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The Modified-Emory Functional Ambulation Profile: Convergent Validity in 5-11 Year Olds

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Submitted in partial fulfillment of the requirements for the degree of

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DEDICATION

This project is dedicated to my nieces and nephews. May you always strive to be the best, always thirst for new knowledge, find the riches you deserve, and always be happy with what you're doing. Never let anyone stop you from achieving your dreams. I will always love and support you in whatever paths you choose to take –

Auntie

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ABSTRACT

THE MODIFIED-EMORY FUNCTIONAL AMBULATION PROFILE: CONVERGENT VALIDITY IN 5-11 YEAR OLDS

Cheryl Anne Enslee

Seton Hall University, 2017

Dissertation Chair: Dr. Deborah A. DeLuca, M.S., J.D.

Background *The Patient Protection and Affordable Care Act of 2010* and the *Middle Class Tax Relief and Job Creation Act of 2012* mandate patient centered, objective functional outcome reporting tied directly to limitations in mobility related to activity and participation in daily life (House of Representatives, 2009). These mandates apply to all persons, including children receiving therapy-based services. Literature on outcome measures in children has focused almost exclusively on capacity-based assessments that generally lack robust environmental context or demonstrate issues with objectivity. While constructs of the modified-Emory Functional Ambulation Profile (m-EFAP), a quantitative, objective outcome measure of functional mobility, support current standards of practice and meet federal regulations for quality and payment policies, studies supporting the validity of using the test in school-age children with disabilities have been sparse.

The aim of this dissertation is to evaluate the feasibility of using the m-EFAP in school-age children. It was hypothesized that total scores and subtasks on the m-EFAP would be correlated with the Activity Performance subsection of the School Function Assessment (SFA), which is a well-developed instrument used in the school setting. Results of this study will provide information regarding valid use of the m-EFAP as an alternative

assessment tool of functional mobility that meets federal regulations for quality and effectiveness as well as practice standards, that is objective, timely, and cost efficient. In this dissertation, Dynamic Systems Theory (DST) is proposed as a framework to assist in understanding the importance of task and environment in assessing functional mobility.

Study Design Based on methodological studies, a quantitative, prospective correlational design was implemented to test the hypotheses. Using a sample of forty-four students ages 5-11; with Developmental Motor Delay (DD), data was collected from two private schools in North-Central New Jersey serving children with special needs. Data was collected using the m-EFAP and selected categories of the Activity Performance (AP) subsection of the SFA.

Results Statistical analysis using the Spearman Rho Correlational Coefficient revealed no significant relationship between the modified-Emory Functional Ambulation Profile and School Function Assessment Total Scores ($\alpha < 0.05$). There was a significant relationship between a majority of the m-EFAP subtasks and AP categories of the SFA. A key finding was that the m-EFAP Timed Up and Go (TUG) subtask correlated with all of the SFA Performance categories except stairs (r-values ranging from -.298 to -.587; all p values < 0.05).

Conclusion Contrary to expectations, convergent validity of the m-EFAP with the SFA was not supported. However, these findings provide valuable information regarding the use of the TUG as a screening tool in a school-age population, and show that the TUG is more complex than previously

assumed. Overall, this study prompts a revisiting of the topic of informed decision making for therapists, when selecting functional outcome measures. The results, clinical implications and future research are discussed.

Key Words: Functional Outcome Measure; School-Age Children; Developmental Motor Delay; School Function Assessment; Timed Up and Go, Dynamic Systems Theory; Environment; modified-Emory Functional Ambulation Profile; Quality; Payment Policies

Chapter 1

INTRODUCTION

Background of the Problem

With the advent of *The Patient Protection and Affordable Care Act of 2010,* emphasis has been refocused on patient-centered, efficient and effective treatment outcomes (H.R. 3590, P.L. 111-148, 2009). Future payment policies specific to therapy services are already being informed by new reporting requirements on efficiency and effectiveness of therapeutic interventions, as mandated by the *Middle Class Tax Relief & Job Creation Act of 2012* (H.R. 3630, P.L. 112-96, 2011). Noncompliance with reporting of G-code functional limitations and outcomes results in unpaid claims (Centers for Medicare & Medicaid Services CMS, 2013). These G-codes are tied to functional limitations in mobility as described by the categories of activity limitations and participation restriction set forth by the International Classification of Functioning, Disability, and Health [ICF] (World Health Organization [WHO], 2006). Physical therapists must assign a severity of limitation modifier to G-codes in the categories of: Walking, Changing Positions, and Carrying Objects, while documenting the valid, reliable, and objective functional assessment tool used in making this determination (CMS, 2013). In turn, this has placed a greater level of accountability on therapists to produce meaningful quantitative documentation as part of the solution to cost and quality challenges in healthcare.

In order for physical therapists to remain viable in this changing healthcare system, steps must be taken to develop, improve, and expand functional outcome measures. An ideal outcome measure needs to be valid and reliable, objective, widely applicable, timely, cost-efficient, and easily interpreted across healthcare domains and external payment and policy agencies.

Based on the Dynamic Systems Theory of Motor Learning (DST), a new measure is proposed as a patient-centered outcome measure of functional mobility which objectively assesses the quality and effectiveness of interventions for a pediatric population (Balko, 1998). Representative of and adaptable to the school-based environment, the measure contributes to the collection of meaningful data in a timely and cost effective manner. This information not only drives patient centered care, but will serve as an important basis for documentation advocating for the continued need for the skilled role physical therapists play in school-based services.

The ultimate goal of physical therapy has always been to improve functional mobility for all clients, including school-age children. Over the past several decades, as research and evidence-based practice have raised the concept of a person-environment interaction and moved toward a patient centered model of participation, a wide variety of outcome measures have been developed to assess patients' function and evaluate the effectiveness of therapeutic interventions (Shumway-Cook & Woollacott, 2003). The most meaningful measure of treatment efficacy for a patient is the maintenance of

mobility in their usual environment: the home, school, or community (Lam, Noonan, Eng & the SCIR Research team, 2008). While research has shown that children adapt mobility to accommodate for changes in features of these environments, the multiple facets of these settings and situations have generally not been adequately represented (Young, Williams, Yoshida, Bombardier & Wright, 1996; Tieman, Palisano, Gracely & Rosenbaum, 2004; Tieman, Palisano, Gracely & Rosenbaum, 2007; Dotty, McEwen & Parker, 1999). Outcome measures that focus only on an individual's impairments or activity level, without taking into account the contextual features of the task being performed or the environment in which one typically moves, results in an inaccurate measure of functional mobility (Shumway-Cook & Woollacott, 2003).

This dissertation will discuss currently available outcome measures and explore opportunities to improve and expand functional outcome measures which conform to practice guidelines and the national healthcare strategy.

Theoretical Framework

The Dynamic Systems Theory (DST) of motor learning, is used as a framework for understanding how to define and measure functional mobility given the contexts of the task and the environment. This theoretical framework is discussed in more detail in Chapter II.

Statement of the Problems

The Patient Protection and Affordable Care Act of 2010 and the Middle Class Tax Relief & Job Creation Act of 2012 mandate patient centered, objective functional outcome reporting tied directly to limitations in mobility related to activity and participation in daily life. These mandates apply to all persons including children receiving therapy-based services (H.R. 3590, P.L. 111-148, 2009; H.R. 3630, P.L. 112-96, 2011). Underlying constructs of the modified-Emory Functional Ambulation Profile (m-EFAP), a quantitative, objective outcome measure of functional mobility, support current Standards of Practice and meet Federal Regulations for quality and payment policies (Wolf, Catlin, Gage & Gurucharri, et al., 1999: Baer & Wolf, 2001). However, studies supporting the validity of using the m-EFAP for school-age children with disabilities have been sparse.

This study is significant; given the increased level of accountability to address rising healthcare costs, the need to develop, improve and expand outcome measures of functional mobility (FM) for school-age children, and the relationship between the task, environment and individual in assessing FM. The use of an appropriate and objective outcome measure of functional mobility of school-age children, which is aligned with practice guidelines for activity and participation, while fulfilling federally required documentation of efficiency and effectiveness for quality initiatives and payment policies, supports truly patient-centered care.

Purpose of the Study

The purpose of this study is to determine convergent validity of the m-EFAP with the SFA in children aged 5-11 with Developmental Motor Delay.

Significance of the Study

This study is significant, given the level of accountability necessary to address rising healthcare costs in addition to the necessity of developing, improving and expanding evidence based functional outcome measures for children, as well as the relationship between the task, environment and individual in assessing functional mobility. Using an appropriate and objective outcome measure of functional mobility of school-age children, which is aligned with practice guidelines for activity and participation *and* federally required documentation of efficiency and effectiveness for quality initiatives and payment policies, supports truly *Patient-centered Care.*

Research Questions

Overarching Research Question:

Is the modified-Emory Functional Ambulation Profile Valid in Children age 5-11?

RQ1. Is there a relationship between total scores on the modified-Emory Functional Ambulation Profile (m-EFAP) and total scores on the Activity Performance (AP) Subsection of the School Function

Assessment (SFA) for children age 5-11 with Developmental Motor Delay (DD)?

H1. m-EFAP total scores will be significantly correlated with the AP subsection of the SFA for children with DD.

RQ2. Is there a relationship between m-EFAP subtasks and AP categories of the SFA in children age 5-11 with DD?

H2. m-EFAP subtasks will be moderately correlated with AP categories of the SFA in children age 5-11 with DD.

Operational Definitions

In order to understand terms related to this study, the following operational definitions are provided:

Age: defined according to the full calendar year from a child's birthday. For example, a child whose fifth birthday is on the day of testing may participate, however; a child whose twelfth birthday is on the day of testing is ineligible.

Assistive device: any device that is designed, made, or adapted to assist a person to be functionally mobile; in this case: canes, crutches, walkers, or orthoses.

Capacity: used synonymously with capability in this study, defined as the highest level of function achieved in a standardized clinical environment without distractions, external supports such as assistive devices or manual assist, and without time constraints; what a person "can do" (Lam, Noonan, et al., 2008; WHO, 2006; Young, Williams, Yoshida, Bombardier, & Wright, 1996).

Developmental Motor Delay (DD): According to the International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10), Developmental Motor Delay (ICD-10 F82) is defined as: Serious impairment in fine and gross motor skills substantially below chronological age which is not solely explained by general intellect or specific congenital/acquired neurological disorder. DD may be

characterized by clumsiness (e.g., dropping or bumping into objects) or slowness (e.g., catching, handwriting, riding a bike, or sports) and includes: Clumsy Child Syndrome, Developmental Coordination Disorder, and Dyspraxia (WHO, 2015). The American Psychiatric Association (2013), further defines Developmental Coordination Disorder (DSM-V 315.4) as presenting with motor skills substantially below age with significant and persistent interference with activities of daily living, school performance, and play.

Dynamic Systems Theory (DST): a theory of motor development which proposes that movement is produced from the interaction of multiple sub-systems within the person, task and environment (Thelen, 1989).

Environmental contexts: characteristics present in the environment which may influence a person's functional mobility, specifically: ambient conditions, distance/time requirements, physical load, terrain, obstacles, and postural transitions (Patla & Shumway-Cook, 1999; Shumway-Cook & Woollacott, 2003).

Evaluation or Assessment: an examination process of gathering detailed information to identify specific movement related limitations, establish a diagnosis and prognosis, and develop a specific treatment plan meeting an individual's needs (APTA, 2014).

Functional mobility: Restoration of an individual's ability to move independently and purposefully interact to fulfill all the roles necessary to create meaningful living. (Guccione, 2006).

Manual assistance: any form of physical touch provided by a person to help or support another in order to successfully complete a mobility task.

Outcome measure: the use of a standardized tool or instrument in physical therapy to assess a client's functional mobility to determine if treatment was efficient and effective in attaining the client's goals within the relevant components of activity and participation.

Performance: that which is achieved in an everyday situation or environment, dependent not only on the individual's ability to execute a given task, but also on the interplay of a variety of contextual factors surrounding the task and environment during daily life activities; what a person "does do" (Lam, Noonan & Eng, 2008; WHO, 2006).

Screening Tool: helps identify children who might have developmental delays and who may be in need of more detailed evaluation or assessments. "Screening tools do **not** provide conclusive evidence of developmental delays and do not result in diagnoses. A positive screening result should be followed by a thorough [evaluative] assessment." (CDC, n.d.).

Chapter II

REVIEW OF THE LITERATURE

In the following section, a review of the literature addresses practice standards as they relate to current federal regulations regarding quality initiatives and payment policies. Commonly used assessment tools in the pediatric population are reviewed, evaluating their appropriate use for children aged 5-11 in measuring functional mobility as defined in this study, their objectivity, usefulness, and timeliness. In addition, key concepts will be presented to establish a common framework for discussion.

Literature Review

The Individuals with Disabilities Education Act, (2004) and *Recommended Guidelines for the Practice of Physical Therapy in Educational Settings* (APTANJ, 2011) require related services, such as physical therapy, to ensure that children can participate optimally in a general classroom environment (IDEA, P.L. 108-446, 2004; Hwang, Davies, Taylor, & Gavin, 2002; David & Sullivan, 2005). In order for a child to participate at school, goals must be functional, school-related mobility tasks such as: walking long distances in a timely manner, around obstacles, over uneven ground, maneuvering crowded halls or cafeterias, and negotiating stairs (APTANJ, 2011). These practice requirements grew out of the DST of motor learning and are supported by the World Health Organization's ICF for activity and participation (Balko Perry, 1998; Thelen, 1989; WHO, 2006). Recall that these models recognize

mobility as a complex process influenced by the interaction of factors from the individual, task, and environment (Westcott, Lowes & Richardson,1997).

Despite supporting evidence and policy mandates, outcome measures frequently used by school-based physical therapists do not focus on tasks and environmental factors that impact a child's functional mobility in the school setting. Among commonly used assessment tools are: the Bruininks-Oseretsky (BOT-II), Peabody Developmental Motor Scales-2 (PDMS-2), the Timed Up and Go (TUG), the Timed Up and Down Stairs (TUDS), the Gross Motor Function Measure (GMFM), the Pediatric Evaluation of Disability Index (PEDI), and the School Function Assessment [SFA] (Bruininks & Bruininks, 2005; Folio & Fewell, 2000; Deitz & Kopp, 2007; Williams, Carroll, Reddihough, Phillips & Galea, 2005; Zaino, Marchese, & Westcott, 2004; Haley, Coster, Ludlow, Haltiwanger & Andrellos, 1992; Russell, Rosenbaum, Avery & Lane, 2002; Coster, Deeney, Haley, & Haltiwanger,1998). These tools capture the complexities of functional mobility by measuring related constructs such as balance, gait, coordination, and endurance (Hwang et al., 2002; Westcott, Lowes & Richardson, 1997). Many of these standardized tests tend to reflect a student's ability to perform isolated (capacity-based) tasks such as single leg stance, walking on a balance beam, or jumping in place (Hwang et al., 2002; Westcott et al., 1997; Franjoine, Gunther & Taylor, 2003).

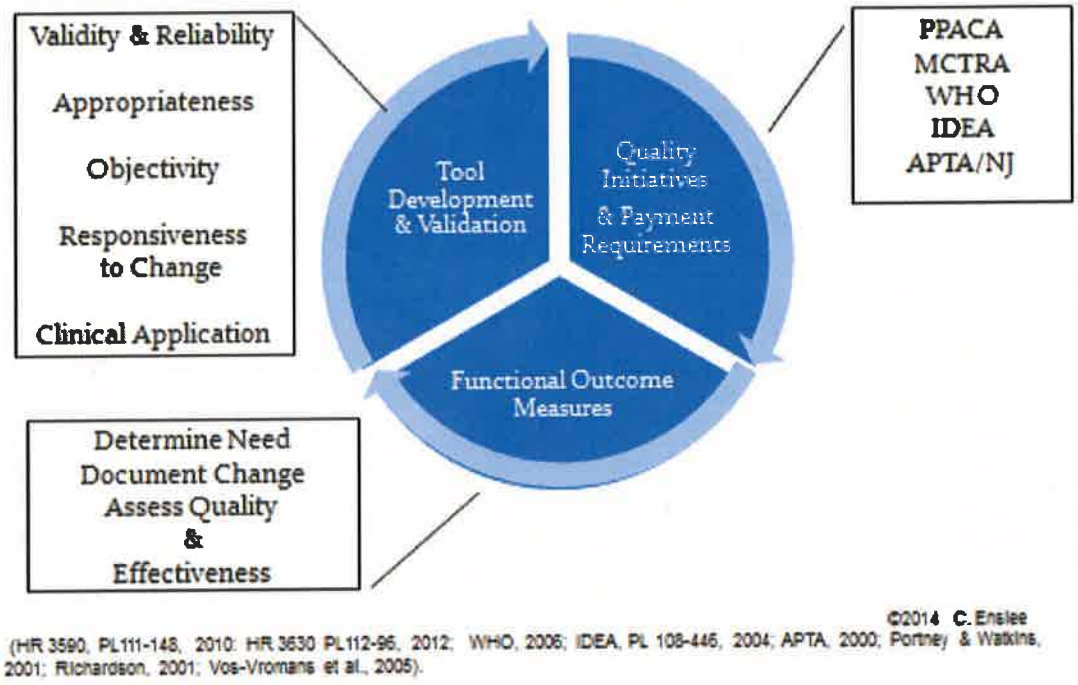


Figure 1. Outcome Measures & Health Policy. This model depicts how quality initiatives and payment policies are driving the need for more objective, patient-centered outcome measures tied directly to activities and participation, which in turn drive the need for therapists to develop and improve appropriate outcome measures to meet health policies as well as practice standards.

