the rights of individuals with disabilities to be included and participate in all aspects of society. Professionals and researchers have linked participation to positive developmental outcomes, well-being, and quality of life, including the promotion of learning, friendships, self-determination, self-efficacy, sense of mastery, and fulfillment.1-3 Supporting home and community participation of children with physical disabilities is thought to be important for optimizing their life roles and lived experiences.4,5 Yet, despite at least 2 decades of scholarly perspectives and research, embracing participation in pediatric physical therapy appears hindered by an incomplete understanding of the construct, challenges in measurement, limited evidence for interventions,6 and inadequate service delivery systems restricting novel approaches to care. Participation is complex and we still have more questions than answers, including: what is participation, what factors influence participation, and how can we measure and intervene to support participation? The purpose of this article is to explore the construct of participation for pediatric rehabilitation and to propose the need to mind our Ps (prevention, prediction, plasticity, and participation) and Cs (client-centered care, consideration of complexity, collaboration, coaching, capacity building, contextualization, creativity, community, curricular changes, and curiosity) to transform service delivery.

Our profession has progressed from a primary focus on impairments in body structure and function to activity-focused intervention. Today, pediatric physical therapy practice is more client centered and goal directed, but we still have a way to go to ensure that our services support meaningful participation in real-life contexts. Since before II STEP, through the systems models of motor control, we have acknowledged that individuals perform tasks within a physical and social environment and that context matters. I am optimistic that an appreciation for what we know and a vision for our field will help change the focus of therapy from activity to participation.

To make this change happen, I believe the first step is to strengthen the foundation by explicitly defining participation. The second step requires establishing a common philosophy for practice and clear expectations that pediatric rehabilitation and educational teams support children’s participation. The third step entails putting support for participation into action by identifying clients’ participation goals, doing a “participation analysis,” and implementing participation-based interventions.
Furthermore, we can ensure continued transformation by educating others and conducting research on participation-based therapy.

DEFINING AND UNDERSTANDING PARTICIPATION

As pediatric physical therapists we are familiar with the World Health Organization’s definition of participation as “involvement in life situations.” Although this definition respects the broad nature of participation, it may not be particularly useful to guide research, teaching, and practice. Definitions proposed in the literature have highlighted that participation refers to engagement in a set of activities that is meaningful to the individual and setting specific. Key attributes of participation include its individuality, complexity, and subjectivity. Participation has multiple elements and occurs in various contexts. Individuals can participate in a range of routines including those related to family life, school, leisure and recreation, spirituality, citizenship, and employment.

Imms and colleagues conducted a systematic review to examine the language and definitions used by researchers to describe participation. The 25 studies reviewed were diverse in regard to participants, settings, and intervention focus. Although 4 studies specifically defined participation, the language used to describe the construct lacked consistency and clarity. From this review they conceptualized preference as a precursor to participation, and participation as having 2 dimensions, attendance and involvement, leading to key outputs of activity competency and sense of self. These outputs influence future participation, thus reflecting a cyclic nature. Their framework also depicts the external factors that influence participation, including the environment and how available, accessible, affordable, accommodating, and acceptable opportunities are for individuals with disabilities. Researchers, educators, and practitioners can use this framework to unify and guide their work in advancing the field.

Preferences, as the precursor to participation, was defined as “the opportunity to choose and be able to undertake activities that are meaningful and valued.” The authors highlighted how preferences relate to previous personal experiences and serve as a motivator for participation. Hoogsteen and Woodgate, in a concept analysis of participation, identified choice or control as one of the defining attributes of participation. The consideration of preferences may need to be modified in some situations. When we think of participation in activities that someone needs to or is expected to do, the opportunity for choice and how the activities are valued may be very different from activities that someone wants to do. When the goal is participation in a set of activities that the child is required to do, I believe it is important for therapists to partner with the child to identify the benefits of participation and aspects where the child may be able to exert control. When the preference for participation is a set of activities that the child has no prior experience with, therapists may need to explore experiences in related situations and partner with the child and family to prepare them for the new opportunity.

Involvement, the actual in-the-moment aspect of participation, is complex. Involvement reflects what the experience is like during the situation. Imms and colleagues use the term engagement when describing involvement, and they found that almost half of the studies reviewed used the terms participation and engagement interchangeably. Although Imms and colleagues defined involvement as affect, motivation, and social connection, I believe that involvement in the moment includes affective, cognitive, and behavioral elements; how the person is feeling, thinking, and behaving. The social component of participation, viewed as important by researchers, youth, and parents, is not, however, universal to all situations. It is recognized that individuals can participate alone in a set of activities. Coster and Khetani’s inclusion of “personally or socially meaningful” when defining participation, honors this consideration.

Participation can be valued for the experience itself, as well as the benefits arising from the experience. Imms and colleagues identified activity competence and sense of self as resulting from the participation experience. Activity competence refers to the quantity or quality of the activities compared with an expected standard. The output, sense of self, refers to a person’s satisfaction and how participation affects his or her confidence and self-esteem. Although these are observable outcomes of participation, activity competence could also be considered part of behavioral involvement and sense of self could be expressed through affective and cognitive involvement during the experience.

As we continue to explore and understand participation, it is important to expand our conceptual framework from the clients’ perspective. Parents also expressed that participation comprises both the amount of and engagement in activities. Parents and children with physical disabilities emphasized the importance of enjoyment, being with family and friends, performing activities as independently as possible, and feeling successful. Parents also identified the critical influence of environmental context, resources, supports, and barriers.

My colleagues and I conceptualized optimal participation as arising from the dynamic interaction among the child, family, and environmental determinants of participation, and the elements of participation, which we identified as the physical doing, social belonging, and self being, including how a person is thinking and feeling. Much of the research on determinants of participation has focused on participation in leisure and recreational activities, and aspects of the child have consistently been found to be associated with this type of participation. These predictors of participation include child preferences, enjoyment, age, gender, motor and communication abilities, cognition, self-care, adaptive behaviors, associated health conditions, and body structures and functions. This knowledge helps therapists understand how participation varies by child characteristics, but it may be challenging to apply this information to an individual child to guide intervention decisions. The situation is further complicated by the influence of family income and ecology as well as geographic area of residence, policies, attitudes of others, transportation, and availability and accessibility of community programs. Models for participation-based practice, developed in the past 5 years, can assist therapists in using the knowledge on determinants of participation for focused examination and intervention.
PRINCIPLES AND MODELS FOR PARTICIPATION-BASED PRACTICE

Two models for participation-based pediatric rehabilitation, Palisano and colleagues’ participation-based therapy and Pathways and Resources for Engagement and Participation (PREP), emphasize the importance of the following principles: child and family-centered, strengths-based, goal-oriented, collaborative, ecological, self-determined, and capacity building. As therapists broaden their approach to support children’s participation, I believe it is important for them to consider if their philosophy of care embraces these principles. Because these models are goal-oriented and capacity building, interventions are provided during a short-term episode of care.

The principle of collaboration is a key feature of the model of participation-based service delivery. This model reflects child and family engagement as well as collaboration with other service providers and the community. The model includes 5 processes. First, the therapist attends to building and sustaining a relationship that is founded on respect between themselves and the family. Second, the therapist supports the family and child in identifying a personally, meaningful goal for community participation. Third, the therapist guides an assessment process that consists of a participation analysis specific to the child’s goal. Fourth, the therapist and family implement the intervention in the real-world setting where the goal occurs. The therapist serves as a coach to the child, family, and community members to support them in discovering their own solutions. Fifth, the family and child also collaborate in the evaluation of the processes and the outcomes. They identify their current participation level across the dimensions relevant to them—performance of the activities, social involvement, enjoyment, and satisfaction as well as what they learned from the experience. These outcomes and reflections on the intervention approach (what was most helpful, what worked, what did not work) guide the future direction of services as well as provide the family and child with the capacity to realize new participation experiences.

PREP is an environment-based intervention approach consisting of 5 steps: make goals, map out a plan, make it happen, measure the process and outcomes, and move forward. These steps are similar to the processes in the model by Palisano et al. PREP emphasizes identifying the environmental barriers and facilitators (physical, social, and organizational) to participation, including the demands of the activity. Further explanation of how to implement these models and case illustrations has been previously published and can serve as a roadmap for therapists to address participation in their practice.

Both the Palisano et al and PREP practice models are founded on a deep understanding of family/client-centered care. Therapists foster the development of a relationship and partnership with the family and child, and support them to participate in the intervention process. It is important for therapists to display positive beliefs about the client’s strengths and capabilities and to demonstrate respect, sensitivity, trust, and empathy. Therapists support participation by focusing on client priorities, offering choices, sharing information, and working together. The therapist and family members discuss and establish individual roles and responsibilities, ensuring that they are clear and manageable. Therapists strive to support client engagement and their active investment and involvement in the process.

Coaching principles and processes also resonate with participation-based intervention and both practice models described include aspects of coaching. Coaching is a client-centered, interactional, collaborative approach to engage clients and other team members. Clients are actively involved in the intervention through joint planning, action, reflection, and feedback. The therapist may model, demonstrate, teach, and practice activities with the child; however the child, family, and community members are supported to problem-solve, try the identified strategies, modify them as indicated, and develop new solutions. The therapist serves as a partner, listener, facilitator, and consultant. To apply the participation-based models to practice, it is important for therapists to be comfortable and competent in family-centered and coaching approaches to service delivery.

PHYSICAL THERAPISTS’ ROLE, INTERPROFESSIONAL PRACTICE, AND TEAM COLLABORATION

Because participation is complex and multidimensional, service providers need to consider who should support a child’s participation goal and we need to have open discussions around this question. For some clients it will be physical therapists and for other clients it may be other providers. Participation-focused interventions complement but do not replace or specifically address other important aspects of physical therapy services; however, I believe it is essential that we have clear expectations that our practice includes direct support for participation. For individuals with physical disabilities, physical therapists have a unique role in supporting participation. As movement specialists, we have expertise to support safe mobility within the context of interactions with people, objects, and the environment. We can foster fitness, energy conservation, and pain management to optimize health for participation in physical activity. We offer skilled interventions such as environmental modifications, task adaptations, and application of assistive technology. Our training in health promotion enables us to conduct environmental surveillance and train others in safety measures and precautions to prevent accidents and injuries and to minimize secondary health complications. Furthermore, as health care professionals with a strong medical background and interprofessional experiences, we have the knowledge and skill to identify when referrals to other professionals are warranted or to consult with other providers to support a client’s participation goal.

I believe it takes a collaborative community to realize full inclusion of individuals with disabilities. Interprofessional practice is “a partnership between a team of health professionals and a client in a participatory, collaborative and coordinated approach to shared decision-making around health issues.” With children it is appropriate to extend this partnership to include their educational team as well as community members. Sharing of information, knowledge, perspectives, resources, and responsibilities is an effective and efficient way to ensure that children receive the supports they need. Team collaboration is essential, including communication, coordination, and
consultation with others. Competence in these 4 Cs as well as leadership skills are needed to effectively develop and enrich partnerships and to efficiently and precisely take the steps necessary to realize participation for children.

Depending on the setting in which a therapist is serving children, team collaboration may occur through a transdisciplinary/primary service provider or interdisciplinary/multiple service provider approach to care. Developmental services to support home and community participation of children birth to 3 years of age, use both the transdisciplinary and interdisciplinary approaches, and educational-based services to support school participation for children and youth 3 to 21 years of age predominantly, use the interdisciplinary approach. Both participation-based models presented include a primary service provider approach that could be adapted across settings. I believe that a gap exists in service provision in that we do not have an adequate mechanism to support home and community participation for children and youth 3 to 21 years of age. Hospital and outpatient therapy address immediate health and functional needs. Both outpatient and school services may indirectly support home and community participation, but I believe we need to advocate for a paradigm shift and transform services to focus on measuring participation and designing effective interventions to directly support participation in all environments, for all ages.

MEASURING PARTICIPATION

Measuring participation is challenging and complex. Great strides have been made in the development of tools to measure participation. The various tools such as the Children’s Assessment of Participation and Enjoyment, Participation and Environment Measure for Children and Youth, and the Child Engagement in Daily Life recognize that participation is multidimensional. A key message is that there is a need for researchers and practitioners to measure what we are trying to accomplish. Imms and colleagues noted a mismatch between researchers’ description of participation and the outcome measures used. Frequency of participation was a common measured element. If we are trying to impact attendance or overall participation in a variety of contexts, then measuring frequency is appropriate. If we want to optimize participation within a specific activity setting then we need to carefully consider the best approach to measure the child’s involvement. As our research and practice may be directed toward the environment and building a community to foster participation, a related consideration is the usefulness of measuring the environment and activity setting itself.

Imms and colleagues found that a common element of involvement measured by researchers was the performance of the activities. This included frequency counts of observed behaviors, time to perform a task, and degree of independence. They noted that researchers measured performance on the basis of what was “appropriate” for the child’s development or situation or “correct” in regard to interactions with objects or people. The authors cautioned that “the inference associated with this language is that an increase in skill is equal to an increase in participation,” which may not be an accurate assumption. Activity competence may or may not be important, and when important it is necessary to consider what standard should be used as a criterion. I believe it is essential to ask the client what aspect of doing they want to change. There are many possible ways to measure doing, including but not limited to, what parts of the activities a person is doing, the extent a person uses adaptations and modifications, how painful a person is, and how hard a person is working during activities.

In a pilot study for participation-based therapy, a client and his peers provided our research team with valuable lessons regarding what aspects of doing were important and that competency can be framed from various perspectives. The client’s goal was participation in the church youth group. The physical therapist and youth leader identified that eating was a primary activity and began to consult with an occupational therapist on adaptive utensils. The youth made it clear that this was not the important part for him, that it was acceptable to him to have assistance from a person for eating, and that he would rather put his energies into participating more fully in other activities, such as singing. The client sang the lyrics, albeit, after they were sung by the rest of the group. The therapist wondered whether this was acceptable to the other youth and discovered that the youth perceived this as “harmonizing,” a very acceptable performance.

Deciding on the best approach to capture the essence of participation is further complicated by consideration of the type of measure. Qualitative approaches document the client’s own words or pictures about the experience through interviews, focus groups, journals, and media. Another approach that also gathers client perceptions is self-report measures, an approach commonly used in most existing participation measures. For young children and/or older children with significant cognitive limitations, these questionnaires have been designed to be completed by parents as proxy. Use of individual goals, written as behavioral objectives through standardized approaches, such as Goal Attainment Scaling or the Canadian Occupational Performance Measure, is aligned with the outcome of participation and the frameworks discussed. The rating of goal attainment can be conducted collaboratively, by client report, or by independent observation. The experience of the research teams that I have been part of, including collaborative research with parents, suggests that including individualized goal attainment when measuring participation is most meaningful and valued by clients. Observational rating approaches of participation offer another option. Last, physiological responses during participation can be used to capture the clients’ body functions.

PARTICIPATION-BASED INTERVENTIONS: PLANNING AND IMPLEMENTATION

I believe it is essential that the client’s goal guide our intervention. Table 1 includes an example of the evolution of goal development. In the past, therapists identified an impairment in balance, established a goal for balance, and provided interventions to improve this focused outcome. Presently, therapists demonstrate an awareness of the link between the balance goal and an important participation goal identified by the child, doing a dance routine. Therapists intervene and monitor outcomes at the body function and activity levels, including a
functional task such as kicking a ball. Therapists are now beginning, or are encouraged, to explicitly use the client’s goal. To impact a child’s ability to participate in dance class, it is important for a therapist to consult with the dance teacher to understand the dance moves, collaborate to adapt the routine or modify the environment as indicated, and to optimize balance within the context of dancing. Listening to music and dancing in therapy is motivating and fun, especially in a group setting. If it is not possible to provide intervention in the real-life setting of the dance class, today’s technology makes it possible for a therapist to view a video of the child’s dance class, videoconference with the dance instructor, and send a video of possible strategies and suggestions that have been tried during a therapy session.

To effectively provide participation-based interventions, I believe that therapists need to conduct a “participation analysis.” As therapists we have been trained to conduct task analysis to use motor learning principles to guide a client in learning a new task. In a participation analysis, an ecological assessment enables us to broaden our frame of reference to gather information on the child-environment interaction. Therapists collaborate with the family and child and actively involve them in the assessment process. Information is gathered on aspects of the child, family, and environment individualized specifically to the participation goal.12 The therapist interviews the people involved in the activity, observes the child in the activity setting, and conducts a focused functional examination within the real-life context. When examinations cannot take place in the natural setting of the activity, the process can be modified through the use of video technology, as exemplified earlier. Knowledge of the child’s interest and understanding of the participation goal, physical and communication abilities and social interactions related to the participation activities, and health considerations provide a foundation to guide intervention. Similarly, the family’s interest and desire for the child’s participation in the activities, their routines and resources to support the participation goal, their concerns, and their insights on the child’s abilities and readiness inform the development of a collaborative partnership. Information on the accessibility and safety of the community environment, availability of physical assistance and social/emotional supports, and community resources to support the child’s goal provide a vital link for the feasibility of goal attainment. Through this process the goal, intervention focus, and environment for service are confirmed, the intervention strategies are selected, and first action steps and responsibilities are discussed.

The ecological approach to participation suggests that effective interventions will be specific for a client within the setting and context of the desired goal. I propose that the active ingredient may be the collaborative, ecological process and not necessarily a particular intervention strategy. A systematic review last year found only 3 intervention studies with children with disabilities that focused specifically on participation.29 These studies with interventions by educators, occupational therapists, and psychologists provide support for both individual and group sessions that use individualized education, coaching, and mentoring. Pilot work and initial testing of the participation-based therapy models by Palisano et al12 and Law and colleagues25,26 show promise for the individualized, collaborative, and environmental approach. These models use intervention strategies that have been associated with participation: environmental accommodations, tasks adaptations, assistive technology, and the extent services have focused on function and meeting the child’s needs.13,40,41 Community partnerships and resources such as transportation, funding, and environmental modifications are necessary to ensure availability, accessibility, and affordability of participation opportunities. Providing real-life experiences and solution-focused coaching enable children to respond to environmental situations, broaden their repertoire of behaviors, request adaptations and modifications when necessary, and try new things. Adaptations and modifications to avoid “token” participation and facilitate meaningful participation require creativity and envisioning the possibilities. As the life course of children with disabilities includes associated health conditions and given the uniqueness of various activity settings, it is important for therapists to be available for periodic guidance and support.

**IMPLICATIONS FOR DPT CURRICULUM AND PHYSICAL THERAPY RESEARCH AGENDA**

On the basis of the past 2 decades of legislation, professional perspectives, and research, curricular changes are warranted to prepare future health care providers to optimize services and participation outcomes. I encourage educators to advocate for the construct of participation to be a theme embedded across the curriculum. Students need to be exposed to the top-down model of examination where examination and intervention planning is guided by the client’s goal. It is important for students to learn and practice the art of doing a participation analysis, teaming, and coaching. Health care users, youth with disabilities, and parents of children with disabilities should be valued instructors. Physical therapist students should have opportunities to learn with, interact, and develop solutions together with students from other health care professionals. Experiential learning in real-world activity settings and collaborating with other providers and clients around participation goals are essential. Interprofessional education is now mandated by CAPTE, but I encourage programs to embrace this approach not because we have to do it but because it prepares our students with the values and competencies they need to communicate with other providers, establish roles and responsibilities, and provide team-based practice to effectively support client’s health and goals.42 Resources to support this approach are available through the National Center for Interprofessional Practice and Education.43

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**TABLE 1**

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<th>Past</th>
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<th>Present and future</th>
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<tr>
<td>Charlotte balances on one foot with her hands on her hips for 10 s.</td>
<td>Charlotte balances on one foot with her hands on her hips for 10 s so that she can participate in a dance class.</td>
<td>Charlotte participates in a 3-min dance routine during her dance class without falling.</td>
</tr>
</tbody>
</table>

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Curiosity and creativity are needed to drive research to discover the knowledge we need to transform practice. We can learn a lot from qualitative studies and case series to better unravel the complexities of participation from the perspectives of clients and service providers across various activity settings and populations. Research needs to focus on examining the effectiveness of interventions aimed at participation goals and outcomes. To accomplish this task, it is important that families and clients be active members of the research team. It is also imperative that we advocate for funding for this line of research. Determining the cost-benefit analysis and broad societal effect will take time and require longitudinal research. Although participation-focused research is not as powerful as discovering a cure, it has the potential to improve the quality of lives of individuals with disabilities aimed at prevention of social isolation and depression and supporting employment, physical and mental well-being, and inclusion in society. To realize the transformation of practice, outcomes-oriented research and grassroots advocacy are needed to justify insurance reimbursement, policy change to create other funding sources, or use of fee for service mechanisms for participation-based interventions.

I encourage all of us to reflect on our current practice, teaching, and research; call forth our own plasticity and take small steps to make a change. Table 2 summarizes recommended approaches. We need to challenge boundaries and expand horizons to support participation of children with disabilities. In doing so I am optimistic that we discover answers to our many questions. What competencies do providers need to support participation? How can we step out of the box to provide services in the home and community for preschool and school-aged children? What infrastructures need to be in place in the community to support participation?

ACKNOWLEDGMENTS

I acknowledge my collaboration with my colleagues from the following research teams: CAPS, Move and PLAY, PT COUNTS, On Track, and Participation-Based Therapy.

REFERENCES


TABLE 2

<table>
<thead>
<tr>
<th>Practice</th>
<th>Education</th>
<th>Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Client-centered care</td>
<td>• Participation as curricular thread</td>
<td>• Qualitative and case series research</td>
</tr>
<tr>
<td>• Collaboration with client, family, other service providers, and community</td>
<td>• Children and adults with disabilities and their families as teachers</td>
<td>• Intervention studies with participation as the primary focus</td>
</tr>
<tr>
<td>• Ecological participation analysis</td>
<td>• Interprofessional learning</td>
<td>• Families and individuals with disabilities as part of the research team</td>
</tr>
<tr>
<td>• Interventions in context of real-world activity settings</td>
<td>• Experiential learning</td>
<td>• Advocate for funding</td>
</tr>
<tr>
<td>• Coaching</td>
<td>• Competencies in collaboration and coaching</td>
<td>• Longitudinal studies to demonstrate societal effect and cost/benefit ratio</td>
</tr>
<tr>
<td>• Environmental and task supports</td>
<td>• Participation-focused examinations and interventions</td>
<td></td>
</tr>
</tbody>
</table>


Virtual Reality and Serious Games in Neurorehabilitation of Children and Adults: Prevention, Plasticity, and Participation

Judith E. Deutsch, PT, PhD, FAPTA; Sarah Westcott McCoy, PT, PhD, FAPTA

Rivers Lab, Department of Rehabilitation and Movement Sciences (Dr Deutsch), School of Health Professions, Rutgers University, Newark, New Jersey; and Department of Rehabilitation Medicine (Dr Westcott McCoy), University of Washington, Seattle.

Use of virtual reality (VR) and serious games (SGs) interventions within rehabilitation as motivating tools for task specific training for individuals with neurological conditions are fast-developing. Within this perspective paper we use the framework of the IV STEP conference to summarize the literature on VR and SG for children and adults by three topics: Prevention; Outcomes: Body-Function-Structure, Activity and Participation; and Plasticity. Overall the literature in this area offers support for use of VR and SGs to improve body functions and to some extent activity domain outcomes. Critical analysis of clients’ goals and selective evaluation of VR and SGs are necessary to appropriately take advantage of these tools within intervention. Further research on prevention, participation, and plasticity is warranted. We offer suggestions for bridging the gap between research and practice integrating VR and SGs into physical therapist education and practice.

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Key words: neurologic physical therapy, participation, pediatric physical therapy, plasticity, prevention, serious games, virtual reality

INTRODUCTION

Virtual reality (VR) was developed in the early 1900s through application of in-flight simulations. VR is the generation of simulated or virtual environments (VE) that allow user interactions through multiple sensory (visual, auditory, and haptic-sense of touch) channels. Customized VR systems have been designed using specialized hardware, such as haptic robotic interfaces, or off-the-shelf hardware such as the Kinect camera. Specialized VEs are based on enriched environments and designed with principles of motor learning for example, with feedback and task specificity.

