MEASURING COGNITIVE OUTCOMES OF STROKE PATIENTS IN THE INPATIENT REHABILITATION UNIT

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To the Dean of the Graduate School:

I am submitting herewith a dissertation written by Mary Grace Gaber entitled "Measuring Cognitive Outcomes of Stroke Patients in the Inpatient Rehabilitation Unit." I have examined this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy with a major in Occupational Therapy.

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We have read this dissertation and recommend its acceptance:

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Accepted:

Interim-Dean of the Graduate School

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ABSTRACT

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MEASURING COGNITIVE OUTCOMES OF STROKE PATIENTS
IN THE INPATIENT REHABILITATION UNIT

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The Cognitive FIM™ (Cog FIM™) and the Applied Cognitive domain of the Boston University Activity Measure for Post Acute Care (AC AM-PAC) were analyzed in three studies. The responsiveness to change during inpatient rehabilitation of stroke patients was studied for both the Cog FIM™ and the AC AM-PAC. The Cog FIM™ and the AC AM-PAC were then compared with the Reintegration to Normal Living Scale (RNL). The final study concerned the experience of utilizing outcome measures.

The first study sample included 30 FIM™ scores from admission and discharge during inpatient rehabilitation. The hypotheses were: there will be significant change in the Cog FIM™, and there is a relationship between change in the Motor FIM™ and the Cog FIM™. The first hypothesis used the *t* test and the second, the Pearson correlation coefficient. The 50 stroke patients enrolled in the second study were assessed using the AC AM-PAC at admission and discharge from inpatient rehabilitation and with the Reintegration to Normal Living Scale (RNL) at three months. The hypotheses were: there will be a significant change in the AC AM-PAC, and the AC AM-PAC will predict the RNL more than the Cog FIM™. The first hypothesis used the *t*-test and the second used

hierarchical multiple regression. The third study involved a focus group of clinicians discussing outcome measures.

The Cog FIM™ demonstrated significant change with a moderate effect. There was no relationship between the change of the motor FIM™ and the Cog FIM™. The change in the AC AM-PAC was not significant but had a moderate effect size. The AC AM-PAC was a better predictor of the RNL than the Cog FIM™, although neither reached significance. The failure to reach significance was likely caused by small sample size. In the third study, the focus group findings revealed concerns about reliability and validity of both measures. This information may lead to future research. In conclusion, the innovations of the AM-PAC have allowed this instrument to overcome some of the limitations of the FIM™.

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CHAPTER I

INTRODUCTION AND SPECIFIC AIMS

Stroke is the leading cause of serious, long-term disability in the United States. Each year, 795,000 people suffer a stroke, and nearly three-quarters of them are over age 65 years (The Internet Stroke Center, 2009). Functional loss can be caused by impairments in the sensorimotor, cognitive and psychosocial systems.

The majority of patients receiving rehabilitation for stroke are insured by Medicare since they are older than 65 years. Although there are stroke patients that are not covered by Medicare, it is Medicare that regulates rehabilitation in the United States, including which patients qualify for rehabilitation, how long they can stay, and the type of facility that will provide their rehabilitation. The four different rehabilitation settings designated by Medicare are inpatient rehabilitation, skilled nursing facilities, outpatient rehabilitation and home health. Each of these settings has different types of programs available which can include occupational therapy along with physical therapy, speech language pathology, neuropsychology, and social work. The goal of rehabilitation programs is to help these clients to become as independent as possible in their daily activities.

Although the best program for an individual patient would be the one that results in the greatest gains in independence for the lowest cost, it can be difficult to determine which setting is best for each patient. There is no direct way to compare rehabilitation

programs in different settings because different outcome measures are used in each type of setting. It would be beneficial for Medicare to have a single outcome measure that can be used across the rehabilitation spectrum, so that programs can be directly compared. A single outcome measure used in all rehabilitation settings would facilitate the formation of a national rehabilitation outcome database, providing a rich source of data for researchers in various disciplines to conduct new studies and compare programs to inform practice.

The outcome measure used in inpatient rehabilitation is the FIM™ (Keith, Granger, Hamilton & Sherwin, 1987). Starting in 2002, Medicare instituted a prospective payment system which determines how much will be paid to the rehabilitation provider for each patient. Part of the determination of the payment amount is based on the FIM™ score at admission as a measure of the level of severity of the patient's functional status (Granger, 2011).

The FIM™ is designed to provide a burden of care score, that is, the amount of assistance a person needs to perform daily activities (McDowell, 2006). The original form of the FIM™ had four levels of scoring (Keith, Granger, Hamilton & Sherwin, 1987) that was later expanded to seven. The score ranges from 1to7, 1 representing that the person needs total assistance and 7 representing that the person is completely independent.

A different outcome measure, the Boston University Activity Measure for Post Acute Care (AM-PAC) has been endorsed by the American Occupational Therapy

Association as a functional outcome measure for rehabilitation (AOTA, 2009). AOTA's goal is to create a national outcomes database of AM-PAC scores to be used for research purposes. The AM-PAC is divided into three functional areas – basic mobility, daily activities and applied cognitive. Unlike the FIM™, the three scores are not combined into a single score.

The AM-PAC was developed using the World Health Organization's International Classification of Functioning, Disability and Health (ICF). It examines function at the level of activity limitation, which is defined in the ICF as "difficulty in the execution of a task or action by an individual" (Jette, Haley, Coster & Ni, 2007). The respondent has four choices for each item, from "unable" to do the activity to "none" indicating no difficulty performing the activity.

The AM-PAC and the FIM™ , although they cover similar areas of function and are both intended for use with patients in rehabilitation, are very different in their methods of data acquisition, scoring, and presentation of results. The FIM™ is scored by observation by trained observers, usually clinicians. The data are gathered and recorded by clinicians and are compiled for transmission to Medicare. The score of the FIM™ is an ordinal scale number which represents the total score on all 18 items.

The AM-PAC is a self-report, although a proxy can be used in some circumstances. The AM-PAC score on each domain ranges from 0-100 on an interval scale. The data are gathered using Computer Assisted Technology (CAT) so that each individual only needs to answer a representative number of items to obtain a score.

Rather than examine the total FIM™ and all three domains of the AM-PAC, this dissertation specifically compared the Cog FIM™ with the Applied Cognitive domain of the AM-PAC (AC AM-PAC). Three studies were conducted. The first study examined the responsiveness of the Cog FIM™ as it is currently used with stroke patients in an inpatient rehabilitation setting. The second study compared the responsiveness of the Cog FIM™ and the AC AM-PAC during the inpatient rehabilitation period of stroke patients. This study also examined the correlation of the discharge scores of the Cog FIM™ and the AC AM-PAC with the Reintegration to Normal Living Scale (RNL), a measure of functional recovery, three months after stroke. The third study focused on the subjective experience of the rehabilitation team in utilizing cognitive outcome measures, including their perspective on some possible uses of such instruments in the future.

CHAPTER II

LITERATURE REVIEW

Cognitive Impairment of Stroke Patients

Cognitive impairment is common in people who have experienced a stroke. In a population study of 1259 patients, 43.9% were found to have impaired cognition (Lawrence, et al., 2001). These impairments affect the ability of individuals to carry out the tasks of daily life. Cognition is an important factor in predicting the discharge destination and activity limitation in stroke rehabilitation according to a study conducted by Massucci, et al. (2006). In particular, executive dysfunction in the post-acute stage after stroke was a significant predictor of a poor functional outcome one year after stroke (Lesniak, Bak, Czepiel, Seniow, & Czlonkowska, 2008). A review of nine studies on stroke patients found that certain cognitive impairments, specifically sustained attention, apraxia, pathological emotional reactions, and language impairment were predictive of functioning and independence at discharge from acute rehabilitation (Barker-Collo & Feigin, 2006).

Fortunately, research has shown that patients with cognitive impairment following stroke demonstrate functional gains in inpatient rehabilitation settings. Even severely cognitively impaired patients improve significantly in function (Rabadi, Edelstein, & Peterson, 2008). However, there is little information about how different inpatient

rehabilitation programs compare to one another, and how inpatient rehabilitation compares to other post-acute care settings for stroke patients with cognitive impairment.

Outcome Measures

Outcomes research seeks to understand the end results of interventions (Agency for Healthcare Research and Quality, 2000). In order to perform useful outcomes research, there must be outcome measures available that capture change in the phenomena of interest. In the rehabilitation of stroke patients, this may include the ability to do activities more independently, quality of life following rehabilitation, reduced need for assistance and/or decreased utilization of medical services. An outcome measure is defined as a measure of the quality of medical care, the standard against which the end result of the intervention is assessed (Mosby, 2009).

The use of consistent outcome measures across the post-acute care spectrum would make it possible to compare different programs. Unlike patient evaluations, outcome measures are not designed to give specific information for individualized care but rather are used to evaluate and determine the quality of a specific program. For occupational therapists as well as other providers, outcome measures can provide evidence of the efficacy of therapeutic interventions when randomized controlled trials are not ethical or practical. They can be used to compare different therapy programs to each other as well as assess the effectiveness of programmatic change.

Outcome measures need to have sound psychometric properties of reliability, validity, sensitivity and sensibility. Reliability is the consistency or dependability of an

instrument to measure the attribute of interest (Polit & Beck, 2004). Validity is defined as the "degree to which an instrument measures what it is intended to measure" (Polit & Beck, 2004, p. 735). Sensibility is defined as "the overall appropriateness, importance, and ease of use of the instrument" (Barak & Duncan, 2006, p. 505).

However, if outcome measures are not sensitive to the changes that are occurring as a result of therapeutic intervention, then it may be the measure that needs to be changed, not the therapeutic approach. As Coster stated in her Slagle lecture, "if a study or a systematic review concludes that a therapy program 'does not improve function,' then we must examine whether the outcome measure examined more than basic physical function and challenge the conclusions if they do not" (2008). In addition, payers benefit from good outcome measures in evaluating programs. Medicare has called for research to develop better measures for outcomes of care that can be used in all post-acute care settings (Heinemann, 2008).

The FIM™

This outcome measure, formerly named the Functional Independence Measure and abbreviated as the FIM, is now known only as the FIM™. It consists of two sections, the Motor FIM™ and the Cog FIM™. The Motor FIM™ has 13 items to be scored, including self-care, sphincter control, transfers and locomotion. The Cog FIM™ has five items to score, and is divided into communication (two items) and social cognition (three items). The FIM™ is scored by observing the patient as they perform activities and interact with others. Each item is scored on a seven point system, with 7 indicating

complete independence and 1 indicating complete dependence (defined as the patient being able to assist 25% or less with the task) (IRF-PAI Training Manual, 2004).

Development of the FIM™. The Motor FIM™ was based on the Barthel Index and the Cog FIM™ was added early its development during the piloting phase. Because of the difficulty in measuring cognitive function in any simple form, a subcommittee was formed to work on cognition and the result of their work was to include five items: Memory, Cognition/Problem Solving, Visual Perception, Emotional Behavior, and Social Behavior (Keith, Granger, Hamilton & Sherwin, 1987). Further refinement and testing resulted in the five items that comprise the Cog FIM™ today: Comprehension, Expression, Social Interaction, Problem Solving and Memory.

The FIM™ is used as the central measurement for the Uniform Data System for Medical Rehabilitation (UDS), along with information about demographic characteristics, diagnoses, impairment groups, hospital charges, and length of stay. The FIM™ is based on burden of care. Thus, the items are scored on the basis of the amount of assistance that the patient needs to carry out each activity of daily living (McDowell, 2006).

In 2002 Medicare began requiring the use of the FIM™ in inpatient rehabilitation facilities as part of the new prospective payment system (PPS), although many inpatient rehabilitation facilities were already using the FIM™ (Granger, Deutsch, Russell, Black & Ottenbacher, 2007). According to CMS (Centers for Medicare and Medicaid Services) the required patient assessment instrument which includes the FIM™ is used to "classify

patients into distinct groups based on clinical characteristics and expected resource needs" and "separate payments are calculated for each group" (CMS, 2012).

Reliability of the FIM™. In 1996, a review of 11 investigations of the reliability of the FIM™ revealed that the median reliability of the total FIM™ for all patients was .95 and for stroke patients specifically (two studies) was .92. However, when individual subscales are examined, the lowest reliability values are in the Communication and Social Cognition subscales (median of .87 and .78 respectively). The authors of this study suggest that, because these items are difficult to observe directly, the lower reliability scores may be related to levels of training of individuals reporting these scores (Ottenbacher, Hsu, Granger & Fiedler, 1996). In two subsequent interrater reliability studies raters were influenced in their ratings when they saw the ratings of other items that had previously been completed by other raters (Doctor, Wolfson, McKnight & Burns, 2003; Wolfson, Doctor & Burns, 2000).

An interrater reliability study was conducted at two adjacent rehabilitation hospitals. Patients were rated at discharge from one facility and then transferred to the other facility where they were assessed at admission. The raters were not aware of the study and did not have the FIM™ scores from the discharging facility. The intraclass correlation coefficient (ICC) was .85 for the motor subscore and .83 for the Cog FIM™, however Bland-Altman plots demonstrated poor agreement. Only 35 of 143 Cog FIM™ scores had perfect agreement, and most of those had agreement because of the ceiling effect of the measure (Kohler, Redmond, Dickson, Connolly & Estell, 2010).

Validity of the Cog FIM™. Studies concerning the convergent validity are prevalent in the literature. Convergent validity is defined as "an approach to construct validation that involves assessing the degree to which two methods of measuring a construct are similar" (Polit & Beck. 2004, p. 715).

In 2001, a research study found that the Cog FIM™ did not correlate as well with the total FIM as two cognitive screening tests (the Clock Drawing Task and the Mini-Mental State Examination) (Adunsky, Fleissig, Levenkrohn, Arad, & Noy, 2001). In another study, the Cog FIM™ did not correlate with the CAMCOG (0.27 - .035) or the MMSE (0.22 – 0.27) (Te Winkel-Witlox, Post, Visser-Meily & Lindeman, 2007). In addition, the Cog FIM™ does not correlate well with performance measures of cognitive functioning (such as the Stroke Unit Mental Status Examination, the Mini Mental State, Raven Matrices, and Boston Naming Test) (Hajek, Gagnon & Ruderman, 1997). According to this study "the low correlations between the FIM™ and the cognitive tests confirm that cognition is obviously too complex to be contained in only a few items of a functional scale" (Hajek, Gagnon & Ruderman, 1997, p. 1334).