Outcome Measures and Healthcare Policy

Outcome measures in rehabilitation are used for three main purposes: to determine need for services, document change, and to assess the quality, efficiency, and effectiveness of therapeutic interventions (Portney & Watkins, 1993). Efficiency is defined as the amount of resources used to meet treatment and patient goals. Effectiveness represents the extent to which intended treatment goals for maximizing functional mobility and quality of life are achieved. A functional mobility assessment is just one aspect of the much broader concept of outcome measures. It offers a more individualized assessment of whether treatment and patient goals for mobility, activity, and participation were met. Together this data contributes to continuous patient-centered quality improvement. In order for this information to be meaningful, the outcome measure must be objective, appropriate to its intended purpose and specific population, be sensitive to change, and be clinically relevant (Portney & Watkins, 1993). Additionally, data collection should be standardized with a uniform set of measurements for ease in understanding, interpretation, and comparison across healthcare domains, third-party payers, and external agencies at federal, state, and local levels.

Having functional outcome measures that are easy to understand, interpret, and compare becomes especially important, as sixty percent of federally required school-based services for individuals with disabilities are funded by states and local governments with Medicaid (CMS) and the State

Children's Health Insurance Program (SCHIP) supplementing the costs (Bachman & Flanagan, 1999). Due to current budget constraints at state and local levels, results from outcome measures are key to ensuring reimbursement.

At the national level, healthcare reform calling for quantitative data has also placed increased pressure on all medical service providers to control costs and demonstrate the effectiveness and appropriateness of what they do (Kane, 1994). *The Patient Protection and Affordable Care Act of 2010* emphasizes patient-centered, efficient and effective treatment outcomes, placing a greater level of accountability on therapists to produce meaningful quantitative documentation as part of the solution to cost and quality challenges in healthcare (H.R. 3590, P.L. 111-148, 2010).

As part of this national restructuring, The Physicians' Quality Reporting System (PQRS) asks therapists to voluntarily report on a variety of measures related to functional outcome measures in order to improve quality of care and reduce healthcare costs (H.R 3590, P.L. 111-148, 2010). According to the CMS guidelines, physical therapists not actively participating by CY 2015 will incur penalties of up to 2% (Centers for Medicare and Medicaid Services/PQRS).

Even more timely and pressing of a payment issue for therapists are the new G-code functional reporting requirements, as mandated by the *Middle Class Tax Relief & Job Creation Act of 2012* (H.R. 3630, P.L. 112-96,

2012). Noncompliance with reporting of G-code functional limitations and outcomes results in unpaid claims. These G-codes are tied to functional limitations in mobility as described by the categories of activity limitations and participation restrictions set forth by the International Classification of Functioning, Disability, and Health [ICF] (Centers for Medicare & Medicaid Services, 2013; WHO, 2006). Physical therapists must assign a severity of limitation modifier to these codes in the categories of Walking, Changing Positions, and Carrying Objects, while documenting the valid, reliable, and objective functional assessment tool used in making this determination (CMS, 2013). While PQRS reporting only occurs on initial evaluation, G-codes must be reported on evaluation, every 10th visit, upon reassessment, and upon discharge (CMS, 2013).

Clearly, outcomes are driving healthcare, necessitating evidence-based practice and payer sources to demand empirical support for the effectiveness of treatments, represented by daily participation and functional mobility (Sullivan, Barnes, Linton, & Calmes, et al, 2007; WHO, 2006). Presently, there is no universal method for assessing functional mobility outcomes in school-age children. While there are many outcome assessment tools in the literature, the problem is that they have limited usefulness, questionable objectivity, or are indicated for measuring capacity. Examples include: the Bruininks-Oseretsky (BOT-II), Peabody Developmental Motor Scales-2 (PDMS-2), the Pediatric Evaluation of Disability Index (PEDI), the Gross Motor Function Measure (GMFM), and the School Function

Assessment [SFA] (Bruininks & Bruininks, 2005; Folio & Fewell, 2000; Haley, Coster, Ludlow, Haltiwanger & Andrellos, 1992; Russell, Rosenbaum, Avery & Lane, 2002; Coster, et al., 1998). Without a standardized, objective outcome measure, it becomes difficult to track progress toward functional patient goals in a comprehensive and systematic manner.

In order for physical therapists to remain viable in this changing healthcare system, steps must be taken to develop, improve, and expand functional outcome measures that are patient-centered and objectively assess quality and effectiveness of pediatric interventions.

The question becomes, what constitutes a good outcome measure? As mentioned earlier, an ideal instrument must be well defined, widely applicable, appropriate to the purpose and population of interest, responsive to change, timely, cost-efficient, and easily interpreted across healthcare domains.

Validity and reliability are critical when selecting an outcome measure, and encompass three key elements: 1. different people obtain the same results when applying the measure; 2. results on a single patient are consistently the same even when tested on different days or times, and; 3. items which comprise the outcome measure adequately represent the larger content domain of what is being measured; in this case functional mobility (Portney & Watkins, 1993). It is important to understand that properties of validity differ from those of a diagnostic tool than an outcome measure

(Roach, 2006). Diagnostic measures require sensitivity and specificity studies for identifying the presence or absence of a particular condition (Roach, 2006; Portney & Watkins, 1993). Therefore, the term, "outcome measure" refers to the use of a tool or instrument in physical therapy to assess a client's functional mobility to determine if treatment was efficient and effective in attaining the treatment and client's goals. Thus, appropriate selection of an outcome measure relies on a clear definition of "functional mobility".

Measures of Mobility

Shumway-Cook & Woollacott (2003) have focused on understanding the relationship between the environment and mobility, identifying environmental dimensions that operationally define functional mobility: Ambient conditions, Distance/Time, Physical load, Terrain, Postural transitions, Obstacles and Attention.

Further emphasizing the complex relationship between the task and the environment as part of understanding mobility, Pardasaney, et al. (2013) endorse seven conceptual measures related to task and environment be considered in selecting an optimal functional outcome measure: 1. Task role – static, dynamic, transfers, gait, and gait + transfers; 2. Environmental variation – support surface, vision, vision + support surface; 3. External forces – gravity; 4. Object negotiation; 5. Object manipulation; 6. Dual-tasks; and 7. Moving people/objects.

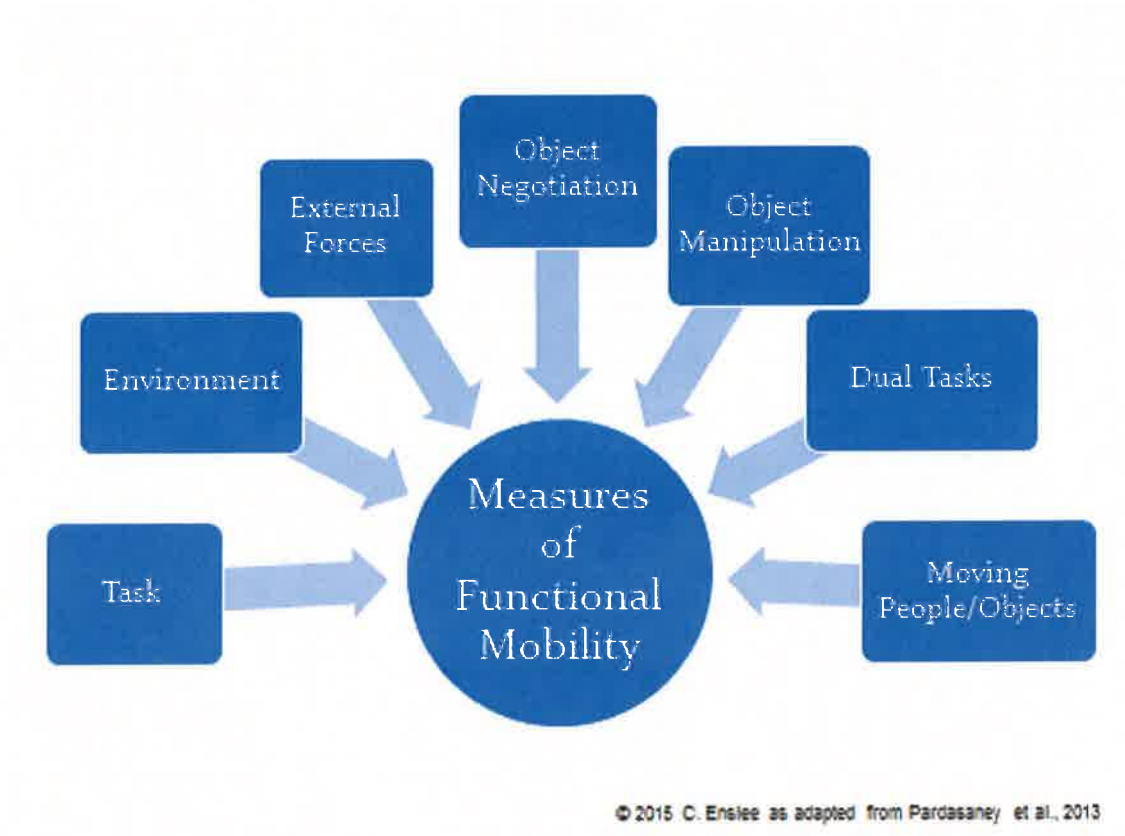


Figure 2. Conceptual Measures of Functional Mobility. This figure represents the seven conceptual measures related to task and environment that should be considered in selecting an optimal functional outcome measure according to Pardasaney, et al. (2013).

While each of these concepts contributes to a better understanding of functional mobility, for research purposes, there must be a clear and precise understanding of what is being measured.

Functional Mobility

As stated earlier, the term functional mobility (FM) is one of the many broader concepts of outcome measurement. For purposes of this writing, the term "functional mobility" will be defined as:

> An individual's ability to move independently and *purposefully interact* in a *dynamic environment*, to fulfill all the roles necessary to create meaningful living (Guccione, 2001).

Notice that this definition emphasizes the terms 'purposefully interact' and 'dynamic environment', which implies that there must be some form of participation under real-life conditions. Simply stated, life *does not* occur in a vacuum. This is where accurate measurement of FM becomes critical. Based on this definition is it evident that the construct of FM is complex. These phrases will remain key to the precise and powerful definition of FM addressed throughout this study.

Conceptual Framework

It is helpful to look at the Dynamic Systems Theory (DST) of motor learning as a framework to explore the multiple interactions that contribute to functional mobility; see *Figure 3* (Thelen,1989; Thelen & Ulrich, 1991; Balko, 1998). This model demonstrates that both individual and contextual factors

influence FM. Additionally, the model directly speaks to PPCA, MCTA, WHO and IDEA guidelines which call for function to be assessed under environmental conditions representative of daily activity and participation (H.R 3590, P.L. 111-148, 2010; H.R. 3630,: P.L. 112-96, 2012; WHO, 2006; IDEA, P.L. 108-446, 2004).

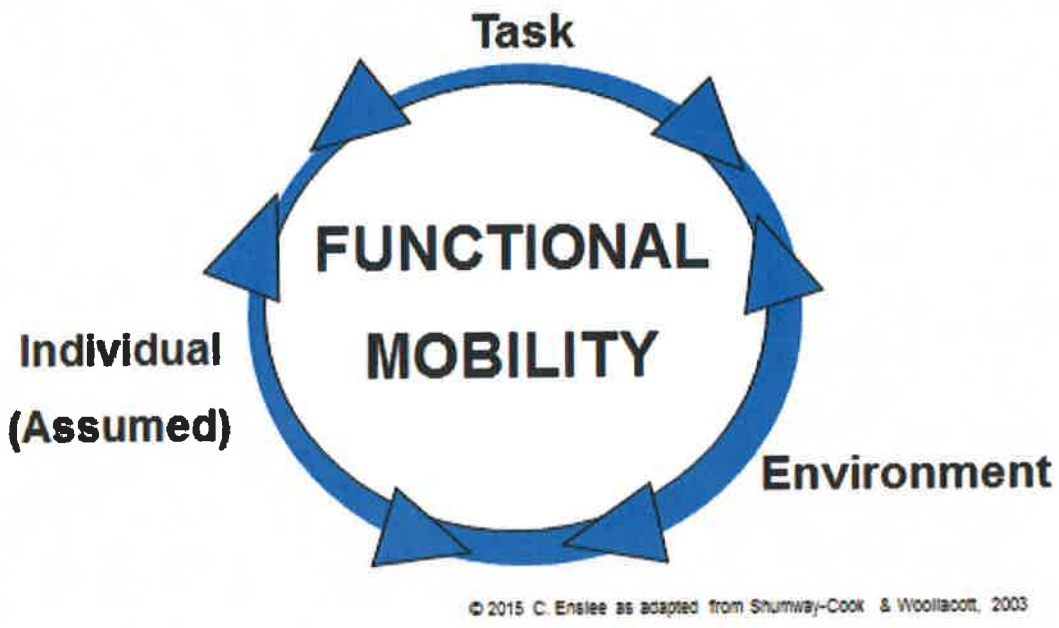


Figure 3. Conceptual Framework: Dynamic Systems Theory of Motor Learning. The cyclic nature of this figure is significant because it represents the inter-relatedness of the individual, the task, and the environment in measuring functional mobility. Impaired functional mobility is the result of a mismatch between the environment or task and the individual's ability to meet those demands.

According to the DST, efficient movement is produced through spontaneous organization and interaction of multiple factors intrinsic to the individual (cognition, perception, motivation, body structure and function), and extrinsic such as task requirements, and environmental contexts (Thelen, 1989; Thelen & Ulrich, 1991; Smith & Thelen, 1993). Small changes in any one factor may disrupt the whole system, producing what therapists measure as impaired functional mobility. Therefore, therapists must understand the relationship between the task, the environment and mobility, as well as the impact of individual differences.

Capacity v Performance

The challenge in developing an accurate objective outcome measure of FM lies in a clear understanding of related concepts. Looking at task as a component of FM, we need to discuss the terms *capacity* and *performance*, which frame a task as static and isolated, or dynamic and contextual.

Capacity and performance have been defined as two distinct aspects of mobility, and are addressed by the International Classification of Functioning, Disability, and Health (ICF) for all activities and participation domains (WHO, 2006; Conway, Tomkins, & Haig, 2011; Holsbeeke, Ketelaar, Schoemaker & Gorter, 2009). Clinically defined, capacity is the highest level of function achieved in a standardized environment, at a given moment (Holsbeeke et al., 2009; Lam, Noonan, et al., 2008; WHO, 2006). In simple terms, it is what a person "can do" in a defined situation; often a controlled clinical setting without distractions, external supports such as assistive

devices or manual assist, and without time constraints (Haley, Coster, Kao, Dumas, Fragala-Pinkham & Kramer et al., 2010; Young, Williams, Yoshida, Bombardier & Wright, 1996; WHO, 2006). Performance is what one achieves in the context of the "lived experience" or everyday environment – what an individual "does do".

Many gross motor assessments frequently assess capacity for skill achievement, and while this is important to physical mobility, capacity does not fulfill the operational definition of FM, which addresses participation in a typical environment the way a performance measure does. Tasks and environments that are normally encountered and actually performed must be emphasized. Performance is dependent not only on the individual's execution of a given task, but is grounded in the interplay of a variety of contextual factors surrounding the task and environment during daily life activities (Lam, Noonan, et al., 2008).

Young and colleagues (1996) explored the relationship between measuring physical mobility from the perspective of capacity and performance. Young emphasizes the difference between the two as one of context. Twenty-eight physically disabled children completed the Activities Scale for Kids. Out of 73 items, capacity was found to exceed performance by an average of 17% (Young et al., 1996). This indicates that although a child is capable of executing 95% of their daily skills, there was not a translation to performance in real-life daily activities. This is clinically important to physical therapists, because it suggests measures of capacity overestimate a child's

actual functional mobility. This creates critical concerns when continued need for services and payment are based upon possibly erroneous measurement and documentation. Therefore, emphasis at the level of performance becomes essential to capturing a valid assessment of functional mobility.

Environment

According to Shumway-Cook et al., (2002), "Understanding the relationship between environment and mobility is crucial to mobility rehabilitation." After extensive studies examining what affected community mobility in healthy elderly, Patla & Shumway-Cook (1999) have identified environmental dimensions that operationally define functional mobility: Ambient Conditions, Distance/Time, Physical Load, Terrain, Postural Transitions, Obstacles, and Attention.

Speaking to natural environments and conditions, Doty and colleagues (1999) conducted a study to determine if the execution of a ball task was effected by two different environmental contexts. They found a significantly higher mean score in the isolated therapy setting on a one-to-one basis than in the gym with peers and distractions. This study supports a strong link to environmental conditions.

Tieman et al. (2004) further explored the effects of environment by comparing the gross motor capacity and performance of children with Cerebral Palsy (CP) across environmental settings of home, school, and community. Out of (134) children who were capable of walking alone, 10% did

not do so at school, and 19% did not walk alone in the community. These results reveal a discrepancy between the capacity and performance of mobility methods used by children with CP, and suggest an influence of contextual features in the various settings on mobility performance (Tieman, Palisano, Gracely & Rosenbaum, 2004). As we continue to review studies on performance, we begin to see how performance ties back to the second key phrase of 'dynamic environment' in defining FM.