A special characteristic of VR systems is that they create the illusion that a person is interacting with a synthetic world. These states have been defined as presence, immersion, and flow. The state of presence, or the experience that the environment is real, is created in part by the system’s capacity to deliver the illusion of reality or degree of immersion. Hardware used to deliver the VE creates the immersion characterized along a continuum, with highly immersive customized environments using head-mounted displays and caves. Caves are room-size visualizations that multiple users sharing the same experience. It is the most immersive with desktop computers or tablets using off-the-shelf video games as the least immersive. The degree of immersion is not necessarily related to the effectiveness of the VR system. The interactivity of the VE is important to create engagement. The user experience is characterized by attributes of challenge, positive affect, “endurability” aesthetic and sensory appeal, attention, feedback, novelty, interactivity, and perceived user control. VR and video games create a state of flow, a multidimensional construct, describing the user in an optimal performance zone. For people to sustain intense activity, regarded as central for neurorehabilitation, the person’s attention and motivation matter. Although not the main focus of this article, it is important to realize that the manipulation of the virtual environments, feedback, and the state of the person in the VE are all important considerations for rehabilitation.

Rehabilitation applications of VR emerged for adults and then children for the management of pain associated with burns. The term “virtual rehabilitation” was created at the

first Workshop on Virtual Rehabilitation. The first publications in adult rehabilitation focused on people poststroke, with publications in pediatrics primarily focused on children with cerebral palsy, although children with other disabilities have been studied. Physical therapists have used both customized VEs and active video games or commercial off-the-shelf games. The active video, off-the-shelf games were developed for recreation but are adapted for rehabilitation and take advantage of the motion-sensing features of the games. For this article, we refer to these commercial games, such as Nintendo or Kinect, as serious games (SG) because they were adapted for a purpose other than entertainment. Studies of rehabilitation have incorporated the games as safe, motivating, engaging, and fun task-specific practice to facilitate restoration of movement capabilities. Customized laboratory-based systems in parallel with SGs have been explored for their potential to motivate and provide meaningful intensive repetitive practice in ecologically valid environments.

PREVENTION

VR and SG offer an engaging and affordable way to encourage and increase physical activity. VR and SG as a secondary prevention intervention to increase fitness and decrease obesity and the related health risks in children with neuromotor conditions began in 2006. Widman et al demonstrated that 8 children with spina bifida could increase their energy expenditure to a moderate level while arm cycling within a VE. More recently, Fehlings et al reported on 4 studies enrolling 52 children with cerebral palsy (CP) using Wii Sports, DanceDanceRevolution, Sony Playstation Eye Toy, a robot for ankle impairments, and an Internet-mediated interactive motor and cognitive training program. The VR or SG dose prescribed within these studies varied. Common outcomes reported were the metabolic equivalent for tasks (METs) and the 6-minute walk test (6MWT) with varied improvements reported. Most participants did show moderate energy expenditure, with some children reaching vigorous levels; however, the 6MWT results were conflicting between studies. More recently, Robert et al measured energy expenditure in 10 children with CP playing Wii games and also found children could reach moderate levels of energy expenditure. Similar findings were reported for children with autism. The length of time spent at a higher intensity of physical activity could be increased with use of VR and SG.

For adults with neurological conditions, direct evidence for use of VR in a secondary and tertiary prevention model is sparse. The research exists primarily in the form of modifying risk factors for falls. Reducing fall risk has been reported both in studies for people with Parkinson disease (PD) and people with multiple sclerosis (MS). There is work with active video games for wellness fitness for prevention.

There are several research groups reported energy expenditure of people poststroke while playing Wii and Kinect games. There is a hierarchy for energy expenditure with standing balance games having the lowest requirements and standing activities that involved the upper limb, such as boxing with the largest expenditure. People poststroke worked in the lower end of the moderate range, which was comparable to overground walking. The games therefore may be suitable for wellness, but are not intense enough for fitness.

One of the limitations to increasing energy expenditure is that it takes place in an environment where the movement type and intensity is self-selected. It is possible that coupling video games as well as VEs with a closed system such as bicycling may address this limitation. Pilot work with a “sensorized” bicycle yoked to a virtual cycling environment supported that people poststroke could train for up to an hour, 2 times a week over a period of 8 weeks, and improve their VO2 as well as their gait speed. For people with PD, a cycling VE embedded with cueing and feedback increases cycling speed. VEs coupled with bicycles may augment the existing cycling programs used to improve fitness for people with PD. Similar improvements in fitness have been shown with VR arm and leg cycling systems in children with CP. Although these studies are promising for secondary prevention, larger and longitudinal evaluations of the effects of active VR and SG on wellness or health and fitness are necessary to demonstrate efficacy, determine dose, and document prevention of future health problems. Health and wellness outcomes after VR should be compared with active physical exercise in the natural environment.

OUTCOMES OF VR AND SG INTERVENTIONS

VR and SG offer the potential of practice in VEs that simulate natural environments yet allow for safer practice by individuals with neuromotor disorders. The majority of studies of adults and pediatrics had body function and structure and activity outcomes. We included a brief review of intervention studies of children and adults with outcomes across the International Classification of Function (ICF) domains.

Studies With Children as Participants

VR and SG applications for children include the use of SG and customized systems for specific motor practice. Outcomes varied in the ICF domains, with most measurements related to body structure and function and overall gross or fine motor activity. Some studies focused on sensory impairments including visual spatial training and sensory attention for balance, and some focused on intensity of exercise for improving fitness. Children with CP have been the most common participants; however, there are several studies with children with Down syndrome, developmental coordination disorder, autistic spectrum disorder, muscular dystrophy, and spina bifida. Studies are underway for children with acquired brain injury. The primary VR and SG systems used in the studies are the Wii Fit, sports, and balance systems. Many specialized systems have been developed for both upper extremity applications as well as greater motor control. Improvement in postural control have been studied primarily with use of the Wii and Kinect systems.

Outcomes: Body Structure/Function and Activity ICF Domains

Twelve published systematic reviews (Table 1) included 9 that focused on VR and SG intervention with motor
<table>
<thead>
<tr>
<th>Authors</th>
<th>Purpose and Participants</th>
<th>Participants (Studies Reviewed), n</th>
<th>VE/VR-SG</th>
<th>BSF Outcomes (+; ±; −)</th>
<th>Activity Outcomes (+; ±; −)</th>
<th>Participation Outcomes (+; ±; −)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mitchell et al[17]</td>
<td>To determine effectiveness of VR on physical activity capacity and performance in children with early brain injuries (TBI/ABI) including CP</td>
<td>28 (4)</td>
<td>Miti, Wii, IREX, SonyPlay Station</td>
<td>Isometric strength ± Functional strength + Time over 3 METs ± 1MWT −</td>
<td>UE Function ± Melbourne ± QUEST − MAUULF ± Reaching + AHA − MABC-2 + BOTMP-UE ± MACS LE SWOC + GMFM + MABC-2 + BOTMP − SANC + Cardio</td>
<td>COPM ± AMPS + Level of participation +</td>
</tr>
<tr>
<td>Fehlings et al[14]</td>
<td>To determine effectiveness of interactive computer play to improve motor performance (including motor control, strength, or cardiovascular fitness) in individuals with cerebral palsy</td>
<td>364 (24)</td>
<td>Nintendo Wii Sports or Fit, Miti, EyeToy for Sony PlayStation, VE + CIMT, VE + Cycling, VE + Treadmill, other custom system</td>
<td>UE kinematics + Active ROM + Muscle activation + Movement speed + Movement accuracy − LE</td>
<td>UE Function ± Melbourne ± QUEST − MAUULF ± Reaching + AHA − MABC-2 + BOTMP-UE ± MACS LE SWOC + GMFM + MABC-2 + BOTMP − SANC + Cardio</td>
<td>COPM ± AMPS + Level of participation +</td>
</tr>
<tr>
<td>LeBlanc et al[88]</td>
<td>To explain the relationship between AVGs and 9 health and behavioral indicators in the pediatric population (CP, DS, autism)</td>
<td>161 (9) (only studies for children with neuromotor conditions reported)</td>
<td>Wii, DDR, Kinect</td>
<td>VO2 + 6MWT ± Bruce treadmill test + METs + Total energy expenditure + VIM + TVMI + TSIF + Time in MVPA + Correct responses on VR game + Max work capacity +</td>
<td>MAUULF + BOTMP + Functional mobility +</td>
<td></td>
</tr>
</tbody>
</table>
### TABLE 1
Summary of Current Systematic Reviews of VR, VE, and SG Research in Pediatrics (Continued)

<table>
<thead>
<tr>
<th>Authors</th>
<th>Purpose and Participants</th>
<th>Participants (Studies Reviewed), n</th>
<th>VE/VR-SG</th>
<th>BSF Outcomes (+; ±; −)</th>
<th>Activity Outcomes (+; ±; −)</th>
<th>Participation Outcomes (+; ±; −)</th>
</tr>
</thead>
</table>
| Monge Pereira et al<sup>15</sup> | To determine the effect of the use of VR systems in the improvement and acquisition of functional skills in children with CP                                                                                   | 97 (13)                          | Wii, IREX, EyeToy, other custom system | Postural tone +  
Postural alignment +  
Proximal stability +  
Balance +  
Coordination +  
Quality UE movement +  
Bone health +  
fMRI +  
1MWT −  
Gait speed and stride length +  
Knee joint torque +  
sEMG faster activation +                                          | SACND ±  
QUEST −  
Active function +  
MABC 2 +  
BOTMP −  
Steps/meter traveled + | COPM −                                                                                                                                                  |
| Chen et al<sup>89</sup>         | To determine the effect of VR on UE function in children with CP                                                                                           | 125 (14)                         | EyeToy, Gesture Extreme, Wii, Ultra-glove, other custom system | PDMS-2 (UE) +  
BOTMP ±  
JB −  
ABILHAND +  
CHEK +  
MAUULF ±  
QUEST ±  
SHUEE ±  
PMAL +  
BBT −                                                                                                                                                           | COPM ±                                                                                                                                                       |
| Bonnechere et al<sup>85</sup>   | To determine the use of SG in rehabilitation in children with CP                                                                                          | 419 (31)                         | Wii, Miti, VE + Cycling, EyeToy,  
Kinect, other custom system | Benton Judgment of Line +  
Orientation test +  
Arrows subtest of the Nepsy +  
Roads test +  
SPPC +  
Strength +  
PBS +  
Bone mineral density +  
Knee muscle torque +  
Pediatric Volitional Questionnaire (motivation) +  
Reaching kinematics +  
IMRI +  
ROM +  
Borg Scale of Perceived Exertion +  
Total energy expenditure +  
Number of steps +  
Time spend to play +  
MAS −  
Computer-based and non-computer-based games −  
QUEST −  
BOTMP ±  
MACS −  
Reaching task +  
GMFM −  
Fine motor +  
TUG BBT +  
JT +  
ABILHAND-Kids +  
TUDS −  
MAUULF ±  
PMAL +  
FMA (UE) +  
Functional mobility +  
Hand function + | COPM ± =  
Participation +  
ToP +  
questionnaire on engagement and participation +   |

(continues)
### TABLE 1
Summary of Current Systematic Reviews of VR, VE, and SG Research in Pediatrics

<table>
<thead>
<tr>
<th>Authors</th>
<th>Purpose and Participants</th>
<th>Participants (Studies Reviewed), n</th>
<th>VE/VR-SG</th>
<th>BS/F Outcomes (+; ±; −)</th>
<th>Activity Outcomes (+; ±; −)</th>
<th>Participation Outcomes (+; ±; −)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dewar et al⁹⁰</td>
<td>To evaluate the efficacy and effectiveness of exercise interventions to improve postural control in children with CP</td>
<td>34 (3)</td>
<td>Wii, IREX</td>
<td>MTS −</td>
<td>BOTMP −</td>
<td>ROM −</td>
</tr>
</tbody>
</table>

### Activity Outcomes
- MTS −
- SCALE +
- 6MWT +
- Balance ±
- Gait speed +
- Heart rate +
- fMRI −
- Visual perceptual skills +
- Posture Scale Analyzer +
- Number of correct movements +
- Forearm bone density +
- Pelvic ROM +
- Trunk control +
- Standing balance ±
- Reactive balance −
- Directional control and synchronized standing −
- Functional balance +
- CBMS +
- 6MWT +

### Participation Outcomes
- GMFM −
- BOTMP −
- TUDS −
- GMFM −
- BOTMP −
- TUDS −
- GMFM −

---

Abbreviations: +, supporting evidence; ±, inconclusive evidence; −, no change/no difference; ABILHAND, ABILHAND-Kids Questionnaire; AHA, Assisting Hand Assessment; AMPS, Assessment of Motor and Process Skills; AVG, active video game; BBT, Box and Blocks Test; BOTMP, Bruininks-Oseretsky Test of Motor Performance; CBMS, Community Balance and Mobility Scale; CHEK, Children’s Hand Use Experience Questionnaire; CMIT, constraint-induced movement therapy; COPM, Canadian Occupational Performance Measure; CP, cerebral palsy; DDR, Dance Dance Revolution; DS, Down syndrome; FMAM, Fugl-Meyer Assessment; fMRI, functional magnetic resonance imaging; GMFM, Gross Motor Function Measure (66 or 88 items); IREX, Interactive Rehabilitation Exercise System; JTHF, Jebsen-Taylor Hand Function Test; MABC-2, Movement Assessment Battery for Children-2; MACS, Manual Ability Classification System; MAS, Modified Ashworth Scale; MAUULF, Melbourne Assessment of Unilateral Upper Limb Function; MET, metabolic equivalent of task; MTS, Modified Tardieu Scale; MVPA, moderate to vigorous physical activity; 1MWT, 1-minute walk test; PBS, Pediatric Balance Scale; PDMS-2, Peabody Developmental Motor Test-2nd ed; PITTTS, Pediatric Intensive Therapy System; PMAL, Pediatric Motor Activity Log; QUEST, Quality of Upper Extremity Skills Test; ROM, range of motion; SACND, Sitting Assessment for Children with Neuromotor Dysfunction; SCALE, selective control assessment of lower extremities; sEMG, surface electromyography; SG, serious games; SHUEE, Shriners Hospital Upper Extremity Evaluation; 6MWT, 6-minute walk test; SPPC, self-perception profile for children; SWOC, Standardized Walking Obstacle Course; ToP, Test of Playfulness; TSIE, Test of Sensory Integration Function; TUDS, Timed Up and Down Stairs; TUG, Timed Up and Go; TVMI, Developmental Test of Visual Motor Integration; UE, upper extremity; VE, virtual environment; VMI, Visual Motor Integration test; VO₂, maximum volume of oxygen; VR, virtual reality

---

⁹⁰Within the systematic reviews, there was repetition of some articles, with 62 original studies included overall among all reviews.

⁹⁵A search of the literature was completed within PubMed in June 2016 limited by age (birth to 18 years), English language, and the search words of Bonnechere et al⁸⁵ (serious gaming, serious games, virtual reality, tele-rehabilitation, virtual environment, computer game, exergaming) and additionally “interactive computer play” all with “rehabilitation.”
outcomes. The 9 systematic reviews were completed between 2009 and 2015 and varied in focus (Table 1). Within the reviews, there were 12 randomized controlled trials (RCT) and 85 other types of intervention studies, suggesting a relatively larger amount of research on VR and SG in pediatrics. Each review, however, suggested that the overall design quality of the research studies was low, level 2b through 5 on the Center for Evidence Based Medicine scale. Children aged 4 to 20 years participated in these studies, including 776 children with neuromotor conditions. Seventy percent of the participants were children with CP, with the remaining participants having Down syndrome and coordination disorders. The recommended VR or SG dose was between 1 and 70 hours (mean 15 hours, standard deviation 12; median and mode 9 hours). Improvements in body structure/function included balance, range of motion, strength, coordination, and kinematics, with activity domain outcomes improving in some studies and not in others.

Two recent RCTs and 2 nonrandomized clinical trials, not included in the above reviews, compared VR and SG interventions to control conditions with children with CP and children with fetal alcohol spectrum disorder who had motor disabilities. Mixed results for children with CP using MiTii exercise are reported. One group reported statistically but not clinically significant higher performance with MiTii than the standard care group. Whereas Lorentzen et al. used double the dose of the previous study, reported a large training effect for changes in gross and fine motor activity as compared with a group who received no intervention. Tarakci et al. reported similar findings for children with CP as per the previous reviews with positive improvements on balance outcomes after use of the Wii Balance system. Jirikowic et al. evaluated a customized game-based VR system delivered through an head-mounted display (Sensorimotor Training to Affect Balance Engagement and Learning, STABEL) to provoke practice of standing balance in a sensory environment designed to require a shift of sensory attention from vision and somatosensation to vestibular sensation to maintain balance. Statistically and clinically significant improvements in both balance and overall motor ability after 4 hours of intervention were reported in the intervention but not in the control group who received no intervention. These recent results are similar to the earlier research, with generally positive improvements in body structure/function domain but mixed results in activity domain outcomes.

Outcomes: Participation Domain

Eight of these studies measured a participation outcome. Five used the Canadian Occupational Performance Measures (COPM), which includes the collaborative creation of individualized goals, one study used the Test of Playfulness, and 2 used the Assessment of Motor and Process Skills. Most studies indicated a positive improvement in participation. However, 2 studies indicated that the differences between the VR and SG system and standard care groups were not clinically significant.

Adults as Participants

The use of VR and video games for adults with neurological conditions can be grouped into enhancement of upper limb (UL) use, balance and mobility training, sometimes termed lower limb training, activities of daily living, neglect, and cognition. We report on movement outcomes for people with stroke, PD, and MS but not activities of daily living, neglect, or cognition.

Body Structure/Function and Activity Domains

The largest body of work is with people poststroke reflected by a Cochrane review that was updated until July 2014, with a 2015 publication and currently being revised for a third time. Since the Cochrane review there are 6 systematic reviews with meta-analyses on balance and mobility. These reviews (Table 2) have different objectives including the evidence on the Wii, discriminating between VR coupled with treadmills, customized systems that do not involve a treadmill and off-the-shelf games. Treadmills coupled with VR, off-the-shelf video games, and custom systems built by investigators that are not available commercially, were used. There is a small but consistent benefit for VR in gait measured by gait speed, balance measured by the Berg Balance Scale, and the Timed Up and Go. The meta-analyses favor VR with balance outcomes; these studies do not meet the minimal clinically important difference.

Three systematic reviews synthesize the work on use of VR-based activities for the UL poststroke. The early studies reviewed by Saposnik and Levin were primarily single-group studies that measured body function/structure and activity-level outcomes. VR improved UL function for people in the chronic phase poststroke. The review by Lohse et al. considered SGs and VEs and described support for an additive effect for SGs and VR-based activities over traditionally presented UL rehabilitation activities. The most detailed analysis was provided by Laver et al. in the Cochrane review and support that VR-augmented therapy for the UL enhances UL use; people in the acute phase poststroke fare better than those in the chronic phase and the dose of intervention matters. People who received more than 15 hours of intervention improved more than those who received less than fifteen. Taken together these studies show a steady progression of support to incorporate VR into UL interventions for people poststroke. Innovation and optimization of these therapies are underway, with the advent of smaller sensing devices as well as less intrusive and less expensive UL supports.

For people with MS, there are a combination of SG used for rehabilitation, primarily the Wii and treadmills coupled with VEs. Taylor and Griffin published a narrative systematic review of 11 studies and 1 protocol using gaming technology, both the Wii and the Kinect, for rehabilitation of people with MS. They reported that use of Wii Fit games in a clinical setting yielded improvements in postural control as well as functional balance. One group of investigators designed a dynamic platform that was coupled with the Wii games. This created a more dynamic balance challenge than using the Wii
## TABLE 2
Summary of Systematic Reviews of VR and SG for Balance and Mobility of Persons Post-Stroke

<table>
<thead>
<tr>
<th>Author</th>
<th>Purpose</th>
<th>n</th>
<th>VR-SG</th>
<th>Body Function Structure</th>
<th>Activity</th>
<th>Participation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cheok et al(^9)</td>
<td>Use of Wii for stroke rehab</td>
<td>170 (6)(^b)</td>
<td>Nintendo Wii</td>
<td>Postural control ±</td>
<td>WMFT + BBS ±</td>
<td>SIS ±</td>
</tr>
<tr>
<td>Corbetta et al(^10)</td>
<td>VR for balance and walking poststroke</td>
<td>341 (15)</td>
<td>Treadmill + VR</td>
<td>Kinematics postural Control</td>
<td>Gait speed + TUG + BI FIM TUG + 6MWT FIM ABC</td>
<td>Community ambulation +</td>
</tr>
<tr>
<td>Li et al(^11)</td>
<td>VR for balance + gait poststroke</td>
<td>428 (16)</td>
<td>Treadmill + VR</td>
<td>Postural control ±</td>
<td>BBS ± FRT ±</td>
<td>TUG + ABC ±</td>
</tr>
<tr>
<td>Gibbons et al(^12)</td>
<td>VR for LL outcomes poststroke</td>
<td>522 (22)</td>
<td>Treadmill + VR</td>
<td>Postural control +</td>
<td>BBS + Gait Speed + 6MWT + ABC</td>
<td>FRT + TUG + WAQ + DGI ±</td>
</tr>
<tr>
<td>Iruthayarajah et al(^13)</td>
<td>VR for balance + gait for chronic stroke</td>
<td>984 (20)</td>
<td>Nintendo Wii Fit</td>
<td>Postural control ±</td>
<td>BBS + FRT ± 6MWT ± Tinneti</td>
<td>TUG + 10MWT + BBA ±</td>
</tr>
<tr>
<td>de Rooij et al(^14)</td>
<td>VR for gait and balance poststroke w/ matched dosing</td>
<td>(21)</td>
<td>Treadmill + VR</td>
<td>Temporal spatial ±</td>
<td>Gait speed + 10MWT ± FRT + Tinneti</td>
<td>BBS + TUG + BBA ±</td>
</tr>
</tbody>
</table>

Abbreviations: ++, favor VR; ±, inconclusive; −, favor control; ABC, Activity Based Confidence Questionnaire; BBA, Brunel Balance Assessment; BBS, Berg Balance Scale; BBT, Box and Blocks Test; BI, Barthel Index; DGI, dynamic gait index; FAC, Functional Ambulation Capacity; FIM, Functional Independence Measure; FM, Fugl-Meyer; FRT, Functional Reach Test; LL, lower limb; MMAS, Modified Motor Assessment Scale; SG, serious games; SIS, Stroke Impact Scale; 6MWT, 6-minute walk test; 10MWT, 10-m walk test; TUG, Timed Up and Go; VR, virtual reality; WAQ, Walk Activity Questionnaire; WMFT, Wolf Motor Function Test.

Systematic reviews of the literature on VR and SG for adults were searched on PubMed (published by June 2016) using the following terms: virtual reality, virtual environments, video games, serious games, Wii, Kinect, and specific conditions stroke, Parkinson disease, and multiple sclerosis. These populations were selected because they represent people who are seen frequently by physical therapists and the corresponding VR literature is sufficiently valid to have been summarized in systematic reviews.

Hall the studies were dose matched, included upper limb and lower limb studies.
platform alone, which did not result in improved postural control or functional balance.110 Feasibility of a telerehabilitation model was tested and demonstrated improvements in activity-based balance measures for both the local group and remote groups using Kinect. The remote group had postural control improvements, which the control group did not.111 A walking study, coupling VR with a treadmill, produced gait and dual task balance improvements.112 Overall there is a small body of work with studies at level 2b to 5 on the Center for Evidence Based Medicine scale.91

For people with PD, the literature has been summarized (Table 3) with narrative reviews on assessment and treatment of balance and gait using VR113 and exergaming (use of video games for physical activity).114 Nine studies used either the Sony Playstation115 the Wii,116-121 a customized balance board,122 or a treadmill VR combination.26 The findings generally have activity-based outcomes that favor VR. More recently, investigators have used the Kinect to develop customized applications for balance training123 and reported preliminary positive balance findings in a cohort study. Another study suggested no difference when comparing home-based therapy with home-based VR therapy.124 In a study with dancing (with the K Pop Dance Festival from the Wii) added to the standard of care, participants had reduced symptoms of depression and improved balance.125 The results of the largest multicenter clinical trial on walking with VR, VTIME, are pending.126

Across all the populations studied, researchers have examined SGs, predominantly the Wii (although newer studies are reporting use of the Kinect), customized balance systems, and treadmills yoked to VR and UL robotic interfaces connected to VR. Research has evolved to more dose-matched studies of higher quality. The highest levels of evidence are for studies on UL use and balance and mobility training for people poststroke. There is a lag between commercial video game development and application to practice as evidenced by very few studies using the Kinect.