Sensitivity of the FIM™. Sensitivity is defined as the ability of an instrument to correctly diagnose a condition (Polit & Beck, 2004). Developing a single outcome measure that can be used across the spectrum of rehabilitation settings may be difficult because of the wide variability of function of stroke patients due to the initial severity of their stroke as well as the amount of recovery that has occurred. Although evaluation of basic activities of daily living (BADL) may be sufficient for patients with severe stroke,

more than 80% of those with mild stroke will reach maximum improvement in BADL within three weeks, so for these patients it is necessary to assess instrumental activities of daily living (IADL) and participation in order to detect persistent activity limitations (Barak & Duncan, 2006).

Another aspect related to sensitivity is responsiveness. Responsiveness is defined as "the ability of a measure to detect changes over time" (Schepers, et al., 2006, p. 1035). One threat to responsiveness is when a measure produces a ceiling effect. A ceiling effect "occurs when scores on a variable are approaching the maximum they can be. Thus, there may be bunching of values close to the upper point." (Cramer and Howitt, 2004, p. 21) A study of patients admitted to inpatient rehabilitation in the Netherlands was conducted which examined the responsiveness of the FIM™. The Cog FIM™ score showed a ceiling effect at the first administration during inpatient rehabilitation. The total FIM™, the Cog FIM™ and the Motor FIM™ all had considerable ceiling effects at six and 12 months post stroke (Schepers, et al., 2006).

Sensibility of the FIM™. The FIM™ takes 30 to 45 minutes to administer. The only required training is reading of the manual. However, more training may be required to obtain good interrater reliability on the Cog FIM™ (Ottenbacher, Hsu, Granger & Fiedler, 1996). The instruction manual recommends that the clinician "must read the definitions of the items carefully before beginning to use the FIM™ instrument, committing to memory what each activity includes" (IRF-PAI Training Manual, 2004).

Psychometrics using FIM™ data. There may be difficulties using quantitative statistical methods with the FIM™. The FIM™ uses a seven level ordinal scale rather than an interval scale that is preferable when using quantitative statistical methods. This particular issue has been partially resolved through the use of Rasch analysis (Linacre, Heinemann, Wright, Granger & Hamilton, 1994; Nilsson, Sunnerhagen, & Grimby, 2005). Nilsson (2005) states that "the Rasch model converts raw ordinal data into equal interval data and provides a formal evaluation of whether or not acceptable measurement has been achieved". Through Rasch analysis it was determined that the motor FIM™ and the Cog FIM™ "define two statistically and clinically different indicators" (Linacre, Heinemann, Wright, Granger & Hamilton, 1994, p.127). Nilsson, et al. (2005) found that the use of the seven level scale caused disordered thresholds and that a four level scale produces better results. In research studies, however, even though these limitations of the FIM™ have been identified, the FIM™ score is often used without modification.

Since cognitive functioning is impaired in almost half of stroke patients Lawrence, et al., 2001), it is important that cognition be seriously considered in outcome measures designed to describe or predict the independence of patients. The FIM™ includes 18 total items to be scored, of which only five are concerning cognition. Thus, according to Hajek et al. (1997) "even if scales such as the FIM™ include items concerning the assessment of cognitive functional level, the question as to whether cognitive disability is given enough weight remains when the scales' total scores are used as rehabilitation outcome predictors." (p.1331)

Use of the FIM™ in Inpatient Rehabilitation. In 2002 Medicare began requiring the use of the FIM™ in inpatient rehabilitation facilities as part of the new prospective payment system (PPS), although many inpatient rehabilitation facilities were already using the FIM™ (Granger, Deutsch, Russell, Black, & Ottenbacher, 2007). According to CMS (Centers for Medicare and Medicaid Services) the required patient assessment instrument which includes the FIM™ is used to "classify patients into distinct groups based on clinical characteristics and expected resource needs" and "separate payments are calculated for each group" (CMS, 2009).

Because the FIM™ is required by Medicare for all patients in inpatient rehabilitation, it has become an important aspect of clinical evaluation of patients. In inpatient rehabilitation the FIM™ is used not only for reporting to Medicare and other payers, but also for treatment and discharge planning. It is also commonly used in research because it is readily available for all patients in inpatient rehabilitation, therefore reducing the burden on the researcher compared to using other outcome measures.

The Boston University Activity Measure for Post Acute Care (AM-PAC).

The AM-PAC as previously described is an instrument to measure activity limitations in post-acute settings for all patient diagnoses in the areas of mobility, daily activity and applied cognition. It is a self-report questionnaire, although the questions can be answered by another knowledgeable person (by proxy). The patient has four choices for response: unable, lots of trouble, a little trouble, or no trouble (Jette, Haley, Coster & Ni, 2007).

This outcome measure has three domains titled Basic Mobility, Daily Activity, and Applied Cognitive. Each domain results in a separate score which is not combined with the other scores. The scores resulting on each domain are an interval measure between 0 and 100 (Jette, Haley, Coster & Ni, 2007).

The AM-PAC was designed to be used as a functional outcomes system across post-acute care settings. The AM-PAC "examines a set of functional activities that are likely to be encountered by most adults during daily routines within the context of either an inpatient episode of care or outpatient post-acute services" (Jette, Haley, Coster, and Ni, 2007, p.4).

Development of the AM-PAC CAT. The AM-PAC was developed using "contemporary measurement techniques, such as Item Response Theory (IRT) to overcome the limitations of traditional outcome measures" (Jette, Haley, Coster & Ni, 2007, p.4). According to Jette and Haley (2005):

> Using this approach, probabilities of patients scoring a particular response on an item at various functional ability levels can be modeled. Persons with more functional ability have higher probabilities of responding positively to functional items than persons with lower functional abilities....To apply IRT to functional outcome assessment, an appropriate item pool of functional tasks or activities needs to be assembled...IRT methods have been used to calibrate items from existing instruments onto a common scale, thus developing a structure and order of domain-specific items. (p. 341)

Computer Adaptive Testing (CAT) makes the use of a large item pool that is developed using IRT easier to administer. According to Barak and Duncan:

> CAT tests provide different test-item sets for each examinee based on that person's estimated trait (or ability level). An adaptive test first asks questions in the middle of the ability range, and then, based on the responses, asks subsequent questions that focus on relevant functional levels. Thus, precise information regarding an individual's functional ability level is obtained, with fewer items administered, and the information about each individual can be assessed most efficiently. (2006, p.513)

The AM-PAC was developed as a large item bank using IRT and then was converted into a CAT form. The total item pool of the AM-PAC ranges from 59 to 101for each domain. In one study, the total item AM-PAC was compared to both a short-form AM-PAC (10 items for each domain) and the AM-PAC CAT. The correlation between the AM-PAC CAT and the total item pool was over .90 for all three domains. The short form correlation with the total item pool ranged between .85 and .91 (Haley, Coster, Andres, Kosinski & Ni, 2004).

Reliability of the AM-PAC. Andres, Haley, and Ni (2003) conducted a study of the test-retest and subject-proxy reliability of the AM-PAC. The results demonstrated acceptable reliability with correlation coefficients ranging between 0.91 and 0.97 for test-retest and subject proxy ranging between 0.68 and 0.98.

Another study comparing patient and proxy responses demonstrated adequate agreement between the two when the AM-PAC was utilized at admission to all post-acute settings (inpatient rehabilitation, skilled nursing, home care and outpatient therapy) (Jette, et al., 2012). This study suggested that the use of proxies would make it possible for all patients to be included in a study using the AM-PAC, because use of proxies would allow inclusion of patients who could not respond due to speech difficulties or severe cognitive impairment.

Validity of the AM-PAC. Content validity is defined as "the degree to which an instrument has an appropriate sample of items for the construct being measured." (Polit & Beck, 2004, p. 423). The items in the AM-PAC item bank were developed from two sources. Some of the items were newly developed from the functional content of the three domains (Mobility, Daily Activity and Applied Cognition) and other items were taken from outcome measures currently used in post-acute care settings (Sandel, et al, 2012). Because the use of IRT and CAT, the number of items did not have to be limited and therefore could include items for both low functioning and high functioning individuals.

Convergent validity examines the correlation between different methods measuring the same trait (Polit & Beck, 2004). Traditionally, the validity of a measure was determined by comparing the new measure to a "gold standard" instrument, one that is considered to be the benchmark to compare all other measures. According to Veloso,

Kielhofner and Lai (1999), choosing a gold standard instrument can cause significant problems, such as ceiling or floor effects when the measurement is used with different populations.

An alternative to convergent validity testing is using IRT methods to link individual items from one instrument to another, allowing direct conversion of the score on one tool into a score for the other. The AM-PAC was linked in this way to the Quality of Life Outcomes (QoL), allowing direct conversion from one scale to the other (Haley et al, 2011).

Sensitivity of the AM-PAC. A prospective, longitudinal study of patients with a variety of diagnoses (neurological, orthopedic and complex medical conditions) was conducted to examine the sensitivity of the AM-PAC up to 12 months after discharge from inpatient rehabilitation. The study showed that all three domains of the AM-PAC were sensitive to change throughout the follow-up period. In this study, the AM-PAC was found to be more sensitive than the FIM™ in measuring change (Coster, Haley and Jette, 2006).

A recent study of the AM-PAC with stroke patients examined use across the spectrum of rehabilitation care (acute hospital, inpatient rehabilitation, skilled nursing facility, home care and outpatient) as well as in the home setting six months post-stroke. There was a ceiling effect for the Applied Cognitive AM-PAC (AC AM-PAC) of 10.10%, which is considered acceptable (Sandel, et al, 2012).

Sensibility of the AM-PAC. In the same study (Sandel, et al, 2012), the average time to administer all three domains of the AM-PAC was 7.9 minutes. On average, the number of items administered for each domain was nine. This is a result of the CAT and IRT features of the AM-PAC.

Psychometrics using the AM-PAC. Due to the use of IRT methods in developing the AM-PAC, the scores are interval scores and need no modification to use all quantitative statistical methods. Using IRT, as previously mentioned, also permits direct comparison between AM-PAC scores and other instrument scores that measure the same domain.

The AM-PAC used as a Functional Staging System. One study (Tao, Haley, Coster, Ni, and Jette, 2008) examined whether the AM-PAC can be used as the basis of a functional staging system, similar to the way the FIM™ is used for the PPS, to assign patients to different hierarchic levels of function. This study determined that it was possible to determine stages that were comparable to FIM™ stages. Although the FIM™ was more sensitive in detecting changes between baseline and one month follow-up, the AM-PAC was more sensitive in detecting changes in follow up visits at six and twelve months.

Table 1

Comparison of the Cog FIM™ and the AC AM-PAC

	Cog FIM™	AC AM-PAC
Reliability (inter-rater, test-retest and subject/proxy)	Acceptable	Acceptable
Validity - Convergent	Poor with other cognitive screening tools	Not applicable, due to IRT, able to convert scores from one instrument to another
Validity – Content (source of items)	Expert panel	Expert panel + other outcome measures
Validity - Sensitivity	Ceiling effect with high level cognitive patients Acceptable for most patients in inpatient rehabilitation	Minimal ceiling effect Acceptable for patients in all post-acute settings
ICF Component Area	Activity categories	Specific activities
Focus of items	Amount of assistance needed	Amount of difficulty with activity
Respondent	Clinician	Patient or proxy if needed
Amount of time to administer	30 – 45 minutes (total FIM)	7.9 minutes (all domains)
Training	Read and memorize items, may need additional training to increase inter-rater reliability	Read manual
Psychometrics	Ordinal score, can be converted to interval using Rasch methods	Interval score

CHAPTER III

EXAMINATION OF THE COGNITIVE FIM™ AS IT IS CURRENTLY UTILIZED IN INPATIENT REHABILITATION OF STROKE PATIENTS

Significance of Study

Although the total FIM™ is the measurement used for the PPS system of Medicare payments, for this study the cognitive and motor components of the FIM™ will be analyzed separately and compared to each other. The Cog FIM™ has been shown to lack convergent validity with a variety of cognitive screening tests. It also appears to have more issues with ceiling effects than the Motor FIM™.

During the inpatient rehabilitation stay of stroke patients, they are expected to improve both physically and cognitively. In fact, for 80% of patients who have stroke, best neurological recovery occurs within 4.5 weeks (Jφrgensen, Nakayama, Raaschou, Vive-Larsen, Stφier & Olsen, 1995). It would be important for the principle outcome measure to be able to detect this change accurately. In this study, the question being considered is, can the Cog FIM™, separate from the Motor FIM™, detect the cognitive changes that take place during inpatient rehabilitation of stroke patients? In addition, the Cog FIM™ change was compared to the Motor FIM™ change to see if there was any relationship between the two.

Research Design

This study uses a retrospective design, utilizing FIM™ data that was gathered routinely at admission and discharge in inpatient rehabilitation for reporting to Medicare. This data was used to determine the sensitivity of the Motor FIM™ and the Cog FIM™ with stroke patients in inpatient rehabilitation.

Methodology

Subject Characteristics

To complete this retrospective study, the medical records of thirty consecutive stroke patients admitted to the inpatient rehabilitation unit of a major metropolitan hospital were examined. Sample characteristics are summarized in Figure 1.

Sampling Procedures

Permission was obtained from the hospital to access patient records and the study was approved by the Institutional Review Board for the hospital and participating institutions. The sample was ascertained by accessing records from eRehabData of 30 consecutive stroke patients, starting in January of 2010. This database is described as "an inpatient rehabilitation outcomes system offered to inpatient rehabilitation providers by the American Medical Rehabilitation Providers Association. eRehabData® serves as a complete online patient assessment system to assist inpatient rehabilitation facilities in their compliance with CMS regulations under the IRF-PPS, based on the IRF-PAI" (eRehabData.com).

