Commentary

I commend Dr McEwen for her undertaking a type of clinical research that is vital for investigation of treatment outcome not only for individuals with severe neuromotor disabilities but also for those with other conditions that require physical therapy. The preliminary nature of the study limits generalization of the results. This is typical of initial attempts to examine an intervention provided in a natural setting in which there is a small heterogeneous sample and minimal knowledge of the expected treatment effect or the responsiveness of the dependent measures. Rather than focus on the specifics of the study, I have chosen to comment more generally on three aspects of the design that I believe are important to consider in conducting treatment outcome research.
A distinguishing feature of Dr. McEwen's study is that it has ecological validity. The intervention occurs in an environment that is meaningful for the subjects, and the outcome measures are relevant to everyday function in that environment. The design is well suited for clinical populations such as children with profound multiple disabilities, whose ability to generalize across settings is limited and whose motor disability has an impact on their communication and social interaction. The design of Dr. McEwen's study is in contrast to that of many of the studies that have examined the effectiveness of physical therapy in children with cerebral palsy.\(^1\) In these studies, intervention has focused on direct, individual treatment that is provided by a physical therapist in a clinical setting. Treatment has emphasized reducing impairments in muscle tone, range of motion, and automatic righting and equilibrium reactions rather than specific functional outcomes. Furthermore, outcome measures have consisted largely of motor development and reflex assessments that do not directly measure whether treatment has had an impact on the child's ability to function in the home, school, or community. The results of these studies have not provided conclusive evidence in support of physical therapy. This may be attributable, in part, to the emphasis of treatment and the inability to hypothesize and measure functional outcomes. Investigation of treatments directed toward improving function in settings that are meaningful for daily life may prove a fruitful direction for clinical research in physical therapy.

Dr. McEwen's study is also notable for being theory based. Dr. McEwen makes specific reference to dynamical systems theory in hypothesizing that body position is a control parameter for communication in students with profound multiple disabilities. This base provides a sound rationale for investigation of the effects of assisted positioning equipment on communication behaviors. In a guest editorial published in *Physical Therapy*, concern was expressed that clinical practice is not based on theory and that therapy has not served to generate hypotheses that are examined through clinical research.\(^2\) Hypotheses that are based on theory provide a link between research and practice and allow for systematic investigation of treatment outcomes.

The finding that the lowest-functioning students interacted more during structured communication when positioned in freestyle as opposed to a wheelchair or sidelying is interesting and demonstrates the importance of a conceptual framework in interpreting results and discussing clinical implications. Based on reflex and hierarchical models of motor control, freestyle positioning would not be considered a desirable position for communication because of the negative influence of primitive reflexes. This perspective has influenced clinical practice and, perhaps, Dr. McEwen's original intent to use a stander rather than the freestyle position. In contrast, based on dynamical systems theory, Dr. McEwen suggests that the characteristics of the subjects and the context of the task are important considerations in interpreting student communication in the freestyle position. Furthermore, she suggests that arousal level and attentiveness are additional variables that should be investigated. Theory, therefore, provides a framework for examining the effects of a treatment in a systematic manner that can guide clinical practice.

The third aspect of Dr. McEwen's study that warrants comment pertains to statistical conclusion validity. Cook and Campbell\(^3\) consider statistical conclusion validity one of four types of validity necessary to ensure the integrity of clinical research. Statistical conclusion validity refers to the sensitivity of experimental procedures and methods of data analysis with respect to the ability to make inferences about the relationships among the variables that are being investigated. Sample size, the significance level used in the study, effect size, and the clinical significance of the results all contribute to statistical conclusion validity. Small sample size is a frequent limitation of treatment outcome research because of the low incidence and heterogeneity of many populations who receive physical therapy and limited resources to conduct large multicenter studies. A consequence of a small sample is low statistical power and hence a high probability of incorrectly concluding that there was not a significant treatment effect (Type II error).

Dr. McEwen's study, which had a sample size of 10, clearly demonstrated low statistical power. In attempts to avoid a Type II error, she selected .10 as the level of significance and calculated effect-size statistics. The rationale for the level of significance is clearly presented and referenced and provides a good example for those not familiar with the process of selecting an alpha level. I will briefly provide a rationale for the use of effect-size statistics in physical therapy research.