**Participation Domain**

Measures of participation were absent from all the systematic reviews on balance and mobility of people poststroke, with the exception of Mirelman et al.127 who measured improvements in ambulation in the community for 1 week before and 1 week after the conclusion of the VR intervention. For the UL studies in people poststroke, the Stroke Impact Scale is reported, as a participation measures in only 2 studies.106,128 By contrast, in a review article on use of Wii for rehabilitation of people with MS participation, measures were included in 3 of the 9 RCTs or cohort studies.107 A study protocol129 included measures of participation. Participation outcomes improved on measures such as the Physical Activity and Disability Survey, the SF-36, the Multiple Sclerosis Fatigue Impact Scale,27,130 and the Multiple Sclerosis Impact Scale.109

For people with PD, change in participation was reported on the basis of scores on the Parkinson Disease Questionnaire (PDQ) in 2 cohort studies and 1 RCT.116,121,131 People with PD who were on average 5 years postdiagnosis played Wii Sports (specifically tennis, boxing, and bowling) for 12 1-hour

<table>
<thead>
<tr>
<th>TABLE 3</th>
<th>Summary of Reviews on VR and SG for Persons With Parkinson Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Author</td>
<td>Purpose</td>
</tr>
<tr>
<td>Mirelman et al.113</td>
<td>VR and MI for balance and gait in Parkinson disease</td>
</tr>
<tr>
<td>Barry et al.114</td>
<td>VR’s effectiveness in Parkinson disease</td>
</tr>
<tr>
<td>Taylor and Griffin107</td>
<td>VR effectiveness in multiple sclerosis</td>
</tr>
</tbody>
</table>

**Abbreviations:** –, favors VR; +, favors control; ABC, Activity Balance Confidence Questionnaire; BBS, Berg Balance Scale; DGI, dynamic gait index; FRT, functional reach test; FSST, Four-Square Step Test; MFS, Modified Fatigue Impact Scale; MSIS, Multiple Sclerosis Impact Scale; MSWS-12, Multiple Sclerosis Walking Scale; SG, serious games; SLS, simple-limb stance; SOT, Sensory Integration Test; TUG, Timed Up and Go; 25-FWT, 25-Foot Walk Test; UPDRS, Unified Parkinson Disease Rating Scale; VR, virtual reality.

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sessions over 1 month and improved in the PDQ that lasted 4 months postintervention. Changes in the PDQ were reported by a group that used the Wii as a balance training tool and similarly by a group that used the Kinect Adventures games to improve balance. By contrast, a home-based VR intervention for balance and mobility was no different from standard of care home physical therapy in changing the PDQ. The frequency with which participation is used as an outcome in studies of people poststroke was lower than that reported for people with PD or MS. This may in part be explained because of the progressive nature of MS and PD and the belief that participation may be altered but body function/structure may not.

PLASTICITY

Plasticity is a complex cellular and molecular process depending on genetic, epigenetic, and environment and activity. VR and SG interventions potentially offer a method to promote meaningful, through engagement and flow, repetitions of movements to change brain structures. Noninvasive measurement of brain changes, however, is complex and little data are available related to either pediatric or adult VR and SG interventions. This is partially due to the relative discomfort and difficulty remaining still for brain scans, especially for children, and the cost of the scans. Other issues relate to the variability of neural activity between individuals, reliability and sensitivity of brain scan results in children, and lower relationships between magnetic resonance imaging (MRI) results and motor ability.

Two studies of children with hemiplegic CP (n = 4) evaluated for brain changes after VR and SG interventions. Functional MRI findings from one participant in the You et al study suggest that IREX (Interactive Rehabilitation Exercise System), a computer interaction with sensor gloves intervention, influenced greater contralateral control of the child’s affected arm. Golomb et al, using a sensor glove and the PlayStation 3 system, found expanded activation of the primary motor cortex and cerebellum and greater contralateral activation.

Two studies with larger numbers of participants are ongoing that include brain scans in children with acquired brain injury and CP.

Five studies of adults with neurologic conditions have evaluated use-dependent plasticity associated with learning. Two early studies of people poststroke reported functional improvements in UL use and gait that paralleled a shift from contralateral sensorimotor activation posttherapy to predominantly ipsilesional activation posttherapy. More recently, Saleh et al reported changes in connectivity between the lesioned and nonlesioned hemisphere, with one subject demonstrating increases and the other subject decreases in the lesioned hemisphere. In contrast, Orihuela et al reported contralesional activation of the unaffected motor cortex as well as cerebellar recruitment and compensatory prefrontal activation. These studies included participants in the chronic phase poststroke and the total number was fewer than 20; thus, the findings are limited. The remaining 2 studies included participants with MS. Prosperini et al reported balance improvements after a 12-week training program with the Wii that were associated with increased structural integrity of the superior cerebellar peduncle. Cognitive-based video games reporting experience-dependent plasticity are not included in this article.

Short-term plasticity has been demonstrated with VR manipulations of visual representations. Using the phenomenon of visuomotor discordance, that is reconciling the discrepancy between intended actions and discrepant visual feedback, investigators have shown that motor area (M1) activation is increased, as healthy adults try to reconcile this discrepancy. This manipulation may result in use-dependent plasticity and more permanent structural changes.

The use of brain scans within pediatric and adult practice could add significantly to the understanding of the baseline neurologic problems of individuals with neuromotor conditions and also could provide guidance for evaluating and adjusting intervention programs that use VEs. Scanning could potentially determine neurological reorganization and assist with understanding restoration versus compensation.

BRIDGING THE GAP FROM EVIDENCE TO PRACTICE

VEs and SG have appealed to practitioners and participants. Transferring the technology to the clinic and home and the knowledge to implement technologies remain a challenge. VR systems that were customized in a laboratory are not available for purchase. With the wide availability of VR through motion-controlled games such as Wii and Kinect, the technology has become more accessible and clinicians have indicated willingness to adopt them in practice. However, barriers exist to implementing these technologies in clinical practice including lack of knowledge about the VR systems and time to implement them into practice are barriers. There are concerns that the variety of games makes it difficult to find the best exercise to meet a person’s needs and may shift the person’s attention from the movement practice itself to the game play, which may degrade the movement practice. We offer suggestions for education, practice, and research that may enhance informed adoption of the technology.

Education

Education may take the form of continuing education for clinicians and formative education for students in training. Researchers suggest that training should result in students and therapists being able to problem-solve the active ingredients within various VE and VR or SG systems and use the systems to their clients’ advantage.

For students at entry to the profession, we suggest that selecting the correct technology and application is an extension of clinical reasoning that may be best taught in a distributed model across classes rather than as a unit in one class. Specific suggestions include students learning to evaluate the evidence supporting the technology as well as practicing the implementation of the technologies as tools for therapeutic exercise and movement reeducation on themselves and through integrated clinical experiences before their clinical internships. Practicing therapists should consider the VR and SG systems as one more addition to their intervention toolbox that should be systematically analyzed and applied judiciously.
Resources for Clinicians and Educators

Although clinicians were enthusiastic with the introduction of VR and SG in practice, there are challenges with understanding the content and application of the systems. Early publications incorporating SG into practice aimed to describe the games as well as the rationale for selecting them for a specific practice application. Galvin and Levac suggested a method for consideration of VR and SG systems for pediatric rehabilitation that may generalize to adult rehabilitation. They created an algorithm for selection of the most appropriate system on the basis of an analysis of system variables including ability to manipulate, track, target body movements, adjust motor demand, and focus on quality of movement and user variables such as upper and lower limb requirements to play the game. With this system, students and therapists can consider the intensity of physical activity, the nature of movement, amount and frequency of active movement, and adjustment to the therapeutic goals for the client. Levac and Galvin offer case examples of using the classification system for decisions about VR and SG systems for children.

There have been efforts to analyze the Wii and Wii Fit games that are bundled with the console and balance board for ease of use and practice. This game analysis identified game applications for rehabilitation of balance, strength, and endurance, and it extracted both the knowledge of results and knowledge of performance information. The games provided more knowledge of results and positive feedback than knowledge of performance. Clinicians need to be mindful of the movement strategies clients use while playing the games. More recently, 5 investigators have collaborated on a game analysis of the Kinect Adventure Games. The Kinecting with Clinicians (Kwic) resource is used online with cases and videos (http://kinectingwithclinicians.com/). This online resource illustrates with case studies the implementation of video games into the rehabilitation for children and adults. The authors have created descriptions of the games using motor learning definitions and practice terminology. Studies are underway to determine its usefulness and whether it is scalable and sustainable.

Linking Clinicians and Researchers

Although the SG systems are appealing because of their low cost, they are limited by the lack of customization and rehabilitation-relevant theoretical framework that informs their design. Customized systems are superior to SG in balance and mobility studies in people poststroke and with upper extremity interventions should be standardized and described in addition to the VR and SG programs.

If these technologies are to be used in practice, a synergy between commercial entities, researchers, educators, clinicians, and clients needs to occur. We advocate for partnering of communities through professional organizations such as the American Physical Therapy Association, Academies of Neurology and Pediatric Physical Therapy, the International Society of Virtual Reality, International Industry Society Advanced Rehabilitation Technology, and interested academic and industry partners to standardize technology development and research. This work should be guided by a patient-centered approach to achieve the goal of clinical application of VR/VE and SG to improve movement, function, and participation in clients with neuromotor conditions.

REFLECTIONS AND RECOMMENDATIONS

Virtual reality is a rapidly developing area with advances in technology that often outpace the research. Evidence is accumulating to support the use of VR and SGs either alone or in addition to standard of care. The body of evidence remains confounded by the challenge of parsing the customized laboratory-based simulations with the off-the-shelf games and the hybrid systems that use off-the-shelf hardware with customized software. As the development, research, knowledge translation, and application move forward, physical therapists play an integral role in shaping the process. Physical therapists are currently involved in all aspects and can influence the types of technologies that are developed for their clients by contributing to development as well as application.

Prevention, plasticity, and participation effects of VR and SG are understudied. Larger numbers of participants are needed for prevention studies, and the studies need to be directed at primary as well as secondary and tertiary prevention. Evaluations of brain changes through the process of plasticity from VR and SG intervention depend to a great extent on the brain scanning technology and cost of these services. Research investigating recovery in more acute stages postnervous system insult could guide use of VR and SG. Most of the research on VR and SG has been done at the body structure/function and activity domain, particularly in studies of balance and locomotion. For chronic adult conditions such as PD and MS, participation is more regularly documented. In the pediatric literature, there are reports including participation outcomes, based on individualized client goals as measured with the COPM, but participation is not included in the majority of studies. The COPM customizes goals, which can be directed toward participation. This tool may be well suited across a variety of populations. Because of some conflicting evidence on carryover of motor improvements within VR systems to the natural environment, future research on participation outcomes should also evaluate VR and SG practice alone and within natural environments to determine programs leading to the best movement outcomes. Standardization of behavioral outcome measures across studies would increase the usefulness of meta-analyses. Control interventions should be standardized and described in addition to the VR and SG programs.
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Coupling Timing of Interventions With Dose to Optimize Plasticity and Participation in Pediatric Neurologic Populations

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Purpose: The purpose of this article is to propose that coupling of timing of interventions with dosing of interventions optimizes plasticity and participation in pediatric neurologic conditions, specifically cerebral palsy. Dosing includes frequency, intensity, time per session, and type of intervention. Interventions focus on body structures and function and activity and participation, and both are explored. Known parameters for promoting bone, muscle, and brain plasticity and evidence supporting critical periods of growth during development are reviewed. Although parameters for dosing participation are not yet established, emerging evidence suggests that participation at high intensities has the potential for change. Participation interventions may provide an additional avenue to promote change through the life span. Recommendations for research and clinical practice are presented to stimulate discussions and innovations in research and practice. (Pediatr Phys Ther 2017;29:S37–S47)

Key words: cerebral palsy, critical periods, dose, participation, plasticity

INTRODUCTION

Optimizing plasticity and participation of pediatric populations with neurologic conditions is aligned with the profession’s vision to “transform society by optimizing movement.”1 To enact this vision, education at the doctorate level provides us with skills to be evidence-based practitioners, clinician-researchers, advocates, and community leaders. Determining treatment effectiveness for pediatric populations with neurologic conditions is a priority identified by the Institute of Medicine2 and by pediatric physical therapists.3 It is a complex problem with many factors.4 Our knowledge of children, families, environment, development, and interventions can inform practice and research.3,5,6 Dose is operationally defined by its parameters: (1) frequency; the number of sessions a week and number of weeks; (2) intensity; strenuousness of exercise; (3) time per session; and (4) the type of intervention.7 Type of intervention refers to the focus of the intervention, for example, changing body structures and function, or activity and participation. Critical periods of plasticity reinforce the importance of age of intervention, that is, the timing of the intervention. The challenge is to integrate knowledge about the effective dose (frequency, intensity, and time per session) given the different types of interventions with attention to the optimal timing of interventions to maximize plasticity and participation.

The optimal dose of an intervention ideally produces sustainable changes at the level of body structures and function and activity and participation.4 Determining the optimal dose given a child’s individual, family, and community characteristics is a national priority for the Federal Government,8 third-party payers, school districts, pediatricians, rehabilitation centers, therapists, and the children.2 Development of practice guidelines that promote optimal outcomes (satisfaction, function, health, participation) and minimize costs to families, society, the individual, and the providers are is.4,9

Interventions cannot be optimally dosed if there is no evidence of demonstrated effectiveness at either the structural or functional level. Effective interventions are “worth it”10 if the effort yields positive short- and long-term outcomes. We have previously described a path model for dosing4 pediatric rehabilitation services (Figure 1), and moderating and mediating factors of treatment effectiveness. Dose is a factor that can be modified. Exercise dosing includes the type of intervention, frequency, intensity, and time per session. Regardless of type, the time per session, effort, and frequency of performance of an activity appear to be a key factor.3 Age is a moderating factor, and optimizing timing of interventions, or age at intervention, has potential to improve treatment effectiveness. Interventions may have the greatest effect when harnessing the increased potential for plastic changes during critical periods of brain, bone, and muscle development. Moreover, activity based and participation interventions have the potential to increase dose in the natural...
environment, and if dosed high enough may yield changes. Combining the 2 factors of dose and timing of interventions may open new pathways for promoting positive outcomes.

The path model for dosing (Figure 1) classifies type of intervention according to the International Classification of Functioning, Health, and Disability (ICF). These classifications are impairments, activity limitations, or participation restrictions. Type of intervention also refers to the specific physiological mechanisms by which the intervention creates change (e.g., muscle hypertrophy, motor learning, increased trabecular bone formation, or increased movement or engagement in everyday life). Types of interventions can be at the level of body structures and function and plasticity supported (changes in muscle, bone, or brain); at the level of activity and participation (changes in movement and interaction with the environment) and participation driven, or both. The differential effect of optimal type of intervention is explored with recommendations for research and clinical practice.

**COUPLING TIMING AND DOSE**

Dose is important in determining the effectiveness of pediatric rehabilitation interventions. Interventions at the body structures level may affect changes at the level of body structures and function and link to performance in everyday life (Figure 2). Interventions at the activity and participation level may affect changes in performance capacity and in everyday life and capacity with changes in structure and function. Age at time of interventions moderates outcomes. Optimal timing of interventions has the potential to increase treatment effectiveness.

Dosing parameters for interventions focused on body structures and function and activity and participation are described next. For each type of each of intervention described, evidence for effective frequency, intensity, and time per session are reviewed. Evidence is given to support optimal timing or age at intervention. Tables 1 and 2 summarize interrelationships among factors that mediate and moderate interventions that capitalize on the plasticity of the musculoskeletal system of the central nervous system or those that increase participation in daily life to create structural and functional change.

**Interventions That Harness Plasticity to Create Change**

**Improving Bone Structure and Function.** There are interventions that optimize skeletal development during critical periods in early infancy and prepuberty. Most of the fetal bone accrual occurs in the last trimester of pregnancy and is dependent on movement. Newborns with limited movement in utero have smaller, weaker bones and are at greater risk for fracture. Infants who are born prematurely may have fewer opportunities for movement during the first few weeks of life compared with infants who are born full term and are able to move in utero. Evidence supports passive, flexion, and extension range of motion exercises of the upper and lower extremities in preterm infants, 10 minutes for 4 to 8 weeks, with an increased effect after 8 weeks to positively impact bone health. Growth hormones facilitate bone modeling that occurs prepuberty and during puberty. Adolescents accumulate 25% of their adult bone during the 2 to 3 years after maximal height is reached, on average 13.4 years for boys and 11.8 for girls. Interventions provided before maximal height is reached may provide the greatest treatment effect. Interventions for bone during childhood may provide a lifetime of benefit.
Dose. Key factors for exercise interventions to improve bone health for children developing typically are frequency and duration of the activity, loading on the skeleton during the activity, and age at the time of activity. For activities with lower loading on the skeleton, increasing the frequency of the activity within a session or during the week can increase osteogenic potential. The osteogenic index of an exercise is calculated as intensity × ln (frequency + 1) × times per week. An example of an exercise intervention that was effective immediately, after 3 and 8 years with healthy prepubertal children, required children to jump high enough for a ground reaction force 8 times their body weight, 100 times (10 minutes), 3 times a week, for 7 months. This yielded an osteogenic index of 110. For children who cannot perform activities that produce a ground reaction force of 8 times their body weight (jumping off a 60-cm box), but can produce a ground reaction force 2 times their body weight, an osteogenic index of 110 to 115 can be obtained by increasing the number of loading cycles to 1200 and the frequency to 9 episodes per week. Bone requires about 8 to 10 hours’ rest, so a frequency of twice-a-day bone loading is possible.

Bone health should be monitored in children with cerebral palsy (CP); however, there is no consensus for dosing exercise interventions. In a systematic review, Novak et al identify a “worth it” line of interventions for children with CP. Whole body vibration is on the line of just being “worth it,” and standing frames are closer to “probably do it.” Bone response to skeletal loading in children with CP appears to be more positive when standing programs are performed frequently and for a long duration (3 times a week for 9 months). Dynamic standers may have increased effect on bone in children with severe CP as compared with static standers. Multimodal programs that include aquatics, body weight support (BWS) treadmill training, and progressive resistive exercises have evidence of effectiveness for children with Gross Motor Functional Classification System (GMFCS) levels I to IV.

Vibrating pads placed on long bones while children are sitting in chairs have demonstrated some effect on bone. Insufficient evidence exists to support any of the types of bone interventions for prevention of spinal and hip deformity into adulthood.

| TABLE 1 |
| Features of Intervention Types |

<table>
<thead>
<tr>
<th>Type</th>
<th>Characteristics</th>
<th>Other Factors</th>
<th>Site Specific</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harnessing plasticity</td>
<td>Resistance training for muscle strength</td>
<td>Muscle length, type of contraction</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Velocity training for muscle performance</td>
<td>Muscle length, type of contraction</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Bone loading for bone health</td>
<td>Adequate nutrition, effects of medications</td>
<td>Yes</td>
</tr>
<tr>
<td>Participation driven</td>
<td>Activity-based interventions to improve motor skills and body structure and function</td>
<td>Feedback, task variation, Opportunities for practice</td>
<td>Usually</td>
</tr>
<tr>
<td>Contextual interventions to improve activity and participation</td>
<td>Functional context, many repetitions, Active engagement, Time spent performing</td>
<td>Individualized to preferences and context</td>
<td>Not determined</td>
</tr>
</tbody>
</table>

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### TABLE 2

<table>
<thead>
<tr>
<th>Type</th>
<th>Load</th>
<th>Repetitions</th>
<th>Frequency</th>
<th>Duration</th>
<th>Rest</th>
<th>Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strength resistance training</td>
<td>85% of 1 RM, 40%–80% of 1 RM</td>
<td>Build to 3–6 sets of 6–10</td>
<td>High ground reaction force</td>
<td>2–3 times/wk (nonconsecutive)</td>
<td>1–10 s between reps; Need for consolidation sessions</td>
<td>Task dependent, more than competing movement pattern</td>
</tr>
<tr>
<td>Velocity training</td>
<td>40%–80% of 1 RM, 3–6 times/wk (nonconsecutive)</td>
<td>Build to 6–10 sets of 5–6</td>
<td>Mental engagement</td>
<td>2–3 h before meal, 10 min</td>
<td>Concentric part “as fast as possible,” return, slow, and controlled</td>
<td>Task dependent</td>
</tr>
<tr>
<td>Bone mass and structure</td>
<td>High ground reaction force</td>
<td>50–100</td>
<td>Mental engagement</td>
<td>2–3 h before meal, 10 min</td>
<td>Concentric part “as fast as possible,” return, slow, and controlled</td>
<td>Task dependent</td>
</tr>
<tr>
<td>Motor learning for reaching</td>
<td>40%–80% of 1 RM, 3–6 times/wk (nonconsecutive)</td>
<td>Doses to hundreds</td>
<td>Mental engagement</td>
<td>2–3 h before meal, 10 min</td>
<td>Concentric part “as fast as possible,” return, slow, and controlled</td>
<td>Task dependent</td>
</tr>
</tbody>
</table>

**Abbreviation:** RM, repetition max.

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**Improving Muscle Structure and Function**

Interventions for muscle are generally focused on improving joint range of motion or muscle performance including strength and power.

**Timing for Change in Muscle.** Muscles are highly plastic and responsive to activity or inactivity. Development of muscle architecture is closely connected to the development of the spinal central pattern generators, corticospinal development, motor unit formation, and motor activation patterns from early fetal development, through infancy and early childhood. Activity refines both systems, including cell differentiation (e.g., muscle fibers from type 1 to type 2 and nerve cell types), maturation of cells, and epigenetic transcription. Dotan et al argue a complex interrelationship among a muscle’s metabolic profile, muscle structure, fiber composition, and the cortical impulses directing firing of motor units, accounts for differences in muscle performance between adults and children. Both the muscle and its relationship with the motor unit create differences in activation patterns. Muscles develop in response to interaction with their neurophysiological environment, and differences are present in infants with early brain injury.

Evidence suggests that “critical muscle symptoms” begin early in life. Infants with brain injury spontaneously kick fewer times, at slower velocity, and within a more constrained range of movement than age-matched peers without brain injury. A study of infants born preterm and full term correlated magnetic resonance spectroscopy metabolic findings (indicating brain injury) with kinematic measures of infant motor performance, specifically greater knee flexion and plantar flexion in standing. In addition, infants at high risk for CP had less musculotendinous extensibility and cross-sectional area of ankle musculature at 6 and 12 weeks’ corrected gestational age compared with infants at low risk, indicating muscular architectural differences may occur much earlier than previously thought in infants at high risk for CP.

Children who develop CP may have moved less in utero, and because of prematurity, had less time to move in utero, moved less as infants, and as children, moved less than peers. The lack of activity during these critical periods of muscle development may also predispose children with CP to metabolic disease, fatty infiltrate in muscle, early-onset sarcopenia, and negative consequences for diseases of aging.

Self-initiated movements in infancy combined with active assistive and passive movements that are developmentally appropriate take advantage of plasticity in muscle structure, motor unit, and corticospinal tracts during this time and may influence genetic transcription for later in life. Promotion of muscle activation and muscle performance should continue throughout life, and become more aggressive at about age 5 years. Resistance training can begin as early as age 5 years. Training rate of force development has potential for increasing gait speed or reaching by promoting changes in muscle structures. Training at the structural level to increase performance at earlier ages has the potential for an increased treatment effect. Changes in movement activity, gait speed or reaching, may sustain changes at the structural level of the muscle. Maintaining muscle volume and strength across the lifespan requires a regular exercise program.
Dosing Joint Range of Motion. Range of motion in children with CP decreases with age. Reviews of physiological and clinical studies suggest that manual resistance is not effective for maintaining or improving range of motion. Stretching before strengthening activities is not recommended by the National College of Strength and Conditioning for youth adults, as it reduces the ability of the muscle to generate force as the tendon and sarcomeres become overlengthened, although a dynamic warm-up is recommended. Evidence supports that although CP is a brain injury, “critical symptoms” appear in the muscle including change in muscle sarcomere length, fiber type, extracellular concentration, fiber and fiber bundle stiffness, reduced stem cell numbers, and epigenetic transcription that may perpetuate these traits.

Interventions that focus on changing pathology in muscle structures may provide new avenues for treatment. Combined active and passive movement (using a robotic device) per week for more than 30 minutes for at least 9 months. Positioning links structure, in terms of joint motion and function. Yet, it is unclear as to the mechanism on the structural level. The overlengthened tendons and sarcomeres may be elongating such that the muscle is more inefficient. Joint range of motion is enhanced by changes in movement activity such as rock climbing, horseback riding, bike riding, and soccer.