Selection was based on whether their principle diagnosis was listed as stroke. Using the patients' record numbers, additional information could be accessed from the hospital's electronic record. The inclusion criteria were: 1. first ever stroke and 2. no history of brain injury or neurological disease. The information gathered from the hospital chart included the description of the stroke and demographic information about the patient.

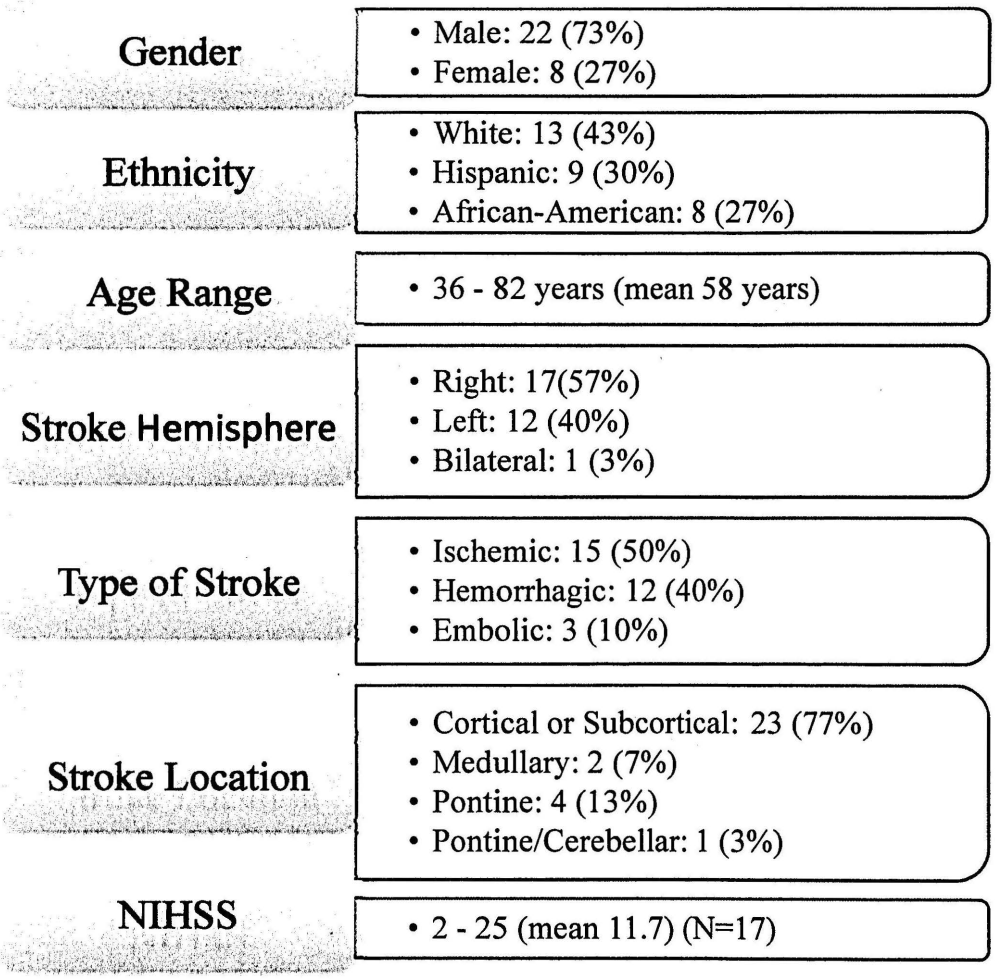

Figure 1: Sample I characteristics

Outcome Measures

The measures of interest in this study were the total FIM™ which was further broken down into the Cog FIM™ and the Motor FIM™. The FIM™ scores were collected on admission and discharge from the inpatient rehabilitation unit. These scores were compiled from the individual FIM™ scores which were submitted by the clinicians on the inpatient rehabilitation unit (physical therapy, occupational therapy, speech language pathology, and nursing). The compiled scores that resulted were the lowest scores on the first three days from admission (initial score) and the lowest scores from the last three days (discharge score). These scores were compiled by a designated staff member who was specifically trained to complete this task and she then entered the data into the eRehabData software to be submitted to Medicare.

Research Design

This study is a retrospective study. The patients were admitted from January 22 to May 3, 2010 and selected consecutively. Although FIM™ has been used in this particular hospital unit since 1994, the researcher chose a time period recent enough that there has been routine and systematic training of the staff in accurate use of the FIM™.

This study examined the sensitivity of the Cog FIM™ in measuring cognitive change during the inpatient rehabilitation period and the relationship of the Cog FIM™ and the Motor FIM™ score. The hypotheses are as follows:

1. There is a significant change in the Cog FIM™ during the inpatient rehabilitation period of stroke patients.

2. There is a relationship between the change in the Motor FIM™ and the change in the Cog FIM™ scores during the inpatient rehabilitation of stroke patients.

Results

The *t* test for correlated samples was used to compare initial and discharge Cog FIM™ scores. The Pearson correlation coefficient was used to compare the change in Motor FIM™ (discharge Motor FIM™ – initial Motor FIM™) to the change in Cog FIM™ (discharge Cog FIM™ – initial Cog FIM™).

For hypothesis one, a paired *t*-test revealed that the Cog FIM™ score of stroke patients in inpatient rehabilitation significantly increases between the initial and discharge scores (t=7.15, df=29, p <.05). Using Cohen's *d* to calculate the effect size, the effect size for the Cog FIM™ difference is 0.62, a medium effect size. The Motor FIM™ score of stroke patients in inpatient rehabilitation also increases significantly between the initial and discharge scores (t=14.4, df=29, p < .05); however, the effect size is 2.0, a very large effect. For hypothesis two, using the Pearson Correlation Coefficient, there was no relationship between the magnitude of change of the motor FIM™ and the magnitude of change of the cog FIM™ during the inpatient rehabilitation period of stroke patients (r=-.03, N=30). The results are summarized in Tables 2 and 3.

Table 2

Change in the Cog FIM™

Hypothesis 1	Mean Initial Score	Mean Discharge Score	Std. Deviation	t-test	*df*	Effect Size
Change in Cog FIM™	23.50	27.97	9.15 – 9.82	7.15	29	0.62
Change in Motor FIM™	31.67	50.43	7.32 – 5.94	14.4	29	2.0

Table 3

Relationship of the Motor FIM™ and the Cog FIM™

Hypothesis 2	Pearson Correlation Coefficient	N
Relationship Between Motor FIM™ Δ and Cog FIM™ Δ	.03	30

Discussion

Although both the motor FIM™ and cog FIM™ scores increase over the Inpatient Rehabilitation stay as would be expected, they do not change with the same magnitude. The change in the cog FIM™ during inpatient rehabilitation is less than the change in the Motor FIM™. Two possible explanations are that either cognition does not improve as much as motor function during the inpatient rehabilitation or the Motor FIM™ is a better measure of improvement in function during inpatient rehabilitation than Cog FIM™.

Other research (Hajek, Gagnon & Ruderman, 1997) demonstrated that the Cog FIM™ does not correlate to other cognitive outcome measures. If the Cog FIM™ is not

a good measure of cognitive change, then combining it with the Motor FIM™ in a total FIM™ score to measure improvement in inpatient rehabilitation of stroke patients may not be an effective way of showing how much change has taken place. The Cog FIM™ may be diluting the Motor FIM™ effect with extraneous information that doesn't add meaning.

Considering the second hypothesis, there is no correlation between the Motor FIM™ and the Cog FIM™. Motor FIM™ and Cog FIM™ are independent measures and do not relate to each other, rather they change independently.

In addition, when the total FIM™ score is used, there are 18 items, 13 (72%) of which are Motor FIM™ scores and 5 (28%) are Cog FIM™ scores. Although the total FIM™ is weighted toward the motor score, cognitive status may prove to be more important in the overall functional recovery of the some stroke patients. Because of this bias, the emphasis in treating the stroke patients in rehabilitation has been to focus on motor recovery with less attention given to cognitive rehabilitation. This may be appropriate for rehabilitation patients who do not have significant cognitive impairment, such as orthopedic patients, but it may be more beneficial for stroke patients if more emphasis was given to cognitive rehabilitation.

Linacre, Heinemann, Wright, Granger & Hamilton through Rasch analysis divided the FIM™ into "two statistically and clinically different indicators" (1994, p. 127), the Motor FIM™ and the Cog FIM™. This further supports the idea that the scores should not be combined.

The results of this current study, together with the results of other research, would suggest that the best way to measure change in the functional status of stroke patients in inpatient rehabilitation is to use two separate measures, one for the motor recovery and the other for cognitive recovery, and that the scores should not be combined. This is supported in the literature by Hajek, Gagnon & Ruderman (1997) who concluded that "rehabilitation outcome could be better predicted if the results of a functional assessment were coupled with in-depth cognitive assessment" (p.1331). Using two separate scores would delineate between those stroke patients who have a significant cognitive impairment due to the stroke and those who do not have a significant cognitive impairment. The Motor FIM™ could be combined with a cognitive measure other than the Cog FIM™, which has been shown to have low convergent validity with other cognitive outcome measures. These two measures together may produce a more accurate assessment of functional change during inpatient rehabilitation of stroke patients than the total FIM score.

Implications for Occupational Therapy

Although it appears unlikely that a new outcome measure will be considered and adopted by Medicare for use in rehabilitation in the near future, it is important that occupational therapists as well as other clinicians working in rehabilitation continue to emphasize the effect of cognitive impairment on the functional ability of stroke patients. The overall effect of the use of the Prospective Payment System has been a reduction of the average length of stay of patients, lower functional levels as discharge, and higher

rates of institutional discharge (Gillen, Tennen & McKee, 2007). The emphasis of the FIM™ on the motor aspects of recovery and relative disregard for the cognitive aspects may be a significant contributor to this trend. It may be beneficial to consider increasing the length of stay in order to better address cognitive impairments that affect function, so that patients are more independent at discharge.

One way that occupational therapists can identify and document functional cognitive impairments is by utilizing discipline specific evaluations such as the Kohlman Evaluation of Living Skills (Kohlman Thomson, 1992) and the Executive Function Performance Test (Baum, Connor, Morrison, Hahn, Dromerick & Edwards, 2008). These evaluations clearly demonstrate the effect of cognitive impairment on typical activities of daily life. When these evaluations are implemented with appropriate patients, the results provide evidence of their need for continued intervention beyond recovery of motor skills. In the IRF-PAI Manual, it is noted:

> The FIM™ instrument may be added to information that has already been gathered by a facility. This information may include items such as independent living skills, ability to take medications, to use community transportation, to direct care provided by an aide, or to write or use the telephone, and other characteristics such as mobility outdoors, impairments such as blindness and deafness, and pre-morbid status. (2004, p. III-2)

In inpatient rehabilitation, speech language pathologists or occupational therapists routinely complete the Cog FIM™. Occupational therapists also complete the Basic

Activities of Daily Living (BADL) portion of the Motor FIM™. In order to be accurate in scoring the FIM™, it is essential that the cognitive aspects of Motor FIM™ items are considered as well as completing the Cog FIM™ correctly. For instance, in assessing the patient's ability to transfer to the bathtub, cognitive issues could lower the score from a 7 (independent) to a 6 (modified independent) if there is concern that the patient does not recognize and correctly respond to safety issues such as a wet floor or insufficient lighting. Although these items are usually addressed automatically by the OT or other staff in the inpatient rehab setting, when the patient is discharged it will become the responsibility of the patient or their caregiver. According to the IRF-PAI Manual:

> Implicit in all of the definitions, and stated in many of them, is a concern that the individual perform these activities with reasonable safety. With respect to level 6, you must ask yourself whether the patient is at risk of injury while performing the task. As with all human endeavors, your judgment should take into account a balance between an individual's risk of participating in some activities and a corresponding, although different risk if (s)he does not. (2004, p. III-2)

The institution of the PPS has made it a priority for inpatient rehabilitation facilities to discharge patients as early as possible, since the payment will be the same for a patient no matter the length of stay. As advocates for our patients and their families, occupational therapists need to consider whether earlier discharge will provide the best outcome for the patient or if a longer length of stay will result in meaningful

improvement in functional status. Using other evaluation tools in addition to the FIM™ will provide the best evidence to support the appropriate decision.

CHAPTER IV

TRIAL OF THE APPLIED COGNITIVE SCALE OF THE AM-PAC IN INPATIENT REHABILITATION OF STROKE PATIENTS

Significance of Study

Although the Cog FIM™ showed a moderate effect size in the inpatient rehabilitation period, it does not correlate with the Motor FIM™ or other neurological tests used in stroke rehabilitation (Adunsky, Fleissig, Levenkrohn, Arad, & Noy, 2001; Te Winkel-Witlox, Post, Visser-Meily & Lindeman, 2007; Hajek, Gagnon & Ruderman, 1997). Another outcome measure may give more specific information about cognitive change during inpatient rehabilitation.

There is an emphasis in finding or developing an outcome measure capable of measuring cognition across the spectrum of rehabilitation settings, instead of the current practice of having different outcome measures in each setting. According to Heinemann (2008), one of the critical research needs is "standardizing PAC [post-acute care] measures and timing of routine measurement for payment and quality assurance purposes across sites of care." (p. 255) The Cog FIM™, due to its ceiling effect, is not a good measure for patients who have mild cognitive deficits, especially for those who are in the subacute recovery period of three to six months (Schepers, Ketelaar, Visser-Meily, Dekker & Lindeman, 2006). The AC AM-PAC has a smaller ceiling effect and has

proven to be more sensitive than the Cog FIM™ in the subacute patient population (Sandel, et al, 2012).