Palisano et al. (2003) described usual mobility methods of children with CP in the home, school, outdoors and community, supporting a perspective of a person-environment interaction and recommending assessment of mobility in all settings of the child's daily life. In another study, Tieman et al. (2007) examined the variability of mobility methods of children with CP within Gross Motor Function Classification System (GMFCS) levels. Generally, children within the same GMFCS level demonstrated varying degrees of independence in mobility across the settings of home, school, and community. Mobility methods which required more motor control (less external supports) were performed more often at home than in the school or community. Harvey and colleagues (2009) directly observed the mobility methods of children with CP at home and in the school setting. Similar to Tieman et al. (2007), they found a wide variety of mobility methods used across settings. Tieman et al (2007) concluded that contextual, environmental, and personal factors may explain the differences seen within an individual child and across settings. Knowledge of this information

provides therapists with an opportunity to target a child's barriers and affordances with regard to functional mobility in daily environments and thus tailor a patient-centered plan of care that is efficient and effective.

Recommended Guidelines for the Practice of Physical Therapy in Educational Settings (APTANJ, 2011) specifically require therapeutic goals and interventions that are functional, school-related mobility tasks such as: walking long distances in a timely manner, around obstacles, over uneven ground, maneuvering crowded halls or cafeterias, and negotiating stairs. According to motor learning theories, linking mobility tasks to a child's daily routines and typical environment provides dynamic opportunities to practice, learn, and generalize mobility skills into the natural setting, and conditions required for daily performance, enhancing the validity of the performance being measured (APTANJ, 2011; David & Sullivan, 2005). In fact, the relationship between performance and environment in defining FM has been recognized in the International Classification of Functioning, Disability, and Health (WHO, 2006). It is also a recommended standard of practice, which is in alignment with the PPCA (H.R. 3590, 2009) and MCTA (H.R. 3630, 2011) mandates for mobility assessed under conditions of daily activity and participation. This becomes vital for therapists to keep in mind when selecting an accurate outcome measure of FM.

Common Pediatric Measures: BOT-II, PDMS-2, PEDI

The Bruininks-Oseretsky test of motor performance (BOT-II) is widely used in the school setting to assess both gross and fine motor proficiency for children

aged 4 through 21 (Bruininks & Bruininks, 2005). This test is intended for use by experienced practitioners as a measure of motor performance, particularly in the areas of fine motor control, coordination, body awareness, strength and agility (Deitz & Kopp, 2007). However, these categories appear to fall more under body impairments, rather than activity performance, as defined in this study. Additionally, the 45-60 minute test, conducted in a closed environment under standardized conditions, uses an expensive manipulatives kit, while the student completes isolated tasks: standing on one leg on a balance beam, one-legged side hop, catching a tossed ball, and sit-ups (Bruininks & Bruininks, 2005). A study of the BOT-II in preschoolers by Venetsanou et al. (2009) revealed a threat to validity with a high percentage of zero scores on a number of items and a resultant floor effect.

The Peabody Developmental Motor Scales (PDMS-2) are also frequently used by pediatric therapists; however, it is limited to the motor development of children from birth to age five (Folio & Fewell, 2000). Similar to the BOT-2, there is an expensive manipulatives kit, and administration time can run 20-30 minutes for each motor-related subtest, or 45-60 minutes for the entire assessment (Folio & Fewell, 2000). For these reasons, the PDMS-2 is less appealing in a school setting. While the Pediatric Evaluation of Disability Inventory may be a more practical resource in a school setting, as it requires no expensive equipment and assesses functional capabilities and performance, rather than impairments, in children aged six months to seven years (Haley, et al. 2010). Despite accounting for assistive devices and

caregiver assistance, it fails to address the environmental component of functional mobility, as it is conducted in a closed and controlled environment (Haley et al., 1992). As with many outcome measures, there are issues with objectivity and scoring. The PEDI is administered by parent report, and professional judgment using a scale of 0 "unable" or 1 "capable", which leaves little room to interpret whether any small but potentially meaningful change has occurred (Haley et al., 1992). The measure is not appropriate for use in children with chronic illness, and is more appropriate for children with moderate to severe disability (Haley, et al. 2010).

Gross Motor Function Measure-88/-66

The GMFM-88, a standardized, observational outcome measure, has long been the tool of choice for measuring changes in gross motor function in children with Cerebral Palsy (CP), Down Syndrome (DS) and traumatic brain injury [TBI] (Russell, Avery, Rosenbaum & Raina, 2000; Russell, Palisano, Walter & Rosenbaum et al. 1998; Palisano, Walter, Russell & Rosenbaum, et al., 2001; Gémus, Palisano, Russell & Rosenbaum, et al., 2002; Linder-Lucht, Othmer, Walther & Vry, et al., 2007).

The revised computer based GMFM-66 has thus far been validated only in a population with CP (Linder-Lucht, et al., 2007; Russell, et al., 2002). It is recommended that therapists be highly experienced and knowledgeable in administering the assessment and interpreting computerized results. All items (-88/-66) must be completed with testing conducted on a smooth flat surface in a controlled environment without the use of shoes. Estimated

administration time is approximately 45-60 minutes (Russell, Rivard, Bartlett, Rosenbaum & Palisano, 2003).

With limited time, space, and financial resources available to school-based therapists, the GMFM may not lend itself well to use in the school setting. Approval for expensive computer software and extensive training for a group of therapists can be problematic within limited budgets. Additionally, school-based interventions often consist of a 30-minute session in a crowded hallway or busy gym, as time out of class is minimized, and private space or dedicated rooms for therapy are not available. The length of time and expertise required to complete the GMFM would make frequent reassessments in the school setting cumbersome and inefficient.

Even though the GMFM is used regularly with school-aged children, test items are most representative of a typical child's motor skill development below the age of five. The GMFM-88 and -66 may not be as sensitive to changes in motor skills of children over the age of five, making this tool less useful in the broader disabled population encountered in the school setting (Russell et al., 2003). Clinical change is dependent on judgment (Russell et al., 2003). These characteristics may pose problems when multiple therapists need to document change for continued services or payment. Additionally, both versions are capacity based and do not fulfill IDEA, APTA, or WHO requirements for activity and participation (Russell et al., 2003).

School Function Assessment

The SFA, the gold standard for assessments in the school setting (grades K-6), is an observational judgment-based questionnaire specifically designed to examine a student's ability to manage important functional activities and contextual demands of school-related tasks (Coster et al, 1998). While the GMFM focused on motor skill development, the SFA reflects a multi-system model of functional mobility and addresses current legislation on student participation in typical activities and environments of their peers. More specifically, the Activity Performance subsection evaluates a child's performance of functional activities in an array of environments typical of the school setting (i.e. cafeteria, playground, classroom, transportation) (Coster et al., 1998). While the GMFM should be limited to children with CP, DS, or TBI, the SFA has been field tested with children over a wide variety of disabilities, making it advantageous for use in the school setting (Coster et al., 1998; Coster, Mancini & Ludlow, 1999).

Unlike the GMFM, the SFA does not require specialized training and may be completed in 1.5-2 hours by an observer who regularly works with the student. However, for more accurate representation of performance, observations should be made over 2-3 weeks. For this reason, there are three acceptable methods of administration/completion: 1. by an individual therapist or teacher; 2. the child study team; 3. team leader/interviewer (Coster et al., 1998). Again, as with the GMFM, all sections should be completed; however, research frequently reports only one of the three subsections. Typical

performance is reported as ordinal data on a rating scale of (1-4); (1) indicating "Does not perform" and (4) indicating "Consistent performance". Raw scores for each section are totaled, transferred to a summary form, and compared to criterion scores reflecting the individual's strengths and weaknesses (Coster et al., 1998).

As seen in the GMFM, limited time and financial resources remain an issue. Costs for licensing rights, testing manual, and a limited number of scoring sheets can run hundreds of dollars. While administration does not require special training, and multiple observers can contribute to the final assessment, it still requires significant time to complete (1.5-2 hours), which potentially limits practicality in the school setting and timely functional reporting in accordance with new standards.

While the SFA assesses functional tasks for participation in a school setting, it is still a judgment-based questionnaire, which fails to meet current federal regulations for objective reporting. Additionally, Likert scoring holds the potential for subjective influences and may not be sensitive enough to detect small changes in a student's performance. Cutoff scores were determined using healthy children from a regular educational classroom, with 5% expected to fall below the cutoff (Coster et al., 1998). These statistics raise questions as to whether the correct populations are indeed receiving necessary services. With administrators and payer sources seeking to contain costs and ensure effectiveness of therapy related services, these issues become critical.

Modified Adult Assessments

In an effort to more accurately address the construct of functional mobility, research has been conducted using modified adult assessments in the pediatric population (Westcott et al., 1997; Franjoine et al., 2003; Habib & Westcott, 1998; Held, Kott & Young, 2006; Bartlett & Birmingham, 2003; Zaino, Marchese & Westcott, 2004).

The Pediatric Functional Reach Test (PRT) was developed to assess balance and postural control of children with CP in the community (Bartlett & Birmingham, 2003). It measures the distance (cm) a child is able to reach forward and laterally in a sitting and standing position without loss of balance (Bartlett & Birmingham, 2003). The test is quick, requires little equipment, and allows the child to use their typical footwear and assistive devices. While the test examines balance and postural control components of mobility, it does not fulfill the definition of FM with respect to participation and environmental features.

The Pediatric Balance Scale (PBS), a modified version of the Berg Balance Scale, assesses the balance of school-age children with mild to moderate motor impairments on 14 isolated tasks (i.e. sitting unsupported, eyes closed, standing on one leg, looking behind) which are rated on a 0-4 Likert scale (Franjoine et al., 2003). Testing is conducted without the use of assistive devices. Again, scoring leaves little room to document subtle,

sometimes meaningful changes in functional mobility as described in this paper. As with other tests, this capacity-based assessment is addressing discrete components of a task, with no interaction with the environment, and no locomotor activity.

Two modified adult measures that add basic mobility activities and incorporate at least one aspect of a school environment are the Timed Up & Go (TUG) and the Timed Up & Down Stairs (TUDS) (Lowes, Habib & Bleakney et al., 1996; Zaino, Marchese, & Westcott, 2004). The TUG was developed as a measure of balance and fall risk, while the TUDS was specifically developed as a "functional mobility outcome measure" (Zaino, Marchese & Westcott, 2004). Both of these measures are objective, quick, easy to administer, cost-efficient, and detect small changes based on time in seconds (Lowes, Habib & Bleakney et al., 1996; Zaino, Marchese & Westcott, 2004). Studies similar to TUDS have shown a relationship between stair negotiation and disruption in life habits at school, particularly in areas of mobility and recreation (Lepage, Noreau & Bernard, 1998). However, these tests are only assessing basic mobility, and are not robust enough to provide an accurate representation of a school environment, and do not account for assistive devices and orthoses frequently used as part of a child's mobility methods.

Overall, these tests are contextually sparse, examining only a single component of a task or environmental feature. They fall short in representing school-related mobility tasks such as: walking long distances, around

obstacles, over uneven ground, maneuvering crowded halls or cafeterias, and manipulating objects (APTANJ, 2011).

A New Outcome Measure of Functional Mobility:

The modified-Emory Functional Ambulation Profile

The m-EFAP's theoretical construct incorporates a number of the key characteristics of an ideal outcome measure of functional mobility, making it an attractive alternative for assessing children in the school population. The m-EFAP, a previously validated and reliable assessment tool in 5-7 year olds with disabilities (unspecified) provides objective, quantitative information regarding functional mobility (Enslee & Simpkins, 2007). Mobility is assessed by measuring time (seconds) to negotiate a variety of surfaces, transitions, and obstacles representative of daily tasks and environments, while accounting for assistive devices (AD), orthotics, and manual supports (Wolf et al., 1999; Baer & Wolf, 2001). Completion time including scoring is approximately 10-15 minutes.

As a measure of functional mobility in children with unspecified disabilities, m-EFAP scores have demonstrated moderate correlations with the Maintaining and Changing Positions ($r = .89$), Recreational Movement ($r = .73$), Using Materials ($r = .74$), and Manipulation with Movement ($r = .73$) AP categories of the SFA (Enslee & Simpkins, 2007). Strong inter-rater reliability [ICC] (0.98), and test re-test reliability [ICC] (0.99) were demonstrated in post-stroke adults and children (Baer & Wolf, 2001; Enslee & Simpkins, 2007).

m-EFAP subtasks chosen to represent conditions and environments encountered in daily life, including smooth hard flooring, carpeting, transition from a chair, obstacles, and stairs are very similar to the school-related mobility tasks recommended by IDEA and APTA pediatric practice guidelines (APTANJ, 2011; IDEA., P.L.108-446, 2004; Wolf et al., 1999).

As discussed earlier, studies have shown that it is important to consider assistive devices (AD) and manual assistance (MA) when evaluating a child's functional mobility, in order to obtain a more valid measure (Tieman et al., 2007; Harvey et al., 2009). While the SFA has a checklist and comment section dedicated to AD, m-EFAP scoring is designed to incorporate orthotics, assistive devices, and manual or hand-held assistance into the total score reported. This provides a more comprehensive report of a child's functional mobility while giving credit for transition to a device requiring less support (i.e. walker to crutches).

Similar to the TUG and TUDS, the m-EFAP uses time in seconds to produce continuous data, which may be more sensitive to small changes not detected by Likert scales. This is important to consider in children, as functionally meaningful changes can be difficult to quantify and rationalize to those with outside interests. m-EFAP subtask scores can also be compared to normative values to provide information about the child's mobility in reference to his peers. Additionally, the simple scoring allows clear communication and interpretation of a child's FM with other disciplines, third-party payers and can be easily understood by the parent and the child.

Additionally, m-EFAP offers physical therapists an objective functional outcome tool to document how severity modifiers for G-codes are selected to meet the new MCTA requirements (H.R. 3630, 2011). Recall, G-codes are based on ICF categories of activity limitations and participation: Mobility; Walking and Moving Around; Changing and Maintaining Body Position; Carrying, Moving, and Handling Objects; and Self Care (CMS, 2013; WHO, 2006). The m-EFAP's subtasks already address a number of these categories. With reporting required on initial evaluation, every 10th visit, on reassessment, and discharge, m-EFAP offers a quick, easy, and inexpensive method of providing this frequent information. Currently, school therapists typically report a child's mobility on evaluation at the beginning of the school year and again as a summary at the end of the school year, with reassessments as determined by the child study team or parent.

In review, the m-EFAP meets many of the criteria for an ideal outcome measure of functional mobility in school-aged children. It is well-defined and grounded in the DST for assessing functional mobility through the interaction of the individual, the task, and the environment (Thelen, 1989). The m-EFAP is widely applicable, meeting IDEA, APTA, and ICF guidelines for activity and participation with robust contextual environments and tasks representative of the school setting (APTANJ, 2011; IDEA, P.L. 108-446, 2004; WHO, 2006). Previous studies have supported m-EFAP validity and reliability in assessing functional mobility of children with unspecified disabilities in a school setting, indicating appropriateness for the purpose and population of interest (Enslee

& Simpkins, 2007). Additionally, it is timely, cost-efficient, and easily interpreted across healthcare domains (Wolf et al., 1999). Lastly, it provides objective, patient-centered, quantitative information on the effectiveness and efficiency of therapy interventions conforming to new healthcare policies.

Summary of Literature Review

The following sections summarize the common themes that have emerged and discusses the gaps found in the literature.

What is Known in the Literature

The following is what is known in the literature about outcome measures of functional mobility in children:

- National healthcare changes demand objective outcome measures for payment (H.R. 3590, P.L.111-148, 2009; H.R. 3630, P.L. 112-96, 2011)
- Functional limitations must be tied directly to daily activity and participation (CMS, 2013)
- There's a difference between *capacity* and *performance* (Holsbeeke et al., 2009; Lam et al., 2008; WHO, 2006; Haley et al., 2010; Young et al., 1996)
- Objectivity is problematic in tests used with children (Portney & Watkins, 2001; Vos-Vromans, Ketelaar & Gorter, 2005; Coster et al, 1998; Linder-Lucht et al., 2007)

- Usefulness of scoring: must be meaningful and understood by all parties of interest evaluating information obtained from a particular tool (Portney & Watkins, 1993; Vos-Vromans et al., 2005; Kane, 1994)
- Environmental dimensions are not robust (Patla & Shumway-Cook, 1999; Shumway-Cook & Woollacott, 2003; Lam et al., 2008; Young et al., 1996: Tieman et al., 2004; *APTANJ,* 2011)
- Time, cost, and efficiency is problematic in established tests
- Adult measures show promise (Westcott et al., 1997; Franjoine et al., 2003; Habib & Westcott, 1998; Held et al., 2007; Bartlett & Birmingham, 2003; Zaino et al., 2004; Williams et al., 2005; Enslee & Simpkins, 2007)
- The m-EFAP, a valid adult measure, meets many of the criteria for an ideal outcome measure; it is objective, addresses FM as defined in this study, addresses the lack of environmental robustness, and may be useful in the pediatric population (Baer & Wolf, 2001; Wolf et al., 1999).