Dosing Muscle Performance. Children with CP gain muscle strength by performing open-chain progressive resistive exercise, use of functional electric stimulation, loaded sit-to-stand or functional training, and velocity training using a total gym or isokinetic dynamometer. Despite moderate increases in strength, there is no evidence to support that resistance training improves walking speed or changes in gross motor function. One study demonstrates that resistance and velocity training both increase strength, but only velocity training produced positive changes in muscle architecture and gait speed. Insufficient dose is common for resistance programs for children with CP, and using parameters established by the National Strength and Conditioning Association is recommended.

Participation-Driven Interventions

Activity-based interventions such as reaching training and locomotion training use plasticity of body structures and function to improve activity and participation. Evidence to support the activity dependency of corticospinal projections and the development of spinal motor neurons suggests that lack of activity has a pervasively negative effect on the nervous system. Theories of motor learning and motor control with evidence for neuroplasticity guide interventions designed to improve motor control, and place the focus on plasticity of the central nervous system as the mechanism for improving motor control and function. Plasticity of musculoskeletal and cardiorespiratory systems may also contribute to changes.

Timing for Plasticity of the Central Nervous System. Although brain plasticity is present throughout life, early in development there may be a critical period in which the brain possesses high capacity for reorganization to compensate for injury and the extent of this period is still unknown. This critical period has not been identified, but the period immediately after injury is important. Friel et al. used an animal model to demonstrate the effects of reaching training with constraint of uninvolved side to remediate motor function after developmental injury; early intervention recipients had a greater treatment response.

Preaching behaviors and the development of reaching behaviors in infants who are preterm and high risk are distinguished by lack of movement, speed, and asymmetry. Intervention early in life has potential for improving reaching behaviors, mitigating the consequences of loss of exploration and interaction experienced by infants with poor reaching.

The reciprocal movements of the lower extremities are present at infancy and forward locomotion begins around the first year of life. Infant kicking provides opportunities for decoupling extremities, producing variability in movement patterns, and developing speed of movement. Walking experience is critical to learning to walk. Early locomotion using BWS accelerates walking in children with Down syndrome, and for a child with spinal cord injury has resulted in recovery of walking abilities. The critical period for optimizing gait is not clear for children with brain injury, although precursor movements occur early in life. Gait speed decreases with age in children with CP and adults with CP often stop walking because of pain and fatigue. Hence, locomotion training may be impactful across the lifespan.

Dosing Reaching Training for Changes in Participation. Reaching training is effective in changing motor abilities for both bimanual activities and modified constraint-induced therapy. A key component of effectiveness appears to be time, with a recommendation of more than 90 hours of practice. Changes in brain structure and function (eg, diffuse tensor imaging changes in corticospinal tracts and changes in activation of motor cortex) have been demonstrated with changes in reaching abilities. However, the association of changes in reaching abilities and participation or performance in everyday life is not clear. Contextual factors may shape participation regardless of changes in activity level. The essential components of effectiveness of reaching training to create changes in the central nervous system and in motor abilities are intensity of practice, the number of repetitions, the time per session, and the engagement of the child.

Dosing Locomotion Training for Changes in Participation. A systematic review of interventions to improve gait speed confirms the effectiveness of gait training, whether overground or using BWS. The interventions have similar effectiveness, although there is a trend for greater effect sizes in studies with overground training. Studies with locomotion training that occurred at a frequency of at least twice a week, for 30 minutes, for greater than 9 weeks had the largest effect sizes.
of several studies report changes at the level of body structures and function, including improved endurance, reduced ankle stiffness, increased H-reflex latency, and improved gait kinematics. One investigation used coherence of electromyography (EMG) analysis as a way of measuring and detecting changes in the output of the motor cortex and its transmission to the spinal cord through the corticospinal tract during functional muscle activation. There was improved EMG-EMG coherence of anterior tibialis motor neurons of children with CP after training on an incline treadmill 30 minutes for 30 days consecutively. Evidence to link locomotion training with changes in the central nervous system structure and function is scarce. Maintaining gains from locomotion training requires changes in everyday performance, and little evidence exists to support changes in participation with changes in locomotion abilities. The optimal dose is unclear for locomotion training to obtain changes in activity, body structures, and function and participation.

**Participation Interventions**

Participation interventions, or context-based interventions, are those interventions that change the task or the environment, and do not change the impairments of the child. In the path model (Figures 1 and 3), community and environment influence dose. Environmental modifications can provide additional opportunities for movement. If movement is repeated, there is the potential for changes in body structures and function, for example to brain, muscle, or bone. Context-based interventions can provide more time for practice, more engagement, and movement that is self-initiated, all features that promote change. Interventions occur in the home, school, or community, occurring outside a therapy session.

**Timing for Participation Interventions.** Optimal timing for participation interventions appears to be immediately after birth and throughout lifespan. Evidence supports the importance of interaction with the environment for optimal development of cognitive, social, emotional, visual, perceptual, and motor skills during childhood. Descriptions of typical and atypical mobility and visuospatial development of infants, typical toddler movements in a room, typical infant movements throughout the day, and children’s and adults’ spatial movement patterns in their homes and communities will inform both timing and dose. Understanding the disparity found in time, quality, and space of individual environmental interactions can inform the amount and ages for participation interventions and may yield sustainable changes in activity and participation and body structures and function.

**Dosing Participation Interventions to Create Change.** The evidence to support an optimal dose for participation-based interventions is not clear. A randomized controlled trial demonstrated that context-based interventions are at least as effective as impairment-based interventions in improving participation. The authors suggested that perhaps the interventions were underdosed. Although optimal dose of participation interventions is not known, interventions that provide more time for practice have potential for driving sustainable change. Technology can provide new opportunities for participation. A modified toy car for mobility in the home for children who are not ambulatory provides a high frequency of child-environment interaction and a high level of engagement. A suspension harness can allow toddlers and children with mobility challenges the opportunity to safely explore their environment. A self-initiated prone scooter assists infants with floor mobility and allows exploration. Microsensors on infants’ lower extremities can activate crib mobiles and provide opportunities to improve lower extremity movement patterns. Contextual interventions can be provided throughout the day, and infants, children, and adults can spend more time practicing. How much practice is enough to elicit changes is still unknown.

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**Fig. 3.** Path model abbreviated for participation-driven interventions and age at time of interventions.
Dosing Participation Interventions

For pediatric physical therapists to design effective interventions, which use participation-driven interventions, more information is needed about the dose of a particular participation intervention to change either participation of the individual, body structures and function, or both. What is typical participation across developmental ages and activities? Descriptive longitudinal studies of participation of children, or interaction of infants and children with and within their environment, are needed as baseline reference values of typical child behavior across geographic regions and sociocultural groups. We need a greater understanding of the mobility patterns of children and adolescents in their homes, schools, and communities. More information is needed on typical infant spontaneous leg and arm movements. We need a greater understanding of the physical exploration of toddlers of their environment.

What are the logistics of dosing participation at high intensities? If high-risk infants and children require sophisticated technology for participation interventions, can low-cost technology do the same? How can we build environments to promote participation in home, schools, and communities? Can we increase frequency per week of a particular activity by partnering with community centers, specialized and nonspecialized fitness centers, or local physical therapy education programs? Is it realistic to think that service delivery models, policy, and payment sources will support therapists, as we move from center-based practices to practices in homes, schools, and communities? Will practice patterns and professional training shift, as pediatric physical therapists become coaches, trainers, and supervisors for paraprofessionals and families in the community?

Critical Thresholds

Given the characteristics of the child, family, and environment, what is that threshold when change occurs at the level of body structures and function and activity and participation? What combination of factors is the tipping point at which structure and function are changed? When will the infant be able to crawl independently; when the eyes and head coordinate, or when the infant is very motivated and engaged in obtaining an object? What combination of factors needs to be in place for a child/infant to advance in motor skills? How do these factors vary given individual differences in children, families, and locations? How do these factors vary given the different motor skills?

Optimizing Dosing Given Genotype

The identification of alleles associated with CP and, more recently, clinically relevant copy number variation detected in genetic profile of children with CP provide insight as to why 2 infants can respond differently to the same type of brain injury or intervention. Do children with certain genetic characteristics require pharmacological interventions, such as dopamine, or does the dose of the intervention need to be increased? Does the environment need to be changed, eg, supporting positive family practices for behavior management and stimuli or cognitive behavior therapy for the individual with CP?

Closing the Knowledge Gap About Effective Interventions for Individuals With Severe Motor Involvement

Limited information on effective interventions for children GMFCS IV-V exists; although published reports are available on service utilization, feasibility of intense interventions, and participation interventions to improve health-related quality of life. Patterns of service utilization for children with varying levels of severity are not clear. Palisano et al report children with more severe involvement ages 2 to 6 years receive more therapy in clinic and school settings in the United States and Canada. Conversely, Bailes and Succop report children with higher GMFCS levels receive less therapy in a large outpatient medical center in the United States. Data from the National Survey of Children with Special Health Care Needs reveals children with more functional limitations have more unmet needs for therapy and mobility aids. For children with more severe involvement, patterns of service utilization may vary by geographic locations or setting, and it is not clear how utilization patterns are associated with better outcomes in the short or long term.

Several active clinical trials (clinicaltrials.gov) are investigating effective ways to measure and improve postural control in children with disability, a significant issue for individuals with severe gross motor impairment. Later in life, individuals with severe motor impairment are more likely to incur the greatest cost for care, as they are at highest risk for dependent care and development of costly secondary conditions. Participation interventions dosed appropriately, hold promise for improving body structures and function, and can promote health across the lifespan for individuals with severe motor involvement.

Adult Outcomes

There is a lack of information about interventions to promote participation of adults with CP. This gap in information is even more poignant when we consider that adults with CP outnumber children with CP. The needs of children with CP as they transition to young, middle, and later adulthood are largely unmet. We need to establish links between childhood treatments and positive adult outcomes to investigate whether efforts for some interventions have effect in the long term. How can we harness the potential for change of the cardiovascular, musculoskeletal, and central nervous systems to optimize health, wellness, and function? What are the needs and the differential preventative measures needed for people with different movement disorder subtypes of CP? How can we best address the physical therapy needs of adults with CP?

Health Services Research

Population patterns in utilization of services, health status, participation, activity, consumer satisfaction, and cost for
rehabilitation services for people with chronic childhood conditions are largely unknown. Disease-specific registries can be useful to monitor prevalence as well as long-term outcomes, and cost-benefit ratio. Intervention-specific information, including discipline type, type of intervention, time, and frequency per week, is needed as routine data entry information in electronic health records for hospitals, school systems, and other practice settings. Developing an infrastructure for quality improvement is needed to analyze practice patterns.

**IMPLICATIONS FOR PRACTICE**

Three challenges are provided as an impetus for aligning practice with evidence. Significant social and financial barriers exist to meet these challenges, but reflection on these challenges is warranted.

Are we intervening too late or not at all? We have multiple tools to identify infants at risk. There is much that can be done before the child is diagnosed. Many critical periods are immediately after birth and during the first year of life. How can physical therapists provide information and services more consistently to families and infants at risk? Are we taking advantage of muscle and bone plasticity in middle childhood and throughout adolescence with adequately dosed interventions?

Are we doing enough? Intensity can refer to engagement, effort, or force production depending on intervention type. Are interventions dosed appropriately (thousands of repetitions for motor learning, 70% of 1 repetition max for strengthening) for effectiveness given the information we currently have? Is current evidence being used to prescribe exercise to promote changes for muscle, bone, and brain?

**Measurement**

Are we measuring what we are doing so we can evaluate best practice? Measurement is needed within sessions, across sessions, within hospitals outpatient/outpatient, school, birth to 3. Are we documenting the salient features of the intervention session? Are we documenting important characteristics of the child, such as level of severity, cognition, communication, and family characteristics such as values and coping? How are we using the data we collect to improve practice?

**CONCLUSION**

Although parameters for dosing participation are not yet established, emerging evidence suggests participation at high enough intensities may yield changes. Given plasticity present immediately after birth and in the first year of life, intense participation interventions seem ideal for infants. Participation interventions if dosed appropriately may provide an additional avenue to promote change throughout the lifespan. Technology, social change, and change to the physical environment hold promise to provide participation interventions at high frequencies and intensities to promote change. To break the cycle of accumulated disability in individuals with CP, we need to continue to work on many fronts: bench science, clinical science, knowledge translation, advocacy, and institutional practices.

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Use of Lower-Limb Robotics to Enhance Practice and Participation in Individuals With Neurological Conditions

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Purpose: To review lower-limb technology currently available for people with neurological disorders, such as spinal cord injury, stroke, or other conditions. We focus on 3 emerging technologies: treadmill-based training devices, exoskeletons, and other wearable robots.

Summary of Key Points: Efficacy for these devices remains unclear, although preliminary data indicate that specific patient populations may benefit from robotic training used with more traditional physical therapy. Potential benefits include improved lower-limb function and a more typical gait trajectory.

Statement of Conclusions: Use of these devices is limited by insufficient data, cost, and in some cases size of the machine. However, robotic technology is likely to become more prevalent as these machines are enhanced and able to produce targeted physical rehabilitation.

Recommendations for Clinical Practice: Therapists should be aware of these technologies as they continue to advance but understand the limitations and challenges posed with therapeutic/mobility robots. (Pediatr Phys Ther 2017;29:S48–S56)

Key words: exoskeletons, rehabilitation, robot-assisted gait training, robotics, spinal cord injury, stroke

INTRODUCTION

As the patient population ages in the United States and the prevalence of neurological disorders increases, rehabilitative care for individuals with stroke, spinal cord injury (SCI), and other diseases of the nervous system remains an urgent issue that poses many unique challenges. Regaining functional mobility and walking ability continues to be a top priority for people, as recovery after neurological impairments affects successful reintegration into society. Unfortunately, conventional treatment options for this patient population are still limited in achieving desirable levels of functional mobility.
TREADMILL-BASED ROBOTS

Treadmill-based trainers, developed in the past 30 years, were one of the first types of therapeutic machines specifically designed to augment physical therapy. With these machines, a patient’s body weight is supported through an overhead harness, such that patients can safely begin therapy sessions earlier after disease or trauma onset, and practice symmetrical loading and unloading of the limbs. During therapy sessions, clinicians manually assist patients’ legs to help them produce stepping motions that follow a typical gait pattern.11 By providing task-specific training, body-weight-supported treadmill training may help patients practice physiological gait patterns, strengthen lower-limb muscles, and enhance walking endurance, coordination, and posture.12

Although this therapy showed great promise in animal models13 and became a more widely accepted form of therapy in the 1990s following studies in humans,14 specialized treadmills and support systems still required up to 3 or 4 therapists to manually assist a patient.11 Some patients with severe neurological conditions could not benefit from this therapy because of the high physical burden imposed on both the patient and therapists.

To reduce the demand on physical therapists and provide more specialized rehabilitation care specific to patient needs based on dose, intensity, specificity, and variation, motorized body-weight-supported treadmill training machines emerged in which a robotic control system helps control and move a patient’s walking. Most of these devices require 1 or a maximum of 2 physical therapists to work with 1 patient,12 and devices included assessment and recording tools to measure progress.

One of the most researched, commercially available robotic gait training systems is the Lokomat (Hocoma Inc, Norwell, Massachusetts, and Volketswil, Switzerland), which consists of a robotic gait orthosis, treadmill, weight support through a harness, and software that allows patients to participate in game-like exercises that encourage greater effort.15 It is available in 3 options: LokomatPro (Figure 1), a smaller LokomatNanos, and LokomatPro Pediatric. A recently developed optional “FreeD” module for the LokomatPro supports balance and correct weight shifts through lateral and rotational movements of the pelvis. Other commercialized treadmill-based training machines include the Aretech ZeroG (Aretech, Ashburn, Virginia) and the Gait Trainer GT I (Reha-Stim Medtec GmbH & Co, Berlin, Germany). A few other devices, such as the Lower Extremity Powered Exo Skeleton (LOPES) and the PAM/POGO, are currently used in research settings.16-18

Potential Benefits

Treadmill-based robotic devices have been evaluated for a wide-range of conditions affecting the central nervous system, including stroke, SCI, Guillain-Barré, and multiple sclerosis.19-21 We focus only on studies related to SCI and stroke, 2 of the most researched patient populations. Research studies conducted over the last decade on the potential benefits of these machines have had mixed results, with some studies showing that robotic training provides similar results to other therapy, whereas some studies show superior outcomes.20 We describe some examples.

SCI. In one study conducted in 29 individuals with incomplete SCI, Niu and colleagues found that the Lokomat improved walking capacity and speed, with increased effectiveness in combination with the antispasmodic tizanidine in individuals with limited walking function. Shin et al,17 in a study evaluating 60 patients with incomplete SCI, indicated that robotic training resulted in significant improvements in functional skill progression compared with other care. Similarly, Esclarin-Ruz et al,18 Benito-Penalva et al,22 and Alcobendas-Maestro et al23 suggest that robotic treadmill has positive effects on individuals with SCI.

Stroke. A recent study by Bae et al24 examining high-intensity robot-assisted gait training in patients with chronic stroke found that therapy with the Lokomat improved patients’ motor function, gait ability, and symmetric pattern compared with conventional robot-assisted gait training, supporting its safety and effectiveness. Dundar et al,25 comparing physical therapy versus physical therapy with robotic therapy, found that the combined intervention resulted in better improvements in Functional Independence Measure and Mini-Mental State Examination scores with patients with subacute and chronic stroke. Similarly, in recent publications, Bang et al, Uçar et al, and Schwartz et al have shown significant benefits using robotic treadmill training in individuals with stroke (chronic and subacute), though it has been noted that more long-term studies are needed in the chronic population.26-28 Guidelines by the American Heart Association suggest the importance of robotic training in the lower limb but also acknowledge inconclusive results.29

Limitations

Despite potential benefits, the efficacy of robotic treadmill-based devices remains uncertain. Across studies in individuals with neurological injuries, improvements seen relative to baseline and control data often indicate that robotic training is effective but not significantly better than other therapies.30-35 Mehrholz et al,21 evaluating locomotor training for walking after spinal cord injury, noted that the strongest evidence to support treadmill-based machines was limited to case reports or single cohort studies. Improved walking in neurological populations may be due to improvements in volitional strength, balance, and gait efficiency. However, the authors did not find

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**Fig. 1.** The LokomatPro. Picture: Hocoma, Switzerland.
significant differences between different forms of training. Some of these mixed results could be attributed to the fact that the early versions of the hardware and software of the robotic systems were not well matched to the needs of the specific neurologically impaired populations, and that participants did not volitionally participate in the training and the robot did all the work.35

Based on our review, research on these devices lacks structured discussions on whether the studies used appropriate patient selection, evaluation, and training strategies. For example, it is rarely considered whether the study design and outcome measures are appropriate to both robotic and traditional intervention groups; whether the specific patient populations used in the studies were suitable for robotic training; or whether specific training strategies, progression, and evaluation techniques for each patient population were identified.23-33 Finally, many of these machines are large and expensive; wide-range use and general agreement on specific clinical needs might bring costs to affordable levels, thus making these devices more common in practice.

OVERGROUND LOWER EXTREMITY ROBOTIC EXOSKELETONS

Rehabilitation exoskeletons are emerging as therapeutic technologies. In comparison to treadmill-based robots, which are limited by training guided by the machine on a treadmill, exoskeletons have the potential to provide task-specific over-ground training as well as personal mobility, for individuals with lower extremity paralysis or partial paralysis and weakness. Exoskeletons are marketed for individuals with a wide-range of neurological conditions, including SCI, stroke, and multiple sclerosis. Most studies have investigated exoskeleton potential in persons with incomplete SCI, although research on stroke and other conditions is forthcoming.36-37

Many of the first exoskeletons were designed for military applications to augment soldier capability and were massive, complex machines.38 As batteries, motors, and other materials have become smaller, rehabilitation exoskeletons specifically designed for therapeutic or personal mobility purposes are emerging.38 Each class of exoskeleton differs in its control system and features, but most commercially available devices include a rigid outer frame, sensors that detect a user's desired movements, a computerized controller, motors or actuators, and lightweight batteries. Exoskeletons are regulated as Class II (moderate to high risk) devices by the Food and Drug Administration (FDA). The FDA cited the risk of falling, mechanical failure, and skin abrasions as potentially adverse events.39 At the time of publication, 3 exoskeletons (Table 1) have received FDA approval: the Ekso, ReWalk, and Indego.40-42 The HAL for rehabilitation use (Hybrid Assistive Limb; Cyberdyne Inc, Tsukuba, Japan), a full lower-body exoskeleton for people with SCI or weakened leg muscles due to other neurological conditions, has received Conformité Européenne Marking (CE) or conformity marking [CE 0197], in Europe (similar to FDA) and is being evaluated in Germany.43 Across the world, more than 2 dozen exoskeletons are in research or development (Table 2).44

Based on our experience the progression for using an exoskeleton follows a sequence. Therapists trigger the device at the early learning stage followed by participants and family members triggering the device. As users become more functional they trigger on their own.

### TABLE 1

<table>
<thead>
<tr>
<th>Device (Manufacturer)</th>
<th>FDA Approval</th>
<th>Description</th>
<th>Intended Population</th>
<th>Inclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>ReWalk (ReWalk Robotics, Inc)</td>
<td>Yes: therapy and personal mobility</td>
<td>Independently controlled bilateral hip and knee joint motors, a rigid pelvic frame that links both lower limbs, ankles comprise double-action orthotic joints with limited motion and adjustable spring-assisted dorsiflexion segments. Consists of a hip segment and right and left thigh and shank segments. Four motors, one at each hip and knee joint, power movement, and built-in ankle-foot-orthoses support the ankles</td>
<td>Motor complete/incomplete SCI T7-L5 (for home and community settings) and T4-T6 (rehabilitation institutions)</td>
<td>Age 18-55; ability to stand using a standing device; height between 160 and 190 cm (5′3″ to 6′2″), weight up to 100 kg (220 lb)</td>
</tr>
<tr>
<td>Indego (Parker Hannifin Corporation)</td>
<td>Yes: therapy and personal mobility</td>
<td>Consists of a hip segment and right and left thigh and shank segments. Four motors, one at each hip and knee joint, power movement, and built-in ankle-foot-orthoses support the ankles</td>
<td>Motor complete/incomplete SCI T7-L5 (for home and community settings) and T4-T6 (rehabilitation institutions)</td>
<td>5′1″ to 6′3″, weight under 250 lb, passive range of motion at shoulders, hips, and knees, and ankles, sufficient upper body strength</td>
</tr>
<tr>
<td>Ekso (Ekso Bionics)</td>
<td>Yes: therapy</td>
<td>Incorporates hip and knee motors, passive ankles, and femoral and tibial shanks support body weight</td>
<td>Motor complete paralysis C7 or below or stroke (hemiparesis or hemiplegia)</td>
<td>Functional bilateral upper extremity strength or functional strength of 1 upper extremity and 1 lower extremity; stroke; adequate height and weight (weight of ≤220 lb; height between 5′2″ and 6′2″); near normal range of motion at the hips, knees, and ankles</td>
</tr>
</tbody>
</table>

Abbreviation: SCI, spinal cord injury
TABLE 2
List of Exoskeleton Businesses/Startups