In this study the AC AM-PAC is examined to determine if it is sensitive to any change that occurs between admission and discharge from inpatient rehabilitation of stroke patients. It is also of interest if a cognitive measure used in inpatient rehabilitation can predict the patient's function in the subacute period. To answer this question, this study examines whether the Cog FIM™ or the AC AM-PAC correlate with a measure of function at three months post-stroke, namely, the Reintegration to Normal Living Scale (RNL) (Wood-Dauphinee, Opzoomer, Williams, Marchand, & Spitzer, 1988).

Research Design

This study was designed to examine the use of a new outcome measure, the AM-PAC, and compare it to the current outcome measure, the FIM™, during the inpatient rehabilitation of stroke patients. For this study, only the cognitive portions of the two outcome measures were compared, that is, the Cog FIM™ and the AC AM-PAC. No changes were made to the rehabilitation process. The purpose of the study was to determine which cognitive outcome measure, the Cog FIM™ or the AC AM-PAC, gives more information about cognitive change during the inpatient rehabilitation period of stroke patients and which of these measures is more effective to make predictions about a stroke patient's ability to return to their previous level of function after rehabilitation.

The hypotheses addressed in this study were:

1 The AC AM-PAC is sensitive to change during the inpatient rehabilitation stay of stroke patients.

2. The AC AM-PAC is a better predictor than the Cog FIM™ of reintegration to normal living at three months, in addition to the information given by the NIHSS at admission.

The *t* test for correlated samples was used to compare initial and discharge AC AM-PAC scores. This was then compared to the results from study one demonstrating that the Cog FIM™ was sensitive to change and had a medium effect size, 0.62. Hierarchical multiple regression was used to determine whether the AC AM-PAC at discharge is better at predicting reintegration to normal living at three months than the Cog FIM™. The RNL was used as a measure of the ability of the patient to reintegrate to normal living.

Methodology

Subject Characteristics and Sampling Procedures

Permission was obtained from the hospital to recruit patients and to access patient records and the study was approved by the Institutional Review Board for the hospital and participating institutions. In this study, the ACS AM-PAC was administered to fifty consecutive stroke patients who were admitted to the inpatient rehabilitation department at a large metropolitan hospital. The patients were screened to determine if they met the inclusion and exclusion criteria (Appendix E). The patients were invited to participate in

the study and informed consent was obtained. Demographic information about each patient was then obtained from the patient and the patient's chart. The patient characteristics are summarized in Figure 2.

Data Collection Procedures

The patient was then assessed using the AC AM-PAC on the day following admission. The National Institutes of Health Stroke Scale (NIHSS) was obtained from the chart. The NIHSS is described in Appendix D (Brott, Adams, Olinger, Marler, Barsan, Biller, & Spilker, 1989). The patient was again assessed with the AC AM-PAC on the day of discharge. The Cog FIM™ data were retrieved from eRehabData for admission and discharge scores.

After three months (at least 90 days and not more than 120 days), the patient was interviewed by telephone. The last measurement was taken at three months after discharge because by this time the patient would have likely completed therapy and settled into a home routine. Additionally, research has demonstrated that best ADL function is reached by 80% of stroke patients by three months post stroke (Jørgensen, Nakayama, Raaschou, Vive-Larsen, Støier & Olsen, 1995).

During the three month follow-up assessment, the patients completed the Reintegration to Normal Living Index (RNL) by phone interview. The RNL is described in Appendix C. In most cases the patient completed the three month assessment themselves without assistance from another, but patients were free to ask their family members to help answer questions. In one case, the patient's son acted as proxy for the

patient because he said his father would not be able to answer the questions accurately. In the statistical calculations for this study, the assessments that were used are the NIHSS at admission, the AC AM-PAC at admission and discharge, the FIM™ at admission and discharge, and the RNL. Figure 3 summarizes the process of data acquisition.

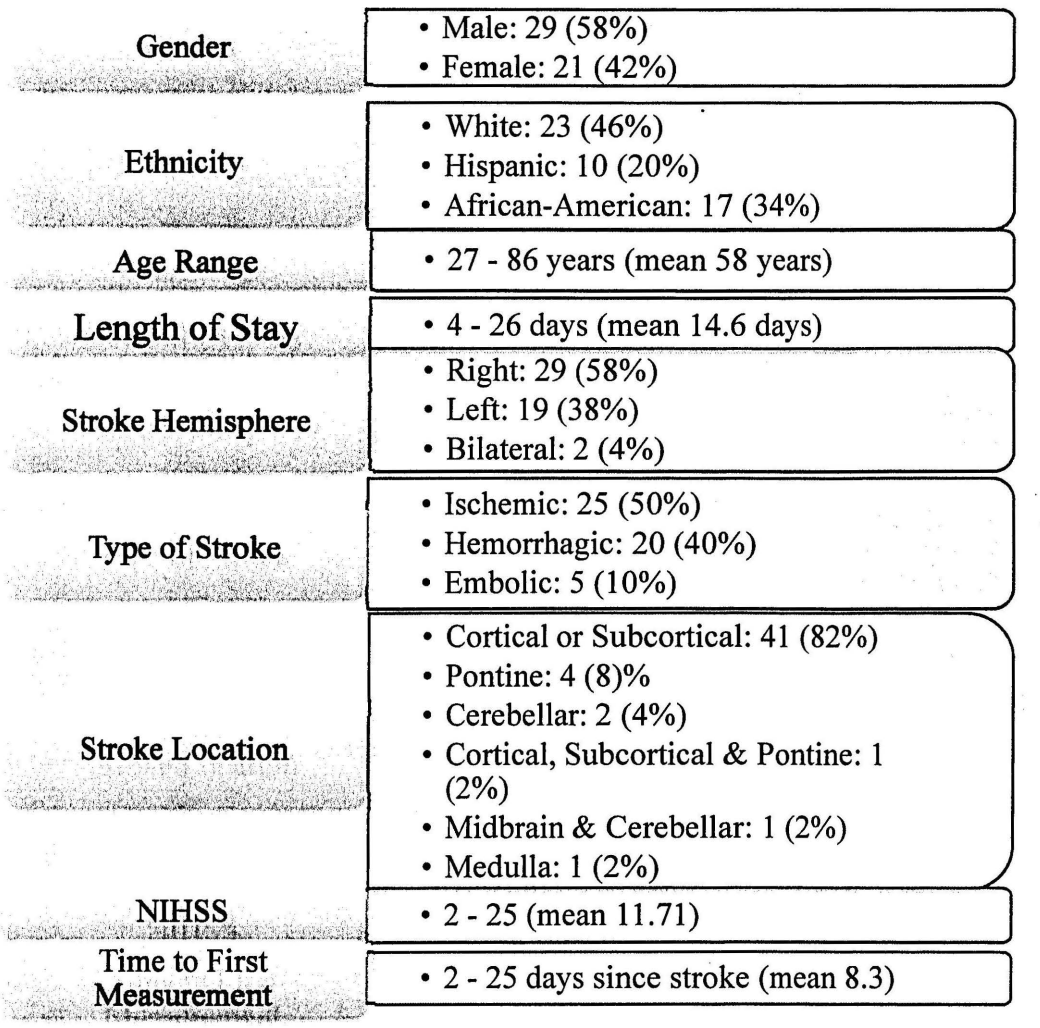

Figure 2: Sample II characteristics

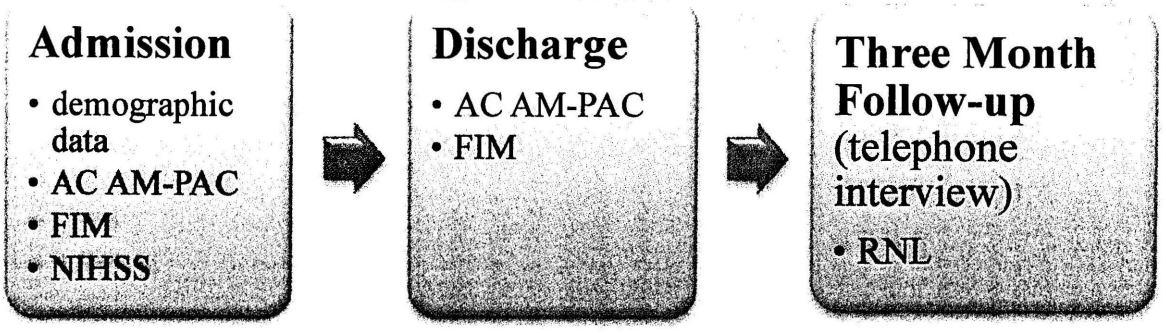

Figure 3: Data acquisition process

Sample Size Determination

Sample size was determined by performing a power analysis considering the outcome measures used and the statistical calculations that were proposed. The results of this power analysis were included in the application for Institutional Review Board approval. The two statistical procedures that were proposed for this study were the *t* test for correlated samples and hierarchical multiple regression.

For *t* tests for dependent samples, assuming a power of .80 and a p =.05 and an effect size of half a standard deviation, a sample size of 34 would be needed. However, given that the AM-PAC is a relatively unproven measure, a smaller effect size may be more reasonable to expect. Using an effect size of g = .40 would result in a requirement for 54 subjects.

For the regression equation, the number of subjects required is the number of independent variables x 10. At the time the proposal was submitted there was a possibility of up to five independent variables, which would indicate a sample size of 50 subjects.

Drop off of about 20% was considered reasonable between the initial recruitment and the three month follow up measurement. Therefore, it was presented in the IRB proposal that 60 patients would be a reasonable number to recruit. When presented with this information, the Institutional Review Board approved 50 subjects for the study.

Outcome Measures

The Cog FIM™ information was retrieved from eRehabData for admission and discharge scores. As previously described, the FIM™ data were gathered by clinicians and submitted to eRehabData along with other information required by Medicare.

The Applied Cognitive domain of the AM-PAC (AC AM-PAC) is one of three domains of the AM-PAC and may be presented as a questionnaire or completed by the subject on the computer without assistance. In this case, the AC AM-PAC was presented as a questionnaire. For each patient in the study, if the participant was not a therapy patient of the primary researcher (there are five occupational therapists in the inpatient rehabilitation department), then the researcher discussed the ability of the patient to accurately answer a questionnaire with his or her occupational therapist and speech language pathologist. If it was determined that the patient was likely to have difficulty answering the questions accurately, then their occupational therapist attended during the questionnaire session and assisted the patient in answering the questions more accurately. If there was a question that neither the occupational therapist nor the patient felt that they would be able to answer accurately because the patient had not encountered any situation

similar to this since his hospital stay, then that question was skipped, which is allowed by this program.

The AC AM-PAC uses item response theory (IRT) and computer assisted technology (CAT) which decreases the number of questions that each patient answers. Each patient is presented the same first question, and from the answer to that questions the program determines the next question. By use of this technology, the program determines which and how many questions to ask each patient in order to determine their score. In practice, there were usually about nine questions presented before the score was obtained. The same procedure was followed at the discharge measurement.

The NIHSS at admission was retrieved from the patient's hospital record. The NIHSS is a measure of the severity of the stroke. In the period immediately following the stroke, it is used to provide a quantitative measure of neurological deficit (Salter, et al, 2012). This score was determined by physician assessment of the patient on the day of their admission to the hospital after the stroke has occurred. In one case, no NIHSS was recorded in the medical record, so this patient's results were unable to be used in one of the statistical analyses that used this score.

The Reintegration to Normal Living Scale (RNL) was determined by phone interview three months after discharge from the inpatient rehabilitation unit. The RNL uses a visual analog scale and is the patient's assessment of their ability to return to their normal activities since the stroke (Wood-Dauphinee et al., 1988). The RNL is a measure of participation rather than activity as defined by the ICF (ICF, 2001).The items do not

consider whether the participant has impaired ability to complete an activity, only if they are able to participate in that activity to their satisfaction. For example, one question asks if the patient is comfortable with how their self-care needs are met, and states that adaptive equipment, supervision and/or assistance may be used (Wood-Dauphinee et al, 1988). Although the RNL uses a visual analog scale, the researcher used it in a telephone interview format by explaining the scale verbally. None of the patients expressed that they were unable to understand or answer the scale with the verbal explanation.

Results

Recruitment

Patients were recruited for Study Two over a span of 16 months. Of the fifty patients recruited for the study, six were excluded before the second outcome measure (discharge measure) because they were discharged from rehabilitation unit to the acute hospital for medical complications. One patient was discharged from the inpatient rehabilitation unit earlier than scheduled, and was unable to be reached for the second measurement.

Six were excluded before the three month follow up measurement because they were readmitted to the hospital since their discharge from rehabilitation. One patient died between her discharge and the follow up at three months. Nine patients were unable to be reached for the three month follow up measurement due to having a disconnected phone, not answering the phone with repeated messages, or refusing to participate.

For the first hypothesis, there were 43 participants (86%) who completed both the first and second measurements to be used in the statistical calculations. For the second hypothesis, the RNL measurement at three months was required. Of the 50 participants originally recruited, 27 patients (54%) were able to complete the third measurement which included the RNL. One of these patients was not included in the calculation for the second hypothesis because there was no NIHSS available from his medical record.

Statistics and Data Analysis

For the first hypothesis, the *t*-test for correlated samples was used to compare the initial and discharge AC AM-PAC scores. The change in the AC AM-PAC scores was not statistically significant ($t = 1.83$, $df=42$, $p <.075$). However, there was a trend toward significance. The effect size determined using Cohen's *d* was 0.29, a medium effect size. These results are summarized in Table 4.

Table 4

Change in the AC AM-PAC

Hypothesis 1	Mean Initial Score	Mean Discharge Score	Std. Deviation	t-test	*df*	Effect Size
Change in AC AM-PAC	43.41	46.15	9.30 – 10.88	1.83	42	0.29

For the second hypothesis, hierarchical multiple regression was used to determine whether the AC AM-PAC at discharge is a good predictor of the RNL, in addition to the NIHSS. The Cog FIM™ at discharge was entered last, as it was predicted to give less information than the AC AM-PAC. The overall model, including the NIHSS, AC AM-

PAC, and Cog FIM did not significantly predict satisfaction in return to normal living (RNL) $F(3, 25)= 2.12$, $p = .13$. However, for the total model, the $R^2 = .224$, $(R^2_{adj} = .12)$. The vast majority of the variance in RNL scores was accounted for by AC AM-PAC scores (R^2 *change* $= .22$, F_{change} $(1,23) = 6.44$, $p < .05$. Specifically, the NIHSS R^2 was .004 while the + AC AM-PAC was .218 and the Cog FIM added .002 to the total model which was not statistically significant.