Gaps in the Literature

An analysis of what is known in the literature reveals a number of concerns when it comes to selecting an appropriate objective outcome measure of functional mobility in the pediatric population that meets practice standards for activity and participation, as well as federal regulations for quality and payment policies. Several themes emerged during the literature review. Many had limited age ranges or were only consistently validated for children having cerebral palsy, Down syndrome, or traumatic brain injury

(Russell et al., 2000; Palisano, et al., 2001; Gémus et al., 2002; Linder-Lucht et al., 2007). Of particular concern was the lack of assessments addressing performance rather than capacity, which fails to address activity and participation. Even many of the adult measures which were adapted to assess FM in children lacked robust environmental dimensions, while others were not valid and reliable in a broader pediatric population. One tool which did stand out as meeting many of the criteria for an ideal measure was the m-EFAP. However, it too lacked studies of validity and reliability in the pediatric population.

It is clear that *no one tool* captures all of the components of functional mobility as defined by the DST of motor learning. Nor is there a tool which addresses all of the conceptual measures of mobility. Given these gaps in the literature, there is a need to explore further the usefulness of using the m-EFAP in school-age children with varied diagnoses.

Therefore, the problem becomes that the *PPAC (2009)* and *MCTA (2011)* mandate patient centered, objective functional outcome reporting for all persons receiving services be tied directly to limitations in mobility related to activity and participation in daily life (H.R. 3590, P.L. 111-148, 2009; H.R. 3630, P.L. 112-96, 2011; CMS, 2013). While the underlying constructs of the m-EFAP – an objective, quantitative measure of functional mobility supports current *standards of practice* and meets *federal regulations* for quality and payment policies – there is a paucity of studies supporting the validity of using the test in school-age children with disabilities. Therefore, given the increased

level of accountability to address rising healthcare costs; the need to develop, improve and expand outcome measures of FM for school-age children; and the relationship between the task, environment and individual in assessing FM; this research study is significant. Using an appropriate and objective outcome measure of functional mobility of school-age children, which is aligned with practice guidelines for activity and participation while fulfilling federally required documentation of efficiency and effectiveness for quality initiatives and payment policies, supports truly patient-centered care. Thus, in search of an ideal outcome measure, the purpose of this dissertation study is to determine convergent validity of the m-EFAP with the SFA in school-age children with DD.

Chapter III

METHODS

Research Design

This methodological study was designed to evaluate the validity of a new assessment tool for balance and functional mobility in children. Methodological research often compares the performance of a new instrument with that of an established instrument for which validity and reliability data are available. These tools are often used for the same or similar purposes (Portney & Watkins, 2001). The selection of this method and design was influenced by the results obtained from a previously conducted pilot study assessing the use of the m-EFAP in school-age children. The pilot is discussed in detail as it relates to the current study results in Chapter V. In this case, a prospective correlational design was chosen to explore the relationship between scores on the m-EFAP and the AP subsection of the SFA to support convergent validity. A correlation between the scores of the two different tests would contribute to the establishment of valid use of the m-EFAP in school-aged children with Developmental Motor Delay (DD).

Participants

A purposive sampling procedure was used to select potential subjects from the sampling pool of students at one of two private schools (Appendix G) serving children with special needs, which approved the research study (Portney & Watkins, 2001). Potential subjects were between the ages of 5-11

with a diagnosis of DD, as defined by the most current versions of the ICD-10 (2015) and the DSM-V (2013). An eligibility clause was included in the consent form sent home to all potential subjects in the sampling pool to facilitate screening. There was no evaluation of IEP, classification information or other protected school and health information. Forty-four students between the ages of 5 and 11 years old, diagnosed with DD, were recruited from two private educational facilities located in North-Central New Jersey

(Appendix G).

Inclusion and Exclusion Criteria

The inclusion criteria for student participants were as follows:

1. Students currently attending one of the approved participating schools serving New Jersey's children with special needs were eligible to participate
2. Of those students, they must be between the ages of 5 and 11 years old to be eligible for participation
3. Have a Developmental Motor Delay (DD) as defined by ICD-10/ DSM-V*
4. Have the ability to walk 5m with assistance, including but not limited to: manual assistance, ankle or hip orthoses, canes/sticks, crutches, or walkers
5. Be able to follow 1-2 step verbal instruction
6. Signed Consent and Oral Assent forms are returned

*According to the International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10), Developmental Motor Delay (ICD-10 F82) is defined as: Serious impairment in fine & gross motor skills substantially below chronological age which is not solely explained by general intellect or specific congenital/acquired neurological disorder. DD may be characterized by clumsiness (e.g., dropping or bumping into objects) or slowness (e.g., catching, handwriting, riding a bike, or sports) and includes: Clumsy Child Syndrome Developmental Coordination Disorder, and Dyspraxia (WHO, 2015).

The American Psychiatric Association (2013), further defines Developmental Coordination Disorder (DSM-V 315.4) as presenting with Motor skills substantially below age with significant and persistent interference of Activities of Daily Living, School Performance, and Play.

The exclusion criteria for student participants were as follows:

1. Students not currently attending one of the approved participating schools serving New Jersey's children with special needs were ineligible to participate
2. Older than 11 or younger than 5 years old
3. Students who are not Developmentally Delayed (DD) per ICD-10/ DSM-V definitions
4. Have an inability to walk 5m with assistance
5. Are unable to follow verbal instructions
6. Are cognitively impaired
7. Have other medical diagnoses (CP, MD, Degenerative Disorders)
8. Uncorrected Vision/Hearing impairments

Instruments

School Function Assessment

Specific questions and formatting of the SFA are protected by licensing agreements and cannot be provided in this context; however, further information on the SFA is available for review in Appendix F or at: http://images.pearsonclinical.com/images/assets/SFA/SFAOverview.pdf

The SFA is a judgment-based questionnaire that examines a student's ability to perform important functional activities that represent the role of the student. (Coster et al., 1998). More specifically, it focuses on adaptive behaviors that have relevance to specific school-related

activities sharing a common functional demand (Coster et al., 1998). It reflects a multi-system model of functional mobility and addresses current legislation for student participation in typical activities and environments of their peers. Of particular interest for this study, the Activity Performance subsection evaluates a child's performance of functional activities in an array of environments typical of the school setting [i.e. cafeteria, playground, classroom, transportation (Coster et al., 1998)].

The SFA is completed by an observer who regularly works with the student. Typical performance is reported as ordinal data on a rating scale of (1-4); (1) indicating "Does not perform" and (4) indicating "Consistent performance". Raw scores for each section are totaled and compared to criterion scores. Criterion scores indicate a child's current level of function on a continuum, reflecting the individual's strengths and weaknesses.

Experts and professionals from two different studies have indicated strong support for the content validity of the SFA [N = 40, 80%] (Hwang, et al., 2002; Coster et al., 1998; Coster et al., 1999). Internal consistency for each scale has been reported as very good, using a Chronbach's alpha (.92-.98). Test-re-test data on students with disabilities were also good [r = .80 to .90] (Coster et al., 1998). Convergent validity with the Vineland Adaptive Behavior Scales was moderately supported with correlation values of [r = .72] (Hwang, et al.,

2002). Discriminative analysis studies demonstrated a high percentage of students being correctly identified: general (93%), cerebral palsy [88.2%] (Hwang, et al., 2002).

modified-Emory Functional Ambulation Profile

The m-EFAP protocol and data collection matrix are protected by licensing rights and copyright laws and cannot be depicted in this manuscript. However, details of the m-EFAP and requests for reprints of the original articles can be obtained from the publisher (Appendix F). Composed of five subtasks, the m-EFAP provides quantitative data regarding functional mobility by measuring time to negotiate a variety of environmental challenges. Subtasks chosen to represent conditions and environments encountered in daily life include (1) hardwood flooring; (2) carpeting; (3) transition from a chair; (4) obstacles; and (5) stairs (Wolf et al., 1999). Specifications for the five individually timed subtasks and the m-EFAP protocol are available from the publisher (Appendix F).

Performance on the m-EFAP is assessed by recording the number of seconds taken to complete each subtask, which is then multiplied by an assistance factor corresponding to the assistive device used. Summation of the five subtask scores yields a total m-EFAP score, providing interval data (Wolf et al., 1999; Baer & Wolf, 2001). Level of assistance required during the testing is also reported

separately from the timed data and is scored as an ordinal on a scale from Independence to Maximal Assistance (Baer & Wolf, 2001).

As a measure of functional mobility, m-EFAP scores have shown to be moderately correlated with performance on the Berg Balance Test (r = .60) and the Timed 10m Walk Test (r = .70) in elderly and post-stroke adults (Wolf et al., 1999). Both of these tests represent previously validated measures of balance and mobility. In children with disabilities, m-EFAP subtasks and total scores have demonstrated moderate correlations with the Maintaining and Changing Positions (r = .89), Recreational Movement (r = .73), Using Materials (r = .74), and Manipulation with Movement (r = .73) categories from the Activity Performance subsection of the SFA (Enslee & Simpkins, 2007). Strong inter-rater reliability [ICC] (0.98), and test re-test reliability [ICC] (0.99) were demonstrated in post-stroke adults and children (Baer & Wolf, 2001; Enslee & Simpkins, 2007). Normalized values for the m-EFAP have not been systematically established. However, several of the individual subtasks have accepted normal values. For example, speeds on the Timed Up & Go in children aged 3-9 have been reported to average (5.9 seconds), the Timed Up and Down Stairs (0.58 seconds) per step, and the floor to stand test for ages 5-21 averages [12.1 seconds] (Williams et al., 2005; Zaino et al., 2004; Haley, Pinkham, Dumas, Skrinar & Cox, 2006). Additionally, the measure is

not intended as a norm referenced measure, but examines a subject's function on a continuum.

Procedures

The sequence of the study procedure is described in the following paragraphs and illustrated below in a process diagram (*Figure 4*). This diagram methodically follows each step and decision made in the process of conducting this study from beginning to end.

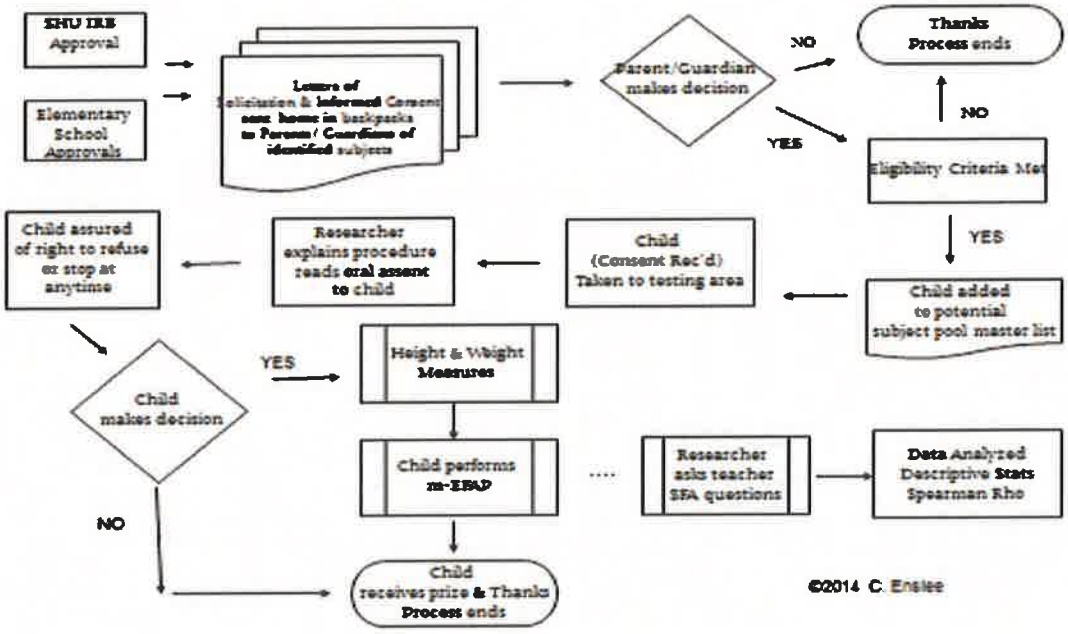


Figure 4. Process Diagram. This diagram follows the entire research process from beginning to end.

Prior to arriving at the elementary school facilities, the Primary Investigator (PI) completed the following:

1. Permission was obtained from the schools' Board of Directors and Institutional Review Boards, in accordance with each school's policies and procedures, at which time signed site approval letters were received (Appendix G).

2. The PI completed the *National Institutes of Health Protection of Human Subjects Training Module.*

Once these tasks were completed, the research proposal was submitted to and approved by Seton Hall University's Institutional Review Board [IRB] (Appendix B).

Participant Recruitment Process

Following Seton Hall University IRB approval (Appendix B), the PI provided the school administrators with packets containing a letter of solicitation, consent form, and oral assent form with an attached return envelope (Appendices C, D, E). This packet, which introduced the PI and explained the research study, was sent home to all potential subjects in Kindergarten through Sixth Grade classrooms, which typically have students between the ages of 5-11. In accordance with the educational facilities' policies and procedures, the information was sent home in students' daily folders/backpacks. Sealed envelopes to protect the anonymity of subjects were collected by the school secretary for approximately 2 weeks, at which

time the PI collected and reviewed the forms for completeness and eligibility based on established inclusion criteria. The PI made the final determination of eligibility based on age cutoffs and ability to follow verbal instructions. Student eligibility was parent-determined based on their review of the inclusion/exclusion criteria, and return of the signed consent form. If the parent/guardian's response was "No" to their child's participation, child assent was automatically assumed to be "No" due to the protected nature of children and the role of the parent/guardian acting in the best interest of the child. Only after parents/guardians indicated an agreement to approach their child for participation was contact made with a student. Anonymity and confidentiality were maintained throughout the duration of the research project. The PI assigned an alpha-numeric code [i.e. S1A, S2B, etc.] that did not represent initials to refer to each subject, to eliminate the threat of identifying participation or personal information (Appendix I).

Student participation was established by the returned and signed oral assent form, which was again read to the child by the PI just prior to data collection to ensure their desire and understanding for participation regardless of parent approval (Appendix E). If, and only if, the child indicated a continued desire to participate did the data collection process proceed.

Data Collection

Manual heights and weights were taken using a fabric tape measure and a standard bathroom scale. Information was recorded on a coded descriptive data collection form (Appendix I). The m-EFAP was administered per

standardized protocol (Appendix F) with the following modifications to accommodate pediatric participants. First, the five-meter walkway was marked off with bright colored tape to indicate the beginning line. A second modification made during the Up & Go subtask was the replacement of the standard 46 cm height armchair with an appropriately sized standard school chair in which the child's knees were at approximately 90° and their feet maintained contact with the floor. Additionally, the exact dimensions for stairs were adjusted to be representative of those available in the school setting. These minor modifications were not expected to have significant influence on testing scores. Based on the literature, anticipated completion time was 10 minutes; however, actual times were closer to 15-20 minutes.

Performance on the m-EFAP was assessed using a digital stopwatch with fresh batteries to record the number of seconds taken to complete each subtask (Walking on Floor, Carpet, Sit to Stand, Obstacle Negotiation and Stairs). Each task was explained to the student and demonstrated as necessary. The student then completed each subtask wearing their typical shoes, braces, or assistive device, as the PI walked within 12 inches, alongside the student, so as not to impede the student's movements, but to allow for immediate contact guard assistance if needed. Students selected a novelty pencil for their participation and were escorted back to their classroom, following completion of the m-EFAP. Follow-up reports were not provided. Parents/Guardians were instructed to direct any concerns regarding their child's mobility to their assigned therapy providers.

Typically, the recorded times are multiplied by an assistance factor corresponding to the assistive device used (Baer & Wolf, 2001). None of the subjects in this study required an assistive device, therefore assistance factors were not calculated. Use of a handrail during stair negotiation was noted under level of assistance, but not calculated into the score. Summation of the five subtask scores yielded a total m-EFAP score, providing interval data (Wolf et al., 1999; Baer & Wolf, 2001). Level of assistance required during the testing was also recorded separately from the timed data, and is scored on an ordinal scale from Independence to Maximal Assistance (Baer & Wolf, 2001).

SFA Administration

The PI read each item on the Activity Performance (AP) subsection of the SFA to the student's teacher and marked down their response using pen and paper. It is assumed that classroom teachers have observed and are familiar with the student's normal mobility in a variety of school settings. According to Hwang et al. (2002), specialized training is not required for SFA administration; however, written guidelines were provided and reviewed for teachers at the time of questioning.

Data Analysis

The PI collected all data in paper format. As soon as all m-EFAP and SFA scores were calculated and reviewed for accuracy and completeness, the data was transcribed into a spreadsheet and stored on a password-

protected USB memory key for electronic data analysis. All data was maintained in a locked file in the PI's home office. The memory key with data was kept locked separately from the coding sheets. All data will be retained and secured for 3 years, at which time it will be destroyed by an approved Shred-it ® method.

Data were analyzed using both descriptive and inferential statistics, using SPSS Version 24.0 (IBM, 2016). Demographic characteristics were presented in tabular form using descriptive statistics.

Chapter IV

RESULTS

Demographic Profile

Demographic characteristics are presented in tabular form using descriptive statistics (see Table I). Out of a sample of forty-four students, twenty-seven male and seventeen female between the ages of 5 and 11 years old, diagnosed with DD, who did not have other medical diagnoses, cognitive impairment, or uncorrected vision or hearing impairments were recruited from two private educational facilities located in North-Central New Jersey. Considering the limited definition of DD allowed by the parameters of this study, and the inconsistent standards encountered for 'protecting children', it can be very challenging to study this population. Therefore, an N of 44 was expected and acceptable for this study.