<table>
<thead>
<tr>
<th>Company (Location)</th>
<th>Project(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 Knots Plus Ltd (Chichester, UK)</td>
<td>Marine Mojo</td>
</tr>
<tr>
<td>Active Bionics Inc (Ottawa, Canada)</td>
<td>MODO</td>
</tr>
<tr>
<td>Againer (Riga, Latvia, EU)</td>
<td>AGAINER System</td>
</tr>
<tr>
<td>AlterG (Freemont, California)</td>
<td>Bionic Leg</td>
</tr>
<tr>
<td>AxoSuit (Oradea, Romania)</td>
<td>AxoSuit</td>
</tr>
<tr>
<td>B-Temia (Quebec City, Canada)</td>
<td>Revision Military Kinetic Operations Suit (PROWLER), KEEOGO</td>
</tr>
<tr>
<td>Bama Teknoji (Ankara, Turkey)</td>
<td>Robo Gait, Visio Gait</td>
</tr>
<tr>
<td>Bionic Power (Vancouver, Canada)</td>
<td>PowerWalk Kinetic Energy Harvester</td>
</tr>
<tr>
<td>Bionik Laboratories (Toronto, Canada)</td>
<td>ARKE</td>
</tr>
<tr>
<td>Bioservo Technologies AB (Kista, Sweden)</td>
<td>Robotic Soft Extra Muscle (SEM) Glove</td>
</tr>
<tr>
<td>CYBERDYNE (Tokyo, Japan)</td>
<td>HAL, Care Support—Lumbar</td>
</tr>
<tr>
<td>Daewoo Shipbuilding &amp; Marine Engineering (Seoul, South Korea)</td>
<td>Prototype Phase</td>
</tr>
<tr>
<td>Daiya Industry (Okayama, Japan)</td>
<td>Pneumatic Power Assist Glove</td>
</tr>
<tr>
<td>Elko Bionics Holdings, Inc (Richmond, California)</td>
<td>Ekso, eLEGS, HULC, ExoHiker, Elko Works, Warrior Web</td>
</tr>
<tr>
<td>ExoAtlet (Moscow, Russia)</td>
<td>ExoAtlet</td>
</tr>
<tr>
<td>Gobio Robot (Carquefou, France)</td>
<td>Various exoskeletons for work &amp; industry</td>
</tr>
<tr>
<td>GOGOA Mobility Robots (Gipuzkoa, Spain)</td>
<td>Hank, Hand of Hope</td>
</tr>
<tr>
<td>GoXstudio (Scottsdale, Arizona)</td>
<td>N/A</td>
</tr>
<tr>
<td>Hocoma (Völketswil, Switzerland)</td>
<td>LokomatPro, Armeo</td>
</tr>
<tr>
<td>Honda (Tokyo, Japan)</td>
<td>Stride Management and Bodyweight Support Assist</td>
</tr>
<tr>
<td>Hyundai Motor Company (Seoul, Korea)</td>
<td>Hyundai Wearable Robotics for Walking Assistance and Industry</td>
</tr>
<tr>
<td>Innophys (Tokyo, Japan)</td>
<td>Hip auxiliary muscle suit</td>
</tr>
<tr>
<td>Interactive Motion Technologies (Watertown, Massachusetts)</td>
<td>InMotion ANKLE, InMotion WRIST</td>
</tr>
<tr>
<td>Kinetek—Wearable Robotics (Ghezzano, Italy)</td>
<td>ALEX, Track-Hold</td>
</tr>
<tr>
<td>Kinetic Innovations Ltd (Faygate, UK)</td>
<td>5k+®-Mojo</td>
</tr>
<tr>
<td>Laevo (Zuid-Holland, Netherlands)</td>
<td>Laevo</td>
</tr>
<tr>
<td>Lockheed Martin (Maryland)</td>
<td>FORTIS, HULC</td>
</tr>
<tr>
<td>Marsi-Bionics (Madrid, Spain)</td>
<td>Based of Atlas</td>
</tr>
<tr>
<td>Mitsubishi Heavy Industries (Tokyo, Japan)</td>
<td>Power Assist Suit (PAS) For Nuclear Disasters</td>
</tr>
<tr>
<td>Myomo Inc (Cambridge, Massachusetts)</td>
<td>MyoPro</td>
</tr>
<tr>
<td>Noonee AG (Rüti, Switzerland)</td>
<td>Chairless Chair</td>
</tr>
<tr>
<td>Otherlab Orthotics (San Francisco, California)</td>
<td>Inflatable Soft Exoskeleton</td>
</tr>
<tr>
<td>Ottobock (Duderstadt, Germany)</td>
<td>C-Brace</td>
</tr>
<tr>
<td>Panasonic—Activeelink (Kadoma, Japan)</td>
<td>Power Loader Light, Power Jacket – REALIVE</td>
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<tr>
<td>Parker Hannifin (Ohio)</td>
<td>Indego</td>
</tr>
<tr>
<td>PhaseX AB (Gävle, Sweden, EU)</td>
<td>Exo-Legs</td>
</tr>
<tr>
<td>RB3D (Aixerre, France)</td>
<td>Hercule</td>
</tr>
<tr>
<td>ReWalk Robotics (Yokneam Ilit, Israel)</td>
<td>ReWalk</td>
</tr>
<tr>
<td>Rex Bionics (Rosedale, New Zealand)</td>
<td>Rex</td>
</tr>
<tr>
<td>Robot Systems (Ses Ziona, Israel)</td>
<td>Crowd Sourced Industrial Exoskeleton</td>
</tr>
<tr>
<td>Sarcos LC (Salt Lake City, Utah)</td>
<td>XOS 2, XOS 1</td>
</tr>
<tr>
<td>SRI International (Menlo Park, California)</td>
<td>Super Flex Exosuit, Pediatric Soft Exosuit</td>
</tr>
<tr>
<td>StrongArmTech (New York)</td>
<td>V22 and FLx</td>
</tr>
<tr>
<td>US Bionics/SuitX (Berkeley, California)</td>
<td>Phoenix</td>
</tr>
</tbody>
</table>

Source: Exoskeleton Report (http://exoskeletonreport.com/2015/02/businesses-that-have-or-are-exploring-exoskeleton-products-in-alphabetical-order/).

experienced with using the device, they initiate steps by triggering the device independently through movement of their trunk, shift of center of gravity, or body weight transition. User progression is also based on the severity, level (in case of SCI) of the disability, cognitive ability, and their physical tolerance to be in the device and ability to initiate movements.

The control system for each exoskeleton is unique (Table 1; Figure 2). For example, one unique feature of the Ekso-exoskeleton is its variable, smart assist function, which allows a therapist to adjust the amount of motor and trajectory assistance the machine provides. This alters targets such that users have to shift depending on their capabilities. With the Ekso, a user must complete forward and lateral weight shifts to initiate steps predetermined by a trainer. The ReWalk has a watch-like wireless communicator that can be worn on the user's wrist, and steps are based on the user's minor trunk forward movements. The Indego, a modular full lower-body exoskeleton, is operated through a tablet. All movements are based on body position, specifically the angle of a user's thigh relative to the ground.

Each device differs in suitability based on an individual's level and extent of injury and residual capabilities. It is important for clinicians to closely consider a person's level of injury, standing tolerance, range of motion, strength, balance and trunk control, spasticity, skin integrity, as well as device fit and proper joint alignment. All the commercially available exoskeletons come with a detailed training manual, and therapists are required to attend a training course and be precertified before using the device with patients.
Potential Benefits

Preliminary data indicate that exoskeletons have the potential to help patients improve their ability to initiate gait or improve gait mechanics through intense overground stepping practice. Overground stepping practice is important, as it may activate dormant cortical pathways, exploiting neuroplasticity and providing muscle loading and sensory feedback for motor recovery.45 Other potential benefits of long-term exoskeleton use include improved posture, reduced spasticity, enhanced bone density, and psychological benefits, as well as reduced secondary complications affecting cardiovascular, gastrointestinal, and renal systems.10,46-50 Exoskeletons provide comfortable and metabolically efficient mobility options, in contrast to cumbersome long-leg braces for individuals with complete or severe incomplete SCI. Thus, exoskeletons may provide an alternative strategy with the same benefits as more labor-intensive, less controlled motor learning strategies.51

A key advantage of exoskeletons is that they are not limited to a laboratory or clinical setting. Users can wear them in community and home settings, providing the opportunity to practice walking outside of a clinic. Exoskeletons may be used for exercise and to promote wellness in outpatient settings. However, injury risk from falls remains an unresolved issue.39

Multicenter trials evaluating the efficacy of exoskeletons are ongoing at institutions in North America and Europe, and will likely expand as the technology progresses.32 In March 2016, the VA announced a 4-year, multicenter trial evaluating use of the ReWalk for veterans with SCI.53 This efficacy study will determine whether veterans with chronic SCI who use the ReWalk improve mental health, bowel and bladder function, patient-reported outcomes, and reduced total body fat mass, compared with those who use a wheelchair for mobility. A study, sponsored by the Department of Defense at the James J. Peters Veterans Affairs Medical Center in New York, is investigating whether patients with chronic SCI can achieve successful walking over 36 sessions in 3 months with the ReWalk and Ekso. Outcome measures include the 10-meter walk test, 6-minute walk test, Timed Up-and-Go test, and secondary outcome measures.9

Safety and Efficacy

A limited number of studies support the safety and efficacy of exoskeletons for individuals with SCI and stroke. Some individuals with paraplegia transitioned to limited community ambulation after only 5, 1.5-hour gait training sessions using the Indego.54 It has been reported that the Indego requires less effort than knee-ankle-foot orthoses, and subjects perform strength and endurance tests 25% to 75% faster.55 In a prospective study with 8 participants with SCI at the T1 level and below, the Ekso could also be used safely, when monitored by a trained therapist.56 People with complete SCI achieved walking speeds and distances comparable to people with motor incomplete injuries, although few changes in leg muscle activation or neuromuscular health were observed.57 Similar studies with the ReWalk indicate that it is safe and can provide ambulation options for individuals with SCI.51

Limitations

Approximately 550 exoskeletons have been sold worldwide (author's estimate based on industry information), and product commercialization has preceded vigorous clinical research. Limited information is available on disease-state-specific patient evaluations, training strategies, and device-based therapeutic strategies to enable the safe and effective use of these devices for therapeutic purposes and to enhance mobility in individuals with neurological conditions. We do not know the specific characteristics of the patient populations who could benefit from these devices.

Exoskeletons have a high cognitive demand. Users must constantly move to control the device and these motions can be strenuous. Thus, exoskeletons may not be suitable for all patients. Further studies on bowel and bladder function, spasticity, bone density, muscle mass, and the amount of use needed for physical benefits are required to justify insurance reimbursement.

Further, hardware and control is constantly adapting and may not address a person's specific rehabilitation needs, which makes it difficult to assess clinical results. Meanwhile, fall preventions and fall recovery strategies are being tested and...
evaluated and will be implemented into the future versions of these devices.

**MODULAR WEARABLE ROBOTIC DEVICES**

As exoskeletons have become smaller and more lightweight, other single joint or modular wearable robotic devices have also emerged in the field. Currently, there are more than 2 dozen modular exoskeletons being tested and evaluated for commercialization. Examples of devices undergoing clinical trials include the Stride Management Assist® (Honda Research and Development Company, Ltd, Wako, Japan),58 AlterG Bionic Leg™ (AlterG Inc, Fremont, California),59 and Keeogo™ (B-Temia Inc, Quebec City, Quebec)60 (Figure 3).

The Stride Management Assist (SMA) is a lightweight (6.17 lb with battery) device that assists hip joint flexion and extension.58 Designed for people with weakness because of stroke or aging, it is worn like a belt and fits around a user's waist and thighs. Motors provide support in hip flexion or extension to help achieve greater stride and thus better physiological gait assist as needed, based on data obtained from hip angle sensors located just above the thigh support frame.61 As other examples of modular robotic devices, the AlterG Bionic Leg and Keeogo are powered knee exoskeletons used for therapeutic and personal mobility.59,60 These devices are not approved by the FDA.

**Potential Benefits**

Emerging modular exoskeletons have the potential to help restore strength, speed, and endurance in the lower limb while also being smaller, lighter, and easier to don and doff in comparison to a full-body exoskeleton. However, data are preliminary and limited to a few peer-reviewed publications and case studies. In comparing the effects of wearing the SMA with functional task-specific training on gait parameters in patients with stroke, Buesing et al.62 concluded that individuals who used the SMA showed additional improvements across more functional gait parameters compared with task-specific training. The authors noted that additional research is needed before using the devices at home. The Keeogo has been studied on persons with multiple sclerosis, knee and hip osteoarthritis, Parkinson disease, and peripheral artery disease at institutions in Quebec, Canada.60 It is currently part of a multicenter clinical trial at institutions in North America aimed at gathering data for FDA approval.60 Research on the AlterG is also ongoing and limited to a few case series, abstracts, and clinical publications.59 One case series, by Wong et al.,63 found that 3 people who were ambulatory after stroke used the device during 18 one-hour sessions within a 6-week physical therapy program and improved balance, gait, and function.

**Limitations**

These devices are designed for people with mild impairments and do not benefit people with more severe injuries. Rigid components of these devices limit the use for people with severe balance problems and joint contractures. Because of the modular nature of these devices, there are limitations on fitting based on a user's weight, limb length, and height. Some are not available in sizes that could accommodate a range of patients. There are no defined patient populations and training protocols have not been established for these modular devices. The lack of data on device use prevents the identification of other potential limitations.

**PHYSICAL THERAPISTS AND ROBOTIC TECHNOLOGY**

The ultimate goal of physical therapy is to help patients achieve the highest quality of life. As technology evolves, rehabilitation robots will gain a widespread role in rehabilitative care and help patients and therapists achieve defined goals. The manufacturer, Medicare and other payers, and the FDA set current guidelines for robotic gait trainers and exoskeletons. Monitoring by therapists is still required. Guidelines include generalized procedures for a broad user population. However, a greater understanding of their use in the clinic and home is needed. Clinicians must understand the limitations and advantages of robotic therapies specific to the patient treated. Regardless of which robotic device is used, standardized patient evaluation and training strategies and specific clinical outcome measures have yet to be established, and are necessary to assess efficacy. The potential of exoskeletons, especially as personal...
mobility devices, has yet to be realized; their speed is far too slow and they are still too complex and expensive to be considered viable alternatives to wheelchairs.

We do not know how to best combine or sequence the various robotic technologies into a coherent therapeutic framework. It is likely that larger treadmill-based trainers, such as the Lokomat, will perform best when patients are weak and have limited or no spontaneous walking. In this case, using fixed guidance gait trainers may reestablish patterned discharge of neural oscillators in the spinal cord. As locomotor functions are reestablished, less rigid training systems, which enable and facilitate voluntary motion, such as exoskeletons or even overground support devices like the ZeroG, may facilitate the emergence of natural locomotion. Finally, if impairment is limited to specific joints, for example knee flexion or foot drop, localized devices may be sufficient.

FUTURE DIRECTIONS

Robotic devices continue to evolve and are becoming more sophisticated, with multiple degrees of freedom and advanced control algorithms to support complex movements.64 With further advances, rehabilitation robots will be developed to augment functional ability while continuing to promote recovery. They will become more adaptable, less expensive, and may provide patients with therapy benefits in a home setting, to further the continuum of care.

Because of their size and cost, treadmill-based robotic gait trainers may continue to be limited to large hospitals and to help patients begin locomotor training earlier. The development of control strategies that are based on clinical insights will be important factors in the evolution of these devices.

The future of exoskeletons also presents unique design challenges for engineers and clinicians. Exoskeletons must become safer and less expensive to be more realistic personal mobility options compared with a wheelchair. Future exoskeletons will likely incorporate functional electrical stimulation to provide additional control, sensors to provide feedback in real time, and brain-machine interfaces for enhanced control. It is also feasible that a hybrid exercise-personal mobility exoskeleton will be developed.

A new generation of soft, wearable robotics and exoskeletons is emerging. These technologies use lighter and less constraining materials to fit more comfortably while reducing energy consumption.65 As one example, ReWalk Robotics, in collaboration with Wyss Institute for Biologically Inspired Engineering at Harvard University, is developing an "assistive exosuit" for people poststroke or with multiple sclerosis. This device transmits power to leg joints through technology similar to that used in the ReWalk, although the device is less rigid and lighter in weight than the full-body exoskeleton.66 Finally, new-generation exoskeletons are expected to include fall prevention and fall recovery strategies into the controls to address risk of falling, a major potential complication from a safety standpoint. Other promising areas of research include modular robots for people with less severe impairments, and advanced real-time controllers that learn and adapt to a person's specific biomechanics.

CONCLUSIONS

Robotics designed to enhance lower-limb recovery and function continue to evolve, as technological advancements allow for smaller and more lightweight devices. The field of robotic devices will continue to progress at a rapid pace. Efficacy of these devices and specific training protocols needed to optimize their performance remains uncertain. Establishing clearer guidelines, safety, and feasibility will create possibilities for exoskeletons to become more widely used in clinics and homes. Therapists should anticipate training with robotic technologies but should also recognize the limitations of these devices.

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Pediatric Physical Therapy Robotics That Target Lower-Limb Function S55


Research Design Options for Intervention Studies

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Purpose: To review research designs for rehabilitation.

Summary of Key Points: Single-case, observational, and qualitative designs are highlighted in terms of recent advances and ability to answer important scientific questions about rehabilitation.

Statement of Conclusions: Single-case, observational, and qualitative designs can be conducted in a systematic and rigorous manner that provides important information that cannot be acquired using more common designs, such as randomized controlled trials. These less commonly used designs may be more feasible and effective in answering many research questions in the field of rehabilitation.

Recommendations for Clinical Practice: Researchers should consider these designs when selecting the optimal design to answer their research questions. We should improve education about the advantages and disadvantages of existing research designs to enable more critical analysis of the scientific literature we read and review to avoid undervaluing studies not within more commonly used categories. (Pediatr Phys Ther 2017;29:S57–S63)

Key words: observational research, qualitative research, research designs, single-case research

INTRODUCTION

The purpose of this article is to report on the proceedings from the Research Design Plenary Session from the IV STEP 2016 Conference on Prevention, Prediction, Plasticity, and Participation. The Academies of Pediatric and Neurologic Physical Therapy recognize that research in the field of rehabilitation would benefit from using a greater breadth of research designs and invited the authors to present 3 types of research designs that could advance rehabilitation science: (1) single case, (2) observational, and (1) qualitative.

As the profession of physical therapy engages in evidence-based practice, a medical research model with a focus on randomized controlled trials (RCTs) has been supported to justify and understand the cost and effect of interventions.1 In the common hierarchy of research designs, RCTs and meta-analyses of RCTs are at the top of a pyramidal structure, suggesting they are superior to the designs below in the structure or to designs that are not in the structure (Figure 1).2,3 Although RCTs can be useful for answering many questions in rehabilitation especially related to pharmaceutical trials, there are other research questions that can best be answered using less common research methods and designs. Publications have increased for disciplines outside of health sciences such as education and psychology that use these less common designs. Federal funding agencies like the Institute of Education Sciences (US Department of Education) have an objective to support the development of improved statistical analysis techniques for these less commonly used methods, recognizing their value in helping us understand how to best optimize therapeutic outcomes. Measures to report and evaluate the quality of research using these designs have been developed.4-6

We define single-case, observational, and qualitative research designs and describe the use of these designs to inform researchers and clinicians in rehabilitation science professions. Table 1 lists recommended readings.
SINGLE-CASE RESEARCH DESIGNS

Single-case research designs (SCDs; single-subject, single-participant, n = 1, intrasubject designs) include the repeated observation of outcomes (dependent variables) across time under different levels of at least one intervention (manipulated independent variable). These studies include phases that can vary in length from minutes to months or longer during which the intervention condition manipulated. Repeated measurements occur throughout each phase and at least one of the phases is a baseline. Case studies and case series are not examples of SCDs because they do not typically involve controls for the levels of intervention across time.

SCDs should involve more than one participant to improve external validity, the ability to generalize the results to a larger population. For this reason, statisticians and methodologists support the use of SCD rather than terms suggesting a single participant as a key feature.

SCDs can be designed to test a causal relationship between an intervention and an outcome. Therefore, SCDs have external validity and internal validity. Causality is demonstrating through repeatability. For instance, when the effects of an intervention are observed immediately after intervention and behavior reverts to baseline when the intervention is removed, repeatability is supported. Repetition can be demonstrated using multiple phase designs such as ABA, ABAB, ABABA, where A signifies a baseline phase (no intervention) and B signifies an intervention phase. This design is useful for studies using feedback, task modification, environmental supports, or technologies (eg, mobility devices, robotics, and exoskeletons) when rapid improvements during intervention with function reverting to baseline after removing the intervention are both expected (Figure 2).

For educational and procedural interventions, immediate effects are not typically observed and return-to-baseline function at the end of the intervention phase is not commonly observed nor is it desirable. Repeatability and determination of causality in these interventions can be achieved when the effects of the intervention are repeated across multiple participants. For example, causality is not determined from an AB design with 1 participant. If similar effects are observed across multiple participants using this design, causality is strengthened.

Although participants are not randomly assigned to groups, they can be randomly assigned to intervention levels. A causal relationship can be inferred from a multiple-participant AB design if participants are randomly assigned to interventions during which baseline length or start time of intervention phase is varied. This may be important when improvements in function could be attributed to experience, maturity, or recovery. For example, an intervention to improve sitting with a baseline from 4 to 6 months of age and an intervention beginning at 6 months of age is confounded by sitting independence typically emerging at 6 months of age. The sitting intervention study could
randomly assign participants to begin baseline at 4 months and
begin intervention at 5, 6, or 7 months (Figure 3). Similarly,
natural recovery, rather than the intervention, may account for
changes in outcomes for people in a stroke rehabilitation study
if the baseline is from 0 to 30 days after stroke and the inter-
vention begins at day 31. Here, the baseline could begin imme-
diately after stroke, with participants randomly assign to begin
intervention at 1, 2, or 3 months poststroke.

Fig. 3. A fictional multiple baseline AB single-case study design that tracks independent sitting time for infants at risk for delays. A represents the baseline phase when no intervention is provided; B represents the intervention phase when the sitting intervention is provided. Participants began the study at 4 months of age, but participant 1 began the intervention at 5 months, participant 2 at 6 months, and participant 3 at 7 months of age. Independent sitting typically emerges around 6 months of age. Duration of independent sitting changed with respect to the onset of intervention rather than in relation to age, strengthening the suggestion that the intervention caused the change in sitting behavior.
A variety of statistical techniques can be used to analyze data from SCDs. The US Department of Education funded the development of improved analysis techniques for these designs.8,9,11,12 An example of a more recent analysis technique includes randomization analysis in which P values can be determined for individual participants and then analyzed using meta-analysis techniques across multiple participants in the same study.13-15

The key characteristics of RCTs can be incorporated into SCDs. These include randomization of participants to conditions, comparison of intervention outcomes with control outcomes, identification of causal relationships between interventions and outcomes, generalization of the outcomes.8,10,16 SCDs can address confounding variables, a key limitation of RCTs and other group designs.8,9 When designing group studies, researchers must identify confounding variables that may impact outcome. These could be a long list of variables such as strength, age, time from injury, gender, social support, medication use, and cognitive level of participants. Researchers aim to control these confounding variables by randomizing participants to groups and large samples, with the assumption that levels of confounding variables are evenly represented among the groups. It is not always possible to identify all confounding variables or to have sufficient sample sizes. An important benefit to SCDs is that each participant serves as his/her own control. Most confounding variables will therefore be the same across conditions for each participant. SCDs require fewer participants and resources to answer rehabilitation questions. They support high-quality, controlled research studies in real-world natural and clinical settings. SCDs also reduce the gap between research and practice by reporting individual changes, where therapists serve people, rather than reporting group averages that may not represent any one individual. SCDs provide details of process and change in relation to interventions by collecting data more frequently on fewer participants. These designs offer an ethical intervention design for people when withholding an intervention compromises safety or ethics.8,9

OBSERVATIONAL RESEARCH DESIGNS

There are a variety of observational research designs. Observational studies make comparisons of differences among people with a condition when observed at a single point in time (ie, cross-sectional designs), change over time among people with a condition (ie, case series or, with large data sets, longitudinal designs), change over time among people with and without the condition of interest (ie, retrospective or prospective cohort designs), and differences between people with a condition and those selected for specific similarities who do not have the condition (ie, case control). These types of studies can take advantage of large data sets.

One difference between observational designs and experimental designs (eg, RCTs) is that causality cannot be concluded from relationships described in observational studies. Observed associations may be due to a variable that was not measured but is related to both predictor and outcome. Randomization in experimental designs accounts for this possibility in a way that observational designs cannot. However, causality can be suspected when an association has specific characteristics: a relationship is found consistently in multiple studies with varying samples, methods, and predictors; a monotonic relationship is observed between a variable and a hypothesized effect (sometimes called a “dose relationship” because the greater the magnitude of the predictor, the greater the effect on the outcome); or, a study includes all known or suspected covariates in an analysis of the relationship, thus, ruling them out as sources of the association. However, some people do not believe that causality can be established without an experimental design.

This decade has seen the creation and development of multiple large data sets with outcomes for populations with neurological conditions, including traumatic brain injury (TBI). Two of these data sets were specifically designed to evaluate rehabilitation outcomes after TBI: the TBI Model Systems National Database (TBIMS-NDB)17 and the TBI Practice Based Evidence (TBI-PBE) Study.18 Both data sets examine rehabilitation outcomes using observational designs, yet differ in structure and composition and, as a result, the observational methods used to examine treatment outcomes.