However, after completing the regression analysis it was determined that the NIHSS did not prove to be a robust measure of disability with this sample since it failed to account for much variance in the model. Therefore a second hierarchical regression model was used, with RNL as the dependent variable and only two independent variables, the AC AM-PAC at discharge and the Cog FIM™ at discharge. The AC AM-PAC was entered first and then the Cog FIM™, since it was hypothesized that the AC AM-PAC is a better predictor of the RNL. The overall model with the AC AM-PAC and Cog FIM™ did not significantly predict satisfaction in return to normal living (RNL), $F(2,26)=1.89$, $p< .05$. However, for the total model, the $R^2= .136$ $(R^2_{adj}=.06)$. As with the previous model, the vast majority of the variance in RNL scores was accounted for by AC AM-PAC scores (R^2 change $= .113$) whilst the Cog FIM added a negligible amount to the total model (R^2 change $= .023$).

Discussion

The change in the AC AM-PAC during inpatient rehabilitation of stroke patients was not significant, although there was a trend toward significance. The AC AM-PAC change was a moderate effect, as was the Cog FIM™ in the first study. Regression analysis also demonstrated that the AC AM-PAC was a better predictor of the RNL than the Cog FIM™.

For the first hypothesis, there were fewer subjects than was recommended by the power analysis. The recommended number was 54 but the actual number that completed the two AC AM-PAC measurements was only 43. This may be one reason that statistical significance was not reached. Of note, however, the effect size was moderate, despite the failure to reach statistical significance.

The number of subjects for the second hypothesis was 26, which was also less than the power analysis indicated. For the first model, there were three variables (NIHSS, AC AM-PAC and Cog FIM™), so ideally there should have been at least 30 subjects. The NIHSS was eliminated from the second model, decreasing the number of required subjects to at least 20, which was met. However, in both models neither the AC AM-PAC nor the Cog FIM™ reached statistical significance. Despite the low number of subjects for the second hypothesis, there were sufficient subjects to demonstrate that the AC AM-PAC was better predictor of the RNL than the Cog FIM™.

There are many factors that would need to be considered to determine satisfaction with living three months after a stroke. Physical and cognitive impairments would be

important determinants of satisfaction. However, other factors are likely to play a significant role, such as familial and social supports, financial status and emotional state. None of these factors were included in this model. The finding that the AC AM-PAC is a better predictor than the Cog FIM™ may be linked to the fact that the AC AM-PAC is better at measuring higher level cognitive impairments which may lead to lower satisfaction when a stroke survivor is faced with the complexities of life outside of the rehabilitation unit.

The NIHSS, which was determined by the physician when the patient was first admitted to the hospital, was included in the regression analysis as a measure of the severity of the stroke. This score, however, may not be a good measure of the severity of the stroke at the time that the patient reaches inpatient rehabilitation. In the stroke unit patients may demonstrate significant recovery due to medical interventions such as the use of tissue plasminogen activator (Berlet et al., 2013). In addition, the amount of time between admission to the hospital and admission to inpatient rehabilitation varies considerably, from two to 25 days. An NIHSS stroke score determined at admission to inpatient rehabilitation would likely be a much better measure of impairment to be used in future studies.

Comparison of the Cog FIM™ and the AC AM-PAC

Although statistical analysis of the ability of the outcome measure to measure change is an important consideration, it is only one aspect to consider in choosing the appropriate outcome measure for a particular setting. Effect size is also important, and

both the Cog FIM™ and the AC AM-PAC demonstrated a moderate effect size. Other factors from the literature will assist in distinguishing the two outcome measures and their appropriateness for use in various post-acute settings.

Validity and reliability. Validity and reliability of these measures are important considerations. There have been multiple studies on the FIM™ because it has been in use for more than thirty years. Although most studies demonstrate acceptable reliability, some researchers have found specific threats to reliability of the Cog FIM™ , especially interrater reliability Ottenbacher, Hsu, Granger & Fiedler, 1996; Doctor, Wolfson, McKnight & Burns, 2003; Wolfson, Doctor & Burns, 2000; Kohler, Redmond, Dickson, Connolly & Estell, 2010). Though there have been fewer studies with the AM-PAC because it is a much newer instrument, test-retest, interrater and subject-proxy reliability have been found to be acceptable (Andres, Haley, and Ni, 2003; Jette et al., 2012).

Likewise, there are issues with the validity of the Cog FIM™, especially convergent validity (Adunsky, Fleissig, Levenkrohn, Arad, & Noy, 2001; Te Winkel-Witlox, Post, Visser-Meily & Lindeman, 2007; Hajek, Gagnon & Ruderman, 1997). The AM-PAC utilizes IRT, enabling there to be a large number of items included, as well as allowing direct linkage of individual items from the AM-PAC to other measures. This direct comparison of items is a different way of comparing measures than the traditional methods used to determine convergent validity. In this way the AM-PAC and the Quality of Life Outcomes (QoL) have been linked so that the score on one measure can be converted to a score on the other measure (Haley, et al., 2011).

Sensibility. Sensibility is defined as "the overall appropriateness, importance, and ease of use of the instrument" (Barak & Duncan, 2006, p. 505). This involves more than the temporal requirements for training and utilization of the instrument. In utilizing these tools there were significant differences in the ease of use.

The Cog FIM™ is composed of two subsections: Communication with two questions (comprehension and expression) and Social Cognition with three questions (social interaction, problem solving and memory). The rating of these areas involves observing the patient in the rehabilitation setting and rating their performance on a scale of 1 to 7, with 7 indicating complete independence, 6, modified independence, 5, supervision, 4, minimal assistance, 3, moderate assistance, 2, maximal assistance and 1, total assistance. For instance, a person with global aphasia who is unable to speak or communicate in any way would score a 1 on expressive communication. The two communication questions are relatively easy to answer, especially by a speech language pathologist.

It is more difficult, however, to score problem solving, which, according to the manual, "includes skills related to solving problems of daily living. This means making reasonable, safe, and timely decisions regarding financial, social, and personal affairs, as well as the initiation, sequencing, and self-correcting of tasks and activities to solve problems" (IRF-PAI training manual, 2004, p III-53). Social interaction and memory have similar detailed descriptions. The scoring for these items is based on percentages of instances that the patient is able to do the activity, for instance, if they can solve "routine

problems" 25 to 49% of the time, they would score a 2, or maximal assistance (IRF-PAI training manual, 2004). In practice, observation of a patient for a short period of time during evaluation may not give the clinician enough information to score these items accurately.

There were some issues encountered in using the AC AM-PAC in this setting, some of which were most likely due to the researcher being inexperienced in using the measure. In administering the AC AM-PAC in the inpatient rehabilitation setting there was an opportunity to choose whether the patient was living in an institutional or community setting. The community setting was chosen in this study, as the researcher reasoned that the question referred to the usual place of residence. However, with further review of a recent publication (Sandel et. al., 2012), the institutional setting would have been more appropriate. The institutional item bank is limited to activities that are more commonly experienced in an institutional setting while the community item bank covers a wider range of activities. The researcher overcame this limitation by using the "skip" function if the subject had not experienced the activity in that particular question. If the institutional item bank had been used likely the "skip" function would not have been needed as often. This was especially true at the first administration which took place on the day after the patient's admission to inpatient rehabilitation. By the second administration on the day of discharge the patients had experienced a greater variety of functional activities and generally were able to answer most if not all of the questions presented.

In addition, patients may not have always been accurate in reporting their abilities. One possible explanation for this is that the patient may describe how well they did with that particular activity before the stroke, not considering the changes that have occurred since the stroke. To minimize this effect, the OT was used as a proxy for the patient when it was determined by the OT or SLP that the patient was unlikely to give an accurate report of their current level of function. However, at the first administration on the day after admission, clinicians may still be unsure of the patient's self-awareness.

Another difficulty encountered in using the AC AM-PAC was that physical impairment, either new impairments from the stroke or impairments that the patient had previously, affected their answers on the items asked. For instance, if the item asked about reading a long book, some patients were unable to read due to a physical impairment such as a visual field cut or diplopia (new impairment) or because they were illiterate (prior state). Some patients had difficulty writing down a short message or note because their dominant hand was affected by the stroke making writing difficult (new impairment) but not because of cognitive impairment. In both cases, it was not appropriate to skip the question, because the patient clearly knew the answer, but the answer was not necessarily a reflection of their cognitive status.

Predictive validity. The AC AM-PAC at discharge was found to be a good predictor of the RNL. One question that patients often ask clinicians is, "will I be able to return to life as it was before my stroke?" This result could offer a partial answer. Although it is unlikely that patients will completely recover from stroke unless the stroke

was very mild, through use of compensatory methods and contextual supports, many stroke patients are able to achieve a "new normal" that is personally meaningful and purposeful. The RNL is one way of assessing that a "new normal" has been achieved, because it examines the area of participation, rather than activity.

In summary, both the Cog FIM™ and the AC AM-PAC are able to detect change in the cognitive status of stroke patients during inpatient rehabilitation, but these measures are very different in other factors that are important in choosing the best outcome measure for a particular setting. The ability of the AC AM-PAC to predict the RNL is an additional benefit of this instrument.

Implications for Occupational Therapy

Because of the expense and difficulty of development, testing, and ultimately utilizing an outcome measure, it would likely require years of study before a new outcome measure would be widely utilized. However, if the ultimate goal is to have outcome measures that can be used across all post-acute settings and give accurate information to improve practice, continued research is imperative. Continuing to utilize an outdated measure that has significant limitations is counterproductive to research and development of best practice models.

Occupational therapists as well as other clinicians can be instrumental in promoting the use of new outcome measures by conducting trials and by educating their peers about these outcome measures. They can also actively participate in the decision-

making bodies of healthcare organizations and governmental agencies that determine the measures to be used in different post-acute care settings.

CHAPTER V

CLINICIANS' PERSPECTIVE ON THE USE OF COGNITIVE OUTCOME MEASURES IN INPATIENT REHABILITATION OF STROKE PATIENTS

Introduction

The choice of outcome measures to be used in stroke rehabilitation is a complex problem. It is difficult to choose among the many measures that have been devised. The choice depends on the purpose for using the outcome measure, such as to measure physiological changes, cognitive changes, quality of life, patient satisfaction or efficacy of treatment. An outcome measure that is reliable and valid in one rehabilitation setting may be problematic in another setting. Another concern is whether the preference is for a measure that gives specific information for one type of setting or a more general measure that functions well in a variety of settings.

One important factor in choosing an outcome measure is to examine its psychometric properties. Testing these properties is an important part of outcome measure development and is systematically conducted during that process. The psychometric properties that are considered most important are reliability, validity, responsiveness, sensibility, and minimal clinically important difference (Barak & Duncan, 2006).

Determination of validity involves more than psychometric evaluation. It is typical for new evaluation measures to be evaluated by a panel of experts to determine content validity. Content validity "concerns the degree to which an instrument has an appropriate sample of items for the construct being measured" (Polit & Beck, 2004, p. 423). In developing the Stroke Impact Scale, there were several qualitative components including interviewing patients and conducting focus groups involving patients, caregivers and stroke experts. After completing analysis of the focus group data, there were two additional two consecutive consensus expert panels to finalize the first draft before it was tested in a pilot study (Duncan, Wallace, Studenski, Lai and Johnson, 2001). During the development of the FIM™, a subcommittee was formed to study the issues involved in measuring cognitive functioning (Keith, Granger, Hamilton, & Sherwin, 1987). In development of the AM-PAC, the items were reviewed by ten measurement and content experts and suggestions were also derived from focus groups of people with disabilities (Haley, Andres, Coster, Kosinski, Ni & Jette, 2004)

Once the outcome measure is developed, it needs to be incorporated into the clinic setting in which it will be utilized. Clinicians need to be trained in using the new measure and further studies should be conducted to determine whether the clinicians are using the instrument correctly and reporting the results accurately. The amount of time and attention required by clinicians to learn and use an outcome measure needs to be considered as well. These factors are examined during the trial phase, utilizing the new instrument in its intended setting.

It may be beneficial to have qualitative evaluation during the trial phase as well, such as interviews or focus groups of clinicians and clients. Clinicians and clients can be helpful in determining the sensibility of the instrument, which is defined as the "overall appropriateness, importance, and ease of use of the instrument" (Barak & Duncan, 2006). As they gain experience in using an outcome measure, clinicians may recognize threats to reliability and validity that were not previously addressed. A study of this type was conducted concerning the Palliative Care Outcome Scale, including focus groups of clinicians and clients (Slater & Freeman, 2005).

The outcome measure chosen and used will have an effect on clinical practice in the setting in which it is used. In the case of the FIM™, because it is required and used in all inpatient rehabilitation programs in the United States, it has become the benchmark for measuring progress in this setting. Medicare payments are in part based on the initial FIM™ score. The change in FIM™ score is used by payers to determine if a patient is appropriate to continue in inpatient rehabilitation or if they need to be discharged to another setting. This has caused FIM™ to become an essential part of patient evaluations and therapeutic interventions focus on improving FIM™ scores.

Even though the FIM™ has been used over a number of years, there is still more that may be learned by listening to the experience of clinicians that utilize it on a daily basis. There have been many changes in the inpatient rehabilitation environment over time, including decreased length of stay and changes in payment systems (Ottenbacher,

Smith, Illig, Linn, Oster and Granger, 2004; Gillen, Tennen & McKee, 2007). These changes have affected how clinicians practice and what is valued in outcome measures.