Table I

Demographics of Participants

Characteristic	N	Range	Mean	Std Deviation
Age (yrs.)	44	5-11	7.32	1.79
Height (in.)	44	38.5-60.0	48.5	4.39
Weight (lbs.)	44	42-124	61.36	18.91
Gender	44			
Male	27			
Female	17			

Quantitative Data Analysis

Each of the research questions generated in this study are listed followed by the analyses that were used to statistically address it. Alpha was set at 0.05 for all analyses.

Research Question 1:

The first research question (RQ1) inquired about whether there was a relationship between total scores on the modified-Emory Functional Ambulation Profile (m-EFAP) and total scores on the Activity Performance (AP) Subsection of the School Function Assessment (SFA) for children aged 5-11 with Developmental Motor Delay (DD)? In order to address this research question, a Spearman Rho Correlation was computed between the total score on the m-EFAP and total score on the AP subsection of the SFA. This statistic assesses if there is a relationship between two variables and the strength of the relationship. The results indicated that the relationship between the total score on the m-EFAP and total score of the SFA was not significant:

$r(42) = -.164$, $p = .287$. Therefore, there is no evidence to conclude that the total score on the m-EFAP are related to the total score on the SFA; therefore, H1: m-EFAP total scores will be significantly correlated with the AP subsection of the SFA for children with DD, must be rejected.

Research Question 2:

The second research question (RQ2) inquired if there is a relationship between m-EFAP subtasks and AP categories of the SFA in children aged 5-11 with DD. A series of Spearman Rho Correlations were computed to address this research question. Table II provides the results of this analysis.

m-EFAP Floor Subtask

A review of this table reveals that the m-EFAP Floor subtask correlated with the SFA Stairs category, $r(42) = -.304$, $p = .045$. The negative correlation indicates that as time on the Floor subtask increased, scores on the SFA Stairs category decreased. Recall that slower times on m-EFAP subtasks indicate poorer performance and low scores on the SFA indicate that a child does not perform a task.

m-EFAP Total Score

The m-EFAP Total Score correlated with the SFA Maintaining and Changing Positions category: $r(42) = -.327$, $p = .030$. Again, note the negative correlation indicates that as time on the m-EFAP Total Score increased, the score on the SFA Maintaining and Changing Positions category decreased.

m-EFAP Obstacles Subtask

The m-EFAP Obstacles subtask was correlated with two of the SFA subtasks and the total score of the SFA. The m-EFAP Obstacles subtask was correlated with the SFA Travel subtask, $r(42) = -.305$, $p = .044$. There was also a significant correlation between the m-EFAP Obstacles and the SFA Maintaining and Changing Positions category, $r(42) = -.468$, $p < .001$. Finally, there was a significant correlation between the m-EFAP Obstacles subtask and the SFA Total Score, $r(42) = -.317$, $p = .036$. Notice that each of these had a negative

correlation, indicating that as time on the m-EFAP Obstacles subtask increased, scores on the AP categories of the SFA decreased.

m-EFAP TUG Subtask

What came as a surprise, and a key finding of this study is that the m-EFAP TUG subtask demonstrated significant correlations with all of the SFA AP categories except Stairs. The m-EFAP TUG subtask was correlated with the SFA Travel category, $r(42) = -.314$, $p = .038$. The negative correlation indicates that as time on the TUG subtask increased, scores on the SFA Travel subtask decreased. There was also a significant correlation between the m-EFAP TUG subtask and the SFA Maintaining and Changing Positions category, $r(42) = -.587$, $p < .001$. There was also a significant correlation between the m-EFAP TUG subtask and the SFA Recreational Movement category, $r(42) = -.334$, $p = .027$. The m-EFAP TUG subtask and the SFA Manipulation with Movement category also demonstrated a significant correlation, $r(42) = -.298$, $p = .050$, as did the m-EFAP TUG subtask and the SFA Using Materials category, $r(42) = -.363$, $p = .015$. There was also a significant correlation between the m-EFAP TUG subtask and the SFA Total Score, $r(42) = -.373$, $p = .013$. Notice that each of these correlations are weak to moderate with a negative correlation, indicating that as time on the TUG subtask increased scores on the SFA AP categories decreased. Recall that

slower times indicate poorer performance on the TUG subtask, and low scores on the SFA indicate the child does not perform a task.

Table II

Spearman Rho Correlation between m-EFAP subtasks and Activity Performance subtasks of the SFA.

		m-EFAP Floor	m-EFAP Carpet	m-EFAP TUG	m-EFAP Obstacles	m-EFAP Stairs	m-EFAP Total
SFA Travel	*r*	.121	.058	-.314	-.305	.057	-.127
	p	.433	.709	.038*	.044*	.715	.410
Position	*r*	-.016	-.134	-.587	-.468	-.014	-.327
	p	.918	.386	<.001*	.001*	.926	.030*
Recreation	*r*	-.070	-.094	-.334	-.198	.010	-.142
	p	.650	.545	.027*	.198	.948	.359
Manipulation	*r*	-.100	-.115	-.298	-.293	-.133	-.200
	p	.517	.458	.050*	.054	.390	.193
Materials	*r*	-.069	-.150	-.363	-.295	.041	-.173
	p	.658	.331	.015*	.052	.793	.261
Stairs	*r*	-.304	-.292	-.020	-.064	-.136	-.177
	p	.045*	.055	.900	.680	.380	.251
SFA Total	*r*	.000	-.067	-.373	-.317	.034	-.164
	p	.997	.665	.013*	.036*	.826	.287

*denotes a significant result at $p < 0.05$

Additional Analyses

Additional analyses were conducted to assess the relationship of demographic variables to the total scores of the m-EFAP and SFA and their respective subtasks..

Gender

The first analysis assessed differences between males and females on the m-EFAP and SFA total scores and their subtasks. The results are presented in Table III. An inspection of this table reveals that there were no differences as a function of gender.

Table III

Means, Standard Deviations and t-tests for Total Scores and Subtasks of the m-EFAP and SFA as a Function of Gender

		N	Mean	Std. Deviation	t	p
Floor	Males	27	5.49	1.51	-.336	.739
	Females	17	5.71	2.94		
Carpet	Males	27	5.54	1.57	-.433	.668
	Females	17	5.81	2.46		
TUG	Males	27	8.06	3.27	-.169	.867
	Females	17	8.23	2.89		
Obstacles	Males	27	12.87	5.94	-.279	.782
	Females	17	13.38	5.82		
Stairs	Males	27	10.12	11.79	.509	.614
	Females	17	8.62	3.47		
Total	Males	27	42.11	19.22	.060	.952
	Females	17	41.77	16.04		
Travel	Males	27	67.15	11.47	1.60	.118
	Females	17	60.94	14.11		
Position	Males	27	43.26	6.38	.904	.371
	Females	17	41.53	5.84		
Recreation	Males	27	35.07	10.15	1.54	.131
	Females	17	30.59	8.03		
Manip.	Males	27	53.22	10.50	1.43	.160
	Females	17	48.41	11.43		
Materials	Males	27	76.44	22.85	1.59	.119
	Females	17	65.53	20.94		
SFA stairs	Males	27	20.48	4.15	.712	.480
	Females	17	19.53	4.57		
SFA total	Males	27	295.63	50.83	.1.82	.077
	Females	17	266.53	53.27		

*denotes a significant result at $p < 0.05$

Schools

It was also of interest if there were differences on the m-EFAP and SFA total scores and their respective subtasks as a function of the school the subjects attended. The results are presented in Table IV. An inspection of this table reveals that subjects in School 1 (M = 6.91, SD = 2.86) on the average scored lower than subjects in School 2 (M = 9.15, SD = 2.98, t (42) = -2.53, p = .015) on the TUG subtask of the m-EFAP. There were also differences between School 1 (M = 45.40, SD = 4.51) and School 2 (M = 40.25, SD = 6.46) on the Maintaining and Changing Positions subtask of the SFA (t(42) = 3.00, p = .004). There were no other differences between School 1 and School 2 on the subtasks of the m-EFAP or the SFA.

Table IV

Means, Standard Deviations and t-tests for Total Scores and Subtasks of the m-EFAP and SFA as a Function of School

	School	N	Mean	Std. Deviation	t	p
Floor	1.00	20	5.74	2.68	.461	.647
Carpet	2.00	24	5.44	1.63		
Carpet	1.00	20	5.66	2.28	.043	.966
TUG	2.00	24	5.63	1.65		
TUG	1.00	20	6.90	2.85	-2.53	.015*
Obstacles	2.00	24	9.14	2.97		
Obstacles	1.00	20	11.76	5.96	-1.37	.179
Stairs	2.00	24	14.15	5.61		
Stairs	1.00	20	9.13	4.86	-.261	.796
Total	2.00	24	9.88	12.11		
Total	1.00	20	39.21	15.15	-.933	.356
Travel	2.00	24	44.27	19.87		
Travel	1.00	20	65.50	14.82	.352	.727
Position	2.00	24	64.13	11.07		
Position	1.00	20	45.40	4.51	3.00	.004*
Recreation	2.00	24	40.25	6.46		
Recreation	1.00	20	35.60	7.13	1.45	.154
Manip.	2.00	24	31.46	10.97		
Manip.	1.00	20	54.05	7.57	.150	.141
Materials	2.00	24	49.13	12.93		
Materials	1.00	20	77.30	20.34	1.38	.176
SFA stairs	2.00	24	68.00	23.80		
SFA stairs	1.00	20	19.35	5.12	-1.08	.287
SFA total	2.00	24	20.75	3.44		
SFA total	1.00	20	297.20	43.14	1.48	.146

*denotes a significant result at $p < 0.05$

Based on the PI's practice experience, School 2 appeared to have children with more complex needs compared to School 1, and the results support that perception. School 2 required more time to complete the TUG and had lower scores on the SFA; both indicating poorer performance.

Age, Height, & Weight

It was also of interest if there was a relationship between subjects' age, height, and weight to scores on the SFA and m-EFAP and their respective subtasks. The Spearman Rho Correlations are presented in Table V. A review of this table reveals that the relationship of the TUG subtask of the m-EFAP was significantly related to age, $r(42) = .313$, $p = .038$, indicating as age increased so did scores on the TUG subtask of the m-EFAP. In addition, as subjects' height increased, their scores on the SFA Stairs subtask decreased, $r(42) = -.404$, $p = .007$. No other subtasks of the m-EFAP or the SFA were related to subjects' age, height, and weight (all $p < .05$).

Table V

Spearman Rho Correlations between Subjects' Age, Height and Weight and Scores on the Subtasks of the m-EFAP and SFA

		age	height	weight
Floor	Correlation Coefficient	-.135	.113	-.154
	Sig. (2-tailed)	.382	.464	.319
Carpet	Correlation Coefficient	.062	.275	.054
	Sig. (2-tailed)	.690	.071	.727
TUG	Correlation Coefficient	.313*	.228	.082
	Sig. (2-tailed)	.038*	.137	.597
Obstacles	Correlation Coefficient	.157	.206	.090
	Sig. (2-tailed)	.310	.180	.559
Stairs	Correlation Coefficient	.006	.130	-.011
	Sig. (2-tailed)	.969	.400	.943
Total	Correlation Coefficient	.112	.265	.119
	Sig. (2-tailed)	.470	.083	.441
Travel	Correlation Coefficient	-.260	-.141	-.139
	Sig. (2-tailed)	.088	.362	.367
Position	Correlation Coefficient	-.291	-.041	.078
	Sig. (2-tailed)	.055	.794	.616
Recreation	Correlation Coefficient	-.246	-.137	-.115
	Sig. (2-tailed)	.107	.377	.457
Manip	Correlation Coefficient	-.250	-.184	-.038
	Sig. (2-tailed)	.102	.232	.805
Materials	Correlation Coefficient	-.227	-.091	-.058
	Sig. (2-tailed)	.138	.555	.709
SFA stairs	Correlation Coefficient	-.027	-.404*	-.291
	Sig. (2-tailed)	.862	.007*	.055
SFA total	Correlation Coefficient	-.259	-.161	-.131
	Sig. (2-tailed)	.089	.298	.396

*denotes a significant result at $p < 0.05$

Results Summary

The first research question and hypothesis asked if the Total Scores on the m-EFAP and the SFA would correlate. The results of this study indicated they were not statistically significant and thus the hypothesis was rejected. There is no significant relationship between the m-EFAP and SFA Total Scores.

The second research question and hypotheses evaluated whether the m-EFAP subtasks moderately correlated with the AP categories of the SFA. Findings were statistically significant, indicating there is a significant relationship between a majority of the m-EFAP subtasks and the AP categories of the SFA. There was a moderate correlation of the m-EFAP Floor subtask with the SFA Stairs, and the m-EFAP Obstacles subtask with the SFA AP Maintaining and Changing Position category. There were weak but significant correlations of the m-EFAP Total Scores with SFA AP Maintaining and Changing Position category, and the m-EFAP Obstacles subtask with SFA AP categories of Travel, Maintaining and Changing Position, and Total Scores. A surprising finding was that the m-EFAP TUG subtask correlated with all of the SFA AP categories except stairs: Travel, Maintaining and Changing Position, Recreation Movement, Using Materials, Manipulation with Movement and Total Scores.

There were no significant differences between male and female students. There was a positively significant relationship of age to the TUG subtask with no relationship to weight, and a negatively significant relationship of height on the SFA Stairs.

On average, subjects in School 1 scored lower than subjects in School 2 on the TUG, and performed more poorly on the Maintaining and Changing Positions category of the SFA.

Chapter V

DISCUSSION

The literature, Dynamic Systems Theory and pilot study results suggest a relationship between the m-EFAP and the SFA. This relationship therefore supports validity of using the m-EFAP in the school-age population. However, the results of this study do not substantiate that premise.

Underlying constructs of the m-EFAP, a quantitative, objective outcome measure of functional mobility across five environmentally challenging settings, support current *standards of practice* and *federal regulations* for quality and payment policies. It is reasonable to consider the m-EFAP further as an ideal measure in the school-aged population, as it contains challenging tasks that students *typically encounter* in a *dynamic school environment*. Additionally, it fulfills the definition of FM as defined for this study and addresses the lack of environmental contexts noted in the literature.

The purpose of this dissertation study is to determine convergent validity of the m-EFAP with the AP subsection of the SFA, based on the assumption that m-EFAP constructs are similar to the SFA-AP subsection. Convergent validity refers to the observation of strong correlations between two tests that are assumed to measure the same construct, with correlation being the lowest level in the process of validating a tool (Portney & Watkins, 1993).

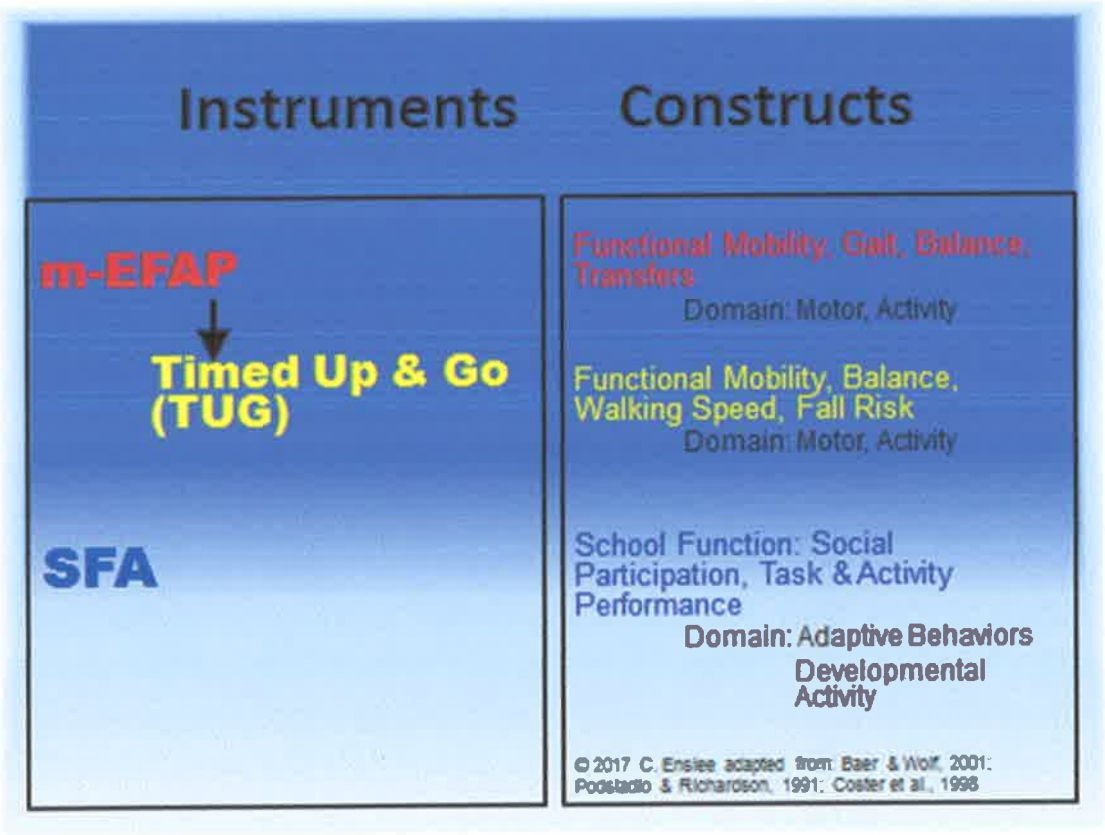
Based on the pilot study, conducted several years prior to this dissertation research, there are promising moderate to strong correlations (r = .73 to .89) found among the m-EFAP subtasks, and Total Scores with the SFA AP subsection in children aged 5-7 years old with non-specific motor and learning delays (Enslee & Simpkins, 2007). Thus, the intention here is to use the pilot results as a starting point to further study the suitability of using the m-EFAP with regard to the larger school-aged population of 5-11 year-olds with a narrow and specific diagnosis of Developmental Motor Delay and a larger sample size.