The TBIMS-NDB is funded by the National Institute on Disability, Independent Living and Rehabilitation Research, US Department of Health and Human Services since 1987.17 It houses data on participants older than 16 years with moderate to severe TBI treated for inpatient rehabilitation at one of the participating centers. Data are collected about preinjury status, injury and inpatient rehabilitation, and longitudinal progress at 1, 2, and 5 years, and every 5 years thereafter. As of March 31, 2016, the TBIMS-NDB included approximately 15,000 participants giving 50,000 interviews, with some interviews 25 years postinjury. Critical to its utility as a longitudinal data set, the TBIMS-NDB has follow-up rates exceeding 82% across all years.19 Standardized protocols for data collection result in very high test, retest reliabilities for follow-up measures.20

The TBIMS-NDB yielded hundreds of peer-reviewed articles. One important contribution is the longitudinal analyses. Analytic techniques, including individualized growth curve analysis, support a different understanding of long-term recovery after TBI. As the TBIMS-NDB gains cases at the 15-, 20-, and 25-year follow-up, more insight is expected into the interaction with comorbidities as well as the effects of aging. These discoveries are aided by increasingly sophisticated analytic techniques for longitudinal data.

Another TBI database, the TBI-PBE, uses a “Practice-Based Evidence” approach to observational research that was first used by Horn et al18 in acute hospital care and nursing homes. PBE studies take advantage of naturally occurring variations in treatment patterns.18,21 Data are analyzed regarding the effect of interventions on outcomes taking into account a myriad of patient differences. PBE studies differ from other observational studies in that they include detailed information about the participants, their disease states, and the interventions. This research technique was first extended to rehabilitation in a study of stroke,22 which was followed by a study of spinal cord injury23 and joint replacement.24

The TBI-PBE study was funded in 2007 to collect data on participants older than 13 years with TBI treated at
The data set contains information about treatment during rehabilitation. Point-of-care (POC) forms capture details of each treatment episode, each day, provided by each member of the rehabilitation team. There are an average of 165 POC forms per patient, nearly 6 forms for each day of stay. The TBI-PBE data set has yielded many results, and the data set continues to be analyzed.

The Propensity Score Analysis from the TBI-PBE study is an analytic technique that is gaining attention. A propensity score is calculated for each case in the data set and is the probability that a given individual would receive a specific treatment. The score is derived from prediction models applied to baseline characteristics known before the initiation of the treatment. There are multiple approaches to matching the samples for their propensity score that, when successful, allow the researcher to examine outcomes for a group of participants who received a treatment when compared with a group that had an equal chance of receiving the treatment but did not. The Propensity Score Analysis is evolving and requires skilled statisticians to assist the researcher. However, the potential to simulate randomization in historical data sets could be a powerful tool.

The TBIMS-NDB and TBI-PBE studies illustrate the application of observational techniques to the study of rehabilitation outcomes. Their strengths are different: the detailed treatment data in the TBI-PBE study provide opportunities for understanding inpatient TBI rehabilitation interventions, whereas the extensive longitudinal scope of the TBIMS-NDB is an unprecedented window into the long-term effects of TBI. A characteristic of both data sets is the rigor used during data collection. As data sets become more available with the electronic capture of clinical records, we have greater opportunities to capture observational techniques to the study of rehabilitation. Qualitative research most broadly aims to tell clinicians what to do under a specific set of circumstances, qualitative inquiry commonly attends more closely to illuminating how to be, what it is to experience a state, process, or situation, and how these experiences feel or what they mean. These human experiences represent various facets of being and meaning, and with consequences for the person receiving physical therapy as well as the physical therapist.

Qualitative research, like in observational research, uses time as a prominent dimension of human experience to define research design. Time undergirds processes, relationships, and other experiences of interest in physical therapy research. Qualitative designs offer capacity to make use of cross-sectional or longitudinal time perspectives by matching data collection methods (eg, individual or group interviews as opposed to field observation) to the representation of time-specified design of the study. Finally, any qualitative design is amenable to different levels of analysis required to address individual, group, community, or defined case as the focus of inquiry.

Time frames possibilities for describing and interpreting phenomena of interest in qualitative research design. The phenomenon may be approached in “snap shot” form using cross-sectional designs. Cross-sectional design offers flexibility in accruing participants, used with the goal of understanding a single or multiple points of interest in an experience. Isolating a point or points of interest in the phenomenon under study implies a chronological perspective and suggests that participants are recruited in relation to predetermined times. Alternatively, emphasizing narrative or experiential time implies using cross-sectional design to gather a variety of perspectives from different points across an experience. This sense of cross-sectional design enables participants to reflect on their experiences and allows investigators to analyze across an experience, capturing how it evolves over time across participants. In contrast to cross-sectional design, longitudinal design in qualitative work offers potential to represent intraindividual experiences over time. Narrative methods, phenomenology, and participatory methods like photo-voice and appreciative inquiry typically value longitudinal design with engagement of participants over the duration of an experience. Qualitative case study design may along with specific research questions to be investigated, must guide selection of study design as well as a specific method. Data collection techniques are matched to the method rather than to the design. Sources of text or visual data such as videos or photographs include spoken and written words from individuals and groups. Data are obtained from interviews, events, documents, or other records of the experience under study. Clarity regarding alignment of approach and method with design and data collection is essential to successfully designed qualitative research and delivery of high-quality results.
make use of either chronological or narrative interpretations of time, as the case is defined and data sources identified.29

Qualitative research relies on participant engagement, over time, to delimit the scope and nature of an investigation. As a result, the role of participants in qualitative studies of any design is prioritized in relation to that of the investigator. Typically, the investigator becomes the agent of data collection in contrast to positivist quantitative science where measures and instruments are used. There is a range of roles for participants depending on the investigator’s approach and on the method used. Participant involvement may appear similar to quantitative studies where qualitative data are collected and analysis may be verified through member checking and other strategies. Conversely, participants may be more engaged with inception of a study, cocreating and serving as researchers as in participatory and action methods. Qualitative case study design uses participant engagement differently, depending on the nature of the case. Reflection on the extent of partnership with participants to whom the phenomenon under investigation belongs helps refine design, leading to more precise identification of the best method suited to the phenomenon and investigative partnership.

Qualitative designs, while similar to quantitative research, differ in the way in which underlying principles, drawn from postpositivist paradigms of science, guide design selection and development. The role of participants, representation of time, and focus of analysis are critical to defining design. Aligning design with aim, method, data collection, and analytic technique support a successful qualitative study. Design is most broadly understood as cross-sectional or longitudinal, with either category requiring a match to the elements of the experience to be explored. The option of defining a case as the focus of a study further refines qualitative design when considering complex, multilayered phenomena. Determining the extent of partnership desired with participants further refines design and thus commensurate identification of method and data collection techniques.

**DISCUSSION**

There is a need for physical therapy to acknowledge that there are many rehabilitation research questions that can best be answered using single-case, observational, or qualitative research designs. We are a profession that values problem solving and determining the optimal intervention for a person. We teach our students to avoid “one size fits all” approaches that claim to work for everyone. Rather, we educate students to critically think about each person’s needs, to review the evidence on potential interventions, and to determine the optimal intervention for each client.

We propose that this same thought process should be applied when selecting the best design to answer a specific research question and applied when teaching students to review literature, articles for publication, and grants. A redesign of the common research design hierarchy would be useful. The redesign should focus on the design characteristics that strengthen internal and external validity, with examples of a variety of designs that describe each of those design characteristics. This would replace the ranking of specific design categories. The hierarchical ranking of research designs presumes that designs within each of the categories are all of higher quality than any design in lower ranking categories. This would emphasize research designs that now fall lower on the pyramid and could incorporate useful designs that are not currently listed in the pyramid.

Physical therapists are typically well educated to appreciate the advantages of RCTs and meta-analyses but may lack education in other types of research design and methods. This can result in a variety of inaccurate assumptions. For instance, RCTs and meta-analyses of RCTs are generally considered optimal for answering most research questions related to intervention, and other designs are often dismissed as weaker or simply as a step in the process of moving toward an RCT.1,2 Qualitative measures may be dismissed as not being objective.30 Basic statistics courses teach that studies with fewer than 30 participants may be dismissed as too small to be useful.31 These are examples of possible assumptions that can reflect a lack of understanding of the benefits of less commonly used research designs. These assumptions may have negative consequences such as enabling the dismissal of entire bodies of literature and research designs that can be informative for clinicians and deterring those without extensive resources from engaging in the research process.

We advocate for a problem-solving-based approach to research design and evidence review, whereby the research question, feasibility, ethical, and safety issues are considered when determining the optimal research design. We propose this will result in the implementation of a larger variety of research designs and will enhance the quality and depth of our understanding of the interventions and the individuals we serve.

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Knowledge Translation in Rehabilitation: A Shared Vision

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Purpose: Advances in rehabilitation provide the infrastructure for research and clinical data to improve care and patient outcomes. However, gaps between research and practice are prevalent. Knowledge translation (KT) aims to decrease the gap between research and its clinical use. This special communication summarizes KT-related proceedings from the 2016 IV STEP conference, describes current KT in rehabilitation science, and provides suggestions for its application in clinical care.

Summary of Key Points: We propose a vision for rehabilitation clinical practice and research that includes the development, adaptation, and implementation of evidence-based practice recommendations, which will contribute to a learning health care system. A clinical research culture that supports this vision and methods to engage key stakeholders to innovate rehabilitation science and practice are described.

Conclusions: Through implementation of this vision, we can lead an evolution in rehabilitation practice to ultimately prevent disabilities, predict better outcomes, exploit plasticity, and promote participation. (Pediatr Phys Ther 2017;29:S64–S72)

Key words: evidence-based practice, knowledge translation, rehabilitation

INTRODUCTION

The Institute of Medicine (IOM) characterizes today’s health system as a 3-stage process, including knowledge development (science), translation into medical evidence, and application of evidence-based care to patients.1 The IOM also described prominent inefficiencies in each stage that result in missed opportunities, waste, and harm.1 Delivery of health care is increasingly fragmented, medical conditions are increasingly complex, and patient care is more demanding and costly.2,4 More than half of the patients receive care that is not evidence based, and approximately one-third of patients experienced harm as a consequence.5,6 These shortfalls lead to suboptimal quality, safety, and outcomes (Figure 1).

Although the IOM was referring to the US health care system, rehabilitation research suggests that current clinical practice in rehabilitation may be consistent with this description. High-quality rehabilitation evidence is exponentially growing, resulting in knowledge development, and a rapid improvement in our understanding of rehabilitation science.7-9 Technological innovations in data collection and analytics provide the infrastructure to use clinical data to improve quality and outcomes, and to generate new knowledge.10,11 As a result of scientific advances, rehabilitation providers have access to evidence that can help prevent complications, predict rehabilitation outcomes, exploit nervous system plasticity, and optimize life participation. However, more than 17 years may pass before this research is used in clinical practice.12 Routine rehabilitation practice across practice settings and geographical locations does not consistently integrate evidence,13-18 suggesting a critical gap in the translation and application of science into practice.

Knowledge translation (KT), a new area of science and practice, aims to decrease this gap between research, evidence, and clinical practice.19 The Canadian Institutes of Health Research defines KT as “a dynamic and iterative process that includes synthesis, dissemination, exchange and ethically-sound application of knowledge to improve the health of [the population], provide more effective health services and products and strengthen the health care system.”20 KT research examines the determinants of knowledge (ie, evidence) use and the effectiveness of strategies to promote its use. KT practice focuses on implementation of evidence and evaluation of its effect.19 KT includes “letting
it happen” by publishing data (diffusion), distributing resources to “help it happen” (dissemination), and actively implementing evidence to “make it happen” (implementation) in clinical and real-life settings. Several theoretical frameworks and models inform KT initiatives.

The implementation of evidence into practice requires collaborative efforts to overcome barriers such as limited access to articles, lack of understanding of critical appraisal and evidence application, and time limitations that prohibit finding and evaluating appropriate articles. Although other individual, organizational, and political barriers exist, rehabilitation-specific barriers should also be considered. Limited funds and reimbursements often result in short episodes of care and treatment time is often distributed among many interventions, possibly to target competing rehabilitation goals. As a result, novel treatment interventions may not be used or the dose of each intervention is substantially lower than recommended doses recommended. This can potentially lead to suboptimal facilitation of change through plasticity and recovery. Successful KT efforts require openness to change, time, and collaborative efforts among rehabilitation providers and stakeholders. Good examples exist such as strategies employed during guideline development for upper limb treatments in people poststroke, and the subsequent development of intensive upper extremity training for children with hemiplegic cerebral palsy.

Albert Einstein stated, “The world as we have created it is a process of our thinking. It cannot be changed without changing our thinking.” To innovate rehabilitation practice and research, we must share a vision and an understanding of its importance. We propose a vision for rehabilitation clinical practice and research that includes development and adaptation of evidence-based practice (EBP) recommendations, systematic implementation of these recommendations, and development of a learning health care system that facilitates use of clinical data for quality improvement and generation of knowledge. This vision vastly differs from the description of the current health care system provided by the IOM (Figure 1), which illustrates the health system as a linear model with several missed opportunities, waste, and harm. As depicted in Figure 2, the proposed
vision includes a circular model in which data collected within clinical practice inform research and are used to improve care quality. Furthermore, preferences and priorities of stakeholders, such as patients, policy makers, clinicians, and administrators, are completely integrated. Although this vision is novel to the field of rehabilitation, it was created using existing KT theories, the EBP literature, and the learning health care system as a foundation. If adopted, each component of the vision should be a part of entry-level education, as well as postprofessional training for rehabilitation clinicians, scientists, and academicians.

Development and Adaptation of Practice Recommendations

The first step to implementing EBP is the prioritization and use of assessments and interventions that are supported by high-quality evidence. Clinical practice guidelines and systematic reviews provide guidance. Publication of guidelines does not directly improve practice; therefore, after guidelines are published, differences in organizational, regional, or cultural circumstances may require guideline adaptations to facilitate their use. Stakeholders should collaborate by providing recommendations for the guideline adaptation while protecting the integrity of the evidence, transparently reporting methods, considering rehabilitation context, and conducting an external review of the adapted guideline. ADAPTE and CAN-Implement are examples of internationally recognized guideline adaptation tools.

Additional factors to be considered while adapting guidelines are (1) assessment recommendations: administration, standardization, interpretation, and use for clinical decision-making; and (2) intervention recommendations: measurement practices that support appropriate intervention, including assessments that assist in selecting the intervention for a patient (ie, rule in/out the appropriateness of the intervention) and outcome measures. An evidence-based intervention dose should be included. The FITT (Frequency of exercise, Intensity [ie, challenge], Time per session, and Type of intervention) principle can be used to guide intervention prescription. Optimal FITT principles (ie, doses) for most rehabilitation interventions are unknown; however, the recommended dose can be adapted from evidence to suit individual patient and clinical needs. Systematic reviews and guidelines are available to support implementation of a new practice. Rigorous review methods can assist with determining the level of existing evidence and necessary adaptations to the specific setting to determine the optimal dosage. The use of reporting guidelines and checklists facilitates appropriate use of the interventions in clinical practice. Poorly described research interventions may result in compromised fidelity during implementation into practice. Tools such as the TIDieR (Template for Intervention Description and Replication) checklist to describe interventions guide intervention description for publication.

Systematic Implementation of Recommended Practices

Theoretical frameworks, such as the knowledge-to-action (K2A) framework, may expedite implementation of EBP. Knowledge creation includes research articles, research synthesis, and creation of user-friendly EBP documents. The “to action” cycle requires problem identification, assessment of facilitators and barriers, local adaptation of evidence (as previously described), KT interventions (ie, audit and feedback, mentoring, education sessions, etc), monitoring use, outcomes assessment, and sustaining the practice. Several studies have demonstrated positive outcomes after using the K2A framework to implement evidence including studies of balance and gait assessment, dysphagia, and vocational rehabilitation. As new practices are implemented, data collection in each phase of the K2A cycle can assist in determining success of implementation (ie, change in clinician behavior and/or improved patient outcomes), ensuring ongoing quality improvement and generating new knowledge.

Development of a Learning Health Care System

The IOM recommends that health care organizations develop a learning health care system (LHCS) that integrates clinical operations, research, patient engagement, and a robust technology infrastructure to improve health care quality and generate new knowledge. Within an LHCS, the standardization and reporting of assessments improve care delivery, increase transparency of outcomes, link clinicians’ performance to patient outcomes against benchmarks, improve processes and public health, and generate new knowledge. An LHCS systematically captures and continuously translates knowledge into practice (Figure 3). Importantly, the patients, clinicians, and communities are at the center of the model, indicating engagement and the alignment of care with their priorities. Broad leadership and incentives are aligned to facilitate a new culture of scientifically based care.

In rehabilitation, an LHCS would facilitate robust data collection, analysis, and rapid generation of practice-based evidence that has potential to quantify rehabilitation outcomes, identify responders/nonresponders to interventions, predict future outcomes, and determine optimal intervention doses.
Availability of clinical data may contribute to prevention of complications, slowing disease progression, exploiting plasticity, and ultimately maximizing participation. Knowledge gained from implementing EBP should continuously improve and refine rehabilitation, creating a vision of ongoing evolution of clinical practice.1

BUILDING A CULTURE THAT SUPPORTS THE VISION

Implementation of the vision of an ongoing evolution of clinical practice requires a fundamental change in the view that the clinician and the researcher, or the clinical environment and the research lab, are distinct and separate. Such a change requires a model that facilitates the interaction between generating science and translating it into clinical practice.

The Clinician as a Researcher

In her 2015 McMillan lecture, Snyder-Mackler56 called for the clinician scientist to advance physical therapy practice. This model calls for some clinicians to engage full-time in research. The model must include more clinicians who adopt the scientist-practitioner model. The concept of a scientist-practitioner, suggested by Thorne as a theoretical basis for advancing clinical psychology,57-59 may be useful for advancing rehabilitation practice and research. The scientist-practitioner is the practicing clinician versed in the scientific method, or specifically, the logical, systematic, and objective process of evaluating a problem or question.57-60 The scientist-practitioner employs the scientific method in every aspect of practice, including application of scientific principles for observation, generation of testable hypotheses, intervention, and evaluation (Figure 4).57,58 The education of the scientist-practitioner should begin during entry-level education for application of the scientific model to clinical practice.

Hayes et al61 suggest 3 roles for the scientist-practitioner, including becoming a critical consumer of the literature who is able to locate and critically assess research, an evaluator of one’s own interventions and programs using validated tools and methods, and a researcher who produces and reports new data from interactions with patients to the scientific community. Recently, a fourth role has emerged for the scientist-practitioner to assist in the dissemination and implementation of knowledge, or disseminator.62 In this role, the scientist-practitioner facilitates the use of self-generated evidence to advance clinical practice. To be successful in these 4 roles, the scientist-practitioner should develop several core competencies, all of which involve the scientific method (Table 1).58,63,64

Common EBP barriers include lack of time, financial constraints, limited access to evidence, lack of a structured engagement process, and limited communication between stakeholders and researchers.59,65 Strategies to overcome these barriers are needed to support and enable the scientist-practitioner to thrive. The clinical and organizational environment must support the application of the scientific method in daily practice.7,58,59,63,64

Establishing the Clinical Research Culture to Foster and Facilitate the Scientist-Practitioner

Establishing this culture requires building an environment of shared values, attitudes, and patterns of behavior that provides structure and significance for the related activities.66 A culture of scientific inquiry and rigor, a clinical research culture, allows for clinicians to engage in the scientific method, helps develop the scientist-practitioner, and facilitates KT and EBP.59,66 Such a culture sets the expectation that all clinicians will engage in the scientific method and participate in the research process. Ultimately, a clinical research culture can advance clinical care, improve patient outcomes, and generate new rehabilitation knowledge.58,59,61,63,64

TABLE 1
The Intersect Between the 4 Key Roles of the Clinician Scientist and These Core Competencies

<table>
<thead>
<tr>
<th>Role</th>
<th>Competencies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Researcher</td>
<td>Conduct a research study, access research support, select valid outcome measures, write research proposal, collect outcomes, manage data, analyze data, do data interpretation.</td>
</tr>
<tr>
<td>Evaluator</td>
<td>Identify valid outcome measures, implement evaluation plan, access research support, conduct a research study.</td>
</tr>
<tr>
<td>Disseminator</td>
<td>Write an abstract, create and present research poster, develop and present scientific talk, write manuscript for publication, develop guidelines.</td>
</tr>
<tr>
<td>Research</td>
<td>Conduct a research study, access research support, select valid outcome measures, write research proposal, collect outcomes, manage data, analyze data, do data interpretation.</td>
</tr>
<tr>
<td>Researcher</td>
<td>Conduct a research study, access research support, select valid outcome measures, write research proposal, collect outcomes, manage data, analyze data, do data interpretation.</td>
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<td>Write an abstract, create and present research poster, develop and present scientific talk, write manuscript for publication, develop guidelines.</td>
</tr>
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</table>

Abbreviation: IRB, Institutional Review Board.
There are several key characteristics shared by institutions that are effective at creating a clinical research culture. Establishing and sustaining a clinical research culture should be a part of the vision and mission of the institutions. At a minimum, clinicians should include scientific inquiry into daily practice. The effective institutions support the breadth of the research experience in which a scientist-practitioner may engage, from being critical consumers of scientific literature to participating in various or all aspects of research. Opportunities are provided (didactic, experiential, or mentored) to attain the skills necessary to participate in these research activities. Clinicians should be engaged early and often in research, and scientist-practitioners should be recognized for research contributions and productivity. This might include recognition at an annual meeting or a research-focused career ladder with appropriate time for participation and financial factors.

Providing opportunities to create research competence and expertise is critical and can be accomplished in many ways, including provision of research education and training (Table 2). Distance learning programs could provide training for clinicians in rural areas. Programs from the nursing and rehabilitation fields provide examples of ways to promote the development of the scientist-practitioner within the clinical setting. Allowing clinicians to work in the clinic while attaining research skills may facilitate EBP implementation, KT champion development, standardized data collection, and dissemination of knowledge. Clinicians may develop a more positive perception and attitude about research (Table 3). Evaluating the effect of preparing the scientist-practitioner and creating a clinical research culture on productivity and finances are important topics for future research.

CREATING A SHARED VISION

Although the vision proposes a gold standard for clinical practice (Figure 2), it is critical to acknowledge that goals of this standard are to improve the function, quality of life, and participation for the people we serve. We must engage clinicians as well as patients, families, organizations, and policymakers (Figure 3), as opposed to assigning them the role of “recipient of knowledge” or “knowledge user” at the end of the research process. Incorporating the stakeholders’ views and experiences assists in the generation of meaningful outcomes and can facilitate KT efforts. Successful KT and implementation must also inform and drive decision making and policy. Integrating stakeholders in the entire K2A cycle contributes to the commitment to spread innovations and implement meaningful and cost-effective clinical and systems-level changes.

However, recent studies comparing research and patient priorities suggest that academic research is not aligned with patients’ beliefs about health care priorities. Policy-makers’ information needs and rehabilitation research outputs are often not aligned. New initiatives such as PCORI (Patient-Centered Outcomes Research Institute), SPOR (Strategic Patient-Oriented Research), and INVOLVE emphasize the

<table>
<thead>
<tr>
<th>Location</th>
<th>Elements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ronald Reagan University of California-Los Angeles Medical Center, Gawinski and Becker</td>
<td>What: Year-long evidence-based practice fellowship to assist staff nurses Goal: Apply current evidence and use research methods to resolve current clinical issues Who: Directed by doctorally prepared research nurse Components: Didactic experience and mentored evidence-based project</td>
</tr>
<tr>
<td>Shepherd Center PT/OT Research Fellow</td>
<td>What: 2-y combined clinical practice and research training (2-d clinic/3-d research) Goal: To train clinicians in research methods and facilitate integration of research into clinical practice Who: PT or OT Components: Didactic experience and mentored research experience; completion of a research project</td>
</tr>
<tr>
<td>Rehabilitation Institute of Chicago</td>
<td>What: 1-y fellowship with protected time to conduct a clinical research project. Time varies based on demands of the project Goal: To train clinicians in all aspects of a clinical research project and facilitate implementation of EBP Who: PT, OT, and SLP Components: Grant development, mentored research experience; completion of a research project; submission of project for publication; presentation about research project at conferences</td>
</tr>
</tbody>
</table>

TABLE 2
Examples of Training Programs to Facilitate the Scientist-Practitioner

| TABLE 3 |
| Return on Investment |
| Develops clinician scientists Develops a clinical leader and scientist Thinks beyond patient to population Mentors staff in research and knowledge translation Improves clinical practice quality and efficiency Increases accountability Leads to innovation |
| Creates supportive environment Creates supportive environment Develops and supports the scientist-practitioner Attracts outstanding clinicians Increases patient access to innovative approaches and treatments |
| Enhances facility reputation as a leader in the field Improves relationships with payer groups |

Abbreviations: EBP, evidence-based practice; OT, occupational therapist; PT, physical therapist; SLP, speech language pathologist.
importance of patient-centered research and outcomes. These initiatives endorse the need and support the development of systematic methods to engage stakeholders in the research process. The integrated knowledge translation (iKT) framework\(^7\) provides guidance in how to use the research process as an opportunity for collaboration with stakeholders, including the development or refinement of the research questions, selection of the methodology, data collection and tools development, selection of outcome measures, interpretation of the findings, crafting of the message and dissemination of the results."