Through the experience of clinicians who use an instrument on a regular basis with a variety of patients, more may be discovered about the reliability, validity and sensitivity of the outcome measure than is learned only using quantitative measures. Psychometric properties are important, but statistical results do not give information on a micro level. For instance, a measure may have good interratter reliability according to the statistics, but there may be times or situations that cause difficulty with interrater reliability. Would it make any difference, for instance, if the rater using the measure is newly trained, if the instructions for using the measure have recently been rewritten, or if the rater received training in another hospital? Similarly, although sensitivity was tested using quantitative methods, it may be that the outcome measure is less sensitive to a particular subset of patients, for instance, patients who don't speak the common language of the facility, are deaf, or are developmentally delayed. This could cause these groups to be underrepresented and underserved.

The pressure to shorten length of stay in inpatient rehabilitation has made accurate use of outcome measures essential, since the scores obtained can be the most significant factor in determining whether a patient is to be discharged or is to continue in rehabilitation. For instance, if a patient's scores do not change from one week to the next, they are often considered to have reached a plateau and are no longer benefitting from therapy. Also, a patient may attain the highest score on a particular measure and is

considered appropriate for discharge, but due to a ceiling effect there may be deficits that remain unreported.

Statistically, a measure may give good information for the vast majority of patients. As demonstrated, however, the chosen instrument has significant effects on individual treatment planning and implementation. It influences the decisions of payers about the appropriate setting and amount of rehabilitation that a patient can receive. Although it is not possible to have an outcome measure that works perfectly for every patient, qualitative methods may uncover factors that affect reliability, validity and sensitivity.

Another important consideration is the time and attention required of clinicians to be trained in using an instrument and the time required to perform the evaluation. Clinicians who routinely use a measure can impart significant information about its usability. Some measures take an inordinate amount of time to perform. In some cases the instructions can be complex and difficult to follow. Knowledge of these issues could be used to improve an existing instrument or to develop better instruments.

For this study, the research questions are,

1. What do clinicians think are positive and negative aspects of the Cog FIM™ and the AC AM-PAC?

2. Can the experience of clinicians add information to improve these outcome measures and utilize them more effectively?

Methodology

This is a qualitative study examining the subjective experience of utilizing the Cog FIM™, as well as evaluating the AC AM-PAC as a possible alternative to the Cog FIM™. The research design involved conducting a focus group of clinical team members from the inpatient rehabilitation department at a large metropolitan hospital. A focus group interview is defined as "an interview with a group of individuals assembled to answer questions on a given topic" (Polit & Beck, 2004, p. 719). Permission was obtained from the hospital to recruit clinicians and the study was approved by the Institutional Review Board for the hospital and participating institutions.

Participant Characteristics

The sample consisted of eight clinicians who were given written information about the AC AM-PAC and had opportunities to ask the researcher any questions they had about this outcome measure prior to the focus group. They had all received formal training in using the FIM™ and utilized it daily. Table 5 gives descriptive information about the focus group members.

Table 5

Focus Group Participants

Discipline	Cred-ential	Degree	Time in profess-sion	Time at hospital	Current position	Time in Current Position	Gender
Social Work	LMSW	MSW	2 years	2 years	Social Worker	2 years	Male
Physical Therapy	PT	MS	4 years	2 years	Physical Therapist II	2 years	Female
Speech Pathologist	CCC, MS	MS	7 years	6 years	Speech Language Pathologist	6 years	Female
Physical Therapy	BS PT, C/NDT	BS	20 years	4 years	Inpatient Rehabilitation Manager	2 years	Female
Occupational Therapy	OTR	MS	6 years	6 years	Occupational Therapist II	4 years	Male
Physical Therapy	MPT, MBA	MPT	17 years	4 years	Director of Rehabilitation	2 years	Male
Nursing	RN	BSN	13 years	12 years	Clinical Manager, Inpatient Rehabilitation	2 mos.	Male
Nursing	RN	ASN	15 years	6 years	Charge Nurse	2 mos.	Female

Research Design

The primary researcher conducted the focus group but participated only to present the questions and to clarify points about the questions if needed. A semi-structured questionnaire format was used and the focus group session lasted one hour. It was recorded and transcribed verbatim. Using qualitative research methods, the transcription was coded and emerging themes were revealed. These themes were used as a basis for the Results and Discussion section of the study.

Focus Group Questionnaire

The primary researcher used these questions to lead the focus group:

- What, for you, are the most important factors that make an outcome measure a good measure?
- What, for you, are the factors that are most problematic in an outcome measure?
- From what you know about the Cognitive FIM™, what makes it a good measure?
- From what you know about the Cognitive FIM™, what is problematic?
- From what you know about the Applied Cognitive AM-PAC, what do you think makes this a good outcome measure?
- From what you know about the Applied Cognitive AM-PAC, what could be problematic?
- Do you think the Applied Cognitive AM-PAC would be more or less useful than the Cognitive FIM™ as an outcome measure in inpatient rehabilitation? How so?
- How could cognitive outcome measures be used in this setting to improve functional outcomes?
- What are your ideas about future uses of cognitive outcome measures in this setting?

Credibility

Member checking and peer review were used to add credence to the results. To insure that the focus group member statements were correctly quoted and interpreted, the group members were given an opportunity to read the first draft of the results section and

to comment if they found anything inconsistent with their experience. The transcript of the focus group was also coded by another individual who was unfamiliar with the research, to insure that the primary researcher's personal insights did not interfere with analysis of the focus group. Peer review revealed no significant disagreement regarding the themes that emerged, although different names may have been used to describe the themes in each case.

Results

Analysis of the transcript revealed positive and negative aspects of both the Cog FIM™ and the AC AM-PAC. The themes have been labeled with terms that are commonly used in the evaluation of outcome measures, and are subtitled by a quotation from the focus group that represents that theme. Each theme is described using the comments of the participants. In addition, the focus group also described ways that these outcome measures could be modified that may result in more accurate and useful information. In the discussion section, the themes are further developed by comparing the comments of the focus group with the results the other two studies and with information from the literature.

Interrater Reliability: "That everyone who's scoring it is scoring it consistently"

There were several concerns raised about the interrater reliability of both the Cog FIM™ and the AC AM-PAC. Concerning the Cog FIM™, there were concerns that the rating system is too subjective because the definitions of the different levels lack specificity. Also, scores can be recorded by any discipline and information may either be

observed directly or obtained from another caregiver or family member. According to the group, so many avenues for gathering information could lead to inconsistent reporting. One clinician stated, "you have so many disciplines that can score this, it's going to be skewed."

Considering the AC AM-PAC, however, there were also concerns. The AC AM-PAC interview questions can be asked directly to the patient, or if the patient is unable to provide the answers, by a knowledgeable caregiver or a clinician that is familiar with the patient acting as a proxy. As one participant expressed it, "many of our patients can't talk and maybe their families don't come around [to act as proxies] so we would have to do it based on our assumptions as well." There was concern that if there were different people acting as proxies (family or clinicians) at different administrations, their answers may be inconsistent.

Even when the patient is able to answer the questions themselves, there are concerns about their ability to answer the questions accurately. One clinician said, "patients who tend to downplay everything may not see the gains that we see as a clinical therapist." Conversely, according to the speech language pathologist, "their insight could be really bad so they're like, 'I'm great, there's nothing wrong with me.'"

Comprehensibility: "That it's easy to score and there's not a lot of room for error"

Another concern about the Cog FIM™ is comprehensibility. Comprehensibility is the degree to which clinicians using the instrument are able to understand the behaviors necessary to produce accurate and valid scores (Polit & Beck, 2004). Comprehensibility

is a factor in interrater reliability. The clinicians thought that Cog FIM™ scoring is ambiguous and difficult to interpret. One participant said, "some people's idea of supervision might be different from someone else's idea...the definitions have to be very specific." Also, it was expressed that there are specific criteria that affect the scores that may be known to some but not all clinicians, such as whether the patient typically wears glasses to read or uses medication to control mood.

Both the nurse and the occupational therapist in the group expressed that they feel less qualified to score the Cog FIM™ compared to speech language pathology. The occupational therapist stated, "I feel sometimes it gets a little ambiguous and you're scoring it based on your interactions with the patient, not necessarily using a formalized assessment tool."

Concerning the AC AM-PAC, it was expressed that it would be easier to follow the directions correctly since it uses computer assisted technology, and all that was required was that the questions be asked as presented on the computer. As one of the nurses explained, "anyone ... would be on equal grounds to administer that part of the AM-PAC."

Language Barrier: "The language barrier makes a big difference"

Another threat to inter-rater reliability was brought up by one clinician who commented that when the patient does not speak the same language as the person scoring the Cog FIM™, it is possible that the language barrier could cause the score to be wrong. For instance, if the patient was unable to follow the clinician's directions due to a

language barrier, it could be misconstrued to be a problem with receptive language. As he stated, "sometimes messages aren't getting across with certain patients and you can say, OK, well, the patient didn't follow my command, therefore they must have some kind of cognitive issue going on, but it could be that you may need to get an interpreter."

Content Validity: "That it encompasses various areas of cognition"

The Cog FIM™ received positive comments about its breadth of coverage because it covers various areas of cognition. It was also expressed that the Cog FIM™ could be scored and show progress in low level patients. As the speech language pathologist said, "it's good in the fact when they are very low level you can document on expression, social interaction, problem solving and memory."

The AC AM-PAC was thought, however, to cover too many different functional tasks for use in inpatient rehabilitation. One participant stated, "when we're trying to work on restoration recovery in two weeks it's hard ... to hit all these points." It was expressed that the AC AM-PAC may function better after discharge when patients would have had opportunities to practice these skills at home and in post-acute therapy and therefore could be more accurate in reporting their abilities.

External Validity: "The FIM™ was not designed as an outcome measure"

It was expressed by one participant that the FIM™ was not designed as an outcome measure, but rather as a measure of burden of care. It was designed, according to this member, "to help predict what the family and caregivers are going to encounter when they get home at two in the afternoon and four in the morning." This clinician was

concerned that the FIM™ may not function as well as an outcome measure used for treatment planning as it does when used by care providers to estimate the level of care needed.

Efficiency (Sensibility): "That it's quick and easy"

Group members agreed that it was beneficial for outcome measures to be easy to use. Those outcome measures that do not require too much time or multiple pieces of equipment are preferred. In this respect, both the Cog FIM™ and the AC AM-PAC meet the clinicians' preferences. The Cog FIM is based on observations that occur during the routine interactions with the patient, and the AC AM-PAC takes a short of amount of time to administer. It was also noted that both of these outcome measures use the computer for recording scores, adding to their efficiency. However, as one participant noted, "if we are going to use it throughout a continuum [of rehabilitation settings], it is very difficult to find a simple measure that does that."

Sensitivity: "It's hard to show progress with a high level patient"

The Cog FIM™ was criticized for not being sensitive to high level cognitive deficits. As one participant said, "it has a ceiling effect …it's not going to show the gains in a higher level patient." As another clinician stated, "that's a limitation of the FIM™ in the cognitive aspect that there's a ceiling effect, that once you're sort of normal you're [scored as] normal but it doesn't account for some of the really higher level cognitive tasks that someone might need to do." It was considered that the AC AM-PAC might be a little better at identifying patients with higher level cognitive deficits.

Precision: "If the outcome measures were more specific"

Clinicians in the focus group felt that the rating system of the Cog FIM™ was not specific enough to show progress in patients with higher level cognitive impairments. One improvement that was suggested was,

> I think if we were to design an outcome tool that would work well in inpatient rehab it would incorporate that cognitive aspect into the functional mobility … so it wouldn't just be about how far they can walk or how far they can push their chair, but can they navigate their way to the therapy gym and back to their room and how much assistance do they need for that? I think if we were to design something it would have the functional component built into the cognition because we as humans don't typically just sit down and do cognitive tasks and then do mobile tasks, we blend it all together, so it would be nice if the outcome tool helped with that.

It was expressed that these patients are being discharged prematurely and that if they stayed longer they would be able to discharge at a community level rather than "going home to their house because everybody's afraid to let them out because they're going to get hurt."

Predictive Validity: "To see where they may get three months down the road"

One clinician felt that because the Cog FIM™ is interpreted by different therapists inconsistently that it may be difficult to use it "as an outcome measure to predict [how the patient will be] at home." On the other hand, the AC AM-PAC, because

it can be used as a outcome measure in the post discharge period "allows you to see their outcome measures at home and then getting back into the real world versus the FIM™ [which] allows you to [see only] up to discharge. So it prepares the patient better realistically to see where they may get three months down the road."

Discussion

Combining qualitative results in this study with information from the literature review and the other two studies may give some insights about these two outcome measures and directions for further research and refinement. In the literature it was noted that the FIM™ had identified interrater reliability issues. The focus group, however, brought up issues that had not been specifically mentioned in the studies, such as the difficulty of interpreting the instructions for grading the FIM™ and possible inconsistency caused by using multiple reporters. These issues would benefit from further quantitative research to determine how significantly these factors may affect scoring. If a problem exists, it may be possible to resolve it by changing the way the FIM™ is administered, modifying the manual, or modifying the training for the FIM™.

In the focus group, the Cog FIM™ was also criticized for lack of sensitivity in identifying high level patients. The focus group participants suggested that more levels could be added to the FIM™ to account for patients with high level cognitive impairments. However, adding more levels may not solve the problem, because of the underlying subjectivity of scoring. Adding levels would increase the scoring complexity, possibly causing more difficulty. According to Polit and Beck (2004), observational

assessments are more accurate when there are a small number of well-defined, non-overlapping choices. Significantly, Rasch analysis of the FIM™ concluded that fewer levels would function better than the seven levels in its current form (Nilsson, Sunnerhagen & Grimby, 2005).

The AC AM-PAC uses CAT which eliminates the need of clinicians to determine the rating. Rather, the rating is determined by the computer program. Due to the use of CAT and IRT, there can be a very large bank of items but only a representative number of items are required for each client. This allows the AC AM-PAC to identify a wide range of cognitive impairment without increasing the complexity or time required to produce a score.