While results of this current study do not support the validity of the m-EFAP; it has uncovered a weak to moderate correlation of the m-EFAP with the SFA based on the assumption that both the m-EFAP and the SFA were measuring the same construct.

Upon further consideration of the results, it becomes apparent when referring back to the constructs of each instrument, that both the m-EFAP and the TUG focus on motor and activity domains, while the SFA looks at multiple domains with several levels, including adaptive behavior, development and activity (Wolf et al., 1999; Podsiadlo & Richardson, 1991; Coster et al., 1998).

Table VI

Instrument Constructs



© 2017 C. Enslee adapted from: Baer & Wolf, 2001; Podsiadlo & Richardson, 1991; Coster et al., 1998.

In light of this new information, the old pilot results have been reconsidered. At that point in the pilot study, the m-EFAP demonstrated moderate to strong correlations with the SFA. This observation may very well have been due to the much broader definition of a population with non-specific motor and learning delays. The studied population could have included students with adaptive behaviors and developmental issues for which the m-EFAP might have been sensitive to picking up during the pilot study.

Additional research will need to be conducted to further evaluate convergent validity of the m-EFAP with a measure containing more appropriate or similar constructs; at least when evaluating a population of children having DD.

Timed Up & Go (TUG):

A Complex Tool Provides Value in Assessing Functional Mobility

This study provides additional valuable information. Looking at Figure 5, it is evident that three of the m-EFAP subtasks correlate with four AP categories of the SFA as seen in purple.

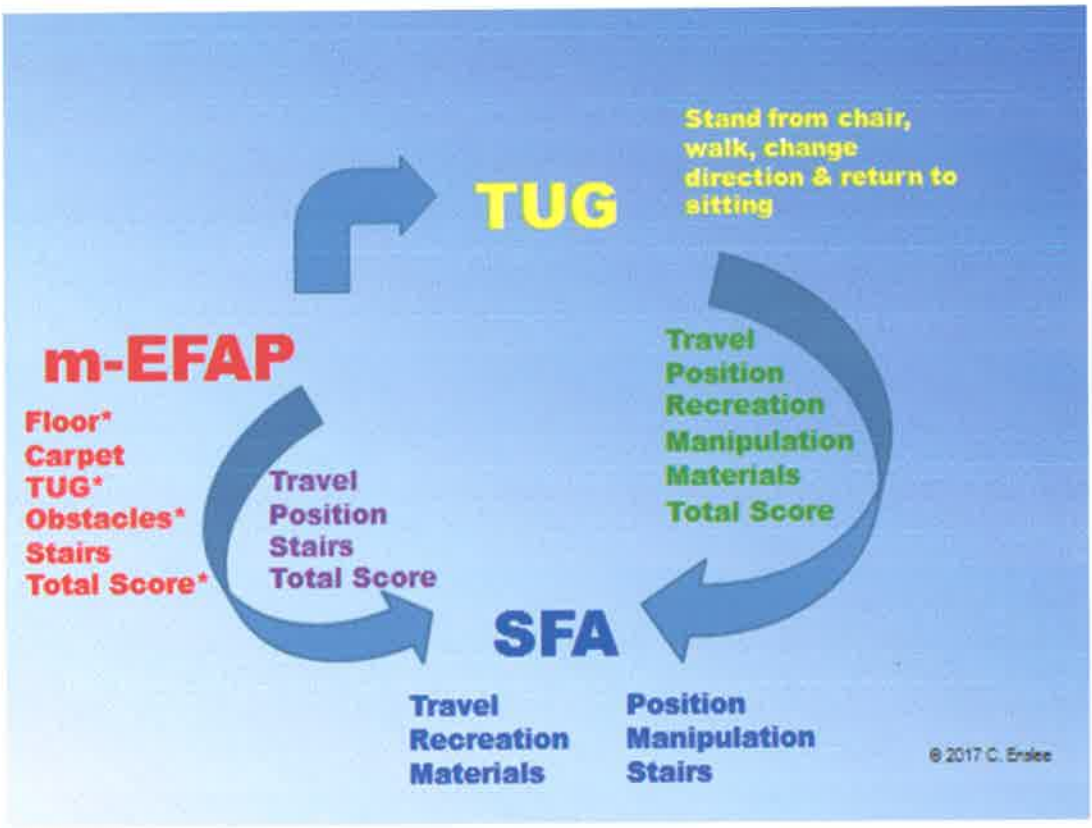


Figure 5. Correlation Between Tools. When the TUG is examined independently, it correlates with all of the SFA Activity Performance categories except Stairs.

Yet, if the TUG is removed from the m-EFAP and examined as an independent tool, it becomes clear that it correlates with all of the SFA items except stairs, as noted in green. At a quick glance, the TUG appears to be a very simple test that lacks robustness. However, when the component parts are broken down, it becomes apparent that the TUG is quite complex. The TUG is comprised of a series of integrated movements: requiring a child to rise from a chair, walk a prescribed distance, perform a speed-dependent change in direction, and return to sitting. These are all activities which are performed frequently at school. For a child to be functionally independent at school, it is critical to have sophisticated control of balance and movement throughout planning, execution and completion of an integrated sequence of movements such as those presented by the TUG (Williams et al., 2005). For these reasons, the TUG is commonly cited as a measure of functional mobility, balance, and postural stability (Podsiadlo & Richardson, 1991; Shumway-Cook et al., 2000; Habib et al., 1999; Westcott et al., 1997).

Although the SFA is a well-developed measure of school function, it can be time consuming and costly to complete, whereas, the TUG is quick and easy to administer, and is cost effective, requiring no special equipment, and yields similar information to the SFA. Based on the correlation of the TUG with all items on the SFA, it is acceptable to say that the TUG may be considered an appropriate *screening tool* for the school therapist.

At this time, it is important to point out that the TUG should only be used as a screening tool. For therapists, screening is a process of identifying

individuals from a larger group based on a specific characteristic (i.e. motor delays) to determine the need for a more detailed evaluation and establish which students require special education and related services in the school (CDC, n.d.). Therapists are experts in identifying functional deficits related to neurological, musculoskeletal and sensorimotor systems, and should be participating in screenings (APTA, House of Delegates, 2000).

According to the APTA (2014), a physical therapist's evaluation or assessment is a process of gathering detailed information to identify specific movement related functional limitations, establish a diagnosis and prognosis, and develop a specific treatment plan meeting an individual's needs. Typically, evaluative tools are selected to provide the most meaningful information about a functional limitation in the most efficient manner possible. While research has shown the TUG to discriminate between persons with and without balance and mobility deficits, measuring only the time taken to complete the cycle of tasks (stand, walk, change direction, sit) neglects to provide specific information for the clinician about which component part of the TUG the student was having difficulty (Podsiadlo & Richardson, 1991; Shumway-Cook, Baldwin, Polissar & Gruber, 1997; Shumway-Cook, Brauer & Woollacott, 2000; Wall, Bell, Campbell, & Davis, 2000; Faria, Teixeira-Salmela, Silva & Nadeau, 2012; Botolfsen, Helbostad & Wall, 2006; Botolfsen, Helbostad & Moe-Nilssen, et al. 2008).

While the TUG is quick and cost efficient, and given these current limitations, the TUG should not be used as an evaluation or assessment tool.

Nevertheless, *it may be used in combination with other valid tools* to provide more detailed information which contributes toward an evaluation process. In spite of this, the TUG does offer pediatric therapists a practical screening tool for use in the school setting.

It is surprising to find that the TUG is actually a complex tool which provides more value in assessing Functional Mobility than initially assumed and warrants further research in the pediatric population.

Informed Decision Making:

Selecting Outcome Measures

While there has been an unanticipated finding that the TUG is applicable in a population of school-aged children, there remains a distressing fact for the clinician. Therapists still have *no one tool* which captures FM as defined by DST or addresses all of the conceptual measures of mobility, that is efficient, cost effective and meets federal requirements and practice standards (see Figure 6).

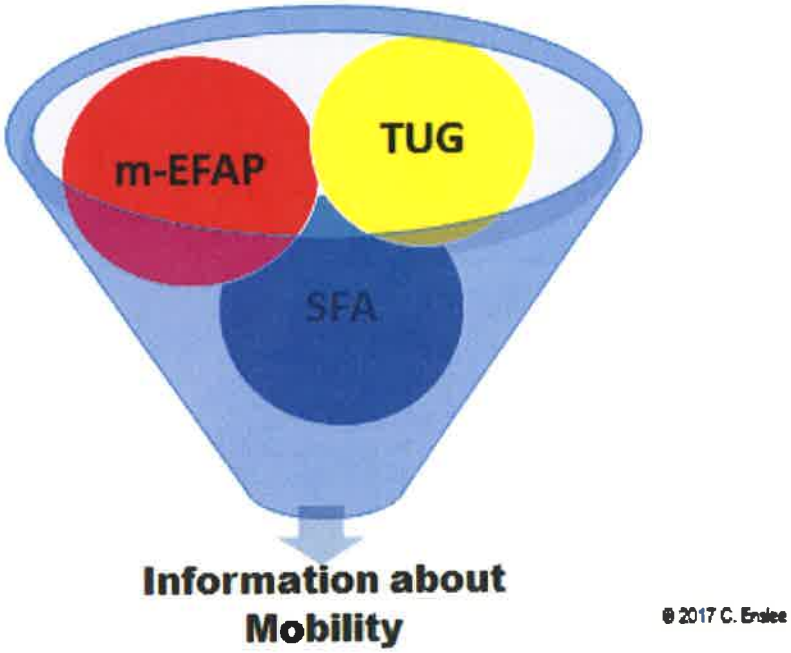


Figure 6. All Three Tools Have Value. Each tool holds value in contributing information about mobility

Therefore, the intention is to use such a tool as the TUG to facilitate the process for the therapist in meeting guidelines for objective functional outcome measures focused on patient centered care, rather than picking and choosing pieces of many different tools to suit the therapist's needs. Using only parts of a standardized test, or not completing it according to protocol, only dilutes the test's validity.

As discussed from the very beginning, an ideal outcome measure must be valid and reliable (Portney & Watkins, 2001):

1. The therapist must understand the purpose of a test

   (Is it really measuring FM?)

2. When should it be used?

   (For screening OR detailed evaluation)

   (In a school setting OR a larger everyday setting)

3. Is it appropriate for the population of interest?

   (School-age children w/ DD)

The evidence now supports the idea of informed decision making for the clinician. The process is easily understood when examining a decision tree (see Figure 7).

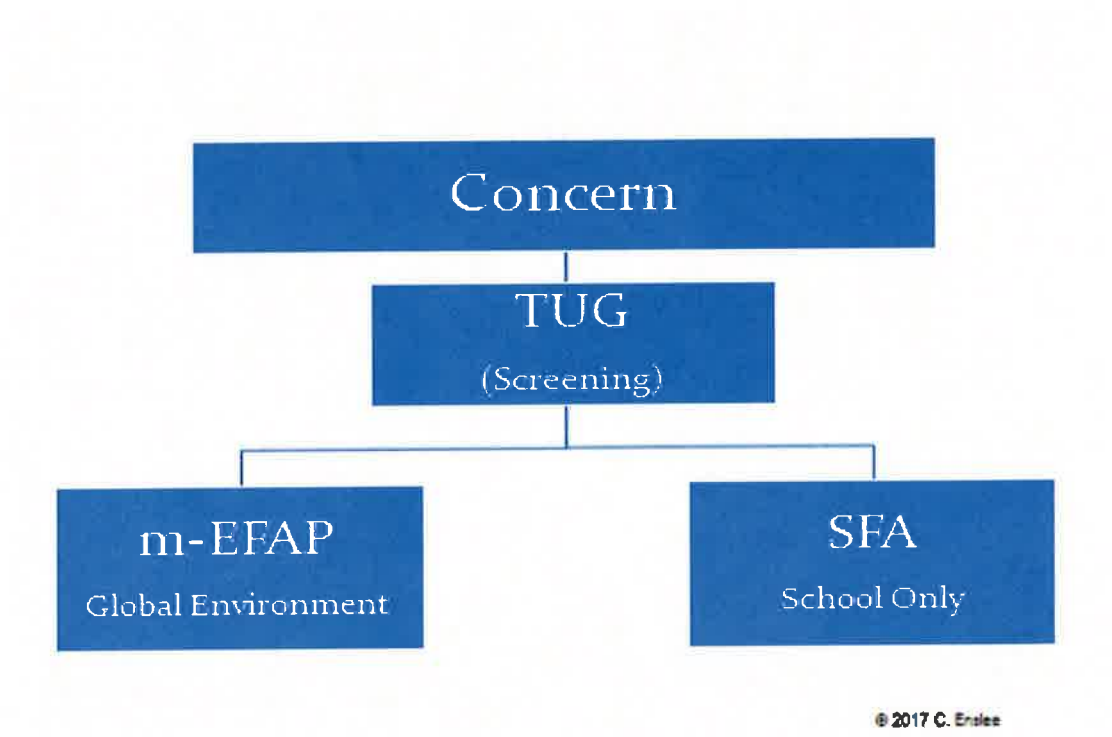


Figure 7. Decision Tree. A key contribution of this study is the idea of informed decision-making, depending on the purpose and setting of interest.

In Figure 7, the first box represents a question of mobility issues, for example, from a parent or teacher labeled as Concern. A quick screen, using the TUG, now identifies individual students who indeed do have a motor delay. These students are referred for a more comprehensive evaluation to establish eligibility for school-related services. Either the m-EFAP or SFA might be selected as evaluative tools to assess detailed and specific functional limitations in order to develop a student-centered plan of care. Selection of the m-EFAP or the SFA is based on whether the intention is to assess Functional Mobility versus School Function as well as the relevant setting of a more global environment versus only the school.

Greenhalgh et al., (2008) explored multidisiplinary teams' use of knowledge and standardized outcome measures in decision making. They concluded that clinical judgments were supported by standarized outcome measures rather than driven by them. As mentioned in the introduction, physical therapists must demonstrate the value and skill of what they provide in order to remain viable in the changing helathcare climate. One of the primary purposes of an outcome measure is to document efficiency and effectivness of therapeituc interventions. This requires therapists to implement informed decision-making and evidence-based practice (EBP): a process of using the best available evidence from the research to make clinical decisions, in this case for selecting an appropriate outcome measure (APTA, 2000; Jette, Bacon, Batty, et al. 2003). For example, a survey of APTA members reports an overall positive attitude toward EBP, but

infrequent application of the literature to guide decisions (Jette, et al. 2003). Most physcial therapists use clincial judgments to make decisions about effective treatment, using standardized outcome measures only when necessary (Greenhalgh, Flynn, Long & Tyson, 2008; McGinnis, Hack, Nixon-Cave & Michlovitz, 2009).

However, as a doctoring profession, physical therapists have a duty to implement this process of informed decision-making on a regular basis. It is the goal of the profession to foster EBP and informed clinical decision-making (McGinnis, 2009). This study contributes a piece of information to that end, providing for differential use of these three measures.

Chapter VI

CONCLUSION

Practical/Clinical Applications

This study provides several practical and clinical applications for pediatric physical therapists in selecting the TUG as a screening tool, as it:

- Correlates with the SFA
- Is quick, efficient, cost effective, and timely; making it a practical choice in the school setting
- Addresses a mobility task related to function and participation the school setting
- Is more likely to be accepted and shared with occupational therapists

While this study reveals new information about the TUG, it really provides evidence to support informed decision making. It is not simply about finding one tool, but understanding that other tools have value depending on the purpose and population of interest.

Limitations

As with most studies, the current research presented a number of limitations. The following highlights should be considered opportunities for future avenues of research.

Generalizability

As with most research studies there is a limitation of generalizability. Two private educational settings in North-Central New Jersey granted access to subjects and testing facilities. This limits geographical accessibility and generalizability to broader regional influences or cultures. Additionally, the relatively small sample size precludes making inferences about study results to the larger population of children with DD, nor can it be generalized to populations of other ages or diagnoses. Future research should consider a larger cross-regional sample size with varying diagnostic criteria.

Threat to Accuracy of Responses

In Chapter III under Instruments, the SFA is described as a judgment-based questionnaire. Therefore, by design, the SFA leaves open the possibility for personal influences. There was a very real and possible threat to the accuracy of responses on the SFA due to a teacher's perception of the student, his/her needs, social situation, or entitlement to services. While SFA administration cannot be changed, this current research has already raised awareness of the need for more objective outcome measures.

Sampling

A purposive sampling technique was implemented with subjects between the ages of 5-11 being recruited from only one of two private schools for children with special needs. Subjects also had to meet the very specific diagnostic criteria for developmental motor delay set forth by the ICD-10 and

DSM-V (WHO, 2015; APA, 2013). Reaching an appropriate sample size was challenging given these parameters, and even more so when potential subjects were eliminated for having other medical diagnoses or cognitive impairments. These factors decrease variability of subjects and, in turn, generalizability.