The objective of iKT is to engage stakeholders across the research continuum from awareness about research, to participation in research, and finally to co-creation of research (Table 4).\(^7\) Barriers and facilitators for stakeholder engagement are reported in health care research, but iKT activities are not adequately described or theoretically supported.\(^7\) In rehabilitation, there are similar gaps with stakeholder groups, such as policy and decision makers rarely included. A stakeholder engagement framework or model may guide engagement and planning of the research approach and result in successful implementation.\(^7\)

The INVOLVE framework suggests a structured approach to stakeholder engagement on the basis of the pillars of respect, support, transparency, and responsiveness. These values should be apparent through constant communication among researchers and stakeholder groups, budget allocation for engagement, and power sharing among all involved.\(^7\)

The Ottawa Model for Research Use supports the understanding of changes in behaviors, such as those needed to implement EBPs and to drive societal change. Behavior change occurs through a structured process, helping in the assessment of individual and system barriers and facilitators to use of new knowledge, tools, or practice.\(^7\) This model can assist in the identification of individual stakeholder barriers (values, social norms, beliefs) and environmental barriers (economics, political climate, built environment, norms) that may prevent stakeholder engagement and research dissemination and implementation.

The K2A model implicitly allows stakeholder engagement throughout the research process (Table 4). Stakeholders can be involved in curating the evidence and validating research findings, evaluating clinical practice guidelines, newsletters, and policy briefs.\(^7\) During implementation, stakeholders may identify new research questions and set priorities.\(^8\) Similarly, stakeholders can monitor use and evaluate outcomes much more closely with a vested interest that researchers and clinicians may not provide.\(^8\)

### Identifying and Addressing Stakeholder Needs

Stakeholders vary on the basis of the type of research that is translated, disseminated, and mobilized (Table 4).\(^7\) Stakeholders should include key leaders within organizations to maximize effect.\(^7\) When selecting stakeholders, consider individuals who share key features with the group they represent, are willing to speak for the group, have effective communication skills, and ensure diversity. The roles of the stakeholder groups and committees should be clearly identified.\(^7\) Consider “who is not at the table” and include stakeholders who are not frequently involved, such as decision makers, extended family and fathers in pediatric research, and community organizations.

Including stakeholders in environmental scans and needs assessments may result in the collection of information that would not be identified by researchers. When asked how research can inform policy, stakeholders agree that researchers and clinicians must have an understanding of policy processes, regulation of service, the rights and benefits of clients, and how existing mechanisms can support participation, equipment purchases, health care access, and overall community engagement.\(^7\) This information guides research question development and clinician-researcher partnerships to ultimately inform policy.

### TABLE 4
Integrating Stakeholders in Research and Knowledge Translation

<table>
<thead>
<tr>
<th>Steps</th>
<th>Map:</th>
<th>Engage:</th>
<th>Measure:</th>
<th>Sustain participation:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuum of engagement(^7)</td>
<td>Awareness of evidence ↓ →</td>
<td>Participation in research studies ↓ →</td>
<td>Contribution to new projects ↓ →</td>
<td>Developing a sense of ownership ↓ →</td>
</tr>
<tr>
<td>Examples of stakeholder engagement through the knowledge to action(^7)</td>
<td>Knowledge creation: Participation in systematic reviews, guideline appraisal, public forums</td>
<td>Implementation: Participation in studies and regular meetings with research team, “stakeholder faculty” models, policy response units</td>
<td>Monitoring: Participation in quality control and users committees</td>
<td></td>
</tr>
<tr>
<td>Stakeholder groups to engage</td>
<td>Patients/clients (including children and youth), families (including extended families), clinicians (across disciplines), administrators (program managers), policy makers (from clinical and hospital administration to elected officials and other bureaucrats and government officials), regulatory bodies (professional orders), industry (eg, adaptive and assistive technology and product developers), funding agencies, scientists in other fields (technology, social sciences, humanities, policy, ethics), community organizations</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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To support the development of iKT projects, a stepped approach is necessary. To illustrate these steps, we provide an example of pediatric research in promoting the participation of children with disabilities.

**Example: Promoting Participation for Children With Disabilities**

Children with disabilities and their families identify participation outcomes as key to their health and well-being. However, most interventions and research target body function or activity limitations. Projects engaging stakeholders in developing solutions that include children, families, rehabilitation professionals, and society could address this gap. Environment-based and context-based rehabilitation interventions are under development. Adopting an iKT framework, researchers and clinicians identified that training monitors who offer leisure activities, partnering with school-based initiatives, developing peer-mentorship programs, and creating policy tables for rehabilitation. A study, using a participatory action research approach, created a network of stakeholders to support the development of participation interventions for children with disabilities. This network, CHILD LeisureNET, includes more than 150 stakeholders such as policy makers, families of children with disabilities, clinicians, education professionals (teachers, school representatives), and community organizations (leisure promotion centers, disability advocacy groups). These stakeholders assembled in forums and were presented evidence on leisure participation. Stakeholders identified existing barriers and possible solutions to promote participation. Using a business model, these solutions were described and prioritized by different stakeholders. Working groups developed solutions. Stakeholder-driven solutions included the development of a mobile app, listing adapted and inclusive community activities, partnering with school-based initiatives, developing peer-mentorship programs, and creating policy tables to disseminate best practices at the municipal and provincial levels in Canada. These examples demonstrate how steps of engagement can generate new practice, stakeholder-driven research, and evidence-based practice.

**Conclusions**

As a rehabilitation community we must equip ourselves with knowledge about how to generate, share, and apply knowledge. KT, including active EBP, is becoming a mandatory step in both research and practice, and is an opportunity to create value for rehabilitation. Through ongoing recommendations and implementation of EBPs, collection and use of practice-based evidence to improve quality and generate new knowledge, development of a clinical research culture, and engagement of patients, families, decision makers, and communities, we can achieve a new culture of rehabilitation care. With a focus on this vision, we will improve clinical practice and research, innovate rehabilitation, and prevent disabilities.

**References**

A new model of diagnostics and treatment for overweight in children is used for implementation of a new approach toward childhood obesity. Although based in a hospital setting, it is part of a cure and care network with other professionals. By psycho-education about the body at a 6-year-old level, parents and children become informed and competent partners. This knowledge increases their autonomy and ability to make choices. Collaboration with the family's support group or network reduces isolation and increases the feeling of being connected and supported. Together with their support network, they can maintain this healthier lifestyle or adjust it where needed. Family workbooks and worksheets support the child and parents and increase their autonomy, self-management skills, and motivation to take part in the cure and care network. The approach is based on the three basic needs that determine motivation, namely autonomy, competence, and connectedness.

PEDiatrics Phys Ther 2017;29:S73–S75

Key words: childhood obesity, overweight, support network

INTRODUCTION

Overweight and obesity have reached epidemic proportions. In the Netherlands, the prevalence of overweight including obesity among children rose from 4% to 15% in boys and from 7% to 18% in girls between 1980 and 2003. In the last decade, the prevalence reached 30% in specific large ethnic minorities.1,2

Obesity adversely affects each of the major risk factors for heart and vessels including diabetes, blood pressure, and lipid profile during childhood and adolescence. As a result, obesity is associated with an increased risk of death, especially from cardiovascular disease. More recently, evidence supports that certain forms of cancer and kidney disease are associated.3 But obesity also affects the well-being of children and their families. Many children experience bullying,4,5 and anxiety, depression, a negative self-image, and behavioral problems are common.6 These negative feelings can lead to “comfort eating,” isolation, and inactivity thus, aggravating the problem. Parents are often criticized and can feel incompetent, guilty, and powerless in helping their children.5

With focus both on prevention and management, the reduction of overweight, obesity, and related chronic diseases are objectives of the Dutch Ministry of Health, Welfare and Sport. A partnership has been established for all relevant stakeholders, including the national organizations of health care providers, health insurance companies, and patient organizations, to collaborate and develop an integrated health care standard for the management and prevention of obesity. This standard involves strategies for diagnosis and early detection of individuals at high risk—strategies for appropriate lifestyle intervention for those who are overweight and obese and, when appropriate, additional medical therapies.7

Despite all efforts in managing the obesity epidemic, the prevalence of overweight is increasing. The general approach of the professionals working in the field of care and prevention of obesity might explain this increase. Professionals’ approach is to advise. Advice includes healthy foods, how to stimulate an active lifestyle, or general advice about a healthy lifestyle, such as getting adequate amounts of sleep. Unfortunately, in only a few cases is this approach successful. Most families with children with obesity know what a healthy lifestyle for their children should be and are willing to invest in the future health of their children, but are often not able to provide this lifestyle. The challenge for the health care professional is to identify the problems for each child and family. This knowledge can help the family solve the problems or work around issues. This may lead to an increase in parents’ intrinsic motivation to provide their children with the best future.8

At the same time, even with motivation, living a healthy lifestyle remains hard work for parents. They have to be good examples for their children and also tolerate the children’s disappointment when they do not get what they want. The desire...
to eat can be very strong and is influenced by the pituitary-hypothalamic area in the brain, the center for hunger and satiety. The satiety center is part of the greater limbic system in the brain that supports a variety of functions including emotion, behavior, motivation, and long-term memory. The limbic system enhances the experience of food with emotion, which powerfully influences behavior. Because of this connection we eat when we feel happy, depressed, or stressed and can also remember the taste of good food for a lifetime. Evolution created this connection for a reason. Because this center continues to influence our eating behavior, this system must be important for survival. Indeed, during evolution the craving for food helped us to survive. The strong influence that craving has on our behavior made and continues to make humans fight for food. Eating may be a necessary addiction. Knowing how strongly the craving for food influences our behavior gives us a different perspective on overweight and urges us to redefine the development of overweight.

**THE NEED FOR A DIFFERENT VIEW ON OBESITY**

A more useful approach toward obesity could be described using the definition “overweight is an ancient and normal reaction to an obesogenic environment.” With this definition, being overweight is no longer a sign of sloth, but merely means the individual is capable of storing the excess calories in his or her body for survival by keeping his or her energy balance positive for a longer period. This person is not aware, willing, or capable of influencing his or her energy balance to decrease his or her weight. And if gaining weight is a normal reaction of our body, we should not “fight” this reaction or start a battle against the kilos and overweight. We should not fight our own body because we cannot win. This is an important mind shift which gives people pride and enhances participation in society.

To lose weight one needs to create a slightly negative energy balance. In practice, parents and children, especially teenagers, want to lose weight quickly. A large and rapid weight loss is seen as a sign of an effective obesity intervention. The success of an intervention is often expressed in amount of weight loss in kilograms per week. However, when overweight is seen as a normal reaction of the body, one could understand that a sudden negative energy balance will create a state of emergency in the body, because weight gain is its goal. And it becomes difficult to maintain this weight loss. Rapid weight loss is the most powerful stimulus for the hunger and satiety center to activate. The body has a large number of defense mechanisms to prevent further weight loss and to stimulate regain of storage weight, and they are all activated. The body is fighting further weight loss and focused on recovering the energy stores by using several defense mechanisms such as lowering of the basal metabolic rate. As a result, this battle is lost with a regain of weight when, in fact, the child’s body demonstrates excellence by surviving (another) famine. This is extremely frustrating and disappointing for the child and his or her parents. They have fought and struggled and suffered for nothing, feeling they have lost the battle, when in fact their child’s body showed strength.

Thinking from this perspective and accepting the idea that fighting with a body that is trying to survive is an almost impossible task, we can acknowledge that a different approach is needed. Instead of fighting the body, the approach is to collaborate. By choosing a lifestyle change that creates only a slightly negative energy balance, the body’s defense mechanisms will less likely be activated. Eating fat, salty, and sweet food has a calming effect on the body and gives a sense of pleasure and safety. By using other replacing activities, like music or positive human interaction, the same reward system that creates a happy satisfactory feeling is activated. And by creating structured moments of enjoyment in the lifestyle adaptation, the new weight-controlling behavior becomes less hostile. These patterned and structured activities influence the brain and are necessary to develop the brain.

Another important step is increasing social support and stimulating the feeling of being connected to family or friends. Our approach to childhood obesity is oriented to the family system. If the family, with parents and caregivers as role models, adopts changes, the obese child will feel less rejected and more accepted. And parents and family members will only do that, if this changed lifestyle is enjoyable, is matched to them and is designed by them. They will only participate and start to self-manage and feel empowered if these choices are theirs. That may take time, because parents may feel powerless. They feel they have failed and often this is an issue within their own histories. By supporting and believing in their strength and competence, the professional invites the parents and caregivers to become the vital part of the treatment team.

In the care for children with obesity, this is a shift in paradigm. Traditionally, care is based on supply whereas when care centers on self-management, it is driven by demand. The self-managing patient creates a health care demand, which is independent of the health care professional. The professional needs to communicate using education to increase competence in parents and children. Professionals may have stigmatizing thoughts, such as assuming that the family lacks perseverance. This prevents professionals from accepting the family as team members. Child and parents, however, not only participate, but also create their own approach and the professionals participate temporarily in the journey.

**THE ACTIVE HEALTHY LIFESTYLE**

Becoming more active may be the most enjoyable and powerful intervention for a new lifestyle. Families are challenged to find activities they enjoy and can enjoy together. A daily pillow fight after dinner with parents and children is easier than sticking to a diet while feeling the craving for sweet, salt, or fatty foods. Physical contact such as massage gives pleasure and creates the feeling of connection. Becoming more active leads to all family members feeling fitter. A more active lifestyle is associated with not only loss of overweight but also a significant improvement in health. An increase in aerobic fitness is associated with a decrease in insulin resistance, thereby improving the cardiovascular risk profile. This type of information is important for the children and their parents to stay motivated when weight loss has not yet occurred. Increasing physical activity is one
element in the treatment of depression in children and adults and may also influence the anxiety level in obese children. Physical therapists are therefore key players in helping, challenging, and motivating less active children to become more active.

This approach is challenging for parents. They need to learn to set boundaries, tolerate negative emotions, and change their own lifestyle. If parents feel empowered, they may view the changes as not only helping them manage their child's weight, but also in other parenting tasks such as chores, homework, and reducing screen time.

A NEW METHOD FOR THE APPROACH OF THE OBESE CHILD WITHIN A FAMILY

In the department of pediatrics of the Jeroen Bosch hospital, this new model of diagnostics and treatment was put into practice. Parents and children become informed and competent partners using education about the body and its mechanisms. Education was aimed at a 6-year-old level. This knowledge increased their autonomy and ability to make choices. Collaboration with the family's support group or network reduced isolation and increased the feeling of being connected and supported. Together with their support network, parents and children can maintain this healthier lifestyle or adjust it as needed. Family workbooks and worksheets support the child and parents to increase their autonomy and self-management skills. According to Deci and Ryan, the level in which the 3 basic needs—autonomy, competence, and a connectedness—are met determines motivation. The approach is based on these needs, in combination with relevant knowledge.

REFERENCES

SUMMARY OF IV STEP

Stepping Up to Rethink the Future of Rehabilitation: IV STEP Considerations and Inspirations

Teresa Jacobson Kimberley, PT, PhD; Iona Novak, OT, PhD; Lara Boyd, PT, PhD; Eileen Fowler, PT, PhD; Deborah Larsen, PT, PhD

Department of Physical Medicine, Division of Physical Therapy and Rehabilitation Science, University of Minnesota, Minneapolis (T.J.K.); Cerebral Palsy Alliance, Discipline of Child and Adolescent Health, The University of Sydney, Camperdown, Australia (I.N.); Department of Physical Therapy and Djavad Mowafaghian Centre for Brain Health, The University of British Columbia, Vancouver, British Columbia (L.B.); Department of Orthopaedic Surgery, Center for Cerebral Palsy, University of California, Los Angeles (E.F.); and School of Health and Rehabilitation Sciences, The Ohio State University, Columbus (D.L.).

Background and Purpose: The IV STEP conference challenged presenters and participants to consider the state of science in rehabilitation, highlighting key area of progress since the previous STEP conference related to prediction, prevention, plasticity, and participation.

Key Points: Emerging from the thought-provoking discussions was recognition of the progress we have made as a profession and a call for future growth. In this summary article, we present a recap of the key points and call for action. We review the information presented and the field at large as it relates to the 4 Ps: prediction, prevention, plasticity, and participation.

Recommendations for Practice: Given that personalized medicine is an increasingly important approach that was clearly woven throughout the IV STEP presentations, we took the liberty of adding a fifth “P,” Personalized, in our discussion of the future direction of the profession. (Pediatr Phys Ther 2017;29:S76–S85)

Key words: IV STEP, participation, personalized, plasticity, prediction, prevention

INTRODUCTION

Taking place roughly every 10 to 15 years, the STEP conferences are designed to disseminate best-available evidence and set future directions in physical therapy education, research, and practice as they relate to individuals with neurologic conditions across the life span. IV STEP took place in July 2016 at The Ohio State University in Columbus, Ohio, and certainly accomplished this goal with enthusiastic presentations and discussion (Table 1). The purpose of this article is to highlight the key messages and themes that emerged from IV STEP. As stated by Marylou Barnes after II STEP, “the enormity of what has taken place at this conference has not yet struck any of us full force.” Indeed, this STEP conference, consistent with its predecessors, served as an unrestrained environment where ideas and plans were not constrained by “real-world” issues. Accordingly, the attendees and this IV STEP summary article coauthor group were challenged to analyze the state of current evidence in physical therapy practice; to develop priorities for education, research, and practice for the coming decade; and to present ideas to spur change for the future.

The IV STEP conference planning committee, after much discussion and review of current trends in practice and research, identified 4 critical themes on which to focus the conference presentations: prediction, prevention, plasticity, and participation (ie, the 4 Ps). The committee strategically observed that the emerging evidence in these 4 thematic areas was escalating and would critically impact the next decade of physical therapy practice in the area of neurologic conditions. Each invited presenter was given a specific charge that included reviewing the current evidence of his or her topic related to one or more of the themes and highlighting future research priorities of the profession (see the Appendix for speakers and charges).

We recap the key findings of the IV STEP conference in a diagram, which has 3 stages: (1) personalization, (2) intervention, and (3) outcomes (Figure 1). Stage 1 involves intervention planning for “personalized” care. In this stage, the physical therapists must consider the “4Ps”: Prediction, Prevention, Plasticity, and Participation. Intervention planning involves inviting the patient to set goals for the intervention; the physical
TABLE 1

<table>
<thead>
<tr>
<th>IV STEP Demographic Information</th>
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</thead>
<tbody>
<tr>
<td><strong>Attendees</strong></td>
</tr>
<tr>
<td>701 (413 ≥ 40 y, 218 &lt;40 y) (M: 67, F: 567; unreported 67)</td>
</tr>
<tr>
<td><strong>Speakers</strong></td>
</tr>
<tr>
<td>34</td>
</tr>
<tr>
<td><strong>Section affiliation</strong></td>
</tr>
<tr>
<td>387 neurology</td>
</tr>
<tr>
<td>124 pediatric</td>
</tr>
<tr>
<td>91 dual membership</td>
</tr>
<tr>
<td>99 nonmembers</td>
</tr>
<tr>
<td><strong>Primary setting</strong></td>
</tr>
<tr>
<td>331 clinicians</td>
</tr>
<tr>
<td>295 academicians</td>
</tr>
<tr>
<td><strong>Geographic representation</strong></td>
</tr>
<tr>
<td>44 US states as well as people from Australia, Canada, Chile, Denmark, Iceland, India, South Korea, Kosovo, Malaysia, Netherlands, South Africa, United Kingdom</td>
</tr>
</tbody>
</table>

therapist then considers the person’s neuroimaging, genetic, and classification data to inform planning and predicting outcomes (left section). Stage 2 is delivering the intervention (center section). Key principles of intervention include teamwork and partnership with the patient and other providers in their team. Physical therapy intervention will likely include exercise; intense motor training; virtual reality; self-efficacy and self-management training; and health promotion activities. Stage 3 is the measurement of intervention outcomes (right section). The desired outcomes of physical therapy intervention include better motor skills; better health; prevention of impairments; and measuring whether or not the patient’s goals are achieved.

**PREDICTION**

A key element that will advance physical therapy practice is the ability to predict outcomes. Prediction of outcomes will lead to clearer patient expectations and better selection of interventions to match the individual. Predicting outcomes and guiding treatment with classification systems, including movement system diagnosis, is an important area of research. Examples of classification systems used in life span neurologic physical therapy practice include the American Spinal Cord Injury Association (ASIA) Impairment Scale (AIS)² and the Gross Motor Function Classification Scale (GMFCS).³ The GMFCS is widely used for children with cerebral palsy to guide treatment and predict outcomes. In adults, no single measure is used in such widespread fashion, perhaps because no single measure is yet this effective in predicting outcomes.

Notably, the American Physical Therapy Association recently published a white paper that defines the human movement system as a foundation for physical therapy practice.⁴ Building on the concept that physical therapists are the experts in diagnosis and treatment of human movement, it is clear that a common language is needed that enables the diagnosis of movement dysfunction, development of appropriate treatment options, and prediction of outcomes for individuals with neurologic disorders. Movement system diagnosis has been proposed as one means of achieving this across medical diagnoses with 9 movement deficit categories: (1) movement pattern coordination, (2) force production, (3) sensory detection, (4) sensory selection and weighting, (5) perception of vertical orientation, (6) fractionated movement, (7) hypermetria, (8) hypokinesia, and (9) cognitive.⁵ Yet, little research to date has examined the practical use of movement system diagnosis, that is, is it effective in determining treatment measures or outcomes by diagnostic category? The thinking behind proposing a movement system diagnosis focus is to promote use of a common language across neurologic conditions that would guide treatment choice, potentially decreasing treatment variability while improving communication between practitioners, and facilitate research through better grouping of study participants.

There is a growing focus in the profession on developing disease-specific classification systems, such as the AIS for spinal cord injury; however, there is considerable variability in the level of function of patients classified within a given category.⁶ In response, the Neuromuscular Recovery Scale

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Fig. 1. Summary of the IV STEP conference key messages.
(NRS) was developed to differentiate function on 11 critical motor tasks for people classified as AIS C and D (motor incomplete), focusing on recovered movement patterns instead of compensatory movements. More recently, a pediatric NRS has been developed. The NRS has been shown to be responsive to change in function over time and can be used as an outcome measure; however, it has not been evaluated as a predictive instrument. The GMFCS, a 5-level motor severity classification system. It is not an outcome measure but has a strong predictive relationship with a child’s development of gross motor function measured on the Gross Motor Function Measure (GMFM-66 items). Cerebral palsy gross motor curves have been generated that further predict gross motor function as a function of age and GMFCS level. These curves can (a) guide the timing of physical therapy intervention through identification of children who lag behind during early development or exhibit an unexpected loss of motor function during adolescence and (b) help predict realistic outcomes from treatment, for example, when to use active motor training versus when to use compensation (such as a powered wheelchair) to achieve independent mobility. Development of disease-specific measures, such as the GMFCS, GMFM, and NRS, is critical for the future of neurologic physical therapy, so that changes in function can be measured across the life span. Specifically, such measures could focus treatment and enable the accurate prediction of outcomes.

Effective prediction, however, may require more than just behavioral measures. For example, the PREP (Predicting Recovery Potential) algorithm that was developed to predict functional arm recovery poststroke uses (a) early motor function (manual muscle testing of Shoulder Abduction, Finger Extension = SAFE), (b) transcranial magnetic stimulation (TMS) (if the 2 SAFE scores sum to <8), and (c) diffusion imaging (if the TMS fails to elicit a motor-evoked potential in the finger extensors) to determine the degree of integrity within the corticospinal tract. This work demonstrates that combining measures of motor function, neurophysiological analysis, and neuroimaging can predict long-term outcomes with 88% specificity and 73% sensitivity in people with mild to moderate stroke severity. The PREP algorithm also illustrates the need for multimodal data to effectively predict outcomes in individuals with neurologic conditions.