Even though the AM-PAC eliminates the need for a clinician to provide a rating for the patient's ability, the question of interrater reliability is still in question. For the AM-PAC, the requirement of reliability falls on either the patient or the proxy, depending on who answers the questions about the patient's level of function. The focus group had questions about the reliability of either patient or proxy. Patient respondents may over or underestimate their abilities. However, if a proxy is used, there may be an issue with interrater reliability if different proxies are used for the same patient at different instances of measurement.

Two studies have been conducted to examine the agreement between self-report and proxy report on the AM-PAC. The first concluded that subject-proxy reliability was acceptable for all three domains; however, there was a greater disparity on subject-proxy

agreement in the inpatient rehabilitation setting than with subjects in the community setting (Andres, Haley & Peng, 2003.

In another study which was conducted specifically with stroke patients, the AM-PAC assessment was performed within 24 hours from discharge from the acute hospital. The timing of this measurement is similar to the scoring of an outcome measure on admission to inpatient rehabilitation. According to this study,

> The overall agreement between patient-reported and proxy-reported function was within acceptable limits, with little evidence of systematic bias between proxy and patient reports of their functional status. That agreement was lowest in the domain of applied cognitive functioning is not surprising because this domain of functioning is less observable than the areas of mobility and daily activities (Jette et al. 2012, p. 826).

It is possible that, regardless of the reporter (patient or proxy), it is difficult to accurately assess the patient at admission, because the patient has had little opportunity to experience enough different activities to determine function. By discharge the patient has had many opportunities to experience functional activities, and this would improve their accuracy in completing the AC AM-PAC. The same would be true, however, of the Cog FIM™, because clinicians have had limited opportunity to observe the patient at the time of the initial scoring but by discharge will have had multiple opportunities to observe the patient's function.

The problem with inaccurate scoring due to language barriers is significant as the percentage of people in the United States whose primary language is other than English continues to increase. This issue concerns both observational measures like the FIM™ and questionnaires like the AM-PAC. Studies using interpreters need to be conducted for both measures, to determine whether they are reliable when interpreters are used. Another alternative for the AM-PAC is to create versions in other languages. The FIM™ would not need to be translated, but the manual must be clear that an interpreter should be used in assessing the Cog FIM™ portion of the assessment if the clinician is not fluent in the language spoken by the patient.

The question of whether the AC AM-PAC includes too many functional categories that are not experienced by patients during an inpatient rehabilitation stay was mentioned by one of the clinicians in the focus group. The AM-PAC, however, is designed to accommodate for this difficulty, by having two item banks of possible questions, one for institutional use and one for community use. Also, any question that cannot be answered can be "skipped" and another question will be presented. The clinicians in the focus group had been given a partial list of possible AC AM-PAC questions but had not experienced using the instrument. It may have appeared that there would be many questions presented to the patient that they would have no basis for answering accurately.

Clinicians in the focus group expressed that cognition and motor function are bound together in human activity and therefore should be evaluated simultaneously and

with the same score. To separate the cognitive score from the motor score is artificial and leads to inaccurate descriptions of the patient's actual functional ability.

One way to examine this concern is to explore the level of measurement of a particular instrument. The AM-PAC was developed using the World Health Organization's (WHO) International Classification of Functioning, Disability and Health (ICF). The AM-PAC items fall under the category of activity limitation, which is defined in the ICF as "difficulties an individual may have in executing activities" (ICF, 2001, p. 12). The question with each AM-PAC item is, "How much difficulty do you have" doing this activity? (Jette, Haley, Coster & Ni, 2007, p.7)

The FIM™, on the other hand, was developed as a burden of care score. Therefore, the scoring is based on how much help is needed for the patient to do each activity. In the Motor FIM™ the items are examined at the activity level. One example is "Transfers: Shower" which is described as "includes getting into and out of the shower" (IRF-PAI Training Manual, 2004, p. III-39). Of the Cog FIM™ items, Comprehension, Expression, Social Interaction, Problem Solving are described as activities in the ICF and Memory is described as a mental function (WHO, 2001). All of the Cog FIM items describe categories rather than discrete activities, making it more difficult to judge the functional ability of the patient.

Although there is no perfect way to capture actual function in an outcome measure, the AC AM-PAC may be more effective than the Cog FIM™, because the items concern specific activities rather than categories of activities. For instance, it is easier to

answer the question, "How much difficulty do you currently have carrying on a conversation with a small group (e.g., family or a few friends)?" (AM-PAC sample test items, 2007, p. 1) than it is to answer, "Does the patient need help expressing complex and abstract ideas, such as family matters, current events or household finances?" (IRF-PAI Training Manual, p. III-50)

In study one, the Cog FIM™ was shown to be sensitive to change during the inpatient rehabilitation stay as was the Motor FIM™. However, the Cog FIM™ and the Motor FIM™ scores did not appear to be related to each other and changed independently of each other. Through Rasch analysis it was determined that the motor FIM™ and the cognitive FIM™ "define two statistically and clinically different indicators" (Linacre, Heinemann, Wright, Granger & Hamilton, 1994). One solution to this difficulty is to measure change in the functional status of stroke patients in inpatient rehabilitation using two separate measures, one for motor recovery and another for cognitive recovery, and to report the two scores separately. This was recommended by Hajek, Gagnon & Ruderman (1997). Using two separate scores would delineate between those stroke patients who have a significant cognitive impairment due to the stroke and those who do not have a significant cognitive impairment.

In study two, it was noted in using the AC AM-PAC that physical impairments could affect the score on cognitive questions. For instance, if the item asked about reading a long book, some patients were unable to read due to a physical impairment such as a visual field cut or diplopia (new impairment) or because they were illiterate (prior

state). Some patients had difficulty writing down a short message or note because their dominant hand was affected by the stroke making writing difficult (new impairment) but not because of cognitive impairment. However, the focus group was supportive of the idea that functional items include both motor and cognitive components together as appears to be the case in these examples.

In the focus group, it was also mentioned that it would be beneficial if an outcome measure could predict future functionality of stroke patients. In study two it was demonstrated that the AC AM-PAC score was able to predict the RNL better than the Cog FIM™. For the individual patient, this information could give a general prognosis of how well they will be able to return to normal function three months after stroke based on the AC AM-PAC score at discharge. However, as in all statistical methods, it would need to be stressed that this is an estimate only, and the satisfaction of the patient with their level of function is based on many factors, including the available contextual supports.

Implications for Occupational Therapy

It is important to understand how an outcome measure can define practice. Because the FIM™ is required in all inpatient rehabilitation settings, it becomes the most important evaluation tool that is used in establishing goals and determining progress. This results in self-imposed limitations to scope of practice. According to Coster (2008), "the type of picture constructed by an instrument often leads to very different kinds of dialogues about the person's needs, potentially useful interventions, and likely outcomes." (p. 748).

Occupational therapists have several ways to resolve this issue. One avenue is to utilize the FIM™ as consistently and specifically as possible. In addition, occupational therapists need to dialogue with others, including administrators, about issues that they routinely encounter in using the FIM™, so that there is an opportunity to discuss and consider solutions.

Additionally, using other evaluation tools in addition to the FIM™ will result in additional and more specific information. Although occupational therapists are aware that other tools are available and use them occasionally, routine use of other evaluation instruments, especially those concerning higher levels of cognition, has the potential to increase the scope of evaluation and thus of practice. In this way, the occupational therapist will be able to provide additional information to the rehabilitation team, informing practice and facilitating decision making and discharge planning.

Another important way to contribute to change is to be active in developing and testing new outcome measures, and to communicate with other team members, administrators and agencies about research. As more evidence is gathered on a new measure such as the AM-PAC, and it is found to have both the psychometric properties that are desired as well as new features that allow it to be used across the spectrum of post-acute settings, it may be possible to eventually adopt a new measure.

CHAPTER VI

DISCUSSION AND IMPLICATIONS

Summary

The choice of an outcome measure in any circumstance is an important factor in the provision of therapy services. In the case of the rehabilitation of stroke patients, the FIM™ has become more than a useful tool for research and quality control. In addition, it is part of the information used to determine length of stay and what the facility will be paid for care of that patient. In addition, the FIM™ also informs practice, identifying the needs of the patient and guiding the clinicians in creating goals and making recommendations about discharge setting. However, as has been shown, the FIM™ may be contributing to a distorted and limited view of the stroke patient's true rehabilitation needs and appropriate goals.

The difficulties with the FIM™ go beyond standards of reliability. Although there are issues with reliability, generally the reliability of the FIM™ has been shown to be acceptable. The validity of the Motor FIM™ has been well studied and found to be acceptable. However, the validity of the Cog FIM™ is questionable, due to the fact that it doesn't correlate with other cognitive screening evaluations. In addition, internal validity is questionable, because the Motor FIM™ and the Cog FIM™ are used as one score but do not appear to be related.

Other difficulties have been identified with the Cog FIM™. It has been shown to have a significant ceiling effect that becomes more pronounced in higher level cognitivepatients and in stroke survivors in the post-acute period beyond inpatient rehabilitation For clinicians other than speech language pathologists, it can be difficult to understand the levels well enough to determine the score. In addition, the Cog FIM™ contributes only 28% to the total FIM™ score. In patients that have significant cognitive impairment, especially if their motor function is relatively spared, the total FIM™ may overestimate their actual functional abilities.

The psychometric properties of the FIM™ are questionable. The scale used for the FIM™ is an ordinal scale, although in research it is frequently treated as an interval scale. Rasch analysis of the FIM™ has demonstrated issues with conversion to an interval scale.

In summary, the FIM™ may not be the most effective instrument to use in rehabilitation. It may be able to be modified to meet current standards for outcome measures, but it may be more efficacious to use another measure that overcomes these issues by use of modern techniques for instrument development.

The AM-PAC is one such outcome measure, though it is not the only one. For the purposes of this paper, though, it was chosen to compare to the FIM™. Although the AM-PAC is designed to be used for a similar population as the FIM™, it is significantly different from the FIM in fundamental ways.

First, the AM-PAC is completed by the patient or a proxy if the patient is unable to complete it. Clinicians who are accustomed to traditional outcome measures are understandably concerned about the ability of patients to assess their functional abilities, especially cognitive abilities. It has been shown, however, that the AM-PAC demonstrates good interrater reliability with the use of patients and proxies when proxies are used appropriately.

Also, the AM-PAC uses IRT and CAT which results in an outcome measure that has a greater breadth of coverage while requiring only a short amount of time per patient to utilize. Due to these innovations, the AM-PAC has been shown to have low ceiling effects with patients at any stage of recovery from stroke. The use of CAT eliminates the necessity of the clinician decision about the level of function of the patient, unless the clinician is acting as proxy for the patient.

IRT methods also result in an interval score that can be analyzed with any quantitative statistical method. In addition, IRT makes it possible for the AM-PAC to be converted to another measure of the same content area. This enables there to be direct comparison of research projects or rehabilitation settings which use different measures.

Whether a new outcome measure is adopted for use in inpatient rehabilitation and other PAC settings is a decision that requires long and careful consideration. However, it is vital that occupational therapists as well as other clinicians understand the impact that the current measures are having on their practice and when necessary, utilize other

evaluations to provide a more complete analysis of the patients' functional status in order to appropriately address their rehabilitation needs.

Limitations

These research studies were conducted in one inpatient rehabilitation facility in a single hospital. It would be beneficial to conduct research in other facilities to further corroborate the findings. Particularly in the second study, the failure to reach statistical significance for both questions may have been a result of small sample size. Future studies with larger samples may be able to provide more conclusive results.

The data for the third study were gathered from a single focus group in an inpatient rehabilitation unit. Combining this data with data from other settings as well as using a variety of methods to gather data would increase the pool of information from which to base any conclusions. There are likely to be different issues with outcome measures in different settings of the same type as well as different types of settings.

Future Research

There are many opportunities to continue this line of inquiry. In addition to replicating the second study with a larger sample size, it would be beneficial to examine the use of the complete AM-PAC in comparison to the total FIM™ in different settings. Similar studies have been conducted, but for widespread consideration of a new outcome measure it would be important to perform pilot studies using the measure in a variety of settings.

The best way to capture cognitive function by use of an outcome measure that can be used across post-acute settings is a difficult issue because it cannot be directly measured by observation in the same way as motor function. The AM-PAC, by utilizing a questionnaire, may be more accurate than clinician observation, but it requires that the respondent be accurate in answering the questions. Further research to clarify when a proxy should be used would be beneficial to provide guidelines for future users of the AM-PAC.

Reflections

Cognition is difficult to describe and measure, especially for those who lack expertise. It is particularly difficult to measure with a short, easily completed outcome measure. An outcome measure like the Cog FIM™, with a few questions, is not likely to provide specific information considering the complexities of cognitive deficits after stroke. The AC AM-PAC has a large item bank, allowing for more specificity, but due to IRT and CAT, it is easier and faster to administer than the Cog FIM™. It is also an advantage that using it eliminates much of the requirement for clinical expertise in observation and judgment.

In occupational therapy, the trend over the last couple of decades has been to focus on physical recovery from stroke over cognitive recovery. This may be because of the emphasis placed on physical recovery in outcome measures like the FIM. In addition, occupational therapists may be more comfortable working in the area of physical recovery, because the processes and results are easier to observe and measure. In

addition, the trend among occupational therapists has been to yield to other disciplines, especially speech-language pathology and neuropsychology, for assessment and treatment of cognitive impairments.

However, occupational therapists can make a unique contribution in the area of cognitive recovery of stroke patients. For occupational therapists, cognition is evaluated and treated ideally when it is imbedded in occupation. This method is particularly suited for recognition of the functional consequences of higher level cognitive impairment. Two readily available evaluations are the Kohlman Evaluation of Living Skills (Kohlman Thomson, 1992) and the Executive Function Performance Test (Baum et al., 2008). These evaluations can be used by occupational therapists in the inpatient rehabilitation facility and will assist in identifying higher level cognitive impairment. This may provide justification for extension of therapy of the patient in the inpatient rehabilitation setting. It also provides the patient and family with information about the kind of support the patient will need after discharge.