Other methods for sampling discussed during planning stages, including snowball sampling from regional associations, foundations, and organizations assisting families with children having special needs, would have provided greater variability of subjects over a larger region, and expanded generalizability.

While some may raise the question: Why not change the study design, or why study this particular "protected population"? One only needs to look back at the literature. All persons, including children, are entitled to effective and efficient, functionally based, patient centered care. Based on the literature reviewed, there needs to be more timely research improving and developing objective outcome measures for children with diagnoses beyond cerebral palsy, traumatic brain injury, or Down syndrome. Children who have functional limitations that are not as visible or apparent, such as those with Autism spectrum disorder, DD, or Clumsy Child syndrome, would benefit from related services; however, very few outcome measures address these subtle diagnostic populations (Academy of Pediatric Physical Therapy, 2014).

Future Directions

The aim of this study was to seek out an appropriate objective, quantitative, functionally based outcome measure for the pediatric population that met practice standards and federal regulations. In the literature, there has been no one tool which meets these requirements and assesses FM with the task and environmental contexts in mind, as defined by DST.

Future research should continue to evaluate and expand validity of the m-EFAP in the pediatric population. Instruments such as the Dynamic Gait Index or the BESTest might more accurately represent constructs similar to the m-EFAP; thus; revealing more accurate information for working with a population having DD (Shumway-Cook, Taylor, Matsuda, Studer & Whetten, 2013; Horak, Wrisley & Frank, 2009).

Further research should be considered in exploring the relationship between the m-EFAP and the SFA, in children having learning disabilities or Autism spectrum disorders. Given the discrepancy in findings obtained between the pilot study involving a broad population of children with non-specific delays, and the current research involving the very narrow diagnosis of DD, the question arose as to whether the m-EFAP was picking up on some of the same social-adaptive issues as the SFA in the broader sample population. Children having dominant auto-regulation or sensorimotor issues may benefit from physical therapy related services to assist in improving

school function (Academy of Pediatric Physical Therapy, 2014). Physical therapy services for these students may be underutilized, since their motor-related issues are subtle in comparison to their cognitive-social supports or adaptive behavioral needs. The benefits of a tool as such as the m-EFAP that could tease out mobility components could be invaluable to this school population and useful for therapists.

While children with uncorrected vision or hearing impairments were excluded from this study, research exploring the possibility of using the m-EFAP with such populations should be pursued. In view of the DST, a case could be made that for those who are visually or hearing impaired, a world without sight or sound is indeed their daily environment. It is reasonable to expect that this population might have an even greater need for related services when it comes to safe functional mobility.

Expanding the conditions under which the m-EFAP can be appropriately used, including outpatient clinics, acute medical, or sports settings, may reveal additional insight into the m-EFAP's true attributes and provide for deeper value and broader application.

The TUG warrants further research in a wider pediatric population with varying diagnoses, in view of the unexpected findings that it is actually a complex tool which provides more value in assessing FM than initially assumed. This will be particularly important since many research studies continue to focus on children having diagnoses of cerebral palsy (Williams et al., 2005).

Additionally, to build on the valid use of the TUG as a screening tool in this population, the ability to discriminate between students with and without functional mobility delays should be assessed using sensitivity and specificity testing. As with the m-EFAP, future research must focus on convergent validity of the TUG with other measures. Studies involving the elderly at risk for falls and those with stroke have re-visited the TUG to evaluate measuring the component parts, and similar studies involving children should also be considered (Faria et al., 2012; Wall et al., 2000).

Significance of the Dissertation Study

While national healthcare changes demand objective patient-centered care and outcome measures for quality and payment initiatives, there is still a distinct need to develop, improve and expand functional outcome measures for children, to ensure this protected population is truly receiving quality care.

Recall that this is the first study to look at the validity of the m-EFAP in children with DD. Physical therapists face many choices when it comes to functional outcome measures, but few of these measures address the requirements of federal regulations. In practice, physical therapists are stringent in their approach to care, and tend to use what they know, or what seems to work. However, without a standardized, objective outcome measure, it becomes difficult to track progress toward functional patient goals in a comprehensive and systematic manner.

Evidence-based practice and informed decision-making are core values of the American Physical Therapy Association (APTA, 2000). However, the challenge becomes persuading clinicians to use informed decision-making when selecting objective outcome measures of functional mobility which support the value of the services provided by therapists.

In order to remain viable in this changing healthcare system, therapists have a responsibility to conduct more timely and up-to-date research in the pediatric population. Steps must be taken to inform other colleagues, the public, and the government of the importance of research to quality patient-centered care. An incentive to encourage more research in the pediatric population is essential to expanding the pool of quality research available.

In a sense, by not conducting timely, quality research, there is greater potential for harm to this protected population. Without the research, can it be said that therapists are providing the best quality care? Looking back over the past decade, there really has not been any ground-breaking research that has changed how we approach and treat children. By expanding the research, therapists will gain new knowledge and thus more power to support our skilled role in providing efficient and effective patient treatments.

As the government continues to review healthcare mandates, someone needs to take a stand and influence them to consider an incentive to encourage more research in the pediatric population.

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APPENDICES

APPENDIX A

Proposal Hearing Sign-Off Sheet

SETON HALL UNIVERSITY
1 8 5 6

PROPOSAL HEARING SIGN OFF SHEET

DOCTORAL CANDIDATES NAME: Cheryl Enslee

PROJECT TITLE: The Modified Emory Functional Ambulation Profile: Convergent Validity in 5-7 Year Olds

PROPOSAL HEARING DATE: June 5, 2014

I HAVE PARTICIPATED IN THE ABOVE NOTED PROPOSAL HEARING AND MY SIGNATURE PROVIDES SUPPORT OF THE PROPOSED METHODOLOGY.

DISSERT. COMMITTEE CHAIR: Deborah DeLuca
COMMITTEE MEMBER SIGNATURE:

DISSERTATION COMMITTEE MEMBER: Terrence Cahill
CHAIR'S SIGNATURE:

DISSERT. COMMITTEE MEMBER: Genevieve Pinto Zipp
COMMITTEE MEMBER SIGNATURE:

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APPENDIX B

Seton Hall University Institutional Review Board (IRB) Approvals

B1. (2/5/15) Request for Approval of Research, Demonstration, or Related Activities Involving Human Subjects

B2. (2/5/15) Letter from Seton Hall IRB Approving Research Protocol

B3. (6/24/15) Letter from Seton Hall IRB Approving Amendments to Research Protocol

B4. (2/1/16) Letter from Seton Hall IRB Approving 2nd Amendment to Research Protocol

B5. (11/22/16) Continuing Review Approval from Seton Hall IRB; Extending Approval for 12 Months for Data Analysis Only

APPENDIX B1.

(2/5/15) Request for Approval of Research, Demonstration, or Related Activities Involving Human Subjects

REQUEST FOR APPROVAL OF RESEARCH, DEMONSTRATION OR RELATED ACTIVITIES INVOLVING HUMAN SUBJECTS

All material must be typed.

PROJECT TITLE: The modified Emory Functional Ambulation Profile: Convergent validity in 5-7 year olds

CERTIFICATION STATEMENT:

In making **this application,** I(we) certify that I(we) have read and understand the University's policies and procedures governing research, development, and related activities involving human subjects. I (we) shall comply with the letter and spirit of those policies. I(we) further acknowledge my(our) obligation to (1) obtain written approval of significant deviations from the originally-approved protocol BEFORE making those deviations, and (2) report immediately all adverse effects of the study on the subjects to the Director of the Institutional Review Board, Seton Hall University, South Orange, NJ 07079.

Cheryl A. Enslee, PT, DPT — 11/13/14

RESEARCHER(S) OR PROJECT DIRECTOR(S) — DATE

Please print or type out names of **all researchers below signature.
Use separate sheet of paper, if necessary.**

My signature indicates that I have reviewed the attached materials and consider them to meet IRB standards.

Dr. Deborah DeLuca — 11/13/2014

\RESEARCHER'S ADVISOR OR DEPARTMENTAL SUPERVISOR — DATE

Please print or type out name below signature

The request for approval submitted by the above researcher(s) was considered by the IRB for Research Involving Human Subjects Research at the Dec. 2014 meeting.

The application was approved ✓ not approved ___ by the Committee. Special conditions were ___ were not ✓ set by the IRB. (Any special conditions are described on the reverse side.)

Mary J. Ruzicka, Ph.D — 2/5/15

DIRECTOR,
SETON HALL UNIVERSITY INSTITUTIONAL
REVIEW BOARD FOR HUMAN SUBJECTS RESEARCH — DATE

APPENDIX B2

(2/5/15) Letter from Seton Hall IRB

Approving Research Protocol

OFFICE OF INSTITUTIONAL
REVIEW BOARD
SETON HALL UNIVERSITY

February 5, 2015

Cheryl A. Enslee

Dear Ms. Enslee,

The Seton Hall University Institutional Review Board has reviewed the information you have submitted addressing the concerns for your proposal entitled "The Modified Emory Functional Ambulation Profile: Convergent Validity in 5-7 Year Olds." Your research protocol is hereby approved as revised under full review.

Enclosed for your records are the signed Request for Approval form, the stamped Oral Assent form, and the stamped original Consent Form. Make copies only of these stamped forms.

The Institutional Review Board approval of your research is valid for a one-year period from the date of this letter. During this time, any changes to the research protocol must be reviewed and approved by the IRB prior to their implementation.

According to federal regulations, continuing review of already approved research is mandated to take place at least 12 months after this initial approval. You will receive communication from the IRB Office for this several months before the anniversary date of your initial approval.

Thank you for your cooperation.

In harmony with federal regulations, none of the investigators or research staff involved in the study took part in the final discussion and the vote.

Sincerely,

Mary F. Ruzicka, Ph.D.

Mary F. Ruzicka, Ph.D.
Professor
Director, Institutional Review Board

cc: Dr. Deborah DeLuca

Please review Seton Hall University IRB's Policies and Procedures on website (http://www.provost.shu.edu/IRB) for more information. Please note the following requirements:

Adverse Reactions: If any untoward incidents or adverse reactions should develop as a result of this study, you are required to immediately notify in writing the Seton Hall University IRB Director, your sponsor and any federal regulatory institutions which may oversee this research, such as the OHRP or the FDA. If the problem is serious, approval may be withdrawn pending further review by the IRB.

Amendments: If you wish to change any aspect of this study, please communicate your request in writing (with revised copies of the protocol and/or informed consent where applicable and the Amendment Form) to the IRB Director. The new procedures cannot be initiated until you receive IRB approval.

Completion of Study: Please notify Seton Hall University's IRB Director in writing as soon as the research has been completed, along with any results obtained.

Non-Compliance: Any issue of non-compliance to regulations will be reported to Seton Hall University's IRB Director, your sponsor and any federal regulatory institutions which may oversee this research, such as the OHRP or the FDA. If the problem is serious, approval may be withdrawn pending further review by the IRB.

Renewal: It is the principal investigator's responsibility to maintain IRB approval. A Continuing Review Form will be mailed to you prior to your initial approval anniversary date. **Note:** No research may be conducted (except to prevent immediate hazards to subjects), no data collected, nor any subjects enrolled after the expiration date.

In harmony with federal regulations, none of the investigators or research staff involved in the study took part in the final discussion and the vote.

APPENDIX B3

(6/24/15) Letter from Seton Hall IRB

Approving Amendments to Research Protocol

SETON HALL UNIVERSITY
1 8 5 6

June 24, 2015

Cheryl A. Enslee

Dear Ms. Enslee,

The IRB hereby approves the requested amendments to your research protocol "The Modified Emory Functional Ambulation Profile: Convergent Validity in 5-7 Year Olds" to:

1. extend the protocol to include children ages 5-11;
2. adapt the title as appropriate.

Sincerely,

Mary F. Ruzicka, Ph.D.

Mary F. Ruzicka, Ph.D.
Professor
Director, Institutional Review Board

cc: Dr. Deborah DeLuca

Please review Seton Hall University IRB's Policies and Procedures on website (http://www.provost.shu.edu/IRB) for more information. Please note the following requirements:
Adverse Reactions: If any untoward incidents or adverse reactions should develop as a result of this study, you are required to immediately notify in writing the Seton Hall University IRB Director, your sponsor and any federal regulatory institutions which may oversee this research, such as the OHRP or the FDA. If the problem is serious, approval may be withdrawn pending further review by the IRB.
Amendments: If you wish to change **any** aspect of this study, please communicate your request in writing (with revised copies of the protocol and/or informed consent where applicable and the Amendment Form) to the IRB Director. The new procedures cannot be initiated until you receive IRB approval.
Completion of Study: Please notify Seton Hall University's IRB Director in writing as soon as the research has been completed, along with any results obtained.
Non-Compliance: Any issue of non-compliance to regulations will be reported to Seton Hall University's IRB Director, your sponsor and any federal regulatory institutions which may oversee this research, such as the OHRP or the FDA. If the problem is serious, approval may be withdrawn pending further review by the IRB.
Renewal: It is the principal investigator's responsibility to maintain IRB approval. A Continuing Review Form will be mailed to you prior to your initial approval anniversary date. **Note:** No research may be conducted (except to prevent immediate hazards to subjects), no data collected, nor any subjects enrolled after the expiration date.

APPENDIX B4

(2/1/16) Letter from Seton Hall IRB

Approving 2nd Amendment to Research Protocol

OFFICE OF INSTITUTIONAL REVIEW BOARD
SETON HALL UNIVERSITY

February 1, 2016

Cheryl A. Enslee

Dear Ms. Enslee,

The Seton Hall University Institutional Review Board has reviewed your Continuing Review application for your research proposal entitled "The Modified Emory Functional Ambulation Profile: Convergent Validity in 5-11 Year Olds."

You are hereby granted another 12-month approval, effective February 5, 2016. Your new stamped Consent Form and Assent Form are enclosed.

The IRB also hereby approves the requested amendments to your research protocol to:

1. Remove the Deron School of New Jersey, Inc. as a performance site;
2. Add the Phoenix Center as a performance site.

If any changes are desired in this protocol, they must be submitted to the IRB for approval before implementation.

Thank you for your cooperation.

Sincerely,

Mary F. Ruzicka, Ph.D.

Mary F. Ruzicka, Ph.D.
Professor
Director, Institutional Review Board

cc: Dr. Deborah DeLuca

Presidents Hall • 400 South Orange Avenue • South Orange, New Jersey 07079-2641 • Tel: 973.313.6314 • Fax: 973.275.2361

Please review Seton Hall University IRB's Policies and Procedures on website (http://www.provost.shu.edu/IRB) for more information. Please note the following requirements:

Adverse Reactions: If any untoward incidents or adverse reactions should develop as a result of this study, you are required to immediately notify in writing the Seton Hall University IRB Director, your sponsor and any federal regulatory institutions which may oversee this research, such as the OHRP or the FDA. If the problem is serious, approval may be withdrawn pending further review by the IRB.

Amendments: If you wish to change **any** aspect of this study, please communicate your request in writing (with revised copies of the protocol and/or informed consent where applicable and the Amendment Form) to the IRB Director. The new procedures cannot be initiated until you receive IRB approval.

Completion of Study: Please notify Seton Hall University's IRB Director in writing as soon as the research has been completed, along with any results obtained.

Non-Compliance: Any issue of non-compliance to regulations will be reported to Seton Hall University's IRB Director, your sponsor and any federal regulatory institutions which may oversee this research, such as the OHRP or the FDA. If the problem is serious, approval may be withdrawn pending further review by the IRB.

Renewal: It is the principal investigator's responsibility to maintain IRB approval. A Continuing Review Form will be mailed to you prior to your initial approval anniversary date. **Note:** No research may be conducted (except to prevent immediate hazards to subjects), no data collected, nor any subjects enrolled after the expiration date.

In harmony with federal regulations, none of the investigators or research staff involved in the study took part in the final discussion and the vote.

APPENDIX B5

(11/22/16) Continuing Review Approval from Seton Hall IRB

Extending Approval for 12 Months for Data Analysis Only

OFFICE OF INSTITUTIONAL
REVIEW BOARD
SETON HALL UNIVERSITY

November 22, 2016

Cheryl A. Enslee

Dear Ms. Enslee,

The Seton Hall University Institutional Review Board has reviewed your Continuing Review application for your research proposal entitled "The Modified Emory Functional Ambulation Profile: Convergent Validity in 5-11 Year Olds".

You are hereby granted another 12-month approval, effective February 5th, 2016 **for data analysis only.**

If any changes are desired in this protocol, they must be submitted to the IRB for approval before implementation.

Thank you for your cooperation.

Sincerely,

Mary F. Ruzicka, Ph.D.

Mary F. Ruzicka, Ph.D.
Professor
Director, Institutional Review Board

cc: Prof. Deborah DeLuca

Presidents Hall • 400 South Orange Avenue • South Orange, New Jersey 07079-2641 • Tel: 973.313.6314 • Fax: 973 275 2361

APPENDIX C

Letter of Solicitation

Dear Parents/ Guardians,

My name is Dr. Cheryl Enslee. I am a licensed physical therapist in New Jersey. I am a student at Seton Hall University's School of Health and Medical Science. I am working toward my Ph.D. in Health Sciences under the Department of Interprofessional Health Sciences and Administration. I am doing a study. I need children between the ages of 5-11 with Developmental Motor Delay. This does not include children with intellectual disability, uncorrected vision or hearing problems, and specific medical diagnoses (cerebral palsy, muscular dystrophy, degenerative disorders). Your school has agreed to take part.