Effect-size statistics measure the magnitude of treatment differences. A large treatment effect can minimize the low statistical power attributable to a small sample size. Unfortunately, treatment outcome studies in physical therapy often involve comparisons of alternate treatments that are provided to subjects who under optimal circumstances are not likely to exhibit dramatic changes. The less contrast there is among treatment conditions and the lower the potential for change in the subjects, the smaller the effect size will be. The probability of a Type II error is magnified further when a study has a small sample and there is also a small treatment effect. In such cases, the effect-size statistic provides the investigator with a means of determining whether treatment differences are meaningful despite the lack of statistical significance. The finding of a small treatment effect that represents a clinically important difference provides support for further research and suggests that the lack of statistical significance is attributable to low power. I would argue that reporting the effect size and discussion of the clinical significance of the results should be integral to all
clinical research, regardless of whether statistical significance is achieved. I would also encourage investigators to use nonconventional methods of analysis when they are appropriate.

In summary, Dr. McEwen's study contributes to the understanding of the effects of assistive positioning on the function of students with multiple profound disabilities and also represents a challenging type of research that is relevant to the investigation of outcomes in physical therapy. As physical therapists become more experienced in clinical research processes, I look forward to reading more field-based research reports in Physical Therapy.

Robert J Palisano, ScD, PT
Associate Professor
Programs in Physical Therapy
Mail Stop 502
Hahnemann University
Broad and Vine Streets
Philadelphia, PA 19102-1192

References

Author Response

When I submitted this article to Physical Therapy, I thought it likely that the small sample size and unorthodox alpha level would be seen as "fatal flaws" and that the dependent variables focusing on communicative interactions, rather than motor outcomes, would complete its demise. I submitted the report, however, because I believed it held some useful considerations for pediatric physical therapists, especially those who work in public schools with students who have severe disabilities.

My fears proved to be unwarranted. Dr. Palisano's supportive and informative commentary echoes several of the reviewers' themes, all of which indicate the considerable expansion of pediatric physical therapy research interests and methodologies over the past few years. Dr. Palisano has also identified some important questions about the focus of our interventions, the strategies we use, and how we assess our outcomes.

I fully support his comments concerning the need to examine meaningful, functional outcomes of physical therapy intervention. As pediatric physical therapists, we often focus our treatment on the presumed prerequisites or components of movement, such as muscle tone, prone propping, and weight shifts, anticipating that movement will improve and functional gains will necessarily follow. When our treatment fails to result in notable changes in basic motor control or accomplishment of developmental milestones, as it often does with older children and children who have severe chronic disabilities, we may believe we have nothing more to contribute to them. This is the basis upon which decisions are often made to discontinue intervention because a child has "plateaued" or to reduce or discontinue physical therapy for older children.

When emphasis is on a child's or adolescent's accomplishment of functional goals, however, it is usually clear how physical therapy can contribute to meaningful, measurable outcomes, regardless of the child's age or severity of disability. Some traditional treatment methods may be helpful for achieving these goals, but their effectiveness is best determined by measured changes in a child's functional skills performed in natural environments. Although we need to expand our knowledge of effects of treatment on fundamental movement variables, such a focus is more appropriate for research than for measurement of treatment outcomes for an individual child.

Dr. Palisano also touched upon the need for researchers and clinicians to examine the effect of physical therapy interventions on non-motor domains. This study, for example, suggested an effect of position on communication. Franks et al. found a relationship between the type of mobility used by children with meningomyelocele and their performance on an academically related task, and others have demonstrated effects of independent mobility on spatial-cognitive tasks. As clinicians and researchers, we need to expand our knowledge of both beneficial and detrimental effects of physical therapy interventions on such critical non-motor domains. Single-subject experimental designs and case studies are two excellent means for clinicians to begin to assess and report such effects.

Dr. Palisano's suggestion that my original intent to use a stander, rather than the freestyle position, was influenced by the reflex-hierarchical models of motor development and motor control is quite true. I was genuinely