As was indicated in the beginning of the literature review, outcome measures are designed to measure aspects of a sample, not for individual treatment planning. As responsible occupational therapists, it is essential that we go beyond the outcome measures required by a particular facility and utilize evaluations that are appropriate for each unique patient in order to provide treatment that is tailored to their specific needs.

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APPENDIX A

THE FIM™

The FIM™ consists of eighteen items that are measured by direct observation of the subject. The items are:

Self-care:	Eating
	Grooming
	Bathing
	Dressing – Upper
	Dressing – Lower
	Toileting
Sphincter Control:	Bladder
	Bowel
Transfers:	Bed – Chair – Wheelchair
	Toilet
	Tub or Shower
Locomotion:	Walk/Wheelchair
	Stairs
Communication:	Comprehension
	Expression
Social Cognition:	Social Interaction
	Problem Solving
	Memory

The Communication and Social Cognition sections are commonly grouped together and are termed the "Cognitive FIM."

Each of the eighteen areas is rated on a seven point scale:

7: Complete independence

6: Modified independence

5: Supervision or set up

4: Minimal assistance (subject performs 75% or more of activity)

3: Moderate assistance (subject performs 50 – 74% of activity)

2: Maximal assistance (subject performs 25 – 49% of activity)

1: Total assistance (subject performs 0-24% of activity)

In addition, a "0" score may be given at admission if the activity is not performed during the initial evaluation period.

The instruction manual for the FIM is available on the Internet from the Centers for Medicare and Medicaid Services, as part of the instructions for completing the "Inpatient Rehabilitation Facility – Patient Assessment Instrument" (IRF-PAI) which is required by Medicare for reimbursement (IRF-PAI training manual,2004).

APPENDIX B

THE BOSTON UNIVERSITY ACTIVITY MEASURE FOR POST ACUTE CARE (AM-PAC)

The AM-PAC is completed by interviewing the patient or another person that is knowledgeable about the patient. The computer-based AM-PAC uses computer adaptive testing technology which limits the number of items needed for each individual assessment. Use of this method requires only a few test items to determine an estimate of a patient's functional level.

The AM-PAC consists of three domains: Basic Mobility, Daily Activity and Applied Cognitive. There are a total of 69 items available in the Applied Cognitive Domain. Sample questions are:

How much difficulty do you (the patient) currently have...

carrying on a conversation with a small group

getting to know new people

reading a long book (over 100 pages) over a number of days

reading and following complex instructions

writing down a short message or note

The scores on each domain range from 0-100. AM-PAC scores in each functional domain have a mean of 50 with a standard deviation of 10 (Jette, Haley, Coster, & Ni, 2007).

APPENDIX C

THE REINTEGRATION TO NORMAL LIVING SCALE (RNL)

This scale was developed as a self-report of a person's ability to reintegrate to normal living after an incapacitating illness or trauma. It does not relate specifically to physical recovery but rather whether the person is satisfied with their level of function and whether they are able to participate in their roles and activities as they desire to do so. Therefore, the use of equipment and assistance is not assessed, but whether the person is satisfied with the level of function regardless of assistance, modification or use of equipment.

The domains assessed in this scale are mobility, self-care activities, daily activities (other than self-care), recreational activities, social activities, family roles, personal relationships, presentation of self, and general coping skills. The person rates each item on a one to ten visual analog scale, with one meaning "does not describe my situation" and ten meaning "fully describes my situation." The scale was designed to be a self-report but has also been tested utilizing a proxy to answer the questions when the person being assessed may not be able to comprehend the questions or answer accurately.

The RNL has been examined for internal consistency, inter-rater reliability, sensitivity, criterion validity and construct validity. The samples were of varied diagnoses up to eighteen months from time of hospitalization (Wood-Dauphinee, Opzoomer, Williams, Marchand, & Spitzer, 1988)

APPENDIX D

THE NATIONAL INSTITUTE OF HEALTH STROKE SCALE

The NIH Stroke Scale (NIHSS) is a widely used scale to quickly assess the severity of stroke. The scores range from 0 – 42, 0 being no impairments and 42 being the maximum impairments in all areas. It includes consciousness, gaze, visual, facial palsy, motor arm, motor leg, limb ataxia, sensory, language, dysarthria, and extinction and inattention. There are eleven separate areas assessed. It takes about two minutes to administer. The NIHSS is used in the stroke unit of the study hospital and is readily available in the patient's chart. The scale was originally developed in 1988 (Brott, Adams, Olinger, Marler, Barsan, Biller, & Spilker, 1989).

APPENDIX E

INCLUSION/EXCLUSION CRITERIA

For studies one and two, the inclusion criteria are:

1. Must have a new diagnosis of stroke (ischemic or hemorrhagic)
2. Must be able to comprehend English to consent to the study
3. Must be between the ages of 18 and 90 years of age

For studies one and two, the exclusion criteria are:

1. Not have a history of stroke, brain injury or brain disease that caused impairment of function prior to the new stroke
2. Not have a documented history of dementia
3. Not have a documented history of psychiatric condition that required inpatient hospitalization
4. Not be discharged from the inpatient rehabilitation unit to another hospital unit for any reason

In addition, for the three month follow up assessment in study two, the additional exclusion criteria are:

1. Not have a readmission to a hospital during the three months since discharge
2. Not to currently be in treatment for an acute infection
3. Not to have been discharged to hospice care

APPENDIX F

DEMOGRAPHIC AND MEDICAL INFORMATION

The following information was ascertained from the medical chart for study one:

1. Age
2. Gender
3. Race or ethnicity
4. Type and location of stroke
5. Dates of stroke, admission to inpatient rehabilitation and discharge
6. Initial NIHSS
7. Prior brain injury history
8. Discharge setting
9. Initial and discharge total FIM scores and cognitive FIM scores

The following information was ascertained from the medical chart for study two:

1. Age
2. Gender
3. Race or ethnicity
4. Type and location of stroke
5. Dates of stroke, admission to inpatient rehabilitation and discharge
6. Initial NIHSS
7. Prior brain injury history
8. Discharge setting
9, The Cog FIM at admission and discharge

The following information was ascertained by the researcher in study two:

1. The AC AM-PAC at admission, discharge and three months post discharge
2. The RNL at three months post discharge.

APPENDIX G

TWU IRB APPROVAL LETTER

TWU
TEXAS WOMAN'S UNIVERSITY
DENTON DALLAS HOUSTON

Office of Research
6700 Fannin Street
Houston, TX 77030-2343
713-794-2480 Fax 713-794-2488

October 3, 2011

Ms. Mary Grace Gaber
School of Occupational Therapy - J. Chan Faculty Adviso
6700 Fannin Street
Houston, TX 77030

Dear Ms. Gaber:

Re: "Measuring Cognitive Outcomes of Stroke Patients in the Inpatient Rehabilitation Unit" (Protocol #: 16770)

Your application to the IRB has been reviewed and approved.

This approval lasts for one (1) year. The study may not continue after the approval period without additional IRB review and approval for continuation. It is your responsibility to assure that this study is not conducted beyond the expiration date.

Any modifications to this study must be submitted for review to the IRB using the Modification Request Form. Additionally, the IRB must be notified immediately of any unanticipated incidents. If you have any questions, please contact the TWU IRB.

The signed consent forms, as applicable, and final report must be filed with the Institutional Review Board in the Office of Research, IHS 10110, at the completion of the study.

Sincerely,

Carolyn Kelley, PT

Carolyn Kelley, PT, DSc, NCS
Institutional Review Board - Houston

APPENDIX H

MEMORIAL HERMANN HEALTHCARE SYSTEM

IRB APPROVAL LETTER

August 8, 2011

MEMORIAL HERMANN
Clinical Innovation & Research Institute

MEMORIAL HERMANN HEALTHCARE SYSTEM
APPROVAL FOR
MEMORIAL HERMANN – TEXAS MEDICAL CENTER

Thank you for choosing Memorial Hermann as your service provider for this research study.

IRB ID:	**HSC-GEN-10-0098** **PRINCIPAL INVESTIGATOR: Mary G. Gaber, ORT**
STUDY TITLE:	**Measuring Cognitive Outcomes of Stroke Patients in the Inpatient Rehabilitation Unit**

Approval is hereby granted by Memorial Hermann Healthcare System to initiate this research study at the Memorial Hermann – Texas Medical Center location. This approval is subject to the Principal Investigator's acceptance of the following stipulations:

STUDY-SPECIFIC STIPULATIONS

1. The Joint Commission requires that a copy of the signed consent form for hospital-based studies be in all subjects' hospital medical records. In addition, the MHHS Authorization for Disclosure of Protected Health Information for Research (with IRB approval stamp) must be placed in all subjects' hospital medical records. The informed consent and disclosure form must remain in the subjects' charts

2. Due to the HIPAA Privacy Rule disclosure requirements associated with research involving HIPAA waivers, the Principal Investigator is required to provide the following information electronically and securely (see attached Spreadsheet) to the System Executive for Privacy Compliance for MHHS, send via email to Erica.Villegas@memorialhermann.org:
   a. Principal Investigator's name;
   b. 8-digit Medical Record Number(s) - with leading 0 for batch purposes - for both paper and electronic records accessed;
   c. Study name and number;
   d. Name of person(s) who accessed each record;
   e. Date(s) records accessed (must have exact date the record was accessed);
   f. Purpose for accessing record (should always be IRB Waiver).

3. All data security computer devices used in this study must be password protected and/or data encrypted.

4. Please remember to acknowledge the Memorial Hermann – Texas Medical Center in any publications resulting from this study, and provide a copy of the publication to the Executive Director of the Memorial Hermann Clinical Innovation & Research Institute (Cheryl.Chanaud@memorialhermann.org). The methods of acknowledgement may include:
   a. Memorial Hermann – Texas Medical Center as an author's affiliation;
   b. mention in an "acknowledgement" section; or
   c. as a footnote.

Please sign and return a copy of this letter to the Memorial Hermann Clinical Innovation & Research Institute, c/o Memorial Hermann Hospital, Mailbox 90, via FAX (713) 704-5124, or scanned .pdf file to Marianne.Riggs@memorialhermann.org to indicate your acceptance of our terms and policies (guidelines attached).

This study may not be initiated until the letter is signed and returned to the Memorial Hermann Clinical Innovation & Research Institute.

If you have questions or need additional information, please contact the Memorial Hermann Clinical Innovation & Research Institute at (713) 704-4228.

MEMORIAL HERMANN
Clinical Innovation & Research Institute

MEMORIAL HERMANN CLINICAL INNOVATION & RESEARCH INSTITUTE GUIDELINES

INSERVICE EDUCATION
The Investigator will provide in-service education regarding study procedures and requirements to all unit, clinic and/or department staff participating in the study including unit directors and managers.

PATIENT RECORDS/INFORMED CONSENT
The Joint Commission requires that the signed copy of the informed consent form for hospital-based studies be in all subjects' hospital medical records. In addition, the MHHS Authorization for Disclosure of Protected Health Information for Research (with IRB approval stamp) must be placed in all subjects' hospital medical records. The informed consent and disclosure form must remain in the subjects' charts.

RESEARCH ORDERS
Investigator must document in the medical record the subject's participation in the research study including consent process, study procedures, and treatments, with notation of research related procedures.

FINANCIAL RESPONSIBILITIES
Investigator agrees to make payment on the research account within 45 days of the billing date and according to the rates set forth in the attached Budget Worksheet. The budget provides a standard discount for research-related services. Research billing statements are distributed on a monthly basis. Please contact the MH Research Institute at (713) 704-4220 with billing questions. Past due accounts may be referred by Memorial Hermann to the appropriate Medical School Department Chair or Memorial Hermann Hospital CFO.

MEDICAL RECORD ACCESS
Requests for medical records must be submitted three (3) business days in advance. The Investigator must provide copies of the signed informed consent and MHHS Authorization for Disclosure of Protected Health Information for Research for each record requested. Records will be held in the Research Room for one week. There is a 20 record limit per request. At Memorial Hermann – TMC, the Research Room is open Monday through Friday, 8am-5pm. Please contact Health Information to make arrangements for after-hours access to records. Investigator must also provide three (3) business days notice of all monitoring visits to the Health Information Department (Medical Records).

DATA SECURITY
All data security computer devices used in this study must be password protected and/or data encrypted.

INVESTIGATIONAL DRUG SERVICE (IDS) PHARMACY
Upon receipt of the Memorial Hermann Approval Letter, IDS will need approximately two weeks to prepare the pharmacy protocol, create a distribution system, and in-service the Pharmacy staffs before enrollment of patients can begin. The Study Set-Up/Administrative Fee will be charged to the Research Billing Account once the preparation process is completed.

CONTINUING IRB REVIEW
Memorial Hermann requires continuous approval by the IRB for all research studies. The Principal Investigator is responsible for maintaining continuing review approval during the conduct of the study.

FEDERAL REGULATORY AGENCY
The MH Clinical Innovation & Research Institute must be notified, in advance, of any regulatory agency visit or review. Contact Cheryl M Chanaud, PhD, MHHS Executive Director of Research, (713) 704-4216.

APPROVED:

8/8/11

Cheryl M. Chanaud, PhD, CCRP Date
Executive Director, Clinical Innovation & Research Institute
Memorial Hermann

ACCEPTANCE:

8/20/11

Principal Investigator Date

cc:
Nakia Pollard – Human Resources
Les Fuchs – Neuroscience
Patricia Tooley, RN, CIPP – System Executive for Privacy Compliance

APPENDIX I

CORRESPONDENCE FROM *THE AMERICAN JOURNAL OF PHYSICAL MEDICINE & REHABILITATION*

10/17/2013
AJ13448
Gaber, Mary
Measuring Cognitive Outcomes of Stroke Patients in the Inpatient Rehabilitation Unit

Dear Dr. Gaber:

We have received the above new manuscript submission. This manuscript is currently in the initial review process. You will receive notification from our office regarding selection of the paper for the extended peer review process.

The manuscript ID number above has been assigned to this paper. Please refer to this number in all correspondence. Please state the Manuscript ID Number in the subject line of all emails concerning this paper. Use email for all correspondence about this paper.

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