The purpose of my study is to find out if an adult test of balance and walking gives the same results in children with Developmental Motor Delay.

This study will take about ten minutes.

The study will take place in the child's school. A teacher or aide will be in the room, so the child will feel comfortable. Height and weight will be measured.

Students will complete the *modified Emory Functional Ambulation Profile*. Each student will walk on the hard floor and carpet. They will walk through an obstacle course (stepping over and around brightly colored cardboard boxes) and climb some steps. The researcher will walk next to the student. Time to complete each item will be noted on coded forms.

The researcher will read questions from the *School Function Assessment* to the teacher. These questions ask about how well a child moves at school. For instance, "Does the student walk through doorways; Run without falling; or Carry small objects?" A scale of (1-4) is used; with (1) indicating, "Does not perform" and (4) indicating "Consistent performance".

Your child is free to choose to take part in this study. Parents, guardians or the student may refuse to take part or stop at any time. There will be no problem with choosing not to participate or stopping.

All identifying data will be kept private and unknown. Names will be coded with numbers.

Data will be locked and stored apart from the codes. All information will be destroyed three years after the study is finished.

If you would like to give permission for the researcher to ask your child whether he/ she would like to take part, please read and sign the attached forms. Please read the Assent to your child. Have your child mark their desire to join the study. Return all forms in the supplied envelope to the school Secretary.

If you have any questions or concerns, I may be contacted at (973) 275-2076 or by E-mail at: Cheryl.Enslee@shu.edu. Thank you for thinking about taking part in this study.

Sincerely,
Cheryl A. Enslee, PT, DPT

APPENDIX D

Parent/Legal Guardian Informed Consent Form

SETON HALL UNIVERSITY
1 8 5 6

Informed Consent Form

Researcher's Background

Dr. Cheryl Enslee is a licensed physical therapist. She is a student at Seton Hall University's School of Health and Medical Science. She is working toward a Ph.D. in Health Sciences under the Department of Interprofessional Health Sciences and Administration.

Purpose & Duration

The purpose of this study is to find out if an adult test of balance gives the same results in children with Developmental Motor Delay. This does not include children with intellectual disability, uncorrected vision or hearing problems, or specific medical diagnoses (cerebral palsy, muscular dystrophy, degenerative disorders). This study will take about ten minutes.

Procedures

The study will take place in the child's school. A teacher or aide will be in the room so the child will feel comfortable. The student will be read the Assent form to be sure they still wish to join the study. Only if the student agrees will the process move forward. Height and weight will be measured.

Students will complete the *modified Emory Functional Ambulation Profile*. Each student will walk on the hard floor and carpet. They will walk through an obstacle course (over and around brightly colored cardboard boxes) and climb some steps. The researcher will walk next to the student. Time to complete each item will be noted on coded forms.

The researcher will read each item on the *Activity Performance* section of the *School Function Assessment* to the student's teacher. It asks, 'How well does a student move across the classroom?' Answers will be marked on coded forms.

Tools

The *modified Emory Functional Ambulation Profile* is a timed test of walking ability. It has five parts. It checks how a student walks over a hard floor, carpet, rises from a chair, steps over and around a box, and climbs steps. Help is given as needed. These tasks are found in daily school activities.

The *School Function Assessment* looks at how a student performs activities at school. The questions look at moving about the lunchroom, playground, and classroom. For instance, "Does the student walk through doorways; Run without falling, or Carry small objects?" A scale of (1-4) is used. One (1) indicates, "Does not perform" and (4) indicates "Consistent performance".

Seton Hall University
Institutional Review Board
FEB 05 2016
Approval Date

School of Health and Medical Sciences
Department of Interprofessional Health Sciences & Health Administration
Tel: 973.275.2076 • Fax: 973.275.2171
400 South Orange Avenue • South Orange, New Jersey 07079 • *grahmelyd@shu.edu*

Expiration Date
FEB 05 2017

Voluntary Nature

The student is free to choose whether to join this study. Parents, guardians or the student may refuse to take part in or stop at any time. There is no penalty for not joining or stopping at any time.

Protection

Forms with student names will be locked safely in a file cabinet. These locked files will be stored in the researcher's home office. A code will ensure all names remain unknown. The code key will be stored separately. No one will ever be able to link the data.

Privacy

Complete privacy will be kept using a code. No one will view this data. Three years after the study, papers will be shredded. The thumb drive will be destroyed. No information will be used or given out without the parent's and student's written okay.

Records

All records will be sealed. Only the parent/guardian or student may ask to view the records in writing.

Risks

There is a small chance a student may trip. The researcher will walk beside the student. Assistance will be offered as needed.

Benefit

There is no direct benefit. The results will provide new information for therapists. It will lead to new methods to assess balance and walking ability in school-aged children.

Payment

Students will be given a pencil.

Seton Hall University
Institutional Review Board
FEB 05 2016
Approval Date

Expiration Date
FEB 05 2017

Contact Information

Questions about the study may be directed to:

Cheryl Enslee (Researcher)

Dr. Deborah DeLuca (Research Advisor)

Phone: (973) 275-2076 Email: Cheryl.Enslee@SHU.Edu

Questions about a participant's rights may be directed to the IRB office at:

(973) 313-6314.

Audio/ Video
Audio and video will not be used in this study.

Copies

Before the study begins, a copy of this signed and dated Informed Consent Form will be provided. Participants will be given a copy of the signed and dated Oral Assent Form.

Parent/Legal Guardian Consent Form

I fully understand the purpose and process of the study described.
I confirm my child ***does not*** have uncorrected **vision or hearing problems.** I also confirm my child has been classified as *Developmental Motor Delay.*

( ) I give permission for the researcher to ask my child to participate in the study.

Parent/Legal Guardian's Name (Please Print) _____

Parent/Legal Guardian's Signature _____

Date _____

Child's Name: _____

Seton Hall University
Institutional Review Board
FEB 05 2016
Approval Date

Expiration Date
FEB 05 2017

APPENDIX E

Child/Student Oral Assent Script/Form

SETON HALL UNIVERSITY
1 8 5 6

Oral Assent Form

About Myself
"My name is Ms. Enslee. I go to school at Seton Hall. I want to be a doctor. I have to do a science project for school. Would you like to help?"

Why & How Long
"This project is to see if a walking game for grown-ups is fun for kids. The game will take ten minutes."

What Will Happen
"You will walk across the room real fast. You will walk on the hard floor and carpet. Then you will walk over and around some boxes and climb some steps. A watch will keep the time to see how long it takes to finish. The teacher will answer questions about how well you move in the school building."

Tools
"The walking game has five parts. Walking on the floor, and carpet, standing and sitting in a chair, stepping over and around boxes, and steps. A watch is used to see how long it takes. There is no pass or fail. It's just about doing your best"

"The teacher will answer questions about how well you move at school. These questions ask, 'How well does a student move across the classroom?' This is answered as 'Not at all' or 'All the time'. This test does not change your grades at school."

Playing
"You do not have to play the game. It is OK to say No. It is also OK to stop playing at any time. Nothing bad will happen if the game is not played."

Secrets
"No one will see you play the walking game. No one will be told about the game. A special code will keep names secret."

Privacy
"No one will know how well you did. Times will be locked in a safe. They will not be locked in the same safe as the secret code. Three years from now the papers will be torn into small pieces. No one will ever know how fast you walked. You're the only person who can say it's OK to share."

Reports
"All papers will be kept private with the secret code. No one may see the papers. Only you or Mom and Dad can see the papers."

Things That Could Happen
"There is a small chance you may trip. I will be there to catch you. You may stop and rest"

Seton Hall University
Institutional Review Board
FEB 05 2016
Approval Date

School of Health and Medical Sciences
Department of Interprofessional Health Sciences & Health Administration
Tel: 973.275.2076 • Fax 973.275.2171
400 South Orange Avenue • South Orange, New Jersey 07079 • gradmd@shu.edu

Expiration Date
FEB 05 2017

Good Things
"This game will be good exercise. Playing this game will allow PTs to help other kids."

Cool Prize
"Students will get a cool pencil when the game is done."

Audio/Video
"There will be no taping of voices or pictures."

_____
Parent/ Legal Guardian Name (printed)

_____ _____
Parent/ Legal Guardian Name (signature) Date

_____
Child's Name (printed)

_____ _____
Child's Signature Date

YES!

- Color in the smiley face if you want to play. Even if Mom and Dad say it is OK, you can choose not to play.
- Please return in the provided envelope to the child's school Secretary.

Seton Hall University
Institutional Review Board
FEB 05 2016
Approval Date

Expiration Date
FEB 05 2017

APPENDIX F

Licensing Agreements/Copyrights

F1. modified-Emory Functional Ambulation Profile

F2. School Function Assessment

APPENDIX F1

Licensing Agreements/Copyrights

modified-Emory Functional Ambulation Profile

This is a License Agreement between Cheryl a Enslee ("You") and Wolters Kluwer Health ("Wolters Kluwer Health") provided by Copyright Clearance Center ("CCC"). The license consists of your order details, the terms and conditions provided by Wolters Kluwer Health, and the payment terms and conditions.

All payments must be made in full to CCC. For payment instructions, please see information listed at the bottom of this form. en_US

License Number	3222500357228
License date	Sep 05, 2013
Order Content Publisher	Wolters Kluwer Health
Order Content Publication	Stroke
Order Content Title	Modified Emory Functional Ambulation Profile: An Outcome Measure for the Rehabilitation of Poststroke Gait Dysfunction
Order Content Author	Heather R. Baer, Steven L. Wolf
Order Content Date	Apr 1, 2001
Volume Number	32
Issue Number	4 en_US
Type of Use	Dissertation/Thesis
Requestor type	Individual Account
Author of this Wolters Kluwer article	No
Title of your thesis / dissertation	Item Analysis of a new functional assessment tool in school children
Expected completion date	Aug 2013
Estimated size(pages)	225 en_US
Billing Type	Invoice
Billing address	986 Rahway Ave AVENEL, NJ 07001 United States en_US
Total	0.00 USD en_US

APPENDIX F2

Licensing Agreements/Copyrights

School Function Assessment

Dear Ms Piersall-Enslee,

Further to my initial response, and referencing your Registered Mail dated June 10, 2013, may I offer the following additional permission comments.

Pearson has no objection to you reproducing one or more copies of the School Function Assessment (SFA) test forms for submission to your Institutional Review Board (IRB) provided you hand-mark across the face of each page the following notice: SAMPLE FOR IRB REVIEW ONLY - NOT FOR ADMINISTRATION.

I believe that should cover you for your research project. If not, please let me know by return email memo.

Kind regards,

William H. Schryver
William H. Schryver
Senior Licensing Specialist

On Wed, May 15, 2013 at 3:14 PM, Licensing, - <pas.licensing@pearson.com> wrote:
Dear Ms Piersall,

Pearson has no objection to your use of the School Function Assessment provided all test materials are purchased and no copying of other reproduction takes place.

Additionally, because of test security concerns, permission is not granted for appending tests to theses, dissertations, or reports of any kind. You may not include any actual assessment test items, discussion of any actual test items or inclusion of the actual assessment product in the body or appendix of your dissertation or thesis. You are only permitted to describe the test, its function and how it is administered; and discuss the fact that you used the Test(s), your analysis, summary statistics, and the results.
Regards,

William H. Schryver

Senior Permissions Specialist

On Wed, May 15, 2013 at 2:08 PM, Cheryl Piersall <cherylpt@hotmail.com> wrote:
May 15 2013
To Whom It May Concern,

I am a graduate student at Seton Hall University, and am entering the research phase for my disseration. I plan to use the School Function Assessment as one of the measurement instruments

in my study. I do not plan to change the test in any manner. However, I am seeking permission/ acknowledgement that your company is aware that I will be using it and will give credit as appropriate. A paper or electronic letter regarding such would assist me in fulfilling the Institutional Review Board's requirements at Seton Hall and allow me to procced with my scholarly pursuits.

If there is more formal paperwork to be completed or you have further questions, please do not hesitiate to contact me.
(732) 602-9392. Your timely consideration and assistance are greatly appreciated.

Sincerely,
Cheryl A. Enslee PT, DPT.

APPENDIX G

Site Approval Letters

G1. The Deron I School of New Jersey. Inc.

G2. The Phoenix Center

APPENDIX G1

The Deron I School of New Jersey. Inc.

THE DERON SCHOOL OF NEW JERSEY, INC.
"A Special School For Special Children"

Lori Alter, M.A.
DIRECTOR

1140 Commerce Avenue, Union, New Jersey 07083
Phone: 908-206-0444 Fax: 908-206-0466

August 6, 2014

To Whom It May Concern:

As Director of the Deron School, I grant permission for Cheryl Enslee to solicit subjects and conduct a research study at our School, located at 1140 Commerce Avenue, Union, NJ; pending Seton Hall University's IRB approval.

Please feel free to contact me if you have any questions or concerns.

Sincerely,
Lori Alter
Director
Deron School of New Jersey
Union/Montclair
(908) 206-0444

APPENDIX G2

The Phoenix Center

THE PHOENIX CENTER

Preparing students for life beyond the classroom
Accredited by NCASES and Middle States Association

1/28/16

Dear Seton Hall University IRB Committee Member(s),
This letter is to certify that Cheryl A. Enslee, PT, DPT has permission to solicit subjects and conduct a dissertation related research study titled, "The Modified Emory Functional Ambulation Profile: Convergent Validity in 5-11 Year Olds" at The Phoenix Center located at 16 Msgr. Owens Place, Nutley, NJ 07110. The Phoenix Center IRB approval has been granted. Please do not hesitate to contact me should you require any further information.

Sincerely,

Geraldine A. Gibbia, Ph.D., CCC/SLP
Executive Director

Geraldine A.Gibbia, Ph.D., CCC-SLP
Speech Language Pathologist
Executive Director

Douglas A. Berrian, Ed.D.
Director Personnel/Staff Development

Julie Mower, MA.Ed.
Principal

An Educational Community for Special Students and Their Families

IRB/University Research Projects Review Form

Disclaimer: It is not the primary mission of the IRB to review research for compatibility with the mission of The Phoenix Center. Rather, the primary mission of the IRB is to ensure the safety and integrity of all human research participants in accordance with the Belmont Report and the Common Rule. The onus of compliance to the mission statement of The Phoenix Center rests with the individual researcher.

1. Name of requestor: Cheryl Enslee.

   Phone number: (

   E-mail: Cheryl_pt@hotmail.com
   Cheryl.Enslee@SHU.edu.

2. Course Requirement: X Yes ___ No *(Skip to Question 4)*

3. Faculty Sponsor *(if applicable)*:

   Name: Dr. Deborah DeLuca

   Phone number: (

   E-Mail: Deborah.DeLuca@SHU.Edu.

   Course Section/Title: Thesis/Dissertation

   Semester: Post-Grad. Research

4. To date, has your research proposal undergone Departmental Review?

   X Yes ___ No

5. Clearly state your research problem, *and attach a brief description of the research project*:

   Please See Attached.

6. Please select *Yes* or *No* for each of the following questions. Please attach a brief explanation for all answers.

Does your research involve procedures that pose not more than minimal risks to participants?	X Yes	X No CR.
Will your selection of participants be equitable?	X Yes	___ No
Will informed consent be sought from each prospective participant?	X Yes	___ No
Are adequate provisions to protect the privacy and confidentiality of participants in place?	X Yes	___ No
Is the consent form attached?	X Yes	___ No

7. Prospective Researcher

Signature: Clausen Date: 1/27/16

8. Faculty Sponsor, Principal Investigator, or Phoenix Center Advisor

Signature: Kim Hyduk, MS, CCC-SLP Date: 1/27/16
Director of Related Services

APPENDIX H

Letter of Approval from Employer

EAST ORANGE
GENERAL HOSPITAL

April 25, 2014

RE: Cheryl Enslee

Dear Sir/Madam:

Please be advised that the above captioned individual is currently employed with East Orange General Hospital in the capacity of a Full Time Registered Physical Therapist.

The hospital is aware that Cheryl will be completing a research project in fulfillment in degree requirements and will accept Seton Hall University IRB.

Ms. Enslee has been employed with this facility since November 9, 2009.

If you require additional information, please contact me at (973) 395-4023.

Sincerely,

Jewel Lyte
Human Resource Manager

APPENDIX I

Data Coding and Collection Sheets

I 1. Data Coding Reference Sheet

I 2. Descriptive Data Sheet

APPENDIX I 1.

Data Coding Reference Sheet

Data Coding Reference Sheet

SUBJECT CODE	SUBJECT NAME	SUBJECT CODE	SUBJECT NAME
S1A		S31AE	
S2B		S32AF	
S3C		S33AG	
S4D		S34AH	
S5E		S35AI	
S6F		S36AJ	
S7G		S37AK	
S8H		S38AL	
S9I		S39AM	
S10I		S40AN	
S11K		S41AO	
S12L		S42AP	
S13M		S43AQ	
S14N		S44AR	
S15O		S45AS	
S16P		S46AT	
S17Q			
S18R			
S19S			
S20T			
S21U			
S22V			
S23W			
S24X			
S25Y			
S26Z			
S27AA			
S28AB			
S29AC			
S30AD			

APPENDIX I 2.

Descriptive Data Sheet

Descriptive Data Sheet

Identifier Code:_____ Assessment Date: _____

Date of Birth (MM/DD/YYYY):_____ Age:_____ Gender: _____

Height (inches):_____ Weight (pounds):_____