Efforts to develop predictive algorithms are exciting; however, it is imperative for our profession to identify the factors that result in change in classification levels for individuals and to explain why, in some cases, there is a disparity in the predictive value of algorithms. Factors that may disrupt the predictive ability of algorithms include environmental, behavioral, motivational, and treatment variations. Furthermore, at this time, predictive algorithms have not accounted for what the individual considers to be meaningful outcomes; this is critical, as the capacity for recovery (the ability to perform a task as measured on objective assessments) does not always mirror performance (task completion within natural environments). Patient report must inform our assessments and classification methods to accurately plan treatments and predict long-term outcomes.

Relatedly, the development of clinical pathways (ie, decision trees/algorithms, and/or practice guidelines) is critical for evidence-based treatments and education of therapists. The utility of clinical pathways stems from their use of individual patient data that enables personalization of treatment, which can lead to prediction of recovery. Adoption of the template for intervention description and replication (TIDIER) guideline for clear reporting of the key ingredients of rehabilitation interventions will help ensure that we are comparing “apples with apples” in the future. The use of electronic medical records and registries also makes treatment comparisons feasible. There is a need to evaluate trajectories of recovery and eventual outcomes based on well-defined treatment approaches; this will ultimately facilitate comparison of outcomes across individuals and settings.

PLASTICITY

It is clear that to move forward as a field, neurologic physical therapists must embrace technologies that facilitate positive plasticity. Technology can be used to enhance intensity, motivation, dosing, and consistency of practice as well as to quantify exercise parameters and outcomes. Technological innovations are progressing at a rapid rate, and a flood of new Food and Drug Association–approved robotics, devices, and so forth, is readying for market release. Yet, we must ensure that rehabilitation needs, not marketing, drive purchasing. Optimal technological design should include all stakeholders including physical therapists, patients, and caregivers. Use of robotic gait orthoses as a component treadmill-based locomotor training has transitioned from research laboratories to common clinical use. Active participation appears to be a key ingredient, if improved overground walking is the goal. Walk-assist exoskeletons, single and multiarticulating, are now commercially available for community use. While promising, device limitations include a lack of balance reaction mechanisms to prevent falls, unnatural gait patterns, low battery life, skin integrity, and cumbersome donning and doffing. Physical therapists must oversee training with these devices to ensure safety and provide feedback for refinement of this technology.

Video gaming technology is another area that shows great promise, but future versions must increase the challenge and reward scheme to optimize and maintain patient engagement and effect. Gaming especially motivates pediatric patients. Children may not fully appreciate the benefit of exercise but must engage fully for optimal motor learning. They can also easily “become bored” by the same game; accordingly, there is a need to find ways to match the speed of technology development with their appetite for novel challenges.

Neural imaging technology techniques are advancing our research and practice. Functional and structural neuroimaging, electrodagnostic, and electrical stimulation technologies, touched upon during plenary sessions, were a focus of many IV STEP poster presentations. Physical therapy intervention can be targeted for specific brain structures and can evaluate the effect of our treatments. Transcranial magnetic stimulation is an exciting and promising area of research that can be used to evaluate neuronal circuitry, promote neural plasticity, and inhibit maladaptive plasticity. Although many repetitive TMS trials to date have been disappointing, this area of research has taught us that priming the brain for motor...
learning and recovery is possible. Further work may elucidate the key parameters of stimulation, which, when combined with practice, are optimal for promoting neural reorganization in the developing child. Other forms of cortical priming are rapidly gaining attention, including transcranial direct current stimulation and acute bouts of exercise. Evidence suggests that epidural stimulation may also provide a level of excitatory priming in the cord that allows those with incomplete spinal cord injuries to activate local circuitry for muscle activation. Furthermore, it appears that the use of repetitive TMS, in at least recovery from stroke, may be influenced by genetic factors. Data such as these simply reinforce the need for predictive algorithms that account for numerous individual factors in decision making regarding optimal interventions.

PREVENTION

The goals of physical therapy must extend beyond function to include health promotion. “Physical activity,” an essential component of health, refers to body movement during playing, working, active transportation, house chores, and recreational activities. Exercise, a subcategory of physical activity, refers to purposeful movement designed to meet a fitness goal (eg, resistive exercise, aerobic training, flexibility). It is critical for physical therapists to recognize the need for physical activity for people with neurologic conditions across the life span. While some exercise is better than none, there is a positive relationship between exercise intensity and enhanced physical function. Even those with chronic disability and very limited mobility may benefit from low levels of exercise to optimize emotional and physical health. The evidence is limited, there is growing evidence that we can prevent secondary conditions associated with chronic health conditions if we intervene early in the disease or injury process and incorporate personalized strategies to prevent recurrence or re-injury.

Exercise interventions can also enhance neural reserve and capacity; interestingly, the type of exercise influences the area of brain affected. With exercise, it is possible to change the trajectory of a progressive disease and delay onset of motor symptoms in others. Physical fitness is positively associated with brain volume, and both aerobic and anaerobic exercise can improve cognition in people with dementia. High levels of physical activity are associated with delayed symptom progression in individuals with the Huntington disease gene. A similar delay in onset of Parkinson disease symptoms has been found.

For childhood-onset disability, physical activity and exercise are essential for optimal development of body systems, and there may be critical time periods for intervention. In addition to the promotion of skilled movement, physical activity and exercise interventions are beneficial for premature infants. Exercise that benefits bone health can begin in the neonatal intensive care unit within days after birth. Children with cerebral palsy are more sedentary and their physical activity levels are approximately 30% lower than recommended guidelines. Less is known about other childhood-onset disabilities.

Children with disability, who are unable to run and play at sufficient intensities to optimize health, must be provided with alternative exercise programs to develop strong musculoskeletal and cardiorespiratory systems. There is evidence that exercise can improve academic performance in adolescents without disability and psychosocial health in children with cerebral palsy. It is hoped that promotion of physical activity in childhood can set the course for a healthy lifestyle that prevents or minimizes fatigue, pain, and depression experienced by adults with cerebral palsy and other childhood-onset disabilities.

Physical therapists need to be involved early to intervene on behalf of individuals with all types of neurologic conditions, incorporating physical activity and exercise into treatment protocols that consider personal preferences. We are the movement experts best able to design safe and effective ways to develop, improve, and maintain physical health for people with or at risk for neurologic conditions. However, we must network with our health promotion colleagues in schools and the community to ensure success in this endeavor.

PARTICIPATION

The ultimate goal of rehabilitation throughout the life span ought to be that people with neurological disabilities are fully included and participating in life activities that matter to them. Participation in a full life is the human right of every person with a disability and a core tenet of the International Classification of Functioning and Disability and is endorsed by the United Nations and the World Health Organization. While much of this work has been done in pediatric populations, the concepts apply to adults as well. There are varying definitions of participation that include “involvement in life situations” and a “set of activities that are completed in order to achieve a setting-specific personally or socially meaningful goal.” Full participation in childhood has been characterized by doing immensely engaging activities that are meaningful to the child, belonging and being accepted socially, and being with a sense of self-purpose and identity.

People with disabilities and their families identify societal attitudes, the built environment, lack of support, low personal confidence, and pain and fatigue as barriers to participation. It is the therapist’s role to optimize home and community participation. A person’s participation will be influenced by his or her preferences, his or her locality and the opportunities it affords, his or her family’s context and routines, and the person’s physical abilities. Evidence indicates that framing intervention by a person’s preferences and priorities increases participation. To develop an optimal intervention plan for a child, both the child and the family should be assessed to identify strengths, interests, desires, and concerns that are specific to the participation goal. In addition, the environment should be evaluated for safety, accessibility, physical/social/emotional supports, and community resources. When planning and carrying out treatment and research, physical therapists must, therefore, remain cognizant that improving a person’s physical performance at the body’ structures function level of the International Classification of Functioning and Disability does not automatically transfer to improved participation. Intervention aiming to improve participation will need first to look at the barriers to participation and address these; some of these may be the...
Remote capture of physical activity and exercise at home and in the community, using wearable technologies, may inform our treatment plans because it can provide quantitative outcome measures of spontaneous self-selected physical activity, and GPS locaters might provide participation profiles, for example, how often does the person leave his or her home? Yet, to date, our attempts at monitoring physical activity remotely (patient compliance logs, accelerometers) have been limited and have provided incomplete information. While lower extremity activity monitors are an effective means of capturing community walking, upper extremity activity monitoring is more complex. Reports have found improved motor function on behavioral measures (e.g., Action Research Arm Test) with and without increased activity measures from accelerometry, conversely, study participants with stroke have reported improved arm use without a concomitant improvement in measured arm function. Attention needs to be paid, and new methods conceived, for integrating self-report with technological measurement of activity. Advances in complex monitoring may allow us to provide therapies that increase Participation, and allow us to accurately measure Participation as an outcome.

Telemedicine is just being established for physical therapy practice and the rules and guidelines are still being developed, but it shows great potential, especially for outreach to rural communities. Telemedicine technology enables people to receive intervention within their own environment, and this is important because ecologically bound intervention is more likely to accurately reflect a person's real-life participation barriers, needs, levels, and opportunities.

PERSONALIZED

Personalized medicine is an increasingly important approach that was clearly woven throughout the IV STEP presentations, so we have taken the liberty of adding a fifth “P” to the 4P model for setting the future direction of the profession.

It is becoming clear that there is no “one size fits all” rehabilitation intervention for individuals with neurological disorders. This is true for both adult and pediatric clients. Thus, the future of our profession is to incorporate individualized health care to create personalized rehabilitation interventions that are informed by (1) capacity—brain and muscle structure or function; genetics, epigenetics, metabolic influences; and (2) client and family goals that define the right treatment at the right time for the right person. Recently, there have been a number of large randomized controlled trials (RCTs) considering novel rehabilitation interventions, the dosing of practice within and across session, the timing of rehabilitation onset, and the numbers of rehabilitation sessions in a week. When considering the “average” individual, each of these trials reported no advantage for their specified intervention over that found for the control intervention, which was described as “standard care” (or in the case of a recent trial on dose response, a lower amount of practice per rehabilitation session). In particular, at IV STEP, the results of this dose-response trial by Lang et al were presented; the finding that there was no additional benefit to larger numbers of practice trials per session was met with much dismay by the attendees. Taken together, the results of these large, well-run, randomized trials may indicate that high-quality “standard care” (i.e., that employs intensive practice at the peak of the patient’s increasing abilities) is adequate for recovery after stroke. However, earlier trials found intensive therapy more effective than standard care, which may indicate that standard care has improved over the last decade, but it may also mean that more is not always better. It is unknown, however, how much variability exists in “standard care” throughout the country.

Studies that emerged out of III STEP suggest that the dosing and type of exercises performed in neurologic rehabilitation were below that which is used in “standard care” control interventions. Relatively, experience suggests that the “standard care” delivered in many clinics may not be at the same level as that tested in the study settings. These data may also be signaling that effective rehabilitation interventions require personalization of their content. Personalized interventions would be designed to address the specific needs of each client and modified to suit the precise capacity of each biological system.

Research disseminated at IV STEP illustrates both the challenge and the promise of moving toward personalized rehabilitation interventions for individuals with neurological disorders. The importance of genetics in numerous aspects of neuroplasticity was articulated. It is clear that different genetic markers have a profound influence on motor learning. As an example, the expression of dopamine genes has a large influence on both motor learning and neuroplastic change in the motor cortex; critically, it was a combination of genes not a single factor that revealed these relationships. At this time, however, the consideration of genetics in responses to rehabilitation is in its infancy. Little work has considered specific neurological populations. Furthermore, the role of epigenetics has yet to be revealed. Epigenetics encompasses the study of modifications to DNA and DNA packaging, which can potentially affect gene expression, without changing the nucleotide sequence. Differential DNA methylation patterns in the BDNF and DRD2 genes impact gene expression and have been associated with psychiatric disorders. Yet at this time, no data exist to explain whether variation in DNA methylation patterns contributes to interindividual variability in individuals with neurological disorders. Given that epigenetics are affected by our environment and behavior throughout the life span, it is likely that their influence on recovery trajectories and treatment responses will be profound.

Although not explicitly considered at IV STEP, other candidate biomarkers that may enable the development of personalized interventions include brain structure and function. Brain imaging is noninvasive and easily accessible, enabling the categorization of brain anatomy, function, chemistry, and connectivity. Another potential recovery biomarker is neurophysiological status as mapped using noninvasive brain stimulation (i.e., TMS). Transcranial magnetic stimulation-based neurophysiological measures of the electrophysiological relationship(s) between the 2 cortical hemispheres and the integrity of the corticospinal tract via the generation of motor-evoked potentials relate to motor outcome in chronic and acute adult stroke. However, their value in predicting the
best type of rehabilitation intervention is not well understood. In addition, work in this area has focused on adults with stroke; a rich opportunity exists to broaden these questions to include other types of neurological disorders as well as ask questions across the life span. Children appear to respond differently since their motor skills and repertoire are still being established, and, therefore, treatment plasticity and reorganization are different to adults with well-defined motor maps and pathways.

Finally, it is crucial that the perspective, goals, and needs of the client be incorporated into personalized rehabilitation interventions. Through focus groups and surveys of individuals with stroke, it has become clear that what is meaningful to this group is the use of their arm in their real-world environments. Research in pediatric populations confirms this finding as well that goal-directed, salient practice of real-life tasks in real-world environments leads to the greatest functional improvements. These data are not surprising as they match the optimal conditions for inducing plasticity. For our rehabilitation interventions to be truly effective for each person, we must identify what is meaningful recovery to the individual and index changes in quality of life. Only when these goals are met will we have created truly effective interventions. Relatedly, future STEP conferences should consider increasing participation from other stakeholders groups, such as patients and families, to further ground our discussion in this important issue.

**PLANNING FOR THE FUTURE**

Research and the critical discussion of findings will continue to fuel the advancement of neurologic physical therapy practice. Critical to this advancement must be a paradigm shift in terms of how we approach rehabilitation research in terms of both design and interpretation. We have known for some time that patients have different outcomes from treatment, some respond, while others do not (ie, nonresponders). More precise data delineating the responder/nonresponder phenomenon would enable more accurate prediction of prognosis. The innovative movement of “individualized (or personalized) medicine” addresses the responder/nonresponder phenomenon by tailoring clinical care to counter an individual’s (epi)genetic makeup, environment, and goals. Individualized medicine also necessitates an expansion of the way in which the field needs to think about designing, analyzing and appraising clinical rehabilitation research. Although RCTs are the current gold standard methodology for evaluating treatment efficacy, they are limited by their analysis at group mean level. Individual responder results can be obscured and washed out by nonresponders in group mean reporting.

The RCT model, which emerged from pharmaceutical trials, appears to be ill suited for rehabilitation interventions. A key limitation of this model in rehabilitation is the identification of the control condition: how do you provide sham physical therapy? A good control must provide similar nonessential experience and test the essential ingredients to the treatment. In the case of a drug, that is a relatively easy pharmacological achievement (eg, a placebo sugar pill). But, what is the “essential ingredient” to physical therapy? Is it salience, dose, intensity, timing, or attention from a caring provider? We have not yet parsed these elements out; thus, the hypothesis-driven questions must continue to attempt to elucidate what is the critical component to be included in our therapies.

Within rehabilitation in the past several years, there has been reference to “failed trials” of rehabilitation. In the reconsideration of rehabilitation research, the term “failed trial” needs to be clarified. This term comes from drug trials where a drug has failed to produce a prespecified effect or the negative effects outweigh the positive. A failed trial means that the drug will not go to market for use. However, in PT, due to the complex and multifaceted aspects of an intervention that cannot necessarily be controlled, an RCT may fail to support a primary hypothesis but often illuminates other critical aspects of an intervention. Potentially important findings could include rate of recovery, treatment effectiveness in the nonprimary outcome measures, predictors of responsiveness, and so forth. Use of the term “failed trial” suggests that the intervention is not effective; when often a more accurate assessment may be that, on average, it is not better than a different PT intervention but for certain individuals it may be. A better term may be “equally effective” or “no difference,” which accurately describes the failed primary hypothesis but may allow appropriate appreciation and discussion of the findings to continue to build the science of rehabilitation. As mentioned previously, important consideration also needs to be made for what the control intervention is and how that relates to true “standard care” being delivered in clinics throughout the country.

Other trial designs, including comparative effectiveness studies, single-subject designs, and pragmatic designs, should be embraced to overcome these aforementioned methodological problems in rehabilitation research. Single case design, comparative effectiveness research, and population registries are 3 alternative research methodologies that enable analysis at the individual level. These designs overcome the problem of average performance not reflecting population variability. The principle benefit of the single case design is that it charts and reports individual results and, therefore, allows the opportunity to provide detailed descriptions of responders. Single case design is useful and often necessary in low-incidence disorders in which adequate statistical power cannot be achieved using traditional empirical designs. The added benefit of comparative effectiveness research and population registries is that big data enable comparison of an individual’s performance to the population of interest. Indeed, the RCT should not be abandoned and will likely continue to be the favored design of funding agencies, but other pragmatic designs are emerging as valid methodologies for high levels of evidence and should be considered.

Comparative effectiveness research allows for the evaluation of treatment outcomes to improve health care quality by providing patients, health care providers, and other stakeholders with better information about the risks and benefits of different treatment options. APTA Connect (http://www.apta.org/CONNECT/) and the Patient-Centered Outcomes Research Institute (http://www.pcori.org/research-results/patient-centered-outcomes-research) are good resources on this topic. However, this type of research requires a set of common data elements that encompass valid, reliable measures.
work demonstrates both the promise and the challenges of this type of approach to research.\textsuperscript{75} To date, few of us report a common set of data elements; this significantly hampers the combination of small studies into what might be considered “big data.” These challenges stem from the plethora of measures that exist. Fortunately, online resources are being developed that can facilitate measurement selection. For example, the National Institute of Neurological Disorders and Stroke has created an open resource Common Data Elements Web site (https://www.commondataelements.ninds.nih.gov) that is disease specific with common measures across multiple diseases. Cerebral palsy common data elements, to be completed in 2016, will include physical therapy classifications and measures. Going forward, the physical therapy profession must embrace single case design research and big data methodologies to stay on the forefront of individualized medicine. Big data methodologies will require us to foster collaborative partnerships between clinicians, providers, insurers, and government. Future work may harness information from a vast network of providers, taking inspiration from crowd source science practices.

As knowledge rapidly advances in the field of physical therapy, an imperative exists to embrace effective knowledge translation strategies. First, ensure that patients receive evidence-based leading-edge therapy. Second, ensure that the policy governing the funding and reimbursement of care matches best-available evidence. Knowledge translation to the policy level must seek to ensure that policy evolves to include billing codes and/or funding for new and proven treatments and at the same time, discontinues reimbursement for ineffective treatments. Numerous systematic reviews exist to guide clinicians, educators, researchers, and policy makers about how best to translate leading-edge research knowledge into routine patient care. Known effective knowledge translation strategies supported by high-quality evidence include audit and feedback; clinical practice guidelines; continuous quality improvement; financial incentives; mass media; opinion leaders; outreach visits; peer comparison feedback; reminders including computerized decision supports; research-active staff in the workplace; tailored interventions; and combinations of these approaches known as multifaceted interventions.\textsuperscript{43,76} Knowledge translation requires clinicians, researchers, and academics to “stretch” their role to include advocacy for evidence-based practice at policy, insurance, and systems levels.

**SUMMARY: FROM CHAOS TOWARD CLARITY**

In Mary Lou Barnes’ summary article of II STEP in 1990,\textsuperscript{1} she spoke of a “breaking down of ideas” and a “sense of chaos” in the profession, where dearly held beliefs were being dismantled. The gurus of the profession and distinct “sects” were finally being harmonized as physical therapists were performing research that was not only informing practice but also advancing understanding of neurophysiologic mechanisms. Rereading of her philosophical epitaph is a worthy reminder of the value of historical reflection. At each of these seminal conferences, we may experience a feeling of chaos or discomfort where current understanding and beliefs are challenged or destroyed; we must face the idea that we were wrong. As Dr Barnes stated, the primary charge for the profession was to embrace the chaos, merging old and new ideas, because from that we advance toward truth. In the poetic manner of history repeating itself, we can draw comfort and inspiration from our predecessors at the conclusion of IV STEP We advocate for embracing the discomfort of challenging ideas and harnessing it to leverage forward movement. We may need to drastically reconsider our dearly held ideas and be willing to be uncomfortable to continue our forward momentum with novel research designs of hypothesis-driven questions. We will not be in the same place as a profession at V STEP, and someday the future may look back at the highly novel and disrupting findings presented at this conference and characterize them as quantal realizations. That is worth of celebration, indeed.

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**Appendix**

Speakers and the Charge From the Planning Committee

<table>
<thead>
<tr>
<th>Speaker(s)</th>
<th>Charge</th>
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<tbody>
<tr>
<td>Carolee Winstein, Susan Harris</td>
<td>Summarize the history of the STEP conferences, your thoughts/reflections on current PT practice and introduce the 4 Ps and their interdependencies.</td>
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<tr>
<td>Ann VanSant</td>
<td>Explain the development of movement system diagnoses and how these will assist with prediction of optimal response to intervention choice, as well as strategies to link classification with accurate predicted outcomes.</td>
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<tr>
<td>Andrea Behrman, Susan Harkema, Elizabeth Ardolino</td>
<td>Provide current knowledge of how movement system diagnoses and/or classifications can predict and direct treatment for neuromuscular recovery in adults and children.</td>
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<tr>
<td>Steve Cramer, Jill Stewart</td>
<td>Provide current knowledge of and future direction for genetics and epigenetics related to prediction and plasticity to achieve the most effective and efficient physical therapy interventions.</td>
</tr>
<tr>
<td>Chet Moritz, Faby Ambrosio</td>
<td>Provide current knowledge of and future direction for regenerative rehabilitation in the context of physical therapy practice for prevention, plasticity, and participation, related to the future of how to provide effective and efficient physical therapy.</td>
</tr>
<tr>
<td>Andrea Behrman, Susan Harkema, Elizabeth Ardolino</td>
<td>Provide current knowledge of how movement system diagnoses and/or classifications can predict and direct treatment for neuromuscular recovery in adults and children.</td>
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<tr>
<td>Jane Burridge, Alan Chon Lee</td>
<td>Discuss current telehealth physical therapy practice and how these services may assist with improving prevention, participation, and perhaps assist with plasticity.</td>
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<tr>
<td>Ellen McGough</td>
<td>Discuss how physical therapists should be involved in primary health promotion practices to prevent or delay the development of neurological disorders.</td>
</tr>
<tr>
<td>Edgar van Mil</td>
<td>Discuss how pediatric physical therapists should be involved in primary health promotion practices to prevent or delay obesity and/or neurological disorders.</td>
</tr>
<tr>
<td>Don Morgan, Lori Quinn</td>
<td>Discuss how physical therapy promotes health and contributes to further motor disorders in adult (Quinn) and pediatric (Morgan) neurologic populations.</td>
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<tr>
<td>Catherine Lang, Michele Basso</td>
<td>Discuss the most effective rehabilitation program from the perspective of amount and timing of services to maximize plasticity and participation in adult neurological populations and whether this is the same when the objective is plasticity or participation or both.</td>
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<tr>
<td>Mary Gannotti</td>
<td>Summarize the research that indicates what the most effective rehabilitation program is from the perspective of amount and timing of services to maximize plasticity, participation, or both in pediatric neurological populations.</td>
</tr>
<tr>
<td>Judy Deutsch, Sally McCoy</td>
<td>Review the types of technology, which have been shown to effectively induce neuroplasticity, and, therefore, likely to improve participation, and discuss how physical therapists could utilize technology presently and in the future.</td>
</tr>
<tr>
<td>Anum Jayaraman</td>
<td>Review the kinds of robotic technology that have presently been shown to be effective from a plasticity perspective, the types of robotics that improve participation, and how PTs could employ robotic technology now and in the future.</td>
</tr>
<tr>
<td>Lisa Chiarello</td>
<td>Discuss how we can measure participation and design effective interventions to improve participation? What research needs to be done in the future to improve rehabilitation services that are focused on assisting our clients to participate in family, recreation, and daily activities?</td>
</tr>
<tr>
<td>Sarah Kagan, Michele Lobo</td>
<td>Present the key points of research designs other than the randomized controlled trials (qualitative, single subject, big data/epidemiology) that may assist researchers in answering important scientific questions about rehabilitation focused on any of the 4Ps, but especially participation.</td>
</tr>
<tr>
<td>Deborah Backus, Jennifer Moore, Keiko Shakako-Thomas</td>
<td>Enlighten the audience about key points of promoting evidence-based practice, how to best achieve knowledge translation, and how service providers can change their behaviors and adopt alternate practice, based on scientific evidence.</td>
</tr>
</tbody>
</table>